**EXHIBIT 2**
**510(k) Summary of Safety and Effectiveness**

FEB 1 9 2003

**Meridian Co., Ltd..**
**9Fl., Seoul Bldg., 222 Jamsilbon-Dong, Songpa-Gu**
**Seoul, 138-863 Korea**
**Phone: 82-2-2103-3320**
**Fax: 82-2-2103-3333**

September 18, 2002
**Contact: Soorang Lee, R&D Director**

1. **Identification of the Device:**
   **Proprietary-Trade Name:** McPulse Photoelectric Plethysmograph
   **Classification Name:** Plethysmograph, Photoelectric, Product code JOM
   **Common/Usual Name:** Photoelectric Plethysomograph

2. **Equivalent legally marketed devices** This product is similar in function to the Novametrix Pulse Oximeter, Model 500 510(k) No. : K853124 Applicant: NOVAMETRIX MEDICAL SYSTEMS INC

3. **Indications for Use (intended use)** : The device provides non-invasive measurement of pulse waveform and heart rate by photoelectric plethysmography.

4. **Description of the Device:** The McPulse Photo-Plethysmograph is intended to be used to measure pulse waveform and heart rate in the finger by lighting a fingertip with combination of infrared LED and photodiode. The measurement probe is an optoelectronic sensor consisted of a light-emitting diode(infrared LED) and a photodiode placed on opposite side as a light receiver. The light from the LED is transmitted through the tissue at the sensor site and a photodiode in the sensor measures the transmitted light and this signal is used to determine how much light was absorbed. This device converts the changes of transmitted light from a photodiode into a waveform and displays a graphic display of the pulse waveform on LCD screen. Pulse rate is measured using the time between successive pulses and displayed digital values on LCD screen. The McPulse system consists of an optoelectronic sensor that is applied to the patient and a microprocessor-based system that processes and displays the measurement. The optoelectronic sensor contains a light-emitting diode(infrared LED) and one photodiode as a light receiver. The light from the LED is transmitted through the tissue at the sensor site. The photodiode in the sensor measures the transmitted light and this signal is used to determine how much light was absorbed..

 K023238 p.2/2

5. **Safety and Effectiveness, comparison to predicate device.** The results of bench and user testing indicates that the new device is as safe and effective as the predicate devices.

6. **Substantial Equivalence Chart**

| Feature | Novametrix Pulse Oximeter, Model 500 (K853124) | McPulse |
|---|---|---|
| INDICATION OF USE | measures pulse waveform , $SaO_2$ and heart rate by photoelectric plethysmograph | measures pulse waveform and heart rate by photoelectric plethysmograph |
| MODE | Non invasive | Non Invasive |
| PRACTITIONER USE | Professional use only | Professional use only |
| DISPLAY | Digital LCD display<br>Analog display | Digital LCD Display |
| POWER SOURCE | AC(100/120/220/240Vac, 50/60Hz)/ DC(Portable rechargeable battery) | AC (100-240Vac, 50/60Hz) |
| TYPE OF SENSOR | LED-Photodiode /<br>finger, ear probe, flexible sensor | LED-Photodiode / finger probe |
| ANATOMICAL SITE | Finger, ear, wrap around | Finger |
| RECORDER OUTPUTS | pulse waveform<br>Heart rate<br>$SaO_2$% | pulse waveform<br>Heart rate |
| HEART RATE RANGE & DISPLAY RESOULTION | 25-250bpm<br>1bpm | 30-230bpm<br>1bpm |
| SIZE (unit : mm) | 228.6(W) × 92.08(H) ×254(D) | 305.5(W) × 296(H) × 92.5(D) |
| WEIGHT | Approx. 3.6kg | Approx. 5.5 kg |

7. **Conclusion**

After analyzing bench, electrical safety, EMC, and user testing data, it is the conclusion of Meridian Co. Ltd.. that the McPulse Photoelectric Plethysmograph is as safe and effective as the predicate device, has few technological differences, and has no new indications for use, thus rendering it substantially equivalent to the predicate device.

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

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 1 9 2003

Meridian Co., Ltd,
c/o Mr. Daniel Kamm, P.E.
Regulatory Associate
Kamm & Associates
P.O. Box 7007
Deerfield, IL 60015

Re: K023238
Trade Name: McPulse Photoelectric Plethysmograph
Regulation Number: 21 CFR 870.2780
Regulation Name: Hydraulic, pneumatic, or photoelectric plethysmographs
Regulatory Class: Class II (two)
Product Code: JOM
Dated: January 14, 2003
Received: January 15, 2003

Dear Mr. Kamm:

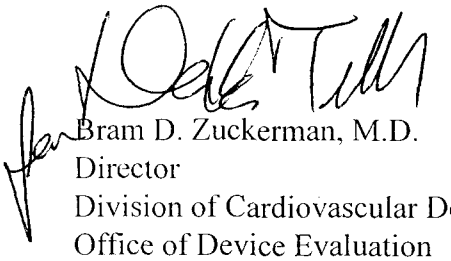
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4646. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address
http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

**j) Indications for Use**

510(k) Number K023238

**Device Name:** McPulse Photoelectric Plethysmograph

**Indications for Use: The device provides non-invasive measurement of pulse waveform and heart rate by photoelectric plethysmography.**

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over the Counter Use_____
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K023238

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 1 9 2003

Meridian Co., Ltd.
c/o Mr. Daniel Kamm, P.E.
Regulatory Associate
Kamm & Associates
P.O. Box 7007
Deerfield, IL 60015

Re: K023238
Trade Name: McPulse Photoelectric Plethysmograph
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This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

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http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

**j) Indications for Use**

510(k) Number K023238

**Device Name:** McPulse Photoelectric Plethysmograph

**Indications for Use: The device provides non-invasive measurement of pulse waveform and heart rate by photoelectric plethysmography.**

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over the Counter Use_____
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K023238

DEPARTMENT OF HEALTH AND HUMAN SERVICES Public Health Service

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

December 18, 2002

MERIDIAN CO., LTD.
C/O KAMM & ASSOCIATES
PO BOX 7007
DEERFIELD, IL 60015
ATTN: DANIEL KAMM

510(k) Number: K023238
Product: MCPULSE

We are holding your above-referenced Premarket Notification (510(k)) for 30 days pending receipt of the additional information that was requested by the Office of Device Evaluation. Please remember that all correspondence concerning your submission MUST cite your 510(k) number and be sent in duplicate to the Document Mail Center (HFZ-401) at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification submission. Also, please note the new Blue Book Memorandum regarding Fax and E-mail Policy entitled, "Fax and E-Mail Communication with Industry about Premarket Files Under Review. Please refer to this guidance for information on current fax and e-mail practices at www.fda.gov/cdrh/ode/a02-01.html.

The deficiencies identified represent the issues that we believe need to be resolved before our review of your 510(k) submission can be successfully completed. In developing the deficiencies, we carefully considered the statutory criteria as defined in Section 513(i) of the Federal Food, Drug, and Cosmetic Act for determining substantial equivalence of your device. We also considered the burden that may be incurred in your attempt to respond to the deficiencies. We believe that we have considered the least burdensome approach to resolving these issues. If, however, you believe that information is being requested that is not relevant to the regulatory decision or that there is a less burdensome way to resolve the issues, you should follow the procedures outlined in the "A Suggested Approach to Resolving Least Burdensome Issues" document. It is available on our Center web page at: http://www.fda.gov/cdrh/modact/leastburdensome.html

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

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

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

Sincerely yours,

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES Public Health Service

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

September 30, 2002

MERIDIAN CO., LTD.
C/O KAMM & ASSOCIATES
PO BOX 7007
DEERFIELD, IL 60015
ATTN: DANIEL KAMM

510(k) Number: K023238
Received: 27-SEP-2002
Product: MCPULSE

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

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

Please remember that all correspondence concerning your submission MUST be sent to the Document Mail Center (DMC)(HFZ-401) at the above letterhead address. Correspondence sent to any address other than the DMC will not be considered as part of your official premarket notification submission. Also, please note the new Blue Book Memorandum regarding Fax and E-mail Policy entitled, "Fax and E-Mail Communication with Industry about Premarket Files Under Review. Please refer to this guidance for information on current fax and e-mail practices at www.fda.gov/cdrh/ode/a02-01.html.

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

Sincerely yours,

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

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K023238

# CDRH Submission Cover Sheet

Date of Submission:

FDA Document Number:

## Section A Type of Submission

| PMA | PMA Supplement | PDP | 510(k) | Meeting |
|---|---|---|---|---|
| ☐ Original submission<br>☐ Modular submission<br>☐ Amendment<br>☐ Report<br>☐ Report Amendment | ☐ Regular<br>☐ Special<br>☐ Panel Track<br>☐ 30-day Supplement<br>☐ 30-day Notice<br>☐ 135-day Supplement<br>☐ Real-time Review<br>☐ Amendment to PMA Supplement | ☐ Presubmission summary<br>☐ Original PDP<br>☐ Notice of intent to start clinical trials<br>☐ Intention to submit Notice of Completion<br>☐ Notice of Completion<br>☐ Amendment to PDP<br>☐ Report | ☑ Original submission:<br>☑ Traditional<br>☐ Special<br>☐ Abbreviated<br>☐ Additional information:<br>☐ Traditional<br>☐ Special<br>☐ Abbreviated | ☐ Pre-IDE meeting<br>☐ Pre-PMA meeting<br>☐ Pre-PDP meeting<br>☐ 180-day meeting<br>☐ Other (specify): |

| IDE | Humanitarian Device Exemption | Class II Exemption | Evaluation of Automatic Class III Designation | Other Submission |
|---|---|---|---|---|
| ☐ Original submission<br>☐ Amendment<br>☐ Supplement | ☐ Original submission<br>☐ Amendment<br>☐ Supplement<br>☐ Report | ☐ Original submission<br>☐ Additional information | ☐ Original submission<br>☐ Additional information | Describe submission: |

## Section B Applicant or Sponsor

| | |
|---|---|
| Company / Institution name: Meridian Co., Ltd.. | Establishment registration number: 9616178 |
| Division name (if applicable): | Phone number (include area code): ( +82 ) 2-2103-3320 |
| Street address: 9Fl., Seoul Bldg., 222 Jamsilbon-Dong, Songpa-Gu | FAX number (include area code): ( +82 ) 2-2103-3333 |
| City: Seoul | State / Province | Country: Korea |
| Contact name: Soorang Lee, | |
| Contact title: R&D Director | Contact e-mail address: |

## Section C Submission correspondent (if different from above)

| | |
|---|---|
| Company / Institution name: Kamm & Associates | Establishment registration number: N/A |
| Division name (if applicable): | Phone number (include area code): ( 847 ) 374-1727 |
| Street address: PO Box 7007 | FAX number (include area code): ( 847 ) 374-1728 |
| City: Deerfield | State / Province: IL- 60015 | Country: USA |
| Contact name: Daniel Kamm, P.E. | |
| Contact title: Regulatory Engineer | Contact e-mail address: dkamm@fda-consultant.com |

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2002 SEP 27 P 2:34
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CV SK 34

Version 2.0

FINAL DRAFT — May 8, 1998

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

- ☐ New device
- ☐ Withdrawal
- ☐ Additional or expanded indications
- ☐ Licensing agreement

- ☐ Process change
  - ☐ Manufacturing
  - ☐ Sterilization
  - ☐ Packaging
  - ☐ Other (specify below)

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

- ☐ Other reason (specify):

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

- ☐ Labeling change:
  - ☐ Indications
  - ☐ Instructions
  - ☐ Performance Characteristics
- ☐ Shelf life
- ☐ Trade name
- ☐ Other (specify below)

- ☐ Location change:
  - ☐ Manufacturer
  - ☐ Sterilizer
  - ☐ Packager
  - ☐ Distributor

- ☐ Report submission:
  - ☐ Annual or periodic
  - ☐ Post-approval study
  - ☐ Adverse reaction
- ☐ Device defect
- ☐ Amendment

- ☐ Change in ownership
  - ☐ Change in correspondent

## Section D2 — Reason for Submission — IDE

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

- ☐ Other reason (specify):

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

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

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

## Section D3 — Reason for Submission — 510(k)

- ☑ New device
- ☐ Additional or expanded indications
- ☐ Other reason (specify):

- ☐ Change in technology
- ☐ Change in design

- ☐ Change in materials
- ☐ Change in manufacturing process

## Section E — Additional Information on 510(k) Submissions

Product codes of devices to which substantial equivalence is claimed:

| | | | |
|---|---|---|---|
| 1 JOM | 2 | 3 | 4 |
| 5 | 6 | 7 | 8 |

Summary of, or statement concerning, safety and effectiveness data:
- ☑ 510(k) summary attached
- ☐ 510(k) statement

Information on devices to which substantial equivalence is claimed:

| | 510(k) Number | Trade or proprietary or model name | Manufacturer |
|---|---|---|---|
| 1 | K853124 | Pulse Oximeter, Model 500 | Novametrix |
| 2 | | | |
| 3 | | | |
| 4 | | | |
| 5 | | | |
| 6 | | | |

## Section F — Product Information — Applicable to All Applications

Common or usual name or classification name:
Plethysmograph, Photoelectric

| | Trade or proprietary or model name | Model number |
|---|---|---|
| 1 | McPulse | |
| 2 | | |
| 3 | | |
| 4 | | |
| 5 | | |

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

| | | | | | |
|---|---|---|---|---|---|
| 1 None | 2 | 3 | 4 | 5 | 6 |
| 7 | 8 | 9 | 10 | 11 | 12 |

Data included in submission: ☑ Laboratory testing ☐ Animal trials ☐ Human trials

## Section G — Product Classification — Applicable to All Applications

Product code: JOM | C.F.R. Section: 870.2780

Classification panel: Cardiovascular

Device class:
☐ Class I ☑ Class II
☐ Class III ☐ Unclassified

Indications (from labeling):
The device provides non-invasive measurement of pulse waveform and heart rate by photoelectric plethysmography.

**Meridian Co., Ltd..**
**9Fl., Seoul Bldg., 222 Jamsilbon-Dong, Songpa-Gu**
**Seoul, 138-863 Korea**
**Phone: 82-2-2103-3320**
**Fax: 82-2-2103-3333**

**This submission was prepared by:**
Daniel Kamm, P.E.
Kamm & Associates
PO Box 7007
Deerfield IL 60015 USA
Phone 1+847-374-1727
Fax 1+847-374-1728
email dkamm@fda-consultant.com

**Please fax or email questions or requests for additional information to Mr. Kamm, who will expedite a reply.**

September 26, 2002

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

Attention: Document Mail Clerk

**Re: 510(k) Notification:**

**Purpose of submission:** This is to notify you of the intention by Meridian Co., Ltd. to market a new but substantially equivalent to a legally marketed device: McPulse Photo-Plethysmograph. There have been no changes to the indications for use and many other essential characteristics as compared to the predicate device.

**Confidentiality:** Sedecal considers the information contained in this submission to be confidential in nature (except for Exhibit 2 as required by the SMDA)

**Fax and Email communications specifically authorized:** Requests for additional information are hereby authorized and may be emailed to dkamm@fda-consultant.com or faxed to 847-384-1728.

**Summary of Safety and Effectiveness:** In response to the requirements addressed by the SMDA of 1990, I am enclosing a summary of the safety and effectiveness information upon which the substantial equivalence determination is based. (Exhibit 2)

Sincerely yours,

Soorang Lee, R&D Director

Daniel Kamm
(Regulatory Engineer)

Enclosures



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|---|---|
| 5 | Comparison Information |
| 6 | Biocompatibility data<br>Sterilization and expiration dating (Not applicable) |
| 7 | Software Development Information<br>1. Level of Concern<br>2. Software Information<br>3. Architecture Design (Flow) Chart<br>4. Device Risk Analysis<br>5. Validation, Verification, and Testing<br>6. Release Version Number<br>7. Known Bugs |
| 8 | CONFORMANCE TO STANDARDS AND GUIDELINES<br>Electrical Safety Test Report<br>Certificate of Medical Device Testing<br>ISO 9001 Certificate |

## EXHIBIT 1

### General Information

**a) Trade name /Proprietary Name:** McPulse Photo-Plethysmograph

**b) Common name /Usual Name:** Plethysmograph, Photoelectric

**c) Establishment registration number and address:**

*Establishment:*
MERIDIAN CO., LTD.
687-6 SANG O AN RI
HONGCHUNEUB, HONGCHUNGUN
KANG WON DO, REPUBLIC OF KOREA
Registration Number: 9616178
Phone: 82-2-2103-3320
Fax: 82-2-2103-3333

**d) Device class:** Class II per regulation 870.2780

**e) Classification Name/Product Code:** 74 JOM

**f) New or Modification:** This notification is for a new device for the US market.

**g) Predicate Device (Substantial Equivalence):** Novametrix Pulse Oximeter, Model 500 510(k) No. : K853124 Applicant: NOVAMETRIX MEDICAL SYSTEMS INC.

**h) 513/514 Compliance (Performance Standard):** None established. Complies with voluntary standards:

1. IEC 60601-1, Safety of Medical Electrical Equipment, Part 1, General Requirements for Safety, including Amendment 1 and 2.
2. EN 60601-1-2 first edition, Standard for Electromagnetic Compatibility.

**i) Truth and Accuracy Certification**

***I certify that, in my capacity as R&D Director of Meridian Co. Ltd, I believe, to the best of my knowledge, that all data and information submitted in this premarket notification are truthful and accurate, and that no material fact has been omitted.***

Soorang Lee, R&D Director
September 18, 2002

**i) Indications for Use**

510(k) Number_____

**Device Name:** McPulse Photoelectric Plethysmograph

**Indications for Use: The device provides non-invasive measurement of pulse waveform and heart rate by photoelectric plethysmography.**

_____ _____ _____ _____ _____ _____ _____ _____ _____

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use_____ OR Over the Counter Use_____

(Per 21 CFR 801.109)

**EXHIBIT 2**

**510(k) Summary of Safety and Effectiveness**

**Meridian Co., Ltd..**
**9Fl., Seoul Bldg., 222 Jamsilbon-Dong, Songpa-Gu**
**Seoul, 138-863 Korea**
**Phone: 82-2-2103-3320**
**Fax: 82-2-2103-3333**

September 18, 2002

**Contact: Soorang Lee, R&D Director**

1. **Identification of the Device:**
   **Proprietary-Trade Name:** McPulse Photoelectric Plethysmograph
   **Classification Name:** Plethysmograph, Photoelectric, Product code JOM
   **Common/Usual Name:** Photoelectric Plethysomograph

2. **Equivalent legally marketed devices** This product is similar in function to the Novametrix Pulse Oximeter, Model 500 510(k) No. : K853124 Applicant: NOVAMETRIX MEDICAL SYSTEMS INC

3. **Indications for Use (intended use)** : The device provides non-invasive measurement of pulse waveform and heart rate by photoelectric plethysmography.

4. **Description of the Device:** The McPulse Photo-Plethysmograph is intended to be used to measure pulse waveform and heart rate in the finger by lighting a fingertip with combination of infrared LED and photodiode. The measurement probe is an optoelectronic sensor consisted of a light-emitting diode(infrared LED) and a photodiode placed on opposite side as a light receiver. The light from the LED is transmitted through the tissue at the sensor site and a photodiode in the sensor measures the transmitted light and this signal is used to determine how much light was absorbed. This device converts the changes of transmitted light from a photodiode into a waveform and displays a graphic display of the pulse waveform on LCD screen. Pulse rate is measured using the time between successive pulses and displayed digital values on LCD screen. The McPulse system consists of an optoelectronic sensor that is applied to the patient and a microprocessor-based system that processes and displays the measurement. The optoelectronic sensor contains a light-emitting diode(infrared LED) and one photodiode as a light receiver. The light from the LED is transmitted through the tissue at the sensor site. The photodiode in the sensor measures the transmitted light and this signal is used to determine how much light was absorbed..

5. **Safety and Effectiveness, comparison to predicate device.** The results of bench and user testing indicates that the new device is as safe and effective as the predicate devices.

6. **Substantial Equivalence Chart**

| Feature | Novametrix Pulse Oximeter, Model 500 (K853124) | McPulse |
|---|---|---|
| INDICATION OF USE | measures pulse waveform , $SaO_2$ and heart rate by photoelectric plethysmograph | measures pulse waveform and heart rate by photoelectric plethysmograph |
| MODE | Non invasive | Non Invasive |
| PRACTITIONER USE | Professional use only | Professional use only |
| DISPLAY | Digital LCD display<br>Analog display | Digital LCD Display |
| POWER SOURCE | AC(100/120/220/240Vac, 50/60Hz)/ DC(Portable rechargeable battery) | AC (100-240Vac, 50/60Hz) |
| TYPE OF SENSOR | LED-Photodiode /<br>finger, ear probe, flexible sensor | LED-Photodiode / finger probe |
| ANATOMICAL SITE | Finger, ear, wrap around | Finger |
| RECORDER OUTPUTS | pulse waveform<br>Heart rate<br>$SaO_2$% | pulse waveform<br>Heart rate |
| HEART RATE RANGE & DISPLAY RESOULTION | 25-250bpm<br>1bpm | 30-230bpm<br>1bpm |
| SIZE (unit : mm) | 228.6(W) x 92.08(H) x254(D) | 305.5(W) x 296(H) x 92.5(D) |
| WEIGHT | Approx. 3.6kg | Approx. 5.5 kg |

7. **Conclusion**

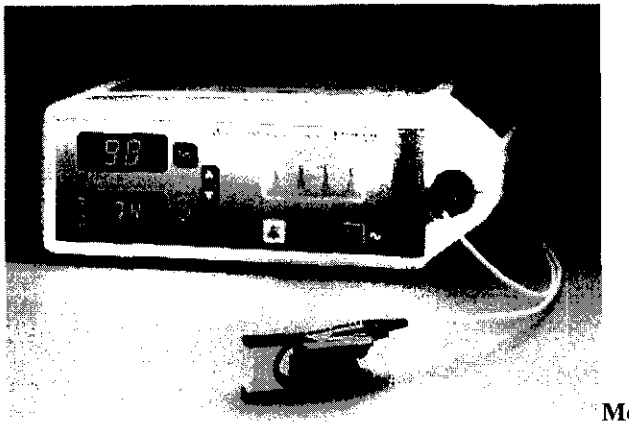
After analyzing bench, electrical safety, EMC, and user testing data, it is the conclusion of Meridian Co. Ltd.. that the McPulse Photoelectric Plethysmograph is as safe and effective as the predicate device, has few technological differences, and has no new indications for use, thus rendering it substantially equivalent to the predicate device.

**EXHIBIT 3**
**Labeling**

Predicate Device Brochure
McPulse Brochure
McPulse User's Manual
McPulse Device Labels

**Predicate Device Brochure**
**(The Model 500 has been replaced by the Model 515, shown below)**

NOVAMETRIX MEDICAL SYSTEMS INC. Pulse Oximetry



**Model 515C**
Pulse Oximeter

Designed for simple operation, the Model 515C pulse oximeter is ideal for use in any clinical setting; from emergency hospital transport to continuous monitoring in Anesthesia, Intensive Care and General Patient Care Settings.

## Product Highlights

- Simplified design allows for quick setup and easy operation.
- Advanced SuperBright™ digital technology provides superior performance in conditions of low perfusion or motion artifact.
- Innovative reusable Y-Sensor™ is sterilizable and can be used with all patient populations.
- Bar graph and optional on-screen plethysmogram provide continuous validation of signal quality.
- Internal rechargeable battery allows for up to 8 hours of continuous monitoring.

## Technical Specifications

**PRINCIPLE OF OPERATION**
Red/Infrared absorption.

**SpO2 (OXYGEN SATURATION)**
Range: 0-100%
Accuracy: ±2% SpO2 (for 80-100% SpO2) (1 SD, or 68% of readings within claim) Unspecified for 0-79% SpO2
Resolution: 1%
Averaging: 8 seconds

**PULSE RATE**
Range: 30-250 bpm
Accuracy: ±2 bpm

Resolution: 1 bpm
Averaging: 8 seconds

**SENSORS**

Reusable Y-Sensor™ (can be sterilized and used with all patient populations) and reusable adult finger sensor.

**PLETHYSMOGRAM**

Pulsatile waveform with autogain.

---

## General

**ALERTS**

Automatic and adjustable limits for SpO2 and Pulse Rate
Audio: Adjustable volume, 2 min. silence or OFF (LED indicators)
Visual: Flashing numerics upon violated limit(s) & red "Alert Bar". Indication of sensor disconnect, sensor off patient, low signal, insufficient light, light interference, pulse out of range, sensor faulty and monitor faulty conditions.

**DISPLAY**

Numerics: 7-Segment LED's
Pulse Bar: LED Pulse Bar Graph proportional to signal strength
Plethysmogram (Model 515C): Liquid Crystal Graphic module, 2.4" W × 1.3" H (6.0 x 3.3 cm)

**PHYSICAL**

Size: 3.3" H × 9.0" W × 8.0" D (8.38 × 22.86 × 20.32 cm)
Weight: 6 lb (2.72 kg)

**ELECTRICAL**

Power requirements: 100-120/200-240 VAC, 50-60 Hz, 30 VA
Battery: Sealed lead acid gel cell, 8 hr. life, 12 hr. recharge
Indicators for battery operation, low battery, and extremely low battery.

**ENVIRONMENTAL**

Operating temperature: 50-104° F (10-40° C)
Operating humidity: 0-90% relative (non-condensing)

MODEL 515B (without plethysmogram)

The Model 515B pulse oximeter has the same technical specifications as the Model 515C, excluding the plethysmogram display.

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**NOVAMETRIX**
**MEDICAL SYSTEMS INC.**

Novametrix reserves the right to change specifications without notice.

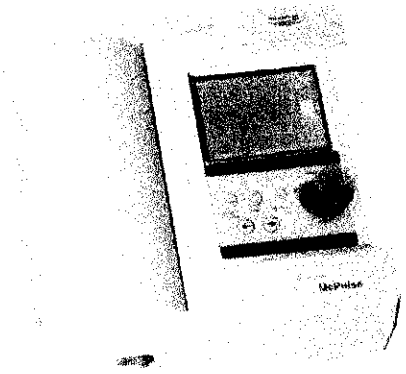
**McPulse Brochure**

## Photo-Plethysmograph

# *McPulse*

### *High performance with versatile functions*

- Real-time measurement and display of pulse waveform
- LCD displays set-up menu and measurement results
- Printing of measurement results
- Measurement of Heart rate
- Setting of patient information and measurement mode etc.

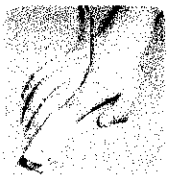


### *Space-free with bench-topped design*

You can use McPulse system in your own desk and it doesn't need special space.

### *Easy to run*

Simplified keypad provides the easiest way to operate the machine for the users.



### *Light and portable mark-up*

Ergonomically designed handle helps you to carry the machine easily place to place.

***Digital Photo-Plethysmograph***

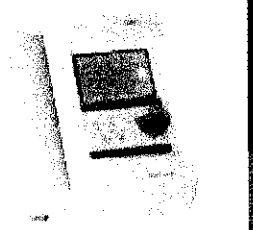
***McPulse***

meridian

9Fl., Seoil Bldg., 222, Jamsilbon-Dong, Songpa-Gu, Seoul, Korea
Phone : 82-2-2103-3300, Fax : 82-2-2103-3333

# McPulse

## *Photo-Plethysmograph*



### McPulse Overview

- An accurate, easy-to-use photo-plethysmograph
- Non-invasive and painless measurement
- Measurement of pulse wave of finger

### General Specification

| | |
|---|---|
| • Dimensions | : 305.5mm(W) × 296mm(H) × 92.5mm(D) |
| • Weight | : 5.5kg |
| • Measurement mode | : continuous mode / automatic measurement mode |
| • Measurement factor | : pulse waveform / heart rate / pulse amplitude |
| • Printing form | : A4 size paper by thermal printer |
| • LCD display | : 320× 240 Graphic LCD |
| • User input | : 5 keys and 1 rotary |
| • Power | : 100-240Vac, 50/60Hz |
| • Power consumption | : Abt. 60W |
| • Language | : English |

CAUTION

Federal Law restricts this device to sale by or on the order of physician.

Photo-Plethysmograph

**McPulse**

# User's manual

# Version 1.0

MERIDIAN CO., LTD.

9Fl., Seoil Bldg., 222, Jamsilbon-Dong,Songpa-Gu

Seoul, Republic of Korea

TEL : +82-2-2103-3300 FAX : +82-2-2103-3333

# *Contents*

# 1. Preface

## 1.1 General

Thank you for purchasing the McPulse, Photo-Plethysmograph device. To ensure safety operating and long-term performance stability, it is essential that you fully understand the functions, operating and maintenance instructions by reading this manual before operating equipment.

**Responsibility of the manufacturer**

- MERIDIAN CO., LTD. is responsible for the effects of safety, reliability, and performance only if :
  - Assembly operations, extensions, re-adjustments, modifications, or repairs are carried out by persons authorized by MERIDIAN.
  - The electrical installation of the relevant room complies with the requirements of the appropriate regulations
  - The equipment is used in accordance with the instructions for use.
- This device is intended for use under the direct supervision of a licensed health care practitioner.
- The intended use of this device is to be used to measure the blood volume changes in the capillary blood vessel by lighting a fingertip and evaluate blood flow.
- To ensure patient safety, use only parts and accessories manufactured or recommended by MERIDIAN CO., LTD.



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## 1.2 Warnings

Particular attention must be paid to all warnings, cautions and notes incorporated herein.

- Incorrect operation, or failure of the user to maintain the equipment relieves the manufacturer or his agent of the system's noncompliance with specifications or of responsibility for any damage or injury.

- The following conventions are used throughout the manual to denote information of special emphasis.

| | |
|---|---|
| **CAUTION** | "CAUTION" is used to indicate the presence of a hazard which can cause severe personal injury, death or substantial property damage if the caution is ignored. |
| **WARNING** | "WARNING" is used to indicate the presence of a hazard which will or can cause minor personal injury or property damage if the warning is ignored. |
| **NOTE** | "NOTE" is used to notify the user of installation operation or maintenance information which is important but not hazard related. |





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## 1.3 Guarantee conditions

- MERIDIAN CO., LTD. offers the following guarantee to the purchaser of this equipment. The guarantee is valid for two years commencing when the equipment is handed over to the first retail purchaser. The guarantee covers all problems caused by faulty workmanship or faulty material. Call the customer department at the headquarters when problems arise. There will be no additional charge for the repair.

- The guarantee is valid only when the equipment is installed in the proper environment as specified in the Usage Guide section. Make sure to use the equipment as instructed in the Usage Guide section.

- The guarantee does not cover the damages and loss caused by outside factors such as fire, flood, storm, tidal wave, lightening, earthquake, theft, abnormal conditions of operation, and intentional destruction of the system.

- Superficial defects do not qualify refund. Prices for the batteries, training materials, and supplies are not covered.

- MERIDIAN CO., LTD. does not take responsibility for damages or loss which appear after the guarantee period.

- The guarantee does not cover additional and indirect damages related with system operation.

- Service may be requested by sending a letter to the overseas Customer Service department at MERIDIAN. The product name, serial number, date of purchase and the details of the problem should be contained in the letter. This after service is provided at no additional cost.

- Defective equipment should be packed in a return box and sent to MERIDIAN.

- This guarantee can replace all other guarantees for detailed parts and product.



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## 1.4 Equipment Symbols

The International Electro-technical Commission (IEC) has established a set of symbols for medical electronic equipment which classify a connections or warn of potential hazards. The classifications and symbols are shown below.

Isolated patient connection (Type BF)

I and O on power switch represent ON and OFF, respectively.

This symbol identifies a safety note. Ensure you understand the function of this control before using it. Control function is described in the operation manual

identifies equipotential ground



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## 1.5 Service Requirements

- Refer servicing for equipment to MERIDIAN CO., LTD. authorized service personnel. Any attempt repair equipment under warranty will void that warranty.

- It is the responsibility of users requiring service to report the need for service to MERIDIAN CO., LTD., or to one of their authorized agents.

- Failure on the part of the responsible individual, hospital, or institution using this equipment to implement a satisfactory maintenance schedule may cause undue equipment failure and possible health hazards.

- If there are any problems with the equipment, please follow the steps below :

  - Contact the MERIDIAN Oversea Service Department immediately. After gathering the model name, serial number, date of purchase, and description of the problem contact MERIDIAN with the information shown below.

  - Try to solve the problem over the phone with the service department personnel. If the problem cannot be solved over the phone, the service personnel can came and fix the problem directly.

  - MERIDIAN or local distributor will make available on request circuit diagrams, component part lists, descriptions, calibration instructions or other information which will assist your appropriately qualified technical personnel to repair those parts of equipment which are designated by MERIDIAN as reparable.

## 1.6 How to reach us

| | |
|---|---|
| **Service Calls** | Following the telephone numbers and addresses for contacting various service, supplies and sales personnel.<br>To open a service call with MERIDIAN, call to below<br><br>+82-2-2103-3300<br>URL : www.meridian.co.kr<br>E-mail : meridian@meridian.co.kr |
| Supply products and Service parts | Order supplies and manuals from MERIDIAN, 9Fl., Seoil Bldg., 222, Jamsilbon-Dong, Songpa-Gu, Seoul, Korea.<br>Telephone : +82-2-2103-3300<br><br>If you want to order service parts, please have the following handy :<br><br>▪ Part number of the defective part, or<br>▪ Model and serial number of the equipment<br>▪ Part number/name of the assembly where the item is used,<br>▪ Item name, and<br>▪ Where applicable, reference designation.<br>▪ When ordering additional operator manuals, remember to get the software version from either the back of the title page or a printed report. |

# 2. Safety Precaution



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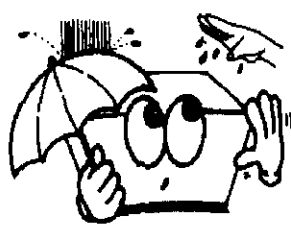
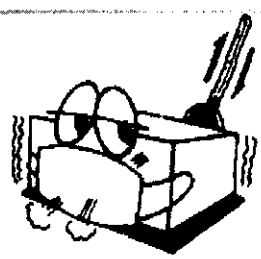
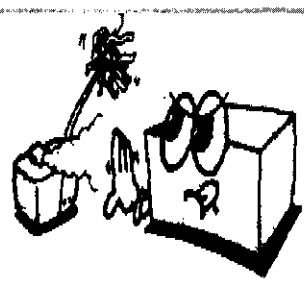
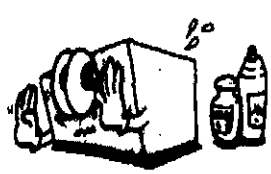
## 2.1 Environmental Consideration and Cautions

Avoid the following environments for operation or storage :

| | |
|---|---|
|  | Where the equipment is exposed to water vapor.<br>Don't operate an equipment with a wet hand. |
|  | Where the temperature changes extremely.<br>Normal Operating temperature range is from 15°C to 35°C, humidity is from 30% to 85%.<br>Transfer and Storage temperature range is from 0°C to 40°C, humidity is from 25% to 90%. |
|  | Where the humidity is extremely high or there is a ventilation problem. |
|  | Where equipment is exposed to chemical material or explosive gas. |



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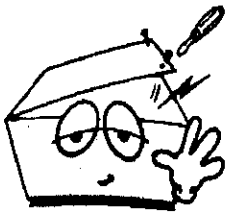
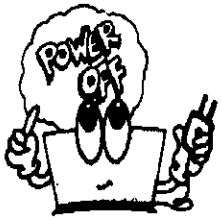
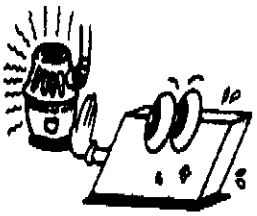
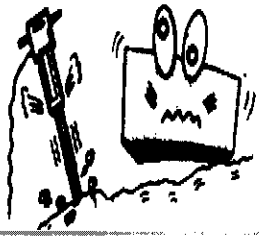
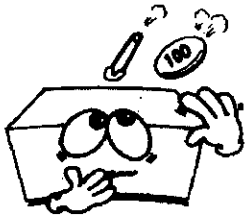
| | |
|---|---|
|  | Don't disassemble the product or open. We aren't responsible for it for nothing. |
|   | Don't plug the AC power cord into the outlet before the connection between devices of the equipment is completed. This can generate the defect. |
|  | Where the equipment is exposed to direct sunlight. |
|  | Where it is near the heat equipment. |
|  | Where the equipment is subject to excessive shocks or vibrations. |
|  | Be careful not to be inserted dust, especially metal. |

## 2.2 Precaution when using

### 2-2-1 Precautions before using

Before using the system, check the following :

- The power supply line is suitable with that of the system (100-240Vac).
- All the connection parts (power line and probe) are connected to the system properly.
- Probe is connected before the system is turned on.

| | |
|---|---|
| **WARNING** | McPulse is classified as ;<br>Class I, type BF against electric shock by standard of IEC 60601-1.<br>Moreover, The McPulse is a Class A product for Noise-emission by standard of IEC 60601-1-2 (Electromagnetic Compatibility Requirements).<br>In a domestic environment, the McPulse may cause interference in which case the user may be required to take adequate operation. |

| | |
|---|---|
| **WARNING** | Don't use the system near the power generator, X-ray generator which require high current in a moment or severely generate the electronic wave. |

### 2-2-2 Precautions during using

- McPulse system must be used only by physician.
- Note that there is any abnormality in equipment and patient. If any problems detected, turn off the system for the safety of patient.
- Don't turn on and off rapidly.
- Don't connect or disconnect the measurement probe on power ON status.

### 2-2-3 Precautions after using

- Turn off the power switch.
- Pull out the power plug.
- Clean main body and probe with a lint free cloth moistened with either warm water (40°C / 104F maximum)

### 2-2-4 Precautions when using measurement probe

- Probe is connected to the system properly.
- Don't pull or bend the probe cable.



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## 2.3 Maintenance and Protection

### 2-3-1 PRELIMINARY MAINTENANCE

The service engineers in each country have a responsibility to provide a preliminary maintenance to all McPulse System products in warranty period.

**WARNING** Always disconnect the McPulse system from the wall outlet before performing maintenance or cleaning.

**CAUTION** Do not use strong solvents such as thinner or benzene, or abrasive cleansers since these will damage the cabinet.

### 2-3-2 SYSTEM Cleaning

To keep probe clean, rub them smoothly with a soft cloth soaked it in the warm water after use and clean it with a soft cloth dampened with alcohol at lest once a month. Do not use lacquer thinner, ethylene oxide or any other organic solutions, as this can destroy the membrane of the probe. Make sure that disinfecting solution or water does not go into the system and other accessories.

To keep the system and cable free of dust and dirt, clean it with a lint free cloth moistened with either warm water (40°C / 104F maximum) after use and clean it with a soft cloth moistened with a standard clinical-grade alcohol at least once in a week. Do not use lacquer thinner or other organic solvents as this can have deleterious effects on the active membrane surface of probes.

**WARNING** To avoid electrical shock, always turn off the system and disconnect the electrode from the McPulse System before cleaning.

# 3. System Overview



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## 3.1 Introduction

- This operator's manual contains the content related to McPulse, Photo-Plethysmograph System. McPulse has been designed for the user's best convenience and the pulse wave of fingertip and second derivative pulse wave is displayed on LCD screen.

- This manual composed of independent chapters, and there are some overlapping sections. Each chapter is written, for convenience of the user, as a stand-alone identity and may be read in this manner.

- If you have any troubles during an operation, please contact our company's oversea service department.

## 3.2 How to use this manual

Customers are kindly requested to read through this user's manual describing general instruction before installing and using.

- In chapter 1, general system overview is described.
- In chapter 2, safety precautions are described.
- In chapter 3, composition and name of each parts are described.
- In chapter 4, operation methodology is described.

## 3.3 System Features

### 3.3.1 General Device Description

- The McPulse, Photo-Plethysmograph is intended to be used to measure pulse waveform and heart rate in the finger by lighting a fingertip with combination of infrared LED and photodiode.

- The measurement probe consists of a light-emitting diode(infrared LED) and a photodiode placed on opposite side as a light receiver.

- The light from the LED is transmitted through the tissue at the probe site and a photodiode in the probe measures the transmitted light and this signal is used to determine how much light was absorbed. Pulse rate is measured using the time between successive pulses.

- It converts the changes of transmitted light into a waveform and it displays digital values of pulse rate as well as a graphic display of the pulse waveform on LCD screen.

- The McPulse is equipped with a micro-controller which manages a vast range of operations :
  - real-time display of measuring pulse waveform and second derivative pulse waveform
  - real-time display of heart rate and pulse amplitude
  - calculation of each peak ratios of second derivative pulse waveform
  - set-up menu : patient information, measurement time, reprint function of measurement results and system clock

- There are two operating modes to the McPulse system. User can determine the desired operation mode using control volume key.

  - Continuous mode displays pulse waveform, second derivative pulse waveform and other data on LCD screen continuously. The user can press [PRINT] key to print the measurement results.

  - Automatic measurement mode displays pulse waveform, second derivative pulse waveform and other data on LCD screen during preset measurement time. During measurement procedure, LCD screen shows a bar indicating measurement processing and then if the measurement procedure is completed, the measurement result is printed by thermal printer automatically. User can select the measurement time in the range of from 1 minute to 10 minutes.

### 3.3.2 McPulse Characteristic

| | |
|---|---|
| **High performance with versatile functions** | ▪ Real-time measurement and display of pulse wave<br>▪ LCD screen displays set-up menu and measurement results.<br>▪ Printing of measurement results<br>▪ Measurement of heart rate<br>▪ Setting of patient information, measurement time, reprint function and system clock. |
| **Space-free with bench-topped design** | ▪ You can use McPulse in your own desk and it doesn't need special space. |
| **Light and portable mark-up** | ▪ Ergonomically designed handle helps you to carry the machine easily place to place. |
| **User friendly operation** | ▪ Simplified keypad provides the easiest way to operate the machine for the users. |

### 3.3.3 Standard specification

| | |
|---|---|
| Power Supply | 100-240Vac, 50/60Hz |
| Power Consumption | About. 60W |
| Dimensions | 305.5mm(W) × 296mm(H) × 92.5mm(D) |
| Weight | 5.5kg |
| LCD Display | 320 × 240 Graphic LCD |
| Safety Class | Class I, Type BF according to IEC 60601-1 |

**MEASUREMENT FACTOR**

- Real-time measurement of pulse wave of fingertip and real-time display of measurement signal on LCD screen
- Real-time display of pulse amplitude using bar graph and digital value in the range from 0 to 16.
- Real-time display of the second derivative pulse waveform and each peak ratios
- Heart rate(30-230bpm) measurement (display resolution : 1bpm)

**OPERATING MODE**

- Continuous measurement mode
- Automatic measurement mode(Measurement time set-up mode, 1~10min. in steps of 1min.)

**MEASUREMENT PROBE**

- Composed of an infrared LED and photodiode
- Measurement of fingertip by non-invasive method

**PRINTING FORM**

- Print measured data on A4 size paper by thermal printer

**USER INPUT**

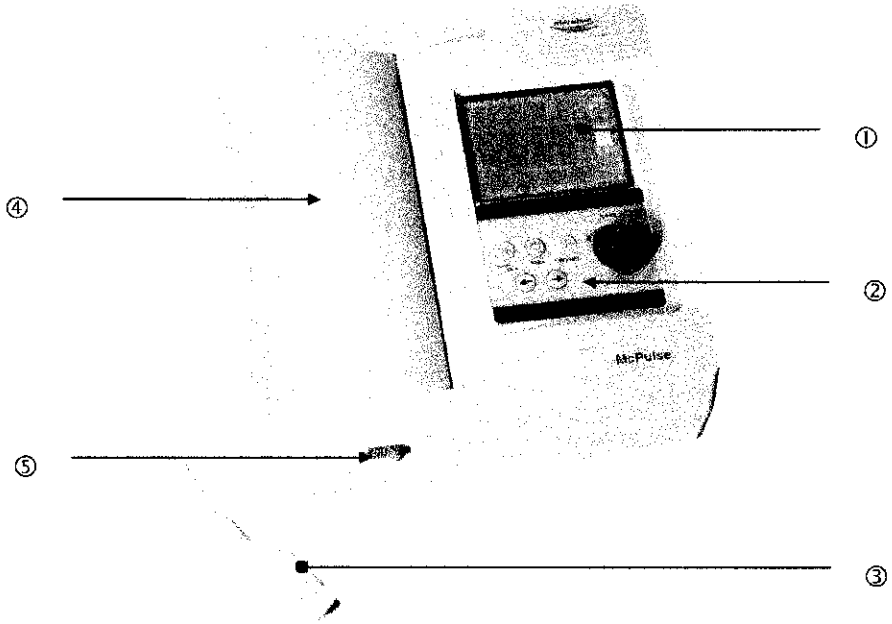
- 5 keys and 1 rotary key input

### 3.3.4 System Configuration

- McPulse Main Body
- Measurement probe
- 2 rolls of thermal paper
- Power cord
- User's manual

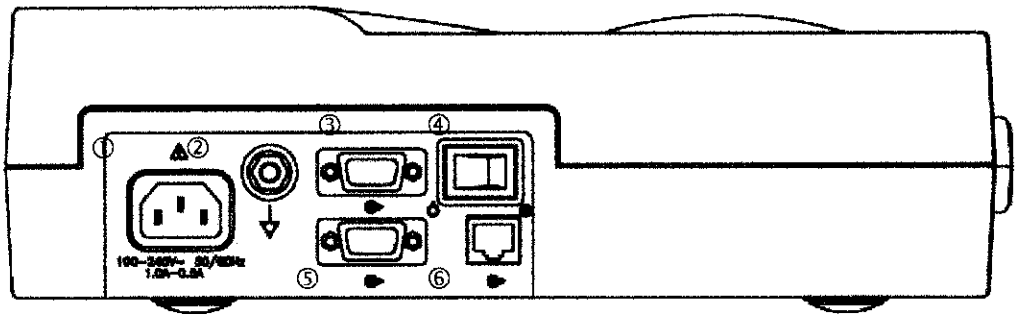
### 3.3.5 System View

■ **Front view**



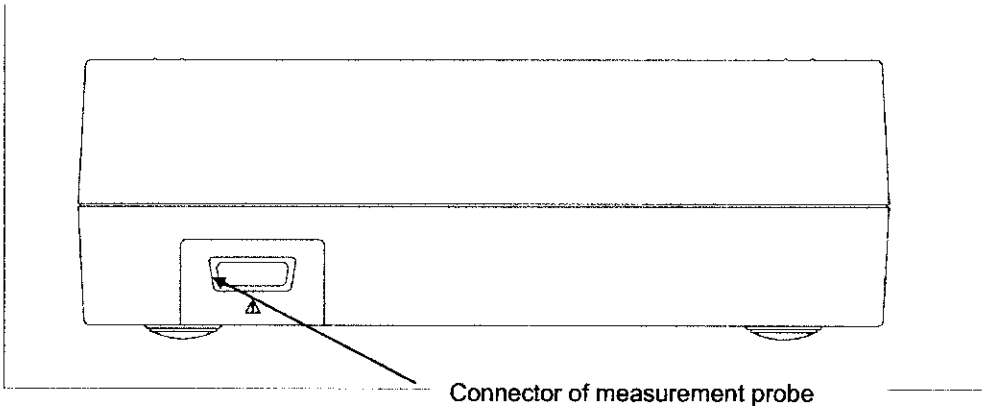

1. LCD Screen
2. Keypad
3. Measurement probe
4. Printer
5. Printer cover open button

■ **Rear view**

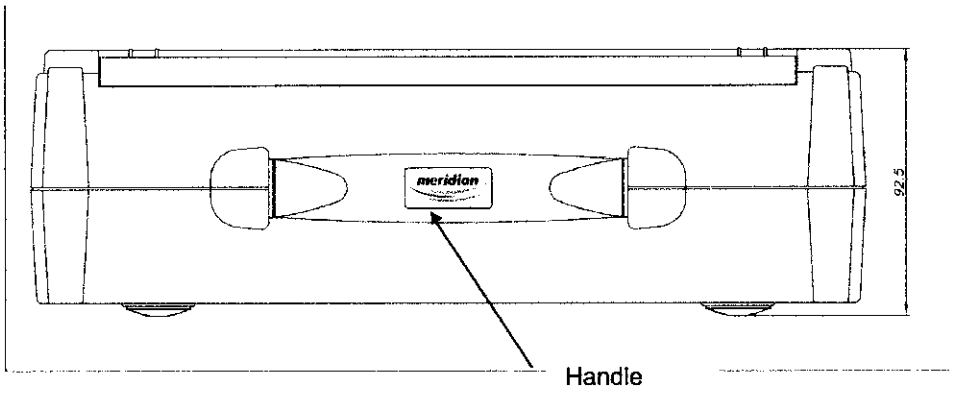


1. Power inlet
2. Equipotential pole
3. Not used
4. Power ON/OFF switch
5. Not used
6. Not used

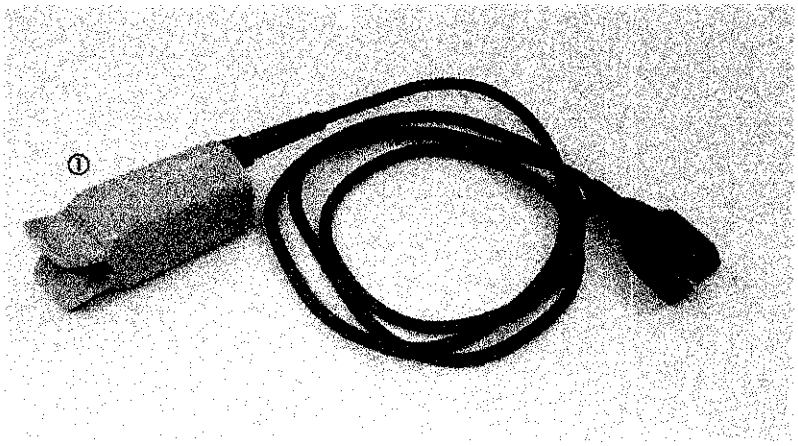
■ **Right side view**



■ **Left side view**

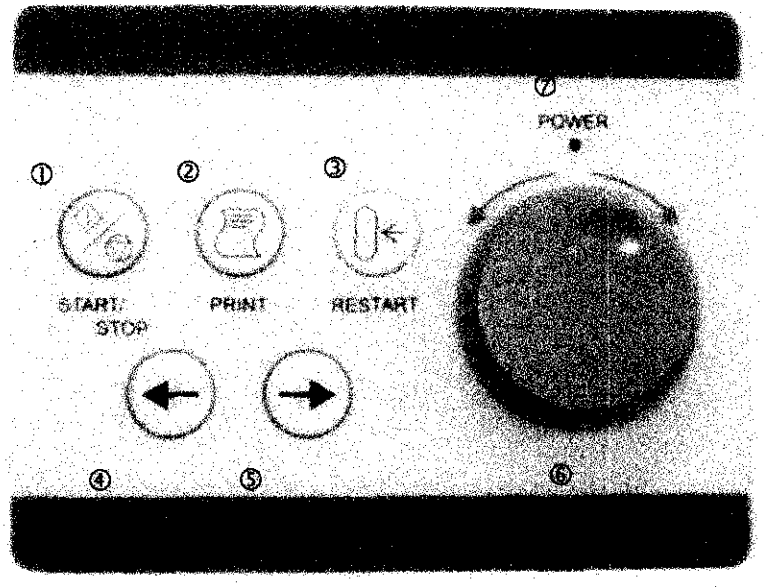



■ **Measurement probe**



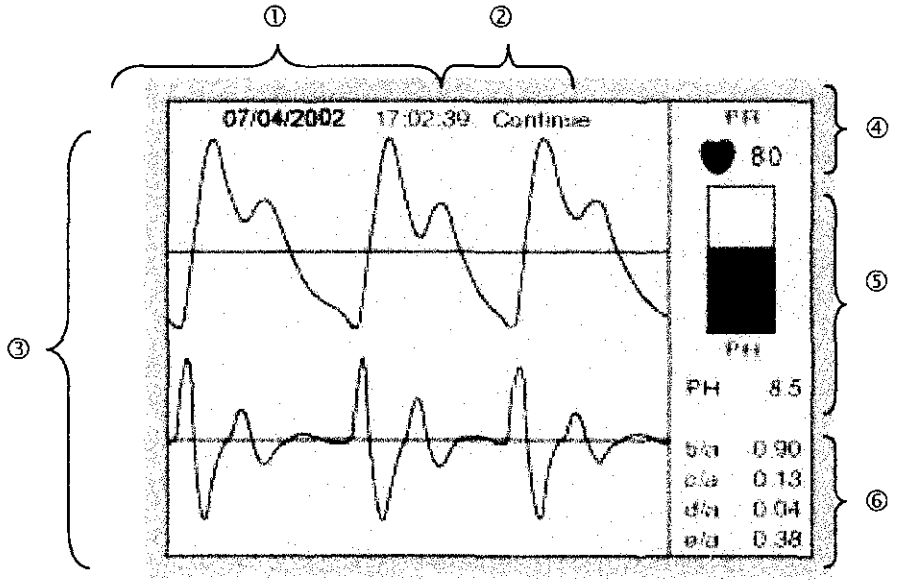

1. Finger probe
2. Terminal connected to main body

■ **Keypad**



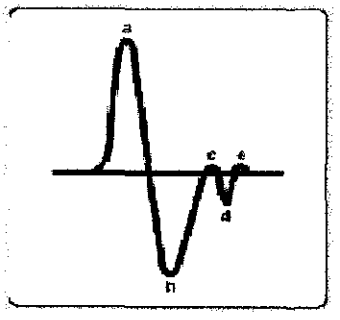

1. START/STOP Key : Start/Stop to display pulse waveform
2. PRINT Key : Print measurement results including pulse waveform and heart rate.
3. RESTART Key : Initiate the records of previous measurement record.
4. Left Arrow Key : Sweep speed down function of pulse waveform
5. Right Arrow Key : Sweep speed up function of pulse waveform
6. Digital Volume Key : Set up patient information, measurement time, reprint function, system clock.
7. POWER : If power is ON, LED radiates green.

■ **LCD Display**




1. Current date and time (system clock)
2. Current operating mode (Continuous measurement mode or Automatic measurement mode)
3. The measuring pulse waveform and second derivative pulse waveform
4. Heart rate
5. Displaying bar graph and digital value of pulse amplitude
6. Each peak ratios of second derivative pulse waveform

<Each peak point of second derivative pulse waveform>




- a : initial positive wave
- b : early negative wave
- c : re-increasing wave
- d : re-decreasing wave
- e : re-increasing wave



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# 4. How to use the device



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## 4.1 To prepare the McPulse for use: Installation

### 4-1-1 Connect the power cord

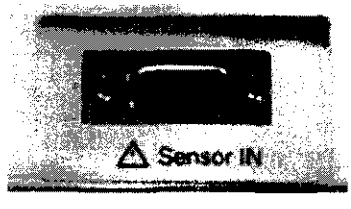
Connect power cable to AC power inlet of system.


1. *Power inlet*
2. Equipotential pole
3. Not used
4. Power ON/OFF switch
5. Not used
6. Not used

**CAUTION** To reduce electromagnetic noise emission, use an auxiliary power cord, supplied with the system, less than 2 meters long.

### 4-1-2 Connect the Measurement probe

Measurement probe is to be connected into the connector of right side panel.



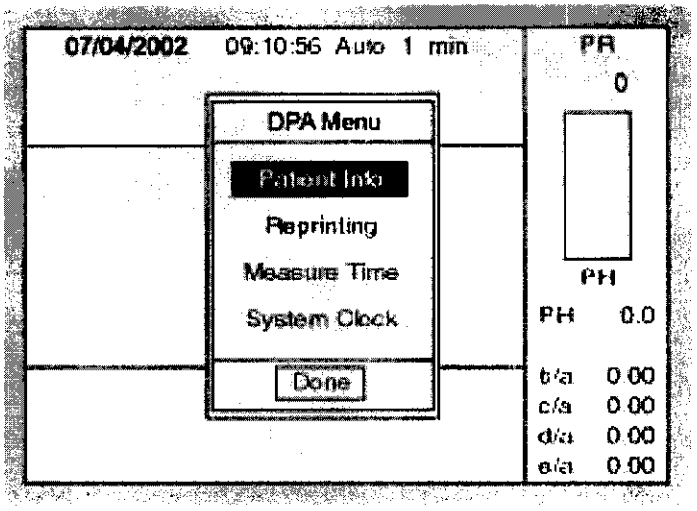

**WARNING** Don't pull or bend the probe cable.

## 4.2 Operating procedure of McPulse

- Turn on the power switch in rear part of system.
- The [POWER] LED on the front of system radiates green and it appears on initial LCD screen.
- Practitioner must lay patient on a bed or sit patient on a chair before measuring.
- If measurement preparation is completed, measure pulse wave of patient according to "4-2-2. Continuous measurement mode" or "4-2-3. Automatic measurement mode".

### 4-2-1 Setting menu

1. There are four user choices on menu. Press the knob on the front of system to access the each menu. The McPulse menu appears in LCD screen.
   After selecting this menu, press the knob to select the values and turn to left or right the knob to modify the values.
   After completing setting, move [ok] by using the knob, and then press the knob.




- Patient Info : Allows user to set the patient information, including ID, name, age, sex, height, weight, blood pressure.
- Reprinting : Allows user to select the reprinting function of measurement results. If user select this function, the current measurement results is printed out.

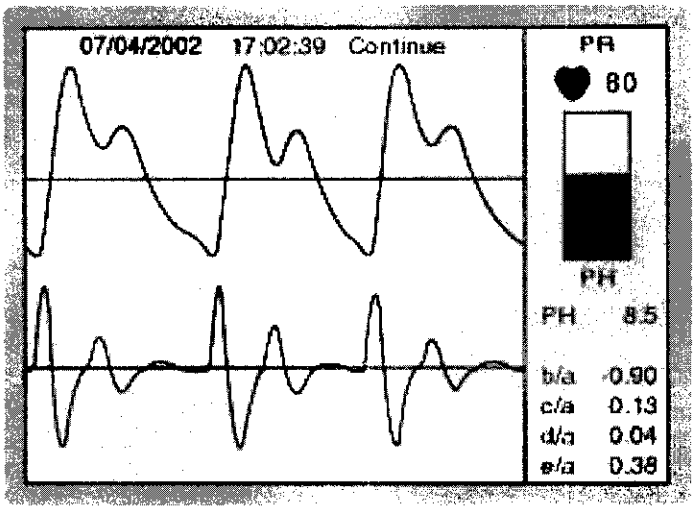
- Measure Time : Allows user to set the measurement mode, continuous mode and automatic measurement mode from 1 min. to 10 min.
- System clock : Allows user to set the system clock, date and time.

### 4-2-2 Continuous measurement mode

This mode measures the pulse wave of patient and displays measurement data on LCD screen continuously.
The measurement results are printed out by press [PRINT] key.

1. "Continue" displays on the above part of LCD screen.

2. The LCD screen displays the pulse waveform and heart rate of patient.




3. When the stable waveform is displayed on LCD screen, print the measurement results by pressing [PRINT] key.

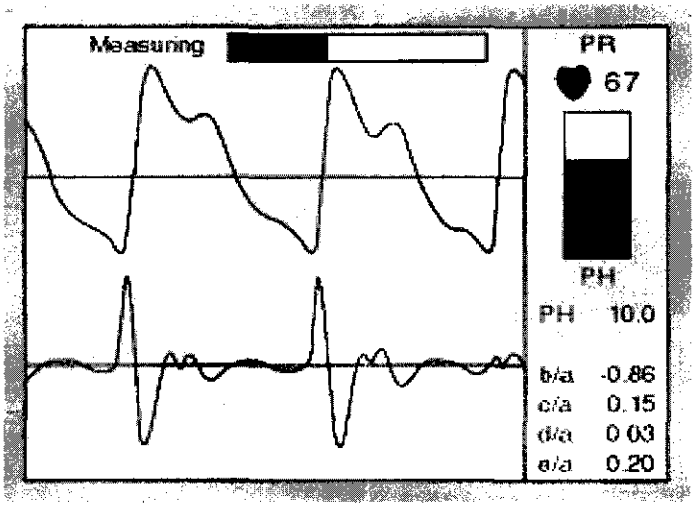
4. Press [RESTART] key to initialize measurement data of previous patient or measure new patient.

### 4-2-3 Automatic measurement mode

This mode displays the measurement data of patient on LCD screen during preset measurement time in menu. If the measurement process is completed, thermal printer prints out the measurement results automatically.

1. The preset measurement time in menu is displayed on above part of LCD screen.

2. When the stable waveform is displayed on LCD screen, press [RESTART] key.
   The system is initialized during 10 seconds and then displays pulse waveform of patient on LCD screen.
   During measurement process, LCD screen shows a bar indicating the elapsed measurement time.

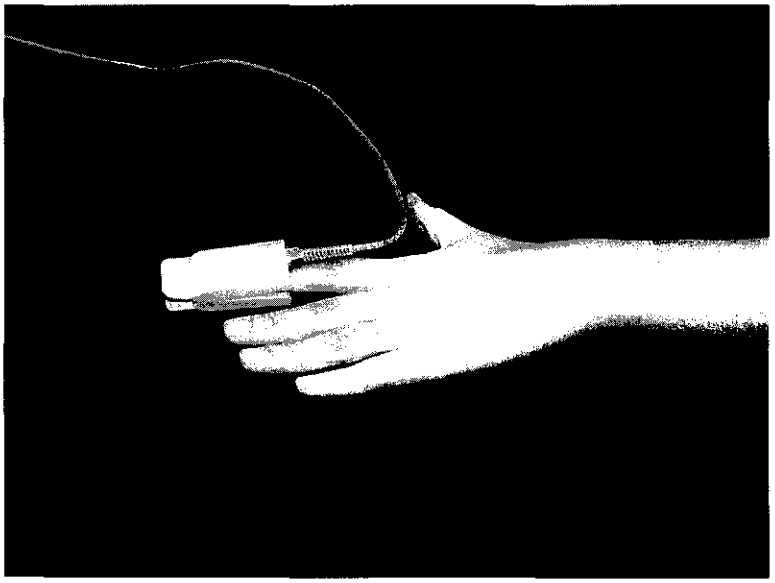



3. When the measurement process is completed, thermal printer prints out the measurement results.

4. Press [RESTART] key to initialize measurement data of previous patient or measure new patient.

### 4.3 Application method of measurement probe

User inserts second or third fingertip of patient into measurement probe as followng figure.



# Limited Warranty Statement

**Duration of Limited Warranty 2 years from the date of purchase**
(If the date of purchase is not proved, the Duration of warranty shall be considered 2.5years from the date of production)

## A. Extent of Limited Warranty

1. Meridian Co., Ltd.(MERIDIAN) warrants to the end-user customer that the MERIDIAN products specified above will be free from defects in materials and workmanship for the duration specified above. Customer is responsible for maintaining proof of date of receipt to fill in and inform(with fax, mail or email) to the attached "USER'S INFORMATION" sheet within 7days after receipt of the MERIDIAN product.

   (Attention : Overseas Sales and Marketing Manager)
   TEL : 82 2 2103 3300 FAX: 82 2 2103 3333
   address : 9Fl., Seoil Bldg., 222, Jamsilbon-Dong, Songpa-Gu, Seoul, Korea
   email : meridian@meridian.co.kr

2. MERIDIAN's limited warranty covers only those defects which arise as a result of normal use of the product and do not apply to any;
   a. Improper or inadequate maintenance or modification
   b. Operation outside the product's specification

3. If MERIDIAN products failure or damage is attributable to the use of non-MERIDIAN confirmation parts, MERIDIAN will charge its standard time and materials charges to service for the particular failure or damage.

4. If MERIDIAN receives, during the applicable warranty period, notice of a defect in any software, media or hardware which is covered by MERIDIAN warranty, MERIDIAN shall either repair or replace the defective product at MERIDIAN's option.

5. If MERIDIAN is unable to repair or replace as applicable, a defective product which covered by MERIDIAN's warranty, MERIDIAN shall, within a reasonable time after being notified of the defect, refund the purchase price for the product.

6. Any replacement product may be either new or like-new, provided that it has functionality at least equal to that of the product being replaced.

7. MERIDIAN's limited warranty is valid from any authorized MERIDIAN service facility where the product is distributed by MERIDIAN or by an authorized importer.

## B. Limitation of Warranty

To the extent allowed by local law, neither MERIDIAN nor its third party suppliers make any other warranty or condition of any kind, whether express or implied, with respect to the MERIDIAN products, and specifically disclaim the implied warranties or conditions of merchantability, satisfactory quality, and fitness for a particular purpose.

## C. Limitation of Liability

1. To the extent allowed by local law, the remedies provided in this Warranty Statement are the customer's sole and exclusive remedies.
2. To the extent allowed by local law, except for the obligations specifically set froth in this Warranty Statement, in no event shall MERIDIAN or its third party suppliers be liable for direct, indirect, special, incidental, or consequential damages, whether advised of the possibility of such damages.

**Meridian Co., Ltd. (MERIDIAN)**

**President** Hyungsu



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# USER'S INFORMATION SHEET

(Please fill in the blank and send us within 7days after receipt of product)

1. SERIAL NUMBER :_____
2. MODEL :_____
3. NAME :_____
4.POSITION : _____
5. MAJOR FIELD :_____
6. ADDRESS :_____

_____

_____

_____

7. TEL/FAX :_____

8.E-MAIL :_____

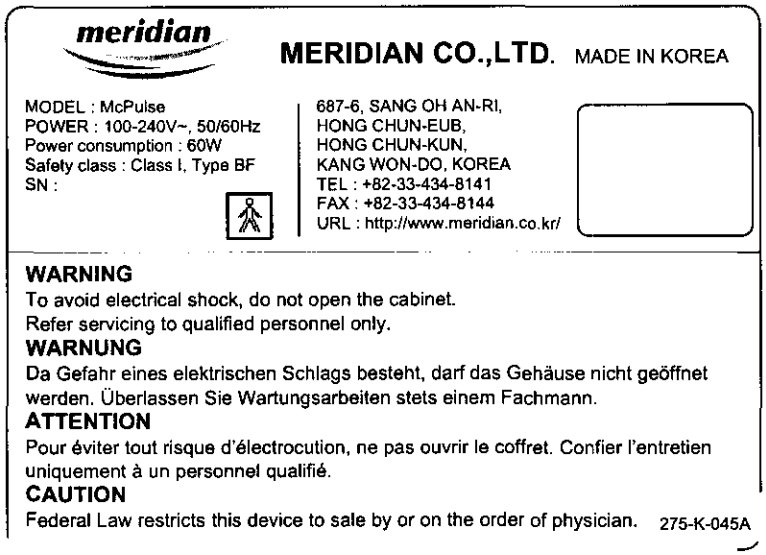
***USERS' ADVICE***

_____

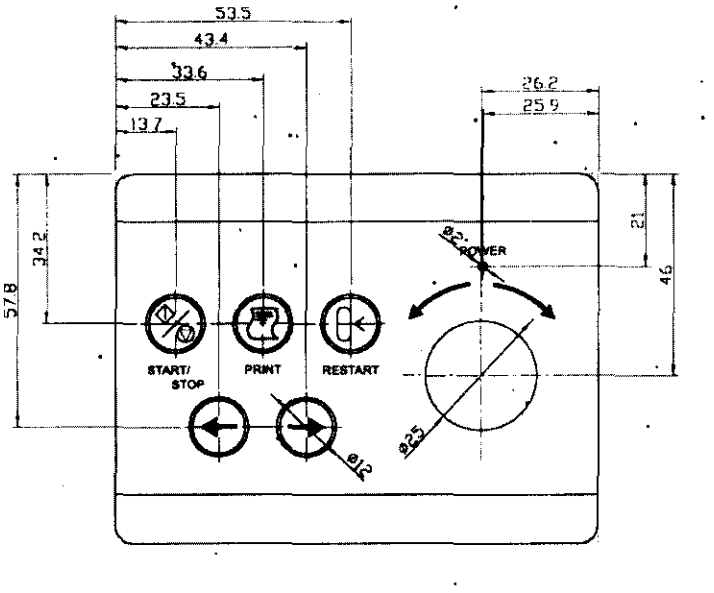
SIGNATURE

## McPulse Device Labels

## Product Label (draft): on the bottom of the device



**Key overlay : on the keypad(unit :mm)**



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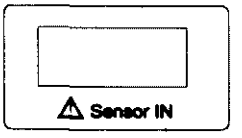
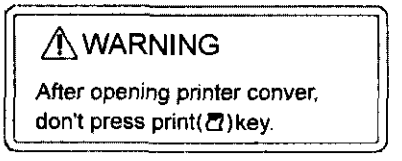
**Sensor connection label : on the sensor connector**



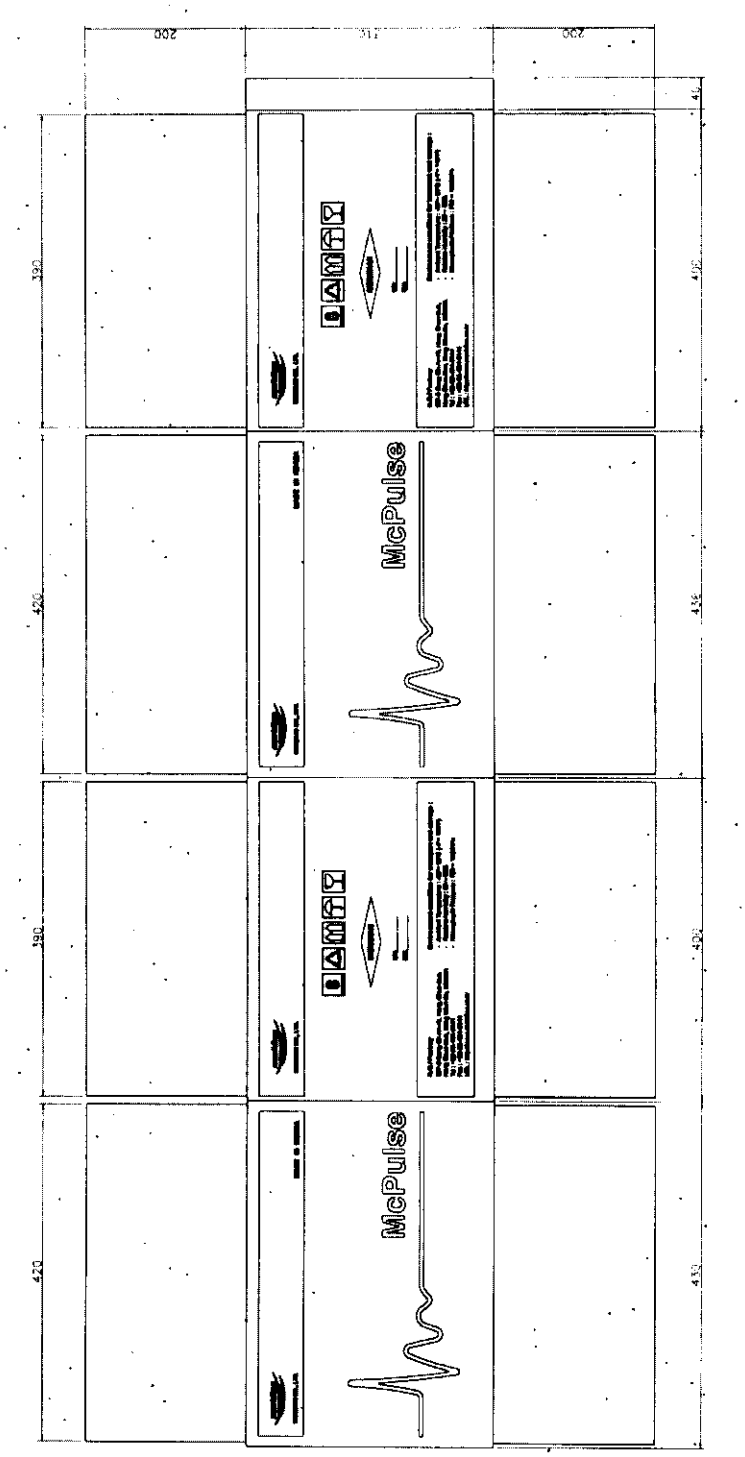

**Printer warning label : under printer open switch**




**Other labeling (on the surface of device)**

| Symbol | Description | Location |
|---|---|---|
| I | Power On | Power switch |
| O | Power Off | |
|  | Equipotential ground | under Equipotential terminal |

**Carton box (unit : mm)**



# EXHIBIT 4
## Description of Device



### 4.1 Description of the Device

The McPulse Photo-Plethysmograph is intended to be used to measure pulse waveform and heart rate in the finger by lighting a fingertip with combination of infrared LED and photodiode.
The measurement probe is an optoelectronic sensor consisted of a light-emitting diode(infrared LED) and a photodiode placed on opposite side as a light receiver.
The light from the LED is transmitted through the tissue at the sensor site and a photodiode in the sensor measures the transmitted light and this signal is used to determine how much light was absorbed.
This device converts the changes of transmitted light from a photodiode into a waveform and displays a graphic display of the pulse waveform on LCD screen.
Pulse rate is measured using the time between successive pulses and displayed digital values on LCD screen.

The McPulse system consists of an optoelectronic sensor that is applied to the patient and a microprocessor-based system that processes and displays the measurement.

The optoelectronic sensor contains a light-emitting diode(infrared LED) and one photodiode as a light receiver. The light from the LED is transmitted through the tissue at the sensor site. The photodiode in the sensor measures the transmitted light and this signal is used to determine how much light was absorbed. The signals received by the photodiode are small and may contain noise, so the first step involves amplification and filtering.
These signals are filtered using low pass filter to remove electrical and ambient noise, and then amplified by logarithm amplifier and linear amplifier.
And then these amplified signals are filtered by low pass filter and high pass filter to acquire the adequate pulse wave signals. The cutoff frequencies of low pass filter and high pass filter are 20Hz and 0.284Hz respectively.
Then using programmable DC offset eliminators and programmable gain amplifiers, the signals are multiplexed along with other analog signals prior to being fed into an A/D converter. Offset amplifiers offset the signals by a small positive level. This ensure that the offsets caused by chain of amplifiers do not allow the signal to be negative as this is the input to the A/D converter, and the A/D converter only accepts inputs from 0 to 5V.

A/D converter used in this device is 12 bit plus sign, parallel I/O, self-calibrating, sampling analog-to-digital converter and the sampling rate is 800Hz.
The signals transmitted into A/D converter are digitized and these digital signals are transmitted into a digital board and processed by the microprocessor to identify individual pulses.

The digital board has microprocessor and Peripheral control block mainly. On the digital board, the system calculates heart rate and displays the measured pulse waveform and twice differentiated pulse waveform on the LCD simultaneously.
This device applies Tayler Series to differentiate pulse waveform. The sampling rate of this Tayler Series is 400Hz.
During once differentiating process, the once differentiated signal is 5 samples(12.5ms) late than original pulse waveform. Therefore during twice differentiating process, the twice differentiated signal is 10 samples(25ms) late than original pulse waveform.
The MCPULSE software calculates this late time and then displays pulse waveform and twice differentiated waveform in same time on LCD screen.

The microprocessor block is consists of master CPU, Flash ROM, SDRAM and controls Peripheral control block and display block. CPU block also sends the audio signal to buzzer. The Peripheral control block controls thermal printer and keypad.

## 4.2 Photo: McPulse Photoelectric Plethysmograph

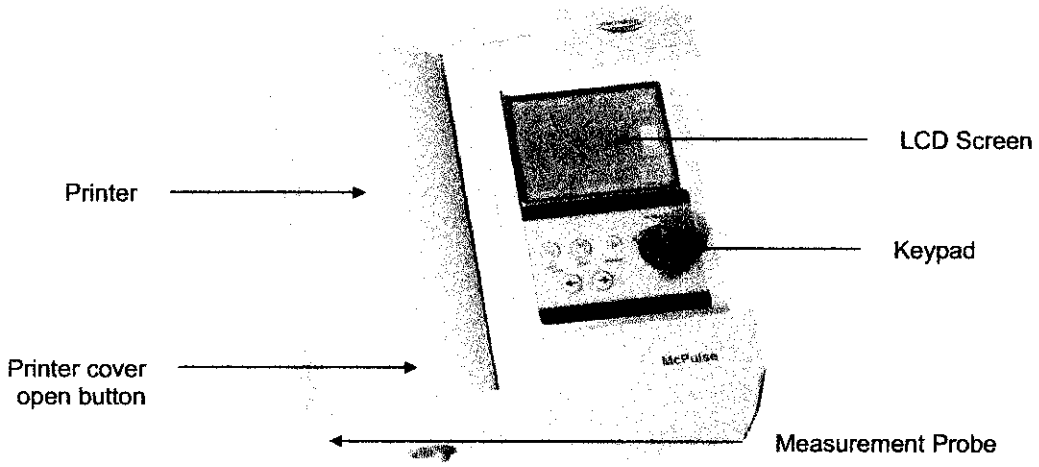



Fig. 1

McPulse view

- McPulse Dimensions (mm)
  - 305.5(W) x 296(H) x 92.5(D) mm
  - Weight : 5.5kg

## 4.3 Measurement Probe

This probe is used to measure pulse waveform and heart rate of fingertip. It is an optoelectronic sensor composed of an infrared LED and a photodiode.
An infrared LED is emitted into the skin of fingertip and more or less light is absorbed, depending on the blood volume in the skin. Consequently, the backscattered light



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corresponds with the variation of the blood volume and a photodiode measures this backscattered light.
This signal is used to determine how much light was absorbed.

A infrared LED is an optoelectronic semiconductor and the material of this LED is gallium aluminum arsenide, GaAlAs.
The wavelength of an infrared LED is 889nm(typ.).

The measurement probe is to be connected into connector of side panel of McPulse main body.

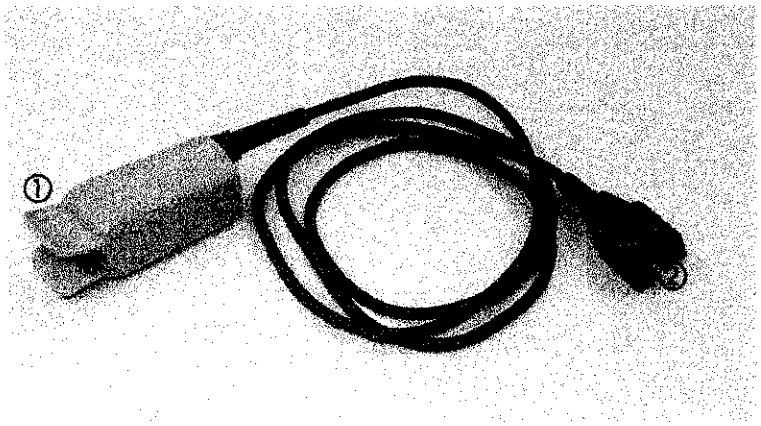


Fig 4. Measurement probe

Dimensions :
Length : 2000 ± 50 mm

Features :
① Finger probe
② Terminal connected to main body



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Photo 2. Measurement probe

4.3.1 Inner view of probe

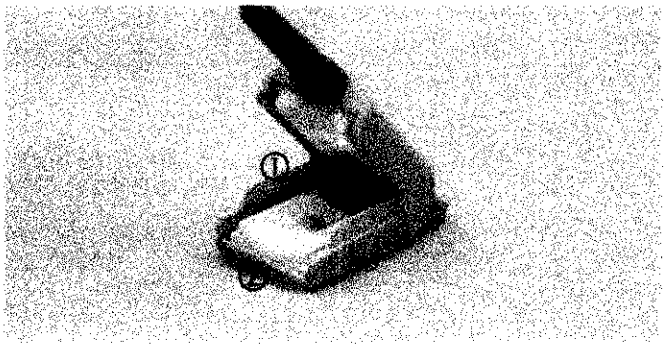


Fig. 5 Inner view of probe

1 Infrared LED : emits light to fingertip.
2 Photodiode : detects the transmitted light used to determine how much light was absorbed as blood flow changes in the fingertip.

4.3.2 Application method of probe
User inserts second or third fingertip of patient into measurement probe.

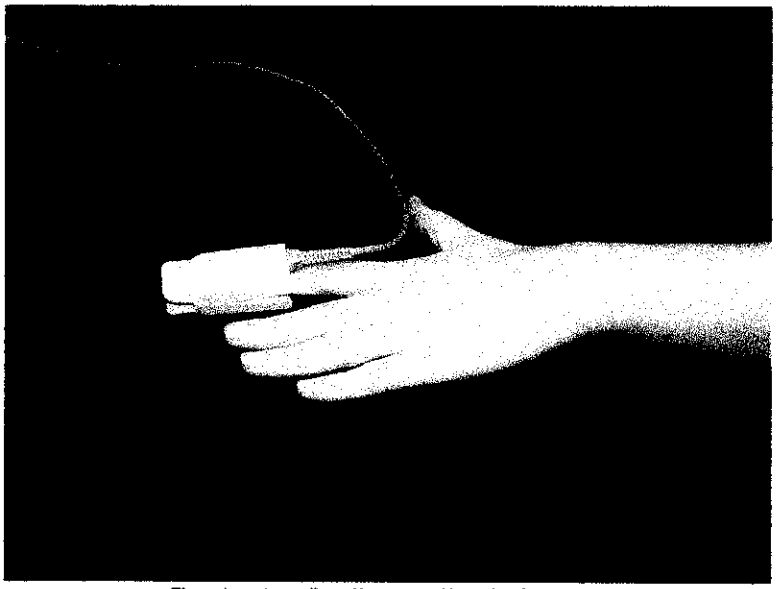
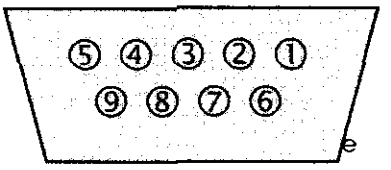


Fig. 6 Application method of probe

4.3.3 Terminal of probe




1. : Reference 2.75V
2. : IR Driver IN
3. : Not used
4. : Not used
5. : Sensor Out
6. : GND
7. : GND
8. : Not used
9. : Vcc

NOTE :
If the cable of measurement probe is mis-connected, there is no danger to the patient. It cannot be plugged accidentally into an AC outlet.

## 4.4 Control Panel

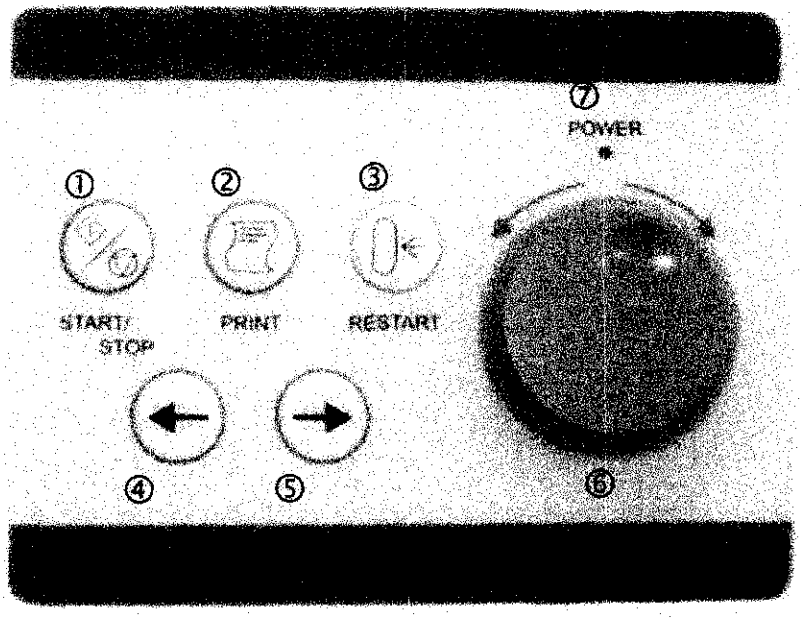



Fig. 8 Control panel

1 START/STOP Key : Start/Stop to display pulse waveform
2 PRINT Key : Print measurement results including pulse waveform and heart rate.
3 RESTART Key : Initiate the records of previous measurement record.
4 Left Arrow Key : Sweep speed down function of pulse waveform
5 Right Arrow Key : Sweep speed up function of pulse waveform
6 Knob : Setting patient information, measurement time, reprint function, system clock.
7 POWER : If power is ON, LED radiates green.

## 4.5 Displays

The McPulse has an easy-to-read LCD display that presents the menu and status information including pulse waveform and heart rate.

4.5.1 Continuous measurement mode

The following screen appears continuous measurement mode. The pulse waveform is displayed on LCD screen continuously and measurement results are printed through thermal printer by pressing [PRINT] key.

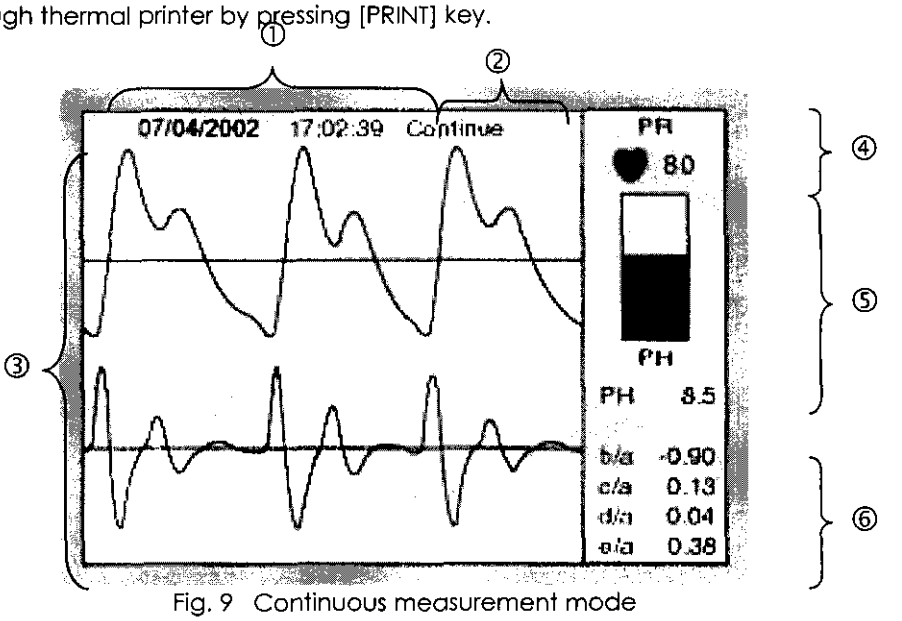



Fig. 9 Continuous measurement mode

- ? Current date and time (system clock)
- ? Current operating mode (continuous measurement mode or Automatic measurement mode)
- ? The measuring pulse waveform and second derivative pulse waveform
- ? Heart rate
- ? Displaying bar graph and digital value of pulse amplitude
- ? Each peak ratios of second derivative pulse waveform

4.5.2 Automatic measurement mode

The following screen appears automatic measurement mode.
This mode displays the measurement data of patient on LCD screen during preset measurement time in menu.
If the measurement process is completed, thermal printer prints out the measurement results automatically.
And during measurement process, LCD shows a bar indicating the elapsed measurement time.



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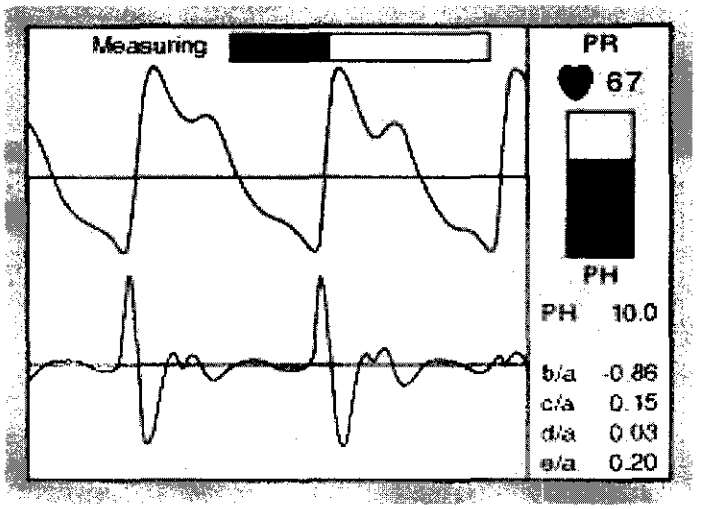


Fig. 10 Automatic measurement mode

4.5.3 Setting menu

The following screen appears main menu to set patient information, measurement time, reprint function of measurement results and system clock.
User can set the values of each menu using the knob on front of system.

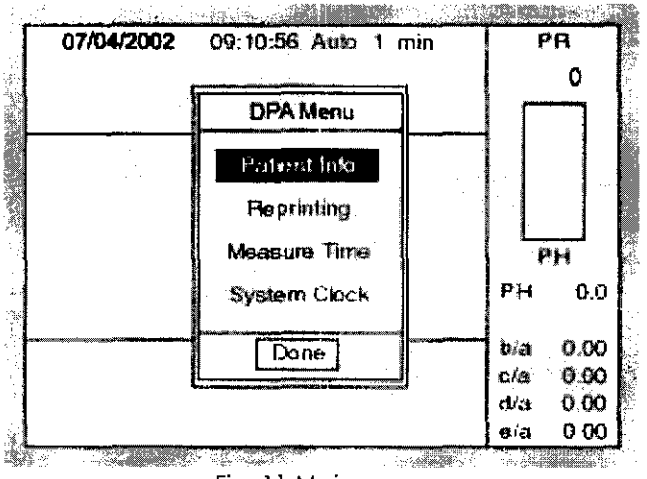


Fig. 11 Main menu

## 4.6 Connections

4.6.1 INPUT – for measurement probe
This connector locates in left side part of main body.

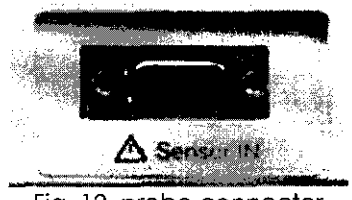

Fig. 12 probe connector

Sensor IN : terminal connected by measurement probe

4.6.2 OUTPUT
This connectors locate in rear part of main body.

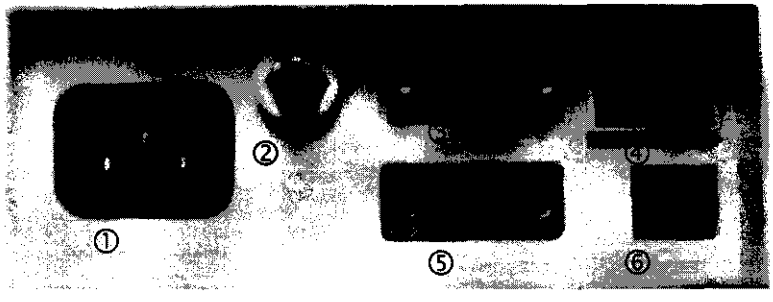

Fig. 13 connectors of rear part

1. Power inlet
2. Equipotential pole
3. Not used
4. Power ON/OFF switch
5. Not used
6. Not used



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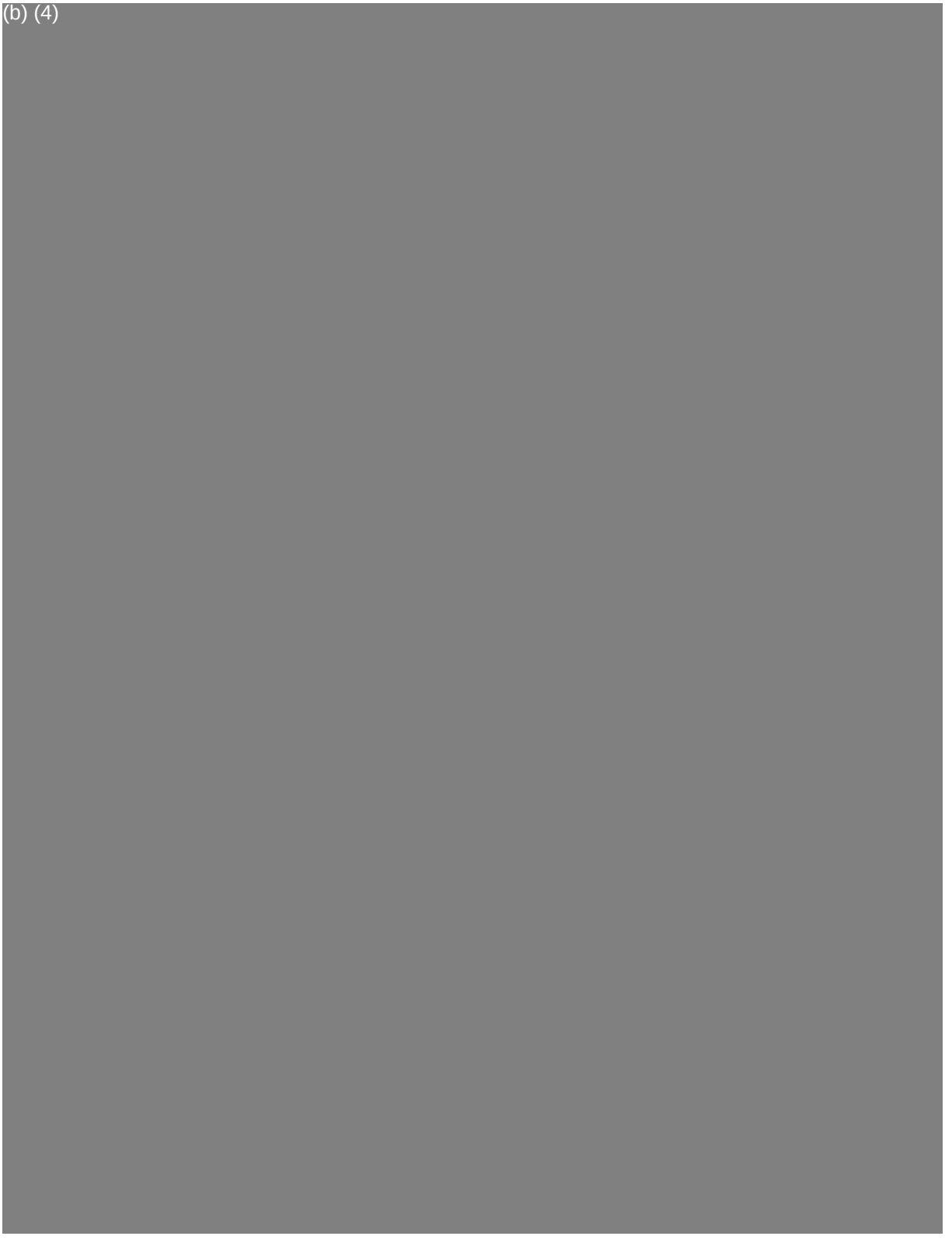
## 4.7 Engineering Drawings

(b) (4)





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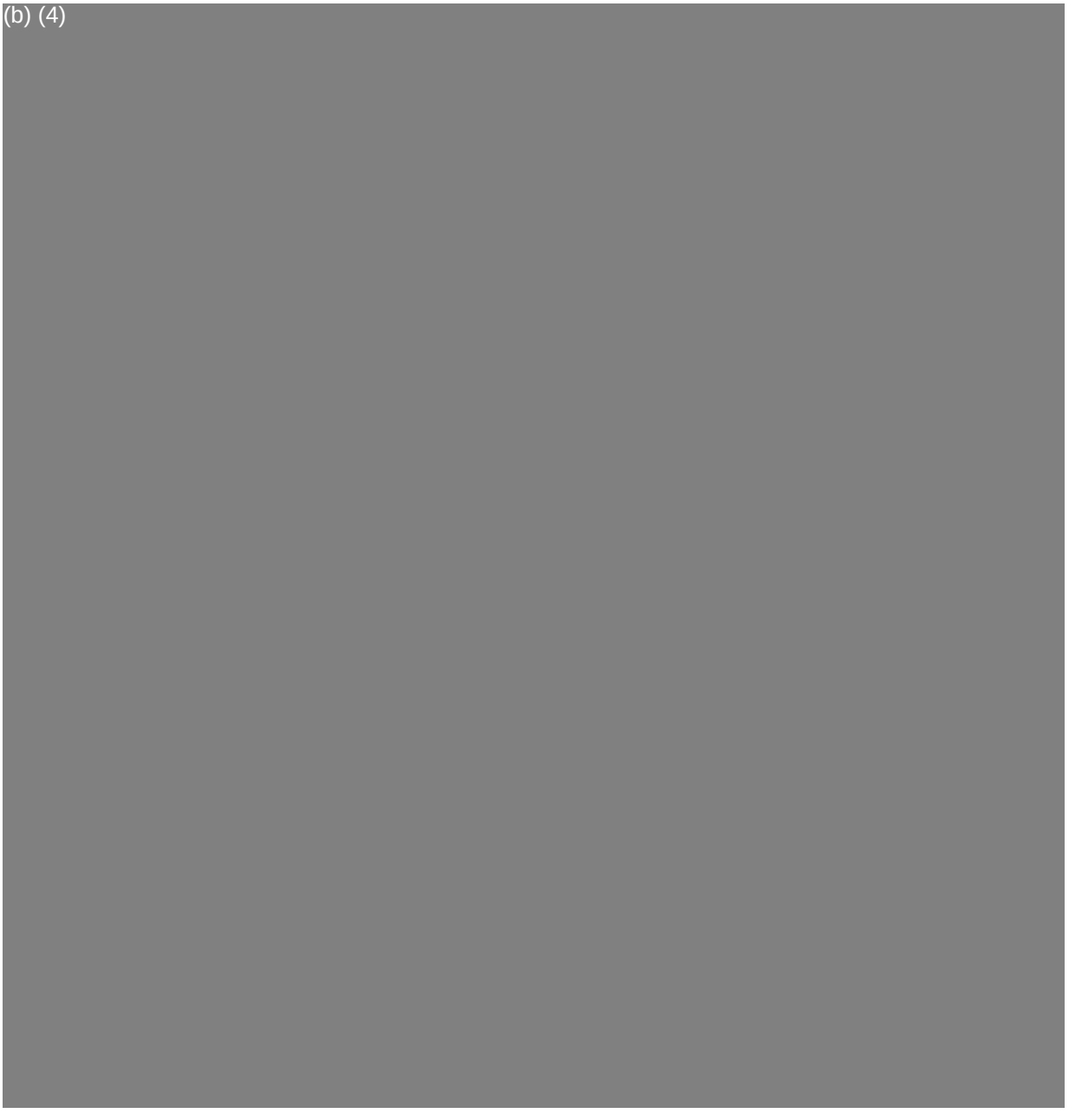
(b) (4)



## 4.8 Bill of Materials

| Component No | Description | Technical data or Material |
|---|---|---|
| (b) (4) | | |

**Bill of Materials, continued.**

| Component No. | Description | Technical data or Material |
|---|---|---|
| (b) (4) | [redacted] | [redacted] |

### 4.8 Safety Characteristics

The McPulse has been designed to conform to the following standards:

1. IEC 60601-1, Safety of Medical Electrical Equipment, Part 1, General Requirements for Safety, including Amendment 1 and 2.
2. EN 60601-1-2 first edition, Standard for Electromagnetic Compatibility.

Electrical safety of the McPulse is achieved by means of reinforced or double insulated parts. Electrical isolation of at least 4000Vac between Applied part (patient circuit) and Live Part. This electrical isolation is in accordance with IEC 60601-1.
Patient leakage current (Current flowing from the APPLIED PART via PATIENT to earth or flowing from the PATIENT via a F-TYPE APPLIED PART to earth originating from the unintended appearance of a voltage from an external source on the PATIENT) is certified to be less than 100μA.

Enclosure leakage current (Current flowing from the ENCLOSURE or from parts thereof, excluding APPLIED PARTS, accessible to the OPERATOR or PATIENT in NORMAL USE, through an external CONDUCTIVE CONNECTION other than the PROTECTIVE EARTH CONDUCTOR to earth or to another part of the ENCLOSURE) are certified to be less than 100μA.

Attached in Exhibit 8: Test report (Medical 2001-261, issued by Korean Electric Testing Institute)

## 4.9 In-Process Inspection Standard (Performed on every unit)

| meridian | Quality Instruction | Document No. | MQI-BC-007 |
|---|---|---|---|
| | | Date of Issue | 2001-09-27 |
| | | Revision No. | 0 |
| | In-process Inspection Standard | Revision Date | - |
| | | Page | 1/6 |

| Item | Specification | Method | Tools | Remark |
|---|---|---|---|---|
| LEAKAGE CURRENT | (b) (4) | | | All products are checked by inspection and test results are recorded in certification sheet (MM-QA-95). |
| Dielectric Strength | | | | All products are checked by inspection and test results are recorded in certification sheet (MM-QA-94). |



L07

| meridian | Quality Instruction | Document No. | MQI-BC-007 |
|---|---|---|---|
| | | Date of Issue | 2001-09-27 |
| | | Revision No. | 0 |
| | In-process Inspection Standard | Revision Date | - |
| | | Page | 2/6 |

| Item | Specification | Method | Tools | Remark |
|---|---|---|---|---|
| BURN-IN TEST | (b) (4) | | | All products are checked by inspection and test results are recorded in certification sheet (MM-PD-030). |
| SYSTEM INPECTI | | | | |
| INITINAL TEST | | | | All products are checked by inspection and test results are recorded in certification sheet (MM-PD-030). |
| Measurement probe | | | | |



801

| meridian | Quality Instruction | Document No. | MQI-BC-007 |
|---|---|---|---|
| | | Date of Issue | 2001-09-27 |
| | | Revision No. | 0 |
| | In-process Inspection Standard | Revision Date | - |
| | | Page | 3/6 |

| Item | Specification | Method | Tools | Remark |
|---|---|---|---|---|
| FUNCTION INSPECTION | | | | |
| LCD | (b) (4) | | | All products are checked by inspection and test results are recorded in certification sheet (MM-PD-030). |
| KEYBOARD | | | | |
| BUZZER | | | | |
| POWER SWITCH | | | | |
| GENERAL INSPE | | | | |
| LABEL | | | | All products are checked by inspection and test results are recorded in certification sheet (MM-PD-030). |
| ENCLOSURE | | | | |



b01

| meridian | Quality Instruction | Document No. | MQI-BC-007 |
|---|---|---|---|
| | | Date of Issue | 2001-09-27 |
| | | Revision No. | 0 |
| | In-process Inspection Standard | Revision Date | - |
| | | Page | 4/6 |

| Item | Specification | Method | Tools | Remark |
|---|---|---|---|---|
| PERFORMANCE INSPECTION | | | | |
| SENSOR CONTROL SIGNAL | (b) (4) | | | All products are checked by inspection and test results are recorded in certification sheet (MM-PD-030). |
| IR LED DRIVER WAVEFORM | | | | |



011

| meridian | Quality Instruction | Document No. | MQI-BC-007 |
|---|---|---|---|
| | | Date of Issue | 2001-09-27 |
| | | Revision No. | 0 |
| | In-process Inspection Standard | Revision Date | - |
| | | Page | 5/6 |

| Item | Specification | Method | Tools | Remark |
|---|---|---|---|---|
| BOARD DEBUGGING TEST | | | | |
| LOG AMP OUTPUT WAVEFORM | (b) (4) | | | All products are checked by inspection and test results are recorded in certification sheet (MM-PD-030). |
| PULSE WAVEFORM | | | | |



111

| meridian | Quality Instruction | Document No. | MQI-BC-007 |
|---|---|---|---|
| | | Date of Issue | 2001-09-27 |
| | | Revision No. | 0 |
| | In-process Inspection Standard | Revision Date | - |
| | | Page | 6/6 |

| Item | Specification | Method | Tools | Remark |
|---|---|---|---|---|
| PERFORMANCE INSPECTION | | | | |
| HEART RATE | (b) (4) | | | All products are checked by inspection and test results are recorded in certification sheet (MM-PD-030). |
| PULSE WAVEFROM | | | | |
| PULSE AMPLITUDE | | | | |



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### 4.10 Final Inspection Standard (Performed on every unit)

| meridian | Quality Instruction | Document No. | MQI-AO-008 |
|---|---|---|---|
| | | Date of Issue | 2001-09-01 |
| | | Revision No. | 0 |
| | Final Inspection Standard | Revision Date | - |
| | | Page | 1/4 |

| Item | Specification | Method | Tools | Remark |
|---|---|---|---|---|
| Leakage current | (b) (4) | | | All products are checked by inspection and test results are recorded in certification sheet (MM-QA-95). |
| Dielectric Strength | | | | All products are checked by inspection and test results are recorded in certification sheet (MM-QA-94). |



h11

| meridian | Quality Instruction | Document No. | MQI-AO-008 |
|---|---|---|---|
| | | Date of Issue | 2001-09-01 |
| | | Revision No. | 0 |
| | Final Inspection Standard | Revision Date | - |
| | | Page | 2/4 |

| Item | Specification | Method | Tools | Remark |
|---|---|---|---|---|
| SYSTEM INPECTION | | | | |
| INITINAL TEST | (b) (4) | | | All products are checked by inspection and test results are recorded in certification sheet (MM-QA-104). |
| Measurement probe | | | | |
| FUNCTION INSP | | | | |
| LCD | | | | All products are checked by inspection and test results are recorded in certification sheet (MM-QA-104). |
| KEYBOARD | | | | |



511

| meridian | Quality Instruction | Document No. | MQI-AO-008 |
|---|---|---|---|
| | | Date of Issue | 2001-09-01 |
| | | Revision No. | 0 |
| | Final Inspection Standard | Revision Date | - |
| | | Page | 3/4 |

| Item | Specification | Method | Tools | Remark |
|---|---|---|---|---|
| BUZZER | (b) (4) | | | All products are checked by inspection and test results are recorded in certification sheet (MM-QA-104). |
| POWER SWITCH | | | | |
| GENERAL INSPE | | | | |
| LABEL | | | | All products are checked by inspection and test results are recorded in certification sheet (MM-QA-104). |
| ENCLOSURE | | | | |
| PERFORMANCE I | | | | |
| HEART RATE | | | | All products are checked by inspection and test results are recorded in certification sheet (MM-QA-104). |



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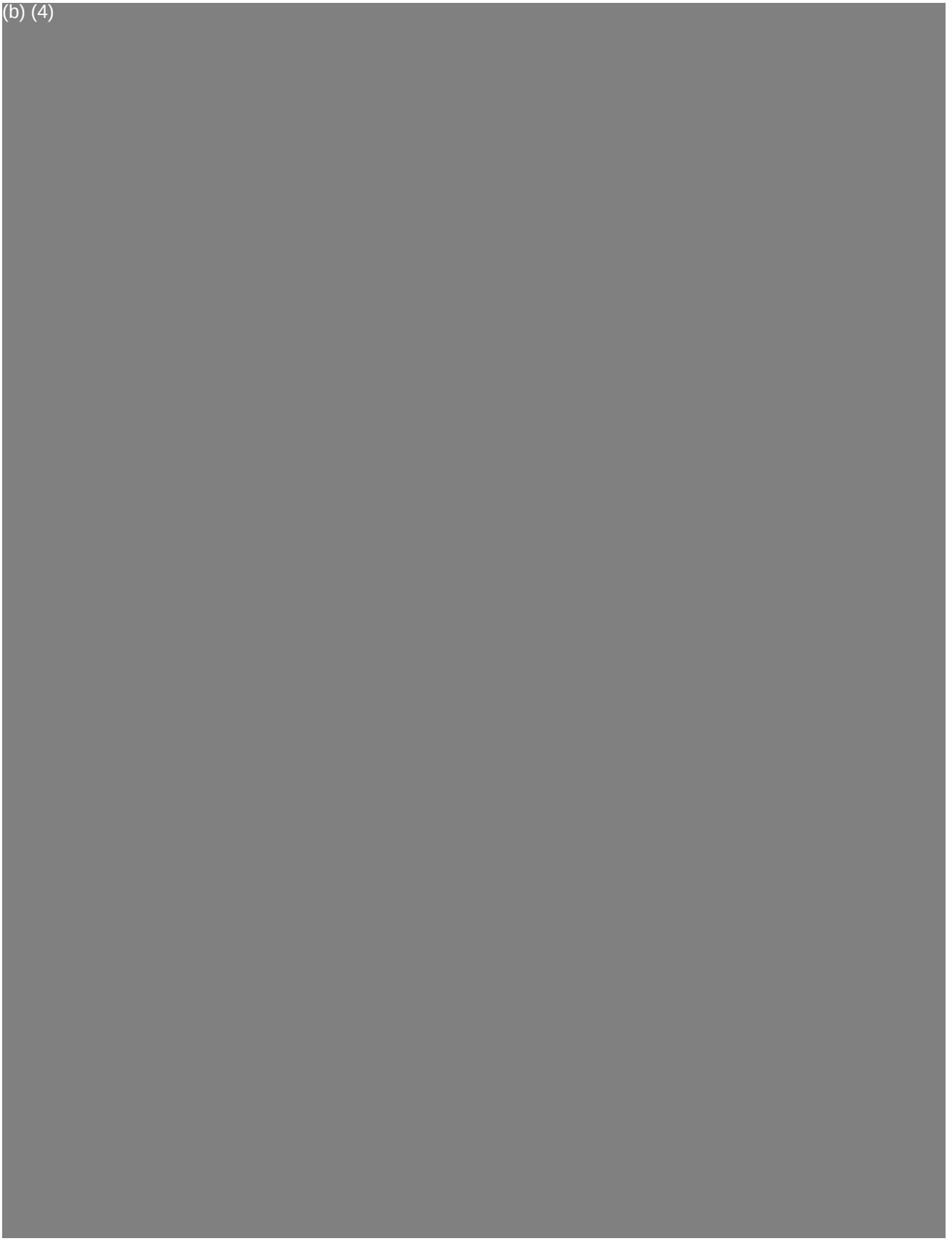
| meridian | Quality Instruction | Document No. | MQI-AO-008 |
|---|---|---|---|
| | | Date of Issue | 2001-09-01 |
| | | Revision No. | 0 |
| | Final Inspection Standard | Revision Date | - |
| | | Page | 4/4 |

| Item | Specification | Method | Tools | Remark |
|---|---|---|---|---|
| PULSE WAVEFROM | (b) (4) | | | All products are checked by inspection and test results are recorded in certification sheet (MM-QA-104). |
| PULSE AMPLITUDE | | | | |

## 4.11 Completed In-Process Inspection Report (Performed on every unit)

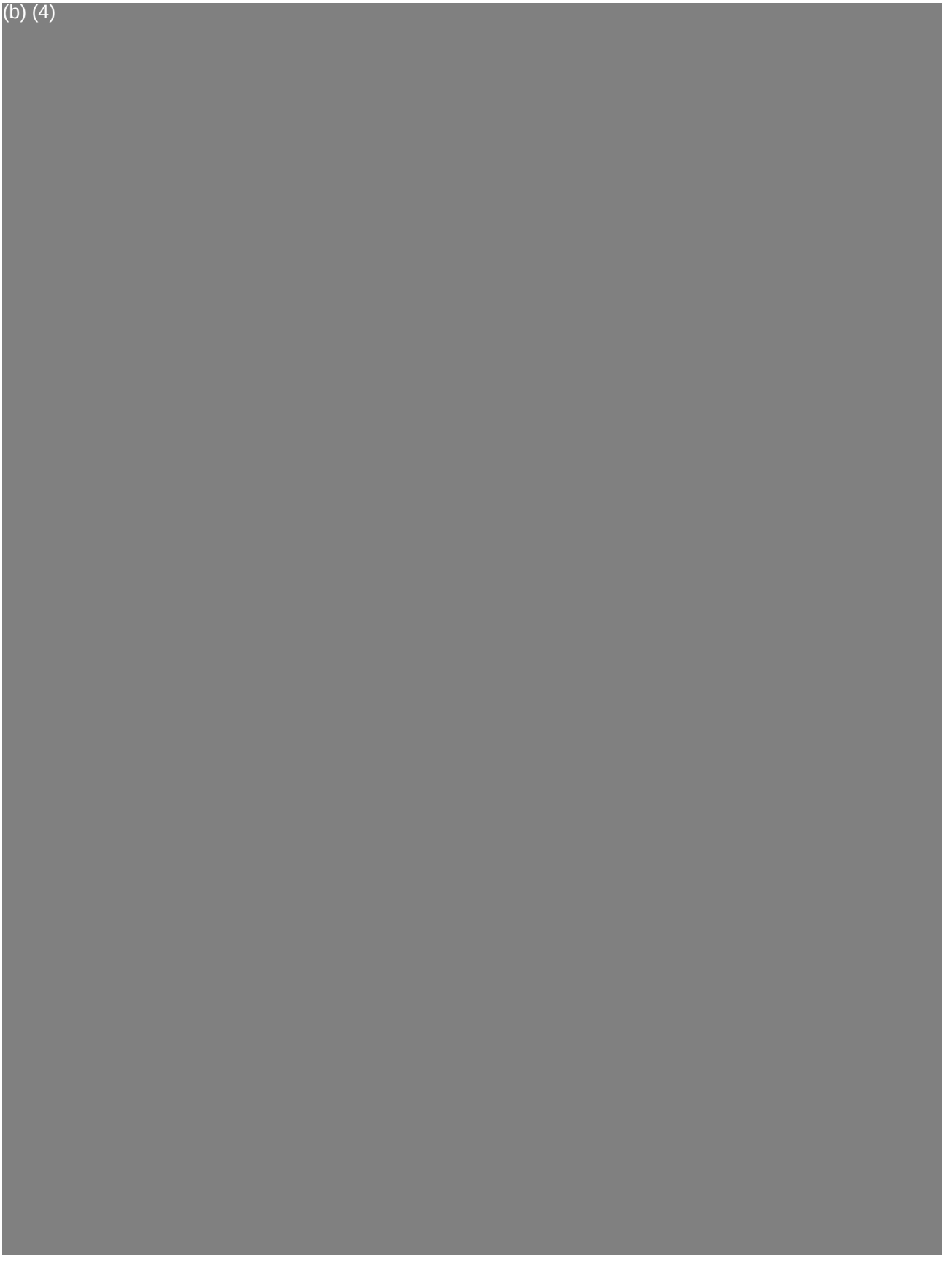
# IN-PROCESS INSPECTION REPORT

(b) (4)



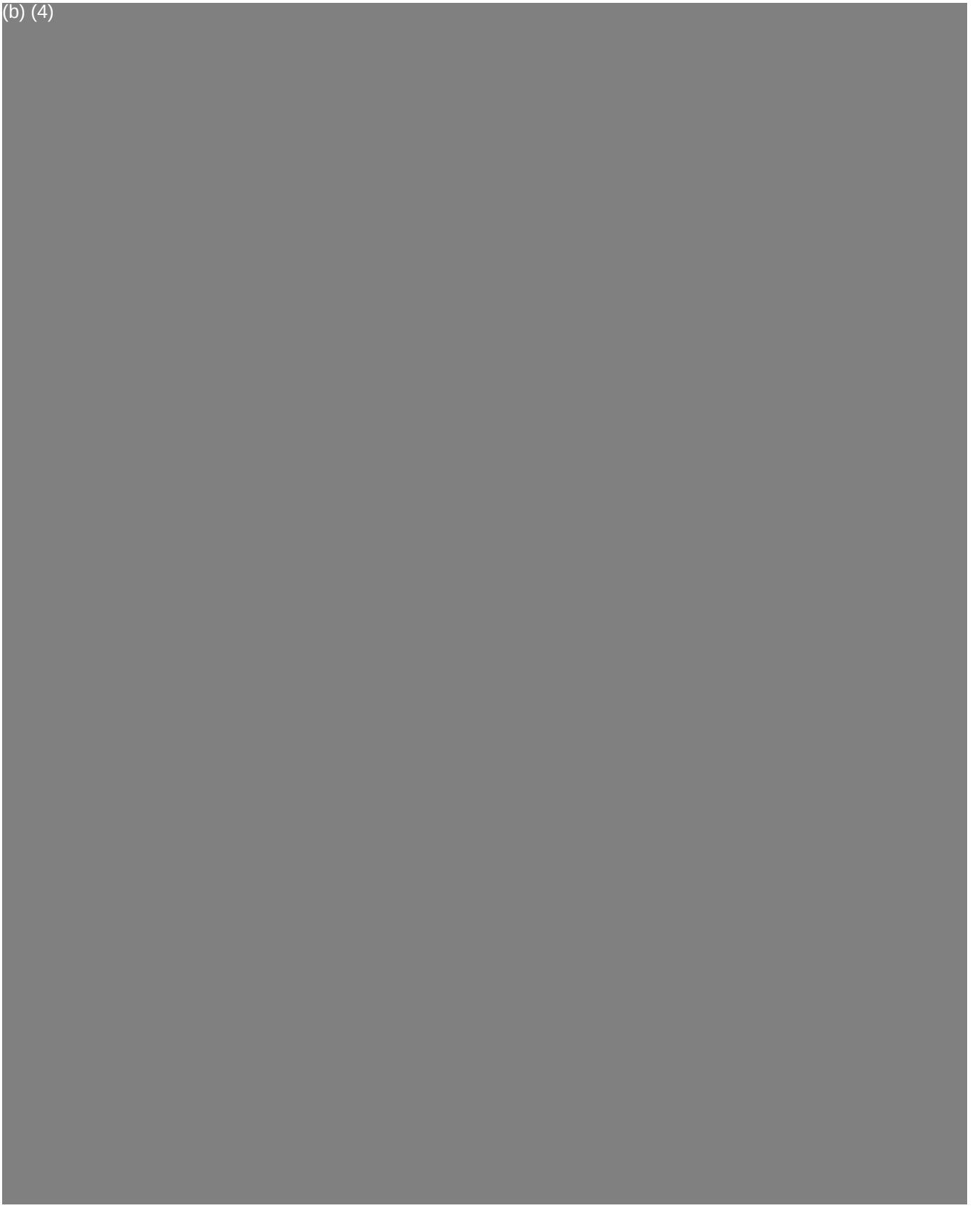
# IN-PROCESS INSPECTION REPORT

(b) (4)



# IN-PROCESS INSPECTION REPORT

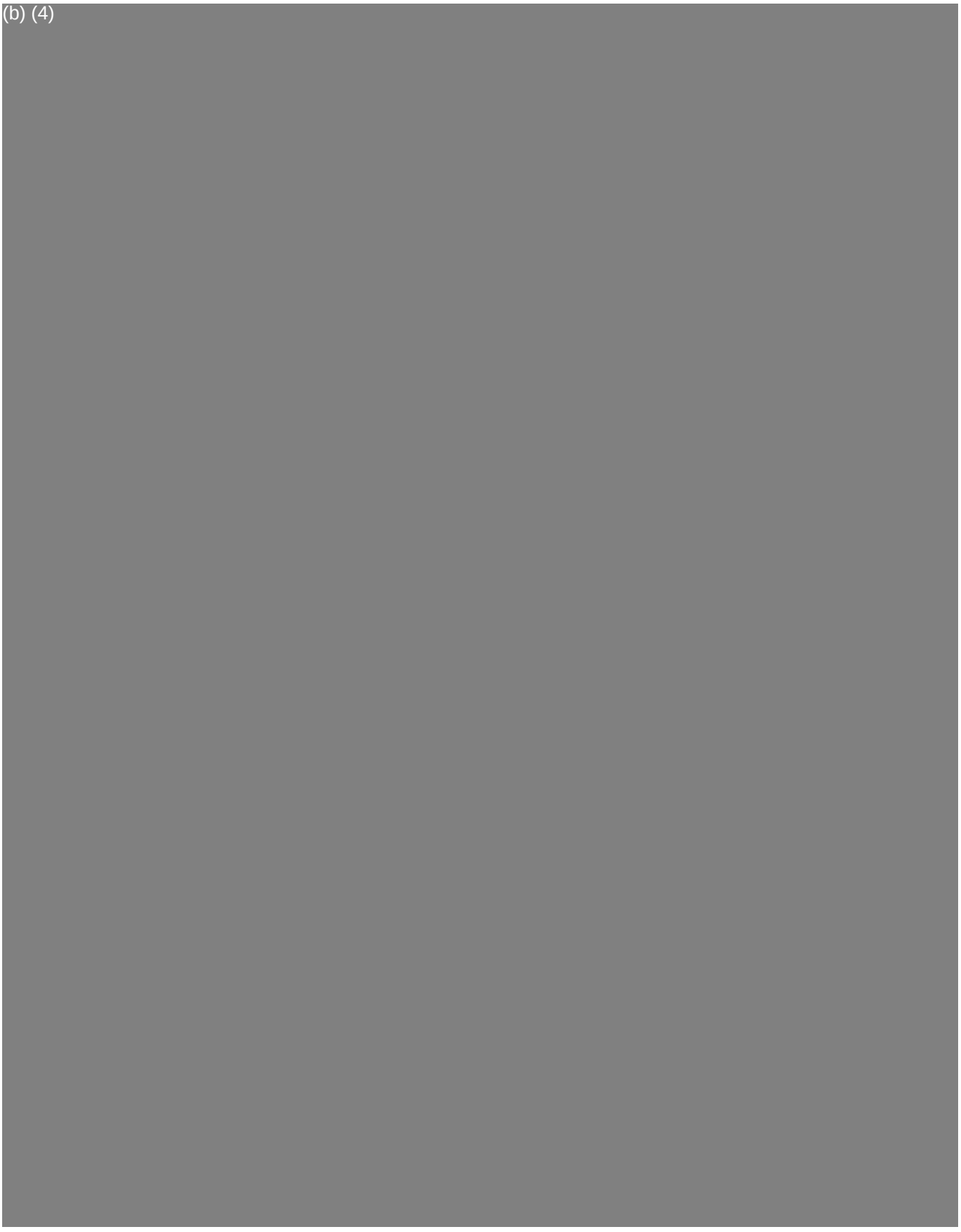
(b) (4)



## 4.12 Completed Final Inspection Report (Performed on every unit)

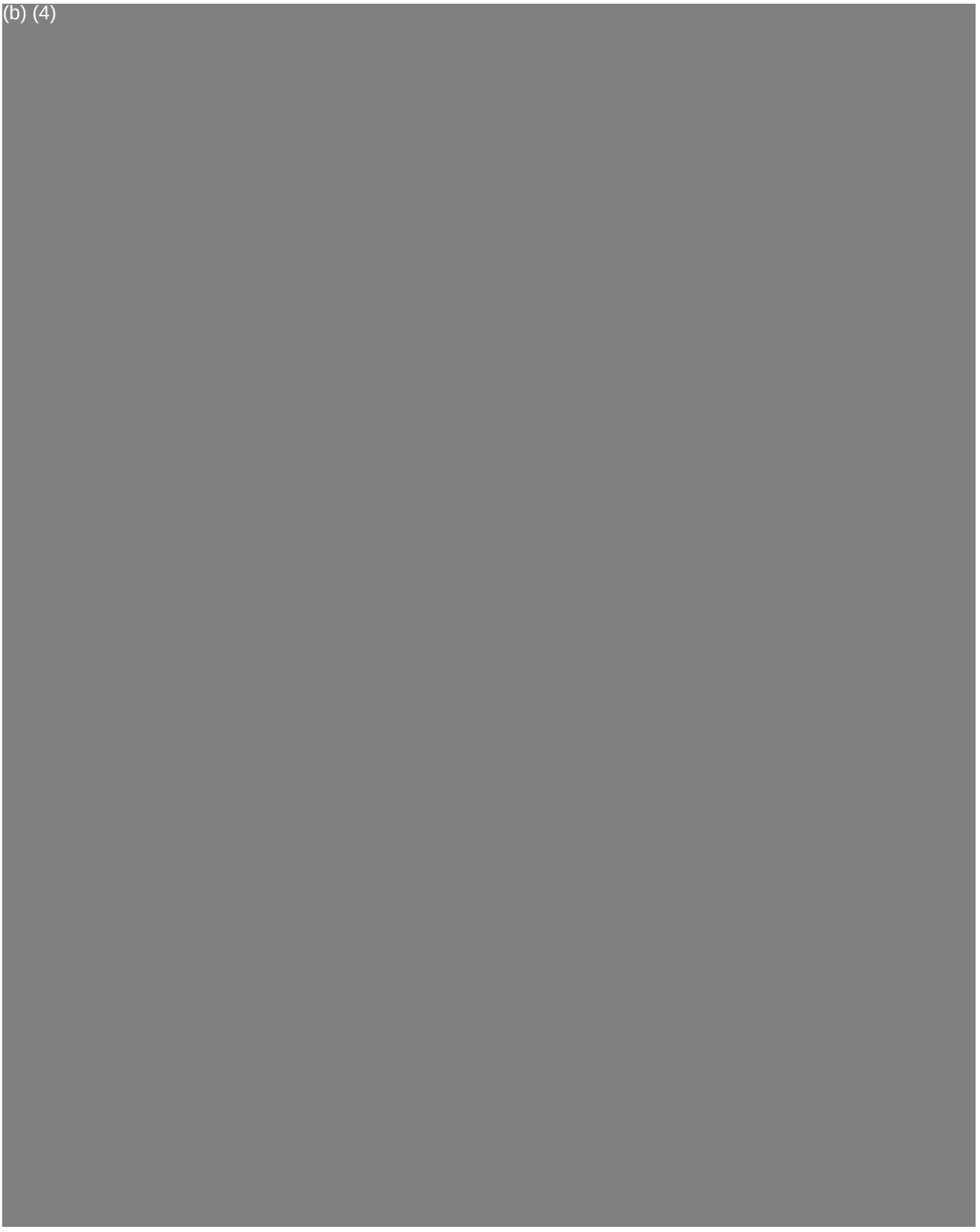
# FINAL INSPECTION REPORT

(b) (4)



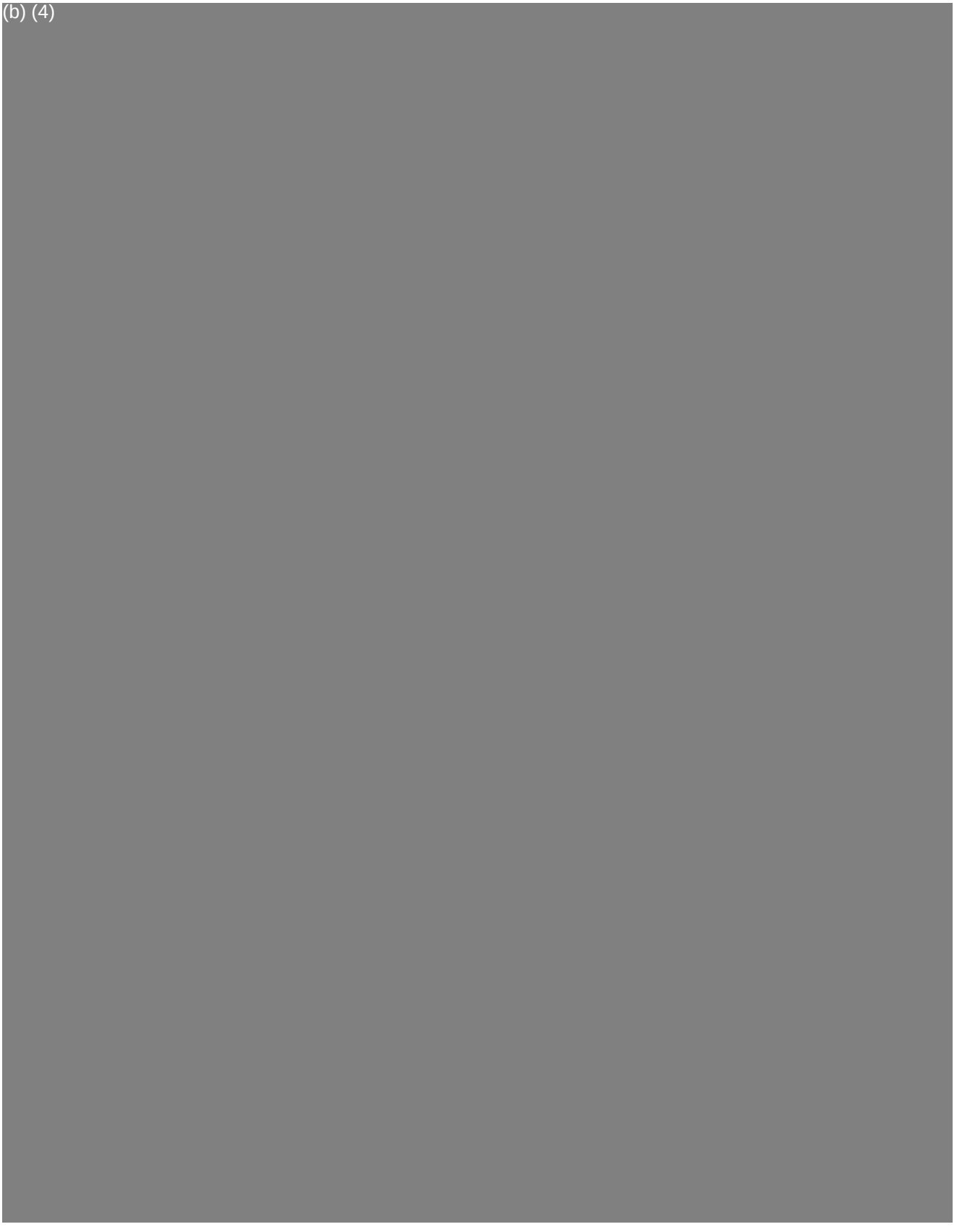
# FINAL INSPECTION REPORT

(b) (4)



# FINAL INSPECTION REPORT

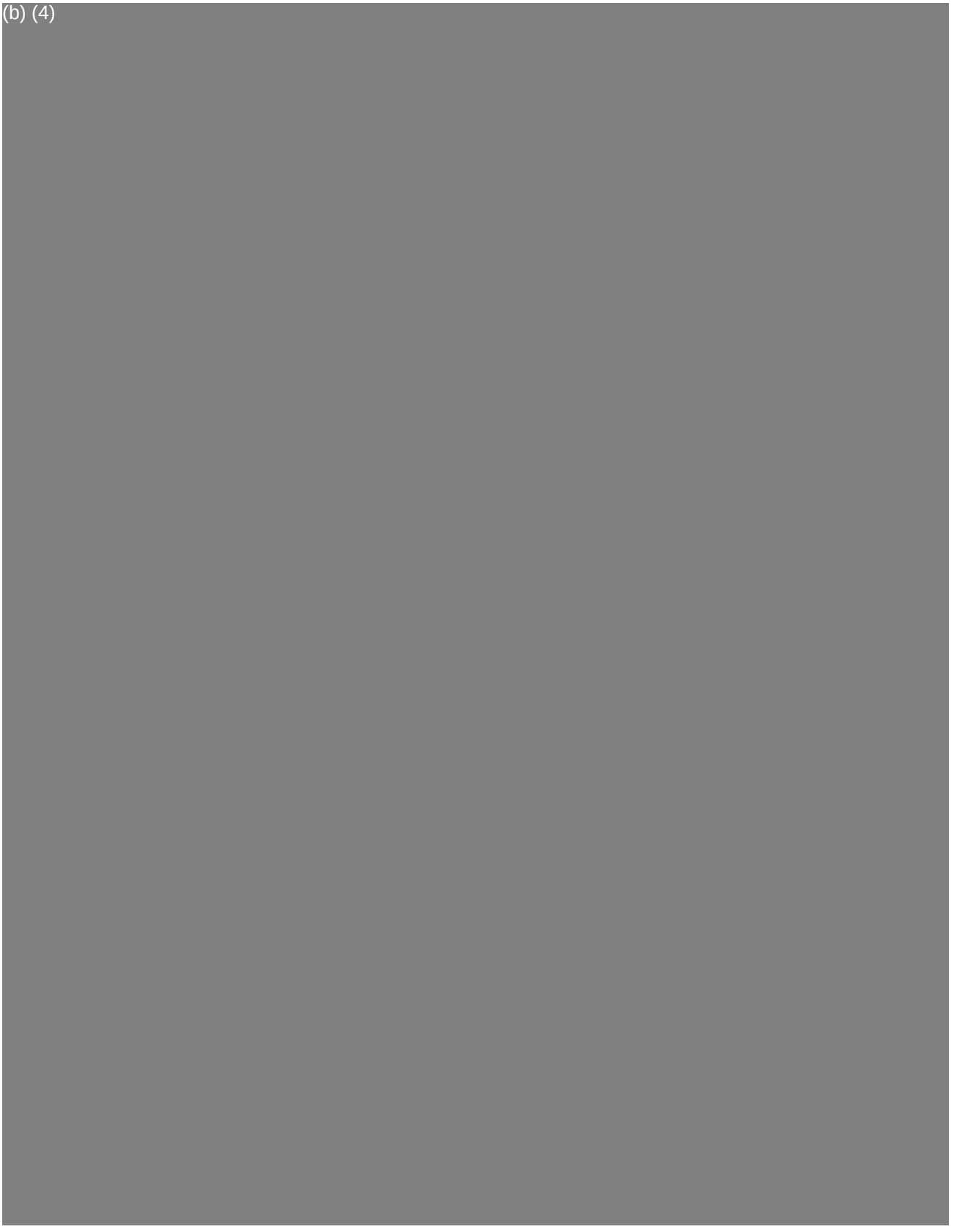
(b) (4)



## 4.13 Completed Leakage Current Test Report

# Leakage Current Test Report

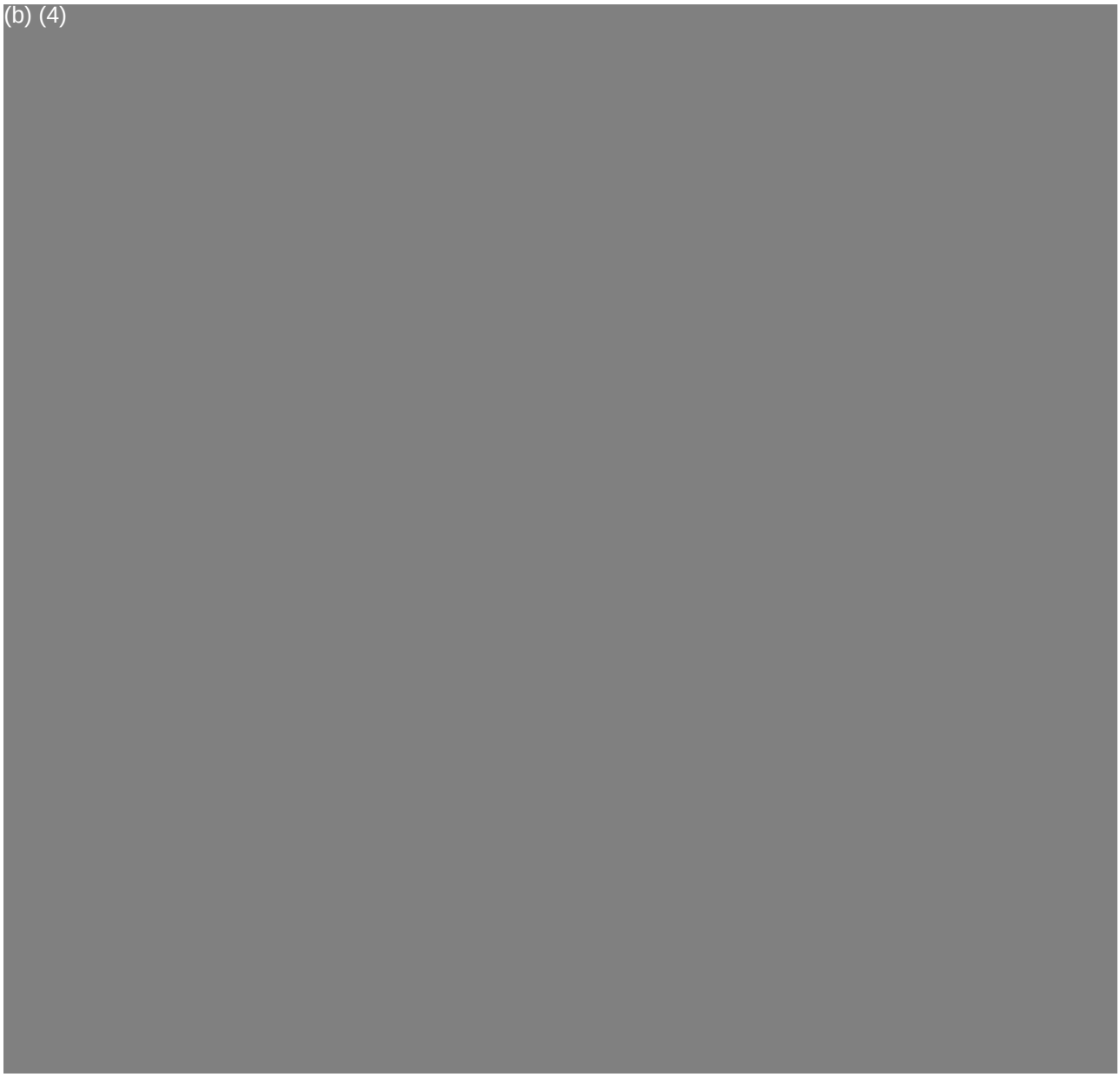
(b) (4)



## 4.13 Completed Dielectric Strength Test Report

# Dielectric Strength Test Report

(b) (4)



## 4.14 Company History

| | |
|---|---|
| 1994 Jan. | Formed a new East-West medical operation division in MEDISON. |
| Jan. | Applied technology patent with Bio-functional Medical System. |
| July | Announced the first model of MERIDIAN system. |
| Nov. | Founded Meridian Co., Ltd. as a first spin-off company from MEDISON. |
| 1995 May | Approved as a manufacturing industry by the Minister of Health and Social Affairs. |
| July | Approved by the overseas safety standard of Canada CSA . |
| Aug. | Designated as a bright-prospected company with advanced technology by the Small and Medium Industry Office. |
| Sep. | Setting up a research center attached to Meridian company recognized by the Ministry of Science and Technology. |
| Oct. | Built the first Meridian Factory in Sang-oh An, Kwang-won Province. |
| Nov. | Selected as a company of military service exemption by the Officer of Military Manpower Administration. |
| Dec. | Acquired a license of factory registration by the Hongchun County Office. |
| Dec. | Selected as a superior technology company by the Technology Trust Guarantee Funds. |
| 1996 Aug. | Designated as a bright-prospected company with advanced technology by the Small and Medium Industry Office. |
| 1997 Apr. | Recognized as an excellent Korean Technology (KT) by the Small and Medium Industry Office. |
| July | Announced the second model of MERIDIAN-II and M-Plus. |
| Aug. | Approved from German TUV of overseas safety standard. |
| Sep. | Adopted Meridian systems as the medical insurance item from the Government. |
| 1998 June. | Merged medical sales organization of Hippo Medical Land, one of the subsidiary company of Medison. |
| July. | Granted "Venture Company Recognition" officially from the Small and Medium Industry Office. |
| Dec. | ISO 9001 / EN46001 of international standard certification is Approved |
| 1998 July. | Grant Venture Company Recognition from the Small and Medium industry office |
| Nov. | ISO 9001/EN46001 |
| 1999 Sep. | Announce MERIDIAN-portable |
| Oct. | Award ¡°The Best Korean Venture Company¡± |
| Nov. | SDA, China |
| 2000 Mar. | Award ¡°The Korea Chamber Of Commerce & Industry |
| Sep. | Announce Laser thearapy Lapex-2000 |
| Nov. | FDA, USA |

## EXHIBIT 5
## Detailed Comparison Information

The following Table 1 provides a comparison of McPulse and its predicate device, Novametrix Pulse Oximeter, Model 500.

| Feature | Novametrix Pulse Oximeter, Model 500 (K853124) | McPulse |
|---|---|---|
| INDICATION OF USE | measures pulse waveform , $SaO_2$ and heart rate by photoelectric plethysmograph | measures pulse waveform and heart rate by photoelectric plethysmograph |
| MODE | Non invasive | Non Invasive |
| PRACTITIONER USE | Professional use only | Professional use only |
| CONTRAINDICATION | none | none |
| DISPLAY | Digital LCD display<br>Analog display | Digital LCD Display |
| POWER SOURCE | AC(100/120/220/240Vac, 50/60Hz)/<br>DC(Portable rechargeable battery) | AC (100-240Vac, 50/60Hz) |
| TYPE OF SENSOR | LED-Photodiode /<br>finger, ear probe, flexible sensor | LED-Photodiode / finger probe |
| ANATOMICAL SITE | Finger, ear, wrap around | Finger |
| RECORDER OUTPUTS | pulse waveform<br>Heart rate<br>$SaO_2$% | pulse waveform<br>Heart rate |
| HEART RATE RANGE & DISPLAY RESOULTION | 25-250bpm<br>1bpm | 30-230bpm<br>1bpm |
| SIZE (unit : mm) | 228.6(W) × 92.08(H) ×254(D) | 305.5(W) × 296(H) × 92.5(D) |
| WEIGHT | Approx. 3.6kg | Approx. 5.5 kg |
| 510(k) NUMBER | K853124 | |

**EXHIBIT 6**

**Biocompatibility data**

**Patient Contact material is ABS plastic, identical to predicate device.**

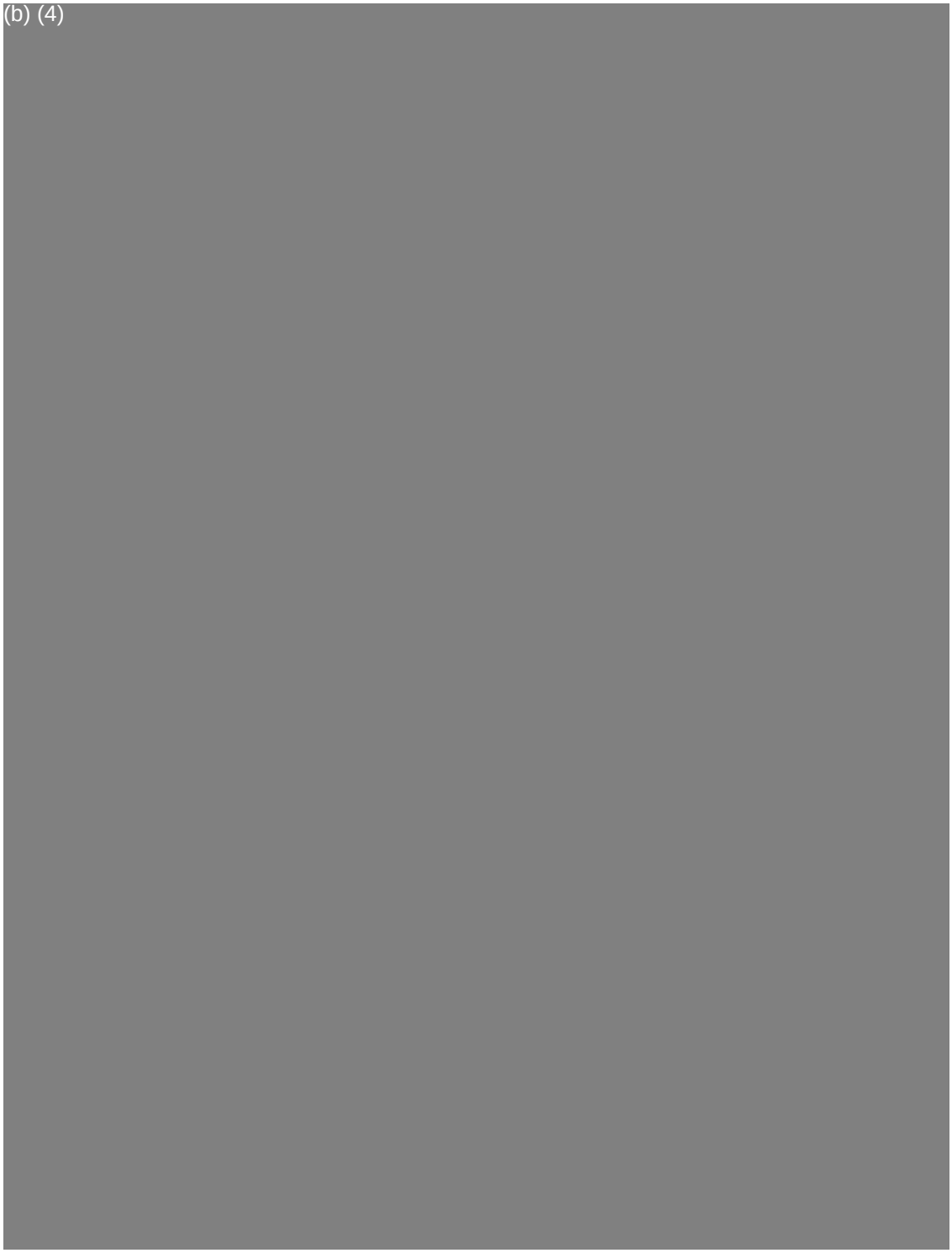
Soorang Lee, R&D Director
September 19, 2002

**Sterilization and expiration dating (Not applicable)**

**EXHIBIT 7**
**Software Development Information**

1. Level of Concern
2. Software Information
3. Architecture Design (Flow) Chart
4. Device Risk Analysis
5. Validation, Verification, and Testing
6. Release Version Number
7. Known Bugs

(b) (4)



8

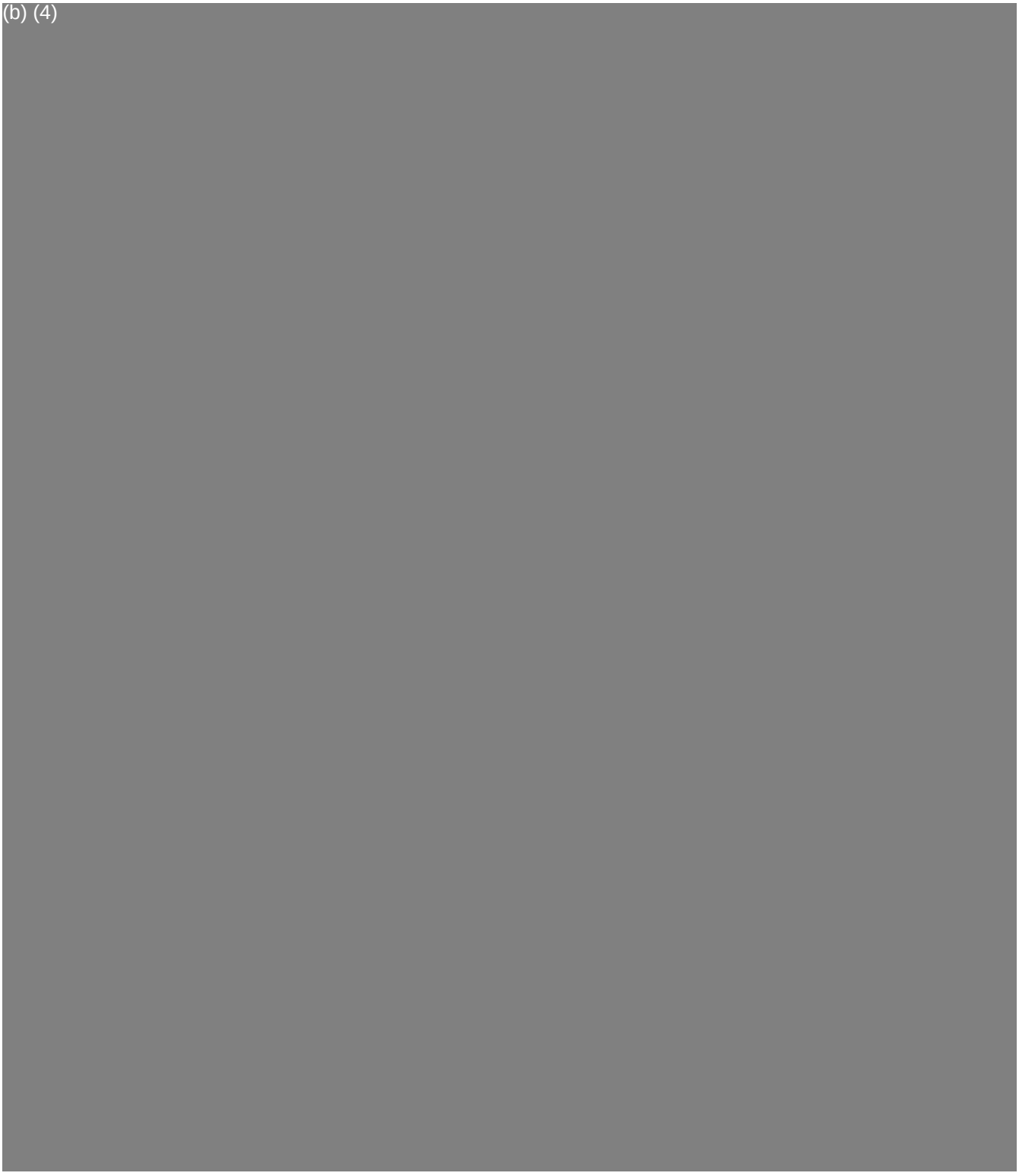
....

**Software Information**

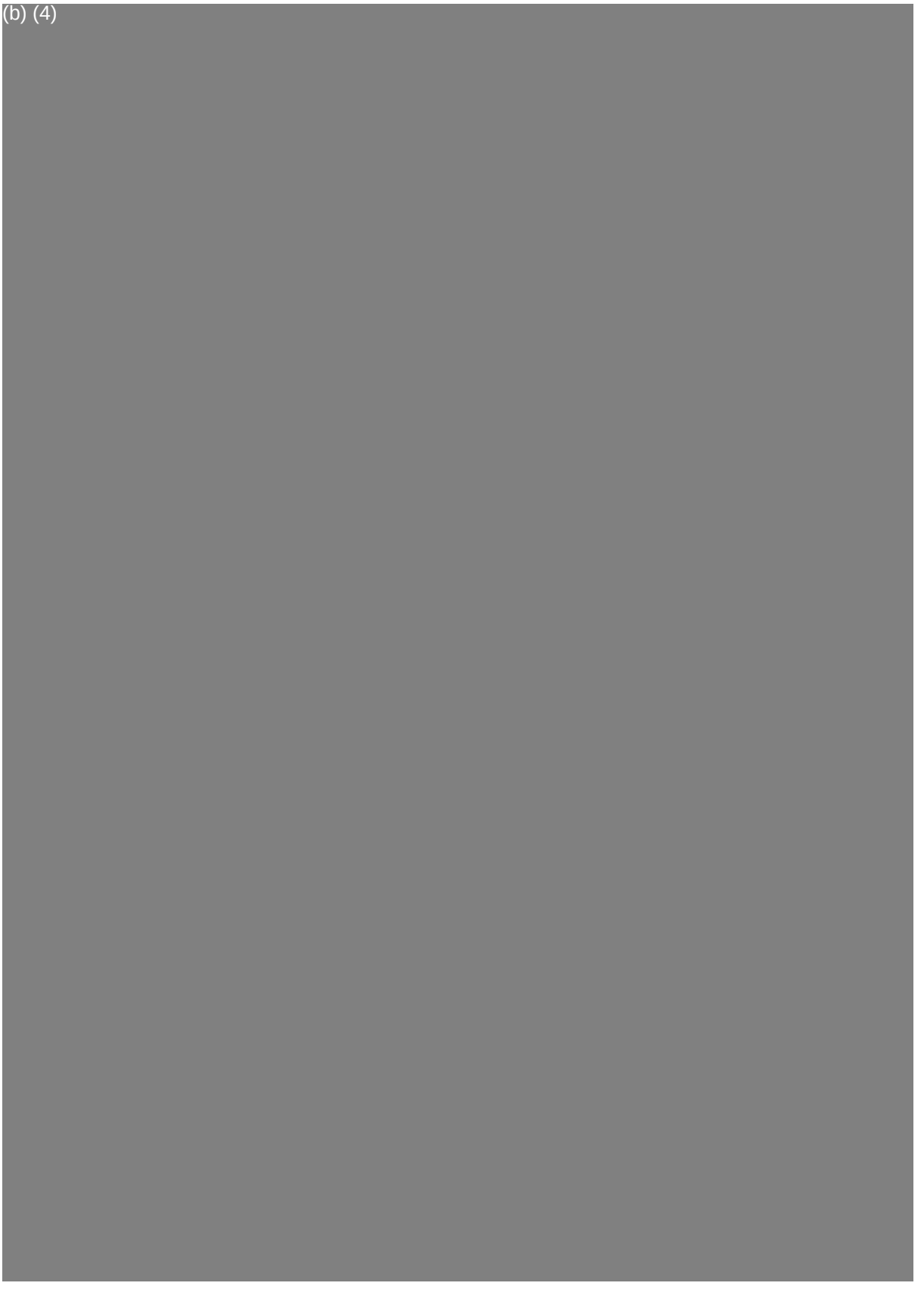
(b) (4)

## Architecture Design (Flow) Chart

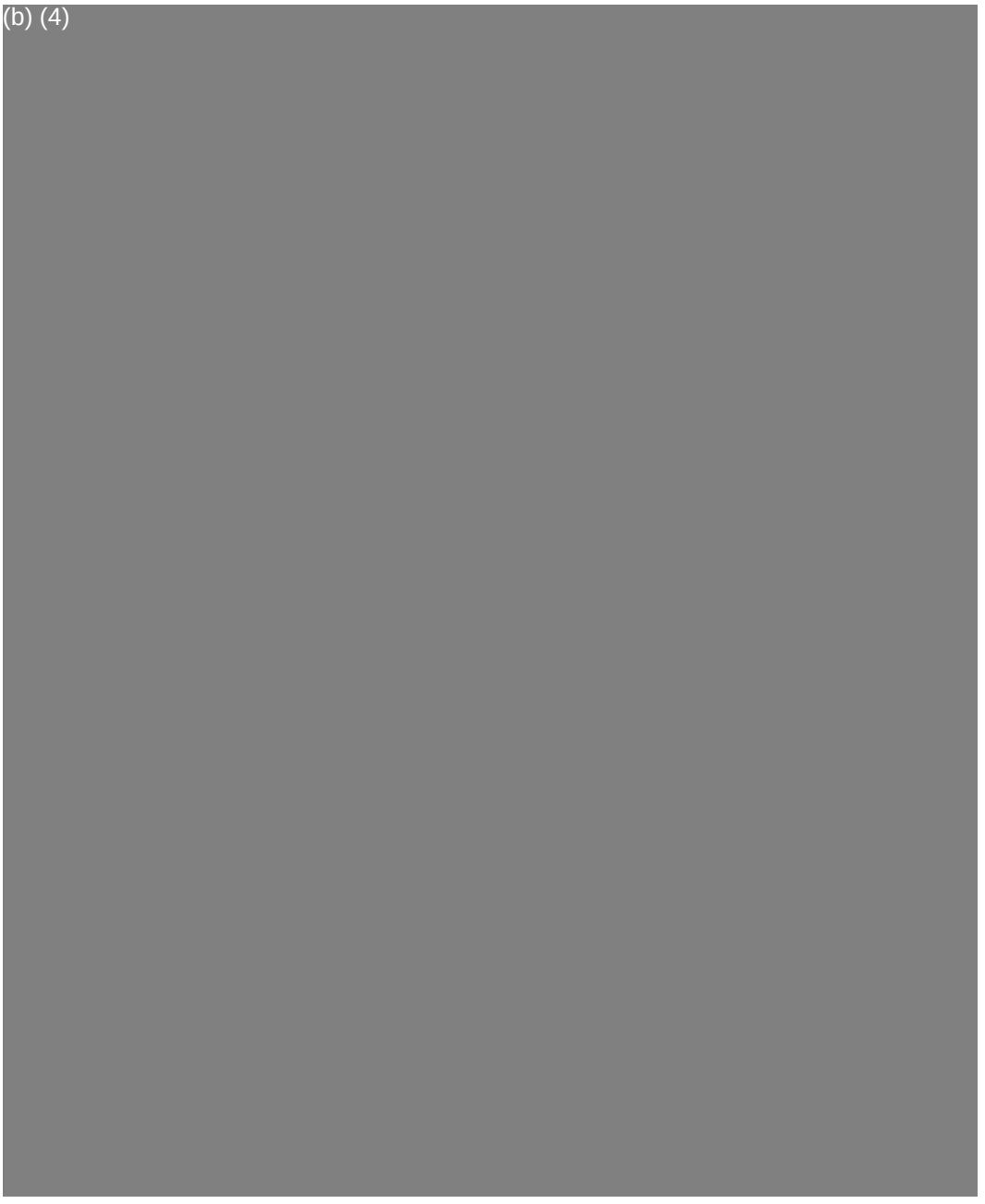
(b) (4)



(b) (4)



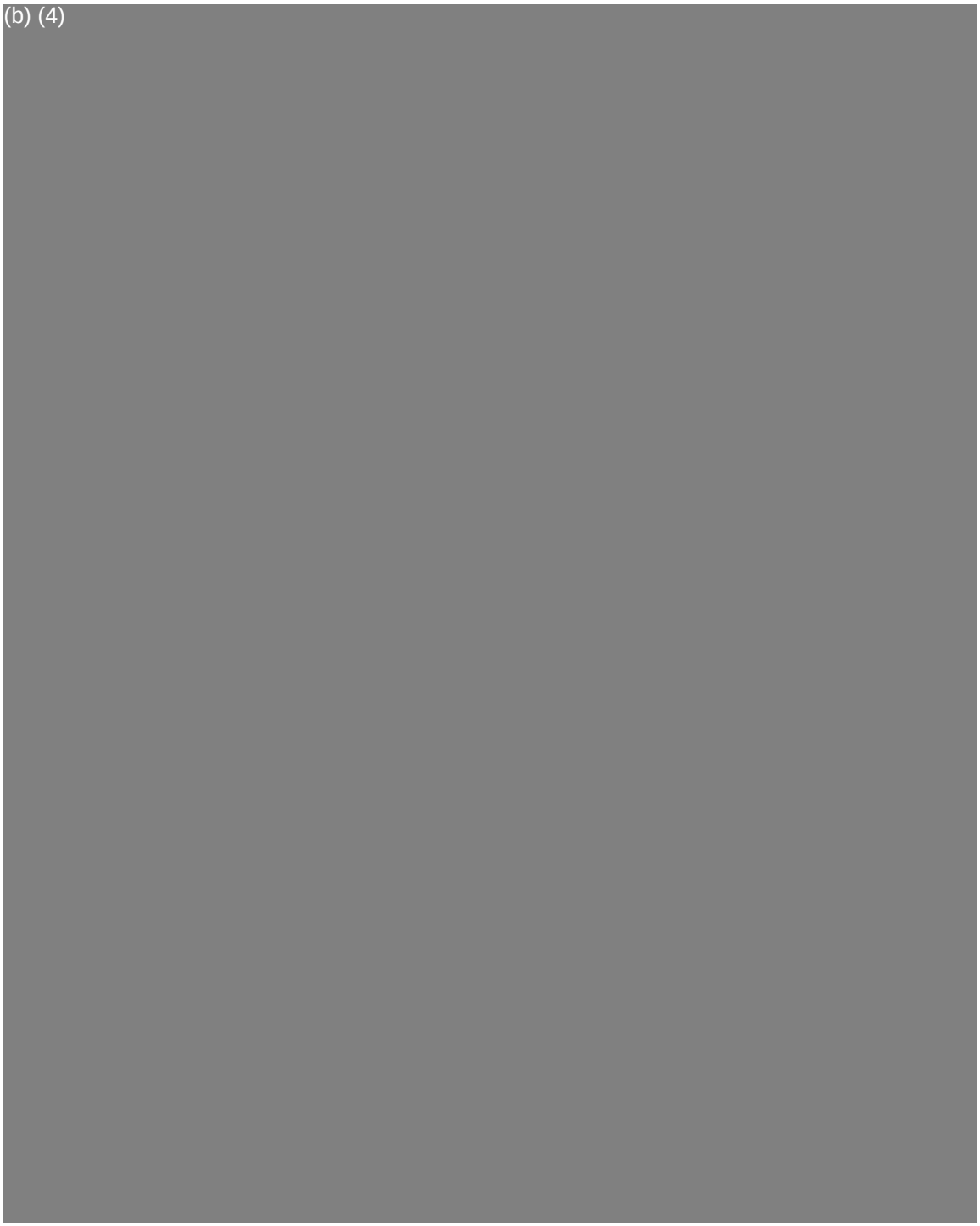
(b) (4)



(b) (4)

3. Key Process Routine

4. Print Routine



**Risk Analysis**

# RISK ANALYSIS REPORT

- Report No: RA-001.
- Manufacturer: MERIDIAN CO., LTD.
- Model: McPulse
- Date: Aug 22, 2002

The risk analysis was performed according to the EN 1441:1997 during the design phase of the medical device.
The risk analysis can be carried out as part of a quality system. It shall consider all those characteristics that can affect safety of the particular device and/or accessory being analyzed.
The conduct and the results of the risk analysis procedure shall be documented and maintained by MERIDIAN CO., LTD.

This document is based on the procedure detailed by the documents EN 1441:1997 and EN 60601-1-4:1997.

## CONTENT

## A - GENERAL

***A1 - Complete description and identification of the device(s) and/or accessory under consideration***

The McPulse, Photo-Plethysmograph is intended to be used to measure pulse waveform and heart rate in the finger by lighting a fingertip with combination of infrared LED and photodiode.

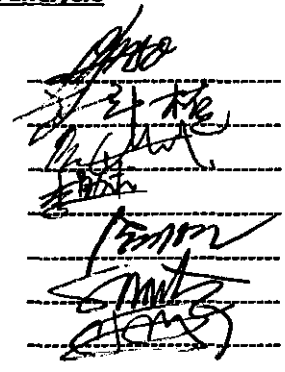
The measurement probe is an optoelectronic sensor consisted of a light-emitting diode(infrared LED) and a photodiode placed on opposite side as a light receiver.
The light from the LED is transmitted through the tissue at the sensor site and a photodiode in the sensor measures the transmitted light and this signal is used to determine how much light was absorbed.

This device converts the changes of transmitted light from a photodiode into a waveform and displays a graphic display of the pulse waveform on LCD screen.

Pulse rate is measured using the time between successive pulses and displayed digital values on LCD screen.

***A2 - Identification of the person/department carrying out the risk analysis***

| | |
|---|---|
| Soo-Rang Lee | R&D Director |
| Doo-Sik Kang | Analog & Digital Enginner |
| Ha-Min Jang | Software Engineer |
| Hoon-Gu Lee | Analog Engineer |
| Hye-Yeon Song | Regulatory Affairs Engineer |
| Dong-Ho Seo | Q&A Engineer |
| Sun-Jin Kim | Q&A Engineer |



## B – Identification of Qualitative and Qualitative Characterisctics Related to Medical Devices.

***B1 - USE OF THE DEVICE***

*B1.1 - Intended use of the device*

The McPulse, Photo-Plethysmograph is intended to be used to measure pulse waveform and heart rate in the finger by lighting a fingertip with combination of infrared LED and photodiode.

*B1.2 - Required skill of the user*

The user should be acquired operation method of this device before attempting to use device.

*B1.3 - Required training of the user*

See the subclause B1.2.

*B1.4 - Environment in which the device is to be used*

| | | |
|---|---|---|
| ■ PATIENT ENVIRONMENT | ☐ NON PATIENT ENVIRONMENT | |
| ■ PATIENT ROOM | ☐ OPERATING THEATRE | ☐ ANALYSIS LAB |
| ☐ SURGICAL ROOM | ☐ THERAPY ROOM | |

*B1.4.1 - Characteristics of the environment:*

- humidity range : 30% ~ 85%
- temperature range : 15°C ~ 35°C
- atmospheric pressure range : 700mbar ~ 1060mbar
- presence of chemicals : N/A
- presence of flammable gases : N/A
- sterilization process : N/A

*B1.5 - Installation*

■ MANUFACTURER ☐ USER ■ PROFESSIONAL INSTALLER

*B1.5.1 - Required skill of installer*

N/A

*B1.5.2 - Required training of installer*

N/A

*B1.5.3 - Supervision of installation by manufacturer*

N/A

*B1.5.4 - Commisioning/start-up (list of tests to be carried out)*

N/A

*B1.5.5 – Possible criticisms of installation*

N/A

*B1.6 - Influence on use of the device by the patient*

☐ POSSIBLE ■ NOT POSSIBLE

*B1.6.1 - Interaction between patient and device and possible influence on the use*

N/A

*B1.7 - Special needs required for the use of the device by handicapped persons, the elderly and children*

N/A

***B2 - CONTACT BETWEEN THE DEVICE AND THE PATIENT OR OTHER PERSONS***

*B2.1 - Type of contact*

■ INTENDED ■ SURFACE ☐ INVASIVE ☐ IMPLANTATION

(The measurement probe is contact with skin of patient.)

*B2.2 - Period and frequency of contact*

The measurement probe is contact with skin of patient during measurement processing.

The adhesive part of probe is made by silicon.

***B3 - MATERIALS AND/OR COMPONENTS INCORPORATED OR USED IN THE DEVICE***

*B3.1 - List of critical materials/components (following materials/components must be approved)*

See the Appendix A. "List of critical component parts".

***B4 - DELIVERY TO AND/OR EXTRACTION OF ENERGY FROM THE PATIENT***

*B4.1 - Type of energy transferred*

N/A

*B4.2 - Quality, quantity and time function of the energy transferred*

N/A

*B4.3 - Means of control of the energy*

N/A

***B5 - DELIVERY TO AND/OR EXTRACTION OF SUBSTANCES FROM THE PATIENT***

*B5.1 - Type of substance*

N/A

☐ SINGLE (detail) ☐ MULTIPLE (detail) ☐ DELIVERED ☒ EXTRACTED

*B5.2 - Maximum and minimum transfer rates*

N/A

*B5.3 - Means of control of the transfer of the substance*

N/A

***B6 - PROCESS OF BIOLOGICAL MATERIALS FOR SUBSEQUENT RE-USE***

*B6.1 - Type of process*

N/A

*B6.2 - Substance(s) processed*

N/A

*B6.3 - Means of control of the process*

N/A

***B7 - STERILIZATION OF MICROBIOLOGICAL CONTROLS***

*B7.1 - Type of product*

☐ SUPPLIED STERILE ■ TO BE STERILIZED BY THE USER

☐ FOR SINGLE-USE ☐ RE-USABLE max number of re-use cycles:

*B7.2 - Max shelf-life and environmental conditions*

MERIDIAN recommends users to disinfect or sterlize the probe at least once a month. MERIDIAN also does to use the disinfecting solutions and follow the manufacturer's instructions in the "Maintenance and Protection" of the operator's manual.

*B7.3 - Type of packaging and packaging process*

N/A

*B7.4 - Type of sterilization process for re-usable devices*

Meqasurement probe must be cleaned after each use. User should follow the manufacturer's instructions when using disinfectants for disinfection and sterilization. MERIDIAN provides users with information on cleaning, disinfection, and sterilization in the "Maintenance and Protection" of the operator's manual.

## ***B8 - MODIFICATION OF THE PATIENT ENVIRONMENT***

*B8.1 - Type of modifications produced by the device*

■ TEMPERATURE ☐ HUMIDITY ☐ ATMOSPHERIC PRESSURE

☐ ATMOSPERIC GAS COMPOSITION

*B8.2 - Means of control of the process*

Under normal operation, the probe surface do not exceed 41°C and this temperature test was verified by external laboratory.

## ***B9 - MEASUREMENTS MADE BY THE DEVICE***

*B9.1 - Variables measured, accuracy and precision*

Heart rate(Pulse rate)

- range : 30~230bpm, - accuracy : 1%±1bpm

Pulse amplitude

- range : 0~16, - accuracy : ±10%

Measurement point(C point) of pulse waveform

- accuracy : ±1.5mm from base line

*B9.2 - Means of control of accuracy and precision*

tested in in-process and final inspection procedure.

☐ PERIODICAL CALIBRATION - to be carried out by: ☐ OPERATOR ☐ SPECIALIST
☐ AUTOCHECK ☐.....

***B10 - INTERPRETATION OF ACQUIRED DATA***

*B10.1 - Type of data acquired/input*

Measurement results are displayed on LCD display with type of waveform and figures.

*B10.2 - Algorithms used to interpretate the acquired data*

Software detects main points of pulse waveform and second derivative waveform and calculates result values from formula consisted each point.

*B10.3 - Confidence limits and method of calculation of the limits*

- Heart rate : Max. 230bpm
  → If heart rate is more than 230bpm, this value is detected 230.

- Pulse amplitude : Max. 16
  → If data of pulse amplitude is more than 16, this input data is detected 16.

- Each peak rations of second derivative pulse waveform : ±9.99
  → If value of ratio is more than +9.99 or less than –9.99, this value is detected +9.99 or –9.99 respectively.

***B11 - CONTROL OR INTERACTION WITH OTHER DEVICES OR DRUGS***

*B11.1 - Identification of other devices and/or drugs*

N/A

*B11.2 - Problems related to control or interaction*

N/A

***B12 - UNWANTED OUTPUTS OF ENERGY AND SUBSTANCES***

*B12.1 - Possible unwanted outputs of energy and substances*

☐ NOISE ☐ VIBRATION ■ HEAT ☐ IONIZING RADIATION
☐ NON-IONIZING RADIATION ☐ UV RADIATION ☐ IR RADIATION

☐ VISIBLE RADIATION ■ CONTACT TEMPERATURES
■ LEAKAGE CURRENTS ■ EM FIELDS

☐ DISCHARGE OF CHEMICALS ☐ WASTE PRODUCTS ☐ BODY FLUIDS

N.B. - The parameters are to be measured when performing type testing.

## ***B13 - ENVIRONMENTAL INFLUENCES ON THE DEVICE***

*B13.1 - Possible environmental influences that can affect safety*

■ OPERATIONAL ENVIRONMENT

- Temperatature : 15°C ~ 35°C
- Humidity (RH) : 30% ~ 85%
- Atom. Pressure : 700hPa ~ 1060hPa

■ TRANSPORT ENVIRONMENT

- Temperatature : 0°C ~ 40°C
- Humidity (RH) : 25% ~ 90%
- Atom. Pressure : 700hPa ~ 1060hPa

■ STORAGE ENVIRONMENT

- Temperatature : 0°C ~ 40°C
- Humidity (RH) : 25% ~ 90%
- Atom. Pressure : 700hPa ~ 1060hPa

■ POWER SUPPLY

- 100-240Vac, 50/60Hz, 2.0/1.0A

☐ COOLING SUPPLY - cooling means (air/water/....) $m^3/h$

☐ SPILLAGE OF SUBSTANCES - type of substance

## ***B14 - ESSENTIAL CONSUMABLES OR ACCESSORIES ASSOCIATED WITH THE DEVICE***

*B14.1 - Specifications for consumables or accessories associated with the device*

1) Measurement probe: MERIDIAN provides the probe to measure pulse waveform.

2) Thermal printer paper : MERIDIAN provides theraml printer paper to print measurment results.

3) FUSE : MERIDIAN informs users of the fuse ratings and its replacement in the "Maintenance and Protection" of the operator's manual. The specification is in the Appendix A. "List of critical component parts".

*B14.2 - Restrictions to be placed upon users in the selection of consumables and accessories to be associated with the device*

See the subclause B14.1

***B15 - MAINTENANCE***

*B15.1 - Parts to be submitted to maintenance*

Probe, System, and Fuse replacement. This information is provided in the "Maintenance and Protection" of the operator's manual.

*B15.2 - Periodicity of maintenance and person in charge*

MAINTENANCE TO BE CARRIED OUT EVERY (detail part(s) and periodicity) BY

■ USER/OPERATOR ☐ SPECIALIST

***B16 - SOFTWARE***

*B16.1 - Installation, modification or exchange of the software*

☐ USER/OPERATOR ■ SPECIALIST

*B16.2 - Interaction of the software with the safety of the device*

☐ HIGH ■ MEDIUM ☐ LOW ☐ NONE

N.B. - See also annex A, "Risk analysis of programmable electrical medical systems".

***B17 - RESTRICTED SHELF-LIFE***

*B17.1 - Indication of the restricted shelf-life*

N/A

☐ LABELLING (detail) ☐ OTHER INDICATORS (detail)

*B17.2 - Instructions for the disposable of the device*

N/A

***B18 - DELAYED AND/OR LONG TERM USE EFFECTS***

*B18.1 - Ergonomic effects*

N/A

*B18.2 - Cumulative effects*

N/A

***B19 - MECHANICAL FORCES APPLIED TO THE DEVICE***

*B19.1 - Detail of parts and related mechanical forces*

The McPulse has a handle to move easily. If the handle separates form device, it could cause injury to user or others.

*B19.2 - Control of the mechanical forces*

■ USER ☐ INTERACTION WITH OTHER PERSONS

*B19.3 - Means of control of the mechanical forces*

Verify design by testing and system complies with agency requirements.

***B20 - LIFETIME OF THE DEVICE***

*B20.1 - Factors determining the lifetime of the device*

■ AGEING ☐ STERILIZATION ☐ ENVIRONMENT

☐ ....

*B20.2 - Max lifetime and parameters to keep under control*

N/A

## C. IDENTIFICATION OF POSSIBLE HAZARDS

The following table gives a non-exaustive list of possible hazards and contributing factors associated with different medical devices. Use the REMARKS column to detail, when necessary, the part of the device associated to the potential hazard.

*Legend*: Y=*yes* N=*no* NA=*not applicable*

| REF. No. | HAZARD | NORMAL CONDITION | SINGLE FAULT CONDITION | REMARKS |
|---|---|---|---|---|
| ***C1*** | ***ENERGY*** | — | — | — |
| C1.1 | Electricity | Y | Y | |
| C1.2 | Heat | Y | Y | |
| C1.3 | Mechanical force | Y | Y | |
| C1.4 | Ionizing radiation | NA | NA | |
| C1.5 | Non-ionizing radiation | NA | NA | |
| C1.6 | EM fields | Y | Y | |
| C1.7 | Moving parts | N | Y | |
| C1.8 | Suspended masses | NA | NA | |
| C1.9 | Patient support device failure | NA | NA | |
| C1.10 | Pressure (vessel rupture) | NA | NA | |
| C1.11 | Acoustic pressure | NA | NA | |
| C1.12 | Vibration | NA | NA | |
| C1.13 | Magnetic fields (e.g. MRI) | NA | NA | |
| ***C2*** | ***BIOLOGICAL*** | — | — | — |
| C2.1 | Bio-burden | NA | NA | |
| C2.2 | Bio-contamination | NA | NA | |
| C2.3 | Bio-incompatibility | Y | NA | |
| C2.4 | Incorrect output (substance/energy) | NA | NA | |
| C2.5 | Incorrect formulation (chemical composition) | NA | NA | |
| C2.6 | Toxicity | Y | NA | |
| C2.7 | (Cross-)infection | NA | NA | |

| | | | | |
|---|---|---|---|---|
| C2.8 | Pyrogenicity | NA | NA | |
| C2.9 | Inability to maintain hygienic safety | NA | NA | |
| C2.10 | Degradation | NA | NA | |
| **REF. No.** | **HAZARD** | **NORMAL CONDITION** | **SINGLE FAULT CONDITION** | **REMARKS** |
| ***C3*** | ***ENVIRONMENTAL*** | — | — | — |
| C3.1 | EM interference | Y | Y | |
| C3.2 | Inadequate supply of power of coolant | NA | NA | |
| C3.3 | Restriction of cooling | NA | NA | |
| C3.4 | Likelihood of operation outside prescribe environmental conditions | Y | NA | |
| C3.5 | Incompatibility with other devices | NA | NA | |
| C3.6 | Accidental mechanical damages | N | Y | |
| C3.7 | Contamination due to waste products and/or device disposal | NA | NA | |
| ***C4*** | ***HAZARDS RELATED TO THE USE OF THE DEVICE*** | — | — | — |
| C4.1 | Inadequate labelling | Y | NA | |
| C4.2 | Inadequate operating instructions | Y | NA | |
| C4.3 | Inadequate specification of accessories | Y | NA | |
| C4.4 | Inadequate specification of pre-use checks | NA | NA | |
| C4.5 | Over-complicated operating instructions | Y | NA | |
| C4.6 | Unavailable or separated | Y | NA | |

| | | | | |
|---|---|---|---|---|
| | operating instructions | | | |
| C4.7 | Use by unskille/untrained personnel | Y | NA | |
| C4.8 | Reasonably foreseeable misuse | Y | NA | |
| C4.9 | Insufficient warning of side effects | Y | NA | |
| **REF. No.** | HAZARD | **NORMAL CONDITION** | **SINGLE FAULT CONDITION** | **REMARKS** |
| C4.10 | Inadequate warning of hazards likely with re-use of single use devices | NA | NA | |
| C4.11 | Incorrect measurement and other metrological aspects | Y | Y | |
| C4.12 | Incorrect diagnosis | NA | NA | |
| C4.13 | Erroneus data transfer | NA | NA | |
| C4.14 | Mispresentation of results | Y | Y | |
| C4.15 | Incompatibility with consumables/accessories/other devices | Y | NA | |
| ***C5*** | ***HAZARDS ARISING FROM FUNCTIONAL FAILURE, MAINTENANCE AND AGEING*** | — | — | — |
| C5.1 | Inadequacy of performance characteristics for the intended use | Y | Y | |
| C5.2 | Lack of, or inadequate specification for maintenance including inadequate specification of post maintenance functional check | Y | NA | |

| | | | | |
|---|---|---|---|---|
| C5.3 | Lack of adequate determination of end of device life | Y | NA | |
| C5.4 | Loss of mechanical integrity | Y | Y | |
| C5.5 | Inadequate packaging (contamination and/or deterioration of the device) | Y | NA | |
| C5.6 | Improper re-use | N | N | |

## D - ESTIMATION OF THE RISK FOR EACH HAZARD

Each of the risks identified in clause C are to be estimated in both normal and single fault condition using available information/data obtained.

The procedure for probabilistic safety analysis used is FMEA.

The analysis results are attached hereafter.



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**D - ESTIMATION OF THE RISK FOR EACH HAZARD**

(Hazard Analysis considers the initiating causes such as human factors, hardware faults, software faults, integration errors and environmental condition and also considers matters as applicable as compatibility of system, user interface, command language, error message, etc.)

[Hazard Analysis Technique used: FMEA (Failure Mode and Effect Analysis)]

| ID No. | Function / Component | Hazard | Failure Mode | Failure Effect | Likelihood | Severity | Risk Category | Description of control |
|---|---|---|---|---|---|---|---|---|
| B1.1 | Intended use of the device | C4.11 Incorrect measurement and other metrological aspects<br><br>C4.13 Erroneus data transfer<br><br>C4.14 Mispresentation of results<br><br>C5.1- Inadequate of performance characteristics for the intended use | time calculation error | Incorrect measurement time | Rare | Moderate | Reducible | Design/Code review<br>Verification test |
| | | | Inconsistent information | Inappropriate physician action based on software errors | Rare | Moderate | Reducible | Operator's manual will clearly describe data that is intentionally formatted differently. Uniform U/I, units included in all numerical displays. |
| | | | Algorithm error | Inappropriate point detect of pulse waveform and incorrect calculation | Rare | Critical | Reducible | Design/Code review<br>Verification test<br>Patient and user should be wear safety goggle for operating. |
| | | | Flash ROM error | User data is not memorized. | Rare | Critical | Reducible | Design/Code review<br>Verification test<br>Exchange of Flash ROM |



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| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | | C5.2-<br>Inadequate specification for maintenance including inadequate specification of post maintenance functional check | LCD connecting error | Inadequate LCD display | Rare | Critical | Reducible | Verification test<br>Check whether LCD is connected correctly or not. |
| | | | Printing error | Inappropriate printing for results | Rare | Moderate | Reducible | Design/Code review<br>Verification test |
| | | | Key error | Inappropriate physician action based on software errors | Rare | Moderate | Reducible | Design/Code review<br>Verification test |
| B1.2<br>B1.3 | Required skill of the user<br>Required training of the user | C4.7 -<br>Use by unskilled / Untrained personnel | Unclear use of software or user generated parameters | Inappropriate physician action based on insufficient training | Rare | Moderate | Reducible | Provide explanation of where parameters are generated and where they are used in the operator's manual. |
| | | | Unclear training of operation method | Inappropriate physician action based on insufficient training | Rare | Moderate | Reducible | Provide explanation of the related contents the operator's manual. |

| ID No. | Function / Component | Hazard | Failure Mode | Failure Effect | Likelihood | Severity | Risk Category | Description of control |
|---|---|---|---|---|---|---|---|---|
| B1.4.1 | Characteristics of the environment | C3.4 -<br>Likelihood of operation outside prescribe environmental conditions. | User does not follow the environmental conditions. | Inappropriate physician action based on insufficient information | Rare | Moderate | Reducible | Provide explanation of the operating and storage and transport conditions in the operator's manual. |

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| B2.1<br>B2.2 | Type of contact<br>Period and frequency of contact | C1.1 – Electricity (Electrical shock) | Probe shocking patient. | Electrical shock to patient or operator | Rare | Moderate | Reducible | Electrical isolation in accordance with IEC(EN) standards. |
| | | | Probe grounding "charged" patient. | Electrical shock to patient or operator | Rare | Moderate | Reducible | Electrical isolation in accordance with IEC(EN) standards. |
| | | | Access through enclosure to electrically live parts | Electrical shock to patient or operator | Rare | Critical | Reducible | Electrical isolation in accordance with IEC(EN) standards. |
| | | | Operator contact with live parts | Electrical shock to patient or operator | Rare | Critical | Reducible | Electrical isolation in accordance with IEC(EN) standards. |
| | | | System acting as source / link for electric shock | Electrical shock to patient or operator | Rare | Moderate | Reducible | Metal parts of chassis are electrically grounded. |
| | | C1.2 – Heat (or Burn) (Excessive temp.) | Probe may have a defect that causes it to over heat. | Patient heated or burned by the face of the probe. | Rare | Moderate | Reducible | Face of probe not exceed 41°C for normal operation. Heat testing of probe face in accordance with IEC(EN) standards. |
| | | C2.3 – Bio-incompatibility<br>C2.6 – Toxicity | Non-biocompatible material used in construction of probe | Patient contaminated | Rare | Moderate | Reducible | Adhesive part of probe is made by silicon. |



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| ID No. | Function / Component | Hazard | Failure Mode | Failure Effect | Likelihood | Severity | Risk Category | Description of control |
|---|---|---|---|---|---|---|---|---|
| B3.1 | List of critical materials/components. | C1.1 – Electricity (Electrical shock) | Component failure shocking patient | Electrical shock to patient or operator | Rare | Critical | Reducible | System will comply with with IEC(EN) standards. |
| | | C1.2 – Heat (Exceesive temp.) | Hazardous fire/heat causing damage to patient or operator | Burn hazard to patient or operator. | Rare | Critical | Reducible | System will comply with with IEC(EN) standards. |
| | | C1.6 – EM field C3.1 – EM interference | Components produce EMI. | EMI from system | Occasional | Moderate | Reducible | System will comply with IEC60601-1-2 limits for EMI. |
| | | C2.3 – Bio-incompatibility C2.6 – Toxicity | Non-biocompatible material used in construction of probe | Patient contaminated | Rare | Moderate | Reducible | Adhesive part of probe is made by silicon. |
| B7.1 B7.2 B7.4 | Type of product Max shelf-life and environmental conditions Type of sterilization process for re-usable devices | C2.3 – Bio-incompatibility C2.6 – Toxicity | Non-biocompatible and non-chemical compatible disinfectant used for disinfection or sterilization for probe | Patient contaminented | Occasional | Moderate | Reducible | Bio-compatible disinfectants or sterilants will be listed in the operator's manual. |
| | | C4.9 – Insufficient warning of side effects | Insufficient warning of using disinfectant and sterilant. | Probe is damaged Patient or user contaminated. | Rare | Moderate | Reducible | Provide warnings which user shall take for proper sterilization and disinfection. |

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | | C4.15 – Incompatibility with disinfectants | Non-biocompatible and non-chemical compatible disinfectant used for disinfection or sterilization for probe, hand electrode | Patient contaminated. | Occasional | Moderate | Reducible | Bio and chemical compatible disinfectants or sterilants will be listed in the operator's manual. |
| | | C5.2 – Inadequate specification for maintenance | Insufficient disinfectant or sterilant specification is provided. | Probe is damaged. | Rare | Moderate | Reducible | Provide information that user should follow the manufacturer's manual in operator's manual. |

| ID No. | Function / Component | Hazard | Failure Mode | Failure Effect | Likelihood | Severity | Risk Category | Description of control |
|---|---|---|---|---|---|---|---|---|
| B8.1<br>B8.2 | Type of modifications produced by the device<br>Means of control of the process | C1.2 – Heat (Excessive temp.) | Hazardous heat causing damage to patient or operator | Patient heated or burned by the face of the probe. | Rare | Moderate | Reducible | Face of probe not exceed 41°C for normal operation. Heat testing of probe face in accordance with IEC(EN) standards. |
| B9.1<br>B9.2 | Measurement made by the device | See B1.1 | | | | | | |
| B10.1<br>B10.2<br>B10.3 | Interpretation of acquired data | See B1.1 | | | | | | |



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| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| B12.1 | Possible unwanted outputs of energy and substances | C1.1 – Electricity (Electrical shock) | Probe shocking patient. | Electrical shock to patient or operator | Rare | Moderate | Reducible | Electrical isolation in accordance with IEC(EN) standards. |
| | | | Probe grounding "charged" patient. | Electrical shock to patient or operator | Rare | Moderate | Reducible | Electrical isolation in accordance with IEC(EN) standards. |
| | | | Access through enclosure to electrically live parts | Electrical shock to patient or operator | Rare | Critical | Reducible | Electrical isolation in accordance with IEC(EN) standards. |
| | | | Operator contact with live parts | Electrical shock to patient or operator | Rare | Critical | Reducible | Electrical isolation in accordance with IEC(EN) standards. |
| | | | System acting as source / link for electric shock | Electrical shock to patient or operator | Rare | Moderate | Reducible | Metal parts of chassis are electrically grounded. |
| | | C1.2 – Heat (Excessive temp.) | Probe may have a defect that causes it to over heat. | Patient heated or burned by the face of the probe. | Rare | Moderate | Reducible | Face of probe not exceed 41°C for normal operation. Heat testing of probe face in accordance with IEC(EN) standards. |
| | | C1.6 – EM field<br>C3.1 – EM interference | Components produce EMI. | EMI from system | Occasional | Moderate | Reducible | System will comply with IEC60601-1-2 limits for EMI. |

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| B13.1 | Possible environmental influences that can affect safety | C3.4 – Likelihood of operation outside prescribe environmental conditons<br>C4.1 – Inadequate labeling<br>C4.2 – Inadequate operating instructions | User does not follow the environmental conditions. | Inadequate physician action based on insufficient information | Rare | Moderate | Reducible | Provide explanation of the operating and storage and transport conditions in the operator's manual. |

| ID No. | Function / Component | Hazard | Failure Mode | Failure Effect | Likelihood | Severity | Risk Category | Description of control |
|---|---|---|---|---|---|---|---|---|
| B14.1<br>B14.2 | Specifications for consumables or accessories associated with the device<br>Restrictions to be placed upon users in the selection of consumables and accessories to be associated with the device | C4.3 – Inadequate spedification of accessories<br>C4.15 – Incompatibility with consumables/accessories/ other devices | Inadequate accessories or consumables are connected to device. | Electrical hazard to patient or user, or performance degradation occurred to device | Rare | Moderate | Reducible | Provide information on specifications of accessories or consumables in operator's manual. |

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| B15.1<br>B15.2 | Parts to be submitted to maintenance<br>Periodicity of maintenance and person in charge | C5.2 – Inadequate specification for maintenance including inadequate specification of post maintenance functional chenck | Insufficient maintenance of cleaning, disinfection, or sterilization, fuse replacement | Degradation of system, probe<br>Contamination to user or patient | Occasional | Moderate | Reducible | Provide explanation for cleaning, disinfection, or sterilization, fuse replacement in operator's manual. |
| B16.2 | Interaction of the software with the safety of the device | See the S/W related parts in this report. | | | | | | |
| B19.1<br>B19.2 | Details of parts and related mechanical forces. | C1.3 – Mechanical forces<br>C3.6 – Accidental mechanical damages<br>C5.4 – Loss of mechanical integrity | Handle breaking | Injury to patient or user | Rare | Moderate | Reducible | Verify design by testing |
| B19.3 | Control of the mechanical forces<br>Means of control of the mechanical forces | | Pinch points on system | Injury to patient or user | Rare | Moderate | Reducible | System complies with agency requirements. |

## E - ACCEPTABILITY OF RISK

All the risks for all given hazards are appropriately addrressed by compliance with a relevant standard or acceptability is demonstrated by other means. Thus this analysis step goes to H directly.

## F - RISK REDUCTION

Describe means to reduce, in a staged process, to acceptable levels any risk which is judged unacceptable.

## G - GENERATION OF OTHER HAZARDS

N/A

## H - EVALUATION OF ALL IDENTIFIED HAZARDS

*H1 - Estimation of risks*

Risks for all identified hazards

■ HAVE BEEN ESTIMATED ☐ HAVE NOT BEEN ESTIMATED (in this case return to D and re-start the procedure)

## I – CONCLUSIONS

■ ALL THE POTENTIAL RISKS WITH REGARD TO THE INTENDED APPLICATION AND USE OF THE DEVICE HAVE BEEN ESTIMATED AND ELIMINATED

☐ ALL THE POTENTIAL RISKS WITH REGARD TO THE INTENDED APPLICATION AND USE OF THE DEVICE HAVE BEEN ESTIMATED AND THE REMAINING ONES, HEREBELOW LISTED, ASSOCIATED WITH THE IDENTIFIED HAZARDS ARE ACCEPTABLE.

| Prepared by | | Reviewed by | |
|---|---|---|---|
| Hye-Yeon Song | Date : | Soo-Rang Lee | Date : |

Regulatory affair engineer
Meridian Co., Ltd.

R&D Lab. Director
Meridian Co., Ltd.

# Appendix A. List of critical component parts

| Part No. | Component /Object | Manufacturer | Type/Model | Ratings/ Technical Data | Complies with the following standard | Approved by |
|---|---|---|---|---|---|---|
| | Power cord | KUK JE TONG SHIN | KKJ-1004AH03VVH2F | 2.5A 250Vac 0.75mm$^2$ | IEC60601-1 | NEMKO |
| | Appliiance inlet | BAE EUN | FCP-03 | 250Vac 10A | | VDE, UL CSA |
| FU1,FU2 | Mains fuse | SAMJOO | 50T | 250Vac 3.15A | | VDE, UL |
| FU3 | Fuse | SAMJOO | 50T | 250Vac, 6.3A | | VDE,UL |
| | Mains swtich | | SRA1101 | 250Vac 5A | | UL, CSA NEMKO |
| | AC connector | BEE RYONG Elec | BR-762 | 250Vac 10A | | UL |
| T1 | Mains transformer | DAEAN | BI-001T1 | Class A | IEC60601-1 | Tested in appl. |
| L1, L2 | Line Filter | DAEAN | UU1116 | Class A 0.3×80T | IEC60601-1 | Tested in appl. |
| PC1 | Photo coupler | SHARP | PC817 | External crrepage distance : 8mm | | FIMKO |
| | LCD panel | SAMSUNG DISPLAY DEVICES CO., LTD. | UG-32F03-BCBN8-C | VDD : 5V IDD : 4mA | IEC60601-1 | Tested in appl. |
| | Probe | WOO CHANG | PB-013-P/W-01 | Vin : 5V | IEC60601-1 | Tested in appl. |
| | PCB | Various | Various | V-1 or better | | UL |

## Validation, Verification, and Testing

# Software Validation Report

(b) (4)

691

(b) (4)

Q21

(b) (4)

(b) (4)

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**Software Version No. : Version 1.0**

**Known Bugs: None.**

**EXHIBIT 8**

**CONFORMANCE TO STANDARDS AND GUIDELINES**
**Electrical Safety Test Report Performed by Korean Electric Testing Institute**
**Certificate of Medical Device Testing**
**ISO 9001 Certificate**

## CONFORMANCE TO STANDARDS AND GUIDELINES

**I certify that, in my capacity as R&D Director of Meridian Co, Ltd, I believe, to the best of my knowledge, that the McPulse conforms to the applicable sections of the following standards:**

1. IEC 60601-1, Safety of Medical Electrical Equipment, Part 1, General Requirements for Safety, including Amendment 1 and 2.

2. EN 60601-1-2 first edition, Standard for Electromagnetic Compatibility.

3. ISO-9001 Quality management systems-Requirements

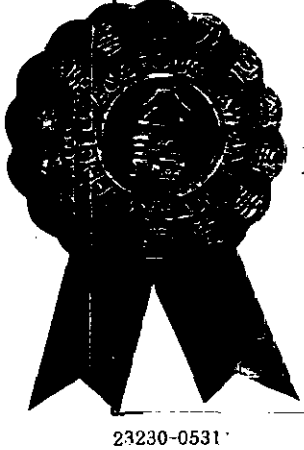
Soorani Lee, R&D Director
September 19, 2002

**Electrical Safety Test Report**
**Performed by Korean Electric Testing Institute**

〔제41호 서식〕

Registered No. 2002 - 1228

# NOTARIAL CERTIFICATE



HANSEONG LAW AND NOTARY OFFICE

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## Certificate of Medical Device Testing

(b) (4)

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

Memorandum

From: Reviewer(s) - Name(s) James Cheng

Subject: 510(k) Number K023238

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

- ☐ Refused to accept.
- ☑ Requires additional information (other than refuse to accept). email AI request
- ☐ Is substantially equivalent to marketed devices.
- ☐ NOT substantially equivalent to marketed devices.
  - De Novo Classification Candidate? ☐ YES ☐ NO
- ☐ Other (e.g., exempt by regulation, not a device, duplicate, etc.)

| | | |
|---|---|---|
| Is this device subject to Postmarket Surveillance? | ☐ YES | ☒ NO |
| Is this device subject to the Tracking Regulation? | ☐ YES | ☐ NO |
| Was clinical data necessary to support the review of this 510(k)? | ☐ YES | ☐ NO |
| Is this a prescription device? | ☐ YES | ☒ NO |
| Was this 510(k) reviewed by a Third Party? | ☐ YES | ☐ NO |
| Special 510(k)? | ☐ YES | ☐ NO |
| Abbreviated 510(k)? Please fill out form on H Drive 510k/boilers | ☐ YES | ☐ NO |

This 510(k) contains:

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

- ☐ A 510(k) summary OR ☐ A 510(k) statement
- ☐ The required certification and summary for class III devices
- ☐ The indication for use form (required for originals received 1-1-96 and after)
- Animal Tissue Source ☐ YES ☐ NO

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

☐ No Confidentiality ☐ Confidentiality for 90 days ☐ Continued Confidentiality exceeding 90 da

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

Review: [signature] (Branch Chief) CDRH (Branch Code) 12/17/02 (Date)

Final Review: _____ (Division Director) (Date)

Revised:8/17//99

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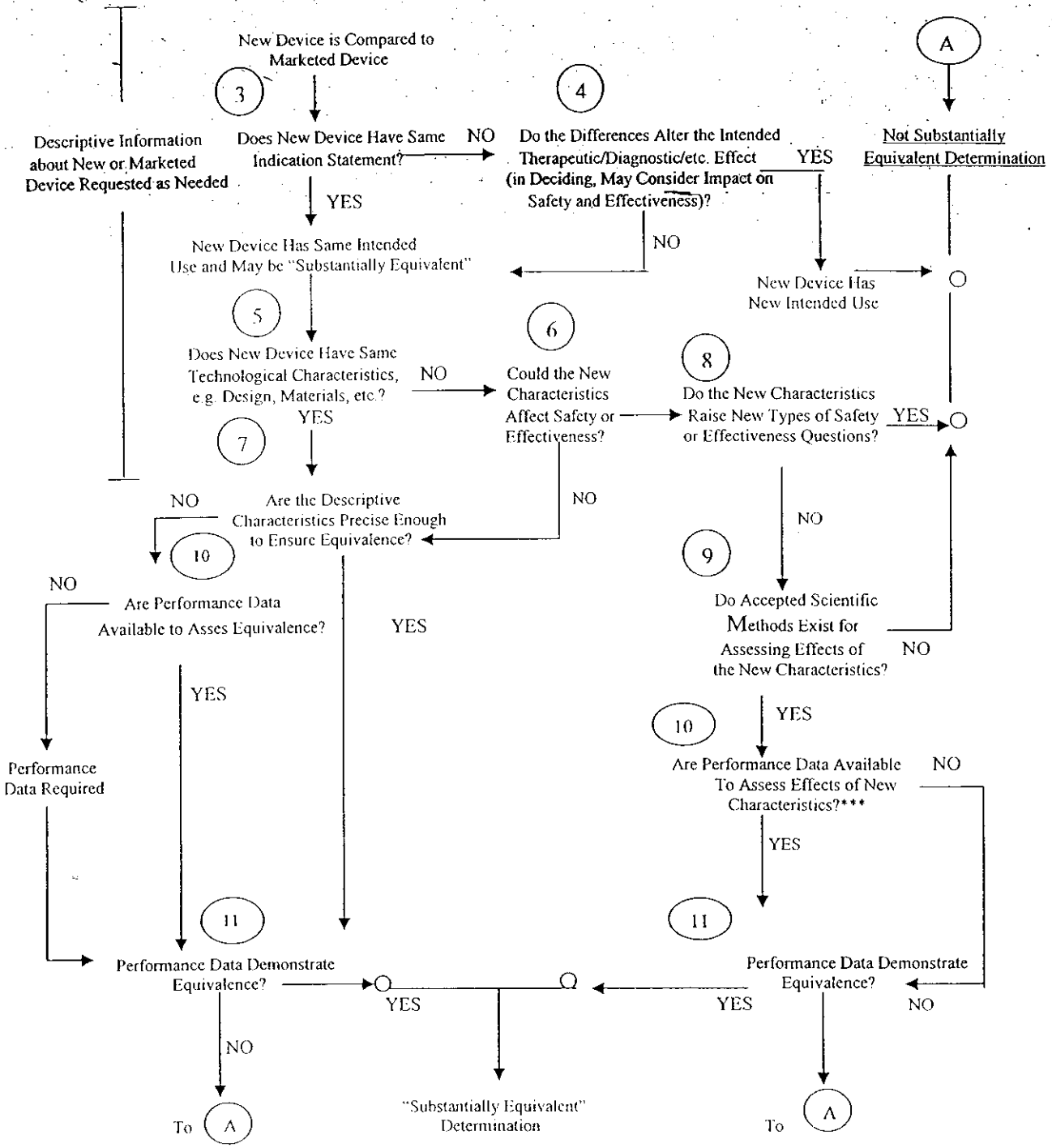
# 510(k) "SUBSTANTIAL EQUIVALENCE" DECISION-MAKING PROCESS




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

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

✣✣✣ Data maybe in the 510(k), other 510(k)s, the Center's classification files, or the literature.

**MEMO RECORD**

**From:** James Cheng JMC 12/17/02
**To:** File K023238
**Subject:** Meridian Co., Ltd.
McPulse PhotoPlethsymograph

**Date:** 12/17/02
**Office:** ODE
**Division:** DCD

**SUMMARY**

**Contact Person**

Mr. Daniel Kamm, P.E.
Kamm & Associates
P.O. Box 7007
Deerfield IL 60015 USA
Tel: 847-374-1727
Fax: 847-374-1728
Email: dkamm@fda-consultant.com
Fax and mail communications have been specifically authorized by the submitter. Requests for additional information may be emailed to dkamm @fda-consultant.corn or faxed to 847-384-1728.

for

Meridian Co., Ltd.
9Fl., Seoul Bldg.
222 Jamsilbon-Dong
Songpa-Gu Seoul, 138-863
Korea
Phone: 82-2-2103-3320
Fax: 82-2-2103-3333

This 510(k) submission is for the Meridian Co., Ltd., McPulse PhotoPlethsymograph, which senses blood pulsatile waveforms and heart rate via infrared optical transducers.

| | |
|---|---|
| **Trade name:** | McPulse Photo-Plethysmograph |
| **Common name:** | Plethysmograph, Photoelectric |
| **Device class:** | Class II |
| **CFR:** | 870.2780 |
| **Classification Name:** | Hydraulic, pneumatic, or photoelectric plethysmograph |
| **Product Code:** | 74 JOM |

**Indications for Use**

The device provides non-invasive measurement of pulse waveform and heart rate by photoelectric plethysmography.

**Device Description**

The McPulse Photo-Plethysmograph is intended to be used to measure pulse waveform and heart rate in the finger by by using an infrared LED and photodiode. The measurement probe is an optoelectronic sensor consisting of a light-emitting diode (infrared LED) and a photodiode placed on the opposite side. The light from the LED is transmitted through the tissue at the sensor site and the photodiode sensor measures the transmittance of infrared light. This signal is used to determine the absorbance of the

infrared light by hemoglobin in blood. The device converts the signal from the photodiode into a waveform and displays the pulse waveform on an LCD screen. Pulse rate is measured using the time between successive pulses and is displayed as digital values on LCD screen.

The signals received by the photodiode are small and may contain noise, so the first step involves amplification and filtering.

These signals are filtered using a low pass filter to remove electrical and ambient noise, and then amplified by a logarithm amplifier and linear amplifier. These amplified signals are then filtered by a low pass filter and a high pass filter to acquire the pulse wave signals. The cutoff frequencies of the low pass and high pass filters are 20Hz and 0.284Hz, respectively.

Using programmable DC offset eliminators and programmable gain amplifiers, the signals are multiplexed along with other analog signals prior to being fed into an A/D converter. Offset amplifiers offset the signals by a small positive level. This ensures that the offsets caused by the chain of amplifiers do not allow the signal to be negative as this is the input to the A/D converter, and the A/D converter only accepts inputs from 0 to 5V.

The A/D converter used in this device is 12 bit sampling analog-to-digital converter. The sampling rate is 800Hz.

The digitized signals are processed by the microprocessor to identify individual pulses. The system calculates the heart rate and displays the measured pulse waveform and twice differentiated pulse waveform on the LCD simultaneously.

The device applies Taylor Series to differentiate the pulse waveforms. The sampling rate of this Taylor Series is 400Hz.

**Measurement Probe**

The probe is an optoelectronic sensor composed of an infrared LED and a photodiode. The infrared light is transmitted into the skin of fingertip and the light absorbed is dependent on the blood volume in the fingertip. Consequently, the backscattered light corresponds with the variation of the blood volume and the photodiode measures this backscattered light. This signal is used to determine how much light was absorbed.

The infrared LED is an optoelectronic gallium aluminum arsenide semiconductor. The wavelength of the infrared light emitted from the LED is 889nm (nominal).

**Substantial Equivalence**

The McPulse is stated to be substially equivalent to the Novametrix Medical Systems, Inc., Pulse Oximeter, Model 500 (K853124).

| Feature | Novametrix Pulse Oximeter, Model 500 (K8531 24) | McPulse |
|---|---|---|
| **Indications** | measures pulse waveform, SaO2 and heart rate by photoelectric plethysmograph | measures pulse waveform and heart rate by photoelectric plethysmograph |
| **Mode** | Non invasive | Non Invasive |

| | | |
|---|---|---|
| **Practitioner Use** | Professional use only | Professional use only |
| **Display** | Digital LCD display Analog display | Digital LCD Display |
| **Power Source** | AC(100/120/220/240 VAC, 50/60Hz)<br>DC(Portable rechargeable battery) | AC (100-240 VAC, 50/60Hz) |
| **Type of Sensor** | LED-Photodiode finger, ear probe, flexible sensor | LED-Photodiode finger probe |
| **Anatomical Site** | Finger, ear, wrap around | Finger |
| **Recorder Outputs** | pulse waveform<br>heart rate<br>SaO2% | pulse waveform<br>heart rate |
| **Heart Rate Range & Display Resolution** | 25-250 bpm<br>1bpm | 30-230 bpm<br>1bpm |
| **Size (Unit: Mm)** | 228.6(W) x 92.08(H) x 254(D) | 305.5(W) x 296(H) x 92.5(D) |
| **Weight** | Approx. 3.6kg | Approx. 5.5 kg |

**Standards**

The McPulse has been designed to conform to the following standards:

1. IEC 60601-1, Safety of Medical Electrical Equipment, Part 1, General Requirements for Safety, including Amendment 1 and 2.
2. EN 60601-1-2 first edition, Standard for Electromagnetic Compatibility.

The electrical safety of the McPulse is achieved by means of reinforced or double insulated parts. Electrical isolation is at least 4000 VAC between the applied part (patient circuit) and power supply in accordance with IEC 60601-1.

The patient leakage current is certified to be less than 100 uA. The enclosure leakage current is also certified to be less than 100 uA.

**Summary**

The supporting information provided by the manufacturer is appropriate and acceptable with the exceptions noted below. The manufacturer has not adequately described the patient safety features designed into the device that prevent single fault failures from causing the LED to overheat and pose a potential patient skin burn threat. Nor has the manufacturer explicitly stated whether their device is designed to accept other manufacturers' probes, which would raise additional questions regarding how these additional probes were validated for use with this particular device.

**Recommendation**

Based on the outstanding issues it is recommended that additional information be requested.

**Action**

Additional information was requested using an email inquiry to the contact person, Mr. Daniel Kamm. The 510(k) specifically authorized the use of email and fax to contact Mr. Kamm. (Please see attached email)

(b) (4)

# EMAIL REQUEST FOR ADDITIONAL INFORMATION

**FROM:**

James Cheng
Reviewer
Office of Device Evaluation
Center for Devices and Radiological Health
FDA
HFZ-450
9200 Corporate Blvd
Rockville, MD 20850
phone: 301-443-8517 x164
fax: 301-594-3076
email: jmc@cdrh.fda.gov

**TO:**

Mr. Daniel Kamm, P.E.
Kamm & Associates
P.O. Box 7007
Deerfield IL 60015 USA
Tel: 847-374-1727
Fax: 847-374-1728
Email: dkamm@fda-consultant.com

**RE:**

K023238
Meridian Co., Ltd., McPulse PhotoPlethysmograph
Dated: September 26, 2002
Received: September 27, 2002

December 17, 2002

Dear Mr. Kamm,

We have reviewed your Section 510(k) notification of intent to market the device referenced above. We cannot determine if the device is substantially equivalent to a legally marketed predicate device based solely on the information you provided. To complete the review of your submission, we require the following information:

(b) (4)

(b) (4)

Your file will be placed on administrative hold pending receipt of the requested additional information. Please contact me if you have any questions.

Sincerely yours,

James Cheng
Reviewer
Division of Cardiovascular and Respiratory Devices
Office of Device Evaluation
Center for Devices and Radiological Health

## Cheng, James M.

**To:** dkamm@fda-consultant.com
**Cc:** Mallis, Elias
**Subject:** K023238 Request for additional information

**EMAIL REQUEST FOR ADDITIONAL INFORMATION**

**FROM:**

James Cheng
Reviewer
Office of Device Evaluation
Center for Devices and Radiological Health
FDA
HFZ-450
9200 Corporate Blvd
Rockville, MD 20850
phone: 301-443-8517 x164
fax: 301-594-3076
email: jmc@cdrh.fda.gov

**TO:**

Mr. Daniel Kamm, P.E.
Kamm & Associates
P.O. Box 7007
Deerfield IL 60015 USA
Tel: 847-374-1727
Fax: 847-374-1728
Email: dkamm@fda-consultant.com

**RE:**

K023238
Meridian Co., Ltd.
McPulse PhotoPlethysmograph
Dated: September 26, 2002
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December 17, 2002

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(b) (4)



35

(b) (4)

Please contact me if you have any questions.

Sincerely yours,

James Cheng
Reviewer
Division of Cardiovascular and Respiratory Devices
Office of Device Evaluation
Center for Devices and Radiological Health







36

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

Memorandum

From: Reviewer(s) - Name(s) James Cheng

Subject: 510(k) Number K023238/S1

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

- ☐ Refused to accept.
- ☐ Requires additional information (other than refuse to accept).
- ☑ Is substantially equivalent to marketed devices.
- ☐ NOT substantially equivalent to marketed devices.
  - De Novo Classification Candidate? ☐ YES ☐ NO
- ☐ Other (e.g., exempt by regulation, not a device, duplicate, etc.)

| | | |
|---|---|---|
| Is this device subject to Postmarket Surveillance? | ☐ YES | ☑ NO |
| Is this device subject to the Tracking Regulation? | ☐ YES | ☑ NO |
| Was clinical data necessary to support the review of this 510(k)? | ☐ YES | ☑ NO |
| Is this a prescription device? | ☑ YES | ☐ NO |
| Was this 510(k) reviewed by a Third Party? | ☐ YES | ☑ NO |
| Special 510(k)? | ☐ YES | ☑ NO |
| Abbreviated 510(k)? Please fill out form on H Drive 510k/boilers | ☐ YES | ☑ NO |

This 510(k) contains:

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

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

Animal Tissue Source ☐ YES ☑ NO

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

☐ No Confidentiality ☐ Confidentiality for 90 days ☐ Continued Confidentiality exceeding 90 days

Predicate Product Code with class: 74 JOM(2)

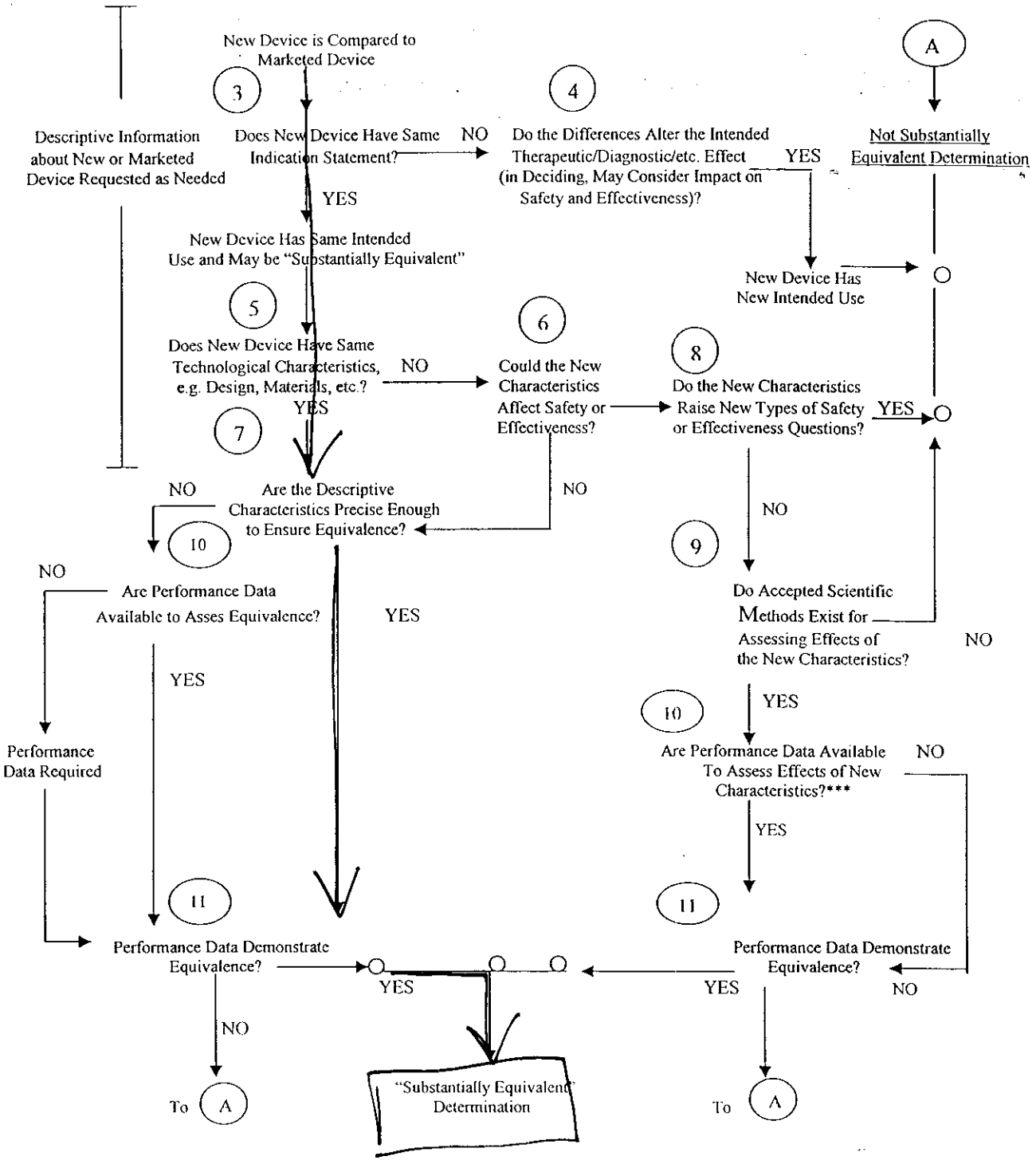
Additional Product Code(s) with panel (optional):

Review: Chris Millar (Branch Chief) CEMB (Branch Code) 02/13/03 (Date)

Final Review: (Division Director) 2/19/03 (Date)

Revised:8/17//99

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




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

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

❖❖❖ Data maybe in the 510(k), other 510(k)s, the Center's classification files, or the literature.

REVISED:3/14/95

**"SUBSTANTIAL EQUIVALENCE" (SE) DECISION MAKING DOCUMENTATION**

K023238

Reviewer: James Cheng

Division/Branch: DCD/CEMB

Device Name: Meridian Co., Ltd., McPulse PhotoPlethsymograph

Product To Which Compared (510(K) Number If Known): Novametrix Medical Systems, Inc., Pulse Oximeter, Model 500 (K853124).

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

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

1. Intended Use:

The device provides non-invasive measurement of pulse waveform and heart rate by photoelectric plethysmography.

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

The McPulse Photo-Plethysmograph is intended to be used to measure pulse waveform and heart rate in the finger by by using an infrared LED and photodiode. The measurement probe is an optoelectronic sensor consisting of a light-emitting diode (infrared LED) and a photodiode placed on the opposite side. The light from the LED is transmitted through the tissue at the sensor site and the photodiode sensor measures the transmittance of infrared light. This signal is used to determine the absorbance of the infrared light by hemoglobin in blood. The device converts the signal from the photodiode into a waveform and displays the pulse waveform on an LCD screen. Pulse rate is measured using the time between successive pulses and is displayed as digital values on LCD screen.

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

1. Explain why not a device:

2. Explain why not subject to 510(k):

3. How does the new indication differ from the predicate device's indication:

4. Explain why there is or is not a new effect or safety or effectiveness issue:

5. Describe the new technological characteristics:

6. Explain how new characteristics could or could not affect safety or effectiveness:

7. Explain how descriptive characteristics are not precise enough:

8. Explain new types of safety or effectiveness questions raised or why the questions are not new:

9. Explain why existing scientific methods can not be used:

10. Explain what performance data is needed:

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

ATTACH ADDITIONAL SUPPORTING INFORMATION

**MEMO RECORD**

**From:** James Cheng JMC 2/5/03
**To:** File K023238/S001
**Subject:** Meridian Co., Ltd.
McPulse PhotoPlethsymograph

**Date:** 2/5/03
**Office:** ODE
**Division:** DCD

**SUMMARY**

**Contact Person**

Mr. Daniel Kamm, P.E.
Kamm & Associates
P.O. Box 7007
Deerfield IL 60015 USA
Tel: 847-374-1727
Fax: 847-374-1728
Email: dkamm@fda-consultant.com
Fax and mail communications have been specifically authorized by the submitter. Requests for additional information may be emailed to dkamm @fda-consultant.corn or faxed to 847-384-1728.

for

Meridian Co., Ltd.
9Fl., Seoul Bldg.
222 Jamsilbon-Dong
Songpa-Gu Seoul, 138-863
Korea
Phone: 82-2-2103-3320
Fax: 82-2-2103-3333

This 510(k) submission is for the Meridian Co., Ltd., McPulse PhotoPlethsymograph, which senses blood pulsatile waveforms and heart rate via infrared optical transducers.

| | |
|---|---|
| **Trade name:** | McPulse Photo-Plethysmograph |
| **Common name:** | Plethysmograph, Photoelectric |
| **Device class:** | Class II |
| **CFR:** | 870.2780 |
| **Classification Name:** | Hydraulic, pneumatic, or photoelectric plethysmograph |
| **Product Code:** | 74 JOM |

**Indications for Use**

The device provides non-invasive measurement of pulse waveform and heart rate by photoelectric plethysmography.

**Device Description**

The McPulse Photo-Plethysmograph is intended to be used to measure pulse waveform and heart rate in the finger by by using an infrared LED and photodiode. The measurement probe is an optoelectronic sensor consisting of a light-emitting diode (infrared LED) and a photodiode placed on the opposite side. The light from the LED is transmitted through the tissue at the sensor site and the photodiode sensor

measures the transmittance of infrared light. This signal is used to determine the absorbance of the infrared light by hemoglobin in blood. The device converts the signal from the photodiode into a waveform and displays the pulse waveform on an LCD screen. Pulse rate is measured using the time between successive pulses and is displayed as digital values on LCD screen.

The signals received by the photodiode are small and may contain noise, so the first step involves amplification and filtering.

These signals are filtered using a low pass filter to remove electrical and ambient noise, and then amplified by a logarithm amplifier and linear amplifier. These amplified signals are then filtered by a low pass filter and a high pass filter to acquire the pulse wave signals. The cutoff frequencies of the low pass and high pass filters are 20Hz and 0.284Hz, respectively.

Using programmable DC offset eliminators and programmable gain amplifiers, the signals are multiplexed along with other analog signals prior to being fed into an A/D converter. Offset amplifiers offset the signals by a small positive level. This ensures that the offsets caused by the chain of amplifiers do not allow the signal to be negative as this is the input to the A/D converter, and the A/D converter only accepts inputs from 0 to 5V.

The A/D converter used in this device is 12 bit sampling analog-to-digital converter. The sampling rate is 800Hz.

The digitized signals are processed by the microprocessor to identify individual pulses. The system calculates the heart rate and displays the measured pulse waveform and twice differentiated pulse waveform on the LCD simultaneously.

The device applies Taylor Series to differentiate the pulse waveforms. The sampling rate of this Taylor Series is 400Hz.

**Measurement Probe**

The probe is an optoelectronic sensor composed of an infrared LED and a photodiode. The infrared light is transmitted into the skin of fingertip and the light absorbed is dependent on the blood volume in the fingertip. Consequently, the backscattered light corresponds with the variation of the blood volume and the photodiode measures this backscattered light. This signal is used to determine how much light was absorbed.

The infrared LED is an optoelectronic gallium aluminum arsenide semiconductor. The wavelength of the infrared light emitted from the LED is 889nm (nominal).

**Substantial Equivalence**

The McPulse is stated to be substially equivalent to the Novametrix Medical Systems, Inc., Pulse Oximeter, Model 500 (K853124).

| Feature | Novametrix Pulse Oximeter, Model 500 (K8531 24) | McPulse |
|---|---|---|
| **Indications** | measures pulse waveform, SaO2 and heart rate by photoelectric plethysmograph | measures pulse waveform and heart rate by photoelectric plethysmograph |

| | | |
|---|---|---|
| **Mode** | Non invasive | Non Invasive |
| **Practitioner Use** | Professional use only | Professional use only |
| **Display** | Digital LCD display Analog display | Digital LCD Display |
| **Power Source** | AC(100/120/220/240 VAC, 50/60Hz)<br>DC(Portable rechargeable battery) | AC (100-240 VAC, 50/60Hz) |
| **Type of Sensor** | LED-Photodiode finger, ear probe, flexible sensor | LED-Photodiode finger probe |
| **Anatomical Site** | Finger, ear, wrap around | Finger |
| **Recorder Outputs** | pulse waveform<br>heart rate<br>SaO2% | pulse waveform<br>heart rate |
| **Heart Rate Range & Display Resolution** | *25-250 bpm*<br>1bpm | *30-230 bpm*<br>1bpm |
| **Size (Unit: Mm)** | 228.6(W) x 92.08(H) x 254(D) | 305.5(W) x 296(H) x 92.5(D) |
| **Weight** | Approx. 3.6kg | Approx. 5.5 kg |

**Standards**

The McPulse has been designed to conform to the following standards:

1. IEC 60601-1, Safety of Medical Electrical Equipment, Part 1, General Requirements for Safety, including Amendment 1 and 2.
2. EN 60601-1-2 first edition, Standard for Electromagnetic Compatibility.

The electrical safety of the McPulse is achieved by means of reinforced or double insulated parts. Electrical isolation is at least 4000 VAC between the applied part (patient circuit) and power supply in accordance with IEC 60601-1.

The patient leakage current is certified to be less than 100 uA. The enclosure leakage current is also certified to be less than 100 uA.

**Summary**

The supporting information provided by the manufacturer is appropriate and acceptable. The manufacturer has appropriately responded to the request for additional information. There are no outstanding issues.

**Recommendation**

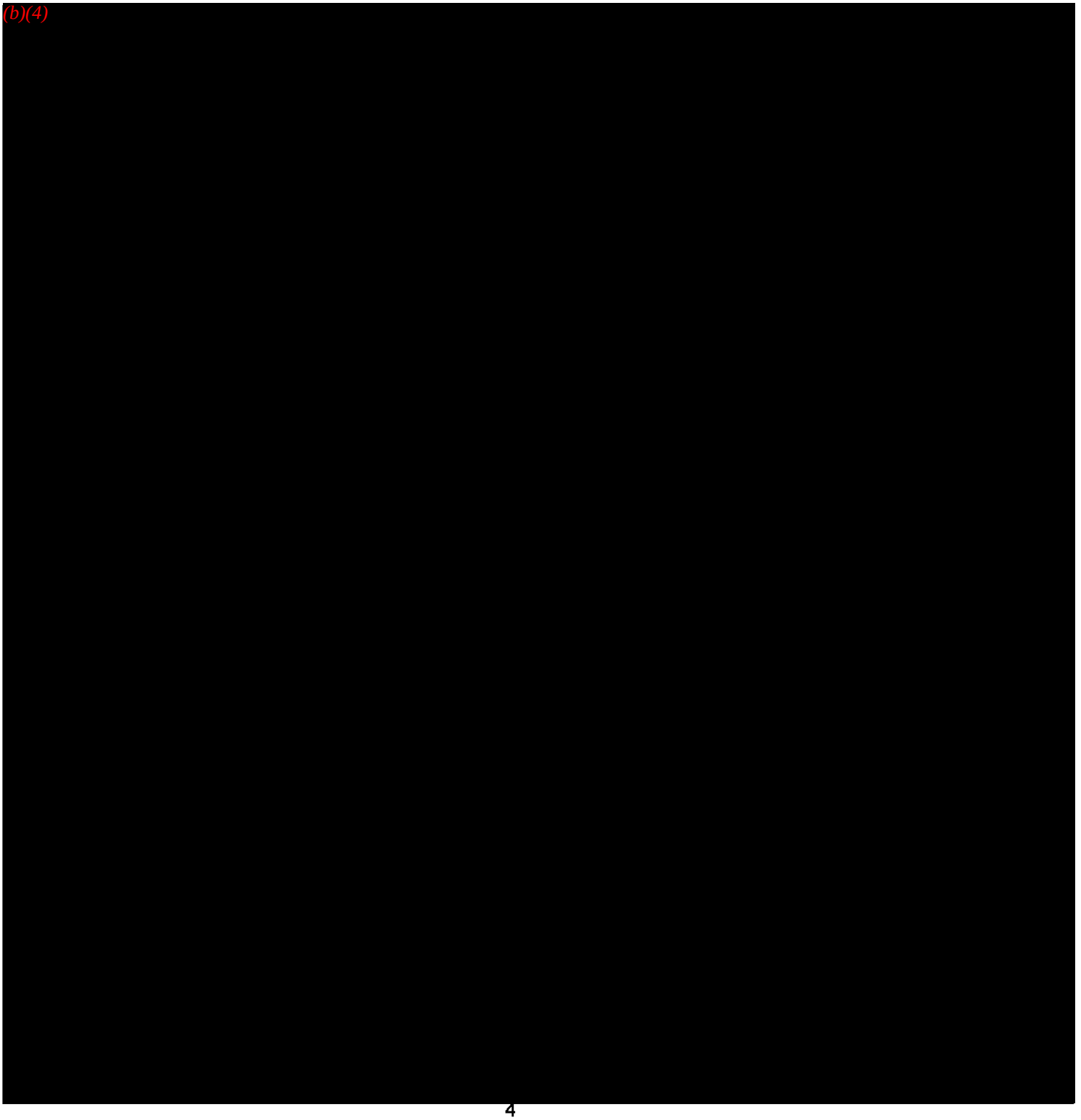
It is recommended that the device be found substantially equivalent.

**Action**

SE Letter

**Questions and Responses**

(b)(4)



DEPARTMENT OF HEALTH AND HUMAN SERVICES Public Health Service

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

January 16, 2003

MERIDIAN CO., LTD.
C/O KAMM & ASSOCIATES
PO BOX 7007
DEERFIELD, IL 60015
ATTN: DANIEL KAMM

510(k) Number: K023238
Product: MCPULSE

The additional information you have submitted has been received.

We will notify you when the processing of this submission has been completed or if any additional information is required. Please remember that all correspondence concerning your submission MUST be sent to the Document Mail Center (HFZ-401) at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification submission. Also, please note the new Blue Book Memorandum regarding Fax and E-mail Policy entitled, "Fax and E-Mail Communication with Industry about Premarket Files Under Review. Please refer to this guidance for information on current fax and e-mail practices at www.fda.gov/cdrh/ode/a02-01.html.

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

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

Sincerely yours,

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

13

K023238/S1

**Meridian Co., Ltd..**
**9Fl., Seoul Bldg., 222 Jamsilbon-Dong, Songpa-Gu**
**Seoul, 138-863 Korea**
**Phone: 82-2-2103-3320**
**Fax: 82-2-2103-3333**

**This submission was prepared by:**
Daniel Kamm, P.E.
Kamm & Associates
PO Box 7007
Deerfield IL 60015 USA
Phone 1+847-374-1727
Fax 1+847-374-1728
email dkamm@fda-consultant.com

**Please fax or email questions or requests for additional information to Mr. Kamm, who will expedite a reply.**



January 14, 2003

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

Attention: Document Mail Clerk

**Re: 510(k) Notification:** K023238

**Purpose of submission:** Requested additional information, K023238 SEE BELOW:

Sincerely yours,

Soorang Lee, R&D Director



Sim 40

14

Daniel Kamm

Daniel Kamm
(Regulatory Engineer)

Enclosures

**EMAIL REQUEST FOR ADDITIONAL INFORMATION**

**FROM:**

James Cheng
Reviewer
Office of Device Evaluation
Center for Devices and Radiological Health
FDA
HFZ-450
9200 Corporate Blvd
Rockville, MD 20850
phone: 301-443-8517 x164
fax: 301-594-3076
email: jmc@cdrh.fda.gov

**TO:**

Mr. Daniel Kamm, P.E.
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P.O. Box 7007
Deerfield IL 60015 USA
Tel: 847-374-1727
Fax: 847-374-1728
Email: dkamm@fda-consultant.com

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K023238
Meridian Co., Ltd.
McPulse PhotoPlethysmograph
Dated: September 26, 2002
Received: September 27, 2002

December 17, 2002

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(b) (4)





15

(b) (4)

[redacted]

Please contact me if you have any questions.

Sincerely yours,

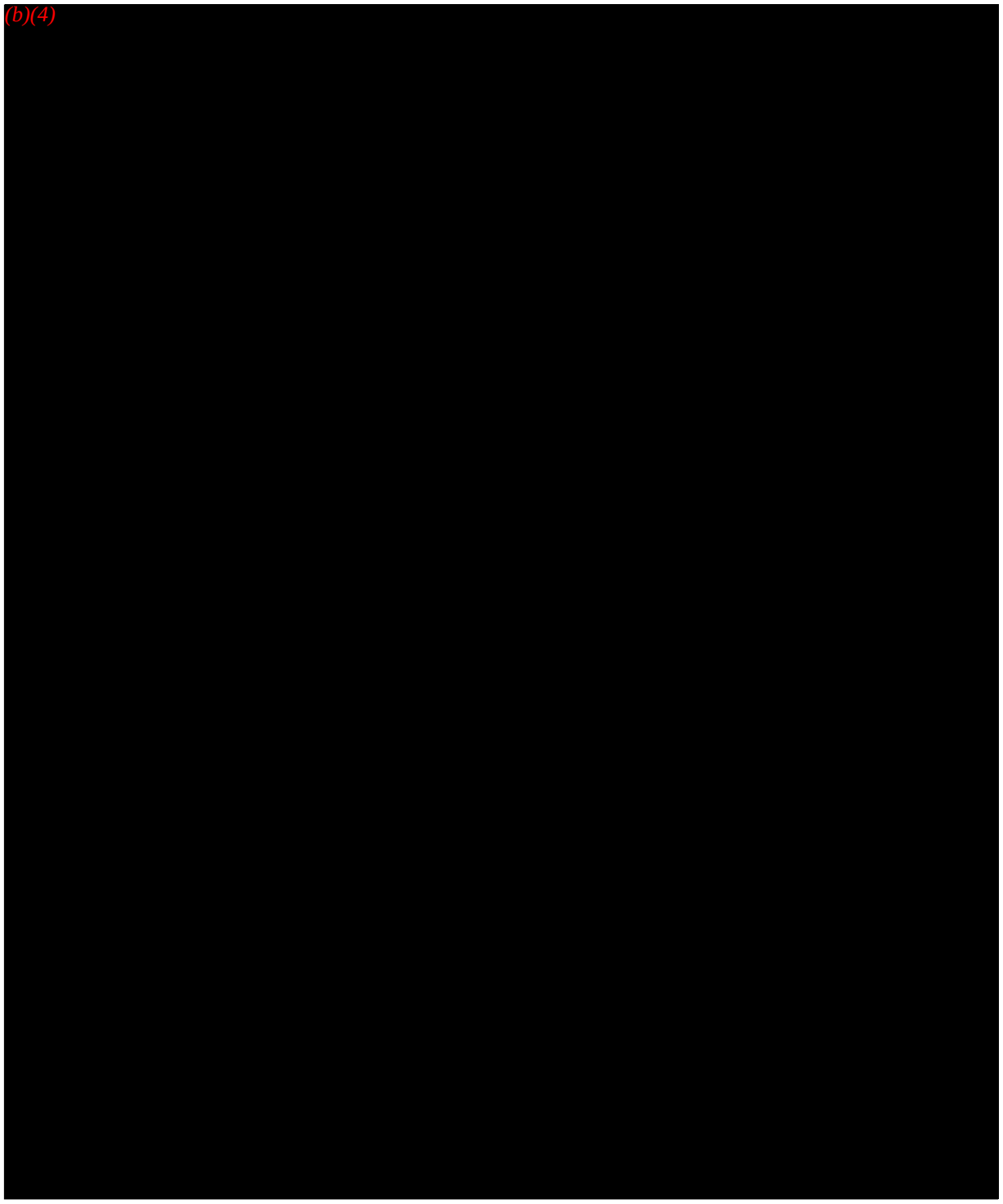
James Cheng
Reviewer
Division of Cardiovascular and Respiratory Devices
Office of Device Evaluation
Center for Devices and Radiological Health



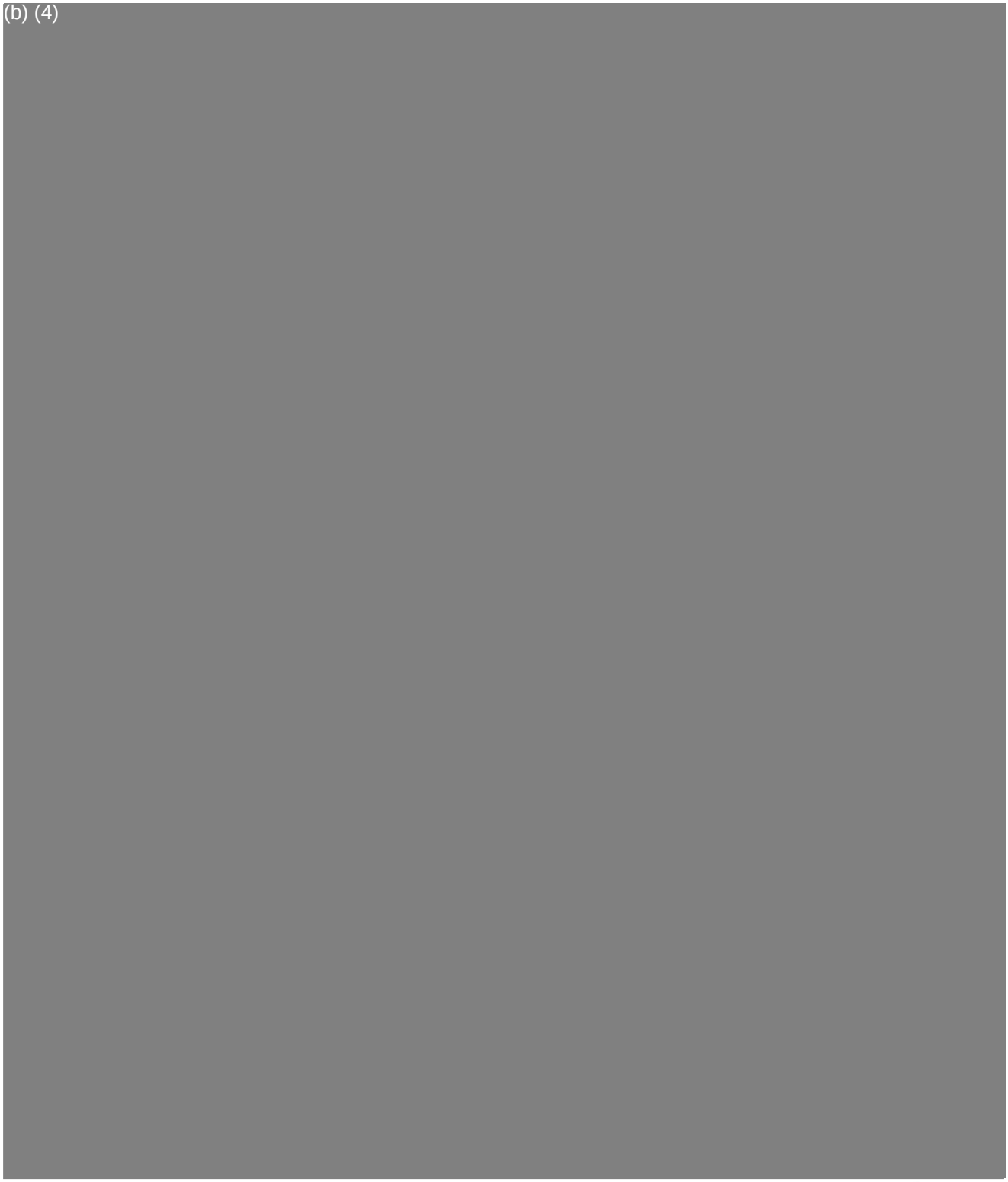
**COMPANY REPLY BELOW**

Additional information for the FDA question

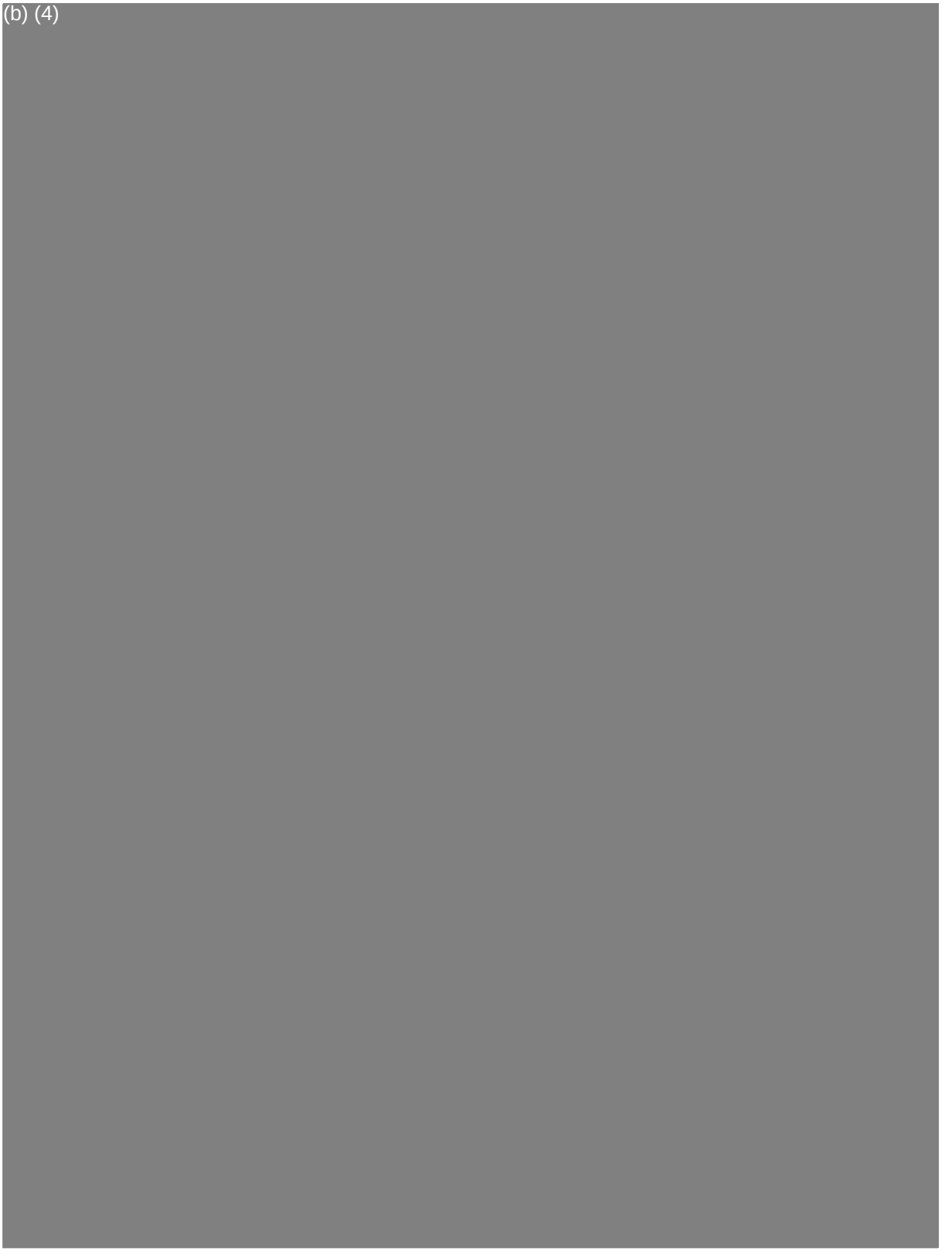
(b)(4)



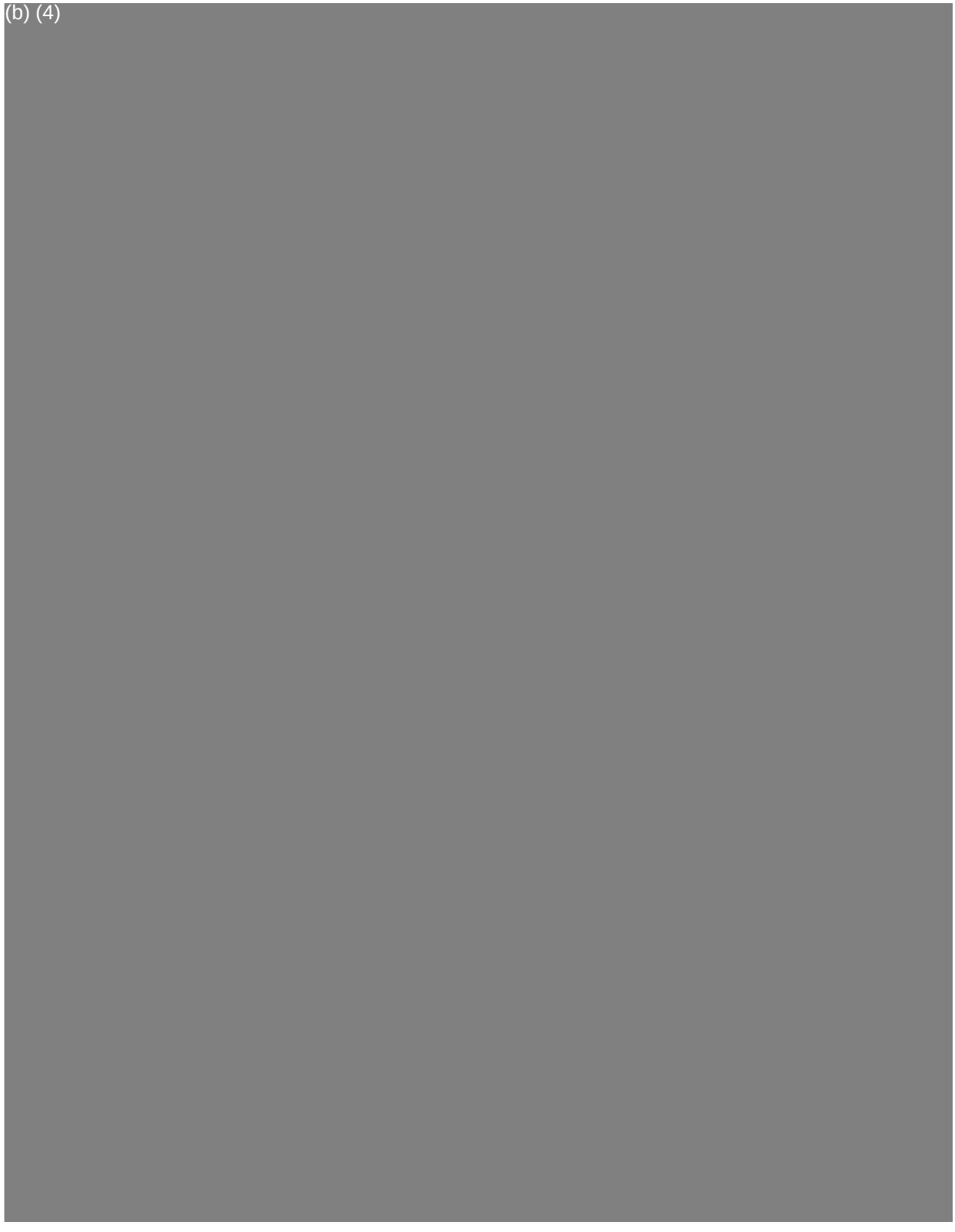
(b) (4)



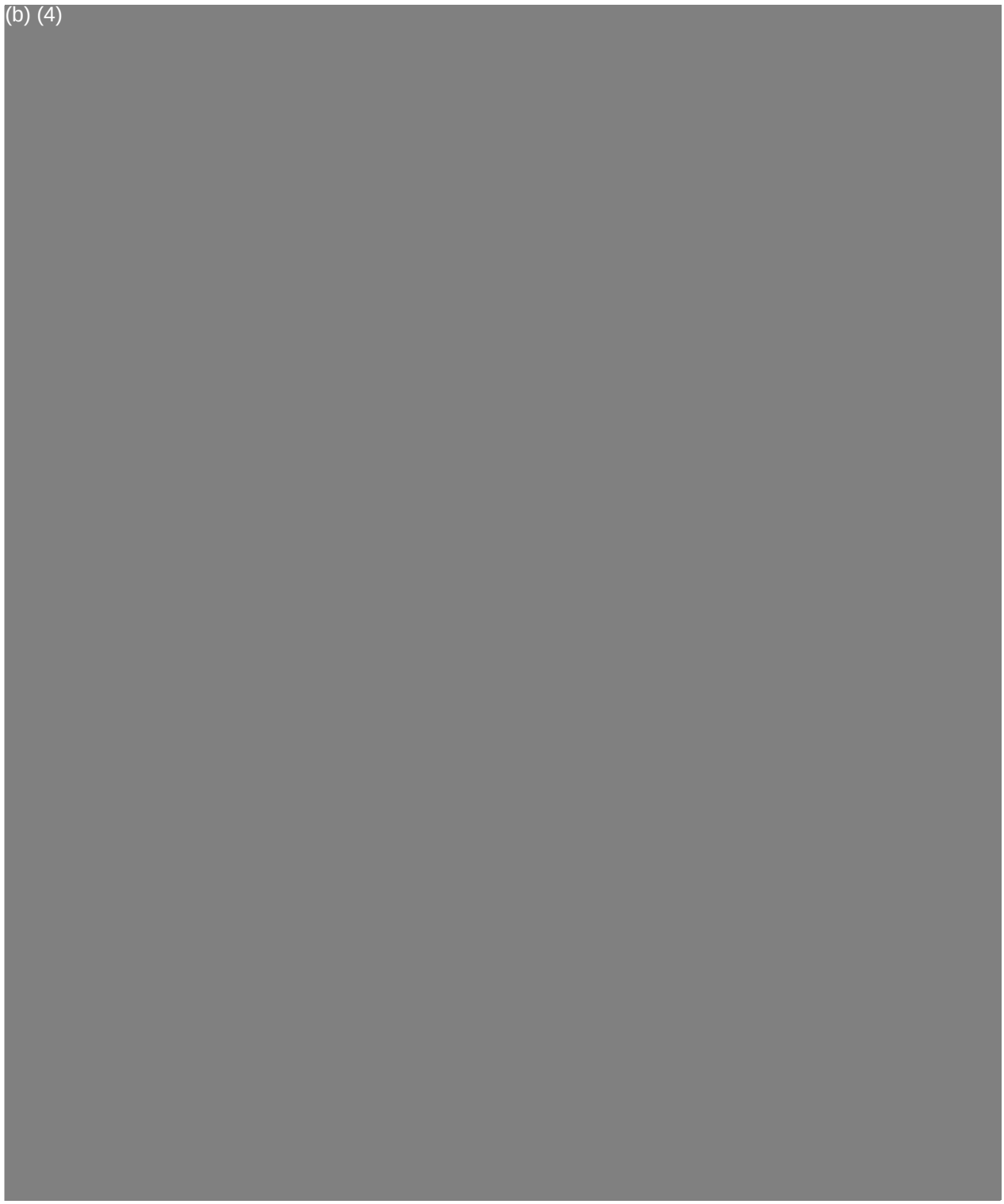
(b) (4)



(b) (4)



(b) (4)



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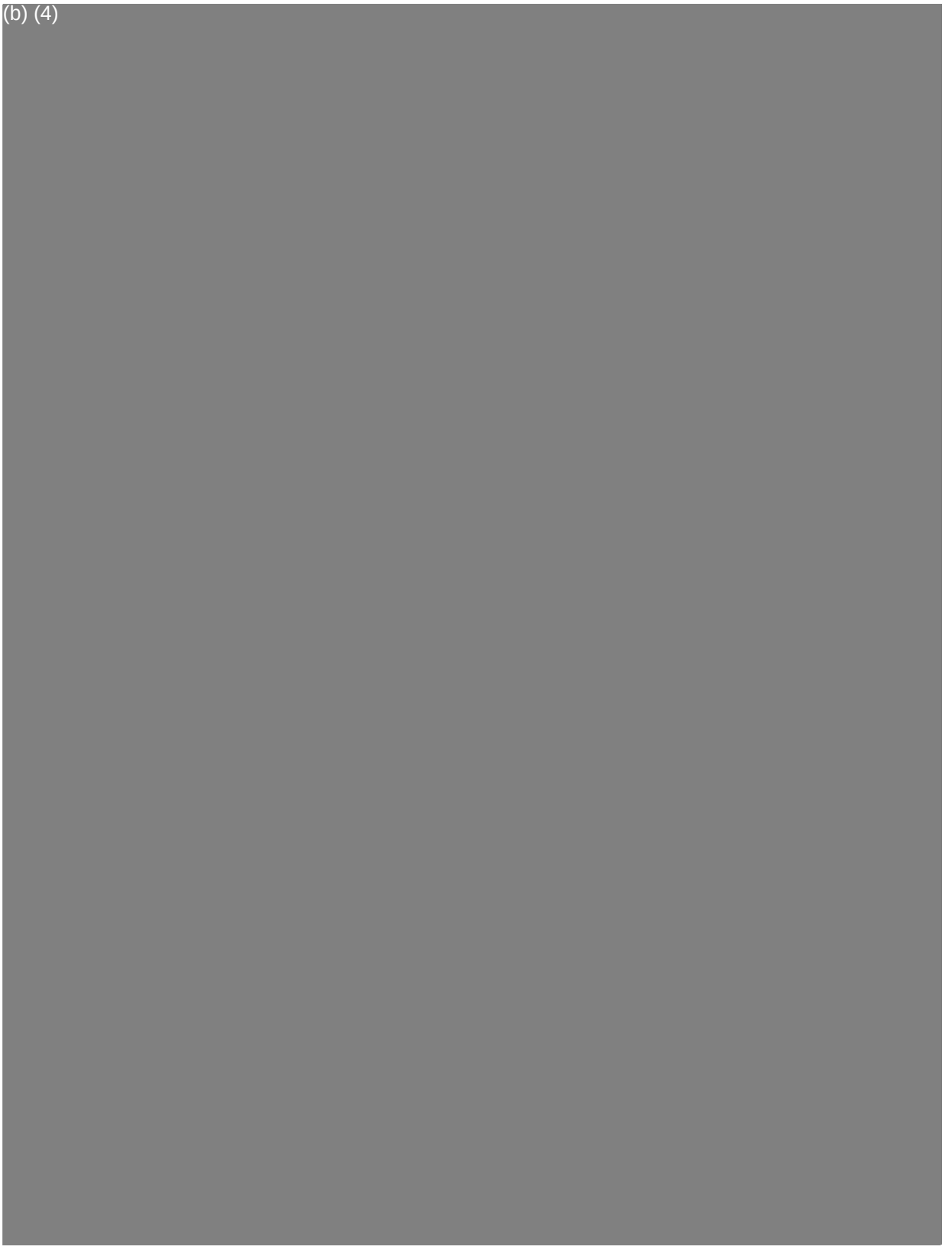
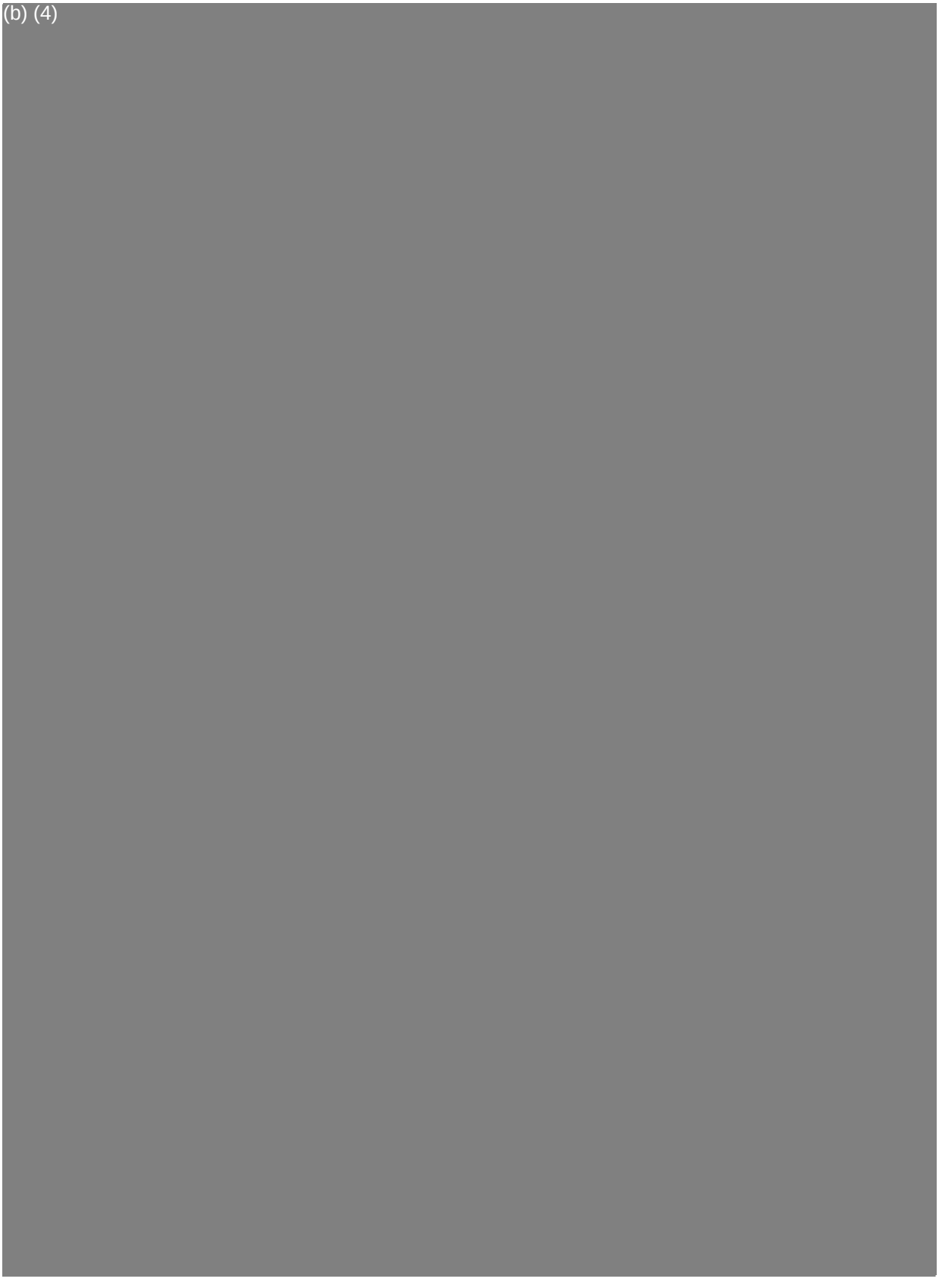


(b) (4)



(b) (4)