Records processed under FOIA Request #2016044103; Released by CDRH on 06-06-2016.

11 January 2011

Monica Healthcare

V9

FEB - 3 2011

K101801 510(K) Summary

Monica AN24

Submitters Name:

Ian How
Monica Healthcare Ltd
Biocity
Pennyfoot Street
Nottingham NG1 1GF
UK

Tel: +44 (0)115 912 4541
Email: ianhow@monicahealthcare.com

Name of Device: Monica AN24

Manufactured by:

Monica Healthcare Ltd
Biocity
Pennyfoot Street
Nottingham NG1 1GF
UK

Date of Summary: 4th January 2011

Classification Name: 21 CFR 884.270 System Monitoring Perinatal

Predicate Device: Philips 50XM (K954351)

Device Description:
The Monica AN24™ is a small, battery-powered device for L&D surveillance of fetal well-being. The AN24™ is designed to passively monitor Fetal Heart Rate (FHR) from the fetal electrocardiogram (fECG) and Uterine Activity (UA) from the Electrohysterogram (EHG) during pregnancy and can be used at any time from > 36 completed weeks gestation in laboring patients. The AN24™ is suitable for singleton pregnancies only.

Intended Use:

The Monica AN24 is an intrapartum maternal-fetal monitor that non-invasively measures and displays fetal heart rate (FHR) and uterine activity (UA). The AN24 acquires and displays the FHR tracing from abdominal surface electrodes that pick up the fetal ECG (fECG) signal. Using the same surface electrodes, the AN24 also acquires and displays the UA tracing from the uterine electromyography (EMG) signal. The AN24 is indicated for use on women who are at term (>36 completed weeks), in labor, with singleton pregnancies, using surface electrodes on the maternal abdomen.

The AN24 maternal-fetal monitor is intended for use by healthcare professionals in a clinical setting.

Technology Characteristics:
The Monica AN24 is a small, battery powered electrophysiological monitor (specifically fetal ECG and uterine EMG). The electrical signals are passively monitored on three channels using five electrodes placed on the pregnant abdomen in specific locations. From these electrical signals the Fetal Heart Rate (FHR) and

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Uterine Activity (UA) are continuously extracted and displayed in **the same standard format** as the predicate device.

The detection technology of the Monica AN24 differs from the predicate device which uses Doppler ultrasound to measure Fetal Heart Rate (FHR) and a tocodynamometer (TOCO) to measure Uterine Activity (UA). The predicate device detects the mechanical RR interval of the fetal heart whilst the Monica AN24 detects the electrical RR interval. However, from this data both instruments produce the same output i.e. fetal heart rate (expressed as number of heart beats per minute).

Uterine activity in the Monica AN24 is derived from the electrohysterogram which is the electric signal of the contracting/moving uterine muscle. The uterine activity in the TOCO predicate is derived from an external strain gauge to measure the abdominal pressure of the contracting/moving uterine muscle. However from this data both instruments produce the same uterine activity output trace.

For the actual detection of both FHR and UA the Monica AN24 does not emit any energy into the patient and hence the above differences in detection technology do not raise any new type of safety and effectiveness questions. In addition for FHR and uterine activity both the AN24 and predicate device are external, skin contacting devices. Differences in materials in contact with the patient are resolved with biocompatibility testing and compliance with standards.

To ensure clinical effectiveness the clinical performance data was collected as described in the "Clinical Study" section below. This study demonstrates that the Monica AN24 device is at least as accurate and reliable as the predicate device for monitoring both FHR and UA.

In summary, the differences in technology between the AN24 and the predicate device do not affect safety or effectiveness.

Clinical Study

1. Introduction

This section summarizes the six-way clinical equivalence trial and subsequent Multi-Reader-Multi-Case (MRMC) studyI supporting the effectiveness of the Monica AN24. The study enrolled 60 women at term, in labor, at two clinical sites, of which 33 women contributed to the Fetal Heart rate (FHR) study and 30 to the Uterine activity (UA) study. Each study subject was instrumented with three technologies for measuring fetal heart rate (FHR) and with three technologies for measuring uterine activity (UA). These are:

Fetal Heart Rate (FHR):

1) Doppler ultrasound cardiotocograph (Philips Series 50XM) – predicate device
2) Monica AN24 abdominal fetal ECG – test device
3) Direct fetal Scalp ECG (second Phillips Series 50XM device) – gold standard (GS)

Uterine Activity (UA):

1) Tocodynamometry (Philips Series 50XM) – predicate device
2) Monica AN24 Electrohysterogram (EHG) - test device
3) Intrauterine Pressure Catheter (IUPC), Philips Series 50XM – gold standard (GS)

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Using fetal scalp electrode and IUPC as the "gold standards", this study methodology allowed a six-way comparison for evaluating how well the Monica AN24 performed vs. Doppler for FHR measurement and Monica AN24 versus tocodynamometry for uterine activity.

2. Study Design

2.1 Study Objective

The primary objective was to demonstrate that during the intrapartum period the Monica AN24 is equivalent to the Doppler FHR and tocodynamometer-derived uterine activity when both are compared simultaneously to direct scalp FHR and IUPC uterine activity, respectively.

Inclusion Criteria:

- Pregnant, age 15-40
- Term gestation (>36 completed weeks)
- Singleton fetus
- Active labor
- Vertex presentation
- Requiring internal monitoring

Exclusion Criteria:

- Clinical contraindication for IUPC
- Major fetal malformation

2.2 Study Methodology

Each study subject agreed to be simultaneously instrumented with three different technologies for measuring FHR and with three different technologies for measuring uterine activity (UA). Sensors and/or catheters were applied and removed as clinically indicated. For the UA comparison, three 30-minute segments of data were randomly selected from the entire monitored period for each subject, two 30-minute tracings from Stage 1 and one 30-minute trace from Stage 2 of labor. Therefore, 90 minutes of recording was analyzed for each subject for UA. For the FHR comparison, all the FHR data was analyzed for the entire monitoring period when the direct scalp FHR data was present.

2.3 Outcome Measures

Both the Monica AN24 (FHR and EHG) and the predicate devices (Doppler or TOCO) were compared with the gold standard (GS) device (i.e. direct scalp fetal ECG or IUPC). Monica AN24 was tested against the predicates using null hypotheses of inferiority and alternative hypotheses of non-inferiority, for the measurement of FHR and UA in terms of: Interpretability and *Accuracy* - resulting in four separate endpoints as follows:

Fetal Heart Rate

The data from all 3 FHR instruments was processed into synchronized 0.25 second epochs. The following primary end points were calculated for FHR:

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End Point 1: For *FHR* interpretability the Monica FHR (or the Doppler FHR) versus the GS was organized into a 2x2 table of interpretable and uninterpretable data, i.e., where uninterpretable data are defined as those where the device in question does not report a valid FHR reading. A positive percent agreement (PPA) with GS was generated for each patient giving two values per patient – one for Monica AN24 vs GS and one for Doppler vs GS. PPA is defined as the percent of epochs with valid GS figures that are interpretable by the device in question

End Point 2: For FHR *accuracy*, a single Bland Altman (BA) difference plot was generated for Monica FHR (or Doppler FHR) vs the GS for each patient and a root mean square (RMS) error was determined for each device comparison. A BA difference plot is a scatter plot of the difference between the device and GS measurements vs. the GS measurement. RMS error is the square root of the mean of the squared differences.

Uterine Activity

The uterine activity data were independently reviewed in a Multi-Reader Study by four Board Certified Obstetricians who independently indicated on randomized trace segments the following features: "*Interpretable or Un-interpretable*" data, and "*Individual Contractions*", with each individual contraction marked as "*Good Quality*" or "*Bad Quality*". The marking was blind with respect to the device that produced the tracing. The four sets of data were again processed in terms of interpretability and accuracy. The following primary end points were calculated for UA:

End Point 3: For *UA interpretability*, a 2x2 Table of interpretable/uninterpretable data of Monica EHG (or TOCO) vs GS (IUPC) was constructed and the PPA was determined in the same manner as for FHR.

End Point 4a: For UA sensitivity accuracy, a Table of individual contractions identified by both Monica AN24 (or TOCO) and GS (IUPC) and those detected only by GS (IUPC) was constructed. To determine sensitivity, the proportion of contractions as determined by GS that were detected within ± 30 seconds by the device in question were calculated

End Point 4b: A second UA accuracy parameter (UA timing accuracy) was calculated as the difference in timing of corresponding contractions between Monica AN24 (or TOCO) and the GS (IUPC).

3. Description of Study Population

Thirty-four of 60 subjects enrolled provided evaluable data. Mean gestational age was 39 weeks 3 days (37 w 2d to 42 w 0d). Mean age was 26 years (18 to 38). Mean body mass index (BMI) was 32 (19 to 54). Thirty-one subjects were successfully instrumented with all six technologies, two subjects were successfully instrumented with three FHR technologies and one subject was successfully instrumented with three uterine activity technologies.

4. Results

The following key statistical outcomes, all validated with 95% confidence limits, were:

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FHR compared to fetal scalp ECG

1. FHR Interpretability: The mean positive percent agreement (PPA) for interpretable data for Monica was 85% compared with 72% for Doppler
2. FHR Accuracy: The mean RMS error from Bland Altman was 5 bpm for Monica compared with 12 bpm for Doppler, indicating that the Monica AN24 FHR output is more similar to the gold standard fetal scalp electrode measurement compared to Doppler.

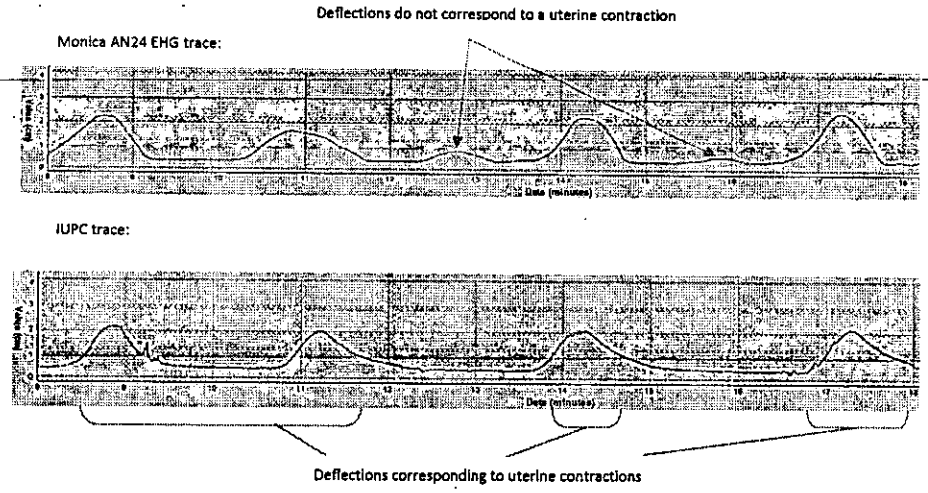
Uterine Activity compared to IUPC (average of 4 board certified obstetricians):

1. UA Interpretability: The mean PPA for UA trace interpretability of Monica was 97% compared with 67% for TOCO
2. UA Sensitivity Accuracy: The mean sensitivity for detecting individual contractions observed on IUPC, within ± 30 seconds, was 89% (84% to 91%) for Monica compared with 55% (48% to 62%) for TOCO.
3. UA Timing Accuracy: The mean timing difference of corresponding contractions was 2.5 seconds lag (2.06 to 2.94 seconds lag) when comparing Monica AN24 with IUPC and 3.3 seconds lag (2.92 to 3.69 seconds lag) when comparing TOCO with IUPC.

5. False Positives

When Monica AN24 or tocodynamometry tracings exhibit a deflection above baseline that does not have a corresponding deflection on the gold standard IUPC, that deflection may be considered a "False Positive" (FP). The Monica "Multi-Reader Study" evaluated the relative FP rate for Monica AN24 and tocodynamometry. The results of this analysis demonstrated that clinician judgement on individual deflections varied widely among the four clinical reviewers. Therefore, it is unclear whether comparison of the FP rate for Monica AN24 vs. tocodynamometry in the Multi-Reader Study is generalizable.

To illustrate how individual clinical judgment may vary, the following example displays a Monica AN24 tracing with two discernable deflections above baseline that do not correspond to deflections on the IUPC tracing:



If most or all of the types of Monica AN24 deflections above are counted as contractions, then the Monica AN24 may display more FP contractions compared to

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K101801 page 6 of 6

tocodynamometry. This difference, however, is unlikely to have an adverse impact on clinical outcomes in full term laboring patients.

5. Acknowledgements
Monica Healthcare Ltd, UK, would like to thank: the clinical teams at QHC, New York and Temple University, Philadelphia for undertaking this study and the USA mothers who kindly agreed to take part in the study.

Non Clinical Test Summary
The Monica AN24 and Accessories comply with voluntary standards. The standards were employed in the following areas:

- Electrical Safety
- EMC
- Material Safety
- Software Validation

Conclusion
The non clinical tests used voluntary standards employed at accredited independent test facilities to demonstrate that the Monica AN24 is as safe and effective in performance to the predicate device, the main standards employed were

- IEC60601-1 electrical safety
- IEC60601-1-2 EMC
- IEC 60601-1-2-47 Performance standard for electrocardiographs
- IEC60601-1-4 Software
- ISO10993 Biocompatibility
- ISO14385 QMS

To demonstrate that the Monica AN24 is as clinically safe and effective as the predicate device, the clinical study described above measured the clinical performance of the Monica AN24 and the predicate device against the gold standards fetal scalp ECG and IUPC. The outcomes showed that in a clinical setting the Monica AN24 achieved for FHR: a positive percent agreement (PPA) for interpretability of 85% compared to 72% for the predicate; whilst for accuracy a mean RMS error from Bland Altman of 5 bpm for Monica AN24 when compared with 12 bpm for the predicate. For Uterine Activity the Monica AN24 achieved: a mean PPA for interpretability of 97% compared with 67% for predicate (TOCO); whilst for accuracy the mean sensitivity for detecting individual contractions was 89% for Monica AN24 compared with 55% for the predicate (TOCO); further the mean timing difference of corresponding contractions was 2.5 seconds (lag) when comparing Monica AN24 with IUPC and 3.3 seconds (lag) when comparing TOCO with IUPC. The Monica AN24 had an increased false positive contraction count compared to the predicate however, this was not clinically significant.

The conclusions drawn from the nonclinical tests and clinical study demonstrate that the Monica AN24 is as safe, as effective and performs as safely and effectively as the legally marketed predicate device.

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

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

Mr. Ian How
Regulatory Affairs Manager
Monica Healthcare
Biocity
Pennyfoot Street
Nottingham
United Kingdom NG1 1GF

FEB - 3 2011

Re: K101801
Trade Name: Monica AN24
Regulation Number: 21 CFR §884.2740
Regulation Name: Perinatal monitoring system and accessories
Regulatory Class: II
Product Code: HGM, OSP
Dated: December 1, 2010
Received: December 3, 2010

Dear Mr. How:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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); medical device reporting (reporting of medical device-related

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adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Herbert P. Lerner, M.D., Director (Acting)
Division of Reproductive, Gastro-Renal
and Urological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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

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Indications for Use Statement

510(k) Number (if known): K101801

Device Name: AN24

Indications For Use:

The Monica AN24 is an intrapartum maternal-fetal monitor that non-invasively measures and displays fetal heart rate (FHR) and uterine activity (UA). The AN24 acquires and displays the FHR tracing from abdominal surface electrodes that pick up the fetal ECG (fECG) signal. Using the same surface electrodes, the AN24 also acquires and displays the UA tracing from the uterine electromyography (EMG) signal. The AN24 is indicated for use on women who are at term (>36 completed weeks), in labor, with singleton pregnancies, using surface electrodes on the maternal abdomen.

The AN24 maternal-fetal monitor is intended for use by healthcare professionals in a clinical setting.

Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Gastro-Renal, and Urological Devices
510(k) Number K101801

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

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Services
Food and Drug Administration

Memorandum

Date:

From: DMC (HFZ-401)

Subject: Premarket Notification Number(s): K101801 | A1

To: Division Director: OB/DRARD

The attached information has been received by the 510(k) DMC on the above referenced 510(k) submission(s). Since a final decision has been rendered, this record is officially closed.

Please review the attached document and return it to the DMC, with one of the statements checked below.

_____ Information does not change the status of the 510(k); no other action required by the DMC; please add to image file. (Prepare K-25) THIS DOES NOT APPLY TO TRANSFER OF OWNERSHIP. PLEASE BRING ANY TRANSFER OF OWNERSHIP TO POS.

_____ Additional information requires a new 510(k); however, the information submitted is incomplete; (Notify company to submit a new 510(k); [Prepare the K30 Letter on the LAN]

✓ No response necessary (e.g., hard copy of fax for the truthful and accuracy statement, 510(k) statement, change of address, phone number, or fax number).

CLIA CATEGORIZATION refers to laboratory test system devices reviewed by the Division of Clinical Laboratory Devices (HFZ-440

_____ Information requires a **CLIA CATEGORIZATION**; the complexity may remain the same as the original 510(k) or may change as a result of the additional information (Prepare a CAT letter)

_____ Additional information requires a **CLIA CATEGORIZATION**; however, the information submitted is incomplete; (call or fax firm)

_____ No response necessary

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

Reviewed by: _____

Date: _____

DCC 2/4/11

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

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K101801/A1

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www.monicahealthcare.com

K-15

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center - WO66-G609
10903 New Hampshire Avenue
Silver Spring, Maryland 20993-0002

FDA CDRH DMC

AUG 02 2010

Received

29 July 2010

K101801

Dear Sir or Madam Please find enclosed

A full submission in paper format including all Appendices except for the Data traces that have been supplied electronically as agreed with Colin Pollard and Kathy Daws – Kopp.

This is an addendum to K101801 that started the 90 day process on 28 June for the Monica Healthcare AN24 Fetal Monitor.

(b)(4) [redacted]

Yours Sincerely

.....

Ian How

Regulatory Affairs Manager

Monica Healthcare Ltd

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

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Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center - WO66-G609
10903 New Hampshire Avenue
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29 July 2010

K101801

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(b)(4) [redacted]

Yours Sincerely

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Regulatory Affairs Manager

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Monica Healthcare

Confidential

510(K) PREMARKET NOTIFICATION

MONICA HEALTHCARE LIMITED

MONICA AN24

Submission date:
June 2010

The term "predicate device(s)"as used throughout this entire premarket notification (cover letter, body, attachments, and summary), and the supporting information pertaining to equivalence, are intended to demonstrate equivalence to the predicate device(s) for the purposes of obtaining clearance of the subject device(s) under the Federal Food, Drug and Cosmetic Act. Any references to equivalence in this submission are in no way related to any form of equivalence under patent laws.

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

Records processed under FOIA Request #2015-4103; Released by CDRH on 06-06-2016.

Monica Healthcare

SCREENING CHECKLIST FOR ALL PREMARKET NOTIFICATION [510(k)] SUBMISSIONS

510(k) Number: _____

The cover letter clearly identifies the type of 510(k) submission as **(Check the appropriate box)**:

☐ Special 510(k) - Do Sections 1 and 2

☐ Abbreviated 510(k) - Do Sections 1, 3 and 4

☐ Traditional 510(k) or no identification provided - Do Sections 1 and 4

Section 1: Required Elements for All Types of 510(k) submissions:

	Present or Adequate	Missing or Inadequate
Cover letter, containing the elements listed on page 3-2 of the Premarket Notification [510)] Manual.		
Table of Contents.		
Truthful and Accurate Statement.		
Device?s Trade Name, Device?s Classification Name and Establishment Registration Number.		
Device Classification Regulation Number and Regulatory Status (Class I, Class II, Class III or Unclassified).		
Proposed Labeling? including the material listed on page 3-4 of the Premarket Notification [510)] Manual.		
Statement of Indications for Use that is on a separate page in the premarket submission.		
Substantial Equivalence Comparison, including comparisons of the new device with the predicate in areas that are listed on page 3-4 of the Premarket Notification [510)] Manual.		
510(k) Summary or 510(k) Statement.		
Description of the device (or modification of the device) including diagrams, engineering drawings, photographs or service manuals.		

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Monica Healthcare

Identification of legally marketed predicate device. *		
Compliance with performance standards. * [See Section 514 of the Act and 21 CFR 807.87 (d).]		
Class III Certification and Summary. **		
Financial Certification or Disclosure Statement for 510(k) notifications with a clinical study. * [See 21 CFR 807.87 (i)]		
510(k) Kit Certification ***		

Section 4: Additional Requirements for ABBREVIATED and TRADITIONAL 510(k) submissions (If Applicable):

	Present	Inadequate or Missing
a)?? Biocompatibility data for all patient-contacting materials, OR certification of identical material/formulation:	-	-
b)?? Sterilization and expiration dating information:		
i) sterilization process		
ii) validation method of sterilization process		
iii) SAL		
iv) packaging		
v) specify pyrogen free		
vi) ETO residues		
vii) radiation dose		
viii) Traditional Method or Non-Traditional Method		
c)?? Software Documentation:		

Items with checks in the? Present or Adequate? column do not require additional information from the sponsor.? Items with checks in the ? Missing or Inadequate? column must be submitted before substantive review of the document.

Passed Screening _____Yes _____No

Reviewer:_____

Concurrence by Review Branch:_____

Date:_____

Records processed under FOIA Request #2015-4103; Released by CDRH on 06-06-2016.

Monica Healthcare

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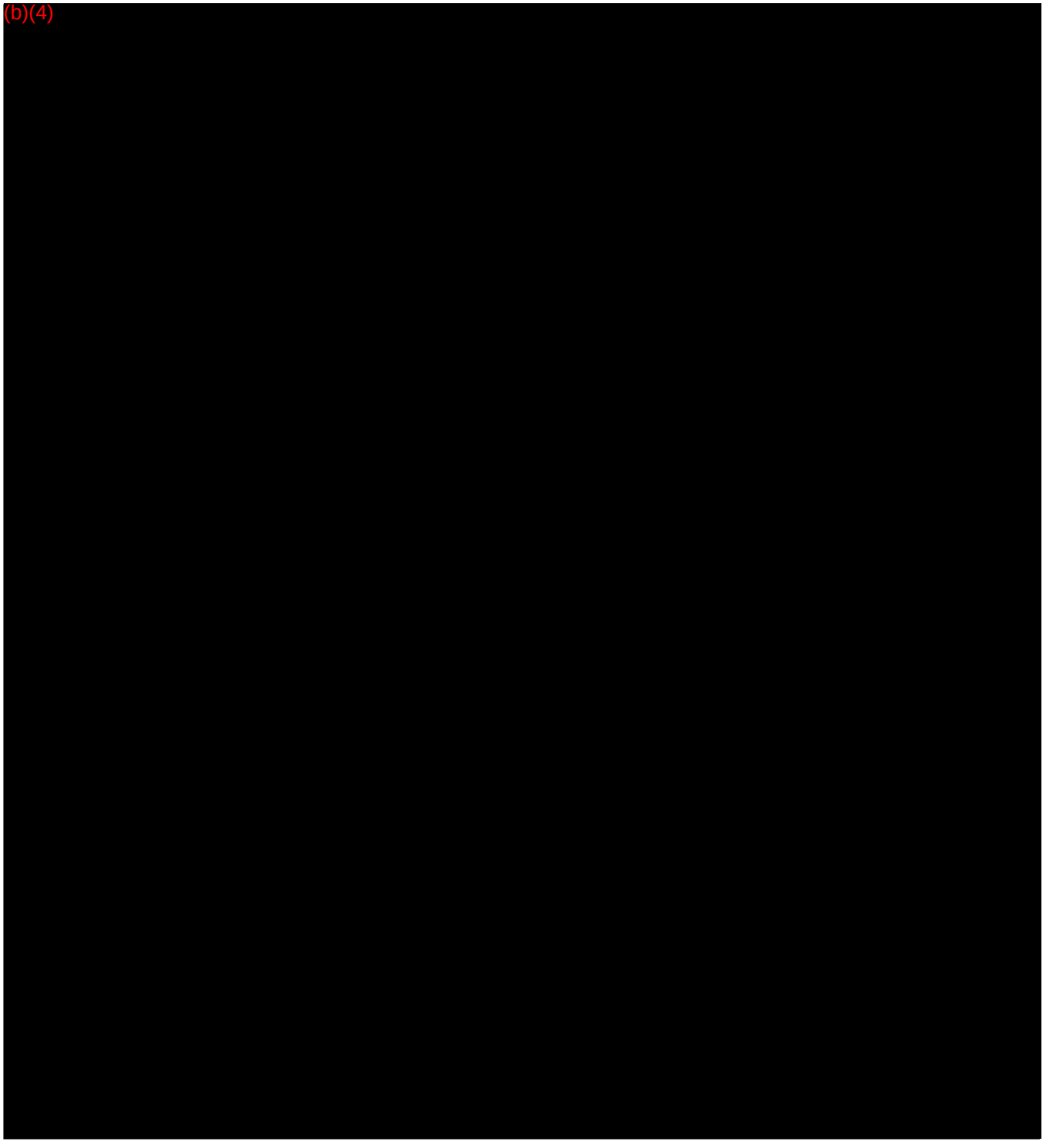
(b)(4)



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

Records processed under FOIA Request #2015-4103; Released by CDRH on 06-06-2016.

Section 1

- Medical Device User Fee Cover Sheet
- CDRH Premarket Review Submission Cover Sheet
- 510(k) Cover Letter
- Indications for Use Statement
- 510(k) Statement
- Truthful and Accuracy Statement
- Class III Summary and Certification
- Financial Certification or Disclosure Statement

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

Records processed under FOIA Request #2015-4103; Released by CDRH on 06-06-2016.

Monica Healthcare

Medical Device User Fee Cover Sheet (FDA3601)

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION **MEDICAL DEVICE USER FEE COVER SHEET**	PAYMENT IDENTIFICATION NUMBER: (b)(4) Write the Payment Identification Number on your check.

A completed cover sheet must accompany each original application or supplement subject to fees. If payment is sent by U.S. mail or courier, please include a copy of this completed form with payment. Payment and mailing instructions can be found at: http://www.fda.gov/oc/mdufma/coversheet.html

1. COMPANY NAME AND ADDRESS (include name, street address, city state, country, and post office code)	2. CONTACT NAME
MONICA HEALTHCARE LIMITED Biocity Pennyfoot Street Nottingham NG1 1GF GB	Ian How
1.1 EMPLOYER IDENTIFICATION NUMBER (EIN)	2.1 E-MAIL ADDRESS ianhow@monicahealthcare.com
	2.2 TELEPHONE NUMBER (include Area code) 44115-9124540
	2.3 FACSIMILE (FAX) NUMBER (include Area code) 44115-9124289

3. TYPE OF PREMARKET APPLICATION (Select one of the following in each column; if you are unsure, please refer to the application descriptions at the following web site: http://www.fda.gov/oc/mdufma

Select an application type:	3.1 Select a center
[X] Premarket notification(510(k)); except for third party	[X] CDRH
[ ] 513(g) Request for Information	[ ] CBER
[ ] Biologics License Application (BLA)	3.2 Select one of the types below
[ ] Premarket Approval Application (PMA)	[X] Original Application
[ ] Modular PMA	Supplement Types:
[ ] Product Development Protocol (PDP)	[ ] Efficacy (BLA)
[ ] Premarket Report (PMR)	[ ] Panel Track (PMA, PMR, PDP)
[ ] Annual Fee for Periodic Reporting (APR)	[ ] Real-Time (PMA, PMR, PDP)
[ ] 30-Day Notice	[ ] 180-day (PMA, PMR, PDP)

4. ARE YOU A SMALL BUSINESS? (See the instructions for more information on determining this status)

[ ] YES, I meet the small business criteria and have submitted the required qualifying documents to FDA

[X] NO, I am not a small business

4.1 If Yes, please enter your Small Business Decision Number:

5. FDA WILL NOT ACCEPT YOUR SUBMISSION IF YOUR COMPANY HAS NOT PAID AN ESTABLISHMENT REGISTRATION FEE THAT IS DUE TO FDA. HAS YOUR COMPANY PAID ALL ESTABLISHMENT REGISTRATION FEES THAT ARE DUE TO FDA?

[X] YES (All of our establishments have registered and paid the fee, or this is our first device, and we will register and pay the fee within 30 days of FDA's approval/clearance of this device.)

[ ] NO (If "NO," FDA will not accept your submission until you have paid all fees due to FDA. This submission will not be processed; see http://www.fda.gov/cdrh/mdufma for additional information)

6. IS THIS PREMARKET APPLICATION COVERED BY ANY OF THE FOLLOWING USER FEE EXCEPTIONS? IF SO, CHECK THE APPLICABLE EXCEPTION.

[ ] This application is the first PMA submitted by a qualified small business, including any affiliates	[ ] The sole purpose of the application is to support conditions of use for a pediatric population
[ ] This biologics application is submitted under section 351 of the Public Health Service Act for a product licensed for further manufacturing use only	[ ] The application is submitted by a state or federal government entity for a device that is not to be distributed commercially

7. IS THIS A SUPPLEMENT TO A PREMARKET APPLICATION FOR WHICH FEES WERE WAIVED DUE TO SOLE USE IN A PEDIATRIC POPULATION THAT NOW PROPOSES CONDITION OF USE FOR ANY ADULT POPULATION? (If so, the application is subject to the fee that applies for an original premarket approval application (PMA).

[ ] YES [X] NO

8. USER FEE PAYMENT AMOUNT SUBMITTED FOR THIS PREMARKET APPLICATION

(b)(4)

15-Jun-2010

Form FDA 3601 (01/2007)

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

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Monica Healthcare

CDRH Premarket Review Submission Cover

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

CDRH PREMARKET REVIEW SUBMISSION COVER SHEET

Form Approval
OMB No. 0910-0120
Expiration Date: August 31, 2010.
See OMB Statement on page 5.

Date of Submission	User Fee Payment ID Number	FDA Submission Document Number *(if known)*

SECTION A — TYPE OF SUBMISSION

PMA	PMA & HDE Supplement	PDP	510(k)	Meeting
☐ Original Submission	☐ Regular (180 day)	☐ Original PDP	☒ Original Submission:	☐ Pre-510(K) Meeting
☐ Premarket Report	☐ Special	☐ Notice of Completion	☒ Traditional	☐ Pre-IDE Meeting
☐ Modular Submission	☐ Panel Track (PMA Only)	☐ Amendment to PDP	☐ Special	☐ Pre-PMA Meeting
☐ Amendment	☐ 30-day Supplement		☐ Abbreviated (Complete section I, Page 5)	☐ Pre-PDP Meeting
☐ Report	☐ 30-day Notice		☐ Additional Information	☐ Day 100 Meeting
☐ Report Amendment	☐ 135-day Supplement		☐ Third Party	☐ Agreement Meeting
☐ Licensing Agreement	☐ Real-time Review			☐ Determination Meeting
	☐ Amendment to PMA & HDE Supplement			☐ Other *(specify)*:
	☐ Other			

IDE	Humanitarian Device Exemption (HDE)	Class II Exemption Petition	Evaluation of Automatic Class III Designation (De Novo)	Other Submission
☐ Original Submission	☐ Original Submission	☐ Original Submission	☐ Original Submission	☐ 513(g)
☐ Amendment	☐ Amendment	☐ Additional Information	☐ Additional Information	☐ Other *(describe submission)*:
☐ Supplement	☐ Supplement			
	☐ Report			
	☐ Report Amendment			

Have you used or cited Standards in your submission? ☒ Yes ☐ No *(If Yes, please complete Section I, Page 5)*

SECTION B — SUBMITTER, APPLICANT OR SPONSOR

Company / Institution Name	Establishment Registration Number *(if known)*		
Monica Healthcare Ltd			
Division Name *(if applicable)*	**Phone Number *(including area code)***		
	+44 (0)115 912 4540		
Street Address	**FAX Number *(including area code)***		
Biocity, Pennyfoot Street	+44 (0)115 9124289		
City	**State / Province**	**ZIP/Postal Code**	**Country**
Nottingham		NG1 1GF	UK
Contact Name			
Ian How			
Contact Title	**Contact E-mail Address**		
Regulatory Affairs Manager	ianhow@monicahealthcare.com		

SECTION C — APPLICATION CORRESPONDENT (e.g., consultant, if different from above)

Company / Institution Name			
Division Name *(if applicable)*	**Phone Number *(including area code)***		
Street Address	**FAX Number *(including area code)***		
City	**State / Province**	**ZIP Code**	**Country**
Contact Name			
Contact Title	**Contact E-mail Address**		

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

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Monica Healthcare

SECTION D1 REASON FOR APPLICATION - PMA, PDP, OR HDE

- ☐ New Device
- ☐ Withdrawal
- ☐ Additional or Expanded Indications
- ☐ Request for Extension
- ☐ Post-approval Study Protocol
- ☐ Request for Applicant Hold
- ☐ Request for Removal of Applicant Hold
- ☐ Request to Remove or Add Manufacturing Site
- ☐ Process change:
  - ☐ Manufacturing ☐ Packaging
  - ☐ Sterilization
  - ☐ Other *(specify below)*
- ☐ Response to FDA correspondence:
- ☐ Change in design, component, or specification:
  - ☐ Software / Hardware
  - ☐ 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
- ☐ Report Submission:
  - ☐ Annual or Periodic
  - ☐ Post-approval Study
  - ☐ Adverse Reaction
  - ☐ Device Defect
  - ☐ Amendment
- ☐ Change in Ownership
- ☐ Change in Correspondent
- ☐ Change of Applicant Address
- ☐ Other Reason *(specify)*:

SECTION D2 REASON FOR APPLICATION - IDE

- ☐ New Device
- ☐ New Indication
- ☐ Addition of Institution
- ☐ Expansion / Extension of Study
- ☐ IRB Certification
- ☐ Termination of Study
- ☐ Withdrawal of Application
- ☐ Unanticipated Adverse Effect
- ☐ Notification of Emergency Use
- ☐ Compassionate Use Request
- ☐ Treatment IDE
- ☐ Continued Access
- ☐ Change in:
  - ☐ Correspondent / Applicant
  - ☐ Design / Device
  - ☐ Informed Consent
  - ☐ Manufacturer
  - ☐ Manufacturing Process
  - ☐ Protocol - Feasibility
  - ☐ Protocol - Other
  - ☐ Sponsor
- ☐ Report submission:
  - ☐ Current Investigator
  - ☐ Annual Progress Report
  - ☐ Site Waiver Report
  - ☐ 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
  - ☐ Request Hearing
- ☐ Other Reason *(specify)*:

SECTION D3 REASON FOR SUBMISSION - 510(k)

- ☒ New Device
- ☐ Additional or Expanded Indications
- ☐ Change in Technology
- ☒ Other Reason *(specify)*:

Continuation from K081435, to address FDA concerns and include a 6 way substantial equivalence trial

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

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Monica Healthcare

SECTION E ADDITIONAL INFORMATION ON 510(K) SUBMISSIONS

Product codes of devices to which substantial equivalence is claimed

1	HGM	2		3		4	
5		6		7		8	

Summary of, or statement concerning, safety and effectiveness information

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

Information on devices to which substantial equivalence is claimed *(if known)*

	510(k) Number	Trade or Proprietary or Model Name	Manufacturer
1	K954351	Phillips Series 50XM	Phillips
2			
3			
4			
5			
6			

SECTION F PRODUCT INFORMATION - APPLICATION TO ALL APPLICATIONS

Common or usual name or classification name

Classification 884.2740 Perinatal Monitoring System

	Trade or Proprietary or Model Name for This Device	Model Number
1	Monica AN24	
2		
3		
4		
5		

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

1 K081435	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 - APPLICATION TO ALL APPLICATIONS

Product Code	C.F.R. Section *(if applicable)*	Device Class
HGM	884.2740	☐ Class I ☒ Class II ☐ Class III ☐ Unclassified

Classification Panel

Obstetrics / Gynecology

Indications *(from labeling)*

The Monica AN24 is a monitoring device for non-invasively measuring the Fetal Heart Rate (FHR) and Uterine Activity (UA). The Monica VR software, which accompanies the AN24, enables the measured parameters to be reviewed graphically using a PC or notebook computer and to generate hard copy traces in a "standard" user defined format. This data is intended to aid in assessment of the wellbeing of the fetus and mother for laboring singleton pregnancies who are of gestation age >37 weeks. The AN24 device typically generates standard length FHR and UA traces from a single setup. Application of the device must be by trained personnel, but monitoring sessions can be carried out in hospital and clinics.

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

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Monica Healthcare

Note: Submission of this information does not affect the need to submit a 2891 or 2891a Device Establishment Registration form.	FDA Document Number *(if known)*

SECTION H MANUFACTURING / PACKAGING / STERILIZATION SITES RELATING TO A SUBMISSION

(b)(4)

☐ Original ☐ Add ☐ Delete	Facility Establishment Identifier (FEI) Number	☐ Manufacturer ☐ Contract Manufacturer	☐ Contract Sterilizer ☐ Repackager / Relabeler
Company / Institution Name		Establishment Registration Number	
Division Name *(if applicable)*		Phone Number *(including area code)*	
Street Address		FAX Number *(including area code)*	
City	State / Province	ZIP Code	Country
Contact Name	Contact Title	Contact E-mail Address	

☐ Original ☐ Add ☐ Delete	Facility Establishment Identifier (FEI) Number	☐ Manufacturer ☐ Contract Manufacturer	☐ Contract Sterilizer ☐ Repackager / Relabeler
Company / Institution Name		Establishment Registration Number	
Division Name *(if applicable)*		Phone Number *(including area code)*	
Street Address		FAX Number *(including area code)*	
City	State / Province	ZIP Code	Country
Contact Name	Contact Title	Contact E-mail Address	

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

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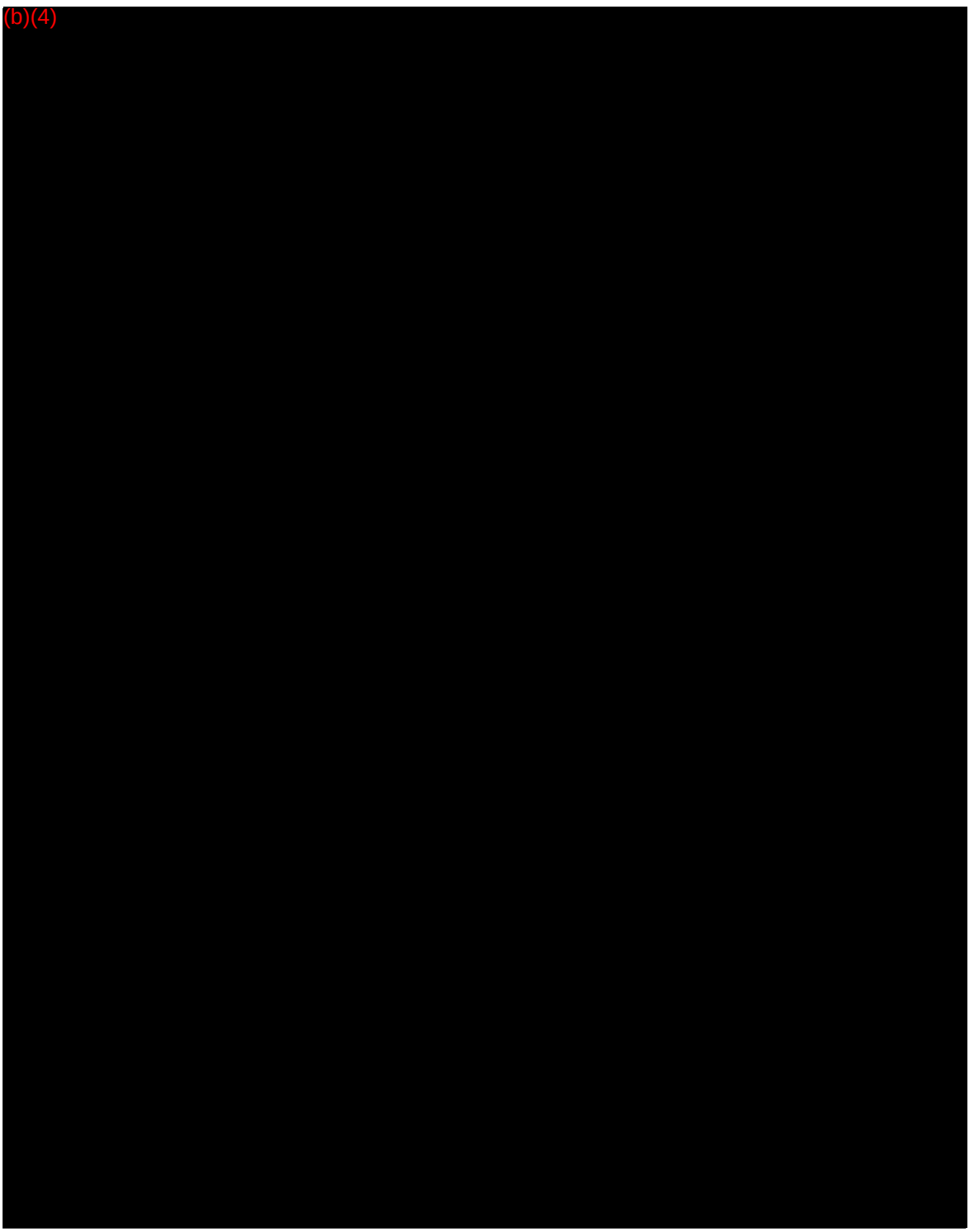
Monica Healthcare

(b)(4)



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

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Monica Healthcare

510(k) Cover Letter

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

Date: June 2010

Dear Sir/Madam,

510(k) Notification (21 CFR 807.90(e)) – Traditional Submission

This letter accompanies two (2) copies of documentation in support of a 510(k) Notification (21 CFR 807.90(e)) for the Monica Healthcare AN24 Fetal Heart Rate Monitor and accessories. One of the copies provided is an electronic copy and it is an exact duplicate of the paper copy. As per 21 CFR 807.95, we are requesting continued confidentiality of the intent to market this device. Please see the enclosed CDRH Premarket Review Submission Cover Sheet (Section 2 of this submission) for additional required administrative information as per the CDRH Guidance Document Format for Traditional and Abbreviated 510(k)s", issued August 12, 2005.
The principal factors pertaining to the design and use of the Monica AN24 device are provided below:

Type of 510(k) Submission:	Traditional
Device Type:	Fetal Maternal Monitor
510(k) Submitter:	Monica Healthcare
Contact details:	Mr. Ian How Regulatory affairs Manager Tel: +44 115 9124540 Email: ianhow@monicahealthcare.com
Classification Name:	Perinatal monitoring system and accessories
Classification Reference:	HGM
Recommended classification:	Class II
Product Code:	884.2740
Panel:	Obstetrics/Gynecology
Former Correspondence:	K081435 510(K) submission (Appendix E)
Basis For submission:	New device

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

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Monica Healthcare

Design and Use of the Device

Question	YES	NO
Is the device intended for prescription use (21 CFR 801 Subpart D)?	YES	
Is the device intended for over-the-counter use (21 CFR 807 Subpart C)?		NO
Does the device contain components derived from a tissue or other biologic source?		NO
Is the device provided sterile?		NO
Is the device a reprocessed single use device?		NO
If yes, does this device type require reprocessed validation data?		
Does the device contain a drug?		NO
Does the device contain a biologic?		NO
Does the device use software?	YES	
Does the submission include clinical information?	YES	
Is the device implanted?		NO

Preference for continued confidentiality: Monica Healthcare considers its intent to market the AN24 device and accessories as confidential commercial information. The Company has not disclosed its intent to market this device to anyone except its employees, others with a financial interest in the Company, its advertising or law firms, and its consultants. The Company, therefore, requests that FDA not disclose the existence of this application until such time as final action on the submission is taken. In addition, some of the material in this application may be trade secret or confidential commercial or financial information within the meaning of 21 CFR § 20.61 and therefore not disclosable under the Freedom of Information Act, even after the existence of the application becomes public. We ask that you consult with the Company as provided in 21 CFR § 20.45 before making any part of this submission, other than the 510(k) statement, publicly available.

Thank you for your review of this 510(k) submission. If you have any questions or require clarification of any information in this document, please do not hesitate to contact the undersigned.

Yours sincerely,

Carl Barratt

CEO
Monica Healthcare
BioCity, Pennyfoot Street,
Nottingham,NG1 1GF, UK
T:+44(0)115 9124540
F:+44(0)115 9124289
E:info@monicahealthcare.com
W:www.monicahealthcare.com

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

Records processed under FOIA Request #2015-4103; Released by CDRH on 06-06-2016.

Monica Healthcare

Indications for Use Statement

510(k) Number (if known):

Device Name: AN24

Indications For Use:

The Monica AN24 is a monitoring device for non-invasively measuring the Fetal Heart Rate (FHR) and Uterine Activity (UA). The Monica VS software, which accompanies the AN24, enables the measured parameters to be reviewed graphically using a PC, notebook computer or any compatible Series 50 format device, and to generate hard copy traces in a "standard" user defined format. This data is intended to aid in assessment of the wellbeing of the fetus and mother for laboring singleton pregnancies who are of gestation age ≥37 weeks. The AN24 device typically generates standard length FHR and UA traces from a single setup. Application of the device must be by trained personnel.

Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Page 1 of 1

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

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Monica Healthcare

510(k) Statement

I certify that, in my capacity as CEO, of Monica, I will make available all information included in this premarket notification on safety and effectiveness within 30 days of request by any person if the device described in the premarket notification submission is determined to be substantially equivalent. The information I agree to make available will be a duplicate of the premarket notification submission, including any adverse safety and effectiveness information, but excluding all patient identifiers, and trade secret and confidential commercial information, as defined in 21 CFR 20.61.

Name .....

Signed .....

Date .....

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

Records processed under FOIA Request #2015-4103; Released by CDRH on 06-06-2016.

Monica Healthcare

Truthful and Accuracy Statement

I certify that, in my capacity as CEO, of Monica Healthcare Limited, I believe to the best of my knowledge, that all data and information submitted in the premarket notification are truthful and accurate and that no material fact has been omitted.

_____

(Signature)

_____

(Typed Name)

_____

(Date)

_____

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

*For a new submission, leave the 510(k) number blank.

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

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Monica Healthcare

Class III Summary and Certification

A class III summary and certification are not required in this 510(k) submission because the AN24 is not a class III device.

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

Records processed under FOIA Request #2015-4103; Released by CDRH on 06-06-2016.

Monica Healthcare

Financial Certification or Disclosure Statement

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

CERTIFICATION: FINANCIAL INTERESTS AND ARRANGEMENTS OF CLINICAL INVESTIGATORS

Form Approved: OMB No. 0910-0396
Expiration Date: August 31, 2012

TO BE COMPLETED BY APPLICANT

With respect to all covered clinical studies (or specific clinical studies listed below (if appropriate)) submitted in support of this application, I certify to one of the statements below as appropriate. I understand that this certification is made in compliance with 21 CFR part 54 and that for the purposes of this statement, a clinical investigator includes the spouse and each dependent child of the investigator as defined in 21 CFR 54.2(d).

Please mark the applicable checkbox.

☐ (1) As the sponsor of the submitted studies, I certify that I have not entered into any financial arrangement with the listed clinical investigators (enter names of clinical investigators below or attach list of names to this form) whereby the value of compensation to the investigator could be affected by the outcome of the study as defined in 21 CFR 54.2(a). I also certify that each listed clinical investigator required to disclose to the sponsor whether the investigator had a proprietary interest in this product or a significant equity in the sponsor as defined in 21 CFR 54.2(b) did not disclose any such interests. I further certify that no listed investigator was the recipient of significant payments of other sorts as defined in 21 CFR 54.2(f).

(b) (6) [redacted]

☒ (2) As the applicant who is submitting a study or studies sponsored by a firm or party other than the applicant, I certify that based on information obtained from the sponsor or from participating clinical investigators, the listed clinical investigators (attach list of names to this form) did not participate in any financial arrangement with the sponsor of a covered study whereby the value of compensation to the investigator for conducting the study could be affected by the outcome of the study (as defined in 21 CFR 54.2(a)); had no proprietary interest in this product or significant equity interest in the sponsor of the covered study (as defined in 21 CFR 54.2(b)); and was not the recipient of significant payments of other sorts (as defined in 21 CFR 54.2(f)).

☐ (3) As the applicant who is submitting a study or studies sponsored by a firm or party other than the applicant, I certify that I have acted with due diligence to obtain from the listed clinical investigators (attach list of names) or from the sponsor the information required under 54.4 and it was not possible to do so. The reason why this information could not be obtained is attached.

NAME	TITLE
FIRM/ORGANIZATION	
SIGNATURE	DATE *(mm/dd/yyyy)*

Paperwork Reduction Act Statement

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. Public reporting burden for this collection of information is estimated to average 1 hour per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the necessary data, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information to the address to the right:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
1350 Piccard Drive, 420A
Rockville, MD 20850

FORM FDA 3454 (10/09)

PSC Graphics (301) 443-1090 EF

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

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Section 2

- Declaration of Conformity and Summary Reports

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

Records processed under FOIA Request #2015-4103; Released by CDRH on 06-06-2016.

Monica Healthcare

Declarations of Conformity and Summary Reports

The following recognised and consensus standards, guidance documents, general standards and directives have been applied to the AN24 (note: at time of testing the AN24 was known as the OB24). Certifications and FDA Forms 3654 can be found in Appendix A.

(b)(4)

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

Records processed under FOIA Request #2015-4103; Released by CDRH on 06-06-2016.

Section 3

- Executive Summary
- Device Description

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

Records processed under FOIA Request #2015-4103; Released by CDRH on 06-06-2016.

Monica Healthcare

Executive Summary

Background

Continuous electronic monitoring of the fetal heart rate (FHR) and uterine contractions (UC) during labor remains the standard of care, and is used in more than 80% of labors in US hospitals. The pattern of changes in the FHR is used to assess the status of fetal oxygenation and perfusion of the brain. The frequency, duration and amplitude of uterine contractions is sometimes used to assess the quality of the labor. UCs also influence fetal oxygenation, and clinical responses to abnormal heart rate patterns must be informed by information about uterine contractility.

Current instrumentation for electronic FHR monitoring employs either an electrode applied directly to the fetal scalp to detect fetal electrocardiographic (EKG) voltages, or an ultrasound transducer strapped to the mother's abdomen that uses Doppler technology to detect fetal heart motion. The EKG or Doppler signal information is processed by the monitor, which accurately calculates the fetal heart rate. The output of the monitor is a continuous 2-channel strip chart recording or computer display of the fetal heart rate pattern on one channel with contraction information on the second channel. The graph is generated with a horizontal rate of 3 cm per minute. The vertical scaling is 30 bpm / cm. ..

Both ultrasound and direct scalp electrode techniques are used commonly for FHR monitoring. The direct electrode provides the most accurate and reliable information, but because it is invasive, it is associated with a greater risk of complications than the ultrasound approach. Also, the electrode can only be used when the cervix is sufficiently dilated and the fetal membranes are ruptured, making it unsuitable for many parturients in early labor and for some later in labor when a contraindication exists to rupture of the fetal membranes. The ultrasonic approach is safe, without known risks, but under some circumstances provides less accurate information. It is subject to movement artifact (from either mother or fetus), and is more uncomfortable for the patient. The ultrasound transducer is strapped to the parturient's abdomen. The scalp electrode or the ultrasound transducer is attached to the monitor with wires. Both techniques restrict the patient's movements, requiring her to remain in bed. The ultrasound method sometimes functions well only if the mother remains quite still, making it especially problematic during the second stage of labor, when most women move actively during their bearing-down efforts.

In addition to monitoring the FHR, most fetal monitoring devices also record uterine contractions (UC). Contractions are detected either externally (using a small tocodynamometer strapped to the patients abdomen) or internally (using an intrauterine catheter that detects changes in intrauterine pressure). The external device is used most commonly, and is strapped to the patient's abdomen in the same manner as the external ultrasound device. The position of both on the mother's abdomen frequently needs adjustment during the course of labor in order to obtain the best possible recording. The internal uterine catheter provides better information about the onset and duration of contractions and adds the dimension of determining the relative intensity of the contractions, which the external technique cannot do. However, the more complete and reliable information comes at the expense of a somewhat greater risk of complications, such as infection.

The FHR and UC detection devices are hardwired to a monitor that is large (about 20 pounds) and somewhat cumbersome to use. As noted previously, the parturient must remain relatively immobile in order for the monitor to function optimally and continuously. Many women feel more comfortable if they are able to move about during labor, and therefore feel constrained by the monitor.

The ultrasound signal is easily lost if the mother is moving, and if she must leave her bed to use the bathroom or for other reasons, the monitor must be disconnected. These problems hinder the

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118. 25

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obstetrician or midwife's ability to fully evaluate the fetus and contractions, and can create considerable inconvenience for the patient and staff. The availability of a noninvasive monitoring technique that would provide a reliable continuous FHR and UC signal and that would be relatively unperturbed by

(b)(4)

[redacted]

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

Records processed under FOIA Request #2015-4103; Released by CDRH on 06-06-2016.

electrical equipment in close proximity in accordance with the Electromagnetic Compatibility standard

(b)(4) [redacted]

(b)(4) [redacted] no adverse incidents having been reported.

Biocompatibility

Biocompatibility of the Monica AN24 Device and the applied parts and accessories likely to make contact with the subject (i.e. patient cable and electrodes) demonstrated good results during biocompatibility testing and the electrodes are FDA approved for cardiac monitoring. The device itself is constructed from standard polycarbonate and in normal operation will not touch the patient.

Clinical

(b)(4) [redacted]

Substantial Equivalence

From the executive summary and the outcome of the clinical investigation Monica Healthcare are able to demonstrate substantial equivalence to the listed predicate devices. The remaining sections of this application contain the necessary data to support this 510(K) submission.

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

Records processed under FOIA Request #2015-4103; Released by CDRH on 06-06-2016.

Description

Description of AN24

(b)(4)

[redacted]

Hardware

(b)(4)

[redacted]

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

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Figure 1: Main Component Parts of the AN24

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

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Figure 2 - Block diagram of the main board

Kit contents

Table 1 below details the options and accessories available with the Monica AN24; items that are included as standard have been highlighted.

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

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Table 1 - The Monica AN24 accessories

Part No.	Description
100-PT-100	Monica VS10 Monitor (b)(4)
100-PT-101	Monica VS10 Monitor (b)(4) (b)(4)
100-PT-110	Monica VS15 Monitor (b)(4)
100-PT-111	Monica VS15 Monitor
100-PT-001	Monica AN24
100-PT-130	Monica Cart (b)(4)
100-PT-131	Monica Cart - printer shelf (b)(4)
100-PT-132	Monica Desktop Stand (b)(4)
100-PT-140	Monica Printer (Real-time) - Thermal Z-fold ((b)(4)
100-PT-160	Monica VS Network Viewer
100-PT-002	ECG Lead Assembly - Standard; (b)(4)
100-PT-004	Battery Charger (UK\ EU\ USA please specify)
100-PT-005	AN24 – USB computer connection cable
100-PT-015	Soft silicon rubber protective boot (x5)
100-PT-016	3M red Dot 2236 skin prep tape (x5)
100-PT-017	Monica approved electrodes – 25 pouches x 10 electrodes (250 electrodes)
100-PT-018	Monica approved electrodes – 150 pouches x 10 electrodes (1500 electrodes)
100-PT-019	Monica AN24 Neck Cord (x5)
100-PT-020	Monica Healthcare glossy sales literature folder (x50)
100-PT-021	Sales Literature sheets
100-PT-022	Skin preparation pen
100-PT-141	Z-Fold paper printer (3 cm/min, 30 - 240 bpm) Analogic US
100-PT-142	Z-Fold paper printer (1 cm/min, 50 - 210 bpm) Analogic International
100-PT-143	Z-Fold paper printer (3 cm/min, 30 - 240 bpm) Philips US
100-PT-144	Z-Fold paper printer (1 cm/min, 50 - 210 bpm) Philips International

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

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Specifications

Table 2: AN24 specifications

(b)(4)

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Electrode lead cable

(b)(4)

[redacted]

Table 3: Electrode lead cable lengths

(b)(4)

[redacted]

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

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Figure 4: Cradle PCB Outline Drawing showing attachment of ECG lead

Table 4: Connection of ECG lead clips to Cradle PCB

(b)(4)

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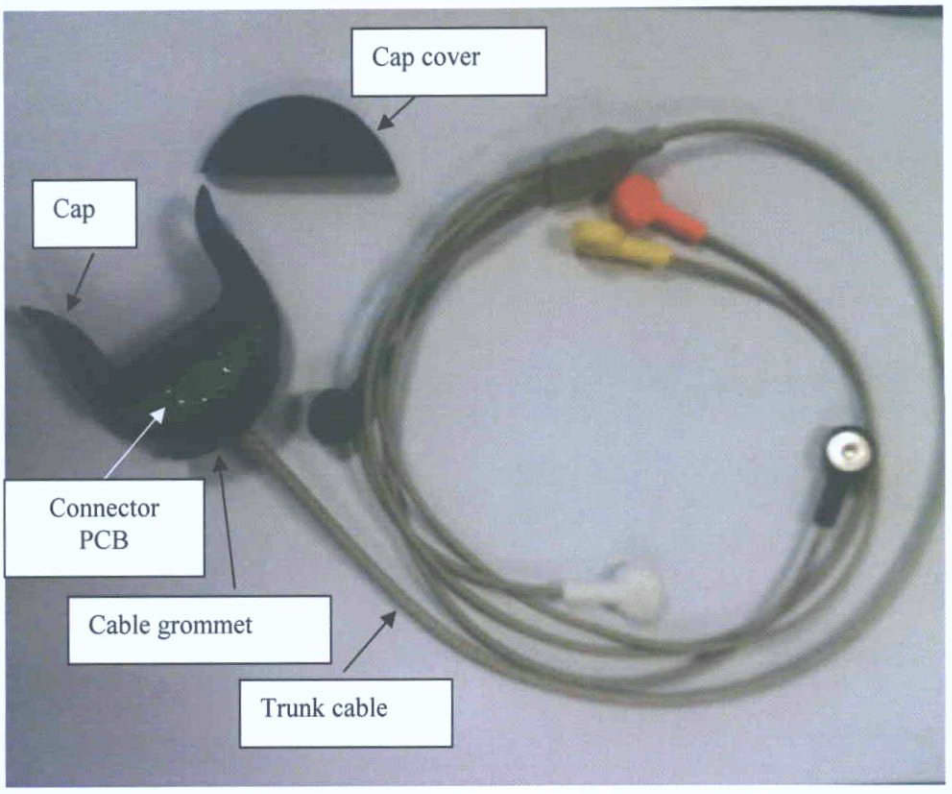

Figure 5: Connector PCB housed in cap with cap cover removed

Electrodes

(b)(4)

[redacted]

Application

(b)(4)

[redacted]

with back-end software to allow the processed data to be viewed – this software is compatible with the listed Monica accessories or laptops, notebooks, pda's and standard PC's.

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

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Requirements for Proper Functioning of the Device

The AN24 Reference Operating Manual details the set-up procedure of the device, including the positioning and attachment of electrodes to the subject's abdomen. The AN24 can only be applied to the patient by trained personnel. Once attached, the AN24 carries out a series of self-checks to determine if it is working correctly and has been set-up in accordance with the instructions in the operating manual. The status of the device is then reported to the clinician during set-up to help assess that the device is working correctly by means of LED indicators on the AN24 itself. These self-check indications are referenced in the User instructions:

(b)(4)

[redacted]

Battery Status Self-Check – If the Yellow battery status LED begins to flash when the AN24 has been turned on, this means that the battery charge is too low for recording to begin. The LED will flash 10 times and then the AN24 will be automatically turned off. The battery must then be recharged in order to continue with the recording.

Explanation of how the AN24 works

Analogue Front End (AFE)

(b)(4)

[redacted]

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

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(b)(4)

Interfaces

(b)(4)

Electrical Current and noise reduction

(b)(4)

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Section 4

- Substantial Equivalence Discussion

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Substantial Equivalence Discussion

Identification of legally marketed predicate device

Philips Series 50XM K954351

The following table makes comparisons between the AN24 and the predicate device, comparisons have been made towards their physical, technical, clinical, regulatory and biological attributes. Equivalence is being made against the Doppler & Tocco functionality.

Comparison table

(b)(4)

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[redacted]

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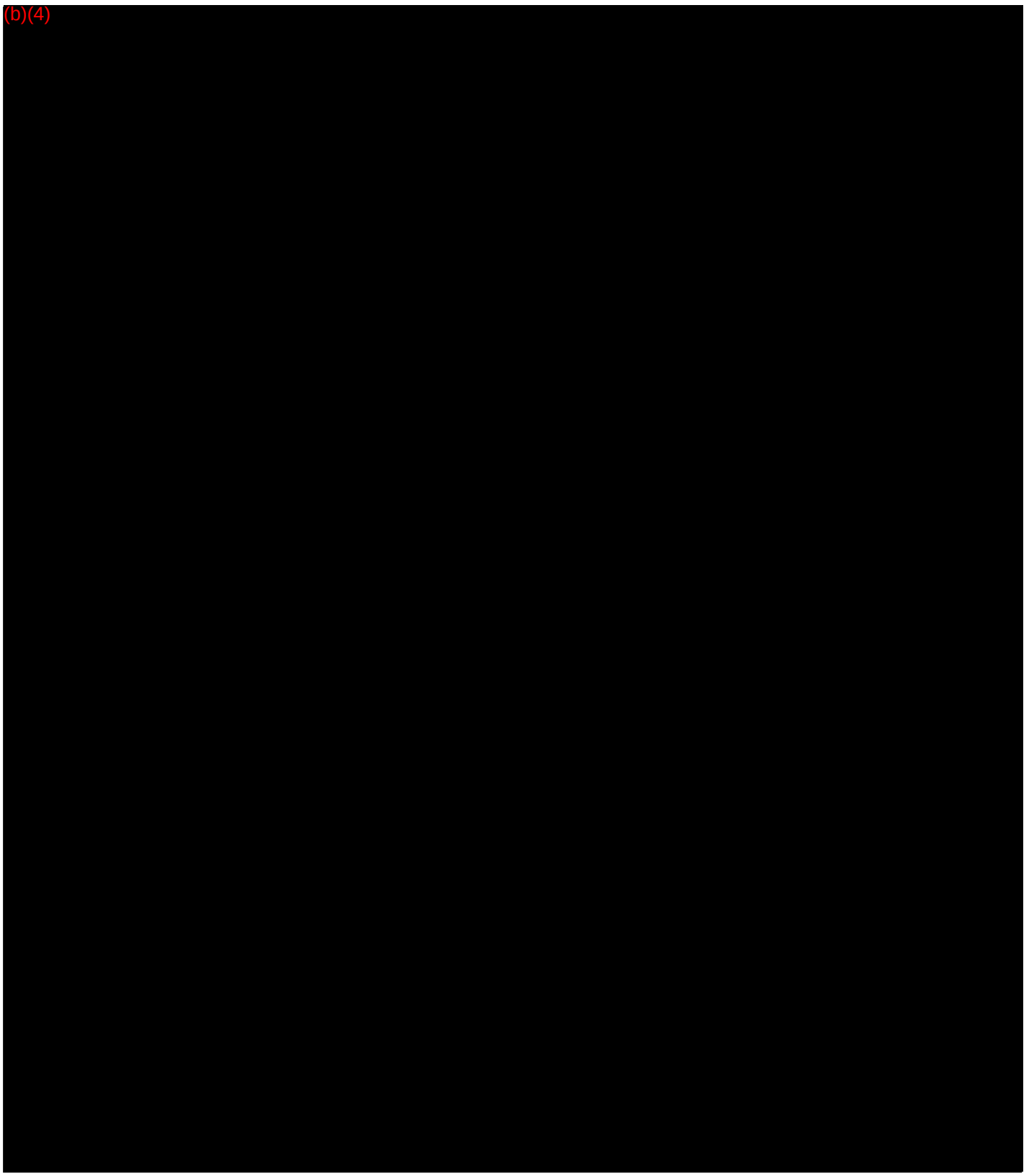

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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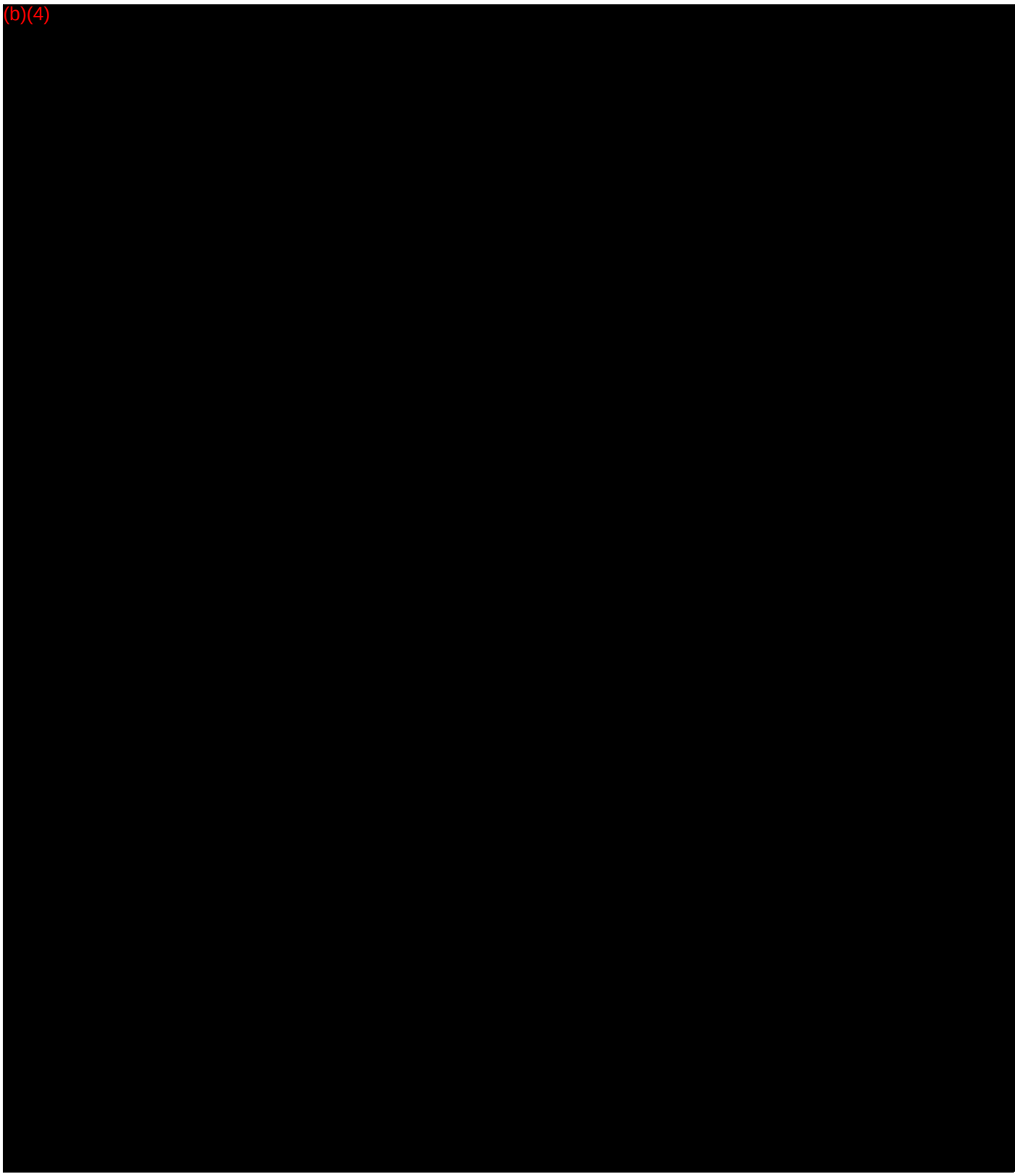

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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Section 5

- Proposed Labeling

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

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Labeling

The labeling of the AN24 can be separated in to 3 areas: device labels, instructions for use and marketing material. Supplied with the AN24 are Ambu VLC electrodes (K041026) and 3m Red Dot Trace Prep, both accessories are approved by the FDA and are legally available for sale in the USA. There have been no changes to the labeling and instructions for use.

AN24 Device Labels

There are 7 labels on the AN24 (x2), patient leads (x2), charger, CD and outer packaging.

Instructions for use

Provided within the outer packaging is a printed CD containing a detailed AN24 Reference Operating Manual; VS Reference Operating Manual; a concise version of these manuals (Concise Operating Manual) provided in 6 different languages (Italian, Portuguese, Netherlands, Spanish, French, Dutch).

Provided loose within the outer packaging is a double sided colour Quick Reference Guide

Sales and Marketing Material

There is a sales sheet, providing details of the AN24.

Labelling conclusion

The labeling detailed throughout section 13 complies with international standards and satisfies the requirements of 21 CFR Part 801. In comparing the labeling of the AN24 to that of the predicate device, there are no significant differences in the format or depth of information made available. Labeling is provided in Appendix B

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

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Section 6

- Sterilization and Shelf Life

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Sterilization and Shelf Life

This section is not applicable, as none of the component parts of the Monica AN24 device are supplied sterile.

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Section 7

- Biocompatibility

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

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Biocompatibility

The following list describes the components used within the Monica AN24 which may come into contact with a patient or healthcare user during the course of normal operation.

Table 1 – Materials used in the Monica AN24 which may come into contact with the patient

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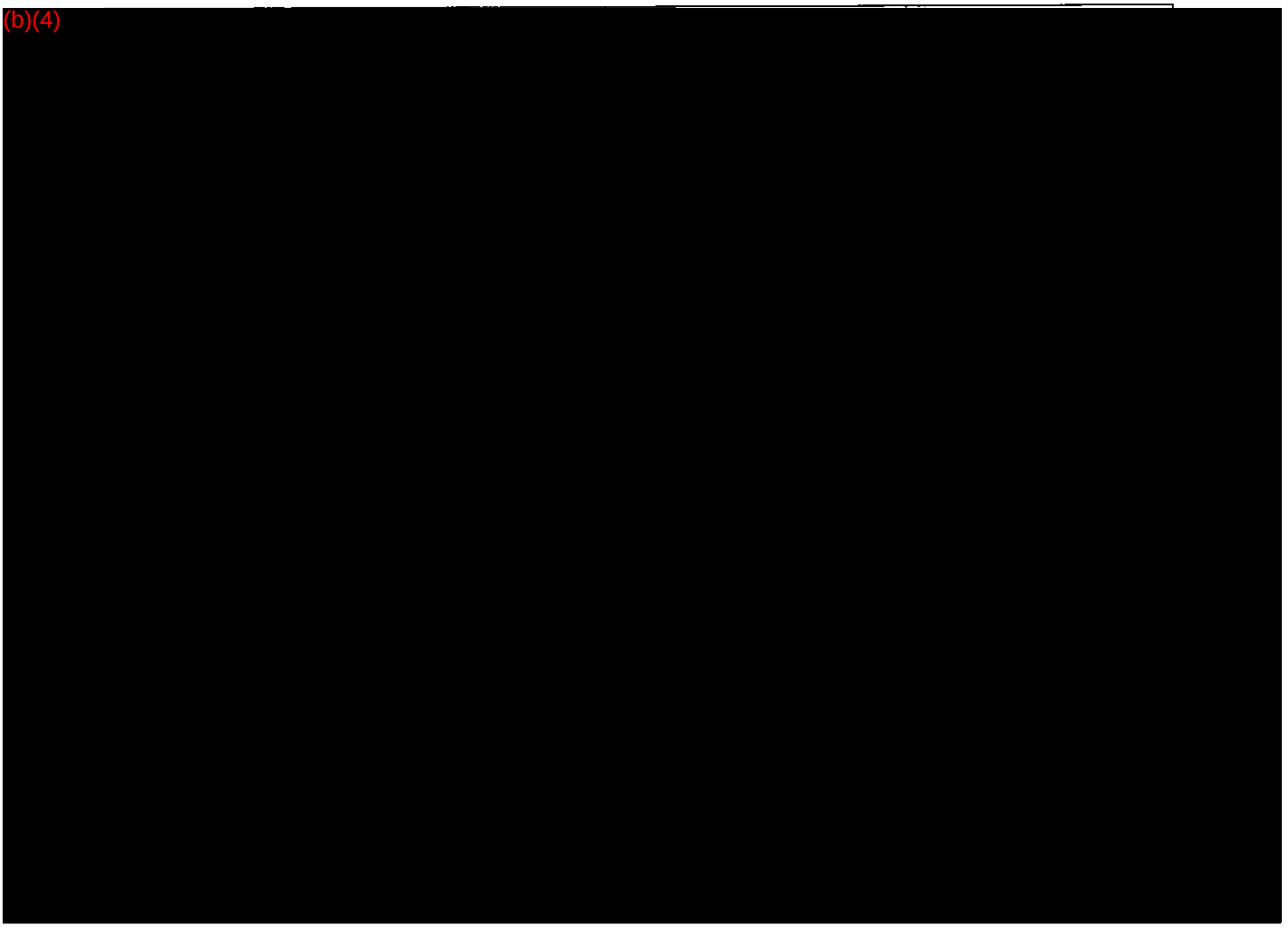

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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AN24 Electrode Lead cable

Biological evaluation of the AN24's Electrode Lead Cable has been separated in to the constituent components:

- Trunk Cable
- Yoke
- Patient Lead Wire
- Patient Connector
- Press Stud

(b)(4) [redacted]

AN24 supplied electrodes

(b)(4) [redacted]

AN24 neck strap

The neck strap provided with the AN24 is a commercially available product in the US for use with

(b)(4) [redacted]

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

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Section 8

- Software

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

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Software

Software Overview

The Monica AN24 software is made of two main parts:

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Level of Concern

The Level of Concern refers to an estimate of the severity of injury that a device could permit or inflict, either directly or indirectly, on a patient or operator as a result of device failures, design flaws, or simply by virtue of employing the device for its intended use. Depending on that estimate, the Level of Concern is Major, Moderate or Minor.

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

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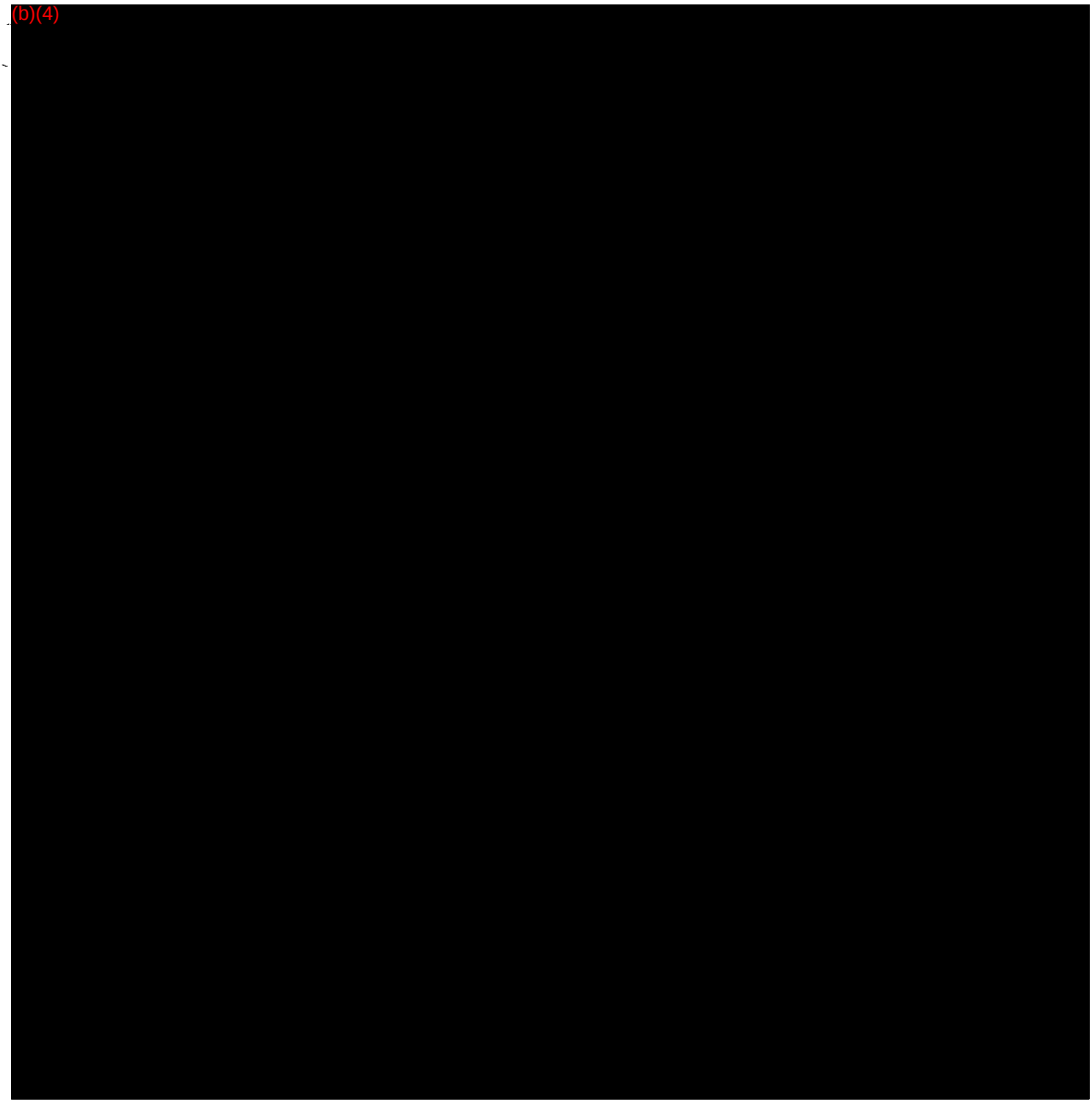

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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(b)(4)

Conclusion

(b)(4)

Guidance document 337 (Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices) was used to compile the recommended documentation, see Appendix F. Table 1 below, details the documentation supplied to support each area.

Table 1: Software documentation recommended and supplied

(b)(4)

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

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The pathway in which these documents interact has been detailed in figure 1 on the next page:

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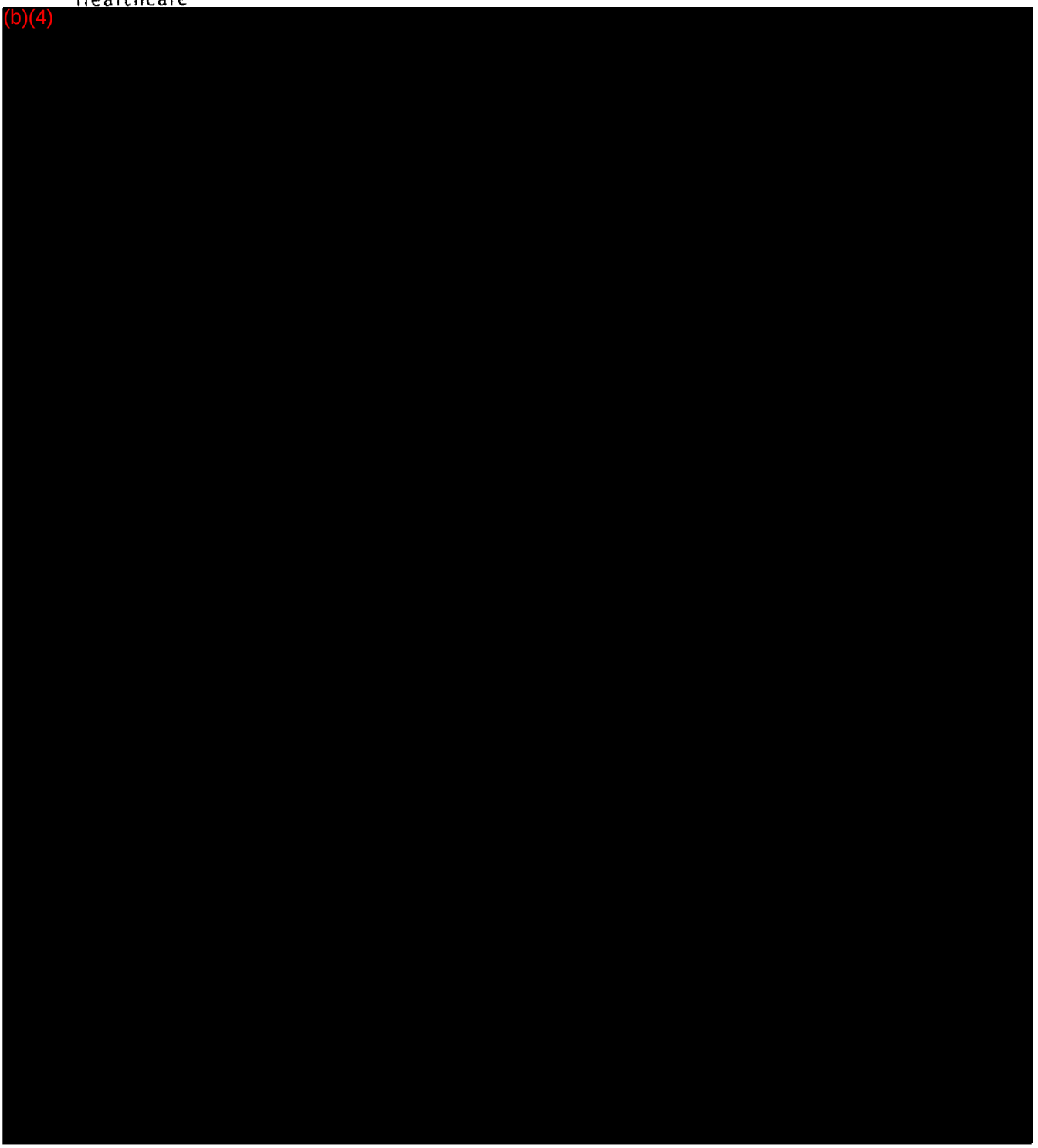

Figure 1: Flowchart mapping software documentation

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

SS

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Section 9

- Electromagnetic Compatibility and Electrical Safety

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Electromagnetic Compatibility and Electrical Safety

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Section 10

- Performance testing Bench
- Performance testing animal
- Performance testing Clinical

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

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Performance Testing – Bench

(b)(4)

[redacted]

Performance Testing – Animal

No animal tests were performed during the development of the AN24.

Performance Testing – Clinical

Executive summary of clinical performance

Introduction

(b)(4)

[redacted]

Study

(b)(4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118. 59

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(b)(4)

KEY STATISTICAL RESULTS

(b)(4)

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

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Records processed under FOIA Request #2015-4103; Released by CDRH on 06-06-2016.

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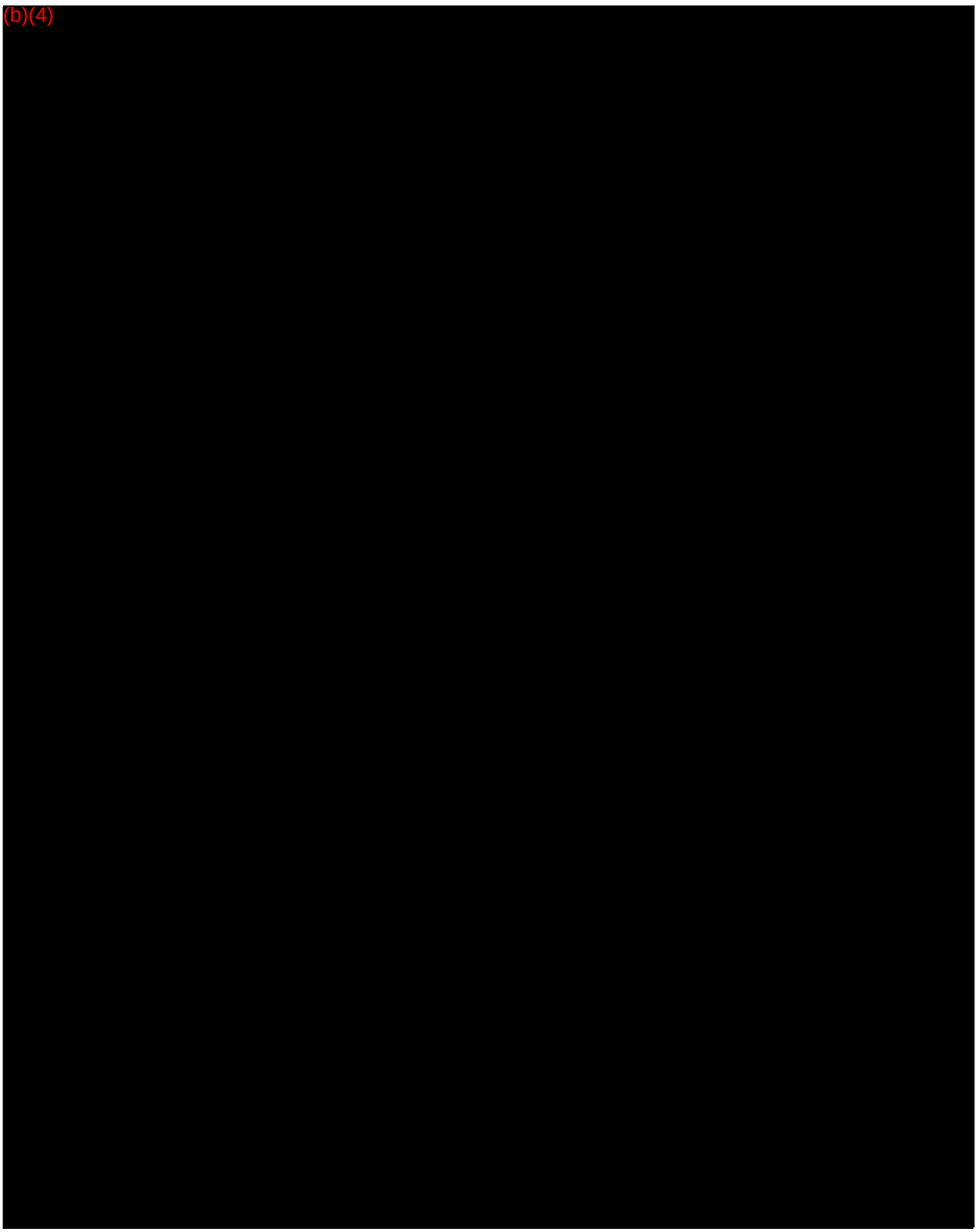
(b)(4)



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

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Section 11

- Appendices

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

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Appendices

The following Appendices and corresponding data have been supplied on the CD and are not in the paper copy

Appendix A

European Product and Quality System Certifications and FDA 3654 Forms for Standards employed

Appendix B

Proposed Labeling

Appendix C

Biocompatibility Certificates

Appendix D

Predicate Device – Product Information and Labeling

Appendix E

Prior FDA Correspondence

Appendix F

Software Documentation

Appendix G

Clinical Trial Data

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

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Appendix A

- Standards Data Reports
- Copy of test Certificates
- Copy of test reports

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

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Form Approved: OMB No. 0910-0120; Expiration Date: 8/31/10

Department of Health and Human Services
Food and Drug Administration

STANDARDS DATA REPORT FOR 510(k)s

(To be filled in by applicant)

This report and the Summary Report Table are to be completed by the applicant when submitting a 510(k) that references a national or international standard. A separate report is required for each standard referenced in the 510(k).

TYPE OF 510(K) SUBMISSION

☑ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

(b)(4)

[redacted]

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U.S.C. 360d], www.fda.gov/cdrh/stdsprog.html

[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[4] The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

[5] The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[6] The online search for CDRH Guidance Documents can be found at www.fda.gov/cdrh/guidance.html

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

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EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

(b)(4) [redacted]

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
All	All	☑ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

All applicable sections comply

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

DESCRIPTION

JUSTIFICATION

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

◆ Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.

Paperwork Reduction Act Statement

Public reporting burden for this collection of information is estimated to average 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to:

Center for Devices and Radiological Health
1350 Piccard Drive
Rockville, MD 20850

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

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

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Form Approved: OMB No. 0910-0120; Expiration Date: 8/31/10

Department of Health and Human Services
Food and Drug Administration

STANDARDS DATA REPORT FOR 510(k)s

(To be filled in by applicant)

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TYPE OF 510(K) SUBMISSION

☑ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

(b)(4)

[redacted]

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U.S.C. 360d], www.fda.gov/cdrh/stdsprog.html

[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[4] The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

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Records processed under FOIA Request #2015-4103; Released by CDRH on 06-06-2016.

EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

(b)(4) [redacted]

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
All	All	☑ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

All applicable sections comply

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

DESCRIPTION

JUSTIFICATION

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

◆ Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.

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Center for Devices and Radiological Health
1350 Piccard Drive
Rockville, MD 20850

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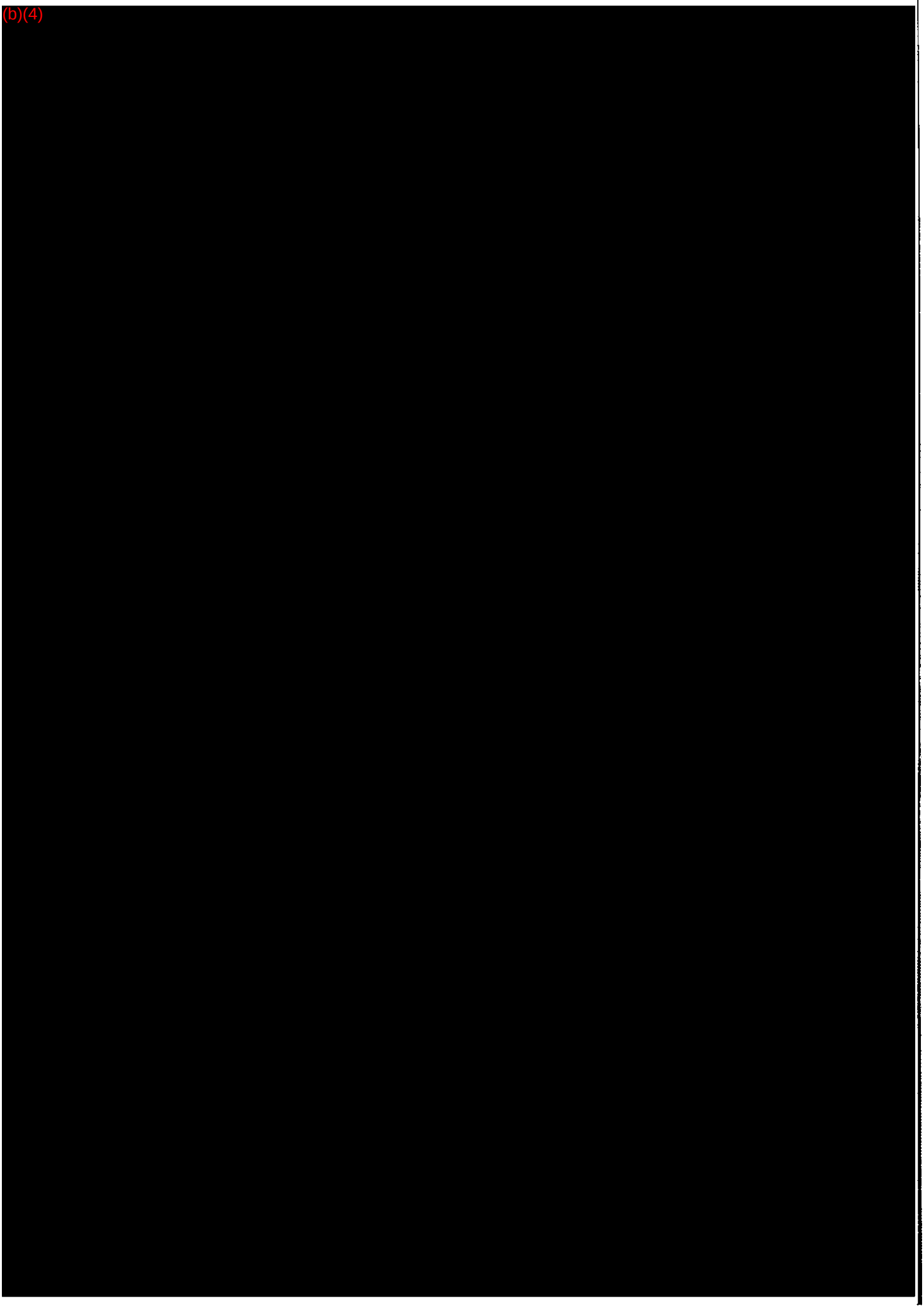
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Form Approved: OMB No. 0910-0120; Expiration Date: 8/31/10

Department of Health and Human Services
Food and Drug Administration

STANDARDS DATA REPORT FOR 510(k)s

(To be filled in by applicant)

This report and the Summary Report Table are to be completed by the applicant when submitting a 510(k) that references a national or international standard. A separate report is required for each standard referenced in the 510(k).

TYPE OF 510(K) SUBMISSION

☑ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

(b)(4)

[redacted]

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U.S.C. 360d], www.fda.gov/cdrh/stdsprog.html

[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[4] The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

[5] The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[6] The online search for CDRH Guidance Documents can be found at www.fda.gov/cdrh/guidance.html

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EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

(b)(4) [redacted]

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
All	All	☑ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

All applicable sections comply

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

DESCRIPTION

JUSTIFICATION

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

◆ Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.

Paperwork Reduction Act Statement

Public reporting burden for this collection of information is estimated to average 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to:

Center for Devices and Radiological Health
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Copy of marking plate

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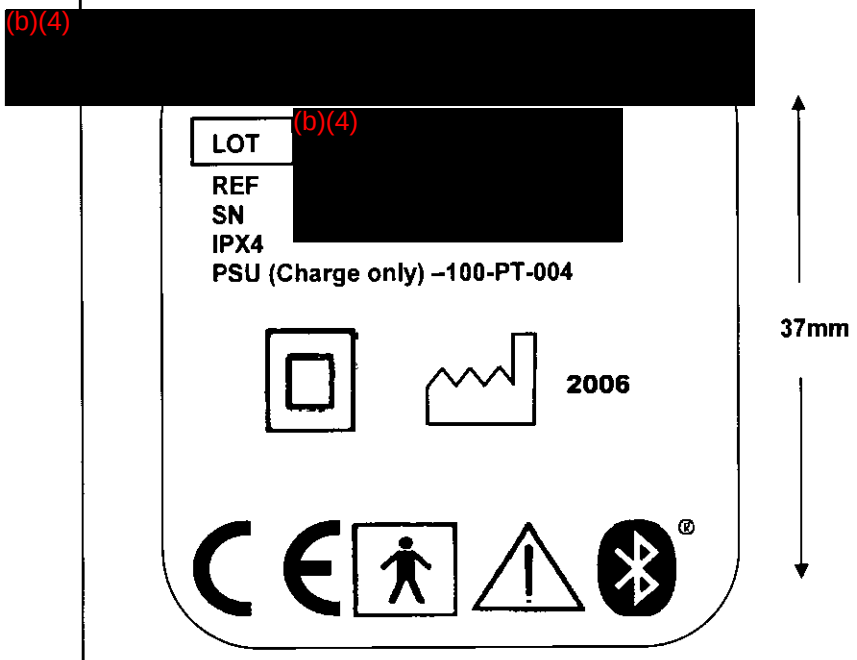
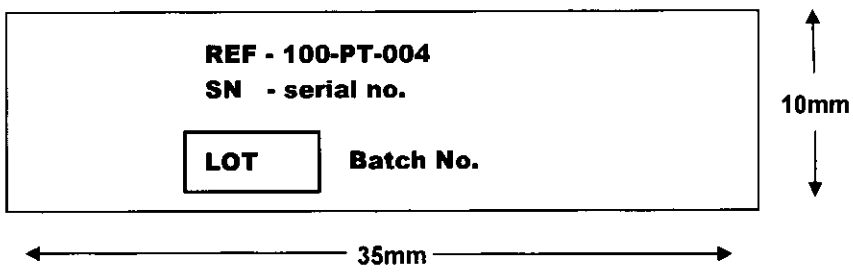


Mains charger:



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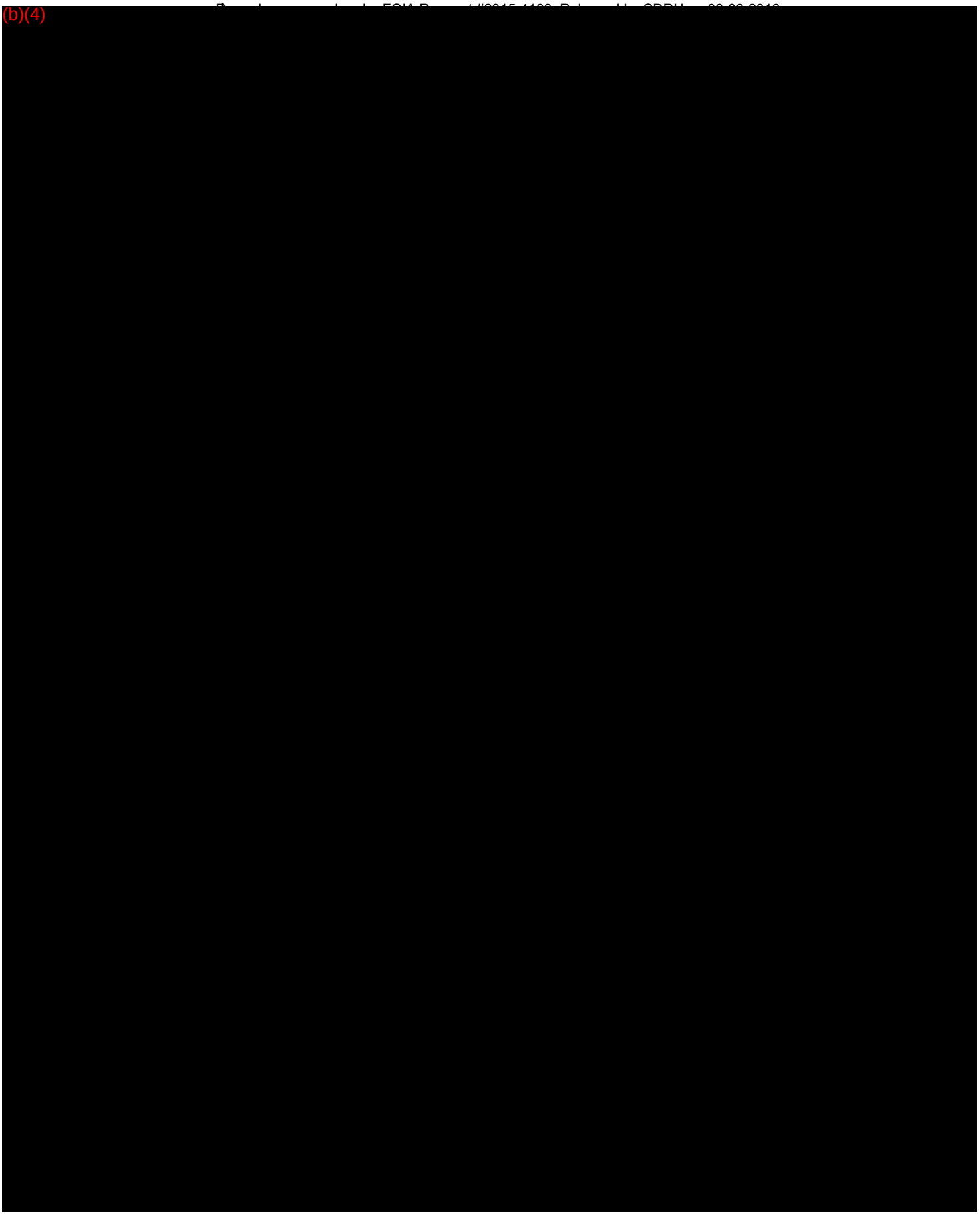

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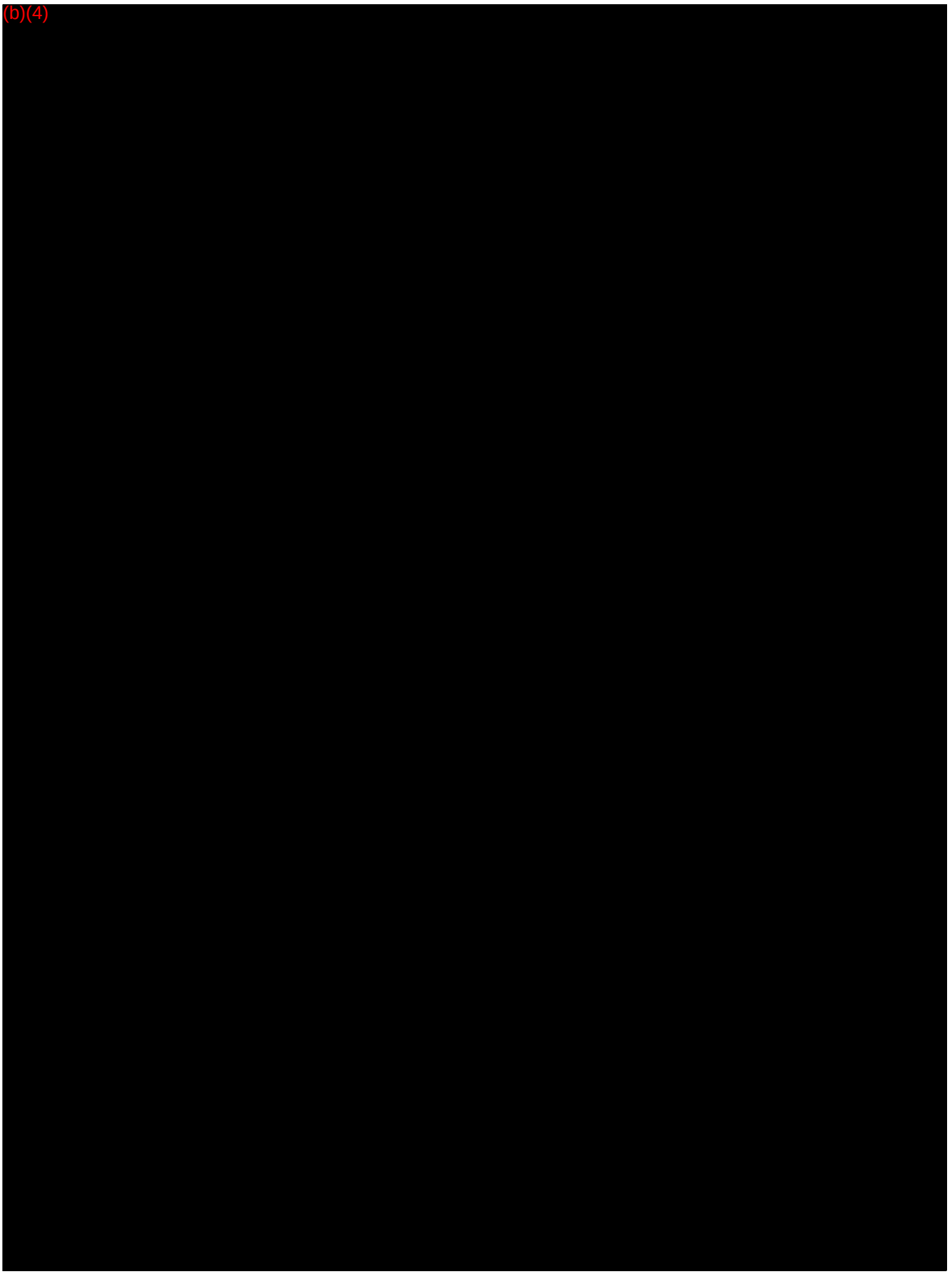

TRF No. I6011__C

TRF originator: UL

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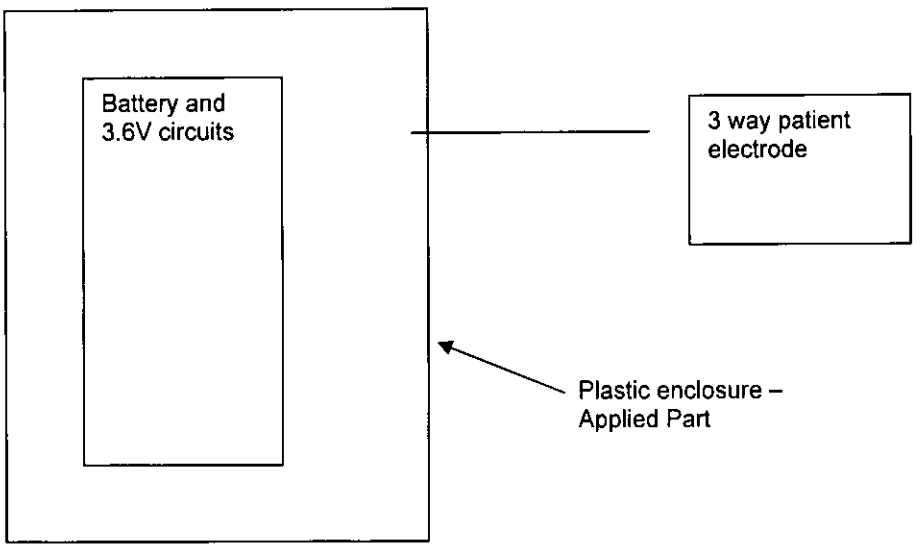
INSULATION DIAGRAM



A = all 3V circuit to Applied Part

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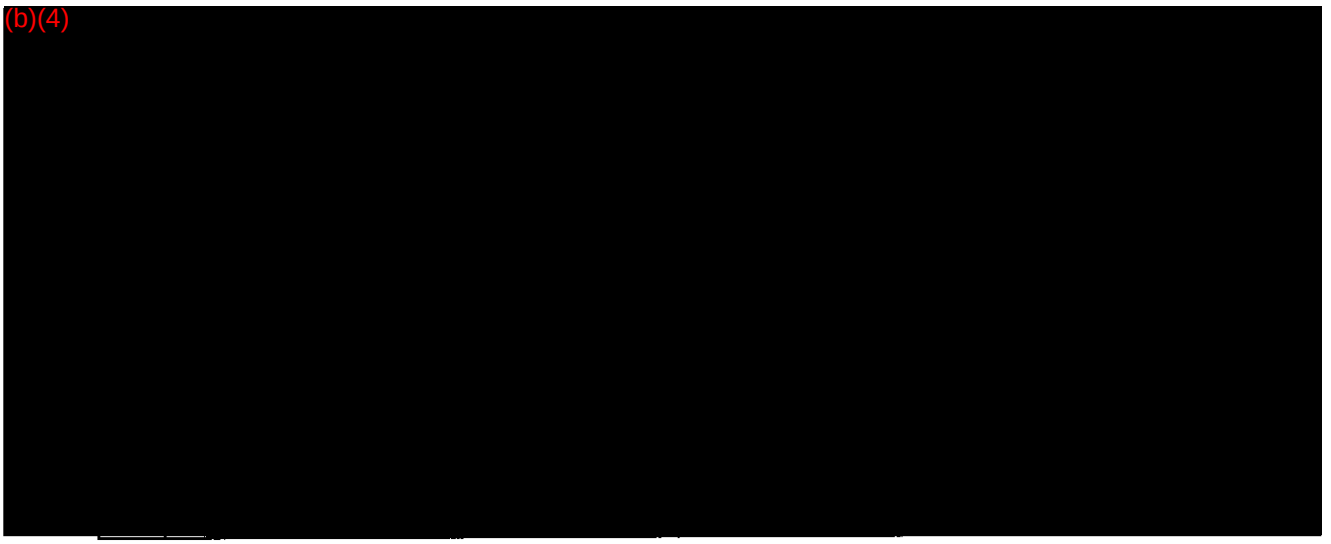

INSULATION DIAGRAM CONVENTIONS

Insulation diagram is a graphical representation of equipment insulation barriers, protective impedance and protective earthing. If feasible, use the following conventions to generate the diagram:

1. All isolation barriers are identified by letters between separate parts of diagram, for example separate transformer windings, optocouplers, wire insulation, creepage and clearance distances.
2. Parts connected to earth with large dots are protectively earthed. Other connections to earth are functional
3. Applied parts are extended beyond the equipment enclosure and terminated with an arrow.
4. Parts accessible to the operator only are extended outside of the enclosure, but are not terminated with an arrow.
5. Blocks containing the letter "Z" indicate protective impedance.
6. Operational Insulation (OP) - indicates insulation that may be required for function of the equipment, but is not required or relied on for compliance with the requirements of clauses 17, 20 and 57.

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6	**IDENTIFICATION, MARKING AND DOCUMENTS**		
6.1	Marking on the outside of equipment or equipment parts		
	c) Markings of the specific power supply affixed		N
	d) If marking is not practicable due to size or nature of enclosure, information is included in accompanying documents		N
	e) Name and/or trademark of the manufacturer or supplier ..... :		P
	f) Model or type reference ..... :		P
	g) Rated supply voltages or voltage range(s)		N
	Number of phases ..... :		N
	Type of current ..... :		N
	h) Rated frequency or rated frequency range(s) (Hz) ..... :		N
	j) Rated power input (VA, W or A) ..... :		N
	k) Power output of auxiliary mains socket-outlets		N
	l) Class II symbol		N
	Symbol for degree of protection against ingress of water provided ..... :		N
	Symbol for protection against electric shock ..... :		
	If equipment has more than one applied part with different degrees of protection, the relevant symbols are clearly marked on such applied parts, or on or near relevant outlets		N
	Symbol for protection of defibrillation-proof applied parts		N
	Symbol 14 from Table DI for defibrillation-proof with protection partly in patient cable		N
	m) Mode of operation (if no marking, suitable for continuous operation)		N
	n) Types and rating of external accessible fuses .... :		N
	p) Ratings of external output ..... :		N
	q) Symbol for physiological effect(s):		N
	- attention, consult accompanying documents		N
	- non-ionizing radiation, or symbols as adopted by ISO or IEC 417		N
	r) Anaesthetic-proof symbol: AP or APG ..... :		N

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(b)(4) [redacted]

	s) Dangerous voltage symbol	
	t) Special cooling requirements	
	u) Limited mechanical stability	
	v) Protective packing requirement(s)	
	- Marking(s) for unpacking safety hazard(s)	
	- Equipment or accessories supplied sterile, marked as sterile	
	y) Potential equalization terminal	
	- Functional earth terminal	
	z) Removable protective means	
	Durability of marking test	
6.2	Marking on the inside of equipment or equipment parts	
	a) Nominal voltage of permanently installed equipment	
	b) Maximum power loading for heating elements or holders for heating lamps	
	c) Dangerous voltage symbol	
	d) Type of battery and mode of insertion	Not user replaceable
	- Marking referring to accompanying documents used for battery not intended to be changed by the operator	
	e) Fuses accessible with a tool identified either by type and rating or by a reference to diagram	
	f) Protective earth terminal	
	g) Functional earth terminal	
	h) Supply neutral conductor in permanently installed equipment (N)	
	j) Markings required in 6.2 f), h), k) ,and l) remain visible after connection and are not affixed to parts which have to be removed	
	- Markings comply with IEC 445	
	k) For permanently connected devices the supply connections are clearly marked adjacent to the terminals (or in accompanying documents for small equipment)	
	l) Statement for suitable wiring materials at temperatures over 75 °C	

(b)(4) [redacted]

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(b)(4) [redacted]

	n) Capacitors and/or circuit parts marked as required in Sub-clause 15c		(b)(4) [redacted]
6.3	Marking of controls and instruments		
	a) Mains switch clearly identified		
	- ON and OFF positions marked according to Symbols 15 and 16 of table D1 or indicated by an adjacent indicator light		
	b) Indication of different positions of control devices and switches		
	c) Indication of the direction in which the magnitude of the function changes, or an indicating device		
	f) The functions of operator controls and indicators are identified		
	g) Numeric indications of parameters are in SI uni s except for units listed in Am. 2		
6.4	Symbols		
	Used symbols comply with Appendix D or IEC 417 and/or IEC 878 or ISO publications (if applicable)		
6.5	Colors of the insulation of conductors		
	a) Protective earth conductor has green/yellow insulation		
	b) All insulations of internal protective earth conductors are green/yellow at least at their terminations		
	c) Only protective or functional earthing, or potential equalization conductors are green/yellow		
	d) Color of neutral conductor .....:		
	e) Colors of phase conductor(s) .....:		
	- Compliance with IEC 227 and IEC 245		
	f) Additional protective earthing in multi-conductor, cords are marked green/yellow at the ends of the additional conductors		
6.6	Medical gas cylinders and connections		
	a) In accordance with ISO ISO/R 32		
	b) Identification of connection point		
6.7	Indicator lights and push-buttons		

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(b)(4) [redacted]

(b)(4) [redacted]

	a) Red indicator lights used exclusively to indicate a warning of danger and/or a need for urgent action	
	- Yellow used to indicate caution or attention required	
	- Yellow used to indicate caution or attention required	
	b) Color red used only for push-buttons by which a function is interrupted in case of emergency	
6.8	ACCOMPANYING DOCUMENTS	
6.8.1	Equipment accompanied by documents containing at least instructions for use, a technical description and an address to which the user can refer	
	Classifications specified in Clause 5 included in both the instructions for use and the technical description	
	Markings specified in Sub-clause 6.1 included in the accompanying documents if they have not been permanently affixed to equipment	
	Warning statements and the explanation of warning symbols provided in the accompanying documents	
6.8.2	Instructions for use	
	a) General information provided in instructions for use	
	- state the function and intended application of the equipment	
	- include an explanation of: the function of controls, displays and signals	
	- the sequence of operation	
	- the connection and disconnection of detachable parts and accessories	
	- the replacement of material which is consumed during operation	
	- information regarding potential electromagnetic or other interference and advice regarding avoidance	
	- include: indications of recognized accessories, detachable parts and materials, if the use of other parts or materials can degrade minimum safety	

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(b)(4) [redacted]

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	- instructions concerning cleaning, preventive inspection and maintenance to be performed including the frequency of such maintenance	
	General information provided in instructions:	
	- information for the safe performance or routine maintenance	
	- parts on which preventive inspection and maintenance shall be performed by other persons including the periods to be applied	
	- explanation of figures, symbols, warning statements and abbreviations on the equipment	
	c) Signal output or signal input parts intended only for connection to specified equipment described	
	d) Details about acceptable cleaning, disinfection or sterilization methods included	
	e) Warning statement for mains operated equipment with additional power source	
	f) A warning to remove primary batteries if equipment is not likely to be used for some time	
	g) Instructions to ensure safe use and adequate maintenance of rechargeable batteries	
	h) Identification of specified external power supplies or battery chargers necessary to ensure compliance with the requirements of IEC 601-1	
	j) Identification of any risks associated with the disposal of waste products, residues, etc.	
	- Advice in minimizing these risks	
6.8.3	Technical description	
	a) All characteristics essential for safe operation provided	
	b) Required type and rating of fuses utilized in the mains supply circuit external to permanently installed equipment	
	- Instructions for replacement of interchangeable and/or detachable parts which are subject to deterioration during normal use	
	c) Instructions or reference information for repair of equipment parts designated by the manufacturer as repairable provided	

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(b)(4) [redacted]

	d) Environmental conditions for transport and storage specified in accompanying documents and marked on packaging		(b)(4) [redacted]

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(b)(4) [redacted]

(b)(4) [redacted]

7	POWER INPUT	
	Power Input Measurements	

10	ENVIRONMENTAL CONDITIONS	
10.1	Equipment is capable while packed for transport or storage of being exposed to the conditions stated by the manufacturer	
10.2.2a	Rated voltage not exceeding 250 V for hand-held equipment	
	Rated voltage not exceeding 250 V d.c. or single-phase a.c. or 500 V polyphase a.c. for equipment up to 4kVA	
	Rated voltage not exceeding 500 V for all other equipment	
	Rated input frequency not more than 1kHz	
10.2.2b	Internal replaceable electrical power source specified	

14	REQUIREMENTS RELATED TO CLASSIFICATION	
14.4a	Class I and Class II equipment in addition to basic insulation provided with an additional protection	
14.4b	Equipment supplied from external dc source of reverse polarity results in no safety hazard	
14.5b	Internally powered equipment complies with requirements for Class I or Class II equipment while connected to supply mains, and with requirements for internally powered equipment when not connected	
14.6c	Applied parts intended for direct cardiac application are of type CF	

15	LIMITATION OF VOLTAGE AND/OR ENERGY	
15b	Voltage measured one sec after disconnection of the mains plug does not exceed 60V	
15c	For live parts accessible after equipment has been de-energized the residual voltage does not exceed 60 V nor residual energy exceed 2 mJ	
	Marking provided for manual discharging	

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(b)(4) [redacted]

(b)(4) [redacted]

16	**ENCLOSURES AND PROTECTIVE COVERS**	
16a	Equipment enclosed to protect against contact with live parts, and with parts which can become live (finger, pin, hook test)	
	Insertion or removal of lamps - protection against contact with live parts provided	
16b	Opening in a top cover positioned that accessibility of live parts by a test rod is prevented	
16c	Conductive parts accessible after the removal of handles, knobs, levers	
	- have a resistance of not more than 0.2 Ω	
	- separated from live parts by one of the means described in Sub-clause 17g	
16d	Parts with voltage exceeding 25V a.c. or 60V d.c. which cannot be disconnected by external mains switch or plug protected against contact	
16e	Removable enclosures protecting against contact with live parts	
	- Removal possible only with the aid of a tool	
	- Use of automatic device making parts not live when the enclosure is opened or removed	
	- Exception 16e applied to the following parts.....:	
16f	Openings for the adjustment of controls using a tool. The tool not able to touch basic insulation or any live parts	

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(b)(4) [redacted]

(b)(4) [redacted]

17	**SEPARATION**	
17a	Separation method of the applied part from live parts:	
	1) basic insulation: applied part earthed	
	2) by protectively earthed conductive part (e.g. screen)	
	3) by separate earthed intermediate circuit limiting leakage current to applied part in event of insulation failure	
	4) by double or reinforced insulation	
	5) by protective impedances limiting current to applied part	
	- Additional leakage current test in single fault conditions	
17c	There is no conductive connection between applied parts and accessible conductive parts which are not protectively earthed	
17d	Supplementary insulation between hand-held flexible shafts and motor shafts (Class I)	
17g	Separation method of accessible parts other than applied parts from live parts:	
	1) basic insulation: accessible part earthed	
	2) by protectively earthed conductive part (e.g. screen)	
	3) by separate earthed intermediate circuit limiting leakage current to enclosure in event of insulation failure	
	4) by double or reinforced insulation	
	5) by protective impedances limiting current to accessible part	
	- Additional leakage current test in single fault conditions	
17h	Arrangements used to isolate defibrillation-proof applied parts so designed that:	
	- no hazardous electrical energies appear during a discharge of a cardiac defibrillator	
	- after exposure to the defibrillation voltage, the equipment continues to perform its intended function	

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(b)(4) [redacted]

18	**PROTECTIVE EARTHING, FUNCTIONAL EARTHING AND POTENTIAL EQUALIZATION**		(b)(4) [redacted]
18a	Accessible parts of Class I equipment separated from live parts by basic insulation connected to the protective earth terminal		
18b	Protective earth terminals suitable for connection to the protective earth conductor		
18e	Potential equalization conductor		
	- Readily accessible		
	- Accidental disconnection prevented in normal use		
	- Conductor detachable without the use of a tool		
	- Power supply cord does not incorporate a potential equalization conductor		
	- Connection means marked with Symbol 9, Table DI		
18f	For equipment without power supply cord, impedance between protective earth terminal and accessible metal part ≤ 0.1 Ω		
	- For equipment with an appliance inlet, impedance between protective earth contact and any accessible metal part ≤ 0.1 Ω		
	- For equipment with a non-detachable power supply cord, impedance between protective earth pin in mains plug and accessible metal part ≤ 0.2 Ω		
18g	If the impedance of protective earth connections other than in Cl. 18 f) exceeds 0.1 Ω, the allowable value of the enclosure leakage current is not exceeded in single fault condition		
18k	Functional earth terminal not used to provide protective earthing		
18l	Class II equipment with isolated internal screens		
	- insulation of screens and all internal wiring connected to them is double insulation or reinforced insulation		
	- functional earth terminal clearly marked		
	- explanation of functional earth terminal provided in the accompanying documents		

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(b)(4) [redacted]

(b)(4) [redacted]

19	CONTINUOUS LEAKAGE CURRENTS AND PATIENT AUXILIARY CURRENTS	
19.1b	Leakage currents	(see appended table 19)
	- earth leakage current	
	- enclosure leakage current	Enclosure is Applied Part
	- patient leakage current	
	- patient auxiliary current	

20	DIELECTRIC STRENGTH	
	Overall compliance with Clause 20	(see appended table 20)

21	MECHANICAL STRENGTH	
21a	Sufficient rigidity of an enclosure tested by: force of 45 N	(see appended table 21)
21b	Sufficient strength of an enclosure tested by: impact hammer	(see appended table 21)
21c	On portable equipment carrying handles or grips withstand the requirements of the loading test	
21.3	No damage to parts of patient support and/or immobilization system after the loading test	
21.5	Hand held equipment or equipment parts are safe after drop test	(see appended table 21)
21.6	Portable and mobile equipment is able to withstand rough handling	

22	MOVING PARTS

23	SURFACES, CORNERS AND EDGES	
	Rough surfaces, sharp corners and edges which may cause injury or damage avoided or covered	

24	STABILITY IN NORMAL USE (see appended table 24)	
24.1	Equipment does not overbalance during normal use when tilted through an angle of 10°	
24.3	Equipment overbalances when tilted through an angle of 10°	

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(b)(4) [redacted]

(b)(4) [redacted]

	- does not overbalance when tilted through an angle of 5° in any position excluding transport	
	- carry a warning notice stating that transport should only be undertaken in a certain position	
	- in the position specified for transport does not overbalance when tilted to an angle of 10°	
24.6a	Equipment or its parts with a mass of more than 20 kg is provided with:	
	- suitable handling devices (grips etc.), or	
	- instructions for lifting and handling during assembly	
24.6b	b) On portable equipment with a mass of more than 20 kg carrying handle(s) is (are) so situated that equipment may be carried by 2 or more persons	

25	**EXPELLED PARTS**	
25.1	Protective means are provided where expelled parts of the equipment could be a hazard	
25.2	Display vacuum tubes with a face dimension exceeding 16 cm are provided with adequate protection against implosion	

28	**SUSPENDED MASSES**	

29	**X-RADIATION**	
29.2	EQUIPMENT not intended to produce X-radiation produces an exposure ≤ 130 nC/kg (0.5 mR)	(see appended table 29)

36	**ELECTROMAGNETIC COMPATIBILITY**	
	Equipment complies with IEC 601-1-2	Not tested

37	**COMMON REQUIREMENTS FOR CATEGORY AP AND CATEGORY APG EQUIPMENT**	
	Requirements for category AP and APG equipment (Cl. 37 - 41)	

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(b)(4) [redacted]

(b)(4) [redacted]

42	EXCESSIVE TEMPERATURES	
42.1	Equipment does not attain temperatures exceeding the values given in Table Xa over the range of ambient temperatures per Clause 10.2.1	(see appended table 42)
42.2	Equipment does not attain temperatures exceeding the values given in Table Xb at 25°C ambient	
42.3	Applied parts not intended to supply heat have surface temperatures not exceeding 41°C	
42.5	Guards to prevent contact with hot surfaces removable only with a tool	

43	FIRE PREVENTION	
	Strength and rigidity necessary to avoid a fire hazard	

44	OVERFLOW, SPILLAGE, LEAKAGE, HUMIDITY, INGRESS OF LIQUIDS, CLEANING, STERILIZATION AND DISINFECTION	
44.2	Equipment contain a liquid reservoir:	
	- the equipment is electrically safe after 15% overfill steadily over a period of 1 min	
	- transportable equipment is electrically safe after additionally having been tilted through an angle of 15° in the least favorable direction(s) (if necessary with refilling)	
44.3	Electrical properties of the equipment do not change in connection of spillage test (200 ml of water)	
44.4	Liquid which might escape in a single fault condition does not wet parts which may cause a safety hazard	
44.5	Equipment sufficiently protected against the effects of humidity	
44.6	Enclosures designed to give a protection against harmful ingress of water classified according to IEC Publication 529	
44.7	Equipment capable of withstanding cleaning, sterilization or disinfection without deterioration of safety provisions	

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(b)(4)

[redacted]

(b)(4)

[redacted]

45	**PRESSURE VESSELS AND PARTS SUBJECT TO PRESSURE**	
48	**BIOCOMPATIBILITY**	
	Parts of equipment and accessories intended to come into contact with biological tissues, cells or body fluids are evaluated in accordance with ISO 10993-1	CE marked electrodes used
49	**INTERRUPTION OF THE POWER SUPPLY**	
49.1	Thermal cut-outs and over-current releases with automatic resetting not used if they may cause a safety hazard	
49.2	Interruption and restoration of power supply does not result in a safety hazard other than interruption of intended function	
49.3	Means are provided for removal of mechanical constraints on patient in case of a supply mains failure	
51	**PROTECTION AGAINST HAZARDOUS OUTPUT**	
51.4	Equipment furnishing both low-intensity and high-intensity outputs provided with means minimizing possibility of a high intensity output being selected accidentally	
52	**ABNORMAL OPERATION AND FAULT CONDITIONS**	
52.1	Equipment is so designed and manufactured that even in single fault condition no safety hazard as described under 52.4 exists (see 3.1 and Cl. 13)	(see appended table 52)
	The safety of equipment incorporating programmable electronic systems is checked by applying IEC 601-1-4	
52.5.2	Failure of thermostats presents no safety hazards	
52.5.3	Short-circuiting of either part of double insulation presents no safety hazard	
52.5.5	Impairment of cooling: temperatures not exceeding 1.7 times the values of Clause 42 minus 17.5°C	(see appended table 52)
52.5.6	Locking of moving parts presents no safety hazard	
52.5.7	Interruption and short-circuiting of motor capacitors presents no safety hazard	

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52.5.8	Duration of motors locked rotor test in compliance with Cl. 52.5.8	
52.5.9	Failure of one component at a time presents no safety hazard	(see appended table 52)
52.5.10	Overload of heating elements presents no safety hazard	
	f) Motors intended to be remotely controlled, automatically controlled, or liable to be operated continuously provided with running overload protection	
	h) Equipment with three-phase motors can safely operate with one phase disconnected	

56	**COMPONENTS AND GENERAL ASSEMBLY**	
	List of critical components	(see appended table 56)
56.1b	Ratings of components not in conflict with the conditions of use in equipment	
	Ratings of mains components are identified	
56.1d	Components, movements of which could result in a safety hazard mounted securely	
56.1f	Conductors and connectors secured and/or insulated to prevent accidental detachment resulting in a safety hazard	
56.3a	Connectors provide separation required by Sub-clause 17g	
	Plugs for connection of patient circuit leads can not be connected to other outlets on the same equipment	(b)(4) (b)(4)
	Medical gas connections not interchangeable	
56.3b	Accessible metal parts can not become live when detachable interconnection cord between different parts of equipment is loosened or broken	
56.3c	Leads with conductive connection to a patient are constructed such that no conductive connection remote from the patient can contact earth or hazardous voltages.	
56.4	Connections of capacitors	
	Not connected between live parts and non-protectively earthed accessible parts	

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(b)(4) [redacted]

	If connected between mains p rt and protectively earthed metal parts comply with: IEC Publication 384-14	
	Enclosure of capacitors connected to mains part and providing only basic insulation, is not secured to non-protectively earthed metal parts	
	Capacitors or other spark-suppression devices are not connected between contacts of thermal cut-outs	
56.5	Protective devices which cause disconnection from the supply mains by producing a short-circuit not provided in equipment	
56.6	Temperature and overload control devices	
	a) Thermal cut-outs which have to be reset by a soldering not fitted in equipment	
	Thermal safety devices provided where necessary to prevent operating temperatures exceeding the limits	
	Independent non-self-resetting thermal cut-out provided where a failure of a thermostat could constitute a safety hazard	
	Audible warning provided where the loss of function caused by operation of a thermal cut-out presents a safety hazard	
	Self-resetting thermal cut-outs and self-resetting over-current releases operated 200 times	
	Non-self resetting over-current releases operated 10 times	
56.6b	Thermostats with varying temperature settings clearly indicated	
	Operating temperature of thermal cut-outs indicated	
56.7	Batteries	
	a) Battery compartments:	
	- adequately ventilated	
	- accidentally short-circuiting is prevented	
	b) Incorrect polarity of connection prevented	
56.8	Indicators - unless indication provided by other means (from the normal operation position), indicator lights are used (color see 6.7):	
	- to indicate that equipment is energized	

(b)(4) [redacted]

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(b)(4) [redacted]

	- to indicate the operation of non-luminous heaters if a safety hazard could result	
	- to indicate when output exists if a safety hazard could result	
	- charging mode indicator provided	
56.10	Actuating parts of controls	(see appended table 56.10)
56.10b	Actuating parts are adequately secured to prevent them from working loose during normal use	
	Controls are secured to prevent the movement relative to scale marking (safety related only)	
	Detachable indicating devices are prevented from incorrect connection without the use of tool	
56.10c	Stops are provided on rotating controls:	
56.11	Cord-connected hand-held and foot-operated control devices	

57	**MAINS PARTS, COMPONENTS AND LAYOUT**	
57.1	Isolation from supply mains	
	a) Equipment provides means to isolate its circuits electrically from the supply mains on all poles simultaneously	Mains charger is separately approved.
	Means for isolation incorporated in equipment or, if external, specified in the accompanying documents	Direct plug-in power supply
	d) Switches used to comply with Sub-clause 57.1a comply with the creepage distances and air clearances as specified in IEC Publication 328	
	f) Mains switches not incorporated in a power supply cord	
	h) Appliance couplers and flexible cords with mains plugs provide compliance with Sub-clause 57.1a	
	m) Fuses and semiconductor devices not used as isolating devices	
57.2	Mains connectors and appliance inlets	
57.3	Power supply cords	
57.4	Connection of power supply cords	
57.5	Mains terminal devices and wiring of mains part	
57.6	Mains fuses and overcurrent releases	

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(b)(4) [redacted]

	Fuses or over-current releases provided accordingly for Class I and Class II		(b)(4)
	Current rating of mains fuses and over-current releases such that they reliably carry the normal operating current		
	Protective earth conductor not fused		
	Neutral conductor not fused for permanently installed equipment		
57.8	Wiring of the mains part		
57.9	Mains supply transformers		
57.9.1	Overheating		
	External to the transformer protective devices connected in such a way that failure of any component cannot render the protective devices inoperative		
57.9.1a	Short-circuit of secondary windings not caused excessive temperature		
57.9.1b	Overload of secondary windings not caused excessive temperature		
57.9.2	The dielectric strength of the electrical insulation of a mains supply transformer such that it passes tests		
57.9.4	Construction		
	a) Separation of primary and secondary windings		
	- separate bobbins or formers		
	- one bobbin with insulating partition		
	- one bobbin with concentric windings and having copper screen with a thickness of not less than 0.13 mm		
	- concentrically wound on one bobbin with windings separated by double insulation		
	c) Means provided to prevent displacement of end turns		
	d) Insulated overlap of not less than 3 mm if a protective earthed screen has only one turn		
	e) Insulation between the primary and secondary in transformers with double insulation		
	- 1 insulation layer with thickness of at least 1 mm		

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(b)(4) [redacted]

(b)(4) [redacted]

	- at least 2 insulation layers with a total thickness of at least 0.3 mm	
	- three layers provided that each combination of two layers can withstand the dielectric strength test for reinforced insulation	
	g) Exit of the wires of toroidal transformers provided with double sleeving complying with requirements for double insulation and having total thickness at least 0.3 mm extending at least 20 mm outside the winding	
57.10	Creepage distances and air clearances	
	a) Values: compliance with at least the values of Table XVI	(see table for insulation diagram)
	Creepage distances for slot insulation of motors at least 50% of the specified values	
	b) Minimum creepage distances and air clearances in the mains part between parts of opposite polarity not required if short-circuting does not produce a safety hazard	
	c) Creepage distances or clearances of at least 4 mm are maintained between defibrillation-proof applied parts and other parts	
58	**PROTECTIVE EARTHING - TERMINALS AND CONNECTIONS**	

59	**CONSTRUCTION AND LAYOUT**	
59.1	Internal wiring	
	a) Cables and wiring protected against contact with a moving part	
	Wiring having basic insulation only protected by additional fixed sleeving	
	Components are not likely to be damaged in the normal assembly or replacement of covers	
	b) Movable leads are not bent around a radius of less than five times the outer diameter of the lead	
	c) Insulating sleeving adequately secured	
	If the sheath of a flexible cable or cord is used as supplementary insulation it complies with requirements of IEC 227 and IEC 245 and dielectric test	
	Conductors subjected to temperatures exceeding 70°C have an insulation of heat-resistant material	

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(b)(4) [redacted]

			(b)(4)
	d) Aluminum wires of less than 16 mm^2 cross-section not used		
	f) Connecting cords between equipment parts considered as belonging to the equipment		
59.2	Insulation		
	b) Mechanical strength and resistance to heat and fires retained by all types of insulation		
	c) Insulation not likely to be impaired by deposition of dirt or by dust resulting from wear of parts		
	Parts of rubber resistant to ageing		
59.3	Excessive current and voltage protection		
	Internal electrical power source provided with device for protection against fire hazard		
	Fuse elements replaceable without opening the enclosure fully enclosed in a fuseholder		
	Protective devices between an isolated applied part and the body of the equipment do not operate below 500 V r.m.s.		
59.4	Oil containers		
	Oil containers adequately sealed		
	Container allow for the expansion of the oil		
	Oil containers in mobile equipment sealed to prevent the loss of oil during transport		
	Partially sealed oil-filled equipment or equipment parts provided with means for checking the oil level		

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(b)(4)

6.1	TABLE: marking durability	P
Marking tested	Remarks	
Sample label	No damage	
Supplementary information:		

7	TABLE: power input					N
Operating condition	Voltage	Frequency	Current	Power	Remarks	
Supplementary information:						

15b	TABLE: residual voltage in attachment plug										P
Voltage measured between:	Measurements [V]										Remarks
	1	2	3	4	5	6	7	8	9	10	
supply pins (pin 1 & pin 2)											
line pin 1 and enclosure											
line pin 2 and enclosure											
pin 1 and earth pin											
pin 2 and earth pin											
Approved plug-in power supply											

15c	TABLE: residual voltage or energy in capacitors				N
Capacitor and its location	Residual voltage (V)	Time after disconnection (s)	Capacitance value (µF)	Residual energy (mJ)	Remarks
Supplementary information:					

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(b)(4) [redacted]

19	TABLE: leakage current				P
Type of leakage current and test condition (including single faults)		Supply voltage	Supply frequency	(b)(4)	Remarks
Before humidity preconditioning:					
Patient auxiliary current between one electrode and all others connected together		-	-		
Patient auxiliary current between foil around enclosure and each electrode and all electrodes		-	-		
Mains on main body		-	-		
After humidity preconditioning:					
Patient auxiliary current between one electrode and all others connected together		-	-		
Patient auxiliary current between foil around enclosure and each electrode and all electrodes		-	-		
Mains on main body		-	-		

(b)(4) [redacted]

Abbreviations used:	
ER - Earth leakage current EN - Enclosure leakage current P - Patient leakage current PM - Patient leakage current with mains on the applied parts PA -Patient auxiliary current Fig. 15 - refers to Fig. 15 in IEC601-1 MD - Measuring device	A - After humidity conditioning B - Before humidity conditioning 1 - Switch closed or set to normal polarity 0 - Switch open or set to reversed polarity NC - Normal condition SFC - Single fault condition

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(b)(4)

20	TABLE: dielectric strength	P

(b)(4)

Supplementary information:

21	TABLE: mechanical strength	P
Part under test	Test (impact, drop, force, handle, rough handling, mobile)	Remarks

(b)(4)

Supplementary information:

24	TABLE: - stability	N
Part under test	Test condition	Remarks

Supplementary information:

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[redacted]

Supplementary information: COR - indicates measurements taken using change-of-resistance method		

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(b)(4)

44	TABLE: overflow, spillage, leakage, humidity, ingress of liquids, cleaning, sterilization, desinfection	P

Test type and condition	Part under test	Remarks
(b)(4)		
Supplementary information:		

52	TABLE: abnormal operation	

(b)(4)		
Supplementary information:		

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(b)(4)

56.1	TABLE: lists of critical component parts				P
Object/part No	Manufacturer/ trademark	Type/model	Technical data	Standard	Mark(s) of conformity[1])
(b)(4)					
[1]) an asterisk indicates a mark which assures the agreed level of surveillance					

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(b)(4)

56.10	TABLE: actuating parts and controls	P
Part under test	Torque applied	Remarks
Supplementary information: 2 membrane push buttons only		

57.4	TABLE: cord anchorages				N
Cord under test	Mass of equipment	Pull	Torque	Remarks	Verdict
Supplementary information:					

57.4b	TABLE: cord bending			N
Cord under test	Test mass	Measured curvature	Remarks	
Supplementary information:				

57.9.1a	TABLE: transformer short circuit					N
Winding under test	Protection	Measured temperatures (°C)			Test duration	Remarks
		Primary	Secondary	Ambient		
Supplementary information: Approved power supply unit						

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(b)(4)

(b)(4)

(b)(4)

Requirement	
Ionizing radiation or radio isotopes	
Particular factory identification	
Multiple voltage equipment marking	
Replace 75°C by 60°C	
Identification of gas cylinders: ANSI/NFPA 99	
Components compliant with USA recognized standards or Internationally Harmonized Component Standards: a) Printed wiring boards	(b)(4)
b) Lithium batteries	
c) Optical isolators	
d) Wiring & tubing	
e) CRTs > 5"	
Primary components up to isolation transformer	
Instructions indicate type of attachment plug for connection to alternate voltage.	
(600V not 500V)	
All Fixed and Permanently installed equipment shall be Class I	
X-ray equipment : m) Protective Earth	
n) Accessible non-current carrying parts	
Leakage currents: X-ray equipment & that covered by note 3) table IV	
Patient Care Equipment	
Non Patient equipment	
Moving parts: End stops etc	
Mechanical strength of end stop etc	
Applies to Operator as well as Patient	
Emergency stop device	

(b)(4)

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(b)(4)			(b)(4)
	Suspension systems Relying on safety Device		
	Without Safety Devices		
	X-ray equipment		
	Compliance with UL1446 if temperatures > 105°C		
	Oxygen enriched atmospheres		
	Abnormal conditions: Not applicable if 15W or less		
	Enclosures: Conductive coatings		
	Flame spread (area > 9.47m2)		
	External surface (area > 4.74m2)		
	Polymeric enclosures compliant with UL 746C: Mold Stress Relief	(b)(4) (b)	
	Flammability		
	6.78Nm impact		
	Hand held equipment: drop test		
	Permanently connected equipment		
	Fixed & Stationary X-ray equipment		
	Mains plugs "Hospital only"	(b)(4)	
	Radiography equipment		
	Other than X-ray equipment: 125% rated current		
	Polarized attachment plug		
	Second fuse holder in grounded side of line.		
	Mains cords: Detachable power supply cord: Unlikely to become detached,		
	1) Acceptable for application: Ampacity as NEC,		
	Not less than equipment rating,		
	Constructed as UL62 or equivalent AWM		
	2) At least 18 AWG, and		
	i) Not less than SJE, SJT, SJO or equivalent for transportable equipment		
	ii) Not less than SV where extreme weight or		

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(b)(4)	flexibility is a factor,		(b)(4)
	Iii) Oil resistant if subjected		
	Mains terminal devices		
	Transformer overload protection: Repeat action of protective devices 2 more times		
	PTC left in circuit		
	Internal earthing: mechanical fixing as well as solder		
	Internal wiring (sub-section f) replacement: For non- SELV, connecting cords between equipment parts meet NEC		
	1) If exposed: Type SJT, SJTO, SJO, ST, SO, STO or equivalent		
	2) If not exposed: i) Type SPT-2, SP-2 or SPE-2, or equivalent, or		
	ii) Type SVT, SVTO SVE or equivalent, or		
	Iii) An assembly of insulated wires each 0.8mm nominal insulation thickness in acceptable insulated tubing of 0.8mm nominal thickness, or		
	iv) SELV separated as in 17g).		
	If exposed to abuse: a) 914mm above floor	(b)(4)	
	b) guarded against contact with equipment		
	c) retractable		
	Separate power units: Packaged with the equipment or labelled		
	Plug-in units: Compliance with UL 1310 for mechanical assembly, enclosure, input connections, accessibility and grounding.	(b)(4)	
	Performance: Compliance with UL 1310 for blade secureness, security of input contacts and abuse.		
	External temperature (cl 59.1) < 65C or 125C if o/c within 1 hour.		

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(b)(4)	Markings: Compliance with UL 1310		(b)(4)

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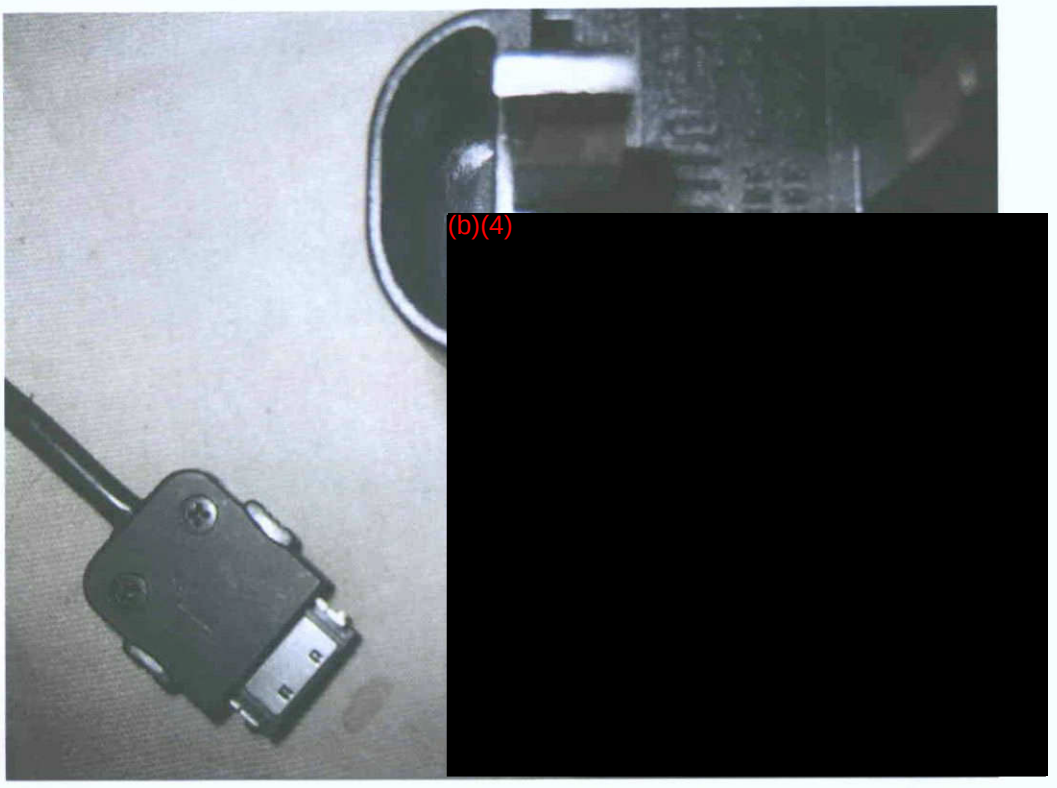

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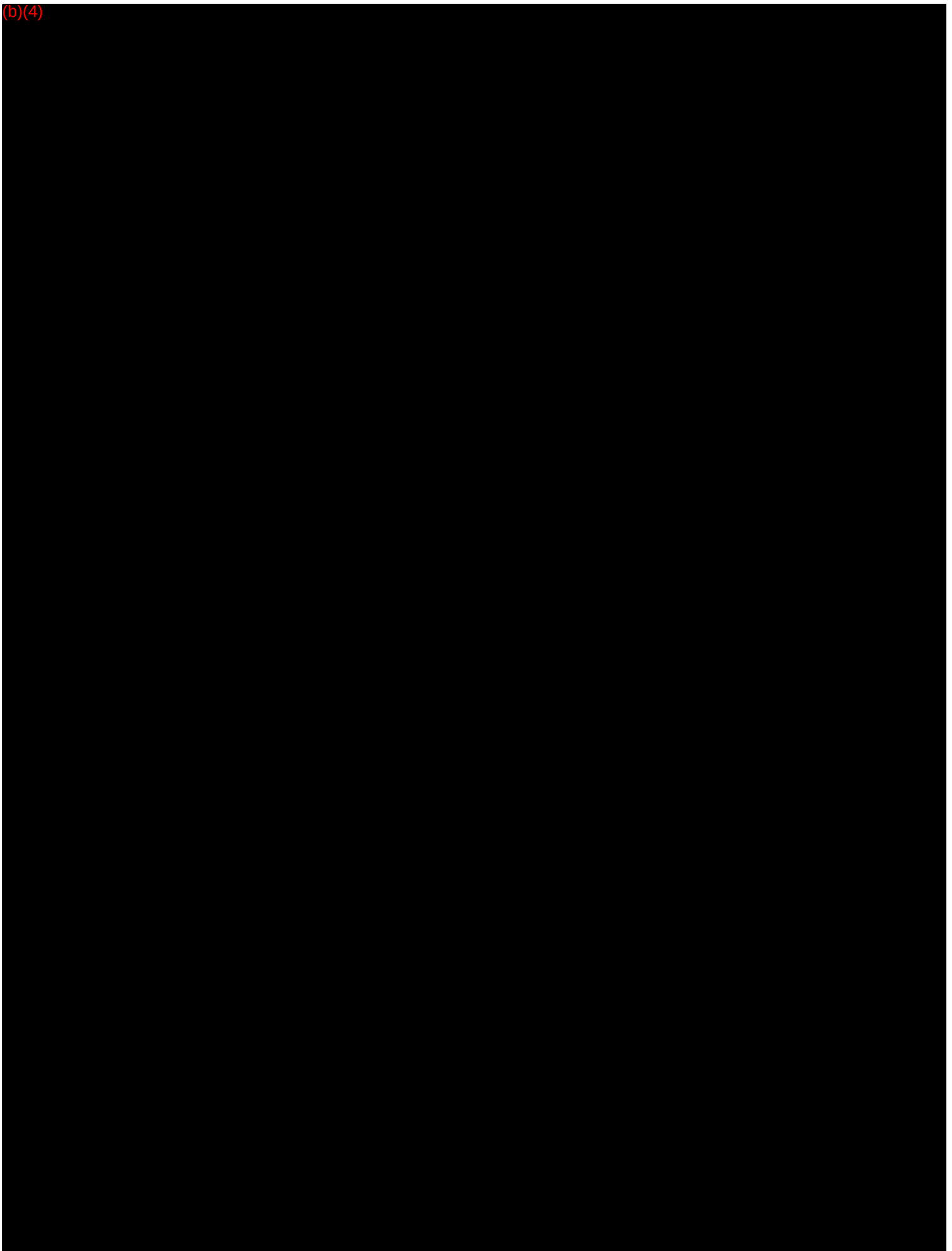

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Form Approved: OMB No. 0910-0120; Expiration Date: 8/31/10

Department of Health and Human Services
Food and Drug Administration

STANDARDS DATA REPORT FOR 510(k)s

(To be filled in by applicant)

This report and the Summary Report Table are to be completed by the applicant when submitting a 510(k) that references a national or international standard. A separate report is required for each standard referenced in the 510(k).

TYPE OF 510(K) SUBMISSION

☑ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

(b)(4)

[redacted]

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U.S.C. 360d], www.fda.gov/cdrh/stdsprog.html

[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[4] The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

[5] The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[6] The online search for CDRH Guidance Documents can be found at www.fda.gov/cdrh/guidance.html

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EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

(b)(4) [redacted]

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
All	All	☑ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

All applicable sections comply

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

DESCRIPTION

JUSTIFICATION

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

◆ Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.

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Department of Health and Human Services
Food and Drug Administration

STANDARDS DATA REPORT FOR 510(k)s

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EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE

(b)(4) [redacted]

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
All	All	☑ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED◆

All applicable sections comply

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

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DESCRIPTION

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Department of Health and Human Services
Food and Drug Administration

STANDARDS DATA REPORT FOR 510(k)s

(To be filled in by applicant)

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☑ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

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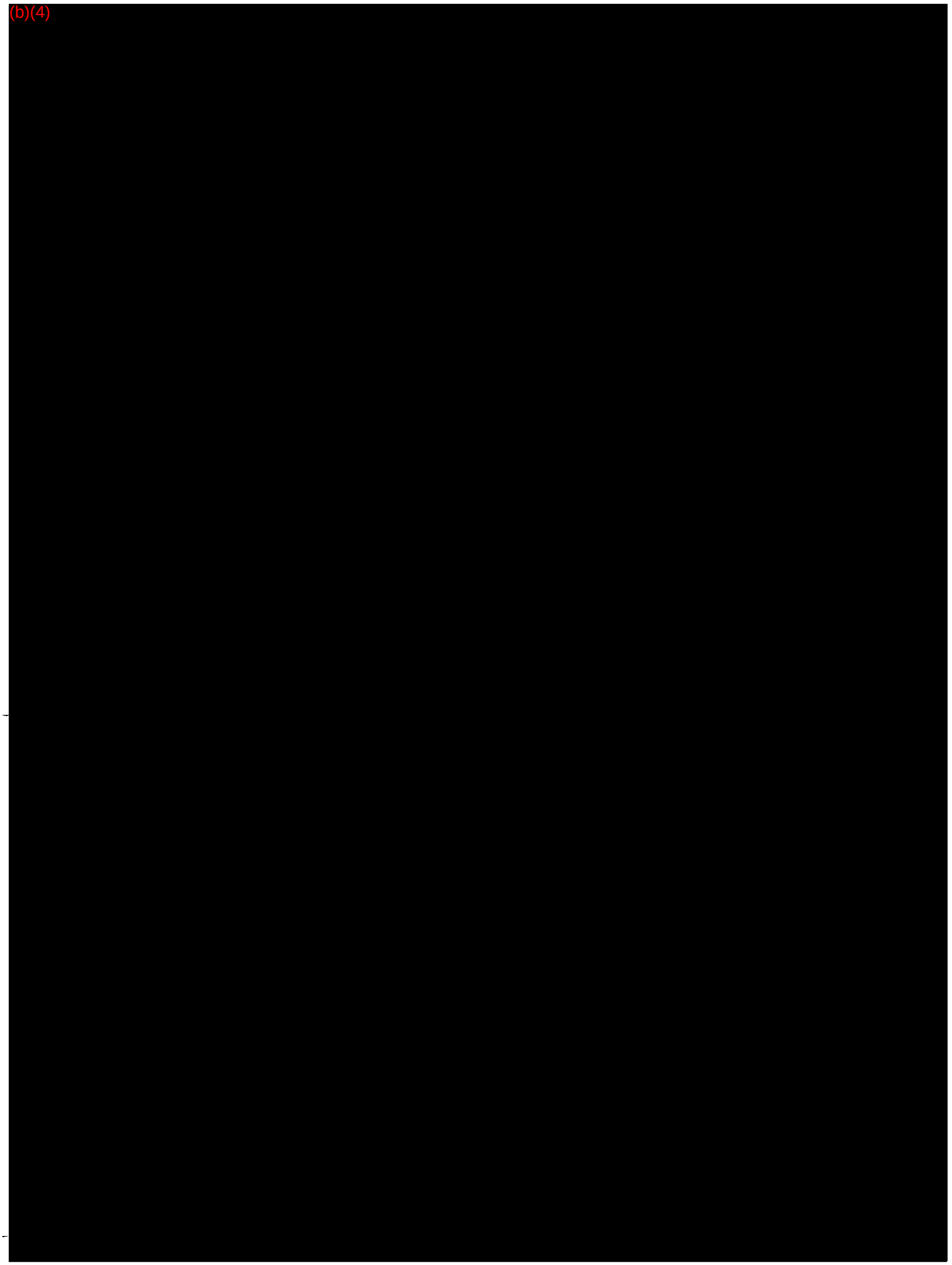
(b)(4)



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EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

(b)(4)

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TYPE OF DEVIATION OR OPTION SELECTED ◆		
DESCRIPTION		
JUSTIFICATION		

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(b)(4)

(b)(4)

[redacted]

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(b)(4)

(b)(4)

[redacted]

Photograph:

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1AO

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DESCRIPTION

JUSTIFICATION

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VSI

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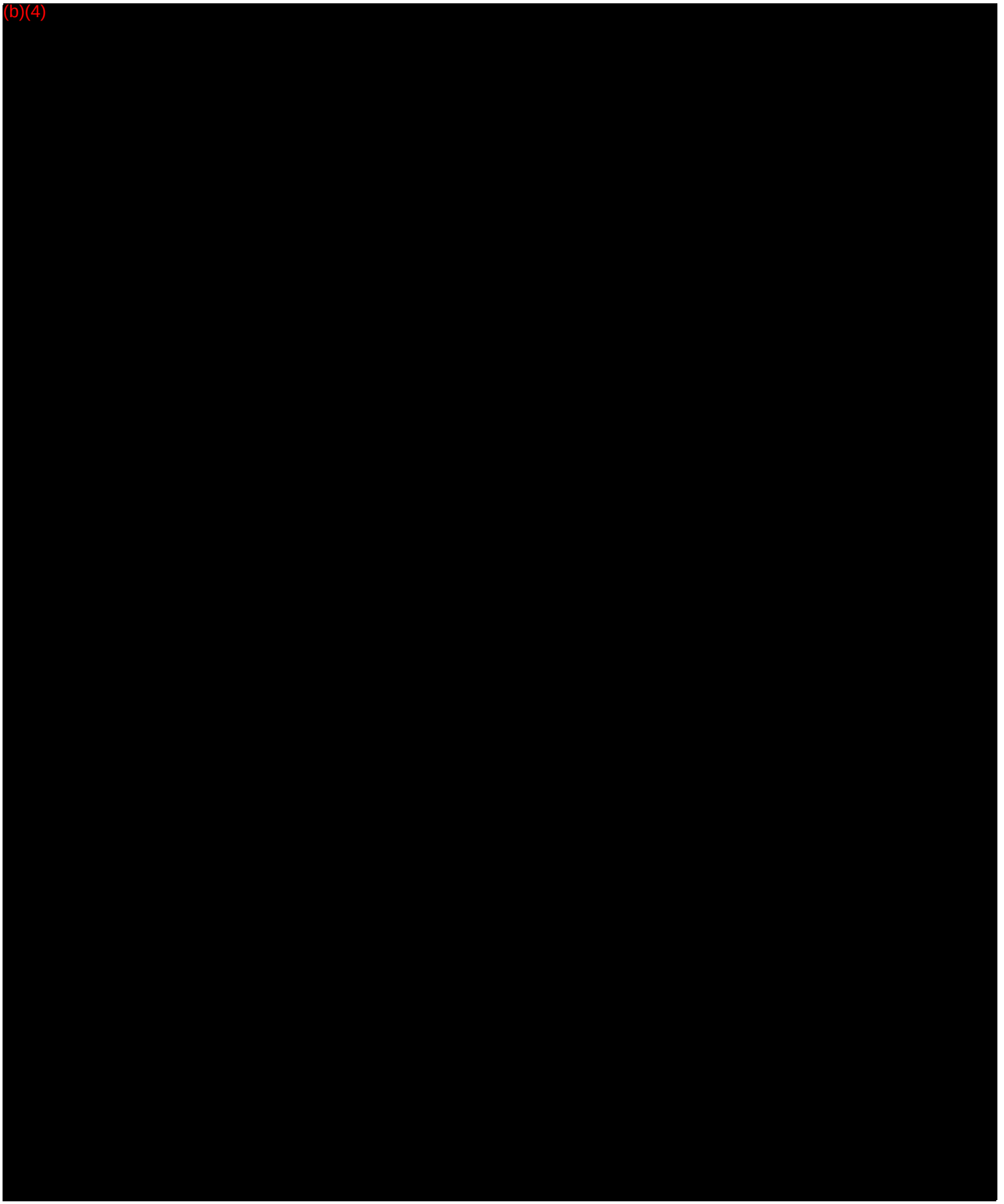
(b)(4)



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EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

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VS

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WS7

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Appendix B

- Device Labels
- Sales Sheet
- User Manuals

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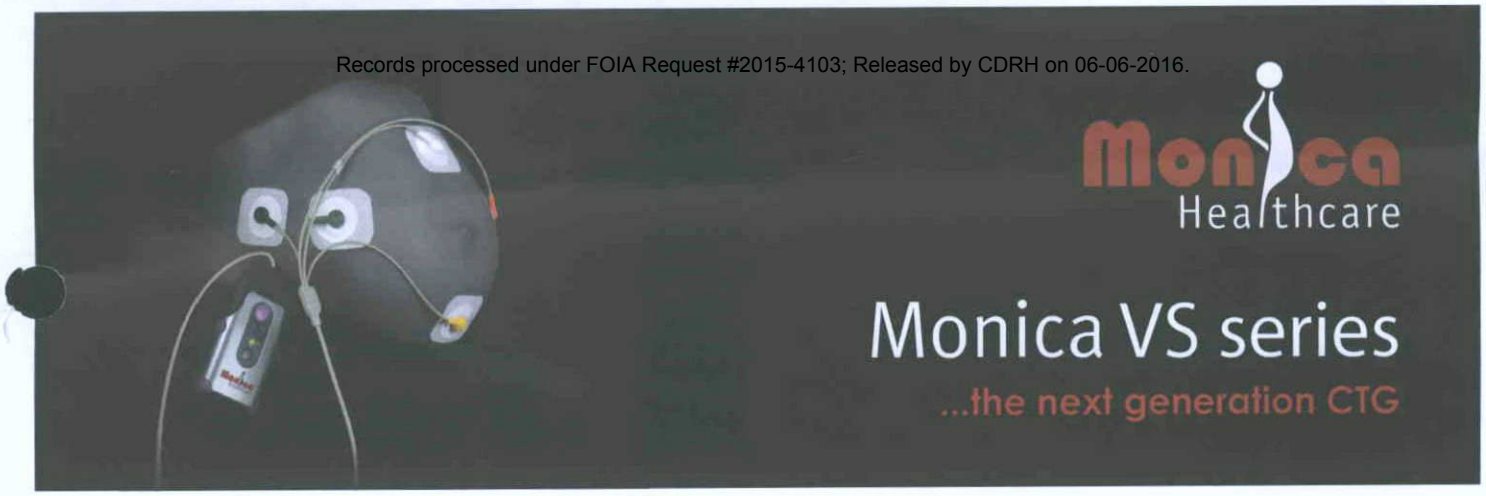
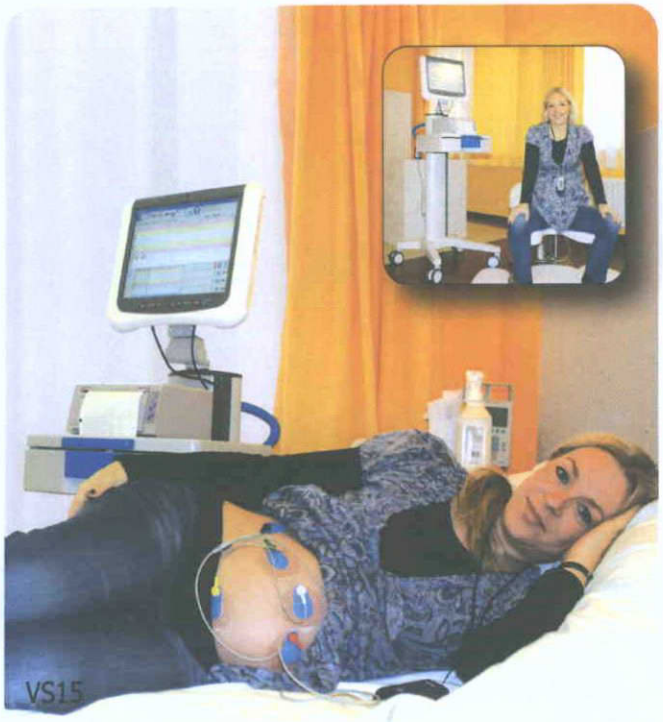


Monica Healthcare

Monica VS series

...the next generation CTG



Wireless Mobility

- Can reduce time in labour[1]
- Natural Birthing positions
- Patient Satisfaction

Beltless

- Patient Comfort
- Continuity of monitoring during procedures

Reduced User Intervention

- No repositioning of transducers
- Continuous monitoring for 20+ hours

Accurate Surveillance

- Direct FHR monitoring from fECG
- Monitors maternal heart rate[3] to easily identify potential MHR / FHR confusion
- Uterine Activity validated against IUPC

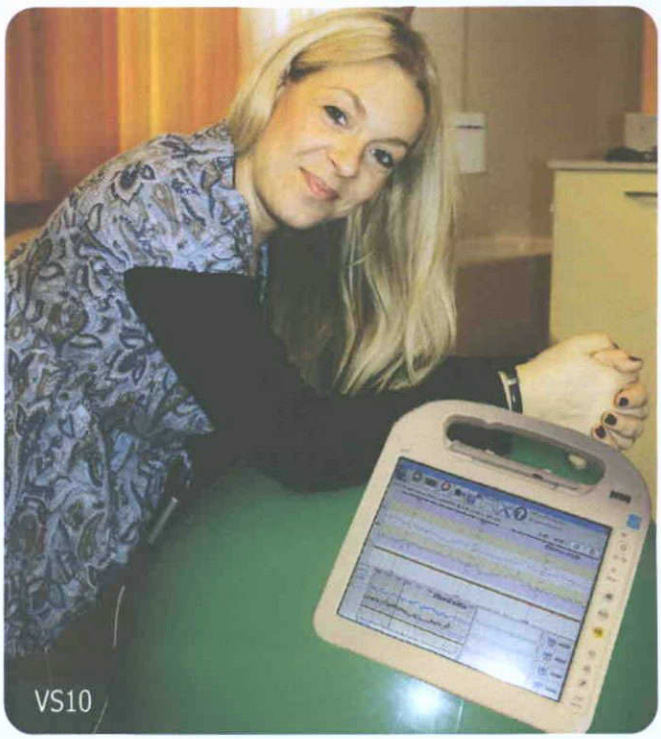
Improved work flow

- Electronic storage / Paperless
- Remote viewing & Central Station connectivity[2]
- Event annotation & decision support

Obesity

- Minimal performance loss with obese patients

1 Enabling patients to mobilise can reduce the time in labour
"Maternal positions and mobility during first stage labour" Lawrence et.al. 2009
2 Requires CS interface
3 Not available in the US



VS1

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www.monicahealthcare.com

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Monica VS series ...the next generation CTG

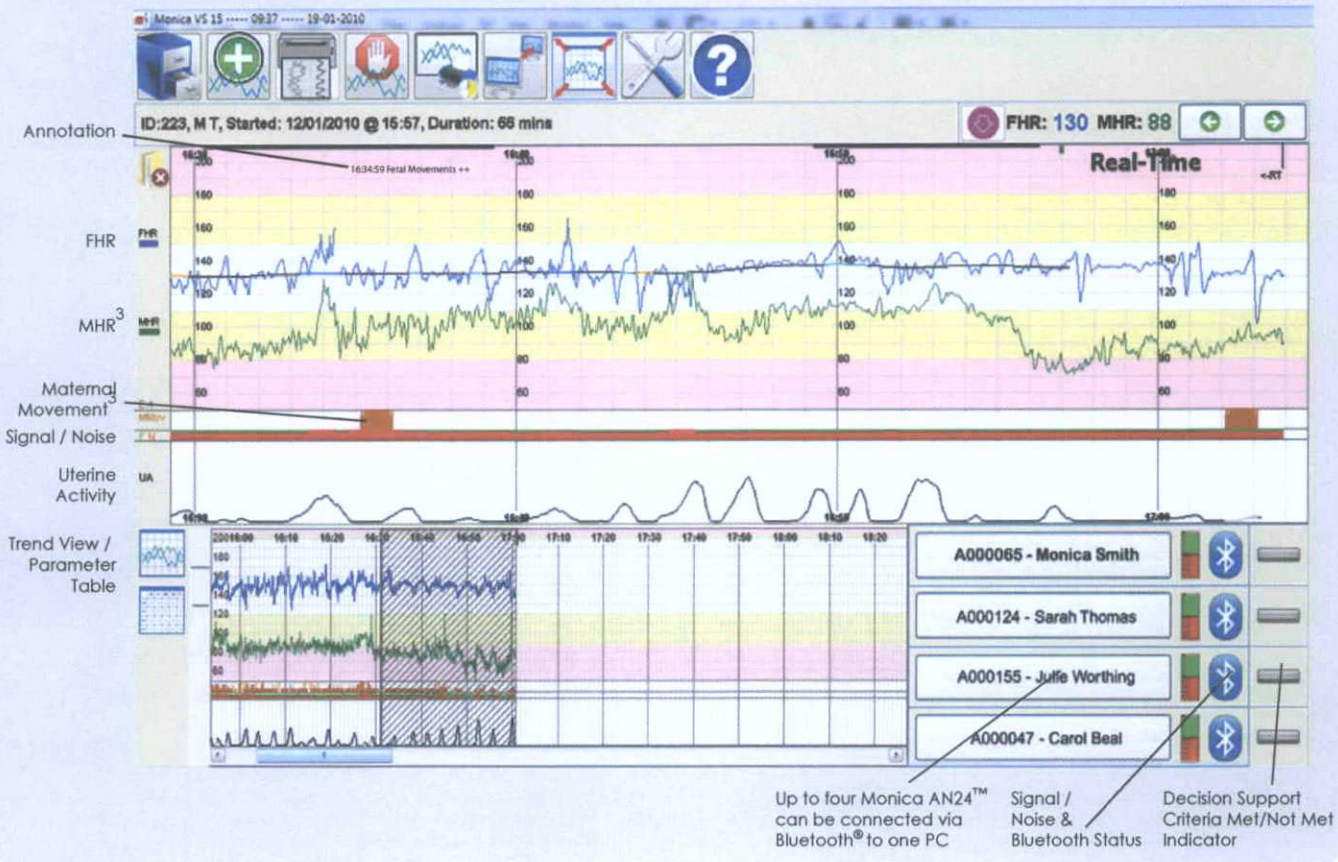
Monica's VS series of wireless fetal-maternal monitors opens up a whole new world of passive surveillance, flexible management, and patient comfort during pregnancy and labour in the hospital, clinic or home[3].

Using innovative abdominal fECG FHR and EHG UA technology the VS series provides a new solution for Labour and Delivery monitoring and performs well in women with a high BMI.

Featuring FHR, UA, MHR[3], maternal activity[3], event annotation and decision support the Monica VS series of monitors offer simple set-up, minimal supervision and robust solutions for clinical use.

Available as a 15" monitor (VS15) mountable on a desk or cart with optional real-time 'Z-fold' thermal printer or as a 10" portable monitor (VS10). The Monica VS series provides a level of information and connectivity never before available to the clinician.

CTG display using the Monica VS15 or VS10 Monitor



Non-Invasive	✓	Early gestation	✓
Passive	✓	Late gestation	✓
Requires Minimal Supervision	✓	Throughout Induction & Labour	✓
Maternal Freedom	✓	High Maternal BMI	✓
FHR & MHR[3] - based on accurate R-R interval	✓	Monitor Multiple Beds - from 1 VS Monitor (in range)	✓
Concurrent FHR & MHR	✓		
Maternal Movement Detection[3]	✓		
Uterine Activity (EHG)	✓	Central Station Link	✓
Event Marker	✓	Remote Network Viewing	✓
Real-Time thermal print option	✓	High Level of data integrity	✓

For more information on the Monica VS series please contact your local Monica representative or visit www.monicahealthcare.com

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

100-PT-001 Monica AN24™

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Product	Abdominal Fetal ECG recorder
Document name	Labelling
Document type	**Drawings**
Abstract	This file documents the labelling related to the AN24 device. **Notified Body: UL** **Notified Body ID number: 0843**

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1 SCOPE

1.1 Document Identification

This document provides drawings of all labelling related to the AN24 product.
The document is identified as follows:

- ✓ Identification Number: 100-SH-006.
- ✓ Title: Abdominal Fetal ECG recorder – Drawings, labelling.

1.2 Document Scope

This document is part of the hardware documentation of the AN24 product. It provides a description of all labelling.

1.3 AN24 Product Overview

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2 RELATED DOCUMENTS

N°	*Title*	*Reference*
[1]	AN24 Assembly Instructions	100-TF-007
[2]	Four part label kit drawing	100-SH-006 App A
[3]	Main Label Outline Drawing	100-SH-006 App B
[4]	Electrode check label drawing	100-SH-006 App C
[5]	Outer case artwork drawing	100-SH-006 App E

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3 General Labelling requirements

3.1 Applicability

Each AN24 device requires.

3.2 Location

- Label 1 – Rear of AN24 device (see Assembly instructions [1])
- Label 2 – Front of Cable yoke (see Assembly instructions [1])
- Label 3 – Rear of Cable yoke (see Assembly instructions [1])
- Label 4 – Front of power supply (see Assembly instructions [1])
- Label 5 – Rear of AN24 device (above label 1)
- Label 7 – Outer packaging

3.3 Colour and Finish

- Background colour - (b)(4)
- Foreground colour - (b)(4)
- Other colours – Red for the logo (Label 1) and the four coloured circles (Label 2).
- Finish - The labels require a matt finish as per the membrane panel

3.4 Durability

The label must be able to withstand the following tests:

(b)(4)

4 Labelling Artwork

4.1 Four (4) Part Label Kit

The part number format for the four part label kit is AN24_4PARTLAB_V* where * denotes the version number.

Related Drawings - Appendix A 100-SH-006 Four part label kit iss D

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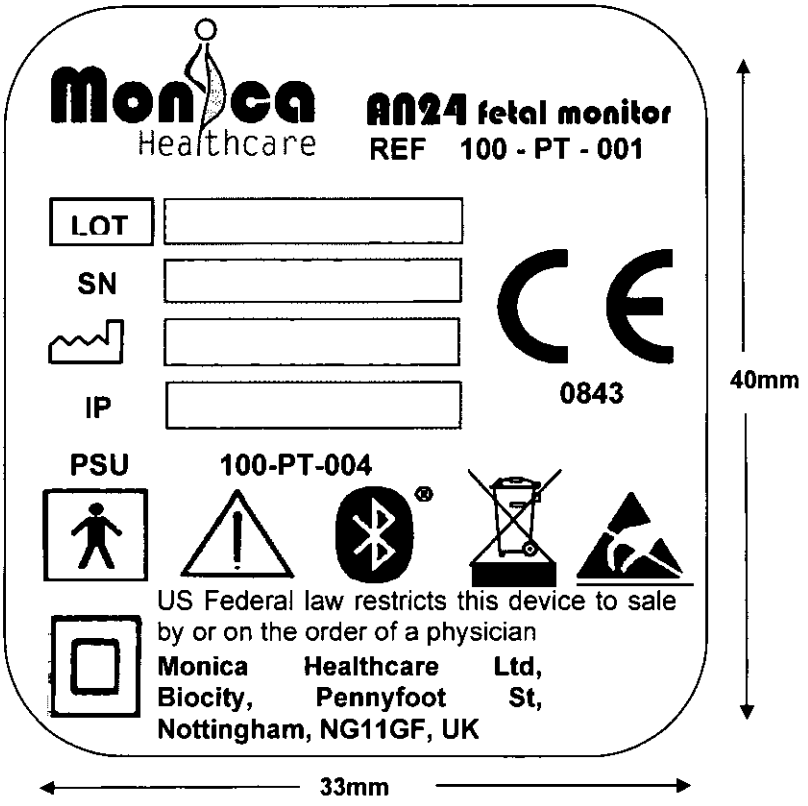
4.1.1 AN24 Label (label 1)

The four part label kit includes this label.

Related Drawings - Appendix A 100-SH-006 Four part label kit iss D
Related Drawings - Appendix B 100-SH-006 Main label outline iss A

Dimensions shown alongside the label shown below are approximate – for details of corner radius and exact dimensions see Appendix B. The relative scale of the symbols\ text should be maintained – but the "CE" mark logo should be at least 7mm high i.e. scale the other symbols to suit.

There are transparent windows to allow numbers to show through from a separate label printed to stick onto the AN24 device behind this label. These windows relate to the; Batch number, Serial Number, date of manufacture and IP rating.



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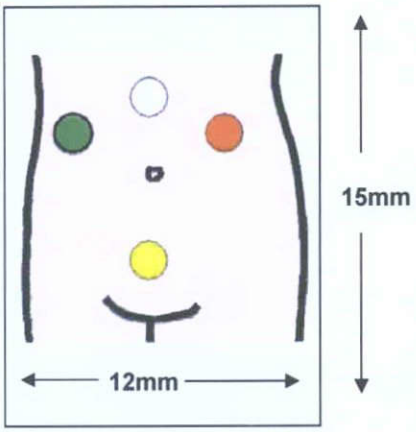
4.1.2 Cable Label part A (label 2)

The four part label kit includes this label.

Related Drawings - Appendix A 100-SH-006 Four part label kit iss D



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[redacted]

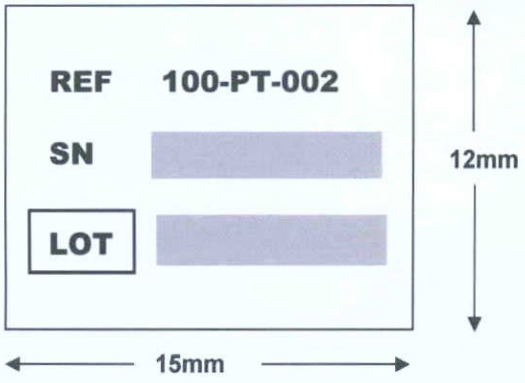
4.1.3 Cable Label part B (label 3)

The four part label kit includes this label.

Related Drawings - Appendix A 100-SH-006 Four part label kit iss D

(b)(4)

[redacted]



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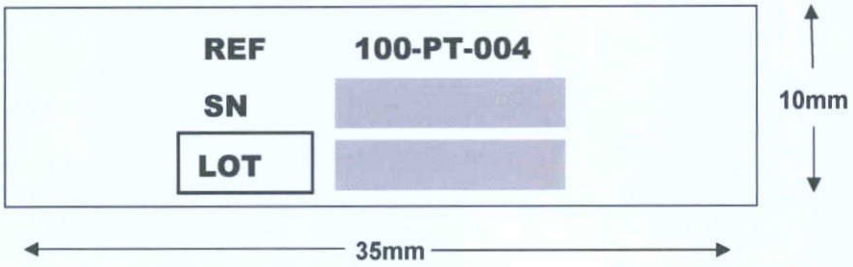
4.1.4 Power Supply Label (label 4)

The four part label kit includes this label.

Related Drawings - Appendix A 100-SH-006 Four part label kit iss D

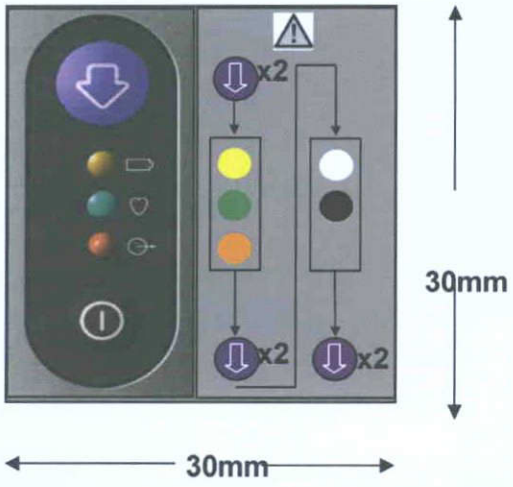
There are transparent windows to allow numbers to show through from a separate label printed to stick onto the cable behind this label. These windows relate to the; Batch number and Serial Number. The background colour should be Pantone grey 426 as per the membrane panel and the foreground colour (for the lettering) should be Pantone cool grey.



4.1.5 Electrode Check Label (label 5)

The four part label kit does not include this label. The part number format for the electrode check label is AN24_ELECTLAB_V* where * denotes the version number.

Related Drawings - Appendix C 100-SH-006 Electrode check label iss A



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*** The background colour should be Pantone grey 426 as per the membrane panel. The colours for the circles should be: Orange, White, Black, Green and Yellow as shown.

4.1.6 Outer packaging label (label 7)

The outer packaging is a hard plastic 'clam shell' case, which will have the following label screen printed onto one side (the top).

Related Drawings - Appendix E 100-SH-006 Outer Case Artwork iss A

5 Applicable Standards

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[redacted]

End of Document

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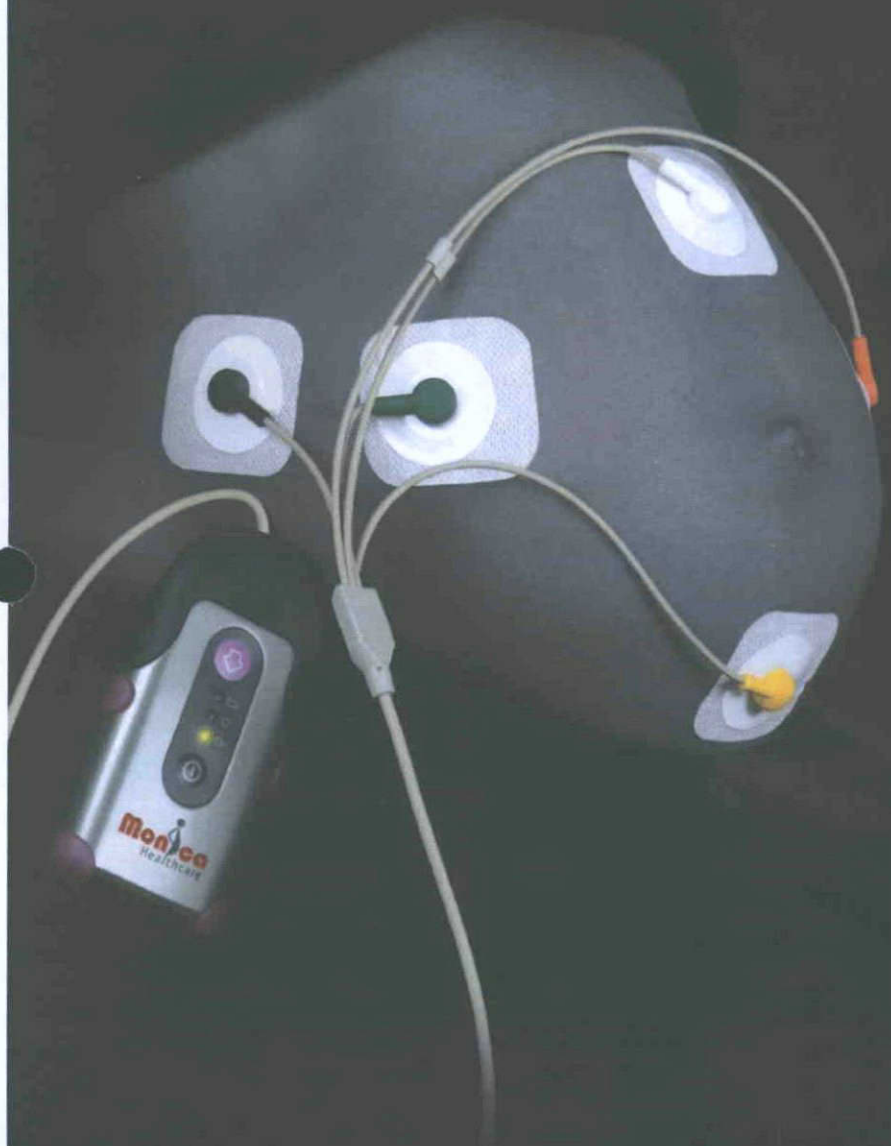

Monica AN24™

Reference Operator Manual

100-TF-006 Revision I

CE 0843

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This Operator's Manual is intended for trained medical personnel (including obstetricians, midwives, nurses, and physicians) who are familiar with obstetric procedures. Keep this operator's manual with the unit for use by the operator.

Conventions Used in This Operator Manual

Warning: A warning alerts you to a potential serious outcome, adverse event, or safety hazard. Failure to observe a warning may result in death or serious injury to the user or patient.

Caution: A caution alerts you to situations where special care is necessary for the safe and effective use of the product. Failure to observe a caution may result in minor or moderate personal injury or damage to the product or other property, and possibly in a remote risk of more serious injury.

On your monitor, this sign indicates that there is detailed information in this book, which you must read before proceeding with your task.

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Numbers in brackets ( ) refer to the key number in Figure 1 or the index of Table 1

Healthcare

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Section 1 - Unpacking the AN24™

Table 1 - The Monica AN24™ case should contain the following items

	Description
10	Monica AN24™ Device [Item1, Figure 1]
11	Electrode lead connector [Item 2, Figure 1]
12	AN24™ neck strap
13	Battery Charger and lead
14	AN24™ monitor connector/computer USB cable
16	10 Electrodes
17	Roll of abrasive skin tape
18	AN24™ protective cover
20	Quick Start Guide
	Skin Preparation Pen

Please confirm that you can identify all the items in the case.

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Figure 1 Monica AN24™ Controls and Indicators

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Section 2 - Product Description

2.1 General description

The Monica AN24™ is a wearable, battery-powered device for antenatal and L&D surveillance of fetal and maternal well-being. The AN24™ is designed to passively monitor Fetal Heart Rate (FHR), Maternal Heart Rate (MHR)[1] and Uterine Activity (UA) from the Electro Hysterogram (EHG) during pregnancy[2] and can be used at any time from ≥ 37 weeks gestation to the end of second stage labour. Excessive vernix formation in the 27+0-33+6 week gestation period may result in a significant reduction in FHR detection in some patients. The AN24™ is currently suitable for singleton pregnancies only[3]. One AN24™ is suitable for extended monitoring sessions of up to 18 hours.

2.2 Patient attachment

The Monica AN24™ is attached via a detachable lead assembly that in turn attaches to 5 disposable ECG electrodes placed on the abdomen of a pregnant woman to generate 3 signal channels. The AN24™ then records the electrical signals present at these electrodes that contains information relating to the maternal heart[1], fetal heart and other sources of electrical energy inside the body.

2.3 Data processing

The acquired signals are then converted by the AN24™ into a digital format and processed in real-time to extract clinically relevant information, such as the Fetal Heart Rate (FHR), Maternal Heart Rate (MHR)[1] and Uterine Activity from the Electro Hysterogram (EHG).

2.4 Data viewing and storage

The processed data can either be stored by the AN24™ and downloaded to a computer or VS monitor at the end of the monitoring session, or wirelessly transmitted in real-time for viewing on a dedicated monitor. Monica VS monitors enable the data to be viewed, stored, and printed.

2.5 Heart rate calculation

The time between the R-wave of consecutive fetal QRS complexes in the ECG signal is used to calculate the FHR. This is called the fetal RR interval. Similarly, the time between

---

[1] Not available in the USA

[2] Other Fetal/Maternal parameters will be available at a later date.

[3] Multiple pregnancy monitoring will be available at a later date.

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the R-wave of consecutive maternal QRS complexes in the maternal ECG signal is used to calculate the MHR[1]. This is called the maternal RR interval. See Figure 2.

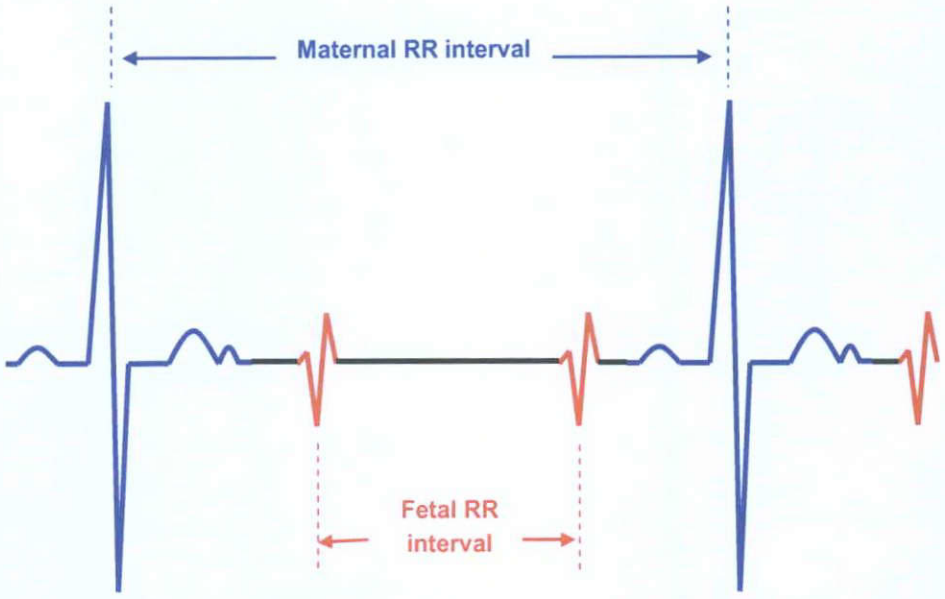

Figure 2 Calculation of FHR and MHR from ECG

The FHR and MHR[1] are also with a ¼ second rolling window update'. The amount of averaging is dependant on the ratio of the fetal height to noise and the number of fECG complexes detected, but it is never more than 2seconds.

2.6 Heart rate data accuracy

The FHR and MHR[1] data is only made available for viewing when the AN24™ is confident that this data is accurate. Confidence is based upon the general noise in the recorded data and characteristic shape of the ECG complex. In the event that the AN24™ is not confident of the accuracy of either the FHR or MHR[1], they will not be made available; the AN24™ will not 'fill in 'or 'coast' when FHR data is not available.

2.7 Uterine Activity from EHG

The Uterine Activity is extracted from the slow-wave of the EHG, i.e. its envelope. The envelope is obtained by low-pass filtering the rectified fast-wave of the EHG. The UA is updated every 2 seconds as a number between 0 and 255, representing an EHG envelope from 0 to 500 microvolts.

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Section 3 - Installation

3.1 Battery Charging

The Monica AN24™ (Figure 1) is dispatched with a non-removable rechargeable battery which, for shipping, is not fully charged.

The battery must be fully charged prior to use as described below.

Please refer to Figure 1

A. Connect the lead on the supplied battery charger into the socket inside the top of the AN24™ body (**1**). Plug the battery charger into a mains outlet and switch on the mains outlet. The amber battery status LED (**6**) will flash if a connection has been made (this should be confirmed) until the device is charged, when it will be constantly lit. This should take no more than 2½ hrs.
B. When the electrode leads connector (**2**) is connected to the Monica AN24™ Recorder (**1**) disconnect the lead connector (**2**) from the AN24™ body (**1**) by pressing the two buttons (**7**) on either side of the recorder, and gently pulling apart the AN24™ body (**1**) from the lead connector (**2**).

3.2 Instructions

Please fully read these instructions before using the AN24™.

Section 4 - Operating the AN24™

4.1 Set-up procedure when not using the VS monitor

4.1.1 Select mode.

The Monica AN24™ can be operated in two modes, namely:

Mode 1 - Retrospective mode
The Monica AN24™ records fetal heart rate (FHR), maternal heart rate (MHR)[1] and Uterine Activity (UA) for retrospective upload and viewing on a Monica VS Monitor.

Mode 2 - Real time mode
The Monica AN24™ transfers FHR, MHR[1] and UA using Bluetooth® wireless transmission in 'real-time' to a Monica VS Monitor for real-time viewing of the data.

The default mode when the Monica AN24™ is turned on for the first time is Mode 1 (Retrospective mode). Connection via USB to a VS Monitor is required to set the time for the first recording.

The AN24™ already running in Mode 1 can be set up to run in Mode 2 by making a wireless Bluetooth® connection using the Monica VS Monitor (see section 4.4).

4.1.2 Electrode attachment

Prior to applying the electrodes, the skin must be prepared correctly using an alcohol wipe and abrasive skin tape (**17**) as described in Supplement 1 – Electrode Placement.

Additionally, the electrodes (**16**) must be positioned correctly on the women's abdomen.

For skin preparation and electrode positions please refer to Supplement 1 – Electrode Placement

4.1.3 Lead connection

Attach the electrode leads connector (**2**) to the electrodes (**16**) following the colour code guide in Supplement 1 – Electrode Placement. Ensure that the electrode leads connector (**2**) is securely attached to the AN24™ (**1**), by pushing the two sections firmly together such that the two buttons (**7**) are engaged.

For monitoring in Labour and Delivery always use the AN24™ Protective cover (supplied). Please refer to Supplement 1 – Electrode Placement for instructions on fitting the protective cover.

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4.1.4 Turn on

Turn the AN24™ on by pressing the on/off button (3). All three LEDs (4, 5 and 6) will flash 3 times to indicate that the AN24™ has been turned on.

4.1.5 Memory status self-check

If the Orange memory status LED (**4**) begins to flash when the AN24™ has been turned on, this indicates there is data from a previous patient stored in the memory of the AN24™.

The stored data can be a) downloaded using Monica VS Monitor via a USB cable or b) deleted remotely via Bluetooth® connection to the Monica VS monitor.

a) To download the data via USB, turn off the recorder (see 'Turn Off' section below), and connect the AN24™ to the VS Monitor with the USB cable provided (please refer to the Monica VS Reference Manual for detailed instructions). Once the data has been downloaded, the recorder can be used for a new recording.

b) To delete the data via Bluetooth®, use a Monica VS monitor to connect to the recorder. The VS monitor will automatically recognise that there is data stored on the AN24™ and offer to delete the data or allow the user to disconnect it from VS to download as per a) above (please refer to the Monica VS Reference Manual for detailed instructions). Once the data is deleted the recorder can be used for Real Time mode recording.

4.1.6 Battery status self-check

If the Yellow battery status LED (6) begins to flash when the AN24™ has been turned on, this means that the battery charge is too low for recording to begin. The LED will flash 10 times and then the AN24™ will be automatically turned off. See 'Recharging the batteries later in this section.

N.B. If there is data on the recorder, the Memory Status led will flash alongside the battery status LED.

4.1.7 Electrode attachment self-check

After turn on, the AN24™ will check the electrodes are attached correctly. The green signal quality LED (**5**) will go into one of three states:

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- GREEN LED FLICKERS

The green LED flickers rapidly when the electrodes are not correctly attached. To solve this problem please refer to Section 10 - Troubleshooting. The AN24™ will continue this self-check until the problem has been resolved and recording will not begin until it has.

- GREEN LED ON

The green LED is constantly on to indicate that all electrodes are correctly attached to the skin. Once the AN24™ is satisfied that the electrodes are correctly attached the recording will begin. The AN24™ will then look for the maternal ECG.

- GREEN LED SLOWLY FLASHES

The green LED will flash (once every 2 seconds) when the AN24™ is satisfied that the electrodes are correctly attached and that the maternal ECG has been located (note – maternal ECG location may take up to 30 seconds once the correct electrode attachment has been confirmed). If the LED remains constantly on, please refer to Section 10 - Troubleshooting. If the problem persists please contact your distributor.

NB: Monica VS monitors provide an on-screen electrode attachment check during the setup of a new patient see the VS Reference Operating Manual for details.

4.1.8 Secure the AN24™

If the patient wishes to carry the AN24™ it can either be held in their clothing (e.g. a pocket) or carried around the neck using the supplied neck strap (12). If the patient wishes to use the neck strap, attach it to the AN24™ main body (1) using the neck strap connection (9) and hang the neck strap around the patient's neck. Adjust the length of the neck strap so that the lowest part of the AN24™ is above the sternum and not touching the electrodes.

4.1.9 Secure Cables

If the ECG cable(s) are loose or hanging, secure them with hypoallergenic tape (not supplied) to the patient's abdomen to prevent the cables from pulling on or detaching from the ECG electrodes.

4.2 During monitoring

Self checks during a recording

During recording the AN24™ will regularly perform self-checks. The AN24™ can only be in one of the following four states:

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MONITORING OK – GREEN LED FLASHES

The green signal quality LED (**5**) will continue to flash once every 2 seconds to indicate that the electrodes remain attached correctly and that the maternal ECG beat has been detected.

MATERNAL SIGNAL LOST – GREEN LED ON

The green signal quality LED (**13**) will remain constantly illuminated to indicate that the electrodes remain attached correctly but that the maternal heart beat cannot be located. This is not a cause for alarm and may be temporary and due to interference from other sources, for example the noise generated by maternal muscle/movement. Section 10 - Troubleshooting

ELECTRODE DETACHED – GREEN LED FLICKERS

The green signal quality LED (**5**) will flicker rapidly to indicate that one of the electrodes has become detached. The recording will not be stopped at this point, if suitably trained staff are available the electrodes should be re attached to resolve the problem, see Section 10 - Troubleshooting.

BATTERY LOW – YELLOW LED FLASHES

If the Yellow battery status LED (**6**) begins to flash, this indicates that the battery is running low. A short while after this occurs; the AN24™ will automatically turn off. If the device is in Mode 1 (recording mode) the recorded data will be retained until it is uploaded, see Mode 1 - USB upload later in this section.

NB: Monica VS monitors also provide on-screen device status feedback see the VS Reference Operating Manual for details.

4.3 Turn off

When the recording session is completed, turn the AN24™ off by pressing the on/off button (**3**) followed by the event button (**8**) followed by the event button (**8**) again.

This sequence of button presses must be completed within 4 seconds to turn the device off. When the AN24™ is switched off all three LED's (**4, 5** and **6**) will flash three times.

If using a Monica VS Monitor to end a real time recording (mode 2) the Monica AN24 can be switched off remotely by the VS Monitor.

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

Data Upload - If the AN24™ was used in Mode 1 (recording mode), the recorded data must be uploaded to a computer running the Monica VS Monitor, see 'USB Upload' later in this section.

Clean the AN24™ (**1**) and electrode lead connector (**2**) as described in Section 6 - Cleaning and Maintenance

Battery Charging - recharge the AN24™ (**1**) as described in 3.1 Battery Charging.

4.4 Connecting to a VS Monitor

Monica devices are an integral part of a diagnostic system. The user must adhere to warnings in order to ensure safe and reliable performance of the system.

- Monica VS Monitors complies with IEC 60601-1 the international product safety standard for electrical medical equipment
- Non-medical electrical equipment (e.g. Wireless remote printer) must be situated outside the patient environment (patient environment according to IEC 60601-1-1: = radius 1.5m around the patient).
- The Monica VS Monitors (PT-101-010, PT-101-015) fully comply with the above and are required when using the Monica AN24™ to monitor in real-time within the patient environment (as defined by IEC 60601-1-1).

When connecting to a VS Monitor in either Retrospective or Real-Time mode it is firstly necessary to ensure that the Monica VS Monitor is on and running.

To connect to a VS Monitor in **Retrospective mode**:

A. Disconnect the electrodes from the leads - Disconnect the electrode lead connector (**2**) from the AN24™ (**1**) as described in 3.1 Battery Charging.
B. Power up the VS Monitor, log in and wait until the system is fully loaded
C. Connect USB lead - Connect the AN24™-to-USB lead (**14**) into the socket inside the top of the AN24™ (**1**). Plug the USB end of the lead into a free USB port on the Monitor. The Monica AN24™ device will be automatically recognised by the monitor and will provide status information.

From this point the Monica VS software will know if there is data stored on the device ready for upload (Mode 1 operation). If there is data stored on the device the VS Monitor will guide you through the correct process to upload or delete the stored data.

To connect to a VS Monitor in **Real-Time mode**:

Place the electrodes on the patient as described in in the Getting Started Wizard (press the help icon on the VS screen) or Supplement 1; connect the Monica AN24 to the patient and turn it on.

Select the New Recording button from the Monica VS menu which will then take you through the set-up process.

Section 5 - Safety and Standards

5.1 General

This section describes safety precautions that may appear within the manual and those that appear as symbols labels on the AN24™ itself. Furthermore, this section describes a group of precautions that are applicable, in general, when using the AN24™.

The Monica AN24™ is intended for trained medical personnel (including midwives, nurses, and physicians) who are familiar with obstetric procedures. Keep this operator's manual with the unit for use by the operator.

5.2 Symbols

Attention - Refer to manual

Class II Medical Device

Type BF

Batch number

Manufacture date

Bluetooth® approved device

ESD - Static sensitive device

CE approved

WEEE logo

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5.3 Indications For Use

The Monica AN24 is a monitoring device for non-invasively measuring the Fetal Heart Rate (FHR) and Uterine Activity (UA). The Monica VS software, which accompanies the AN24, enables the measured parameters to be reviewed graphically using a PC, notebook computer or any compatible Series 50 format device, and to generate hard copy traces in a "standard" user defined format. This data is intended to aid in assessment of the wellbeing of the fetus and mother for laboring singleton pregnancies who are of gestation age ≥37 weeks. The AN24 device typically generates standard length FHR and UA traces from a single setup. Application of the device must be by trained personnel.

5.4 Standards

The Monica AN24™ complies with the following safety standards

Standard	Description
IEC EN 60601-1: 1990 UL60601-1:2003 CSA C22.2 No 60601.1	Medical Electrical Equipment Part 1: General requirements for safety
EN 60601-1-2: 2002 IEC 60601-1-2: 2001	Medical Electrical Equipment Part 1-2: General requirements for safety – Collateral Standard: Electromagnetic Compatibility – requirements and tests
Partial compliance of: EN 60601-2-47: 2001 IEC 60601-2-47: 2001	Medical Electrical Equipment Part 2-47: Particular requirements for the safety, including essential performance, of ambulatory electrocardiographic systems
IEC EN 60601-1-4: 1996	Medical electrical equipment Collateral standard: Programmable Electrical Medical Systems
EN 980: 1996	Graphical symbols for use in the labelling of medical devices
EN 1041: 1998	Information supplied by the manufacturer with medical devices

5.5 Interpreting Results

Monica Healthcare recommend that a repeat test is undertaken, using either the AN24™ or an alternative device to confirm the results from the initial test. The repeat test should be carried out in the case of either normal or abnormal results generated by the AN24™.

Good Practise:

When the MHR is high, or the signal quality is poor (section4.7 VS Operator manual), check the FHR using auscultation (Pinard) or hand held Doppler every 15min to confirm the FHR, and if in any doubt, ask the women to stop pushing during the second stage, until the FHR is confirmed.

5.6 Safety

WARNING: The Monica AN24™ is splash proof but is not designed for submersion in water. Patients must be warned not to immerse the AN24™ or any of its accessories in water, or to take a shower or bath whilst being monitored.

WARNING: The Monica AN24™ is not explosion-proof and must not be used in the presence of flammable anaesthetics.

WARNING: SHOCK HAZARD — Do not attempt to connect the battery charger with wet hands. Make certain that your hands are clean and dry before touching a power lead or plug.

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WARNING: Use only the electrode lead cables supplied with the device. Use of any other cables may result in out-of-specification performance and possible safety hazards.

WARNING: Unplug the AN24™ from the AC power source (battery charger and detach all accessories before cleaning. Do not immerse the unit in water or allow liquids to enter the case.

WARNING: Examine the AN24™ and any accessories periodically to ensure that the leads, connectors and the device itself do not have visible evidence of damage that may affect patient safety or monitoring performance. The recommended inspection interval is once per week or less. Do not use the device if there is any visible sign of damage.

WARNING: The protective silicone rubber cover must be used during Labor and Delivery. Not using the protective silicone rubber cover could result in the ingress of contaminated blood and other fluids into the Monica AN24 case.

WARNING: Only the Battery Charger and mains plug supplied with the Monica AN24™, or its equivalent, is approved for use with the AN24™.

WARNING: Do not attempt to service the Monica AN24™. Only Monica approved and qualified service personnel should attempt any necessary internal servicing.

WARNING: The Monica AN24™ is not specified or intended for operation in conjunction with any other type of monitoring equipment except the specific devices that have been identified for use in this Operator's Manual.

WARNING: Since the Monica AN24™ detects the electrical signals generated from the fetal heart, if other equipment which introduces electrical energy in to the mother is used (e.g. TENS machine, diathermy, impedance meter), then the AN24™ will not be able to detect the fetal heart rate.

WARNING: Do not operate the Monica AN24™ if it fails to pass the power on self-test procedure, see Section 4.

WARNING: Any unexpected data generated by the Monica AN24™ must result in further examination of the mother and fetus in a hospital environment. The data generated by the AN24™ must be backed up by alternative monitoring technologies.

WARNING: For Electromagnetic Compatibility (EMC). Use of accessories, electrodes and leads other than those specified in this manual may result in increased EMC emissions and/or decreased immunity of the Monica AN24™ to other electrical equipment.

WARNING: For Electromagnetic Compatibility (EMC). The Monica AN24™ has been tested for to IEC EN 60601-1-2 for EMC. However, the Monica AN24™ picks up very small electrophysiological signals and so occasionally if other electrical equipment is in the immediate vicinity of monitoring the AN24™ may produce spurious results. The operator should ensure that any such

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interfering electrical equipment is not in close proximity to the AN24™ during monitoring.

WARNING: The lithium polymer battery pack used within this device has the potential for fire or burning. Do not disassemble, crush, heat or burn.

WARNING: The lithium polymer battery pack cannot be replaced by the user. Replacement may only be made with the battery pack specified by Monica Healthcare, and replacement can only be carried out by Monica Healthcare. Fire or burning may occur if the customer uses a battery pack other than specified by Monica Healthcare.

CAUTION: Keep the operating environment free of dust, vibrations, corrosive, or flammable materials, and extremes of temperature and humidity. The AN24™ and all lead connectors should be kept clean and free of electrode gel and other substances.

CAUTION: Do not operate the unit if it is damp or wet because of condensation or spills. Avoid using the equipment immediately after moving it from a cold environment to a warm, humid location.

CAUTION: Never use sharp or pointed objects to operate the two front-panel membrane switches.

CAUTION: General-purpose personal computers and modems are not designed to meet the electrical safety requirements of medical devices.

CAUTION: Do not autoclave the AN24™ or any accessories. Follow cleaning and disinfection instructions in Section 6 - Cleaning and Maintenance

CAUTION: Do not immerse AN24™, connector or leads in liquid. When using solutions, use sterile/clean wipes to avoid pouring fluids directly on to the AN24™ and connector. Follow cleaning and disinfection instructions in Section 6 - Cleaning and Maintenance

CAUTION: The water temperature must not exceed 40℃ (104℉). Do not use chlorine bleach.

CAUTION: Take extra care when cleaning the membrane switches and LED surfaces, which are sensitive to rough handling.

CAUTION: Do not autoclave. Do not gas sterilize.

CAUTION: Only the Battery Charger supplied with the device is approved for use in recharging the internal batteries.

CAUTION: The Monica AN24™ is not specified or intended for operation during the use of defibrillators or during defibrillator discharge.

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CAUTION: The Monica AN24™ is not specified or intended for operation in the presence of electrosurgical equipment.

CAUTION: There are minimum signal amplitudes under which the Monica AN24™ will not be able to measure physiological signals.

5.7 CE

CE The CE Mark on this product denotes conformity with the European Council Medical Device Directive 93/42/EEC.

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Section 6 - Cleaning and Maintenance

6.1 AN24™ Device

To avoid damage to the AN24™, connector and leads, clean and disinfect only according to the following instructions. Care MUST be taken to preserve both the AN24™ label and the connector label.

CAUTION: Do not remove, conceal or deface the labels.

CAUTION: Do not autoclave. Do not gas sterilize.

CAUTION: Do not immerse the device or any accessories in liquid and do not expose the connector pins to the cleaning solution. Do not apply oil at any point.

CAUTION: Do not use undiluted bleach or any other cleaning solution other than those recommended here because permanent damage to the AN24™ and leads could occur.

Clean - Wipe the AN24™ and leads with a soft non-abrasive cloth or disposable wipe soaked in aqueous detergent/ disinfectant or other solution such as 70% isopropyl alcohol. Do not use aerosol preparations since they might contain organic solvents. Do not pour fluids directly on the unit and its accessories. Wipe the exterior of the AN24™ and leads three times. Prepare the detergent according to the manufacturer's recommendations. If necessary scrub the AN24™, and leads with the solution using a soft bristled brush for five minutes.

Wash off & Dry - When using solutions, use sterile wipes or gauze to avoid pouring fluids directly on the unit and its accessories. Wipe the AN24™, and leads three times with sterile or distilled water to remove cleaning solution residue. Dry the AN24™, connector and leads thoroughly with a sterile soft towel or gauze surgical sponge.

Disinfect - If a low-level disinfection is required, use a 1:10 bleach solution after the AN24™ and leads have been cleaned following the same procedure described above. After the low level disinfections, wipe the AN24™ and leads three (3) times with sterile or distilled water to remove diluted bleach residue. Dry the AN24™, connector and leads thoroughly with a sterile soft towel or gauze surgical sponge.

Store the clean AN24™, connector, and leads in a clean bag, covered tray, or other suitable system when not in use.

Monica recommends the patient neck cord included with the Monica AN24 is washed thoroughly or replaced between patients.

6.2 Batteries

The 3.6V rechargeable lithium polymer battery pack should be stored at 0-35°C. Typically the batteries will last for two years or more with regular use. If you need to replace the battery, contact Monica Healthcare directly or your Monica healthcare representative.

6.3 Firmware version

AN24™ Firmware
VS Monitor update

Periodically there will be a need to release new versions of the Firmware and VS Monitor updates, please check with your local distributor to see if you have the latest version.

6.4 Calibration

Calibration of the Monica AN24™ is not required

6.5 Servicing

Maintenance of the AN24™ is carried out by Monica Healthcare. The only routine maintenance which is necessary is battery replacement when failing to hold charge and cleaning as outlined earlier in this Section. Further information is available from:

Monica Healthcare Ltd
BioCity
Pennyfoot Street
Nottingham NG1 1GF
UK
Tel: +44 1159124540
Email: info@monicahealthcare.com
Web: www.monicahealthcare.com

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Section 7 - Monica Accessories

Part No.	Description
100-PT-100	Monica VS10 Monitor (Panasonic Toughbook CF-H1)
100-PT-101	Monica VS10 Monitor (Panasonic Toughbook CF-H1, upgrade for existing AN24 customers only)
100-PT-110	Monica VS15 Monitor (Arbor M1525)
100-PT-111	Monica VS15 Monitor (Arbor M1525 upgrade for existing AN24 customers only)
100-PT-001	Monica AN24

100-PT-130	Monica Cart (ITD PRO3OU)
100-PT-131	Monica Cart - printer shelf (ITD PRO3OU
100-PT-132	Monica Desktop Stand (Vesa desktop stand ARM 150 or equivalent)
100-PT-140	Monica Printer (Real-time) - Thermal Z-fold (Fetalgard Lite)
100-PT-160	Monica VS Network Viewer

100-PT-002	ECG Lead Assembly - Standard; ~28 weeks to term
100-PT-004	Battery Charger (UK\ EU\ USA please specify)
100-PT-005	AN24 – USB computer connection cable
100-PT-015	Soft silicon rubber protective boot (x5)
100-PT-016	3M red Dot 2236 skin prep tape (x5)
100-PT-017	Monica approved electrodes – 25 pouches x 10 electrodes (250 electrodes)
100-PT-018	Monica approved electrodes – 150 pouches x 10 electrodes (1500 electrodes)
100-PT-019	Monica AN24 Neck Cord (x5)
100-PT-020	Monica Healthcare glossy sales literature folder (x50)
100-PT-021	Sales Literature sheets
100-PT-022	Skin preparation pen
100-PT-141	Z-Fold paper printer (3 cm/min, 30 - 240 bpm) Analogic US
100-PT-142	Z-Fold paper printer (1 cm/min, 50 - 210 bpm) Analogic International
100-PT-143	Z-Fold paper printer (3 cm/min, 30 - 240 bpm) Philips US
100-PT-144	Z-Fold paper printer (1 cm/min, 50 - 210 bpm) Philips International

Section 8 - Monica VS Monitors

8.1 Overview

Monica VS series of monitors (VS15/VS10) allow the FHR, MHR[1], UA, maternal movement[1] and event annotation data to be viewed, stored and printed as a conventional CTG trace. It is also provides the Monica AN24™ set-up tools to configure the unit and label and store the monitoring sessions for easy identification and retrieval. The functionality of the Monica VS Monitors is explained in detail in the Monica VS Reference Operating Manual.

8.2 System Requirements

Monica devices are an integral part of a diagnostic system. The user must adhere to warnings in order to ensure safe and reliable performance of the system.

- Monica VS Monitors complies with IEC 60601-1 the international product safety standard for electrical medical equipment
- Non-medical electrical equipment (e.g. Wireless remote printer) **must be** situated outside the patient environment (patient environment according to IEC 60601-1-1: = radius 1.5m around the patient).
- The Monica VS Monitors (PT-101-010, PT-101-015) fully comply with the above and are required when using the Monica AN24™ to monitor in real-time within the patient environment (as defined by IEC 60601-1-1).

Section 9 - AN24 Specifications

9.1	**Measured**	Time	Real-Time clock
		Maternal Movement[1]	3 axis accelerometer
		Clinical Event Marker	Button
		Abdominal Electrophysiological Signal	3 different channels
9.2	**Calculated**	FHR	Range 60-240 beats per minute 2 second average or better
		MHR[1]	Range 40-240 beats per minute 2 second average
		Maternal Movement[1]	4 levels – (Inactive to very active)
		Uterine Activity	Range 0-500 microvolts (0-255 levels)
9.3	**Storage**	Internal Micro SD Card	
9.4	**Interfaces**	Download	USB – download stored data to computer Wireless – Real-Time data transfer using Bluetooth®
		User	LED indicator 1: Yellow – Battery status LED indicator 2: Green – Signal quality LED indicator 3: Orange – Memory status Button 1: On/Off Button Button 2: Event marker
9.5	**Data Format**	Series 50 Protocol via Bluetooth®	
9.6	**Battery**	Rechargeable lithium polymer 3.6V 2400mA-hours	
9.7	**Battery Charger**	Input	100-240V, 50-60Hz UK\EU\US adapter
		Output	DC 5V 1A USB PC connection
9.8	**Dimensions**	11.5 x 5.5 x 2.0 cm Including lead assembly	
9.9	**Weight**	105g excluding lead assembly	
9.10	**Operating Temperature**	0 to + 40℃	
9.11	**Storage Temperature**	0 to + 40℃	
9.12	**Approval**	CE approved (Directive 93/42/EEC) as amended by 2007/47/EEC	

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Section 10 - Troubleshooting

10.1 Signal Quality (Green LED flickers)

Electrodes are not attached correctly.

If the green LED flickers, first check that the electrode lead connector cap is connected securely on both sides of the AN24™ (both buttons engaged). If this does not resolve the problem, put AN24™ into electrode check **'Phase 1'** by pressing event button twice within a 2-second period. (NB: this is not required if connected to a VS Monitor which will display the problem electrode(s) on screen without the need to touch the AN24).

x2

The system will then 'display' the electrode/skin impedance for the electrodes connected to the yellow, green and orange leads.

The electrode/skin impedance will be communicated to the user as follows:

- LED on continuously – the electrode connected to the lead defined by the LED colour has a good connection / low skin impedance
- LED flickers - the electrode connected to the lead defined by the LED colour has a bad connection / high skin impedance

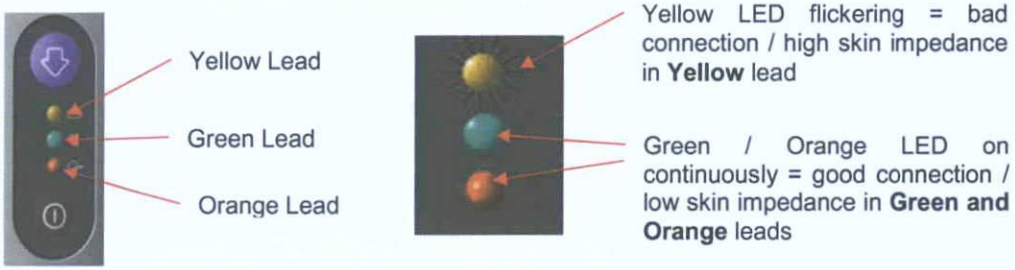

Figure 3 Phase 1 Lead check

If a bad connection is identified in the Yellow, Orange or Green leads, disconnect the lead from the electrode(s) that has a bad connection (leave AN24™ on), remove the electrode(s) and again prepare the skin as described in Supplement 1 – Electrode Placement. When all the electrode(s) have been replaced the leads should be reconnected.

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

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If all the LED are on continuously (good connection), put the AN24™ into electrode check **'Phase 2'** by pressing event button twice within a 2 second period.

x2

In 'mode 2' the electrode/skin impedance will be communicated to the user for the remaining two electrodes as follows:

- Yellow LED on continuously – the electrode connected to the **White** lead has a good connection / low skin impedance
- Yellow LED flickers - the electrode connected to the **White** lead has a bad connection / high skin impedance
- Green LED on continuously – the electrode connected to the **Black** lead has a good connection / low skin impedance
- Green LED flickers - the electrode connected to the **Black** lead has a bad connection / high skin impedance

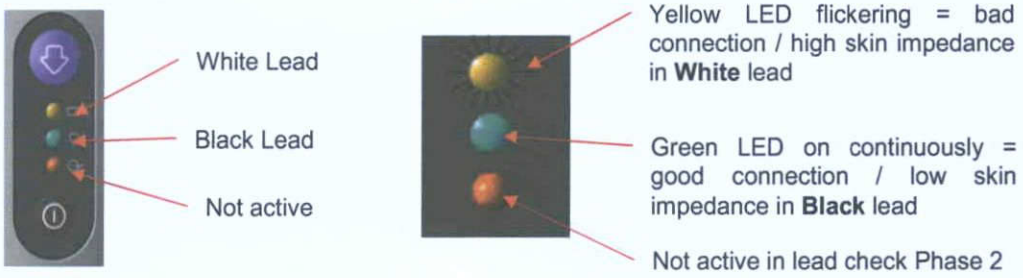

Figure 4 Phase 2 Lead check

If a bad connection is identified in the black or white leads, disconnect the lead from the electrode(s) that has a bad connection (leave AN24™ on), remove the electrode(s) and again prepare the skin as described in Supplement 1 – Electrode Placement. When all the electrode(s) have been replaced the leads should be reconnected.

If the Green and Yellow LED's are on the user should start their monitoring session by pressing the event button twice within a 2-second period

x2

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

In the unusual event that it is not possible with repeated skin preparation and correct electrode placement to bring the impedance down and gain a good connection; impedance check may be by-passed or can be halted and repeated at a later date.

To by-pass the impedance checks:

Press the following key sequence in succession:
Power On Button > Pink Event Button > Power Button

If after by passing the impedance check the green LED remains continuously on – Maternal ECG cannot be found – the monitoring session can be halted and repeated at a later date. This failure should be reported to Monica Healthcare Ltd. Please make a note of which electrode or electrodes failed to pass the impedance check. Monitoring the patient at a future time/date may still be possible.

To abort the electrode check phases (Phase1 or Phase2): switch off the AN24™ as usual (press ON button, then press pink Event button, then press pink Event button)

Alternatively, the lead may be broken. Turn the AN24™ off. Disconnect the lead from both the AN24™ and the electrodes. Attach a spare lead and retry.

If problem is not resolved, contact Monica Healthcare for advice.

Excessive vernix formation in the 26-34 week gestation period may result in a significant reduction in FHR detection in some patients.

10.2 Signal Quality (Green) LED constantly on

The maternal heartbeat cannot be picked up by the AN24™, though the electrodes are correctly connected. This is a common occurrence, which may be due to interference from other sources, for example the noise generated by maternal muscle/ movement. The mother should relax and remain in a supine position for as long as practicable during the recording for optimal results. If problem is not resolved, contact Monica Healthcare for advice.

10.3 Battery Status (Yellow) LED flashing when unit is not being charged

Battery is low. The AN24™ will shortly automatically turn off. Upload the data and recharge the batteries (see 3.1 Battery Charging). If problem is not resolved, contact Monica Healthcare for advice.

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10.4 Memory Status (Orange) LED flashing

This indicator will only light just after the AN24™ has been turned on and indicates that there is > 1 minute of data on the device. Upload / delete the data currently stored on the device (see Section 4 -). Turn on the device and resume the monitoring session. If problem is not resolved, contact Monica Healthcare for advice.

10.5 AN24™ will not turn on

Recharge the AN24™ for at least an hour even if the AN24 battery does not flash. If after recharge the AN24™ still does not turn on, return to Monica Healthcare for service.

10.6 AN24™ will not turn off

Return to Monica Healthcare for service

10.7 AN24™ will not recharge

Disconnect AN24™, reconnect battery charger and check charger is connected at both the wall socket and the device. Leave the recorder connected to the charger for half an hour. Then disconnect the AN24™ from the charger and reconnect it again. If problem is not resolved, contact Monica Healthcare for advice.

10.8 AN24™ will not connect via USB

Disconnect USB lead from both the AN24™ and VS Monitor. Reconnect USB lead and retry. If problem is not resolved, connect the AN24™ to the charger for half an hour and try connecting the recorder to the VS Monitor again. If the problem is not solved, contact Monica Healthcare for advice.

10.9 AN24™ will not connect via USB and will not recharge

If the AN24™ does not charge and is not recognised by the VS Monitor, disconnect the AN24™, reconnect battery charger and check charger is connected at both the wall socket and the device. Leave the recorder connected to the charger for half an hour. Then disconnect the AN24™ from the charger and reconnect it again. If problem persists there may be an issue with the Bluetooth® module in the AN24™ - please contact Monica Healthcare for advice.

If the AN24™charges but is not recognised by the VS Monitor disconnect USB lead from both the AN24™ and computer. Reconnect USB lead and retry. If the problem persists there may be an issue with the USB cable – please contact Monica healthcare for advice

10.10 AN24™ will not connect via Bluetooth®

Bring the AN24™ physically close (i.e. within 2 metres) of the VS Monitor and retry. If problem is not resolved, contact Monica Healthcare for advice.

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Section 11 - Returns Procedure

11.1 Maintenance

There are no user serviceable parts in the Monica AN24™ or accessories. In the event of device failure or the battery needs to be changed, please contact Monica Healthcare or your local representative.

11.2 Returns

To return a defective product to Monica, you will need to obtain a Return Goods Authorization (RGA) number from the Monica Healthcare Support Group. Please contact a Service Coordinator at:

Telephone: +44 1159124540
Email: support@monicahealthcare.com

You will need to supply the Service Coordinator with the following information:

- The Model number(s) and Serial number(s) of the product, this information can be found on the label on the rear of the AN24™.
- The quantity of items you wish to return.
- Your "Bill to" address for invoice purposes.
- Your "Ship to" address.
- Your Purchase Order number.
- Details of the reported failure.

The Service Coordinator at Monica Healthcare will then inform you of:

- The Return Goods Authorization (RGA) number.
- The warranty or non-warranty status of the units being returned.
- Any repair charge.

All returned material must be shipped "PREPAID" to the address below for both warranty and non-warranty repairs. Please reference your RGA number on both your purchase order and the shipping label:

RGA reference number:
Tioga
St Thomas House
St Mary's Wharf
Mansfield Road
Derby
DE1 3TN
UK

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Monica Healthcare

Supplement 1 – Electrode Placement

I. Patient Posture

It is very important that the woman's stomach muscles are relaxed and she should be encouraged to 'relax' on a bed either on her back (recumbent or semi-recumbent) or on her side (left/right) for as long as practicable during the monitoring session. The patient should **avoid** whenever possible:

1. Any position or activity where the abdominal muscles are contracted e.g. sitting upright or lying down with her back raised from the hips at an angle of 45°. If this is unavoidable then using a cushion to support the back can help.
2. A tense stressful situation which will cause abdominal muscle tone to increase even though the patient is in a comfortable position e.g. When the room where the patient is being monitored is filled with Drs, Midwives, Family, Children and other onlookers. In this situation it is advisable to leave the Monica AN24 in place and return when the patient situation has changed.

The VS series of monitors provide a real-time indication of signal to noise in the signal quality indicator where the muscle noise (red-bar height) and the fetal ECG height (green bar) are displayed.

If the fetal ECG height is small and the muscle noise is high then FHR extraction may be compromised; ask the mother to get into a position that is comfortable for her and relax. In addition, changes in maternal posture like lying on the left or right can change the fetal position in relation to the abdomen and uterus and improve the ECG conducting pathway.

II. Electrode Location

It is important to correctly prepare the skin before the application of the electrodes. You are advised to read all of this section before starting the procedure.

The instrument has three separate detection channel leads. The connectors on these leads are colour coded as **orange**, **white** and **green**. All three channels share a common connection point and this lead connector is coloured **yellow**. Finally, a ground lead with a **black** colour coded connector is also used. These leads are connected to 5 electrodes positioned on the maternal abdomen. Please refer to the table and figures below for guidance in positioning the electrodes.

Electrode / Connector	Position
Yellow	Place the yellow electrode on the mid-line 6cm above the symphysis pubis or as close to 6cm above the symphysis pubis as you can achieve without requiring removal of the pubic hair.
White	**For gestations < 27+6 weeks & > 33+0 weeks through to L&D** Place the white electrode on the mid-line so that the bottom edge of the electrode is just below the top edge of the umbilicus.
	For gestations 28+0 to 32+6 weeks Place the white electrode on the mid-line so that the centre is 7cm above the top edge of the umbilicus
	For ANY gestation *If the centre of the white electrode is **above** the fundus, reposition the white electrode so that the centre is **below** the fundus and the electrode is clear of the umbilicus*
Green and Orange	Place the centre of the green and orange electrodes either side of the umbilicus and on the same horizontal line as the umbilicus. The centre of the green electrode should be **10cm** from the **left hand edge** of the umbilicus and the centre of the orange electrode **5cm** from the **right hand edge** of the umbilicus.
Black	The black electrode is the reference electrode and is positioned towards the back behind the green electrode. Its exact position is not critical.

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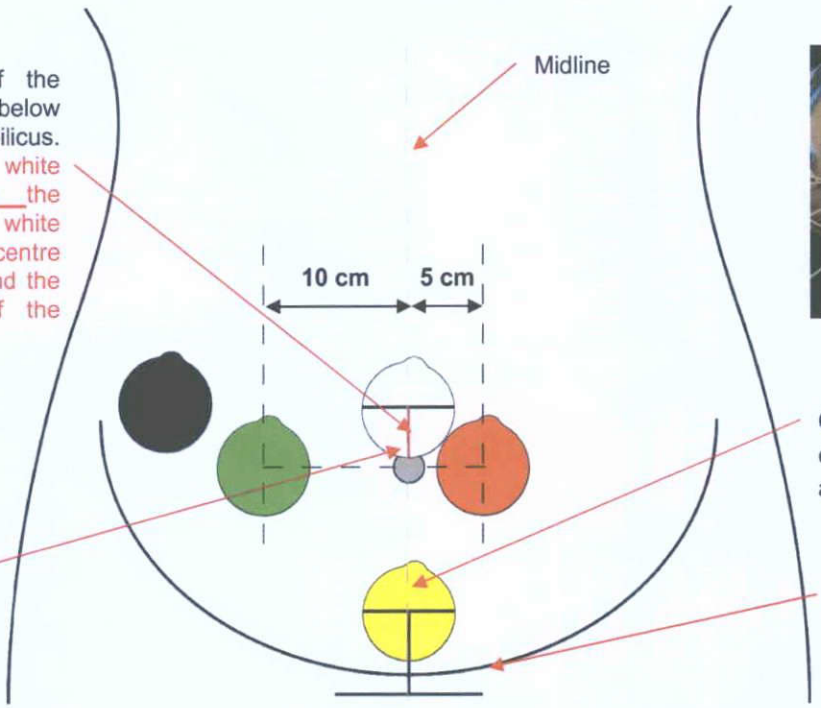
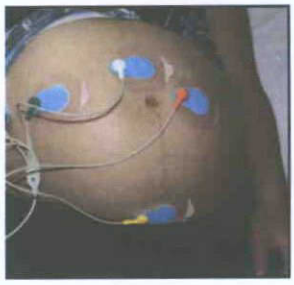
Gestation <28 weeks, >33 Weeks & through L&D

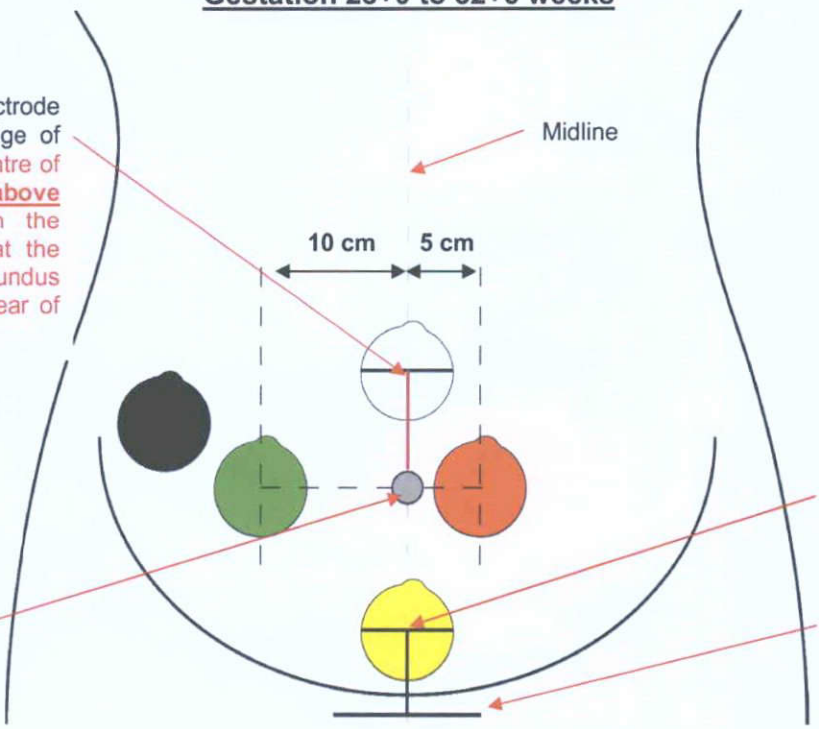
The bottom edge of the White electrode is just below the top edge of the umbilicus. (If the centre of the white electrode is **above** the fundus, reposition the white electrode so that the centre is **below** the fundus and the electrode is clear of the umbilicus)





Gestation 28+0 to 32+6 weeks

Centre of the white electrode 7cm above the top edge of the umbilicus (If the centre of the white electrode is **above** the fundus, reposition the white electrode so that the centre is **below** the fundus and the electrode is clear of the umbilicus)



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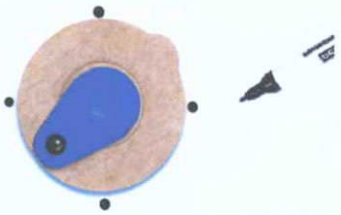
For patients with a large pannis (apron of fat) overhanging the symphysis pubis it is recommended that the yellow electrode be placed **on top** of the pannis on the mid-line such that the centre of the electrode is 6cm above the upper margin of the symphysis pubis or as close to 6cm above the upper margin of symphysis pubis without covering the yellow electrode with the pannis.

These instructions only apply to **Ambu VLC-00-S** electrodes.
Results may be impaired if any electrode is used other than those recommended by

III. Preparation of the skin and electrode application

1. Mark the electrode positions – using the electrode as a template and an alcohol based permanent marker pen.



Note: *If unable to use a pen to mark the site an alternative* ***MUST*** *be used to mark the site. Example: patient's fingers or a small piece of skin prep-tape*

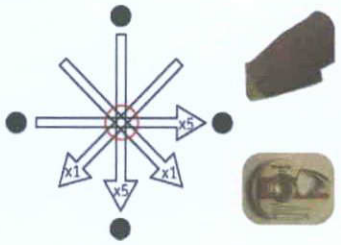
Caution: When using a marker pen ALWAYS follow local cross-contamination protocols.

Warning: DO NOT use a marker pen if the woman has any cuts or open sores on her abdomen

2. If the patient has been using skin care products wash the abdomen with a mild soap and water solution and **dry** first. On **all women** clean the electrode area vigorously with an alcohol swab and allow to dry.

Caution: Using an alcohol wipe on abraded skin may cause patient discomfort and skin irritation.

3. Once the alcohol has dried off, abrade the area, using the supplied prep-tape, stroking the skin in one direction only (5 North to South, 5 East to West, 1 NW-SE, 1 SW- NE) as shown below



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Caution: Use only moderate force since excessive use of prep tape may cause patient discomfort and skin irritation. In some patients local skin reactions to the electrode adhesive\gel may occur causing slight reddening of the skin.

4. Apply the electrodes (check the use by date and the gel on the electrode is still wet)

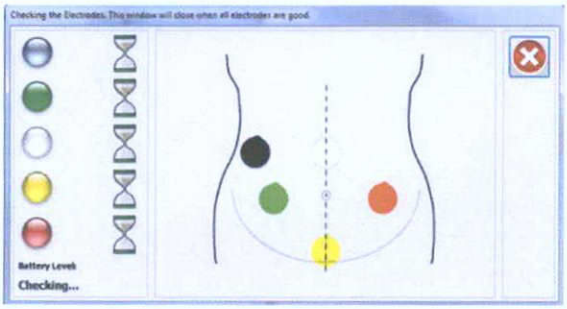
   a. Select one electrode and remove the plastic backing holding the electrode by the single strip of paper remaining so as not to touch the sticky part of the electrode.
   b. Place the electrode on the patient in the exact location that has been prepared. Do not press down in the middle of the electrode since the gel will be forced out. Only press the electrode around the outside and ensure that the material of the electrode does not crease.
   c. Remove the remaining strip of paper and stick down. When positioning the electrode ensure that the connection stud /tab is pointing to the right side of the patient, so that the cable be in the same direction in which the cables are being pulled

Repeat steps 1 – 4 (above) until all five electrodes have been placed.

Caution: Do not use any electrodes which are dry or from a pack that has been opened by more than one week. When opening a fresh packet of electrodes, if all the electrodes are not used, write on the pack the date opened and make sure the pack is sealed to prevent the remaining electrodes from drying out.

Warning: Only use any electrodes specified by Monica healthcare. Failure to use the specified electrode could result in unacceptable noise levels resulting in poor FHR detection.

5. Check the electrode impedance (AN24 or VS Monitor – please refer to the Reference VS Operating Manual)
   a. Impedance Check using Monica VS Monitor



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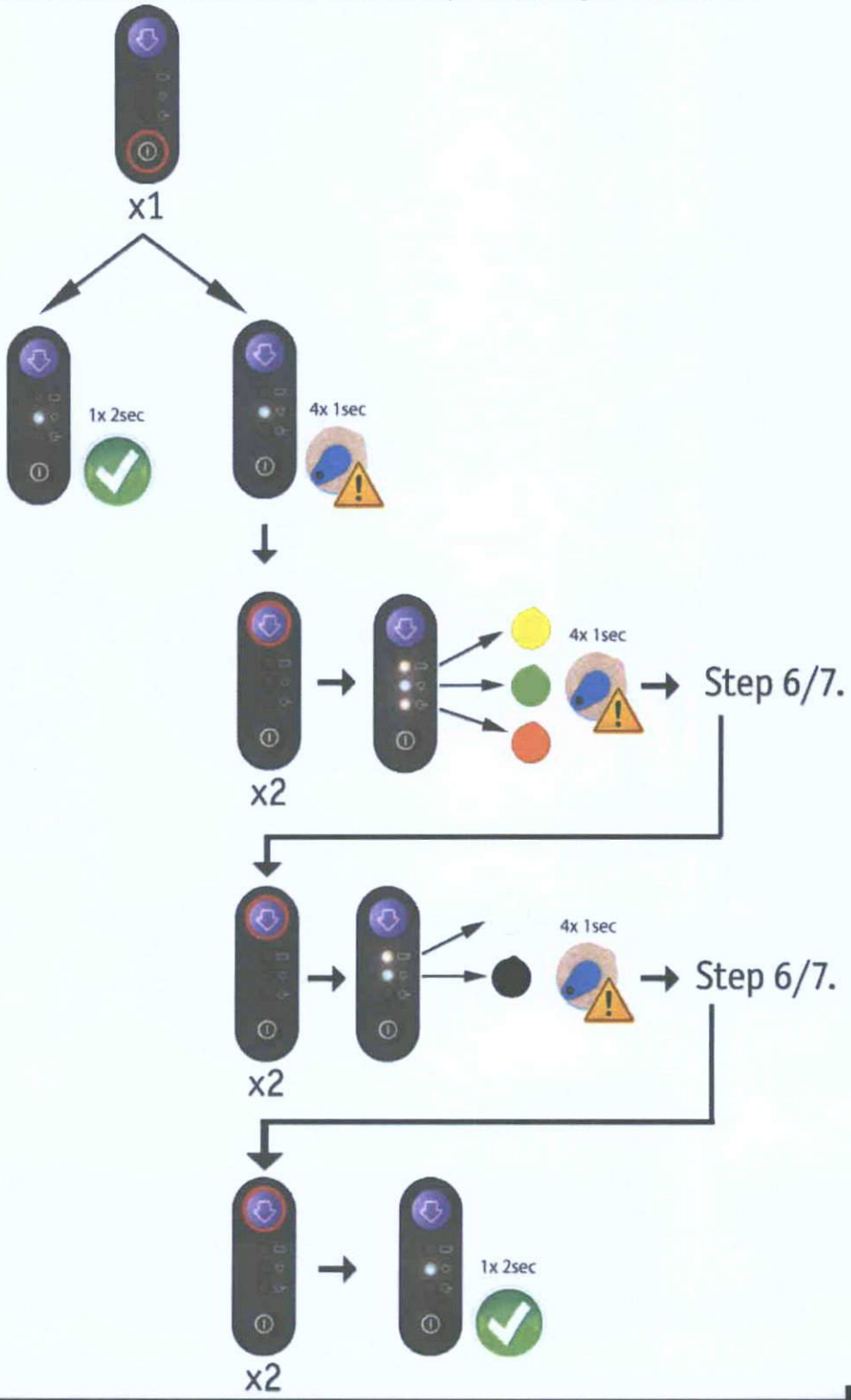
b. If the VS monitor is not available check the Impedance using the Monica AN24



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6. If impedance check fails
    a. Peel back electrode
    b. Dry wipe the area to remove gel and moisture left by the electrode
    c. Re-abrade the same area of skin pressing firmly
    d. Re-attach the same electrode
    e. Wait 2-3 minutes for the electrode to settle
    f. Check the impedance again (Step 5)

7. If the impedance check fails a second time
    a. remove and discard the electrode
    b. Dry wipe the area to remove gel and moisture left by the electrode
    c. Re-abrade the same area of skin pressing firmly as long as the mother does not become uncomfortable
    d. attach a new electrode
    e. Wait 2-3 minutes for the electrode to settle
    f. Check the impedance again (Step 5)

8. If the impedance check fails a third time on one or more of the Green, White, black or Orange electrodes then the impedance check can be by-passed (see AN24 Reference Operating Manual – 10.1 Troubleshooting Guide). **This is not recommended**. Alternatively, leave the electrodes in place for 30 minutes and try the impedance check again (Step 5).

9. **'Do Not'** by-pass the impedance check if the impedance check for the yellow electrode fails – go to step 6 and repeat process as long as the mother does not become uncomfortable.

10. If it is still not possible to pass the yellow electrode impedance check,

    Option 1: go back to step 8 and by-pass the impedance check. The fetal abdominal ECG can be good in early and late gestation monitoring so noise introduced by high skin electrode impedance can be mitigated. However the quality of the signal cannot be confirmed until the recording commences by looking at the signal to noise bar graph on the VS display or on the Quick-View PDA.

    Option 2: halt the recording and try again at a future time/date.

Caution: Do not use water to remove the electrodes

Before attaching the electrodes on to a patient, the user should prepare the skin and place five electrodes on themselves or a volunteer, connect the Monica AN24™ and switch on. The positioning of the electrodes is not important, but this will provide an insight into the skin preparation needed in order to obtain a steady green LED (**5**) indicating that all the electrodes have been correctly attached to the skin.

IV. Lead connection

The 'button' connector on the electrode is located on a 'flap' that is not stuck down. This means that, (a) the flap can be lifted and the correct colour coded lead connector can be pressed/snapped onto the button without pressing on the skin and disturbing the gel electrode contact with the skin and (b) no downward force is applied to the maternal abdomen.

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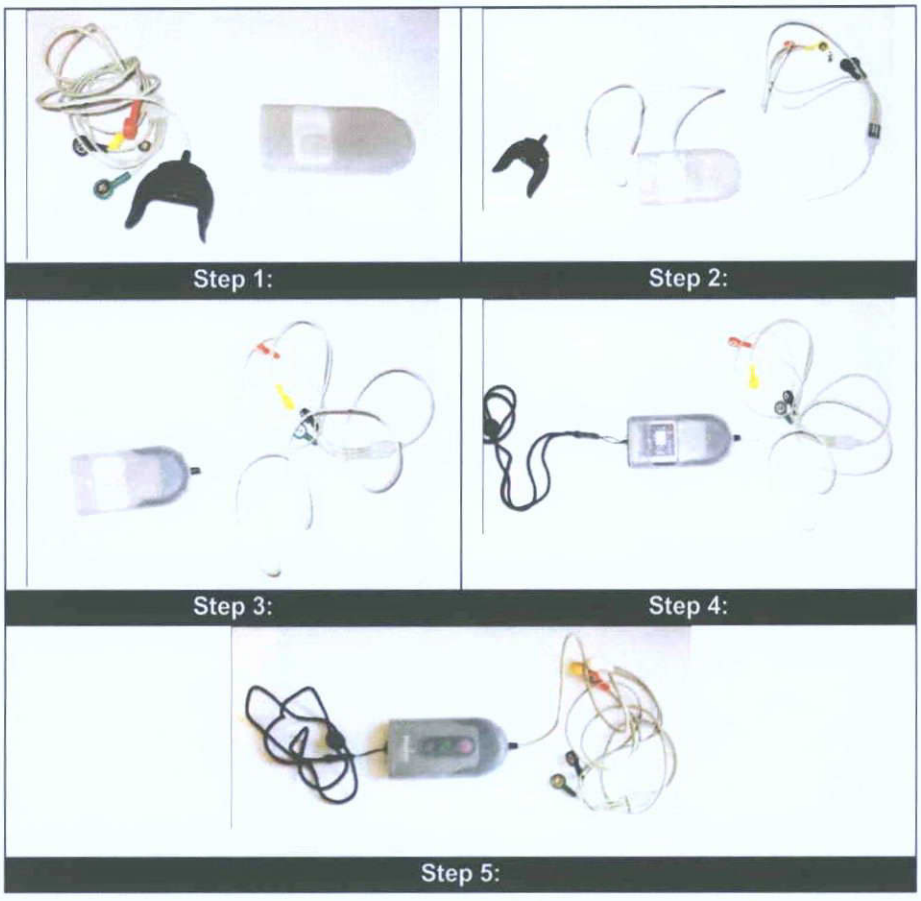
V. Protective cover and neck strap

The protective silicone rubber cover is designed to protect the Monica AN24™ during use, keep it clean and to keep it dry and avoid the ingress of fluids. **It must be used on all L&D subjects.**



Warning: Not using the protective silicone rubber cover could result in the ingress of contaminated blood and other fluids into the Monica AN24 case.

VI. Lead security

It is important to secure and tidy the electrode leads to avoid lead or electrode detachment during operation. The electrode leads are of different lengths to aid in their correct placement and are fitted with two small plastic lead separators, which can be repositioned to avoid lead tangles and aid placement. The long single lead is fitted with a Velcro band so that it can be neatly coiled and secured when the patient is mobile.

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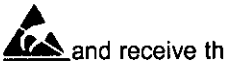
VII. Electrostatic Discharge (ESD) precautions

Although precautions have been taken to ensure otherwise, static electricity could cause damage to the sensitive input circuits of the AN24™ and render the device inoperable. In the context of the AN24™, static is most likely to reach the AN24™ via a user\ patient touching static sensitive parts of the device.

ESD precautionary measures should be taken to minimise the risk of damage to the AN24™. More specifically:

- The connector which joins the AN24™ and lead connector together should not be touched by any part of the body, including the fingers
- The metallic (conducting) part of the electrode (press-stud) clips at the extremities of the electrode leads should not be touched by any part of the body, including the fingers

All staff that use the AN24™ should receive an explanation of the ESD warning symbol  and receive the following basic training\ instruction in ESD precautions before use of the AN24™:

- How to fit the AN24™ to the patient, and;
- How to attach the electrodes to the AN24™, and;
- How to attach the electrodes to the patient.

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The Monica AN24™™ complies with the requirements of the European Council Directives: 93/42/EEC as amended by 2007/47/EEC, concerning medical devices
ISO 13485 Monica Healthcare Ltd operates Quality Management Systems that have been approved and audited to ISO 13485.

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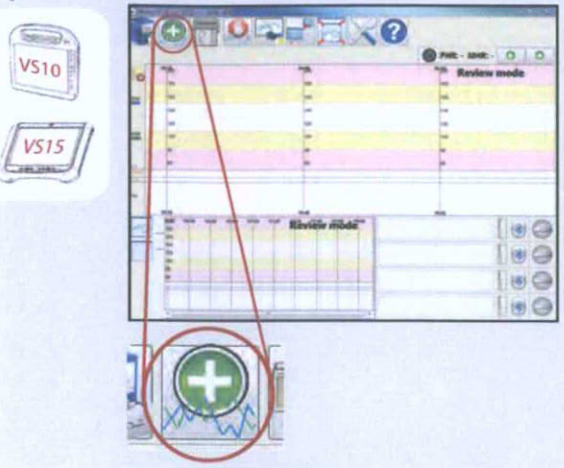

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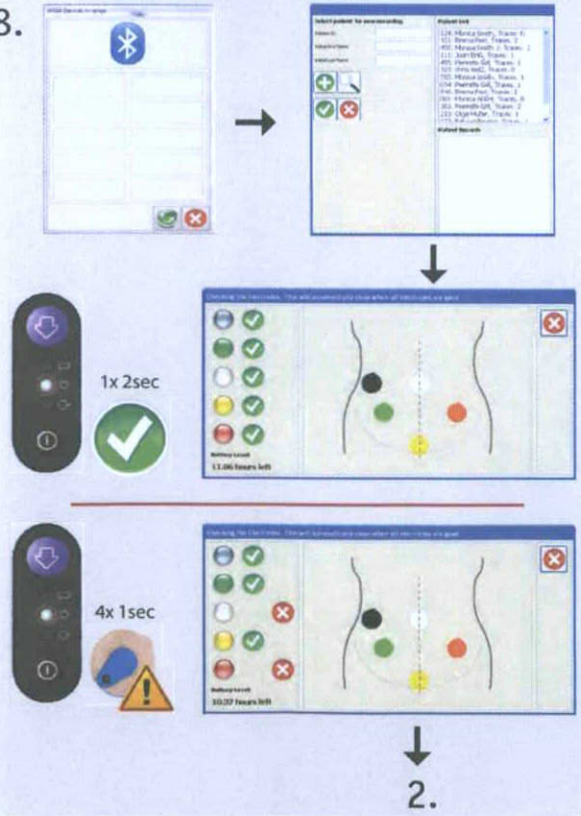

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10.

11.

Monica Healthcare

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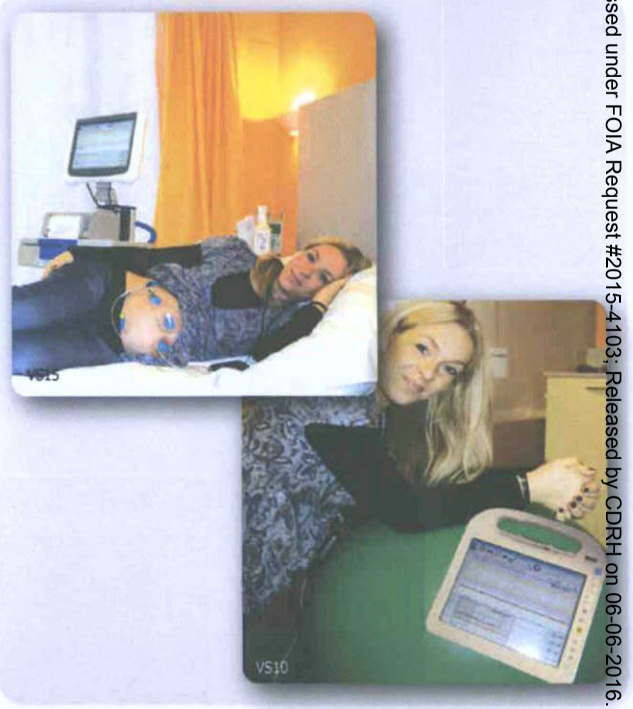

Monica VS series

...the next generation CTG

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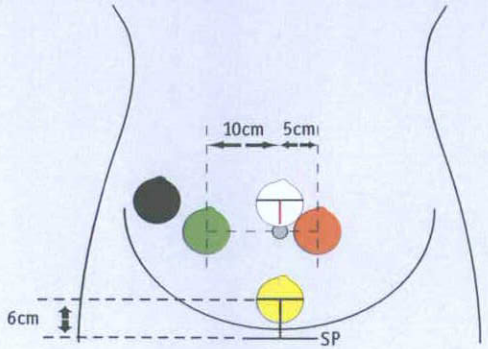
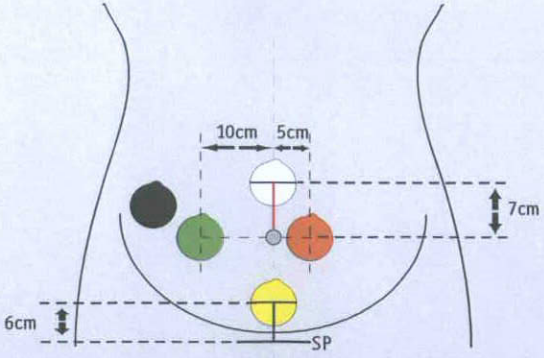
<28 & >32+6 Weeks



28 - 32+6 Weeks



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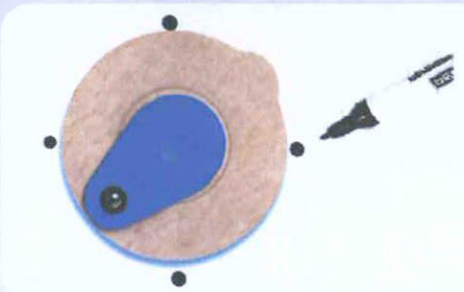

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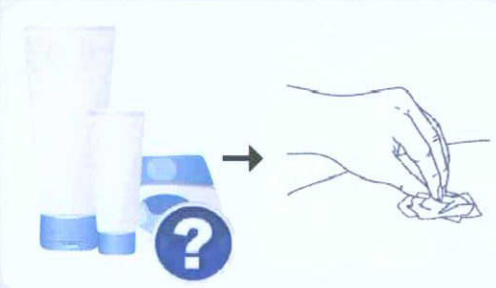

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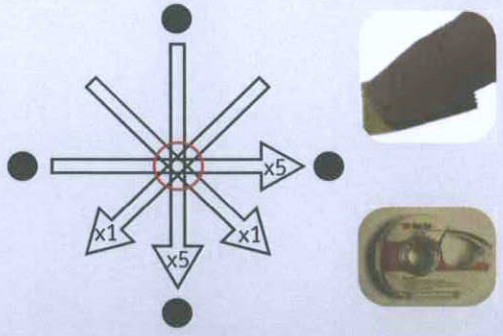
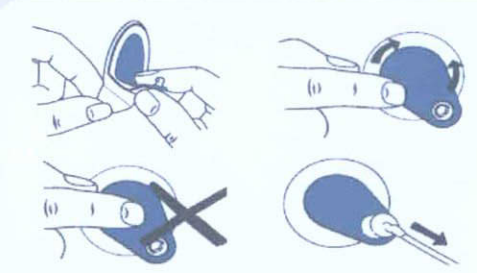
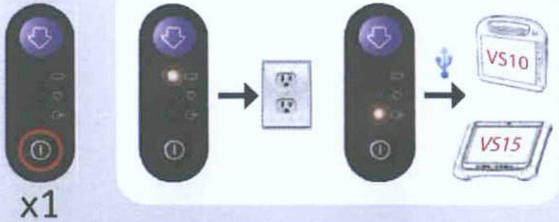


4. AMBU® Blue Sensor VLC-00-S

5.



6. AN24™



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Appendix C

- Cleaning Test Report
- Biocompatibility Test Reports

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(b)(4)

Technical Report

(b)(4)

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(b)(4) [redacted]

1. INTRODUCTION

The purpose of the study is to evaluate the significant effectiveness of cleaning and disinfectant procedures (see Annex 1) of the Fetal Monitor AN24 device. The monitor is a non-invasive (low-risk) device designed to be in contact with intact skin. The effectiveness of cleaning is to be determined by the evaluation of reduction of lipid, glucose and protein from the surface of the device.

The methods proposed were as follows:

(b)(4) [redacted]

After initial investigations it was demonstrated that the Gas Chromatography procedure was most suitable for the Lipid determination and that the Bradford Test was most suitable for Protein determination.

2. SUMMARY

The procedure for the cleaning and disinfectant procedures of the AN24 Fetal Monitor device has been shown to be significantly effective.

3. RESPONSIBILITIES

(b) (6) [redacted]

4. LOCATIONS

Customer — Monica Healthcare
BioCity, Pennyfoot Street
Nottingham, NG1 1GF

(b)(4) [redacted]

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(b)(4)

[redacted]

5. DATES

Start Date: 18 December 2008
Analysis Complete: 09 January 2008

6. MATERIALS

The materials used for this study have been detailed in Tables 1 to 3.

(b)(4)

[redacted]

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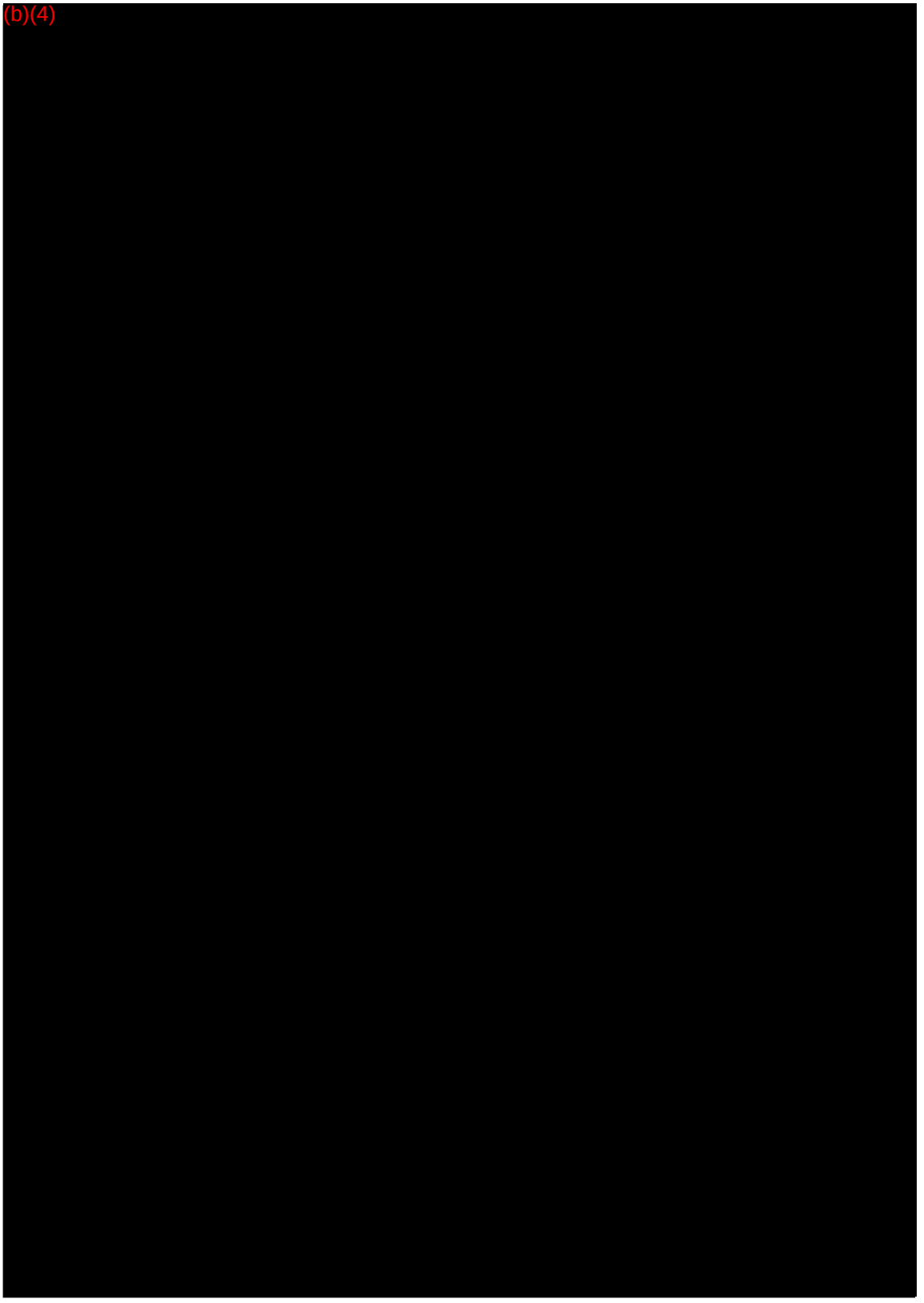

#1 The cleaning procedure has been presented in Annex 1.

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(b)(4)

7.0 TEST METHOD

(b)(4)

7.1 Lipids / Fatty Acids (as Palmitic Acid)

(b)(4)

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8.0 Sampling of Devices

(b)(4)

9.0 Results

The results generated have been presented in Tables 4 to 6.

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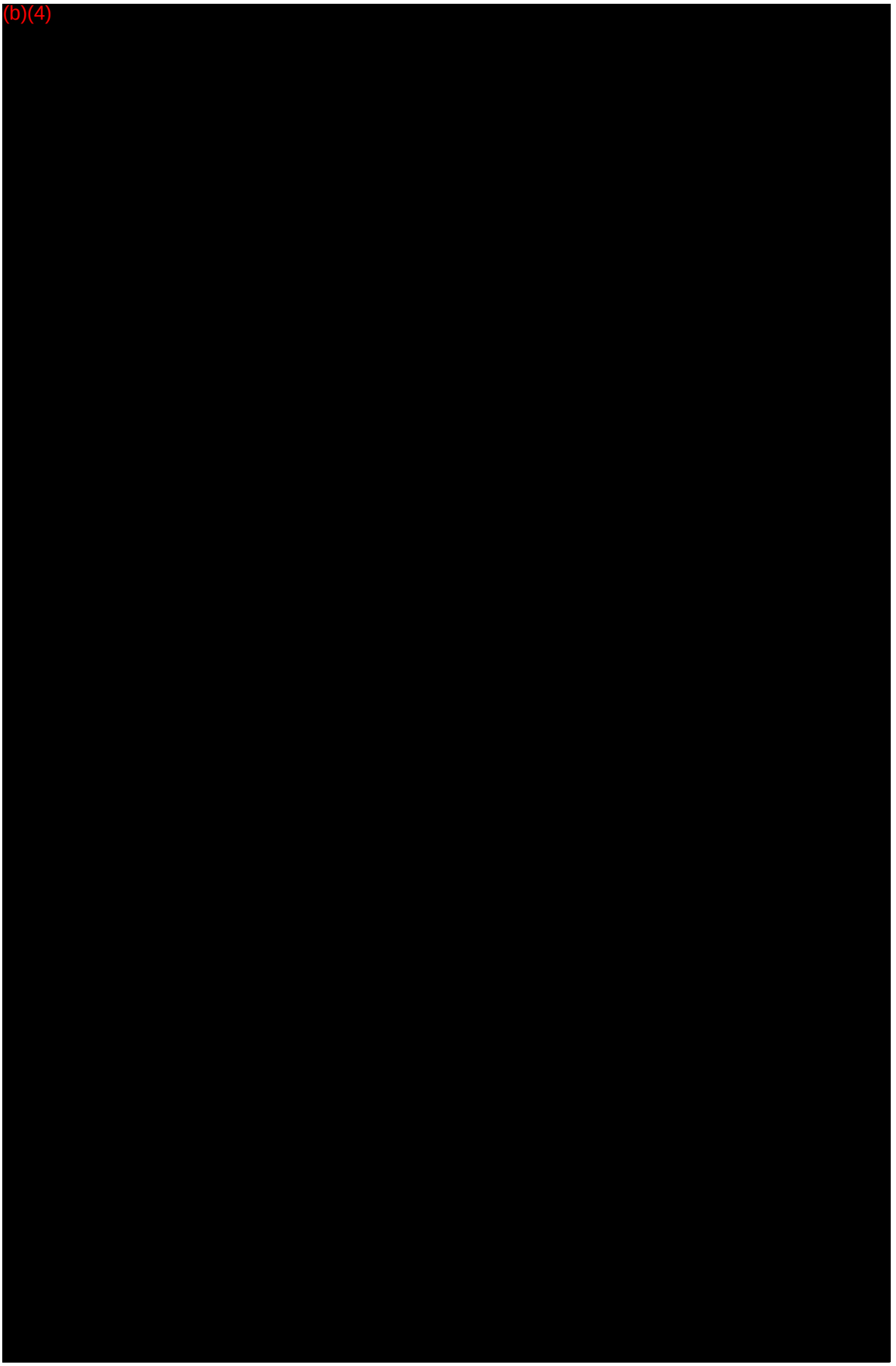

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[redacted]

9.3 Protein (as Albumin)

(b)(4)

[redacted]

10.0 Conclusion

(b)(4)

[redacted]

In summary the results demonstrate that in typical use the device becomes contaminated with measurable levels of fat and protein. These levels are reduced following cleaning according to manufactures recommended procedure. The levels of contamination following cleaning are comparable to those of a new unused device. The cleaning procedure is therefore considered as acceptable.

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(b)(4)

[redacted]

11 .0 References

(1) *Journal of Investigative Dermatology Symposium Proceedings, ISSN 1087-0024 EISSN 1529-1774*

(2) *James, William; Berger, Timothy; Elston, Dirk (2005) Andrews' Diseases of the Skin: Clinical Dermatology (10th ed.). Saunders. pp 7. ISBN 0721629210*

(3) *Alfa MJ, Olson N, Degagne P, and Jackson M. A survey of reprocessing methods, residual viable bioburden and soil levels in patient-ready endoscopic retrograde choliangiopancreatography duodenoscopes used in Canadian Centers. Infect Control Hosp Epidemiol, 2002, vol. 23, pp. 198-206*

(b)(4)

[redacted]

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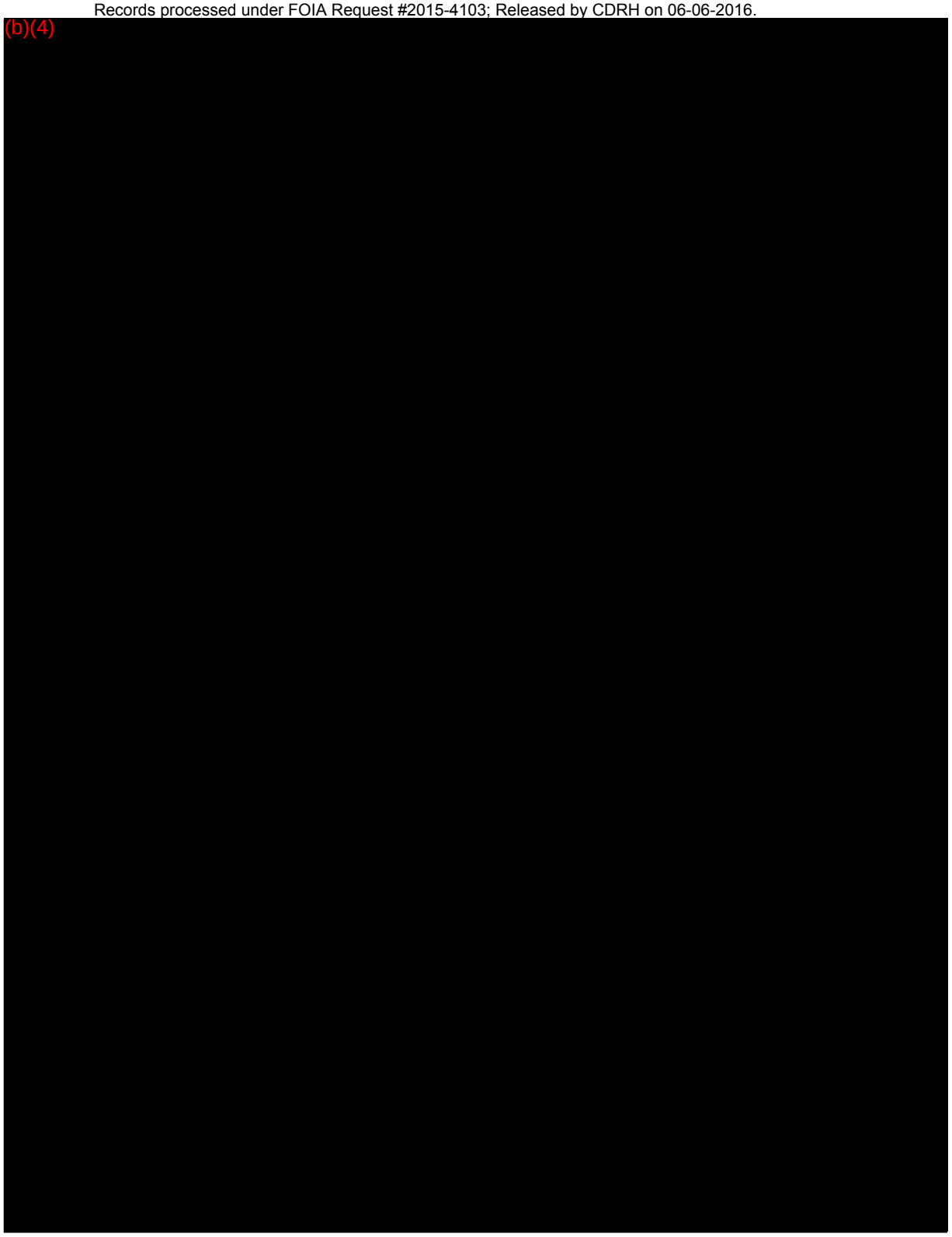

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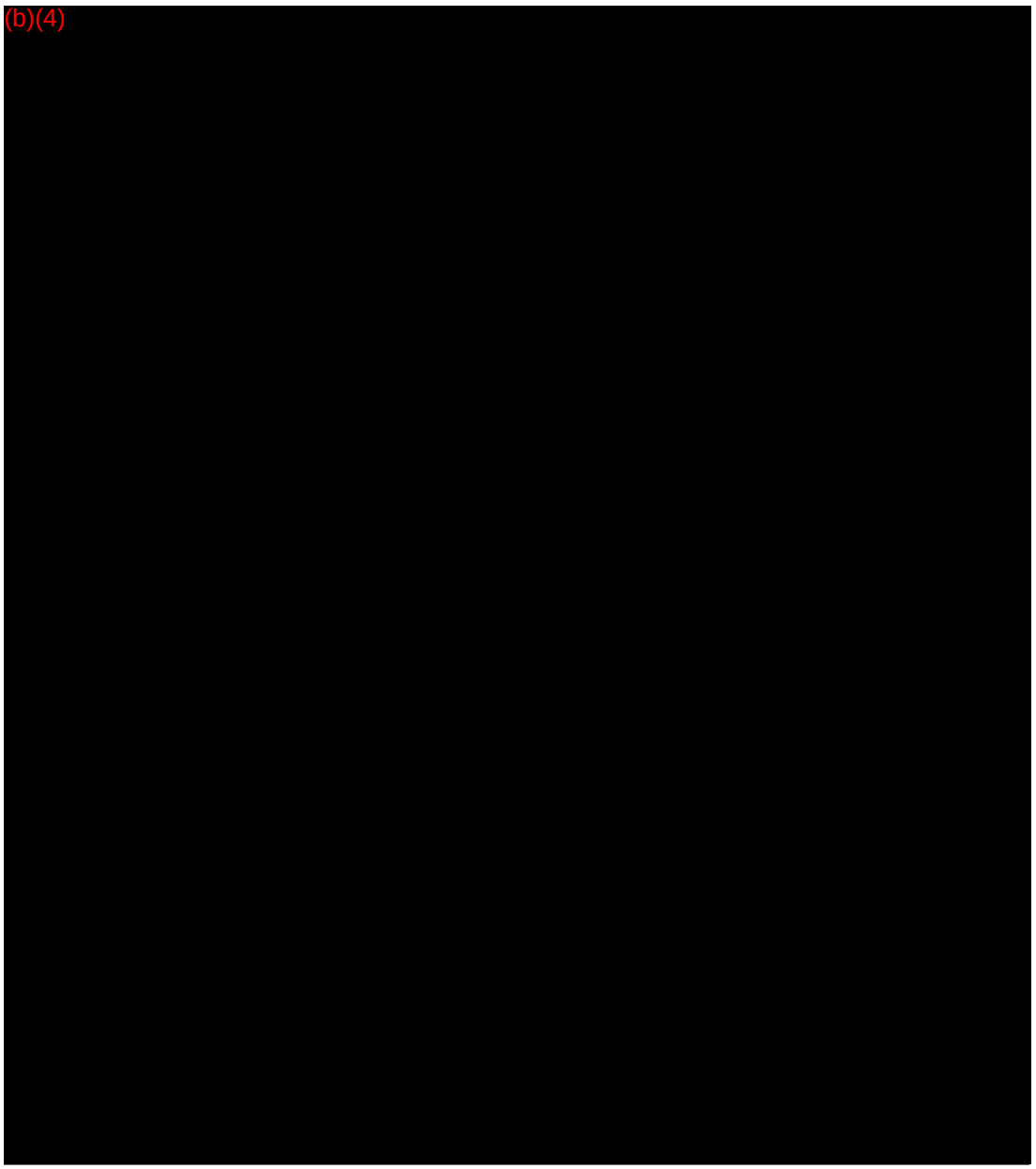

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(b)(4)

ECG cable LD05 001:

BS EN ISO 10993-5
TISSUE CULTURE CYTOTOXICITY TEST USING
L929 CELLS – EXTRACT METHOD

(b)(4)

(b) (6)

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Nottingham
NG1 1GF
UNITED KINGDOM

(b)(4)

2892-0001.doc/MSOffice

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

Records processed under FOIA Request #2015-4103; Released by CDRH on 06-06-2016.

QUALITY ASSURANCE REPORT

This study type is classed as short-term. The standard test method for this study type ("General Study Plan" in OECD terminology) was reviewed for compliance once only on initial production. Inspection of the routine and repetitive procedures that constitute the study is carried out as a continuous process designed to encompass the major phases at or about the time this study was in progress. In addition, inspection of general facilities not specifically related to this study are done monthly or annually in accordance with QA Standard Procedure.

This report has been audited by the Quality Assurance Unit, and is considered to be an accurate account of the data generated and of the procedures followed.

In each case, the outcome of QA evaluation is reported to the Study Director and Management on the day of evaluation. Audits of study documentation, and process inspections appropriate to the type and schedule of this study were as follows:

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[redacted]

..... DATE: .....

For the Quality Assurance Unit*

(b) (6)

[redacted]

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2.6

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GLP COMPLIANCE STATEMENT

The work described was performed in compliance with UK GLP standards (Schedule 1, Good Laboratory Practice Regulations 1999 (SI 1999/3106 as amended by SI 2004/0994)). These Regulations are in accordance with GLP standards published as OECD Principles on Good Laboratory Practice (revised 1997, ENV/MC/CHEM(98)17); and are in accordance with, and implement, the requirements of Directives 2004/9/EC and 2004/10/EC.

This report fully and accurately reflects the procedures used and data generated.

..... DATE: .....

(b) (6) [redacted]

This report may be presented in final form as a digital (pdf) document. Such documents are prepared by scanning the paper original, and are considered of equivalent integrity and authenticity to versions produced by optical photocopy. However, in all cases the hand-signed paper original, held in secure archives, is the definitive document.

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ECG cable LD05 001:

BS EN ISO 10993-5

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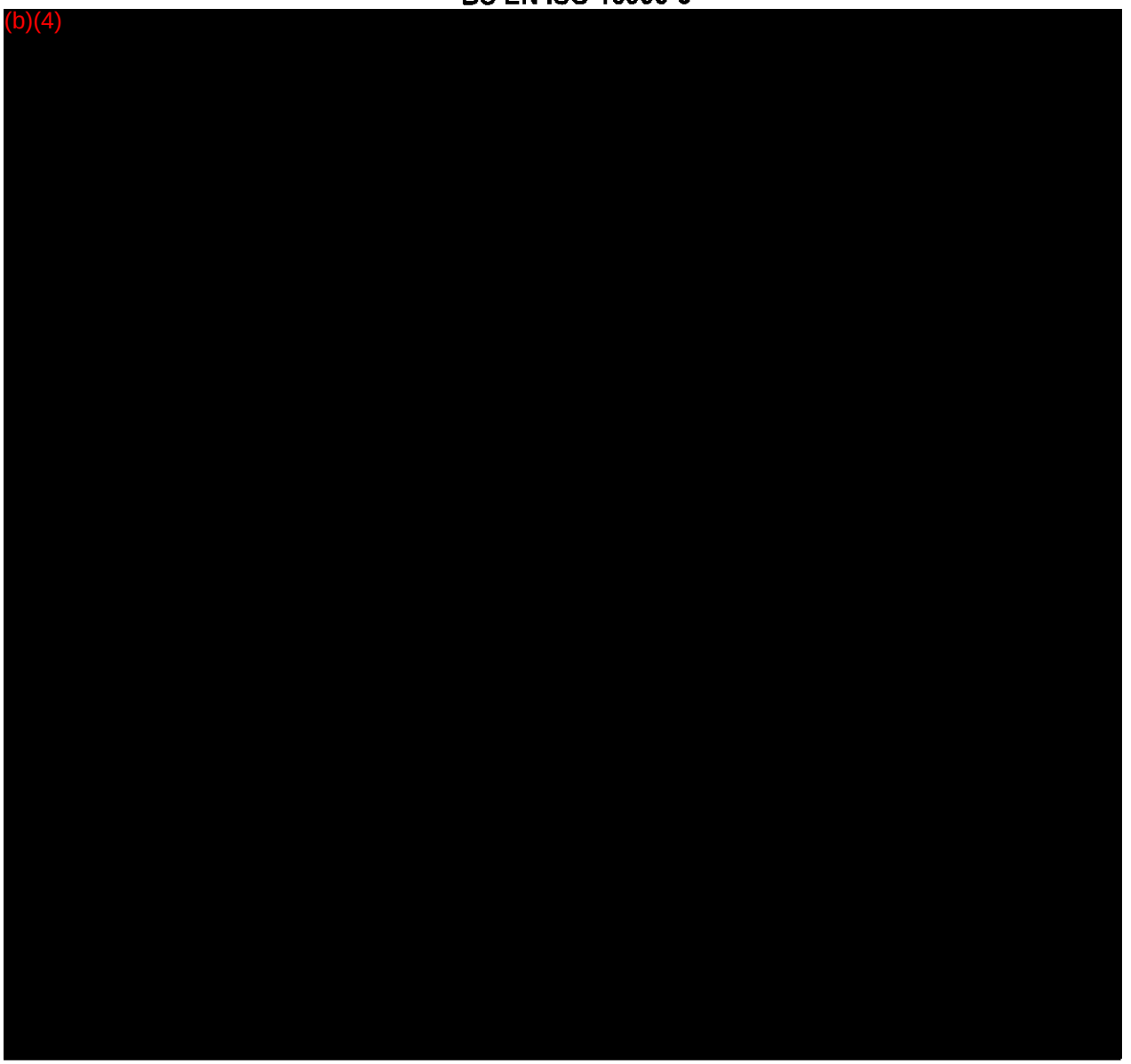

Conclusion. The extract of the test material was non-cytotoxic to L929 cells under the conditions of this test.

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

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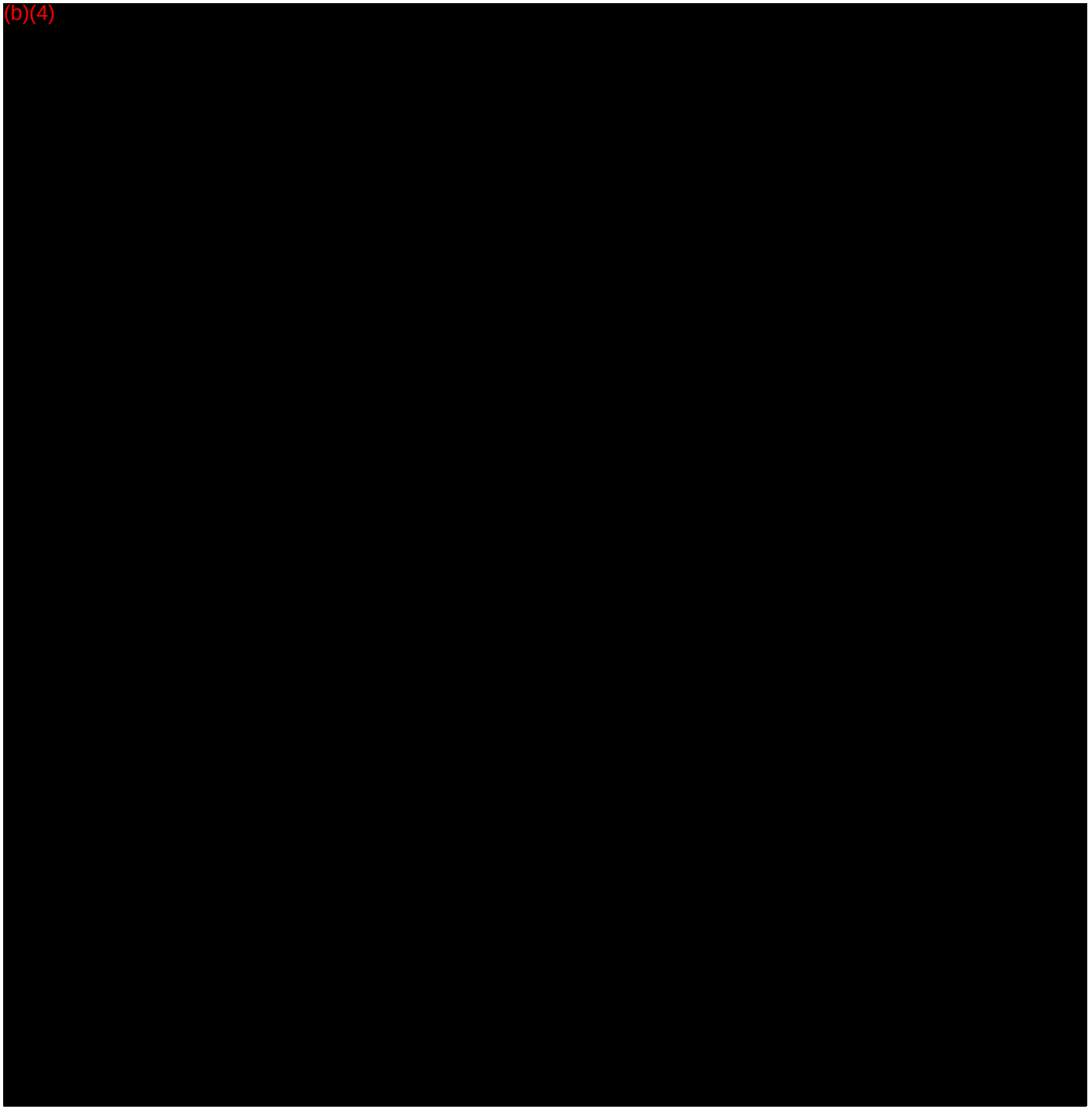

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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3. METHODS

3.1 Cells

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3.2 Control Preparation

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3.3 Method of Extraction

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[redacted]

3.5 Grading of Cytotoxicity/Reactivity

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[redacted]

The scoring is a qualitative evaluation and involves assessing changes in cell morphology *ie* rounding of cells and withdrawal of processes, vacuolisation, detachment and cell lysis. The grading will take into account both the extent of the affected zone of cells and the qualitative nature of the effects.

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4. ARCHIVES

Unless instructed otherwise by the Sponsor, all original data and the final report will be (b)(4) [redacted] instructions will be sought as to further retention or disposal.

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

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SULTS

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Sample	Extract Dilution
MEM Control	Neat
Negative Control	Neat
Positive Control	Neat
Test Material	Neat

The magnitude of the cytotoxicity grade is related to the concentration and toxicity of soluble components extracted from the test material. A positive response is an indication of the presence of an extractable toxic substance in the test material.

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The extract of the test material showed no evidence of cytotoxicity.

6. CONCLUSION

The extract of the test material was non-cytotoxic to L929 cells under the conditions of this test.

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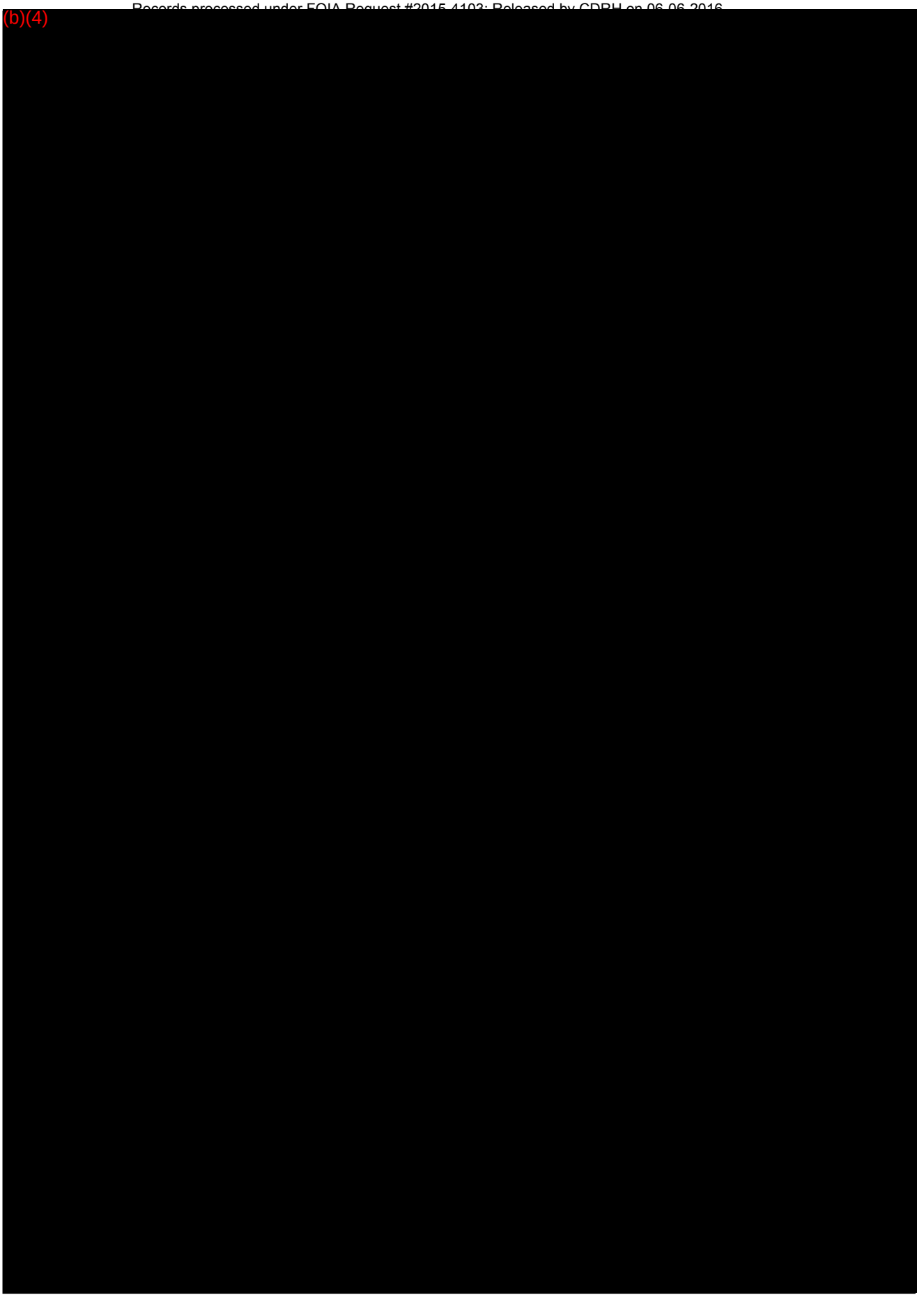

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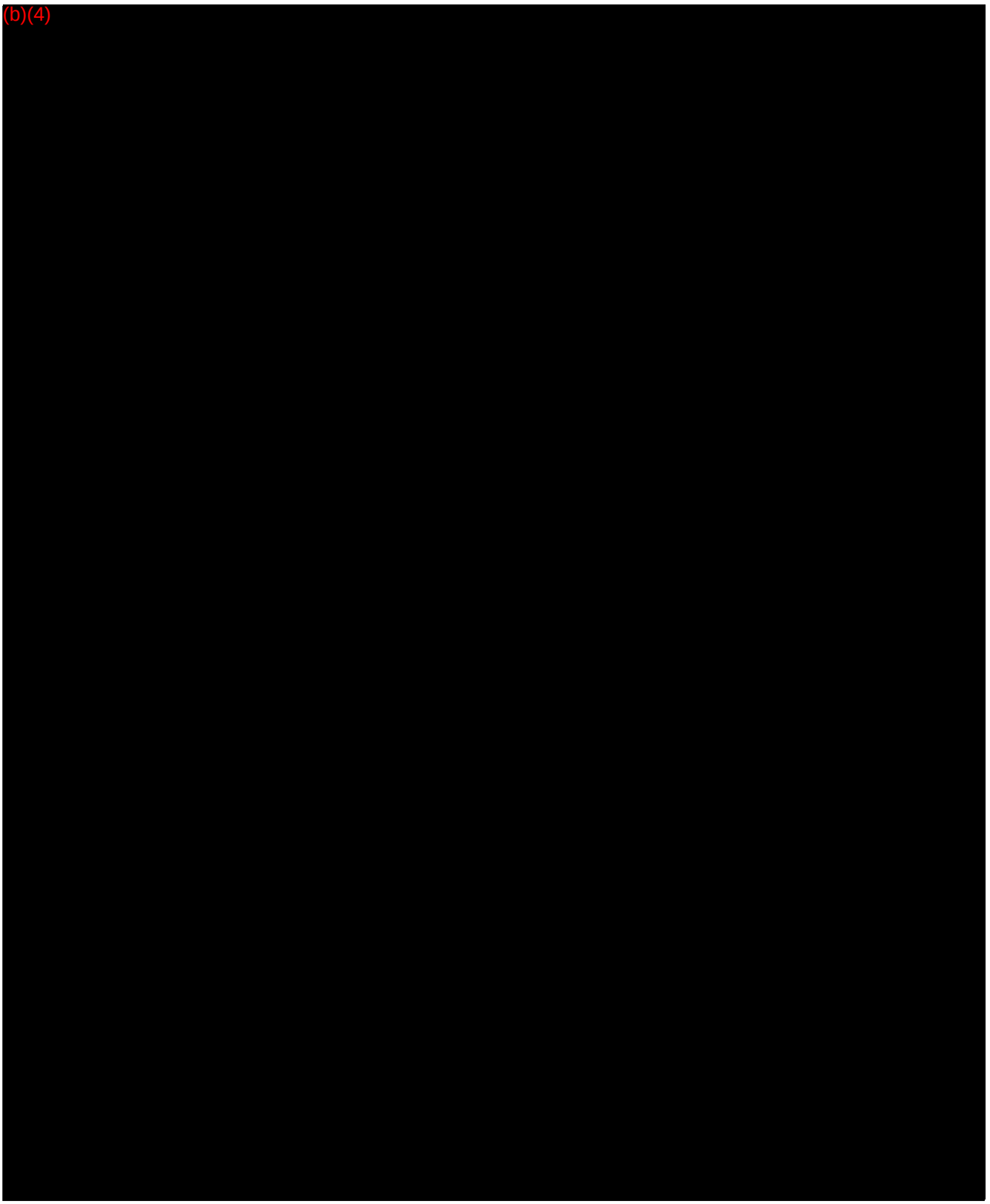

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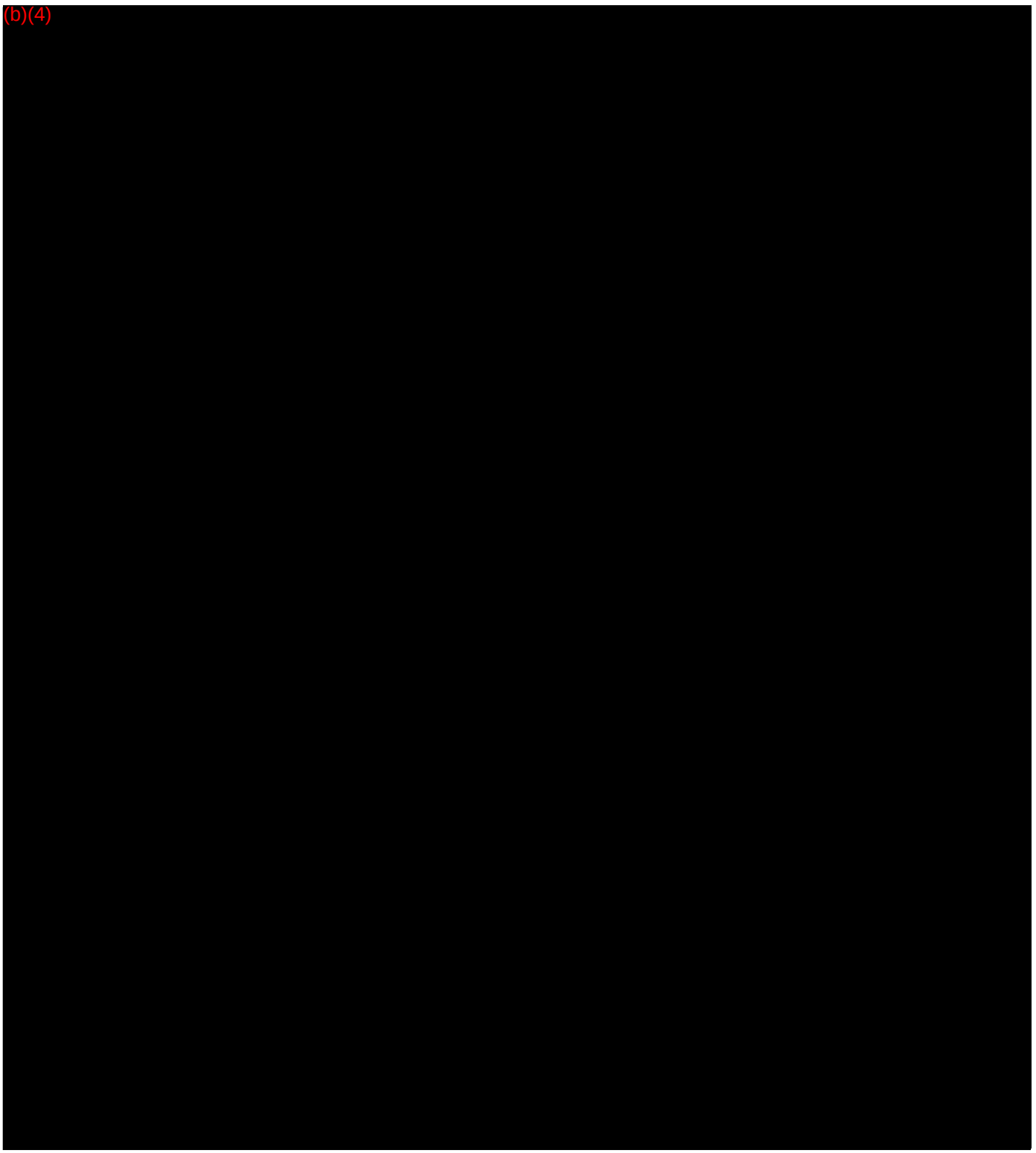

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Justification

(b)(4)

[redacted]

4. ANIMAL HUSBANDRY

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[redacted]

5. ANIMAL WELFARE

Environmental Enrichment

Animals will be provided with suitable environmental enrichment items.

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Study Conduct

(b)(4) [redacted]

6. PRE-TEST PROCEDURES

(b)(4) [redacted]

Identification

(b)(4) [redacted]

Preparation of Animals

(b)(4) [redacted]

7. TEST ITEM

Identification

Supplied by Sponsor, with details of hazardous properties, if known. Data relating to the identity, purity and stability of the test item will be the responsibility of the Sponsor.

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Storage

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[redacted]

8. EXTRACTION MEDIA

(b)(4)

[redacted]

9. SAMPLE PREPARATION

Determination of Surface Area

Surface area calculations will be used for samples which can be considered as resembling simple geometric shapes. Porous samples such as gauze, woven articles or spongy items with simple geometric shapes will be regarded and measured as solid objects.

If the thickness of the test item is less than 0.5 mm, a total surface area equivalent to 120 cm^2 will be used for each 20 ml of extraction medium.

If the thickness of the test item is 0.5 mm or greater, a total surface area equivalent to 60 cm^2 will be used for each 20 ml of extraction medium.

Mass

For items with an irregular shape whose surface area cannot easily be determined, a ratio of 2 g to 4 g of sample, depending upon the density of the test item, to 20 ml of extraction medium will be used.

Other Items

If the characteristics of the item are such that the volume of extraction medium will not cover the required surface area or mass of homogenous subdividable sample (eg foam, sponge) it will be necessary to use the maximum amount of sample that can be covered by the required volume of

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Non-subdividable items

(b)(4)

Absorbents and Hydrocolloids

(b)(4)

Final preparation

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10. EXTRACTION PROCEDURE

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[redacted]

11. PROCEDURE

Dosage

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[redacted]

Procedure

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[redacted]

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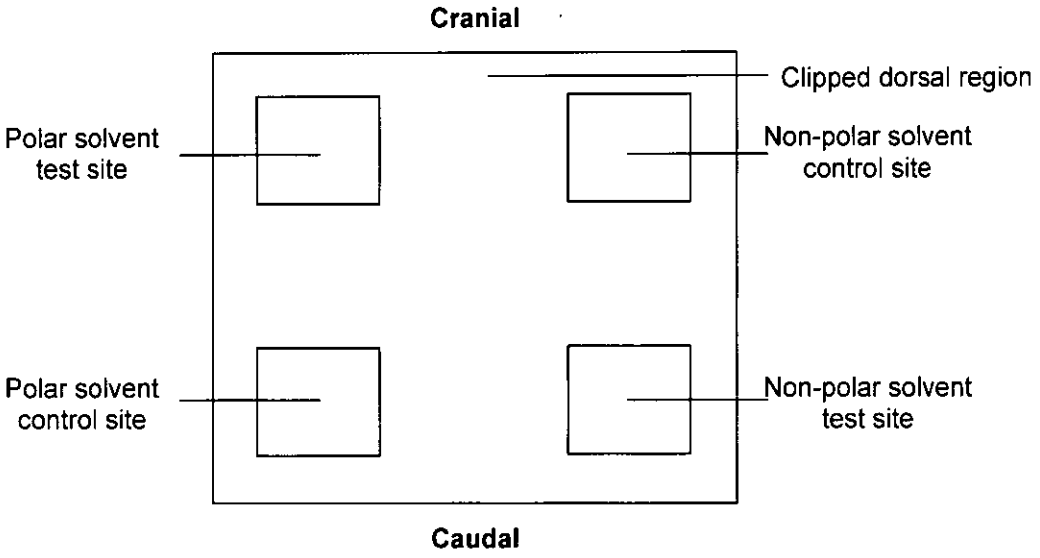
Figure 1 Location of Skin Application Sites



Exposure of Animals

(b)(4)

[redacted]

Removal of Residual Test Item

(b)(4)

[redacted]

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12. OBSERVATIONS

(b)(4)

13. INTERPRETATION OF RESULTS

Calculation of Cumulative Irritation Index and Grading of the Irritancy Potential

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[redacted]

14. QUALITY ASSURANCE

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[redacted]

subject to process-based QA inspection designed to encompass the major phases once per month.

15. PROTOCOL AMENDMENTS

Amendments to protocol will be made only by completion of an amendment to protocol form authorised by the Study Director.

16. FINAL REPORT

The final report will include, as a minimum, the following information:

Details of test item and, if appropriate, details of vehicle used
Species, strain, supplier, number and sex of animals
Environmental conditions and animal diet
Test conditions
Results of all individual observations in tabular form
Narrative description of the degree and nature of irritation
Cumulative irritation index and classification of irritancy
Description of any toxic effects other than dermal irritation.

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17. ARCHIVE

Unless instructed otherwise by the Sponsor, all original data and the final report will be retained

(b)(4) [redacted]

data will be chargeable to the Sponsor.

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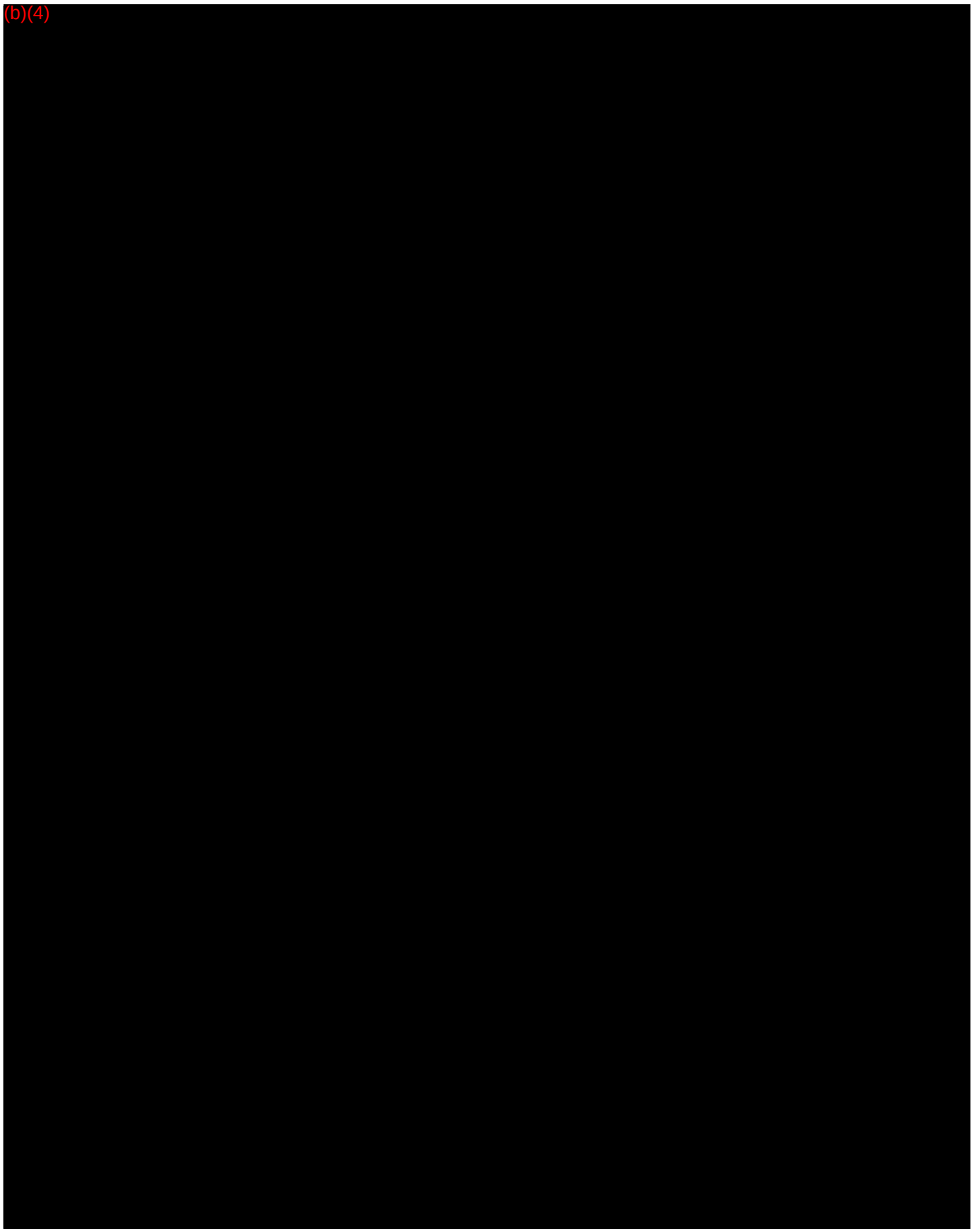

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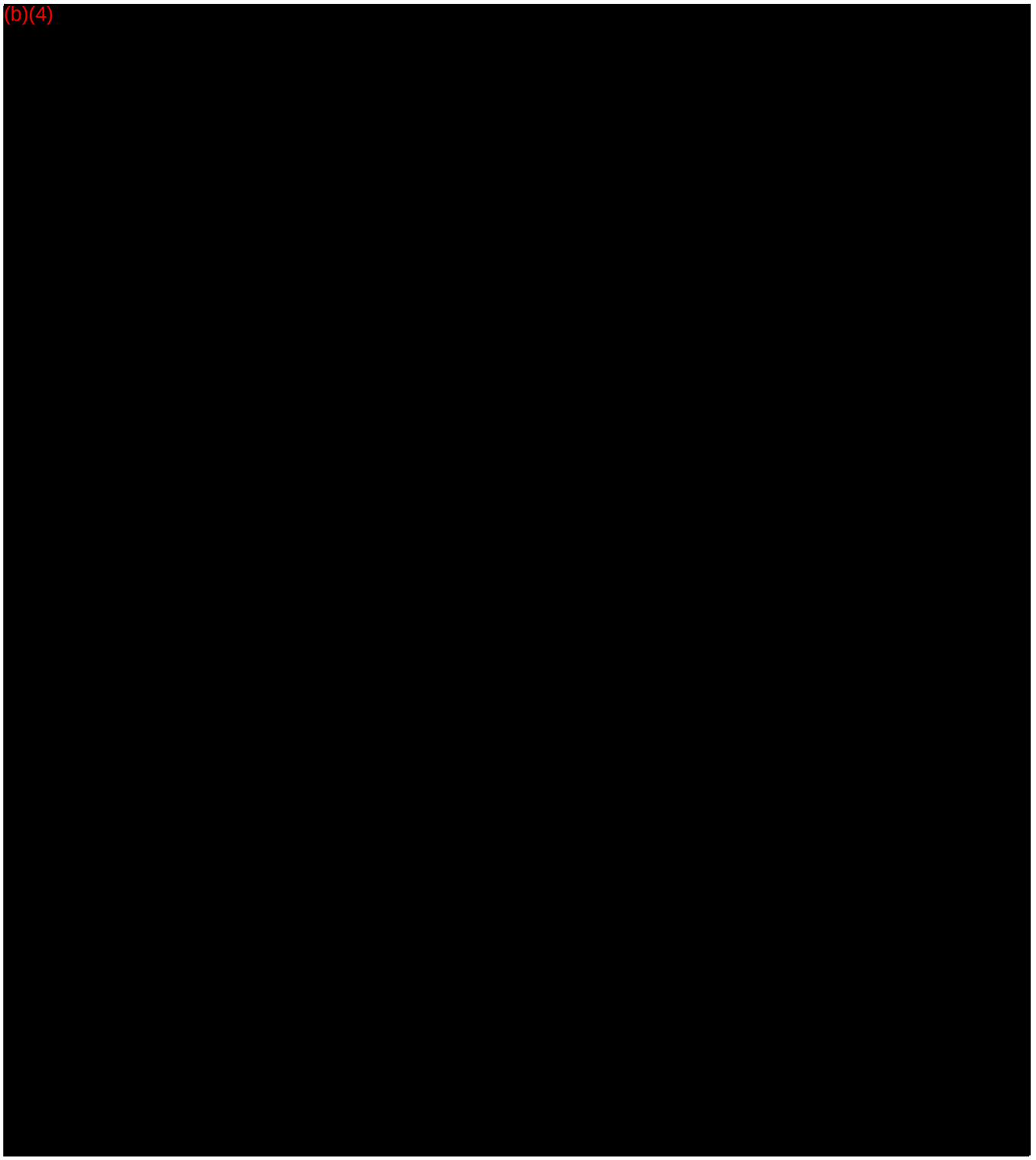

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(b)(4)

[redacted]

5. ANIMAL WELFARE

(b)(4)

[redacted]

6. INITIAL CONSIDERATIONS

(b)(4)

[redacted]

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(b)(4)

[redacted]

7. PRE-TEST PROCEDURES

(b)(4)

[redacted]

8. TEST MATERIAL AND EXPERIMENTAL PREPARATION

(b)(4)

[redacted]

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

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Preparation

(b)(4)

[redacted]

Analysis

All formulations will be used within two hours of preparation and will be assumed to be stable for this period unless specified otherwise by the Sponsor. The concentration and homogeneity of the formulations will not be determined by analysis.

Absorption

The absorption of the test material will not be determined.

9. SELECTION OF CONCENTRATIONS OF TEST MATERIAL

(b)(4)

[redacted]

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

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10. PROCEDURE

Test Material Administration

(b)(4)

[redacted]

^{3}H-methyl thymidine Administration

(b)(4)

[redacted]

11. OBSERVATIONS

(b)(4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118. 254

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12. TERMINAL PROCEDURE

(b)(4)

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13. INTERPRETATION OF RESULTS

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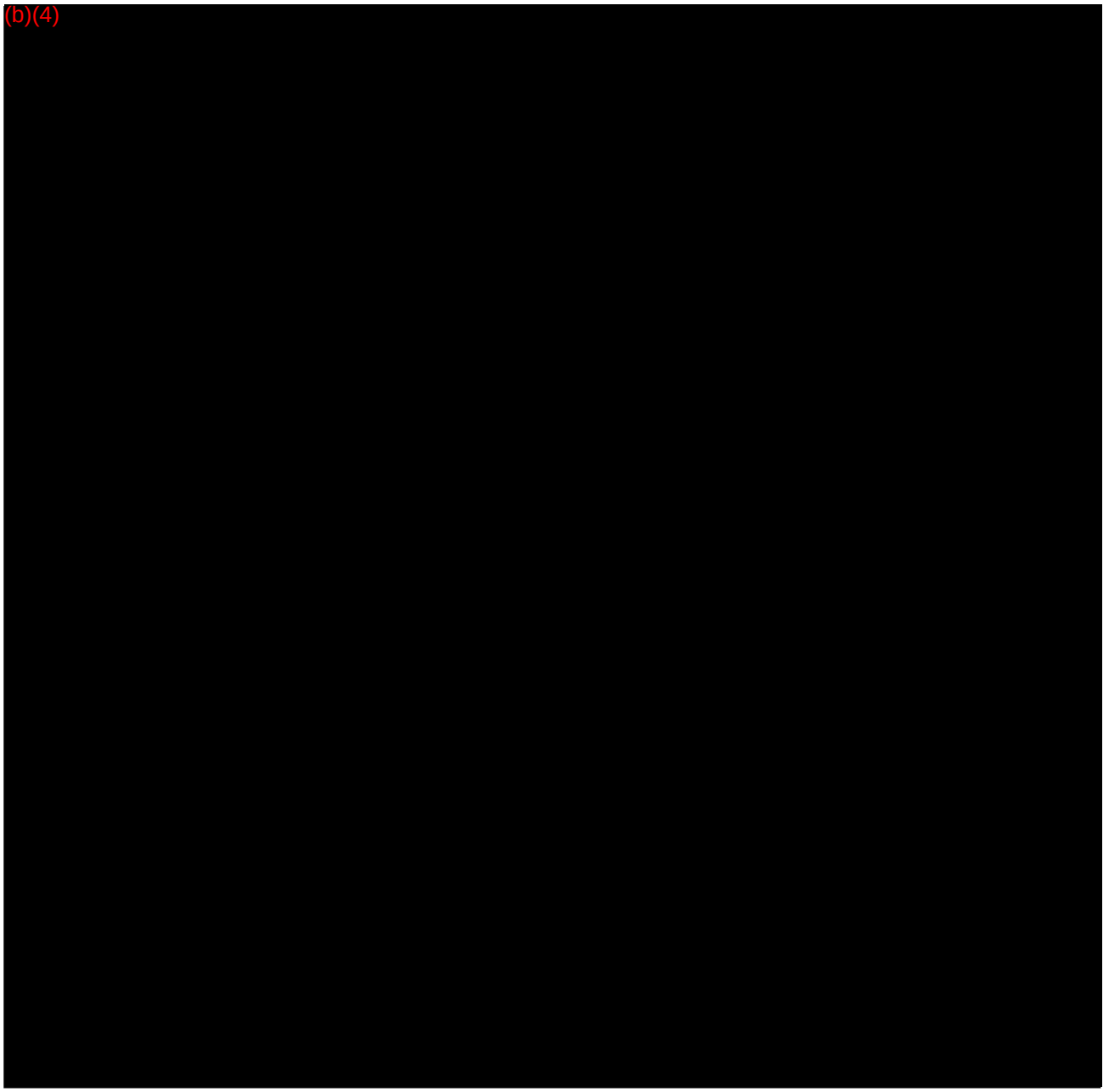

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14. STATISTICAL ANALYSIS

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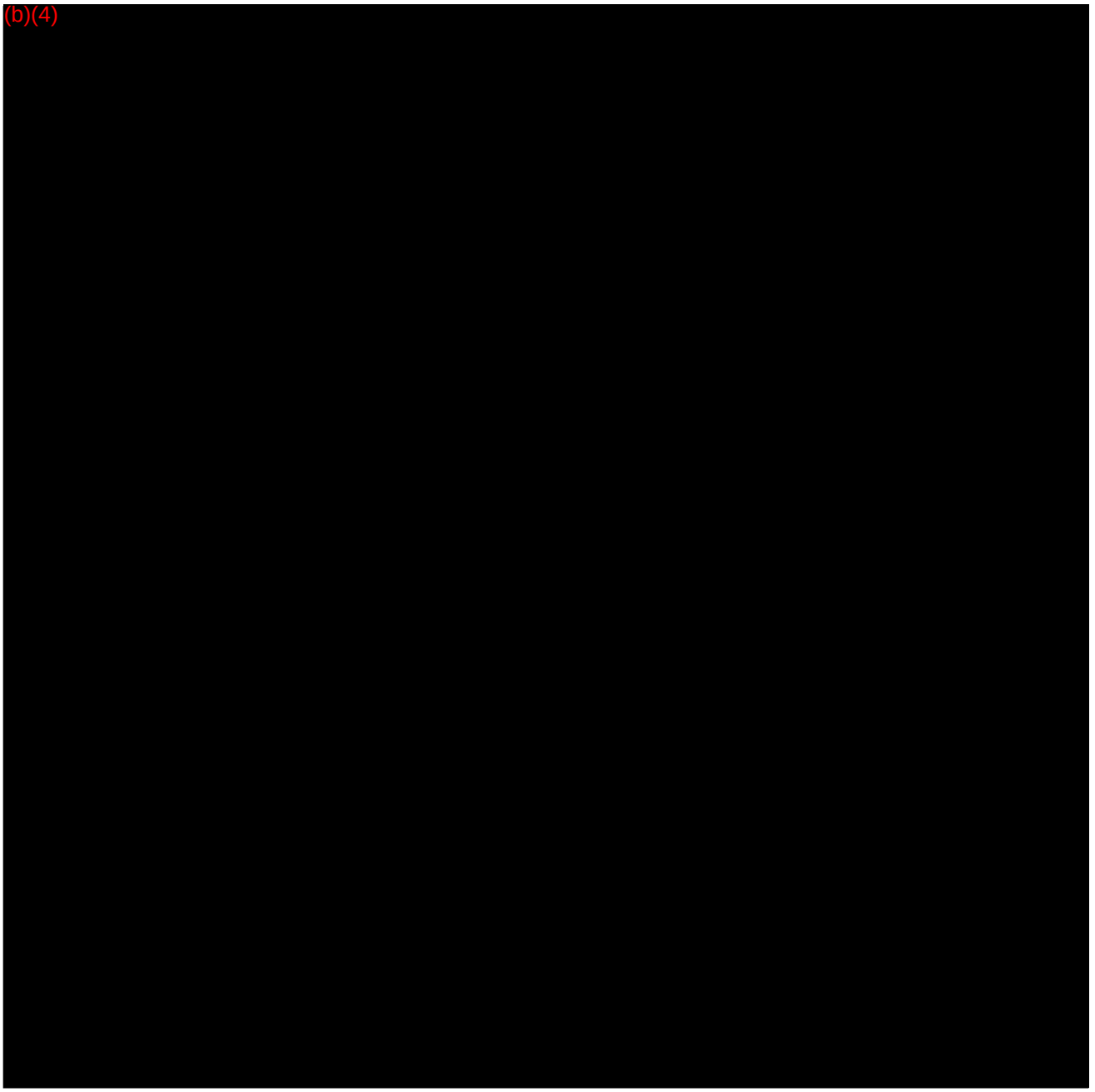

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118. 257

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18. FINAL REPORT

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Appendix D

- Predicate Device Documentation

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8116

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K954351

P -- [510(k)] Summary of Safety and Effectiveness

The Series 50XM (M1350B) is a combination of two subsystems which represent either the functionality of the Fetal Monitor Series 50IX (M1350A) or it will represent the functionality of parts of the Patient Monitors HP 78352C or M1020A (SpO2) and M1008B (NBP).
The Series 50 XM (M1350B) therefore combines all of the basic fetal monitoring requirements and maternal NBP, SpO2 and ECG in one monitor which is the same intended use as for the predicate device Corometrics Model 118.

The intended use of the fetal monitoring is the same as for the predicate device Series 50IX (M1350A).
It allows non- invasive or invasive monitoring of an ambulant patient during both antepartum testing and labor and delivery in that the monitoring of the FHR via ultrasound or direct ECG, and uterine activity via an external Toco transducer or an internal IUP transducer is possible, additionally it allow maternal heart rate recording via the MECG transducer.

The intended use of the maternal parameters NBP and SpO2 is the same as for the predicate devices HP78352C, M1020A and M1008B
It allows the non-invasive measurement of the Noninvasive Bloodpressure ans the Oxygen Saturation ,generate alarms, and generate recording on maternal patients.

The fetal parameters are displayed in the same way as that currently used on the Series 50IX (M1350A).

The additional maternal parameters are displayed on a separate LCD display situated between the fetal parameters and the recorder.

The Series 50XM (M1350B) slightly modifies existing software modules of the Series 50IX (M1350A) Fetal Monitor (which was originally cleared under K900480) and adds a new Software Modules for the maternal parameters, which were original transported from the predicate devices of HP.

The HP Series 50XM (M1350B) was fully validated (including regression testing).

The comparison of intended use and technological characteristics of this device to other legally marketed devices taken together with the validation results and other information in this submission indicate that this device is substantially equivalent to legally marketed predicate devices in safety, effectiveness, and intended use.

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

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K954351

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Series 50 XM (M1350B)
Series 50 XMO (M1350C)
Fetal/Maternal Monitors

INSTRUCTIONS FOR USE

M1350-9001S
Printed in Germany March 2002
Edition 1

PHILIPS

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- the electrical installation of the relevant room complies with national standards, and
- the instrument is used in accordance with the *Instructions for Use* or *User's Guide*.

Intended Use (M1350B)

The Series 50 XM Fetal/Maternal Monitor (M1350B) allows non-invasive or invasive monitoring of an ambulant patient during both antepartum testing and labor and delivery in that the monitoring of the fetal heart rate (FHR) via ultrasound or direct electrocardiogram (DECG), and uterine activity via an external Toco transducer or an internal intrauterine pressure (IUP) transducer is possible, additionally it allows maternal heart rate recording via the MECG transducer. Alarms are generated from maternal heart rate.

The Series 50 XM allows the non-invasive measurement of the Noninvasive Blood Pressure and the Oxygen Saturation parameters, generate alerts, and the generation of alerts and recordings on maternal patients.

The device is intended to be used in Labor-Rooms and Delivery-Rooms and in Antepartum-Testing-Areas. It is not intended to be used for transport monitoring and home use.

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Intended Use (M1350C)

The Series 50 XMO Fetal/Maternal Monitor (M1350C) allows non-invasive or invasive monitoring of an ambulant patient during both antepartum testing and labor and delivery in that the monitoring of the fetal heart rate (FHR) via ultrasound or direct electrocardiogram (DECG), and uterine activity via an external Toco transducer or an internal intrauterine pressure (IUP) transducer is possible, additionally it allows maternal heart rate recording via the MECG transducer. Alarms are generated from maternal heart rate.

The Series 50 XMO allows the non-invasive measurement of the Noninvasive Blood Pressure and the Oxygen Saturation parameters, generate alerts, and the generation of alerts and recordings on maternal patients. Additionally, the Series 50 XMO allows you to record fetal pulse oximetry ($FSpO_2$).

The device is intended to be used in Labor-Rooms and Delivery-Rooms and in Antepartum-Testing-Areas. It is not intended to be used for transport monitoring and home use.

The Series 50 XMO (M1350C) is not available in the U.S.A.

Conventions Used in This Guide

Warning
A warning alerts you to a potential serious outcome, adverse event or safety hazard. Failure to observe a warning may result in death or serious injury to the user or patient.

Caution
A caution alerts you where special care is necessary for the safe and effective use of the product. Failure to observe a caution may result in minor or moderate personal injury or damage to the product or other property, and possibly in a remote risk of more serious injury.

***Note*—A note calls your attention to an important point in the text.**

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On your monitor, this sign indicates that there is detailed information in this book which you must read before proceeding with your task

The monitor should only be used by, or under the direct supervision of, a licensed physician or other health care practitioner who is trained in the use of fetal and maternal heart rate monitors and in the interpretation of fetal and maternal heart rate traces. US law restricts this device to sale by, or on the order of, a physician.

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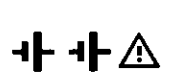
1 Safety

General Safety Information

	This symbol indicates that you should consult the *Instructions For Use* (this guide), and particularly any warning messages.
	Equipotential Terminal This symbol identifies terminals which are connected together, bringing various equipment or parts of a system to the same potential. This is not necessarily earth potential. The value of potentials of earth may be indicated adjacent to the symbol.
	Protective Earth Terminal This symbol identifies the terminal for connection to an external protective earth system.
2 x 1.5 V 	**Battery 2 x 1.5V** This symbol identifies the battery holder containing two 1.5 V batteries.

The monitor is designed to fulfil safety requirements according to IEC 60601-1/EN 60601-1 (Class I), UL 2601-1, CSA-C22.2 No 601.1-M90.

It complies with the essential requirements of the Medical Device Directive 93/42/EEC. The monitor is classed:

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ORDINARY EQUIPMENT - Enclosed equipment protected against ingress of water.

CONTINUOUS OPERATION - Can be operated continuously.

The Series 50 XMO and the Series 50 XM are not "ECG-Monitors", are not defibrillator-protected, and are not designed for direct cardiac application.

Electrical Safety

Equipment	Equipment Type	Information
External Toco transducer (M1355A) and IUP quartz transducer (1290C) and IUP transducer (CPJ840J5)	B	Patient Connector is electrically isolated. Connecting the transducer to the Toco channel results in CF condition.
Ultrasound transducer (M1356A)	B	Connecting the transducer to a Cardio channel results in a B condition.
DECG transducer (M1357A) and MECG transducer (M1359A)	CF	Connecting the transducers to a Cardio channel results in a CF condition.
US/MECG combi transducer (M1358A)	B (Ultrasound) CF (MECG)	Connecting the combi transducer to the Cardio 1 channel results in a CF condition for MECG and a B condition for US application.
SpO_2 transducer (M1191A) Adapter cable (M1940A)	CF	Connecting the SpO_2 transducer results in a CF condition.
NIPB cuffs (M1574A and M1575A) Interconnect tubing (M1599A)	CF	Connecting the NIBP tubing results in a CF condition.
$FSpO_2$/ECG patient module (M1365A) ECG only patient module (M1364A)	CF	Connecting a patient module results in a CF condition.

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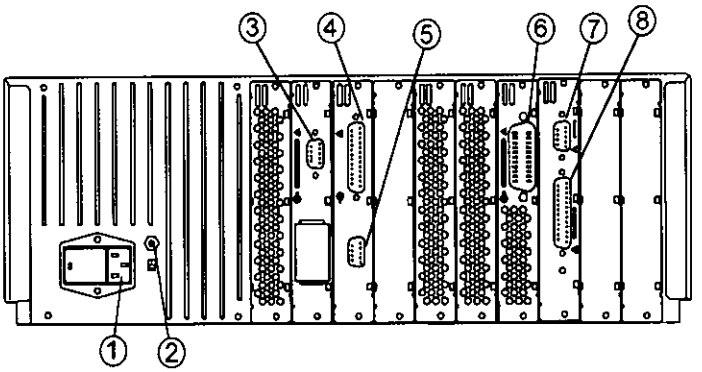
Maximum Input/Output Voltages

The following diagram shows the sockets for peripheral devices.



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1. Mains Socket.

2. Equipotential Grounding Point.
   To use the monitor with other equipment in an operating room environment, connect the equipotential grounding point (2) to earth potential. Use the grounding cable supplied with the monitor.

3. +5V input socket for the HBSW8200 Barcode Reader.

4. Socket for the Philips M1310A Series 50 T Fetal Telemetry System. +5V input **except for**:
   Pins 1, 14, 15 and 16: ± 12V input
   Pin 2 -12V output
   Pin 3 +5V output
   Pin 4 ±12V output

5. RS232 Digital System Interface:
   Pin2 ±12V input
   Pin 3 ±12V output

6. Socket for one of the following:
   - 80225A or 80235A/B Obstetrical Information Management System (OBMS)
   - M1370A Obstetrical Display Information System (ODIS)
   - ±12V except for Pins 17, 18 and 22 which are +5V input.

7. Socket (9-pin) for an external device:
   Pin 3 ±12V

8. Socket (25-pin) for an external device:
   Pin 2 ±12V
   Pins 9 and 10 +5 Volt

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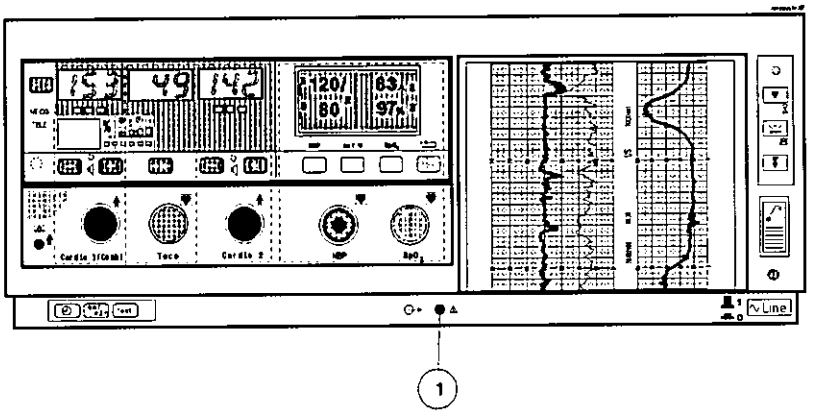
Service Socket for Upgrade Key

The Service Engineer can connect a compatible PC to this socket (1) to carry out extended configuration and service functions.



Maximum voltage of ±12V.

Protective Earth

To protect hospital personnel and the patient, the monitor's casing must be grounded. Accordingly, the monitor has a 3-wire power cable that grounds it to the power line ground when plugged into an appropriate 3-wire receptacle. Do not use a 3-wire to 2-wire adapter with the monitor. Any interruption of the protective earth grounding will cause a potential shock hazard that could result in serious personal injury.

Whenever it is likely that the protection has been impaired, the monitor must be made inoperative and be secured against any unintended operation.

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Warning
Check each time before use that the monitor is in perfect working order and properly grounded.

Position the patient cable so that it does not come into contact with any other electrical equipment. The cable connecting the patient to the monitor must be free of electrolyte.

Make sure that during operation, the monitor is free from condensation. This can form when equipment is moved from one building to another, and is exposed to moisture and differences in temperature.

Warning
Possible explosion hazard if used in the presence of flammable anaesthetics.

Environment

Use the monitor in an environment that is reasonably free from vibration, dust, corrosive or explosive gases, flammable agents, extremes of temperature, humidity and so forth. It operates within specifications at ambient temperatures between 0 and 55°C. Ambient temperatures that exceed these limits can affect the accuracy of the monitor and cause damage to the components and circuits. Only products that fulfil the necessary safety and electrical standards should be used in conjunction with the monitor (contact your local response center for details).

Allow at least 5cm (2in) clearance around the monitor for proper air circulation. If the monitor is mounted in a cabinet, allow sufficient space at the front for operation and at the rear for servicing with the cabinet door open.

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Spillage

When the maternal display is in a tilted position, take additional care to prevent spillage of liquid. If liquid accidentally enters the monitor through the maternal display recess, you must cease using the monitor immediately. Contact an authorized engineer for a safety inspection.

Electromagnetic Compatibility (EMC)

The electromagnetic compatibility (EMC) validation includes testing performed according to the international standard for EMC with medical devices. See the Manufacturer's Declaration for details.

EMC Testing

Caution

If operating under conditions according to the EMC-standard 60601-1- 2 (Radiated Immunity 3 V/m), field strengths above 1 V/m may cause erroneous measurements at various frquencies. Therefore it is recommended to avoid the use of electrically radiating equipment in close proximity to these measurements.

During the test program the monitor was subjected to international standard and Philips proprietary EMC tests. During most of the testing no anomalies were observed. Some reduced performance was observed with the IEC 801-3 Radiated Immunity and IEC 801-4 Fast Transient/ Bursts Immunity tests.

IEC 801-3 specifies that the product must be subjected to a field of 3V/m over a frequency range of 26 to 1000 MHz with no degradation of performance. At many of the test frequencies over the specified range no anomalies were observed. However increased jitter of SpO_2 values and DECG derived fetal heartrate values was observed at a number of test points. For these test points the radiated field was reduced to the level at which the trace returned to normal. These reduced levels are shown in the following table.

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Parameter	Sensor	Frequency Range	Immunity Level
SpO_2	M1191A M1192A M1194A	52 MHz to 70 MHz	2.3 V/m

IEC 801-4 specified that the product is subjected to high speed pulses up to 1000 V applied to the power cord and all I/O cables. During and after most of the test pulses, no anomalies were observed. However in rare cases the ultrasound channel had been triggered.

Parameter	Sensor	Burst Immunity Level
Ultrasound	M1356A M1358A	600 V
SpO_2 with adapter cable M1940A	M1191A M1192A M1194A	≤ 200V

System Characteristics

The phenomena discussed above are not unique to the monitor but are characteristic of patient monitors in use today. This performance is due to very sensitive high gain front end amplifiers used to process the physiological signals from the patient. Among the many similarly performing monitors already in use by customers, interference from electromagnetic sources is rarely a problem.

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Avoiding Interference

When electromagnetic interference (EMI) is encountered there are a number of things that can be done to mitigate the problem.

1. Eliminate the source. Possible sources of EMI can be turned off or moved away to reduce their strength.
2. Attenuate the coupling. If the coupling path is through the patient cables the interference may be reduced by moving and/or rearranging the cables to a different location of the monitor. If the coupling path is through the power cord, plugging the monitor into a different mains circuit may help.
3. Connect the equipotential terminal of the monitor to the corresponding terminal of your mains installation.
4. Add external attenuators. If EMI becomes an unusually difficult problem, external devices such as an isolation transformer or a transient suppressor may help. An Philips customer engineer can assist you in determining the need for external devices.

ESU, MRI and Defibrillation

Warning
Remove all transducers, patient modules, sensors and accessories before performing electrical surgery, defibrillation, and MRI. High frequency current can flow through the equipment and burn the skin.

The equipment has not been tested with defibrillators.

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Leakage Current

Leakage current can be hazardous to the patient.

Warning
If the monitor is connected directly to other equipment, such as an additional patient monitor, or a second monitor is to be connected directly to the mother, you must carry out all relevant safety tests in accordance with safety standard IEC 60601-1-1.

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2
Overview

About This Guide

This guide tells midwives, nurses and other healthcare professionals how to use the Series 50 XMO fetal/maternal monitor and the Series 50 XM fetal/maternal monitor. It discusses and illustrates all possible features and parameters of both monitors. Your monitor may not have every one of these features and may look slightly different to the monitor shown in the illustrations in this guide. It can be upgraded to incorporate them.

About the Monitors

Both monitors let you observe and record:

- Fetal heart rate (including twins)
- Uterine activity
- Maternal heart rate (MHR) and ECG waveform
- Maternal pulse oximetry (SpO_2)
- Fetal movement profile (FMP)
- Maternal blood pressure, non-invasively.

The Series 50 XMO also allows you to record fetal pulse oximetry ($FSpO_2$).

You can monitor fetal heart rate externally with ultrasound from approximately 20 weeks and with the other parameters internally during labor and delivery.

Not all parameters and features detailed in this manual are available on all monitors.

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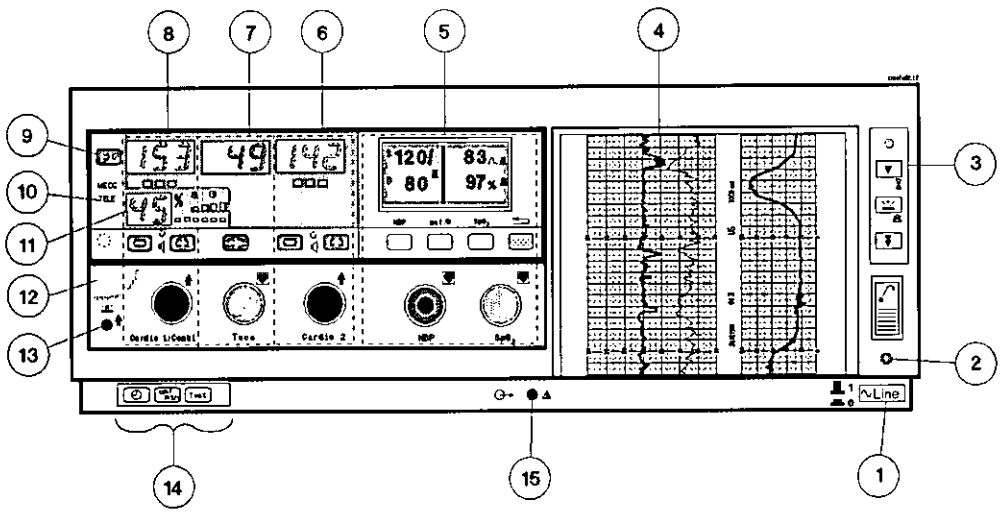
Major Parts and Keys



The display panel can be viewed flat in the monitor, or tilted at an angle.

1. Monitor on/off switch
2. Monitor on/off light
3. Recorder keys
4. Recorder
5. Maternal parameters
6. Cardio 2 channel
7. Toco channel
8. Cardio 1/ combi channel
9. Function key
10. Telemetry indicator
11. $FSpO_2$ parameter
12. Opening recess
13. Socket for remote event marker
14. Setting keys
15. Service socket

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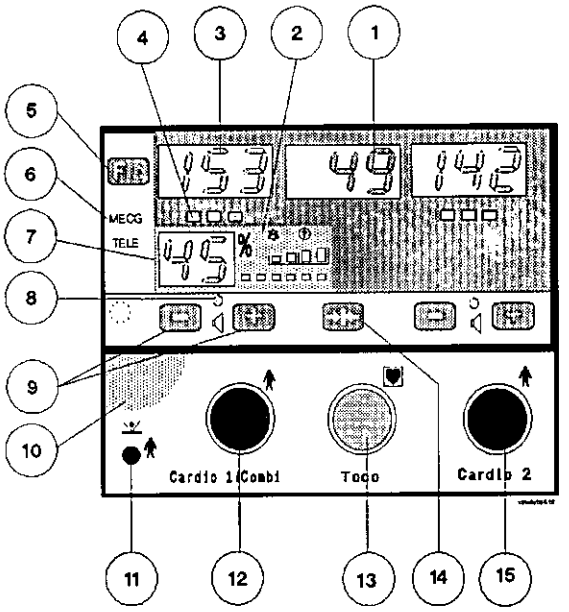
Cardio, Toco and FSpO$_2$ Channels



1. **Toco Display** shows uterine activity.
2. **Fetal SpO$_2$ display** shows fetal pulse indicator, signal quality, alarm status, and cross channel verification plus indicator.
3. **Cardio Display** shows the FHR.
4. **Signal Quality Indicator** shows the quality of heart rate signal detected by the transducer:
   - Green (good).
   - Yellow (fair to potentially poor).
   - Red (unacceptable).
5. Function Key: selects menus for:
   - FMP, twins offset, logic, FHR alert and FSpO$_2$.
   - returns to the normal display.
6. **MECG Indicator** shows when MECG is being measured through this channel. (Indicator location different for Series 50 XM.)

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7. **Fetal SpO_2 display** shows current value of $FSpO_2$.
8. **Speaker Lamp** shows which heartbeat is heard from the loudspeaker.
9. **Volume Keys** set the volume and select the channel to which you are listening. Changes current setting of FMP, twins offset, logic, FHR alert and $FSpO_2$ alarms.
10. **Recess** for use when tilting the display.
11. **Remote Event Marker Socket** for connecting remote event marker (15249A).
12. **Cardio 1/Combi Transducer Socket** for connecting:
    - $FSpO_2$/ECG combined patient module (M1365A).
    - ECG patient module (M1364A).
    - Ultrasound transducer (M1356A).
    - DECG transducer (M1357A).
    - US/MECG Combi transducer (M1358A).
    - MECG transducer (M1359A).
13. **Transducer Socket** for connecting:
    - external Toco transducer (M1355A).
    - IUP transducer (1290C, 13972A, or M1333A).
14. **Toco Baseline Key** zeroes the Toco display and trace to 20 units (when monitoring uterine activity externally) or 0 units (when monitoring uterine activity internally).
15. **Cardio 2 Transducer Socket** for connecting:
    - ECG patient module (M1364A).
    - US transducer (M1356A).
    - DECG transducer (M1357A).
    - MECG transducer (M1359A).

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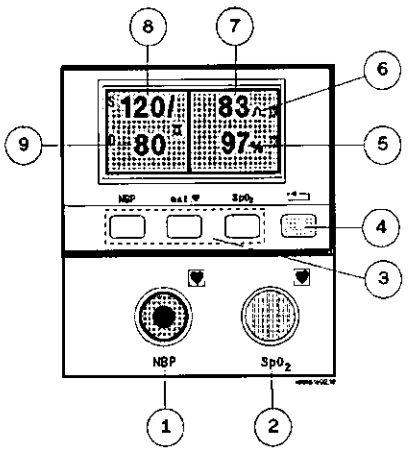
Maternal Parameters



1. **NBP Transducer Socket** for connecting:
   - NBP cuff interconnect tubing (M1599A) and blood pressure cuff.
2. **SpO_2 Transducer Socket** for connecting:
   - SpO_2 transducer (M1940A adapter cable connected to M1191A transducer).
3. **Softkeys** for setting maternal parameters.
   - NBP selects modes and alarm limits for NBP.
   - mat ♥ selects modes and alarm limits for MHR.
   - SpO2 selects modes and alarm limits for SpO_2.
4. **Reset Key** acknowledges alarms and returns monitor from setting mode to maternal parameter display.
5. **SpO_2 Value** indicates the current reading for patient's SpO_2 level.

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6. **Maternal heart/pulse rate icon** indicates measurement source of maternal heart/pulse rate.

   indicates heart rate value comes from MECG.

   indicates pulse rate value comes from SpO_2.

   indicates average pulse rate value comes from NIBP.

7. Maternal Heart Rate shows the current heart/pulse rate.
8. **Systolic Value** shows the value for the systolic parameter of the non-invasive blood pressure measurement.
9. **Diastolic Value** shows the value for the diastolic parameter of the non-invasive blood pressure measurement.

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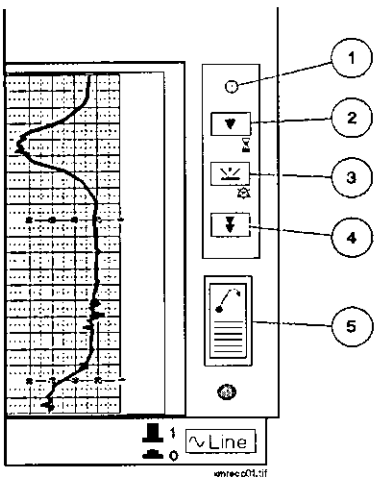
Recorder Keys



1. **Recorder On/Off Light** lights when the recorder is working. Flashes when monitor detects five or fewer pages remaining in the pack, or if the paper runs out.
2. **Recorder On/Off Key** switches recorder on and off. Also starts NST timer (switch off recorder and press for two seconds).
3. **Event Marker Key** records event on paper. Acknowledges all alerts and alarms.
4. **Paper Advance Key** advances paper automatically to the next fold. Tear paper at fold. Never pull paper to advance it.
5. **Paper-Eject Key** unlocks drawer when you press it once. Press a second time and hold when removing paper.

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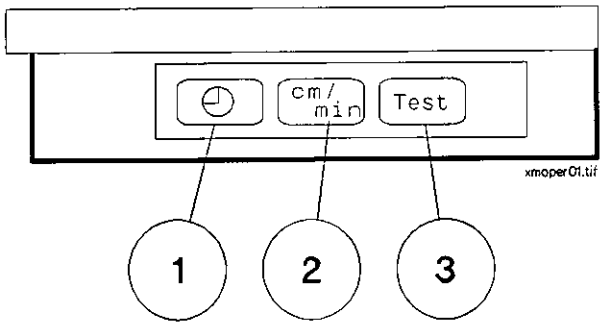
Setting Keys



1. **Time and Date Key** for changing the time and date. Press to show the current time in the Cardio 1/Combi and Toco displays, to cycle through the settings to be changed (hours, minutes, day, month and year) and to return to the normal display.
2. **Paper Speed Key** for changing the paper speed. Press to show the current paper speed in the Cardio 1/Combi display, and to return to the normal display.
3. **Test Key** for starting monitor's self test.

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3
General Information

Introduction

This section contains information common to a number of parameters and discusses the intended use of the monitor. Your monitor may not have all these features.

Features

The Philips Series 50 XMO fetal/maternal monitor and the Philips Series 50 XM fetal/maternal monitor combine advanced fetal monitoring with integrated maternal non-invasive blood pressure, pulse oximetry and ECG measurement. Easy to use, they offer:

- Fetal pulse oximetry ($FSpO_2$) measurement for direct, continuous assessment of fetal oxygenation during labor and delivery.
- Nellcor's fetal oxygen sensors.
- Maternal ECG waveform display.
- Automatic printing of maternal and fetal parameters on the trace.
- Transmission of maternal and fetal parameters to an obstetrical overview system.
- Audible and visual alarms.
- Gross fetal body movements (Fetal Movement Profile) and statistics recording for advance information on fetal well being.
- Twin heart rate trace separation for easier interpretation.
- NST timer and paper-end alarm.
- Watertight transducers.
- Heart rate/pulse rate from maternal ECG, SpO_2 or NIBP.

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The monitors give you flexible monitoring capability for both high-risk patients and those with normal labor and delivery. Both monitors can measure traditional fetal parameters, including twins. Maternal vital signs - blood pressure, pulse oximetry, and maternal ECG - are monitored non-invasively. These are displayed on a tiltable LCD screen. When monitoring maternal ECG, you can display and freeze the waveform on the LCD screen to assist in interpretation. You can also print the waveform on the FHR trace.

The Series 50 XMO also offers measurement of fetal pulse oximetry. Based on proven technology from Nellcor, it monitors fetal oxygen saturation during labour and delivery. This is non-invasive to the fetus and non-traumatic to the mother. Fetal pulse oximetry gives status information about fetal oxygenation to help you interpret non-reassuring fetal heart rate traces.

Suspected Fetal Demise

Be very careful when interpreting a trace if you suspect fetal demise. The maternal heartrate may be atypically high and therefore confused with that of a live fetus. Apparent fetal movement may also be detected by the monitor but this may be a result of maternal movement causing the fetus to move within the amniotic fluid. Please refer to "Cross-Channel Verification" on page 125.

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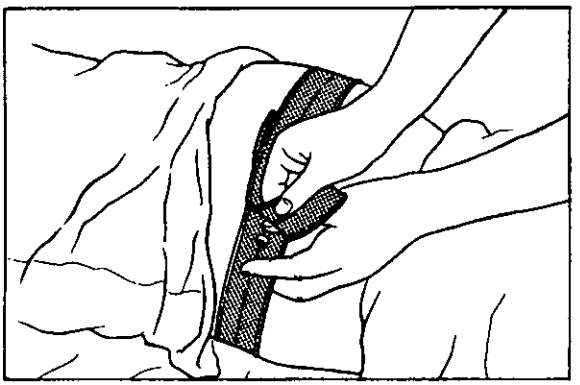
Fastening a Belt

Arrange the belt around the patient until it is tight but still comfortable. Fasten it by pushing the fixing button through the overlapping section of the belt, with the point facing away from the patient. Ensure that the fixing button and the loose ends of the belt are at the patient's side.



You can use more than one belt if, for example you are measuring fetal heart rate using ultrasound and uterine pressure simultaneously.

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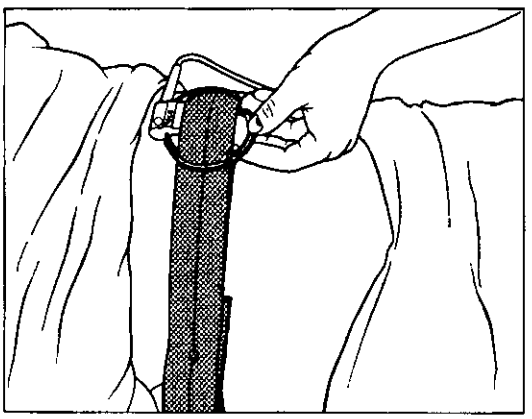
Clipping a Transducer to the Belt

When you have positioned a transducer satisfactorily, you can clip it to the belt.



Alternatively, you can affix a button to the transducer and use this to attach the transducer to the abdominal belt. See the Installation Note that comes with the Transducer Knob Adapter for assembly instructions.

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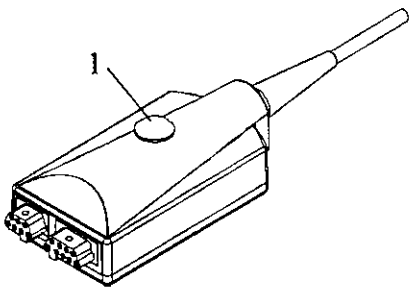
Attaching a Patient Module to the Belt

You can attach a patient module to the belt by sliding the patient module under the belt and pushing the fixing knob (1) on the patient module through one of the holes in the belt.



Connecting a Transducer or Patient Module to the Monitor

When you connect a transducer or patient module to either the Cardio 1/ Combi socket, the Toco socket or the Cardio 2 socket, the three dashes in the display go out. The signal quality light for the heart rate display turns red (because the transducer is not yet receiving a good signal from the patient). The monitoring mode is printed on the paper, and repeated every three to four pages.

If you are measuring:

- Uterine activity, the display jumps to 20 (the Toco baseline).
- Intrauterine pressure, the display shows 0.

Warning
NEVER immerse a transducer in liquid when it is connected to the fetal monitor.

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Signal Quality

During monitoring, if the signal quality indicator fluctuates between red, yellow and green, it does not necessarily means that the transducer needs repositioning. The fluctuation may be caused by fetal movement. Allow time for the signal to stabilize before deciding whether to reposition the transducer (ultrasound) or apply a new electrode (ECG). A trace is possible when the indicator is yellow, but for the best trace it should be continuously green.

Note—**Disconnect NON-USED ultrasound transducer, as continuous mechanical influence of the transducer may result in an artificial trace.**

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Input Channels at a Glance

This table indicates which combination of transducers and patient modules you can use in the Cardio input sockets.

Cardio1/Combi	Cardio 2	Measurements
US (M1356A)	US (M1356A or M1358A)	Dual ultrasound.
	DECG (M1357A or M1364A)	Single ultrasound and fetal ECG.
FSpO2/ECG combined patient module (M1365A): with DECG adapter cable (M1362A or M1362B)	US (M1356A)	Fetal SpO2 with fetal ECG and single ultrasound.
	MECG (M1364A or M1359A)	Fetal SpO2 with fetal ECG and maternal ECG.
with MECG adapter cable (M1363A)	US (M1356A)	Fetal SpO2 with maternal ECG and single ultrasound.
ECG only patient module (M1364A): with MECG adapter cable (M1363A)	US (M1356A)	Maternal ECG and single ultrasound.
	DECG (M1357A or M1364A) with DECG adapter cable (M1362A or M1362B)	Maternal ECG and fetal ECG.
DECG adapter cable (M1362A or M1362B)	US (M1356A)	Fetal ECG and single ultrasound.
	MECG (M1359A or M1364A) with MECG adapter cable (M1363A)	Fetal ECG and maternal ECG.
DECG (M1357A)	US (M1356A)	Fetal ECG and single ultrasound.
MECG (M1359A)	US (M1356A)	Maternal ECG and single ultrasound.
	DECG (M1357A or M1364A or M1365A)	Maternal ECG and fetal ECG.
US/MECG (M1358A)	DECG (M1357A or M1364A) with DECG adapter cable (M1362A or M1362B)	Single ultrasound with maternal ECG and fetal ECG.
	US (M1356A)	Single ultrasound with maternal ECG and second ultrasound.

You can use the combined US/MECG transducer (M1358A) in the Cardio 2 socket to measure ultrasound only. However if you want to use the combination of US/MECG, you must connect it to the Cardio 1/ Combi socket.

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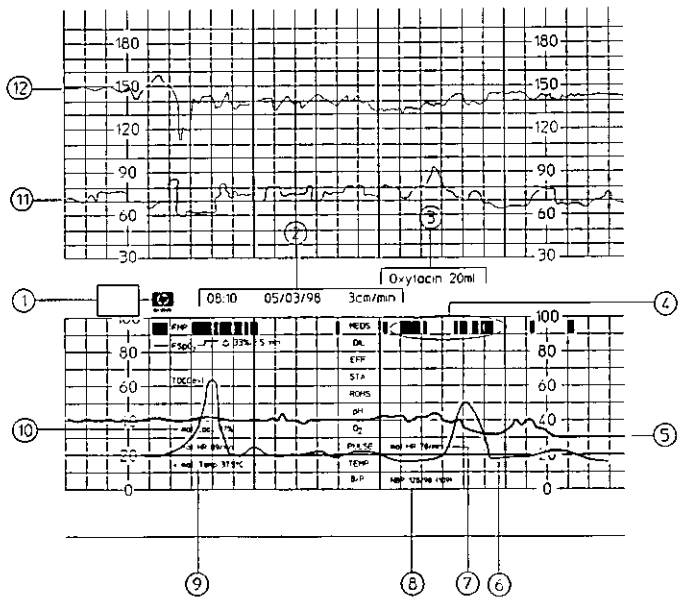
Example Trace



1. Manufacturer's logo.
2. Time, date and paper speed.
3. Barcode notes.
4. Fetal movement profile.
5. Fetal blood oxygen saturation level ($FSpO_2$) trace.
6. Uterine activity trace.
7. Maternal heart rate (78 bpm) (either $Sp0_2$ or NBP pulse rate).
8. Maternal blood pressure:
   - Systolic blood pressure is 128 mmHg.
   - Diastolic blood pressure is 98 mmHg.
   - Mean arterial pressure is 109 mmHg.
9. Maternal temperature (37.5°C). An asterisk * marks measurements from external devices.
10. Maternal blood oxygen saturation level (97%).
11. Maternal heart rate trace (either MECG or $Sp0_2$ pulse).
12. Fetal heart rate from Ultrasound or DECG.

Your trace may not look exactly like this - the actual appearance depends on which options you have installed, and which features are in use.

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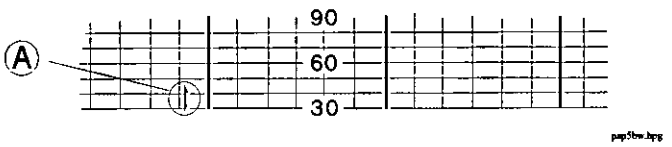
Marking an Event

Use the event marker key or the remote event marker to record significant events on the paper (for example, when pain medication is administered or when the mother changes position). To mark an event on the paper:

- Press the event marker key on the monitor or
- Press the button on the remote event marker.

A small arrow (A) prints on the FHR Scale. The arrow starts with the peak to show the exact time when the key or button is pressed. If the key or button is not released, a black bar is printed on the paper. The width of the bar corresponds to the length of time the key or button is pressed.



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Marking an Event

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4
Getting Started

Introduction

This chapter tells you how to prepare your monitor to begin monitoring your first patient. You should:

- Ensure that your monitor is set for the correct voltage for your country
- Check the time, date, and paper speed
- Load paper into the recorder.

Before Connecting Power

Operate the monitor from an ac (alternating current) power source of

- 100 V (± 10%)
- 120 V (± 10%)
- 220 V (± 10%)
- 240 V (± 10%)

and 50 to 60 Hz (± 5%). The maximum power consumption is 60 VA.

Before connecting power, ensure that the voltage selector (A) on the monitor's rear panel shows the correct setting for your country.

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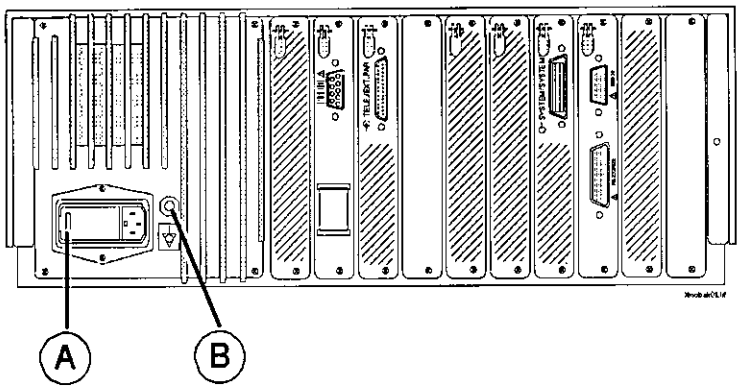
To use the monitor with other equipment in an operating room environment, connect the equipotential grounding point (B) to earth potential. Use the grounding cable supplied with the monitor.



Switching On the Monitor

Connect the power cord to the rear of the monitor.

Press Line~ to switch on the monitor. When you switch on:

- The monitor on/off light and the displays come on.
- There are two clicks from the loudspeaker.
- The monitor carries out a self test. For details of the self test see page 150. The error messages that may be displayed are given in Chapter 19, "Troubleshooting".
- The maternal display screen shows an egg-timer symbol for a few seconds and then its alarm parameters screen.
- All parameter displays show two or three dashes, indicating there is no transducer or patient module plugged in.
- The maternal display lights up, showing the default alarm parameters.

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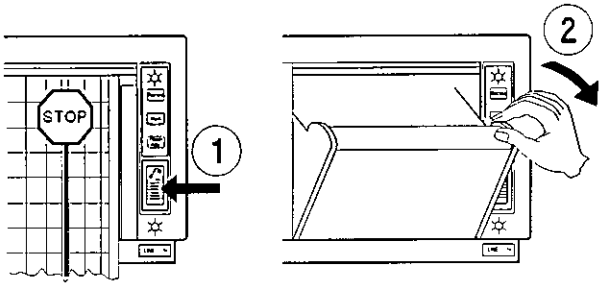
Loading Paper

To load a new pack of paper:

a. Switch off the recorder.



rep5_bw.bpg

b. Push the paper-eject key (1) to unlock the drawer. Make sure that the drawer is fully open (2).
c. Push and hold the paper-eject key and lift out any remaining paper.
d. Place the new paper in the tray with the bottom side down. The bottom side is indicated by the word STOP on the final page of the new pack.
e. Unfold the top page of the pack.

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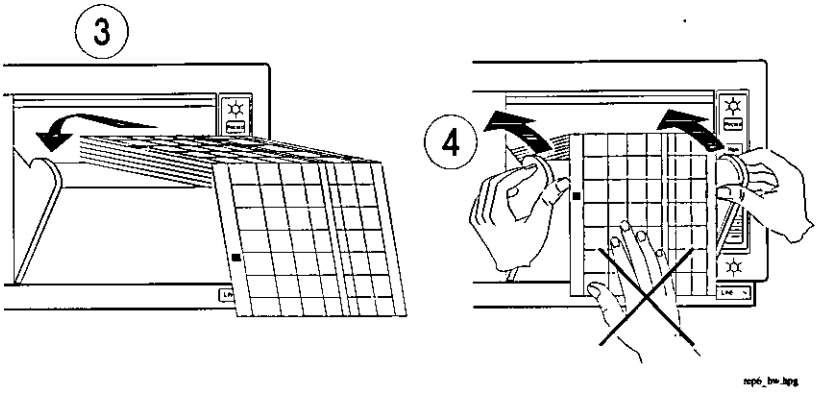
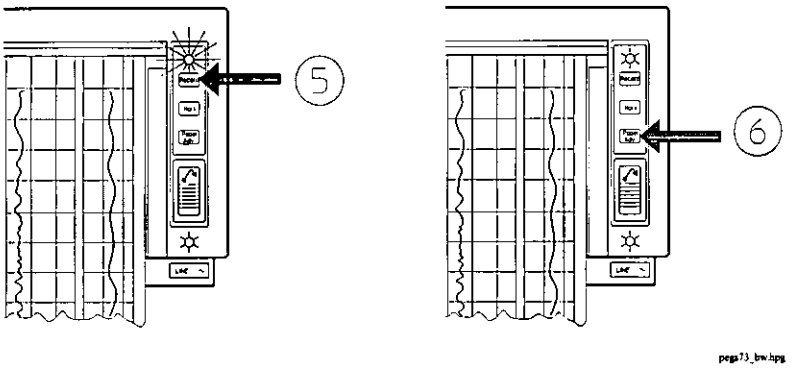
f. Position the uterine activity scale on the right.



g. Slide the pack into the tray (3).
h. Push the drawer back until it "clicks" closed. Don't push on the paper when closing the drawer (4).



i. Press the recorder on/off key(5) to switch on the recorder. If the recorder on/off light flashes after the paper is loaded and the recorder is switched on, the drawer is not closed properly.
j. Press and release the paper advance key (6) to advance the paper automatically to the next fold. Check that the paper feeds straight.

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Caution

Using recorder paper that is not approved by Philips can damage the monitor. This type of damage is not covered by warranty.

If you have difficulty removing the paper, ensure that you have pushed the paper-eject key twice. The first push releases the paper drawer. The second push engages the paper eject mechanism which pushes the remaining paper up the drawer towards you, making it easy to remove.

Switching on the Recorder

Press the recorder on/off key to switch on the recorder if necessary. When you switch on:

- The recorder on/off light comes on.
- The paper advances quickly for 2 cm and then returns to the set speed.
- The time, date and paper speed are printed.
- The current monitoring modes (if any transducers are connected to the monitor) are printed.

The monitor prints the time, date, paper speed and monitoring modes when first switched on, every ten minutes after, and if the monitoring modes change.

The recorder on/off light flashes when the monitor detects that there are five pages or fewer remaining in the pack. If you switch on the recorder or press the paper advance key when there are fewer than five pages remaining, it may take two pages before the recorder on/off light flashes. Load a new pack as soon as possible.

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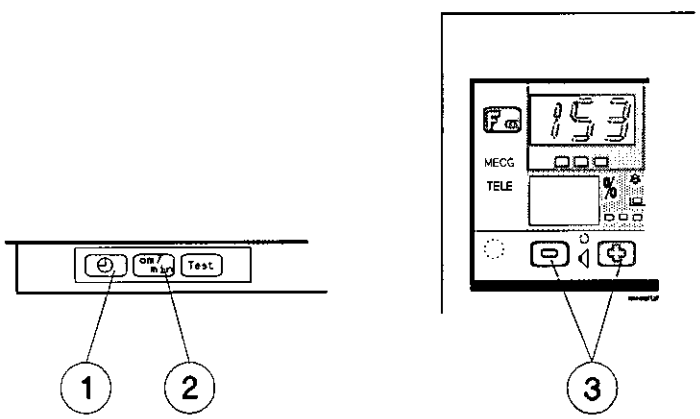
Displaying the Time and Date

The date and time are printed on the trace. You can choose from a variety of standard date and time formats, such as 12 hour format or 24 hour format, US or European date format. If you have a barcode reader you can change the time and date display format by scanning the desired format from the barcode sheet. If you do not have a barcode reader, you can set the desired format using a service setting. See the Installation and Service Guide for this monitor for instructions.

Setting the Time and Date

Use the following keys to view and change the time and date:



1. **Clock key** displays the time.
2. **Paper speed** displays the paper speed.
3. **Volume keys** change the time, date and paper speed.

After you make changes and return to the normal display, the new time and date are set, and the time, date and paper speed are printed on the paper immediately and then every 10 minutes. You return to the normal display automatically if you don't press any key for a few seconds.

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To set the time and date:

1. Press and release [clock] to display the current time. The Cardio 1/ Combi display flashes to show that the hour can be changed.
2. Press [−] or [+] to set the hour. Press and hold the keys to change the setting more quickly.
3. Press and release [clock] and the Toco display flashes to show that the minutes can be changed.
4. Press [−] or [+] to set the minutes.
5. Repeat the procedure:
   a. To set the month (in North America) or the day (in other countries).
   b. To set the day (in North America) or the month (in other countries).
   c. To set the year.
6. Press and release [clock] to return to the normal display.

Choosing Paper Speed

You can choose a paper speed of 1, 2 or 3 centimeters per minute (cm/min). The default for North America is 3 cm/min; the default for other countries is 2 cm/min.

The ACOG technical bulletin on FHR monitoring states that "*accurate pattern recognition is difficult if not impossible at 1 cm/min and that 1 cm/min is only recommended for more economic screening. When FHR abnormalities arise, the faster paper speeds will enhance FHR pattern recognition*".

Additionally, because a change in paper speed results in a change in the appearance of an FHR trace, you are advised to ensure ALL monitors in your institution are set at the same speed.

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Setting the Paper Speed

Use the paper speed key to display the current paper speed and to return to the normal display. You also return to the normal display automatically if you don't press any key for a few seconds. Use the volume keys to change the speed. When you return to the normal display, the new paper speed is set, and the time, date, speed and monitoring modes are printed on the paper.

To set the paper speed:

1. Press and release to display the current speed.
2. Press or to set the speed.
3. Press and release to return to the normal display.

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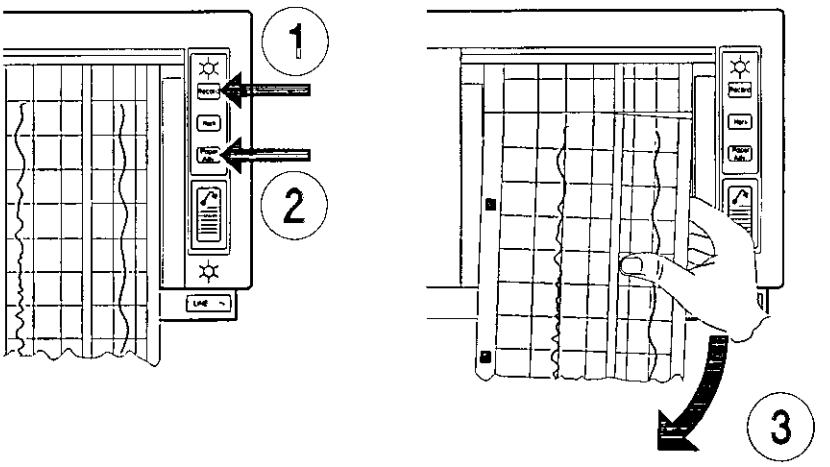
Switching Off After Monitoring

1. Switch off the recorder (1).
2. Press and release the paper advance key (2) to advance the paper automatically to the next fold.
3. While you wait for the paper to advance to the next fold, remove the transducers from the patient. Use a soft tissue to remove any gel from the transducers.
4. Tear off the paper at the fold (3). Don't pull on the paper to advance it, and tear off the paper at the fold only.
5. Switch off the monitor.



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Switching Off After Monitoring

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5
Monitoring FHR and FMP Using Ultrasound

Introduction

This chapter describes how to monitor a single fetal heart rate using ultrasound. Monitoring using ultrasound is recommended from the 25th week of gestation for non-stress or normal routine fetal monitoring. The monitor can also detect fetal movements and display the resulting fetal movement profile (FMP) on the trace.

Warning
NEVER immerse the ultrasound transducer in liquid when it is connected to the monitor.

If you simultaneously monitor a single FHR using both ultrasound and DECG, the ultrasound trace is delayed by approximately two to three beats per minute.

Performing ultrasound imaging or Doppler flow measurements together with the ultrasound fetal monitoring may cause false FHR readings, and the trace recording may deteriorate.

What You Need

- Ultrasound transducer
- Gel
- Transducer belt and button

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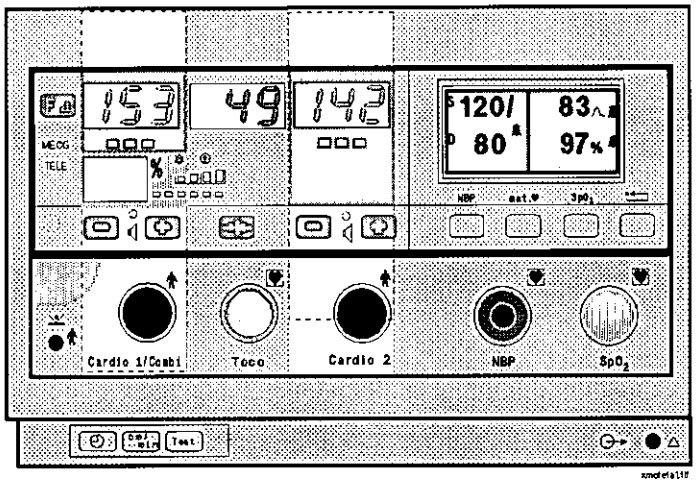
Getting Started

1. Fasten the belt around the patient.
2. Switch on the monitor and the recorder.
3. Connect the transducer to either the Cardio 1/Combi socket, or to the Cardio 2 socket.



4. Find the fetal heart position by palpation, auscultation or ultrasound imaging.

Caution

Using ultrasound gel that is not approved by Philips may reduce signal quality and may damage the transducer. This type of damage is not covered by warranty.

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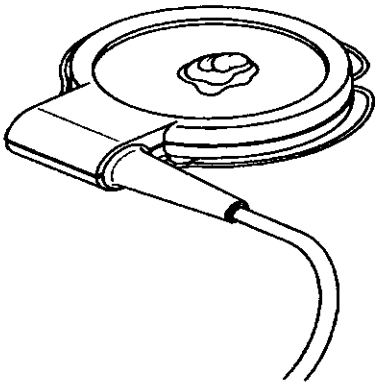
5. Apply a small amount of ultrasound gel in a thin layer to the transducer.



6. Apply the transducer to the patient, working it in a circular motion to ensure the gel layer makes good contact.
7. When you have a good signal, clip the transducer in position on the belt.

Note—**Disconnect NON-USED ultrasound transducers as the continuous mechanical influence of the transducer will result in an artificial trace.**

Warning

Periodically compare the mother's pulse with the signal coming from the monitor's loudspeaker to ensure that you are monitoring fetal heart rate. Do not mistake a doubled maternal heart rate for FHR. When you monitor maternal heart rate simultaneously with FHR, cross-channel verification alerting warns you if maternal and fetal heart rates coincide.

Please refer to "Cross-Channel Verification" on page 125.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118. 294

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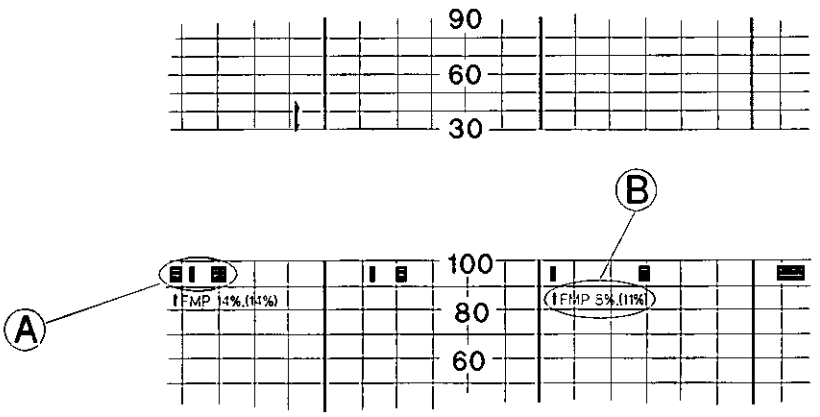
Fetal Movement Profile

The monitor can detect fetal movements via an ultrasound transducer plugged into the Cardio 1/Combi socket. The resulting fetal movement profile (FMP) appears as "activity blocks" (A) along the top of the Toco Scale, the length of each block showing the duration of the activity.

FMP Statistics

FMP Statistics (B) are printed below the activity blocks every 10 minutes.



The first value shows the percentage of detected fetal movements in the previous 10 minutes, and the value in parentheses shows the percentage of detected fetal movements since the recorder was switched on. During the first 10 minutes of monitoring, the values will be identical.

If you plug an ultrasound transducer into the Cardio 1/Combi socket, FMP statistics start again from zero.

The FMP output activates after about half a minute of valid heart rate signals (green or yellow signal quality indicator) to minimize transducer positioning artifact. ↑FMP is printed on the paper to mark the starting point of the FMP statistic.

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

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Note—**The transducer detects gross fetal body movements. Eye movements are not detected and movement of the feet and hands may not be detected. Positioning or repositioning the transducer is recorded as fetal movement. Maternal movement, excessive fetal breathing or fetal hiccups may also be recorded as fetal movement. You can mark this artifact on the paper using either the remote event marker or the event marker key. Ignore these movements when you interpret the FMP.**

When monitoring twins, remember that movements recorded for twin 1 may also be caused by movement of twin 2.

Switching FMP Off and On

Switching the monitor on also switches FMP on, unless M1310A fetal telemetry is connected. You can use either the function key or the optional barcode reader to switch FMP off and on.

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

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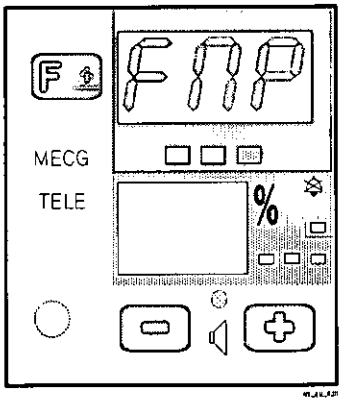
Using Keys

You must connect an ultrasound transducer to the Cardio 1/Combi socket before you can change the FMP setting.



1. Press F.⚠ repeatedly until the monitor displays FMP .

The Signal Quality Indicator shows:

RED if FMP is OFF.
GREEN if FMP is ON.

2. Press − or + to change the setting.
3. Press and release F.⚠ to return to the normal display.
4. FMP is printed on the paper.

You return to the normal display automatically if you don't press any key for a few seconds.

Using the Barcode Reader

Enter FMP Off or FMP On from the barcode sheet.

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

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Troubleshooting

Problem	Possible Causes	Solutions
Erratic trace. Erratic display.	Fetal arrhythmia. Obese patient. Transducer wrongly positioned. Belt loose. Too much gel. Very active fetus. Maternal movement. Insufficient gel.	None. None. Reposition transducer until signal quality indicator is green. Tighten belt. Remove excess. None. Relax the patient. Use recommended amount.
Signal quality indicator is red continuously.	Transducer wrongly positioned. FHR less than 50 bpm.	Reposition transducer until signal quality indicator is green. None.
Questionable FHR.	Recording MHR by mistake. Recording periodic signals when the transducer is not applied to the patient.	Reposition transducer.
	FHR exceeds 300 bpm.	FHR is half-counted (for example 320 bpm is recorded as 160 bpm).
FHR not recorded.	FHR is less than 50 bmp or over 300.	None.
Light or no trace.	Wrong paper or dirty printhead.	Use recommended paper or clean printhead.
End of paper noted when pack not finished.	Bad paper feed or wrong paper.	Check paper feed and use recommended paper.
Error message is displayed.		See Chapter 19, "Troubleshooting" for a table of error messages, their causes and their solutions.
If you suspect the transducer.		Carry out the Parameter Test as described on page 152.
If you suspect the recorder or display.		Carry out the Quick Test as described on page 151.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118. 248

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Troubleshooting

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

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6
Monitoring FHR Using DECG

Introduction

This chapter describes how to monitor a single fetal heart rate using a spiral Fetal Scalp Electrode.

Because the tip of the electrode penetrates the fetal epidermis, the possibility of trauma, hemorrhage and infection exists. Use the electrode only under aseptic conditions. Do not apply the electrode:

- To the fetal face, to the fontanels, or to the genitalia
- When placenta previa is present
- When you cannot identify the portion of the fetal body where application is contemplated
- Before the membranes are ruptured
- If genital infection exists
- When the patient is less than two centimeters dilated
- When the fetal station is less than minus two.

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

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What You Need

- If you are measuring fetal DECG using the traditional open-wire method with a legplate transducer:
  - DECG legplate transducer (M1357A)
  - Transducer leg belt and button
  - Open-wire Fetal Scalp Electrode (M15133A/M15133C).
- If you are measuring fetal DECG using the traditional open-wire method with a patient module:
  - Either ECG only patient module (M1364A) or $FSpO_2$/ECG combined patient module (M1365A)[1]
  - Adapter cable (M1362A)
  - Pre-gelled electrode (40493E)
  - Open-wire Fetal Scalp Electrode (M15133A/M15133C).
- If you are measuring fetal DECG using the DECG Adapter Cable M1362B with a legplate transducer:
  - DECG legplate transducer (M1357A)
  - DECG adapter (M1347A)
  - DECG Adapter Cable (M1362B)
  - Transducer leg belt and button
  - Pre-gelled Pad Electrode (M1349A)
  - Fetal Scalp Electrode (15133E/15133D).
- If you are measuring fetal DECG using the DECG Adapter Cable M1362B with a patient module:
  - Either ECG only patient module (M1364A) or $FSpO_2$/ECG combined patient module (M1365A)[1]
  - DECG Adapter Cable (M1362B)
  - Pre-gelled Pad Electrode (M1349A)
  - Fetal Scalp Electrode (15133E/15133D).

1. The $FSpO_2$/ECG combined patient module (M1365A) can be used only with the Series 50 XMO Fetal Monitor (M1350C).

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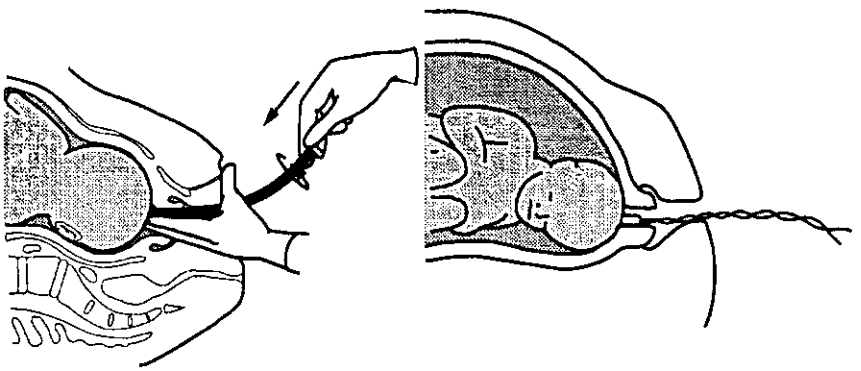
Getting Started

Prepare as you would for a routine sterile vaginal examination. Ensure that the fetus is in a position to be monitored by DECG. Attach the electrode to the fetus as described in the instructions that come with the Fetal Scalp Electrode.



Attaching the Fetal Scalp Electrode **Fetal Scalp Electrode Attached**

Warning
Do not insert the fetal scalp electrode wires into the AC mains socket.

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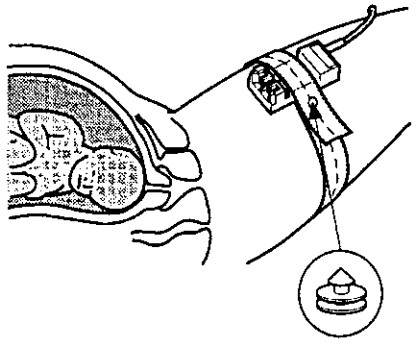
Using the Traditional Open-wire Method to Monitor DECG
(applicable to Fetal Scalp Electrode 15133A and 15133C)

With DECG legplate M1357A

To monitor fetal DECG using the traditional open-wire method and a DECG legplate M1357A, follow these instructions.

1. Fasten the belt around the patient's upper thigh. Ensure that the belt is correctly attached to prevent tension in the cable from pulling on the Fetal Scalp Electrode and injuring the fetus.

2. Slide the transducer under the belt, pointing the connectors towards the abdomen. To get the best signal the transducer must have good contact to the mother's skin. Do not apply Redux creme or any other conductive gel to the silver plate on the bottom of the DECG transducer.



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

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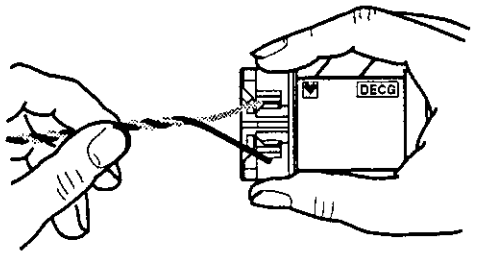
3. Connect the Fetal Scalp Electrode wires to the DECG transducer.

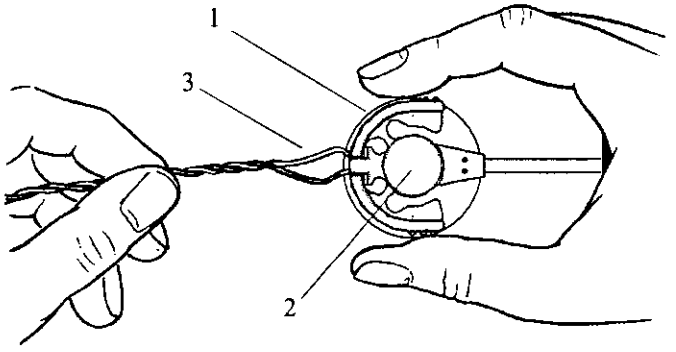


4. You are now ready to begin monitoring DECG: see the section "Monitoring DECG" for your next step.

With Patient Module M1364A or M1365A

To monitor fetal DECG using the traditional open-wire method and either an ECG-only patient module (M1364A), or an $FSpO_2$/ECG combined patient module (M1365A), follow these instructions.

1. Fix the DECG cable clip (2) to a pre-gelled electrode 40493E (1).
2. Connect the Fetal Scalp Electrode wires (3) to the DECG cable clip as shown below:



3. Peel the backing from the electrode (40493E) and affix it to the mother's thigh. A good contact between the electrode and the mother's skin will improve the FHR signal. To get the best signal, ensure that the skin is clean and dry before attaching the electrode.

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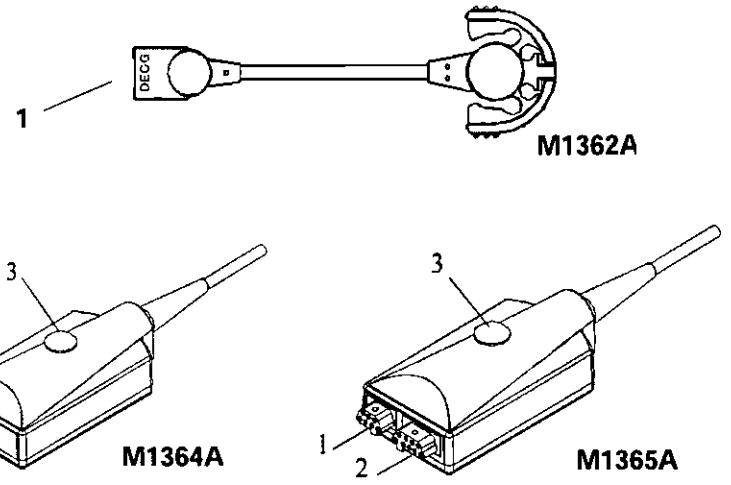
Ensure that the electrode is correctly positioned to prevent tension in the cable from pulling on the Fetal Scalp Electrode and injuring the fetus.

4. Attach the pink connector (1) on the DECG Cable (M1362A) to the ECG pink connector (1) on the patient module (M1364A/ M1365A).



5. Position the patient module under the abdominal transducer belt wherever it is comfortable for the mother, securing it to the belt using the fixing knob (3).

6. You are now ready to begin monitoring DECG: see the section "Monitoring DECG" below for your next step.

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

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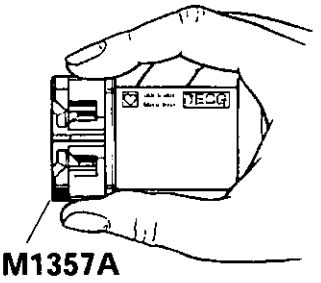
Using the DECG Adapter Cable M1362B to Monitor DECG (Applicable to Fetal Scalp Electrode 15133D/15133E)

With DECG Legplate M1357A

To monitor fetal DECG using the DECG Adapter Cable (M1362B) and a DECG legplate transducer (M1357A), follow these instructions.

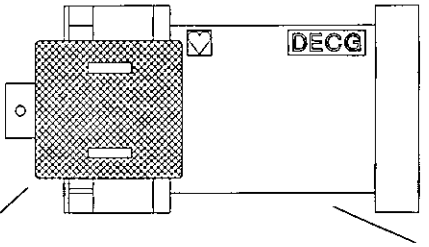
1. Connect the DECG adapter (M1347A) to the DECG legplate transducer (M1357A):

   - With the finger and thumb of one hand, press in the spring clips on the legplate.



M1357A

   - Fit the DECG adapter (M1347A) onto the legplate and release the spring clips to lock the adapter into place.



M1347A M1357A

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

(b)

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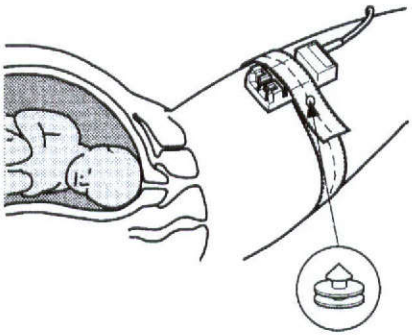
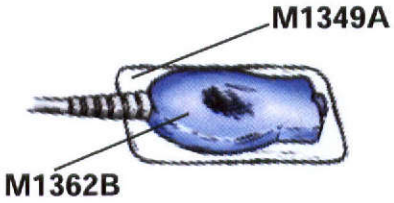
2. Secure the legplate transducer under the abdominal belt or under the leg belt. To get the best signal the transducer must have good contact to the mother's skin. Do not apply Redux creme or any other conductive gel to the silver plate on the bottom of the DECG transducer.



3. Attach a pre-gelled electrode (M1349A) to the DECG Adapter Cable (M1362B).



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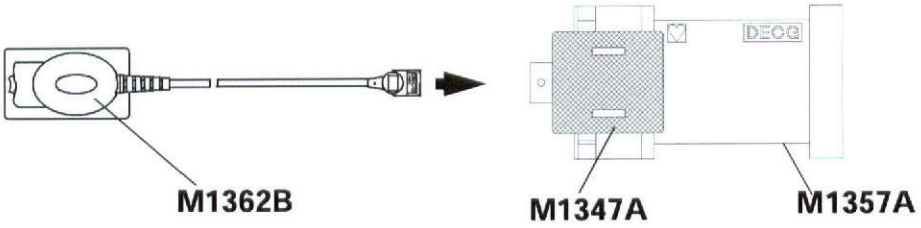
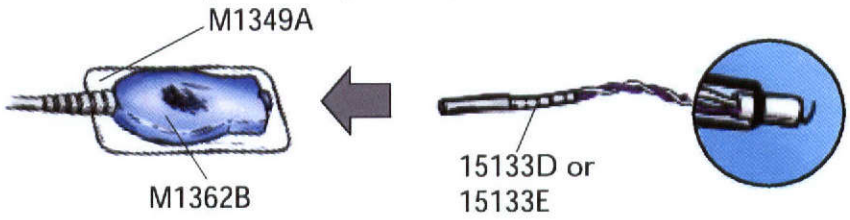
4. Connect the DECG Adapter Cable (M1362B) to the DECG Adapter (M1347A).



5. Connect the Fetal Scalp Electrode (15133D/15133E) to the DECG Adapter Cable (M1362B).



6. Peel the backing from the electrode (M1349A) and affix it to the mother's thigh. Make sure that the skin is clean and dry before attaching the electrode. Ensure that the electrode is correctly positioned to prevent tension in the cable from pulling on the Fetal Scalp Electrode and injuring the fetus.
7. You are now ready to begin monitoring DECG: see the section "Monitoring DECG" for your next step.

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

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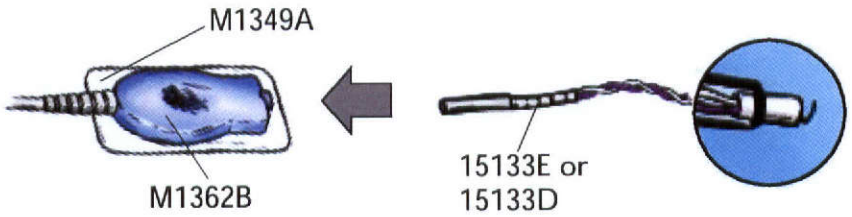
With Patient Module M1364A or M1365A

To monitor fetal DECG using the DECG Adapter Cable M1362B and either an ECG-only patient module (M1364A) or an $FSpO_2$/ECG combined patient module (M1365A), follow these instructions.

1. Attach a pre-gelled electrode (M1349A) to the DECG Adapter Cable (M1362B).



2. Connect the Fetal Scalp Electrode (15133E/15133D) to the DECG Adapter Cable (M1362B).

3. Peel the backing from the electrode (M1349A) and affix it to the mother's thigh. A good contact between the electrode and the mother's skin will improve the FHR signal. To get the best signal, ensure that the skin is clean and dry before attaching the electrode. Ensure that the electrode is correctly positioned to prevent tension in the cable from pulling on the Fetal Scalp Electrode and injuring the fetus.

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

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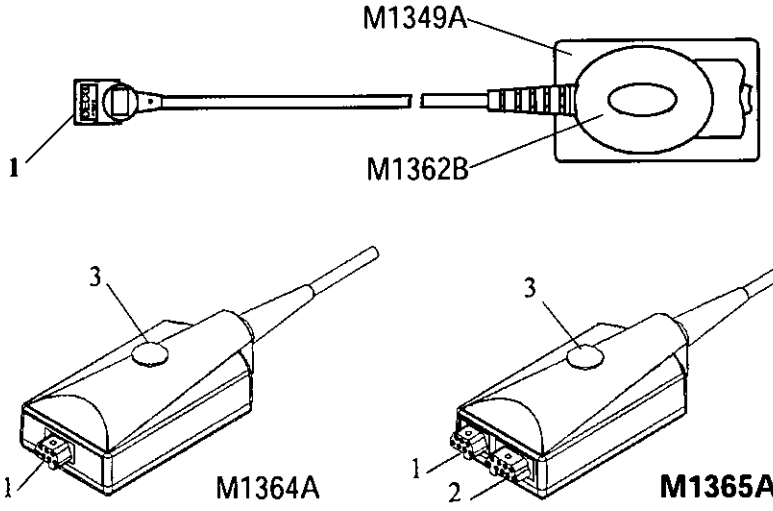
4. Attach the pink connector (1) on the DECG Adapter Cable (M1362B) to the ECG pink connector (1) on the patient module (M1364A/M1365A).



5. Fix the patient module to the patient's belt using the fixing knob (2).

6. You are now ready to begin monitoring DECG: see the section "Monitoring DECG" for your next step.

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

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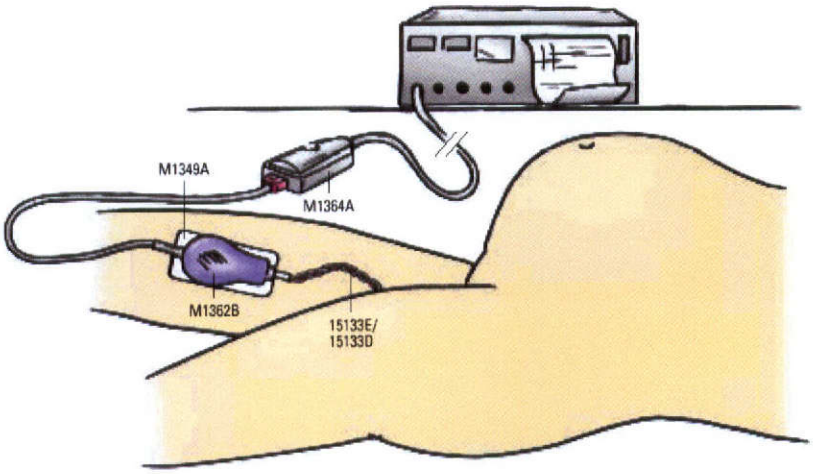

Typical Configuration Showing Fetal Scalp Electrode 15133E/D, DECG Adapter Cable M1362B, and Patient Module M1364A

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

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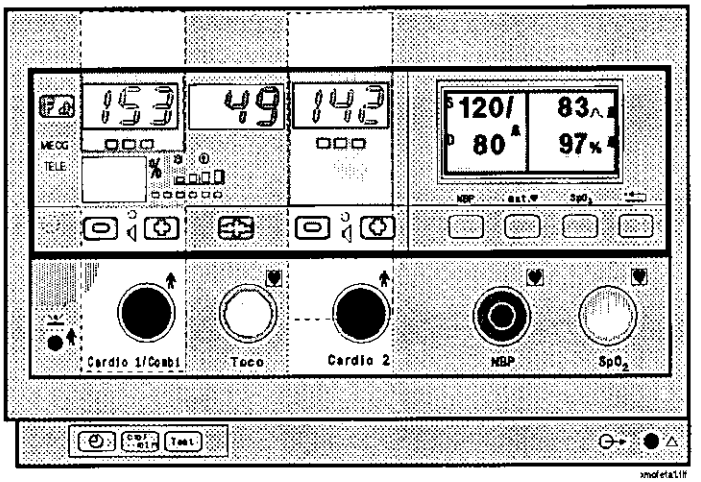
Monitoring DECG

1. Switch on the monitor and the recorder.
2. Connect the legplate, or patient module, to the monitor. To simultaneously measure fetal pulse oximetry and DECG you must connect the patient module to the Cardio 1/Combi socket. If you are measuring DECG only you may use either the Cardio 1/ Combi socket or the Cardio 2 socket.



3. Check the arrhythmia logic setting. A red Signal Quality Indicator indicates logic is OFF. Green indicates logic is ON. You can change the setting by pressing F.⚠ until the monitor displays LOG. Use + and − to change the color of the signal quality indicator. You must have a DECG transducer connected to either Cardio 1/Combi socket or the Cardio 2 socket.

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

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Warning
Periodically compare the mother's pulse with the signal coming from the monitor's loudspeaker to ensure that you are monitoring fetal heart rate. Do not mistake a high maternal heart rate for FHR. When you monitor maternal heart rate simultaneously with FHR, cross-channel verification alerting warns you if maternal and fetal heart rates coincide.

Why use Arrhythmia Logic?

When arrhythmia logic is on, instantaneous heart rate changes of 28 bpm or more are not recorded. Recording resumes when successive beats again fall within predetermined limits. This avoids recording artifacts but does not show genuine arrhythmia. When logic is off, all recorded fetal heartbeats are shown. If you suspect fetal arrhythmia, switch logic OFF. Unless you suspect fetal arrhythmia, we recommend that you use the default setting, with logic on, as this makes the trace easier to read and interpret.

After Monitoring

Turn the spiral electrode counter-clockwise to remove it, either with the presenting part crowning and the application site visible, or after delivery. Never pull it off or reuse it.

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

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Troubleshooting

Problem	Possible Causes	Solutions
Erratic trace. Erratic display.	No ECG signal. Poor contact between the reference electrode and the mother. Patient module is not securely fixed.	Use a new spiral electrode. Attach the patient module to the patient's belt with the fixing button.
Signal quality indicator is red continuously.	Fetal arrhythmia.	Be sure that logic is off.
nop displayed.	Electrode leads not properly connected to cable block.	Check electrode lead connection.
	No contact or poor contact between reference electrode and mother.	Use a new spiral electrode.
	Spiral electrode detached.	Reattach the spiral electrode.
An error message is displayed.		See Chapter 19, "Troubleshooting."
If you suspect the signal from the transducer.		Carry out the Parameter Test as described on page 152.
If you suspect the recorder or display.		Carry out the Quick Test as described on page 151.

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

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Heart Rate Out of Limits

A questionable heart rate is rare but these are some of the possible causes.

Problem	Possible Cause
Questionable heart rate.	**FHR less than 30 bpm** FHR is not recorded and the signal quality indicator is red.
	FHR between 30 and 50 bpm 50-210 bpm paper records a straight line at 50 bpm. 30-240 bpm paper records the FHR.
	FHR is between 210 and 240 bpm 50-210 bpm paper records a straight line at 210 until 240 bpm is exceeded. 30-240 bpm paper records the FHR up to 240 bpm.
	FHR exceeds 240 bpm FHR is not recorded and the signal quality indicator is red.

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

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7
Monitoring Twin FHRs

Introduction

You can monitor twins throughout labor and delivery after rupture of the membranes by monitoring one twin externally using ultrasound and the other internally using DECG.

If you want to monitor twins externally, you can use two ultrasound transducers, or one ultrasound transducer and a US/MECG transducer. The external method is possible only if your monitor has dual ultrasound capability.

Refer to the appropriate preceding chapters for contra-indications and other information about the measurement methods you have chosen.

Things to Remember During Monitoring

When monitoring you should:

- Make sure that you are recording two different heart rates. The cross-channel verification feature alerts you if the two heart rates coincide (that is, if both transducers are recording the same FHR). If this happens, reposition an ultrasound transducer until you detect the second FHR.
- Note that the trace recorded for the Cardio 1/Combi channel is thicker (darker) than that recorded for the Cardio 2 channel. This ensures that the two heart rates are easily distinguishable.
- Remember that only one fetal heartbeat can be heard from the loudspeaker at any time. To hear the other fetal heartbeat, press either of the volume keys for the channel monitoring that fetus.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118. 316

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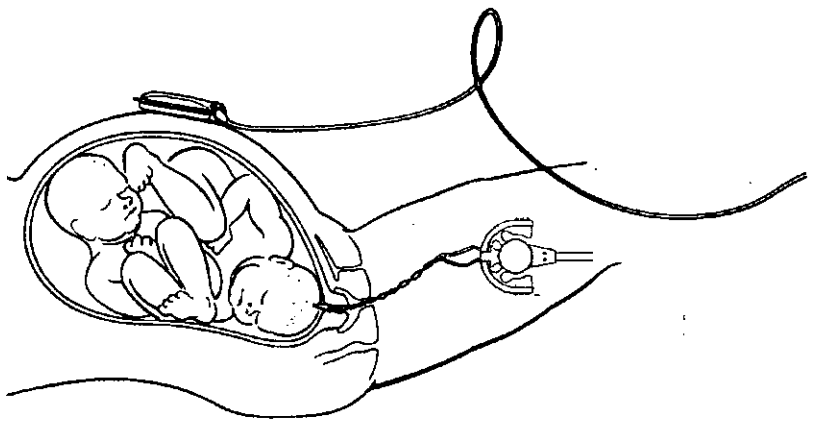
- Monitor maternal heart rate, especially during later stages of labor, to avoid mistaking maternal heart rate for FHR. Cross-channel verification then alerts you if this occurs.

Monitoring Internally

Monitor one twin using the procedures described in Chapter 5, "Monitoring FHR and FMP Using Ultrasound". Monitor the second twin using the procedures described in Chapter 6, "Monitoring FHR Using DECG".



pop43fin.gif

Monitoring Externally

Monitor both twins using the procedures described in Chapter 5, "Monitoring FHR and FMP Using Ultrasound". You will need either two ultrasound transducers, or one ultrasound transducer and a US/MECG combi transducer. If you are using two US transducers, removing the white clips from both ends of one transducer will help you

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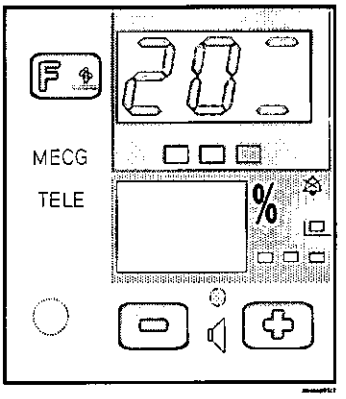
to distinguish at a glance the Cardio 1/Combi US transducer from the Cardio 2 US transducer.

Separating Twin FHR Traces

To help interpretation of traces with similar baselines, you can separate the baselines, so that one is displayed on the trace as if it is 20 bpm higher than the other. Use either the Function Key or the optional Barcode Reader to separate the traces. This feature is also known as "Twins Offset".

Using Keys

You must connect transducers to the Cardio 1/Combi and Cardio 2 sockets. You may use either two ultrasound transducers or a combination of one ultrasound and one DECG transducer. You cannot use two DECG transducers.



1. Press F.⚠ and release to display 20.
   The Signal Quality Indicator shows:
   - REDif the traces are NOT SEPARATED.
   - GREENif the traces are SEPARATED.
2. Press − or + to change the setting.
3. Press F.⚠ several times to return to the normal display.

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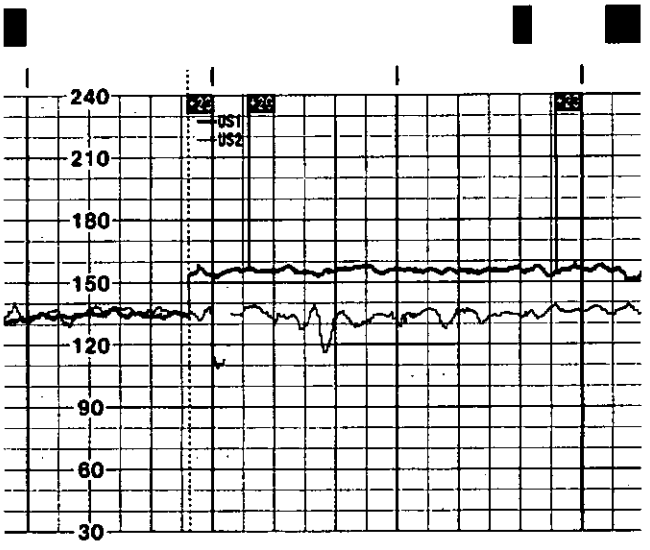
Using the Barcode Reader

Enter "Twins Offset" from the barcode sheet.

Twins Offset: On

To indicate that Twins Offset is switched on and the Cardio 1/Combi trace is offset:

- A dotted line labeled '+20' prints across the FHR scale.
- The Cardio 1/Combi trace is labeled '+20' every 5cm. The following trace shows Twins Offset switched on.



Only the trace from the Cardio 1/Combi transducer is offset. The numerical FHR value displayed on the monitor remains unchanged. The Cardio 2 trace and display do not change. Subtract 20 from the Cardio 1/Combi recorded trace to calculate the true FHR. For example, if the recorded trace shows 160 then the true FHR is 140.

If you disconnect the Cardio 2 transducer, the Cardio 1/Combi trace returns to normal. But if you later reconnect the Cardio 2 transducer, the Cardio 1/Combi trace is automatically offset again.

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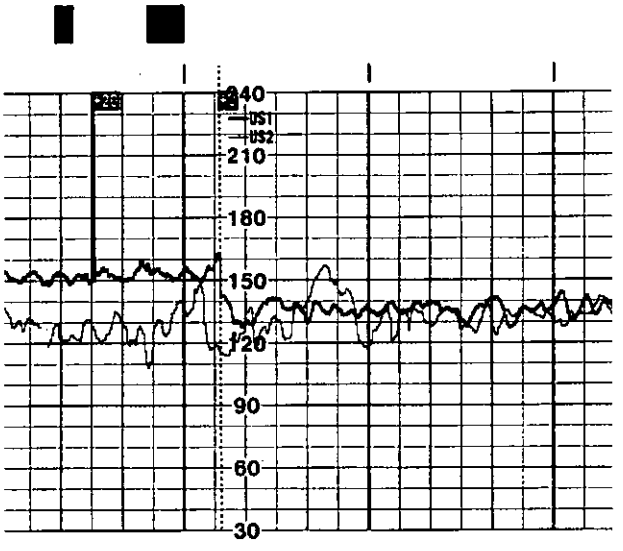
Twins Offset: Off

To indicate that Twins Offset is switched off a dotted line labeled "+0" prints across the FHR scale.



Switching off the monitor automatically switches off Twins Offset.

Troubleshooting

The following problem may occur when monitoring twins.

Problem	Possible Cause	Solution
? is printed repeatedly.	Both transducers are recording the same FHR.	Reposition an ultrasound transducer.

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Troubleshooting

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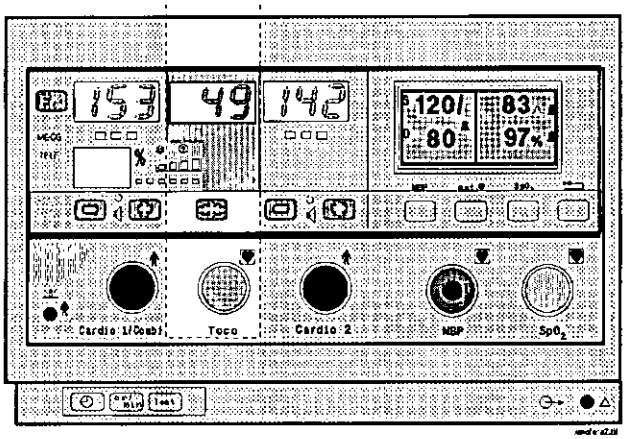
8
Monitoring Uterine Activity

Introduction

You can measure uterine activity externally using a Toco transducer, or internally using an intrauterine catheter. A Toco transducer measures the frequency and duration of contractions but not their intensity. Amplitude and sensitivity depend on various factors such as the position of the transducer, the belt tension and the size of the patient. To obtain an absolute measurement, you must monitor intrauterine pressure.

External Toco Monitoring

1. Fasten the abdominal transducer belt around the patient.
2. Connect the Toco transducer to the Toco socket on the monitor.



3. The Toco display shows 20. "Toco ext", indicating external uterine measurement, is printed on the trace intermittently.

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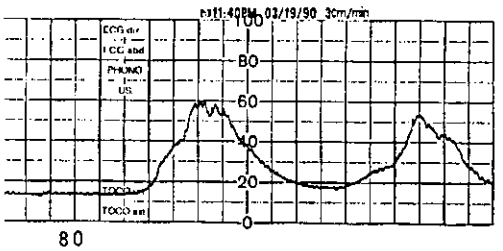
4. Place the transducer on the patient's fundus to ensure the optimum recording of uterine activity.
5. When you have a good signal, clip the transducer in position on the belt.
6. Between contractions, press the Toco Baseline Key ⊣⊢ . This zeroes the display and trace to 20.

The following example trace shows two contractions.



Internal Toco Monitoring (IUP Monitoring)

You can monitor intrauterine pressure (IUP) using either a reusable or a disposable intrauterine catheter. Each catheter comes with its own detailed user instructions. Read the instructions that come with your intrauterine catheter before you start monitoring. Ensure that you zero the monitor when instructed.

Perform a complete clinical evaluation. Catheterize after membrane rupture. Do not catheterize if placenta previa is diagnosed or if uterine bleeding from an undetermined source is present.

1. Insert the catheter according to its accompanying instructions.
2. Connect the catheter to the monitor's Toco socket. Some catheters link to a cable that connects to the monitor. The Toco display

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shows 0. "Toco int", indicating internal measurement, is printed intermittently on the trace.

3. Zero the monitor by pressing the Toco Baseline Key . This zeroes the display and trace to 0. If you do not zero the monitor properly, the pressure trace may exceed the paper scaling. To correct this, ensure that the transducer is level with the maternal xiphoid (lower end of the sternum), then zero the monitor.
4. Flush periodically during monitoring. A pressure spike appears on the trace if you flush after connecting the transducer to the monitor.

Troubleshooting

External Toco

Problem	Possible Causes	Solutions
Quality of the trace deteriorates or the Toco baseline varies.	The belt is incorrectly fastened and is too slack or too tight or the belt has lost its elasticity.	The belt must be tight enough to ensure good contact between the patient's skin and the entire surface of the transducer without causing discomfort. Ensure your are using the correct Philips belt. Adjust it as necessary.
	Maternal movement.	Relax the patient.
	Fetal movement.	None.
	Maternal respiration superimposed on trace.	Check belt is not too loose.
Toco sensitivity is too high (above 100 units).	Physical transmission of pressure from the uterus to the sensor is much higher than the average value.	Ensure a good contact between the patient's skin and the entire surface of the transducer. Reposition transducer if necessary.
An error message is displayed.		See Chapter 19, "Troubleshooting."
If you suspect the signal from the transducer.		Carry out the Parameter Test as described on page 152.
If you suspect the recorder or display.		Carry out the Quick Test as described on page 151.

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Internal Toco

Problem	Possible Causes	Solutions
No trace.	Catheter blocked.	Flush with sterile solution.
No change in pressure during contraction.	Dry environment or possible extra-ovular placement of sensor tip.	Flush with sterile solution or reposition sensor.
Only pressure peaks can be seen (baseline not visible).	Zero adjustment is incorrect.	Zero the system.
"-" indicator flashes.		
Trace is a straight line.	Transducer is defective.	Remove and touch the catheter. If the trace does not show up and down movements, use a new transducer.
Trace is superimposed with noise.	End of catheter is in the uterine wall or dry column.	Retract the catheter a little and flush.
An error message is displayed.		See Chapter 19, "Troubleshooting."
If you suspect the signal from the transducer.		Carry out the Parameter Test as described on page 152.
If you suspect the recorder or display.		Carry out the Quick Test as described on page 151.

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9
Fetal Pulse Oximetry

Introduction

Fetal pulse oximetry ($FSpO_2$) gives you a continuous real-time measurement of the percentage of oxygen saturation in the fetal arterial blood. Identifying adequately oxygenated fetuses and those at risk of hypoxia may help clarify whether or not intervention in the case of a non-reassuring fetal heart rate trace is necessary.

The $FSpO_2$ parameter is built into the Series 50 XMO (M1350C) fetal/maternal monitor. You can upgrade the following monitors to incorporate $FSpO_2$:

- Series 50 XM (M1350B) fetal/maternal monitor.
- Series 50 IX (M1350A) fetal monitor.

This parameter is NOT available for monitors purchased in the USA.

Before You Start

Read the accompanying Sensor Placement Guide carefully. It contains full details about how to place the sensor, and any contra-indications. Only clinical professionals trained in the use of sensor placement may place a fetal oxygen sensor. Use only Nellcor-approved FS14 fetal sensors.

Unlike other fetal measurements, where you get an almost instant display on the monitor as soon as you apply a transducer correctly, the $FSpO_2$ measurement can take several minutes after the sensor is correctly placed before you see a value displayed on the monitor.

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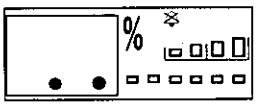
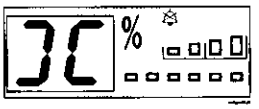
To Begin Monitoring

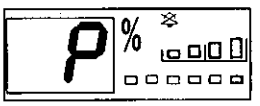
1. Plug the $FSpO_2$/ECG combined patient module into the Cardio 1/Combi socket. The monitor displays the symbol:



2. Check, and if necessary change, the alarm settings.
3. Connect the sensor to the patient module, maintaining sterility by exposing only the connector when you open the sensor package. The connector is color coded blue to ensure that you connect to the blue $FSpO_2$ connector, not the pink ECG input.
4. Make sure that you can see red light coming from the emitter on the sensor body. If there is no light, use a new sensor.
   The monitor displays the sensor lifted symbol:



5. Apply the sensor to the side of the fetal face closest to the maternal spine, according to the instructions in the sensor placement guide. Adjust the sensor until you get skin contact. When you have contact, the monitor displays the pulse search symbol and the pulse bar lights rhythmically as the monitor searches for a signal of sufficient quality to allow it to determine the saturation value.



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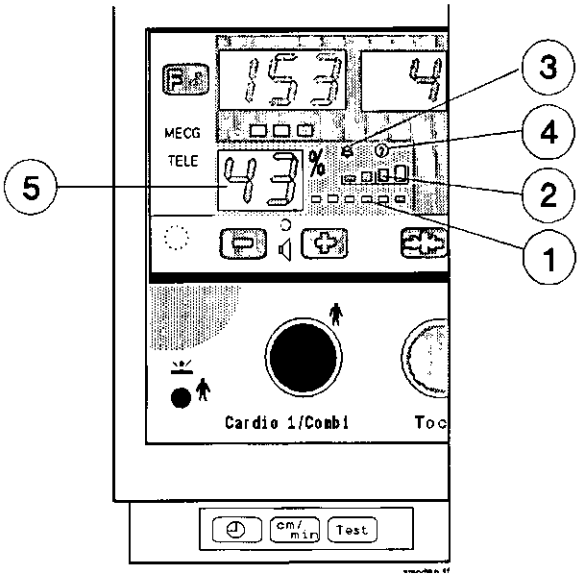
6. Wait until the four-step signal quality indicator shows that it is receiving a medium or good signal (with three or four segments lit). It may take up to a minute after this until the monitor displays the fetal oxygen saturation value. Do not reposition the sensor unless you are certain the monitor is not receiving a signal of acceptable quality.

Understanding the Display

The following diagram shows the elements of the $FSpO_2$ display:



1. **Pulse indicator**
   The six segments pulse rhythmically in conjunction with the fetal pulse rate when the pulsatile activity is of acceptable quality.

   If the indicator pulses regularly but the monitor does not display a fetal oxygen saturation value, wait before you reposition the sensor.

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The monitor may not yet be able to calculate a saturation value from the signal it is receiving.

If the pulse indicator becomes briefly irregular, and then returns to a regular rhythm, do not reposition the sensor. The irregularity is probably caused by fetal or maternal movement.

2. **Signal quality indicator**
   Shortly after the pulse indicator moves rhythmically, the four-segment signal quality indicator illuminates to show how good a signal the monitor is receiving from the sensor. The more segments that light, the better the quality of the signal. Typically, the monitor needs a medium to good quality signal (with three or four lit segments) for up to a minute to calculate and then display the saturation value.

3. **Alarm status indicator**
   When the crossed bell symbol is lit, alarming is switched off. When it is not lit, alarming is switched on.

4. **Cross-Channel Verification Plus (CCV+) indicator**
   The fetal pulse rate from $FSpO_2$ is determined internally by the monitor. It is not displayed, on either the trace or monitor.

   To warn you if you accidentally record maternal SpO_2 instead of fetal SpO_2, (because the sensor is facing the uterine wall instead of the fetus) the monitor compares the heartrate it derives from DECG on the Cardio 1/Combi channel, (or from US on the Cardio 2 channel if DECG is not in use) with the pulse rate it derives from $FSpO_2$. The CCV+ indicator illuminates and (?) is printed on the trace if the monitor:

   - records a pulse rate from $FSpO_2$ and a heart rate from DECG or ultrasound that do not match for more than one minute.
   - records more than 80% fetal saturation for more than one minute.

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You should check the fetus and adjust the sensor until you are sure you are recording fetal oxygen saturation.

5. **Saturation value**
   This displays the level of oxygen saturation in the fetal blood. Typical fetal values lie within the range 40% to 70%.

See Chapter 3, "General Information" on page 19 for a sample trace including $FSpO_2$.

Alarm

The monitor makes a "beeping" noise and the saturation display flashes.

Alarm Limits

$FSpO_2$ has two alarm criteria, which you can change only when a patient module is connected to the monitor. If you change an alarm limit, your change is retained by the monitor, even if you switch the power off. The alarm limits are:

- **Saturation alarm level**
  The alarm triggers if the percentage of fetal oxygen saturation falls below this point. The default setting is 30%.
- **Time delay**
  This is the length of time for which fetal oxygen saturation must be at or below the saturation limit before the alarm triggers. The default setting is one minute.

When you change the monitor's battery, the alarm settings return to the factory settings.

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Triggering an Alarm

For an alarm to trigger:

- The $FSpO_2$ alarm must be switched on **and**
- The percentage saturation must fall below the *saturation alarm level* for the length of time specified by the *time delay.*

Acknowledging an Alarm

Press the acknowledge key on the recorder or the yellow key on the maternal display to acknowledge an $FSpO_2$ alarm.

Turning the Alarm On and Off

1. Connect the ECG/$FSpO_2$ patient module to the Cardio 1/Combi socket.
2. Press F.⚠ until the $FSpO_2$ display shows AL .
3. Press + to toggle between alarming on and off. The signal quality indicator for the Cardio1/Combi channel is red when alarming is OFF and green when it is ON.
4. Press F.⚠ to return to normal monitor function. A crossed bell symbol, near the $FSpO_2$ display, illuminates when the alarm is off.

Changing Alarm Limits

1. Connect the ECG/$FSpO_2$ patient module to the Cardio 1/Combi socket.
2. Press F.⚠ until the $FSpO_2$ display shows AL .
3. Press ⇥ to access the saturation alarm limit setting. The Toco display shows --A , indicating that you are changing the saturation low alarm limit. The $FSpO_2$ display shows the current low limit. There is no high limit.
4. Press + or − to increase or decrease the $FSpO_2$ saturation alarm limit.

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5. Press [⊣⊢] to set the time delay. The Toco display shows '_A, indicating that you are changing the time delay. The FSpO$_2$ display shows the current delay, in minutes.

6. Press [+] or [−] to increase or decrease the time delay in increments of 0.5 minutes.

Press [F.⚠] to return to normal monitor function.

If alarming is enabled, the alarm limits are printed on the trace. If it is disabled, 🔕 is printed.

Inop Alarms

If the signal quality has been good for a minute or longer, and then the quality falls below an acceptable level for more than 30 seconds, the monitor beeps. This feature can be enabled or disabled through the service settings. See the Installation and Service Guide for details.

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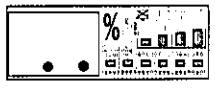
Troubleshooting

Display	Problem	Solution
	Patient module not plugged in.	Plug in patient module.
	Patient module plugged in but sensor not attached.	Check connection of sensor to patient module. Replace patient module or sensor if necessary.
	Patient module and sensor are both correctly connected but no signal is obtained.	The sensor has lost contact with the patient. Reposition the sensor slightly.
	Pulse indicator bar pulses rhythmically but monitor does not display a saturation value.	Observe the quality indicator lights. If you do not obtain a medium to good quality signal (three or four segments lit) after waiting for at least one minute, reposition sensor.

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Loss of Pulse Signal

Temporary loss of pulse signal is normal and the clinical professional must judge whether the trace gives enough information for diagnosis. Loss of pulse signal can occur:

- If there is excessive or prolonged fetal or maternal movement
- During uterine contractions
- If the fetus experiences shock, hypotension, severe vasoconstriction, arterial occlusion proximal to the sensor, or cardiac arrest.

Inaccurate Measurements

Inaccurate measurements may be caused by:

- Incorrect placement of the sensor
- Significant levels of dysfunctional hemoglobin, such as carboxyhemoglobin or methemoglobin
- Excessive fetal or maternal movement
- Uterine contractions
- Venous pulsation
- Side effects from some drugs.

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Inaccurate Measurements

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10
Monitoring Using External Devices

Introduction

This chapter describes how to record maternal non-invasive blood pressure (NIBP), maternal blood oxygen saturation level (SpO_2), maternal temperature and maternal heart rate (MHR) by connecting a supported external device to your monitor. If you have a Series 50 XM you can connect an Nellcor OxiFirst™ Pulse Oximeter (N-400) or compatible fetal pulse oximeter.

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Recording From an External Device

If you connect an external device that replicates parameters already installed in your monitor (such as MHR, maternal SpO_2, NIBP and $FSpO_2$), the external device is ignored.

You can connect:

Supported External Devices	Parameters				
	Maternal				Fetal
	NIBP	SpO_2	Temp	MHR[1]	$FSpO_2$
Philips M1165A/1166A/1175A/ 1176A/1167A/1177A CMS	Yes[2]	Yes[2]	Yes[2]	Yes[2]	No
Philips 78352C/78354C Compact Configurable Monitor (CCM)	Yes[2]	Yes[2]	Yes[2]	Yes[2]	No
Dinamap 1846/8100 NIBP Monitor	Yes	No	No	Yes	No
Press-Mate/Listmini Model BP-8800	Yes	No	No	Yes	No
Accutorr 3, 4	Yes	No	No	Yes	No
Accutorr 3SAT, 4SAT	Yes	Yes	No	Yes	No
Nellcor N-200 SpO_2 Monitor	No	Yes	No	Yes	No
Nellcor N-400 $FSpO_2$ Monitor	No	No	No	No	Yes

1. An MHR measurement is provided in conjunction with maternal NIBP or SpO2 monitoring.

2. Only if this parameter is installed on the external device.

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What You Need

To connect a supported external device you require:

Model	Requirements	
	Option J13[1]	Additional Requirement
Press-Mate/Listmini Model BP-8800 NIBP	Dual Interface Board	COLIN Interface cable (available from COLIN Corporation)
Dinamap 8100	Dual Interface Board	Model 8801 interface adapter (available from General Electric)
Others	Dual Interface Board	None

1. Includes one interface cable (M1350-61609)

Connecting the External Devices to the Monitor

Connect a supported external device via the dual serial interface at the rear of the monitor.

Caution

Before connecting an external device to the monitor, connect the equipotential grounding point (3) to earth potential. Use the grounding cable supplied with the monitor.

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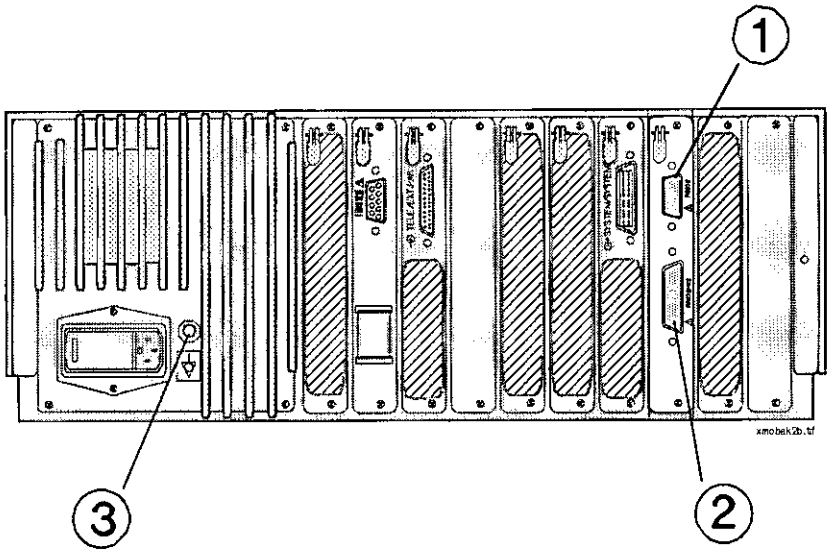
The Dual Serial Interface has two sockets:



Dual Serial Interface

1. Use socket 1 (9 pin) for connecting:
   - Philips M1165A/1166A/1175A/1176A/1167A/1177A CMS.
   - Philips 78352C/78354C Compact Configurable Monitor.
   - Dinamap 1846/8100 NIBP Monitor.
   - Press-Mate/Listmini Model BP-8800.
   - Accutor 3, 4, 3SAT and 4SAT.
2. Use socket 2 (25 pin) for connecting:
   - Nellcor N-200 Maternal SpO_2 Monitor
   - Nellcor N-400 Fetal SpO_2 Monitor (M1350B only).

   If you use both sockets 1 and 2, **and** maternal SpO_2 can be recorded from the external device connected to socket 1, the measurement from this external device has priority over the measurement from the Nellcor Monitor N-200 in socket 2.

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3. Use the interface cable to connect the external device to the appropriate socket.
4. Connect the other end of the interface cable to the external device. (See the service documentation supplied with the external device for the correct socket to use for the connection.)

If you are monitoring maternal SpO_2 or temperature and the monitor is switched on **before** the appropriate sensor is applied, the first value documented may be incorrect as it takes up to five minutes for the correct value to be obtained.

To monitor maternal temperature on the M1165A/1166A/1175A/1176A/1167A/1177A CMS, you must connect the temperature sensor to TEMP1.

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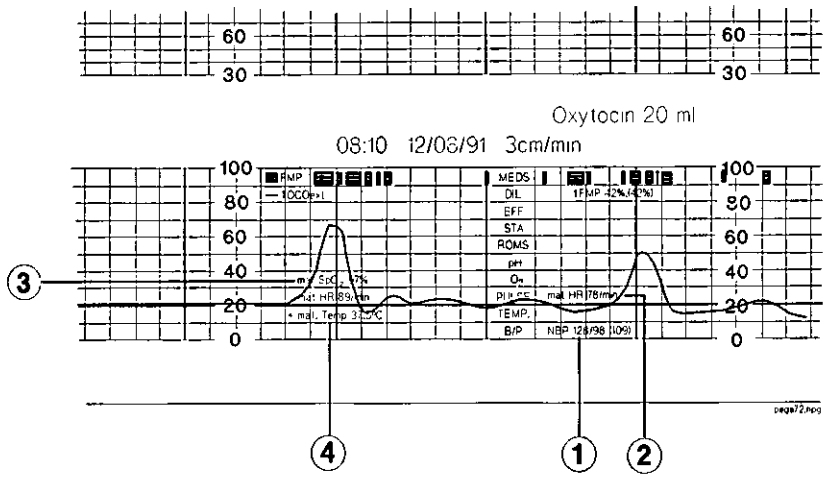
Example Trace



1. Maternal blood pressure:
   - Systolic blood pressure is 128 mmHg.
   - Diastolic blood pressure in 98 mmHg.
   - Mean arterial pressure is 109 mmHg.
2. Maternal heart rate (78 bpm).
3. Maternal oxygen saturation level of blood (97%).
4. Maternal temperature (37.5 °C). Note that trace annotations coming from external monitors are prefixed with an asterisk, "*".

What is printed on the trace?

External Measurement	Print on Trace
Maternal NIBP	Value at each measurement, unless in automatic mode.
Maternal SpO_2	Value every 5 minutes.
Maternal temperature	Value every 5 minutes.
Fetal SpO_2	Fetal SpO_2 trace and annotation printed on Toco scale.

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If you monitor only maternal NIPB, or only SpO_2, a MHR value obtained from the Philips Series 50 monitor is also automatically printed.

Automatic NIBP Measurement

If you are using automatic mode with a short repetition interval, not all measurements can be recorded on the trace. The speed at which the paper moves through the recorder determines when measurements are printed.

Paper Speed	Measurement Notation
1 cm/min	Every 3 minutes
2 cm/min	Every 2 minutes
3 cm/min	Every 1 minute

Trace Display on External Monitoring Systems

The trace displayed on a connected monitoring system, such as OB TraceVue, or retrieved from one, may not be identical to the recorder trace. The following details may not be shown on the system:

- Notes annotated on the paper using the Barcode Reader.
- Fetal Movement Profile.
- Separated twin FHR traces (when the Cardio 1 Combi trace is offset by 20 bpm).
- Maternal parameters.

Cross-channel verification (detecting when two heart rates coincide) is transmitted to OB TraceVue.

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Troubleshooting

$FSpO_2$

If the external Nellcor N-400 $FSpO_2$ monitor has two power switches (a mains switch at the rear of the unit and a standby switch at the front of the unit), take care to switch them on and off in the correct order, as shown below. If you do not, the unit can appear to malfunction by displaying data erratically, or not at all.

- To switch off the N-400 $FSpO_2$ monitor
  - Turn the front switch (on/standby) to standby
  - Turn the rear switch (mains power switch) to off.
- To switch on the N-400 $FSpO_2$ monitor
  - Turn the rear switch (mains power switch) to on
  - Turn the front switch (on/standby) to on.

If the unit malfunctions, switch it off as described above, wait for five seconds and then switch it on again.
If you use the N-400 $FSpO_2$ monitor regularly, we recommend that you keep the rear switch (mains power) in the "on" position and use the front switch (on/standby) to change from on to standby mode.

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External Devices

The following table identifies common problems and solutions you may encounter when connecting external monitoring devices.

Problem	Possible Cause	Solution
General - All External Devices		
No maternal measurements are printed on the trace.	Cable connected incorrectly.	Check cable connections.
	External device is not configured to the fetal monitor.	Check configuration settings on the external device. See external device service guide for details.
	Dual Serial Interface Board is not configured to the external device.	Check Interface Board settings. See the Installation and Service Manual for more information.
	Dual Serial Interface Board is not working.	Carry out the Self Test as described on page 150, and check error messages.
Nellcor N-200 SpO_2 Monitor and OxiFirst™ Fetal Oxygen Saturation Monitor (N-400)		
No SpO_2 and no MHR measurements are printed on the trace.	Nellcor monitor is being powered by its internal battery. (Battery power symbol is lit.)	Switch on AC power, following the instructions in the section on Troubleshooting $FSpO_2$ on page 90. The battery power symbol should go out.
Philips M165A/M1675A/M1676A/M1167A/M1177A		
No maternal measurements are printed on the trace.	The parameters are switched off.	Switch on the parameters in the Parameters On/Off menu. See the Component Monitoring System *User's Reference Guide.*
	Wrong interface cable.	Ensure the interface cable M1350-61609 is used. (The number is printed on the cable.)
No MHR measurement is printed on the trace.	Incorrect parameter source.	If the SpO_2/PLETH module is plugged in, then set the HR/PULSE source to PLETH.
No maternal temperature is printed on the trace.	TEMP1 is not labeled T1.	Change TEMP1 label to T1.
	Temperature sensor is not connected to module TEMP1.	Check cable connection of temperature sensor.

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Troubleshooting

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11
Recording Notes

Introduction

The optional barcode reader and sheets of barcodes let you record your most commonly-used notes, and some patient information on the trace.

Recording A Note

To record a note on the trace:

1. Switch on the recorder.
2. Hold the reader pen as you would a normal pen.
3. Place the tip of the pen in the white margin on one side of the barcode.

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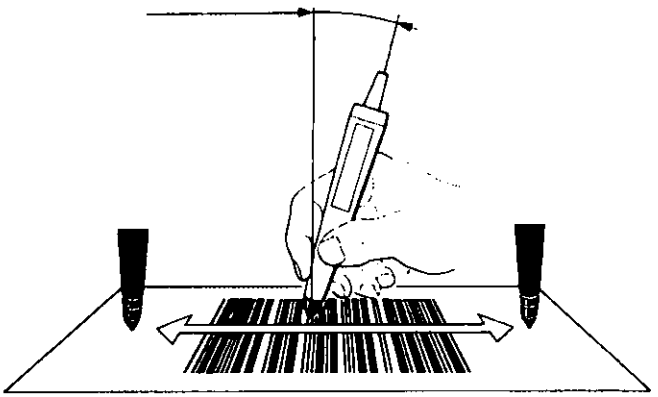
4. Using gentle pressure and constant speed, draw the pen (from right to left, or left to right) over the center of the barcode to the white margin on the other side. Do not let the pen wander from the barcode or stop before it reaches the white margin



The monitor "beeps" when it receives the barcode. If there is no "beep", you should read the barcode again.

Deleting a Barcode Note

Read "CANCEL" to delete an entry. If you do not read "CANCEL" within 15 seconds, the note is entered automatically.

Recording Several Barcodes as One Note

To record several barcodes as one note, read each barcode in turn and then read "ENTER". The maximum length of a note is 30 characters. The note is printed on one line.

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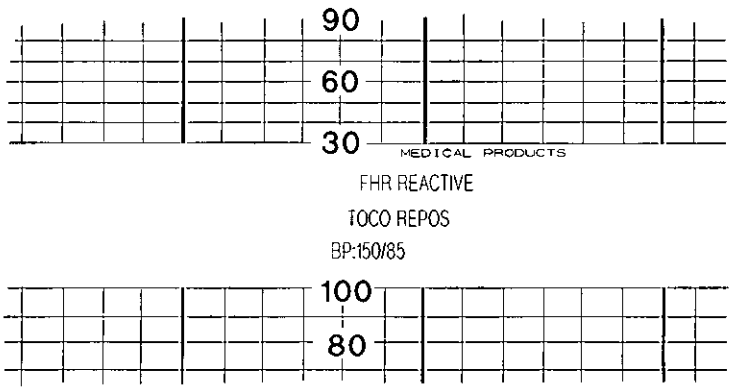
For example, to record a blood pressure of 150/85 as shown in the picture below:

1. Read the following codes:
   BP:
   1
   5
   0
   /
   8
   5
2. Read "ENTER".

Recording Several Barcodes as Separate Notes

To record several barcodes as separate notes:

1. Read a barcode.
2. Read "ENTER".
3. Repeat steps 1 and 2 to read all the barcodes you need. The notes appear on three lines as shown in the example below.



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Recording a Patient's Name

To record a patient's name on the paper:

1. Read each letter of the patient's first name.
2. Read "SPACE".
3. Read each letter of the patient's second name.
4. Read "ENTER".

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12
Fetal Heart Rate Alerting

Introduction

Fetal heart rate alerting can give both audible and visual warning of a non-reassuring fetal condition. Fetal heart rate (FHR) alerting is NOT available for monitors purchased in the USA.

Alerts

Your monitor must be enabled for alerting, via a service setting, before you can use the alert facilities.

Recognizing an Alert

When the fetal heart rate is outside a given **High Alert Limit** (tachycardia) or **Low Alert Limit** (bradycardia) for a defined length of time (**Delay**), the monitor gives an audible alert and flashes the FHR numeric display.

FHR alerting activates after about half a minute of valid heart rate signals (green or yellow signal quality indicator). When the recorder has been switched off, the alerting is reset and another half minute of valid FHR is required to activate the alerting. This prevents the monitor giving a signal loss alert when no patient is being monitored.

Acknowledging an Alert

Press or **Reset**. If the FHR remains outside the given limits after you acknowledge an alert, the alert recurs after the Delay time.

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Turning Alerting ON or OFF

1. You must connect either an ultrasound or a DECG transducer to one of the two Cardio sockets.

2. Press [F.⚠] repeatedly until AL is displayed.
   The Signal Quality Indicator shows:
   - RED if fetal alerting is OFF.
   - GREEN if fetal alerting is ON.

   Press [−] or [+] to change this setting.

Changing Alert Limits

1. Connect either an ultrasound or a DECG transducer to one of the two Cardio sockets.
2. Press [F.⚠] repeatedly until AL is displayed.
3. To display the next alert limit setting press [−·−] .
   Use [−] and [+] to change the next alert setting.

Alert Setting (shown in FHR1 display)	Alert Setting (shown in Toco display)
High alert limit Default 150 bpm, 0 = off	--A
Alert delay for high limit Default 60 seconds	"-A
Low alarm limit Default 110 bpm, 0 = off	_-A
Alert delay for low limit Default 60 seconds	"_A

   The monitor retains these settings, even when switched off. They are printed on the recorder every few pages if alerting is on.

4. Press [F.⚠] to return to the normal display or wait 15 seconds for the data to be automatically entered.

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13
Non Stress Test Timer

Introduction

This chapter explains how to set the non stress test (NST) timer.

Setting the NST Timer

1. Ensure the recorder is off.
2. Press the recorder ON/OFF key ▽ for 2 seconds.
3. Adjust the timer using the − and + keys. The setting is displayed for 15 seconds and the timer starts. An egg timer symbol is printed on the paper to indicate that the NST timer is activated.

To switch the timer off, select a setting of 0.

After the selected time has passed:

1. A 10 second audible tone sounds (optional).
2. The recorder stops (optional).
3. The paper advances to the next perforation.

Optional settings for the NST timer are enabled via a service setting and are listed in the Installation and Service Guide for your monitor.

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Setting the NST Timer

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14
Maternal Monitoring - Overview

Introduction

This chapter gives an overview of the following maternal parameters:

- Maternal blood pressure
- Maternal heart rate
- Maternal pulse oximetry

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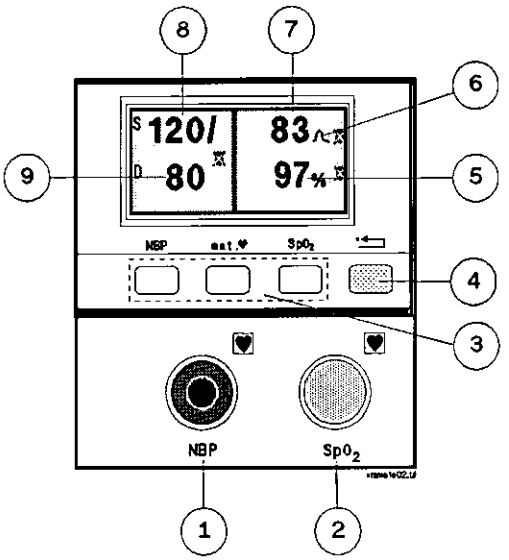
Maternal Parameters - Overview



1. Non-invasive blood pressure transducer socket.
2. Pulse oximetry transducer socket.
3. **Softkeys** for setting maternal parameters. They are:
   - NBP softkey selects the mode and alarm limits for non-invasive blood pressure.
   - MHR softkey selects the alarm limits for maternal heart rate and MECG waveform.
   - SpO_2 softkey selects the alarm limits for pulse oximetry.
4. Reset key returns monitor from setting mode to maternal parameter display. Also used to acknowledge an alarm.
5. SpO_2 value indicates the current reading for patient's SpO_2 level.
6. MHR icon indicates source of MHR. The signals are sorted by accuracy, with the most accurate heart rate value shown first:

   indicates heart rate value taken from MECG measurement.

   indicates pulse rate value taken from SpO_2 measurement.

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indicates average heart rate value taken from NIBP measurement.

7. **Maternal heart rate** shows current heart rate or pulse rate in beats per minute.
8. **Systolic value** shows the value for the systolic parameter of the most recent non-invasive blood pressure measurement.
9. **Diastolic value** shows the value for the diastolic parameter of the most recent non-invasive blood pressure measurement.

Softkeys

A softkey is a key whose function varies according to the task you are performing. When a choice is highlighted on the maternal screen display, pressing the softkey immediately beneath this selects it.

Reset Key

The reset key is yellow for easy identification. It has several functions:

- **One short press**
  Acknowledges warning message or
  Acknowledges alarm or
  Redisplays maternal main screen.

- **One press, held for two seconds**
  Accesses volume and contrast setup screen.

- **Two presses within one second**
  Displays current maternal alarm limits.

These functions are available only when the display shows the maternal main screen (see page 104).

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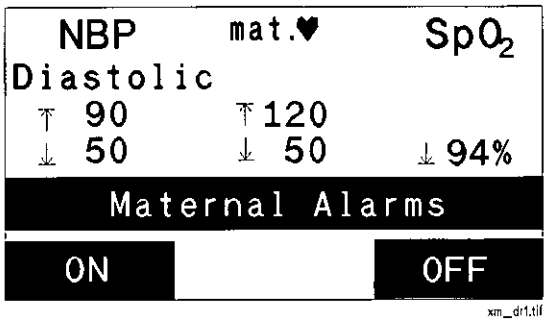
Power on Screen

When you first switch on, the monitor displays its power on screen, with factory set default alarm limits.



To Begin Monitoring Immediately

Step 1. Switch the monitor on.

Step 2. Apply the blood pressure cuff, MECG transducer and SpO_2 transducer to the patient as required.

Step 3. Press ON to turn all maternal alarms on simultaneously with their factory set default limits or OFF to turn all maternal alarms off simultaneously.

The monitor displays the maternal main screen. You will find out how to change and set the alarm limits later in this guide.

Maternal Main Screen

The screen that you will view most often is the maternal main screen. When the monitor is displaying this screen, you can view all the maternal vital signs at a glance, see which parameter alarms are on, and which

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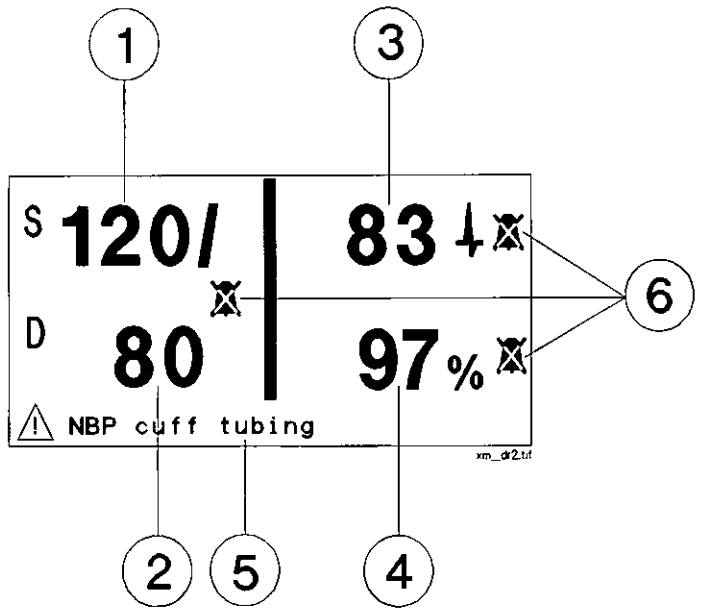
parameters (if any) are currently in an alarm condition.



Maternal Main Screen

1. Systolic blood pressure.
2. Diastolic blood pressure.
3. Maternal heart rate (if derived from MECG) or pulse rate (if derived from pulse oximetry).
4. Current oxygen saturation (SpO_2) level.
5. Warning messages (if any).
6. Alarm status for maternal parameters. The alarms shown in this example are OFF. When alarms are on, no crossed bell icon is shown.

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Returning to the Maternal Main Screen

When you are working with the maternal measurements, individual screens replace the maternal main screen. If you need to view the maternal main screen quickly, press the reset key once. The monitor automatically redisplays this screen if there is an interval of approximately 20 seconds between key presses while you are changing any alarm, volume or contrast setting.

Alarms - Overview

Here are some of the main features of the maternal alarms:

- Each maternal parameter has an alarm that you can both hear and see.
- You choose which maternal alarms to have on or off.
- When an alarm is off the monitor displays a crossed alarm bell icon for that parameter on the maternal main screen.
- You can change the alarm limits to suit each patient.
- The power on alarm limits for alarms are preset at the factory.

The monitor beeps and highlights the alarm parameter with a flashing dark background on the maternal main screen. If the alarm parameter returns to a satisfactory value before you acknowledge it, the alarm stops automatically. Both the beep and the flashing background return to normal.

Acknowledging an Alarm

Acknowledge an alarm by pressing the reset key or the event marker key once. The audible alarm ceases. After acknowledgement if the parameter continues to be over the limit, the highlight remains on the screen.

Reviewing All Alarm Settings

To look at all current alarm settings at one glance, redisplay the power on screen by pressing the reset key twice within one second.

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Setting an Alarm

You can find out how to change each maternal alarm in the section relevant to that parameter. When you change alarm settings for an individual patient, the monitor automatically updates the power on screen with the new values. If the monitor's power is switched off for less than one minute, the monitor remembers any alarm values you have set for a patient. However, if the power is off for more than one to two minutes, the default alarm limits become active when power is restored.

Warning Messages

In some circumstances, such as when the patient is moving excessively, the monitor may have difficulty making measurements. This is not an alarm condition so the monitor does not beep. However, it displays a warning message at the bottom of the maternal main screen.

Acknowledging a Warning Message

Press the reset key once to acknowledge a warning message. When you have rectified the problem, you can continue to make measurements. Warning messages for individual maternal parameters are discussed at the end of the appropriate chapter.

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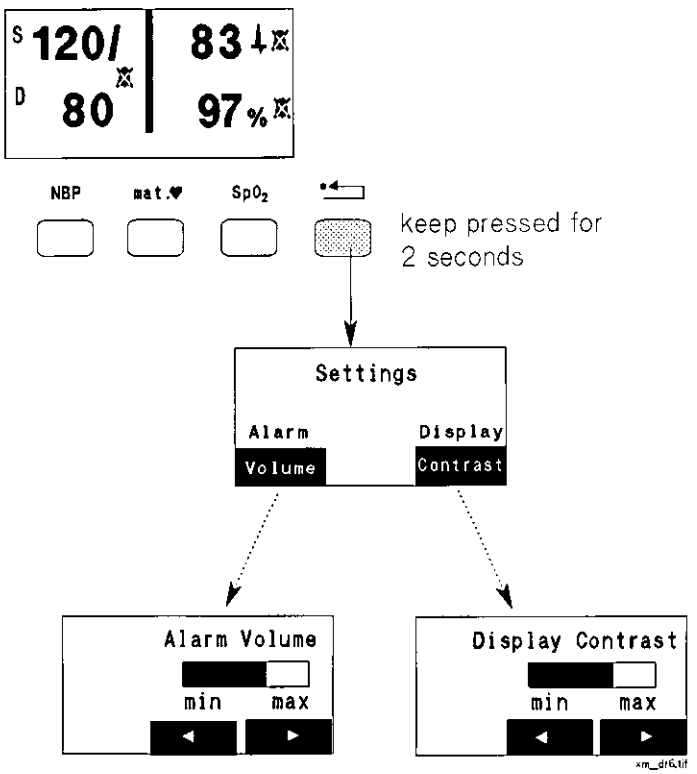
Volume and Contrast Control

You can increase, or decrease, the volume of the alarms and the contrast of the display screen. The method is exactly the same for both.



Volume and Contrast Control

Step 1. Display the maternal main screen.

Step 2. Press the reset key and **keep it pressed** until the settings screen replaces the maternal main screen. This takes about two seconds.

Step 3. Press **Volume** or **Contrast**.

← Press this to decrease the setting.

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Press this to increase the setting.

Step 4. Press the reset key to return to the maternal main screen. A single tone at the current volume accompanies each key press when you change the volume. A single click and contrast change accompanies each key press when you change the contrast. The indicator bar shows you how much further you can adjust the parameter.

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Volume and Contrast Control

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15
Non-invasive Blood Pressure Monitoring

Introduction

When you first switch the monitor on, non-invasive blood pressure measurement is in manual mode. The maternal main screen displays 0 for both systolic and diastolic values.

To Begin Monitoring

1. Ensure that the non-invasive blood pressure cuff is applied correctly to the patient and is not on the same arm as an SpO_2 finger transducer.
2. Connect the cuff to the interconnect tubing.
3. Plug the interconnect tubing into the monitor's NBP socket.
4. Press NBP
5. Press Start

The monitor takes a single measurement, displaying the systolic and diastolic values on the maternal main screen. The rest of this chapter tells you how to change the measurement mode and set the alarms.

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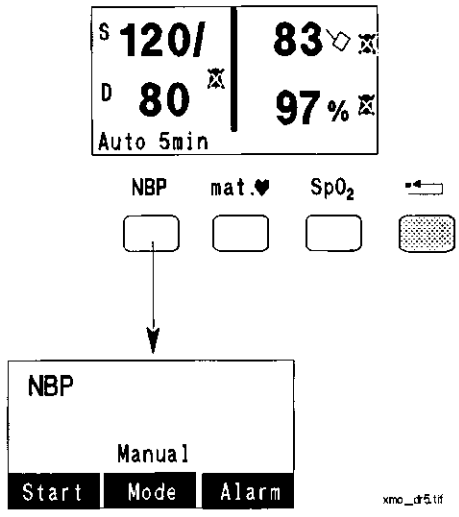
Setup Screen

Use the non-invasive blood pressure setup screen to start measurements, change mode, and enter the alarm setup screen. Press NBP to access the setup screen.



NBP Setup Screen (Manual Mode)

Start Press this to begin a measurement immediately. If the monitor is in stat mode, this commences a stat cycle. When a measurement is taking place, the start key is replaced by Cancel. Press this to cancel the current measurement, if necessary. The cuff automatically deflates.

Mode Press this to change between manual, auto and stat measuring modes.

Alarm Press this to enter Alarm Setup.

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Measurement Modes

Three modes of non-invasive blood pressure measurement are available:

- **Manual**
  The monitor executes a measurement on demand. This is the preferred method.
- **Automatic**
  The monitor continually repeats measurements. You can adjust the time period between measurements from two to 60 minutes.
- **Stat**
  The monitor executes a rapid series of measurements over a five minute period. Do not use stat mode unless your patient is supervised.

Unless you make a subsequent measurement, the monitor displays the most recent measurement for up to one hour.

If possible, avoid measuring during contractions because the measurement:

- May not give a reading that is truly representative of the patient's normal blood pressure.
- May cause additional stress for the patient.

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Changing Measurement Mode

To change measurement mode, press NBP to enter the non-invasive blood pressure setup screen.

Manual	1. Press **Mode** until **Manual** is displayed above the mode key. 2. Press **Start** to make an immediate NBP measurement
Auto	Press **Mode** until **Auto** is displayed above the mode key. A third soft key allows you to set the time interval between automatic measurements. • Press **Repeat** to cycle through the available time intervals (2, 5, 10, 15, 30 and 60 minutes). • Press **Cancel** to stop the current automatic measurement, and remain in automatic mode. • Press **Exit** to leave auto mode and return to manual mode. The **Exit** key replaces the **Mode** key after the first automatic measurement has taken place.
Stat	1. Press **Mode** until **Stat** is displayed above the mode key. 2. Press **Start** to initiate a measurement cycle. Without pausing, measurements are repeated for five minutes. At the end of this time, the monitor returns to manual mode. If the power to the monitor fails during a period of stat measurement, the mode returns to manual when power is restored. 3. Press **Exit** to leave stat mode and return to manual mode. The **Exit** key replaces the **Mode** key after the first stat measurement has taken place. If you press **Cancel** during a stat measurement, the measurement ceases and the monitor returns to manual mode.

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Pulse Rate

When the monitor takes a NIBP measurement, it can also calculate the average pulse rate. This occurs in either manual or automatic mode, when neither MECG nor SpO_2 is being measured. The value is shown on the screen and printed on the trace. It is an average pulse rate, taken during the most recent NIBP measurement. It is not the actual value. The value is updated after each successive NIBP measurement. If you need a continuous measurement, you should monitor using MECG or maternal SpO_2.

When the pulse rate is derived from NIBP the maternal display screen shows to the right of the heart/pulse rate display. No alarming is possible.

Alarms

The non-invasive blood pressure alarm sounds if the patient's blood pressure falls below, or rises above, the set limits. You can choose whether to have the alarm dependent on the systolic or diastolic measurement. You can view the current settings by displaying the power on screen.

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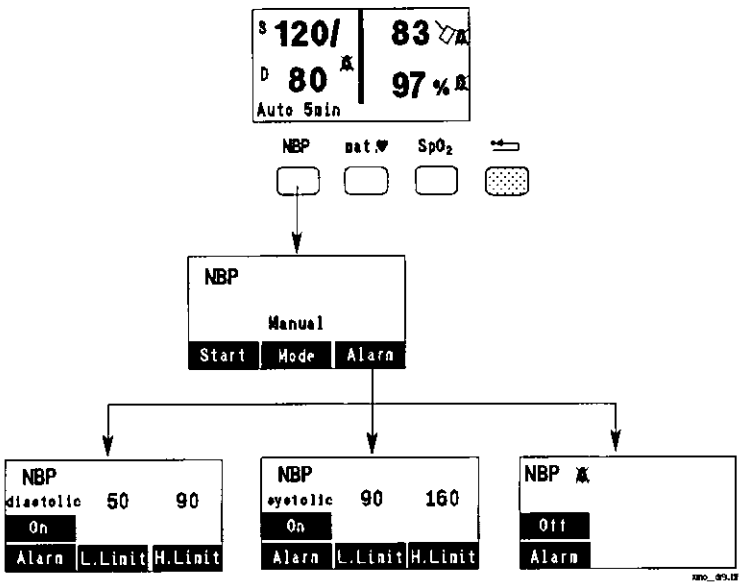
Turning Alarms On and Off

The following illustration shows an example alarm setting for NIBP.



The diastolic low limit is 50, the high limit 90. The systolic low limit is 90, the high limit is 160. NBP alarming is switched off.

1. Press NBP to display the NBP setup screen.
2. Press **Alarm** to display the alarm setup screen.
3. Press **Alarm** repeatedly to cycle between alarm OFF and the alarm limit setting screens for systolic and diastolic values.

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

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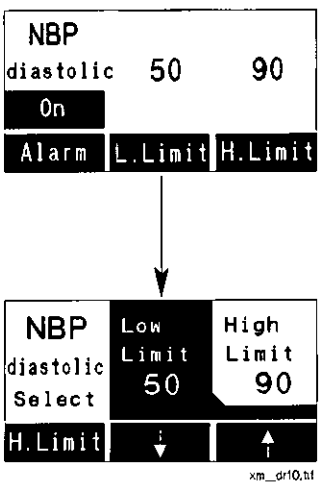
Changing Alarm Limits

Starting from the maternal main screen, to change alarm limits:

1. Press NBP to display the NBP setting screen.
2. Press **Alarm** to display the alarm setup screen.
3. Press **Alarm** until the parameter you want to change (either systolic or diastolic) is displayed, with its current values. You cannot have both systolic and diastolic active. You must choose one or the other.



Setting the Diastolic Low Limit

1. Choose whether you want to change the upper or lower limit. Either:

   Press H Limit to select the high limit alarm. Press ↑ to increase the high limit or ↓ to decrease the high limit in steps of 5 mmHg

   OR

   Press L Limit to select the low limit alarm. Press ↑ to increase the low limit or ↓ to decrease the low limit in steps of 5 mmHg.

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

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Recording

Each new measurement value is recorded only if the previous value printout is finished. The printout shows the mean pressure in brackets.

Troubleshooting

This section details warning messages, possible measurement problems and limitations associated with measuring non-invasive blood pressure.

Warning Messages

Warning Message	Situation	Audible Indication	Action Required
⚠ overpressure	Cuff pressure increases above 300mmHg.	Yes (cannot be switched off).	Check to see if cuff is being pressed manually (perhaps by patient movement) and restart the measurement. Cuff deflates automatically.
⚠ artifacts	Patient is moving.	Yes (if alarming is on).	Restrain patient movement and restart the measurement.
⚠ cuff tubing	Inflation/ deflation takes too long.	Yes (if alarming is on).	Check that all tubes are connected properly, not blocked, leaking or defective. Ensure that the correct cuff is being used. Restart the measurement
⚠ NBP error	Tubing obstructed, or hardware problem.	Yes (if alarming is on).	Check tubing. Switch monitor off and try measurement again. If problem persists, call service personnel.

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

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Measuring Problems

Situation	Possible Cause	Possible Solution
Cuff will not inflate.	Monitor in service mode.	Switch power off, then switch on again.
	Technical defect.	Call service.
	Cuff tubing not connected.	Connect cuff tubing.
High or low values measured (against clinical expectations).	Contraction occurring.	Wait until contraction has finished.
	Patient talking before or during measurement.	Allow patient to rest quietly, then try again after 3 to 5 minutes.
	Incorrect cuff size.	Check cuff size, level and position.
	Cuff too large or not at heart level.	Check cuff size, level and position.
Displays zeros for systolic and diastolic. Measurement automatically repeats.	Severe vasoconstriction at cuff site.	Move cuff to another limb, check for shock, or verify using another method.
	Erratic blood pressure fluctuations due to arrhythmias or rapid-acting drugs or contractions.	Try again, if no success verify using another method. Wait until contraction has finished.
	Excessive patient movement or convulsions.	Restrain movement or verify using another method.
An error message is displayed.		Refer to the table of error messages for their causes and solutions
If you suspect the signal from the transducer.		Carry out the Parameter Test as described on page 152.
If you suspect the Recorder or display.		Carry out the Quick Test as described on page 151.

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

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Limitations

Oscillometric measurement has some limitations according to the patient's condition. The measurement looks for a regular arterial pressure pulse. If this is difficult to detect the measurement time increases and the measurement itself is unreliable.

Measurements will be:

- Impossible if the patient has an extremely **low (beneath 30) or high (above 240) heart rate**.
- Unreliable or impossible if the **patient's blood pressure is changing rapidly** over the period of time during which the arterial pressure pulses are being analyzed to obtain the measurement.
- Unreliable or impossible if the patient displays **cardiac arrhythmias** causing an irregular heart beat. The measurement time increases.
- Unreliable if the patient is in **severe shock or hypothermia**, since reduced blood flow to the peripheries reduces pulsation of the arteries.
- Unreliable if made during **uterine contractions**.

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

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16
Maternal ECG, Heart and Pulse Rate

Introduction

You can monitor maternal ECG, view the waveform on the screen and print it on the trace. You can also set alarms for heart and pulse rate.

To Begin Monitoring

1. Connect the transducer to the required monitor socket. See "Input Channels at a Glance" on page 25 for a list of possible transducer/socket combinations.
2. Apply the transducer to your patient.

   The loudspeaker emits a click when a heart rate is being monitored. The click volume is controlled via the a service setting. The MHR trace (which is thinner than a fetal trace) prints on the paper. There is no signal quality indicator for MECG.

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

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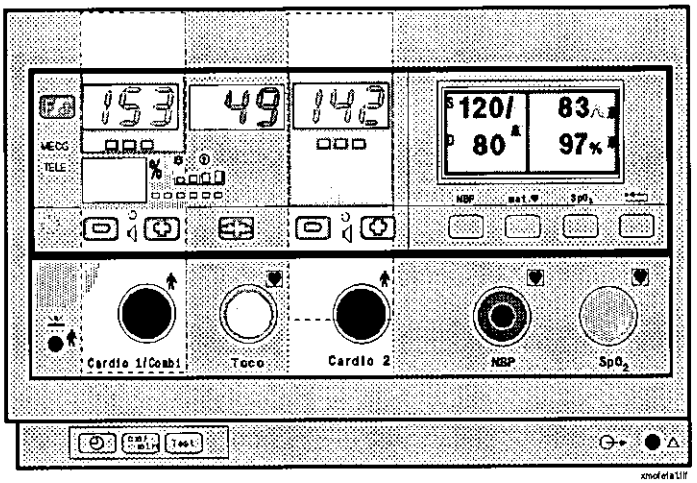
Connecting the Transducer



When you connect the transducer:

1. The "---" display goes out.
2. The MECG indicator comes on.
3. The monitoring mode (either MECG or US1/MECG) is printed on the paper immediately and then every three to four pages.

If a fetal transducer is connected to the Cardio 1/Combi or Cardio 2 channel, then you can change the volume of the maternal heartbeat using the volume keys for the fetal cardio channel.

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

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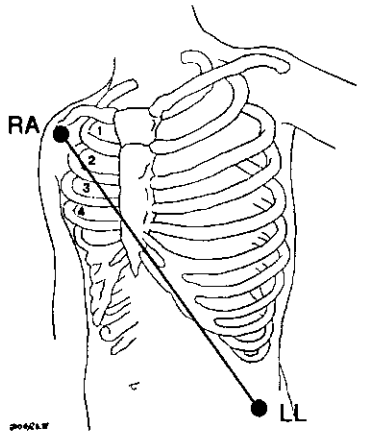
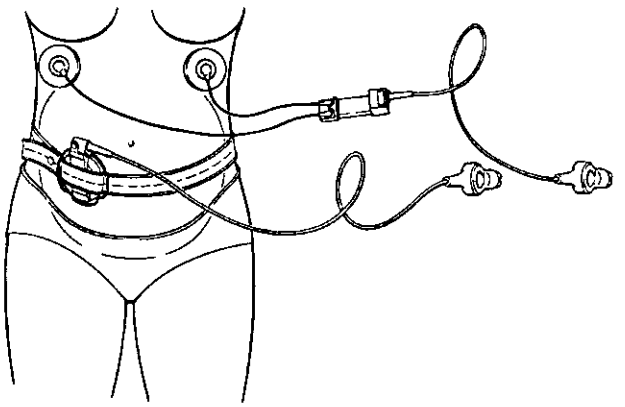
Applying the Electrodes

To obtain a satisfactory maternal ECG waveform you **must** use the RA to LL 2-lead position of the standard 5-lead ECG.



1. Place RA electrode directly below the clavicle and near the right shoulder.
2. Place LL electrode in left lower abdomen.

If you do not want to view the MECG waveform, you can position them as shown in the following diagram. This may be more comfortable for the patient.



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

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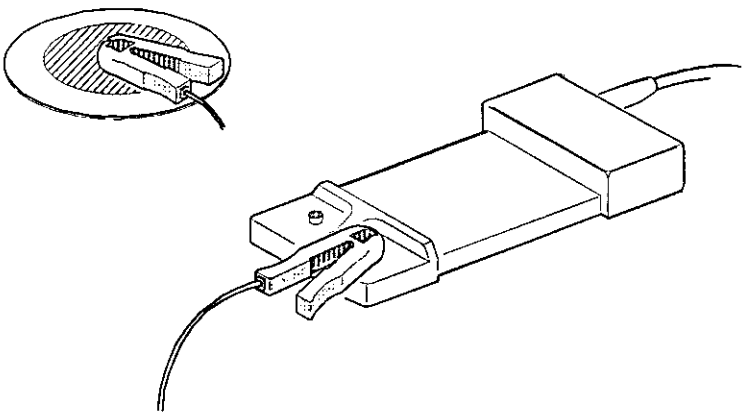
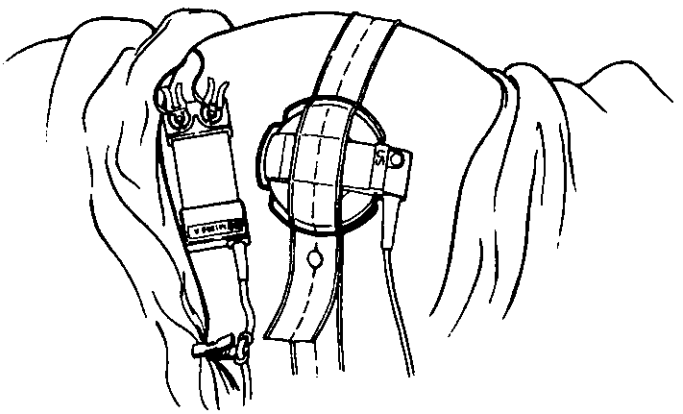
Using MECG transducer M1359A

1. Connect each lead to an electrode and to the transducer.



2. Peel the backing from the electrodes and apply them to the patient.
3. Slide the transducer under the belt or clip the cable to the bed sheet or patient's clothing.



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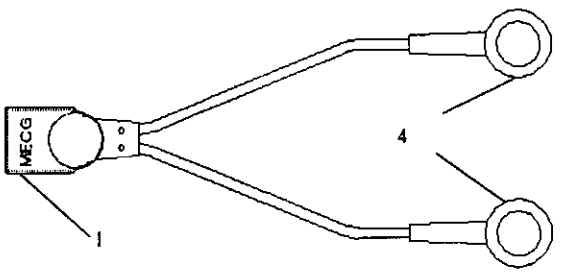
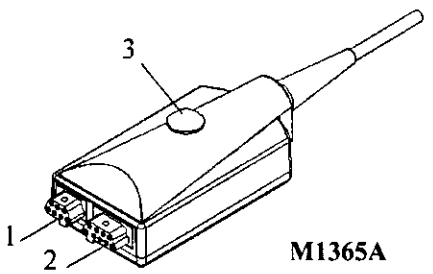
Using a Patient Module (M1364A or M1365A)

1. Connect each lead on the MECG adapter cable to a pre-gelled electrode (4).

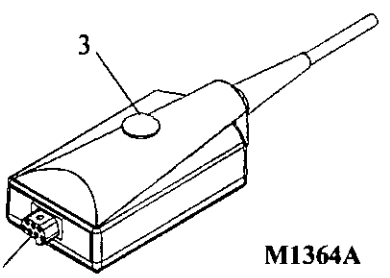


M1363A

2. Peel the backing from the electrodes and apply them to the patient.



M1365A



M1364A

3. Connect the pink connector (1) on the MECG adapter cable to the ECG connector (1) on the patient module.
4. Then fix the patient module to the patient's belt using the fixing knob (3).

Cross-Channel Verification

To reduce the possibility of mistaking maternal heart rate for fetal heart rate (FHR) we recommend that you monitor both maternal and fetal heart rates, especially during the later stages of labor. If FHR and MHR coincide (that is, if the ultrasound transducer records MHR instead of FHR), the monitor's cross-channel verification facility detects this and prints ❓ on the paper after 30 seconds.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118. 378

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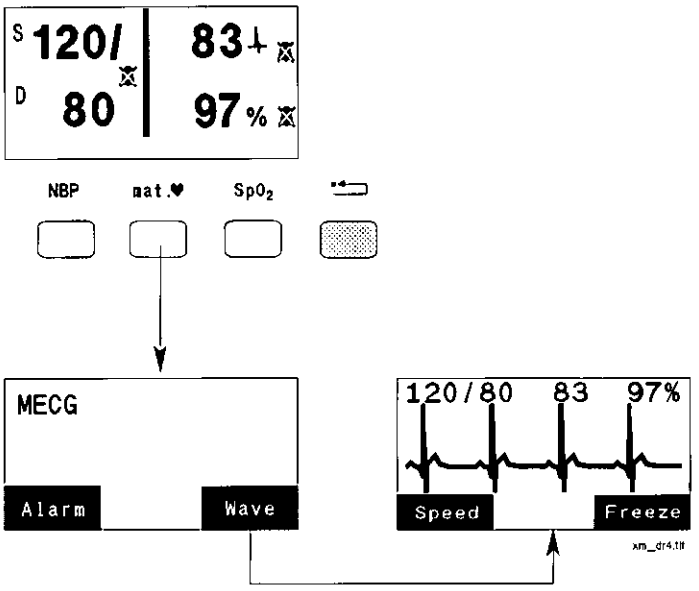
Displaying the MECG Waveform

To display the MECG waveform on the maternal display:

1. Press [mat ♥]. The display changes to the MECG Alarm/wave selection screen.
2. Press Wave. The display changes to the MECG waveform.



Reading from left to right, the figures at the top of the waveform show:

1. Blood pressure (systolic/diastolic)
2. Maternal heart rate (from MECG)
3. SpO_2.

Press the reset key once to return to the maternal main screen while the wave is displayed.

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Changing Display Speed

You can increase or decrease the rate at which waveforms move across the screen. Switch between slow and fast display by pressing Speed.

Freezing and Printing

Freezing the Waveform

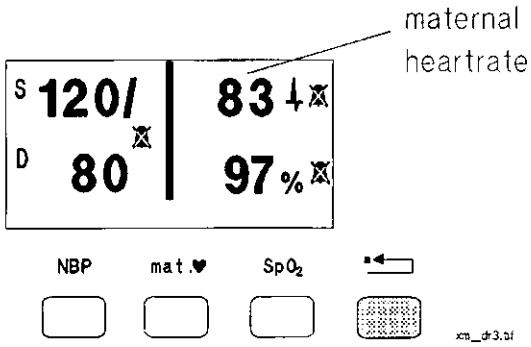
If you want to examine the waveform more closely you can suspend its movement. Press Freeze to halt the display. Press Continue to resume the waveform display. This resumes automatically after 20 seconds if you do not press Continue.

Printing the Waveform

If the recorder is on, you can print the wave onto the paper (after freezing it) by pressing Print. The monitor does not display the Print key if the recorder is off. The recorded waveform is a snapshot covering three to four heart beat periods. You can print wave samples during continuous fetal trace recording.

Maternal Heartrate Source

The maternal main screen shows the maternal heart rate.



There are three possible sources for this:

- MECG (heart rate)
- SpO_2 (pulse rate)
- NIBP (average pulse rate)

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When the MECG transducer is plugged in, an ECG symbol is shown to the right of the heart rate on the maternal display. If both MECG and SpO_2 are being monitored, the MECG heart rate value is used because it is more accurate than the pulse rate value.

If MECG is **not** being measured, but SpO_2 is, the pulse rate is derived from pulse oximetry. A pulse waveform symbol is displayed on the main screen.

If **neither** MECG **nor** SpO2 are being measured an averaged pulse rate from the NIBP measurement is shown. No pulse rate is shown if artifacts are present, or NIBP is used in stat mode. No alarm is possible in this mode. The NIBP symbol is shown on the screen.

Alarm (MECG and SpO_2)

The maternal heart rate (MHR) alarm sounds if the MHR falls below, or rises above, the set limits. You can view the current settings by displaying the power on screen or pressing the yellow key twice. These alarm limits apply to MECG and maternal SpO_2 (if MECG is not being measured).

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

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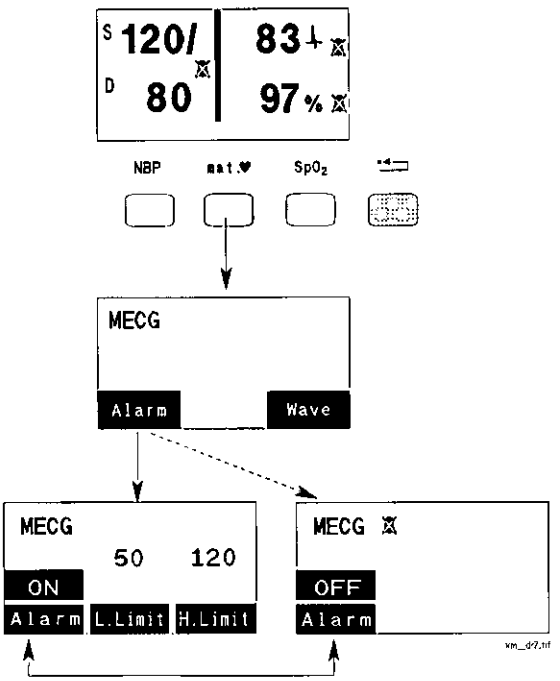
Turning Alarms On and Off



1. Press [mat♥].
   If the maternal heart rate is derived from SpO_2 measurement the alarm setup screen appears immediately. All screens show the word PULSE.

   If the maternal heart rate is derived from MECG, an intermediate screen appears (as shown in the previous diagram). All screens show the letters MECG. You must press **Alarm** to display the alarm setup screen.

2. At the alarm setup screen, press **Alarm** to switch between maternal heart rate alarm on or off. When it is off, the crossed bell icon is displayed. You must switch MHR alarming on before you can change the alarm settings.

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

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Changing Alarm Limits

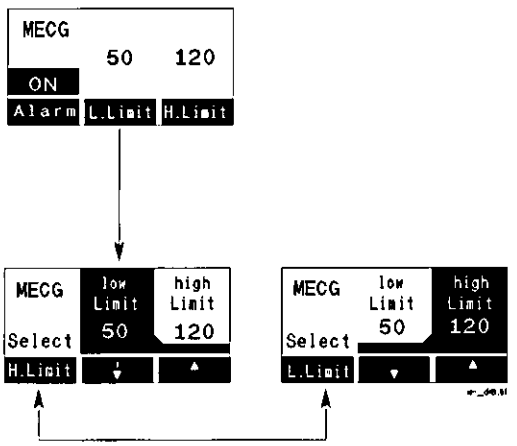
Starting from the maternal main screen, to change MHR alarm limits:

1. Press mat ♥ to display the alarm setup screen.
   Remember, if heartrate is derived from MECG, the monitor displays the intermediate Alarm/Wave selection screen and you must press Alarm for a second time to enter the alarm setup screen.
2. Make sure Alarm is on.
3. Choose whether you want to change the upper or lower limit. Either:

   Press H Limit to select the high limit alarm. Press ↑ to increase the high limit or ↓ to decrease the high limit in steps of five beats per minute.

   OR

   Press L Limit to select the low limit alarm. Press ↑ to increase the low limit or ↓ to decrease the low limit in steps of five beats per minute.



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Troubleshooting

This section details problems that might occur when measuring maternal ECG.

Situation	Possible Cause	Possible Solution
Monitor displays NOP.	Electrodes defective. Bad electrical contact.	Check electrodes and replace if necessary. Check positioning of electrodes.
? prints repeatedly	The ultrasound transducer is recording MHR.	Reposition the ultrasound transducer.
An error message is displayed.		Refer to the table of error messages for their causes and solutions.
If you suspect the signal from the transducer.		Carry out the Parameter Test as described on page 152.
If you suspect the recorder or display.		Carry out the Quick Test as described on page 151.

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

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Troubleshooting

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

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17
Maternal Pulse Oximetry (SpO_2)

Introduction

When you connect a pulse oximetry (SpO_2) transducer to the monitor, you can measure the percentage of oxygen saturation in the maternal blood. The monitor gives an average value calculated across four pulses. The value is recorded on the trace:

- Every five minutes
- After a no pulse condition
- Every 2.5 minutes if an alarm limit is exceeded.

If an MECG transducer is not connected to the monitor, but you are measuring pulse oximetry, the maternal pulse rate is derived from the SpO_2 measurement. The pulse icon ∫⌒ indicates this source.

To Begin Monitoring Immediately

1. Apply the maternal SpO_2 transducer to the patient.
2. Connect the transducer to the monitor, using an adapter cable if necessary. The monitor displays SpO_2 readings as soon as the sensor picks up a pulsatile signal from the patient.

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

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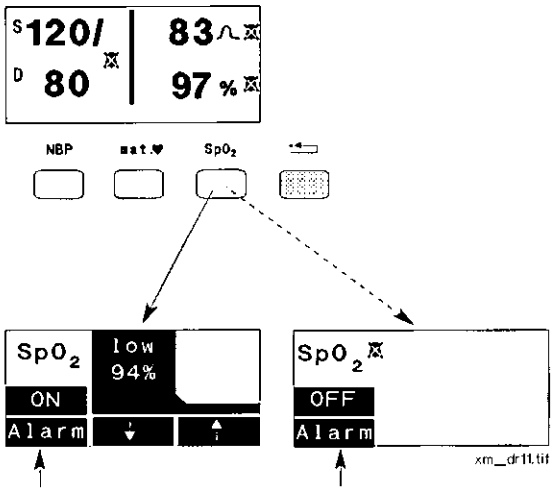
Alarm (SpO_2)

The maternal SpO_2 alarm sounds if the SpO_2 level falls below the alarm value.

Turning Alarm On and Off

1. Press SpO2 to display the pulse oximetry setup screen.
2. Pressing Alarm at the alarm setting screen cycles between alarm OFF and ON.



Changing Alarm Limit

Starting from the maternal main screen, to change SpO_2 alarm limits, press SpO_2 to display the SpO_2 setting screen.

1. Turn Alarm on.
2. Press ↑ to increase the low limit or ↓ to decrease the low limit in steps of 1%. There is no high limit.

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

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Alarm (Pulse rate)

See "Alarm (MECG and SpO2)" on page 128 for how to set the pulse rate alarm.

Troubleshooting

This section details warning messages, possible measurement problems and limitations associated with maternal pulse oximetry measurement.

Warning Messages

Warning Message	Parameter Display	Audible Indication	Possible Cause	What to Do
None.	--%	No.	Transducer or adapter cable disconnected.	Connect transducer or cable.
⚠ SpO_2 no pulse.	NOP.	Yes (if alarming is on).	Pulsation too weak or no pulsation detectable. Transducer incorrectly positioned.	Check patient's pulse. Reposition transducer. Ensure transducer is not on same limb as NIBP cuff.
			Patient wearing colored nail polish.	Remove nail polish.

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Warning Message	Parameter Display	Audible Indication	Possible Cause	What to Do
⚠ SpO_2 low signal.	Normal display.	No.	Weak signal, SpO_2 less accurate.	Reposition transducer or try a different site.
			Wrong transducer selected	Use correct transducer.
			Transducer incorrectly applied.	Reapply transducer.
			Photodetector not opposite light emitter.	Reposition transducer.
			Patient wearing colored nail polish.	Remove nail polish.
⚠ SpO_2 light interference.	-?-	No.	A light source is so high that the SpO_2 transducer cannot measure SpO_2 or HR.	Remove strong light source, or cover transducer with opaque material.
⚠ SpO_2 artifacts.	-0-	No.	Irregular pulse patterns detected, possibly arising from patient movement.	Restrain patient.

Limitations

As with any measurement technique, there are situations that do not allow accurate pulse oximetry readings.

- If the non-invasive blood pressure cuff is on the same limb as the SpO_2 transducer, measurement is compromised during cuff inflation. This may result in a "no pulse" warning. If SpO_2 readings are unsatisfactory, check that the finger transducer is not applied to the same arm as the cuff.
- Pulse oximetry can incorrectly measure the SpO_2 value in the presence of:

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  - COHb, MetHb, and SulfHb
  - Dye dilution chemicals or other disfunctional hemoglobins
  - Intravascular dyes
  - Venous pulsations.
- Severe reduction of pulsatile flow in the arteries can prevent accurate readings. Such a reduction can be caused by:
  - Shock
  - Hypothermia
  - Use of vasoactive drugs.

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

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Troubleshooting

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

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18
Maintenance and Performance Assurance

Preventive Maintenance

Where there are national regulations on the qualification of the testing personnel, and suitable measuring and testing facilities, these must be observed.

You must perform the following checks every 12 months to ensure that your monitor and accessories are in perfect working order.

Caution

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

Visual Inspection

Before using any transducer, patient module, adapter cable or other accessories, you should inspect it carefully to ensure that all its components, such as the housing, cable, and connector are in good condition. If any part is broken or damaged you should not use it.

Routine Inspection

Every 12 months, you must carry out a series of preventive maintenance tasks and performance assurance tests. These ensure that the monitor continues to perform at its best, and reduces the possibility of failures. The tasks to be carried out, their sequence, and the estimated time to complete each one is given in the following table:

Tasks and Tests
Replace the batteries.

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

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Tasks and Tests
Carry out a mechanical inspection of the monitor.
Check transducers, cables, connectors and other accessories for cracks and defects.
Carry out the Quick Test as described on page 151.
Carry out the Parameter Test as described on page 152.

Mechanical Inspection

To carry out a mechanical inspection of the monitor:

- Make sure all exposed screws are tight.
- Check the external cables and housings for splits, cracks or signs of twisting.
- Replace any cables that show serious damage.

Calibration and Electrical Safety Checks

You must calibrate the NIBP function of your monitor every 12 months. Please refer to the Installation and Service Guide for your monitor for details.

Perform electrical safety tests as described in the Installation and Service Guide for you monitor (e.g., after repairs and upgrades).

Disposal

Arrangements for the disposal of your monitor at the end of its working life should conform to your country's laws regarding the disposition of equipment containing electrical parts.

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Care and Cleaning

This section gives you information about how to care for and clean your monitor. Many of the supplies and accessories have their own instructions. You must refer to these for full care and cleaning information. Always follow the manufacturer's directions carefully when cleaning any equipment. Damage caused by using cleaning substances not approved by Philips is not covered under warranty.

Caution

After cleaning, disinfecting, and sterilizing the monitor and accessories, check them carefully. If you see signs of deterioration or damage, do not use the product for further measurements.

Care of the Fetal Monitoring System

Monitor

Keep the outside surfaces of the monitor clean and free of dust and dirt. Do not pour liquid on the monitor or allow any to enter the monitor case. Although the monitor is chemically-resistant to most common hospital cleaners and non-caustic detergents, alternative cleaners are not recommended and may stain the monitor. Take extra care when cleaning the display surfaces; these are more sensitive to rough handling, scratches and breakage than the other external surfaces of the monitor.

Never use an abrasive material such as steel wool or metal polish.

Caution

Wipe around the NIBP connector socket, not over it, to ensure that no water or cleaning solution enters the NBP input connector.

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

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Transducers and Patient Modules

This applies to the following transducers and patient modules:

- $FSpO_2$/ECG combined patient module (M1365A)
- ECG patient module (M1364A)
- Ultrasound transducer (M1356A)
- DECG transducer (M1357A)
- US/MECG Combi transducer (M1358A)
- MECG transducer (M1359A)
- Toco Transducer (M1355A)

Warning
NEVER immerse a transducer in water when it is connected to the monitor.

Note—**The Blue Ultrasound and Toco transducers are protected against the effects of continuous immersion in water according to IEC 529 IP 68.**

DO NOT:

- handle transducers roughly. This could damage the cover, piezoelectric crystals and mechanical movement. Transducer covers are made of soft plastic; avoid contact with hard or sharp objects.
- flex the cables excessively.
- allow cleaning solutions or transducers to exceed a temperature of 45°C (113°F).
- autoclave the transducers and cables or heat them above 70°C (158°F).
- permit the blue Toco transducer's ventilated cable connector to become wet as liquid can enter the ventilation tube through capillary action.

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Adapter Cables

Clean with lint free cloth, moistened with either warm water (40°C/ 104°F maximum) and soap, a diluted non-caustic detergent or one of the approved cleaning agents listed below. Never immerse or soak the cables. Do not allow the cleaning agent to remain on the cable - remove it immediately by wiping with a cloth dampened with water. If you see signs of deterioration or damage, replace the cable. Do not use it for further patient monitoring.

Cleaning

This table lists the recommended cleaning agents for your fetal monitor and accessories.

	Mild soaps	Tensides	Alcohol-based	Aldehyde-based
Monitor	✓	✓	✓	✓
Brown Transducers	✓	✓	✓	✓
Blue Transducers	✓	✓	✓	✓
Belts	✓	✓	✓	✓
Patient Modules M1364A, M1365A	✓	✓	✓	✓
ECG Adapter Cables M1362A, M1363A	✓	✓	✓	✓
DECG Adapter Cable M1362B, ECG legplate adapter M1347A	✓	✓	✓	✓

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Caution

To avoid damage to the product, observe the following general precautions when cleaning unless instructed otherwise in the guidelines supplied with a specific product.

Do not use strong solvents such as acetone or trichloroethylene. Always dilute according to the manufacturer's instructions, or use lowest possible concentration. Never use abrasive materials such as steel wool or silver polish. Never submerge any part of the system and do not allow liquid to enter inside the products. Wipe the cleaning agent off the surface of the equipment immediately with a damp cloth.

Warning

Philips makes no claims regarding the efficacy of the listed chemicals or methods as a means for controlling infection. Consult your hospital's Infection Control Officer or Epidemiologist for information on infection control.

For comprehensive details on cleaning agents and their efficacy refer to "Guidelines for Prevention of Transmission of Human Immunodeficiency Virus and Hepatitis B Virus to health care and public safety workers" issued by the US Department of Health and Human Services, Public Health Service, Center for Disease Control, Atlanta, Georgia, February 1989.

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Disinfecting

We recommend that you disinfect the fetal monitoring equipment only when necessary as determined by your hospital's policy, to avoid long term damage. Never immerse or soak any part of the monitoring system. Do not allow the disinfectant to remain on the equipment. Remove it immediately by wiping with a cloth dampened with water. Clean the equipment before disinfecting it.

This table lists the recommended disinfecting agents for your fetal monitor and accessories

Product	Alcohol-based	Aldehyde-based
Monitor	✓	✓
Brown Transducers	✓	✓
Blue Transducers	✓	✓
Patient Modules M1364A, M1365A	✓	✓
ECG Adapter Cables M1362A, M1363A	✓	✓
ECG legplate adapter cables M1362B, M1347A	✓	✓

Recommended disinfecting agent brands are:

Aldehyde-based	Buraton liquid®, dilution of formaldehyde (3-6%), Cidex®, Gigasept®, Kohrsolin®
Alcohol-based[1]	Ethanol 70%, Isopropanol 70%, Cutasept®, Hospisept®, Kodan®-Tincture forte, Sagrosept®, Spitacid®, Sterilium fluid®

1. Only Ethanol 70% and Isopropanol 70% are tested and qualified

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Caution

To avoid damage to the product, observe the following general precautions when disinfecting unless instructed otherwise in the guidelines supplied with a specific product.

Do NOT use Povodine®, Sagrotan®, Mucovit® or strong solvents.
Do NOT use strong oxidants such as bleach.
Do NOT use bleaches containing sodium hypochlorite.
Do NOT use disinfectants containing iodine complexes.
If you intend to use a cleaning agent not listed here, check its material compatibility first.
ALWAYS dilute according to the manufacturer's instructions.

Recommended Disinfecting Substances

Aldehyde-based	Cidex®
Alcohol-based	Ethanol 70%, Isopropanol 70%

Sterilizing

Monitor, Patient Modules, Transducers

It is not possible to sterilize the monitor, patient modules or tranducers by means of autoclaving, gas treatment, formaldehyde process, or radiation.

Adapter cables M1347A, M1362B

It is not possible to sterilize adapter cables M1347A, M1362B by any means.

Adapter cables M1362A, M1363A

Only ECG adapter cables M1362A and M1363A can be sterilized. They can be sterilized by means of autoclaving or by gas sterilization. We recommend that you sterilize only when necessary as determined by your hospital's policy, to avoid long-term damage to the cable. We also

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recommend that you clean the cables before sterilizing them. The M1362A and M1363A cables have been tested to withstand Ethylene Oxide (Et) gas sterilization. Be sure that all safety precautions regarding aeration after EtO exposure are followed. The cables are tested to withstand autoclaving at 136°C (277°F) maximum.

Caution

Do not use bleaches containing sodium hypochlorite (for example Clorox™) on any of the cables.

IUP (1290C/CPJ840J5)

Refer to the instructions that accompany the transducer.

IUP Transducer Adapter Cable

To remove blood and debris from the adapter cable 1271A Option J05, use Hemesol or an equivalent solvent. Do not:

- Immerse the electrical connectors in liquid. Doing so can damage the connector wiring.
- Steam-autoclave the interface cable. Moisture can damage the connector wiring.
- Use "cold sterilizing" solutions due to possibility of fluid contamination in electrical connectors. Sterilize through an ethylene oxide cycle using standard hospital procedure. When you are not using the interface cable, protect against connector damage by covering with the connector cap provided.

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Belts

Wash soiled belts with soap and water. Water temperature must not exceed 60°C (140°F).

Reusable SpO_2 Transducers

Refer to the instructions that accompany the transducer.

Non-invasive Blood Pressure Cuff

Refer to instructions that accompany the cuff.

Storing Recorder Paper

Recorder paper is not intended for long-term archival storage. Another medium should be considered if this is required.

Dyes contained in thermal papers tend to react with solvents and other chemical compounds that are being used in adhesives. If these compounds come into contact with the thermal print, the print may be destroyed over time. You can take the following precautionary measures to help avoid this effect.

- Store the paper in a cool, dry and dark place.
- Do not store the paper at temperatures over 40°C (104°F).
- Do not store the paper where the relative humidity exceeds 60%.
- Avoid intensive light (UV light), as this may cause the paper to turn gray or the thermal print to fade.
- Avoid storing the thermal paper in combination with the following conditions:

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- Papers that contain organic solvents. This includes papers with tributyl and/or dibutyl phosphates, for example recycled paper.
- Carbon paper and carbonless copy paper.
- Products containing polyvinyl chlorides or other vinyl chlorides for example (but not exclusively) document holders, envelopes, letter files, divider sheets.
- Detergents and solvents, such as alcohol, ketone, ester and others, including cleaning and disinfecting agents.
- Products containing solvent-based adhesives such as (but not exclusively) laminating film, transparent film or labels sensitive to pressure.

To ensure long lasting legibility and durability of thermal printouts, store your documents separately in an air-conditioned place and use

- only plasticizer-free envelopes or divider sheets for protection.
- laminating films and systems with water-based adhesives.

Using such protective envelopes cannot prevent the fading effect caused by other, external agents.

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Self Test

The monitor automatically performs a self test when you switch it on. There are two possible types of error that you might see. A fatal error prevents the monitor from functioning. A non-fatal error allows you to continue to work but warns you of a problem that must be resolved swiftly.

- If a non-fatal error occurs (for example, if the batteries are low):
  - An error message is displayed for ten seconds.
  - Err xxx ⚠, time and date are printed on the paper after ten seconds, and then every ten minutes.
    ("xxx" is the number of the error message.)
  - Switch the monitor off and then on. If the error occurs again, try to solve the problem or, if you cannot, contact your Philips Service Engineer or Medical Response Center.

    (If the recorder is not on when the monitor is switched on, Err xxx ⚠ time and date are printed when it is switched on subsequently.)
- If a fatal error occurs (for example, if a board is defective):
  - An error message is displayed for ten seconds
  - After ten seconds, the monitor tries to restart.

  If the error occurs again contact your Philips Service Engineer or Response Center.

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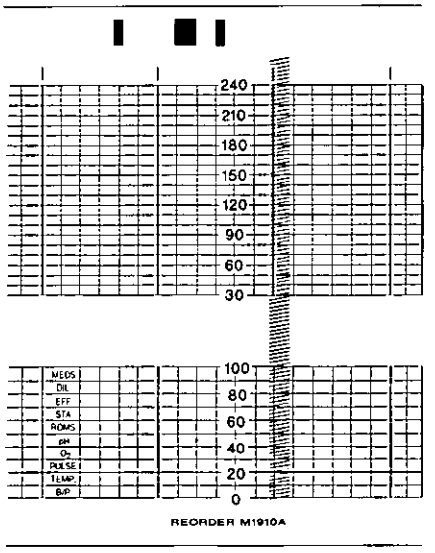
Quick Test

The quick test takes approximately 15 seconds and tests the basic electronics of the monitor. To carry out the test:

1. Remove any monitoring equipment plugged into the input sockets. Switch off or disconnect the telemetry receiver and any external devices connected to the monitor.
2. Switch on the monitor.
3. Press and release the test key. Check that:
   - The fetal displays flash, and the two halves of the maternal display flash alternately.
   - The recorder on/off light blinks in time with the display.
   - A test pattern is printed on the paper.



   - Check the lines in this test pattern to ensure the heating elements on the printer head are operational. Lines printed on the colored grid lines may appear light, but this is not considered to be a fault.
   - The monitor performs its power on test.

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If any of these fail, contact your Philips Service Engineer or Response Center.

If an error occurs:

- An error message is displayed for ten seconds.
- Err xxx ⚠ time and date are printed on the trace after ten seconds, and then every ten minutes.
- ("xxx" is the number of the error message.)

To stop the error annotation printing, switch the monitor off and then on. If the error is repeated, contact your Philips Service Engineer or Response Center.

Parameter Test

The parameter test checks the signal path to and from the input sockets, but not the transducers or patient modules themselves. To carry out the test:

1. Switch on the monitor and the recorder.
2. Connect the appropriate transducer to each socket.
3. Press and hold the test key.

The correct monitor response for each signal is:.

Signal	Correct Monitor Response
US (Cardio 1) using M1356A	190 is displayed and printed. Signal quality indicator is green. Fetal heartbeat is heard from loudspeaker.
US (Cardio 2) using M1356A	170 is displayed and printed. Signal quality indicator is green. Fetal heartbeat is heard from loudspeaker.
Toco using M1355A	A signal alternating between 10 and 60 is displayed and printed.

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Signal	Correct Monitor Response
DECG using M1364A, M1365A or M1357A	200 is displayed and printed. Signal quality indicator is green. Fetal heartbeat is heard from loudspeaker.
MECG using M1364A, M1365A or M1359A	120 is printed. MECG is on.
US/MECG (Cardio 1) using M1358A	190 is displayed. 190 and 120 are printed. Signal quality indicator is green. MECG is on. Fetal and maternal heartbeats are heard from the loudspeaker.
SpO_2 using M1191A with M1940A	99% is displayed on LCD and printed. Pulse 120 ∫⌒ displayed on LCD.
$FSpO_2$ using M1365A	88% displayed.

If your monitor's response is different, contact your Philips Service Engineer or Response Center.

If an error occurs:

- An error message is displayed for ten seconds.
- Err xxx ⚠ time and date are printed on the paper after ten seconds, and then every ten minutes.
  ("xxx" is the number of the error message.)

To stop the error annotation printing, switch the monitor off and then on.

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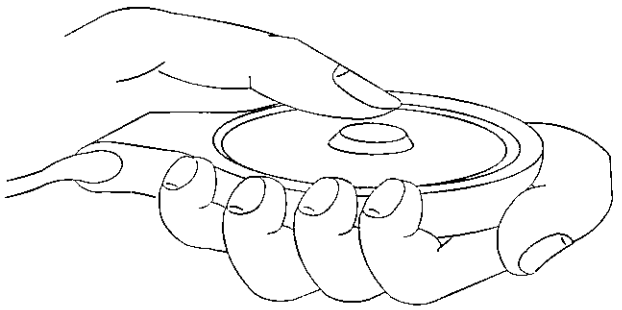
Testing Transducers

If any of the following tests fail, repeat the test using another transducer. If it still fails, contact your Philips Service Engineer or Response Center.

Toco

To test a Toco transducer:

1. Switch on the monitor and the recorder.
2. Connect the transducer to the Toco socket.
3. Gently apply pressure to the pick-up button.



4. Check that the value on the display and paper shows this change in pressure.

Ultrasound

To test an ultrasound transducer:

1. Switch on the monitor and the recorder.
2. Connect the transducer to the Toco socket.
3. Increase the loudspeaker volume to an audible level.

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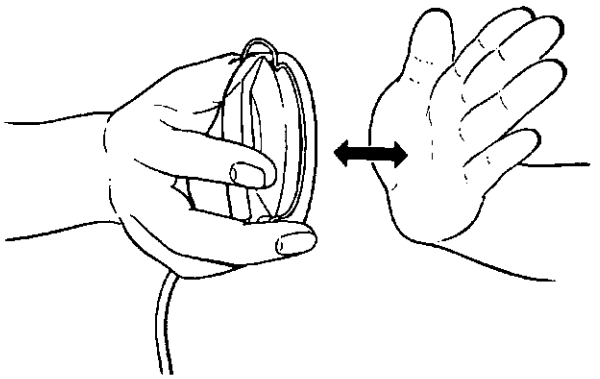
4. Holding the transducer in one hand, move your other hand repeatedly towards and then away from the surface.



5. Check that a noise is heard from the loudspeaker.

IUP

1. Switch on the monitor and the recorder.
2. Connect the transducer to the Cardio 1/Combi socket.
3. Gently apply pressure to the syringe plunger.
   Check that the value on the display and paper shows this change in pressure.

ECG

1. Connect the ECG transducer to the fetal monitor, (M1364A, M1365A, M1357A, M1358A, M1359A).
2. Disconnect any electrodes and adapter cables from the transducer input.
3. Switch on the fetal monitor.
4. After the internal selftest has run, the display should show "NOP". If it does not, the transducer is defective and needs replacing.

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Replacing the Batteries

The monitor's internal clock is powered by two batteries that are located behind a panel at the rear. The average life span of these batteries is one year. We recommend replacing them during the annual preventative maintenance cycle. When the battery charge is low, the message is displayed, and is printed on the recorder trace. When this happens, replace the batteries as soon as possible.

To replace the batteries:

1. Switch off the monitor and disconnect it from the mains supply.
2. Replace the batteries with two alkaline 1.5 Volt size N batteries.
3. Replace the mains supply and switch the monitor on.
4. Reset the time and date to prevent the wrong time and date from being printed on the recorder trace.

If the batteries are not replaced when necessary, the specific settings will return to their default values and will have to be reset each time the monitor is switched on. For example, the date is set to 4.4.44 and Toco baseline to 20 units. Leaking batteries could damage the monitor. If the monitor is not used for long periods, remove the batteries.

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Replacing the Fuses

Fuse values are printed on the rear of the monitor:

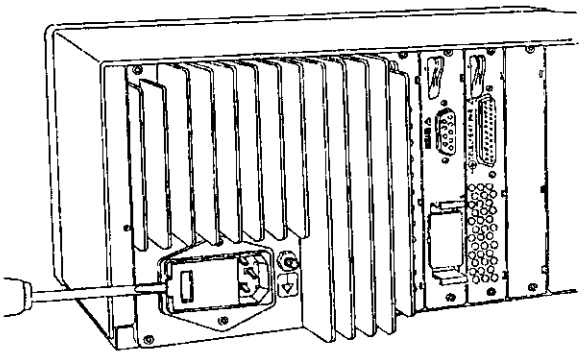
For 100/120V ~ Line Voltage T1A/250V

For 220/240V ~ Line Voltage T500mA/250V

(~ means "alternating current")

To replace the fuses:

1. Switch off the monitor and disconnect it from the main power supply.
2. Using a flat-blade screwdriver, prise open the fuse cover.



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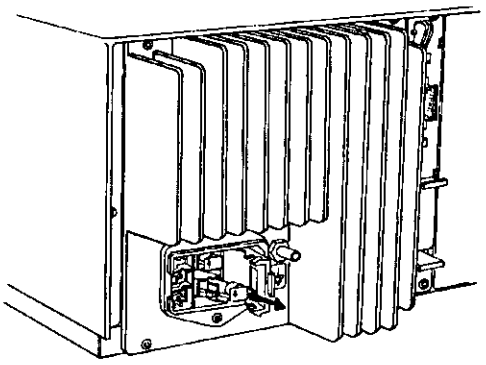
3. Lift the fuse holder slightly and pull it out.



4. Remove the fuse from the holder and replace it with another of the correct value.
5. Slide the holder back into place, aligning the arrow on the holder with the arrow on the cover.
6. Repeat steps 3 to 5 for the second fuse.
7. Close the fuse cover.

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Troubleshooting

Introduction

Common problems that may occur during monitoring are dealt with in the relevant chapters in this book.

More details are given in the *Installation and Service Guide* for your monitor.

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Error Messages

Error	Display	Cause	Solution
Err 1	Cardio 1	Wrong transducer in Cardio 1/ Combi socket.	Connect correct transducer.
Err 1	Cardio 2	Wrong transducer in Cardio 2 socket.	Connect correct transducer.
Err 2	Toco	Wrong transducer in Toco socket.	Connect correct transducer.
Err 4	Cardio 2	US/MECG Combi transducer not allowed in this socket.	Only 1 x MECG or 1 x DECG are permitted in combination. Remove transducer.
Err 6	Cardio 1 Cardio 2	Wrong pairing of US/MECG Combi transducer, MECG transducer and DECG transducer.	Remove one of the transducers.
Err 8	Cardio 1 Cardio 2	Dual Ultrasound Twins option is not fitted.	Remove one of the transducers.
Err 9	Cardio 1 Cardio 2	Invalid telemetry mode.	Check the cable from the telemetry receiver and if, necessary, replace it.
Err 16	Cardio 1 Toco Cardio 2	Wrong pairing of telemetry and transducers.	Either disconnect the transducers or switch off the telemetry receiver.
Err 101	Cardio 1	$FSpO_2$ patient module defective.	Replace patient module M1365A.
Err 102	Cardio 1	Communication error - no connection between $FSpO_2$ patient module and monitor.	Replace patient module M1365A.
Err 103	Cardio 1	$FSpO_2$ sensor defective.	Use a new sensor.
nop	Cardio 1 Cardio 2	No contact, or poor contact, between reference electrode and mother.	Use a new spiral electrode.

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Message	Cause	Solution
Err bAt[1] [2]	Battery low or empty of charge	Change the batteries as soon as possible. If you do not change the batteries, your specific settings will return to their default values when the monitor is switched on. (For example, the date is set to 4.4.44.)
Err PAP 30-240 ⚠ [3] Err 602[4]	Incorrect type of paper loaded	Load paper with 50-210 scale or change the monitor's paper format setting (see the *Installation and Service Guide*).
Err PAP 50-210 ⚠ [3]	Incorrect type of paper loaded	Load paper with 30-240 scale or change the monitor's paper format setting (see the *Installation and Service Guide*).
Err xxx ⚠ [3]	xxx is between 500 and 600. This indicates a technical failure diagnosed by the monitor's self test program.	Contact your Philips Service Engineer or Medical Response Center.
Error 601 ⚠ [3]	Paper speed	Check that correct paper is used. Check the speed by timing how long it takes for the paper to advance 1cm: 60 seconds = 1cm/min 30 seconds = 2cm/min 20 seconds = 3cm/min Contact your Philips Service Engineer or Medical Response Center if the speed is incorrect.

1. Displayed for ten seconds when the monitor is first switched on.
2. Printed every 10 minutes.
3. Printed every three pages.
4. Displayed for 10 seconds.

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Error Messages

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20 Accessories

Introduction

This chapter lists the accessories supplied as standard and as options. Items are subject to availability and this chapter is not, therefore, a definitive listing. Do not use accessories that are not approved by Philips. You may damage the equipment and this type of damage is not covered by warranty.

Standard Accessories

The following accessories are supplied as standard with the monitor:

Fetal Accessories

- 1 x M1365A combined patient module for $FSpO_2$ and DECG or MECG plus adapter cables (Series 50 XMO only)
- 2 x M1356A ultrasound transducers
- 1 x M1355A Toco ext. transducer
- 4 x reusable transducer belts
- 3 x transducer knob adapters
- 1 x bottle of gel
- 5 x fetal scalp electrodes
- 1 x M1364A DECG patient module and adapter cables
- 1 x remote event marker.

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Maternal Accessories

- 1 x M1364A combined DECG/MECG patient module and adapter cable
- 1 x M1574A adult NIBP cuff
- 1 x M1575A large adult NIBP cuff
- 1 x M1599B NIBP monitor to cuff interconnect tubing (3.0m)
- 1 x M1191A reusable adult finger SpO_2 transducer
- 1 x M1940A adapter cable for Philips SpO_2 transducers.

Documentation

- Quick Reference Guide
- Pocket Guide to Fetal Monitoring (English language shipments only)
- Operating Guide
- Installation and Service Guide
- Application Note: Fetal Oxygen Monitoring. Technical Issues (Series 50 XMO only)
- Sensor Placement Guide (Series 50 XMO only).

Optional Accessories

The following accessories can also be supplied when the appropriate option is ordered.

Code	Option
C07	Pressure Transducer and IUP kit.
C08	M1333A disposable intrauterine sensor-tip pressure catheters and M1334A reusable connector cable.
H04	Paper tray.

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Code	Option
H15	Barcode Reader, including a reader and barcode booklet.
J12	Combined analog/digital system interface for OBMS/ODIS.
J13	Maternal parameter interface to connect external patient monitor. Use this only if your monitor has no internal maternal parameters installed. The following external devices can be connected: – M1165A/1166A/1175A/1176A Philips CMS. – 78352C/78354C Compact Configurable Monitors. – Dinamap 1846 and 8100 NIBP Monitors. A model 8801 adapter is required from General Electric to connect the Dinamap 8100. – Press-Mate/Listmini Model-BP-8800 NIBP Monitor. – Accutorr 3, Accutorr 3 (Sat) – Accutorr 4, Accutor 4 (Sat) NIBP (SpO_2) Monitors. – Nellcor N-200 Maternal SpO_2 Monitor – Nellcor OxiFirst™ Fetal Oxygen Saturation Monitor (N-400). One interface cable is provided with this option. If you want to connect a Nellcor monitor in addition to one of the other monitors, order a second interface cable M1350-61609. This is for Series 50 XM only.
2AE	Cart CL.
2AF	Cart CM.
2AG	Cart CX.
0B5	Video Operating Guide.

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

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Paper

Use only the following types of paper:

Product Number	Country	FHR Scale	Color of Grid	kPa Scale	Highlighted 3cm Lines
M1910A	USA/Canada	30-240	Orange	No	Yes
M1911A	Europe/Japan	50-210	Green	Yes	No
M1913A	Japan	50-120	Green	No	Yes
M1913J	Japan	50-210	Green[1]	No	Yes

1. Normal bradycardia and tachycardia ranges alarm ranges are yellow; severe bradycardia and tachycardia ranges are red.

The paper is chemical/thermal, fanfold, with a labor scale of 0 to 100 units @ 25 units/cm. Each pack of paper has 150 numbered pages. Paper is supplied in cases of 40 packs.

Do not use paper with sprocket holes intended for 8040A/8041A Fetal Monitors as the trace may not be legible and a paper jam may occur.

Gels

40483A Aquasonic transmission gel for use with ultrasound transducers.

- Available worldwide.
- Water-soluble.
- Easy patient clean-up.
- Supplied in packs of 12 bottles (each 250ml).
-

40483B 5-liter refill container (with dispenser) to refill 40483A bottles. Shelf life: 24 months maximum; 6 months minimum.

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

Records processed under FOIA Request #2015-4103; Released by CDRH on 06-06-2016.

Transducers and Patient Modules

All transducers are supplied individually.

M1355A Toco Transducer

M1356A Ultrasound Transducer

M1358A US/MECG Combi transducer for ultrasound or MECG monitoring

M1359A MECG Transducer

M1365A $FSpO_2$/ECG combined patient module

M1364A ECG only patient module

MECG Electrodes and Cables

M1363A Reusable MECG adapter cable for M1364A or M1365A patient module.

40493D Disposable pre-gelled electrode for abdominal ECG.

- Silver/silver-chloride sensor
- Pre-gelled
- 54mm (2in) diameter
- Foam-backed
- Supplied in packs of 5
- (1 case = 4 boxes = 60 packs = 300 electrodes)
- Shelf life: 18 months maximum; 6 months minimum.

M1531B Electrode cable for MECG electrode 40493D.

- Supplied in packs of 4.

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

Records processed under FOIA Request #2015-4103; Released by CDRH on 06-06-2016.

DECG Cables

M1362A Reusable DECG adapter cable for M1364A or M1365A patient module, for open-wire electrodes.

M1362B Reusable DECG adapter cable for M1364A or M1365A patient module, scalp electrodes with a connector.

M1349A Pad electrode for fixing M1362B

Disposable Scalp Electrodes

15133D Available in Europe only.

- Double spiral
- Driven by inner drive tube
- Gamma sterilized
- Supplied in packs of 25. Shelf life: 24 months maximum; 6 months minimum.

15133E Available worldwide.

- Single spiral
- Driven by inner drive tube
- Radiation sterilized
- Supplied in packs of 50
- Shelf life: 24 months maximum; 6 months minimum.

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

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Fetal Oxygen Sensor

Nellcor FS14	Must be ordered directly from the local Tyco Healthcare distributor.

IUP Transducers

CPJ840J5

IUP pressure transducer, supplied with transducer holder CPJ84046. Use with sterile disposable domes CPJ84022.

IUP Catheters

M1333A

Disposable intrauterine sensor-tip pressure catheter (5 mV/VmmHg ± 2% tolerance). Supplied in boxes of 10. M1353A Option C08 includes one box of catheters (M1333A) and one reusable connector cable M1334A. Worldwide availability.

- Radiation sterilized
- Contains 10 disposable catheters
- Shelf life 24 months maximum: 6 months minimum

Related products: M1334A reusable connector cable for use with M1333A catheter.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118. 402

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Domes

CPJ84022

Sterile, disposable dome for use with IUP pressure transducer CPJ840J5.

- Supplied in packs of 50.
- Shelf life: 18 months maximum.

IUP Transducer Holder

CPJ84046

IUP Transducer holder

- For use with IUP pressure transducer CPJ840J5.
- Supplied in packs of four.

Maternal Accessories

NIBP Accessories

Non-Sterile Cuffs

- M1876A (small adult)
- M1877A (adult)
- M1878A (large adult)
- M1879A (thigh)

Sterile Cuffs

- M1808A (small adult)
- M1809A (adult)
- M1829A (large adult)

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

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Reusable Cuffs

- M1573A (small adult)
- M1574A (adult)
- M1575A (large adult)
- M1576A (thigh)

Long Life Cuff Kit

- M1578A (contains M1573A, M1574A, M1575A and M1576A)

Interconnect Tubings

- M1598A (1.5m)

SpO_2 Accessories

Philips Transducers

- M1191A (requires M1940A adapter cable)
- M1192A SpO2 Small Adult (requires M1940A adapter cable)
- M1194A SpO2 clip (ear) (requires M1940A adapter cable)

Philips/NELLCOR Disposable Transducers

Each of the following transducers requires adapter cable M1900B which must be ordered separately.

- M1904B (Oxisensor II D-25 adult)
- M1903B (Oxisensor II D-20 small adult)

Adapter Cables

- M1900B connector cable for Philips/NELLCOR transducers
- M1940A adapter cable for Philips transducers

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

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Belts and Buttons

Reusable Abdominal Transducer Belt (M1562A)

- Pre-cut.
- Width: 50mm
- Length: 1.3m
- Supplied in packs of 5.

Belt Buttons (M1569A)

- Supplied in packs of ten.

Transducer Knob Adapter (M1356-43201)

- Supplied in packs of three.

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

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21
Specifications

Introduction

The following section gives the manufacturer's specification for the monitor.

Patient Safety

The monitor is designed to comply with:

- IEC 60601-1/EN 60601-1
- UL 2601-1
- CSA-C22.2 No 601.1-M90

Parameter	Input Connector	Resulting Isolation
IUP, TOCO, NIBP, SpO2	CF	CF
US (M1356A)	B	B
DECG (M1357A)	B	CF
MECG (M1359A)	B	CF
DECG or MECG via M1364A	B	CF
FSpO2 and either MECG or DECG via M1365A	B	CF

None of the ECG modes are electrosurgery proof.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118. 426

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Operating and Environmental

Power Requirements	Operating Voltage	100 - 120 V (± 10%) 220 - 240 V (±10%)
	Line Frequency	50 to 60 Hz
	Power Consumption	60 VA max
Environment	Operating Temperature	0°C to + 55°C
	Storage Temperature[1]	-40°C to +75°C
	Relative Humidity	5% to 95%°
Dimensions and Weight without transducers	Height	147 mm (5.8in)
	Width	422mm (16.6in)
	Depth	392mm (15.4in)
	Weight	14.6kg (31.96lb)

1. Excludes transducers. Transducers can be stored at temperatures from -40°C to +60°C.

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

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Fetal Display

Heart Rate Range	US	50 to 240 bpm
	DECG	30 to 240 bpm
	MHR	30 to 240 bpm (not displayed)
External Toco Range		0 to +127 relative units
IUP Range		-99 to +127 mmHg
Fetal SpO_2 Range	0 - 99%	

Maternal Non-invasive Blood Pressure

Pressure Transducer Accuracy	15°C to 25°C	±3 mmHg
	10°C to 35°C	±3 mmHg (±0.6% of reading)
	0°C to 55°C	±3 mmHg (±1.7% of reading)
Measurement Ranges	Systolic	30 to 270 mmHg
	Diastolic	10 to 245 mmHg
Cuff Inflation Rate	Typically less than 10 seconds	
Auto Mode Repetition Time	2, 5, 10, 15, 30, 60 minutes	
Stat Mode Duration	5 minutes	

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

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Maternal Non-invasive Blood Pressure

Cycle Time (Typical at HR over 60 bpm)	Auto/manual	35 seconds
	Stat	17 seconds
	Maximum	120 seconds
Limit Alarms	Adjustment	5mmHg steps
	Diastolic	10 to 245mmHg
	Systolic	30 to 270mmHg
	Overpressure Safety Limit	300 mmHg for more than 2 seconds
Pulse Rate Range	Measurable within heart rate range of 30 to 240 bpm, averaged during NIBP measurement.	

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

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Maternal Pulse Oximetry

Percentage Range	0 to 100%		
BPM Range	30 to 300 bpm		
Accuracy	± 1%		
Resolution	1 bpm		
Pulse Rate Limit Alarms	Range	70% - 90%	
	Adjustment	1% steps	
Accuracy at 1 standard deviation	M1191A	70 to 100%	± 2.5%
	M1192A	70 to 100%	± 2.5%
	M1194A	70 to 100%	± 4%
	Nellcor sensors	80 to 100%	± 3%

Maternal ECG and Heart Rate

Heart rate Measurement	Range	30 to 240 bpm
	Accuracy	±1 bpm
	Resolution	Recorder: 0.25 bpm
		Display: 1 bpm
Heart rate Alarm Limits (excluding NIBP)	Range	30 to 250 bpm
	Adjustment	5 bpm steps

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

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Maternal Display Section

Numerical Display

Two heart rate displays (orange) and one uterine activity display (green). Type: (10mm) 7 segment LEDs.

Maternal Display

The maternal display shows:

- systolic measurement
- diastolic measurement
- SpO_2 level
- maternal heart rate (if derived from MECG), pulse rate (if derived from pulse oximetry) or average pulse rate (if derived from NIBP)
- Alarm status for each parameter (except NIBP pulse rate)
- Warning message (if any)

Mode Display

Mode display for MECG and Telemetry (Telemetry mode will be displayed when an M1310A Fetal Telemetry System is connected and powered up.)

Two signal quality indicators (cardio channels only): green, yellow and red show signal quality. Acceptance lamps flash with valid heart rate measurement (M1350B only).

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

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Ultrasound, External and Internal Toco

Ultrasound Mode	System	Pulsed Doppler oscillator
	Frequency	998.4kHz
	Repetition Rate	3.2kHz
	Ultrasound Intensity	1.5mW/cm^2 average for each of the seven active surfaces (using M1356A transducer)
External Labor	Signal Range	0 to 100 units
	Offset Compensation	±200 units
Intrauterine Pressure	Signal Range	-99 to +127mmHg
	Patient Leakage Current	10µA. Displayed pressure unit mmHg.
	Sensitivity	Automatically selectable between 40µV/V/mmHg (M1348A) and 5µV/V/mmHg (M1334A and CPJ840J5)

Recorder

Recorder mechanism: 5 channel, high resolution (8 dots per mm, 200 dots per inch) thermal array recorder, paper end detection. Paper speeds 1, 2 and 3cm/min.

Annotation: time of day and date (automatic annotation every 10 minutes), paper sensing mode (annotated with each alteration of parameter).

Paper advance speed: 24cm/min. Automatic stop at perforation line.

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

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FHR (Cardio) Scales

	Scale A	Scale B	Uterine Activity (Toco) Scale
Vertical Scale Size	7cm	8cm	4 cm
Vertical Scale Sensitivity	30 bpm/cm	20 bpm/cm	25 units/cm
Range	30 to 240 bpm	50 to 210 bpm	0 to 100 units

Z-fold paper with numbered pages

Recording times per pack:

8h 20min at 3cm/min.

12h 30min at 2cm/min.

25h at 1cm/min.

Fetal Movement Profile (FMP) recording:

2 mm high bars on upper Toco scale.

Testing Facilities

Test button: With no front end connections to the instrument a thorough instrument test is performed including a display and recorder test. With the appropriate transducer connected the respective mode can be tested. See Chapter 18, "Maintenance and Performance Assurance".

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

Records processed under FOIA Request #2015-4103; Released by CDRH on 06-06-2016.

Declaration

CE 0366

These medical devices comply with the requirements of the Medical Devices Directive (93/42/EEC) concerning medical devices.

This product is classified as Class IIb in accordance with Annex IX of the Medical Devices Directive (93/42/EEC).

Manufactured by:	Philips Medizinsysteme Boeblingen GmbH Hewlett-Packard Str. 2, Boeblingen, Germany
Product Name:	Fetal Monitor Series 50 XM and 50 XMO
Model Numbers:	M1350B and M1350C
Standards complied with:	
Safety, Performance	EN60601-1:1990+A1:1993+A2:1995 {IEC 60601-1:1988+A1:1991+A2:1995}
EMC	EN60601-1-2:1993 {IEC 60601-1-2:1993}

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

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Declaration

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

YJS

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22 Warranty

Manufacturer's Responsibility

Philips only considers itself responsible for any effects on safety, reliability and performance of the equipment if:

- Assembly operations, extensions, re-adjustments, modifications or repairs are carried out by persons authorized by Philips, and
- The electrical installation of the relevant room complies with national standards, and
- The instrument is used in accordance with the instructions for use.

Warranty

Philips hardware products are warranted against defects in materials and workmanship. If Philips receives notice of such defects during the warranty period, Philips shall, at its option, either repair or replace hardware products which prove to be defective. Some newly manufactured products may contain selected remanufactured parts equivalent to new in performance.

Philips software and firmware products which are designated by Philips for use with a hardware product, when properly installed on that hardware product, are warranted not to fail to execute their programming instructions due to defects in materials and workmanship. If Philips receives notice of such defects during the warranty period, Philips shall repair or replace software media and firmware which do not execute their programming instructions due to such defects. Philips does not warrant that the operation of the software, firmware or hardware shall be uninterrupted or error free.

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

WSB

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If Philips is unable, within a reasonable time, to repair or replace any product to a condition as warranted, Customer shall be entitled to a refund of the purchase price upon return of the product to Philips.

1. Duration and Commencement of Warranty Period

The warranty period for each product is one year, depending upon the warranty classification code of the product at time of order. The applicable warranty code shall be specified on the Philips Price List. The warranty period begins either on the date of delivery or, where the purchase price includes installation by Philips, on the date of installation. If Customer schedules or delays installation more than thirty (30) days after delivery, the warranty period begins on the thirty-first (31st) day from the date of delivery.

2. Place of Performance

Within Philips service travel areas, warranty and installation services for products installed by Philips and certain other products designated by Philips will be performed at Customer's facility at no charge. Outside Philips service travel areas, warranty and installation services will be performed at Customer's facility only upon Philips's prior agreement and Customer shall pay Philips's round trip travel expenses and applicable additional expenses for such services.

On-site warranty services are provided only at the initial installation point. If products eligible for on-site warranty and installation services are moved from the initial installation point, the warranty will remain in effect only if Customer purchases additional inspection or installation services at the new site.

For product warranties requiring return to Philips, products must be returned to a service facility designated by Philips. Portable products (battery powered) and products purchased under Philips' international prices can be returned to the closest authorized Philips repair depot worldwide. All other products with return to Philips warranty must be returned to one of the authorized repair depots within the country of original purchase. Customer shall prepay shipping charges (and shall prepay all duty and taxes) for products returned to Philips for warranty service. Except for products returned to Customer from another country, Philips shall pay for return of products to Customer.

Installation and on-site warranty services outside the country of initial purchase are included in Philips' product price only if Customer pays Philips international prices (defined as destination local currency price or

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

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Export price). Service outside the country of initial purchase is subject to the conditions regarding Philips service travel areas and initial installation point described above.

3. Limitation of Warranty

The foregoing warranty shall not apply to defects resulting from:

a. Improper or inadequate maintenance by Customer;
b. Customer-supplied software or interfacing;
c. Unauthorized modification or misuse;
d. Operation outside of the environmental specifications for the product; or
e. Improper site preparation and maintenance.

TO THE EXTENT ALLOWED BY LOCAL LAW, THE WARRANTY SET FORTH ABOVE IS EXCLUSIVE AND NO OTHER WARRANTY, WHETHER WRITTEN OR ORAL, IS EXPRESSED OR IMPLIED AND PHILIPS SPECIFICALLY DISCLAIMS THE IMPLIED WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE

4. Australia and New Zealand Only

For consumer transactions the warranty terms contained in this statement, except to the extent lawfully permitted, do not exclude, restrict or modify and are in addition to the mandatory statutory rights applicable to the sale of this product to you.

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

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Warranty

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

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23
Training Evaluation

M1350 XM, XMO Fetal Monitoring Lab Evaluation

Competency Statement

The Student will be able to perform the basic monitoring functions.

Performance Objectives

The following objectives provides evidence of minimum achievement of the above competency. The student will explain or demonstrate how to:

1. Identify the components of the fetal monitor.
2. Perform a quick test on the monitor.
3. Perform a transducer check.
4. Load and advance the recorder paper.
5. Identify and connect the ultrasound (US) transducers.
6. Adjust the fetal heart rate (FHR) volume.
7. Explain and adjust the FHR offset feature for twin FHR monitoring.
8. Identify and connect the Toco transducer.
9. Identify and connect the intrauterine pressure (IUP) catheter.
10. Identify the maternal vital sign measurements available and connect the appropriate cables for the measurements.
11. Identify the types of maternal alerts available and silence the alerts.
12. Describe the fetal movement profile (FMP) measurement and enable the measurement.
13. Change the clock time and replace the battery.

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

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14. Turn off and on the arrhythmia logic feature.
15. Identify the symbol for cross channel verification that is printed on the recorder paper.
16. Mark an event on the fetal tracing.

Maternal Parameters

17. Distinguish the pulse source for the maternal heart rate.
18. Obtain the maternal ECG waveform.
19. Perform a maternal SpO_2 measurement.
20. Identify the NBP setup screens and obtain a reading.
21. Adjust the screen contrast and the alarm volume on the fetal monitor.

Fetal SpO_2

22. Identify the elements of the $FSpO_2$ display.
23. Identify the causes of $FSpO_2$ alarms.

Fetal Telemetry

24. Identify the components of the fetal telemetry system.
25. Identify causes of transmission INOP conditions.
26. Describe the interface of the telemetry receiver to the fetal monitor.
27. Identify the steps to successful connect the fetal telemetry system to a fetal monitor.

Resources

If there are additional questions the following resources are available:

1. Instructions for Use
2. Quick Instructions for Use
3. Series 50 XM & 50 XMO Fetal Monitor Video Operating Guide
4. M1310A Setting Up and Using Your Fetal Telemetry System

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

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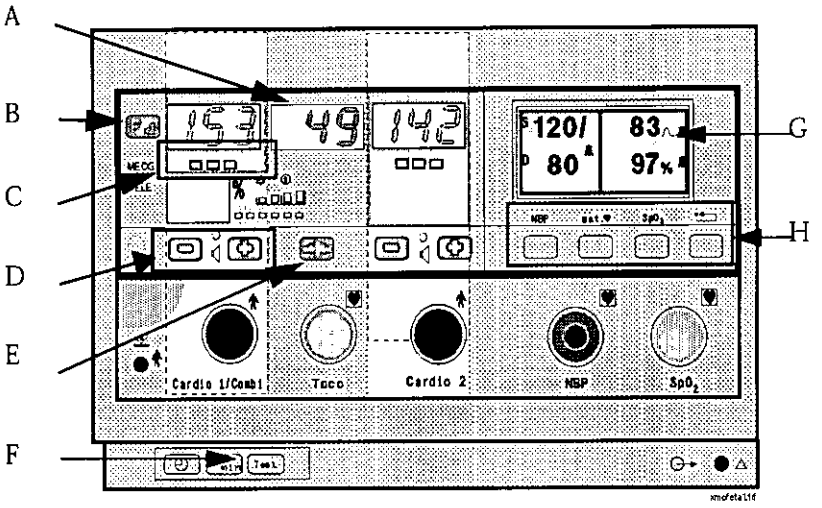
Fetal Monitor Lab Evaluation

1. Identify each of the following components and describe its function:



A. _____ Function: _____

B. _____ Function: _____

C. _____ Function: _____

D. _____ Function: _____

E. _____ Function: _____

F. _____ Function: _____

(Items G. and H. apply if monitors have Maternal parameters)

G. _____ Function: _____

H. _____ Function: _____

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

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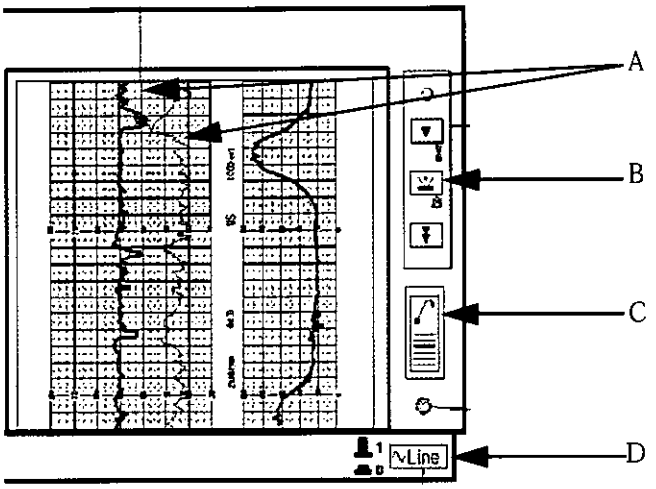
2. Identify each of the following items:



A. _____ B. _____
C. _____ D. _____

3. Load paper in the recorder.

4. a. Perform a Monitor Quick Test.
   b. What displays in the Cardio 1/ Combi, Cardio 2 and Toco digital display windows? _____
   c. Why should you review the test pattern on the recorder paper?
   _____
   d. What does the quick test check? _____

5. a. Perform a parameter test.
   b. In the space below, write the values that are shown in the associated display window and recorded for each parameter during the parameter test.
   US transducer in the Cardio 1/Combi socket _____
   DECG transducer in the Cardio 1/Combi socket _____
   Toco transducer in the toco socket _____
   US and MECG cable in the Cardio 1/Combi socket _____
   c. The parameter test checks the signal path to and from the input sockets but does not check the transducer or the module itself.
   ☐ True or ☐ False

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

Records processed under FOIA Request #2015-4103; Released by CDRH on 06-06-2016.

6. a. How can you check the US and Toco transducers to ensure they are working properly? _____

   _____

   b. List two possible causes of transducer damage in the clinical setting

   _____

7. a. With the recorder on, mark an event.
   b. What symbol displayed on the recorder paper when an event is marked?

   _____

8. List three items that will be visible on a trace recording:
   a. _____ b. _____ c. _____

9. a. FMP is available only in the ☐ Cardio 1/Combi or ☐ Cardio 2 channel.
   b. Turn off the FMP.
   c. How is FMP depicted on a recording?_____
   d. FMP detects _____

10. When you are receiving the best possible signal from the ultrasound transducer, the color of the signal quality indicator light will be _____

11. a. How do you know which baby's heart rate is being heard from the loud speaker?_____
    b. Adjust the volume.

12. a. What is the purpose of Arrhythmia Logic? _____

    _____

    b. It applies to the signal from the ☐ US or ☐ DECG.
    c. Turn the Arrhythmia Logic off.
    d. Why might you turn Arrhythmia logic off? _____

13. a. When monitoring twins, the FHR offset is helpful because _____

    _____.

    b. The +20 offset will display on the FHR trace for the ☐ Cardio 1/Combi or ☐ Cardio 2 channel.
    c. The trace shows that the offset is active by _____

    _____

14. a. When the system detects that ultrasound transducers are picking up the same heart rate (cross channel verification), what symbol is printed on the recording? _____

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

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b. What action should you take when cross channel verification has been detected? _____

c. You should periodically compare the mother's pulse with the signal coming from the fetal monitor's loudspeaker to ensure you are detecting the fetal heart rate. ☐ True or ☐ False.

15. a. Zero the external Toco transducer.
    b. What indication on the recorded trace shows that you are using an external Toco transducer? _____

16. a. Zero the internal uterine Pressure (IUP) catheter.
    b. What value will be displayed? _____

17. a. The key to adjust the clock time is located _____.
    b. The batteries maintain the clock time when the FM is off. The batteries are located _____

18. a. Set the Non Stress Test timer (NST) for 20 minutes.
    b. When the set time interval has passed, which of the following will happen. (select all that apply)
    ☐ A. Audible tone.
    ☐ B. Recorder starts a new recording for another 20 minute interval.
    ☐ C. Recorder stops and advances to next perforation (if configured).
    ☐ D. Fetal monitor turns off.

(question 19 applies to monitors purchased outside the USA)

19. a. Set the high fetal heart rate alarm to 160bpm.
    b. Which key will silence the alarm? _____

Maternal Parameters

20. a. Describe how to apply the correct size NBP cuff for the patient.
    _____
    b. Set the NBP frequency to take a blood pressure every 15 minutes.
    c. An average maternal pulse can be obtained during the blood pressure measurement only when _____ and is indicated by a _____ symbol next to the pulse value.
    d. Which of the following are limitations or situations which could affect the accuracy of the NBP value: (select all that apply)
    ☐ A. Maternal heart rate below 30 or above 240 bpm.
    ☐ B. Arterial pulse pressure which is changing rapidly during the blood pressure measurement.

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☐ C. Hypothermia.
☐ D. Uterine contraction during the blood pressure measurement time.

21. Adjust the alarms for the NBP to alert for a high systolic pressure of 180 mmHg or a low systolic pressure of 90 mmHg.

22. a. When you use the STAT mode for NBP, the monitor will _____
_____

b. The patient should always be supervised while using the STAT mode. ☐ True or ☐ False

23. a. If no MECG waveform is required, describe the electrode placement.
_____

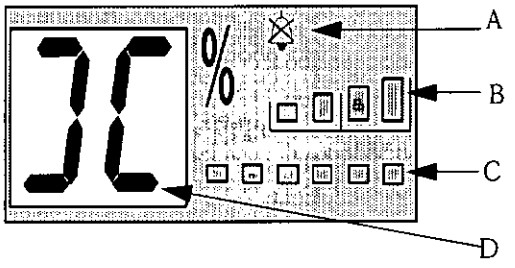
b. If the MECG waveform is required, describe the electrode placement.
_____

c. Display and print the MECG trace.

24. a. Obtain an SpO_2 reading.
b. Describe the icon displayed by the maternal HR value when the pulse source is from the SpO_2 sensor? _____
c. The SpO_2 value is recorded on the trace every _____ minutes, or every _____ minutes if the alarm limit is exceeded.
d. List three situations that could affect accurate SpO_2 monitoring. _____
_____

Fetal SpO_2

25. Identify the following elements of the fetal SpO_2 display.



A. _____
_____
B. _____
_____
C. _____
_____
D. _____
_____

26. The $FSpO_2$ alarms can be generated when: (select all that apply)
☐ A. $FSpO_2$ drops below the defined low limit.
☐ B. $FSpO_2$ elevates above the defined high limit.

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☐ C. $FSpO_2$ is below the low limit longer then the configured delay time.
☐ D. $FSpO_2$ is above the high limit longer then the configured delay time.

Fetal Telemetry

27. The Fetal telemetry system is made up of a _____, a _____ and the patient cables.

28. List two possible reasons why the transmission INOP indicator light will be on. _____
_____.

29. The Fetal telemetry receiver interfaces to the Fetal Monitor by _____
_____.

30. Number each of the steps in the order in which you would perform them to monitor with the Fetal telemetry
___ connect the transducer cables and turn on transmitter
___ connect the interface cable between the receiver and the fetal monitor
___ switch on the receiver
___ remove transducer cables from the fetal monitor then turn it ON.
___ insert the battery into the transmitter
___ check that transmitter and receiver numbers match

Answers

1. A. Toco or IUP Value - shows numeric uterine pressure measurement.
   B. Function key - allows access to other functions such as LOGIC and FMP.
   C. Signal Quality Indicator - indicates how good the signal is from the US transducer.
   D. Speaker key - allows adjustment of the audible volume for Cardio 1/ Combi.
   E. Toco Baseline key - zeros the Toco display and trace to 20 units for external monitoring or to zero for internal pressure monitoring.
   F. Test key - used to perform monitor test before each use of monitor.
   G. Maternal parameter keys - allow access to setting alarms, making adjustments and performing measurements.
   H. Maternal pulse icon - indicates which source is used to obtain the pulse.

2. a. Cardio 1/Combi and Cardio 2 traces
   b. Event marker key
   c. Paper eject button

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d. On/off key

3. With the recorder off, push the paper eject button. With the drawer fully open, push and hold the eject button then lift out the remaining paper. Place the new paper in the tray with the bottom side down. Unfold the top page of the pack. The uterine activity scale will be to the right. Push the drawer back until it clicks. Press the Recorder On/Off key. Press and release the Paper Advance key to advance the paper to the next fold.

4. a. To perform the monitor quick test: remove all cables from the monitor input sockets then switch the monitor on. Press and release the Test key.
   b. The Cardio 1/Combi, Cardio 2 and Toco display windows flash 888 alternately with the signal quality indicator light, MECG and tele lights. The two halves of the maternal display, if present, will flash alternately a dark and light pattern. The recorder on/off light will blink and a test pattern will print.
   c. Observe the test pattern lines for completeness to ensure the printer head is operational.
   d. The basic electronics of the system is checked.

5. a. The parameter test is performed by connecting the appropriate transducer to a monitor which is on. Turn the recorder on. Press and hold the test key.
   b. The following information is displayed and printed
   US in the Cardio 1/Combi socket - 190 is displayed and printed
   DECG in the Cardio 1/Combi socket - 200 is displayed and printed
   Toco in the toco socket - alternating value of 10 and 60 is displayed and printed
   MECG in the Cardio 1/Combi socket - 190 is displayed; 190 and 120 is printed.
   c. True.

6. a. Plug in the US transducer and increase the loudspeaker volume. Move your hand closer to and away from the transducer or softly tap to simulate sound. The loudspeaker should beep for each simulated beat. Plug in the Toco transducer. Press on the Toco transducer and note the pattern on the trace and value on the screen.
   b. The major way a transducer can be damaged is by improper handling such as by dropping, running over the transducers with bed or wrapping the cords too tightly.

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7. a. Press the event marker key or press the button on the remote event marker.
   b. A small arrow prints on the FHR scale at the exact time the button or key was pressed. The width of the arrow depends on the duration the button is pressed.

8. Any three of the following: FHR trace, Toco trace, date and time, paper speed, notes, mode of monitoring, FMP, FMP statistics, $FSpO_2$ trace, maternal BP, maternal ECG, maternal HR, maternal SpO_2, scale, marked event arrow, cross channel verification symbol.

9. a. FMP can only be measured by a transducer in the Cardio 1/Combi socket.
   b. Connect an US cable to the Cardio 1/ Combi socket. Press the Function key until FMP appears. Press the [--] or the [+] key to change the setting. The signal quality indicator is red when FMP is off. Press the Function key.
   c. FMP is depicted above the Toco trace as blocks that vary in width based on the duration of the noted activity. The arrow in front of FMP indicates when the FMP statistics started. The statistics are printed every 10 minutes.
   d. FMP detects gross fetal body movements via an ultrasound transducer.

10. When you are receiving the best possible signal from the ultrasound transducer, the color of the signal quality indicator light will be green.

11. a. The cardio socket with the active speaker will have a light above the speaker icon to identify it as the audio source.
    b. To adjust the volume press [--] to decrease or [+] to increase.

12. a. The purpose of arrhythmia logic is to avoid recording artifact. When on, it does not record instantaneous heart rate changes of greater than 28 bpm and resumes when successive beats fall in predetermined limits. The FHR numeric displays the detected value and the audio speaker beeps appropriately for each beat detected.
    b. It applies to the signal from the DECG.
    c. To turn the Arrhythmia Logic off, with the DECG cable plugged in, press the Function key repeatedly until the monitor displays LOG. Use [--] or [+] to turn the logic off. Red indicates logic is off.
    d. When you suspect fetal arrhythmias.

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13. a. When monitoring twins, the FHR offset is helpful because you can separate the similar baselines for easier interpretation of the recorded trace. The FHR value displayed on the fetal monitor is the correct value.
    b. The trace will display the Cardio 1/Combi with a +20 offset.
    c. The trace depicts that the offset is active by a vertical dotted line on the Cardio 1/Combi trace with the symbol of +20. This is repeated every 5 cm of trace.

14. a. When the system detects that both ultrasound transducers are picking up the same heart rate, a '?' is printed above the FHR trace.
    b. Reposition the transducer to pick up two different signals.
    c. True.

15. a. Connect the transducer to the socket. Place the transducer for optimal pick-up of uterine activity. Between contractions press the Toco baseline key. Note the displayed and recorded value of 20.
    b. The trace will display 'Toco ext' to indicate an external Toco transducer is in use.

16. a. The catheter should be inserted and connected according to the manufacturers instructions. Zero the monitor by pressing the Toco baseline key.
    b. Zero.

17. a. The key to adjust the clock time is located in the lower left corner.
    b. The batteries are located in the back of the monitor in a battery pack.

18. a. With the recorder off, press the recorder ON/OFF key for 2 seconds. Adjust the timer to 20 minutes using [--] or [+] . The timer will start after 15 seconds.
    b. The correct choices are: A,C.

(question 19 does not apply to monitors purchased in the USA)

19. a. With the US or DECG transducer connected to the monitor, press the Function key repeatedly until 'AL' is displayed. Use the [--] or [+] key to set the fetal alerting to On which is indicated by the green light. Use the Zero key to scroll to the option ' ¯A' . Use the [--] or [+] key to set the value to 160. Press the function screen to return to the normal display.
    b. During an alarm event, the event marker key is used to acknowledge the FHR alarm.

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Maternal Parameters

20. a. Ensure that the cuff is completely deflated. Place the ARTERIA marking on the cuff over the appropriate artery. Check that the edge of the cuff falls within the white range marked by the arrows (<-->), (on disposable cuffs this is a blue line without arrows). If it does not, use a larger or smaller cuff that fits.
    b. Apply the cuff to the patient and connect to the interconnect tubing. Insert the interconnect tubing into the NBP socket. Press the NBP key. Press Mode until Auto is shown. Press Repeat until 15 is displayed. Press Start.
    c. No other maternal pulse or heart rate source is present and the symbol is a blood pressure cuff.
    d. A,B,C,D.

21. Press NBP. Press Alarm. Press the Alarm softkey until ON Systolic is displayed. Using the softkeys for L. Limit and H. Limit, then the up/down arrow keys, set the values for a Systolic high to 180 and the Systolic low to 90.

22. a. The monitor will rapidly and repeatedly take the blood pressure for five minutes.
    b. True

23. a. Place the electrodes on the right and left lower ribs.
    b. Place right arm (RA) electrode directly below the clavicle and near the right shoulder. Place the left leg (LL) electrode in left lower abdomen.
    c. Press the maternal heart rate key. Press the softkey for Wave. The waveform is now displayed. With the recorder on, press Freeze, then Print to record a snapshot of the ECG trace.

24. a. Place the sensor with the red light over the nail bed. Connect the cable to the SpO_2 socket. The value will be displayed.
    b. A icon of a pleth wave.
    c. Five Minutes; 2.5 minutes.
    d. Any of the following are limitations to obtaining an accurate SpO_2: SpO_2 sensor is on the same limb as the NBP connect cuff, improperly placed sensor, venous pulsations, dye dilution chemicals or other dysfunctional hemoglobins, shock, hypothermia, use of vasoactive drugs.

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Fetal SpO_2

25. A. Alarm status indicator: when the crossed bell is lit the alarms are off.
    B. Signal Quality indicator lights: reflects the strength of the signal being received by the monitor.
    C. Pulse indicator: lights in conjunction with the fetal pulse rate when pulsatile activity is of acceptable quality.
    D. Value display window: $FSpO_2$ value is displayed and occasionally status indicator symbols. Refer to the $FSpO_2$ troubleshooting section of the Instructions for Use for the definition of the status indicator displayed in this picture.

26. A and C.

Fetal Telemetry

27. Transmitter, receiver.

28. Any two of these situations: transmitter is off, transmitter is out of receiver range, transmitter and receiver do not have matching serial numbers and channel frequency numbers, transmitter batteries are dead or transmitter is defective.

29. An interface cable.

30. The steps are:
    _6_ connect the transducer cables and turn on transmitter.
    _3_ connect the interface cable between the receiver and the fetal monitor.
    _4_ switch on the receiver.
    _5_ remove transducer cables from the fetal monitor then turn it ON.
    _2_ insert the battery into the transmitter.
    _1_ check that transmitter and receiver numbers match.

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M1350 XM, XMO Fetal Monitoring Lab Evaluation

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Philips Series 50 XM and Series 50 XMO Fetal/Maternal Monitors

Quick Operating Guide

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About This Guide

This guide is for experienced Philips Series 50 XM and Philips Series 50 XMO users.

It tells you how to monitor fetal heart rate, uterine activity, fetal pulse oximetry ($FSpO_2$) and maternal parameters such as ECG, NIBP and SpO_2. Full operating instructions are given in the Operating Guide supplied with the monitor. You should also always read the instructions and safety guidelines that come with the supplies for this monitor.

Not all parameters and features detailed in this Quick Reference guide are available on all monitors.

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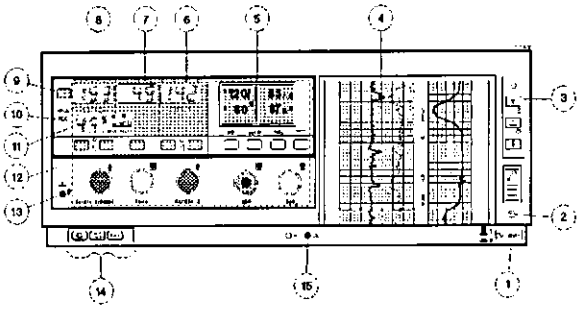

Major Parts

1. Monitor On/Off Switch
2. Monitor On/Off Indicator
3. Recorder Keys
4. Recorder
5. Maternal Parameters
6. Cardio 2 Channel
7. Toco Channel
8. Cardio 1/ Combi Channel
9. Function Key
10. Telemetry Indicator
11. Fetal SpO_2 Parameter
12. Opening Recess
13. Socket for Remote Event Marker
14. Setting Keys
15. Service Socket

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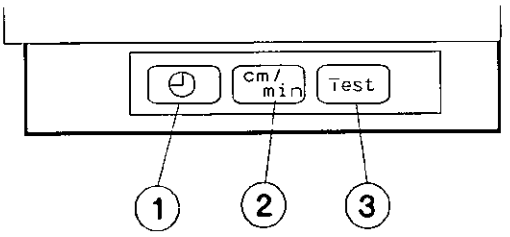
Setting Keys



1. *Time and Date Key.* Used when changing the time and date. Press to show the current time in the Cardio 1/Combi and Toco displays, to cycle through the settings to be changed (hours, minutes, day, month and year) and to return to the normal display.
   Use [−] and [+] to change settings.
2. *Paper Speed Key.* Used when changing the paper speed. Press to show the current paper speed in the Cardio 1/Combi display, and to return to the normal display.
   Use [−] and [+] to change settings.
3. *Test Key.* Used to initiate monitor self test.

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

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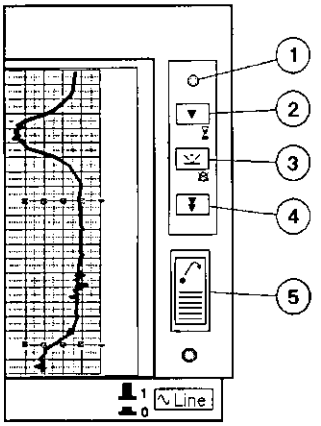
Recorder Keys



1. *Recorder On/Off Light.* Lit when the recorder is switched on. Flashes when there are five or fewer pages remaining in the pack, or if the paper runs out.
2. *Recorder On/Off Key.*
   Single press – turn recorder on/off.
   2-second press – start NST timer. Recorder must be off.
3. *Event Marker Key.* Press to record an event on the paper. Also use this to acknowledge fetal alerts and maternal alarms.
4. *Paper Advance Key.* Press once to advance the paper automatically to the next fold. Press a second time to stop paper before fold.
5. *Paper-Eject Key.* Press once to unlock the drawer, and then press and hold to remove the paper.

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Example Trace

Please note that the appearance of the trace differs slightly from country to country and according to the options you have installed.

1, 2. Company logo, time, date, and paper speed are printed when you begin monitoring and then every 10 minutes.

3. Barcode notes (example text shown).

4. FMP activity blocks.

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

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Example Trace

5. FMP statistics. Printed below the FMP activity blocks every 10 minutes.
   - First value: % of detected fetal movements in the last 10 minutes.
   - Value in parentheses: % of fetal movements detected since the recorder was switched on or an ultrasound transducer plugged into the Cardio1/Combi socket.
6. Fetal blood oxygen saturation level ($FSpO_2$).
7. Uterine activity trace. This trace shows 2 contractions.
8. Maternal heart rate.
9. Maternal blood pressure. In this example, systolic blood pressure is 128 mmHg, diastolic blood pressure is 98 mmHg, and mean arterial pressure is 109 mmHg.
10. Maternal temperature (37.5 °C). An asterisk * indicates that the measurement comes from an external device.
11. Maternal oxygen saturation level of blood (SpO_2) (97%).
12, 13. Monitoring mode. This shows you which parameters are currently being monitored.
14. $FSpO_2$ alarm settings.
15. Event marker arrow.
16. MHR.
17, 18. FHR1 and 2.
19. Cross-channel verification. If two heart rates being measured coincide at any time (that is, if both transducers are recording the same FHR or MHR), this is detected by ccv and ? is printed on the trace paper after approximately 10 seconds.
20. Error sign. Check the digital display on your monitor for the specific error message.

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

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Replacing Paper

Do not use non-Philips paper or paper with sprocket holes intended for HP 8040A/8041A and 8030A/8031A Fetal Monitors. You will invalidate your recorder's warranty.

1. Switch off the Recorder.
2. Push the *Paper Eject Key* and fully open the drawer.
3. Push and hold the *Paper Eject Key* and lift out any remaining paper.
4. Unfold the top page of the new pack of paper.
5. Slide the pack into the tray, with the uterine activity scale on the right.
6. Push the drawer back until it "clicks" closed. Don't push on the paper when closing the drawer.
7. Switch on Recorder.
8. Press and release the *Paper Advance Key* to move the paper automatically to the next fold.

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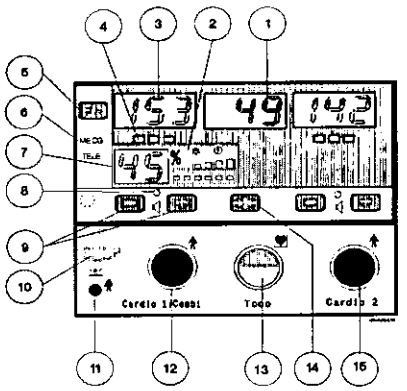
Cardio, Toco and Fetal SpO_2



1. *Toco display* shows uterine activity.
2. *Fetal SpO_2 display* shows fetal pulse indicator, signal quality, alarm status, and cross channel verification plus indicator.
3. *Cardio display* shows the FHR.
4. *Signal Quality Indicator* shows the condition of FHR signal:
   - Green (optimum).
   - Yellow (fair to potentially poor).
   - Red (unacceptable).

   Reposition transducer if signal is red for prolonged period.
5. *Function Key.* Used when separating twin traces, switching arrhythmia logic and FMP off and on. Press to show the current setting of Twins Offset, Logic or FMP in the Cardio 1/Combi display, and to return to the normal display. The function key can also be used to turn fetal alerting on and off, and enter $FSpO_2$ alarming (where available).

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Cardio, Toco and FSpO2

6. *MECG Indicator* shows when maternal ECG is being measured. (Indicator location different for Series 50 XM.)
7. *$FSpO_2$* value shows fetal oxygen saturation value.
8. *Speaker Lamp* shows which heartbeat comes from loudspeaker.
9. *Volume Keys* set the volume level, select the channel to which you are listening, and set alarms for $FSpO_2$ and heartrate. Also used to switch Twins Offset, Logic and FMP on and off.
10. *Recess* for use when tilting the display.
11. *Remote Event Marker Socket* for connecting remote event marker (15249A).
12. *Cardio 1/Combi Transducer Socket.* You can connect:
    - $FSpO_2$ patient module (M1365A) with either MECG or DECG.
    - Patient module (M1364A) with either MECG or DECG.
    - An ultrasound transducer (M1356A).
    - A US/MECG Combi transducer (M1358A).
    - An MECG transducer (M1359A).
13. *Toco Transducer Socket.* You can connect:
    - An external Toco transducer (M1355A).
    - An IUP transducer (CPJ840J5 or M1333A).
14. *Toco Baseline Key* zeroes the Toco display and trace to 20 units (when monitoring uterine activity externally) or 0 units (when monitoring uterine activity internally)
15. *Cardio 2 Transducer Socket.* You can connect:
    - US transducer (M1356A) MECG transducer (M1359A) Patient module (M1364A)

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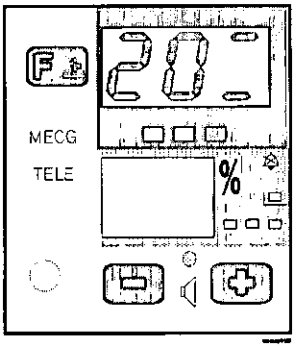
Separating Twin Traces



1. Press [F.⚠] and release to display 20.
   The Signal Quality Indicator shows:
   - RED if the traces are NOT SEPARATED.
   - GREEN if the traces are SEPARATED.
2. Press [−] or [+] to change the setting.
3. Press [F.⚠] several times to return to the normal display.

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

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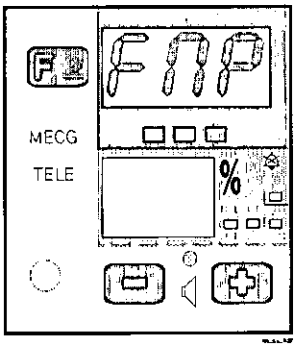
Fetal Movement Profile

You must connect an ultrasound transducer to the Cardio I/Combi socket.



1. Press [F.⚠] repeatedly until FMP is displayed.
   The Signal Quality Indicator shows:
   - RED if FMP is OFF.
   - GREEN if FMP is ON.
2. Press [−] or [+] to change the setting.
3. Press [F.⚠] repeatedly to return to the normal display.

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Fetal Alerting

You must connect either an ultrasound or a patient module with DECG to one of the two Cardio sockets.

1. Press [F.⚠] repeatedly until AL is displayed.
   The Signal Quality Indicator shows:
   - RED if fetal alerting is OFF.
   - GREEN if fetal alerting is ON.

2. Press [−] or [+] to change the setting.
   To display the next alert limit setting press [→|←].
   Use [−] and [+] to change the next alert setting.

Alert Setting	Display
High alert limit Default 150 bpm, 0 = off	--A
Alert delay for high limit Default 60 sec	"-A
Low alarm limit Default 110 bpm, 0 = off	__A
Alert delay for low limit Default 60 sec	"_A

The monitor retains these settings, even when switched off. They are printed on the recorder if alerting is on.

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

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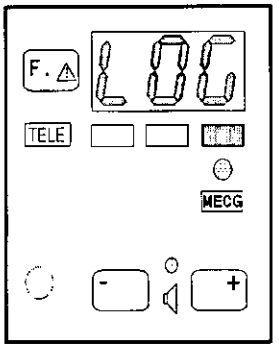
Arrhythmia Logic

Connect a DECG patient module to Cardio 1/Combi socket.



1. Press [F.⚠] repeatedly until LOG is displayed.
   The Signal Quality Indicator shows:
   - RED if logic is OFF (record arrhythmias).
   - GREEN if logic is ON.
2. Press [−] or [+] to change the setting.
3. Press [F.⚠] once or twice (if Cardio 1 and 2 are being used) to return to the normal display.

When arrhythmia logic is ON, an unexpectedly high variation between successive fetal heartbeats is not recorded on the trace. Recording resumes when successive beats again fall within predetermined limits. This avoids recording artifacts. However, it will not show genuine arrhythmia. When logic is off, ALL recorded fetal heartbeats are shown. If you suspect fetal arrhythmia, switch logic OFF.

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

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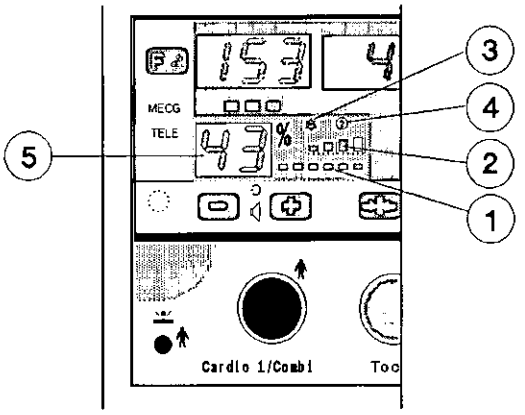
Fetal SpO_2



1. **Pulse indicator** - shows when pulsatile signal is received.
2. **Signal quality indicator** - shows how good a signal the monitor is receiving. The more segments that are lit, the better the signal.
3. **Alarm status indicator** - shows whether $FSpO_2$ alarming is switched on or off. The crossed bell shows alarming off.
4. **Cross channel verification plus (CCV+)** - shows if monitor detects an $FSpO_2$ value that might be maternal, or artifacts due to excessive fetal or maternal movement.
5. **Saturation value** - shows level of oxygen saturation in fetal blood.

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

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Fetal SpO_2

Changing Alarm Limits

Connect the $FSpO_2$/ECG combined patient module to the Cardio 1/Combi socket.

1. Press [F.⚠] until the $FSpO_2$ display shows AL. Then you can enable (press [+]) or disable (press [−]) the alarm **or**
2. Press [⊣⊢] to access the saturation alarm limit setting.

   The Toco display shows --A, indicating that you are changing the saturation low alarm limit. The $FSpO_2$ display shows the current low limit. There is no high limit.
3. Press [+] or [−] to increase or decrease the $FSpO_2$ saturation alarm limit.
4. Press [⊣⊢] to set the time delay. The Toco display shows '_A, indicating that you are changing the time delay. The $FSpO_2$ display shows the current delay, in minutes.
5. Press [+] or [−] to increase or decrease the time delay in increments of 0.5 minutes.
6. Press [F.⚠] to return to normal monitor function.

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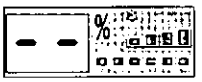
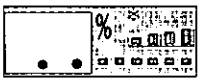
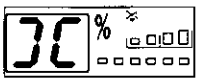
Fetal SpO_2

Display	Problem	Solution
	Patient module not plugged in.	Plug in patient module.
	Patient module plugged in but sensor not attached.	Check connection of sensor to patient module. Replace patient module or sensor if necessary.
	Sensor has no contact with the patient's skin	Reposition the sensor slightly.
	Pulse indicator bar pulses rhythmically but monitor does not display a saturation value.	Observe the signal quality indicator lights. If you do not obtain a medium to good quality signal (three or four segments lit) after waiting for at least one minute, reposition sensor.

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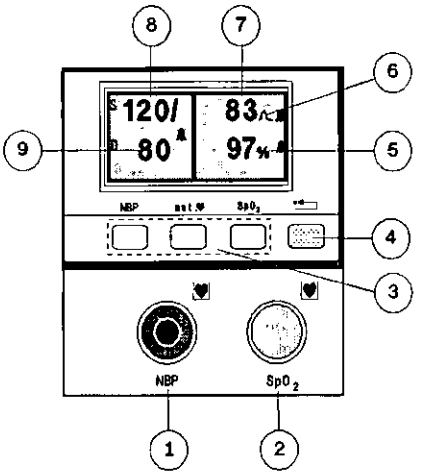
Maternal Parameters



1. *NBP Cuff Socket.* You can connect:
   - An NBP cuff interconnect tubing (M1599A) and cuff (M1574A or M1575A).
2. *SpO_2 Transducer Socket.* You can connect:
   - An SpO_2 transducer (M1940A adapter cable connected to M1191A transducer).
3. *Keys* for operating and setting maternal parameters. They are:
   - NBP Softkey selects modes and alarm limits for NBP.
   - MHR Softkey selects modes and alarm limits for MHR, and freezes MECG wave for recording.
   - SpO_2 Softkey selects modes and alarm limits for SpO_2.

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4. *Reset Key (yellow).*
   - **One short press**
     Acknowledges warning message
     Acknowledges alarm
     Redisplays maternal main screen
   - **One press, held for two seconds**
     Accesses volume and contrast setup screen
   - **Two presses within one second**
     Displays current maternal alarm limits.
5. *SpO_2 Value* indicates current reading for maternal oxygen saturation level.
6. *MHR Icon* indicates measurement source of MHR.
   - indicates heart rate value taken from MECG.
   - indicates pulse rate value taken from SpO_2.
   - indicates average pulse rate value taken from NIBP.
7. *Maternal Heart Rate* shows current heart rate or pulse rate.
8. *Systolic Value* shows the value for the systolic parameter of the most recent noninvasive blood pressure measurement.
9. *Diastolic Value* shows the value for the diastolic parameter of the most recent noninvasive blood pressure measurement.

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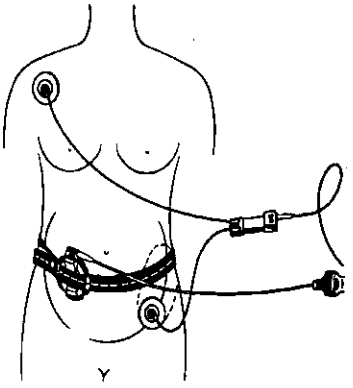
Maternal ECG Waves

Positioning the Electrodes

Position the electrodes as shown in the picture below:



Displaying and Freezing the ECG Wave

1. Press **mat.** ♥ .
2. Press **Wave** .
3. Press **Freeze** .

Printing the Displayed Wave

1. Turn recorder on.
2. Press **Print** .

This prints a "snapshot" of a three to four wave period.

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Maternal Alarms

Acknowledging an Alarm

Press either the yellow key, or the marker key [⩛] once.

Switching an Individual Alarm On or Off

1. Select the alarm you want to change.
2. Press **On** or **Off** to enable or disable the selected alarm.

Changing a Maternal Alarm

1. Select the alarm you want to change.
2. Press **L Limit** or **H Limit** to select the limit you want to change. SpO_2 has only a low limit alarm.
3. Press ▲ or ▼ to change the selected alarm limit.

Turning ALL Maternal Alarms On or Off

1. Press the yellow key twice within one second to display the power on screen.
2. Press **On** or **Off** to change the status of all maternal alarms.

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Maternal SpO_2 Warning Messages

Warning Message	Parameter Display	Audible Indication	Possible Cause	What to Do
None	– – %	No	Transducer or adapter cable disconnected.	Connect transducer or cable.
⚠ **SpO_2 no pulse**	NOP	Yes (if alarming is on)	Pulsation too weak or no pulsation detectable. Transducer incorrectly positioned.	Check patient's pulse. Reposition transducer. Ensure transducer is not on same limb as cuff.
			Patient wearing colored nail polish.	Remove nail polish.
⚠ **SpO_2 low signal**	Normal display	No	Weak signal, SpO_2 less accurate.	Reposition transducer or try a different site.
			Wrong transducer selected.	Use correct transducer.
			Transducer incorrectly applied.	Reapply transducer.
			Patient wearing colored nail polish.	Remove nail polish.
			Photodetector not opposite light emitter.	Reposition transducer.

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Maternal SpO_2 Warning Messages

Warning Message	Parameter Display	Audible Indication	Possible Cause	What to Do
⚠ **SpO_2 light interference**	– ? –	No	A light source is so high that the SpO_2 transducer cannot measure SpO_2 or HR.	Remove strong light source, or cover transducer with opaque material.
⚠ **SpO_2 artifacts**	– 0 –	No	Irregular pulse patterns detected, possibly arising from patient movement.	Restrain patient.

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

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NIBP Warning Messages

Warning Message	Situation	Audible Indication	Action Required
⚠ **overpressure**	Cuff pressure increases above 300 mmHg.	Yes (cannot be switched off)	Check to see if cuff is being pressed manually (perhaps by patient movement) and restart the measurement. Cuff deflates automatically.
⚠ **artifacts**	Patient is moving.	Yes (if alarming is on)	Restrain patient movement and restart the measurement.
⚠ **cuff tubing**	Inflation / deflation takes too long.	Yes (if alarming is on)	Check that all tubes are connected properly, not blocked, leaking or defective. Ensure that the correct cuff is being used. Restart the measurement.
⚠ **NBP error**	Tubing obstructed or hardware problem.	Yes (if alarming is on)	Check tubing. Switch monitor off and try measurement again. If problem persists, call service personnel.

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

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Quick Test

The Quick Test takes approximately 15 seconds and tests the basic electronics of the monitor. To carry out the test:

1. Disconnect any transducers from the monitor (and, if appropriate, switch off or disconnect the Telemetry Receiver and any external devices connected to the monitor).
2. Switch on the monitor.
3. Press and release [Test] and check that:
   - The fetal displays flash, and the two halves of the maternal display flash alternately.
   - The recorder on/off light blinks in time with the display.
   - A test pattern is printed.
   - After a few seconds, the monitor performs its power on test.
4. Check the lines in the test pattern to ensure the heating elements on the printer head are operational.

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Parameter Test

The Parameter Test tests the signal path to and from the transducer sockets, but not the transducers themselves.

1. Switch on the monitor and the recorder.
2. Connect the appropriate transducer to each socket.
3. Press and hold [Test]. The correct responses are:

Signal	Correct Monitor Response
US Cardio 1	**190** is displayed and printed. Signal Quality Indicator is green. Fetal heartbeat heard from loudspeaker.
US Cardio 2	**170** is displayed and printed. Signal Quality Indicator is green. Fetal heartbeat heard from loudspeaker.
Toco	A signal alternating between **10** and **60** is displayed and printed.
DECG	**200** is displayed and printed. Signal Quality Indicator is green. Fetal heartbeat click from loudspeaker.
MECG	**120** is printed and displayed on the maternal screen. **MECG** is on.
US/MECG Cardio 1	**190** is displayed on the LEDs. **120** is displayed on the maternal screen. **190** and **120** are printed. Signal Quality Indicator is green. **MECG** is on.
Maternal SpO_2	**99%** is displayed and printed. Pulse **120** ∫⌒ displayed on LCD screen.
$FSpO_2$	**88%** is displayed and printed.

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

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Error Messages

Acknowledge messages by pressing the yellow key.

Message	Cause and Solution
Err 1	Wrong transducer in either the Cardio 1 Combi or Cardio 2 socket. *Connect the correct transducer.*
Err 2	Wrong transducer in the Toco socket. *Connect the correct transducer.*
Err 4	US/MECG Combi transducer not allowed. *Connect the correct transducer.*
Err 6	Wrong pairing of US/MECG Combi, MECG or DECG transducers. *Remove one of the transducers.*
Err 8	No Dual Ultrasound Twins option. *Remove one of the transducers.*
Err 9	Invalid Telemetry mode. *Check the cable from the Telemetry Receiver.*
Err 16	Wrong pairing of Telemetry and transducers. *Disconnect fetal and Toco transducers or switch off Telemetry Receiver.*
Err 101	$FSpO_2$ patient module defective. *Replace module.*

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Message	Cause and Solution
Err 102	Communication error - no connection between $FSpO_2$ patient module and monitor. *Replace module.*
Err 103	$FSpO_2$ sensor defective. *Replace sensor.*
nop	No contact or poor contact between mother and reference electrodes on sides of fetal scalp electrode or spiral electrode detached. *Use a new spiral electrode.*
Err bAt	Battery low or empty of charge. *Change the batteries as soon as possible.*
Err PAP 30-240 ⚠	Incorrect type of paper loaded. *Load 50-210 paper or change the paper format setting (see Service and Installation Guide).*
Err PAP 50-210 ⚠	Incorrect type of paper loaded. *Load 30-240 paper or change the paper format setting (see Service and Installation Guide).*
Err 500-600 ⚠	Technical failure. *Contact Philips Service Engineer or Response Center.*

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

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Message	Cause and Solution
Err 601 ⚠	Paper speed error. Check the speed by timing how long it takes for the paper to advance 1 cm: 60 seconds @ 1 cm/min. 30 seconds @ 2 cm/min. 20 seconds @ 3 cm/min. *Contact your Philips Service Engineer or Response Center if the speed is incorrect.*

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

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M1350-9021S

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Operator Error Messages

Message	Display	Cause and Solution
Err 1	Cardio 1	Wrong transducer in Cardio 1/Combi socket. Connect correct transducer.[a]
Err 1	Cardio 2	Wrong transducer in Cardio 2 socket. Connect correct transducer.[a]
Err 2	Toco	Wrong transducer in Toco socket. Connect correct transducer.[a]
Err 4	Cardio 2	US/MECG Combi transducer not allowed in this socket. Only 1 x MECG and 1 x DECG are permitted in combination. Remove transducer.
Err 5	Cardio 1 Cardio 2	Wrong pairing of US/MECG Combi transducer, MECG transducer and DECG transducer. Remove one of the transducers.
Err 8	Cardio 1 Cardio 2	Dual Ultrasound Twins option is not fitted. Remove one of the transducers.
Err 9	Cardio 1 Cardio 2	Invalid telemetry mode. Check the cable from the telemetry receiver and if, necessary, replace it.
Err 16	Cardio 1 Toco Cardio 2	Wrong pairing of telemetry and transducers. Either disconnect the transducers or switch off the telemetry receiver.
Err 18	none	Use of paper designed for HP 8040 monitor. Use correct paper for this monitor.
Err 19	Err bAt [b] [c]	Battery low or empty of charge. Change the batteries as soon as possible. If you do not change the batteries, your specific settings will return to their default values when the Monitor is switched on. (For example, the date is set to 4.4.44.)
Err 101	Cardio 1	$FSpO_2$ patient module defective. Replace patient module.
Err 102	Cardio 1	Communication error - no connection between $FSpO_2$ patient module and monitor. Replace patient module.
Err 103	Cardio 1	$FSpO_2$ sensor defective. Use a new sensor.
nop	Cardio 1 Cardio 2	No contact, or poor contact, between any of the contacts of the system. Check all connections, especially the legplate connector. Use a new spiral electrode.

Operator Error Messages (continued)

Message	Cause and Solution
Err PAP 30-240 [d]	Incorrect type of paper loaded. Load paper with 50-210 scale or change the monitor's paper format setting (see the Installation and Service Guide for your monitor).
Err PAP 50-210 [d]	Incorrect type of paper loaded. Load paper with 30-240 scale or change the monitor's paper format setting (see the Installation and Service Guide for your monitor).
Err xxx [b]	xxx is between 500 and 600. This indicates a technical failure diagnosed by the monitor's self test program. Contact your Philips Service Engineer or Response Center.
Error 601 [d]	Paper speed. Check that correct paper is used. Check the speed by timing how long it takes for the paper to advance 1cm: *60 seconds = 1cm/min* *30 seconds = 2cm/min* *20 seconds = 3cm/min* Contact your Philips Service Engineer or Response Center if the speed is incorrect.
Error 602 [d]	Incorrect type of paper loaded. Load with appropriate scale paper or change monitor's paper format setting.

a See Chapter 20 of your monitor's *Instructions for Use* for compatible types of transducers.
b Displayed for ten seconds when the monitor is first switched on.
c Printed every ten minutes.
d Printed every three pages.

LCD Display Warning Messages

Message	Audible Alarm	Cause and Solution
Noninvasive Blood Pressure		
overpressure	Yes (cannot be switched off)	Cuff pressure increases above 300mmHg. Check to see if cuff is being pressed manually (perhaps by patient movement) and restart the measurement. Cuff deflates automatically.
artifacts	Yes (if alarming is on)	Patient is moving. Restrain patient movement and restart the measurement.
cuff tubing	Yes (if alarming is on)	Inflation/deflation takes too long. Check that all tubes are connected properly, not blocked, leaking or defective. Ensure that the correct cuff is being used. Restart the measurement
NBP error	Yes (if alarming is on)	Tubing obstructed, or hardware problem. Check tubing. Switch monitor off and try measurement again. If problem persists, call service personnel.
Pulse Oximetry		
None	No	Transducer or adapter cable disconnected. Connect transducer or cable.
SpO_2 no pulse	Yes (if alarming is on)	Pulsation too weak or no pulsation detectable. Transducer incorrectly positioned Check patient's pulse. Reposition transducer. Ensure transducer is not on same limb as NIBP cuff.
		Patient wearing colored nail polish. Remove nail polish.
SpO_2 low signal	No	Weak signal, SpO_2 less accurate. Reposition transducer or try a different site.
		Wrong transducer selected. Use correct transducer.
		Transducer incorrectly applied. Reapply transducer.
		Photodetector not opposite light emitter. Reposition transducer.
		Patient wearing colored nail polish. Remove nail polish.
SpO_2 light interference	No	A light source is so high that the SpO_2 transducer cannot measure SpO_2 or HR. Remove strong light source, or cover transducer with opaque material.
SpO_2 artifacts	No	Irregular pulse patterns detected, possibly arising from patient movement. Restrain patient.

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Service Error Messages

See the *Installation and Service Guide* for your monitor for more detailed information and troubleshooting flowcharts.

Message	Error
Err 500	Not known (bus error)
Err 502	Power supply board
Err 506	ROM Board
Err 507	DSPII Board
Err 513	CPU Board (Smartwand)
Err 515	Dig If Board
Err 516 or 517	Frontend Board
Err 525 and Err 527	LED Board
Err 526	LCD Board
Err 531	Telemetry Board
Err 532	OBMS Interface Board
Err 533	DSIF Board
Err 534	Maternal SpO_2 Board
Err 535	NBP Assembly
Err 536	Combined Telemetry/System Board
Err 540	Fetal SpO_2 Board
Err 601	Recorder Paper Feed
Err 602	Incorrect Type of Paper

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M1350-9012J

Series 50 XM
Series 50 XMO

Error Reference Card

Fetal/Maternal Monitor

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Appendix E

- Prior FDA Comments on K081435
- Monica Responses to K081435
- Summary of responses to K081435
- Pre IDE Document

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(b)(4) Deficiencies and Responses to FDA Deficiencies

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Product	Monica AN24 Abdominal Fetal/Maternal Monitor
Document name	Clinical Investigation Protocol – Fetal Heart Rate and Uterine Activity during Labor and Delivery For Patients >37 Weeks gestation

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[redacted]

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1 Scope

1.1 Document Identification

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1.2 Document Scope

The purpose of this document is to briefly describe the clinical investigation protocol and provide a detailed statistical analysis plan.

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2 Related Documents

N°	Title	Reference
[1]	Abdominal FECG recorder, SRS	100-SP-001
[2]	AN24 Operating Instructions	100-TF-006

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Glossary

aFECG	Abdominal Fetal Electrocardiography
BMI	Body Mass Index
BT	Bluetooth
CTG	Cardiotocograph
ECG	ElectroCardioGram
EHG	ElectroHysteroGram – measurement of UA using AN24 device
FECG	Fetal ElectroCardioGram
FHR	Fetal Heart Rate
GS	Gold Standard
IUPC	Intra Uterine Pressure Catheter
MHR	Maternal Heart Rate
NPA	Negative Percent Agreement
OPA	Overall Percent Agreement
PC	Personal Computer
PPA	Positive Percent Agreement
PPV	Positive Predictive Value
TOCO	Tocodynometer (external pressure transducer for uterine contraction detection)
UA	Uterine Activity
USB	Universal Serial Bus

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3 Synopsis

3.1 Overview

Table1 below summarises the proposed work for this pre-IDE trial whilst Sections 3.2 - 3.4 provide further summarised details for each component.

Table 1: Summary of Proposed Pre-IDE Trials for Monica AN24

(b)(4)

[redacted]

The purpose of the study is to clinically validate the AN24 device for the "indications for use" referred to in Section 3.2 below.

It should be noted that the L&D trial data is to be recorded via a formal clinical trial.

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3.2 Indications for Use

The proposed "indications for use" for the Monica AN24 device is:

"The Monica AN24 is a monitoring device for non-invasively measuring the Fetal Heart Rate (FHR) and Uterine Activity (UA). The Monica VR software, which accompanies the AN24, enables the measured parameters to be reviewed graphically using a PC or notebook computer and to generate hard copy traces in a "standard" user defined format. This data is intended to aid in assessment of the wellbeing of the fetus and mother for laboring singleton pregnancies who are of gestation age >37 weeks. The AN24 device typically generates standard length FHR and UA traces from a single setup. Application of the device must be by trained personnel, but monitoring sessions can be carried out in hospital and clinics."

3.3 Synopsis – Labor and Delivery for FHR and Uterine Activity

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[redacted]

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- **Fetal Heart Rate (FHR)**

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4 Introduction

4.1 Overview of Monica AN24 Device\ Technology

The AN24 is a portable, battery powered device designed to passively monitor a pregnant mother and unborn baby. The device is attached via a suitable cable assembly which in turn attaches to 5 standard disposable electrodes placed on the abdomen of a pregnant woman and is intended for use in either the home or hospital environment.

The AN24 is based upon the collection of electrophysiological signals from the maternal

(b)(4) [redacted]

For the purpose of this Pre-IDE submission the two processed parameters that are to be compared with FDA-approved predicate devices are:

- *Fetal Heart Rate (FHR)*
- *Uterine Activity (UA or EHG)*

(b)(4) [redacted]

The AN24 (shown in Fig 1) is a passive, battery powered device which, by design, cannot be physically connected to any third party device whilst also connected to a human subject.

Figure 1: Monica AN24 Device

(b)(4) [redacted]

the electrodes on the maternal abdomen. These electrodes are placed in line with the AN24 Operating Instructions.

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4.2 Study Rationale

One of the methods used to assess the condition of the fetus during Labor & Delivery is to monitor the FHR and Uterine Activity non-invasively. Throughout the years, several non-invasive trans-abdominal techniques to monitor the FHR and Uterine Activity have been developed and described.

Of these techniques, Doppler ultrasound and TOCO using a guard ring toco-dynamometer, are currently the most commonly used all over the world for monitoring the FHR and Uterine Activity during pregnancy and labor. The Doppler technique is based upon directing a known high-frequency ultrasound signal at the fetal heart and then examining the reflected signal which is modified by the beating fetal heart – termed "Doppler shifts". This method along with the guard-ring toco-dynamometer for uterine activity is used in routine monitoring during Labor & Delivery to provide reassurance and it is also used in the antenatal period in fetuses considered to be at-risk (pregnancies with co-morbidity: diabetes, growth restriction, placental insufficiency, etc.). These monitoring techniques provide a standardized display of uterine activity at the bottom of the printout and the fetal heart rate above. The recording speed is at 3 cm/minute and allows assessment of uterine activity and fetal heart rate parameters in isolation and in relationship to each other. The information gained by the visual interpretation of this trace assists the clinician in the decision as to when to deliver the fetus and to provide

(b)(4) [redacted]

The purpose of this study is to compare both Doppler FHR and TOCO to direct scalp FHR and IUPC uterine activity respectively and show that the performance of the AN24 is equivalent to Doppler and TOCO when compared with direct scalp FHR and IUPC uterine activity.

4.3 Demonstrating equivalence

Equivalence will be assessed for the measurement of FHR and for UA. For each of these, both the reliability and the accuracy of the measurement will be assessed, making four separate equivalence endpoints. To establish overall equivalence, the primary statistic for each of the four equivalence endpoints will be required to demonstrate equivalence. Secondary statistics will also be presented. Details of the statistics used to establish equivalence are given in Section 9.

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5 Study Objectives

(b)(4)

[redacted]

5.2 Secondary objective

The secondary objective of the study is to demonstrate the clinical safety of the Monica AN24 device when used during the intrapartum period.

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6 Study Design

6.1 Intrapartum Study for UA and FHR

6.1.1 Study Type

The study has been designed as a prospective, single or two-center confirmation study for demonstrating the acceptability of the Monica AN24 device.

6.1.2 Sample Size

(b)(4)

[redacted]

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7 Study Procedures

7.1 Overview

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[redacted]

7.2 Intrapartum

The AN24 device, Doppler transducer and TOCO transducer will be fitted to the patient by the Research Assistant in the hospital once informed consent has been obtained and the patient has been enrolled into the study. The formal procedure for acquiring the intrapartum data is as follows:

(b)(4)

[redacted]

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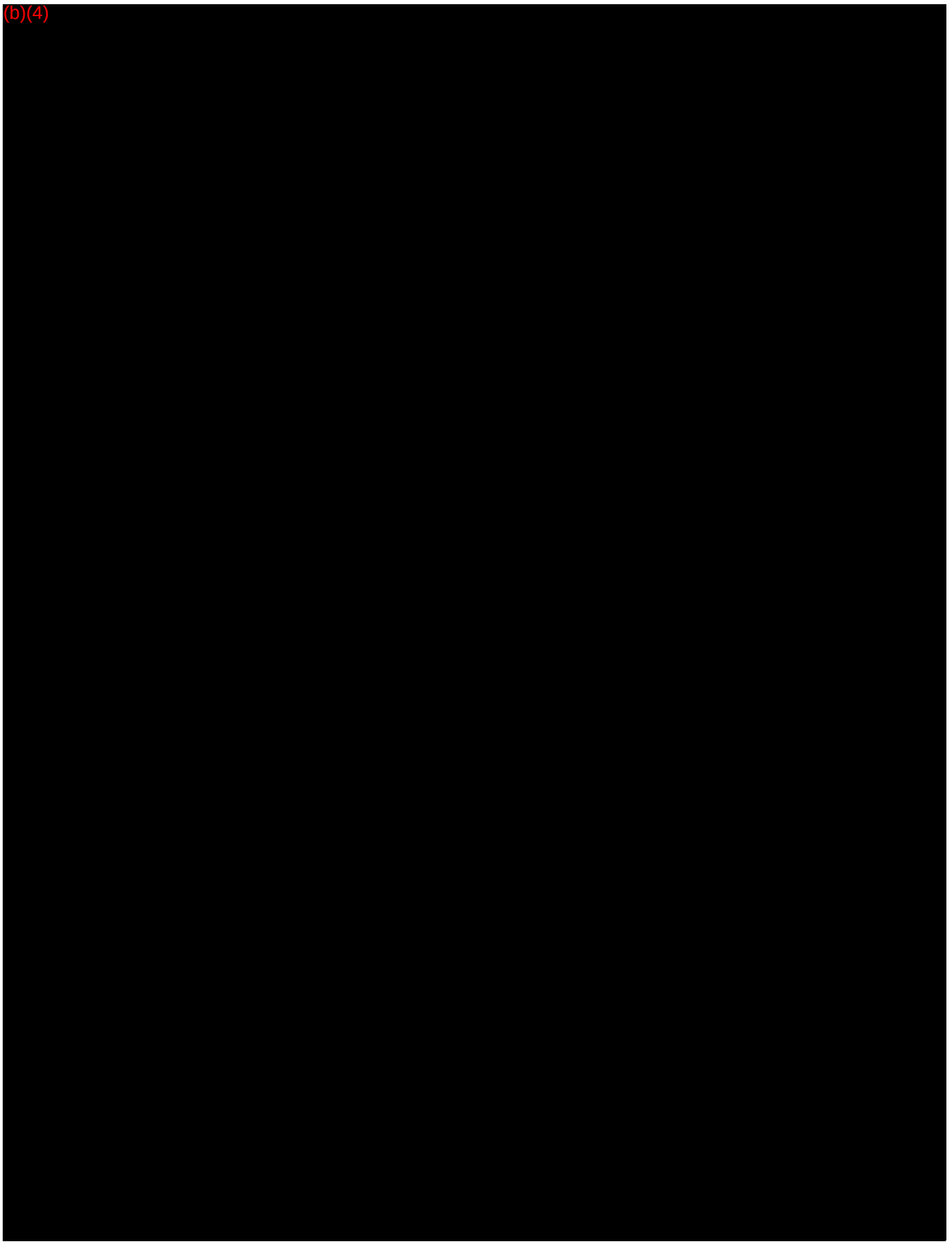

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8 Data Pre- Processing

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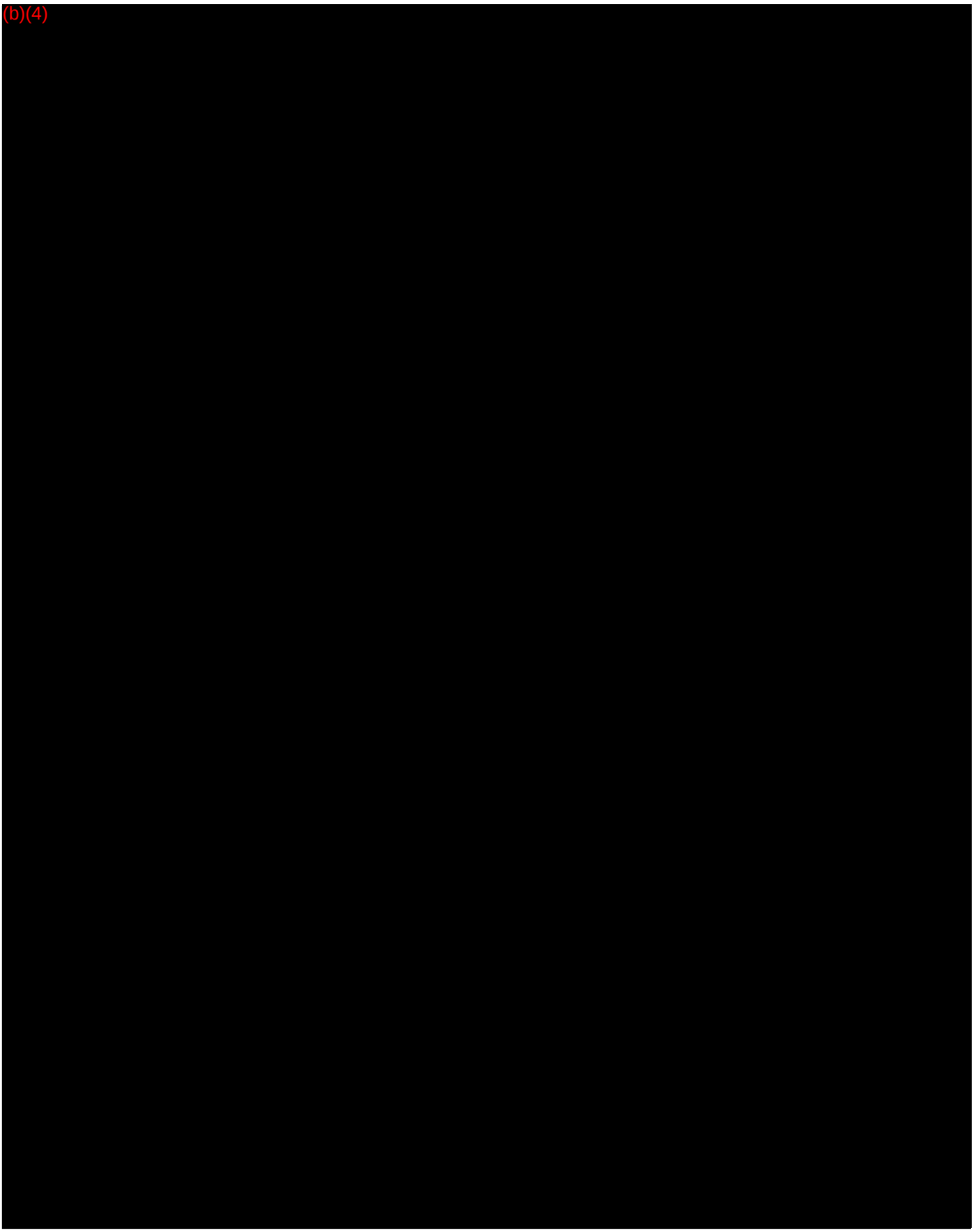

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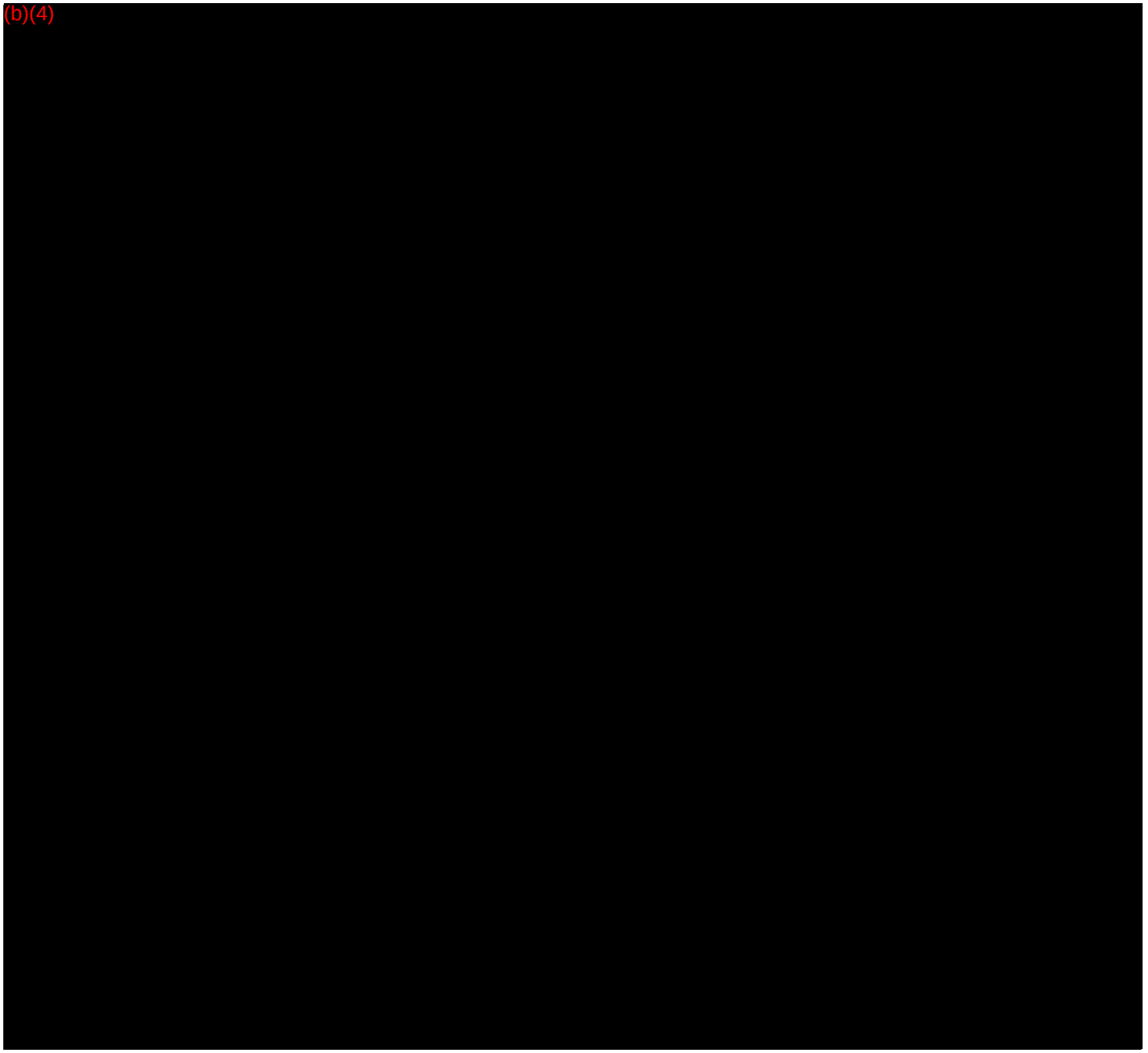

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9 Statistical Analysis of Reliability and Accuracy During the Intrapartum Period

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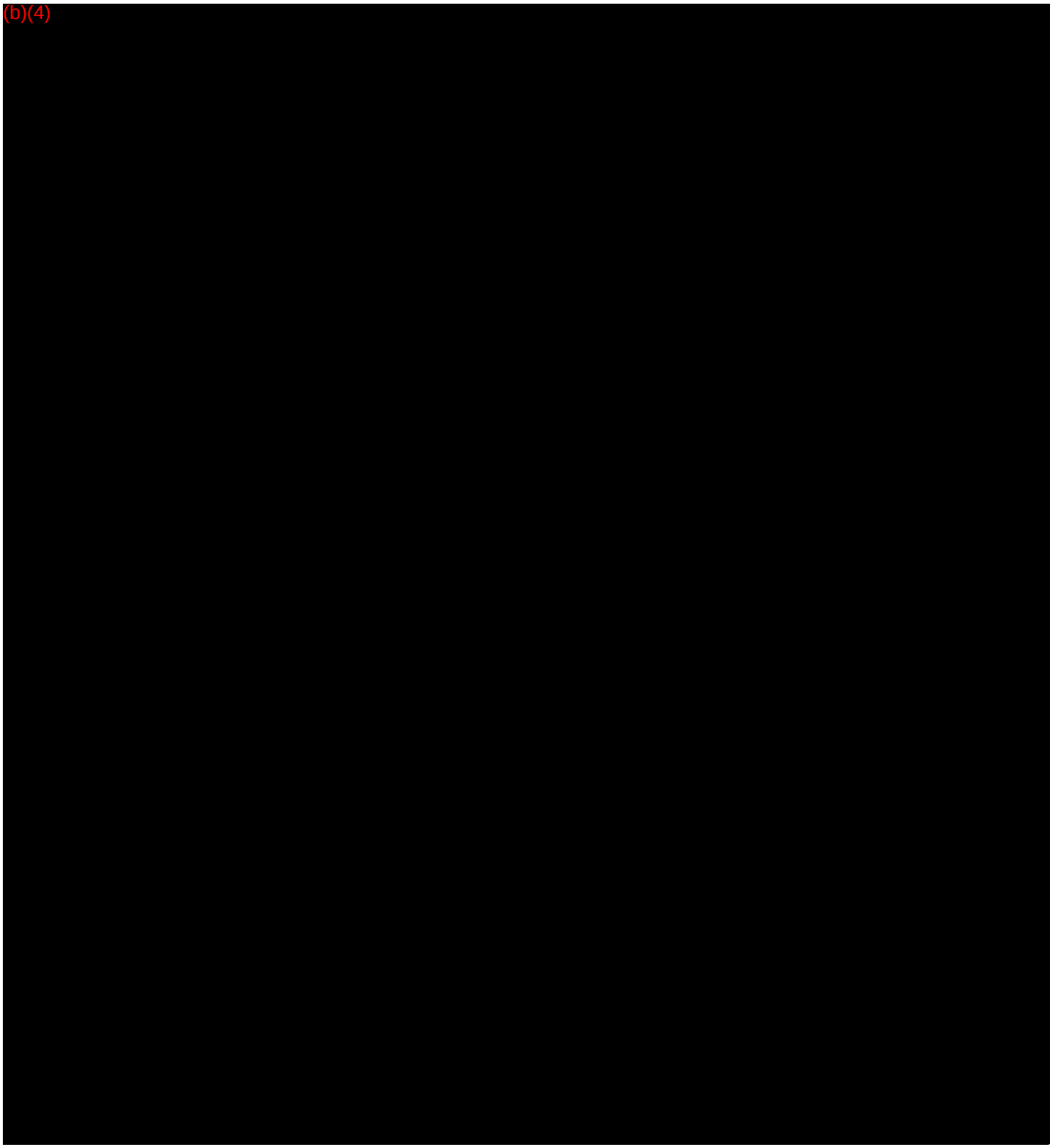

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9.2 Statistical methods for estimating ratios and their confidence limits

(b)(4)

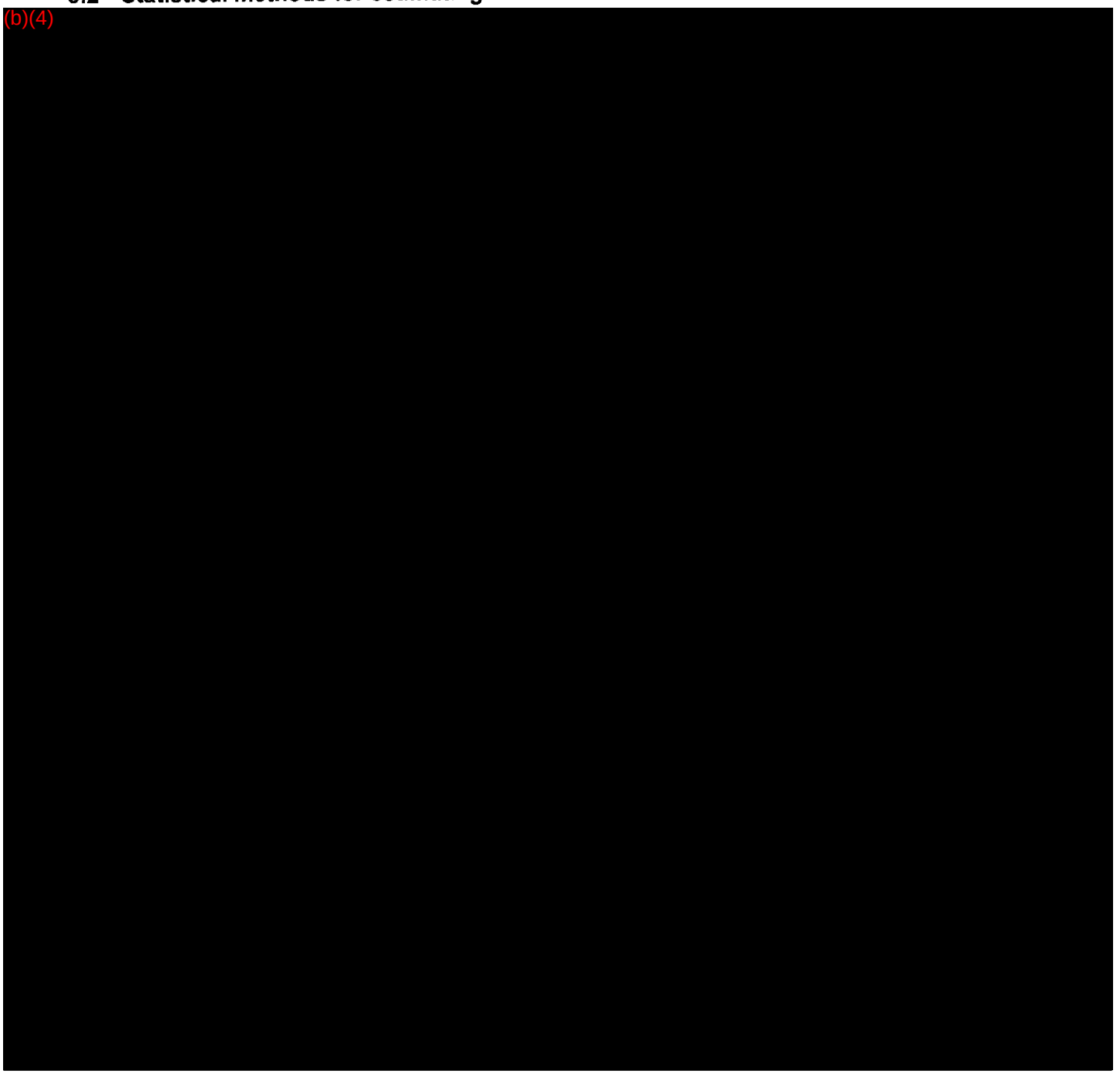

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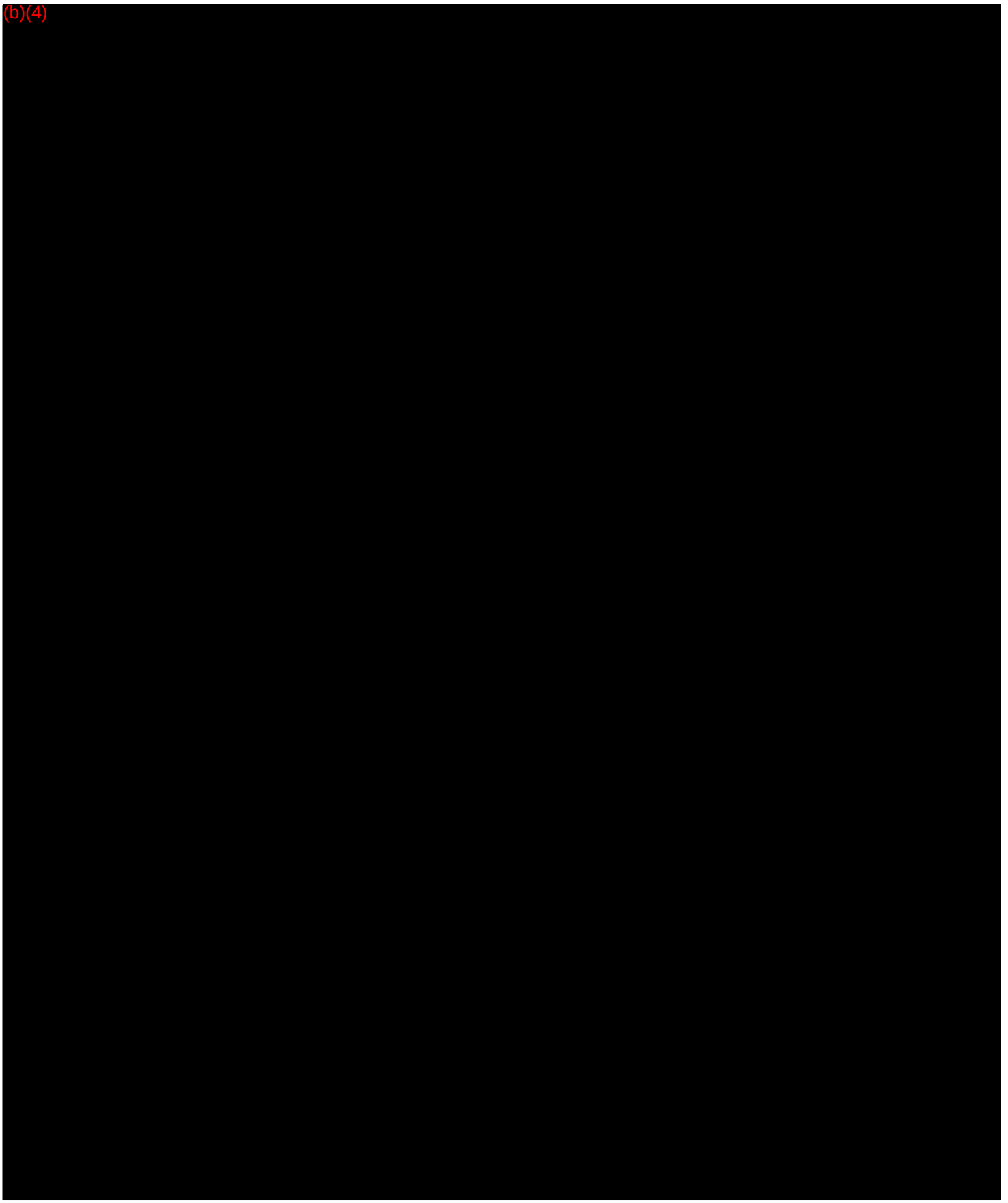
Figure 2 - Example of a Bland-Altman Plot

(b)(4)



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[redacted]

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547

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(b)(4)

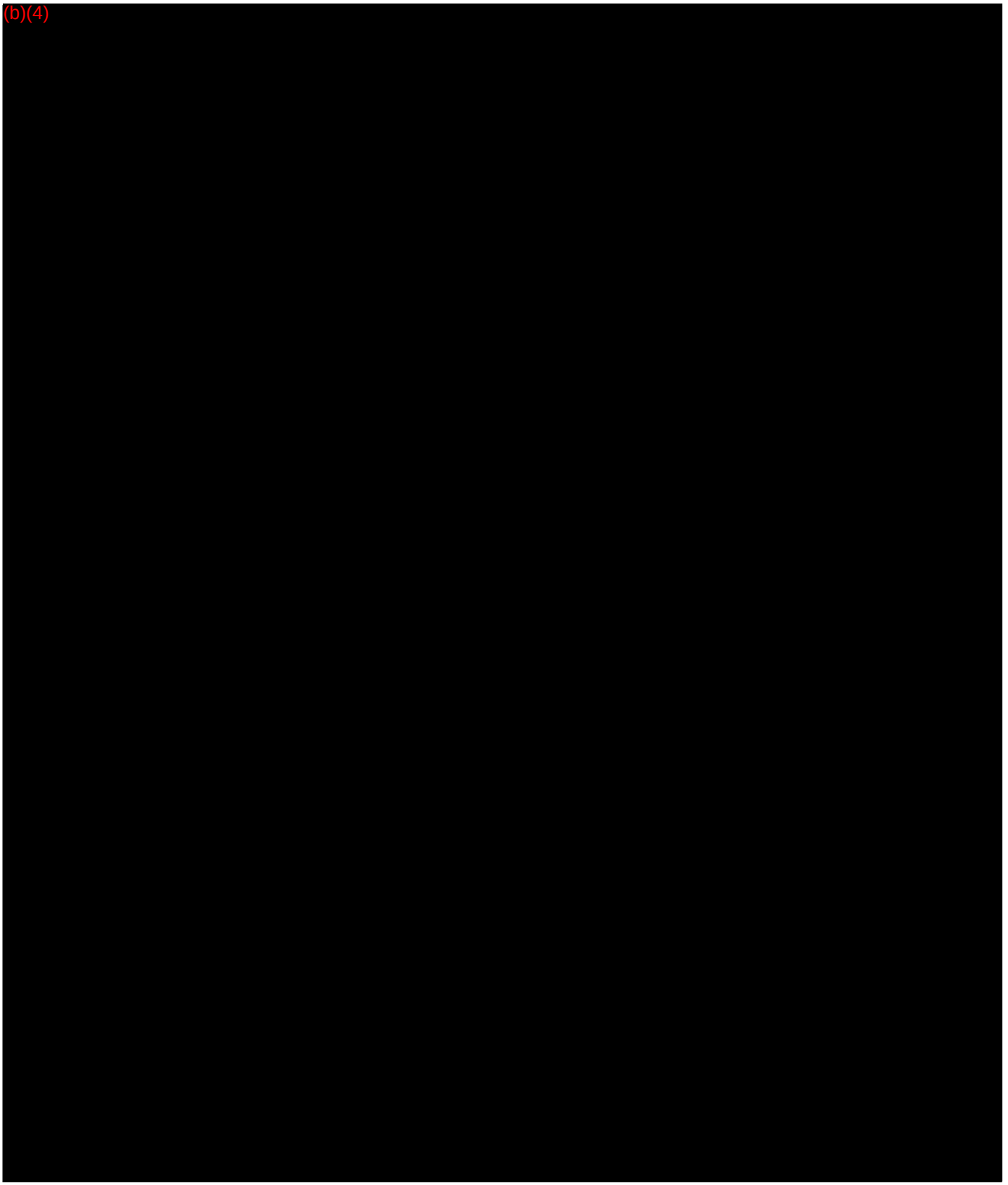

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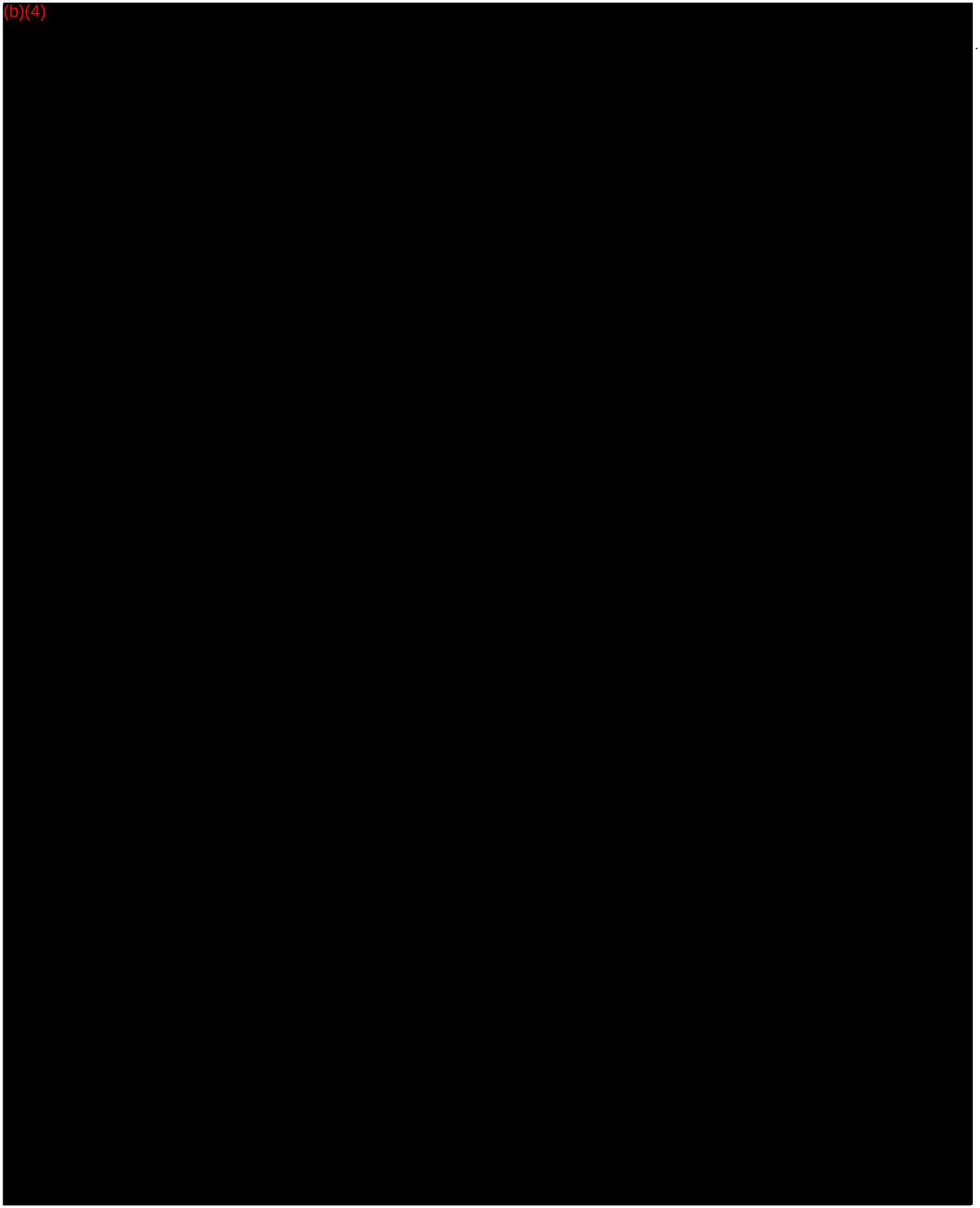
Table 7: Example Table of Sensitivity and PPV of "*Individual Contractions*"

(b)(4)



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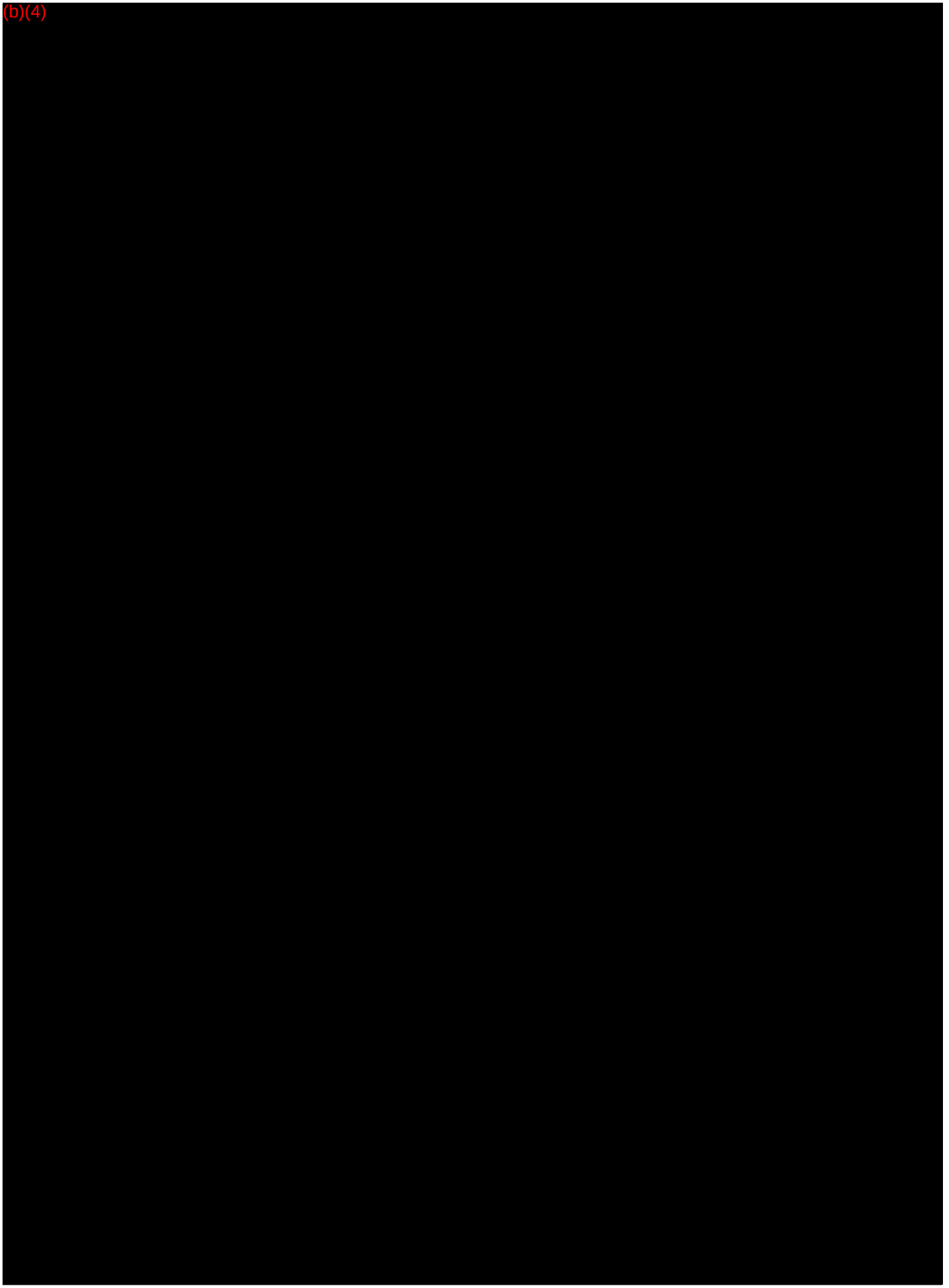

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550

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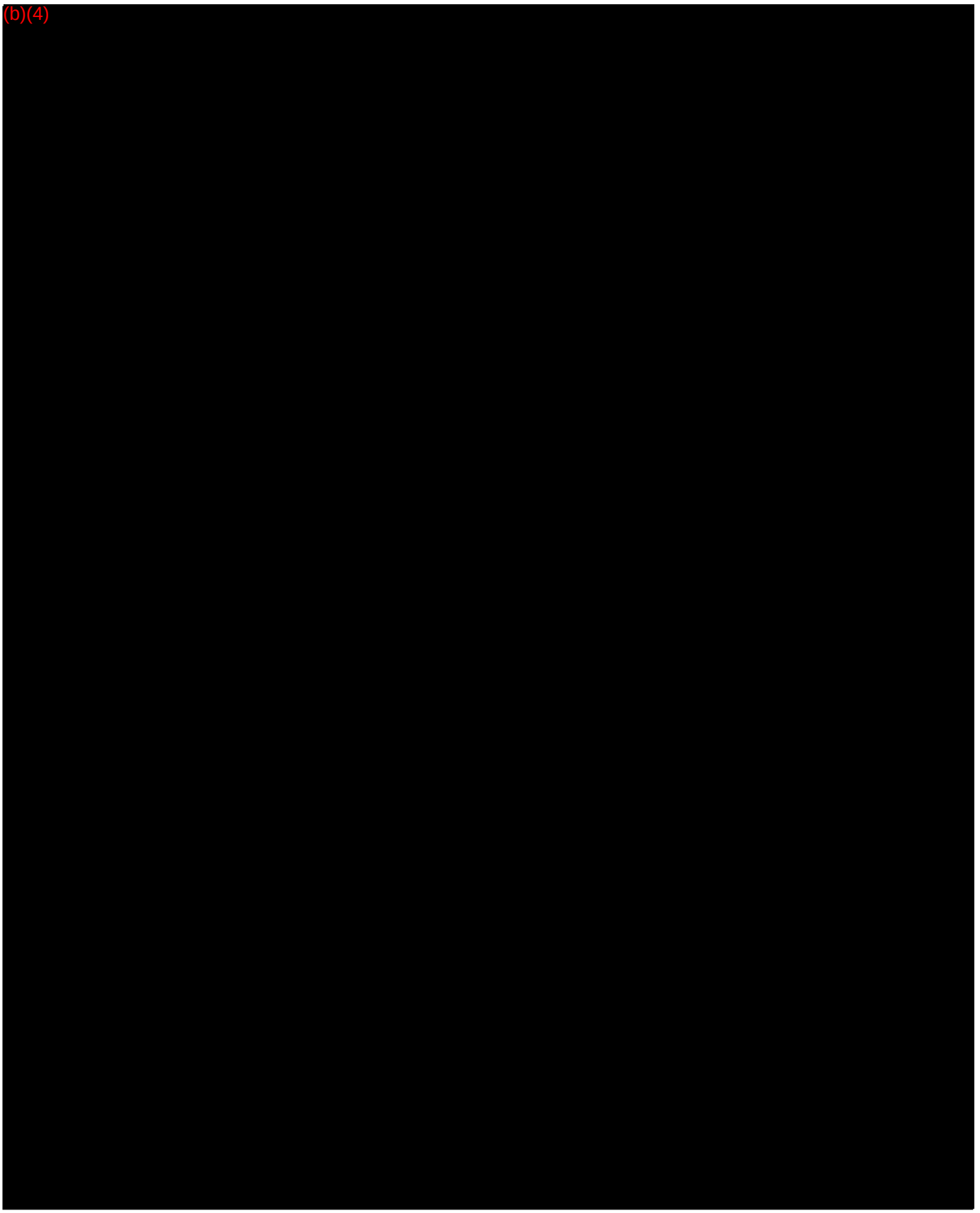

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10 Question To be Addressed to the FDA via this Pre-IDE

Monica Healthcare request this key question to be addressed by the FDA as a result of this Pre-IDE submission:

> "Would successful completion of this protocol clinically validate the AN24 for its indications for use (see Section 3.2) in respect of Fetal Heart Rate and Uterine Activity"

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

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Summary of FDA discussion and questions raised requiring a response from the FDA

(b)(4) FDA Questions and Responses to FDA Questions

[redacted]

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

(b)(4) FDA Questions and Responses to FDA Questions

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Appendix F

- Software Documentation

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118. 565

Records processed under FOIA Request #2015-4103; Released by CDRH on 06-06-2016.

Product	AN24 Abdominal FECG recorder
Document name	C Coding Standard
Document type	**Standard**
Abstract	This document defines the coding standard in use in Monica Healthcare during the design of software that are coded in C

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1 Preamble

1.1 Document Identification

The document is identified as follows:

- ✓ Identification Number: 100-CS-001.
- ✓ Title: AN24 Abdominal FECG recorder - C coding Standard.

1.2 Document Scope

This document describes the C coding guidelines agreed upon by the Monica Healthcare engineering team. These guidelines are expected to be adhered for C software development.

(b)(4)

[redacted]

2 RELATED DOCUMENTS

N°	Title
[1]	The C Programming Language (second edition), Kernighan, B. and Ritchie, D., Prentice-Hall Inc., Englewood Cliffs, New Jersey, 1988
[2]	The Elements of C Programming Style, Ranade, J. and Nash A., , McGraw-Hill, 1993
[3]	Writing Solid Code, Maguire, S., Microsoft Press, 1993

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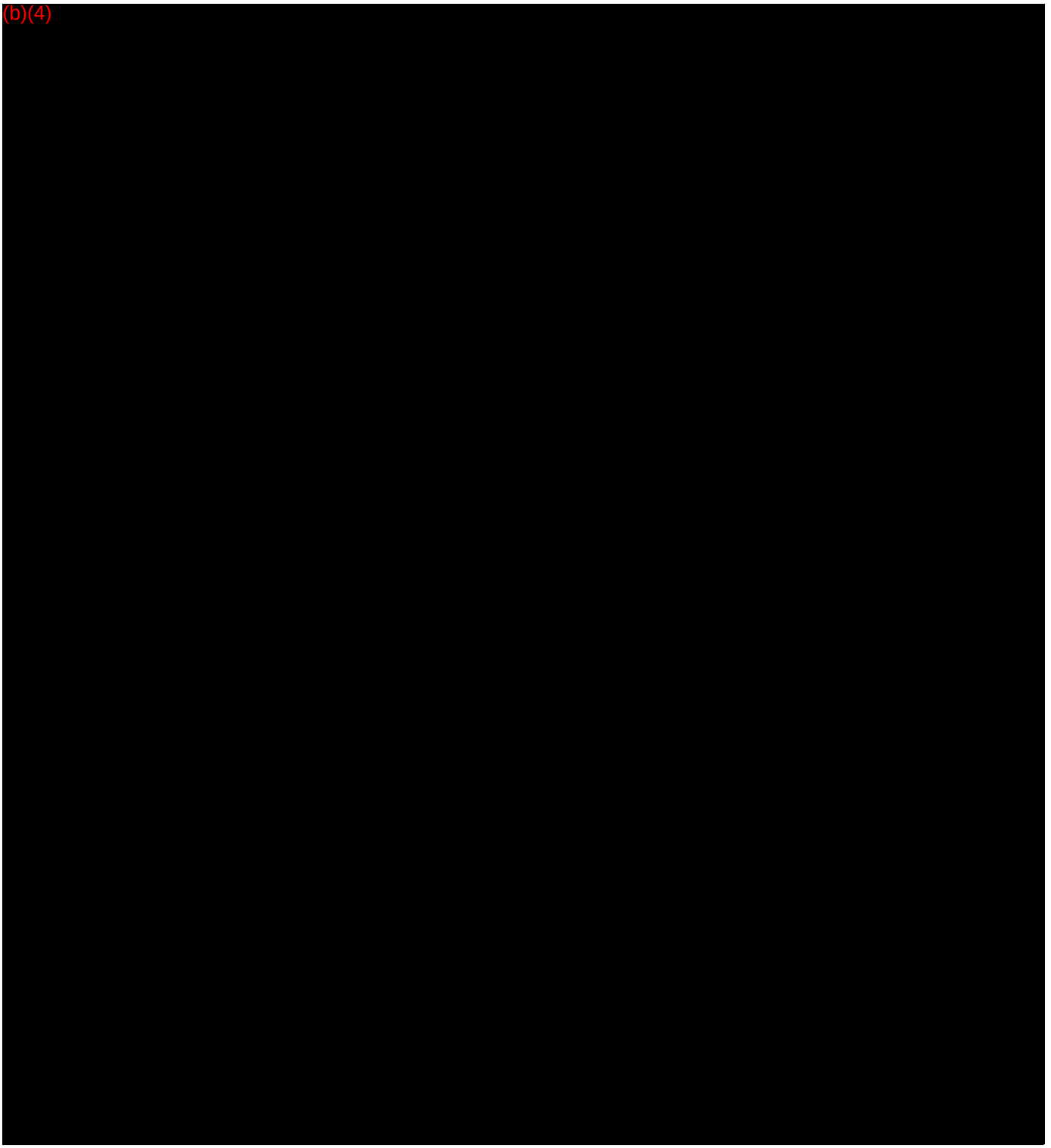
3 General

→All code should be ANSI standard and should compile without warning under its principal compiler. Any warnings that cannot be eliminated should be commented in the code.

4 Naming conventions

(b)(4)



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Records processed under FOIA Request #2015-4103; Released by CDRH on 06-06-2016.

Product	AN24 Abdominal FECG recorder
Document name	C++ Coding Standard
Document type	**Standard**
Abstract	This document defines the coding standard in use in Monica Healthcare during the design of software that are coded in C++

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1 Preamble

1.1 Document Identification

The document is identified as follows:

- ✓ Identification Number: 100-CS-002.
- ✓ Title: AN24 Abdominal FECG recorder – C++ coding Standard.

1.2 Document Scope

This document describes the C++ coding guidelines agreed upon by the Monica Healthcare engineering team. These guidelines are expected to be adhered for C++ software development.

1.3 Introduction

This document was written with the following goals in mind:

- Code should be robust and error free.
- Code should be easy to use and understand.
- Code should be easy to maintain.

(b)(4)

[redacted]

2 RELATED DOCUMENTS

N°	*Title*
[1]	Large Scale C++ Software Design, Lakos, J., Addison-Wesley Publishing Company, 1996
[2]	Effective C++: 50 Specific Ways to Improve Your Programs and Designs, Meyers, S., Addison-Wesley, 1992
[3]	Writing Solid Code, Maguire, S., Microsoft Press, 1993
[4]	More Effective C++: 35 New Ways to Improve Your Programs and Designs, Meyers, S., Addison-Wesley, 1996.

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3 Class Declarations

(b)(4)

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5 Code Commenting

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[redacted]

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Product	AN24 Abdominal Fetal ECG recorder
Document name	System Requirements Specification
Document type	**SPECIFICATION**

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1 SCOPE

1.1 Document Identification

This document is the system specifications for the AN24 fetal ECG monitor.
The document is identified as follows:

- ✓ Identification Number: 100-SP-001.
- ✓ Title: AN24 Abdominal Fetal ECG recorder - System Requirements Specification.

1.2 Document Scope

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[redacted]

1.3 System Overview

(b)(4)

[redacted]

Monica AN24 (shown in Fig 1) is a passive (excluding low-level leakage & operating currents which fall well within the required EN60601-1 safety standards), battery-powered device which by design cannot be physically connected to any third party device whilst also connected to a human subject.

Figure 1: The Monica AN24 Device

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2 RELATED DOCUMENTS

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3 GLOSSARY

ADC	Analog to Digital Converter
AFE	Analog Front End
BMI	Body Mass Index
BPM	Beat Per Minute
CTG	CardioTocoGraph
ECG	Electro CardioGram
EHG	ElectroHisteroGram
EMC	ElectroMagnetic Compatibility
EMG	ElectroMyoGram
FECG	Fetal ElectroCardioGram
FHR	Fetal Heart Rate
HP	Hewlett Packard
IC	Integrated Circuit
LCD	Liquid Crystal Display
LED	Light Emitting Device
L&D	Labour and Delivery
MDA	personal digital assistant
MDS	Monica Decision Support
MHR	Maternal Heart Rate
PC	Personal computer
PCB	Printed Circuit Board
PDA	Personal Digital Assistant
SD	Secure Digital memory card
TX	Transmit
UA	Uterine Activity

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4 AN24 Engineering requirements

4.1 Mechanical requirements

4.1.1 Recorder case

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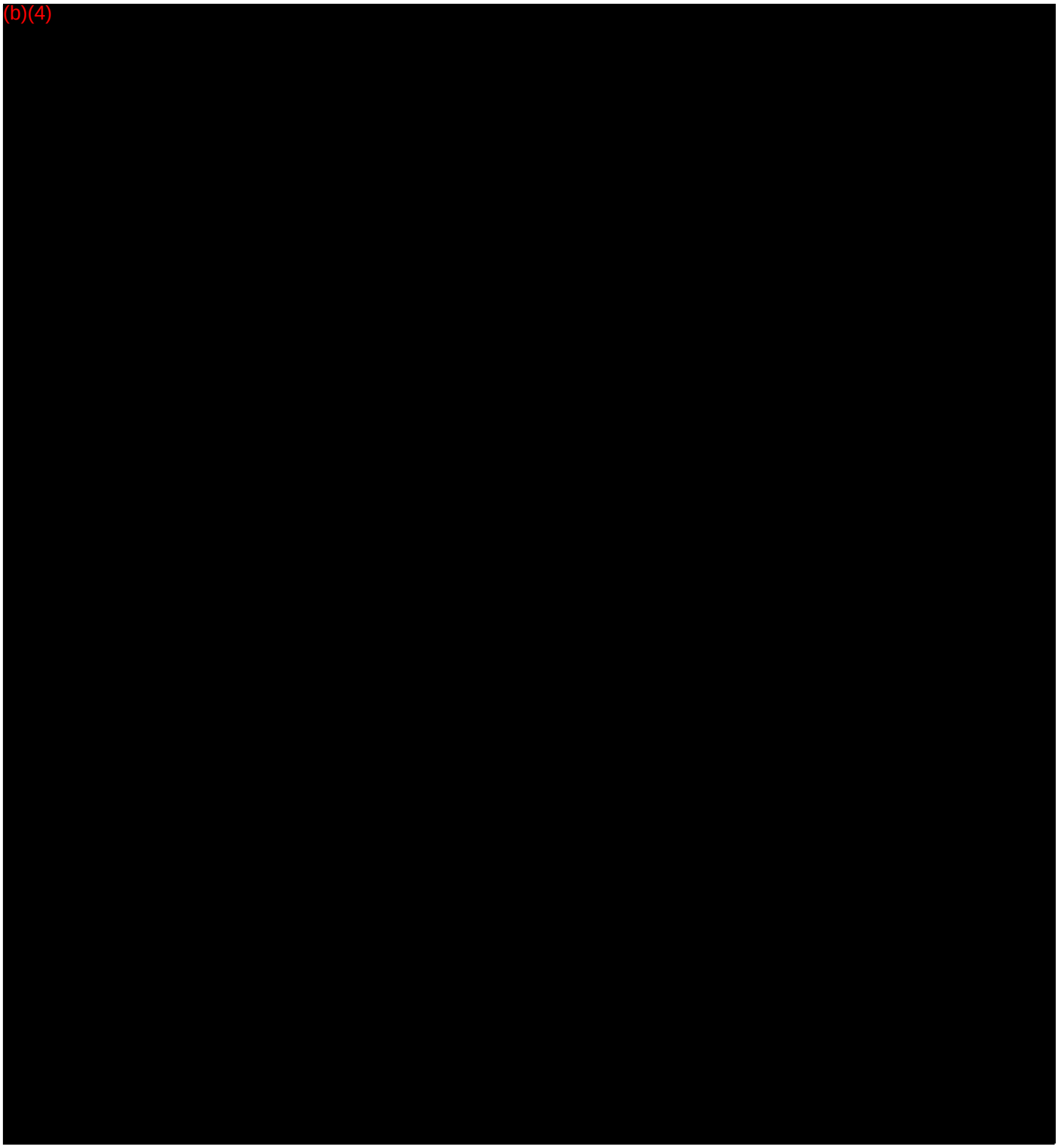

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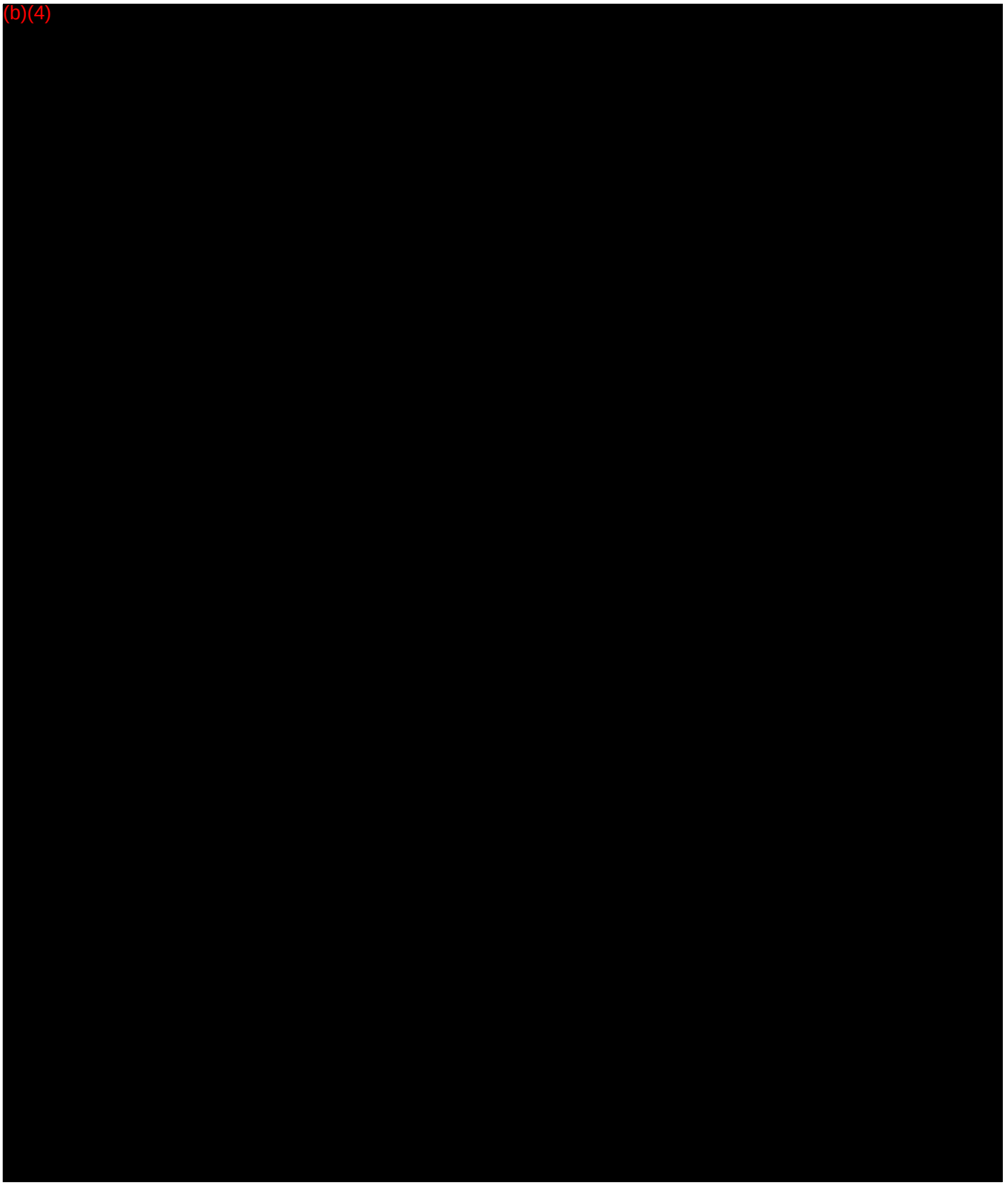

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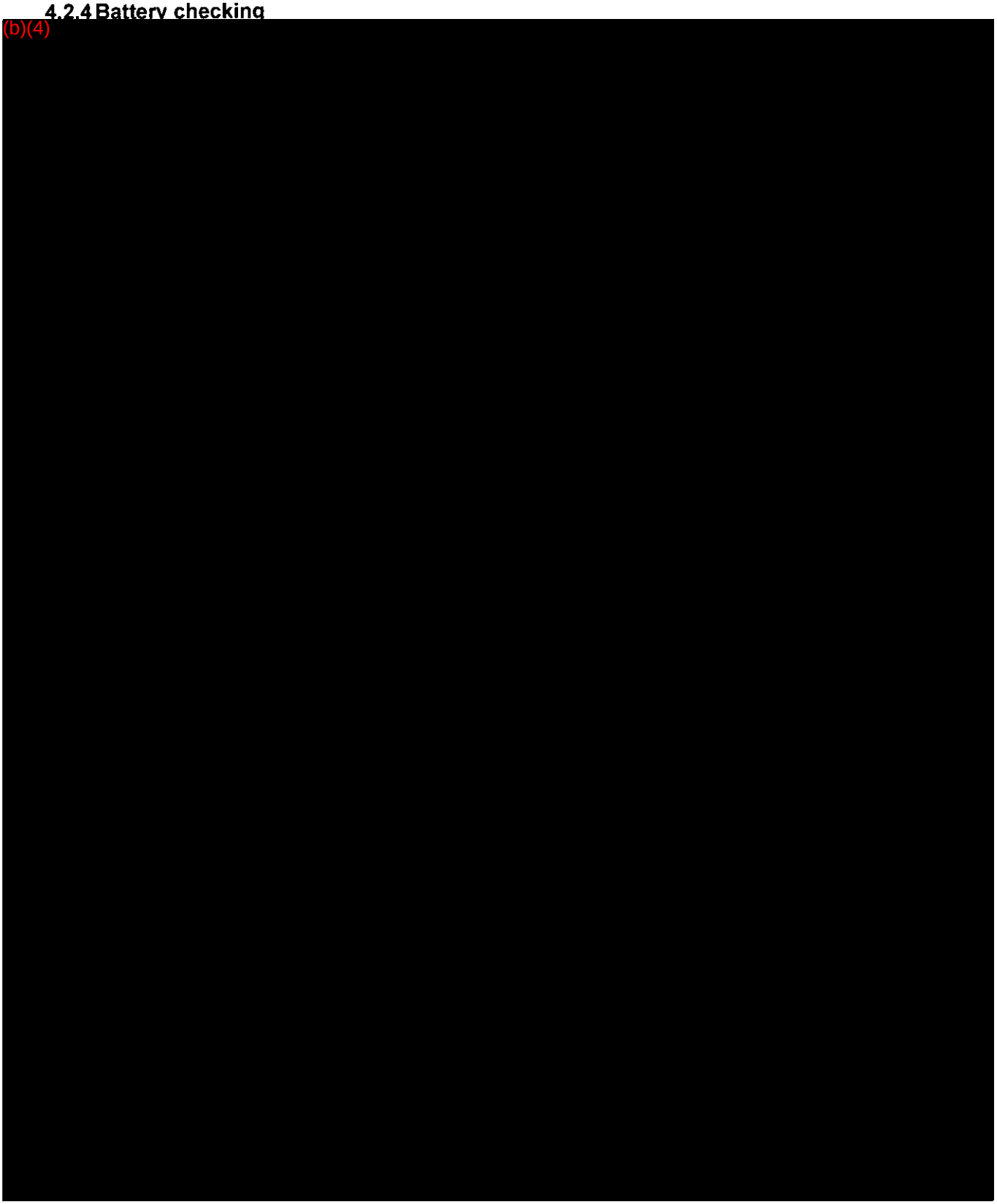
4.2.4 Battery checking

(b)(4)



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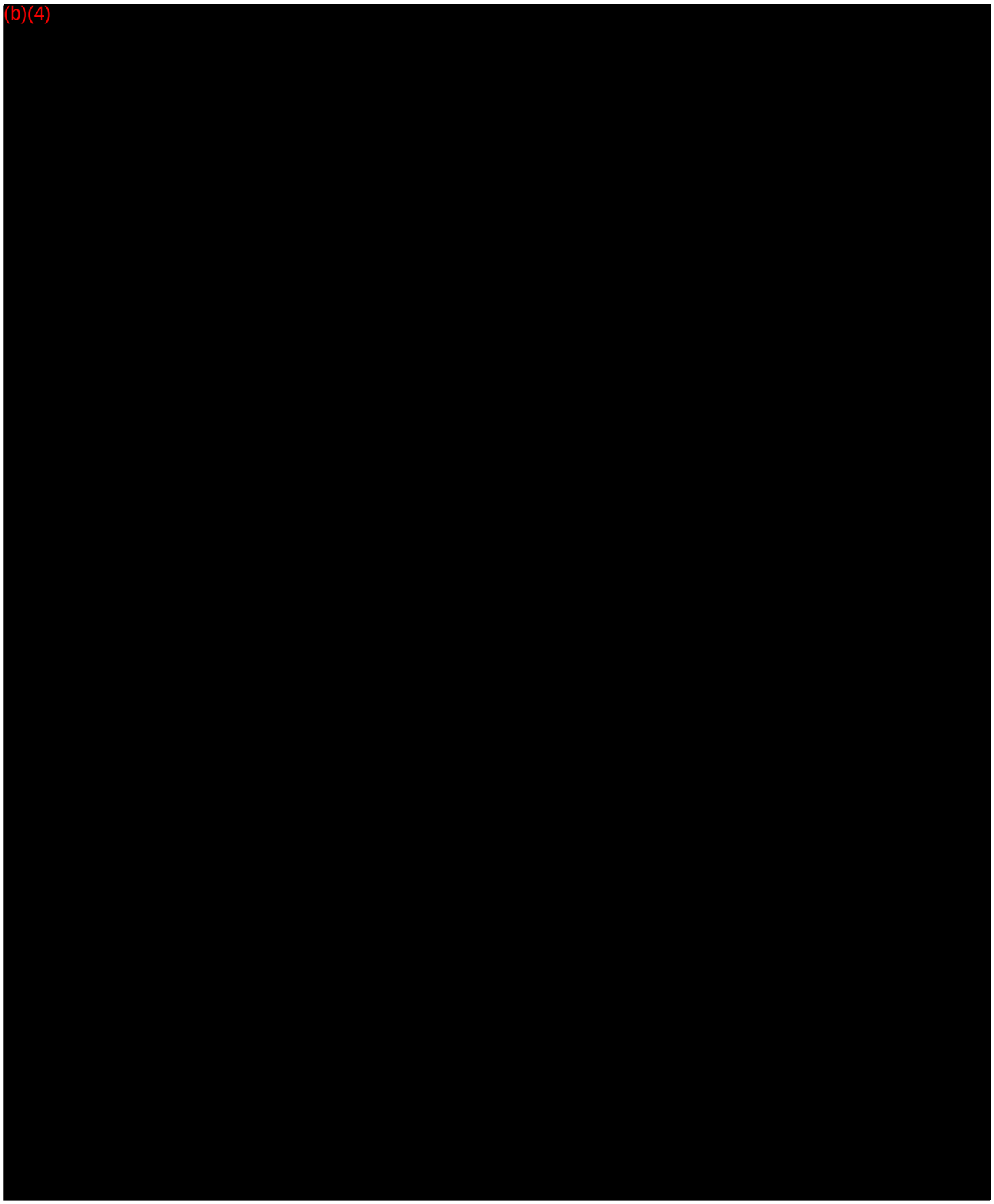

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4.6 Interfaces

4.6.1 User interfaces

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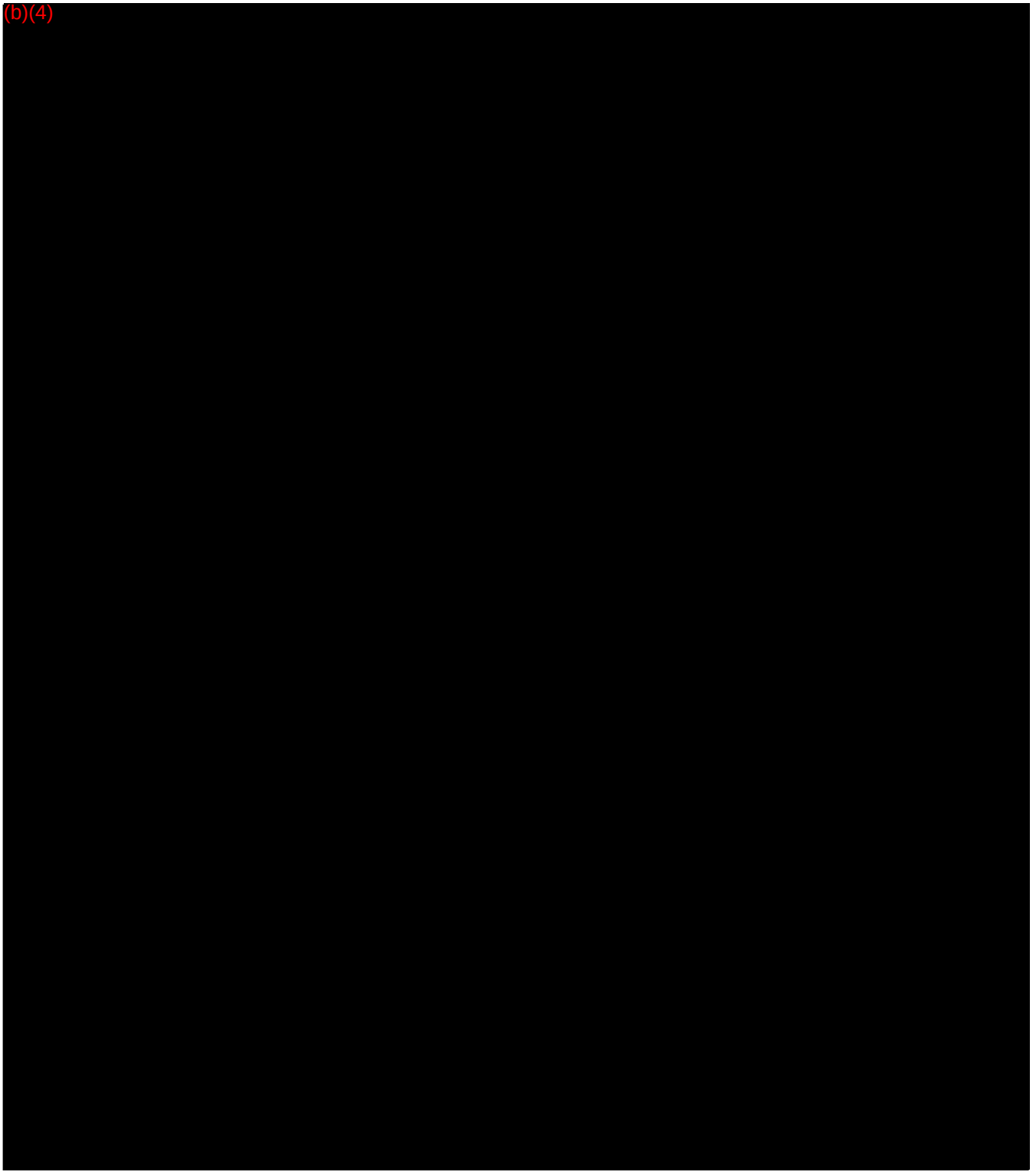

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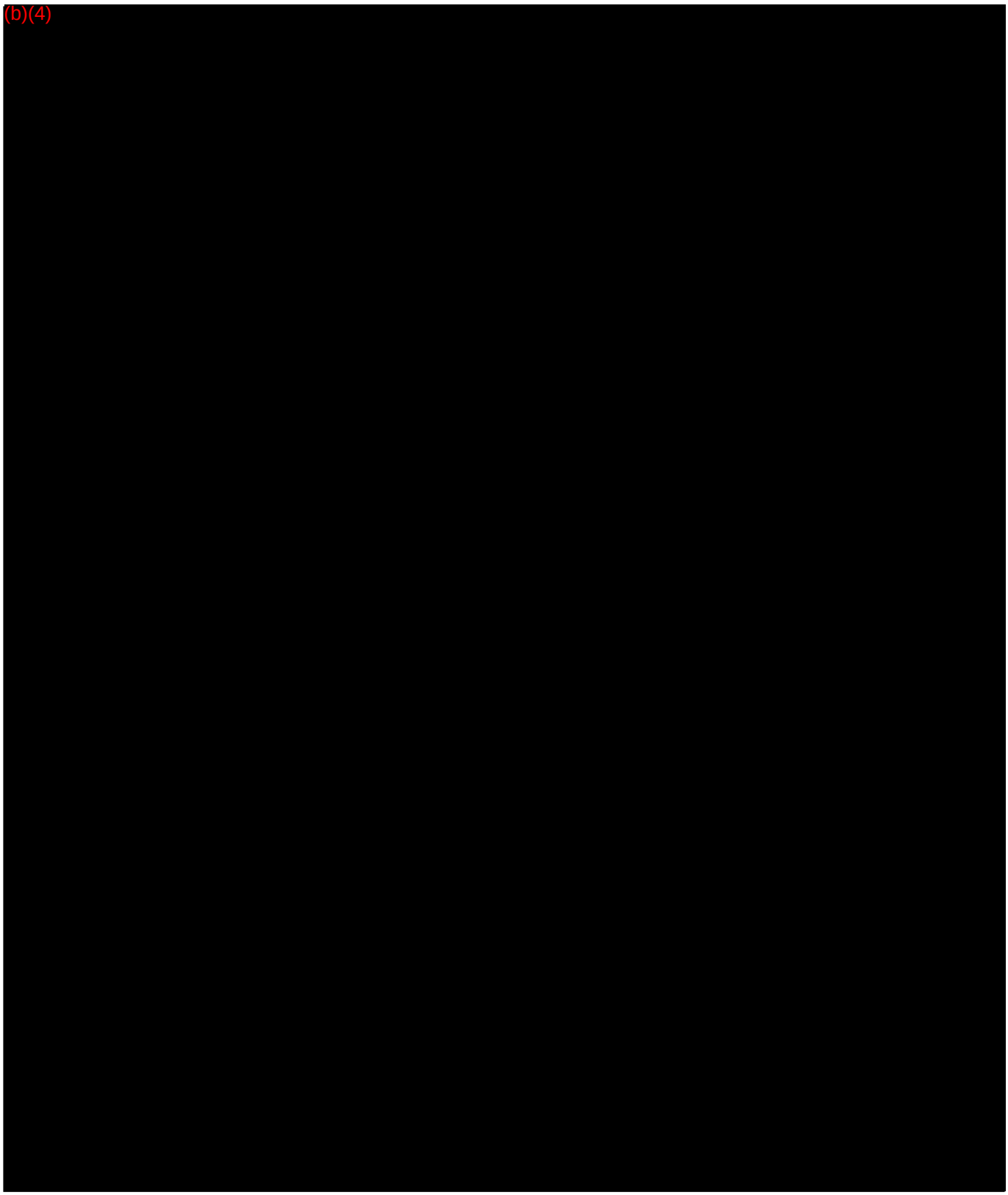

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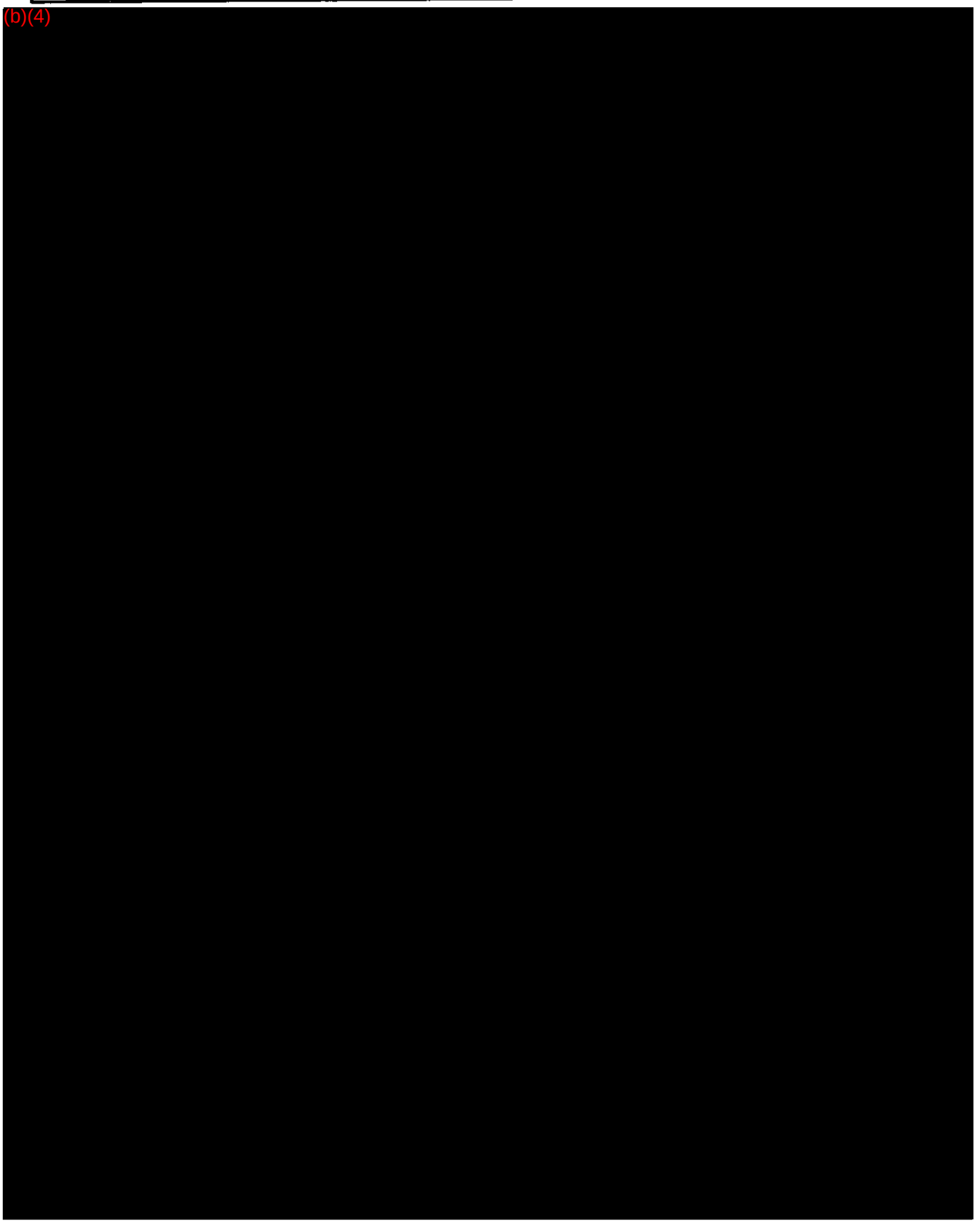

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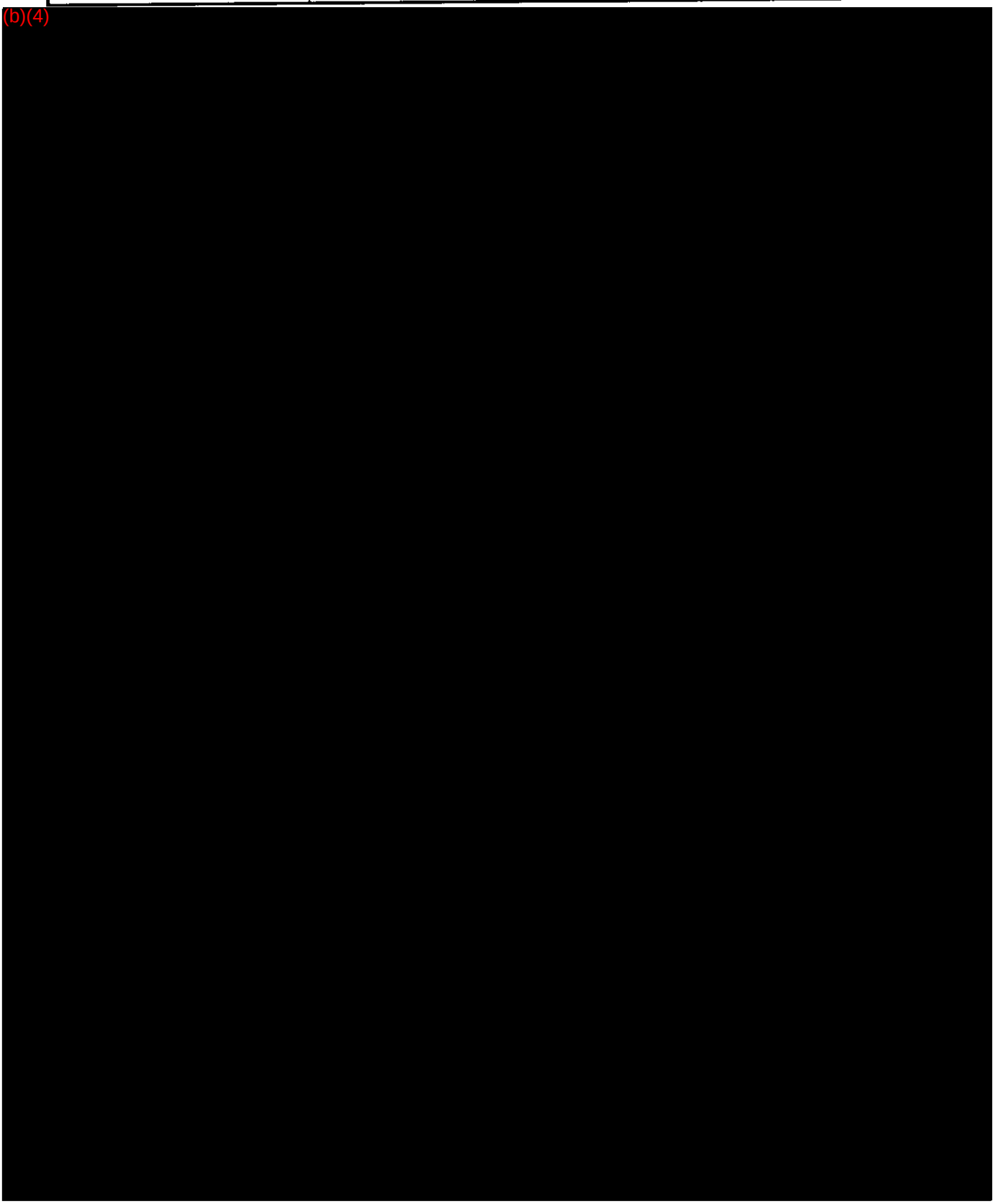

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7 Regulatory requirements

7.1.1 Safety & EMC standards

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[redacted]

8 Requirements traceability

Requirements traceability is described in [1].

9 Qualification requirements

The qualification methods and means are described in [7], [8] and [13].

End of Document

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Product	AN24 Abdominal Fetal ECG recorder
Document name	Requirements Traceability
Document type	**SPECIFICATION**

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1 SCOPE

1.1 Document Identification

This document ensures the traceability of the requirements for the system. It is identified as follows:

- ✓ Identification Number: 100-SP-002.
- ✓ Title: AN24 Abdominal Fetal ECG recorder – Requirements Traceability.

1.2 Document Scope

This document ensures that each system requirement of the AN24 abdominal fetal ECG recorder is met. Each system requirement induces hardware and software requirements. All requirements are tested by an enumerated test.

Test are classified as I (inspection), A (analyse), D (demonstration), T (test).

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2 RELATED DOCUMENTS

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3 GLOSSARY

ADC	Analog to Digital Converter
ECG	Electro CardioGram
EHG	ElectroHisteroGram
EMC	ElectroMagnetic Compatibility
FECG	Fetal ElectroCardioGram
FHR	Fetal Heart Rate
MHR	Maternal Heart Rate

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4 Traceability matrix

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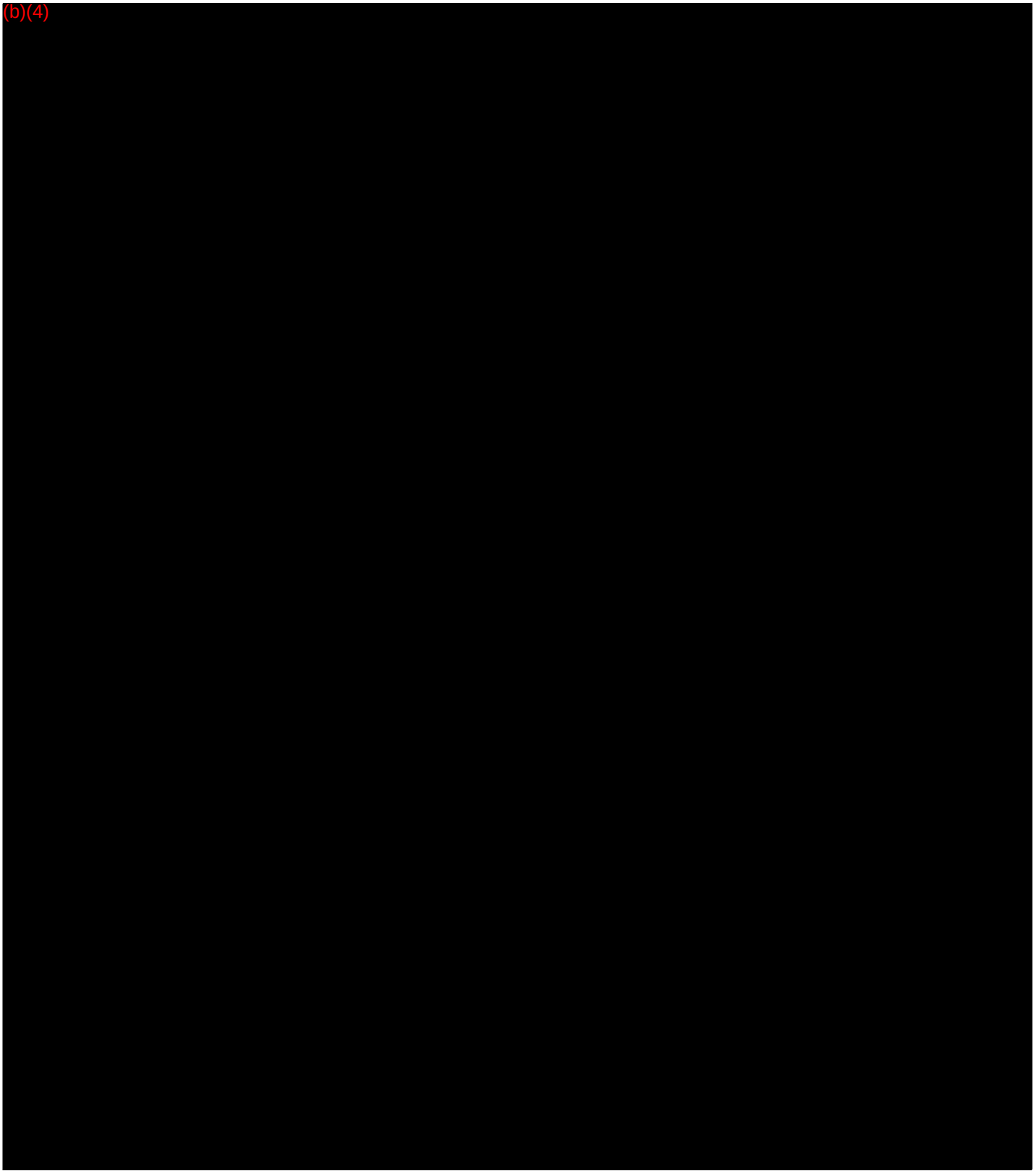

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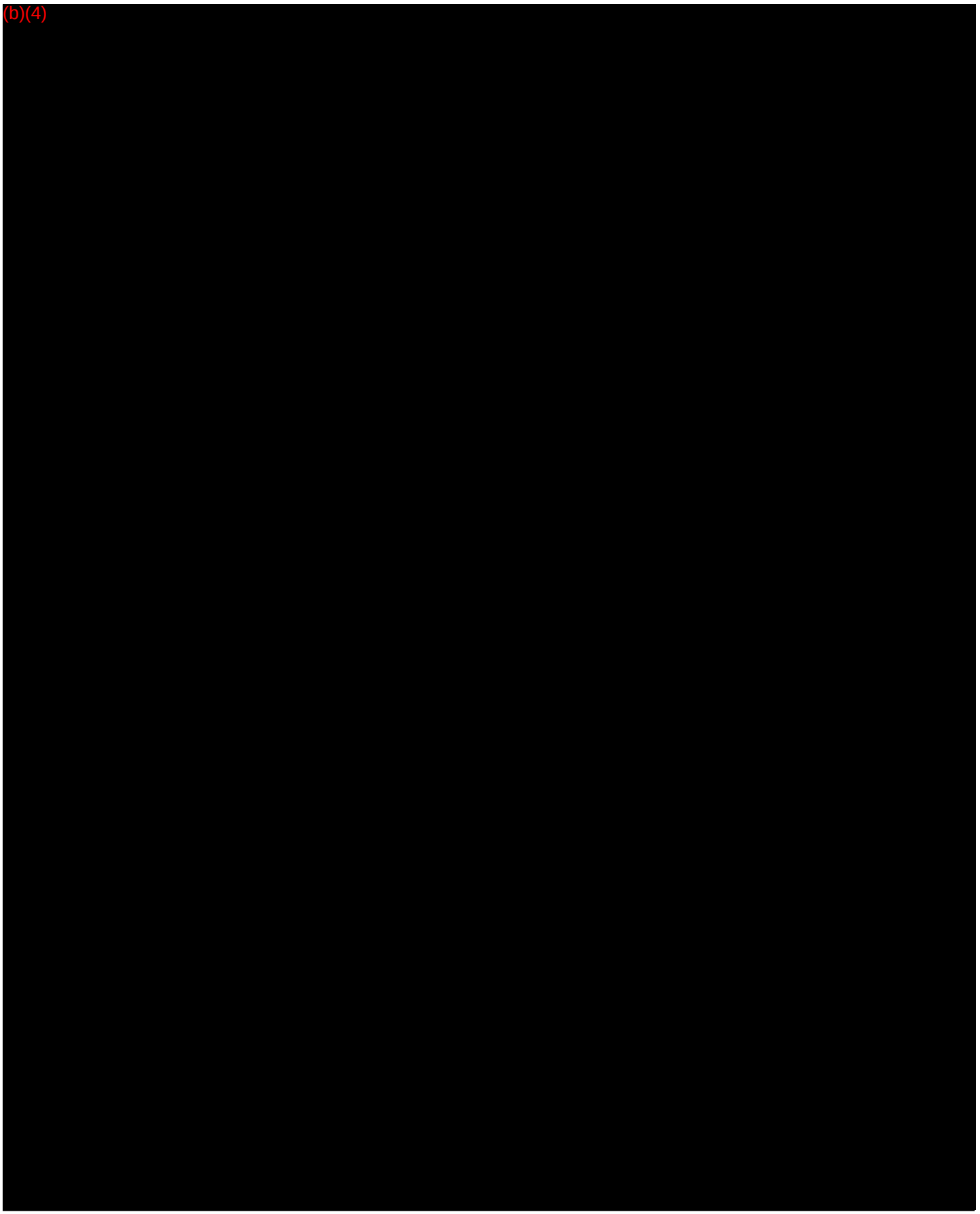

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Records processed under FOIA Request #2015-4103; Released by CDRH on 06-06-2016.

Product	AN24 Abdominal Fetal ECG recorder
Document name	Firmware: Software Requirements Specification (SRS)
Document type	**SPECIFICATION**

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DOCUMENT HISTORY

REVISION INDEX	WRITTEN BY	DATE	DESCRIPTION/CHANGES
(b) (4), (b) (6)	[redacted]		

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1 SCOPE

1.1 Document Identification

This document specifies the engineering and qualification requirements for the abdominal fetal ECG monitor recorder firmware. The document is identified as follows:

- ✓ Identification Number: 100-SP-003.
- ✓ Title: AN24 Abdominal FECG Recorder - Firmware Software Requirements Specification (SRS).

1.2 Document Scope

This document describes the requirements of the recorder firmware. It defines:

- ✓ The capacities provided,
- ✓ The performance requirements,
- ✓ The requirements traceability.

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2 RELATED DOCUMENTS

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[redacted]

3 GLOSSARY

ADC	Analog to Digital Converter
BT	BlueTooth
CTG	CardioTocoGram
ECG	Electro CardioGram
EHG	ElectroHisteroGram
EMC	ElectroMagnetic Compatibility
EMG	ElectroMyoGram
FAT	File Allocation Table
FECG	Fetal ElectroCardioGram
FHR	Fetal Heart Rate
HP	Hewlett Packard
IC	Integrated Circuit
IO	Input Output
LCD	Liquid Crystal Display
L&D	Labour and Delivery
MHR	Maternal Heart Rate
PC	Personal computer
QRS	Q-R-S wave of the Electrocardiogram
RR	R wave to R wave
RX	Reception
RTC	Real Time Clock
TX	Transmission
USB	Universal Serial Bus
UA	Uterine activity

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4 Engineering requirements

4.1 External Interfaces Requirements

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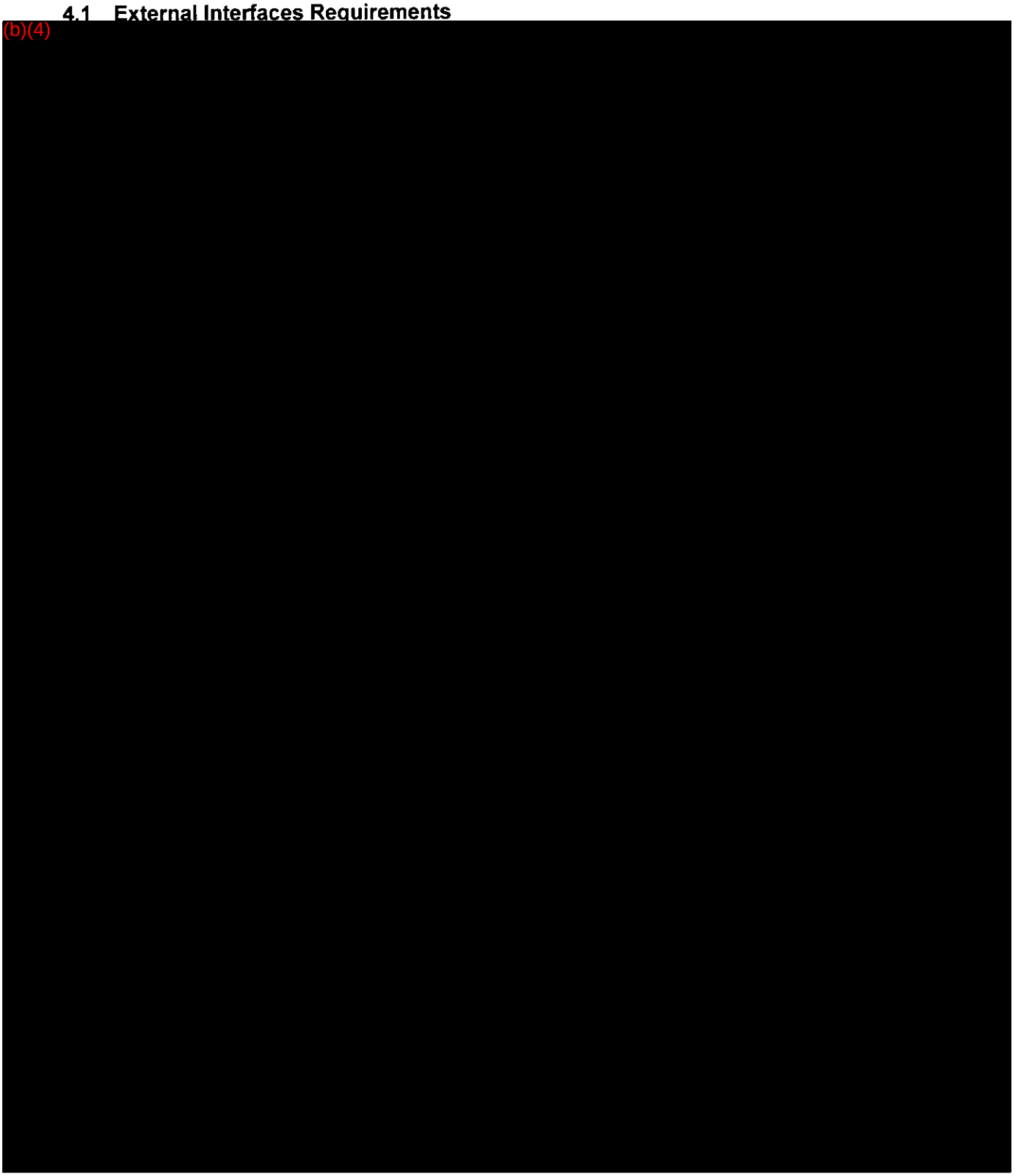

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Figure 3 gives the state diagram of the firmware.

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Figure 3: State diagram of the firmware.

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4.2.2 Capability requirements

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4.2.2.2 Operation state

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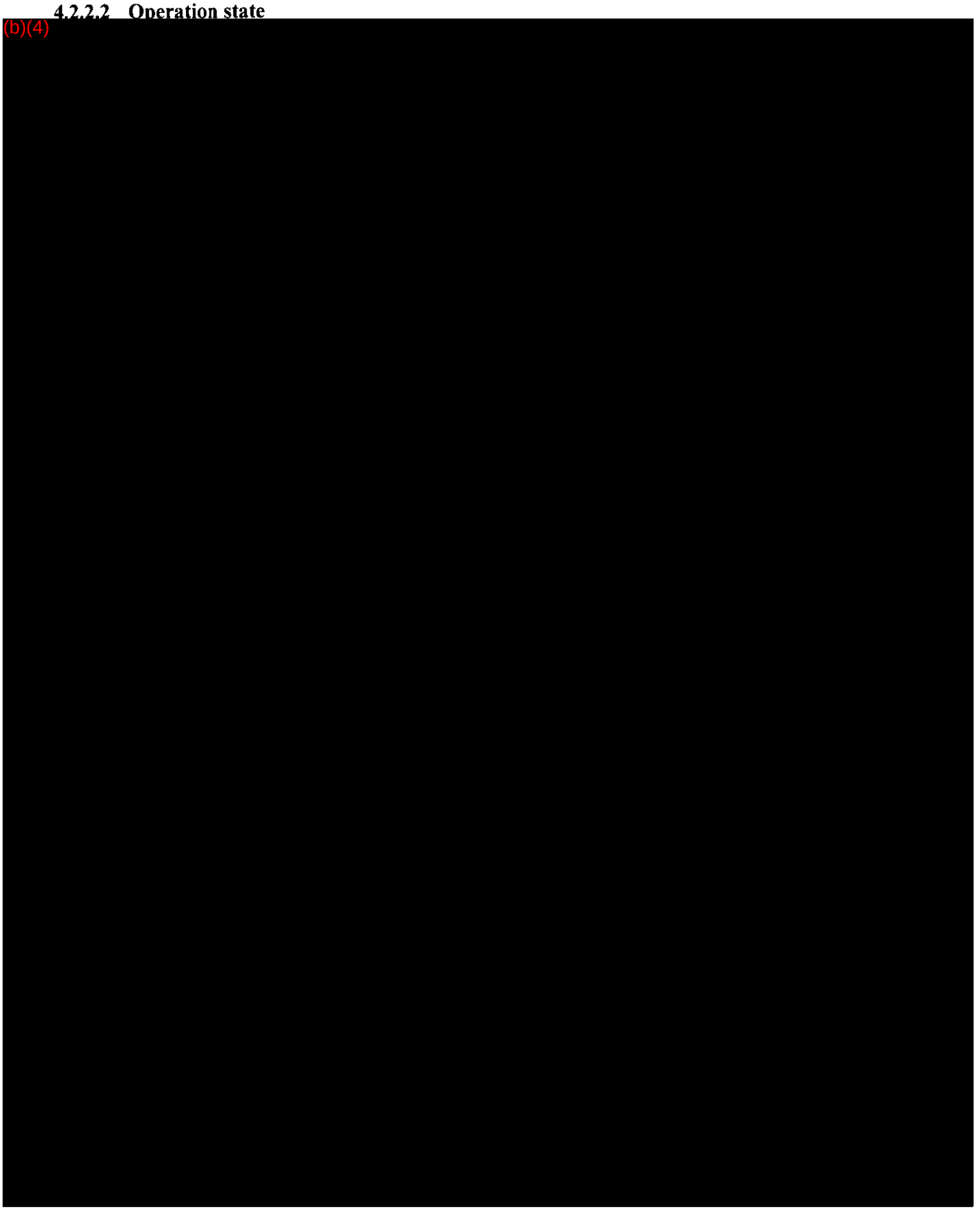

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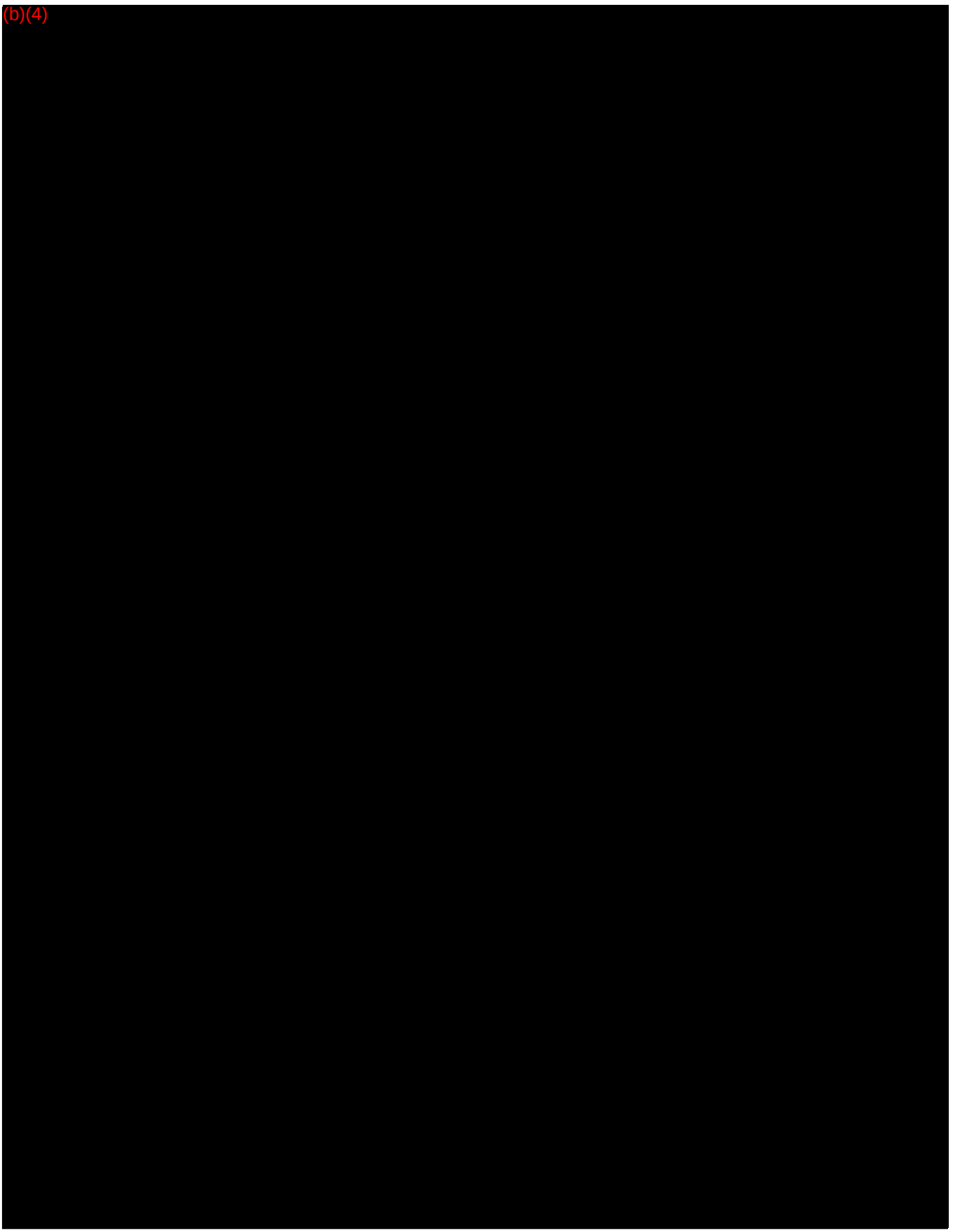

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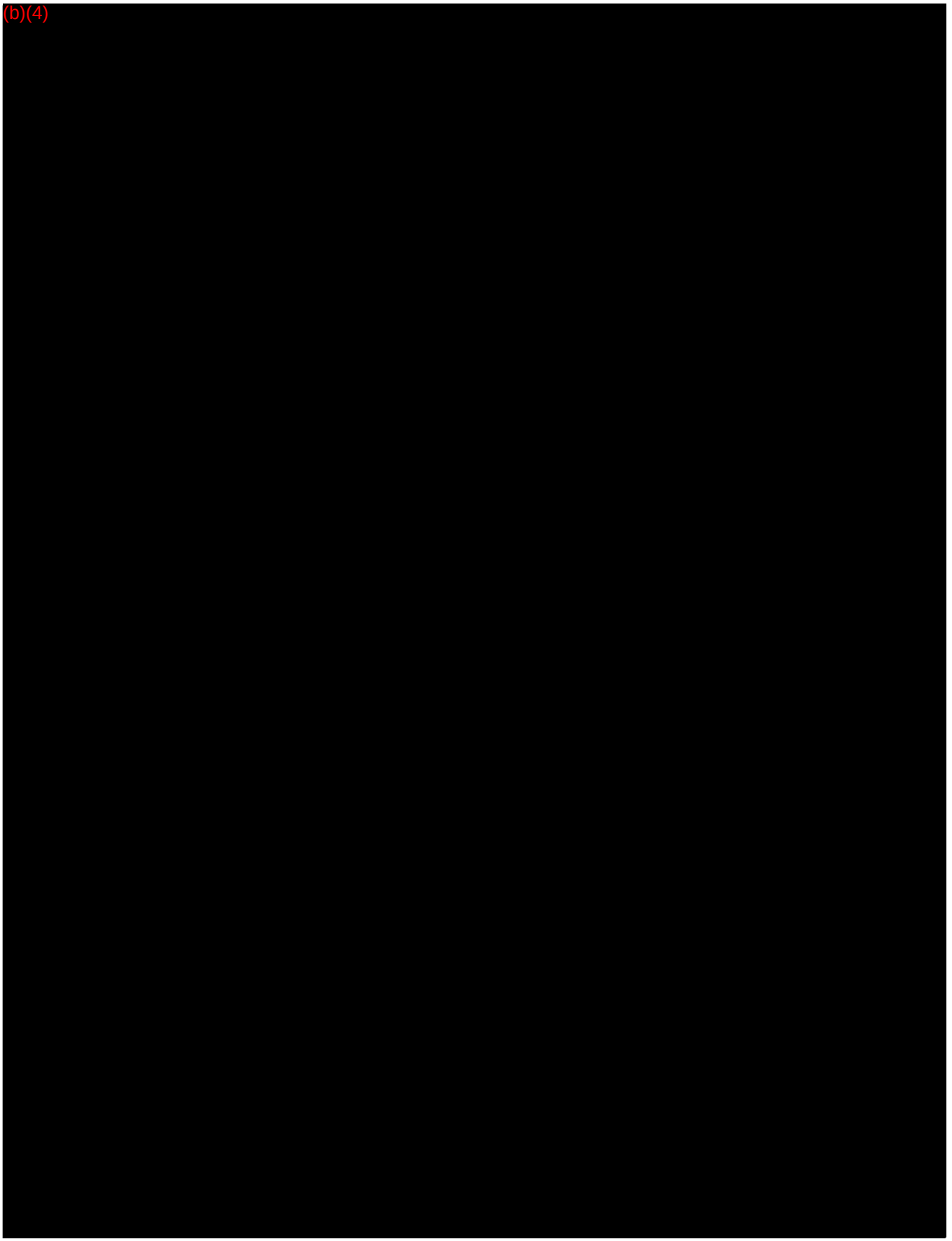

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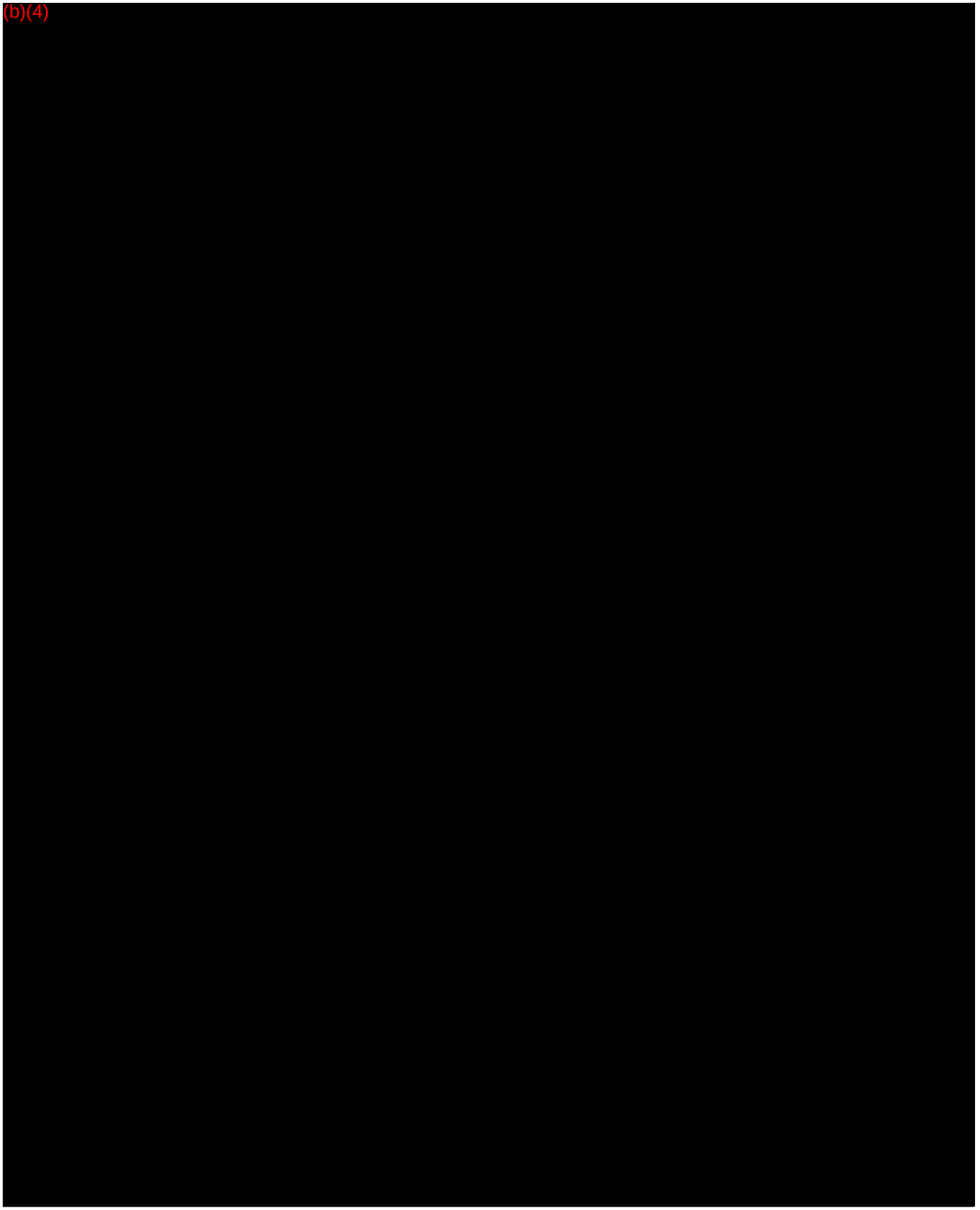

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4.3 Programming requirements, Software performance

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5 Regulatory requirements

5.1.1 Safety Standards

<SW_240> Safety standards

The firmware should be designed for compliance with IEC 60601-1-4:1996 and EN 60601-1-4: 1997

<End>

5.1.2 CE/FDA marking

During the design, care should be taken to make sure that the firmware complies with the Medical Device Directive - MDD93/42/EEC marking and that the design\testing is also suitable to meet the requirements for FDA approval in the future.

5.1.3 Quality System

The complete design process is governed by a Quality System installed at Monica Healthcare in accordance with ISO13485:2003 and 21 CFR 820

6 Requirements traceability

Requirements traceability is described in [2].

7 Qualification requirements

The qualification methods and means are described in [3].

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Appendix A

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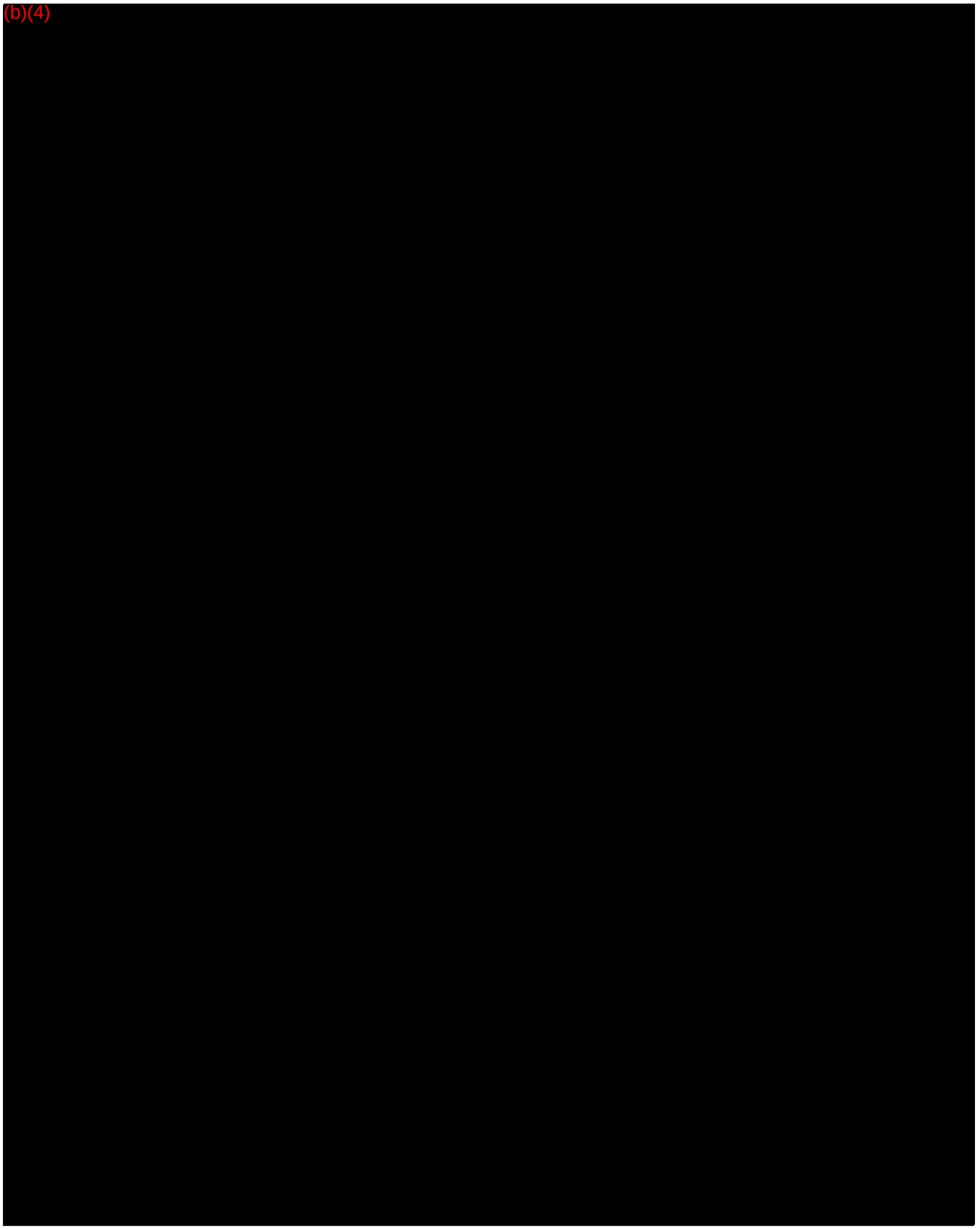

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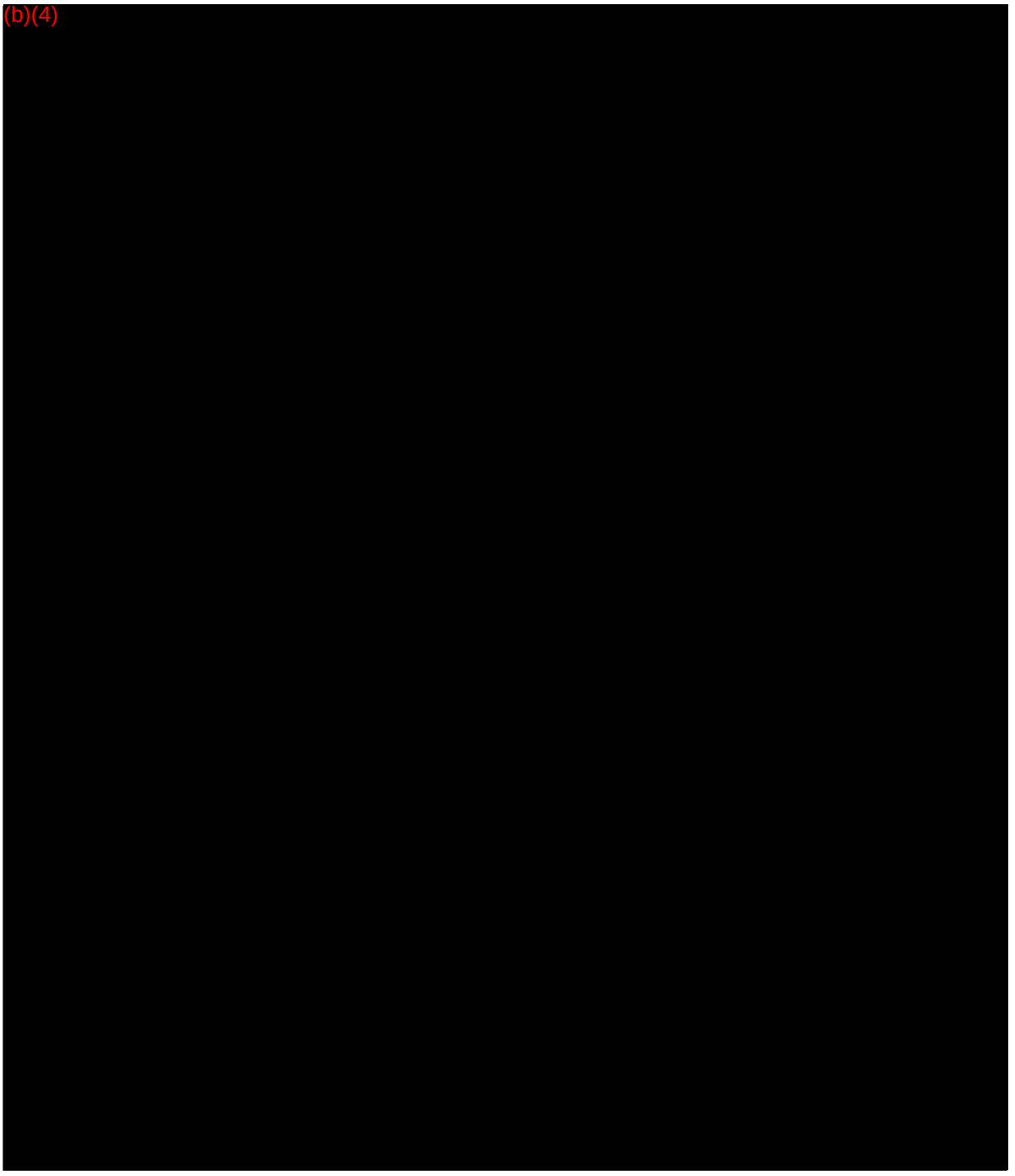

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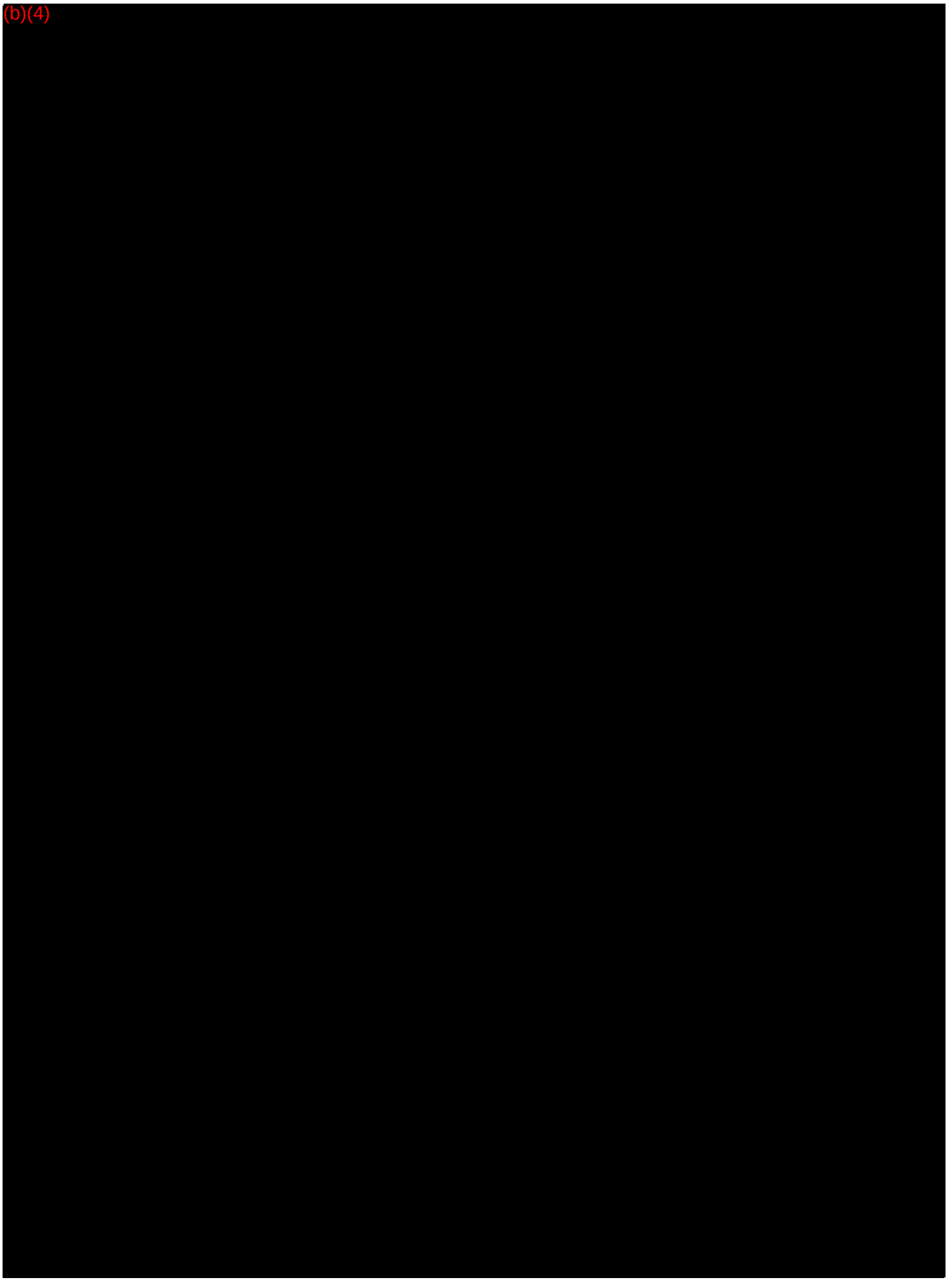

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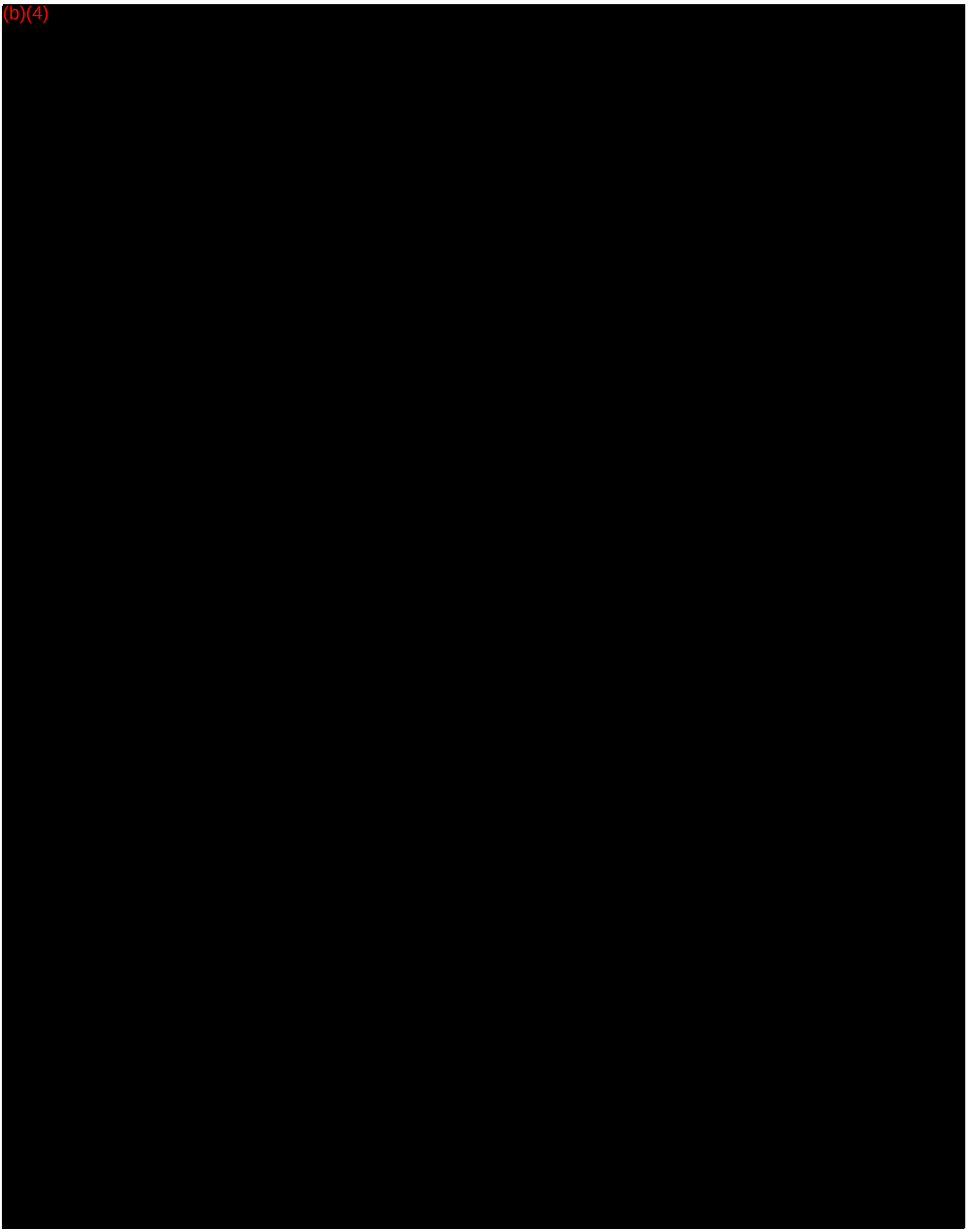

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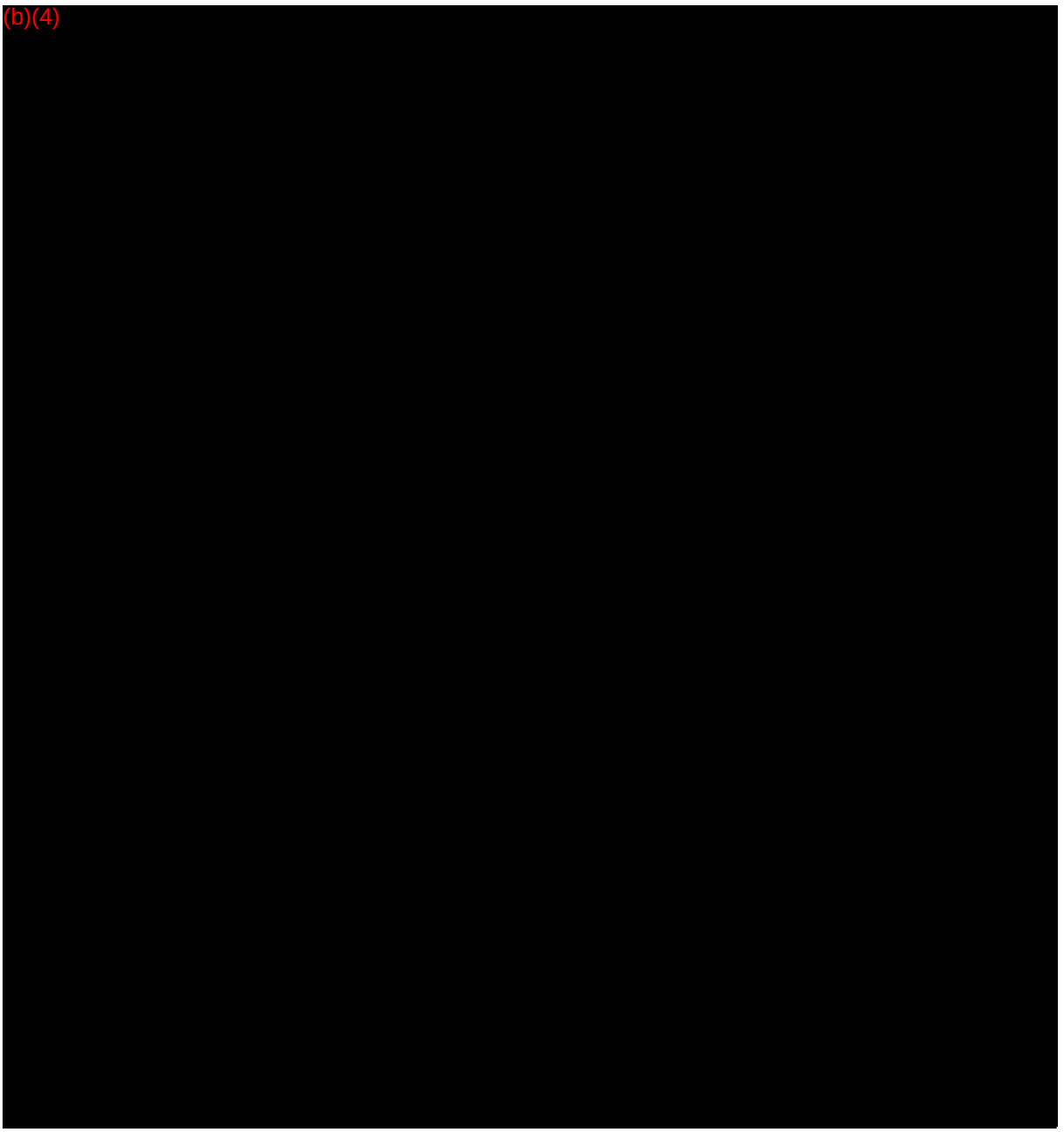

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Monica	DOCUMENT NUMBER	REVISION	PAGE
	100-SP-004	D	1 / 16

Product	AN24 Abdominal Fetal ECG recorder
Document name	USB Link, Software Interface Control Document
Document type	**SPECIFICATION**

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1 SCOPE

1.1 Document Identification

This document defines the functional characteristics of the USB interface between the abdominal fetal ECG body monitor and a computer.
The document is identified as follows:

- ✓ Identification Number: 100-SP-004.
- ✓ Title: AN24 Abdominal Fetal ECG recorder – USB Link, Software Interface Control Document.
- ✓ Acronym: ICD.

1.2 Document Scope

The purpose of this document is to define the functional characteristics and the software protocol of the USB link interface between the AN24 abdominal FECG body monitor (USB device) and a configuration/download computer (USB host). The configuration/download computer is a desktop PC, a laptop or a PDA running the Monica VS software.

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2 RELATED DOCUMENTS

N°	*Title*	*Reference*
[1]	Abdominal FECG recorder, System Requirements Specification	100-SP-001

3 GLOSSARY

EP	End Point
FECG	Fetal ElectroCardioGram
FHR	Fetal Heart Rate
HID	Human Interface Device
MB	Mega Bytes
MECG	Maternal ECG
PC	Personal Computer
PDA	Personal digital assistant
RTC	Real Time Clock
UA	Uterine Activity
USB	Universal Serial Bus

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GJS

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4 Interface specification

4.1 Interface diagram

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4.2 USB Link interface I_002

4.2.1 USB link description

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4.2.2 Data message description

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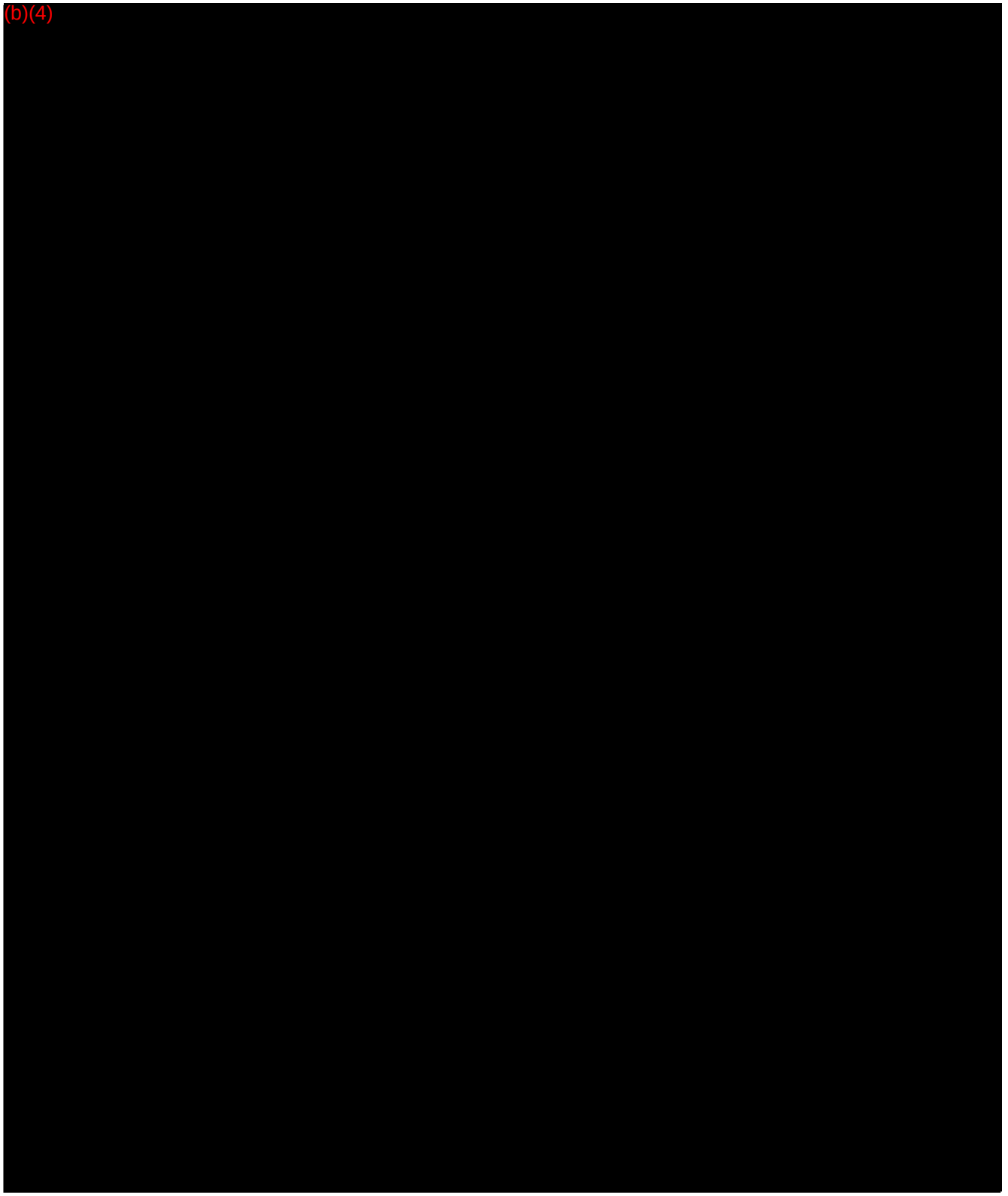

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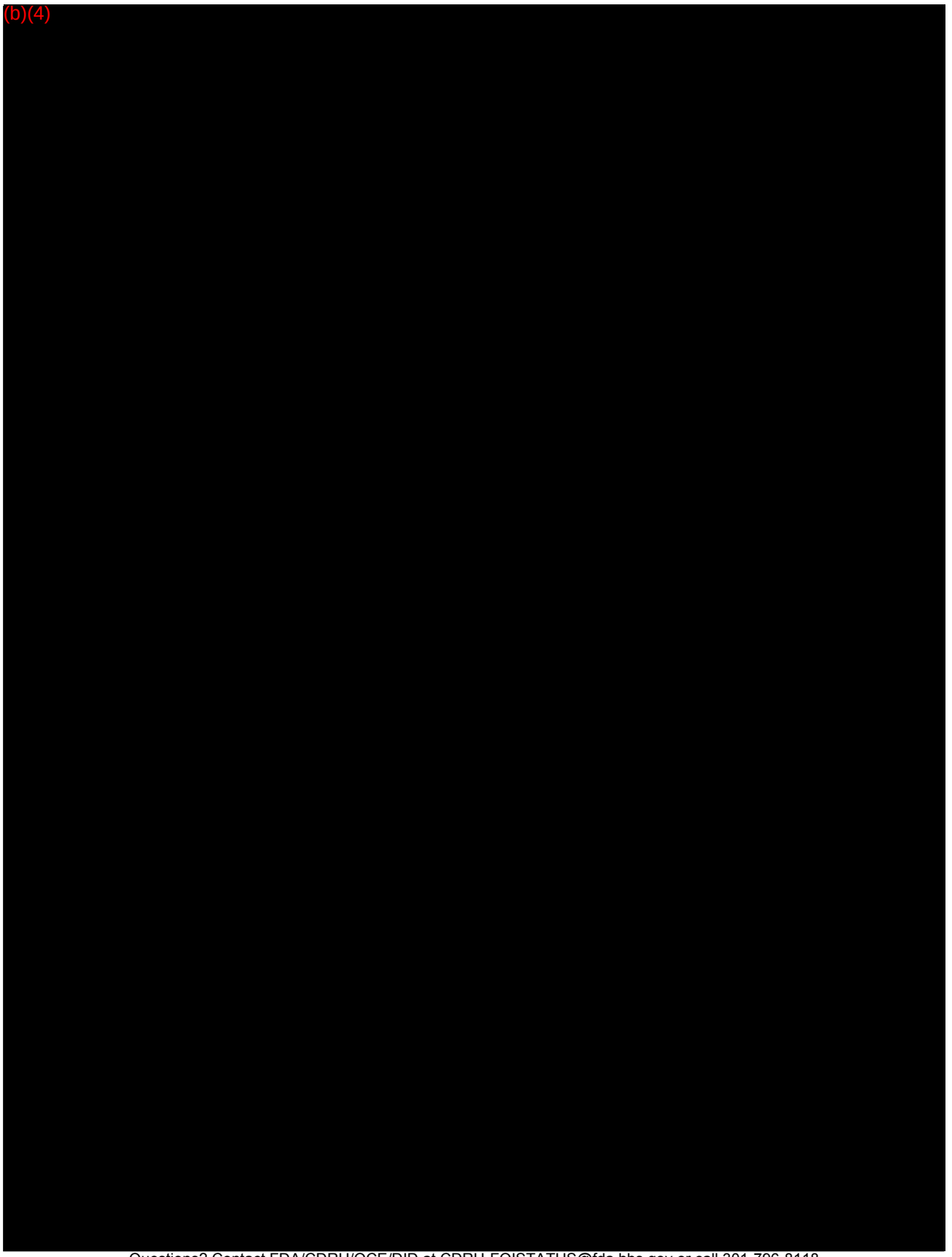

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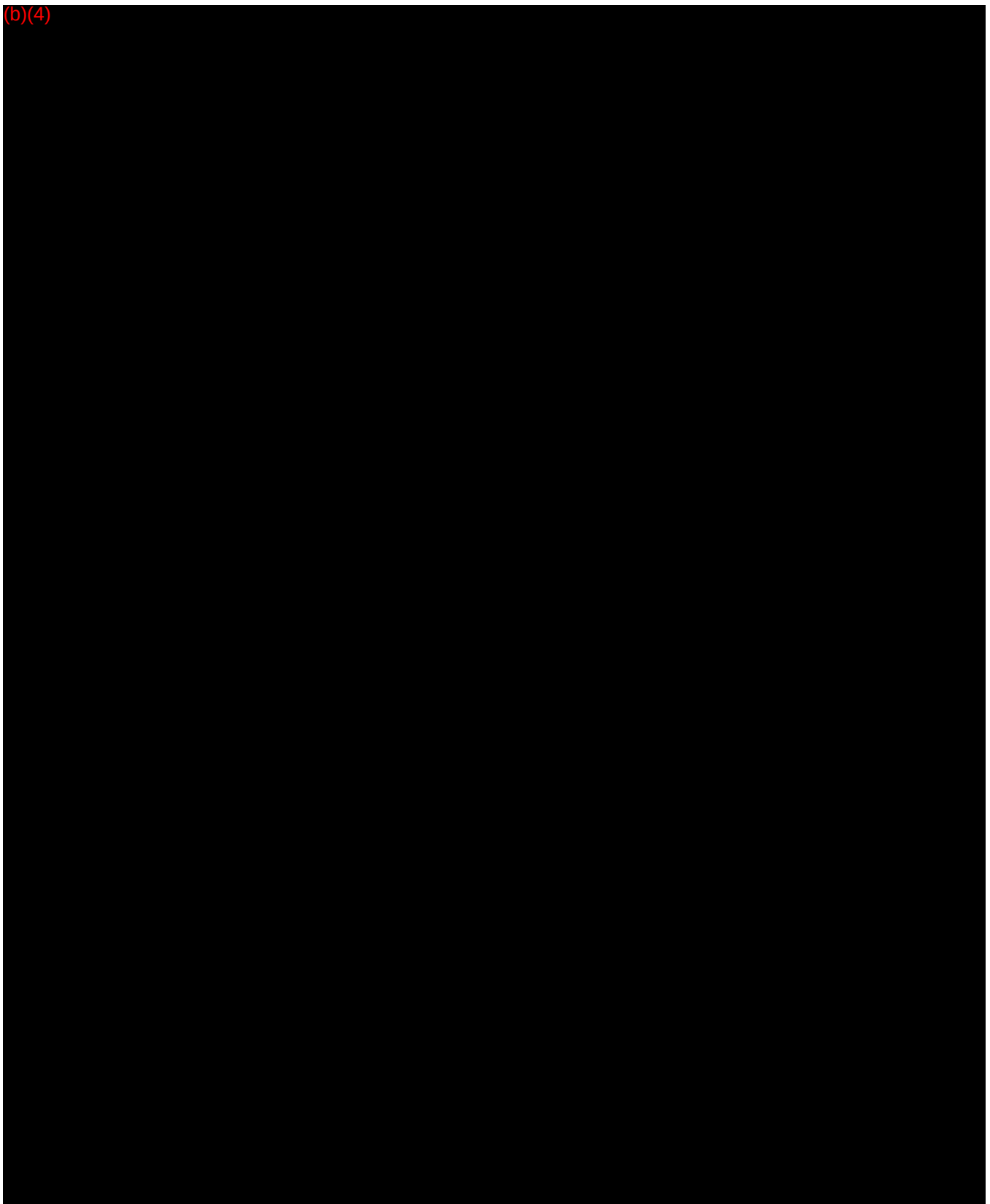

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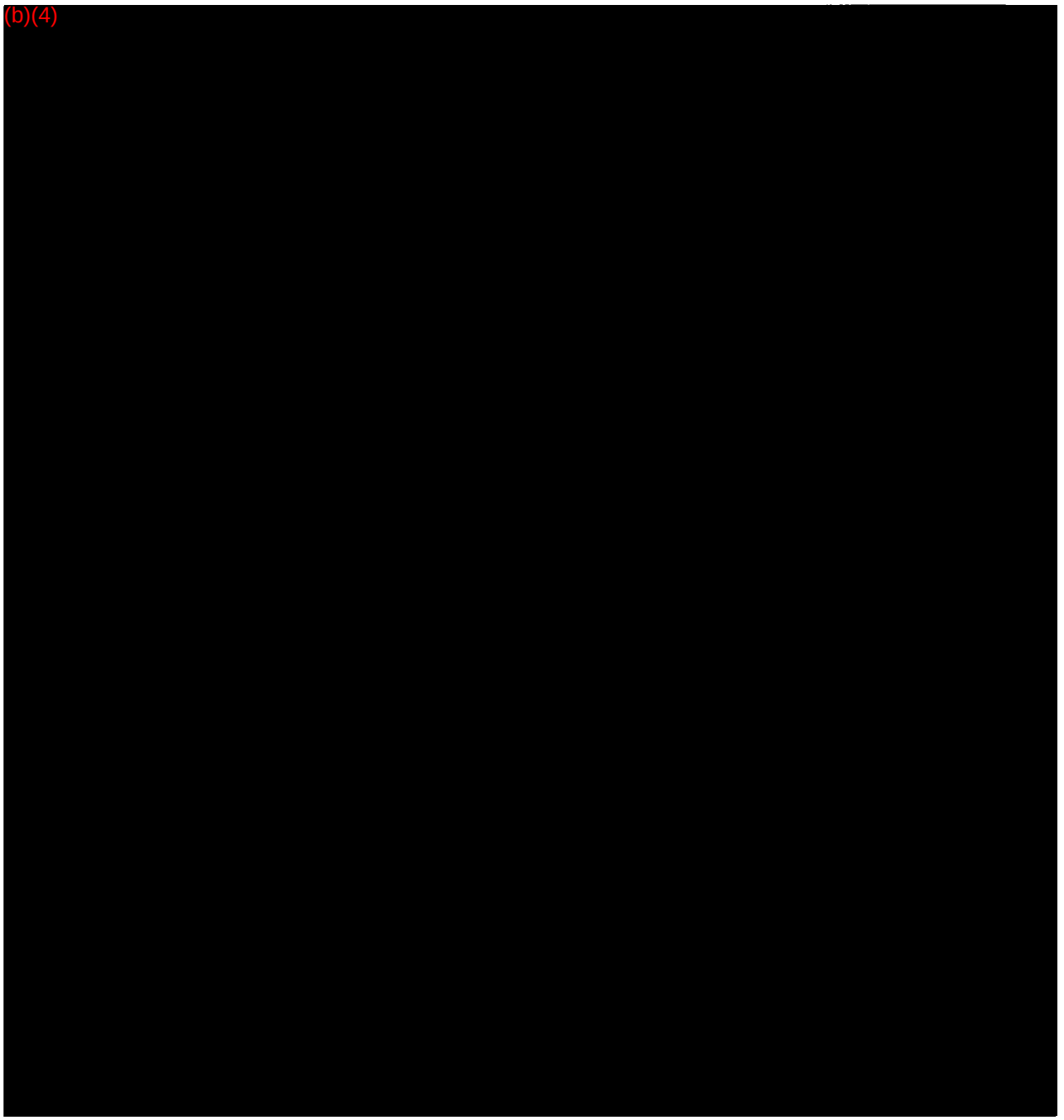

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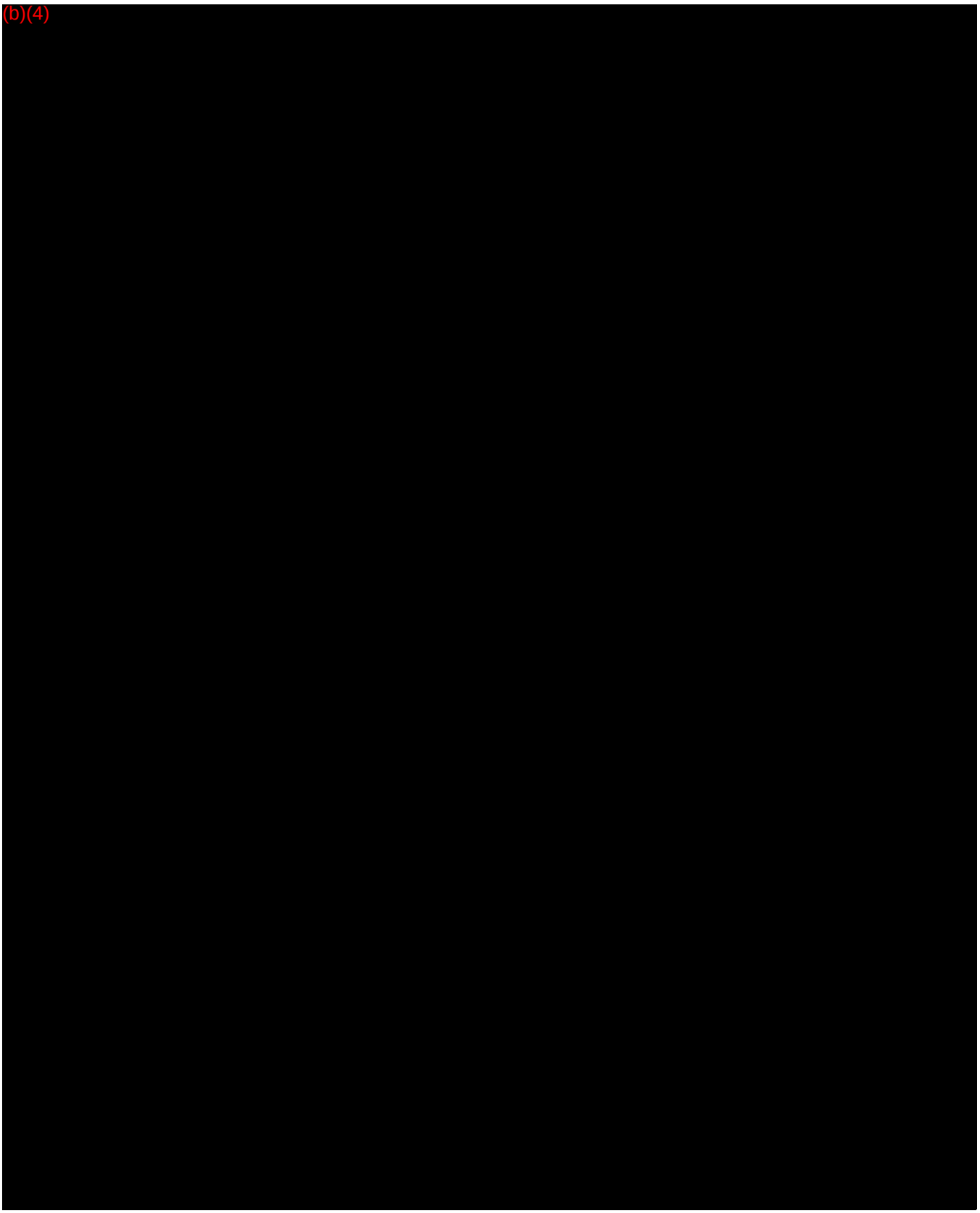

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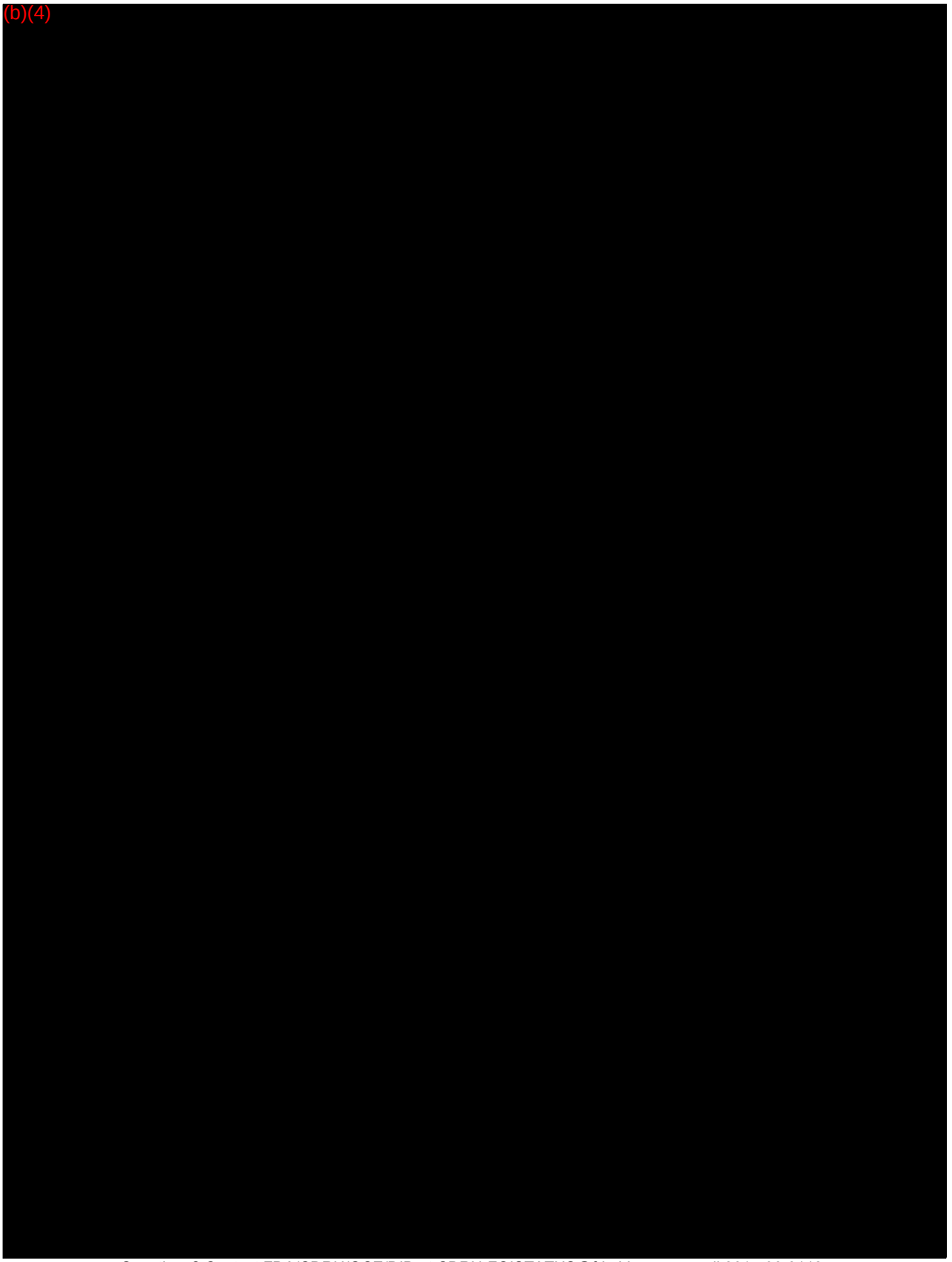

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Records processed under FOIA Request #2015-4103; Released by CDRH on 06-06-2016.

Product	AN24 Abdominal FECG recorder
Document name	Hardware Requirements Specification (HRS)
Document type	**SPECIFICATION**

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1 SCOPE

1.1 Document Identification

This document specifies the engineering and qualification requirements for the abdominal FECG recorder hardware. The document is identified as follows:

- ✓ Identification Number: 100-SP-005.
- ✓ Title: AN24 Abdominal FECG recorder - Hardware Requirements Specification (HRS)

1.2 Document Scope

This document describes the AN24 hardware requirements.

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2 RELATED DOCUMENTS

N°	*Title*	*Reference*
[1]	AN24 Abdominal FECG Recorder - Requirement Traceability	100-SP-002
[2]	AN24 Abdominal FECG Recorder - System Requirements Specification	100-SP-001
[3]	AN24 Abdominal FECG Recorder - Hardware Validation	100-TP-003
[4]	Medical electrical equipment – Part 1: General requirements for safety - Collateral standard - Safety requirements for medical electrical systems	BS EN 60601–1-1:2001
[5]	Medical electrical equipment – Part 1-2: General requirements for safety – Collateral standard: Electromagnetic compatibility – Requirements and tests	BS EN 60601-1-2:2002
[6]	Medical electrical equipment – Part 1-4: General requirements for safety – Collateral standard: Programmable electrical medical systems	BS EN 60601-1-4:1997
[7]	Medical electrical equipment – Part 1-6: General requirements for safety – Collateral standard: Usability	BS EN 60601-1-6:2004
[8]	Medical electrical equipment - Part 1-8: General requirements for safety – Collateral standard: General Requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems	BS EN 60601-1-8:2004
[9]	Medical devices – Application of risk management to medical devices	BS EN ISO 14971:2001
[10]	Clinical Investigation of Medical devices for human subjects – Part 1: General Requirements	BS EN ISO 14155-1: 2003
[11]	ECG cables and lead wires	ANSI/AAMI EC53:1995
[12]	Medical Device Directive L169	MDD93/42/EEC
[13]	Quality systems – Medical devices – particular requirements for the application of EN ISO 9001 (revision of EN 46001:1996) (identical to ISO13485:1996)	BS EN ISO13485:2003

3 GLOSSARY

ADC	Analogue to Digital Converter
AFE	Analogue Front End
ECG	Electro CardioGram
EHG	ElectroHisteroGram
EMC	ElectroMagnetic Compatibility
FECG	Fetal ElectroCardioGram
FHR	Fetal Heart Rate
RTC	Real Time Clock

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4 Engineering requirements

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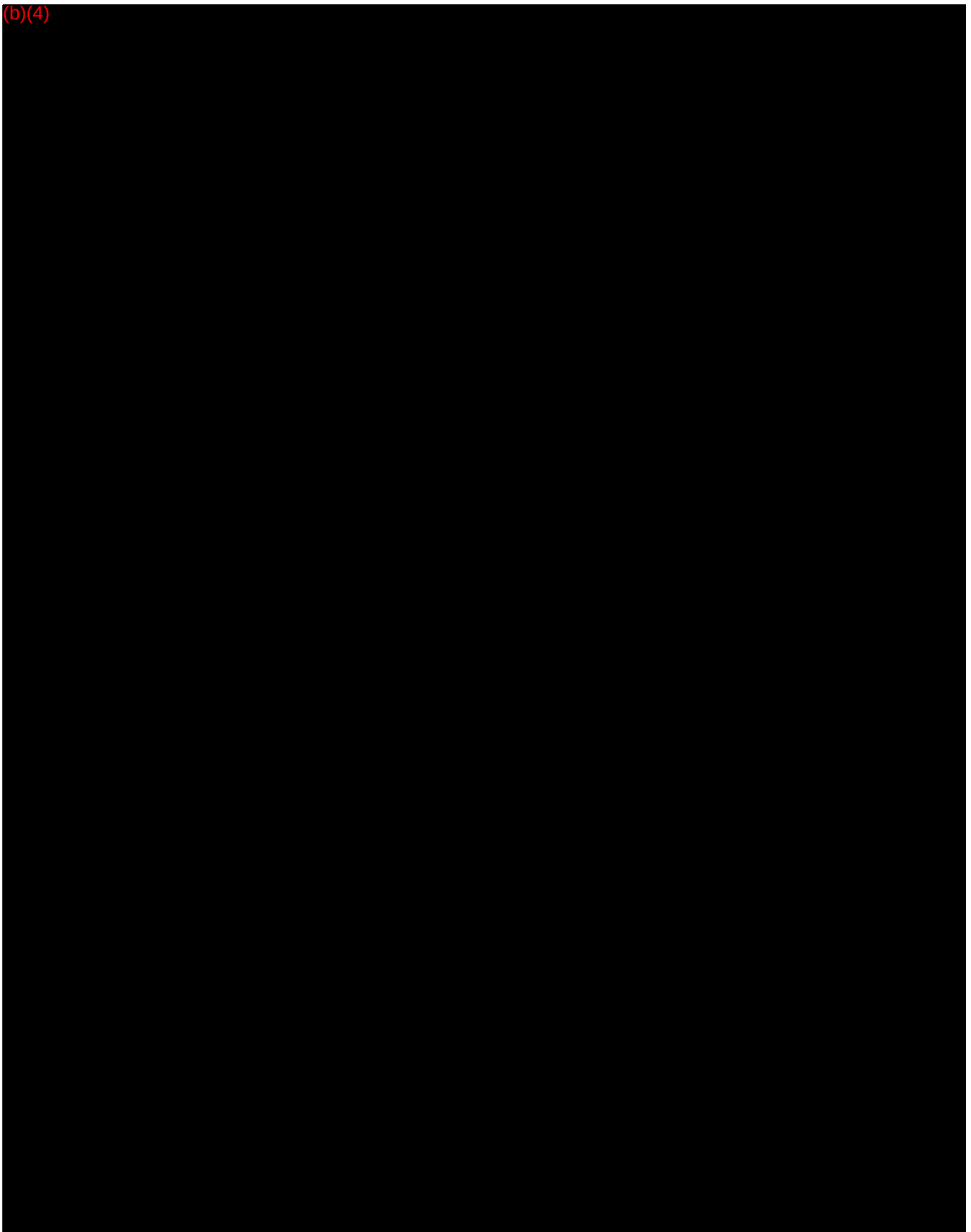

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4.3 Quality requirements

4.3.1 Safety & EMC standards

<HW_260> Safety standards

The AN24 must comply with at least the following standards:
(i) EN60601–1-1:2001 Medical electrical equip – Part 1: General requirements for safety [4]
(ii) EN60601-1-2:2002 Part 1-2: Electromagnetic Compatibility [5]
<End>

4.3.2 CE/FDA marking

During the design, care should be taken to make sure that the product complies with the Medical Device Directive - MDD93/42/EEC marking.

4.3.3 Quality System

The complete design and manufacture process is governed by a Quality System installed at Monica Healthcare in accordance with ISO13485:1996 and 21 CFR 820

5 Requirements traceability

Requirements traceability is described in [1].

6 Qualification requirements

The qualification methods and means are described in [3].

End of Document

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Product	AN24 Abdominal Fetal ECG recorder
Document name	VS software, Software Requirements Specification (SRS)
Document type	**SPECIFICATION**

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1 SCOPE

1.1 Document Identification

This document specifies the engineering and qualification requirements for the PC software of the abdominal fetal ECG monitor product.
The document is identified as follows:

- ✓ Identification Number: 100-SP-006.
- ✓ Title: AN24 Abdominal Fetal ECG recorder – VS software, Software Requirements Specification (SRS).

1.2 Document Scope

This document describes the requirements of the VS software.
It defines:

- ✓ The capacities provided,
- ✓ The performance requirements,
- ✓ The requirements traceability.

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2 RELATED DOCUMENTS

N°	*Title*	*Reference*
[1]	Abdominal FECG recorder, System Requirements Specification	100-SP-001
[2]	Abdominal FECG recorder, Requirements Traceability	100-SP-002
[3]	AN24 Abdominal FECG Recorder - USB Link, Software Interface Control Document	100-SP-004
[4]	AN24 Abdominal FECG Recorder - Wireless Link, Software Interface Control Document	100-SP-007
[5]	(b)(4)	
[6]	AN24 Abdominal FECG recorder, Software validation	100-TP-002
[7]	AN24 Abdominal FECG Recorder – C++ coding standard	100-CS-002
[8]	AN24 Abdominal FECG recorder – Decision Support Specifications	100-SP-010

3 GLOSSARY

BT	BlueTooth
CTG	CardioTocoGram
ECG	Electro CardioGram
EHG	ElectroHisteroGram
FECG	Fetal ElectroCardioGram
FHR	Fetal Heart Rate
MHR	Maternal Heart Rate
PC	Personal computer
RTC	Real Time Clock
UA	Uterine Activity
USB	Universal Serial Bus

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4 Engineering requirements

4.1 External Interfaces Requirements

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[redacted]

4.2 Software Capability Requirements

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[redacted]

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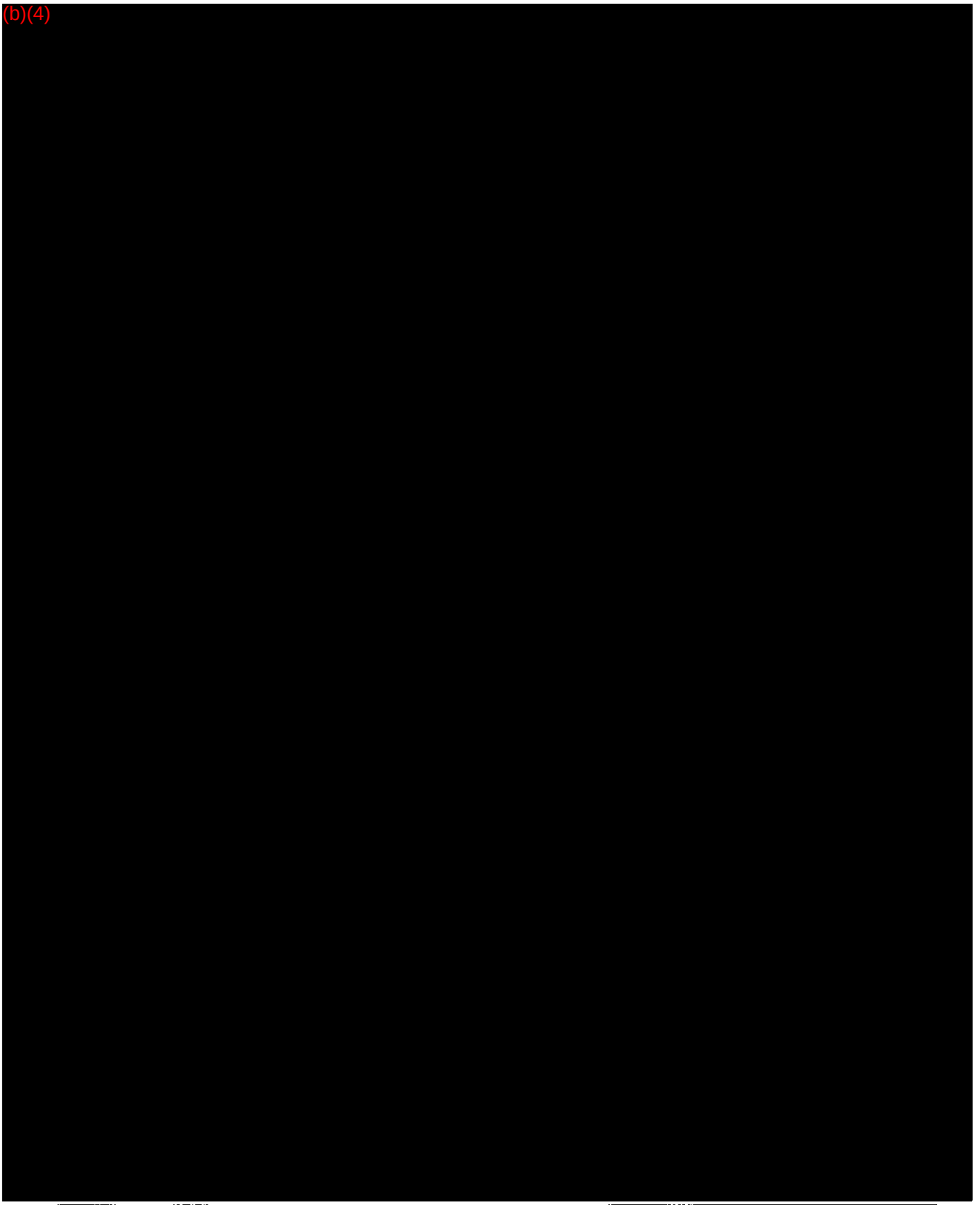

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<End>

5 Regulatory requirements

5.1.1 Safety Standards

<PC_070> Safety standards

The VS software should be designed for compliance with IEC 60601-1-4:1996 and EN 60601-1-4: 1997

<End>

5.1.2 CE/FDA marking

During the design, care should be taken to make sure that the software complies with the Medical Device Directive - MDD93/42/EEC marking and that the design\testing is also suitable to meet the requirements for FDA approval in the future.

5.1.3 Quality System

The complete design process is governed by a Quality System installed at Monica Healthcare in accordance with ISO13485:1996.

6 Requirements traceability

Requirements traceability is described in [2].

7 Qualification requirements

The qualification methods and means are described in [6].

End of Document

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Product	AN24 Abdominal Fetal ECG recorder
Document name	Wireless Link, Software Interface Control Document
Document type	**SPECIFICATION**

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1 SCOPE

1.1 Document Identification

This document defines the functional characteristics of the wireless interface between the AN24 fetal monitor and the data-collecting device.
The document is identified as follows:

- ✓ Identification Number: 100-SP-007.
- ✓ Title: AN24 Abdominal Fetal ECG recorder – Wireless Link, Software Interface Control Document.
- ✓ Acronym: ICD.

1.2 Document Scope

The purpose of this document is to define the functional characteristics and the software protocol of the Bluetooth wireless link interface between the abdominal FECG body monitor and a Bluetooth enable receiving device.

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2 RELATED DOCUMENTS

N°	*Title*	*Reference*
[1]	Abdominal FECG recorder, System Requirements Specification	100-SP-001

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3 GLOSSARY

BT	Bluetooth
ECG	Electro CardioGram
EHG	ElectroHisteroGram
FECG	Fetal ElectroCardioGram
FHR	Fetal Heart Rate
HP	Hewlett Packard
MDA	T-Mobile phone and personal digital assistant
MECG	Maternal ElectroCardioGram
MHR	Maternal Heart Rate
PC	Personal Computer
SSP	Serial Port Profile
UA	Uterine activity
USB	Universal Serial Bus

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4 Interface specification

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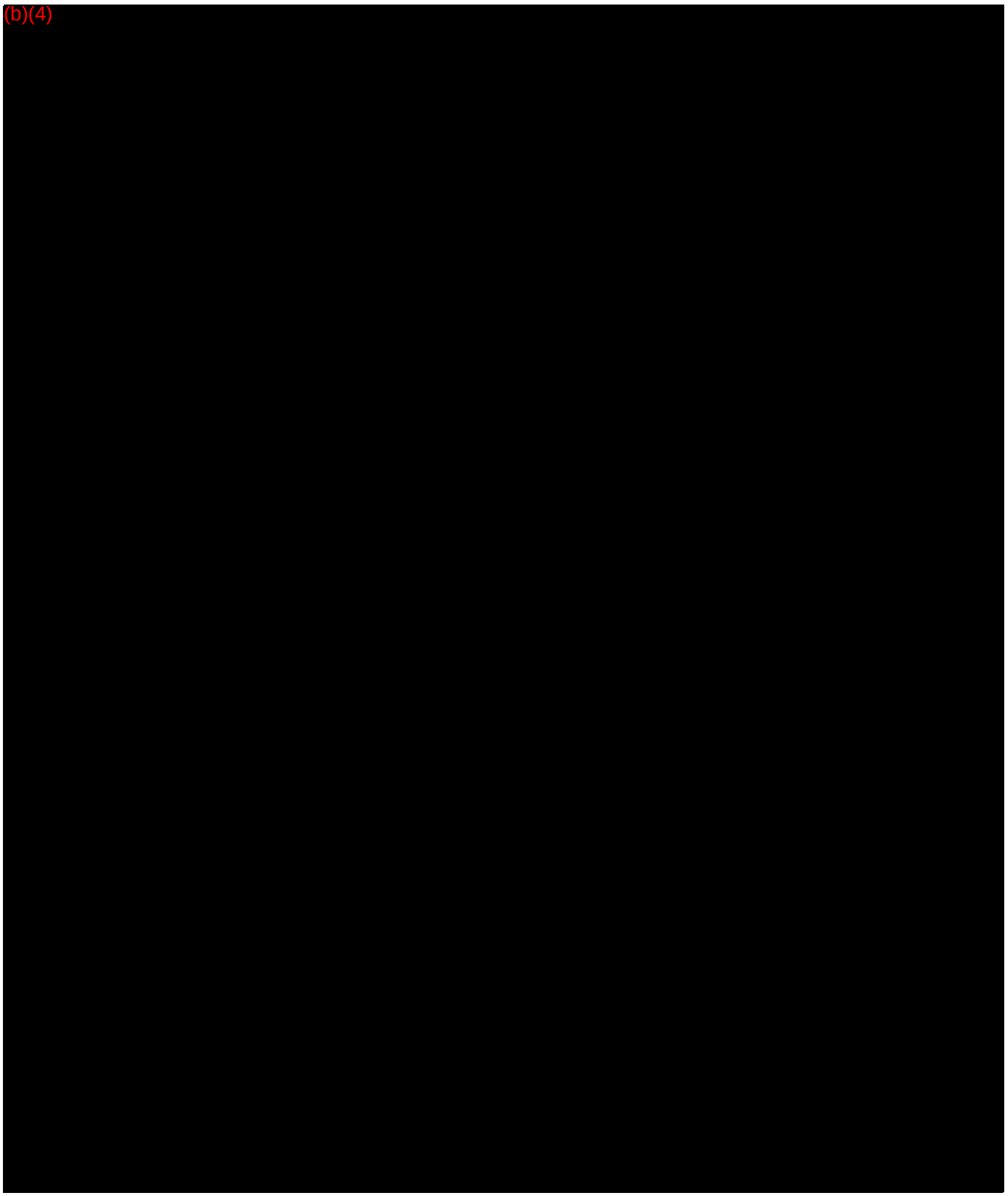

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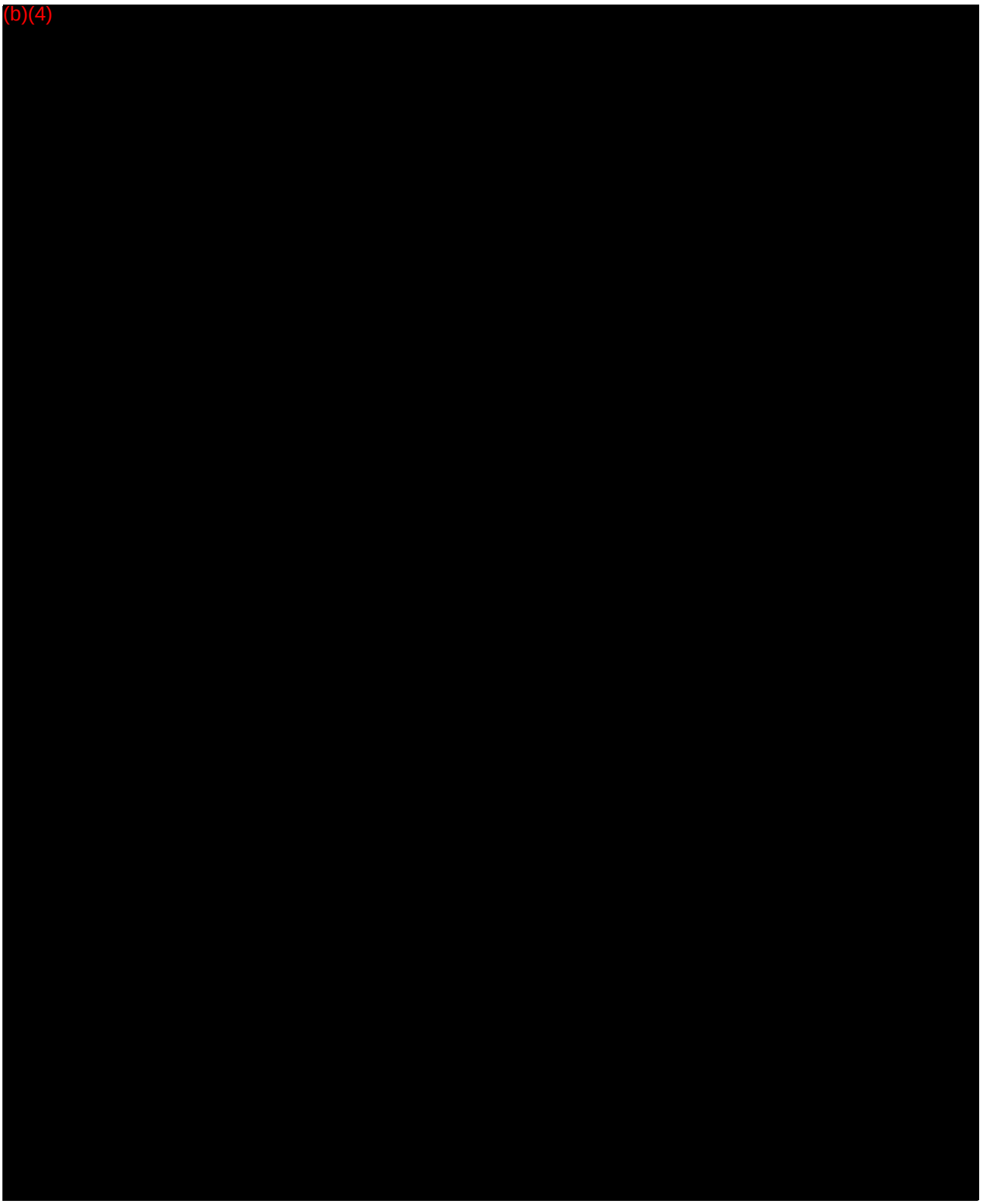

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Records processed under FOIA Request #2015-4103; Released by CDRH on 06-06-2016.

Product	AN24 Abdominal Fetal ECG recorder
Document name	VS software, Software Requirements Specification (SRS)
Document type	**SPECIFICATION**

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1 SCOPE

1.1 Document Identification

This document specifies the engineering and qualification requirements for the PC software of the abdominal fetal ECG monitor product.
The document is identified as follows:

- ✓ Identification Number: 100-SP-006.
- ✓ Title: AN24 Abdominal Fetal ECG recorder – VS software, Software Requirements Specification (SRS).

1.2 Document Scope

This document describes the requirements of the VS software.
It defines:

- ✓ The capacities provided,
- ✓ The performance requirements,
- ✓ The requirements traceability.

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2 RELATED DOCUMENTS

N°	*Title*	*Reference*
[1]	Abdominal FECG recorder, System Requirements Specification	100-SP-001
[2]	Abdominal FECG recorder, Requirements Traceability	100-SP-002
[3]	AN24 Abdominal FECG Recorder - USB Link, Software Interface Control Document	100-SP-004
[4]	AN24 Abdominal FECG Recorder - Wireless Link, Software Interface Control Document	100-SP-007
[5]	(b)(4)	
[6]	AN24 Abdominal FECG recorder, Software validation	100-TP-002
[7]	AN24 Abdominal FECG Recorder – C++ coding standard	100-CS-002
[8]	AN24 Abdominal FECG recorder – Decision Support Specifications	100-SP-010

3 GLOSSARY

BT	BlueTooth
CTG	CardioTocoGram
ECG	Electro CardioGram
EHG	ElectroHisteroGram
FECG	Fetal ElectroCardioGram
FHR	Fetal Heart Rate
MHR	Maternal Heart Rate
PC	Personal computer
RTC	Real Time Clock
UA	Uterine Activity
USB	Universal Serial Bus

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4 Engineering requirements

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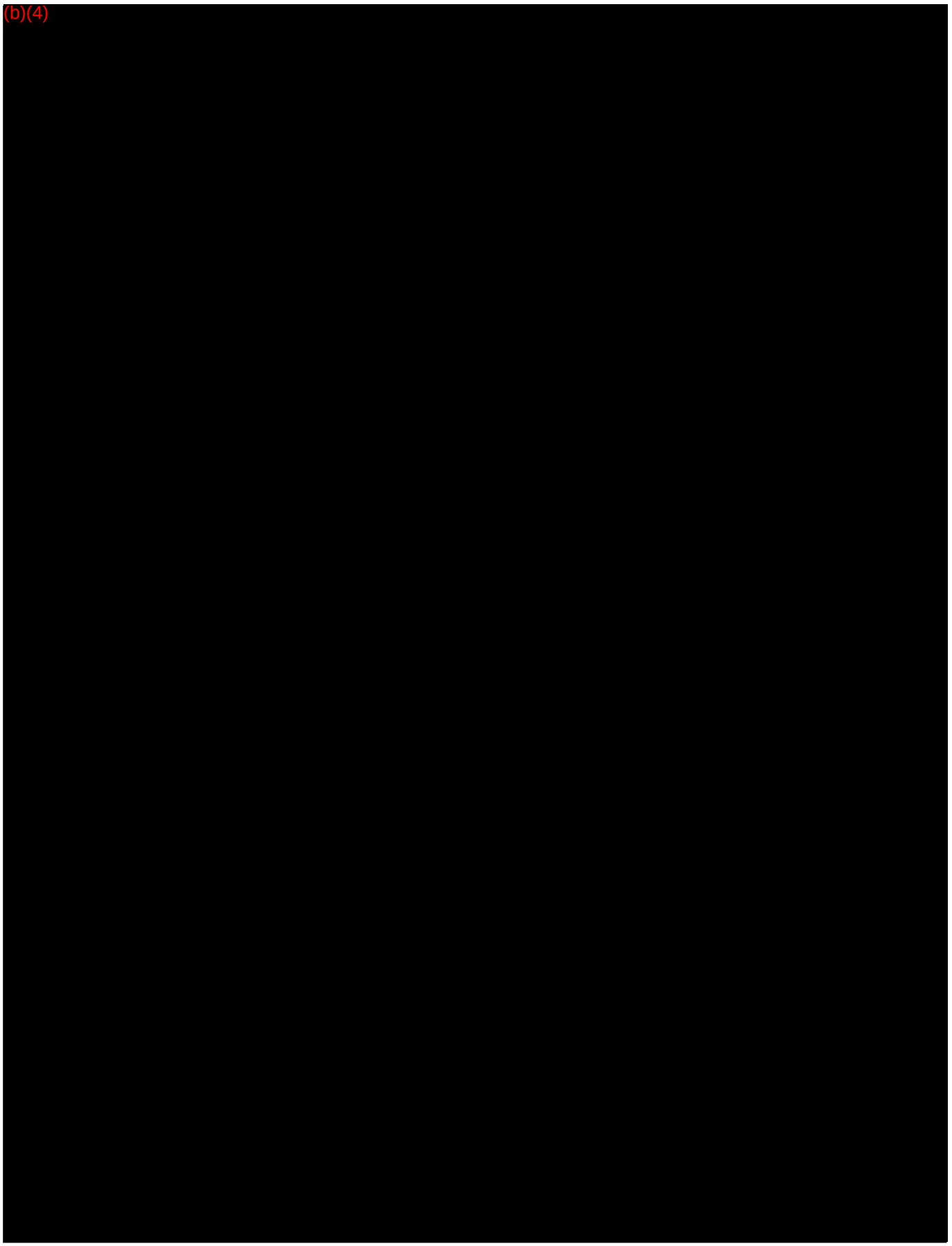

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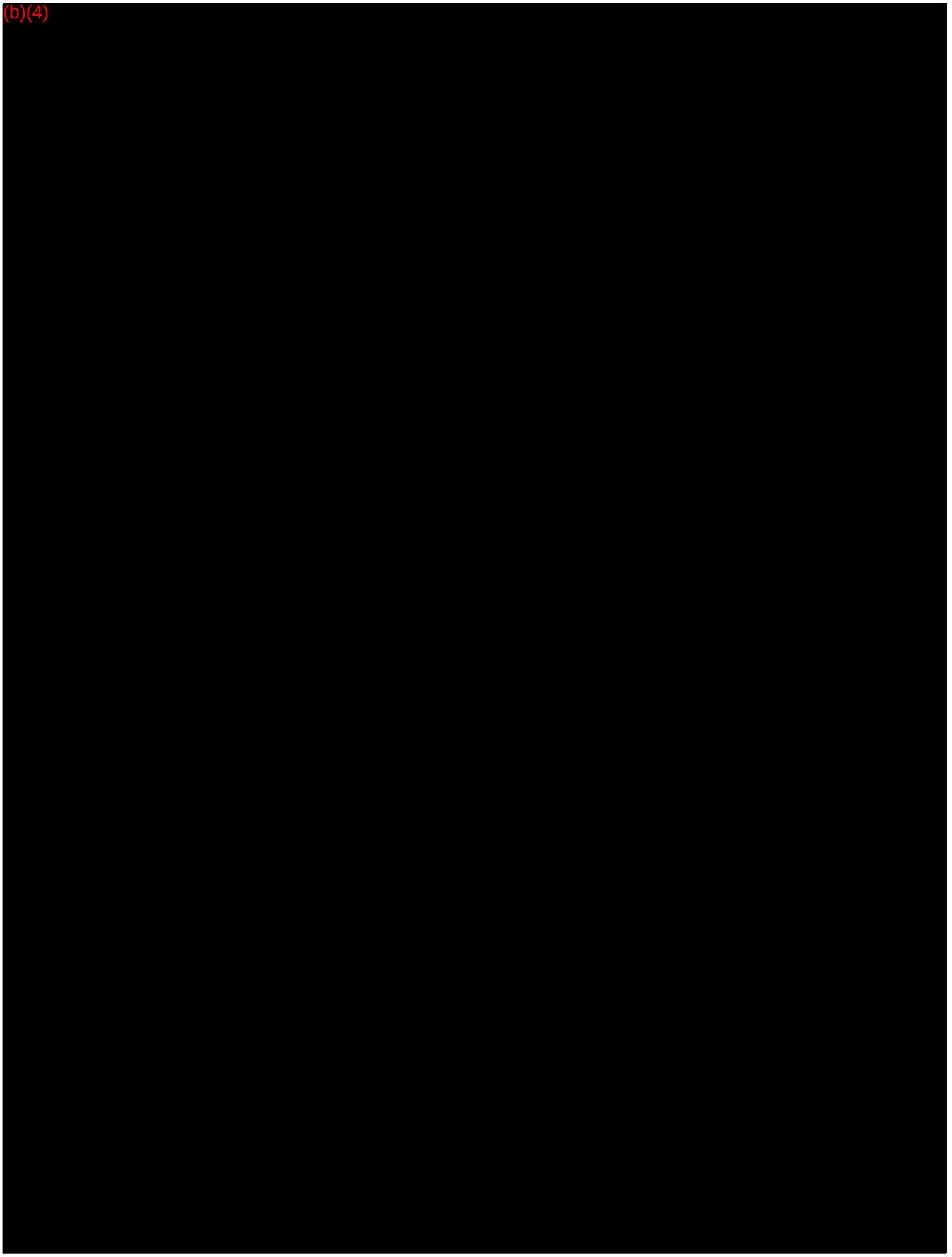

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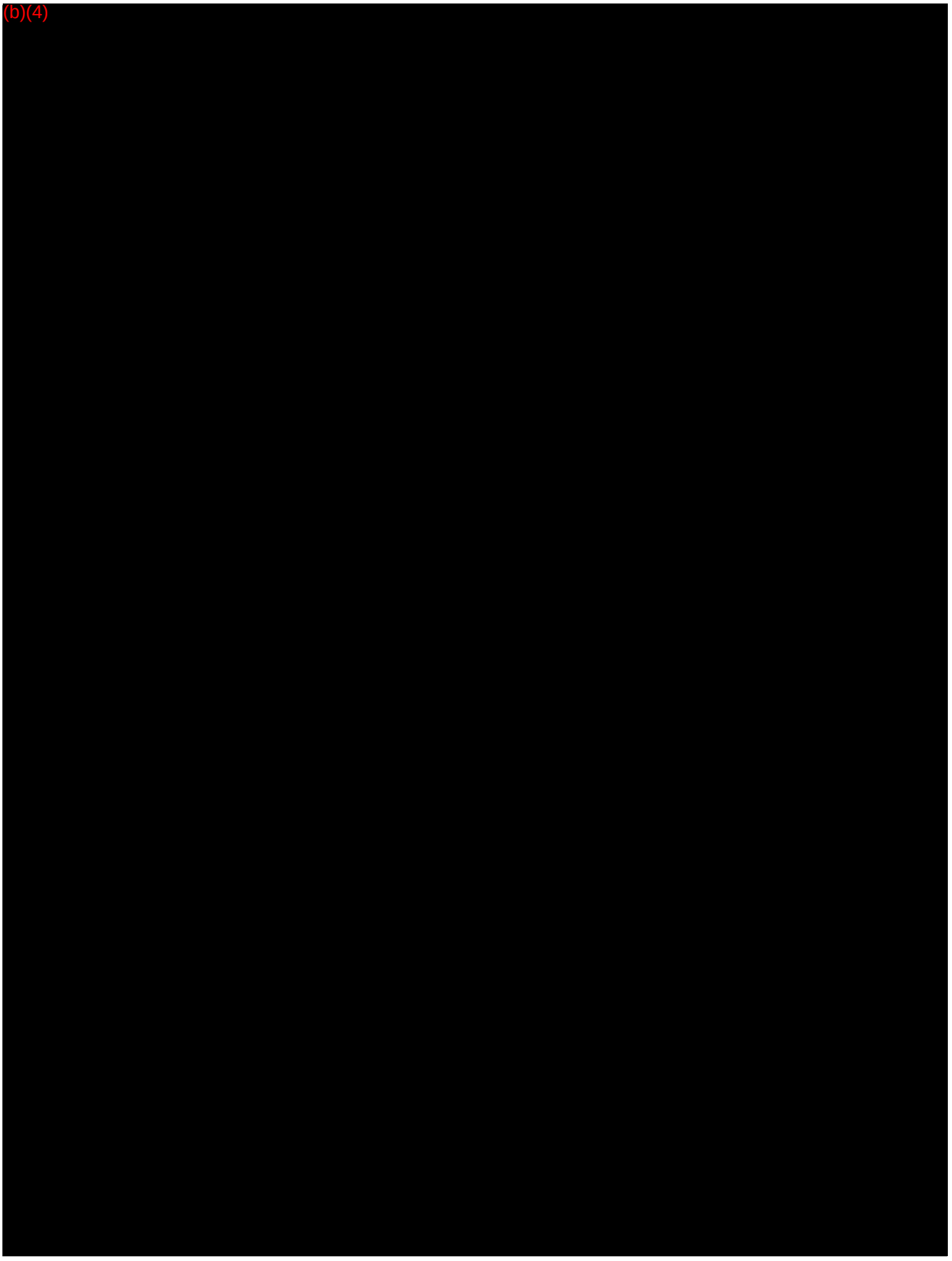

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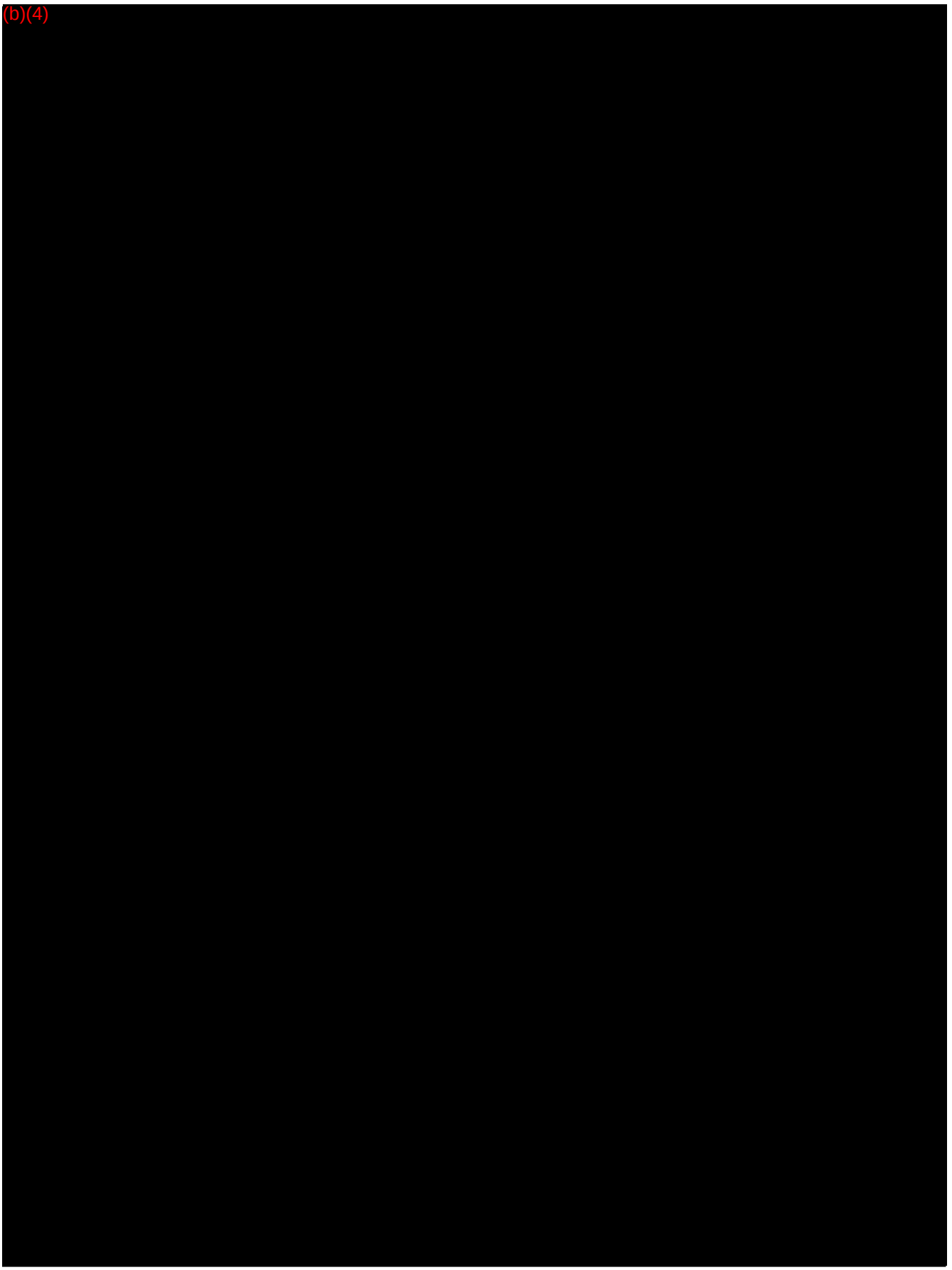

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<End>

5 Regulatory requirements

5.1.1 Safety Standards

<PC_070> Safety standards

The VS software should be designed for compliance with IEC 60601-1-4:1996 and EN 60601-1-4: 1997

<End>

5.1.2 CE/FDA marking

During the design, care should be taken to make sure that the software complies with the Medical Device Directive - MDD93/42/EEC marking and that the design\testing is also suitable to meet the requirements for FDA approval in the future.

5.1.3 Quality System

The complete design process is governed by a Quality System installed at Monica Healthcare in accordance with ISO13485:1996.

6 Requirements traceability

Requirements traceability is described in [2].

7 Qualification requirements

The qualification methods and means are described in [6].

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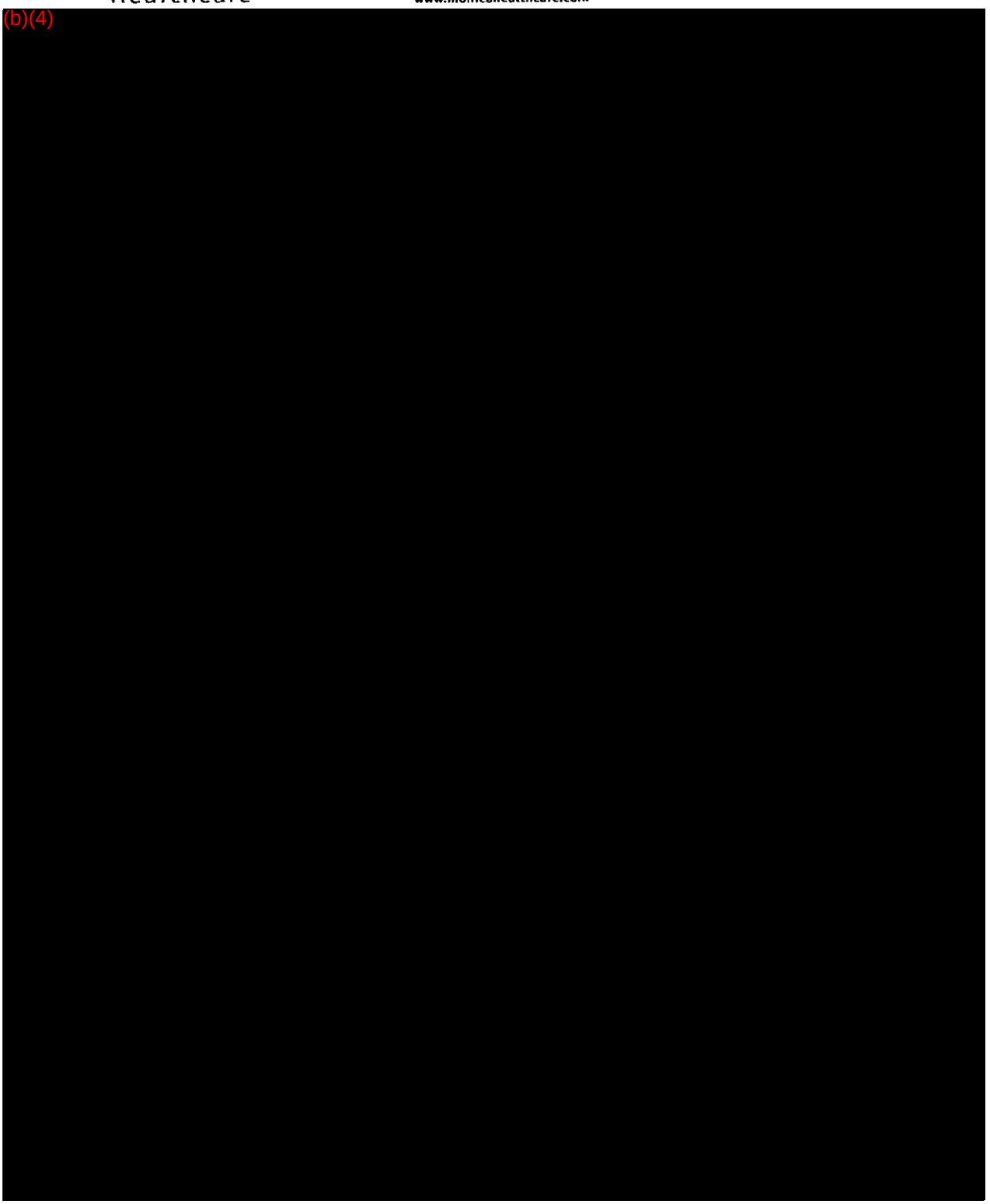

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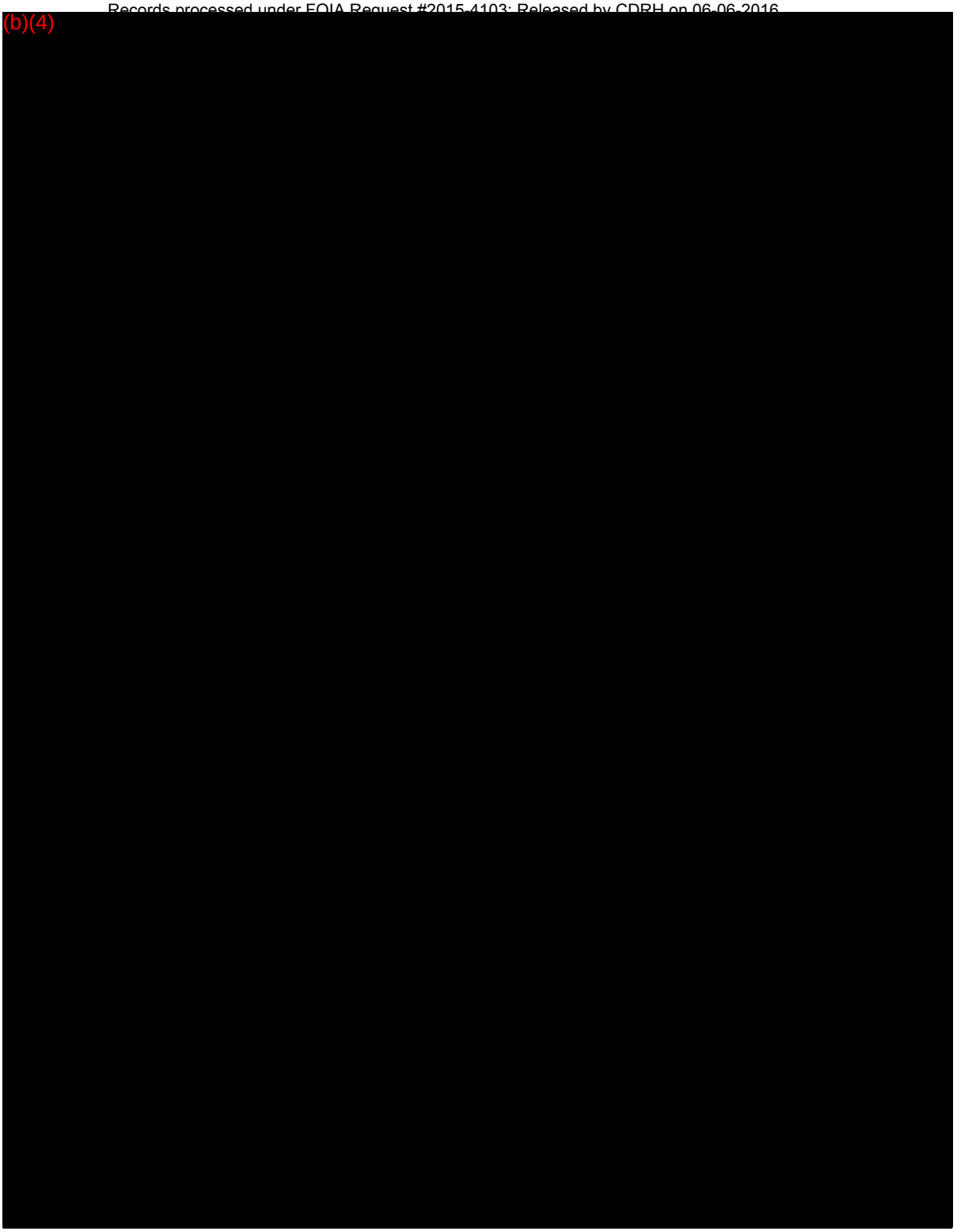

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Product	AN24 Abdominal Fetal ECG recorder
Document name	Risk Assessment
Document type	**Technical File**

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Product	AN24 Abdominal Fetal ECG recorder
Document name	Risk Assessment
Document type	**Technical File**

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1 Scope

1.1 Document Identification

This document outlines a full risk assessment for the AN24 device [1] and VS monitors [16] under ISO 14971:2007 document Scope

2 Related Documents

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3 Glossary

PC	Personal Computer
ECG	Electrocardiogram
EHG	Electrohysterogram
OEM	Original Equipment Manufacturer
UA	Uterine Activity
USB	Universal Serial Bus
ALARP	As Low As Reasonably Possible

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4 Brief Description of Device

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Product	AN24 Abdominal Fetal ECG recorder
Document name	Risk Assessment
Document type	**Technical File**

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1 Scope

1.1 Document Identification

This document outlines a full risk assessment for the AN24 device [1] and VS monitors [16] under ISO 14971:2007 document Scope

2 Related Documents

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4 Brief Description of Device

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5 Risk Analysis

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[1] Information supplied during private correspondence with Uwe Rimkus, designer of GE Medical fetal cordless transducers

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7 Appendices

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Product	AN24 Abdominal FECG recorder
Document name	Hardware Design Document (HDD)
Document type	**TECHNICAL FILE**
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1 SCOPE

1.1 Document Identification

This document describes the design of the hardware for the abdominal FECG recorder hardware. The document is identified as follows:

- ✓ Identification Number: 100-TF-011.
- ✓ Title: AN24 Abdominal FECG recorder - Hardware Design Document (HDD)

1.2 Document Scope

This document is the top document for the AN24 recorder hardware design. It gives an overview of all parts of the hardware design and refers to the relevant documents for detailed hardware design.

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2 RELATED DOCUMENTS

N°	*Title*	*Reference*
[1]	AN24 Abdominal FECG recorder - Hardware Requirements Specification (HRS)	100-SP-005

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4 Hardware Design

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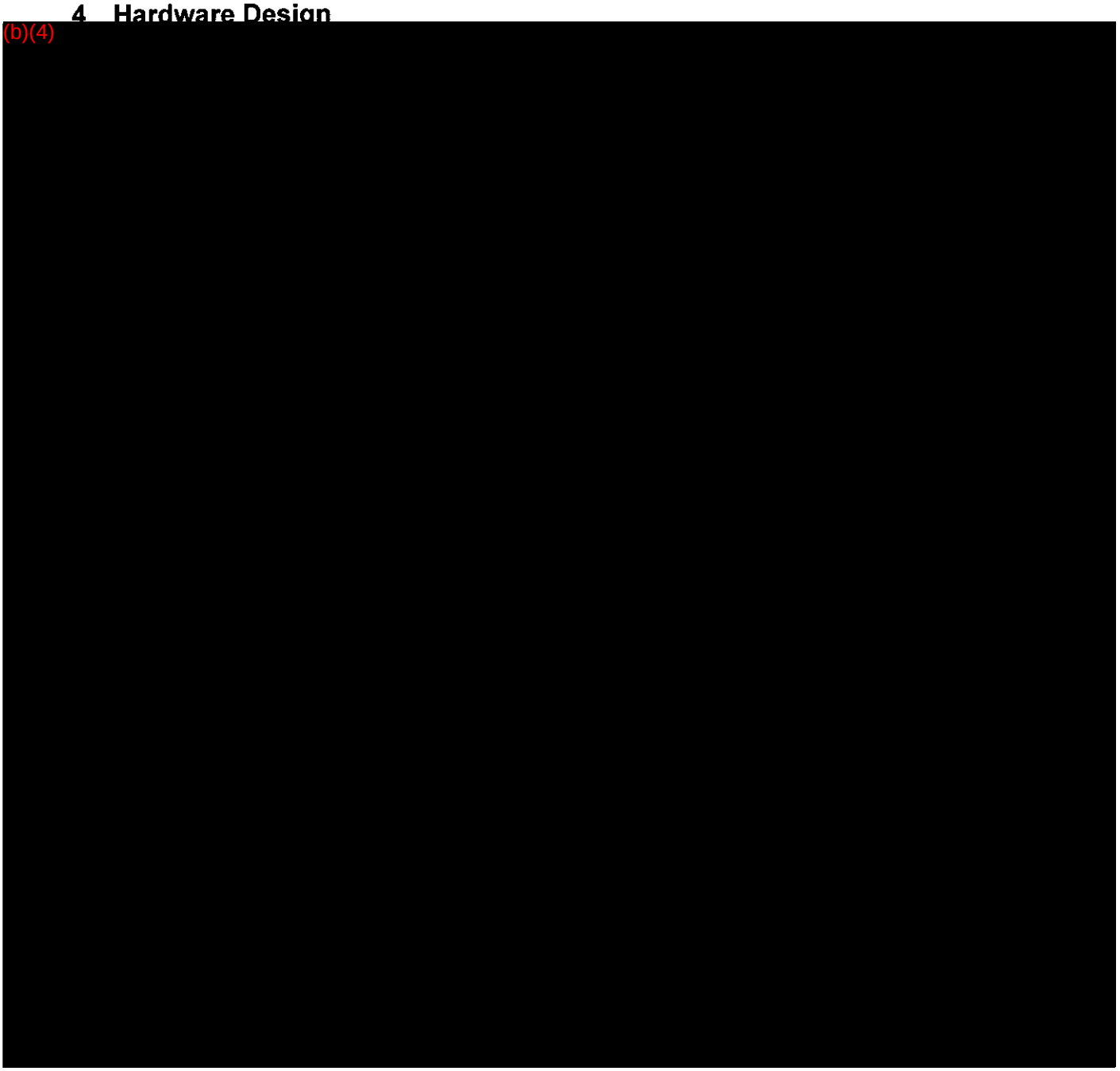

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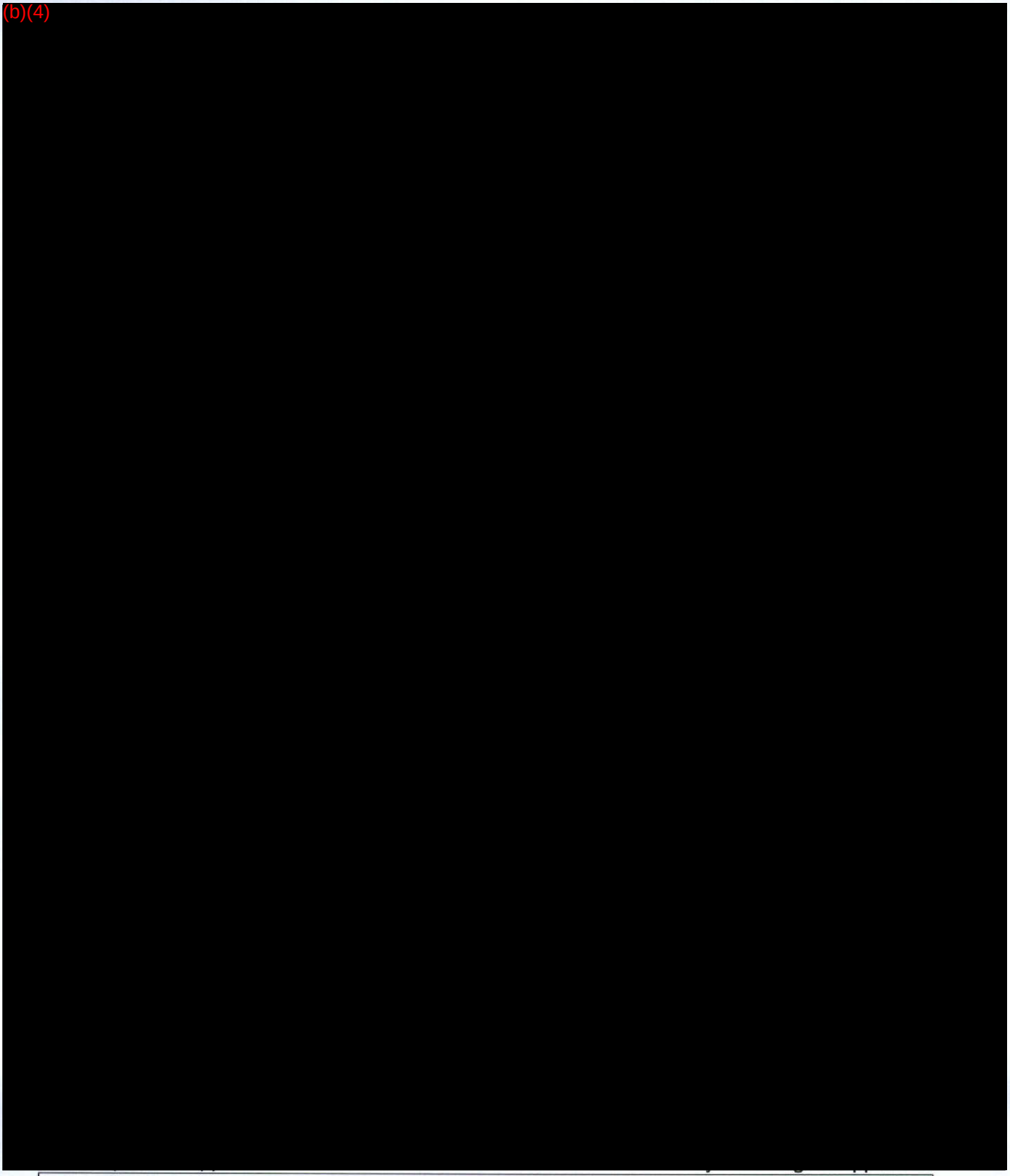

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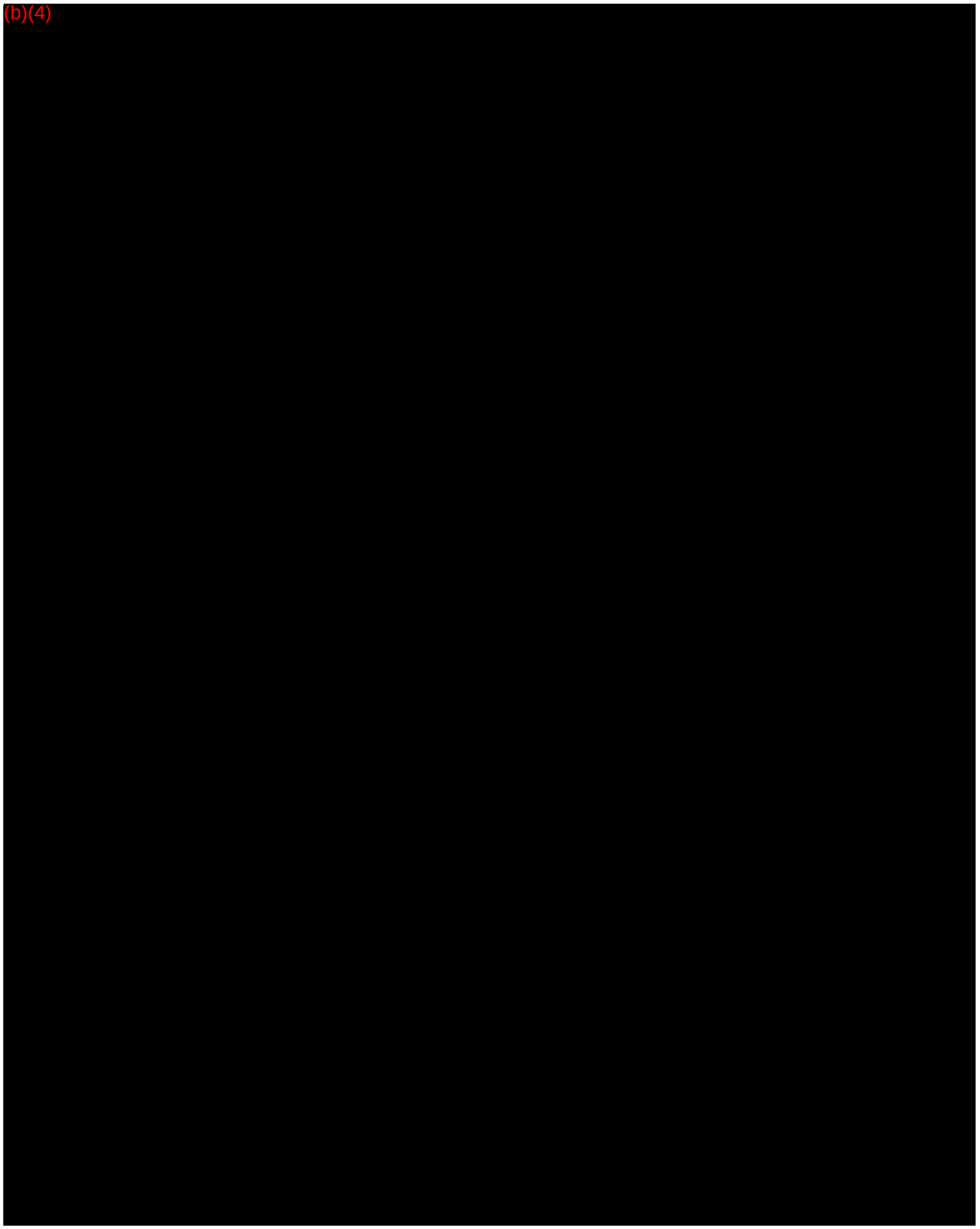

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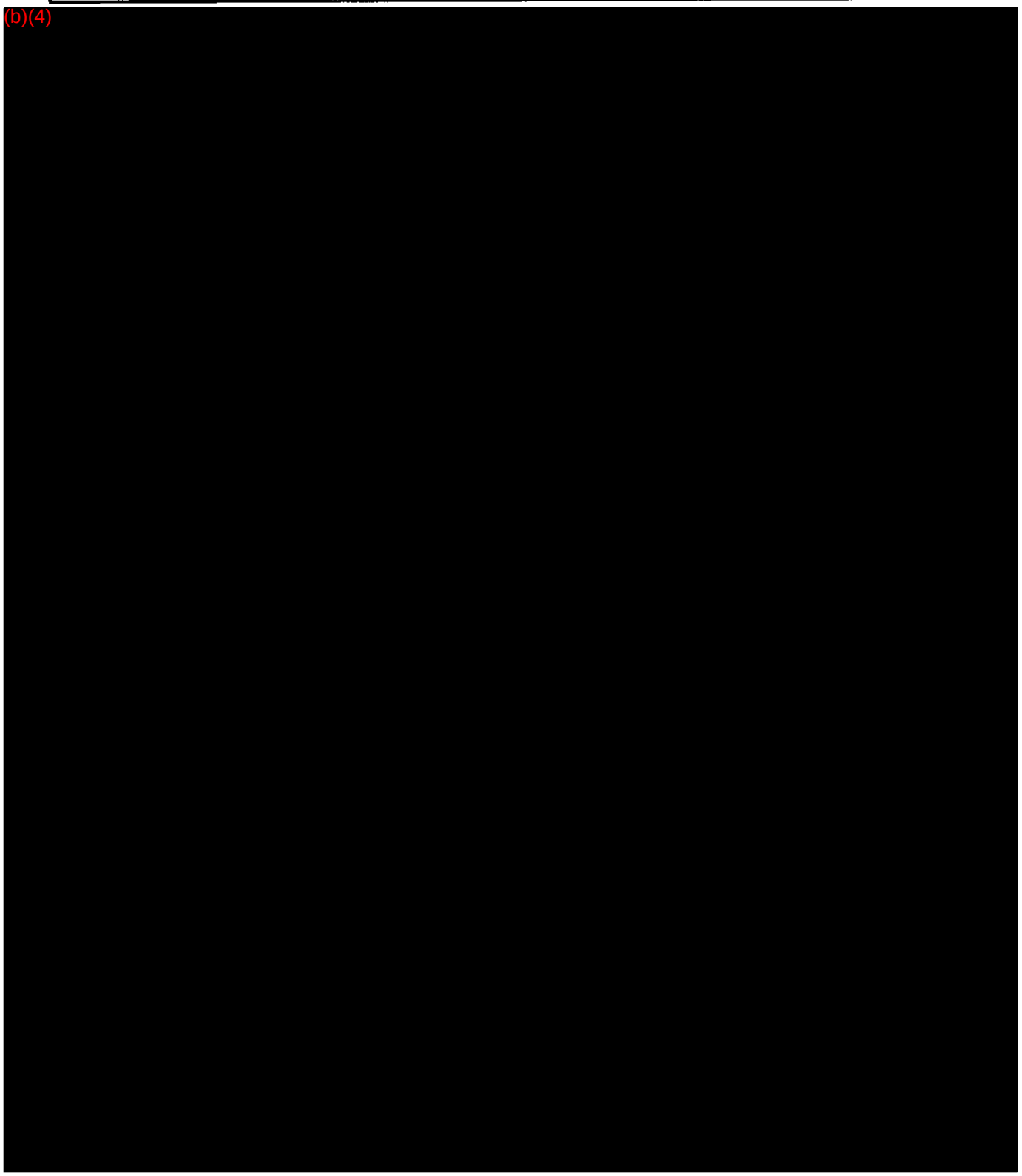

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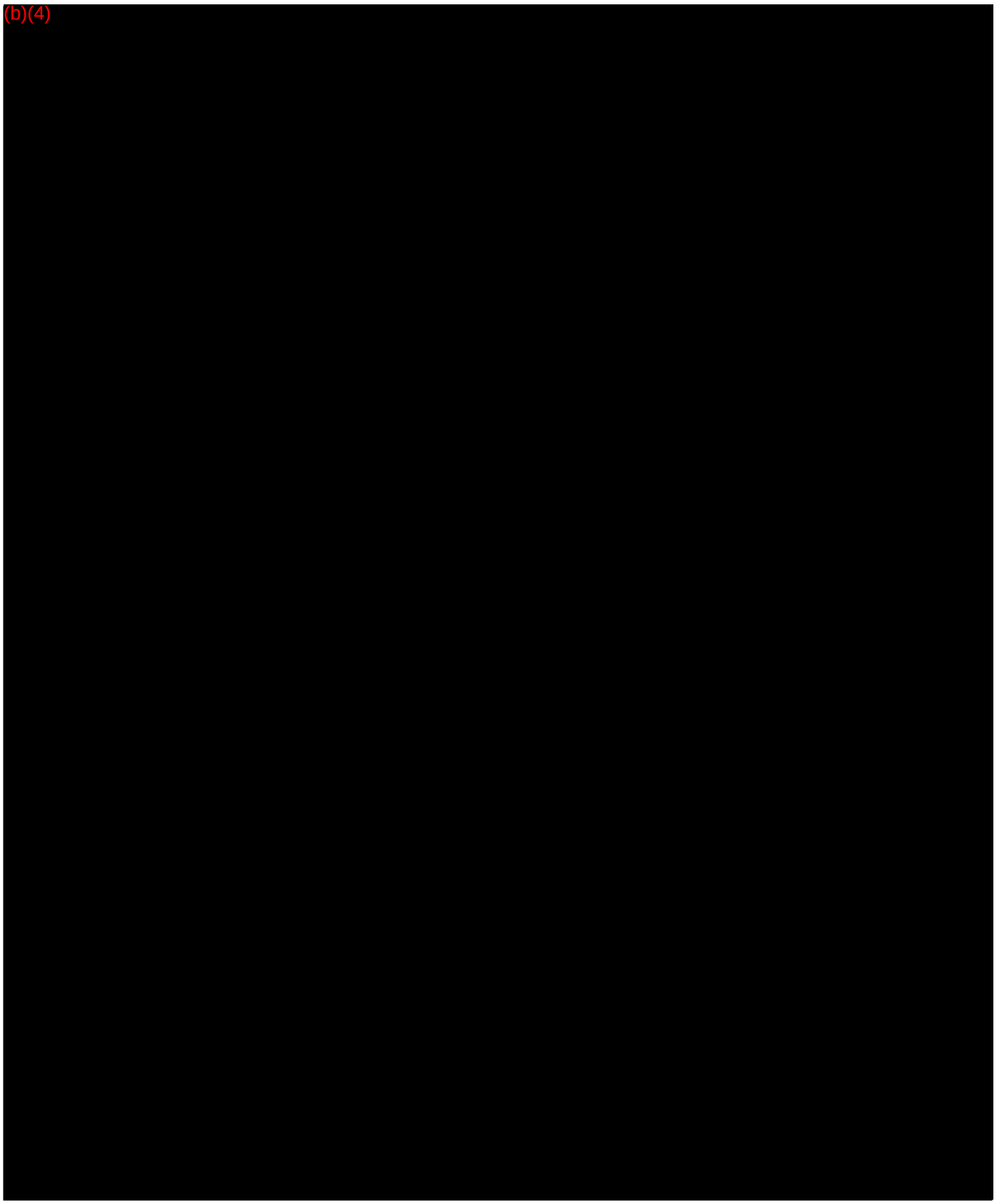

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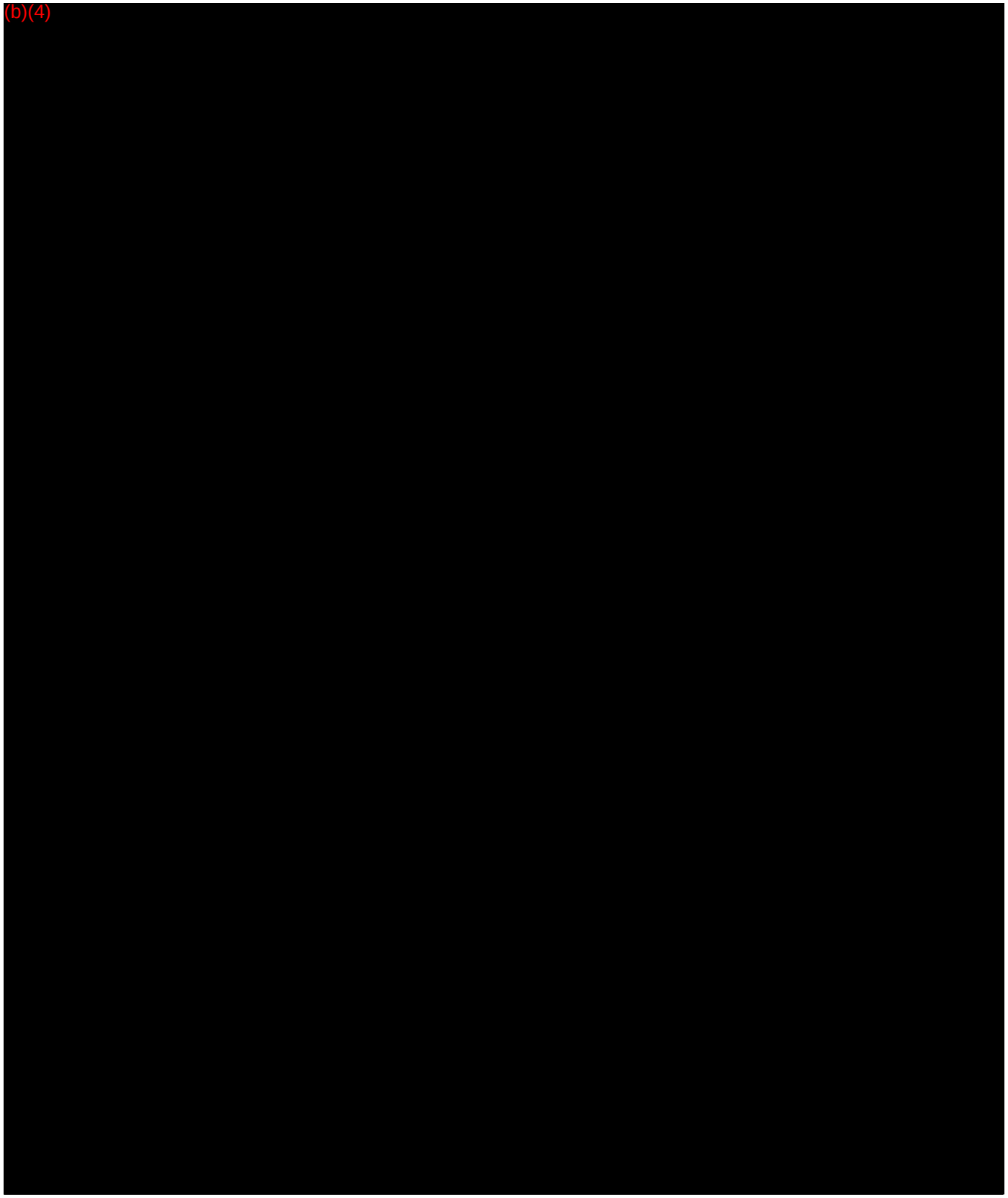

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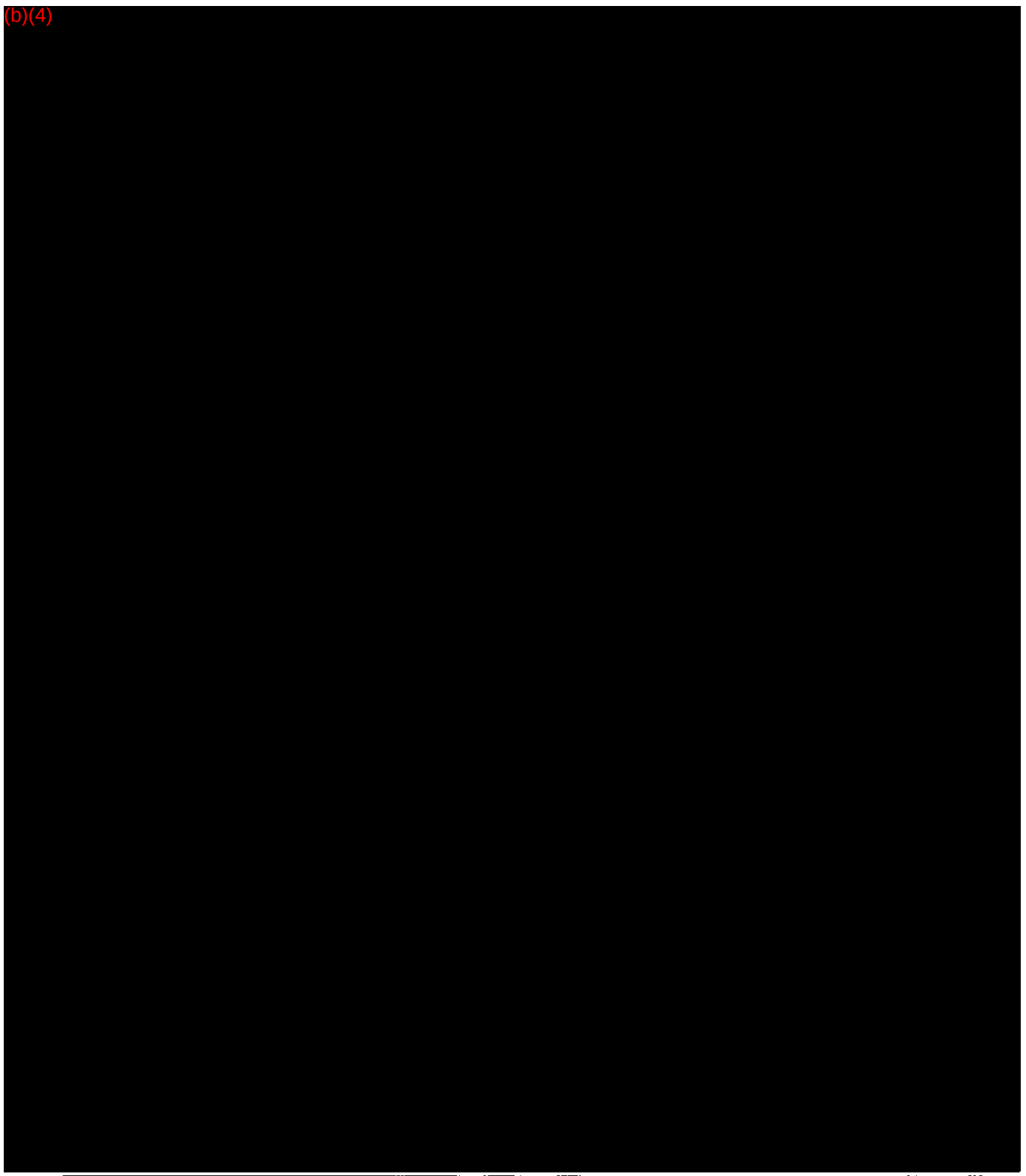

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Product	AN24 Abdominal FECG recorder
Document name	Software Design Document (SDD)
Document type	**TECHNICAL FILE**

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REVISION INDEX	WRITTEN BY	DATE	DESCRIPTION/CHANGES
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1 SCOPE

1.1 Document Identification

This document describes the design of the Monica VS program. The document is identified as follows:

- ✓ Identification Number: 100-TF-019.
- ✓ Title: AN24 Abdominal FECG recorder - Software Design Document (SDD)

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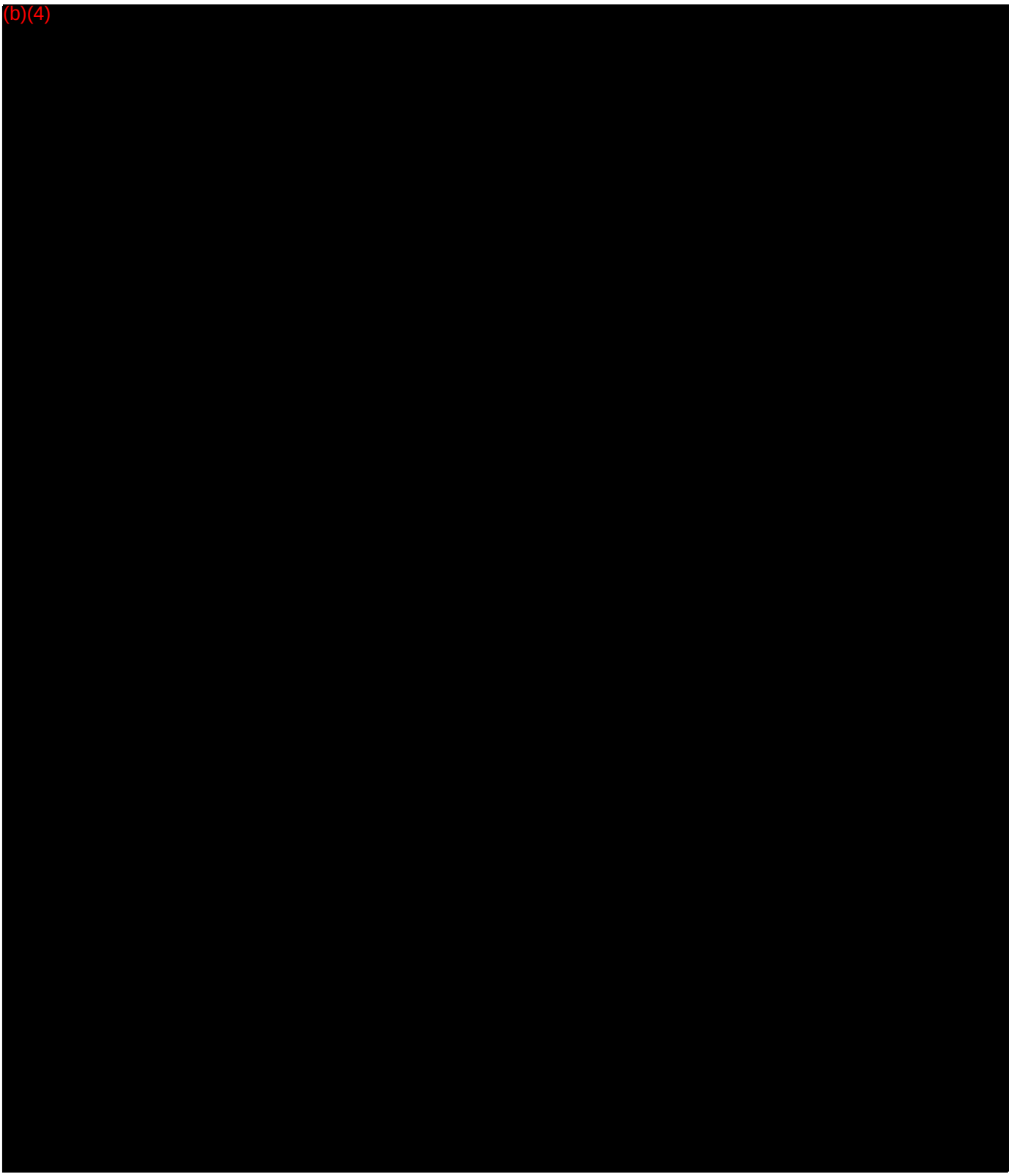

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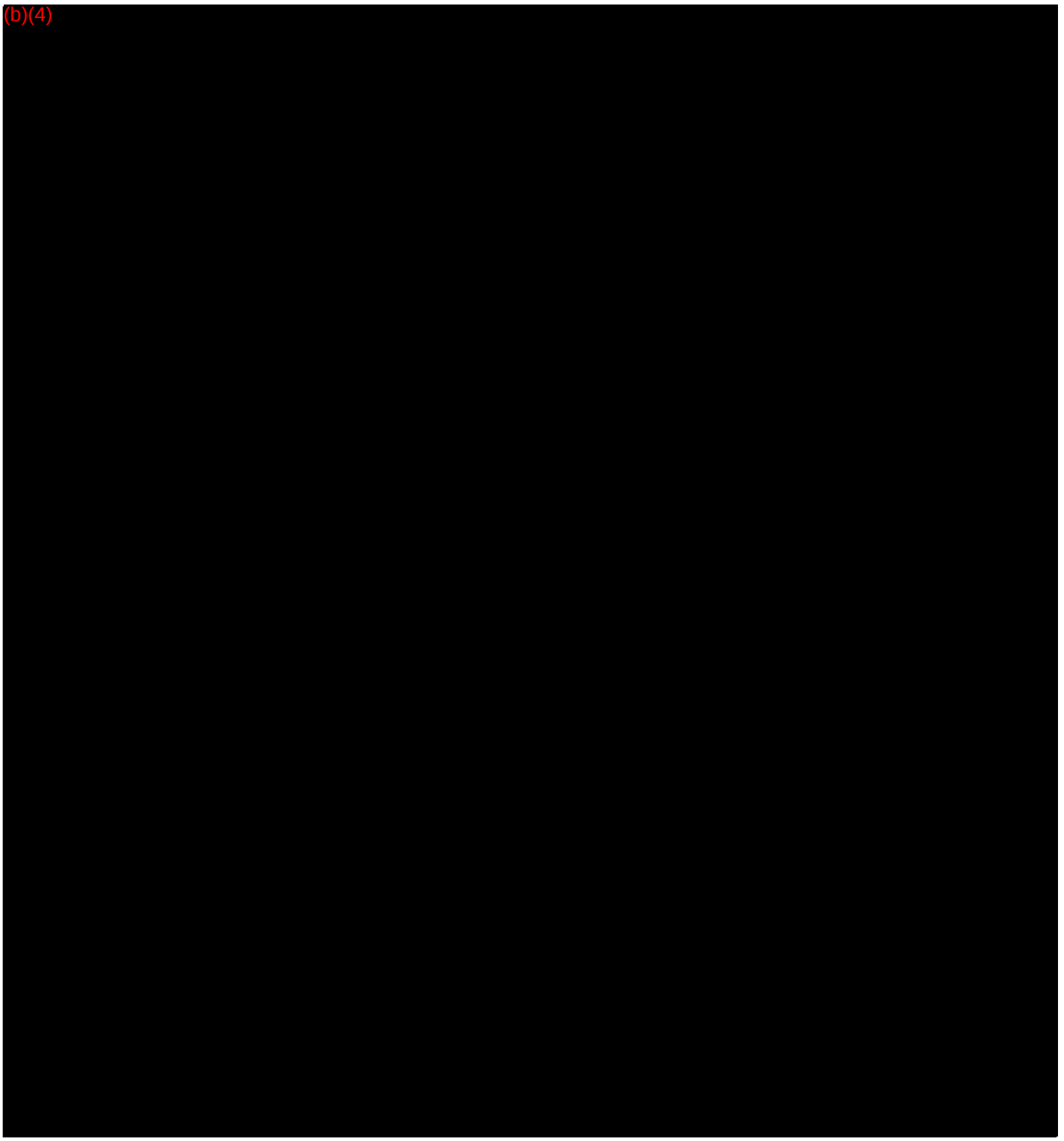

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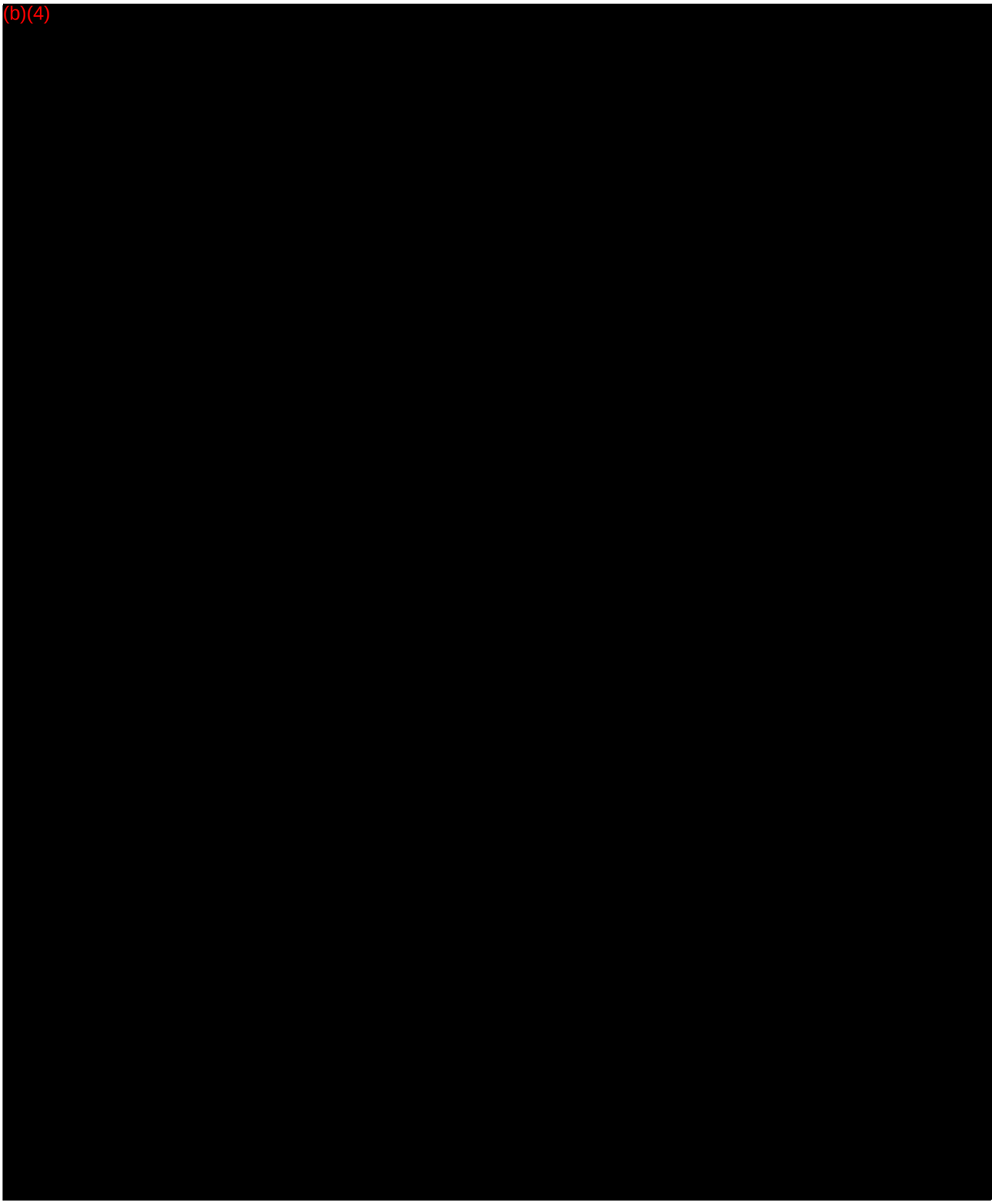

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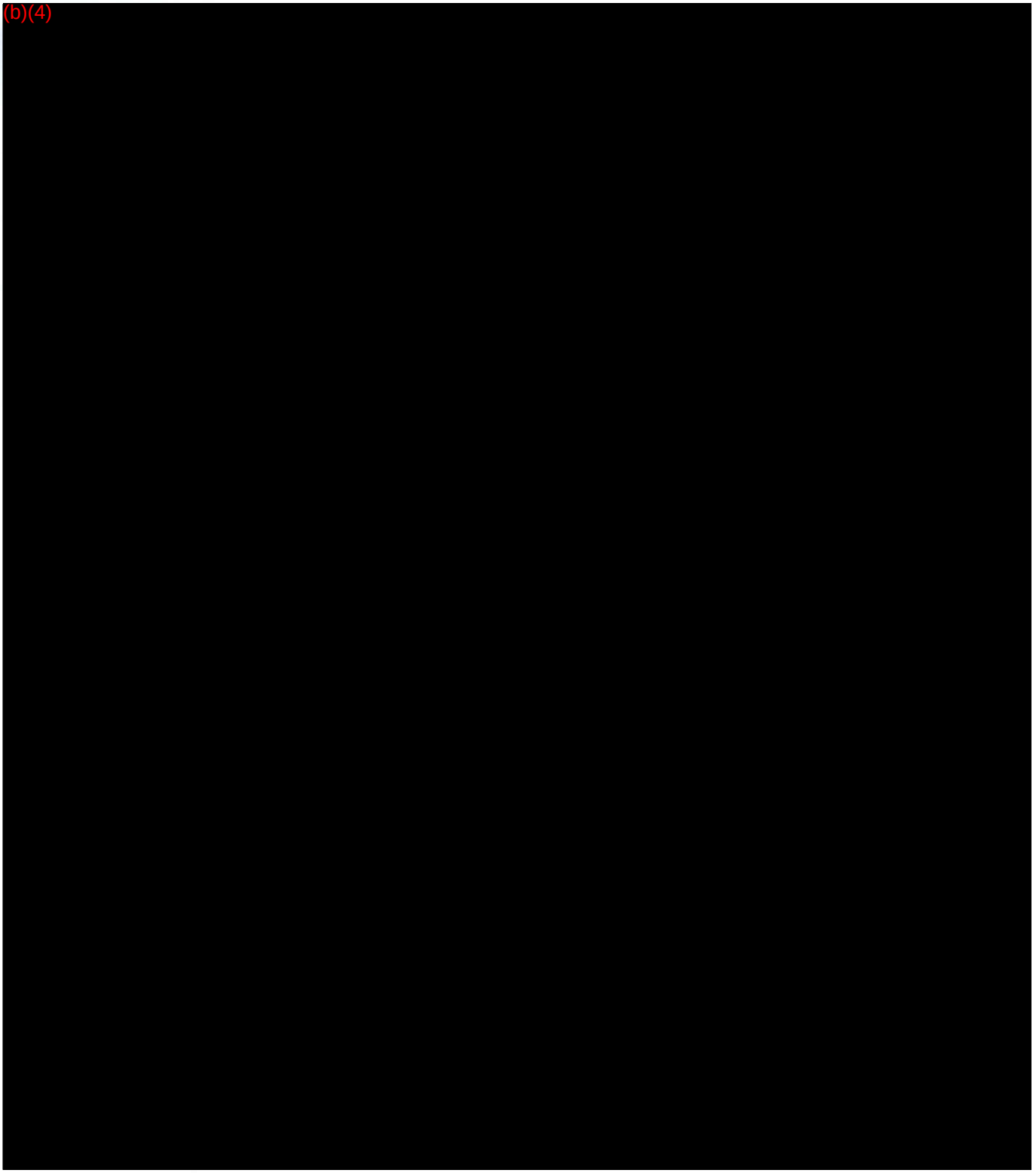

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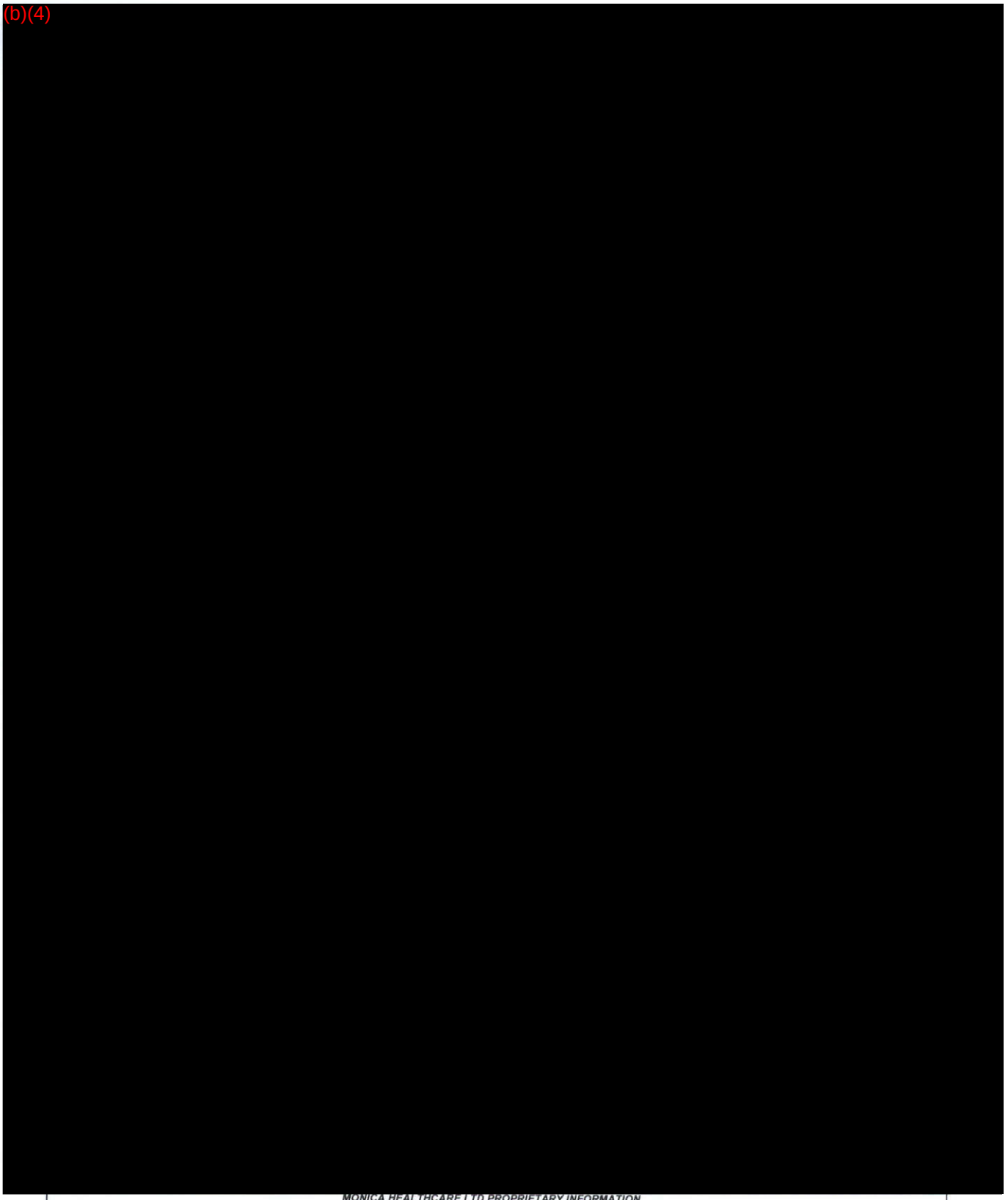

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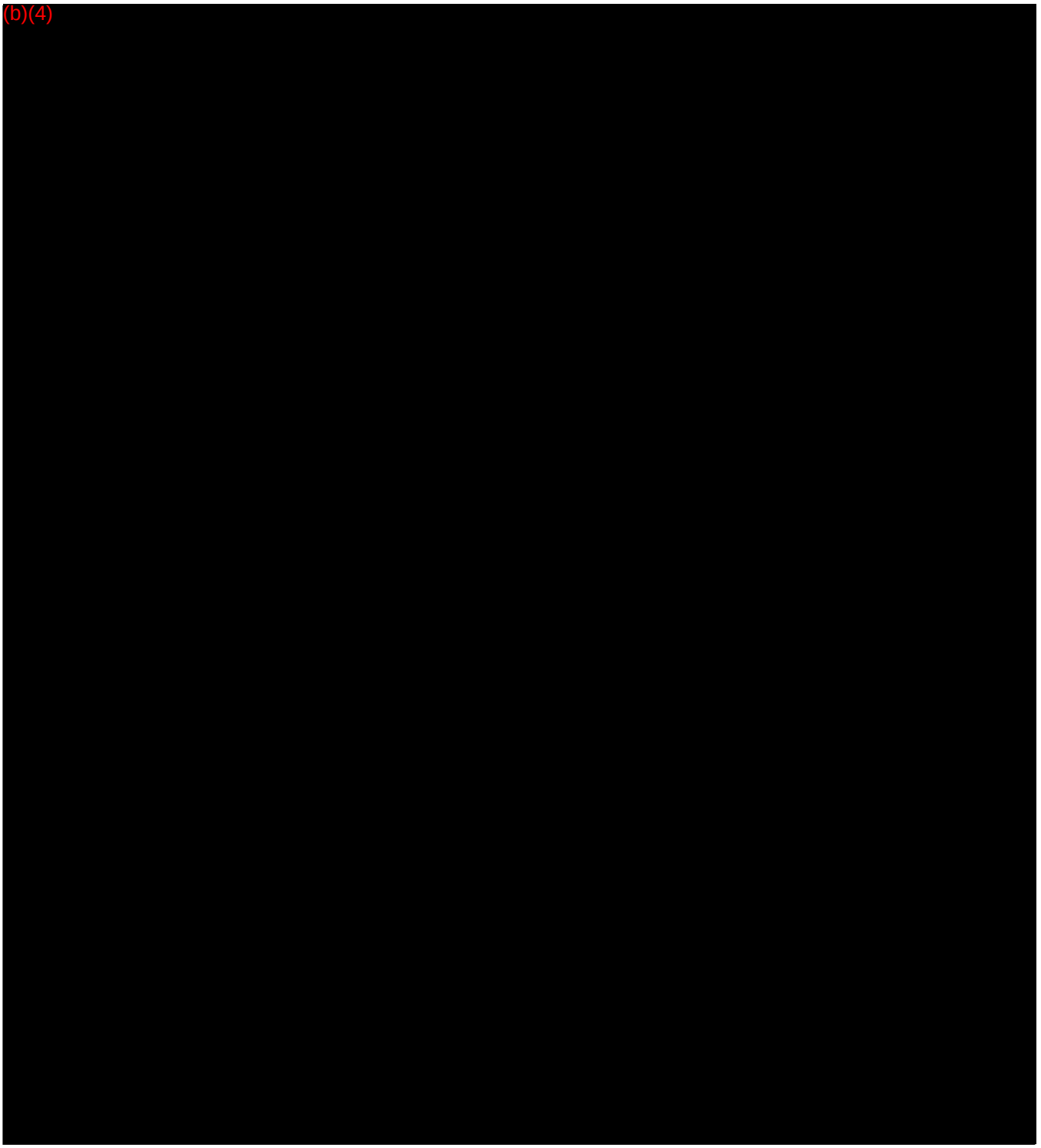

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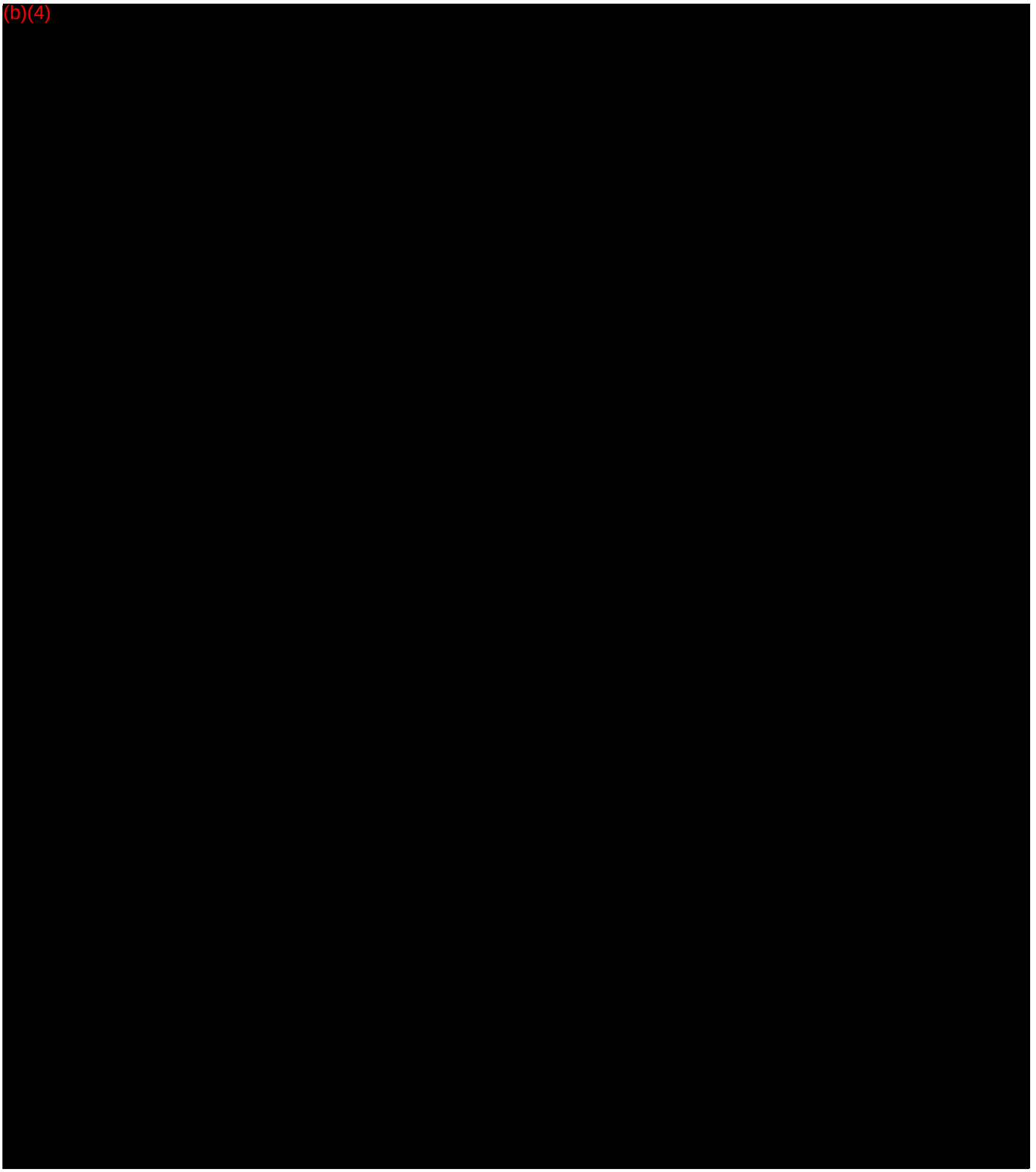

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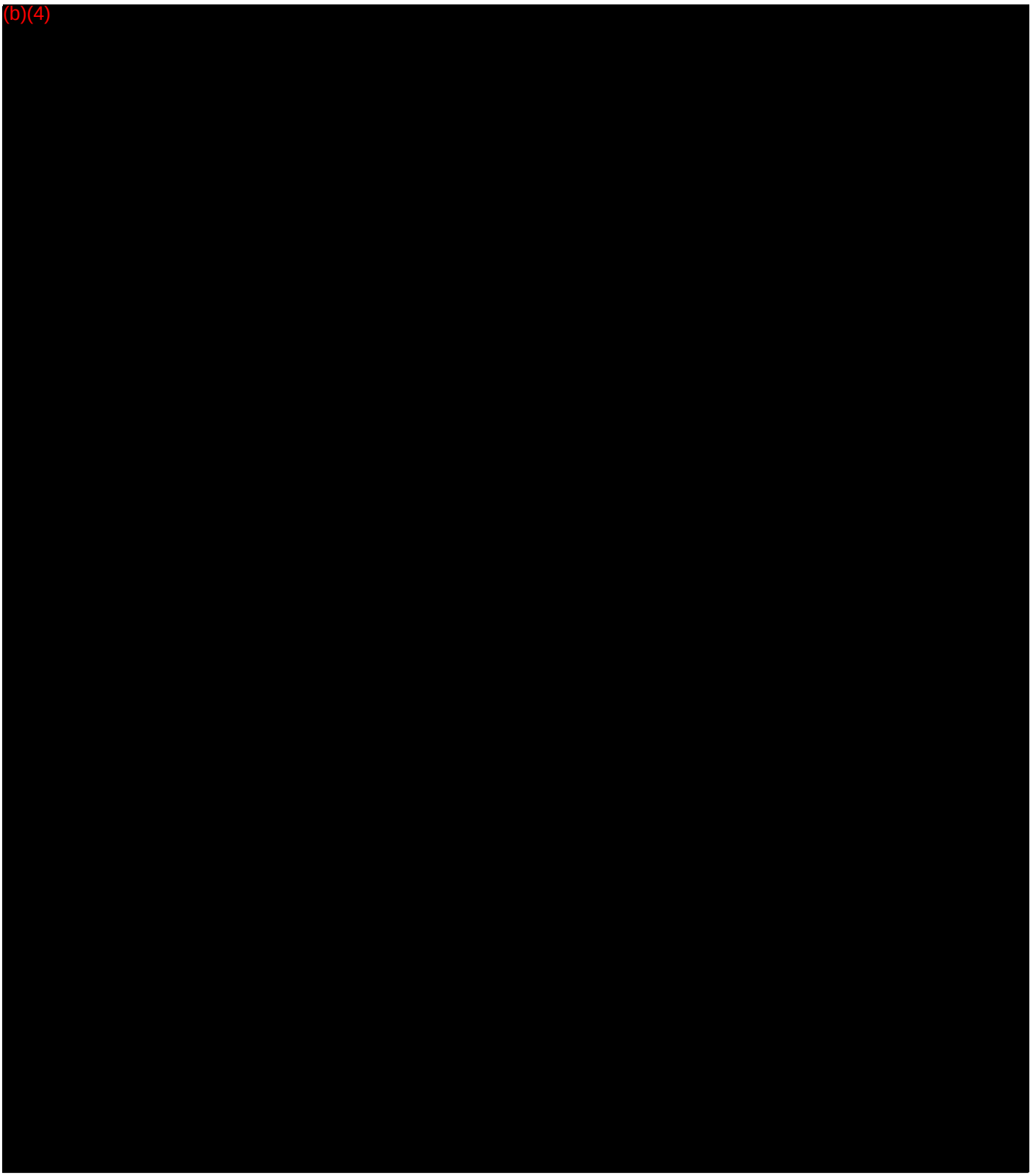

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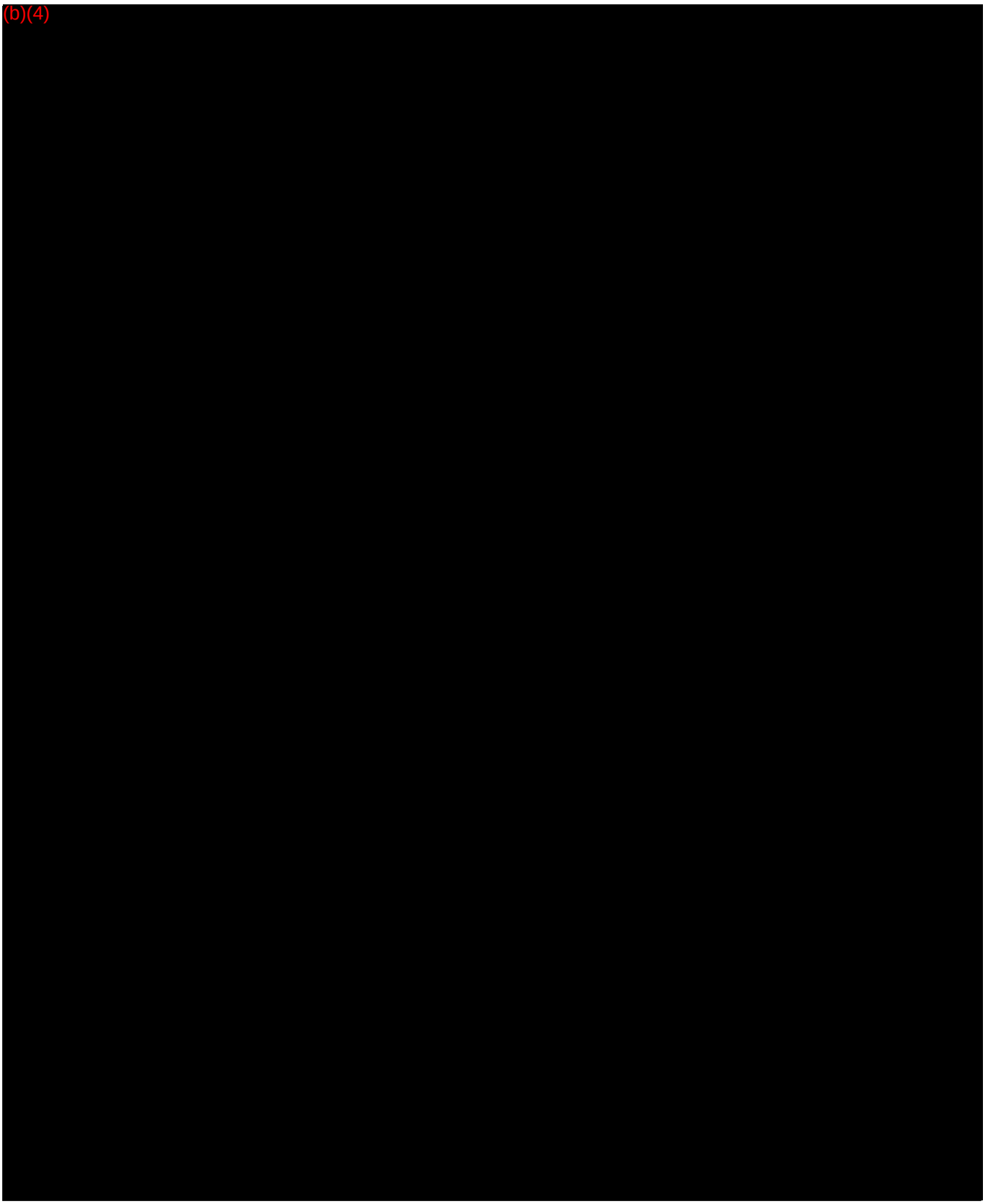

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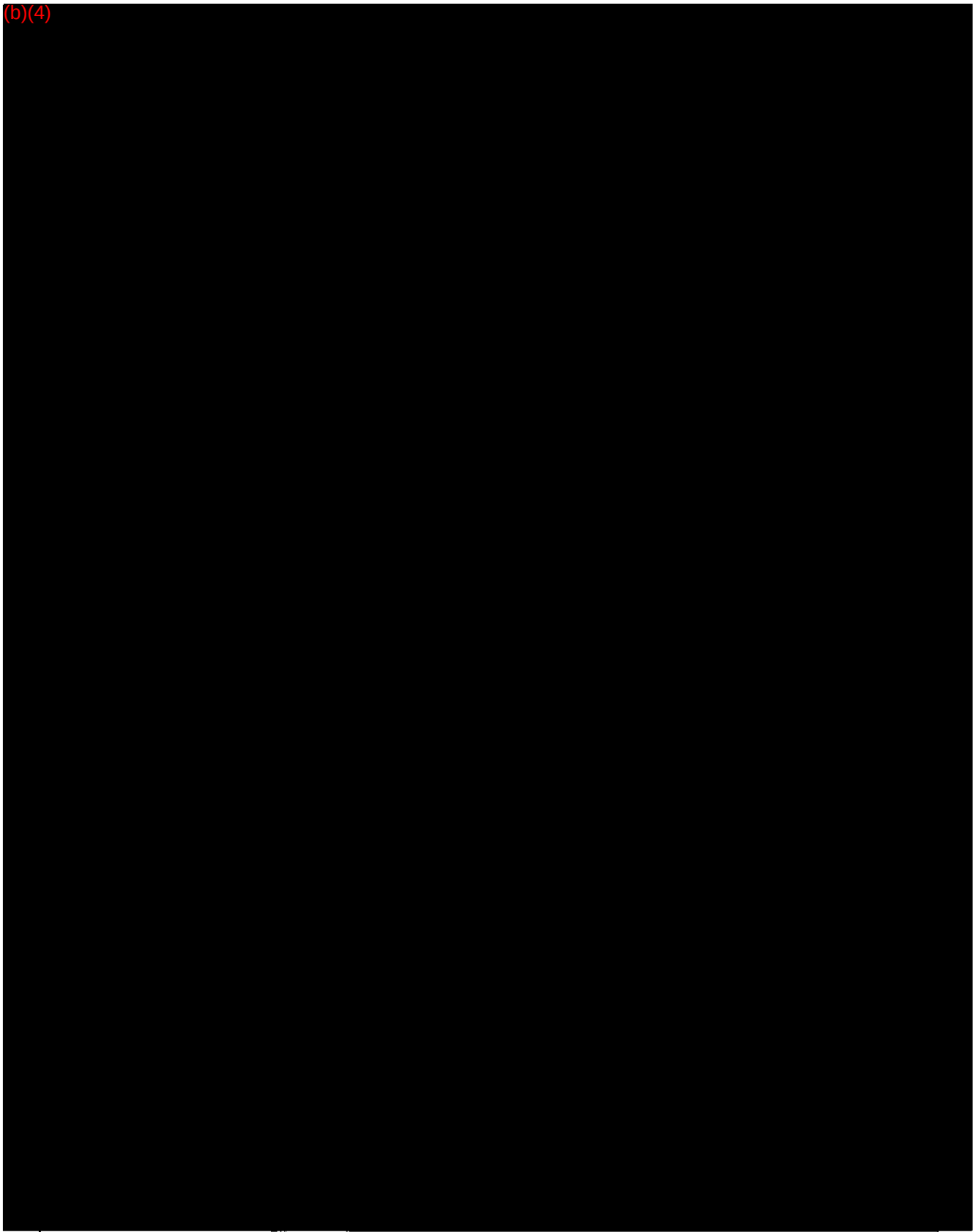

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Product	AN24 Abdominal Fetal ECG recorder
Document name	Software Description
Document type	**Technical File**
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1 SCOPE

1.1 Document Identification

The document is identified as follows:

- ✓ Identification Number: 100-TF-030.
- ✓ Title: AN24 Abdominal Fetal ECG recorder – Software Description.

1.2 Document Scope

The purpose of this document is to provide an overview of the features and software operating environment accordingly to [1].

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4 Software Description

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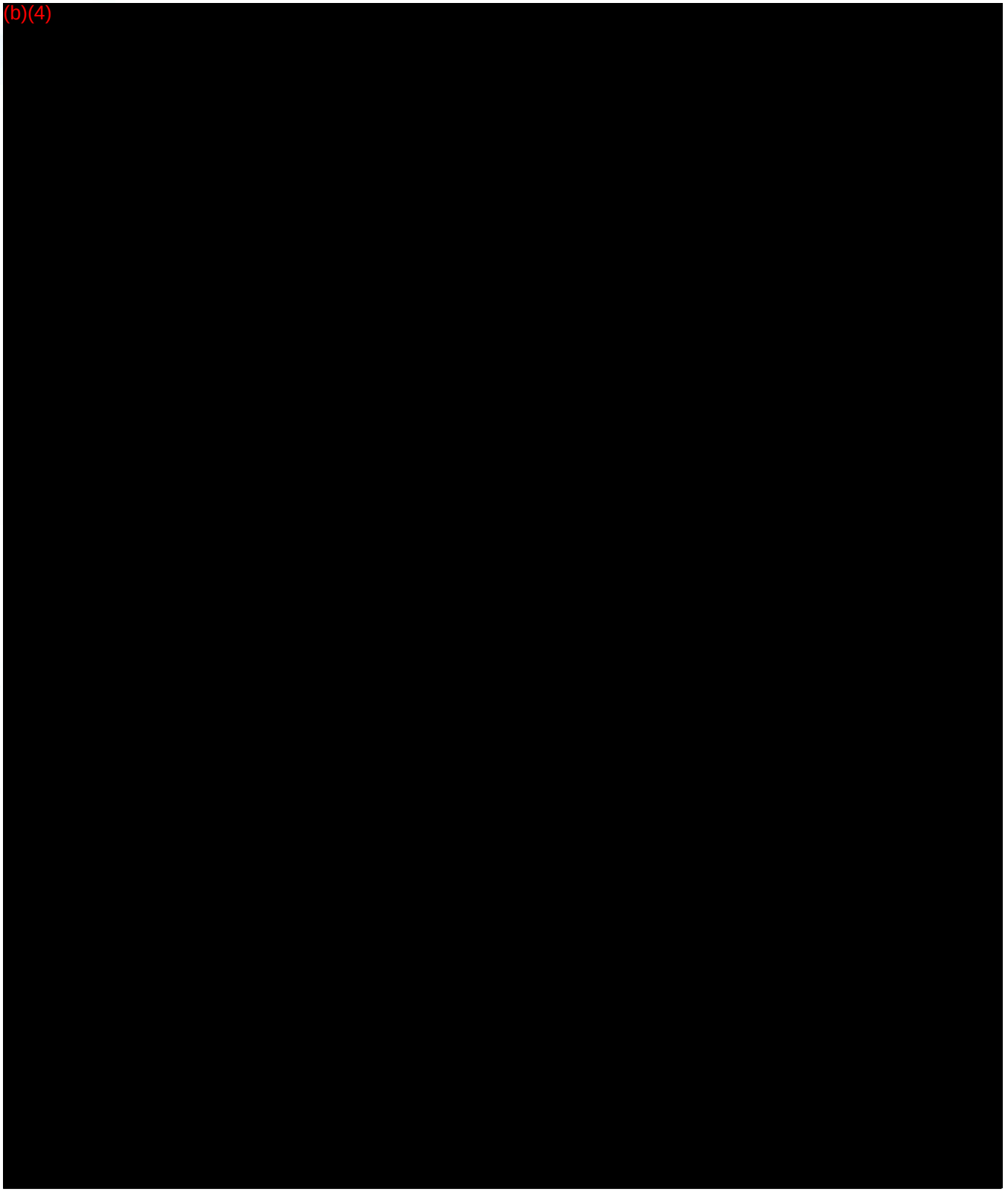

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Product	AN24 Abdominal FECG recorder
Document name	Software Development Environment Description
Document type	**TECHNICAL FILE**
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1 SCOPE

1.1 Document Identification

The document is identified as follows:

- ✓ Identification Number: 100-TF-031.
- ✓ Title: AN24 Abdominal FECG recorder – Software Development Environment Description

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2 RELATED DOCUMENTS

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4 Summary of the software development life cycle plan

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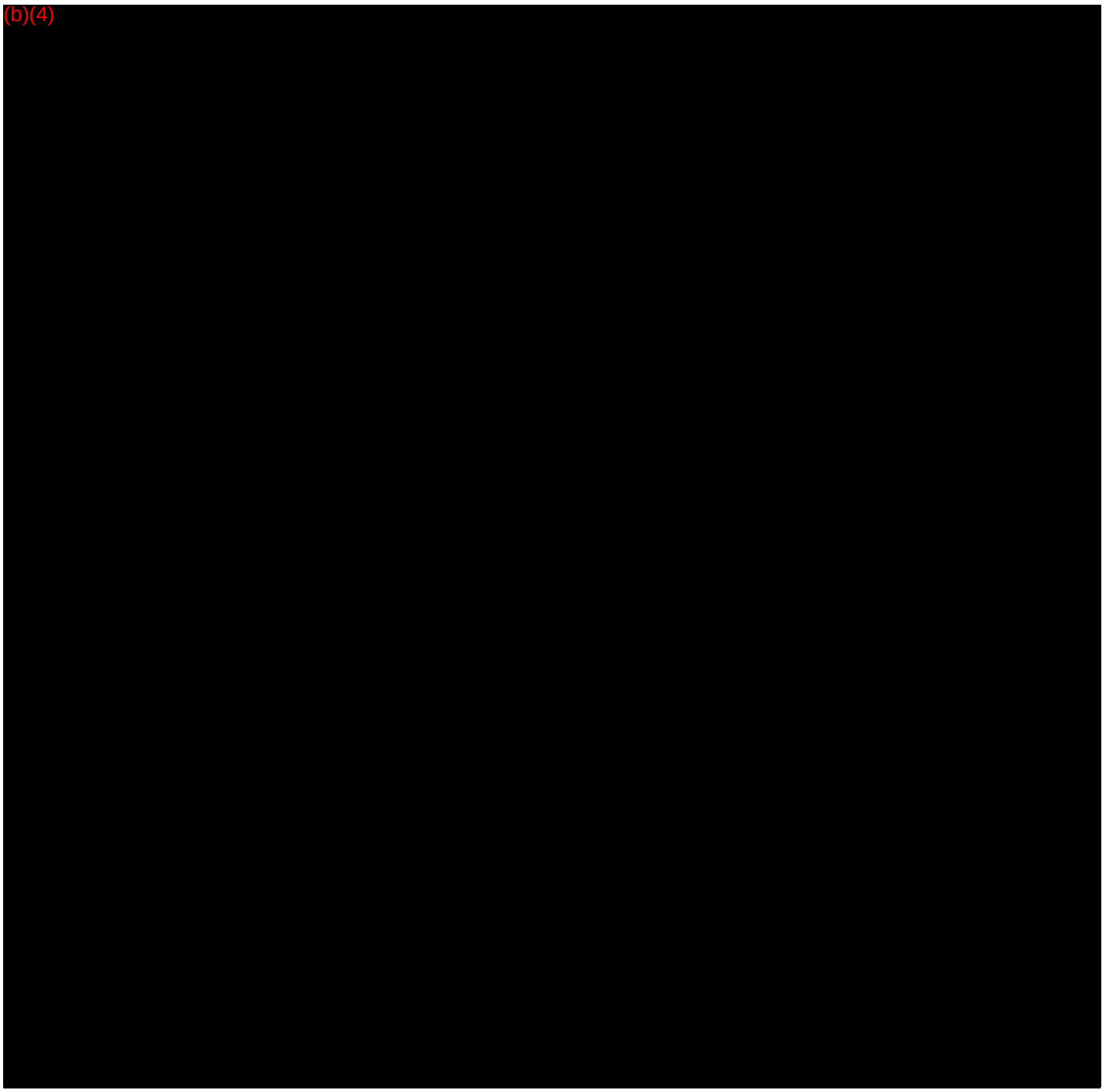

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Product	AN24 Abdominal Fetal ECG recorder
Document name	Level of Concern
Document type	**DECISION**
(b)(4) [redacted]	

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1 SCOPE

1.1 Document Identification

The document is identified as follows:

- ✓ Identification Number: 100-TF-032
- ✓ Title: AN24 Abdominal Fetal ECG recorder – Level of Concern.

1.2 Document Scope

The purpose of this document is to define the Level of Concern for the AN24 device and to describe the rationale for that level.

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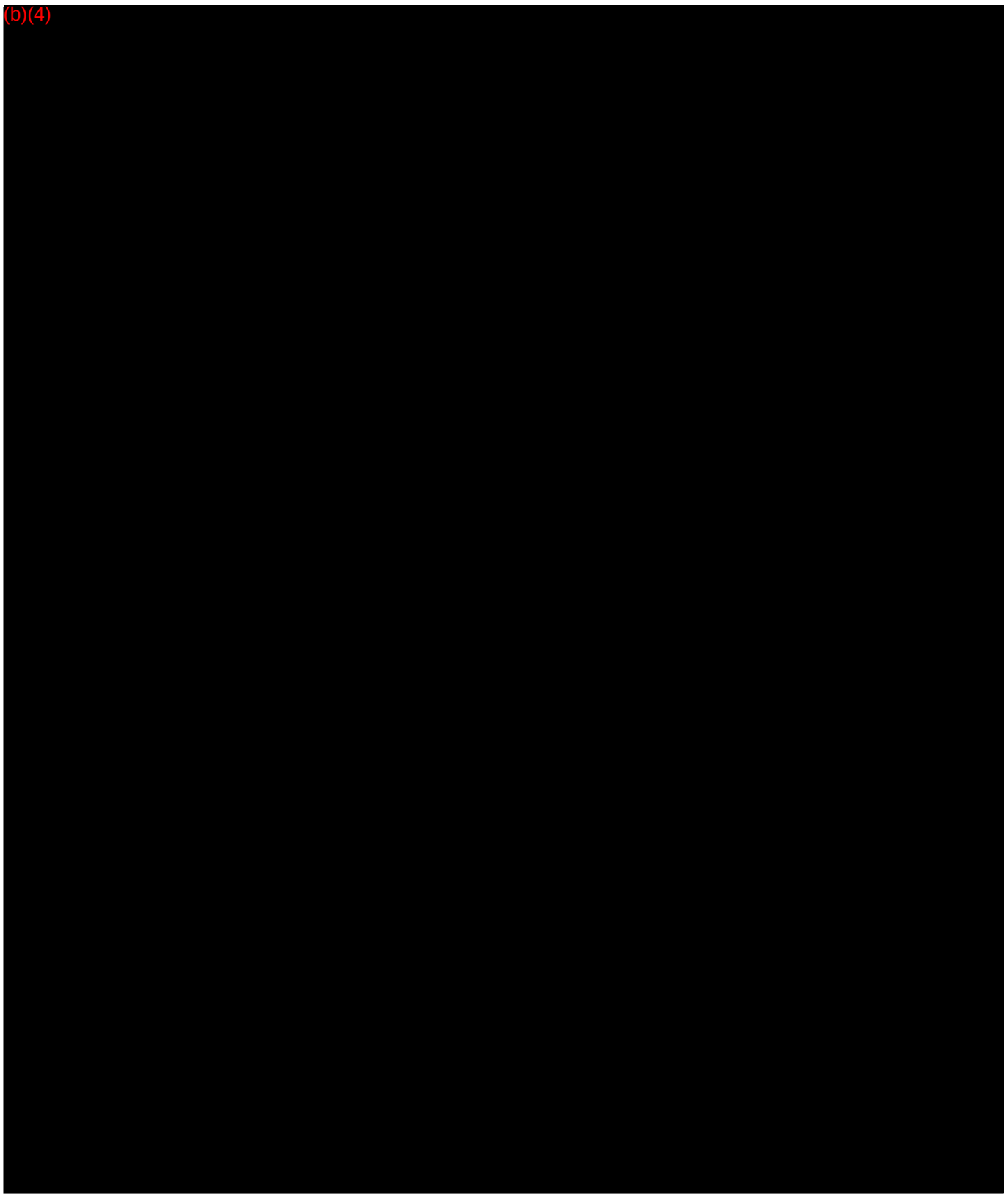

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Product	AN24 Abdominal FECG recorder
Document name	Revision Level History
Document type	**Technical File**

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1.1 DOCUMENT IDENTIFICATION 4

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1 Preamble

1.1 Document Identification

The document is identified as follows:

- ✓ Identification Number: 100-TF-033.
- ✓ Title: AN24 Abdominal FECG recorder – Revision Level History.

1.2 Document Scope

This document describes the history of software revisions generated during the course of product development.

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Product	AN24 Abdominal FECG recorder
Document name	Firmware Design Document
Document type	**TECHNICAL FILE**

(b)(4) [redacted]

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1.1 DOCUMENT IDENTIFICATION 5

1.2 DOCUMENT SCOPE 5

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1 SCOPE

1.1 Document Identification

This document describes the design of the firmware for the abdominal FECG recorder. The document is identified as follows:

- ✓ Identification Number: 100-TF-034.
- ✓ Title: AN24 Abdominal FECG recorder - Firmware Design Document

1.2 Document Scope

This document describes the design of the AN24 firmware. It describes the code design, development tools, code location, and risk management.

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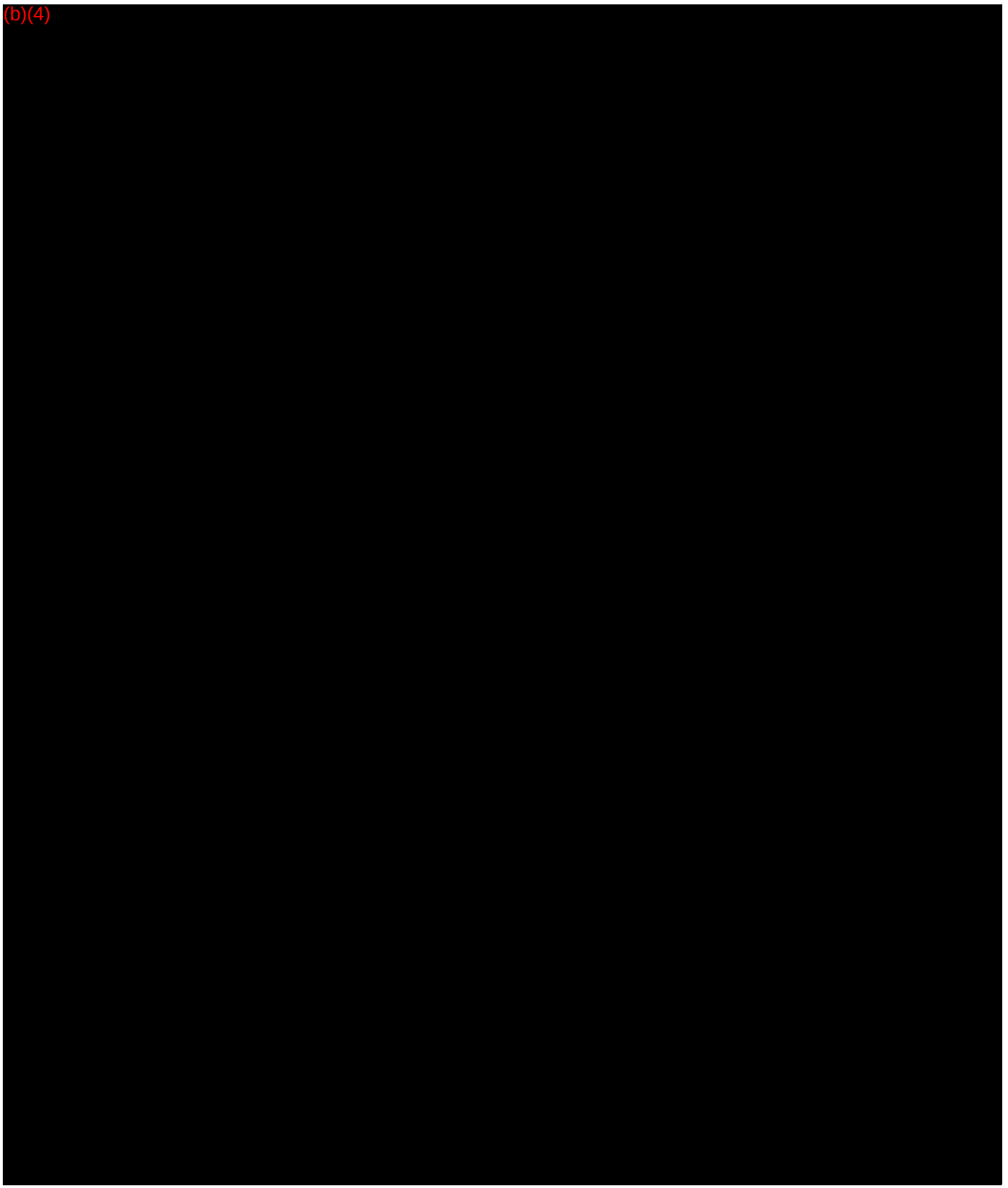

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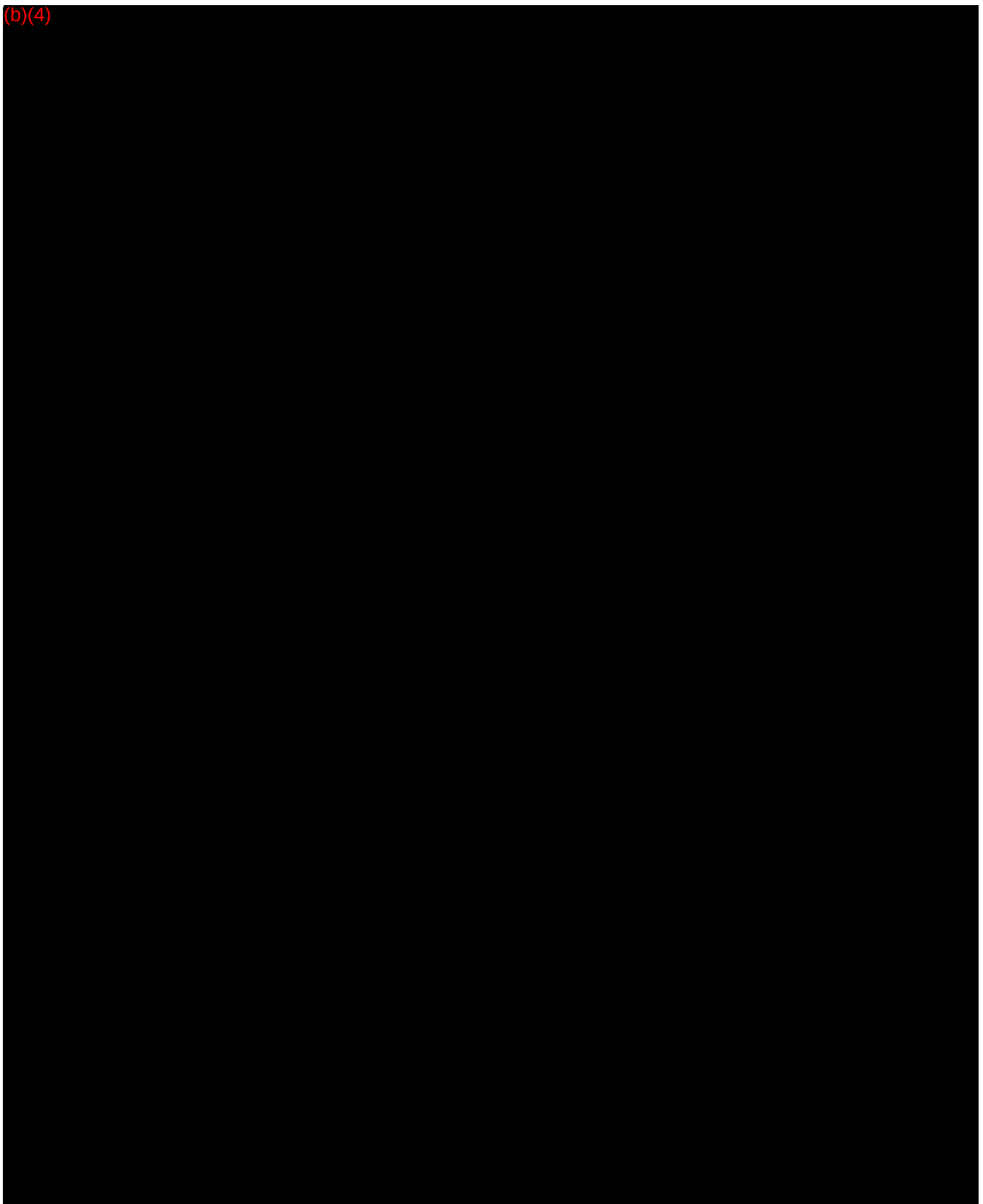

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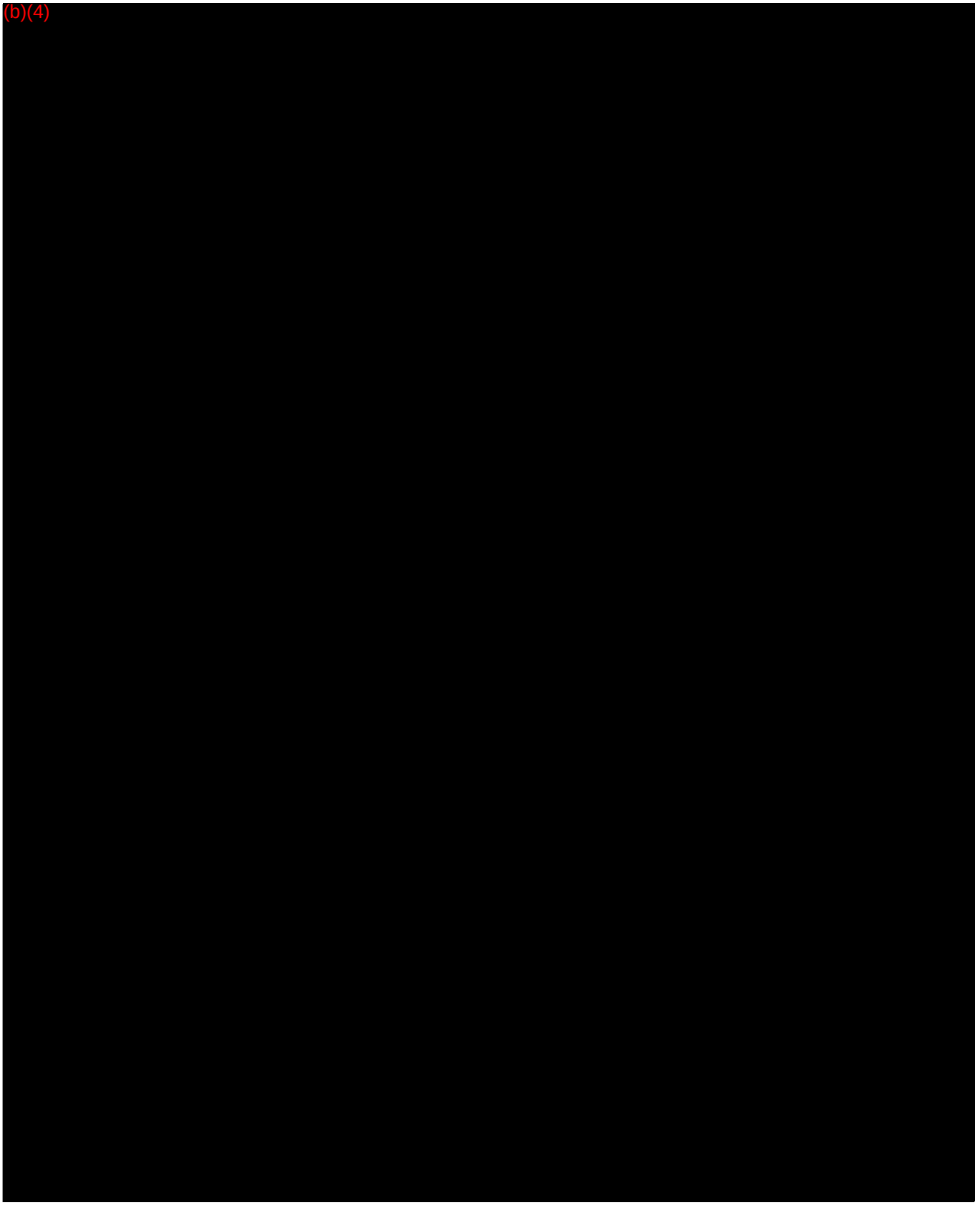

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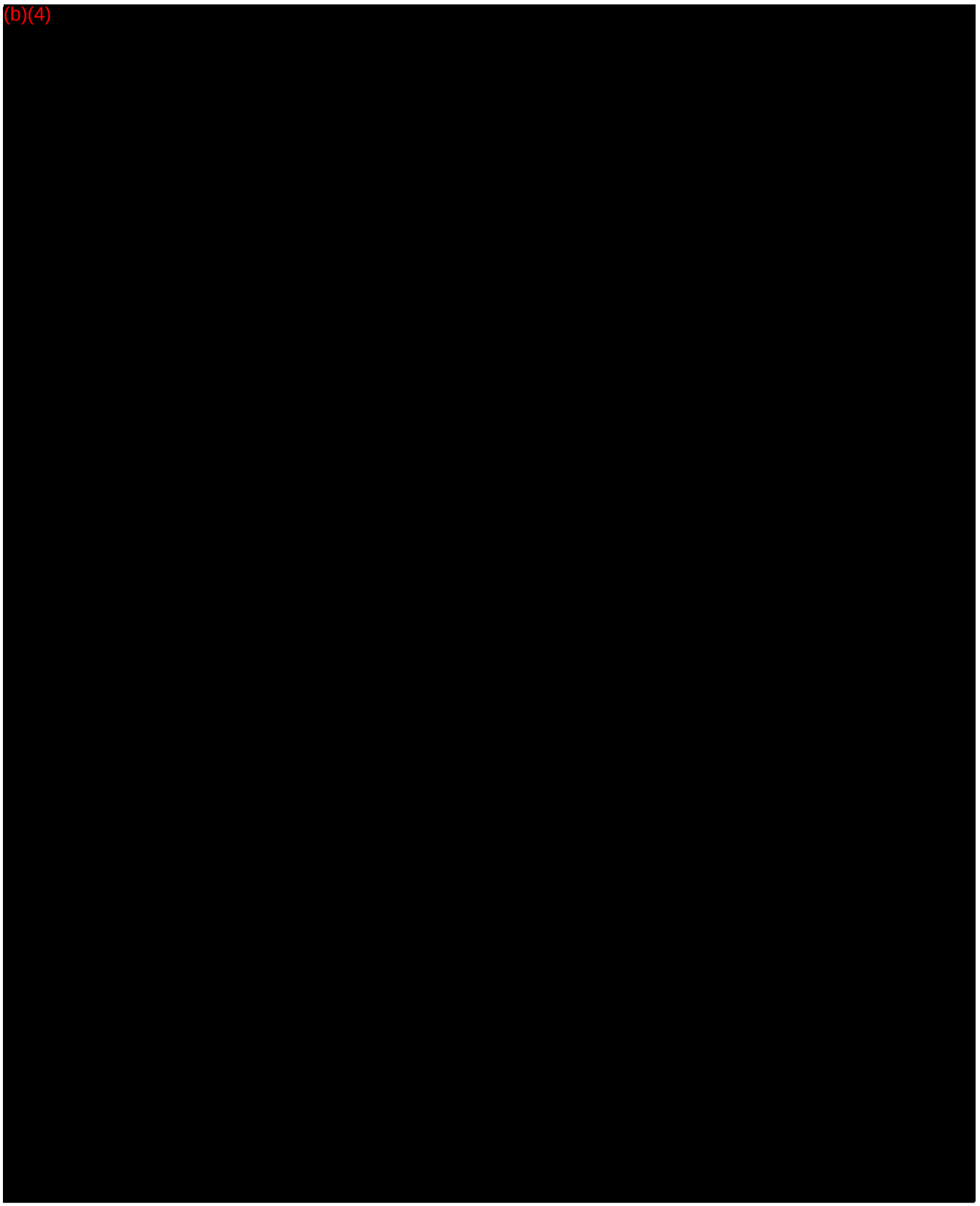

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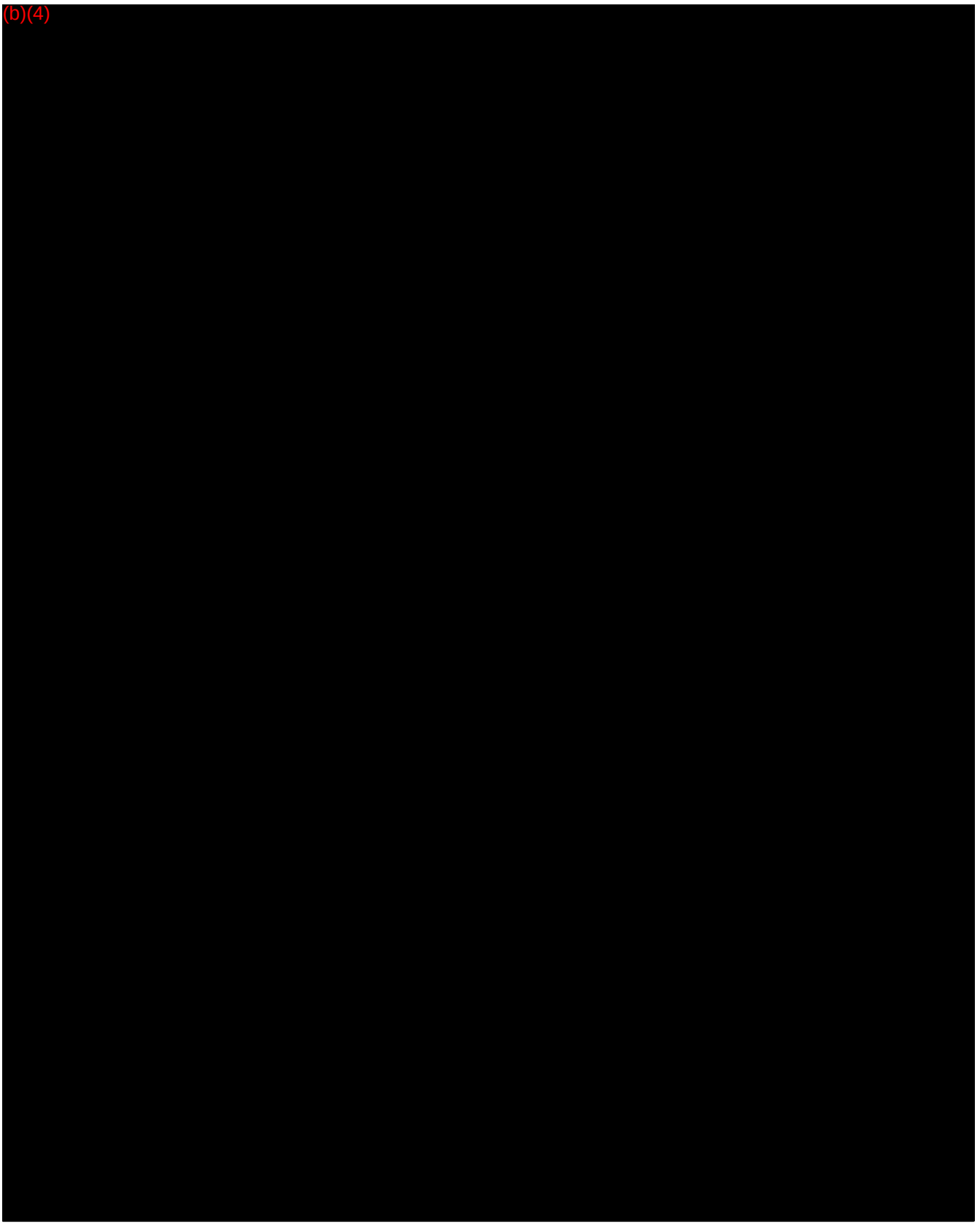

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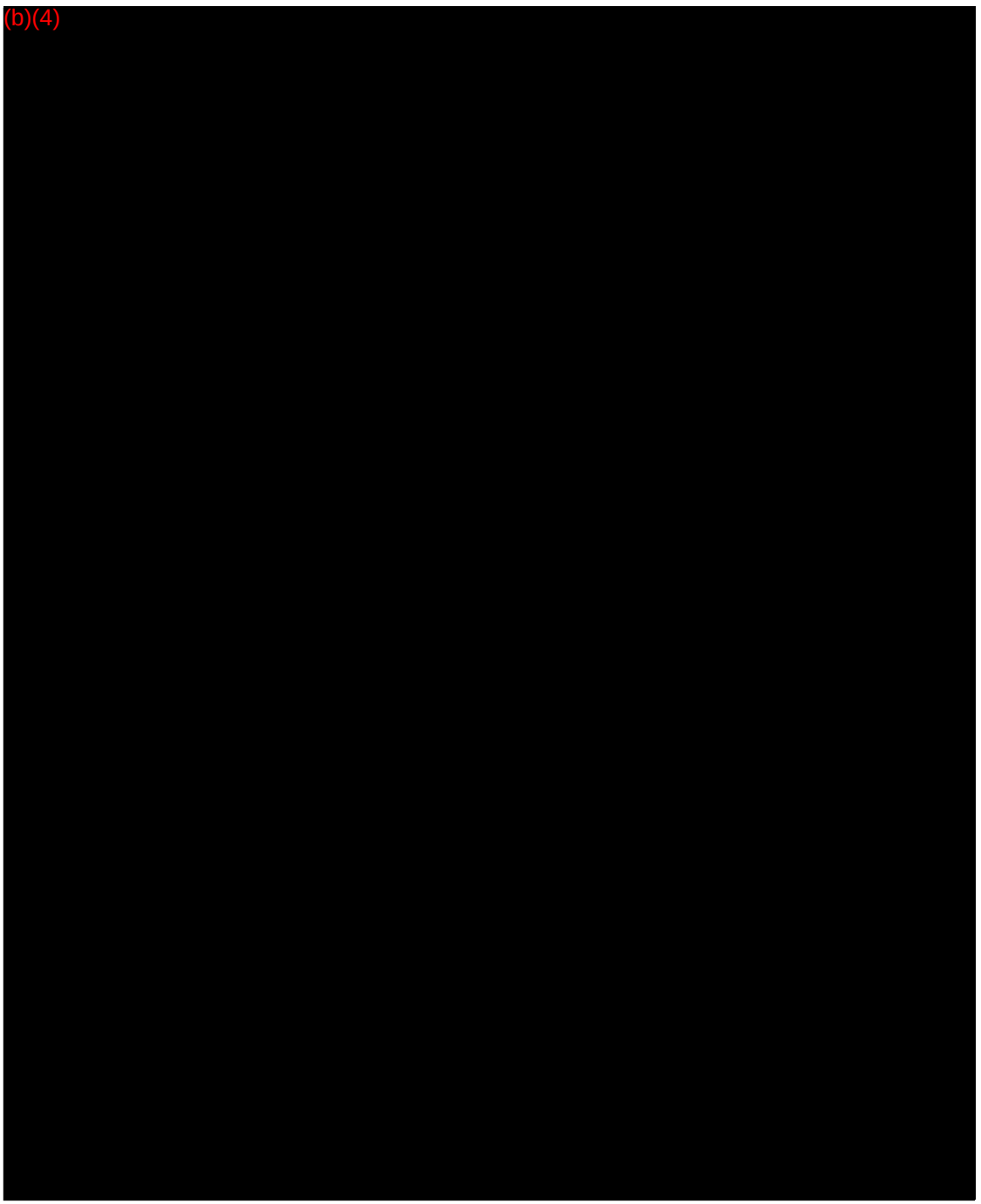

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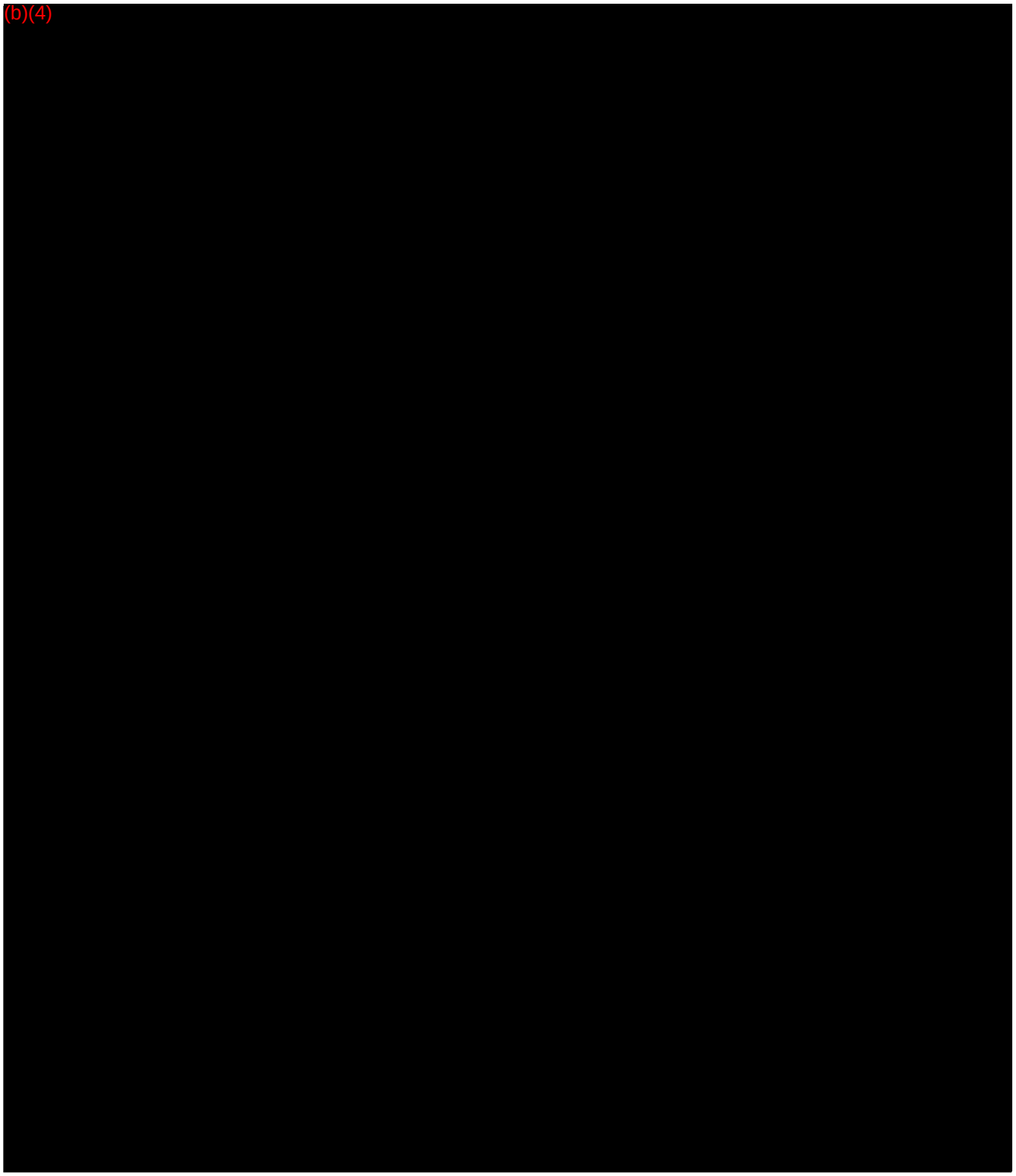

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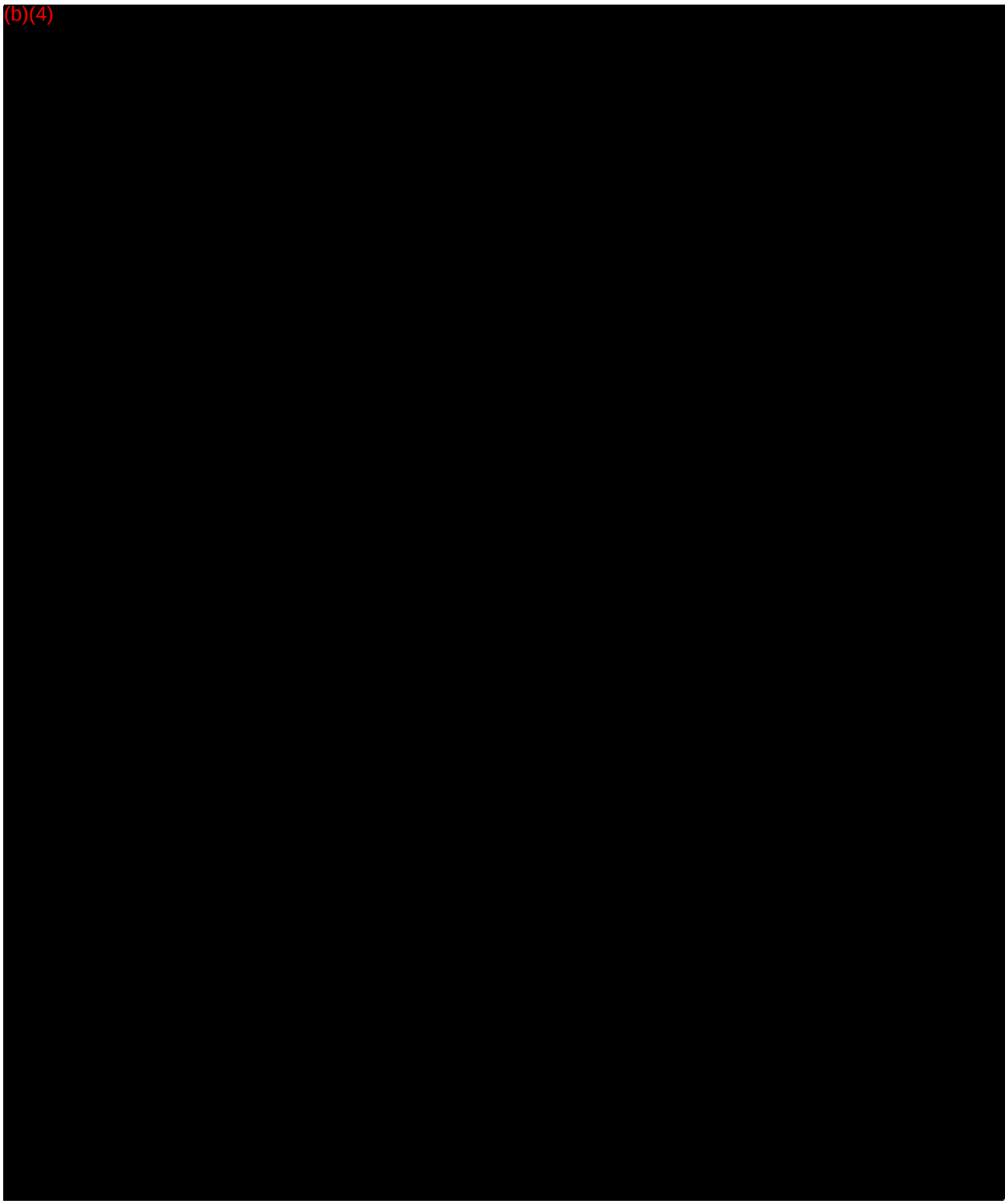

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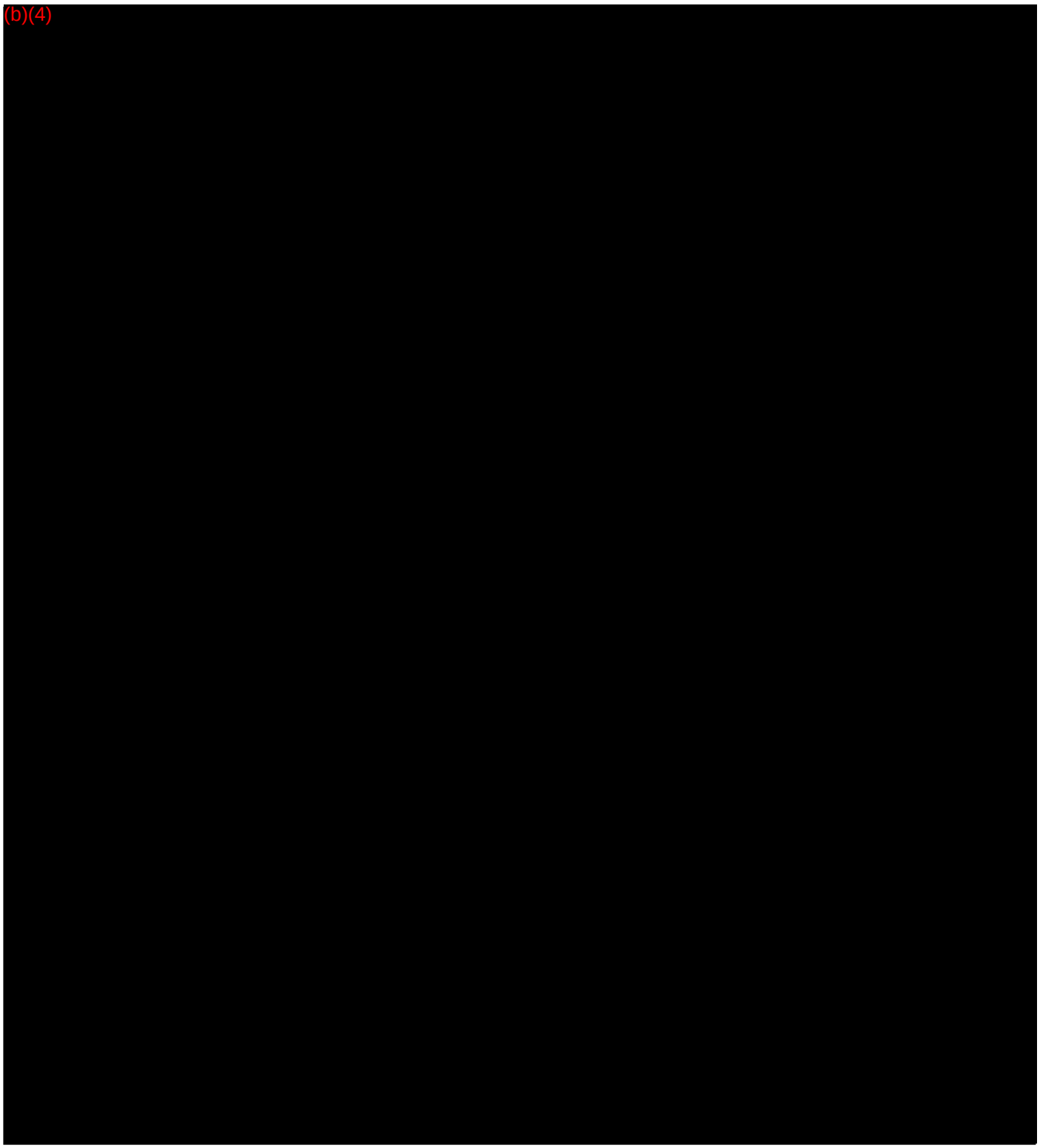

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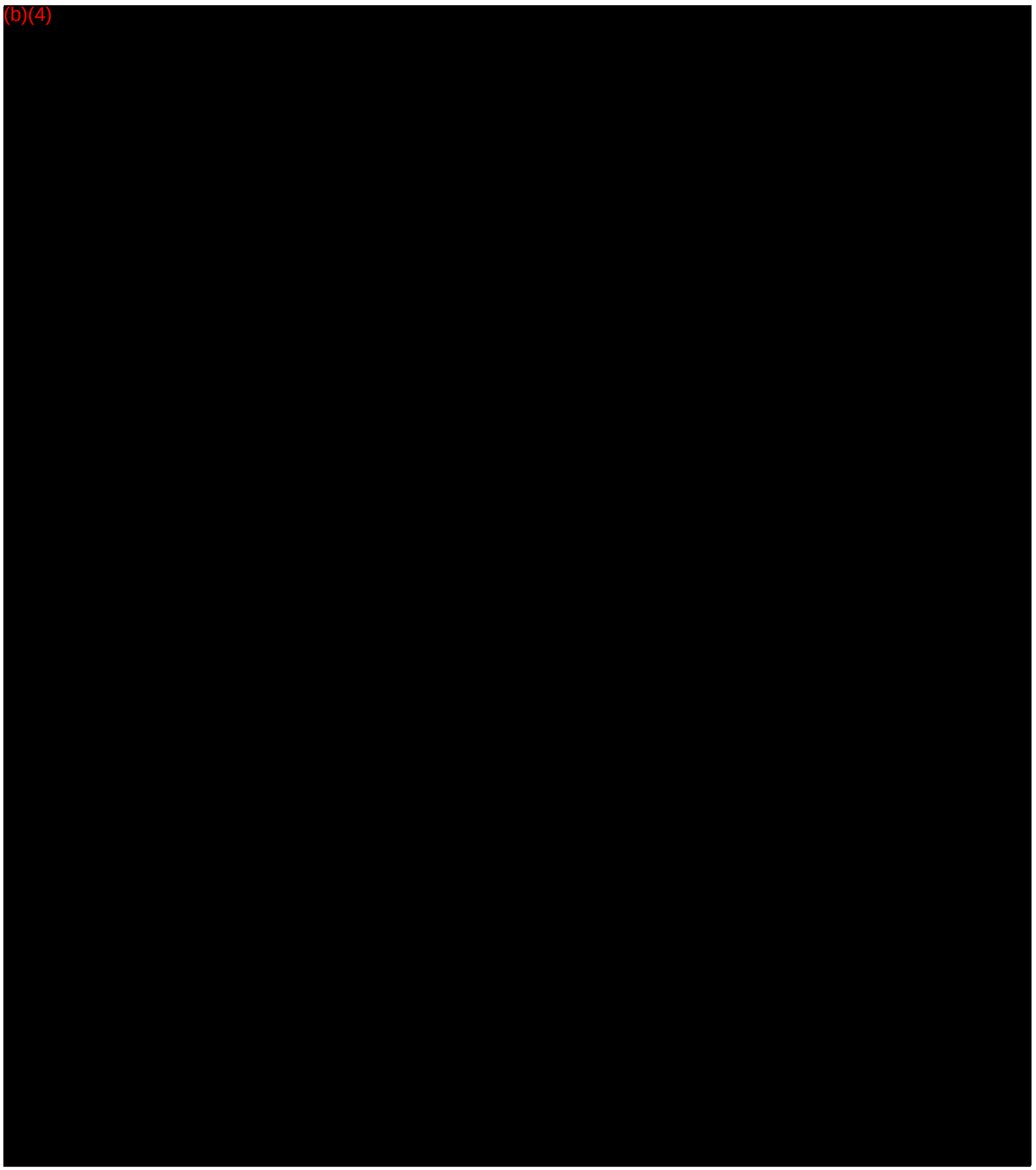

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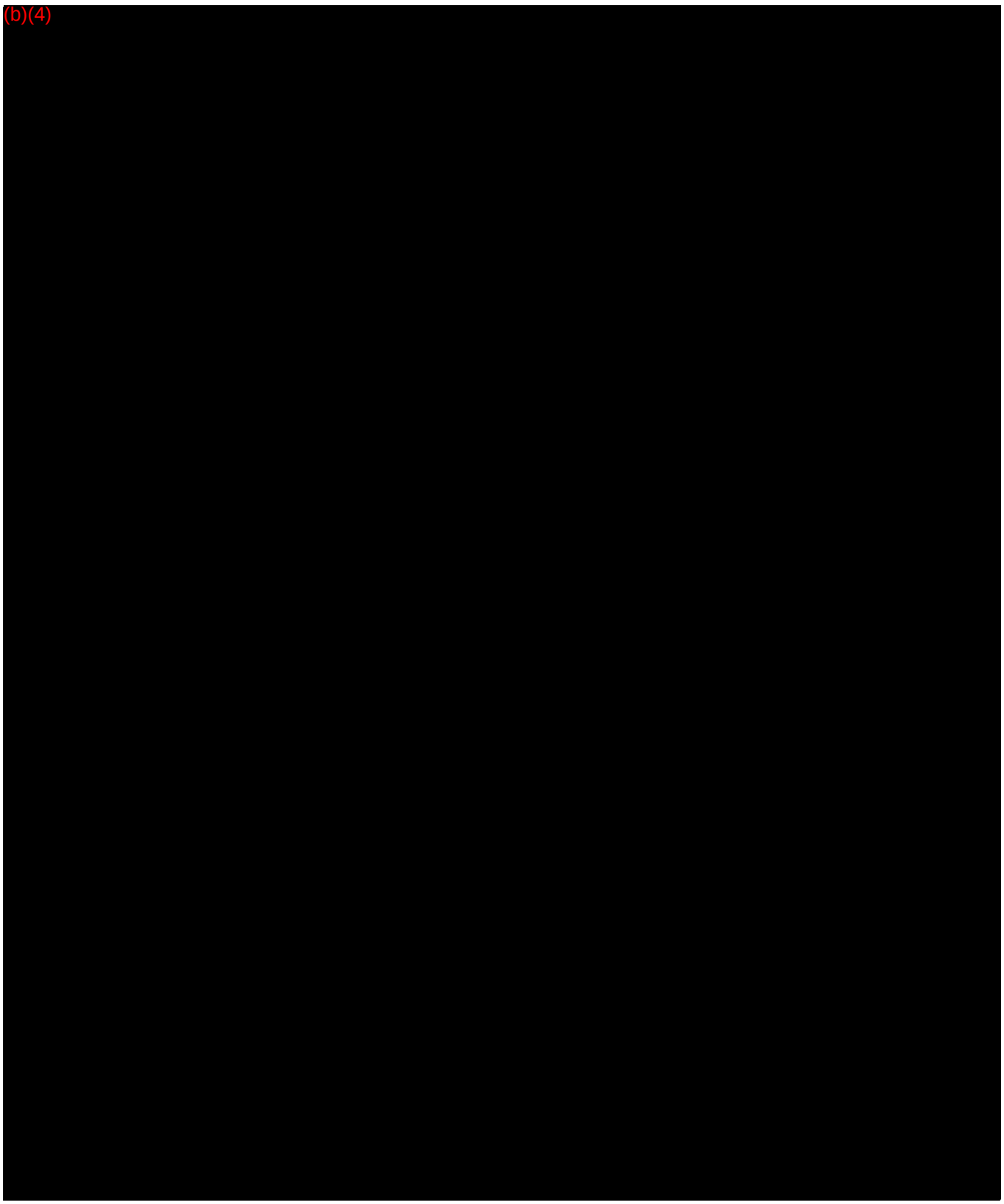

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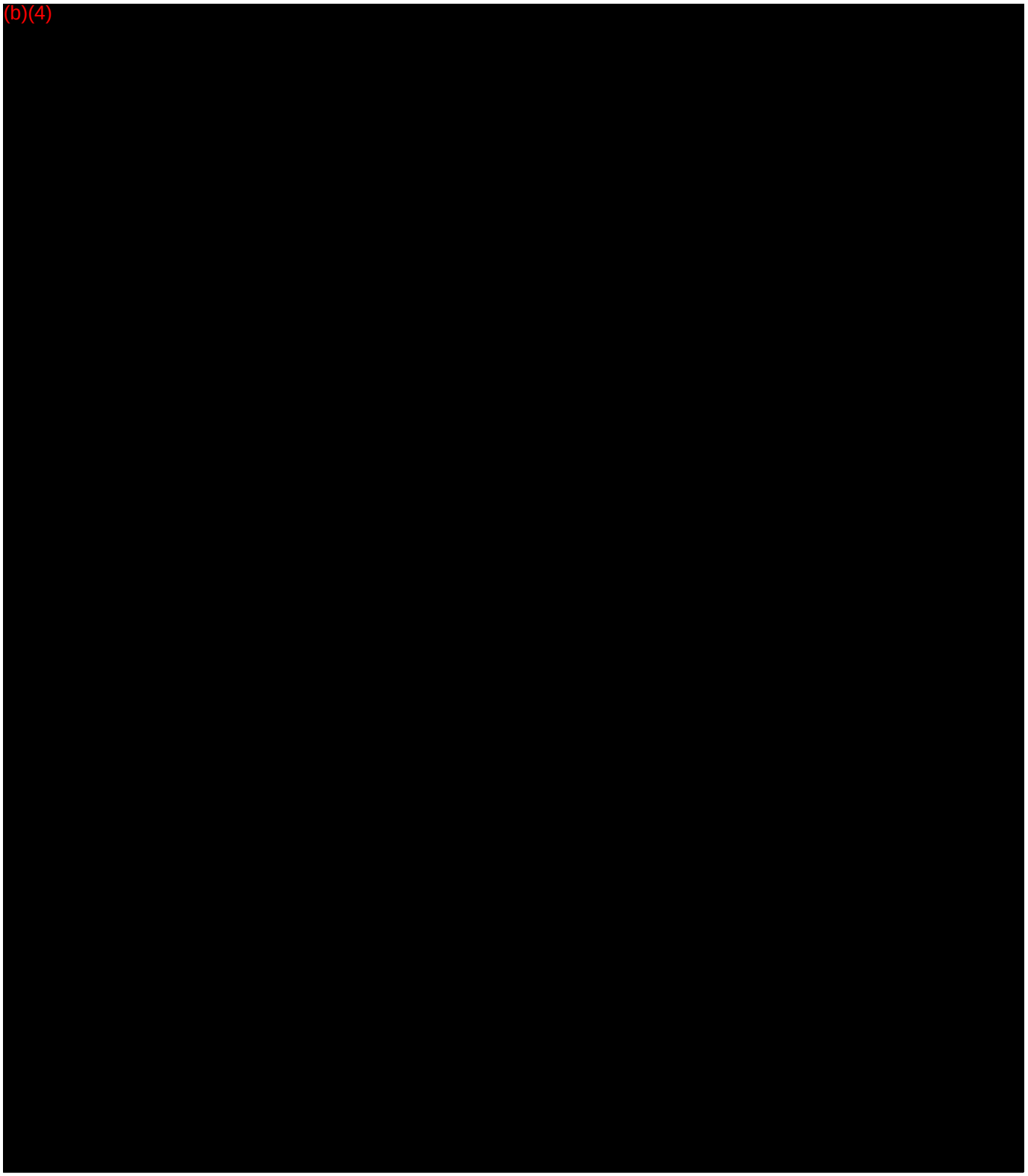

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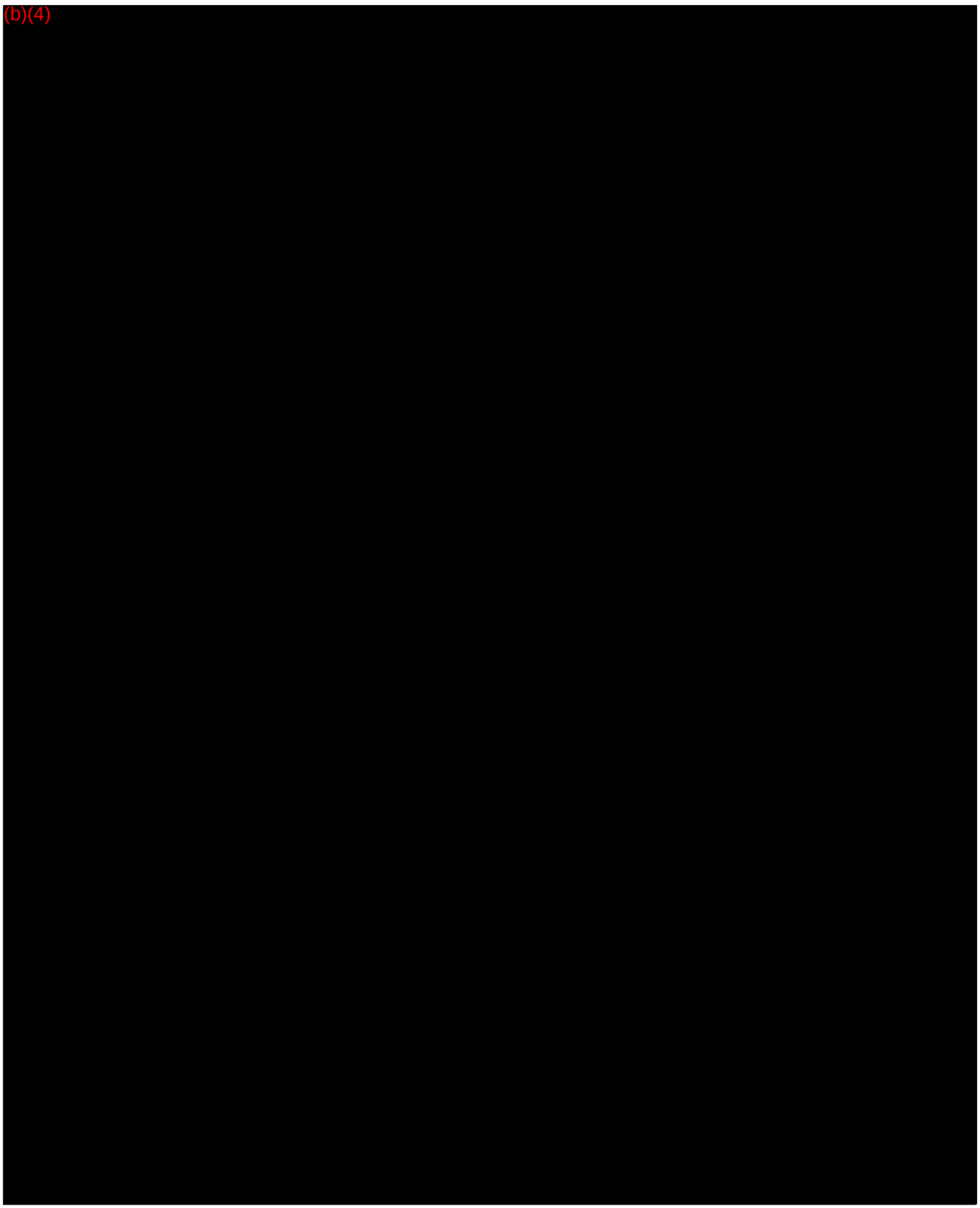

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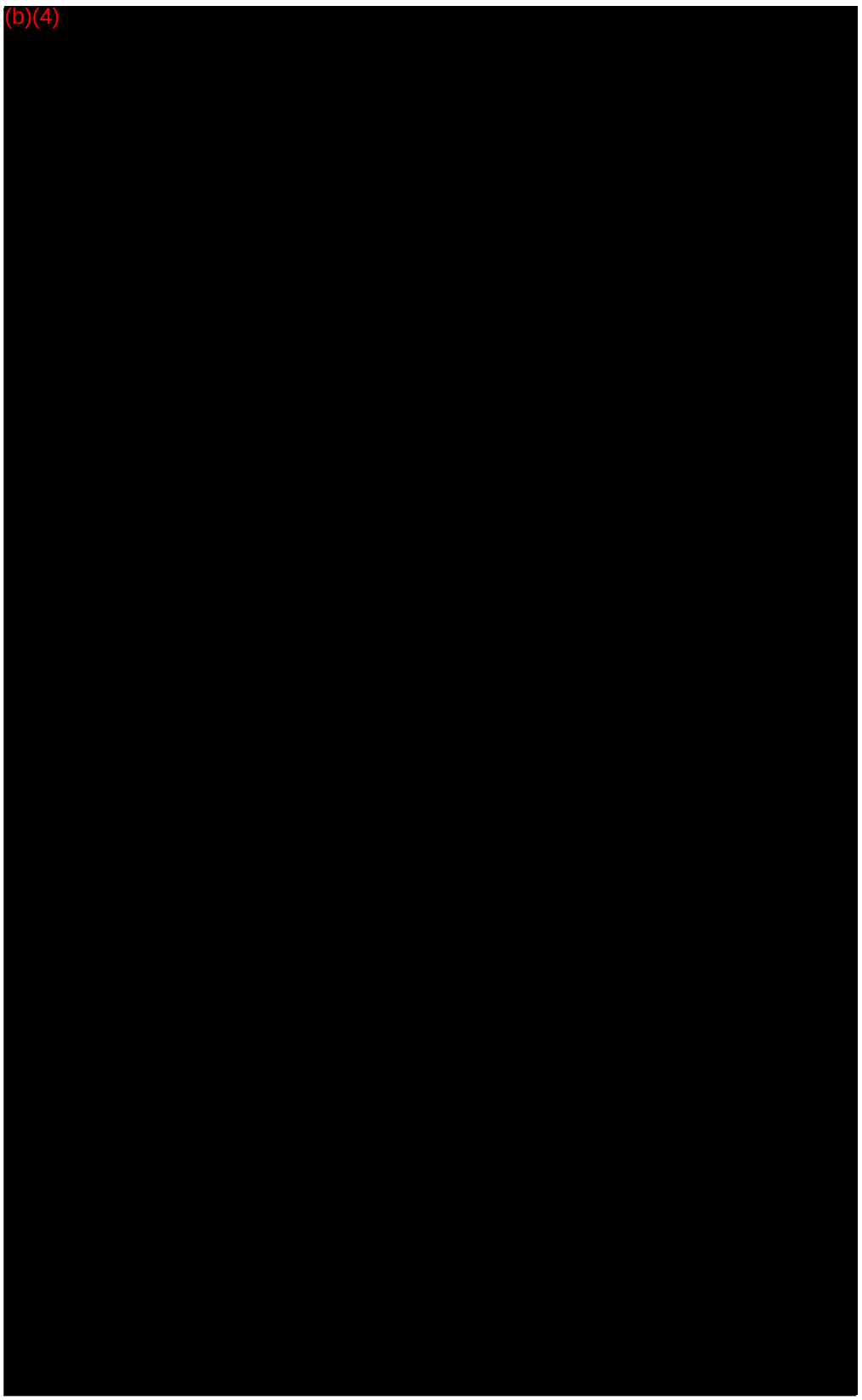

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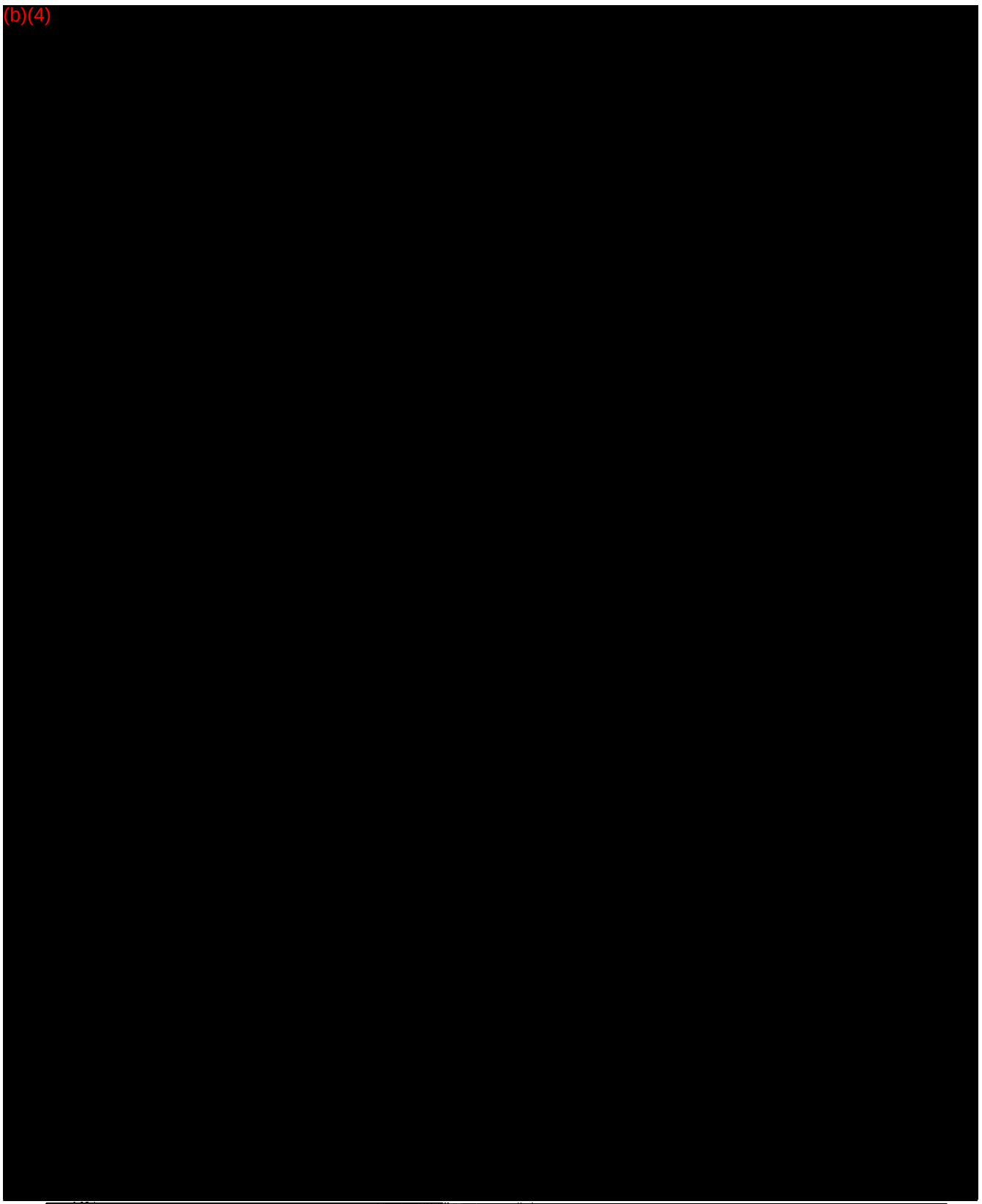

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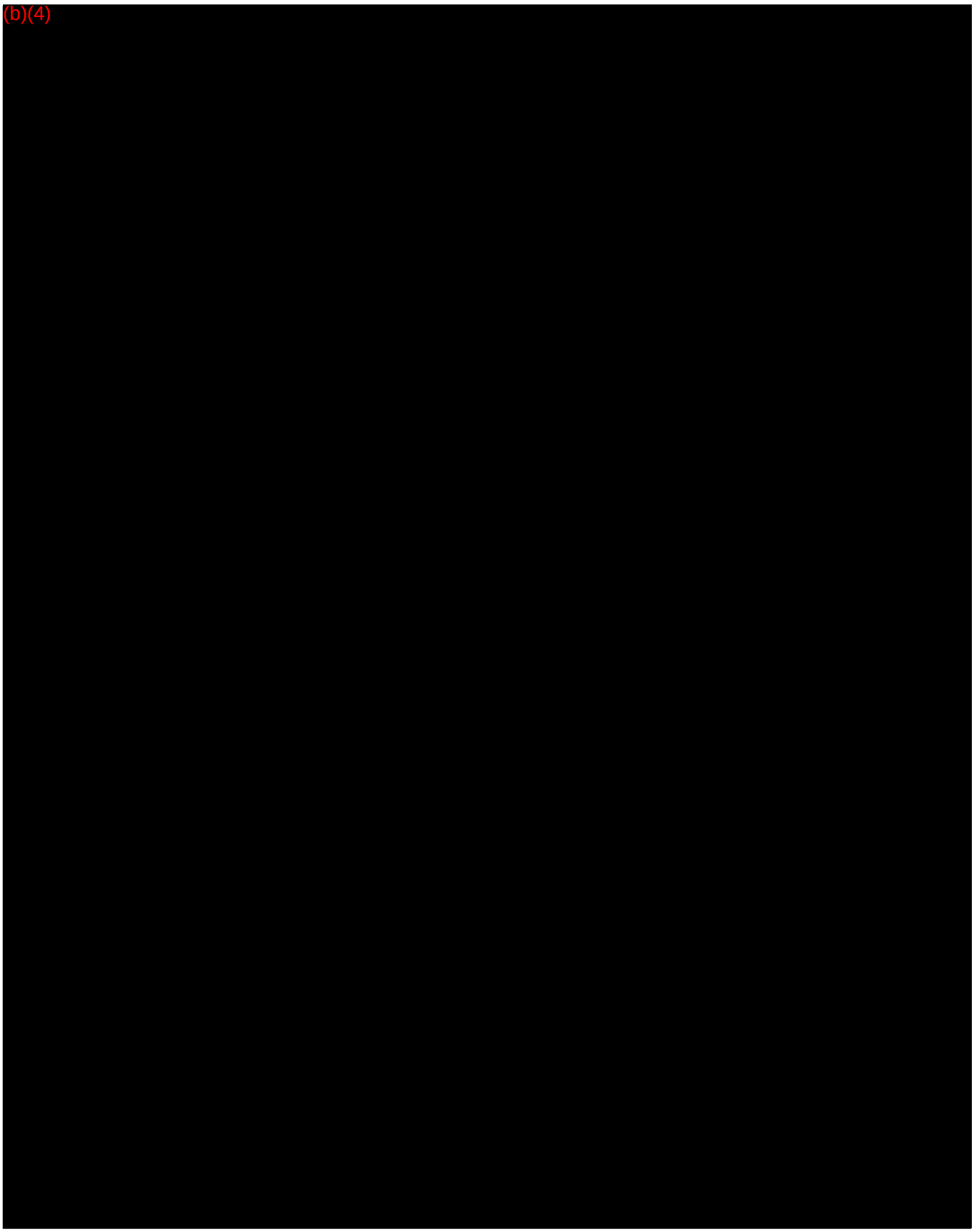

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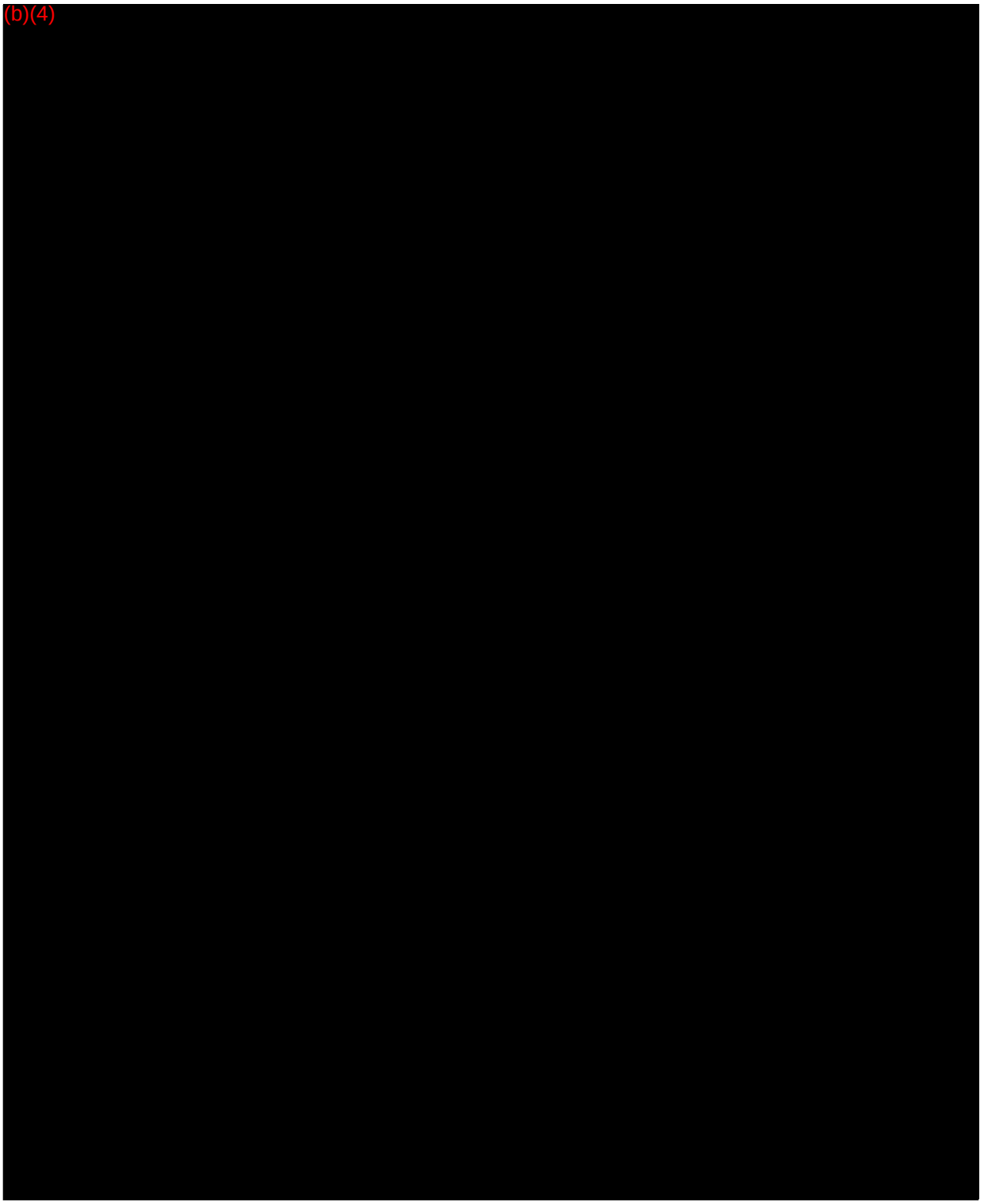

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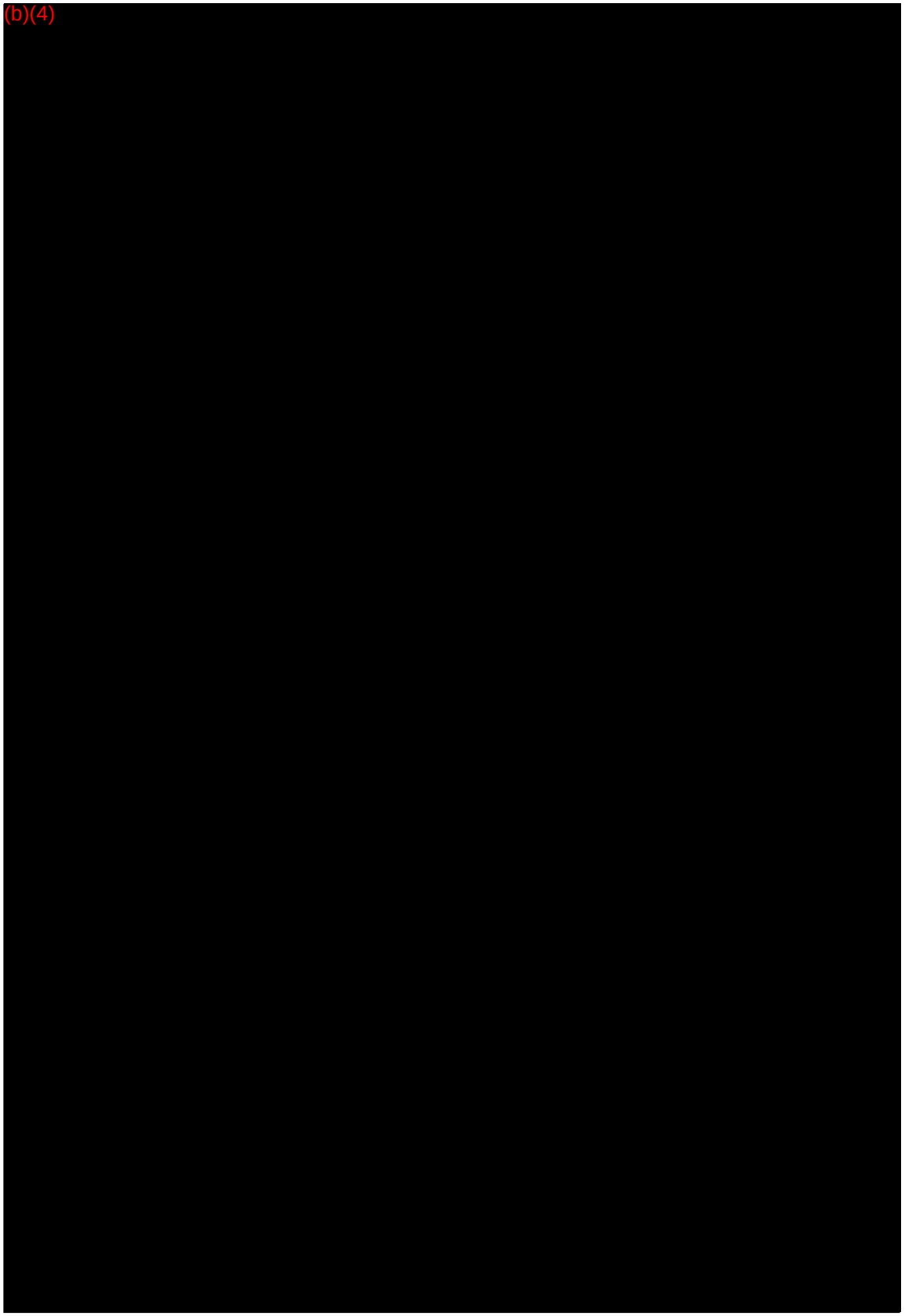

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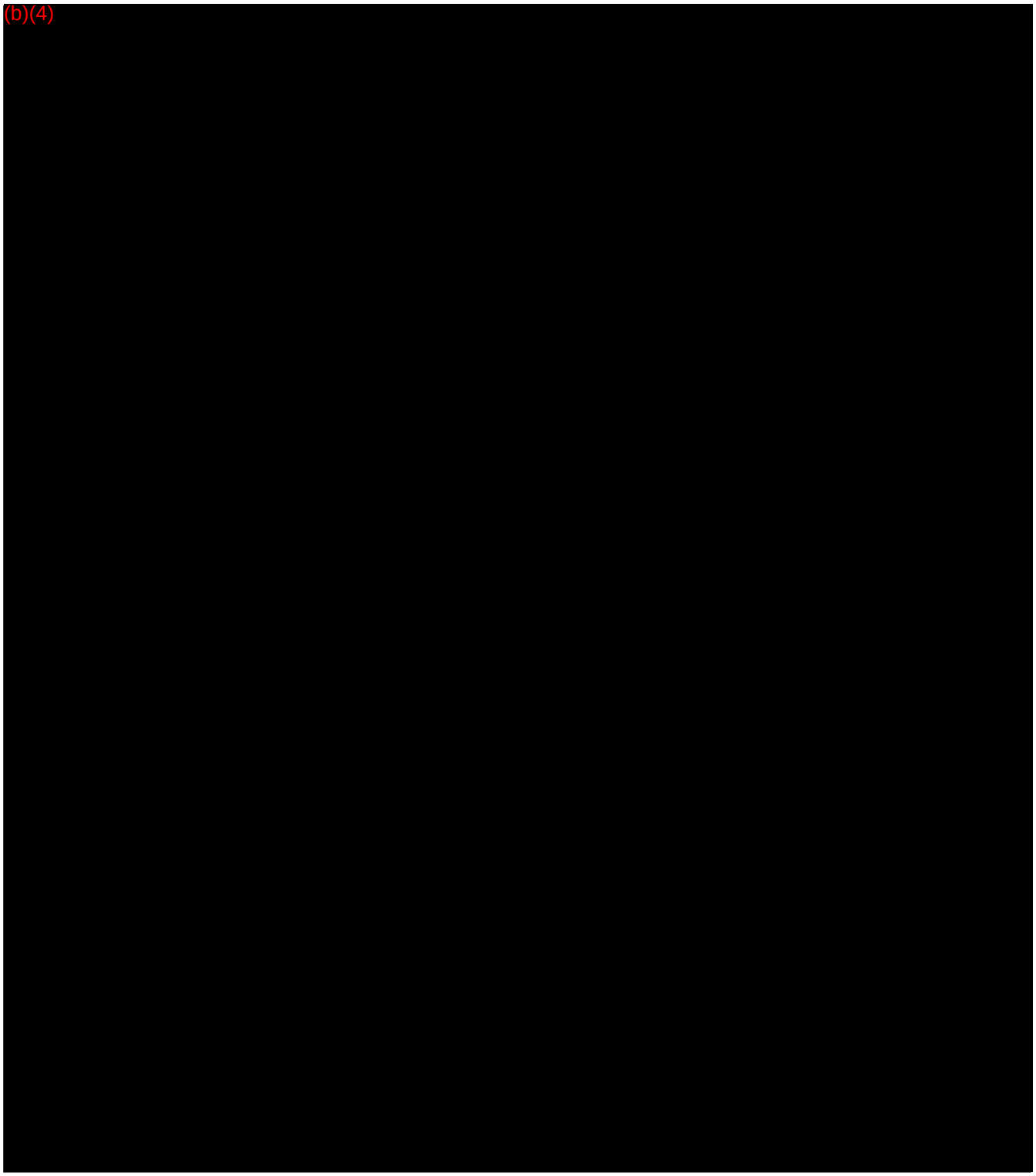

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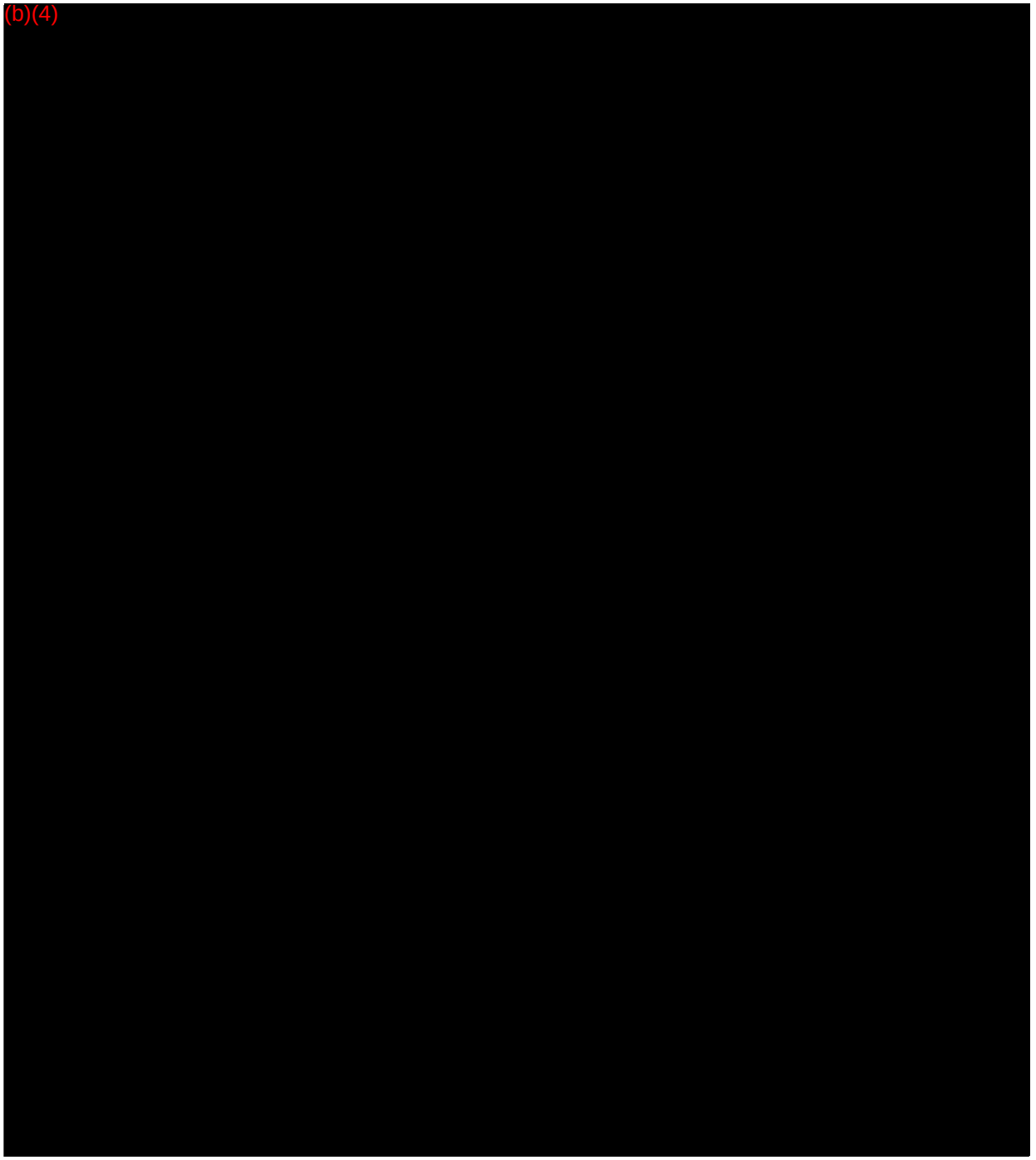

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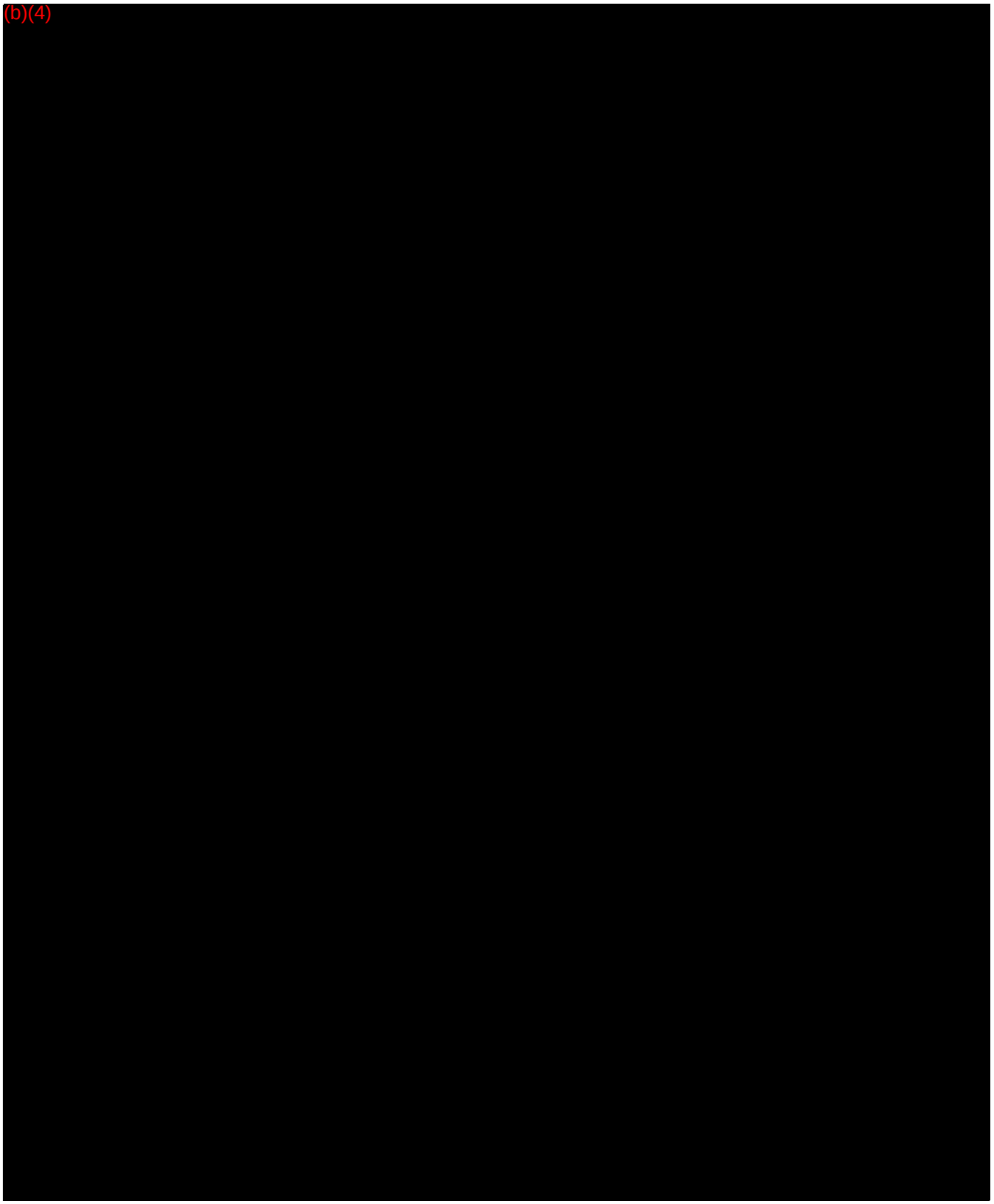

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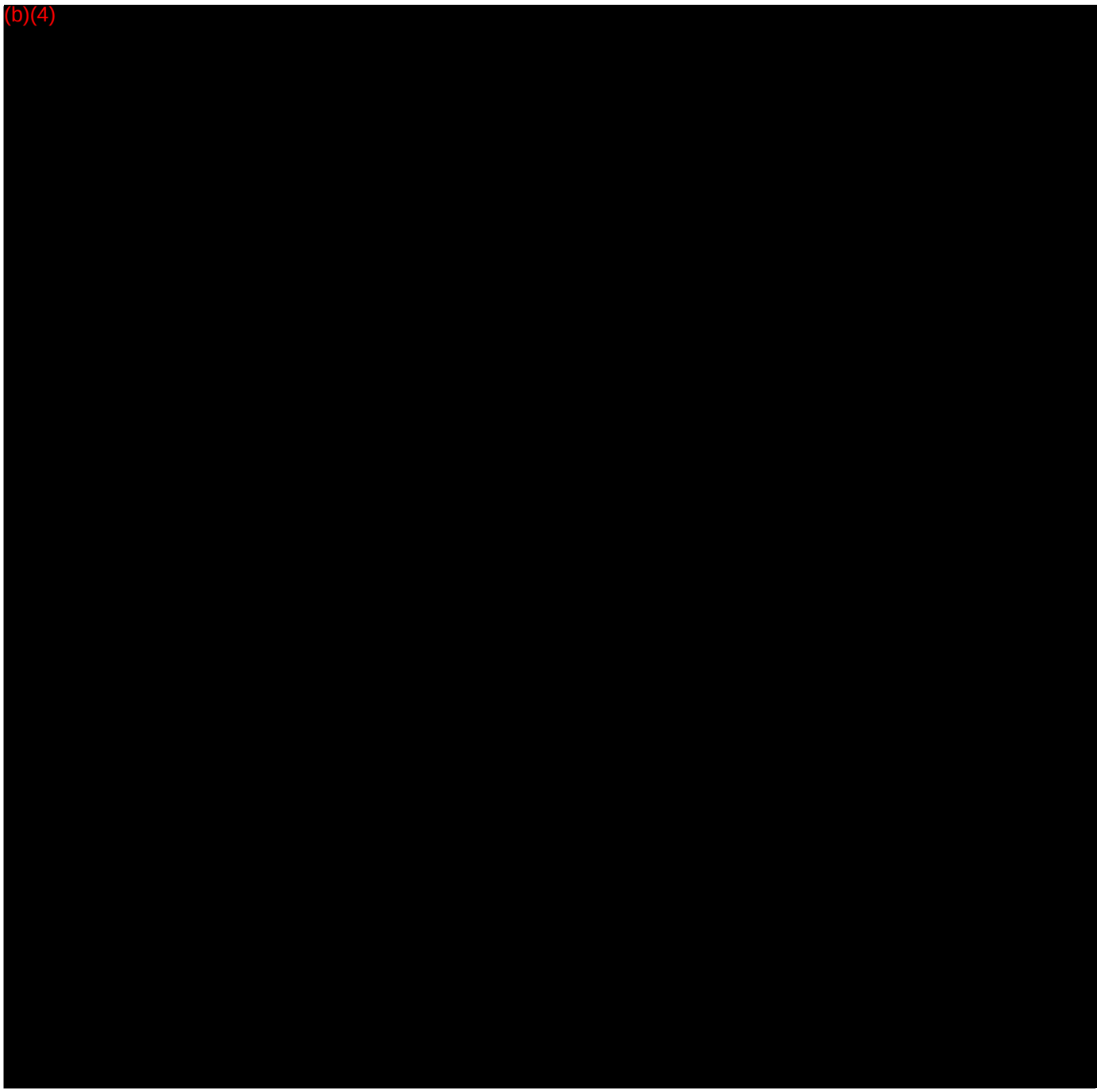

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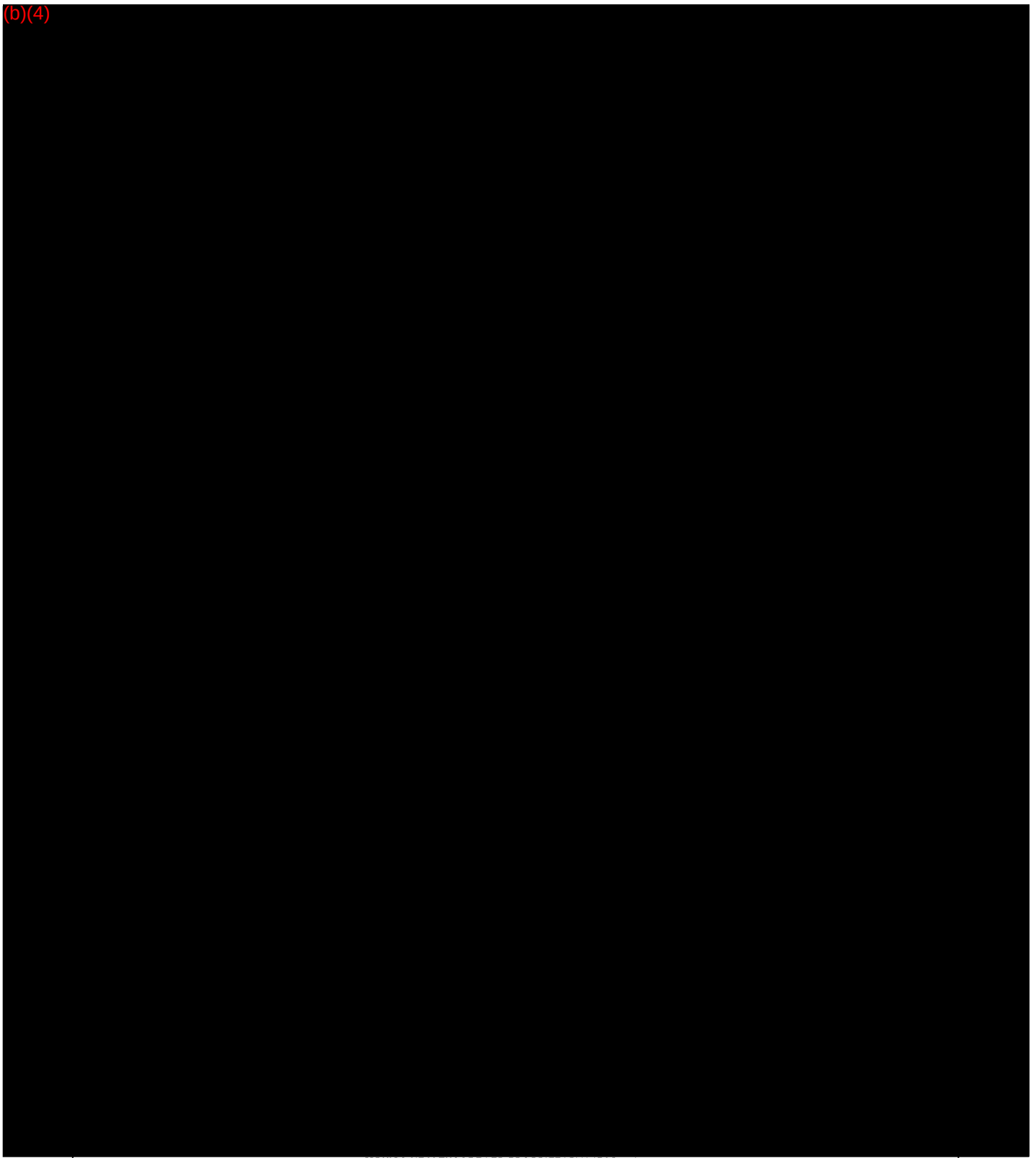

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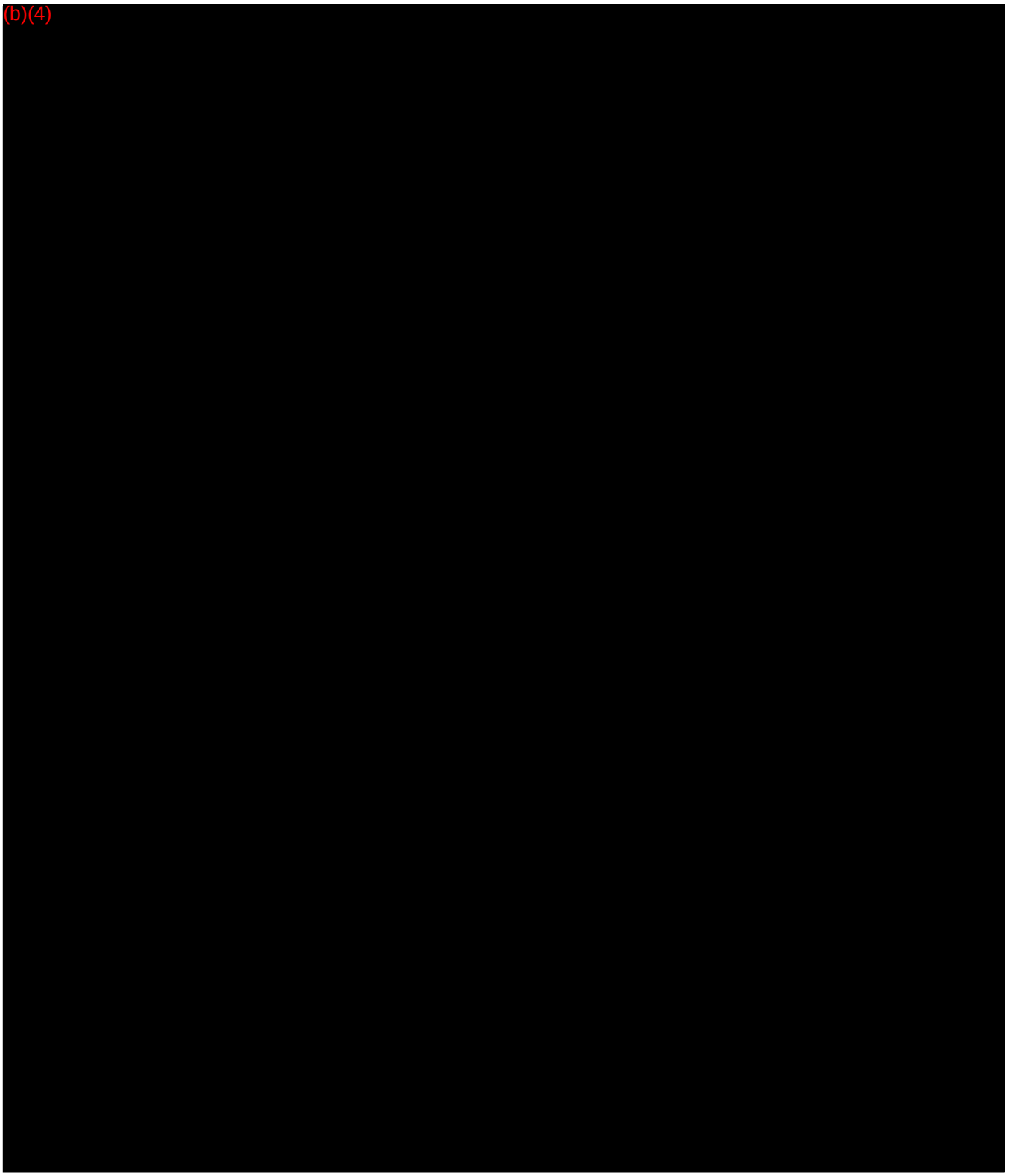

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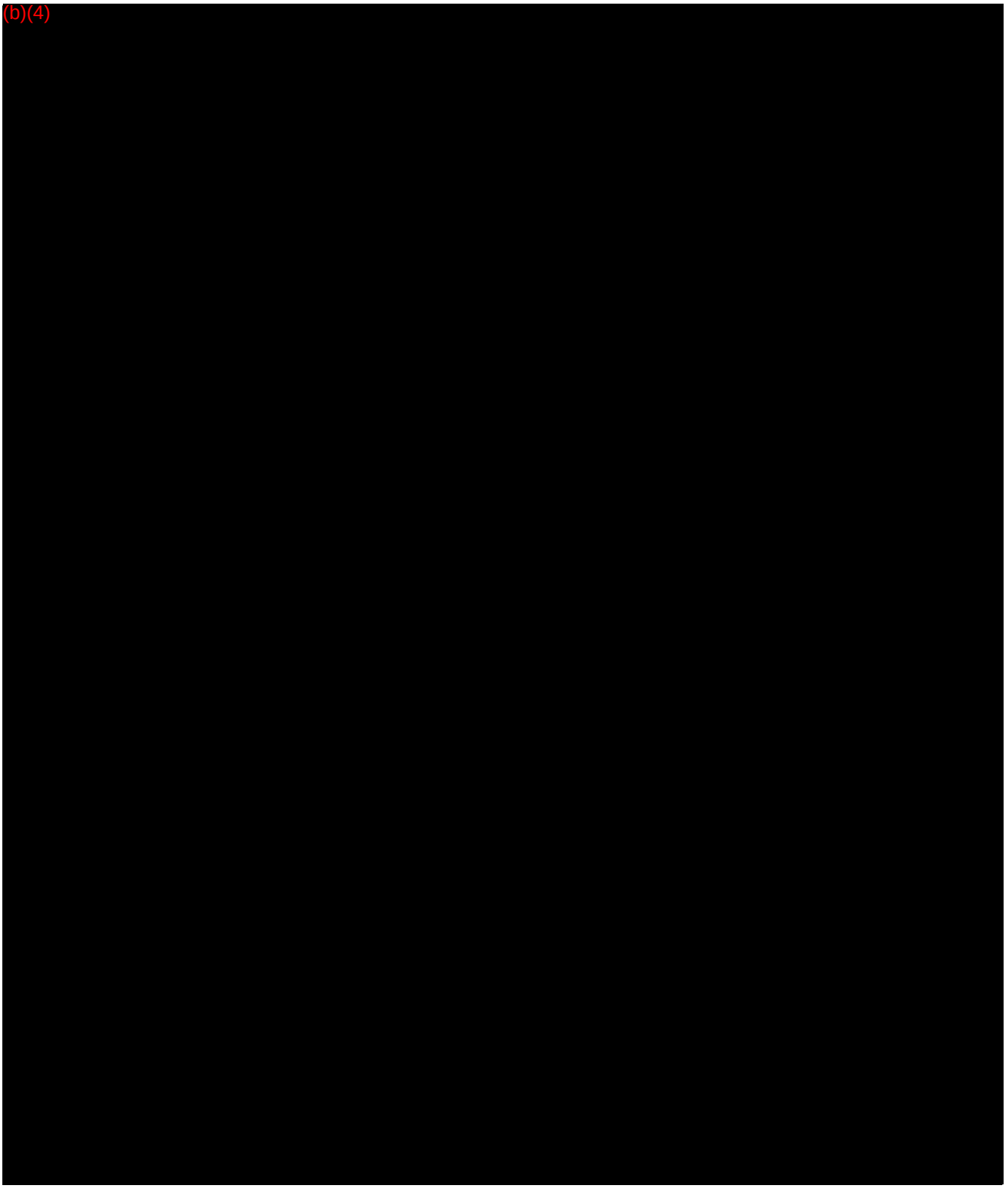

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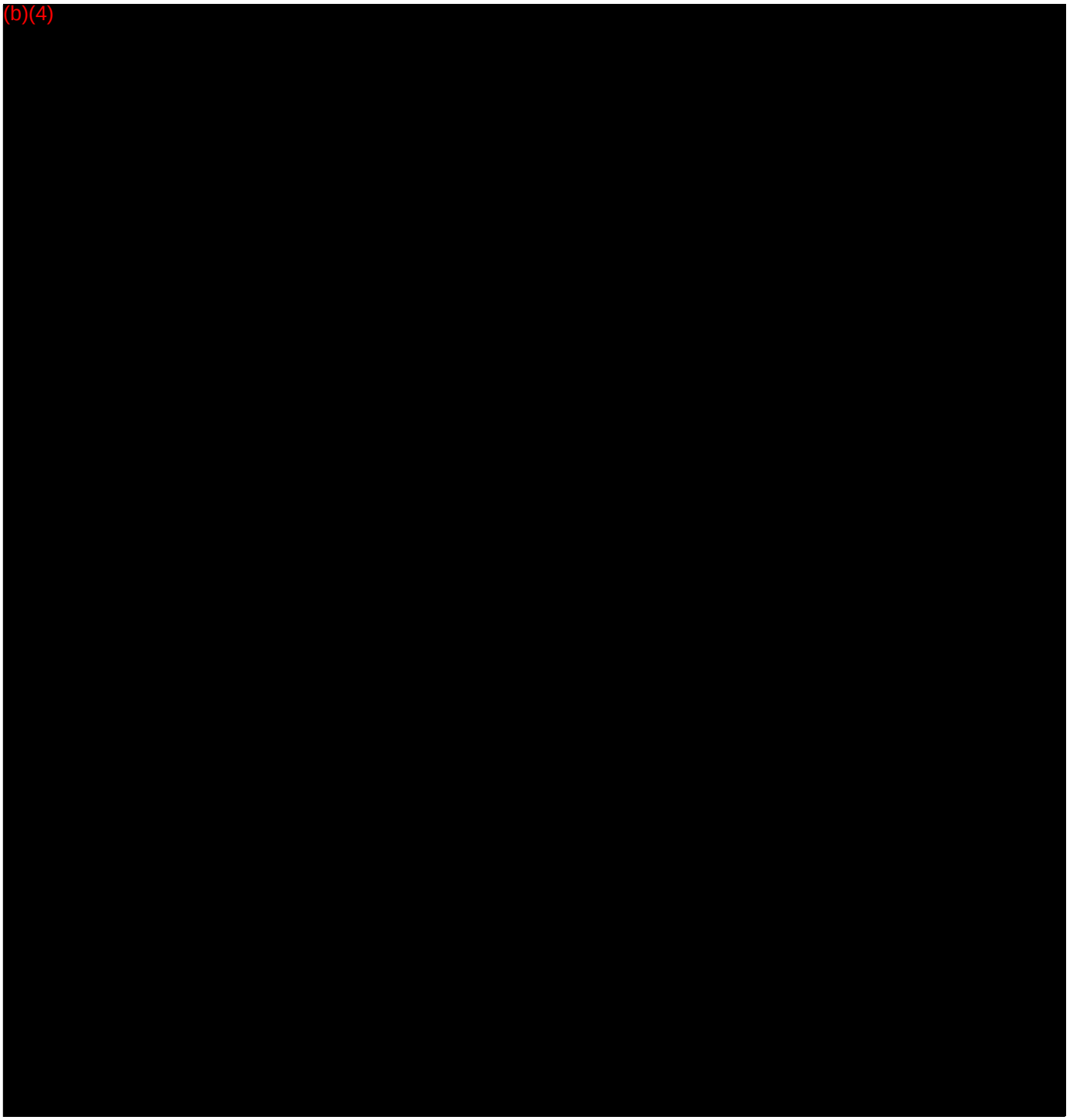

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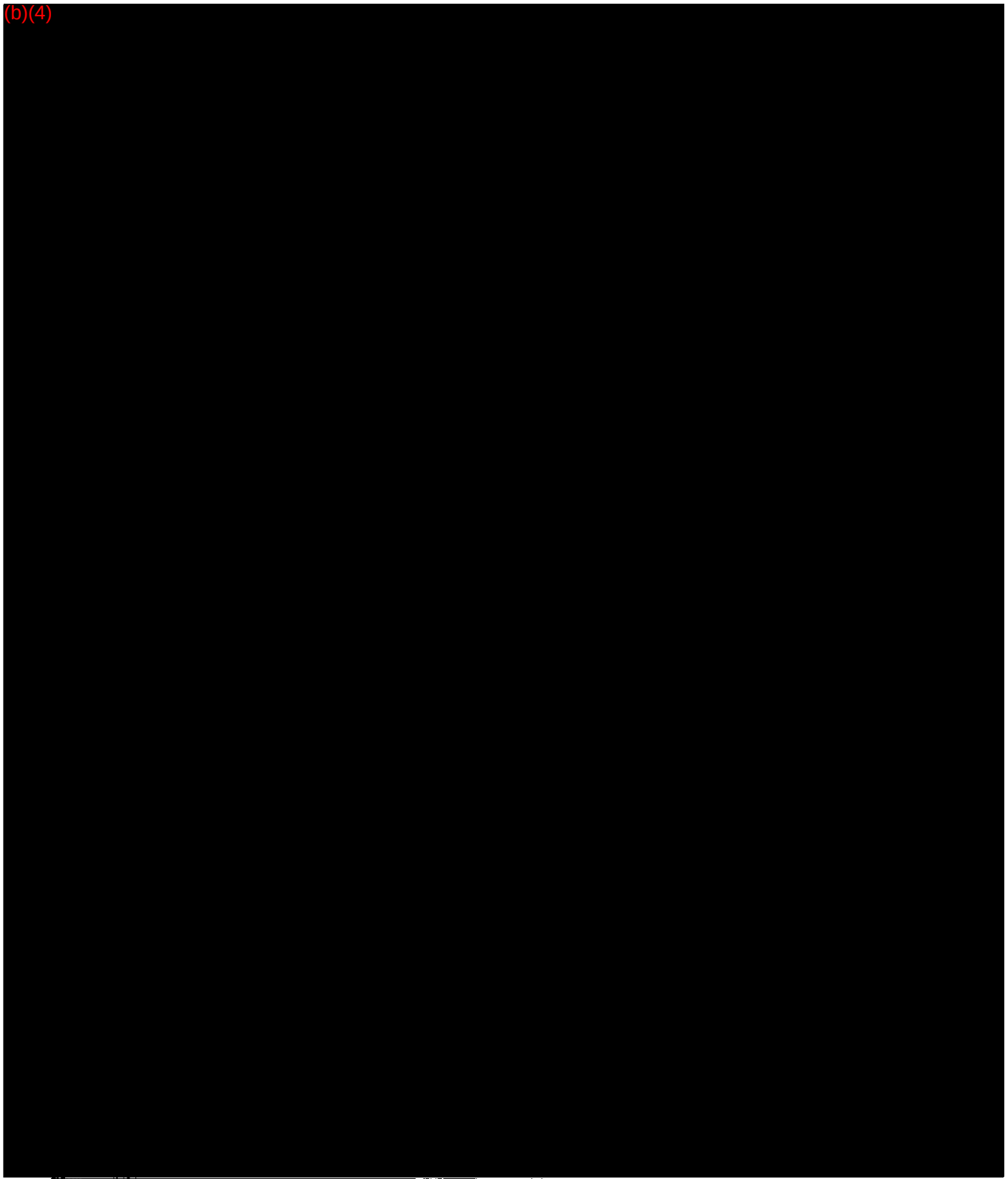

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BJS

Records processed under FOIA Request #2015-4103; Released by CDRH on 06-06-2016.

Product	AN24 Abdominal Fetal ECG recorder
Document name	Off-The-Shelf Software
Document type	**Technical File**

(b)(4) [redacted]

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1.1 DOCUMENT IDENTIFICATION 4

1.2 DOCUMENT SCOPE 4

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1 SCOPE

1.1 Document Identification

The document is identified as follows:

- ✓ Identification Number: 100-TF-035.
- ✓ Title: AN24 Abdominal Fetal ECG recorder – Off-The-Shelf Software.

1.2 Document Scope

The purpose of this document is to provide information about the OTS Software for the AN24 FECG recorder accordingly to [1]. The document describes the OTS software and provides hazard analysis and hazard mitigation of the OTS software.

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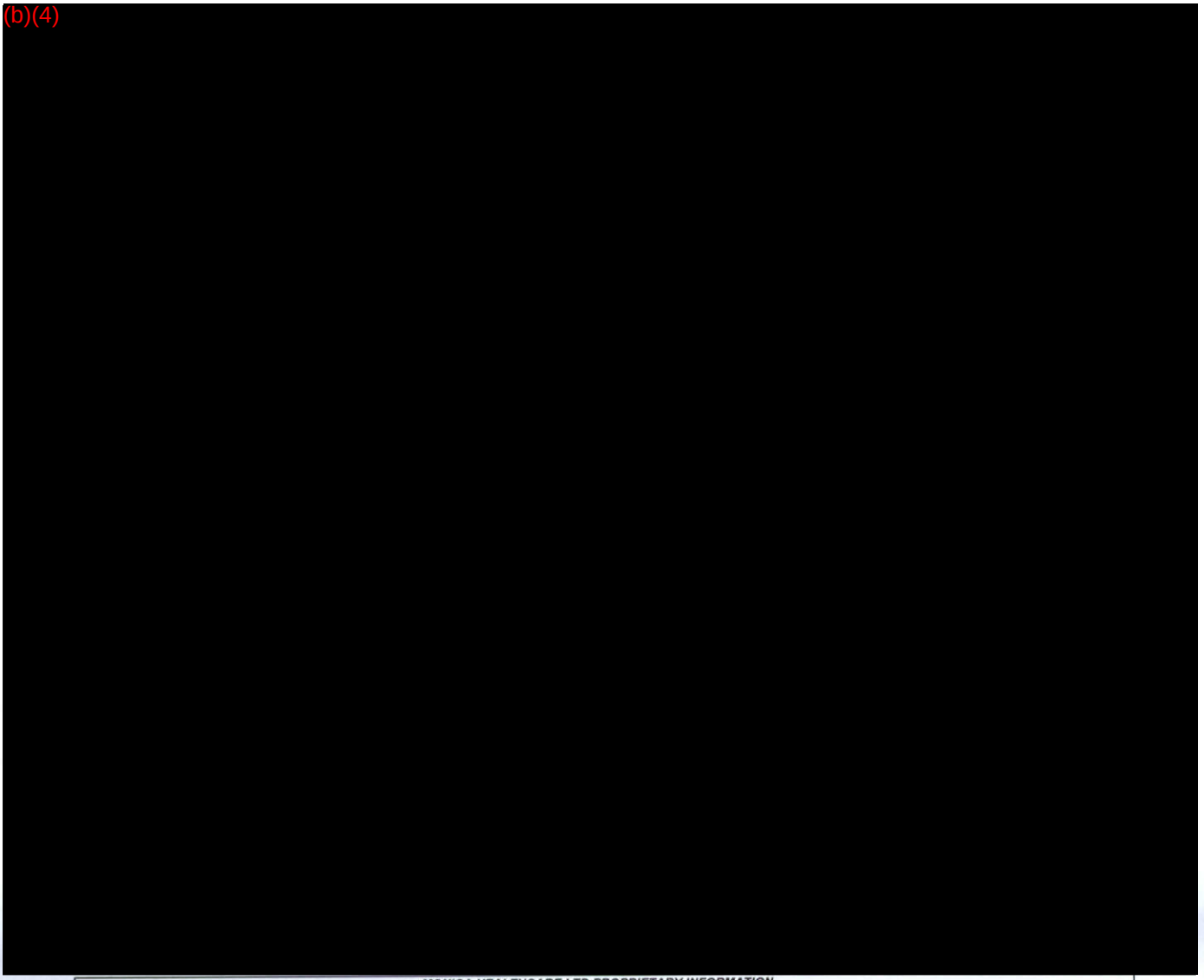

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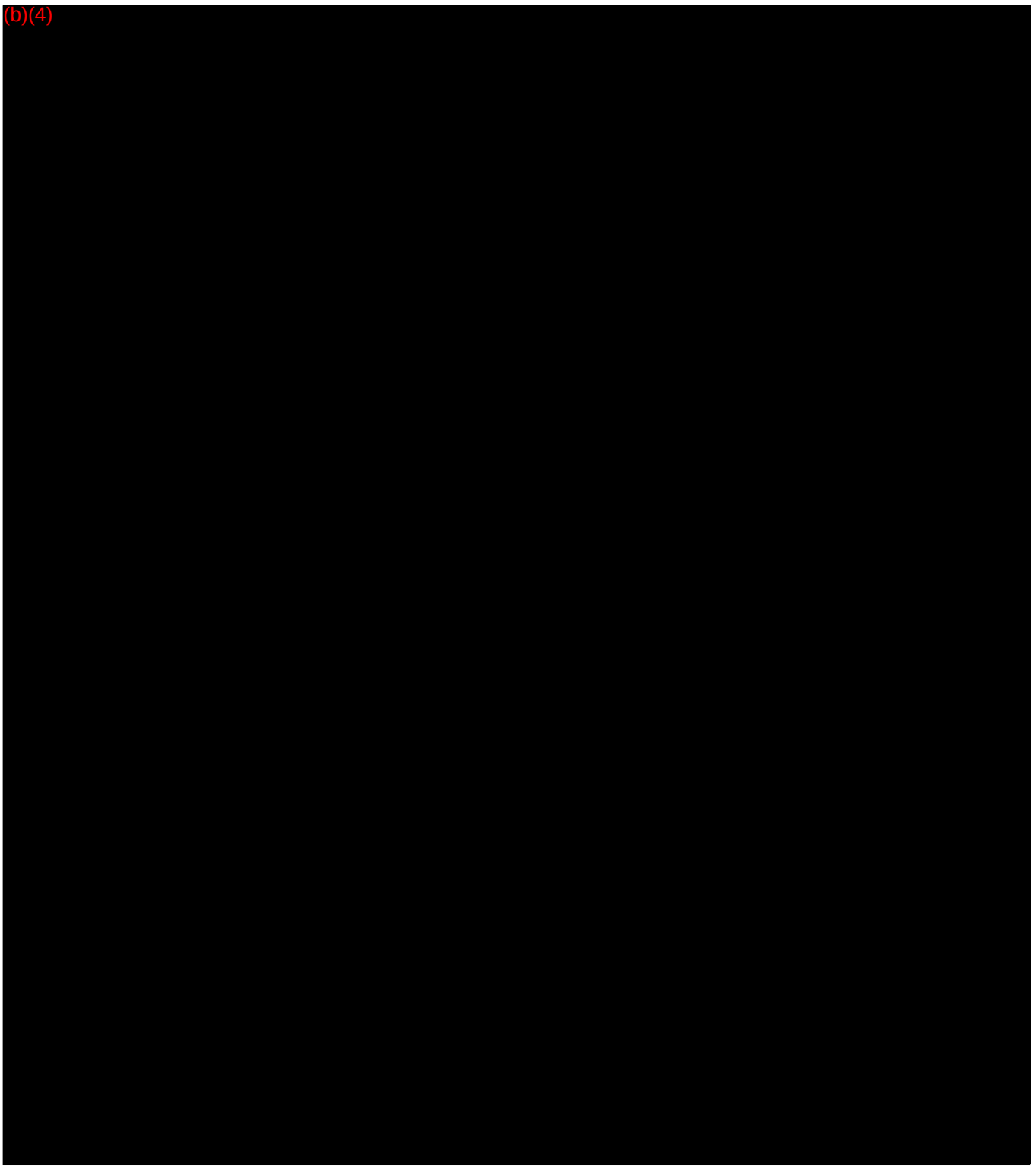

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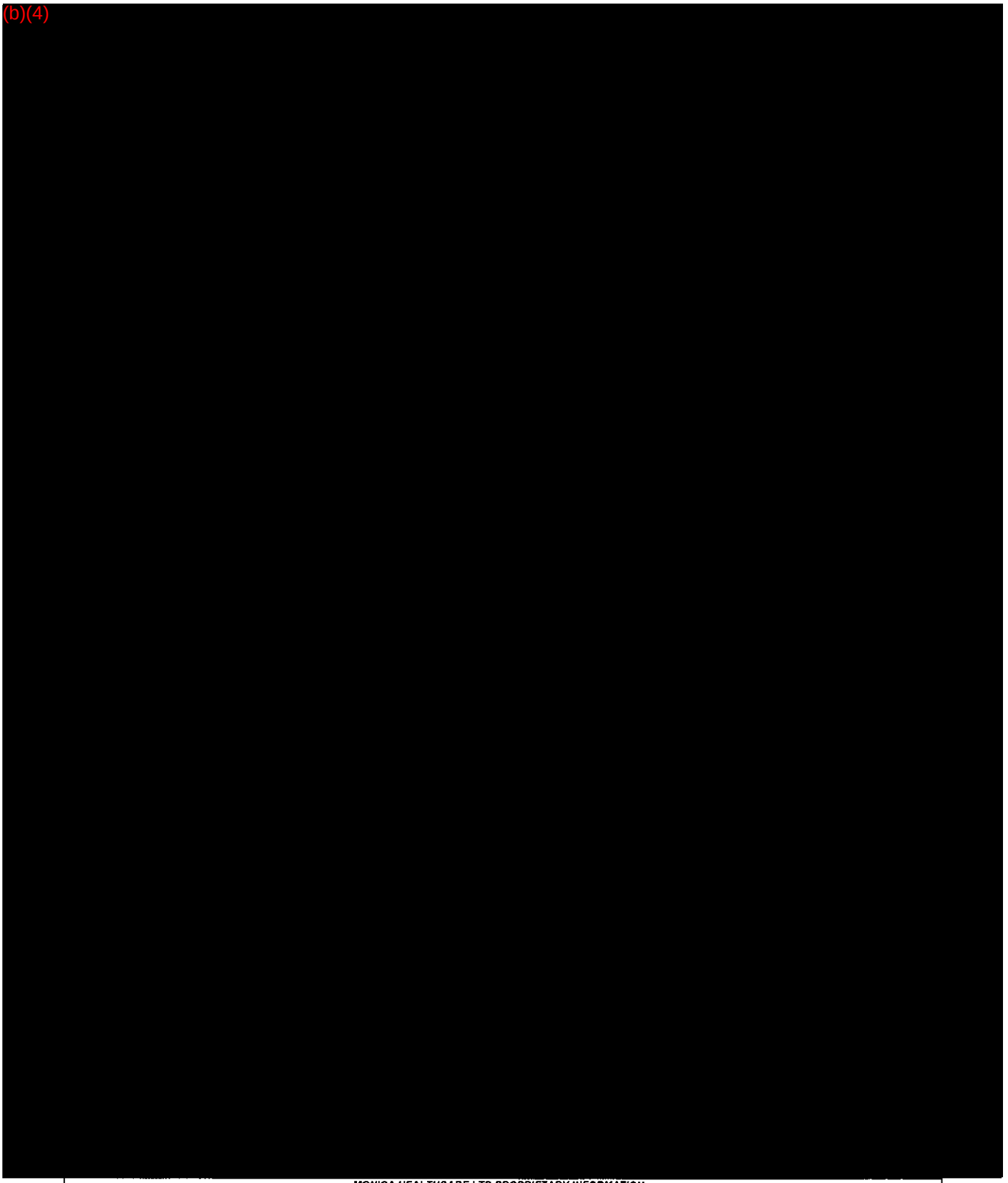

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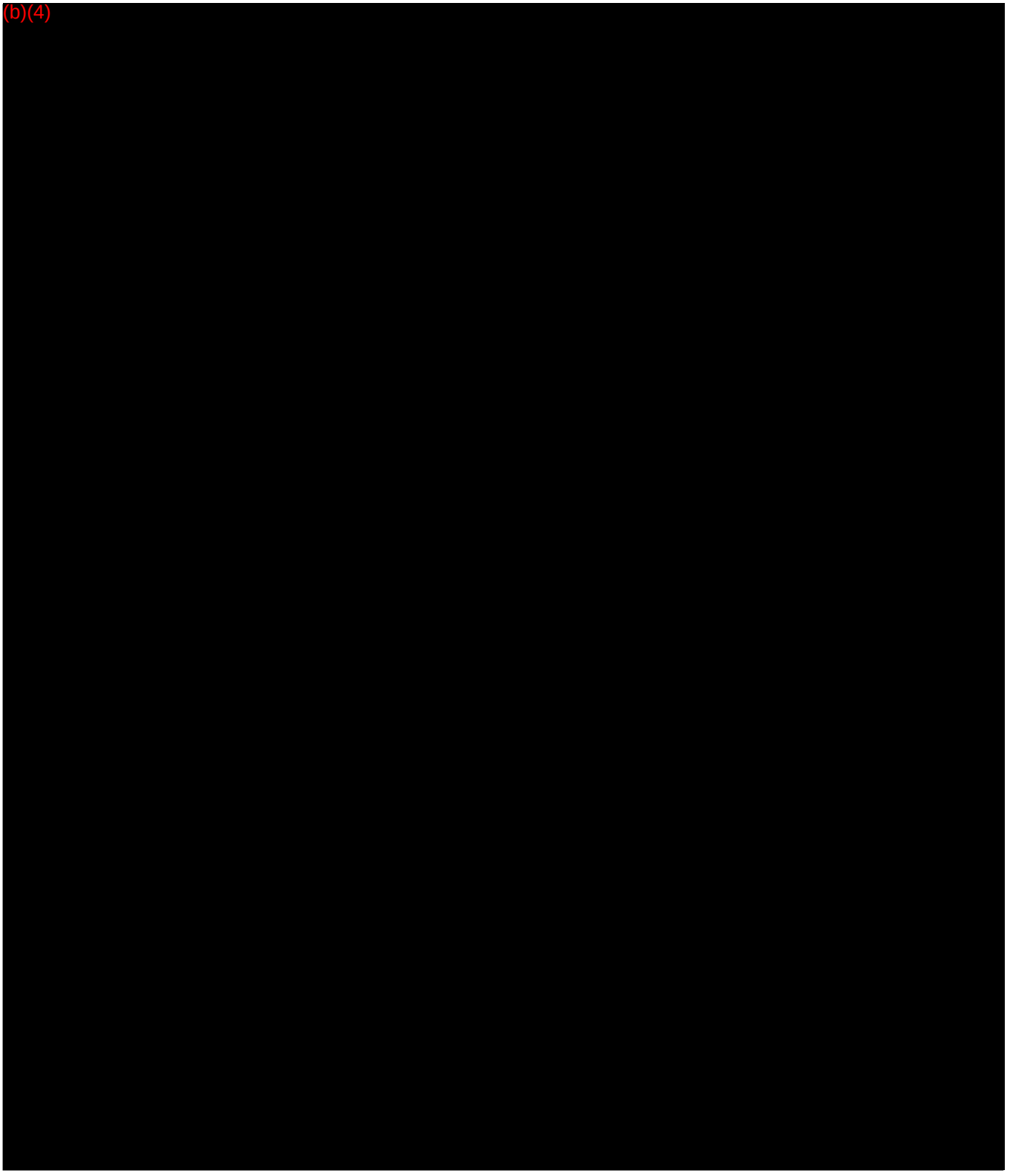

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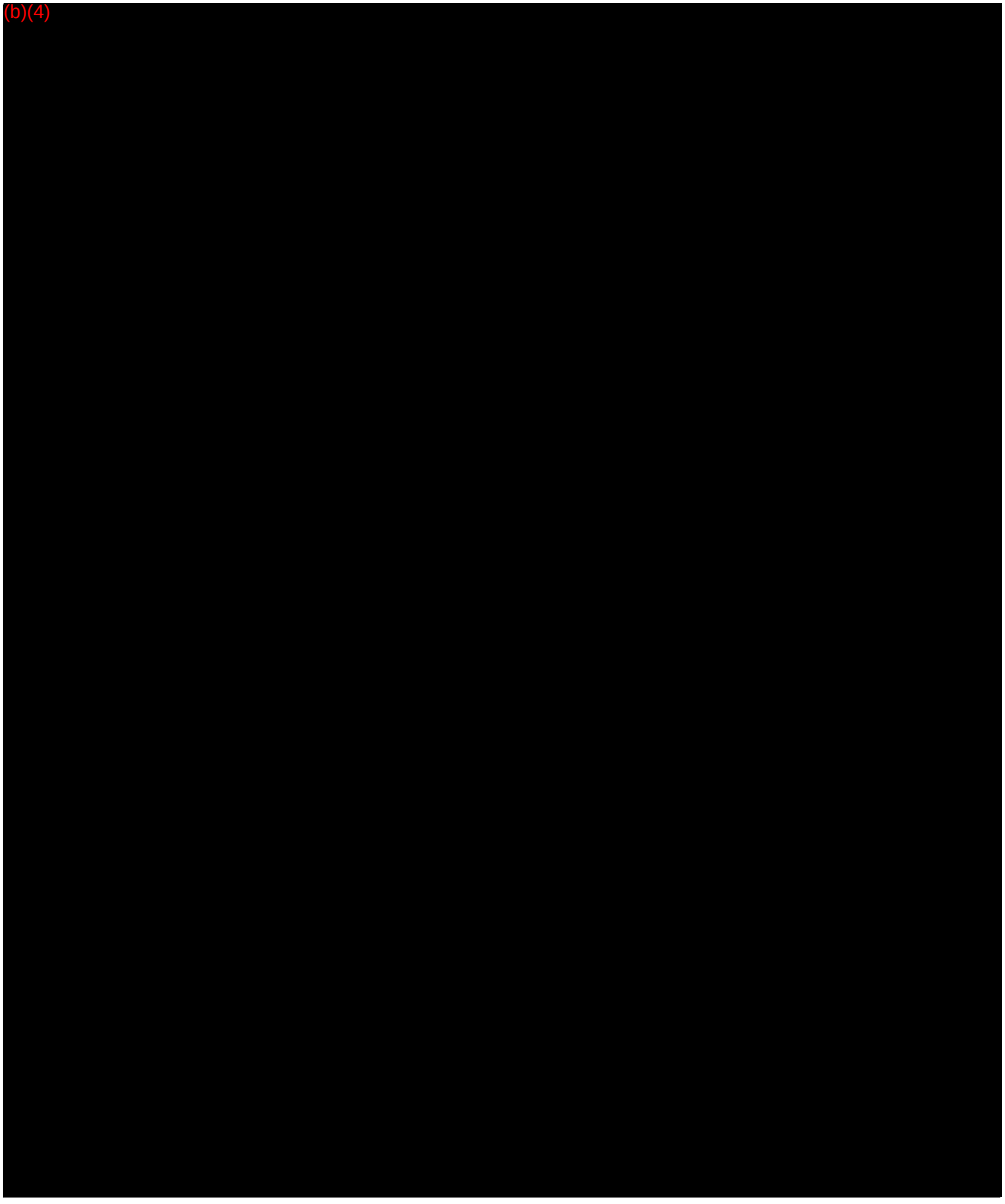

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Product	AN24 Abdominal FECG recorder
Document name	System Validation
Document type	**TECHNICAL FILE**
(b)(4) [redacted]	

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1.1 DOCUMENT IDENTIFICATION 4

1.2 DOCUMENT SCOPE 4

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1 SCOPE

1.1 Document Identification

This document corresponds to the system validation of the AN24 recorder and Monica VS software. The document is identified as follows:

- ✓ Identification Number: 100-TP-001.
- ✓ Title: AN24 Abdominal FECG recorder – System Validation

1.2 Document Scope

This document first describes the tests that will be performed to validate the system. The document also holds the example test report sheets.

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2 RELATED DOCUMENTS

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Product	AN24 Abdominal FECG recorder
Document name	Firmware Validation
Document type	**TECHNICAL FILE**

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Revision of this document supersedes previous revision

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1 SCOPE

1.1 Document Identification

This document corresponds to the firmware validation of the AN24 recorder. The document is identified as follows:

- ✓ Identification Number: 100-TP-002.
- ✓ Title: AN24 Abdominal FECG recorder – Firmware Validation

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Product	AN24 Abdominal FECG recorder
Document name	Hardware Validation
Document type	**TECHNICAL FILE**

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Product	AN24 Abdominal FECG recorder
Document name	Monica (b)(4) software Validation
Document type	**TECHNICAL FILE**
(b)(4)	[redacted]

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Product	AN24 Abdominal FECG recorder
Document name	System Validation Report
Document type	**TECHNICAL FILE**
(b)(4) [redacted]	

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Records processed under FOIA Request #2015-4103; Released by CDRH on 06-06-2016.

Product	AN24 Abdominal FECG recorder
Document name	Hardware Validation
Document type	**TECHNICAL FILE**

(b)(4) [redacted]

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Product	AN24 Abdominal FECG recorder
Document name	Monica (b)(4) Software Validation Report
Document type	**TECHNICAL FILE**
(b)(4)	[redacted]

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- Letter from Wayne Cohen

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(b)(4) Report/Study

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

Mr. Ian How
Regulatory Affairs Manager
Monica Healthcare
Biocity
Pennyfoot Street
Nottingham
United Kingdom NG1 1GF

FEB - 3 2011

Re: K101801
Trade Name: Monica AN24
Regulation Number: 21 CFR §884.2740
Regulation Name: Perinatal monitoring system and accessories
Regulatory Class: II
Product Code: HGM, OSP
Dated: December 1, 2010
Received: December 3, 2010

Dear Mr. How:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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); medical device reporting (reporting of medical device-related

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adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Herbert P. Lerner, M.D., Director (Acting)
Division of Reproductive, Gastro-Renal
and Urological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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

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Indications for Use Statement

510(k) Number (if known): K101801

Device Name: AN24

Indications For Use:

The Monica AN24 is an intrapartum maternal-fetal monitor that non-invasively measures and displays fetal heart rate (FHR) and uterine activity (UA). The AN24 acquires and displays the FHR tracing from abdominal surface electrodes that pick up the fetal ECG (fECG) signal. Using the same surface electrodes, the AN24 also acquires and displays the UA tracing from the uterine electromyography (EMG) signal. The AN24 is indicated for use on women who are at term (>36 completed weeks), in labor, with singleton pregnancies, using surface electrodes on the maternal abdomen.

The AN24 maternal-fetal monitor is intended for use by healthcare professionals in a clinical setting.

Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Gastro-Renal, and Urological Devices
510(k) Number K101801

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Regards

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NG1 1GF
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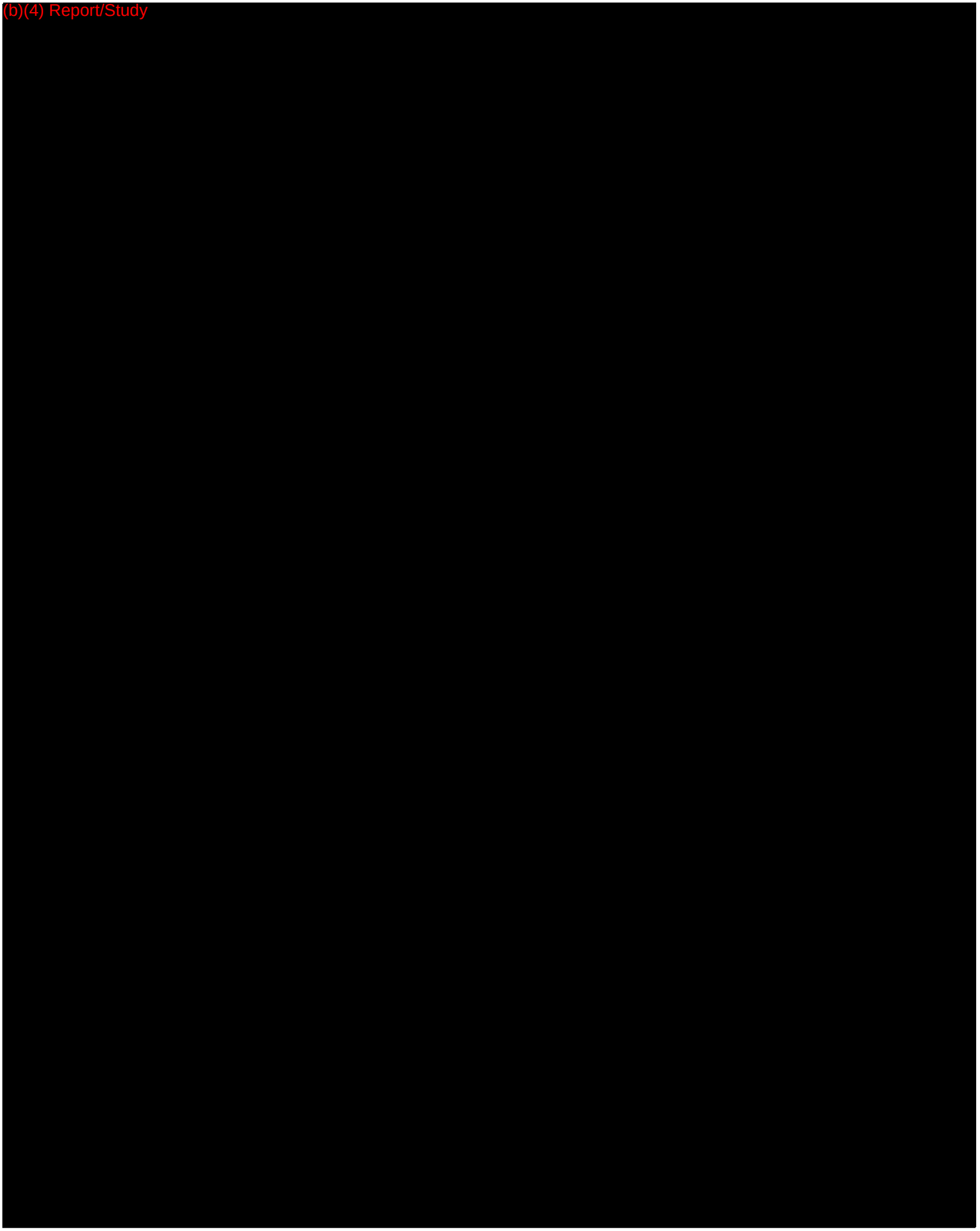

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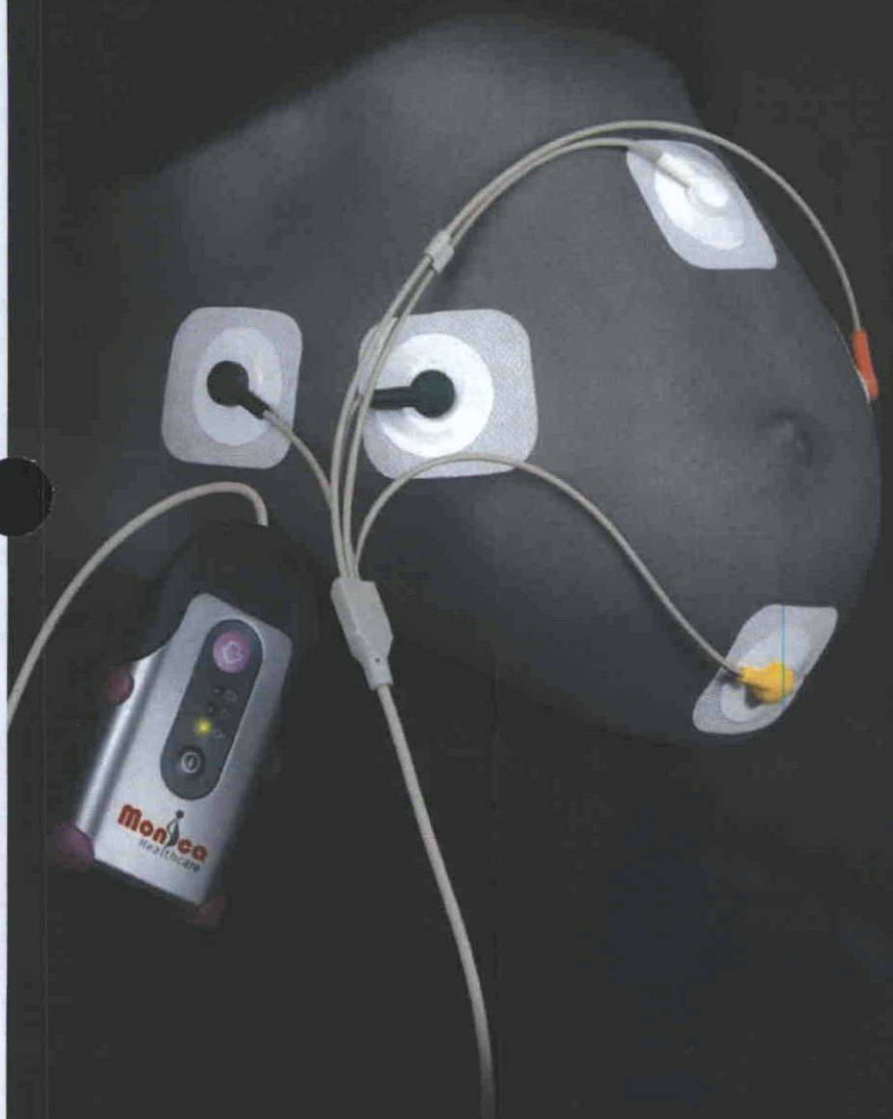

Monica AN24™

Reference Operator Manual

100-TF-006 Revision I

CE 0843

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US law restricts this device to sale by, or on the order of, a physician.

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INDICATIONS FOR USE:

The Monica AN24 is an intrapartum maternal-fetal monitor that non-invasively measures and displays fetal heart rate (FHR) and uterine activity (UA). The AN24 acquires and displays the FHR tracing from abdominal surface electrodes that pick up the fetal ECG (fECG) signal. Using the same surface electrodes, the AN24 also acquires and displays the UA tracing from the uterine electromyography (EMG) signal. The AN24 is indicated for use on women who are at term (>36 completed weeks), in labor, with singleton pregnancies, using surface electrodes on the maternal abdomen.

The AN24 maternal-fetal monitor is intended for use by healthcare professionals in a clinical setting.

CONTRAINDICATIONS:

The Monica AN24 is contraindicated for use in preterm gestation (≤36 completed weeks). The Monica AN 24 may display deflections from baseline that do not represent uterine contractions. These deflections from baseline may represent electrical activity in the myometrium that is not sufficiently organized to cause the uterine smooth muscle to contract. In the context of a preterm pregnancy, clinical misinterpretation of the uterine tracing may lead to unnecessary intervention, such as tocolysis, diagnostic procedures, and/or preterm delivery.

Clinical Warnings

WARNING: The Monica AN24 does not replace observation and evaluation of the mother and fetus at regular intervals, by a qualified care provider, who will make diagnoses and decide on treatments and interventions. Clinical assessment of the monitor display must be combined with knowledge of patient history and risk factors to properly care for the mother and fetus.

WARNING: The safety and effectiveness of uterine electromyography for monitoring uterine activity have NOT been established for the following patient populations:

- Preterm gestation (i.e., ≤ 36 weeks completed gestation)
- Antepartum (i.e., at term, but not in labor)
- Multiple gestations

WARNING: A labor monitor is intended for use by clinical professionals who are trained in the medical procedures, practices, and terminology required to monitor obstetrical patients. The monitor is only one clinical indicator of labor activity. The monitor is designed to assist the clinical staff in assessing the status of the patient.

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

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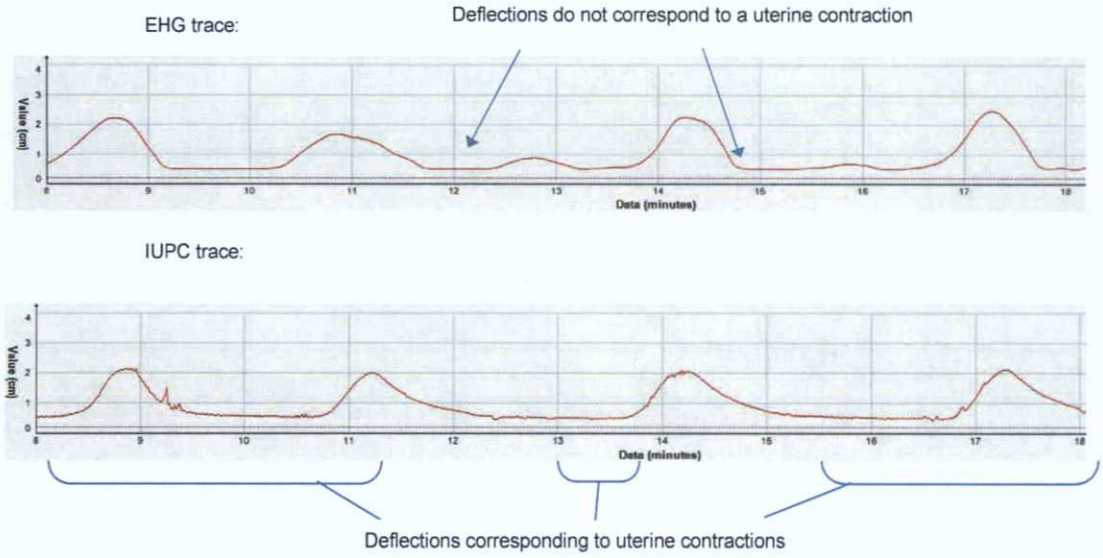
EMG Activity, Deflections Above Baseline: Potential Problems with Clinical Interpretation

WARNING: The Monica AN24 may display deflections from baseline that do not represent uterine contractions. These deflections from baseline may represent electrical activity in the myometrium that is not sufficiently organized to cause the uterine smooth muscle to contract. When this occurs, the "false contraction" often does not attain the amplitude of true uterine contractions. If the interpretation of uterine contractile pattern(s) is uncertain, another modality to monitor uterine contractions should be considered and clinical management of the patient adjusted appropriately.

WARNING: The Monica AN24 displays uterine contractions by measuring electrical activity as opposed to tocodynamometers which display uterine activity as measured by pressure from a strain gauge. Occasionally, low amplitude electrical activity insufficient to cause a contraction detected by a strain gauge is displayed as a deflection above baseline on the Monica AN24 tracing. These deflections from baseline may represent electrical activity in myometrium that is not sufficiently organized to cause the uterine smooth muscle to contract. Thus, caution should be used in interpreting as contractions deflections from baseline that have relatively lower amplitude compared to contractions characteristic of the overall uterine activity pattern.

For example, in the following sample Monica AN24 tracing, there are deflections above baseline in the Monica AN24 tracing that do not correspond to uterine contractions in the IUPC tracing (e.g., deflections identified by arrows).



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WARNING: When assessing FHR decelarations as early, late or variable do not rely on a single deflection above baseline (especially an atypical appearing deflection) as "false" contractions may occur.

Safety

WARNING: The Monica AN24™ is splash proof but is not designed for submersion in water. Patients must be warned not to immerse the AN24™ or any of its accessories in water, or to take a shower or bath whilst being monitored.

WARNING: The Monica AN24™ is not explosion-proof and must not be used in the presence of flammable anaesthetics.

WARNING: SHOCK HAZARD — Do not attempt to connect the battery charger with wet hands. Make certain that your hands are clean and dry before touching a power lead or plug.

WARNING: Use only the electrode lead cables supplied with the device. Use of any other cables may result in out-of-specification performance and possible safety hazards.

WARNING: Unplug the AN24™ from the AC power source (battery charger) and detach all accessories before cleaning. Do not immerse the unit in water or allow liquids to enter the case.

WARNING: Examine the AN24™ and any accessories periodically to ensure that the leads, connectors and the device itself do not have visible evidence of damage that may affect patient safety or monitoring performance. The recommended inspection interval is once per week or less. Do not use the device if there is any visible sign of damage.

WARNING: The protective silicone rubber cover must be used during Labor and Delivery. Not using the protective silicone rubber cover could result in the ingress of contaminated blood and other fluids into the Monica AN24 case.

WARNING: Only the Battery Charger and mains plug supplied with the Monica AN24™, or its equivalent, is approved for use with the AN24™.

WARNING: Do not attempt to service the Monica AN24™. Only Monica approved and qualified service personnel should attempt any necessary internal servicing.

WARNING: The Monica AN24™ is not specified or intended for operation in conjunction with any other type of monitoring equipment except the specific devices that have been identified for use in this Operator's Manual.

WARNING: Since the Monica AN24™ detects the electrical signals generated from the fetal heart, if other equipment which introduces electrical energy in to the mother is used (e.g. TENS machine, diathermy, impedance meter), then the AN24™ will not be able to detect the fetal heart rate.

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WARNING: Do not operate the Monica AN24™ if it fails to pass the power on self-test procedure, see Section 4.

WARNING: Any unexpected data generated by the Monica AN24™ must result in further examination of the mother and fetus in a hospital environment. The data generated by the AN24™ must be backed up by alternative monitoring technologies.

WARNING: For Electromagnetic Compatibility (EMC). Use of accessories, electrodes and leads other than those specified in this manual may result in increased EMC emissions and/or decreased immunity of the Monica AN24™ to other electrical equipment.

WARNING: For Electromagnetic Compatibility (EMC). The Monica AN24™ has been tested to IEC EN 60601-1-2 for EMC. However, the Monica AN24™ picks up very small electrophysiological signals and so occasionally if other electrical equipment is in the immediate vicinity of monitoring the AN24™ may produce spurious results. The operator should ensure that any such interfering electrical equipment is not in close proximity to the AN24™ during monitoring.

WARNING: The lithium polymer battery pack used within this device has the potential for fire or burning. Do not disassemble, crush, heat or burn.

WARNING: The lithium polymer battery pack cannot be replaced by the user. Replacement may only be made with the battery pack specified by Monica Healthcare, and replacement can only be carried out by Monica Healthcare. Fire or burning may occur if the customer uses a battery pack other than specified by Monica Healthcare.

CAUTION: Keep the operating environment free of dust, vibrations, corrosive, or flammable materials, and extremes of temperature and humidity. The AN24™ and all lead connectors should be kept clean and free of electrode gel and other substances.

CAUTION: Do not operate the unit if it is damp or wet because of condensation or spills. Avoid using the equipment immediately after moving it from a cold environment to a warm, humid location.

CAUTION: Never use sharp or pointed objects to operate the two front-panel membrane switches.

CAUTION: General-purpose personal computers and modems are not designed to meet the electrical safety requirements of medical devices.

CAUTION: Do not autoclave the AN24™ or any accessories. Follow cleaning and disinfection instructions in Section 6 - Cleaning and Maintenance

CAUTION: Do not immerse AN24™, connector or leads in liquid. When using solutions, use sterile/clean wipes to avoid pouring fluids directly on to the AN24™ and connector. Follow cleaning and disinfection instructions in Section 6 - Cleaning and Maintenance

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connector. Follow cleaning and disinfection instructions in Section 6 - Cleaning and Maintenance

CAUTION: The water temperature must not exceed 40°C (104°F). Do not use chlorine bleach.

CAUTION: Take extra care when cleaning the membrane switches and LED surfaces, which are sensitive to rough handling.

CAUTION: Do not autoclave. Do not gas sterilize.

CAUTION: Only the Battery Charger supplied with the device is approved for use in recharging the internal batteries.

CAUTION: The Monica AN24™ is not specified or intended for operation during the use of defibrillators or during defibrillator discharge.

CAUTION: The Monica AN24™ is not specified or intended for operation in the presence of electrosurgical equipment.

CAUTION: There are minimum signal amplitudes under which the Monica AN24™ will not be able to measure physiological signals.

Declaration

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This Operator's Manual is intended for trained medical personnel (including obstetricians, midwives, nurses, and physicians) who are familiar with obstetric procedures. Keep this operator's manual with the unit for use by the operator.

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

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Conventions Used in This Operator Manual

Warning: A warning alerts you to a potential serious outcome, adverse event, or safety hazard. Failure to observe a warning may result in death or serious injury to the user or patient.

Caution: A caution alerts you to situations where special care is necessary for the safe and effective use of the product. Failure to observe a caution may result in minor or moderate personal injury or damage to the product or other property, and possibly in a remote risk of more serious injury.

On your monitor, this sign indicates that there is detailed information in this book, which you must read before proceeding with your task.

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Numbers in brackets ( ) refer to the key number in Figure 1 or the index of Table 1

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

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Section 1 - Unpacking the AN24™

Table 1 - The Monica AN24™ case should contain the following items

	Description
10	Monica AN24™ Device [Item1, Figure 1]
11	Electrode lead connector [Item 2, Figure 1]
12	AN24™ neck strap
13	Battery Charger and lead
14	AN24™ monitor connector/computer USB cable
16	10 Electrodes
17	Roll of abrasive skin tape
18	AN24™ protective cover
20	Quick Start Guide
	Skin Preparation Pen

Please confirm that you can identify all the items in the case.

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Figure 1 Monica AN24™ Controls and Indicators

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Section 2 - Product Description

2.1 General description

The Monica AN24™ is a wearable, battery-powered device for L&D surveillance of fetal well-being. The AN24™ is designed to passively monitor Fetal Heart Rate (FHR) and Uterine Activity (UA) from the Electro Hysterogram (EHG) during pregnancy and can be used at any time from >36 completed weeks gestation to the end of second stage labour. The AN24™ is currently suitable for singleton pregnancies only. One AN24™ is suitable for extended monitoring sessions of up to 18 hours.

2.2 Patient attachment

The Monica AN24™ is attached via a detachable lead assembly that in turn attaches to 5 disposable ECG electrodes placed on the abdomen of a pregnant woman to generate 3 signal channels. The AN24™ then records the electrical signals present at these electrodes that contains information relating to the fetal heart and other sources of electrical energy inside the body.

2.3 Data processing

The acquired signals are then converted by the AN24™ into a digital format and processed in real-time to extract clinically relevant information, such as the Fetal Heart Rate (FHR) and Uterine Activity from the Electro Hysterogram (EHG).

2.4 Data viewing and storage

The processed data can either be stored by the AN24™ and downloaded to a computer or VS monitor at the end of the monitoring session, or wirelessly transmitted in real-time for viewing on a dedicated monitor. Monica VS monitors enable the data to be viewed, stored, and printed.

2.5 Heart rate calculation

The time between the R-wave of consecutive fetal QRS complexes in the ECG signal is used to calculate the FHR. This is called the fetal RR interval. See Figure 2.

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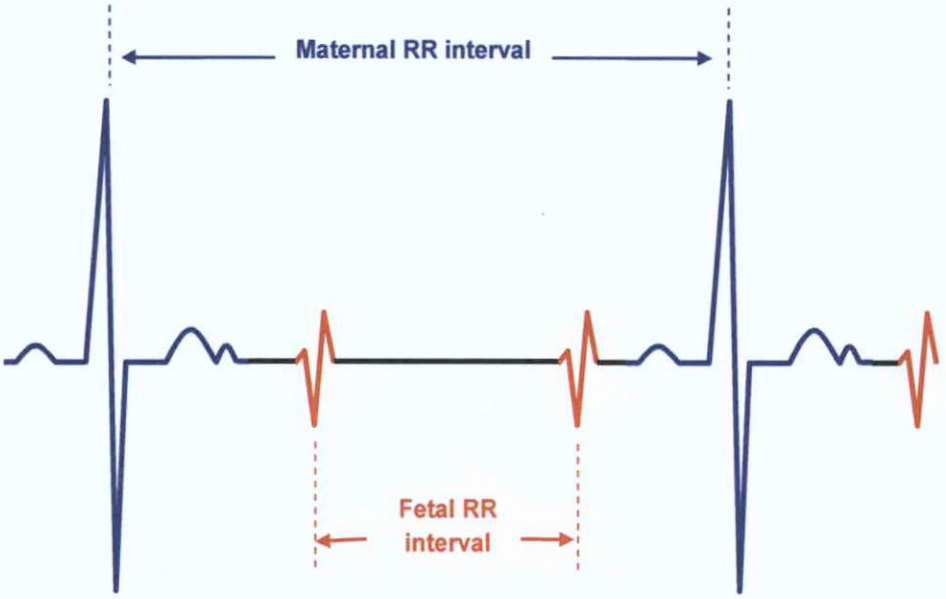

Figure 2 Calculation of FHR from ECG

The FHR is a ¼ second rolling window update. The amount of averaging is dependant on the ratio of the fetal height to noise and the number of fECG complexes detected, but it is never more than 2seconds.

2.6 Heart rate data accuracy

The FHR data is only made available for viewing when the AN24™ is confident that this data is accurate. Confidence is based upon the general noise in the recorded data and characteristic shape of the ECG complex. In the event that the AN24™ is not confident of the accuracy of the FHRit will not be made available; the AN24™ will not 'fill in 'or 'coast' when FHR data is not available.

2.7 Uterine Activity from EHG

The Uterine Activity is extracted from the slow-wave of the EHG, i.e. its envelope. The envelope is obtained by low-pass filtering the rectified fast-wave of the EHG. The UA is updated every 2 seconds as a number between 0 and 255, representing an EHG envelope from 0 to 500 microvolts.

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Section 3 - Installation

3.1 Battery Charging

The Monica AN24™ (Figure 1) is dispatched with a non-removable rechargeable battery which, for shipping, is not fully charged.

The battery must be fully charged prior to use as described below.

Please refer to Figure 1

A. Connect the lead on the supplied battery charger into the socket inside the top of the AN24™ body (**1**). Plug the battery charger into a mains outlet and switch on the mains outlet. The amber battery status LED (**6**) will flash if a connection has been made (this should be confirmed) until the device is charged, when it will be constantly lit. This should take no more than 2½ hrs.
B. When the electrode leads connector (**2**) is connected to the Monica AN24™ Recorder (**1**) disconnect the lead connector (**2**) from the AN24™ body (**1**) by pressing the two buttons (**7**) on either side of the recorder, and gently pulling apart the AN24™ body (**1**) from the lead connector (**2**).

3.2 Instructions

Please fully read these instructions before using the AN24™.

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Section 4 - Operating the AN24™

4.1 Set-up procedure when not using the VS monitor

4.1.1 Select mode.

The Monica AN24™ can be operated in two modes, namely:

Mode 1 - Retrospective mode
The Monica AN24™ records fetal heart rate (FHR) and Uterine Activity (UA) for retrospective upload and viewing on a Monica VS Monitor.

Mode 2 - Real time mode
The Monica AN24™ transfers FHR and UA using Bluetooth® wireless transmission in 'real-time' to a Monica VS Monitor for real-time viewing of the data.

The default mode when the Monica AN24™ is turned on for the first time is Mode 1 (Retrospective mode). Connection via USB to a VS Monitor is required to set the time for the first recording.

The AN24™ already running in Mode 1 can be set up to run in Mode 2 by making a wireless Bluetooth® connection using the Monica VS Monitor (see section 4.4).

4.1.2 Electrode attachment

Prior to applying the electrodes, the skin must be prepared correctly using an alcohol wipe and abrasive skin tape (**17**) as described in Supplement 1 – Electrode Placement.

Additionally, the electrodes (**16**) must be positioned correctly on the women's abdomen.

For skin preparation and electrode positions please refer to Supplement 1 – Electrode Placement

4.1.3 Lead connection

Attach the electrode leads connector (**2**) to the electrodes (**16**) following the colour code guide in Supplement 1 – Electrode Placement. Ensure that the electrode leads connector (**2**) is securely attached to the AN24™ (**1**), by pushing the two sections firmly together such that the two buttons (**7**) are engaged.

For monitoring in Labour and Delivery always use the AN24™ Protective cover (supplied). Please refer to Supplement 1 – Electrode Placement for instructions on fitting the protective cover.

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4.1.4 Turn on

Turn the AN24™ on by pressing the on/off button (3). All three LEDs (4, 5 and 6) will flash 3 times to indicate that the AN24™ has been turned on.

4.1.5 Memory status self-check

If the Orange memory status LED (**4**) begins to flash when the AN24™ has been turned on, this indicates there is data from a previous patient stored in the memory of the AN24™.

The stored data can be a) downloaded using Monica VS Monitor via a USB cable or b) deleted remotely via Bluetooth® connection to the Monica VS monitor.

a) To download the data via USB, turn off the recorder (see 'Turn Off' section below), and connect the AN24™ to the VS Monitor with the USB cable provided (please refer to the Monica VS Reference Manual for detailed instructions). Once the data has been downloaded, the recorder can be used for a new recording.

b) To delete the data via Bluetooth®, use a Monica VS monitor to connect to the recorder. The VS monitor will automatically recognise that there is data stored on the AN24™ and offer to delete the data or allow the user to disconnect it from VS to download as per a) above (please refer to the Monica VS Reference Manual for detailed instructions). Once the data is deleted the recorder can be used for Real Time mode recording.

4.1.6 Battery status self-check

If the Yellow battery status LED (6) begins to flash when the AN24™ has been turned on, this means that the battery charge is too low for recording to begin. The LED will flash 10 times and then the AN24™ will be automatically turned off. See 'Recharging the batteries later in this section.

N.B. If there is data on the recorder, the Memory Status led will flash alongside the battery status LED.

4.1.7 Electrode attachment self-check

After turn on, the AN24™ will check the electrodes are attached correctly. The green signal quality LED (**5**) will go into one of three states:

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- GREEN LED FLICKERS

The green LED flickers rapidly when the electrodes are not correctly attached. To solve this problem please refer to Section 10 - Troubleshooting. The AN24™ will continue this self-check until the problem has been resolved and recording will not begin until it has.

- GREEN LED ON

The green LED is constantly on to indicate that all electrodes are correctly attached to the skin. Once the AN24™ is satisfied that the electrodes are correctly attached the recording will begin. The AN24™ will then look for the signal.

- GREEN LED SLOWLY FLASHES

The green LED will flash (once every 2 seconds) when the AN24™ is satisfied that the electrodes are correctly attached and that monitoring has started (note – this may take up to 30 seconds once the correct electrode attachment has been confirmed). If the LED remains constantly on, please refer to Section 10 - Troubleshooting. If the problem persists please contact your distributor.

NB: Monica VS monitors provide an on-screen electrode attachment check during the setup of a new patient see the VS Reference Operating Manual for details.

4.1.8 Secure the AN24™

If the patient wishes to carry the AN24™ it can either be held in their clothing (e.g. a pocket) or carried around the neck using the supplied neck strap (12). If the patient wishes to use the neck strap, attach it to the AN24™ main body (1) using the neck strap connection (9) and hang the neck strap around the patient's neck. Adjust the length of the neck strap so that the lowest part of the AN24™ is above the sternum and not touching the electrodes.

4.1.9 Secure Cables

If the ECG cable(s) are loose or hanging, secure them with hypoallergenic tape (not supplied) to the patient's abdomen to prevent the cables from pulling on or detaching from the ECG electrodes.

4.2 During monitoring

Self checks during a recording

During recording the AN24™ will regularly perform self-checks. The AN24™ can only be in one of the following four states:

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MONITORING OK – GREEN LED FLASHES

The green signal quality LED (**5**) will continue to flash once every 2 seconds to indicate that the electrodes remain attached correctly.

SIGNAL LOST – GREEN LED ON

The green signal quality LED (**13**) will remain constantly illuminated to indicate that the electrodes remain attached correctly but that the signal has been lost. This is not a cause for alarm and may be temporary and due to interference from other sources, for example the noise generated by maternal muscle/movement. Section 10 - Troubleshooting

ELECTRODE DETACHED – GREEN LED FLICKERS

The green signal quality LED (**5**) will flicker rapidly to indicate that one of the electrodes has become detached. The recording will not be stopped at this point, if suitably trained staff are available the electrodes should be re attached to resolve the problem, see Section 10 - Troubleshooting.

BATTERY LOW – YELLOW LED FLASHES

If the Yellow battery status LED (**6**) begins to flash, this indicates that the battery is running low. A short while after this occurs; the AN24™ will automatically turn off. If the device is in Mode 1 (recording mode) the recorded data will be retained until it is uploaded, see Mode 1 - USB upload later in this section.

NB: Monica VS monitors also provide on-screen device status feedback see the VS Reference Operating Manual for details.

4.3 Turn off

When the recording session is completed, turn the AN24™ off by pressing the on/off button (**3**) followed by the event button (**8**) followed by the event button (**8**) again.

This sequence of button presses must be completed within 4 seconds to turn the device off. When the AN24™ is switched off all three LED's (**4, 5** and **6**) will flash three times.

If using a Monica VS Monitor to end a real time recording (mode 2) the Monica AN24 can be switched off remotely by the VS Monitor.

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Data Upload - If the AN24™ was used in Mode 1 (recording mode), the recorded data must be uploaded to a computer running the Monica VS Monitor, see 'USB Upload' later in this section.

Clean the AN24™ (**1**) and electrode lead connector (**2**) as described in Section 6 - Cleaning and Maintenance

Battery Charging - recharge the AN24™ (**1**) as described in 3.1 Battery Charging.

4.4 Connecting to a VS Monitor

Monica devices are an integral part of a diagnostic system. The user must adhere to warnings in order to ensure safe and reliable performance of the system.

- Monica VS Monitors complies with IEC 60601-1 the international product safety standard for electrical medical equipment
- Non-medical electrical equipment (e.g. Wireless remote printer) must be situated outside the patient environment (patient environment according to IEC 60601-1-1: = radius 1.5m around the patient).
- The Monica VS Monitors (PT-101-010, PT-101-015) fully comply with the above and are required when using the Monica AN24™ to monitor in real-time within the patient environment (as defined by IEC 60601-1-1).

When connecting to a VS Monitor in either Retrospective or Real-Time mode it is firstly necessary to ensure that the Monica VS Monitor is on and running.

To connect to a VS Monitor in **Retrospective mode**:

A. Disconnect the electrodes from the leads - Disconnect the electrode lead connector (**2**) from the AN24™ (**1**) as described in 3.1 Battery Charging.
B. Power up the VS Monitor, log in and wait until the system is fully loaded
C. Connect USB lead - Connect the AN24™-to-USB lead (**14**) into the socket inside the top of the AN24™ (**1**). Plug the USB end of the lead into a free USB port on the Monitor. The Monica AN24™ device will be automatically recognised by the monitor and will provide status information.

From this point the Monica VS software will know if there is data stored on the device ready for upload (Mode 1 operation). If there is data stored on the device the VS Monitor will guide you through the correct process to upload or delete the stored data.

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To connect to a VS Monitor in **Real-Time mode**:

Place the electrodes on the patient as described in in the Getting Started Wizard (press the help icon on the VS screen) or Supplement 1; connect the Monica AN24 to the patient and turn it on.

Select the New Recording button from the Monica VS menu which will then take you through the set-up process.

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Section 5 - Safety and Standards

5.1 General

This section describes safety precautions that may appear within the manual and those that appear as symbols labels on the AN24™ itself. Furthermore, this section describes a group of precautions that are applicable, in general, when using the AN24™.

The Monica AN24™ is intended for trained medical personnel (including midwives, nurses, and physicians) who are familiar with obstetric procedures. Keep this operator's manual with the unit for use by the operator.

5.2 Symbols

Attention - Refer to manual

Class II Medical Device

Type BF

Batch number

Manufacture date

Bluetooth® approved device

ESD - Static sensitive device

CE approved

WEEE logo

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5.3 Standards

The Monica AN24™ complies with the following safety standards

Standard	Description
IEC EN 60601-1: 1990 UL60601-1:2003 CSA C22.2 No 60601.1	Medical Electrical Equipment Part 1: General requirements for safety
EN 60601-1-2: 2002 IEC 60601-1-2: 2001	Medical Electrical Equipment Part 1-2: General requirements for safety – Collateral Standard: Electromagnetic Compatibility – requirements and tests
Partial compliance of: EN 60601-2-47: 2001 IEC 60601-2-47: 2001	Medical Electrical Equipment Part 2-47: Particular requirements for the safety, including essential performance, of ambulatory electrocardiographic systems
IEC EN 60601-1-4: 1996	Medical electrical equipment Collateral standard: Programmable Electrical Medical Systems
EN 980: 1996	Graphical symbols for use in the labelling of medical devices
EN 1041: 1998	Information supplied by the manufacturer with medical devices

5.4 Interpreting Results

Monica Healthcare recommend that a repeat test is undertaken, using either the AN24™ or an alternative device to confirm the results from the initial test. The repeat test should be carried out in the case of either normal or abnormal results generated by the AN24™.

Good Practise:

When the MHR is high, or the signal quality is poor (section 4.7 VS Operator manual), check the FHR using auscultation (Pinard) or hand held Doppler every 15min to confirm the FHR, and if in any doubt, ask the women to stop pushing during the second stage, until the FHR is confirmed.

5.5 CE

CE The CE Mark on this product denotes conformity with the European Council Medical Device Directive 93/42/EEC.

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Section 6 - Cleaning and Maintenance

6.1 AN24™ Device

To avoid damage to the AN24™, connector and leads, clean and disinfect only according to the following instructions. Care MUST be taken to preserve both the AN24™ label and the connector label.

***CAUTION*:** Do not remove, conceal or deface the labels.

CAUTION: Do not autoclave. Do not gas sterilize.

CAUTION: Do not immerse the device or any accessories in liquid and do not expose the connector pins to the cleaning solution. Do not apply oil at any point.

CAUTION: Do not use undiluted bleach or any other cleaning solution other than those recommended here because permanent damage to the AN24™ and leads could occur.

Clean - Wipe the AN24™ and leads with a soft non-abrasive cloth or disposable wipe soaked in a solution such as 70% isopropyl alcohol. Do not use aerosol preparations since they might contain organic solvents. Do not pour fluids directly on the unit and its accessories. Wipe the exterior of the AN24™ and leads three times. If necessary scrub the AN24™, and leads with the solution using a soft bristled brush for five minutes.

Wash off & Dry - When using solutions, use sterile wipes or gauze to avoid pouring fluids directly on the unit and its accessories. Wipe the AN24™, and leads three times with sterile or distilled water to remove cleaning solution residue. Dry the AN24™, connector and leads thoroughly with a sterile soft towel or gauze surgical sponge.

Disinfect - Use a 1:10 bleach solution after the AN24™ and leads have been cleaned following the same procedure described above. After the low level disinfections, wipe the AN24™ and leads three (3) times with sterile or distilled water to remove diluted bleach residue. Dry the AN24™, connector and leads thoroughly with a sterile soft towel or gauze surgical sponge.

Store the clean AN24™, connector, and leads in a clean bag, covered tray, or other suitable system when not in use.

Monica recommends the patient neck cord included with the Monica AN24 is washed thoroughly or replaced between patients.

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6.2 Batteries

The 3.6V rechargeable lithium polymer battery pack should be stored at 0-35°C. Typically the batteries will last for two years or more with regular use. If you need to replace the battery, contact Monica Healthcare directly or your Monica healthcare representative.

6.3 Firmware version

AN24™ Firmware
VS Monitor update

Periodically there will be a need to release new versions of the Firmware and VS Monitor updates, please check with your local distributor to see if you have the latest version.

6.4 Calibration

Calibration of the Monica AN24™ is not required

6.5 Servicing

Maintenance of the AN24™ is carried out by Monica Healthcare. The only routine maintenance which is necessary is battery replacement when failing to hold charge and cleaning as outlined earlier in this Section. Further information is available from:

Monica Healthcare Ltd
BioCity
Pennyfoot Street
Nottingham NG1 1GF
UK
Tel: +44 1159124540
Email: info@monicahealthcare.com
Web: www.monicahealthcare.com

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Section 7 - Monica Accessories

Part No.	Description
100-PT-100	Monica VS10 Monitor (Panasonic Toughbook CF-H1)
100-PT-101	Monica VS10 Monitor (Panasonic Toughbook CF-H1, upgrade for existing AN24 customers only)
100-PT-110	Monica VS15 Monitor (Arbor M1525)
100-PT-111	Monica VS15 Monitor (Arbor M1525 upgrade for existing AN24 customers only)
100-PT-001	Monica AN24

100-PT-130	Monica Cart (ITD PRO3OU)
100-PT-131	Monica Cart - printer shelf (ITD PRO3OU
100-PT-132	Monica Desktop Stand (Vesa desktop stand ARM 150 or equivalent)
100-PT-140	Monica Printer (Real-time) - Thermal Z-fold (Fetalgard Lite)
100-PT-160	Monica VS Network Viewer

100-PT-002	ECG Lead Assembly - Standard
100-PT-004	Battery Charger (UK\ EU\ USA please specify)
100-PT-005	AN24 – USB computer connection cable
100-PT-015	Soft silicon rubber protective boot (x5)
100-PT-016	3M red Dot 2236 skin prep tape (x5)
100-PT-017	Monica approved electrodes – 25 pouches x 10 electrodes (250 electrodes)
100-PT-018	Monica approved electrodes – 150 pouches x 10 electrodes (1500 electrodes)
100-PT-019	Monica AN24 Neck Cord (x5)
100-PT-020	Monica Healthcare glossy sales literature folder (x50)
100-PT-021	Sales Literature sheets
100-PT-022	Skin preparation pen
100-PT-141	Z-Fold paper printer (3 cm/min, 30 - 240 bpm) Analogic US
100-PT-142	Z-Fold paper printer (1 cm/min, 50 - 210 bpm) Analogic International
100-PT-143	Z-Fold paper printer (3 cm/min, 30 - 240 bpm) Philips US
100-PT-144	Z-Fold paper printer (1 cm/min, 50 - 210 bpm) Philips International

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Section 8 - Monica VS Monitors

8.1 Overview

Monica VS series of monitors (VS15/VS10) allow the FHR, UA and event annotation data to be viewed, stored and printed as a conventional CTG trace. It is also provides the Monica AN24™ set-up tools to configure the unit and label and store the monitoring sessions for easy identification and retrieval. The functionality of the Monica VS Monitors is explained in detail in the Monica VS Reference Operating Manual.

8.2 System Requirements

Monica devices are an integral part of a diagnostic system. The user must adhere to warnings in order to ensure safe and reliable performance of the system.

- Monica VS Monitors complies with IEC 60601-1 the international product safety standard for electrical medical equipment
- Non-medical electrical equipment (e.g. Wireless remote printer) **must be** situated outside the patient environment (patient environment according to IEC 60601-1-1: = radius 1.5m around the patient).
- The Monica VS Monitors (PT-101-010, PT-101-015) fully comply with the above and are required when using the Monica AN24™ to monitor in real-time within the patient environment (as defined by IEC 60601-1-1).

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

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Section 9 - AN24 Specifications

9.1	**Measured**	Time	Real-Time clock
		Clinical Event Marker	Button
		Abdominal Electrophysiological Signal	3 different channels
9.2	**Calculated**	FHR	Range 60-240 beats per minute 2 second average or better
		Uterine Activity	Range 0-500 microvolts (0-255 levels)
9.3	**Storage**	Internal Micro SD Card	
9.4	**Interfaces**	Download	USB – download stored data to computer Wireless – Real-Time data transfer using Bluetooth®
		User	LED indicator 1: Yellow – Battery status LED indicator 2: Green – Signal quality LED indicator 3: Orange – Memory status Button 1: On/Off Button Button 2: Event marker
9.5	**Data Format**	Series 50 Protocol via Bluetooth®	
9.6	**Battery**	Rechargeable lithium polymer 3.7V 2000mA-hours	
9.7	**Battery Charger**	Input	100-240V, 50-60Hz UK\EU\US adapter
		Output	DC 5V 1A USB PC connection
9.8	**Dimensions**	11.5 x 5.5 x 2.0 cm Including lead assembly	
9.9	**Weight**	105g excluding lead assembly	
9.10	**Operating Temperature**	0 to + 40°C	
9.11	**Storage Temperature**	0 to + 40°C	
9.12	**Approval**	CE approved (Directive 93/42/EEC) as amended by 2007/47/EEC	

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

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Section 10 - Troubleshooting

10.1 Signal Quality (Green LED flickers)

Electrodes are not attached correctly.

If the green LED flickers, first check that the electrode lead connector cap is connected securely on both sides of the AN24™ (both buttons engaged). If this does not resolve the problem, put AN24™ into electrode check **'Phase 1'** by pressing event button twice within a 2-second period. (NB: this is not required if connected to a VS Monitor which will display the problem electrode(s) on screen without the need to touch the AN24).

x2

The system will then 'display' the electrode/skin impedance for the electrodes connected to the yellow, green and orange leads.

The electrode/skin impedance will be communicated to the user as follows:

- LED on continuously – the electrode connected to the lead defined by the LED colour has a good connection / low skin impedance
- LED flickers - the electrode connected to the lead defined by the LED colour has a bad connection / high skin impedance

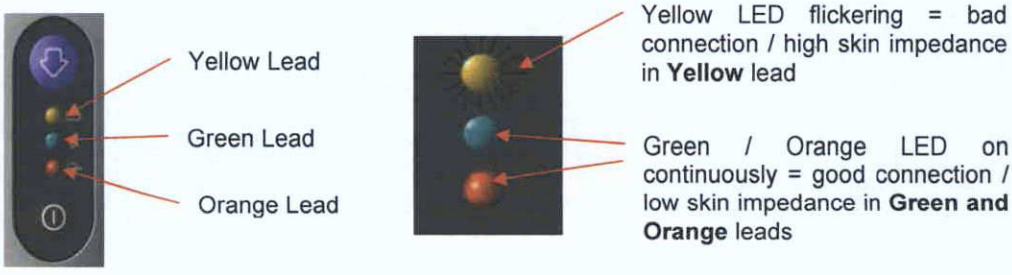

Figure 3 Phase 1 Lead check

If a bad connection is identified in the Yellow, Orange or Green leads, disconnect the lead from the electrode(s) that has a bad connection (leave AN24™ on), remove the electrode(s) and again prepare the skin as described in Supplement 1 – Electrode Placement. When all the electrode(s) have been replaced the leads should be reconnected.

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If all the LED are on continuously (good connection), put the AN24™ into electrode check **'Phase 2'** by pressing event button twice within a 2 second period.

x2

In 'mode 2' the electrode/skin impedance will be communicated to the user for the remaining two electrodes as follows:

- Yellow LED on continuously – the electrode connected to the **White** lead has a good connection / low skin impedance
- Yellow LED flickers - the electrode connected to the **White** lead has a bad connection / high skin impedance
- Green LED on continuously – the electrode connected to the **Black** lead has a good connection / low skin impedance
- Green LED flickers - the electrode connected to the **Black** lead has a bad connection / high skin impedance

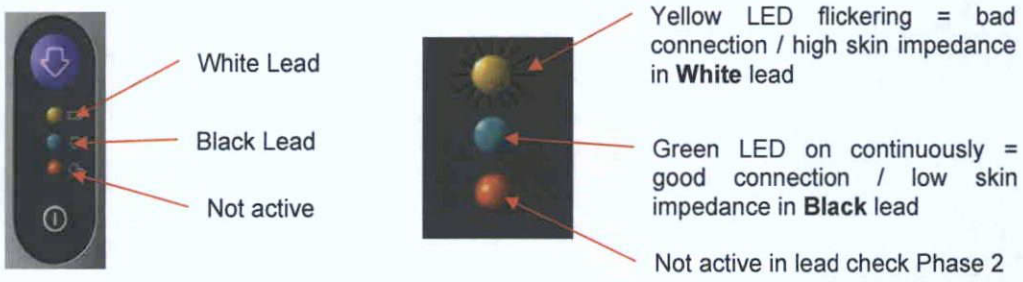

Figure 4 Phase 2 Lead check

If a bad connection is identified in the black or white leads, disconnect the lead from the electrode(s) that has a bad connection (leave AN24™ on), remove the electrode(s) and again prepare the skin as described in Supplement 1 – Electrode Placement. When all the electrode(s) have been replaced the leads should be reconnected.

If the Green and Yellow LED's are on the user should start their monitoring session by pressing the event button twice within a 2-second period

x2

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

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In the unusual event that it is not possible with repeated skin preparation and correct electrode placement to bring the impedance down and gain a good connection; impedance check may be by-passed or can be halted and repeated at a later date.

To by-pass the impedance checks:

Press the following key sequence in succession:
Power On Button > Pink Event Button > Power Button

If after by passing the impedance check the green LED remains continuously on – signal cannot be found – the monitoring session can be halted and repeated at a later date. This failure should be reported to Monica Healthcare Ltd. Please make a note of which electrode or electrodes failed to pass the impedance check. Monitoring the patient at a future time/date may still be possible.

To abort the electrode check phases (Phase1 or Phase2): switch off the AN24™ as usual (press ON button, then press pink Event button, then press pink Event button)

Alternatively, the lead may be broken. Turn the AN24™ off. Disconnect the lead from both the AN24™ and the electrodes. Attach a spare lead and retry.

If problem is not resolved, contact Monica Healthcare for advice.

10.2 Signal Quality (Green) LED constantly on

The signal cannot be picked up by the AN24™, though the electrodes are correctly connected. This is a common occurrence, which may be due to interference from other sources, for example the noise generated by maternal muscle/ movement. The mother should relax and remain in a supine position for as long as practicable during the recording for optimal results. If problem is not resolved, contact Monica Healthcare for advice.

10.3 Battery Status (Yellow) LED flashing when unit is not being charged

Battery is low. The AN24™ will shortly automatically turn off. Upload the data and recharge the batteries (see 3.1 Battery Charging). If problem is not resolved, contact Monica Healthcare for advice.

10.4 Memory Status (Orange) LED flashing

This indicator will only light just after the AN24™ has been turned on and indicates that there is > 1 minute of data on the device. Upload / delete the data currently stored on the device (see Section 4 -). Turn on the device and resume the monitoring session. If problem is not resolved, contact Monica Healthcare for advice.

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

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10.5 AN24™ will not turn on

Recharge the AN24™ for at least an hour even if the AN24 battery does not flash. If after recharge the AN24™ still does not turn on, return to Monica Healthcare for service.

10.6 AN24™ will not turn off

Return to Monica Healthcare for service

10.7 AN24™ will not recharge

Disconnect AN24™, reconnect battery charger and check charger is connected at both the wall socket and the device. Leave the recorder connected to the charger for half an hour. Then disconnect the AN24™ from the charger and reconnect it again. If problem is not resolved, contact Monica Healthcare for advice.

10.8 AN24™ will not connect via USB

Disconnect USB lead from both the AN24™ and VS Monitor. Reconnect USB lead and retry. If problem is not resolved, connect the AN24™ to the charger for half an hour and try connecting the recorder to the VS Monitor again. If the problem is not solved, contact Monica Healthcare for advice.

10.9 AN24™ will not connect via USB and will not recharge

If the AN24™ does not charge and is not recognised by the VS Monitor, disconnect the AN24™, reconnect battery charger and check charger is connected at both the wall socket and the device. Leave the recorder connected to the charger for half an hour. Then disconnect the AN24™ from the charger and reconnect it again. If problem persists there may be an issue with the Bluetooth® module in the AN24™ - please contact Monica Healthcare for advice.

If the AN24™charges but is not recognised by the VS Monitor disconnect USB lead from both the AN24™ and computer. Reconnect USB lead and retry. If the problem persists there may be an issue with the USB cable – please contact Monica healthcare for advice

10.10 AN24™ will not connect via Bluetooth®

Bring the AN24™ physically close (i.e. within 2 metres) of the VS Monitor and retry. If problem is not resolved, contact Monica Healthcare for advice.

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Section 11 - Returns Procedure

11.1 Maintenance

There are no user serviceable parts in the Monica AN24™ or accessories. In the event of device failure or the battery needs to be changed, please contact Monica Healthcare or your local representative.

11.2 Returns

To return a defective product to Monica, you will need to obtain a Return Goods Authorization (RGA) number from the Monica Healthcare Support Group. Please contact a Service Coordinator at:

Telephone: +44 1159124540
Email: support@monicahealthcare.com

You will need to supply the Service Coordinator with the following information:

- The Model number(s) and Serial number(s) of the product, this information can be found on the label on the rear of the AN24™.
- The quantity of items you wish to return.
- Your "Bill to" address for invoice purposes.
- Your "Ship to" address.
- Your Purchase Order number.
- Details of the reported failure.

The Service Coordinator at Monica Healthcare will then inform you of:

- The Return Goods Authorization (RGA) number.
- The warranty or non-warranty status of the units being returned.
- Any repair charge.

All returned material must be shipped "PREPAID" to the address below for both warranty and non-warranty repairs. Please reference your RGA number on both your purchase order and the shipping label:

RGA reference number:
Tioga
St Thomas House
St Mary's Wharf
Mansfield Road
Derby
DE1 3TN
UK

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

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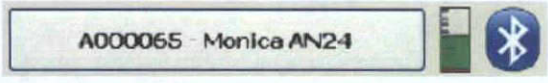
Supplement 1 – Electrode Placement

I. Patient Posture

It is very important that the woman's stomach muscles are relaxed and she should be encouraged to 'relax' on a bed either on her back (recumbent or semi-recumbent) or on her side (left/right) for as long as practicable during the monitoring session. The patient should **avoid** whenever possible:

1. Any position or activity where the abdominal muscles are contracted e.g. sitting upright or lying down with her back raised from the hips at an angle of 45°. If this is unavoidable then using a cushion to support the back can help.
2. A tense stressful situation which will cause abdominal muscle tone to increase even though the patient is in a comfortable position e.g. When the room where the patient is being monitored is filled with Drs, Midwives, Family, Children and other onlookers. In this situation it is advisable to leave the Monica AN24 in place and return when the patient situation has changed.

The VS series of monitors provide a real-time indication of signal to noise in the signal quality indicator where the muscle noise (red-bar height) and the fetal ECG height (green bar) are displayed.



If the fetal ECG height is small and the muscle noise is high then FHR extraction may be compromised; ask the mother to get into a position that is comfortable for her and relax. In addition, changes in maternal posture like lying on the left or right can change the fetal position in relation to the abdomen and uterus and improve the ECG conducting pathway.

II. Electrode Location

It is important to correctly prepare the skin before the application of the electrodes. You are advised to read all of this section before starting the procedure.

The instrument has three separate detection channel leads. The connectors on these leads are colour coded as **orange**, **white** and **green**. All three channels share a common connection point and this lead connector is coloured **yellow**. Finally, a ground lead with a **black** colour coded connector is also used. These leads are connected to 5 electrodes positioned on the maternal abdomen. Please refer to the table and figures below for guidance in positioning the electrodes.

Electrode / Connector	Position
Yellow	Place the yellow electrode on the mid-line 6cm above the symphysis pubis or as close to 6cm above the symphysis pubis as you can achieve without requiring removal of the pubic hair.
White	Place the white electrode on the mid-line so that the bottom edge of the electrode is just below the top edge of the umbilicus. *If the centre of the white electrode is **above** the fundus, reposition the white electrode so that the centre is **below** the fundus and the electrode is clear of the umbilicus*
Green and Orange	Place the centre of the green and orange electrodes either side of the umbilicus and on the same horizontal line as the umbilicus. The centre of the green electrode should be **10cm** from the **left hand edge** of the umbilicus and the centre of the orange electrode **5cm** from the **right hand edge** of the umbilicus.
Black	The black electrode is the reference electrode and is positioned towards the back behind the green electrode. Its exact position is not critical.

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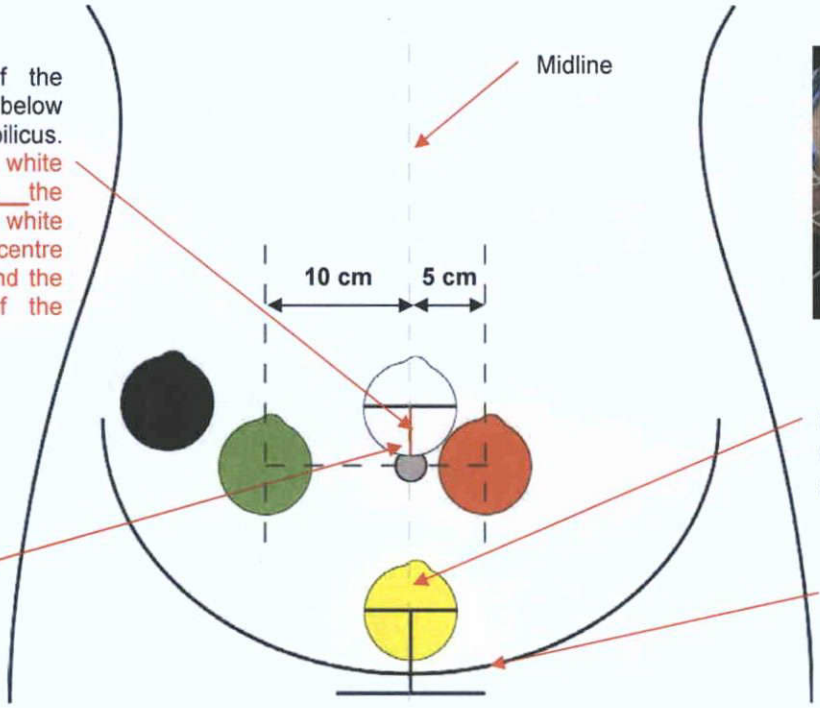
Electrode Positions

The bottom edge of the White electrode is just below the top edge of the umbilicus. (If the centre of the white electrode is **above** the fundus, reposition the white electrode so that the centre is **below** the fundus and the electrode is clear of the umbilicus)



For patients with a large pannis (apron of fat) overhanging the symphysis pubis it is recommended that the yellow electrode be placed **on top** of the pannis on the mid-line such that the centre of the electrode is 6cm above the upper margin of the symphysis pubis or as close to 6cm above the upper margin of symphysis pubis without covering the yellow electrode with the pannis.

These instructions only apply to **Ambu VLC-00-S** electrodes.
Results may be impaired if any electrode is used other than those recommended by

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

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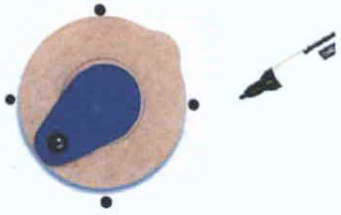
III. Preparation of the skin and electrode application

1. Mark the electrode positions – using the electrode as a template and an alcohol based permanent marker pen.



Note: *If unable to use a pen to mark the site an alternative* ***MUST*** *be used to mark the site. Example: patient's fingers or a small piece of skin prep-tape*

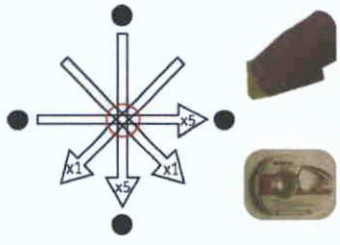
Caution: When using a marker pen ALWAYS follow local cross-contamination protocols.

Warning: DO NOT use a marker pen if the woman has any cuts or open sores on her abdomen

2. If the patient has been using skin care products wash the abdomen with a mild soap and water solution and **dry** first. On **all women** clean the electrode area vigorously with an alcohol swab and allow to dry.

Caution: Using an alcohol wipe on abraded skin may cause patient discomfort and skin irritation.

3. Once the alcohol has dried off, abrade the area, using the supplied prep-tape, stroking the skin in one direction only (5 North to South, 5 East to West, 1 NW-SE, 1 SW- NE) as shown below



Caution: Use only moderate force since excessive use of prep tape may cause patient discomfort and skin irritation. In some patients local skin reactions to the electrode adhesive\gel may occur causing slight reddening of the skin.

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4. Apply the electrodes (check the use by date and the gel on the electrode is still wet)

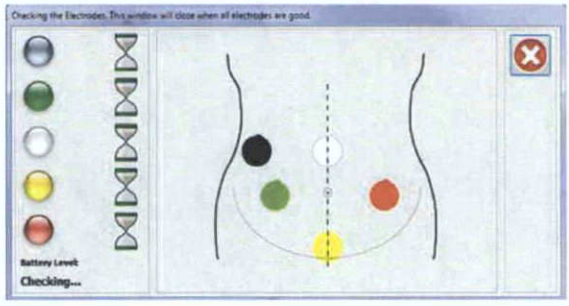
   a. Select one electrode and remove the plastic backing holding the electrode by the single strip of paper remaining so as not to touch the sticky part of the electrode.
   b. Place the electrode on the patient in the exact location that has been prepared. Do not press down in the middle of the electrode since the gel will be forced out. Only press the electrode around the outside and ensure that the material of the electrode does not crease.
   c. Remove the remaining strip of paper and stick down. When positioning the electrode ensure that the connection stud /tab is pointing to the right side of the patient, so that the cable be in the same direction in which the cables are being pulled

Repeat steps 1 – 4 (above) until all five electrodes have been placed.

Caution: Do not use any electrodes which are dry or from a pack that has been opened by more than one week. When opening a fresh packet of electrodes, if all the electrodes are not used, write on the pack the date opened and make sure the pack is sealed to prevent the remaining electrodes from drying out.

Warning: Only use any electrodes specified by Monica healthcare. Failure to use the specified electrode could result in unacceptable noise levels resulting in poor FHR detection.

5. Check the electrode impedance (AN24 or VS Monitor – please refer to the Reference VS Operating Manual)
   a. Impedance Check using Monica VS Monitor



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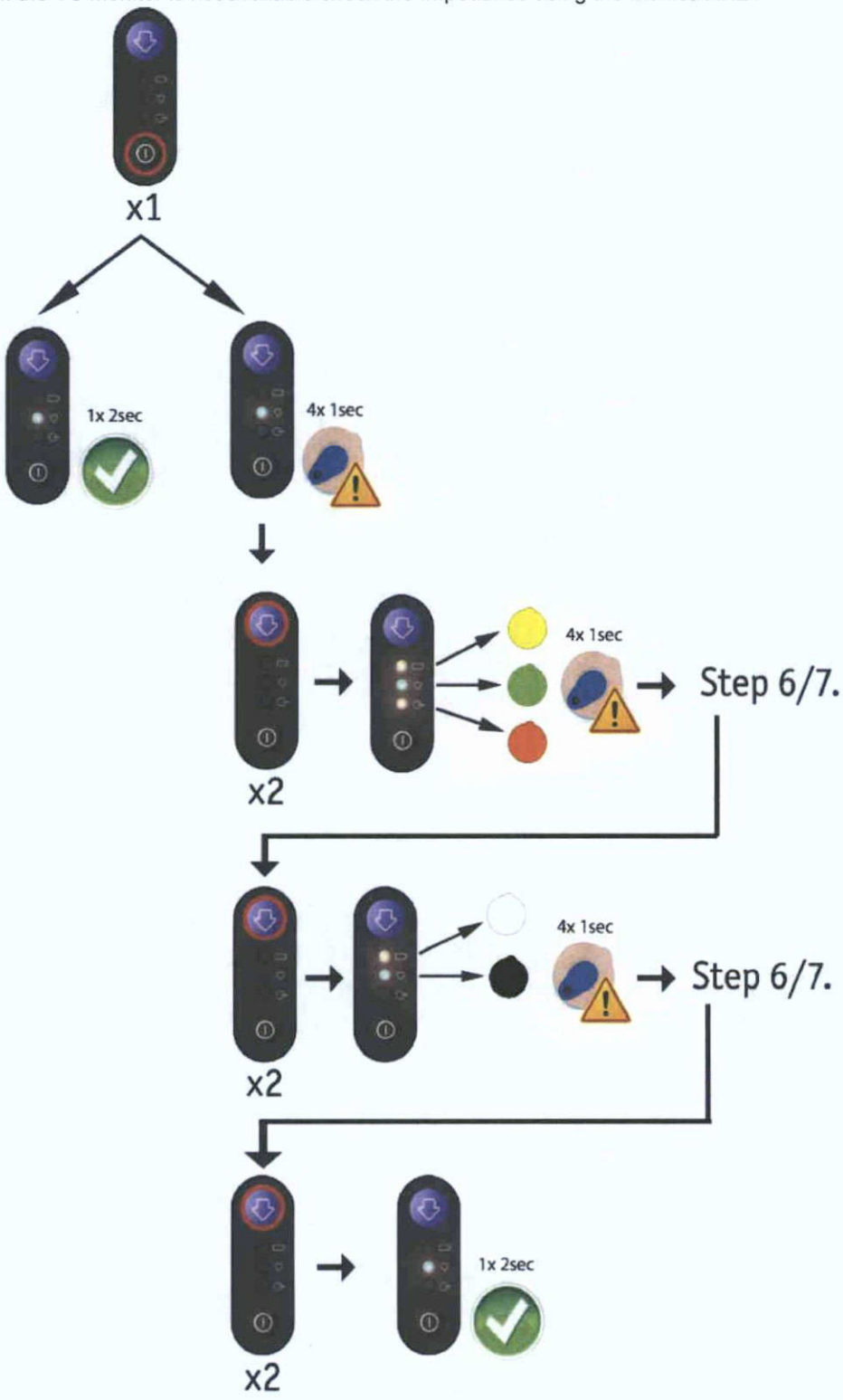
b. If the VS monitor is not available check the Impedance using the Monica AN24



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6. If impedance check fails
    a. Peel back electrode
    b. Dry wipe the area to remove gel and moisture left by the electrode
    c. Re-abrade the same area of skin pressing firmly
    d. Re-attach the same electrode
    e. Wait 2-3 minutes for the electrode to settle
    f. Check the impedance again (Step 5)

7. If the impedance check fails a second time
    a. remove and discard the electrode
    b. Dry wipe the area to remove gel and moisture left by the electrode
    c. Re-abrade the same area of skin pressing firmly as long as the mother does not become uncomfortable
    d. attach a new electrode
    e. Wait 2-3 minutes for the electrode to settle
    f. Check the impedance again (Step 5)

8. If the impedance check fails a third time on one or more of the Green, White, black or Orange electrodes then the impedance check can be by-passed (see AN24 Reference Operating Manual – 10.1 Troubleshooting Guide). **This is not recommended**. Alternatively, leave the electrodes in place for 30 minutes and try the impedance check again (Step 5).

9. '**Do Not**' by-pass the impedance check if the impedance check for the yellow electrode fails – go to step 6 and repeat process as long as the mother does not become uncomfortable.

10. If it is still not possible to pass the yellow electrode impedance check,

    Option 1: go back to step 8 and by-pass the impedance check. The fetal abdominal ECG can be good in early and late gestation monitoring so noise introduced by high skin electrode impedance can be mitigated. However the quality of the signal cannot be confirmed until the recording commences by looking at the signal to noise bar graph on the VS display or on the Quick-View PDA (not available for sale in the USA).

    Option 2: halt the recording and try again at a future time/date.

Caution: Do not use water to remove the electrodes

Before attaching the electrodes on to a patient, the user should prepare the skin and place five electrodes on themselves or a volunteer, connect the Monica AN24™ and switch on. The positioning of the electrodes is not important, but this will provide an insight into the skin preparation needed in order to obtain a steady green LED (**5**) indicating that all the electrodes have been correctly attached to the skin.

IV. Lead connection

The 'button' connector on the electrode is located on a 'flap' that is not stuck down. This means that, (a) the flap can be lifted and the correct colour coded lead connector can be pressed/snapped onto the button without pressing on the skin and disturbing the gel electrode contact with the skin and (b) no downward force is applied to the maternal abdomen.

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

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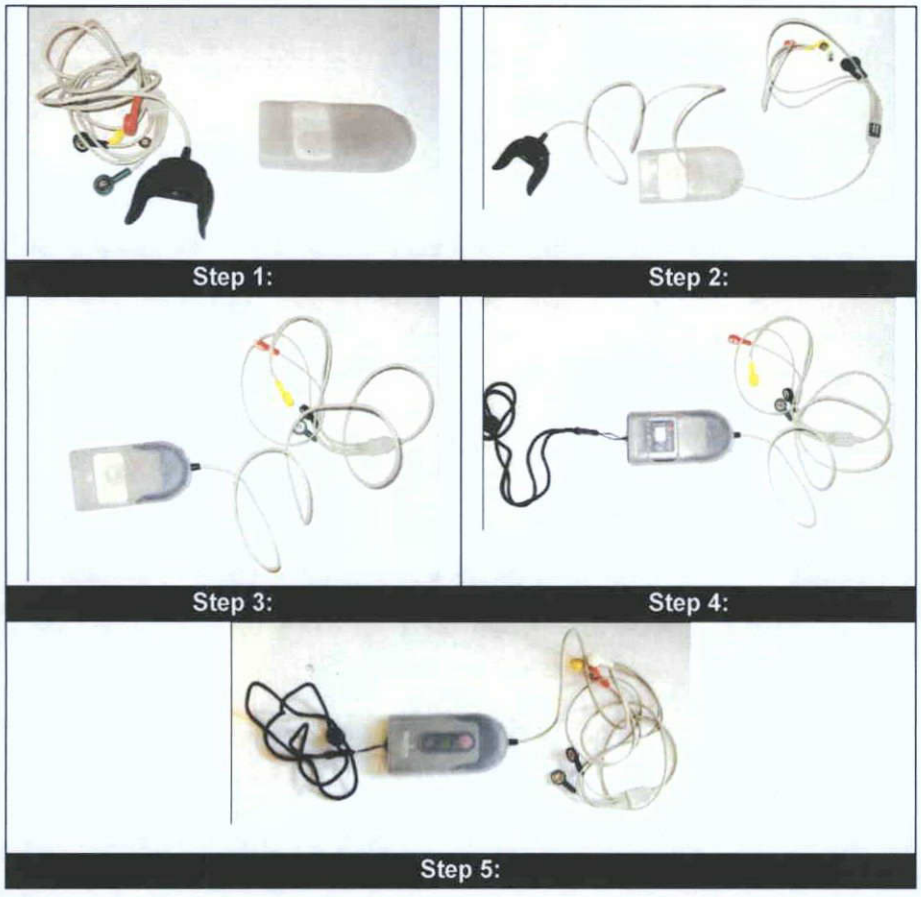
V. Protective cover and neck strap

The protective silicone rubber cover is designed to protect the Monica AN24™ during use, keep it clean and to keep it dry and avoid the ingress of fluids. **It must be used on all L&D subjects.**



Warning: Not using the protective silicone rubber cover could result in the ingress of contaminated blood and other fluids into the Monica AN24 case.

VI. Lead security

It is important to secure and tidy the electrode leads to avoid lead or electrode detachment during operation. The electrode leads are of different lengths to aid in their correct placement and are fitted with two small plastic lead separators, which can be repositioned to avoid lead tangles and aid placement. The long single lead is fitted with a Velcro band so that it can be neatly coiled and secured when the patient is mobile.

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

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VII. Electrostatic Discharge (ESD) precautions

Although precautions have been taken to ensure otherwise, static electricity could cause damage to the sensitive input circuits of the AN24™ and render the device inoperable. In the context of the AN24™, static is most likely to reach the AN24™ via a user\ patient touching static sensitive parts of the device.

ESD precautionary measures should be taken to minimise the risk of damage to the AN24™. More specifically:

- The connector which joins the AN24™ and lead connector together should not be touched by any part of the body, including the fingers
- The metallic (conducting) part of the electrode (press-stud) clips at the extremities of the electrode leads should not be touched by any part of the body, including the fingers

All staff that use the AN24™ should receive an explanation of the ESD warning symbol and receive the following basic training\ instruction in ESD precautions before use of the AN24™:

- How to fit the AN24™ to the patient, and;
- How to attach the electrodes to the AN24™, and;
- How to attach the electrodes to the patient.

Monica Healthcare reserves the right to make changes in specification and/or discontinue any product or accessory at any time without notice or obligation and will not be liable for any consequences resulting from the use of this document.

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Windows XP/Vista are registered trademarks of Microsoft Corporation.
All other trademarks are the property of their respective owners.

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The Monica AN24™™ complies with the requirements of the European Council Directives: 93/42/EEC as amended by 2007/47/EEC, concerning medical devices
ISO 13485 Monica Healthcare Ltd operates Quality Management Systems that have been approved and audited to ISO 13485.

Monica Healthcare Limited
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www.monicahealthcare.com

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DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

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

November 24, 2010

510k Number: K101801
Product: MONICA AN24

MONICA HEALTHCARE
BIOCITY
PENNYFOOT STREET
NOTTINGHAM
UNITED KINGDOM NG1 1GF
ATTN: IAN HOW

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 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 http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089402.htm.

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/MedicalDevices/DeviceRegulationandGuidance/Overview/MedicalDeviceProvisionsofFDAModernizationAct/ucm136685.htm.

If after 30 days the additional information (AI), 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 (21 CFR 807.87(l)). Please note our guidance document entitled, "Guidance for Industry and FDA Staff, FDA and Industry Actions on Premarket Notification (510(k)) Submissions: Effect on FDA Review Clock and Performance Assessment". If the submitter does submit a written request for an extension, FDA will permit the 510(k) to remain on hold for up to a maximum of 180 days from the date of the AI request. The purpose of this document is to assist agency staff and the device industry in understanding how various FDA and industry actions that may be taken on 510(k)s should affect the review clock for purposes of meeting the Medical Device User Fee and Modernization Act. You may review this document at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089735.htm. 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.

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

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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 questions, please contact the Division of Small Manufacturers International and Consumer Assistance (DSMICA) at (301)796-7100 or at their toll-free number (800)638-2041, or contact the 510k staff at (301)796-5640.

Sincerely yours,

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

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DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

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

October 29, 2010

MONICA HEALTHCARE
BIOCITY
PENNYFOOT STREET
NOTTINGHAM
UNITED KINGDOM NG1 1GF
ATTN: IAN HOW

510k Number: K101801

Product: MONICA AN24

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. Pleaseremember that all correspondence concerning your submission MUST be sent to the Document Mail Center 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 http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089402.htm. On August 12, 2005 CDRH issued the Guidance for Industry and FDA Staff: Format for Traditional and Abbreviated 510(k)s. This guidance can be found at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm084365.htm. Please refer to this guidance for assistance on how to format an original submission for a Traditional or Abbreviated 510(k).

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 in 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.

Please ensure that whether you submit a 510(k) Summary as per 21 CFR 807.92, or a 510(k) Statement as per 21 CFR 807.93, it meets the content and format regulatory requirements.

If you have procedural questions, please contact the Division of Small Manufacturers International and Consumer Assistance (DSMICA) at (301)796-7100 or at their toll-free number (800)638-2041, or contact the 510k staff at (301)796-5640.

Sincerely,

510(k) Staff

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

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www.monicahealthcare.com

Ms Marjorie Shulman

Supervisory Consumer Safety Officer

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

20th September 2010

REFERENCE: K101801

TRADE NAME: Monica AN24

Dear Ms Marjorie Shulman

(b)(4)

[redacted]

Thank you for your help.

Yours sincerely,

Ian How

Regulatory Affairs Manager

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

Records processed under FOIA Request #2015-4103; Released by CDRH on 06-06-2016.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

Mr. Ian How
Regulatory Affairs Manager
Monica Healthcare Limited
Biocity, Pennyfoot Street
Nottingham
United Kingdom NG1 1GF

AUG 20 2010

Re: K101801
Trade Name: Monica AN24
Dated: June 24, 2010
Received: June 28, 2010

Dear Mr. How:

We have reviewed your Section 510(k) premarket 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 additional information:

Indications for use

(b)(4)

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

Records processed under FOIA Request #2015-4103; Released by CDRH on 06-06-2016.

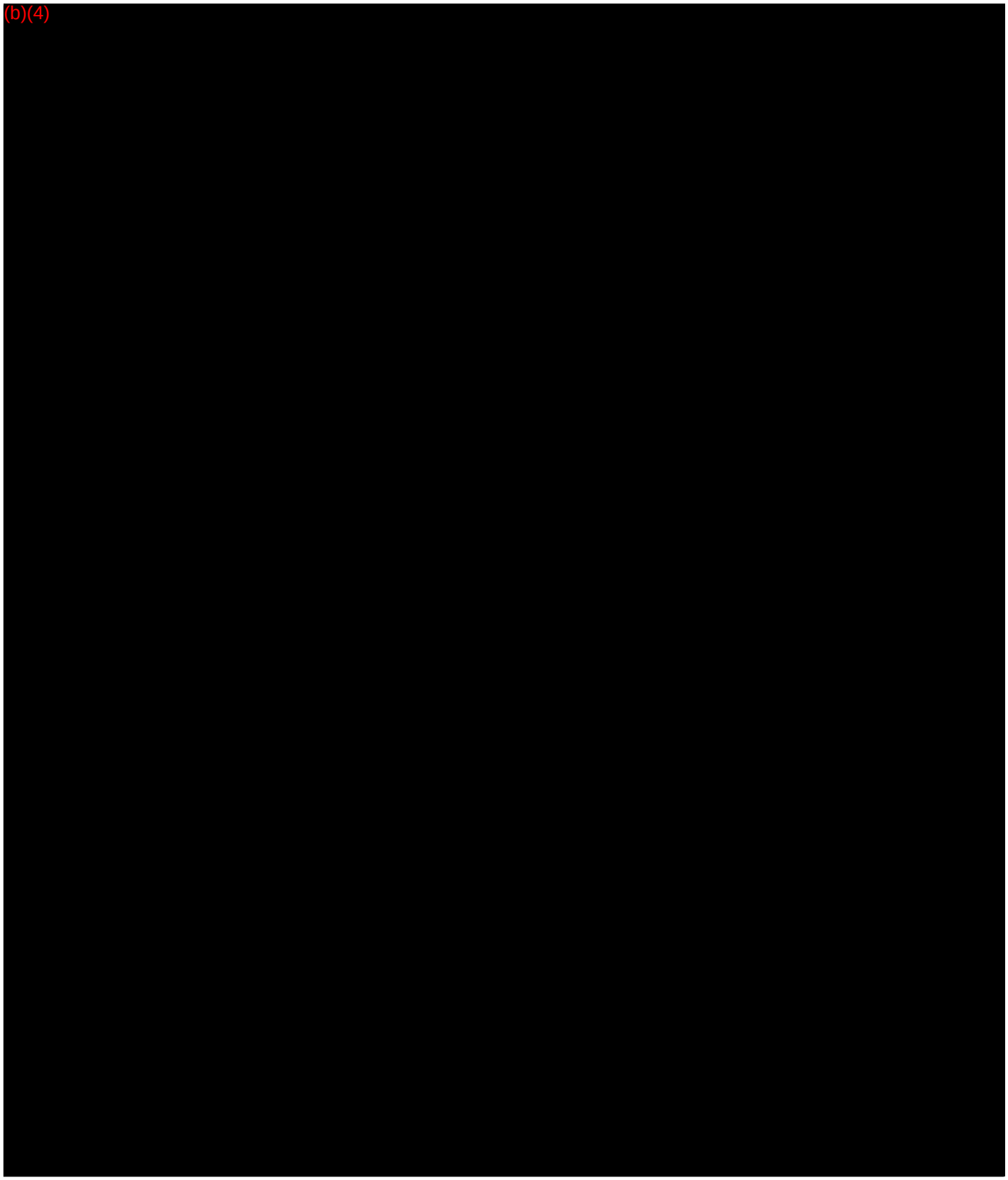
(b)(4)

[redacted]

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

Records processed under FOIA Request #2015-4103; Released by CDRH on 06-06-2016.

(b)(4)



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

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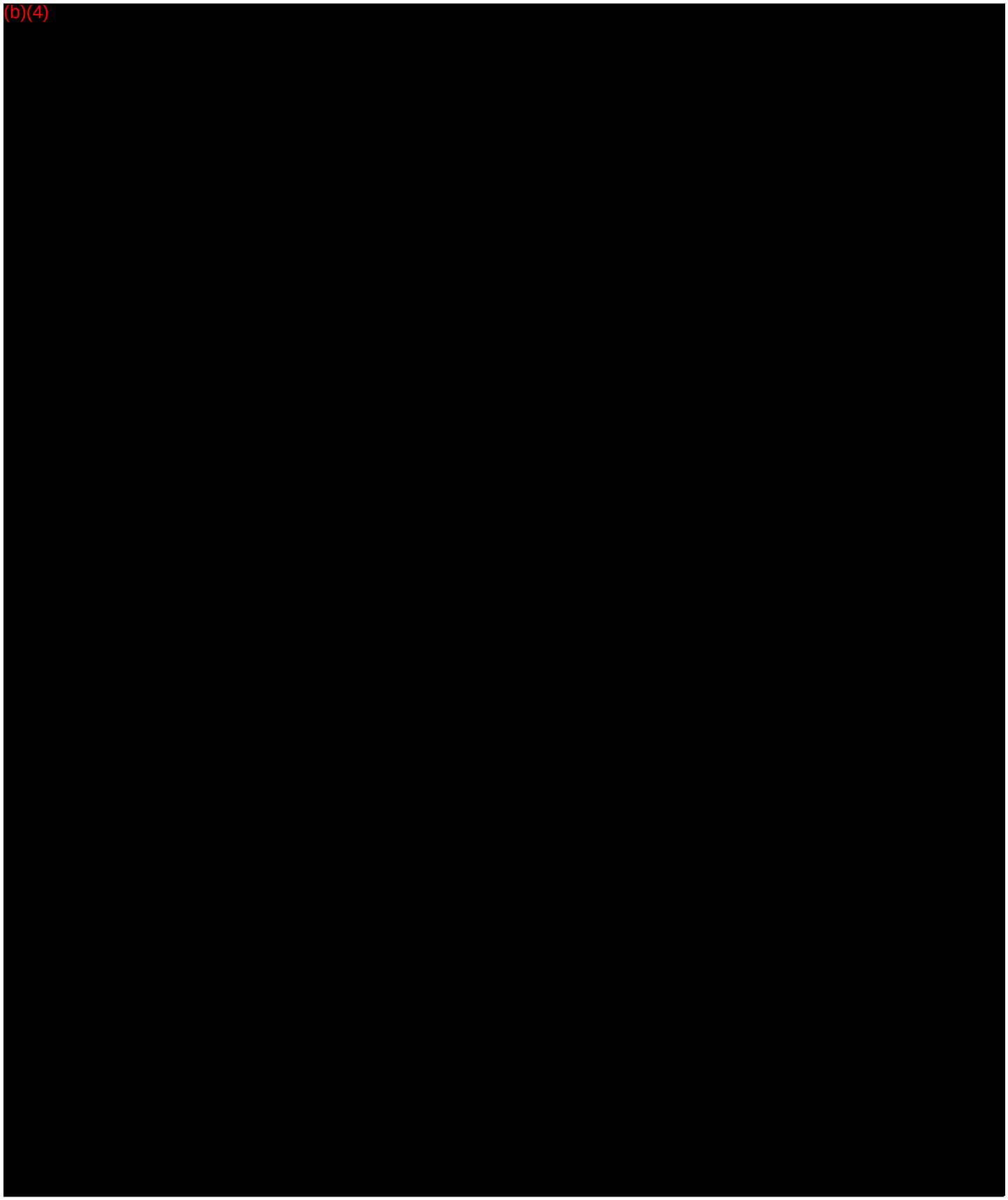
(b)(4)

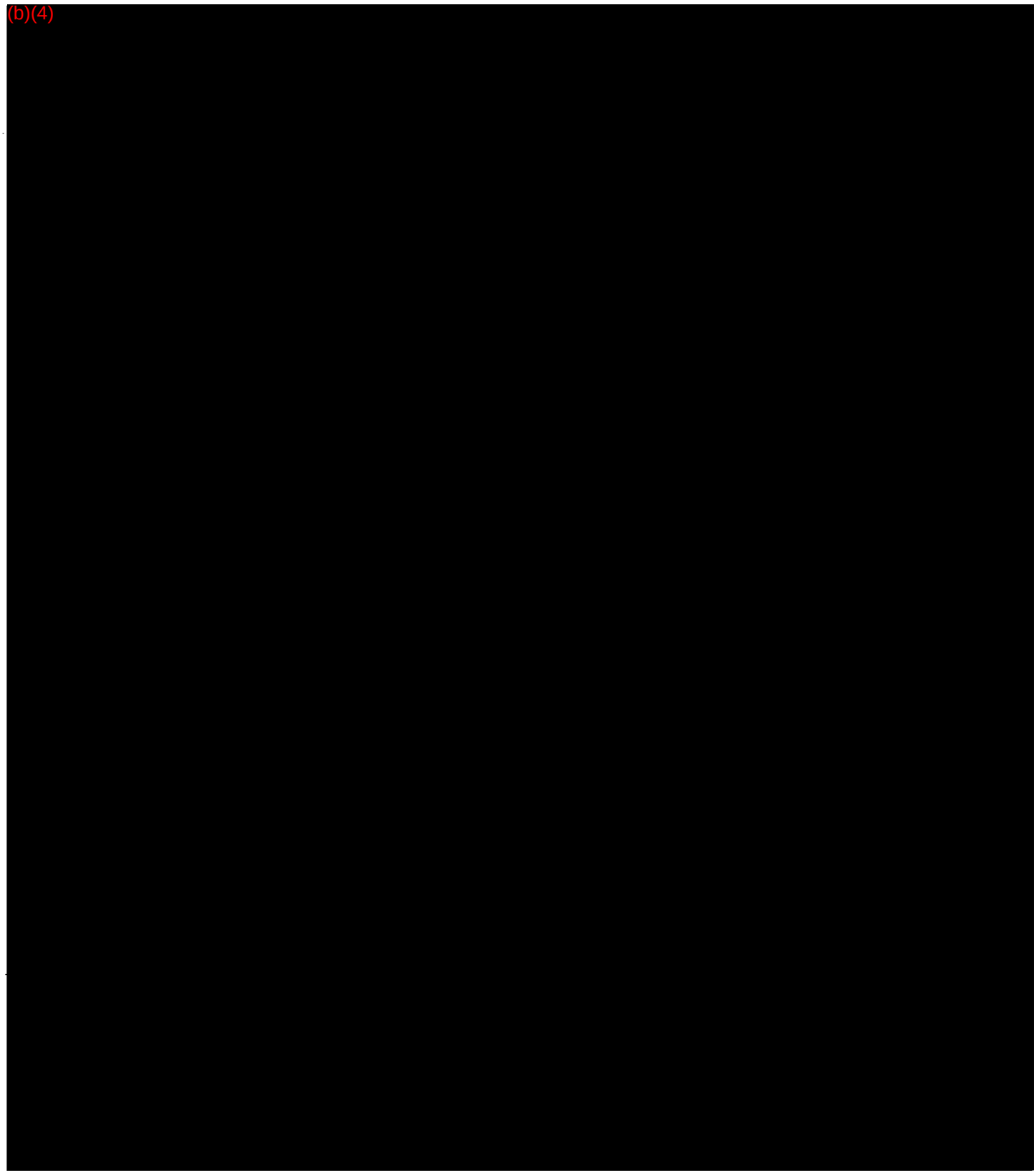


Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

360

Records processed under FOIA Request #2015-4103; Released by CDRH on 06-06-2016.

(b)(4)



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

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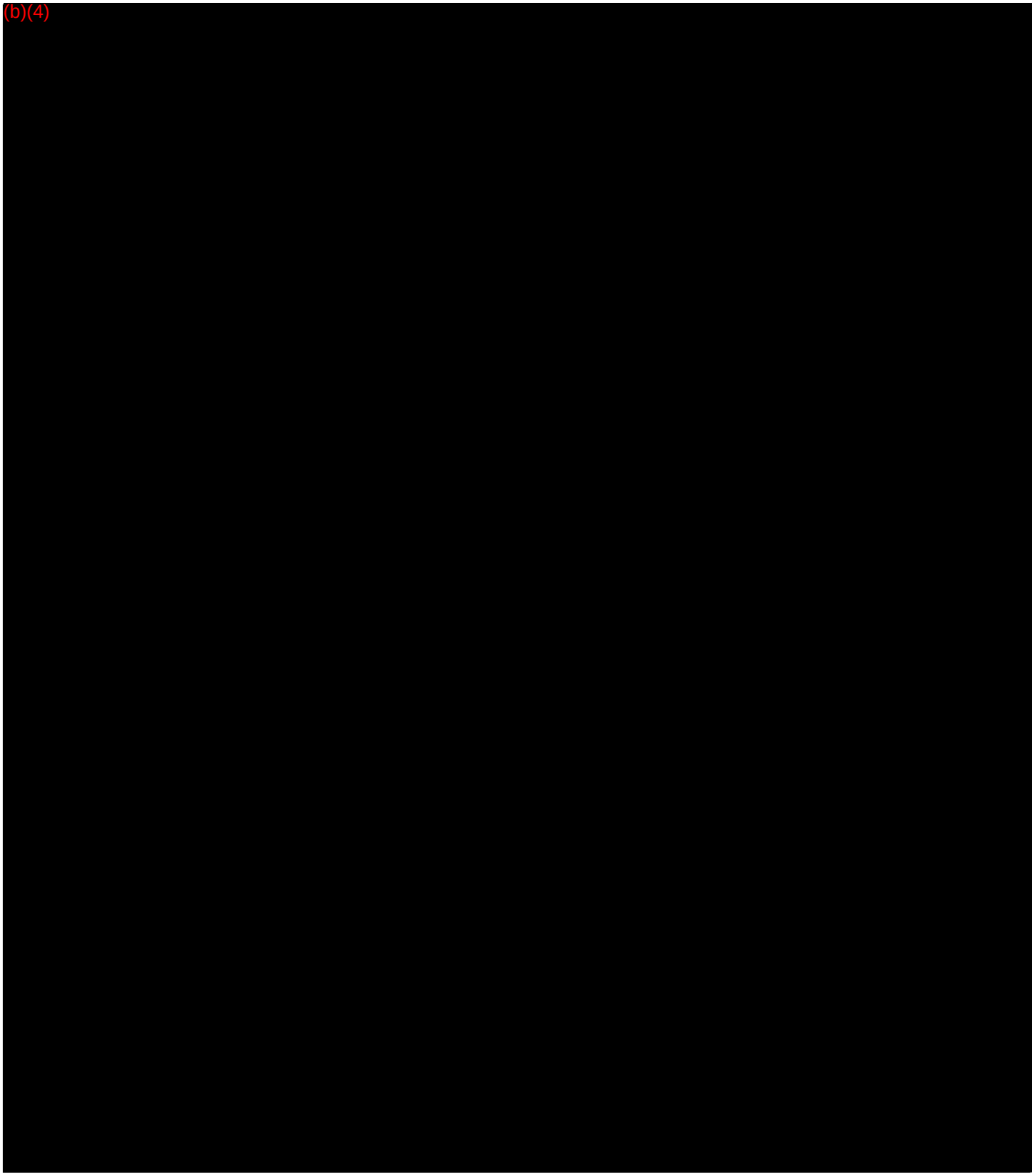
(b)(4)



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

Records processed under FOIA Request #2015-4103; Released by CDRH on 06-06-2016.

(b)(4)

The deficiencies identified above 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 (Act) for determining substantial equivalence of your device.

You may not market this device until you have provided adequate information described above and required by 21 CFR 807.87(l), and you have received a letter from FDA allowing you to do so. If you market the device without conforming to these requirements, you will be in violation of the Act. You may, however, distribute this device for investigational purposes to obtain clinical data if needed to establish substantial equivalence. Clinical investigations of this device must be conducted in accordance with the investigational device exemption (IDE) regulations (21 CFR 812).

If the information, or a request for an extension of time, is not received within 30 days, we will consider your premarket notification to be withdrawn and your submission will be deleted from our system. If you submit the requested information after 30 days it will be considered and processed as a new 510(k)(21 CFR 807.87(l)); therefore, all information previously submitted must be resubmitted so that your new 510(k) is complete. For guidance on 510(k) actions, please see our guidance document entitled, "FDA and Industry Actions on Premarket Notification (510(k)) Submissions: Effect on FDA Review Clock and Performance Assessment" at

Records processed under FOIA Request #2015-4103; Released by CDRH on 06-06-2016.

http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM089738.pdf

If the submitter does submit a written request for an extension, FDA will permit the 510(k) to remain on hold for up to a maximum of 180 days from the date of the additional information request.

The purpose of this document is to assist agency staff and the device industry in understanding how various FDA and industry actions that may be taken on 510(k)s should affect the review clock for purposes of meeting the Medical Device User Fee and Modernization Act. .

The requested information, or a request for an extension of time, should reference your above 510(k) number and should be submitted in duplicate to:

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

If you have any questions concerning the contents of the letter, please contact Kathryn S. Daws-Kopp at (301) 796-6535. If you need information or assistance concerning the IDE regulations, please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or at (301) 796-7100, or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Veronica A Price

for Colin M. Pollard
Chief, Obstetrics and Gynecology
Devices Branch
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

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

Records processed under FOIA Request #2015-4103; Released by CDRH on 06-06-2016.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

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

June 30, 2010

MONICA HEALTHCARE
BIOCITY
PENNYFOOT STREET
NOTTINGHAM
UNITED KINGDOM NG1 1GF
ATTN: IAN HOW

510k Number: K101801
Received: 6/28/2010
Product: MONICA AN24

The Food and Drug Administration (FDA), Center for Devices and Radiological Health (CDRH), has received the Premarket Notification, (510(k)), you submitted in accordance with Section 510(k) of the Federal Food, Drug, and Cosmetic Act(Act) for the above referenced product and for the above referenced 510(k) submitter. Please note, if the 510(k) submitter is incorrect, please notify the 510(k) Staff immediately. We have assigned your submission a unique 510(k) number that is cited above. Please refer prominently to this 510(k) number in all future correspondence that relates to this submission. We will notify you when the processing of your 510(k) 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.

Please remember that all correspondence concerning your submission MUST be sent to the Document Mail Center (DMC) at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official 510(k) submission.

On September 27, 2007, the President signed an act reauthorizing medical device user fees for fiscal years 2008 - 2012. The legislation - the Medical Device User Fee Amendments of 2007 is part of a larger bill, the Food and Drug Amendments Act of 2007. Please visit our website at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/MedicalDeviceUserFeeandModernizationActMDUFMA/default.htm
for more information regarding fees and FDA review goals. In addition, effective January 2, 2008, any firm that chooses to use a standard in the review of ANY new 510(k) needs to fill out the new standards form (Form 3654) and submit it with their 510(k). The form may be found at http://www.fda.gov/AboutFDA/ReportsManualsForms/Forms/default.htm.

We remind you that Title VIII of the Food and Drug Administration Amendments Act of 2007 (FDAAA) amended the PHS Act by adding new section 402(j) (42 U.S.C. § 282(j)), which expanded the current database known as ClinicalTrials.gov to include mandatory registration and reporting of results for applicable clinical trials of human drugs (including biological products) and devices. Section 402(j) requires that a certification form http://www.fda.gov/AboutFDA/ReportsManualsForms/Forms/default.htm accompany 510(k)/HDE/PMA submissions. The agency has issued a draft guidance titled: "Certifications To Accompany Drug, Biological

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

Records processed under FOIA Request #2015-4103; Released by CDRH on 06-06-2016.

Product, and Device Applications/Submissions: Compliance with Section 402(j) of The Public Health Service Act, Added By Title VIII of The Food and Drug Administration Amendments Act of 2007" http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/ucm134034.htm. According to the draft guidance, 510(k) submissions that do not contain clinical data do not need the certification form.

Please note the following documents as they relate to 510(k) review: 1) Guidance for Industry and FDA Staff entitled, "Interactive Review for Medical Device Submissions: 510(k)s, Original PMAs, PMA Supplements, Original BLAs and BLA Supplements". This guidance can be found at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089402.htm. Please refer to this guidance for information on a formalized interactive review process. 2) Guidance for Industry and FDA Staff entitled, "Format for Traditional and Abbreviated 510(k)s". This guidance can be found at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm084365.htm. Please refer to this guidance for assistance on how to format an original submission for a Traditional or Abbreviated 510(k).

In all future premarket submissions, we encourage you to provide an electronic copy of your submission. By doing so, you will save FDA resources and may help reviewers navigate through longer documents more easily. Under CDRH's e-Copy Program, you may replace one paper copy of any premarket submission (e.g., 510(k), IDE, PMA, HDE) with an electronic copy. For more information about the program, including the formatting requirements, please visit our web site at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/ucm134508.html. In addition, the 510(k) Program Video is now available for viewing on line at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/ucm070201.htm .

Please ensure that whether you submit a 510(k) Summary as per 21 CFR 807.92, or a 510(k) Statement as per 21 CFR 807.93, it meets the content and format regulatory requirements.

Lastly, you should be familiar with the regulatory requirements for medical devices available at Device Advice http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/default.htm. If you have questions on the status of your submission, please contact DSMICA at (301)796-7100 or the toll-free number (800)638-2041 , or at their internet address http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/default.htm. If you have procedural questions, please contact the 510(k) Staff at (301)796-5640.

Sincerely,

510(k) Staff

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

Records processed under FOIA Request #2015-4103; Released by CDRH on 06-06-2016.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

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

June 29, 2010

MONICA HEALTHCARE
BIOCITY
PENNYFOOT STREET
NOTTINGHAM
UNITED KINGDOM NG1 1GF
ATTN: IAN HOW

510k Number: K101801
Received: 6/28/2010
User Fee ID Number: 6049448
Product: MONICA AN24

The Food and Drug Administration (FDA) Center for Devices and Radiological Health (CDRH), 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 all future correspondence that relates to this submission. YOU MAY NOT PLACE THIS DEVICE INTO COMMERCIAL DISTRIBUTION UNTIL YOU RECEIVE A LETTER FROM FDA ALLOWING YOU TO DO SO.

The Federal Food, Drug, and Cosmetic Act (the Act), as amended by the Medical Device User Fee and Modernization Act of 2002 (MDUFMA) and the FDA Amendments Act of 2007 (FDAAA) (Public Law 110-85), authorizes FDA to collect user fees for certain types of 510(k) submissions. The submission cannot be accepted for review until the fee is paid in full ; therefore, the file has been placed on hold. When your user fee payment has been received , review of the 510(k) will resume as of that date. Alternatively, you may request withdrawal of your submission. You now have the option to pay online by credit card. We recommend this form of payment. Credit card payments are directly linked to your user fee cover sheet and are processed the next business day. You may also pay by check. If you choose to mail a check, please send a check to one of the addresses listed below:

By Regular Mail
Food and Drug Administration
P.O. Box 956733
St. Louis, MO 63195-6733.

By Private Courier(e.g.,Fed Ex, UPS, etc.)
U.S. Bank
956733
1005 Convention Plaza
St. Louis, MO 63101

The check should be made out to the Food and Drug Administration referencing the payment identification number, and a copy of the User Fee Cover sheet should be included with the check. A copy of the Medical Device User Fee Cover Sheet should be faxed to CDRH at {ODE_POS_FAX_NUMBER} referencing the 510(k) number if you have not already sent it in with your 510(k) submission. After the FDA has been notified of the receipt of your user fee payment, your 510(k) will be filed and the review will begin. If payment has not been received within 30 days, your 510(k) will be deleted from the system. Additional information on user fees and how to submit your user fee payment may be found at www.fda.gov/cdrh/mdufma/fy09userfee.html. In addition, the 510k Program Video is now available for viewing on line at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/ucm070201.htm.

Records processed under FOIA Request #2015-4003 Released in part - 2 of 2006

In all future premarket submissions, we encourage you to provide an electronic copy of your submission. By doing so, you will save FDA resources and may help reviewers navigate through longer documents more easily. Under CDRH's e-Copy Program, you may replace one paper copy of any premarket submission (e.g., 510(k), IDE, PMA, or HDE) with an electronic copy. For more information about the program, including the formatting requirements, please visit our web site at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/ucm134508.htm.

Please note that since your 510(k) has not been reviewed, additional information may be required during the review process and the file may be placed on hold once again. If you are unsure as to whether or not you need to file a 510k Submission with FDA or what type of submission to submit, you should first telephone the Division of Small Manufacturers, International and Consumer Assistance (DSMICA), for guidance at (301)796-7100 or its toll-fee number (800)638-2041, or contact them at their Internet address http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/default.htm, or you may submit a 513(g) request for information regarding classification to the Document Mail Center at the address above. If you have any questions concerning receipt of your payment, please contact Diane Garcia at Diane.Garcia@fda.hhs.gov or directly at (301)796-7200. If you have questions regarding the status of your 510(k) Submission, please contact DSMICA at the numbers or address above.

Sincerely yours,

Diane Garcia
Public Affairs Specialist
Premarket Notification Section
Office of Device Evaluation
Center for Devices and Radiological Health

Records processed under FOIA Request #2015-4103; Released by CDRH on 06-06-2016.

K101801

Monica Healthcare Limited
Biocity, Pennyfoot Street, Nottingham, NG1 1GF, UK
T +44 (0)115 912 4540 / F +44 (0)115 912 4289 / E info@monicahealthcare.com
www.monicahealthcare.com

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center - WO66-G609
10903 New Hampshire Avenue
Silver Spring, Maryland 20993-0002

FDA CDRH DMC

JUN 28 2010

Received

received originae
510-K

11 August 2010

K101801

Dear Sir or Madam Please find enclosed

1 revised electronic copy on CD as requested by Janee Sims. The dat on the CD is identical to the paper copy previously received, except the CD contains the addition of the PDF traces as they are considered to be data and are acceptable due to size and the ability to view the data.

Yours Sincerely

.....

Ian How

Regulatory Affairs Manager

Monica Healthcare Ltd

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

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K10/801

Monica Healthcare Limited
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T +44 (0)115 912 4540 / F +44 (0)115 912 4289 / E info@monicahealthcare.com
www.monicahealthcare.com

Food And Drug Administration

Centre for Devices and Radiological Health

Document Mail Centre – WO66 – G609

10903 New Hampshire Avenue

Silver Spring, Maryland USA 20993-0002

FDA CDRH DMC
JUN 28 2010
Received

June 24 2010

Dear Sir or Madam

Please find enclosed in this package the 51(0)K submission for the Monica Healthcare Fetal Monitor. This has been booked online and payment submitted under number MD6049448-956733.

Included in this package are

- 1 paper copy of the 510(K), with the appendices on a CD, as agreed with the FDA
- 1 electronic copy of the submission on a CD, as per the FDA rules

Yours Sincerely

.....

Ian How

Regulatory Affairs Manager

Tel: +44 (0)115 912 4541

E: ianhow@monicahealthcare.com

K28
OB
JL

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

481

Records processed under FOIA Request #2015-4103; Released by CDRH on 06-06-2016.

Monica Healthcare

Confidential

510(K) PREMARKET NOTIFICATION

MONICA HEALTHCARE LIMITED

MONICA AN24

Submission date:
June 2010

The term "predicate device(s)"as used throughout this entire premarket notification (cover letter, body, attachments, and summary), and the supporting information pertaining to equivalence, are intended to demonstrate equivalence to the predicate device(s) for the purposes of obtaining clearance of the subject device(s) under the Federal Food, Drug and Cosmetic Act. Any references to equivalence in this submission are in no way related to any form of equivalence under patent laws.

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

Records processed under FOIA Request #2015-4103; Released by CDRH on 06-06-2016.

Monica Healthcare

SCREENING CHECKLIST FOR ALL PREMARKET NOTIFICATION [510(k)] SUBMISSIONS

510(k) Number: _____

The cover letter clearly identifies the type of 510(k) submission as **(Check the appropriate box)**:

☐ Special 510(k) - Do Sections 1 and 2

☐ Abbreviated 510(k) - Do Sections 1, 3 and 4

☐ Traditional 510(k) or no identification provided - Do Sections 1 and 4

Section 1: Required Elements for All Types of 510(k) submissions:

	Present or Adequate	Missing or Inadequate
Cover letter, containing the elements listed on page 3-2 of the Premarket Notification [510)] Manual.		
Table of Contents.		
Truthful and Accurate Statement.		
Device?s Trade Name, Device?s Classification Name and Establishment Registration Number.		
Device Classification Regulation Number and Regulatory Status (Class I, Class II, Class III or Unclassified).		
Proposed Labeling? including the material listed on page 3-4 of the Premarket Notification [510)] Manual.		
Statement of Indications for Use that is on a separate page in the premarket submission.		
Substantial Equivalence Comparison, including comparisons of the new device with the predicate in areas that are listed on page 3-4 of the Premarket Notification [510)] Manual.		
510(k) Summary or 510(k) Statement.		
Description of the device (or modification of the device) including diagrams, engineering drawings, photographs or service manuals.		
Identification of legally marketed predicate device. *		

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

Records processed under FOIA Request #2015-4103; Released by CDRH on 06-06-2016.

Monica Healthcare

Compliance with performance standards. * [See Section 514 of the Act and 21 CFR 807.87 (d).]		
Class III Certification and Summary. **		
Financial Certification or Disclosure Statement for 510(k) notifications with a clinical study. * [See 21 CFR 807.87 (i)]		
510(k) Kit Certification ***		

Section 4: Additional Requirements for ABBREVIATED and TRADITIONAL 510(k) submissions (If Applicable):

	Present	Inadequate or Missing
a)?? Biocompatibility data for all patient-contacting materials, OR certification of identical material/formulation:	-	-
b)?? Sterilization and expiration dating information:		
i) sterilization process		
ii) validation method of sterilization process		
iii) SAL		
iv) packaging		
v) specify pyrogen free		
vi) ETO residues		
vii) radiation dose		
viii) Traditional Method or Non-Traditional Method		
c)?? Software Documentation:		

Items with checks in the? Present or Adequate? column do not require additional information from the sponsor.? Items with checks in the ? Missing or Inadequate? column must be submitted before substantive review of the document.

Passed Screening _____Yes _____No

Reviewer:_____

Concurrence by Review Branch:_____

Date:_____

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

Records processed under FOIA Request #2015-4103; Released by CDRH on 06-06-2016.

Monica Healthcare

(b)(4)

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

Records processed under FOIA Request #2015-4103; Released by CDRH on 06-06-2016.

Section 1

- Medical Device User Fee Cover Sheet
- CDRH Premarket Review Submission Cover Sheet
- 510(k) Cover Letter
- Indications for Use Statement
- 510(k) Statement
- Truthful and Accuracy Statement
- Class III Summary and Certification
- Financial Certification or Disclosure Statement

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

Records processed under FOIA Request #2015-4103; Released by CDRH on 06-06-2016.

Monica Healthcare

Medical Device User Fee Cover Sheet (FDA3601)

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION **MEDICAL DEVICE USER FEE COVER SHEET**	PAYMENT IDENTIFICATION NUMBER: (b)(4) Write the Payment Identification number on your check.
A completed cover sheet must accompany each original application or supplement subject to fees. If payment is sent by U.S. mail or courier, please include a copy of this completed form with payment. Payment and mailing instructions can be found at: http://www.fda.gov/oc/mdufma/coversheet.html	
1. COMPANY NAME AND ADDRESS (include name, street address, city state, country, and post office code) MONICA HEALTHCARE LIMITED Biocity Pennyfoot Street Nottingham NG1 1GF GB 1.1 EMPLOYER IDENTIFICATION NUMBER (EIN)	2. CONTACT NAME Ian How 2.1 E-MAIL ADDRESS ianhow@monicahealthcare.com 2.2 TELEPHONE NUMBER (include Area code) 44115-9124540 2.3 FACSIMILE (FAX) NUMBER (Include Area code) 44115-9124289

3. TYPE OF PREMARKET APPLICATION (Select one of the following in each column; if you are unsure, please refer to the application descriptions at the following web site: http://www.fda.gov/oc/mdufma

Select an application type:	3.1 Select a center
[X] Premarket notification(510(k)); except for third party	[X] CDRH
[ ] 513(g) Request for Information	[ ] CBER
[ ] Biologics License Application (BLA)	3.2 Select one of the types below
[ ] Premarket Approval Application (PMA)	[X] Original Application
[ ] Modular PMA	Supplement Types:
[ ] Product Development Protocol (PDP)	[ ] Efficacy (BLA)
[ ] Premarket Report (PMR)	[ ] Panel Track (PMA, PMR, PDP)
[ ] Annual Fee for Periodic Reporting (APR)	[ ] Real-Time (PMA, PMR, PDP)
[ ] 30-Day Notice	[ ] 180-day (PMA, PMR, PDP)

4. ARE YOU A SMALL BUSINESS? (See the instructions for more information on determining this status)

[ ] YES, I meet the small business criteria and have submitted the required qualifying documents to FDA

[X] NO, I am not a small business

4.1 If Yes, please enter your Small Business Decision Number:

5. FDA WILL NOT ACCEPT YOUR SUBMISSION IF YOUR COMPANY HAS NOT PAID AN ESTABLISHMENT REGISTRATION FEE THAT IS DUE TO FDA. HAS YOUR COMPANY PAID ALL ESTABLISHMENT REGISTRATION FEES THAT ARE DUE TO FDA?

[X] YES (All of our establishments have registered and paid the fee, or this is our first device, and we will register and pay the fee within 30 days of FDA's approval/clearance of this device.)

[ ] NO (If "NO," FDA will not accept your submission until you have paid all fees due to FDA. This submission will not be processed; see http://www.fda.gov/cdrh/mdufma for additional information)

6. IS THIS PREMARKET APPLICATION COVERED BY ANY OF THE FOLLOWING USER FEE EXCEPTIONS? IF SO, CHECK THE APPLICABLE EXCEPTION.

[ ] This application is the first PMA submitted by a qualified small business, including any affiliates	[ ] The sole purpose of the application is to support conditions of use for a pediatric population
[ ] This biologics application is submitted under section 351 of the Public Health Service Act for a product licensed for further manufacturing use only	[ ] The application is submitted by a state or federal government entity for a device that is not to be distributed commercially

7. IS THIS A SUPPLEMENT TO A PREMARKET APPLICATION FOR WHICH FEES WERE WAIVED DUE TO SOLE USE IN A PEDIATRIC POPULATION THAT NOW PROPOSES CONDITION OF USE FOR ANY ADULT POPULATION? (If so, the application is subject to the fee that applies for an original premarket approval application (PMA).

[ ] YES [X] NO

8. USER FEE PAYMENT AMOUNT SUBMITTED FOR THIS PREMARKET APPLICATION

(b)(4)

15-Jun-2010

Form FDA 3601 (02/2007)

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

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Monica Healthcare

CDRH Premarket Review Submission Cover

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

CDRH PREMARKET REVIEW SUBMISSION COVER SHEET

Form Approval
OMB No. 0910-0120
Expiration Date: August 31, 2010.
See OMB Statement on page 5.

Date of Submission	User Fee Payment ID Number	FDA Submission Document Number *(if known)*

SECTION A — TYPE OF SUBMISSION

PMA	PMA & HDE Supplement	PDP	510(k)	Meeting
☐ Original Submission	☐ Regular (180 day)	☐ Original PDP	☒ Original Submission:	☐ Pre-510(K) Meeting
☐ Premarket Report	☐ Special	☐ Notice of Completion	☒ Traditional	☐ Pre-IDE Meeting
☐ Modular Submission	☐ Panel Track (PMA Only)	☐ Amendment to PDP	☐ Special	☐ Pre-PMA Meeting
☐ Amendment	☐ 30-day Supplement		☐ Abbreviated (Complete section I, Page 5)	☐ Pre-PDP Meeting
☐ Report	☐ 30-day Notice		☐ Additional Information	☐ Day 100 Meeting
☐ Report Amendment	☐ 135-day Supplement		☐ Third Party	☐ Agreement Meeting
☐ Licensing Agreement	☐ Real-time Review			☐ Determination Meeting
	☐ Amendment to PMA & HDE Supplement			☐ Other *(specify)*:
	☐ Other			

IDE	Humanitarian Device Exemption (HDE)	Class II Exemption Petition	Evaluation of Automatic Class III Designation (De Novo)	Other Submission
☐ Original Submission	☐ Original Submission	☐ Original Submission	☐ Original Submission	☐ 513(g)
☐ Amendment	☐ Amendment	☐ Additional Information	☐ Additional Information	☐ Other *(describe submission)*:
☐ Supplement	☐ Supplement			
	☐ Report			
	☐ Report Amendment			

Have you used or cited Standards in your submission? ☒ Yes ☐ No *(If Yes, please complete Section I, Page 5)*

SECTION B — SUBMITTER, APPLICANT OR SPONSOR

Company / Institution Name	Establishment Registration Number *(if known)*		
Monica Healthcare Ltd			
Division Name *(if applicable)*	Phone Number *(including area code)*		
	+44 (0)115 912 4540		
Street Address	FAX Number *(including area code)*		
Biocity, Pennyfoot Street	+44 (0)115 9124289		
City	State / Province	ZIP/Postal Code	Country
Nottingham		NG1 1GF	UK
Contact Name			
Ian How			
Contact Title	Contact E-mail Address		
Regulatory Affairs Manager	ianhow@monicahealthcare.com		

SECTION C — APPLICATION CORRESPONDENT (e.g., consultant, if different from above)

Company / Institution Name			
Division Name *(if applicable)*	Phone Number *(including area code)*		
Street Address	FAX Number *(including area code)*		
City	State / Province	ZIP Code	Country
Contact Name			
Contact Title	Contact E-mail Address		

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

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SECTION D1 REASON FOR APPLICATION - PMA, PDP, OR HDE

- ☐ New Device
- ☐ Withdrawal
- ☐ Additional or Expanded Indications
- ☐ Request for Extension
- ☐ Post-approval Study Protocol
- ☐ Request for Applicant Hold
- ☐ Request for Removal of Applicant Hold
- ☐ Request to Remove or Add Manufacturing Site

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

- ☐ Response to FDA correspondence:

- ☐ Change in design, component, or specification:
  - ☐ Software / Hardware
  - ☐ 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

- ☐ Report Submission:
  - ☐ Annual or Periodic
  - ☐ Post-approval Study
  - ☐ Adverse Reaction
  - ☐ Device Defect
  - ☐ Amendment

- ☐ Change in Ownership
- ☐ Change in Correspondent
- ☐ Change of Applicant Address

☐ Other Reason *(specify)*:

SECTION D2 REASON FOR APPLICATION - IDE

- ☐ New Device
- ☐ New Indication
- ☐ Addition of Institution
- ☐ Expansion / Extension of Study
- ☐ IRB Certification
- ☐ Termination of Study
- ☐ Withdrawal of Application
- ☐ Unanticipated Adverse Effect
- ☐ Notification of Emergency Use
- ☐ Compassionate Use Request
- ☐ Treatment IDE
- ☐ Continued Access

- ☐ Change in:
  - ☐ Correspondent / Applicant
  - ☐ Design / Device
  - ☐ Informed Consent
  - ☐ Manufacturer
  - ☐ Manufacturing Process
  - ☐ Protocol - Feasibility
  - ☐ Protocol - Other
  - ☐ Sponsor

- ☐ Report submission:
  - ☐ Current Investigator
  - ☐ Annual Progress Report
  - ☐ Site Waiver Report
  - ☐ 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
  - ☐ Request Hearing

☐ Other Reason *(specify)*:

SECTION D3 REASON FOR SUBMISSION - 510(k)

- ☒ New Device
- ☐ Additional or Expanded Indications
- ☐ Change in Technology

☒ Other Reason *(specify)*:

Continuation from K081435, to address FDA concerns and include a 6 way substantial equivalence trial

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

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SECTION E ADDITIONAL INFORMATION ON 510(K) SUBMISSIONS

Product codes of devices to which substantial equivalence is claimed

1	HGM	2		3		4	
5		6		7		8	

Summary of, or statement concerning, safety and effectiveness information

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

Information on devices to which substantial equivalence is claimed *(if known)*

	510(k) Number	Trade or Proprietary or Model Name	Manufacturer
1	K954351	Phillips Series 50XM	Phillips
2			
3			
4			
5			
6			

SECTION F PRODUCT INFORMATION - APPLICATION TO ALL APPLICATIONS

Common or usual name or classification name

Classification 884 2740 Perinatal Monitoring System

	Trade or Proprietary or Model Name for This Device	Model Number
1	Monica AN24	
2		
3		
4		
5		

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

1	K081435	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 - APPLICATION TO ALL APPLICATIONS

Product Code	C.F.R. Section *(if applicable)*	Device Class
HGM	884 2740	☐ Class I ☒ Class II ☐ Class III ☐ Unclassified

Classification Panel

Obstetrics / Gynecology

Indications *(from labeling)*

The Monica AN24 is a monitoring device for non-invasively measuring the Fetal Heart Rate (FHR) and Uterine Activity (UA). The Monica VR software, which accompanies the AN24, enables the measured parameters to be reviewed graphically using a PC or notebook computer and to generate hard copy traces in a "standard" user defined format. This data is intended to aid in assessment of the wellbeing of the fetus and mother for laboring singleton pregnancies who are of gestation age >37 weeks. The AN24 device typically generates standard length FHR and UA traces from a single setup. Application of the device must be by trained personnel, but monitoring sessions can be carried out in hospital and clinics.

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

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Monica Healthcare

Note: Submission of this information does not affect the need to submit a 2891 or 2891a Device Establishment Registration form.	FDA Document Number *(if known)*

(b)(4)

[redacted]

☐ Original ☐ Add ☐ Delete	Facility Establishment Identifier (FEI) Number	☐ Manufacturer ☐ Contract Manufacturer	☐ Contract Sterilizer ☐ Repackager / Relabeler
Company / Institution Name		Establishment Registration Number	
Division Name *(if applicable)*		Phone Number *(including area code)*	
Street Address		FAX Number *(including area code)*	
City		State / Province	ZIP Code / Country
Contact Name	Contact Title	Contact E-mail Address	

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

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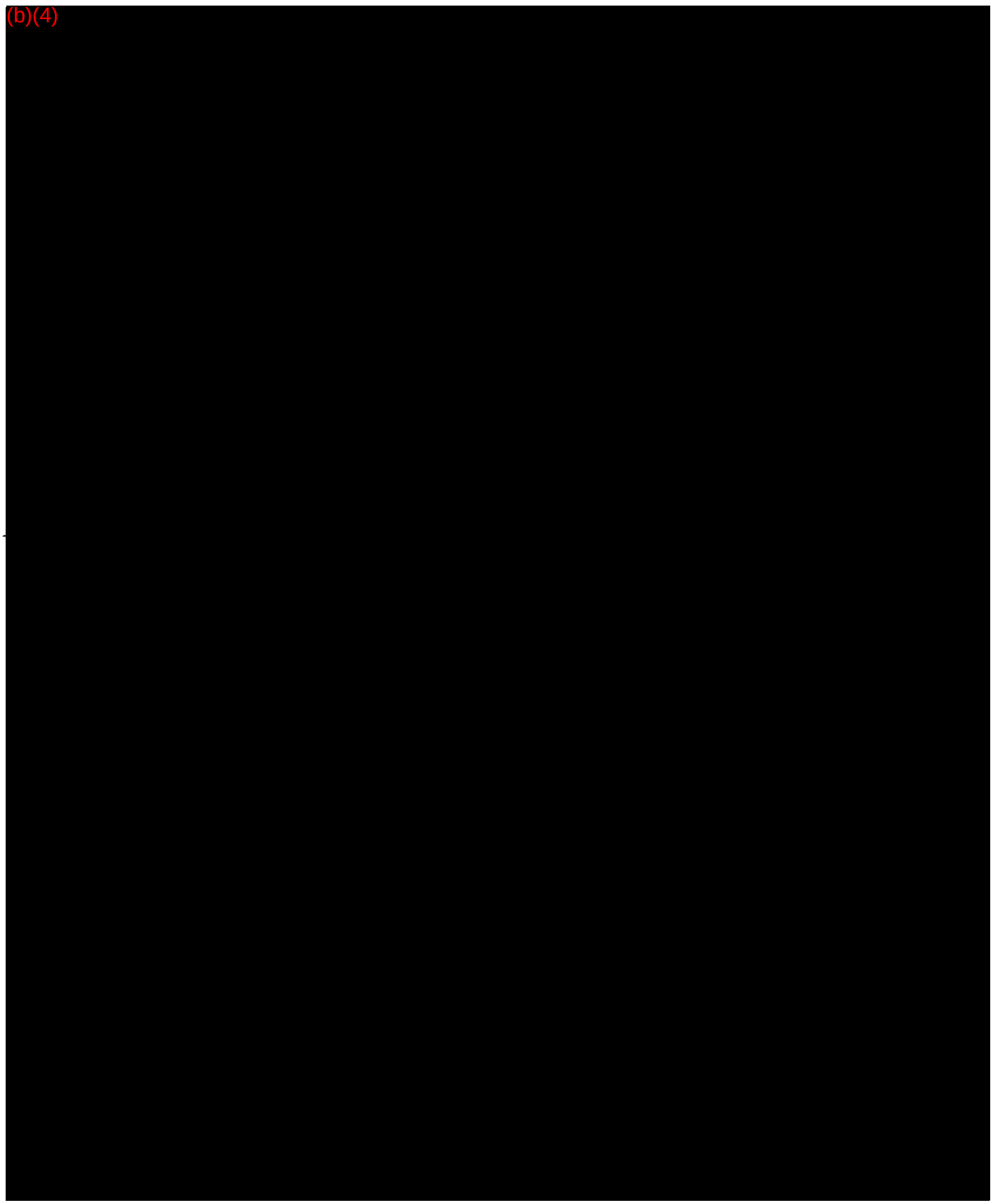
(b)(4)



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

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Monica Healthcare

510(k) Cover Letter

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

Date: June 2010

Dear Sir/Madam,

510(k) Notification (21 CFR 807.90(e)) – Traditional Submission

This letter accompanies two (2) copies of documentation in support of a 510(k) Notification (21 CFR 807.90(e)) for the Monica Healthcare AN24 Fetal Heart Rate Monitor and accessories. One of the copies provided is an electronic copy and it is an exact duplicate of the paper copy. As per 21 CFR 807.95, we are requesting continued confidentiality of the intent to market this device. Please see the enclosed CDRH Premarket Review Submission Cover Sheet (Section 2 of this submission) for additional required administrative information as per the CDRH Guidance Document Format for Traditional and Abbreviated 510(k)s", issued August 12, 2005.
The principal factors pertaining to the design and use of the Monica AN24 device are provided below:

Type of 510(k) Submission:	Traditional
Device Type:	Fetal Maternal Monitor
510(k) Submitter:	Monica Healthcare
Contact details:	Mr. Ian How Regulatory affairs Manager Tel: +44 115 9124540 Email: ianhow@monicahealthcare.com
Classification Name:	Perinatal monitoring system and accessories
Classification Reference:	HGM
Recommended classification:	Class II
Product Code:	884.2740
Panel:	Obstetrics/Gynecology
Former Correspondence:	K081435 510(K) submission (Appendix E)
Basis For submission:	New device

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

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Monica Healthcare

Design and Use of the Device

Question	YES	NO
Is the device intended for prescription use (21 CFR 801 Subpart D)?	YES	
Is the device intended for over-the-counter use (21 CFR 807 Subpart C)?		NO
Does the device contain components derived from a tissue or other biologic source?		NO
Is the device provided sterile?		NO
Is the device a reprocessed single use device?		NO
If yes, does this device type require reprocessed validation data?		
Does the device contain a drug?		NO
Does the device contain a biologic?		NO
Does the device use software?	YES	
Does the submission include clinical information?	YES	
Is the device implanted?		NO

Preference for continued confidentiality: Monica Healthcare considers its intent to market the AN24 device and accessories as confidential commercial information. The Company has not disclosed its intent to market this device to anyone except its employees, others with a financial interest in the Company, its advertising or law firms, and its consultants. The Company, therefore, requests that FDA not disclose the existence of this application until such time as final action on the submission is taken. In addition, some of the material in this application may be trade secret or confidential commercial or financial information within the meaning of 21 CFR § 20.61 and therefore not disclosable under the Freedom of Information Act, even after the existence of the application becomes public. We ask that you consult with the Company as provided in 21 CFR § 20.45 before making any part of this submission, other than the 510(k) statement, publicly available.

Thank you for your review of this 510(k) submission. If you have any questions or require clarification of any information in this document, please do not hesitate to contact the undersigned.

Yours sincerely,

Carl Barratt

CEO
Monica Healthcare
BioCity, Pennyfoot Street,
Nottingham,NG1 1GF, UK
T:+44(0)115 9124540
F:+44(0)115 9124289
E:info@monicahealthcare.com
W:www.monicahealthcare.com

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

Records processed under FOIA Request #2015-4103; Released by CDRH on 06-06-2016.

Monica Healthcare

Indications for Use Statement

510(k) Number (if known):

Device Name: AN24

Indications For Use:

The Monica AN24 is a monitoring device for non-invasively measuring the Fetal Heart Rate (FHR) and Uterine Activity (UA). The Monica VS software, which accompanies the AN24, enables the measured parameters to be reviewed graphically using a PC, notebook computer or any compatible Series 50 format device, and to generate hard copy traces in a "standard" user defined format. This data is intended to aid in assessment of the wellbeing of the fetus and mother for laboring singleton pregnancies who are of gestation age ≥37 weeks. The AN24 device typically generates standard length FHR and UA traces from a single setup. Application of the device must be by trained personnel.

Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Page 1 of 1

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

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Monica Healthcare

510(k) Statement

I certify that, in my capacity as CEO, of Monica, I will make available all information included in this premarket notification on safety and effectiveness within 30 days of request by any person if the device described in the premarket notification submission is determined to be substantially equivalent. The information I agree to make available will be a duplicate of the premarket notification submission, including any adverse safety and effectiveness information, but excluding all patient identifiers, and trade secret and confidential commercial information, as defined in 21 CFR 20.61.

Name DR CARL BARRATT

Signed ..... (ON BEHALF OF MONICA HEALTHCARE LTD)

Date 25TH JUNE 2010

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

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Monica Healthcare

Truthful and Accuracy Statement

I certify that, in my capacity as CEO, of Monica Healthcare Limited, I believe to the best of my knowledge, that all data and information submitted in the premarket notification are truthful and accurate and that no material fact has been omitted.

(ON BEHALF OF MONICA HEALTHCARE LTD)

(Signature)

DR CARL BARRATT

(Typed Name)

25TH JUNE 2010

(Date)

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

*For a new submission, leave the 510(k) number blank.

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

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Monica Healthcare

Class III Summary and Certification

A class III summary and certification are not required in this 510(k) submission because the AN24 is not a class III device.

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

498

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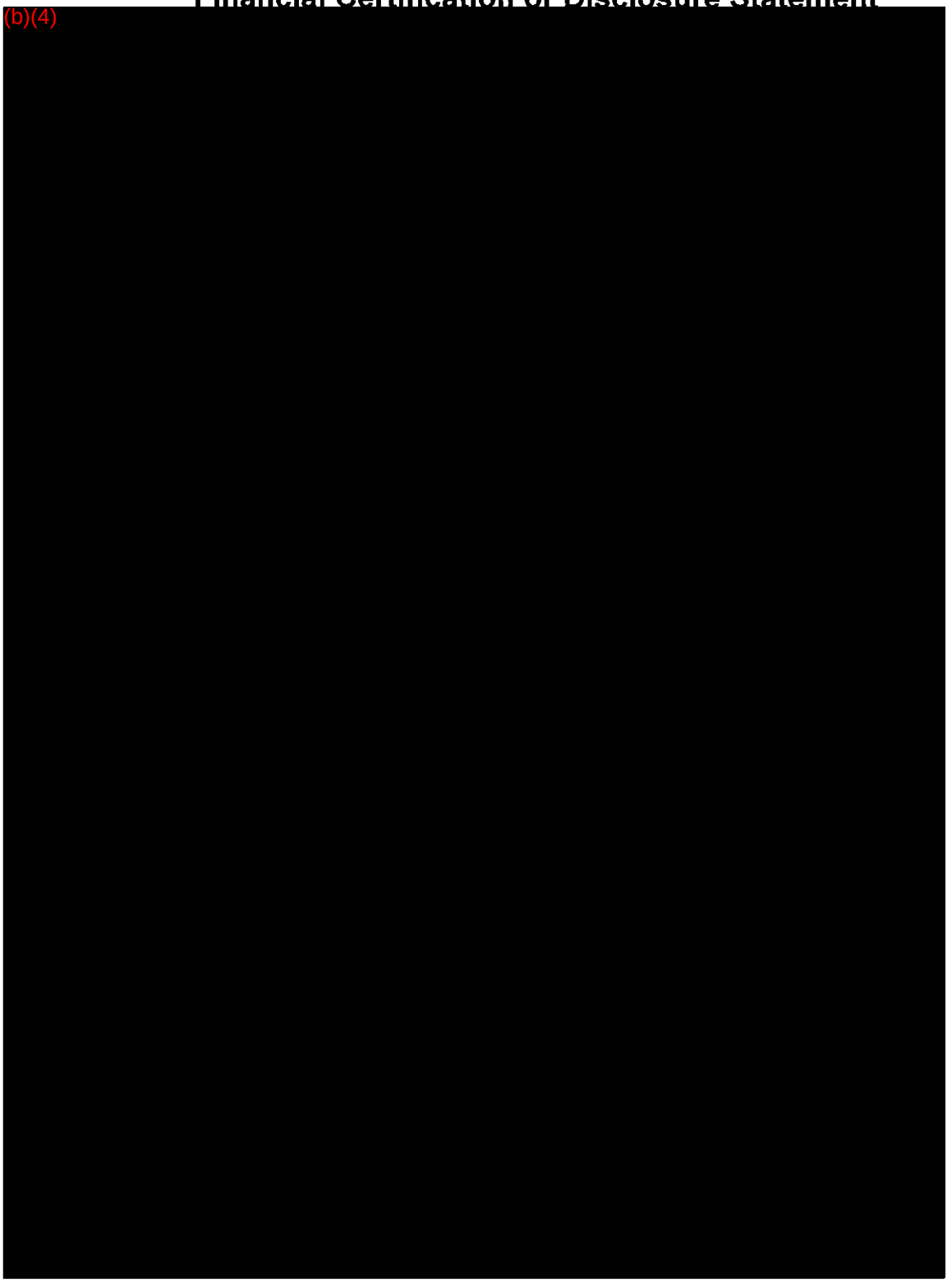
Monica Healthcare

Financial Certification or Disclosure Statement

(b)(4)



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

499

Records processed under FOIA Request #2015-4103; Released by CDRH on 06-06-2016.

Section 2

- Declaration of Conformity and Summary Reports

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

Records processed under FOIA Request #2015-4103; Released by CDRH on 06-06-2016.

Monica Healthcare

Declarations of Conformity and Summary Reports

(b)(4)

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

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Section 3

- Executive Summary
- Device Description

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

(b)(4)

(b)(4)

(b)(4)

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Description

Description of AN24

The AN24 Fetal-Maternal Monitor is designed as an ambulatory device for the monitoring of a pregnant mother. The monitor enables the abdominal electrophysiological signal to be picked up from three different positions on the maternal abdomen using 5 electrodes and a suitable cable assembly. The monitor filters the abdominal signals, converts the three channels of abdominal electrophysiological data into a digital format and then processes it in real time to extract the fetal heart rate and uterine activity. The result of the processing can be stored locally for download at a later date, or can be transmitted in real-time via a Bluetooth connection.

The Monica AN24 is a monitoring device for non-invasively measuring the Fetal Heart Rate (FHR) and Uterine Activity (UA). The Monica VS software, which accompanies the AN24, enables the measured parameters to be reviewed graphically using a PC, notebook computer or any compatible Series 50 format device, and to generate hard copy traces in a "standard" user defined format. This data is intended to aid in assessment of the wellbeing of the fetus and mother for laboring singleton pregnancies who are of gestation age ≥37 weeks. The AN24 device typically generates standard length FHR and UA traces from a single setup. Application of the device must be by trained personnel.

Hardware

(b)(4)

[redacted]

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

S16

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(b)(4)

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(b)(4)

Figure 2 - Block diagram of the main board

Kit contents

Table 1 below details the options and accessories available with the Monica AN24; items that are included as standard have been highlighted.

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

S.8

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Monica Healthcare

Table 1 - The Monica AN24 accessories

Part No.	Description
100-PT-100	Monica VS10 Monitor (b)(4)
100-PT-101	Monica VS10 Monitor (b)(4)
100-PT-110	Monica VS15 Monitor (b)(4)
100-PT-111	Monica VS15 Monitor
100-PT-001	Monica AN24

100-PT-130	Monica Cart (b)(4)
100-PT-131	Monica Cart - printer shelf (b)(4)
100-PT-132	Monica Desktop Stand (b)(4)
100-PT-140	Monica Printer (Real-time) - Thermal Z-fold (b)(4)
100-PT-160	Monica VS Network Viewer

100-PT-002	ECG Lead Assembly - Standard; ~28 weeks to term
100-PT-004	Battery Charger (UK\ EU\ USA please specify)
100-PT-005	AN24 – USB computer connection cable
100-PT-015	Soft silicon rubber protective boot (x5)
100-PT-016	3M red Dot 2236 skin prep tape (x5)
100-PT-017	Monica approved electrodes – 25 pouches x 10 electrodes (250 electrodes)
100-PT-018	Monica approved electrodes – 150 pouches x 10 electrodes (1500 electrodes)
100-PT-019	Monica AN24 Neck Cord (x5)
100-PT-020	Monica Healthcare glossy sales literature folder (x50)
100-PT-021	Sales Literature sheets
100-PT-022	Skin preparation pen
100-PT-141	Z-Fold paper printer (3 cm/min, 30 - 240 bpm) Analogic US
100-PT-142	Z-Fold paper printer (1 cm/min, 50 - 210 bpm) Analogic International
100-PT-143	Z-Fold paper printer (3 cm/min, 30 - 240 bpm) Philips US
100-PT-144	Z-Fold paper printer (1 cm/min, 50 - 210 bpm) Philips International

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

S29

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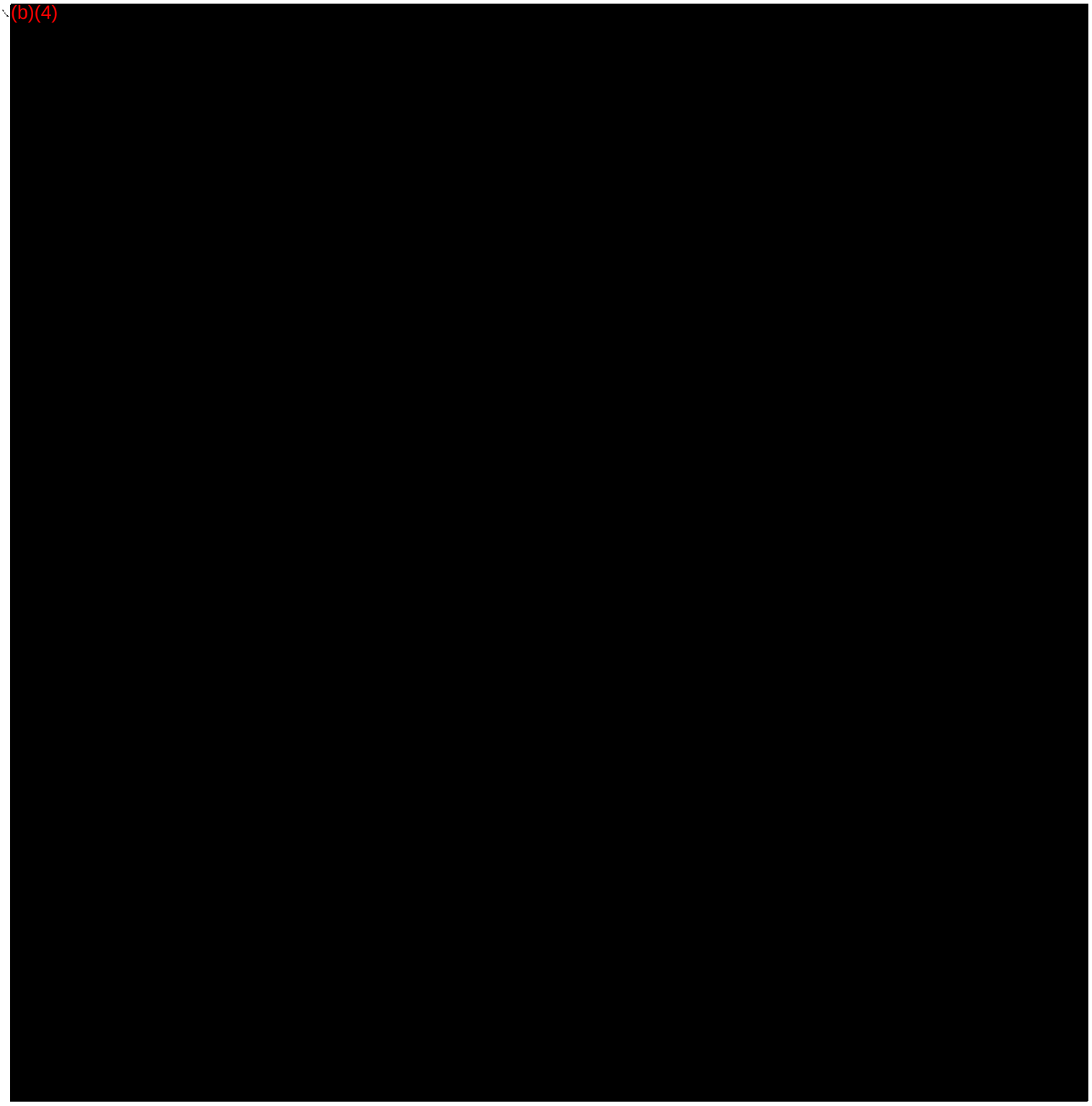
Monica Healthcare

(b)(4)



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

S10

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Monica Healthcare

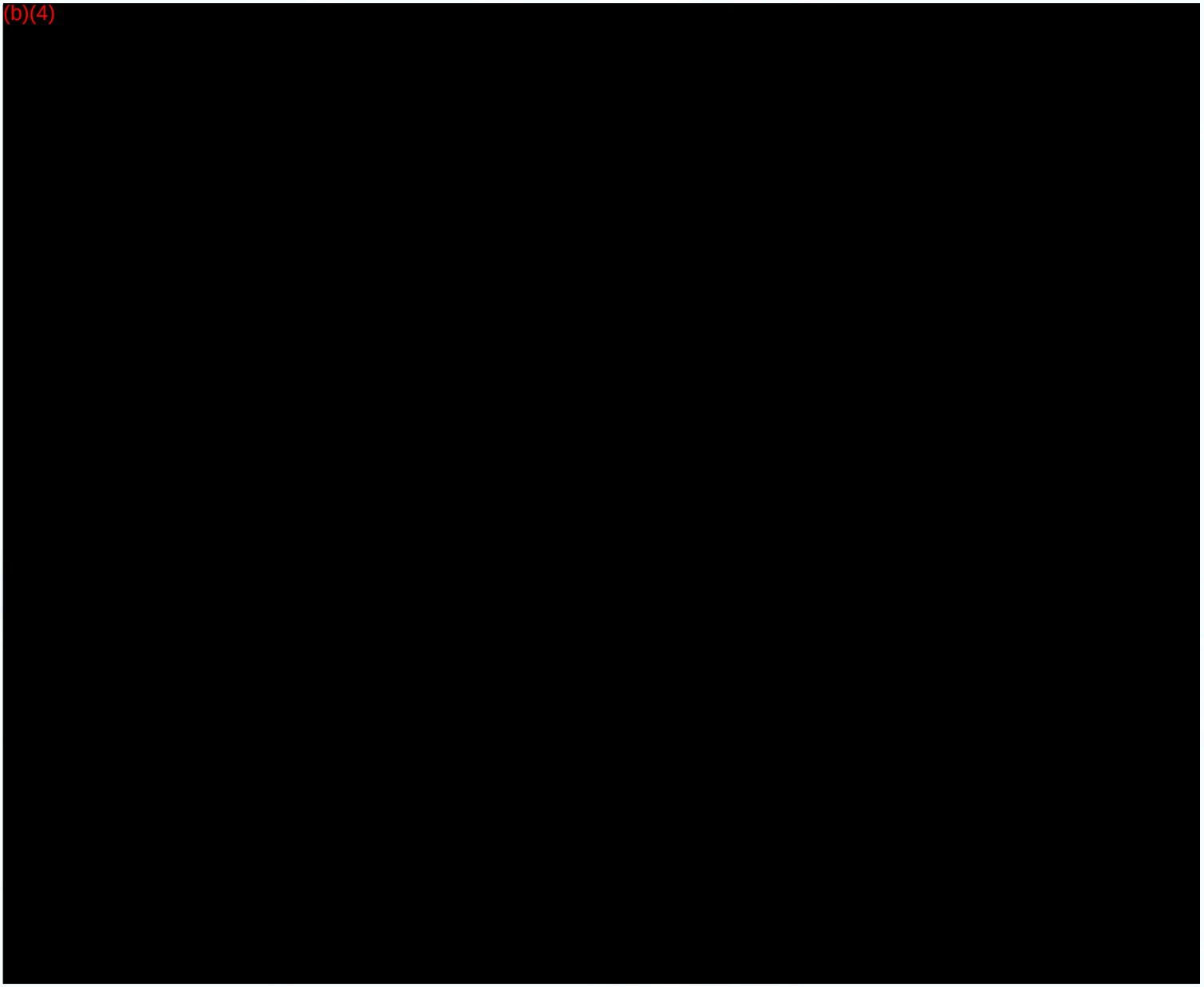
(b)(4)

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

511

Records processed under FOIA Request #2015-4103; Released by CDRH on 06-06-2016.

(b)(4)



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

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Records processed under FOIA Request #2015-4103; Released by CDRH on 06-06-2016.

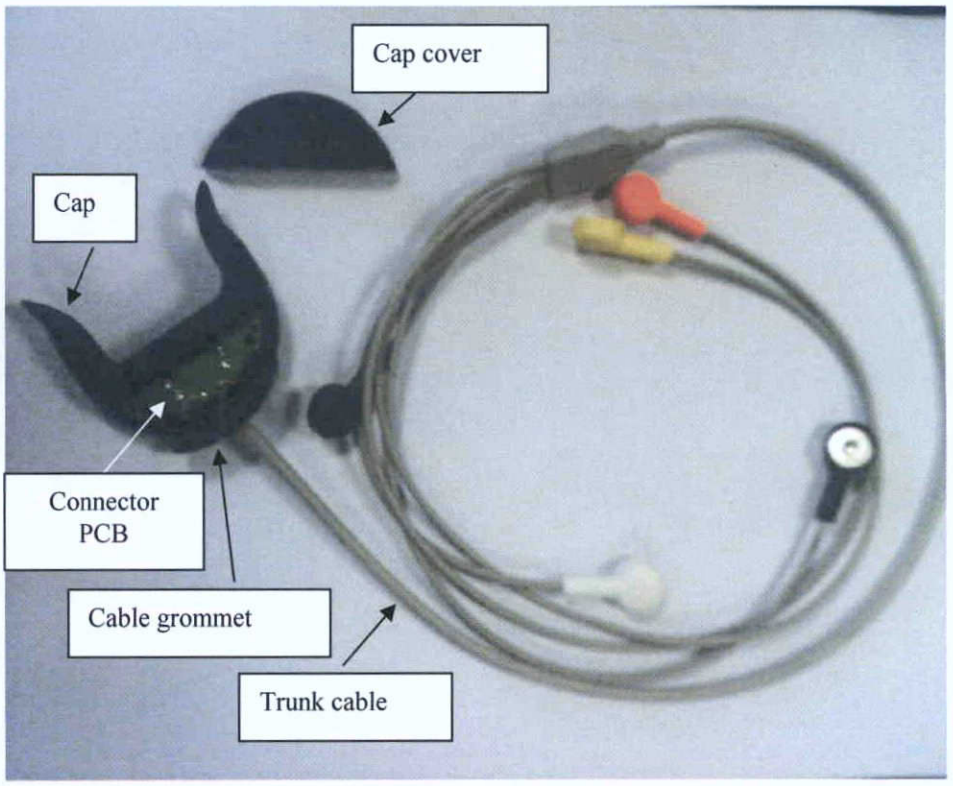

Figure 5: Connector PCB housed in cap with cap cover removed

Electrodes

The Monica specific electrodes are manufactured by Ambu, their product description is 'Blue Sensor VLC' electrodes, which have already been granted Substantial Equivalence (SE) by the FDA (K041026).

Application

The Monica AN24 uses three separate channels to record electrophysiological data from the electrodes on the maternal abdomen. The electrodes are placed in line with the AN24 Reference Operating Manual. In terms of hardware, the AN24 product will comprise of a body-mounted abdominal FECG monitor\ recorder (see Fig 1). This platform will run firmware, which is pre-configured during factory set-up, to extract the fetal heart rate (FHR) and Uterine Activity (UA). The AN24 is packaged with back-end software to allow the processed data to be viewed – this software is compatible with the listed Monica accessories or laptops, notebooks, pda's and standard PC's.

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

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Records processed under FOIA Request #2015-4103; Released by CDRH on 06-06-2016.

Monica Healthcare

Requirements for Proper Functioning of the Device

The AN24 Reference Operating Manual details the set-up procedure of the device, including the positioning and attachment of electrodes to the subject's abdomen. The AN24 can only be applied to the patient by trained personnel. Once attached, the AN24 carries out a series of self-checks to determine if it is working correctly and has been set-up in accordance with the instructions in the operating manual. The status of the device is then reported to the clinician during set-up to help assess that the device is working correctly by means of LED indicators on the AN24 itself. These self-check indications are referenced in the User instructions:

Memory Status Self-Check - If the Orange memory status LED begins to flash when the AN24 has been turned on, this means that there is data from a previous patient which is still stored in the AN24 memory. The LED will flash 10 times and then the AN24 will be automatically turned off. This data must be uploaded to a computer running the Monica VS software before a new monitoring session can be started.

Battery Status Self-Check – If the Yellow battery status LED begins to flash when the AN24 has been turned on, this means that the battery charge is too low for recording to begin. The LED will flash 10 times and then the AN24 will be automatically turned off. The battery must then be recharged in order to continue with the recording.

(b)(4)

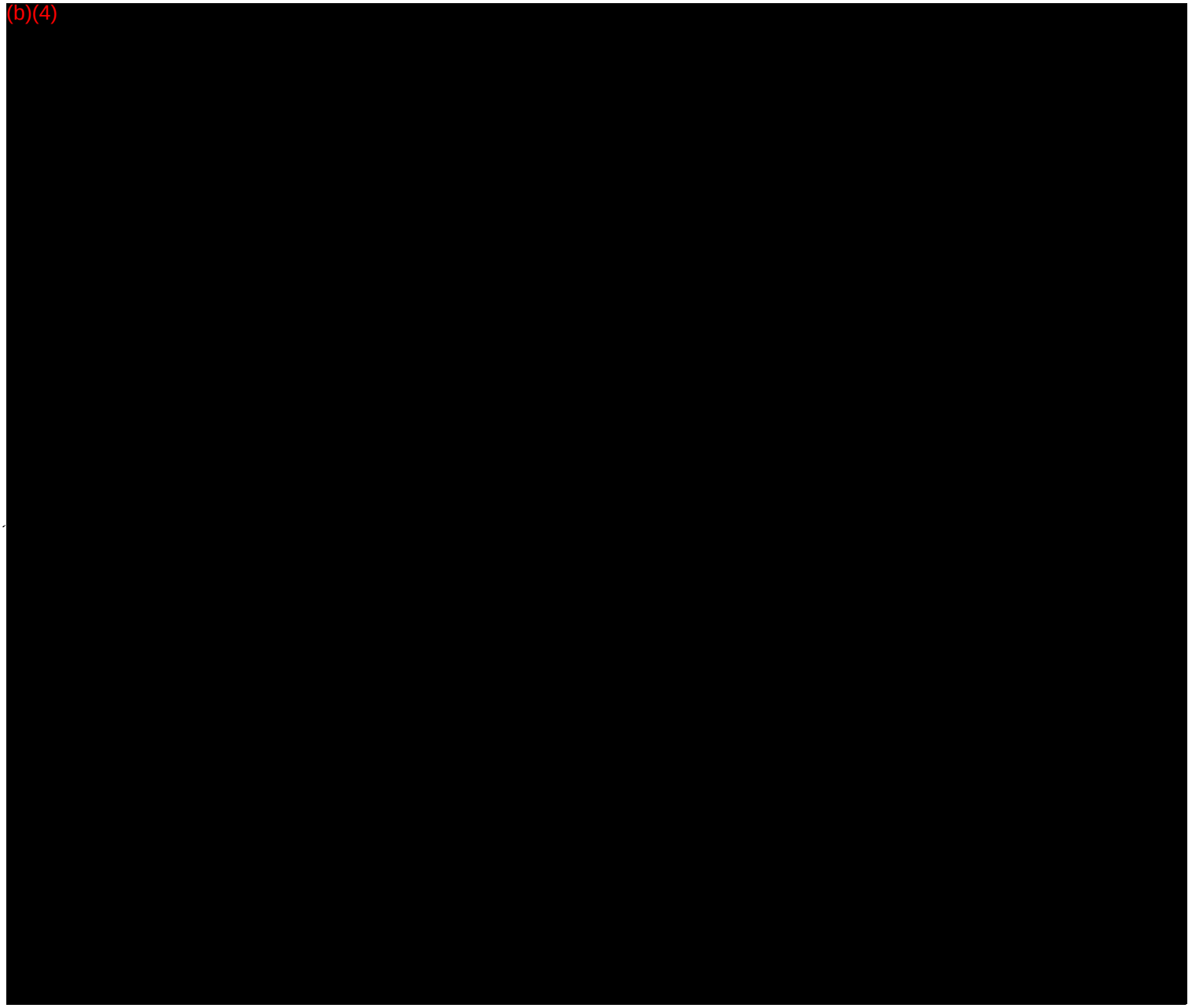
Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

514

Records processed under FOIA Request #2015-4103; Released by CDRH on 06-06-2016.

external part which plugs into the system connector (when the cable assembly is NOT plugged in – note that the two cannot occur concurrently) to generate a 5V 1A DC supply for the internal charging device from an AC mains input.

(b)(4)



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

515

Records processed under FOIA Request #2015-4103; Released by CDRH on 06-06-2016.

Section 4

- Substantial Equivalence Discussion

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

(b)(4)

(b)(4)

(b)(4)

(b)(4)

Records processed under FOIA Request #2015-4103; Released by CDRH on 06-06-2016.

Section 5

- Proposed Labeling

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

Records processed under FOIA Request #2015-4103; Released by CDRH on 06-06-2016.

Labeling

The labeling of the AN24 can be separated in to 3 areas: device labels, instructions for use and marketing material. Supplied with the AN24 are Ambu VLC electrodes (K041026) and 3m Red Dot Trace Prep, both accessories are approved by the FDA and are legally available for sale in the USA. There have been no changes to the labeling and instructions for use.

AN24 Device Labels

There are 7 labels on the AN24 (x2), patient leads (x2), charger, CD and outer packaging.

Instructions for use

Provided within the outer packaging is a printed CD containing a detailed AN24 Reference Operating Manual; VS Reference Operating Manual; a concise version of these manuals (Concise Operating Manual) provided in 6 different languages (Italian, Portuguese, Netherlands, Spanish, French, Dutch).

Provided loose within the outer packaging is a double sided colour Quick Reference Guide

Sales and Marketing Material

There is a sales sheet, providing details of the AN24.

Labelling conclusion

The labeling detailed throughout section 13 complies with international standards and satisfies the requirements of 21 CFR Part 801. In comparing the labeling of the AN24 to that of the predicate device, there are no significant differences in the format or depth of information made available. Labeling is provided in Appendix B

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

Records processed under FOIA Request #2015-4103; Released by CDRH on 06-06-2016.

Section 6

- Sterilization and Shelf Life

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

Records processed under FOIA Request #2015-4103; Released by CDRH on 06-06-2016.

Sterilization and Shelf Life

This section is not applicable, as none of the component parts of the Monica AN24 device are supplied sterile.

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

S24

Records processed under FOIA Request #2015-4103; Released by CDRH on 06-06-2016.

Section 7

- Biocompatibility

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

Records processed under FOIA Request #2015-4103; Released by CDRH on 06-06-2016.

Biocompatibility

(b)(4)

AN24 Electrode Lead cable

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

520

Records processed under FOIA Request #2015-4103; Released by CDRH on 06-06-2016.

(b)(4)

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

527

Records processed under FOIA Request #2015-4103; Released by CDRH on 06-06-2016.

Section 8

- Software

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

Records processed under FOIA Request #2015-4103; Released by CDRH on 06-06-2016.

Software

(b)(4)

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

Records processed under FOIA Request #2015-4103; Released by CDRH on 06-06-2016.

(b)(4)

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

530

Records processed under FOIA Request #2015-4103; Released by CDRH on 06-06-2016.

(b)(4)

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

531

Records processed under FOIA Request #2015-4103; Released by CDRH on 06-06-2016.

(b)(4)

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

532

Records processed under FOIA Request #2015-4103; Released by CDRH on 06-06-2016.

(b)(4)

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

Records processed under FOIA Request #2015-4103; Released by CDRH on 06-06-2016.

Section 9

- Electromagnetic Compatibility and Electrical Safety

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

Records processed under FOIA Request #2015-4103; Released by CDRH on 06-06-2016.

(b)(4)

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

535

Records processed under FOIA Request #2015-4103; Released by CDRH on 06-06-2016.

Section 10

- Performance testing Bench
- Performance testing animal
- Performance testing Clinical

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

(b)(4)

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(b)(4)

(b)(4)

Records processed under FOIA Request #2015-4103; Released by CDRH on 06-06-2016.

Section 11

- Appendices

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

Records processed under FOIA Request #2015-4103; Released by CDRH on 06-06-2016.

Appendix A

European Product and Quality System Certifications and FDA 3654 Forms for Standards employed

Appendix B

Proposed Labeling

Appendix C

Biocompatibility Certificates

Appendix D

Predicate Device – Product Information and Labeling

Appendix E

Prior FDA Correspondence

Appendix F

Software Documentation

Appendix G

Clinical Trial Data

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

813

Records processed under FOIA Request #2015-4103; Released by CDRH on 06-06-2016.

SCREENING CHECKLIST FOR ALL PREMARKET NOTIFICATION [510(k)] SUBMISSIONS

-

510(k) Number: _____

The cover letter clearly identifies the type of 510(k) submission as **(Check the appropriate box)**:

☐ Special 510(k) - Do Sections 1 and 2

☐ Abbreviated 510(k) - Do Sections 1, 3 and 4

☐ Traditional 510(k) or no identification provided - Do Sections 1 and 4

Section 1: Required Elements for All Types of 510(k) submissions:

	Present or Adequate	**Missing or Inadequate**
Cover letter, containing the elements listed on page 3-2 of the Premarket Notification [510)] Manual.		
Table of Contents.		
Truthful and Accurate Statement.		
Device?s Trade Name, Device?s Classification Name and Establishment Registration Number.		
Device Classification Regulation Number and Regulatory Status (Class I, Class II, Class III or Unclassified).		
Proposed Labeling? including the material listed on page 3-4 of the Premarket Notification [510)] Manual.		
Statement of Indications for Use that is on a separate page in the premarket submission.		
Substantial Equivalence Comparison, including comparisons of the new device with the predicate in areas that are listed on page 3-4 of the Premarket Notification [510)] Manual.		
510(k) Summary or 510(k) Statement.		
Description of the device (or modification of the device) including diagrams, engineering drawings, photographs or service manuals.		
Identification of legally marketed predicate device. *****		
Compliance with performance standards. ***** [See Section 514 of		

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

Records processed under FOIA Request #2015-4103; Released by CDRH on 06-06-2016.

the Act and 21 CFR 807.87 (d).]		
Class III Certification and Summary. **		
Financial Certification or Disclosure Statement for 510(k) notifications with a clinical study. * [See 21 CFR 807.87 (i)]		
510(k) Kit Certification ***		

Section 4: Additional Requirements for ABBREVIATED and TRADITIONAL 510(k) submissions (If Applicable):

	Present	Inadequate or Missing
a)?? Biocompatibility data for all patient-contacting materials, OR certification of identical material/formulation:	-	-
b)?? Sterilization and expiration dating information:		
i) sterilization process		
ii) validation method of sterilization process		
iii) SAL		
iv) packaging		
v) specify pyrogen free		
vi) ETO residues		
vii) radiation dose		
viii) Traditional Method or Non-Traditional Method		
c)?? Software Documentation:		

Items with checks in the? Present or Adequate? column do not require additional information from the sponsor.? Items with checks in the ? Missing or Inadequate? column must be submitted before substantive review of the document.

Passed Screening _____Yes _____No

Reviewer:_____

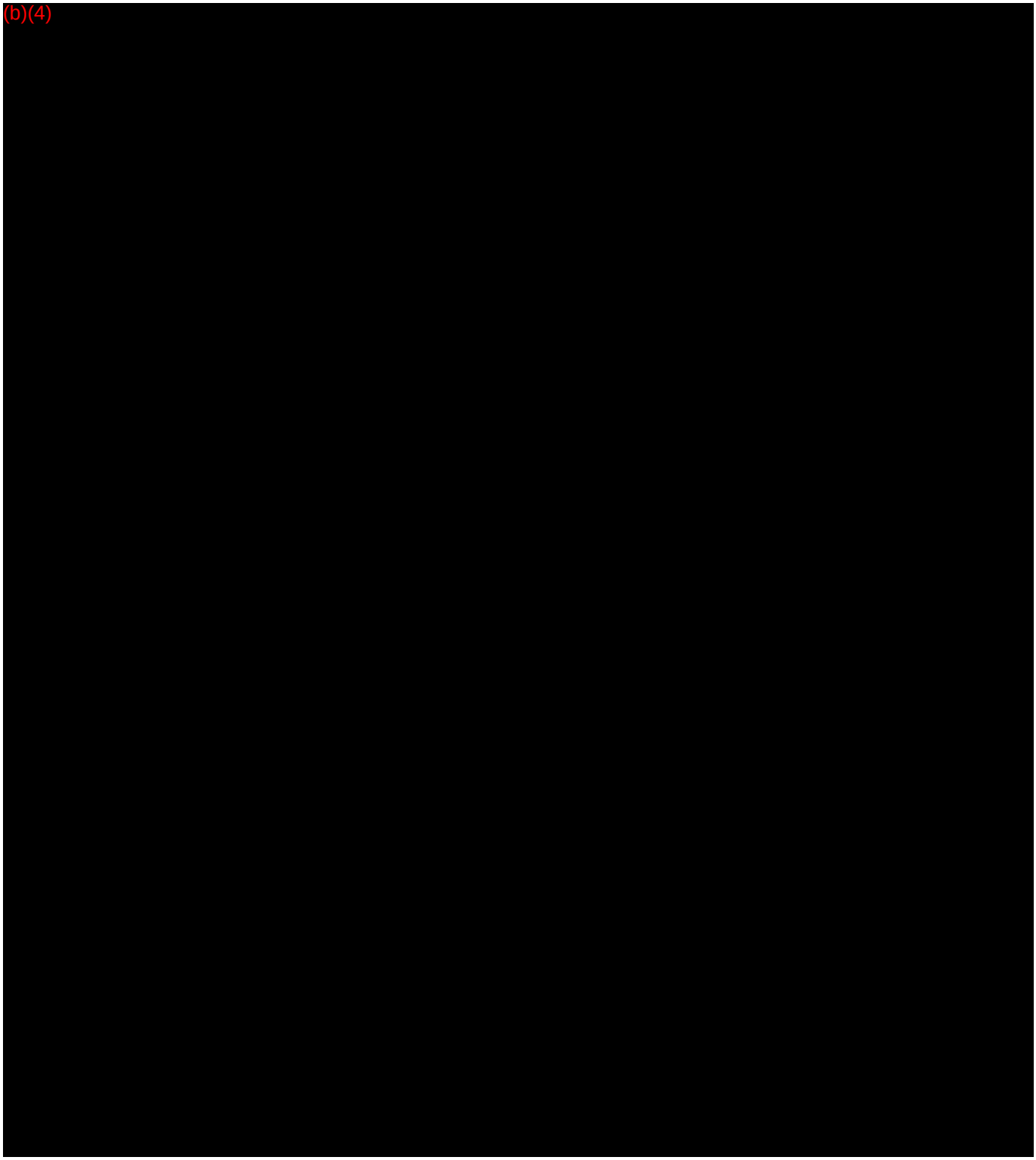
Concurrence by Review Branch:_____

Date:_____

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

Records processed under FOIA Request #2015-4103; Released by CDRH on 06-06-2016.

(b)(4)



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

Records processed under FOIA Request #2015-4103; Released by CDRH on 06-06-2016.

Medical Device User Fee Cover Sheet (FDA3601)

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION
MEDICAL DEVICE USER FEE COVER SHEET

(b)(4)

your check.

A completed cover sheet must accompany each original application or supplement subject to fees. If payment is sent by U.S. mail or courier, please include a copy of this completed form with payment. Payment and mailing instructions can be found at: http://www.fda.gov/oc/mdufma/coversheet.html

1. COMPANY NAME AND ADDRESS (include name, street address, city state, country, and post office code)

MONICA HEALTHCARE LIMITED
Biocity
Pennyfoot Street
Nottingham NG1 1GF
GB

1.1 EMPLOYER IDENTIFICATION NUMBER (EIN)

2. CONTACT NAME
Ian How
2.1 E-MAIL ADDRESS
ianhow@monicahealthcare.com
2.2 TELEPHONE NUMBER (include Area code)
44115-9124540
2.3 FACSIMILE (FAX) NUMBER (Include Area code)
44115-9124289

3. TYPE OF PREMARKET APPLICATION (Select one of the following in each column; if you are unsure, please refer to the application descriptions at the following web site: http://www.fda.gov/oc/mdufma

Select an application type:
[X] Premarket notification(510(k)); except for third party
[ ] 513(g) Request for Information
[ ] Biologics License Application (BLA)
[ ] Premarket Approval Application (PMA)
[ ] Modular PMA
[ ] Product Development Protocol (PDP)
[ ] Premarket Report (PMR)
[ ] Annual Fee for Periodic Reporting (APR)
[ ] 30-Day Notice

3.1 Select a center
[X] CDRH
[ ] CBER

3.2 Select one of the types below
[X] Original Application

Supplement Types:
[ ] Efficacy (BLA)
[ ] Panel Track (PMA, PMR, PDP)
[ ] Real-Time (PMA, PMR, PDP)
[ ] 180-day (PMA, PMR, PDP)

4. ARE YOU A SMALL BUSINESS? (See the instructions for more information on determining this status)
[ ] YES, I meet the small business criteria and have submitted the required qualifying documents to FDA
[X] NO, I am not a small business
4.1 If Yes, please enter your Small Business Decision Number:

5. FDA WILL NOT ACCEPT YOUR SUBMISSION IF YOUR COMPANY HAS NOT PAID AN ESTABLISHMENT REGISTRATION FEE THAT IS DUE TO FDA. HAS YOUR COMPANY PAID ALL ESTABLISHMENT REGISTRATION FEES THAT ARE DUE TO FDA?
[X] YES (All of our establishments have registered and paid the fee, or this is our first device, and we will register and pay the fee within 30 days of FDA's approval/clearance of this device.)
[ ] NO (If "NO," FDA will not accept your submission until you have paid all fees due to FDA. This submission will not be processed; see http://www.fda.gov/cdrh/mdufma for additional information)

6. IS THIS PREMARKET APPLICATION COVERED BY ANY OF THE FOLLOWING USER FEE EXCEPTIONS? IF SO, CHECK THE APPLICABLE EXCEPTION.

[ ] This application is the first PMA submitted by a qualified small business, including any affiliates

[ ] This biologics application is submitted under section 351 of the Public Health Service Act for a product licensed for further manufacturing use only

[ ] The sole purpose of the application is to support conditions of use for a pediatric population

[ ] The application is submitted by a state or federal government entity for a device that is not to be distributed commercially

7. IS THIS A SUPPLEMENT TO A PREMARKET APPLICATION FOR WHICH FEES WERE WAIVED DUE TO SOLE USE IN A PEDIATRIC POPULATION THAT NOW PROPOSES CONDITION OF USE FOR ANY ADULT POPULATION? (If so, the application is subject to the fee that applies for an original premarket approval application (PMA).

[ ] YES [X] NO

8. USER FEE PAYMENT AMOUNT SUBMITTED FOR THIS PREMARKET APPLICATION

(b)(4)

15-Jun-2010

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

Records processed under FOIA Request #2015-4103; Released by CDRH on 06-06-2016.

CDRH Premarket Review Submission Cover

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

CDRH PREMARKET REVIEW SUBMISSION COVER SHEET

Form Approval
OMB No. 0910-0120
Expiration Date: August 31, 2010.
See OMB Statement on page 5.

Date of Submission	User Fee Payment ID Number	FDA Submission Document Number *(if known)*

SECTION A — TYPE OF SUBMISSION

PMA	PMA & HDE Supplement	PDP	510(k)	Meeting
☐ Original Submission	☐ Regular (180 day)	☐ Original PDP	☒ Original Submission:	☐ Pre-510(K) Meeting
☐ Premarket Report	☐ Special	☐ Notice of Completion	☒ Traditional	☐ Pre-IDE Meeting
☐ Modular Submission	☐ Panel Track (PMA Only)	☐ Amendment to PDP	☐ Special	☐ Pre-PMA Meeting
☐ Amendment	☐ 30-day Supplement		☐ Abbreviated (Complete section I, Page 5)	☐ Pre-PDP Meeting
☐ Report	☐ 30-day Notice		☐ Additional Information	☐ Day 100 Meeting
☐ Report Amendment	☐ 135-day Supplement		☐ Third Party	☐ Agreement Meeting
☐ Licensing Agreement	☐ Real-time Review			☐ Determination Meeting
	☐ Amendment to PMA & HDE Supplement			☐ Other *(specify)*:
	☐ Other			

IDE	Humanitarian Device Exemption (HDE)	Class II Exemption Petition	Evaluation of Automatic Class III Designation (De Novo)	Other Submission
☐ Original Submission	☐ Original Submission	☐ Original Submission	☐ Original Submission	☐ 513(g)
☐ Amendment	☐ Amendment	☐ Additional Information	☐ Additional Information	☐ Other *(describe submission)*:
☐ Supplement	☐ Supplement			
	☐ Report			
	☐ Report Amendment			

Have you used or cited Standards in your submission? ☒ Yes ☐ No *(If Yes, please complete Section I, Page 5)*

SECTION B — SUBMITTER, APPLICANT OR SPONSOR

Company / Institution Name	Establishment Registration Number *(if known)*		
Monica Healthcare Ltd			
Division Name *(if applicable)*	Phone Number *(including area code)*		
	+44 (0)115 912 4540		
Street Address	FAX Number *(including area code)*		
Biocity, Pennyfoot Street	+44 (0)115 9124289		
City	State / Province	ZIP/Postal Code	Country
Nottingham		NG1 1GF	UK
Contact Name			
Ian How			
Contact Title	Contact E-mail Address		
Regulatory Affairs Manager	ianhow@monicahealthcare.com		

SECTION C — APPLICATION CORRESPONDENT (e.g., consultant, if different from above)

Company / Institution Name			
Division Name *(if applicable)*	Phone Number *(including area code)*		
Street Address	FAX Number *(including area code)*		
City	State / Province	ZIP Code	Country
Contact Name			
Contact Title	Contact E-mail Address		

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

Records processed under FOIA Request #2015-4103; Released by CDRH on 06-06-2016.

SECTION D1 REASON FOR APPLICATION - PMA, PDP, OR HDE

- ☐ New Device
- ☐ Withdrawal
- ☐ Additional or Expanded Indications
- ☐ Request for Extension
- ☐ Post-approval Study Protocol
- ☐ Request for Applicant Hold
- ☐ Request for Removal of Applicant Hold
- ☐ Request to Remove or Add Manufacturing Site

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

- ☐ Response to FDA correspondence:

- ☐ Change in design, component, or specification:
  - ☐ Software / Hardware
  - ☐ 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

- ☐ Report Submission:
  - ☐ Annual or Periodic
  - ☐ Post-approval Study
  - ☐ Adverse Reaction
  - ☐ Device Defect
  - ☐ Amendment

- ☐ Change in Ownership
- ☐ Change in Correspondent
- ☐ Change of Applicant Address

- ☐ Other Reason *(specify)*:

SECTION D2 REASON FOR APPLICATION - IDE

- ☐ New Device
- ☐ New Indication
- ☐ Addition of Institution
- ☐ Expansion / Extension of Study
- ☐ IRB Certification
- ☐ Termination of Study
- ☐ Withdrawal of Application
- ☐ Unanticipated Adverse Effect
- ☐ Notification of Emergency Use
- ☐ Compassionate Use Request
- ☐ Treatment IDE
- ☐ Continued Access

- ☐ Change in:
  - ☐ Correspondent / Applicant
  - ☐ Design / Device
  - ☐ Informed Consent
  - ☐ Manufacturer
  - ☐ Manufacturing Process
  - ☐ Protocol - Feasibility
  - ☐ Protocol - Other
  - ☐ Sponsor

- ☐ Report submission:
  - ☐ Current Investigator
  - ☐ Annual Progress Report
  - ☐ Site Waiver Report
  - ☐ 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
  - ☐ Request Hearing

- ☐ Other Reason *(specify)*:

SECTION D3 REASON FOR SUBMISSION - 510(k)

- ☒ New Device
- ☐ Additional or Expanded Indications
- ☐ Change in Technology

- ☒ Other Reason *(specify)*:

Continuation from K081435, to address FDA concerns and include a 6 way substantial equivalence trial

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

Records processed under FOIA Request #2015-4103; Released by CDRH on 06-06-2016.

SECTION E ADDITIONAL INFORMATION ON 510(K) SUBMISSIONS

Product codes of devices to which substantial equivalence is claimed

1	HGM	2		3		4	
5		6		7		8	

Summary of, or statement concerning, safety and effectiveness information

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

Information on devices to which substantial equivalence is claimed *(if known)*

	510(k) Number		*Trade or Proprietary or Model Name*		*Manufacturer*
1	K954351	1	Phillips Series 50XM	1	Phillips
2		2		2	
3		3		3	
4		4		4	
5		5		5	
6		6		6	

SECTION F PRODUCT INFORMATION - APPLICATION TO ALL APPLICATIONS

Common or usual name or classification name

Classification 884.2740 Perinatal Monitoring System

	Trade or Proprietary or Model Name for This Device		Model Number
1	Monica AN24	1	
2		2	
3		3	
4		4	
5		5	

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

1 K081435	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 - APPLICATION TO ALL APPLICATIONS

Product Code: HGM

C.F.R. Section *(if applicable)*: 884.2740

Device Class

- ☐ Class I
- ☒ Class II
- ☐ Class III
- ☐ Unclassified

Classification Panel: Obstetrics / Gynecology

Indications *(from labeling)*

The Monica AN24 is a monitoring device for non-invasively measuring the Fetal Heart Rate (FHR) and Uterine Activity (UA). The Monica VR software, which accompanies the AN24, enables the measured parameters to be reviewed graphically using a PC or notebook computer and to generate hard copy traces in a "standard" user defined format. This data is intended to aid in assessment of the wellbeing of the fetus and mother for laboring singleton pregnancies who are of gestation age >37 weeks. The AN24 device typically generates standard length FHR and UA traces from a single setup. Application of the device must be by trained personnel, but monitoring sessions can be carried out in hospital and clinics

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

Records processed under FOIA Request #2015-4103; Released by CDRH on 06-06-2016.

Note: Submission of this information does not affect the need to submit a 2891 or 2891a Device Establishment Registration form.	FDA Document Number *(if known)*

SECTION H MANUFACTURING / PACKAGING / STERILIZATION SITES RELATING TO A SUBMISSION

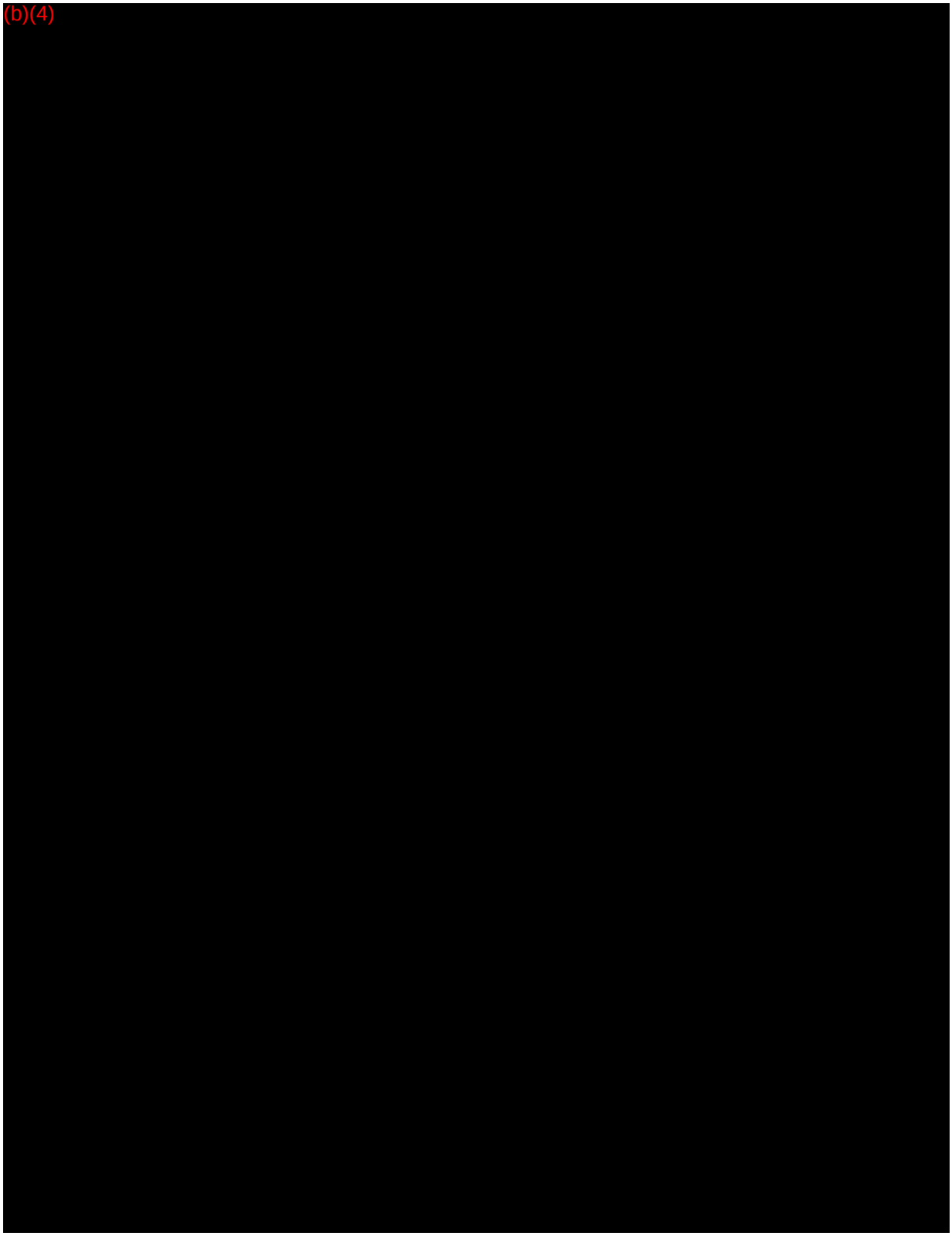
(b)(4)

☐ Original ☐ Add ☐ Delete	Facility Establishment Identifier (FEI) Number	☐ Manufacturer ☐ Contract Manufacturer	☐ Contract Sterilizer ☐ Repackager / Relabeler
Company / Institution Name		Establishment Registration Number	
Division Name *(if applicable)*		Phone Number *(including area code)*	
Street Address		FAX Number *(including area code)*	
City	State / Province	ZIP Code	Country
Contact Name	Contact Title	Contact E-mail Address	

☐ Original ☐ Add ☐ Delete	Facility Establishment Identifier (FEI) Number	☐ Manufacturer ☐ Contract Manufacturer	☐ Contract Sterilizer ☐ Repackager / Relabeler
Company / Institution Name		Establishment Registration Number	
Division Name *(if applicable)*		Phone Number *(including area code)*	
Street Address		FAX Number *(including area code)*	
City	State / Province	ZIP Code	Country
Contact Name	Contact Title	Contact E-mail Address	

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

Records processed under FOIA Request #2015-4103; Released by CDRH on 06-06-2016.



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

Records processed under FOIA Request #2015-4103; Released by CDRH on 06-06-2016.

510(k) Cover Letter

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

Date: June 2010

Dear Sir/Madam,

510(k) Notification (21 CFR 807.90(e)) – Traditional Submission

This letter accompanies two (2) copies of documentation in support of a 510(k) Notification (21 CFR 807.90(e)) for the Monica Healthcare AN24 Fetal Heart Rate Monitor and accessories. One of the copies provided is an electronic copy and it is an exact duplicate of the paper copy. As per 21 CFR 807.95, we are requesting continued confidentiality of the intent to market this device. Please see the enclosed CDRH Premarket Review Submission Cover Sheet (Section 2 of this submission) for additional required administrative information as per the CDRH Guidance Document Format for Traditional and Abbreviated 510(k)s", issued August 12, 2005.
The principal factors pertaining to the design and use of the Monica AN24 device are provided below:

Type of 510(k) Submission:	Traditional
Device Type:	Fetal Maternal Monitor
510(k) Submitter:	Monica Healthcare
Contact details:	Mr. Ian How Regulatory affairs Manager Tel: +44 115 9124540 Email: ianhow@monicahealthcare.com
Classification Name:	Perinatal monitoring system and accessories
Classification Reference:	HGM
Recommended classification:	Class II
Product Code:	884.2740
Panel:	Obstetrics/Gynecology
Former Correspondence:	K081435 510(K) submission (Appendix E)
Basis For submission:	New device

Design and Use of the Device

Question	YES	NO
Is the device intended for prescription use (21 CFR 801 Subpart D)?	YES	

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

Records processed under FOIA Request #2015-4103; Released by CDRH on 06-06-2016.

Is the device intended for over-the-counter use (21 CFR 807 Subpart C)?		NO
Does the device contain components derived from a tissue or other biologic source?		NO
Is the device provided sterile?		NO
Is the device a reprocessed single use device?		NO
If yes, does this device type require reprocessed validation data?		
Does the device contain a drug?		NO
Does the device contain a biologic?		NO
Does the device use software?	YES	
Does the submission include clinical information?	YES	
Is the device implanted?		NO

Preference for continued confidentiality: Monica Healthcare considers its intent to market the AN24 device and accessories as confidential commercial information. The Company has not disclosed its intent to market this device to anyone except its employees, others with a financial interest in the Company, its advertising or law firms, and its consultants. The Company, therefore, requests that FDA not disclose the existence of this application until such time as final action on the submission is taken. In addition, some of the material in this application may be trade secret or confidential commercial or financial information within the meaning of 21 CFR § 20.61 and therefore not disclosable under the Freedom of Information Act, even after the existence of the application becomes public. We ask that you consult with the Company as provided in 21 CFR § 20.45 before making any part of this submission, other than the 510(k) statement, publicly available.

Thank you for your review of this 510(k) submission. If you have any questions or require clarification of any information in this document, please do not hesitate to contact the undersigned.

Yours sincerely,

Carl Barratt

CEO
Monica Healthcare
BioCity, Pennyfoot Street,
Nottingham,NG1 1GF, UK
T:+44(0)115 9124540
F:+44(0)115 9124289
E:info@monicahealthcare.com
W:www.monicahealthcare.com

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

Records processed under FOIA Request #2015-4103; Released by CDRH on 06-06-2016.

Indications for Use Statement

510(k) Number (if known):

Device Name: AN24

Indications For Use:

The Monica AN24 is a monitoring device for non-invasively measuring the Fetal Heart Rate (FHR) and Uterine Activity (UA). The Monica VS software, which accompanies the AN24, enables the measured parameters to be reviewed graphically using a PC, notebook computer or any compatible Series 50 format device, and to generate hard copy traces in a "standard" user defined format. This data is intended to aid in assessment of the wellbeing of the fetus and mother for laboring singleton pregnancies who are of gestation age ≥37 weeks. The AN24 device typically generates standard length FHR and UA traces from a single setup. Application of the device must be by trained personnel.

Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

Records processed under FOIA Request #2015-4103; Released by CDRH on 06-06-2016.

510(k) Statement

I certify that, in my capacity as CEO, of Monica, I will make available all information included in this premarket notification on safety and effectiveness within 30 days of request by any person if the device described in the premarket notification submission is determined to be substantially equivalent. The information I agree to make available will be a duplicate of the premarket notification submission, including any adverse safety and effectiveness information, but excluding all patient identifiers, and trade secret and confidential commercial information, as defined in 21 CFR 20.61.

Name ……

Signed ……

Date ……

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

Records processed under FOIA Request #2015-4103; Released by CDRH on 06-06-2016.

Truthful and Accuracy Statement

I certify that, in my capacity as CEO, of Monica Healthcare Limited, I believe to the best of my knowledge, that all data and information submitted in the premarket notification are truthful and accurate and that no material fact has been omitted.

_____

(Signature)

_____

(Typed Name)

_____

(Date)

_____

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

*For a new submission, leave the 510(k) number blank.

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

Records processed under FOIA Request #2015-4103; Released by CDRH on 06-06-2016.

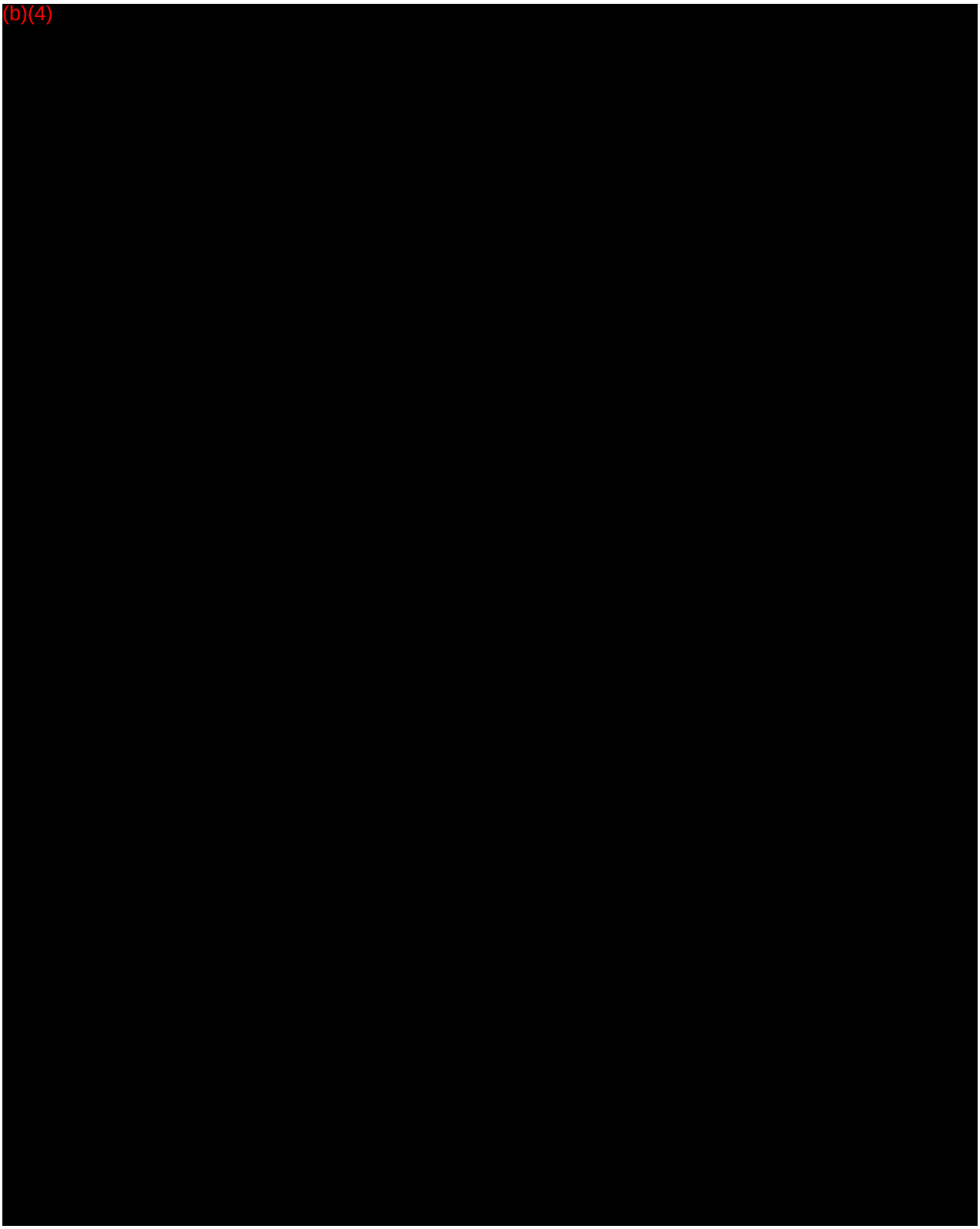
Class III Summary and Certification

A class III summary and certification are not required in this 510(k) submission because the AN24 is not a class III device.

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

Records processed under FOIA Request #2015-4103; Released by CDRH on 06-06-2016.

(b)(4)



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

Records processed under FOIA Request #2015-4103; Released by CDRH on 06-06-2016.

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

Records processed under FOIA Request #2015-4103; Released by CDRH on 06-06-2016.

Declarations of Conformity and Summary Reports

(b)(4)

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

Records processed under FOIA Request #2015-4103; Released by CDRH on 06-06-2016.

Confidential

510(K) PREMARKET NOTIFICATION

MONICA HEALTHCARE LIMITED

MONICA AN24

Submission date:
June 2010

The term "predicate device(s)"as used throughout this entire premarket notification (cover letter, body, attachments, and summary), and the supporting information pertaining to equivalence, are intended to demonstrate equivalence to the predicate device(s) for the purposes of obtaining clearance of the subject device(s) under the Federal Food, Drug and Cosmetic Act. Any references to equivalence in this submission are in no way related to any form of equivalence under patent laws.

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

Records processed under FOIA Request #2015-4103; Released by CDRH on 06-06-2016.

Monica Healthcare

SCREENING CHECKLIST FOR ALL PREMARKET NOTIFICATION [510(k)] SUBMISSIONS

510(k) Number: _____

The cover letter clearly identifies the type of 510(k) submission as **(Check the appropriate box)**:

☐ Special 510(k) - Do Sections 1 and 2

☐ Abbreviated 510(k) - Do Sections 1, 3 and 4

☐ Traditional 510(k) or no identification provided - Do Sections 1 and 4

Section 1: Required Elements for All Types of 510(k) submissions:

	Present or Adequate	Missing or Inadequate
Cover letter, containing the elements listed on page 3-2 of the Premarket Notification [510)] Manual.		
Table of Contents.		
Truthful and Accurate Statement.		
Device?s Trade Name, Device?s Classification Name and Establishment Registration Number.		
Device Classification Regulation Number and Regulatory Status (Class I, Class II, Class III or Unclassified).		
Proposed Labeling? including the material listed on page 3-4 of the Premarket Notification [510)] Manual.		
Statement of Indications for Use that is on a separate page in the premarket submission.		
Substantial Equivalence Comparison, including comparisons of the new device with the predicate in areas that are listed on page 3-4 of the Premarket Notification [510)] Manual.		
510(k) Summary or 510(k) Statement.		
Description of the device (or modification of the device) including diagrams, engineering drawings, photographs or service manuals.		

Records processed under FOIA Request #2015-4103; Released by CDRH on 06-06-2016.

Identification of legally marketed predicate device. *		
Compliance with performance standards. * [See Section 514 of the Act and 21 CFR 807.87 (d).]		
Class III Certification and Summary. **		
Financial Certification or Disclosure Statement for 510(k) notifications with a clinical study. * [See 21 CFR 807.87 (i)]		
510(k) Kit Certification ***		

Section 4: Additional Requirements for ABBREVIATED and TRADITIONAL 510(k) submissions (If Applicable):

	Present	Inadequate or Missing
a)?? Biocompatibility data for all patient-contacting materials, OR certification of identical material/formulation:	-	-
b)?? Sterilization and expiration dating information:		
i) sterilization process		
ii) validation method of sterilization process		
iii) SAL		
iv) packaging		
v) specify pyrogen free		
vi) ETO residues		
vii) radiation dose		
viii) Traditional Method or Non-Traditional Method		
c)?? Software Documentation:		

Items with checks in the? Present or Adequate? column do not require additional information from the sponsor.? Items with checks in the ? Missing or Inadequate? column must be submitted before substantive review of the document.

Passed Screening _____Yes _____No

Reviewer:_____

Concurrence by Review Branch:_____

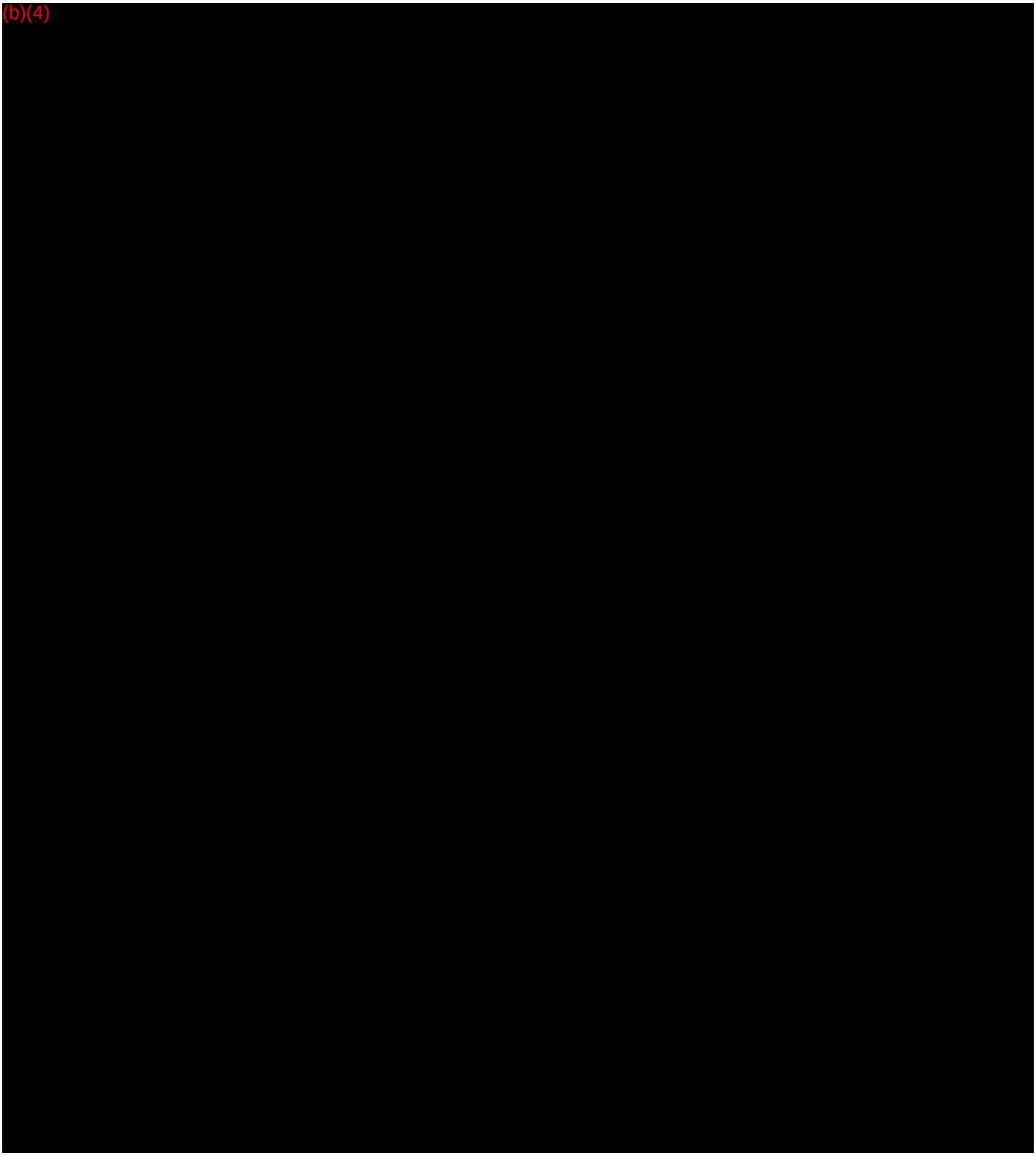
Date:_____

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

Records processed under FOIA Request #2015-4103; Released by CDRH on 06-06-2016.

Monica Healthcare

(b)(4)



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

Records processed under FOIA Request #2015-4103; Released by CDRH on 06-06-2016.

Medical Device User Fee Cover Sheet (FDA3601)

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION **MEDICAL DEVICE USER FEE COVER SHEET**	PAYMENT IDENTIFICATION NUMBER: (b)(4) your check.

A completed cover sheet must accompany each original application or supplement subject to fees. If payment is sent by U.S. mail or courier, please include a copy of this completed form with payment. Payment and mailing instructions can be found at: http://www.fda.gov/oc/mdufma/coversheet.html

1. COMPANY NAME AND ADDRESS (include name, street address, city state, country, and post office code) MONICA HEALTHCARE LIMITED Biocity Pennyfoot Street Nottingham NG1 1GF GB 1.1 EMPLOYER IDENTIFICATION NUMBER (EIN)	2. CONTACT NAME Ian How 2.1 E-MAIL ADDRESS ianhow@monicahealthcare.com 2.2 TELEPHONE NUMBER (include Area code) 44115-9124540 2.3 FACSIMILE (FAX) NUMBER (Include Area code) 44115-9124289

3. TYPE OF PREMARKET APPLICATION (Select one of the following in each column; if you are unsure, please refer to the application descriptions at the following web site: http://www.fda.gov/oc/mdufma

Select an application type:	3.1 Select a center
[X] Premarket notification(510(k)); except for third party	[X] CDRH
[ ] 513(g) Request for Information	[ ] CBER
[ ] Biologics License Application (BLA)	3.2 Select one of the types below
[ ] Premarket Approval Application (PMA)	[X] Original Application
[ ] Modular PMA	Supplement Types:
[ ] Product Development Protocol (PDP)	[ ] Efficacy (BLA)
[ ] Premarket Report (PMR)	[ ] Panel Track (PMA, PMR, PDP)
[ ] Annual Fee for Periodic Reporting (APR)	[ ] Real-Time (PMA, PMR, PDP)
[ ] 30-Day Notice	[ ] 180-day (PMA, PMR, PDP)

4. ARE YOU A SMALL BUSINESS? (See the instructions for more information on determining this status)

[ ] YES, I meet the small business criteria and have submitted the required qualifying documents to FDA

[X] NO, I am not a small business

4.1 If Yes, please enter your Small Business Decision Number:

5. FDA WILL NOT ACCEPT YOUR SUBMISSION IF YOUR COMPANY HAS NOT PAID AN ESTABLISHMENT REGISTRATION FEE THAT IS DUE TO FDA. HAS YOUR COMPANY PAID ALL ESTABLISHMENT REGISTRATION FEES THAT ARE DUE TO FDA?

[X] YES (All of our establishments have registered and paid the fee, or this is our first device, and we will register and pay the fee within 30 days of FDA's approval/clearance of this device.)

[ ] NO (If "NO," FDA will not accept your submission until you have paid all fees due to FDA. This submission will not be processed; see http://www.fda.gov/cdrh/mdufma for additional information)

6. IS THIS PREMARKET APPLICATION COVERED BY ANY OF THE FOLLOWING USER FEE EXCEPTIONS? IF SO, CHECK THE APPLICABLE EXCEPTION.

[ ] This application is the first PMA submitted by a qualified small business, including any affiliates	[ ] The sole purpose of the application is to support conditions of use for a pediatric population
[ ] This biologics application is submitted under section 351 of the Public Health Service Act for a product licensed for further manufacturing use only	[ ] The application is submitted by a state or federal government entity for a device that is not to be distributed commercially

7. IS THIS A SUPPLEMENT TO A PREMARKET APPLICATION FOR WHICH FEES WERE WAIVED DUE TO SOLE USE IN A PEDIATRIC POPULATION THAT NOW PROPOSES CONDITION OF USE FOR ANY ADULT POPULATION? (If so, the application is subject to the fee that applies for an original premarket approval application (PMA).

[ ] YES [X] NO

8. USER FEE PAYMENT AMOUNT SUBMITTED FOR THIS PREMARKET APPLICATION

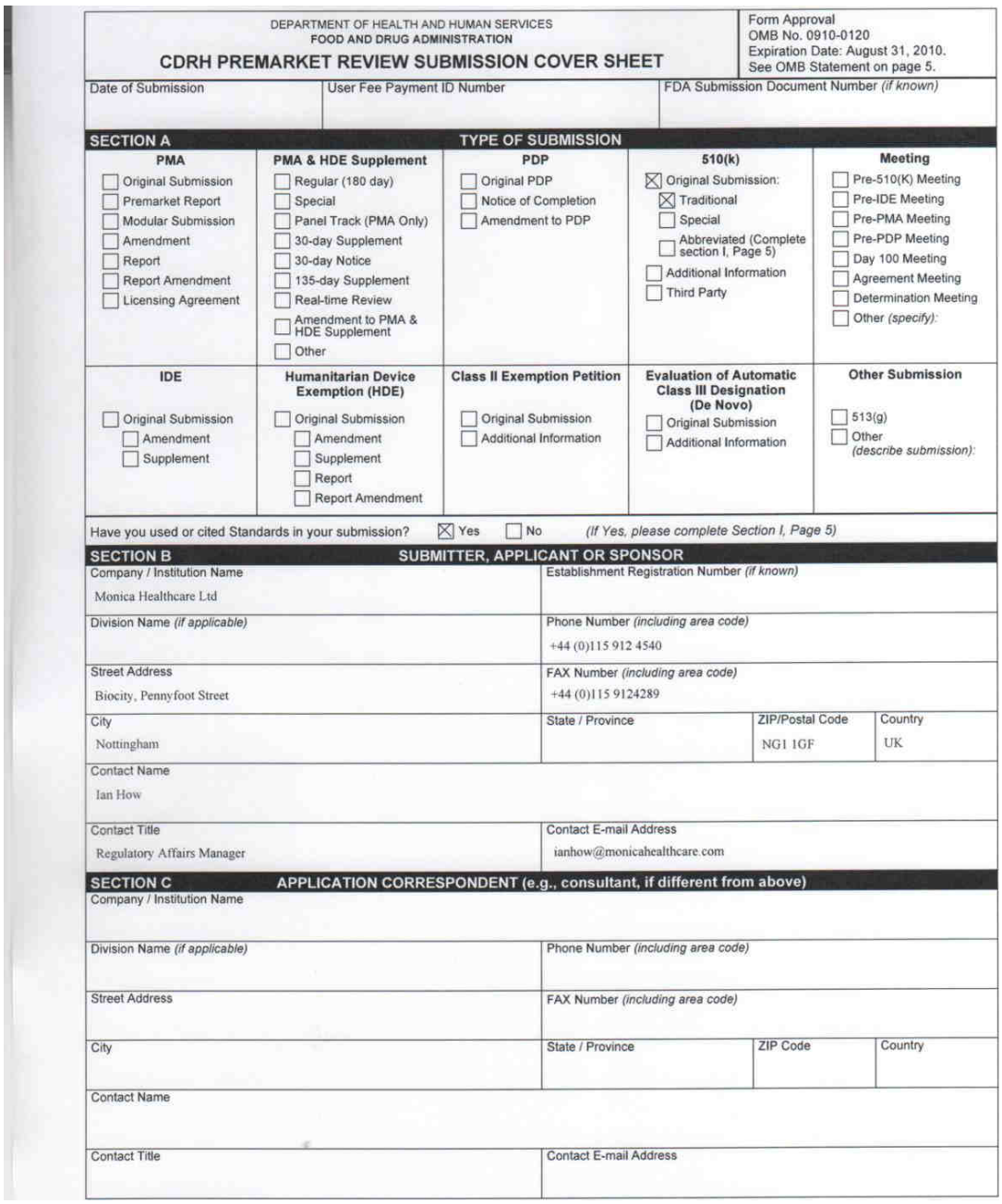
(b)(4)

15-Jun-2010

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

Records processed under FOIA Request #2015-4103; Released by CDRH on 06-06-2016.

CDRH Premarket Review Submission Cover



DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

CDRH PREMARKET REVIEW SUBMISSION COVER SHEET

Form Approval
OMB No. 0910-0120
Expiration Date: August 31, 2010.
See OMB Statement on page 5.

Date of Submission	User Fee Payment ID Number	FDA Submission Document Number *(if known)*

SECTION A — TYPE OF SUBMISSION

PMA	PMA & HDE Supplement	PDP	510(k)	Meeting
☐ Original Submission	☐ Regular (180 day)	☐ Original PDP	☒ Original Submission:	☐ Pre-510(K) Meeting
☐ Premarket Report	☐ Special	☐ Notice of Completion	☒ Traditional	☐ Pre-IDE Meeting
☐ Modular Submission	☐ Panel Track (PMA Only)	☐ Amendment to PDP	☐ Special	☐ Pre-PMA Meeting
☐ Amendment	☐ 30-day Supplement		☐ Abbreviated (Complete section I, Page 5)	☐ Pre-PDP Meeting
☐ Report	☐ 30-day Notice		☐ Additional Information	☐ Day 100 Meeting
☐ Report Amendment	☐ 135-day Supplement		☐ Third Party	☐ Agreement Meeting
☐ Licensing Agreement	☐ Real-time Review			☐ Determination Meeting
	☐ Amendment to PMA & HDE Supplement			☐ Other *(specify)*:
	☐ Other			

IDE	Humanitarian Device Exemption (HDE)	Class II Exemption Petition	Evaluation of Automatic Class III Designation (De Novo)	Other Submission
☐ Original Submission	☐ Original Submission	☐ Original Submission	☐ Original Submission	☐ 513(g)
☐ Amendment	☐ Amendment	☐ Additional Information	☐ Additional Information	☐ Other *(describe submission)*:
☐ Supplement	☐ Supplement			
	☐ Report			
	☐ Report Amendment			

Have you used or cited Standards in your submission? ☒ Yes ☐ No *(If Yes, please complete Section I, Page 5)*

SECTION B — SUBMITTER, APPLICANT OR SPONSOR

Company / Institution Name	Establishment Registration Number *(if known)*		
Monica Healthcare Ltd			
Division Name *(if applicable)*	Phone Number *(including area code)*		
	+44 (0)115 912 4540		
Street Address	FAX Number *(including area code)*		
Biocity, Pennyfoot Street	+44 (0)115 9124289		
City	State / Province	ZIP/Postal Code	Country
Nottingham		NG1 1GF	UK
Contact Name			
Ian How			
Contact Title	Contact E-mail Address		
Regulatory Affairs Manager	ianhow@monicahealthcare.com		

SECTION C — APPLICATION CORRESPONDENT (e.g., consultant, if different from above)

Company / Institution Name			
Division Name *(if applicable)*	Phone Number *(including area code)*		
Street Address	FAX Number *(including area code)*		
City	State / Province	ZIP Code	Country
Contact Name			
Contact Title	Contact E-mail Address		

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

Records processed under FOIA Request #2015-4103; Released by CDRH on 06-06-2016.

Monica Healthcare

SECTION D1 REASON FOR APPLICATION - PMA, PDP, OR HDE

- ☐ New Device
- ☐ Withdrawal
- ☐ Additional or Expanded Indications
- ☐ Request for Extension
- ☐ Post-approval Study Protocol
- ☐ Request for Applicant Hold
- ☐ Request for Removal of Applicant Hold
- ☐ Request to Remove or Add Manufacturing Site

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

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

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

- ☐ Labeling change:
  - ☐ Indications
  - ☐ Instructions
  - ☐ Performance Characteristics
  - ☐ Shelf Life
  - ☐ Trade Name
  - ☐ Other *(specify below)*

- ☐ Report Submission:
  - ☐ Annual or Periodic
  - ☐ Post-approval Study
  - ☐ Adverse Reaction
  - ☐ Device Defect
  - ☐ Amendment

- ☐ Response to FDA correspondence:

- ☐ Change in Ownership
- ☐ Change in Correspondent
- ☐ Change of Applicant Address

- ☐ Other Reason *(specify)*:

SECTION D2 REASON FOR APPLICATION - IDE

- ☐ New Device
- ☐ New Indication
- ☐ Addition of Institution
- ☐ Expansion / Extension of Study
- ☐ IRB Certification
- ☐ Termination of Study
- ☐ Withdrawal of Application
- ☐ Unanticipated Adverse Effect
- ☐ Notification of Emergency Use
- ☐ Compassionate Use Request
- ☐ Treatment IDE
- ☐ Continued Access

- ☐ Change in:
  - ☐ Correspondent / Applicant
  - ☐ Design / Device
  - ☐ Informed Consent
  - ☐ Manufacturer
  - ☐ Manufacturing Process
  - ☐ Protocol - Feasibility
  - ☐ Protocol - Other
  - ☐ Sponsor

- ☐ Report submission:
  - ☐ Current Investigator
  - ☐ Annual Progress Report
  - ☐ Site Waiver Report
  - ☐ 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
  - ☐ Request Hearing

- ☐ Other Reason *(specify)*:

SECTION D3 REASON FOR SUBMISSION - 510(k)

- ☒ New Device
- ☐ Additional or Expanded Indications
- ☐ Change in Technology

- ☒ Other Reason *(specify)*:

Continuation from K081435, to address FDA concerns and include a 6 way substantial equivalence trial

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

Records processed under FOIA Request #2015-4103; Released by CDRH on 06-06-2016.

SECTION E ADDITIONAL INFORMATION ON 510(K) SUBMISSIONS

Product codes of devices to which substantial equivalence is claimed

1	HGM	2		3		4	
5		6		7		8	

Summary of, or statement concerning, safety and effectiveness information

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

Information on devices to which substantial equivalence is claimed *(if known)*

	510(k) Number	Trade or Proprietary or Model Name	Manufacturer
1	K954351	Phillips Series 50XM	Phillips
2			
3			
4			
5			
6			

SECTION F PRODUCT INFORMATION - APPLICATION TO ALL APPLICATIONS

Common or usual name or classification name

Classification 884.2740 Perinatal Monitoring System

	Trade or Proprietary or Model Name for This Device	Model Number
1	Monica AN24	
2		
3		
4		
5		

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

1 K081435	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 - APPLICATION TO ALL APPLICATIONS

Product Code	C.F.R. Section *(if applicable)*	Device Class
HGM	884.2740	☐ Class I ☒ Class II ☐ Class III ☐ Unclassified

Classification Panel

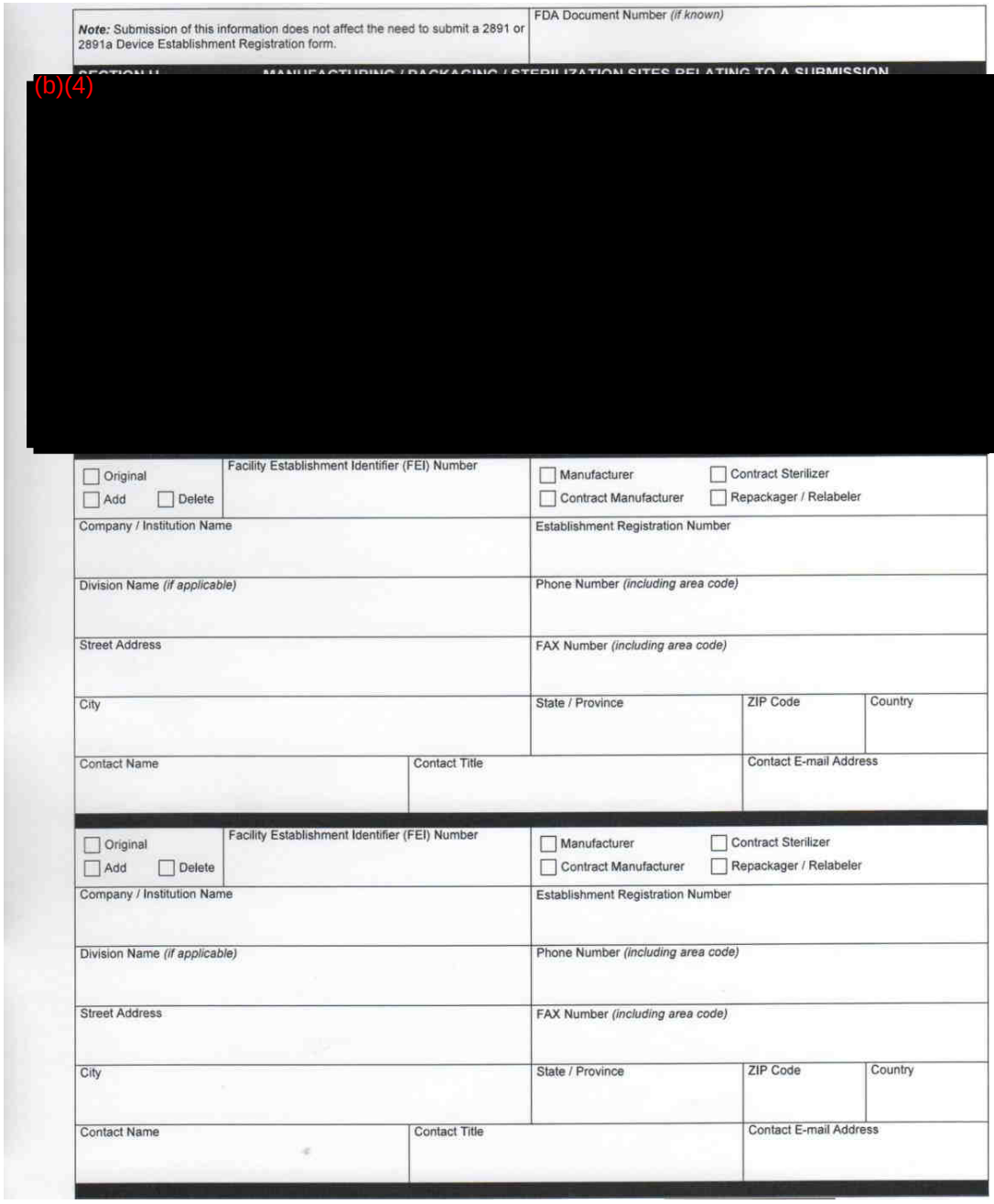
Obstetrics / Gynecology

Indications *(from labeling)*

The Monica AN24 is a monitoring device for non-invasively measuring the Fetal Heart Rate (FHR) and Uterine Activity (UA). The Monica VR software, which accompanies the AN24, enables the measured parameters to be reviewed graphically using a PC or notebook computer and to generate hard copy traces in a "standard" user defined format. This data is intended to aid in assessment of the wellbeing of the fetus and mother for laboring singleton pregnancies who are of gestation age >37 weeks. The AN24 device typically generates standard length FHR and UA traces from a single setup. Application of the device must be by trained personnel, but monitoring sessions can be carried out in hospital and clinics

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

Records processed under FOIA Request #2015-4103; Released by CDRH on 06-06-2016.



Note: Submission of this information does not affect the need to submit a 2891 or 2891a Device Establishment Registration form.	FDA Document Number *(if known)*

(b)(4)

[redacted]

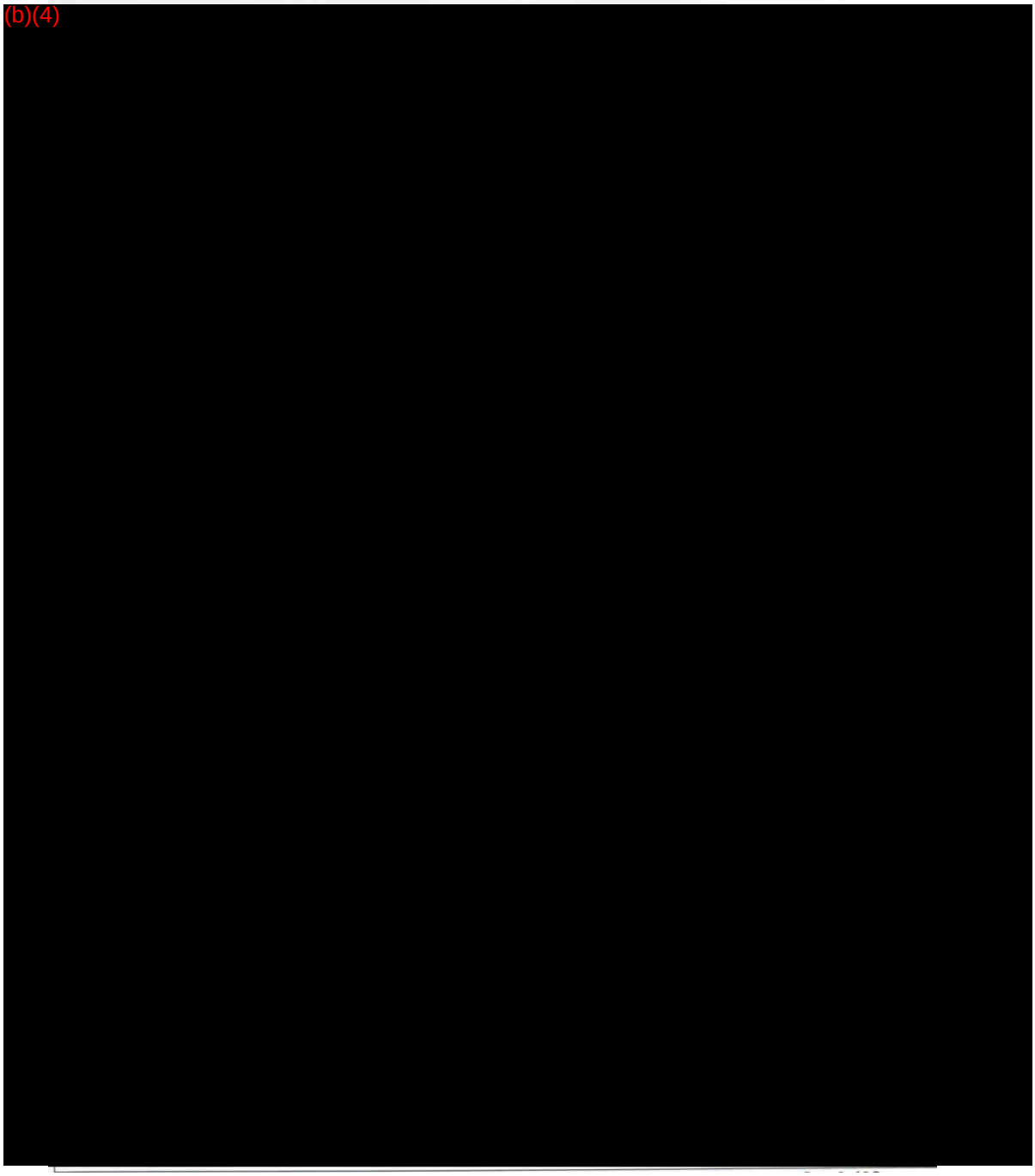
☐ Original ☐ Add ☐ Delete	Facility Establishment Identifier (FEI) Number	☐ Manufacturer ☐ Contract Manufacturer	☐ Contract Sterilizer ☐ Repackager / Relabeler
Company / Institution Name		Establishment Registration Number	
Division Name *(if applicable)*		Phone Number *(including area code)*	
Street Address		FAX Number *(including area code)*	
City	State / Province	ZIP Code	Country
Contact Name	Contact Title	Contact E-mail Address	

☐ Original ☐ Add ☐ Delete	Facility Establishment Identifier (FEI) Number	☐ Manufacturer ☐ Contract Manufacturer	☐ Contract Sterilizer ☐ Repackager / Relabeler
Company / Institution Name		Establishment Registration Number	
Division Name *(if applicable)*		Phone Number *(including area code)*	
Street Address		FAX Number *(including area code)*	
City	State / Province	ZIP Code	Country
Contact Name	Contact Title	Contact E-mail Address	

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

Records processed under FOIA Request #2015-4103; Released by CDRH on 06-06-2016.

(b)(4)



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

Records processed under FOIA Request #2015-4103; Released by CDRH on 06-06-2016.

510(k) Cover Letter

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

Date: June 2010

Dear Sir/Madam,

510(k) Notification (21 CFR 807.90(e)) – Traditional Submission

This letter accompanies two (2) copies of documentation in support of a 510(k) Notification (21 CFR 807.90(e)) for the Monica Healthcare AN24 Fetal Heart Rate Monitor and accessories. One of the copies provided is an electronic copy and it is an exact duplicate of the paper copy. As per 21 CFR 807.95, we are requesting continued confidentiality of the intent to market this device. Please see the enclosed CDRH Premarket Review Submission Cover Sheet (Section 2 of this submission) for additional required administrative information as per the CDRH Guidance Document Format for Traditional and Abbreviated 510(k)s", issued August 12, 2005.
The principal factors pertaining to the design and use of the Monica AN24 device are provided below:

Type of 510(k) Submission:	Traditional
Device Type:	Fetal Maternal Monitor
510(k) Submitter:	Monica Healthcare
Contact details:	Mr. Ian How Regulatory affairs Manager Tel: +44 115 9124540 Email: ianhow@monicahealthcare.com
Classification Name:	Perinatal monitoring system and accessories
Classification Reference:	HGM
Recommended classification:	Class II
Product Code:	884.2740
Panel:	Obstetrics/Gynecology
Former Correspondence:	K081435 510(K) submission (Appendix E)
Basis For submission:	New device

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

Records processed under FOIA Request #2015-4103; Released by CDRH on 06-06-2016.

Design and Use of the Device

Question	YES	NO
Is the device intended for prescription use (21 CFR 801 Subpart D)?	YES	
Is the device intended for over-the-counter use (21 CFR 807 Subpart C)?		NO
Does the device contain components derived from a tissue or other biologic source?		NO
Is the device provided sterile?		NO
Is the device a reprocessed single use device?		NO
If yes, does this device type require reprocessed validation data?		
Does the device contain a drug?		NO
Does the device contain a biologic?		NO
Does the device use software?	YES	
Does the submission include clinical information?	YES	
Is the device implanted?		NO

Preference for continued confidentiality: Monica Healthcare considers its intent to market the AN24 device and accessories as confidential commercial information. The Company has not disclosed its intent to market this device to anyone except its employees, others with a financial interest in the Company, its advertising or law firms, and its consultants. The Company, therefore, requests that FDA not disclose the existence of this application until such time as final action on the submission is taken. In addition, some of the material in this application may be trade secret or confidential commercial or financial information within the meaning of 21 CFR § 20.61 and therefore not disclosable under the Freedom of Information Act, even after the existence of the application becomes public. We ask that you consult with the Company as provided in 21 CFR § 20.45 before making any part of this submission, other than the 510(k) statement, publicly available.

Thank you for your review of this 510(k) submission. If you have any questions or require clarification of any information in this document, please do not hesitate to contact the undersigned.

Yours sincerely,

Carl Barratt

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T:+44(0)115 9124540
F:+44(0)115 9124289
E:info@monicahealthcare.com
W:www.monicahealthcare.com

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

Records processed under FOIA Request #2015-4103; Released by CDRH on 06-06-2016.

Indications for Use Statement

510(k) Number (if known):

Device Name: AN24

Indications For Use:

The Monica AN24 is a monitoring device for non-invasively measuring the Fetal Heart Rate (FHR) and Uterine Activity (UA). The Monica VS software, which accompanies the AN24, enables the measured parameters to be reviewed graphically using a PC, notebook computer or any compatible Series 50 format device, and to generate hard copy traces in a "standard" user defined format. This data is intended to aid in assessment of the wellbeing of the fetus and mother for laboring singleton pregnancies who are of gestation age ≥37 weeks. The AN24 device typically generates standard length FHR and UA traces from a single setup. Application of the device must be by trained personnel.

Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Page 1 of 1

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510(k) Statement

I certify that, in my capacity as CEO, of Monica, I will make available all information included in this premarket notification on safety and effectiveness within 30 days of request by any person if the device described in the premarket notification submission is determined to be substantially equivalent. The information I agree to make available will be a duplicate of the premarket notification submission, including any adverse safety and effectiveness information, but excluding all patient identifiers, and trade secret and confidential commercial information, as defined in 21 CFR 20.61.

Name ……

Signed ……

Date ……

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

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Truthful and Accuracy Statement

I certify that, in my capacity as CEO, of Monica Healthcare Limited, I believe to the best of my knowledge, that all data and information submitted in the premarket notification are truthful and accurate and that no material fact has been omitted.

_____

(Signature)

_____

(Typed Name)

_____

(Date)

_____

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

*For a new submission, leave the 510(k) number blank.

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Class III Summary and Certification

A class III summary and certification are not required in this 510(k) submission because the AN24 is not a class III device.

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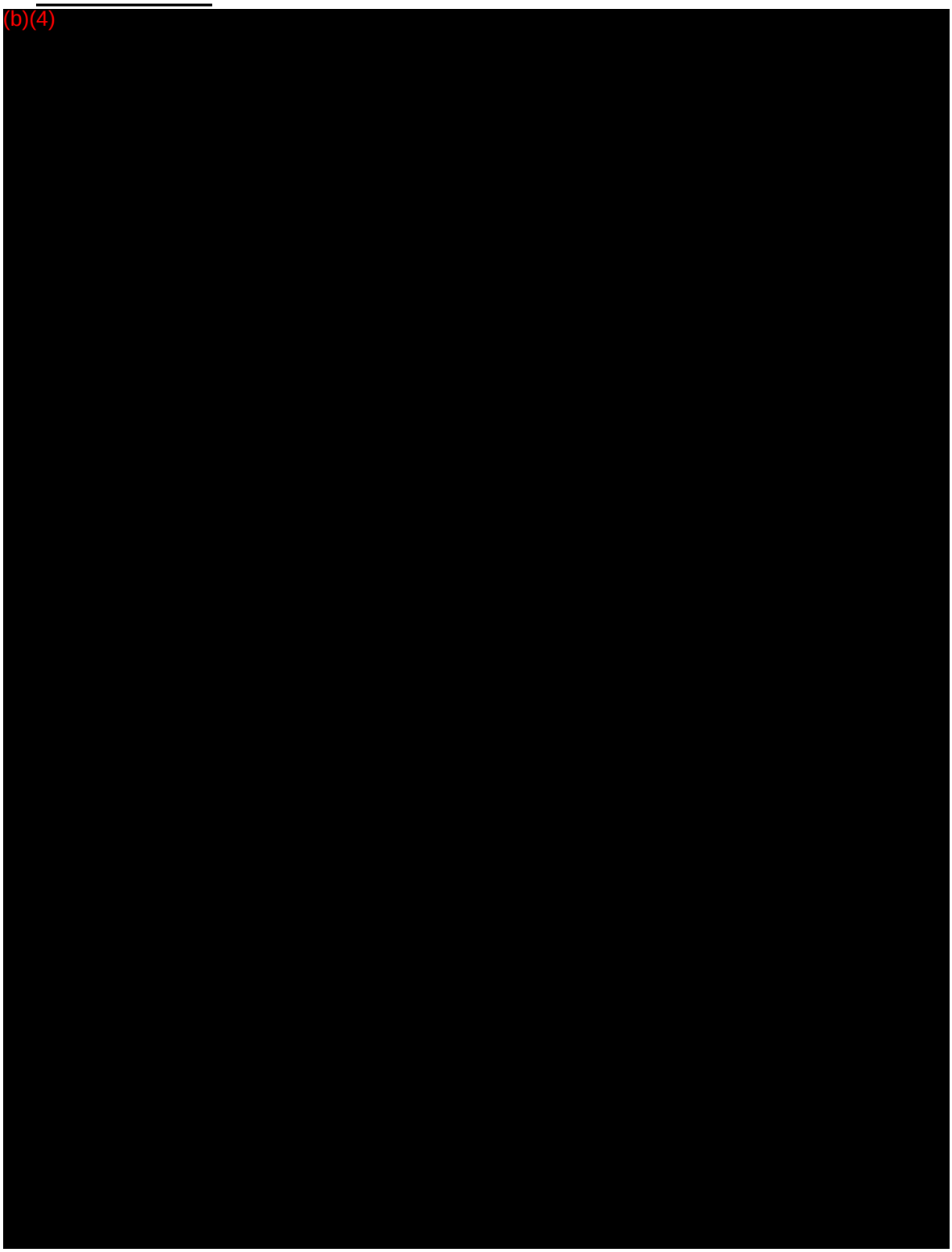

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Declarations of Conformity and Summary Reports

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Executive Summary

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[redacted]

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Kit contents

Table 1 below details the options and accessories available with the Monica AN24; items that are included as standard have been highlighted.

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Table 1 - The Monica AN24 accessories

Part No.	Description
100-PT-100	Monica VS10 Monitor (b)(4)
100-PT-101	Monica VS10 Monitor (b)(4)
(b)(4)	(b)(4)
100-PT-111	Monica VS15 Monitor (b)(4)
100-PT-001	Monica AN24

100-PT-130	Monica Cart (b)(4)
100-PT-131	Monica Cart - printer shelf (b)(4)
100-PT-132	Monica Desktop Stand (b)(4))
100-PT-140	Monica Printer (Real-time) - Thermal Z-fold (b)(4)
100-PT-160	Monica VS Network Viewer

100-PT-002	ECG Lead Assembly - Standard; ~28 weeks to term
100-PT-004	Battery Charger (UK\ EU\ USA please specify)
100-PT-005	AN24 – USB computer connection cable
100-PT-015	Soft silicon rubber protective boot (x5)
100-PT-016	3M red Dot 2236 skin prep tape (x5)
100-PT-017	Monica approved electrodes – 25 pouches x 10 electrodes (250 electrodes)
100-PT-018	Monica approved electrodes – 150 pouches x 10 electrodes (1500 electrodes)
100-PT-019	Monica AN24 Neck Cord (x5)
100-PT-020	Monica Healthcare glossy sales literature folder (x50)
100-PT-021	Sales Literature sheets
100-PT-022	Skin preparation pen
100-PT-141	Z-Fold paper printer (3 cm/min, 30 - 240 bpm) Analogic US
100-PT-142	Z-Fold paper printer (1 cm/min, 50 - 210 bpm) Analogic International
100-PT-143	Z-Fold paper printer (3 cm/min, 30 - 240 bpm) Philips US
100-PT-144	Z-Fold paper printer (1 cm/min, 50 - 210 bpm) Philips International

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Specifications

Table 2: AN24 specifications

Measures Calculated	Time - Real-time clock Clinical Event marker - Button Electrophysiological signal - 3 differential channels FHR - range 60-240 beats/minute, 2 sec average UA - EHG 0-250 uV Maternal Activity (4 levels, inactive to very active)
Storage	Internal micro SD card
Interfaces	Download: - USB – download stored data to computer - Wireless - real-time data transfer using Bluetooth User: - LED indicator 1: Yellow – battery status - LED indicator 2: Green – signal quality - LED indicator 3: Orange – memory status - Button 1: On/ Off button - Button 2: Event marker
Data Format	Series 50 protocol via Bluetooth
Battery Battery Charger	Rechargeable lithium polymer 3.6V 2400mA-hours Input (100-240V, 50-60Hz), UK\EU\US adapter Output DC 5V 1A USB PC connection
Dimensions	11.5 x 5.5 x 2.0cm including lead assembly
Weight	105g excluding lead assembly
OpTemp Storage Temp	0 to + 40 ℃ 0 to + 40 ℃
Approval	CE approved (Directive 93/42/EEC) as amended by 2007/47/EEC

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(b)(4)

Table 3: Electrode lead cable lengths

	Large cable lengths
Trunk	(b)(4)
Leadwire 1	
Leadwire 2	
Leadwire 3	
Leadwire 4	
Leadwire 5	

The individually insulated leadwires are all cut to leave 15mm emerging from the trunk cable. 3mm of insulation is stripped from each of these conductors to allow soldering onto the connection board. It is also important to note that because the Monica device will be positioned on the right hand side of the pregnant woman's abdomen.
The AN24 electrode lead cable is terminated at one end (the patient electrode connection end) by 5 electrode lead clips. The other end of the cable as supplied by the manufacturer (the "grommet" end) is not connected and should be attached as illustrated in figure 4 and Table 4.

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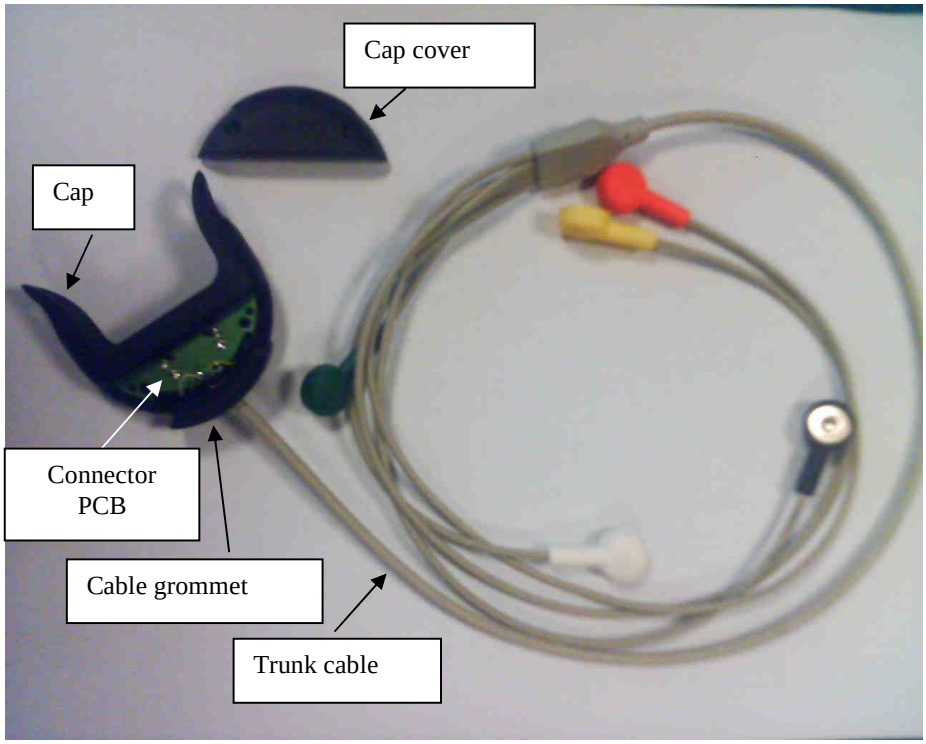

Figure 5: Connector PCB housed in cap with cap cover removed

Electrodes

The Monica specific electrodes are manufactured by Ambu, their product description is 'Blue Sensor VLC' electrodes, which have already been granted Substantial Equivalence (SE) by the FDA (K041026).

Application

The Monica AN24 uses three separate channels to record electrophysiological data from the electrodes on the maternal abdomen. The electrodes are placed in line with the AN24 Reference Operating Manual. In terms of hardware, the AN24 product will comprise of a body-mounted abdominal FECG monitor\ recorder (see Fig 1). This platform will run firmware, which is pre-configured during factory set-up, to extract the fetal heart rate (FHR) and Uterine Activity (UA). The AN24 is packaged with back-end software to allow the processed data to be viewed – this software is compatible with the listed Monica accessories or laptops, notebooks, pda's and standard PC's.

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Requirements for Proper Functioning of the Device

The AN24 Reference Operating Manual details the set-up procedure of the device, including the positioning and attachment of electrodes to the subject's abdomen. The AN24 can only be applied to the patient by trained personnel. Once attached, the AN24 carries out a series of self-checks to determine if it is working correctly and has been set-up in accordance with the instructions in the operating manual. The status of the device is then reported to the clinician during set-up to help assess that the device is working correctly by means of LED indicators on the AN24 itself. These self-check indications are referenced in the User instructions:

Memory Status Self-Check - If the Orange memory status LED begins to flash when the AN24 has been turned on, this means that there is data from a previous patient which is still stored in the AN24 memory. The LED will flash 10 times and then the AN24 will be automatically turned off. This data must be uploaded to a computer running the Monica VS software before a new monitoring session can be started.

Battery Status Self-Check – If the Yellow battery status LED begins to flash when the AN24 has been turned on, this means that the battery charge is too low for recording to begin. The LED will flash 10 times and then the AN24 will be automatically turned off. The battery must then be recharged in order to continue with the recording.

(b)(4)

The battery charger is formed of two parts: (a) an internal charging device which controls the DC input voltage to produce a constant current, constant voltage charge signal for the battery, and (b) and

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external part which plugs into the system connector (when the cable assembly is NOT plugged in – note that the two cannot occur concurrently) to generate a 5V 1A DC supply for the internal charging device from an AC mains input.

The battery is fed directly to two power supplies, one for the digital\ processor part of the device and the other for the analogue part of the device. Power on\ off of the analogue power supply is controlled by the processor. The analogue power supply produces a split rail voltage which is further regulated by low drop out regulators.

Interfaces

The device incorporates interfaces for LED's (providing battery status, data storage and signal quality indication) and two buttons. One button provides on\off facility, whilst the other provides an event marker.

Data can be downloaded from the device wirelessly in real-time via Bluetooth or alternatively it can be recorded on an internal micro SD card for retrospective download via a hardwired USB connection.

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Substantial Equivalence Discussion

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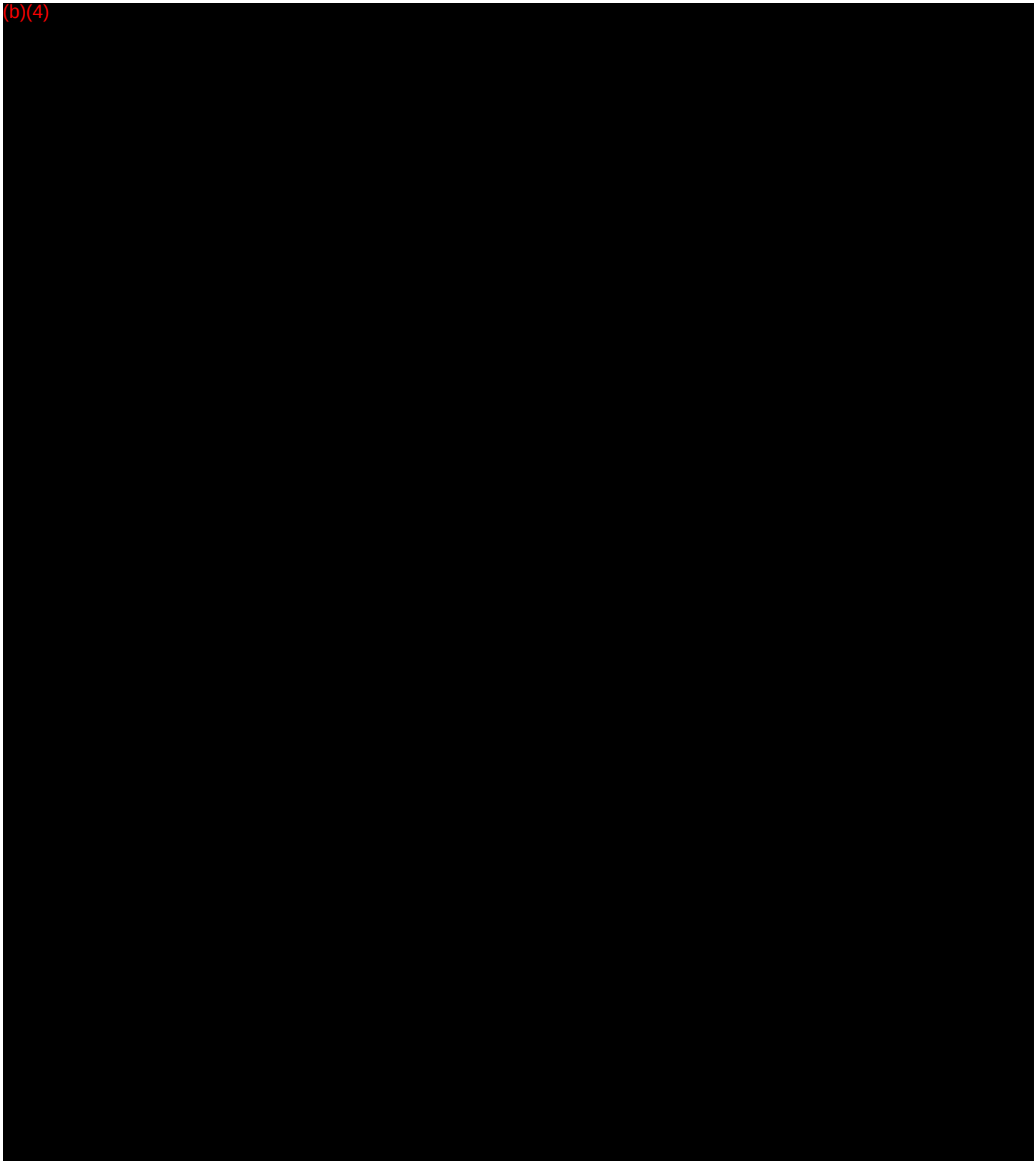

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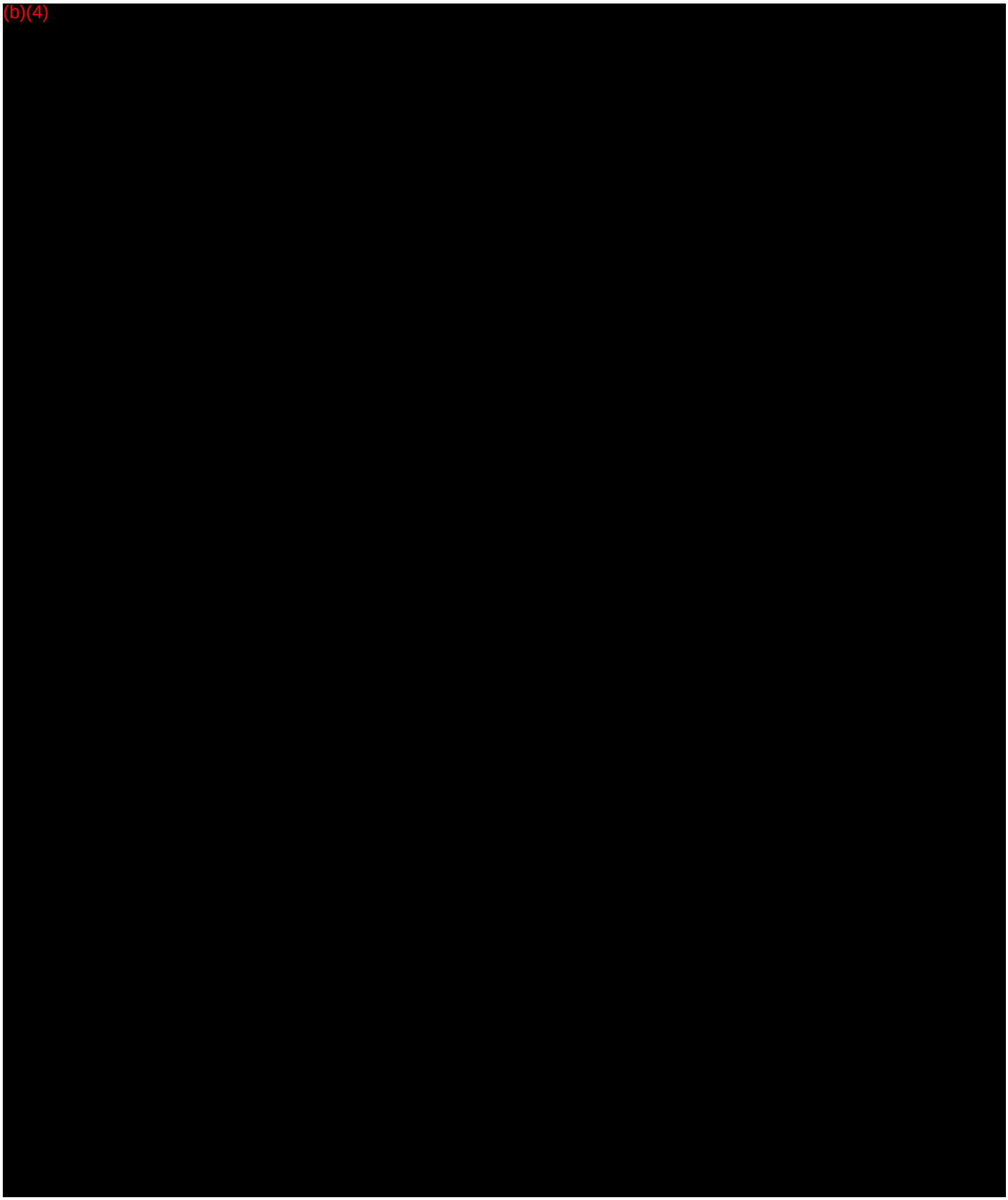

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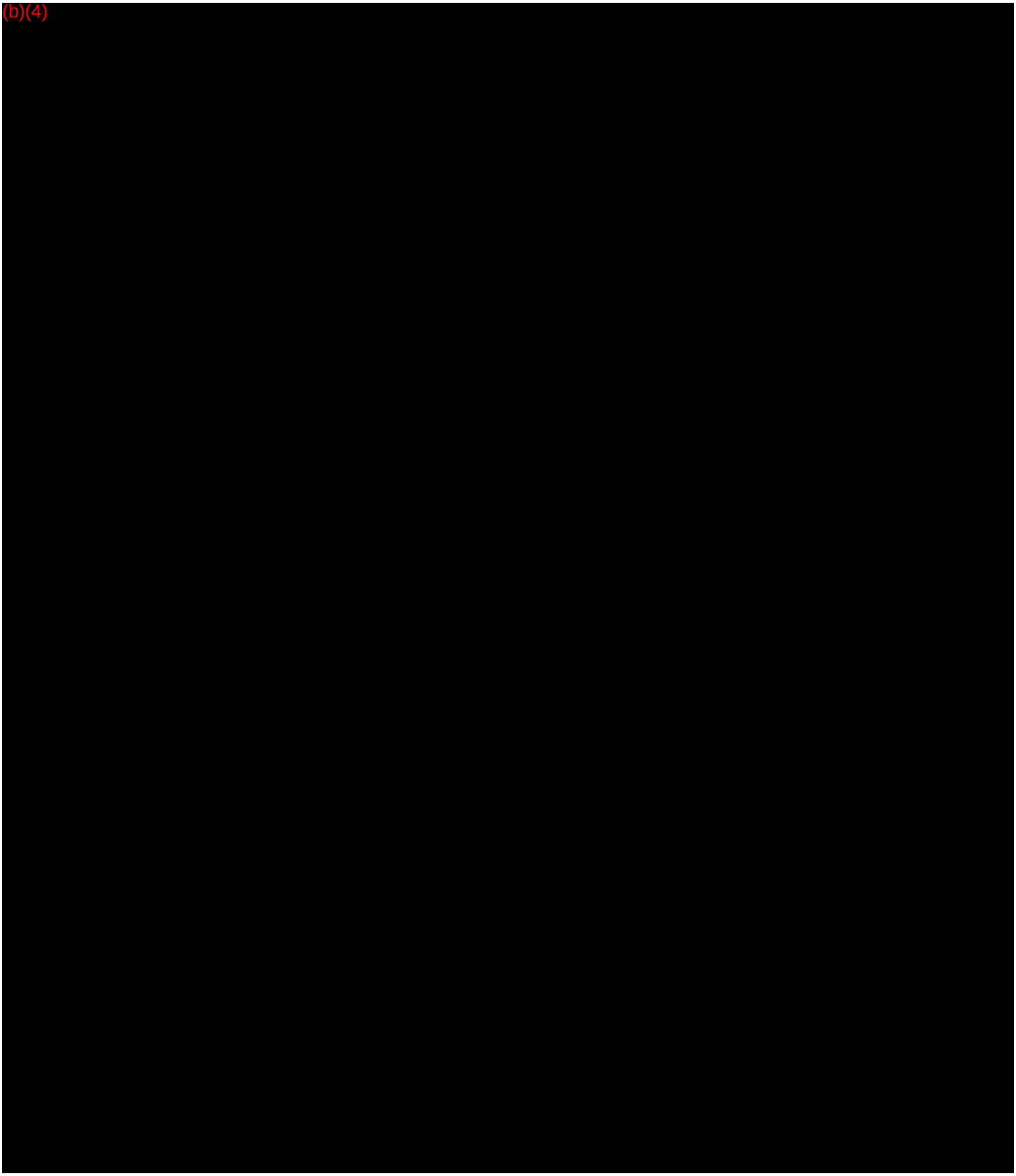

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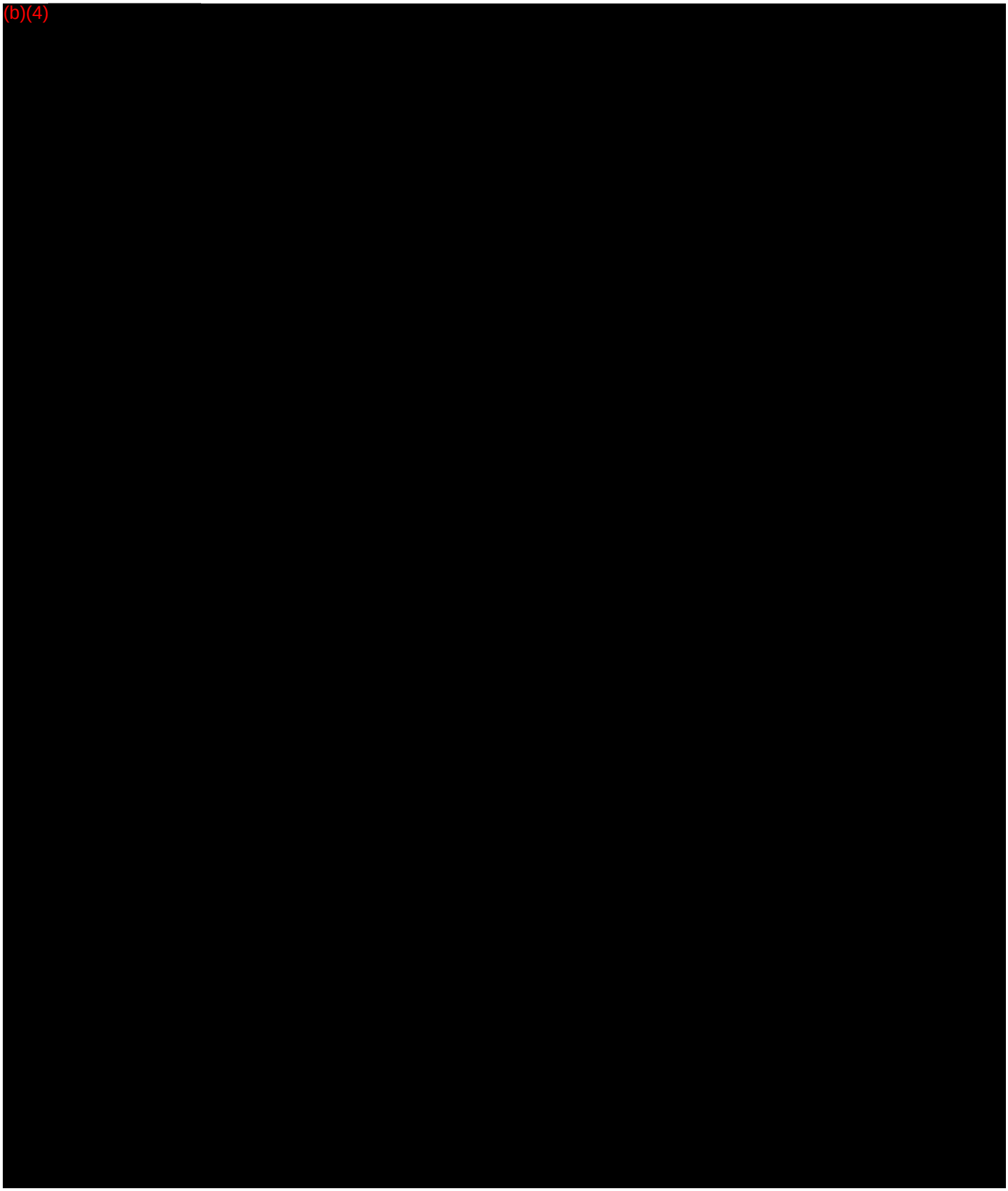

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Labeling

The labeling of the AN24 can be separated in to 3 areas: device labels, instructions for use and marketing material. Supplied with the AN24 are Ambu VLC electrodes (K041026) and 3m Red Dot Trace Prep, both accessories are approved by the FDA and are legally available for sale in the USA. There have been no changes to the labeling and instructions for use.

AN24 Device Labels

There are 7 labels on the AN24 (x2), patient leads (x2), charger, CD and outer packaging.

Instructions for use

Provided within the outer packaging is a printed CD containing a detailed AN24 Reference Operating Manual; VS Reference Operating Manual; a concise version of these manuals (Concise Operating Manual) provided in 6 different languages (Italian, Portuguese, Netherlands, Spanish, French, Dutch).

Provided loose within the outer packaging is a double sided colour Quick Reference Guide

Sales and Marketing Material

There is a sales sheet, providing details of the AN24.

Labelling conclusion

The labeling detailed throughout section 13 complies with international standards and satisfies the requirements of 21 CFR Part 801. In comparing the labeling of the AN24 to that of the predicate device, there are no significant differences in the format or depth of information made available. Labeling is provided in Appendix B

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

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Sterilization and Shelf Life

This section is not applicable, as none of the component parts of the Monica AN24 device are supplied sterile.

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

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Biocompatibility

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Software

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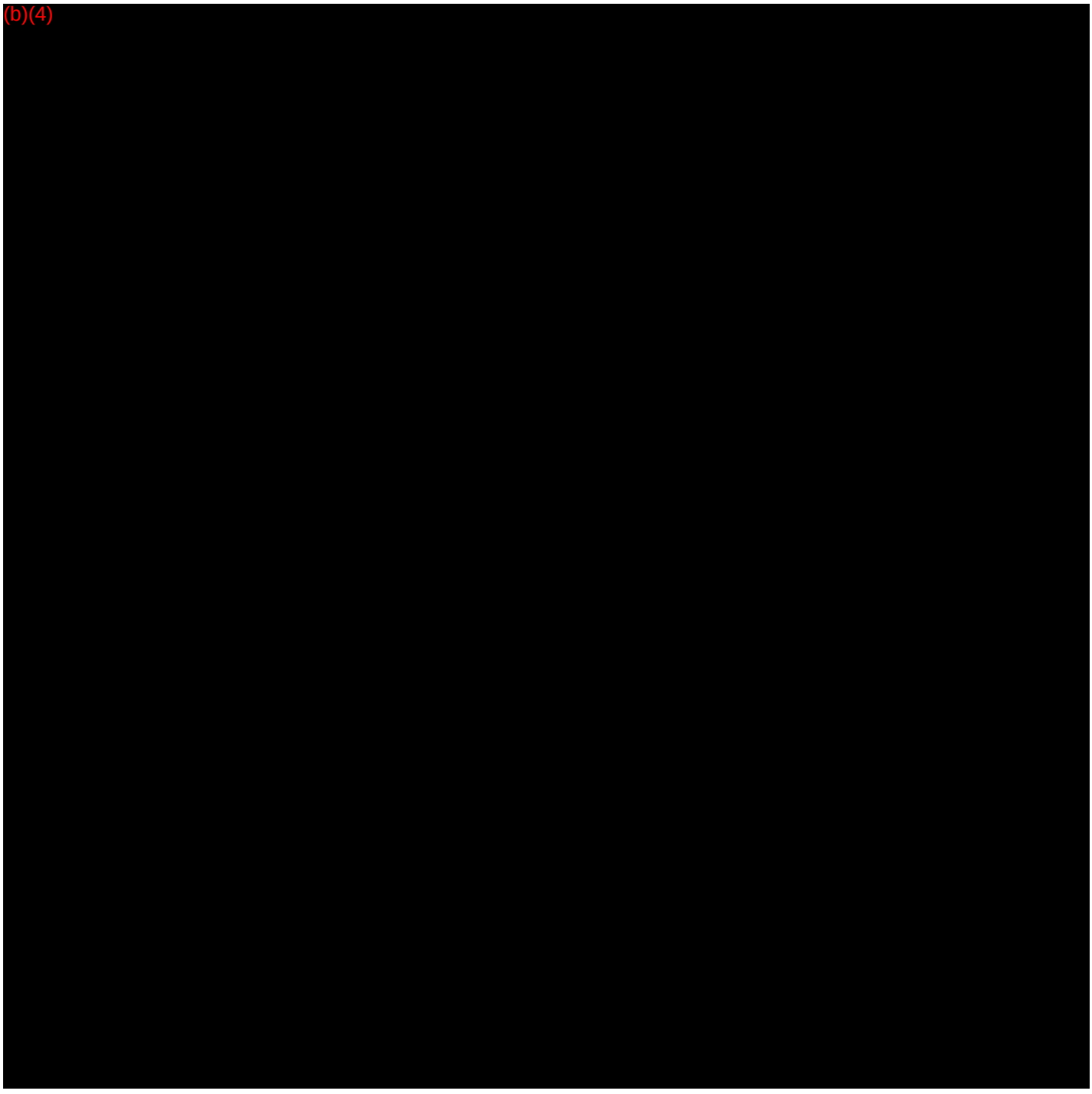

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Appendices

The following Appendices and corresponding data have been supplied on the CD and are not in the paper copy

Appendix A

European Product and Quality System Certifications and FDA 3654 Forms for Standards employed

Appendix B

Proposed Labeling

Appendix C

Biocompatibility Certificates

Appendix D

Predicate Device – Product Information and Labeling

Appendix E

Prior FDA Correspondence

Appendix F

Software Documentation

Appendix G

Clinical Trial Data

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Product	Abdominal Fetal ECG recorder
Document name	Labelling
Document type	**Drawings**
(b)(4) [redacted]	

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1 SCOPE

1.1 Document Identification

This document provides drawings of all labelling related to the AN24 product.
The document is identified as follows:

- ✓ Identification Number: 100-SH-006.
- ✓ Title: Abdominal Fetal ECG recorder – Drawings, labelling.

1.2 Document Scope

This document is part of the hardware documentation of the AN24 product. It provides a description of all labelling.

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2 RELATED DOCUMENTS

N°	*Title*	*Reference*
[1]	AN24 Assembly Instructions	100-TF-007
[2]	Four part label kit drawing	100-SH-006 App A
[3]	Main Label Outline Drawing	100-SH-006 App B
[4]	Electrode check label drawing	100-SH-006 App C
[5]	Outer case artwork drawing	100-SH-006 App E

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3 General Labelling requirements

3.1 Applicability

Each AN24 device requires.

3.2 Location

- Label 1 – Rear of AN24 device (see Assembly instructions [1])
- Label 2 – Front of Cable yoke (see Assembly instructions [1])
- Label 3 – Rear of Cable yoke (see Assembly instructions [1])
- Label 4 – Front of power supply (see Assembly instructions [1])
- Label 5 – Rear of AN24 device (above label 1)
- Label 7 – Outer packaging

3.3 Colour and Finish

- Background colour - Pantone grey 426
- Foreground colour - Pantone cool grey
- Other colours – Red for the logo (Label 1) and the four coloured circles (Label 2).
- Finish - The labels require a matt finish as per the membrane panel

3.4 Durability

The label must be able to withstand the following tests:

- Rubbing by hand, without undue pressure, for 15s with a cloth rag soaked with distilled water.
- Rubbing by hand, without undue pressure, for 15s with a cloth rag soaked with methylated spirit (at ambient temperature).
- Rubbing by hand for 15s with a cloth rag soaked with isopropyl alcohol. All marking shall be clearly legible after all these tests have been performed.

4 Labelling Artwork

4.1 Four (4) Part Label Kit

The part number format for the four part label kit is AN24_4PARTLAB_V* where * denotes the version number.

Related Drawings - Appendix A 100-SH-006 Four part label kit iss D

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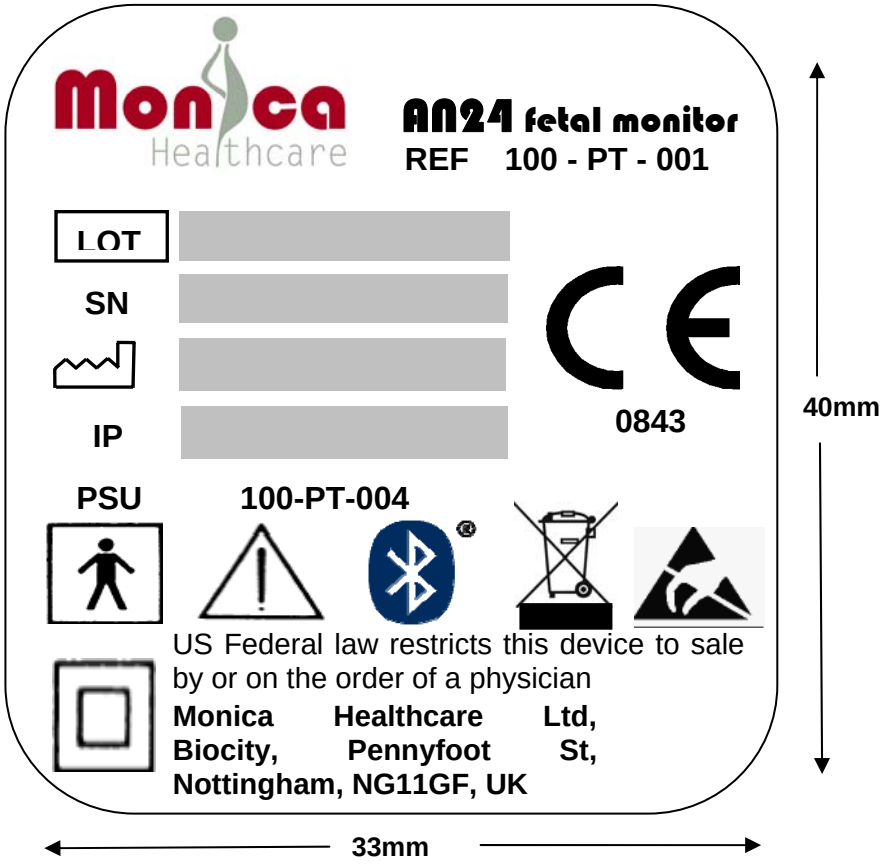
4.1.1 AN24 Label (label 1)

The four part label kit includes this label.

Related Drawings - Appendix A 100-SH-006 Four part label kit iss D
Related Drawings - Appendix B 100-SH-006 Main label outline iss A

Dimensions shown alongside the label shown below are approximate – for details of corner radius and exact dimensions see Appendix B. The relative scale of the symbols\ text should be maintained – but the “CE” mark logo should be at least 7mm high i.e. scale the other symbols to suit.

There are transparent windows to allow numbers to show through from a separate label printed to stick onto the AN24 device behind this label. These windows relate to the; Batch number, Serial Number, date of manufacture and IP rating.



The background colour should be Pantone grey 426 as per the membrane panel and the foreground colour (for everything) should be Pantone cool grey. The only exception is the ‘red’ part of the Monica logo, which should be as above.

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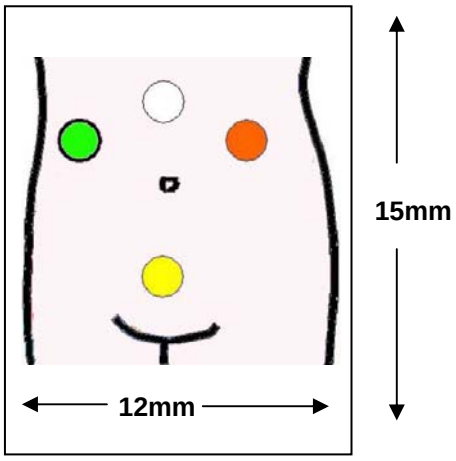
4.1.2 Cable Label part A (label 2)

The four part label kit includes this label.

Related Drawings - Appendix A 100-SH-006 Four part label kit iss D



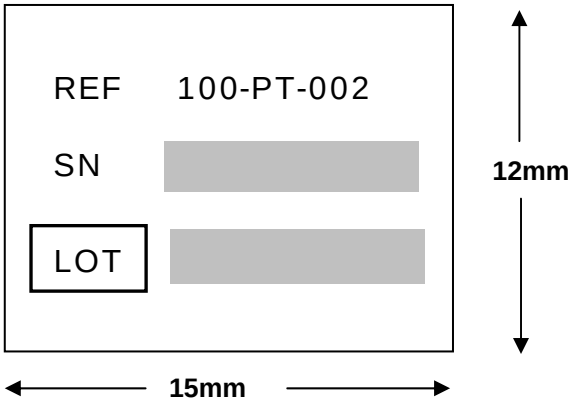
The background colour should be Pantone grey 426 as per the membrane panel and the foreground colour (for the outline of the abdomen) should be Pantone cool grey. The colours for the circles should be: Orange, White, Green and Yellow as shown.

4.1.3 Cable Label part B (label 3)

The four part label kit includes this label.

Related Drawings - Appendix A 100-SH-006 Four part label kit iss D

There are transparent windows to allow numbers to show through from a separate label printed to stick onto the cable behind this label. These windows relate to the; Batch number and Serial Number. The background colour should be Pantone grey 426 as per the membrane panel and the foreground colour (for the lettering) should be Pantone cool grey.



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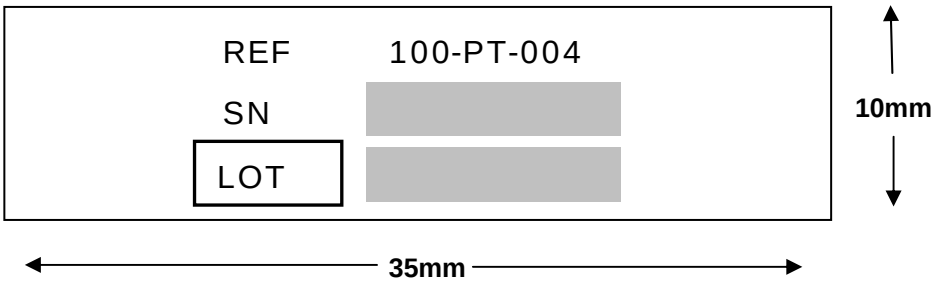
4.1.4 Power Supply Label (label 4)

The four part label kit includes this label.

Related Drawings - Appendix A 100-SH-006 Four part label kit iss D

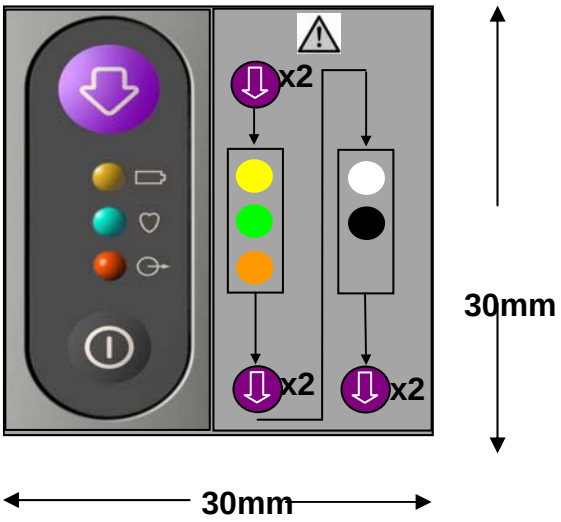
There are transparent windows to allow numbers to show through from a separate label printed to stick onto the cable behind this label. These windows relate to the; Batch number and Serial Number. The background colour should be Pantone grey 426 as per the membrane panel and the foreground colour (for the lettering) should be Pantone cool grey.



4.1.5 Electrode Check Label (label 5)

The four part label kit does not include this label. The part number format for the electrode check label is AN24_ELECTLAB_V* where * denotes the version number.

Related Drawings - Appendix C 100-SH-006 Electrode check label iss A



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*** The background colour should be Pantone grey 426 as per the membrane panel. The colours for the circles should be: Orange, White, Black, Green and Yellow as shown.

4.1.6 Outer packaging label (label 7)

The outer packaging is a hard plastic 'clam shell' case, which will have the following label screen printed onto one side (the top).

Related Drawings - Appendix E 100-SH-006 Outer Case Artwork iss A

5 Applicable Standards

Applicable Standards	Description
EN 980: 1996	Graphical Symbols for use in the labelling of medical devices
EN 1041: 1998	Information supplied by the manufacturer with medical devices
MDD 93/42/EEC	Medical Device Directive
ISO EN 60601-1: 1990	Medical Electrical Equipment – Part 1: General requirements for safety
ISO EN 60601-2-47: 2001	Medical Electrical Equipment – Part 2-47: Particular requirements for the safety, including essential performance, of ambulatory electrocardiographic systems

End of Document

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Monica Healthcare

Monica VS series

...the next generation CTG

Wireless Mobility
- Can reduce time in labour[1]
- Natural Birthing positions
- Patient Satisfaction

Beltless
- Patient Comfort
- Continuity of monitoring during procedures

Reduced User Intervention
- No repositioning of transducers
- Continuous monitoring for 20+ hours

Accurate Surveillance
- Direct FHR monitoring from fECG
- Monitors maternal heart rate[3] to easily identify potential MHR / FHR confusion
- Uterine Activity validated against IUPC

Improved work flow
- Electronic storage / Paperless
- Remote viewing & Central Station connectivity[2]
- Event annotation & decision support

Obesity
- Minimal performance loss with obese patients

1 Enabling patients to mobilise can reduce the time in labour
"Maternal positions and mobility during first stage labour" Lawrence et.al. 2009
2 Requires CS interface
3 Not available in the US

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Monica VS series

...Document processed under FOIA Request #2015-4103, Release...

...the next generation CTG

Monica's VS series of wireless fetal-maternal monitors opens up a whole new world of passive surveillance, flexible management, and patient comfort during pregnancy and labour in the hospital, clinic or home[3].

Using innovative abdominal fECG FHR and EHG UA technology the VS series provides a new solution for Labour and Delivery monitoring and performs well in women with a high BMI.

Featuring FHR, UA, MHR[3], maternal activity[3], event annotation and decision support the Monica VS series of monitors offer simple set-up, minimal supervision and robust solutions for clinical use.

Available as a 15" monitor (VS15) mountable on a desk or cart with optional real-time 'Z-fold' thermal printer or as a 10" portable monitor (VS10). The Monica VS series provides a level of information and connectivity never before available to the clinician.

CTG display using the Monica VS15 or VS10 Monitor

Non-Invasive	✓	Early gestation	✓
Passive	✓	Late gestation	✓
Requires Minimal Supervision	✓	Throughout Induction & Labour	✓
Maternal Freedom	✓		
		High Maternal BMI	✓
FHR & MHR[3]	✓		
- based on accurate R-R interval		Monitor Multiple Beds	✓
Concurrent FHR & MHR	✓	- from 1 VS Monitor (in range)	
Maternal Movement Detection[3]	✓		
Uterine Activity (EHG)	✓	Central Station Link	✓
Event Marker	✓	Remote Network Viewing	✓
Real-Time thermal print option	✓	High Level of data integrity	✓

For more information on the Monica VS series please contact your local Monica representative or visit www.monicahealthcare.com

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

100-PT-001 Monica AN24™

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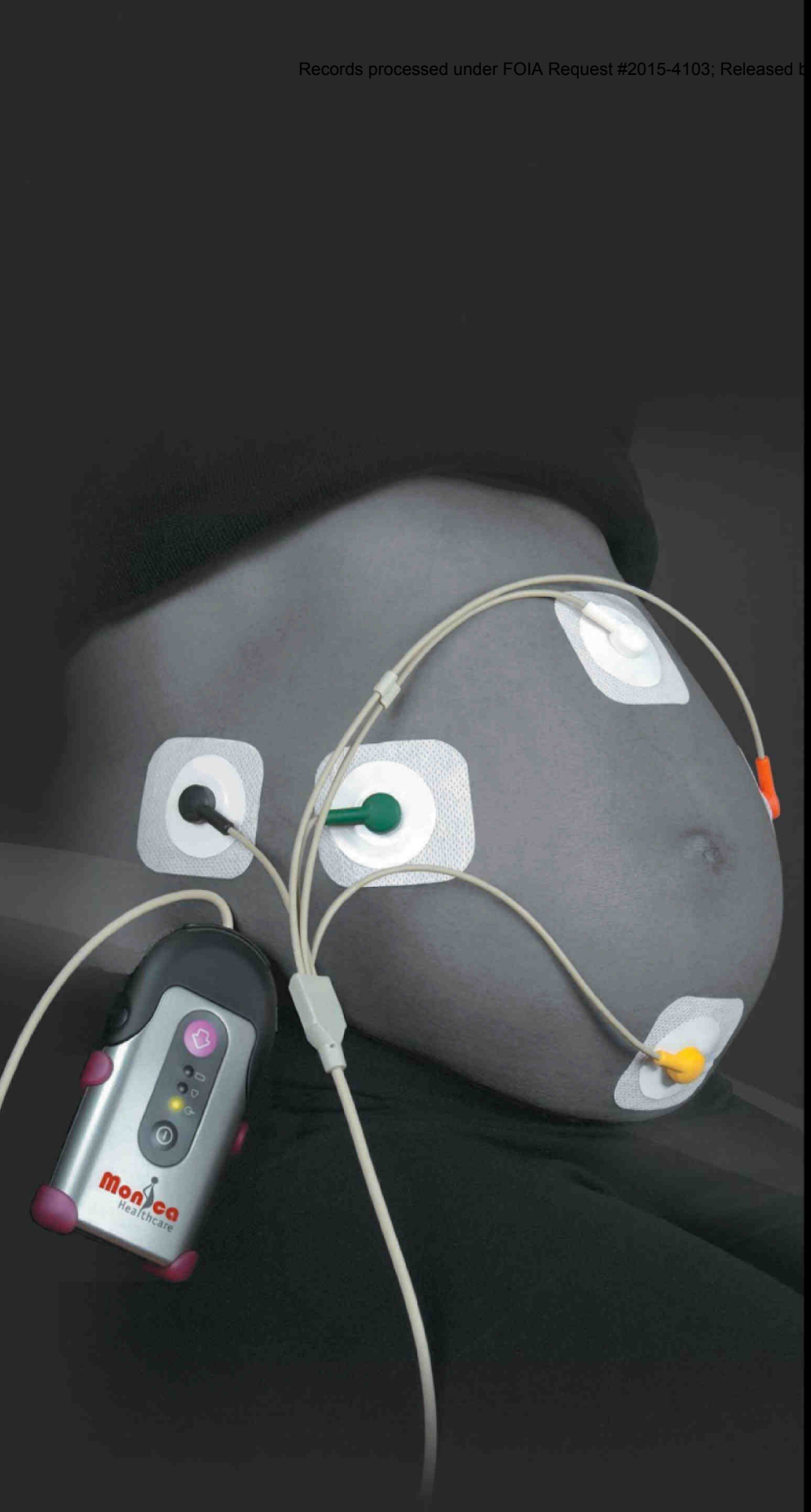

Monica AN24™

Reference Operator Manual

100-TF-006 Revision I

CE
0843

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US law restricts this device to sale by, or on the order of, a physician.

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This Operator's Manual is intended for trained medical personnel (including obstetricians, midwives, nurses, and physicians) who are familiar with obstetric procedures. Keep this operator's manual with the unit for use by the operator.

Conventions Used in This Operator Manual

Warning: A warning alerts you to a potential serious outcome, adverse event, or safety hazard. Failure to observe a warning may result in death or serious injury to the user or patient.

Caution: A caution alerts you to situations where special care is necessary for the safe and effective use of the product. Failure to observe a caution may result in minor or moderate personal injury or damage to the product or other property, and possibly in a remote risk of more serious injury.

On your monitor, this sign indicates that there is detailed information in this book, which you must read before proceeding with your task.

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Numbers in brackets ( ) refer to the key number in Figure 1 or the index of Table 1

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Section 1 - Unpacking the AN24™

Table 1 - The Monica AN24™ case should contain the following items

	Description
10	Monica AN24™ Device [Item1, Figure 1]
11	Electrode lead connector [Item 2, Figure 1]
12	AN24™ neck strap
13	Battery Charger and lead
14	AN24™ monitor connector/computer USB cable
16	10 Electrodes
17	Roll of abrasive skin tape
18	AN24™ protective cover
20	Quick Start Guide
	Skin Preparation Pen

Please confirm that you can identify all the items in the case.

Figure 1 Monica AN24™ Controls and Indicators

Section 2 - Product Description

2.1 General description

The Monica AN24™ is a wearable, battery-powered device for antenatal and L&D surveillance of fetal and maternal well-being. The AN24™ is designed to passively monitor Fetal Heart Rate (FHR), Maternal Heart Rate (MHR)[1] and Uterine Activity (UA) from the Electro Hysterogram (EHG) during pregnancy[2] and can be used at any time from ≥ 37 weeks gestation to the end of second stage labour. Excessive vernix formation in the 27+0-33+6 week gestation period may result in a significant reduction in FHR detection in some patients. The AN24™ is currently suitable for singleton pregnancies only[3]. One AN24™ is suitable for extended monitoring sessions of up to 18 hours.

2.2 Patient attachment

The Monica AN24™ is attached via a detachable lead assembly that in turn attaches to 5 disposable ECG electrodes placed on the abdomen of a pregnant woman to generate 3 signal channels. The AN24™ then records the electrical signals present at these electrodes that contains information relating to the maternal heart[1], fetal heart and other sources of electrical energy inside the body.

2.3 Data processing

The acquired signals are then converted by the AN24™ into a digital format and processed in real-time to extract clinically relevant information, such as the Fetal Heart Rate (FHR), Maternal Heart Rate (MHR)[1] and Uterine Activity from the Electro Hysterogram (EHG).

2.4 Data viewing and storage

The processed data can either be stored by the AN24™ and downloaded to a computer or VS monitor at the end of the monitoring session, or wirelessly transmitted in real-time for viewing on a dedicated monitor. Monica VS monitors enable the data to be viewed, stored, and printed.

2.5 Heart rate calculation

The time between the R-wave of consecutive fetal QRS complexes in the ECG signal is used to calculate the FHR. This is called the fetal RR interval. Similarly, the time between

---

[1] Not available in the USA

[2] Other Fetal/Maternal parameters will be available at a later date.

[3] Multiple pregnancy monitoring will be available at a later date.

the R-wave of consecutive maternal QRS complexes in the maternal ECG signal is used to calculate the MHR[1]. This is called the maternal RR interval. See Figure 2.

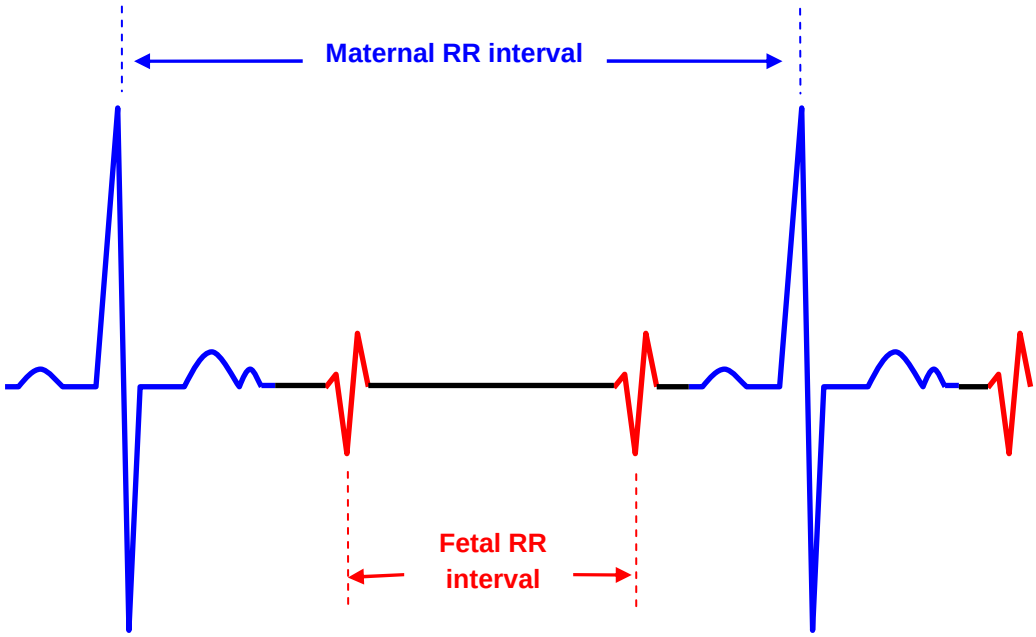


Figure 2 Calculation of FHR and MHR from ECG

The FHR and MHR[1] are also with a ¼ second rolling window update'. The amount of averaging is dependant on the ratio of the fetal height to noise and the number of fECG complexes detected, but it is never more than 2seconds.

2.6 Heart rate data accuracy

The FHR and MHR[1] data is only made available for viewing when the AN24™ is confident that this data is accurate. Confidence is based upon the general noise in the recorded data and characteristic shape of the ECG complex. In the event that the AN24™ is not confident of the accuracy of either the FHR or MHR[1], they will not be made available; the AN24™ will not 'fill in 'or 'coast' when FHR data is not available.

2.7 Uterine Activity from EHG

The Uterine Activity is extracted from the slow-wave of the EHG, i.e. its envelope. The envelope is obtained by low-pass filtering the rectified fast-wave of the EHG. The UA is updated every 2 seconds as a number between 0 and 255, representing an EHG envelope from 0 to 500 microvolts.

Section 3 - Installation

3.1 Battery Charging

The Monica AN24™ (Figure 1) is dispatched with a non-removable rechargeable battery which, for shipping, is not fully charged.

The battery must be fully charged prior to use as described below.

Please refer to Figure 1

A. Connect the lead on the supplied battery charger into the socket inside the top of the AN24™ body (**1**). Plug the battery charger into a mains outlet and switch on the mains outlet. The amber battery status LED (**6**) will flash if a connection has been made (this should be confirmed) until the device is charged, when it will be constantly lit. This should take no more than 2½ hrs.
B. When the electrode leads connector (**2**) is connected to the Monica AN24™ Recorder (**1**) disconnect the lead connector (**2**) from the AN24™ body (**1**) by pressing the two buttons (**7**) on either side of the recorder, and gently pulling apart the AN24™ body (**1**) from the lead connector (**2**).

3.2 Instructions

Please fully read these instructions before using the AN24™.

Section 4 - Operating the AN24™

4.1 Set-up procedure when not using the VS monitor

4.1.1 Select mode.

The Monica AN24™ can be operated in two modes, namely:

Mode 1 - Retrospective mode
The Monica AN24™ records fetal heart rate (FHR), maternal heart rate (MHR)[1] and Uterine Activity (UA) for retrospective upload and viewing on a Monica VS Monitor.

Mode 2 - Real time mode
The Monica AN24™ transfers FHR, MHR[1] and UA using Bluetooth® wireless transmission in 'real-time' to a Monica VS Monitor for real-time viewing of the data.

The default mode when the Monica AN24™ is turned on for the first time is Mode 1 (Retrospective mode). Connection via USB to a VS Monitor is required to set the time for the first recording.

The AN24™ already running in Mode 1 can be set up to run in Mode 2 by making a wireless Bluetooth® connection using the Monica VS Monitor (see section 4.4).

4.1.2 Electrode attachment

Prior to applying the electrodes, the skin must be prepared correctly using an alcohol wipe and abrasive skin tape (**17**) as described in Supplement 1 – Electrode Placement.

Additionally, the electrodes (**16**) must be positioned correctly on the women's abdomen.

For skin preparation and electrode positions please refer to Supplement 1 – Electrode Placement

4.1.3 Lead connection

Attach the electrode leads connector (**2**) to the electrodes (**16**) following the colour code guide in Supplement 1 – Electrode Placement. Ensure that the electrode leads connector (**2**) is securely attached to the AN24™ (**1**), by pushing the two sections firmly together such that the two buttons (**7**) are engaged.

For monitoring in Labour and Delivery always use the AN24™ Protective cover (supplied). Please refer to Supplement 1 – Electrode Placement for instructions on fitting the protective cover.

4.1.4 Turn on

Turn the AN24™ on by pressing the on/off button (3). All three LEDs (4, 5 and 6) will flash 3 times to indicate that the AN24™ has been turned on.

4.1.5 Memory status self-check

If the Orange memory status LED (**4**) begins to flash when the AN24™ has been turned on, this indicates there is data from a previous patient stored in the memory of the AN24™.

The stored data can be a) downloaded using Monica VS Monitor via a USB cable or b) deleted remotely via Bluetooth® connection to the Monica VS monitor.

a) To download the data via USB, turn off the recorder (see 'Turn Off' section below), and connect the AN24™ to the VS Monitor with the USB cable provided (please refer to the Monica VS Reference Manual for detailed instructions). Once the data has been downloaded, the recorder can be used for a new recording.

b) To delete the data via Bluetooth®, use a Monica VS monitor to connect to the recorder. The VS monitor will automatically recognise that there is data stored on the AN24™ and offer to delete the data or allow the user to disconnect it from VS to download as per a) above (please refer to the Monica VS Reference Manual for detailed instructions). Once the data is deleted the recorder can be used for Real Time mode recording.

4.1.6 Battery status self-check

If the Yellow battery status LED (6) begins to flash when the AN24™ has been turned on, this means that the battery charge is too low for recording to begin. The LED will flash 10 times and then the AN24™ will be automatically turned off. See 'Recharging the batteries later in this section.

N.B. If there is data on the recorder, the Memory Status led will flash alongside the battery status LED.

4.1.7 Electrode attachment self-check

After turn on, the AN24™ will check the electrodes are attached correctly. The green signal quality LED (**5**) will go into one of three states:

- GREEN LED FLICKERS

The green LED flickers rapidly when the electrodes are not correctly attached. To solve this problem please refer to Section 10 - Troubleshooting. The AN24™ will continue this self-check until the problem has been resolved and recording will not begin until it has.

- GREEN LED ON

The green LED is constantly on to indicate that all electrodes are correctly attached to the skin. Once the AN24™ is satisfied that the electrodes are correctly attached the recording will begin. The AN24™ will then look for the maternal ECG.

- GREEN LED SLOWLY FLASHES

The green LED will flash (once every 2 seconds) when the AN24™ is satisfied that the electrodes are correctly attached and that the maternal ECG has been located (note – maternal ECG location may take up to 30 seconds once the correct electrode attachment has been confirmed). If the LED remains constantly on, please refer to Section 10 - Troubleshooting. If the problem persists please contact your distributor.

NB: Monica VS monitors provide an on-screen electrode attachment check during the setup of a new patient see the VS Reference Operating Manual for details.

4.1.8 Secure the AN24™

If the patient wishes to carry the AN24™ it can either be held in their clothing (e.g. a pocket) or carried around the neck using the supplied neck strap (12). If the patient wishes to use the neck strap, attach it to the AN24™ main body (1) using the neck strap connection (9) and hang the neck strap around the patient's neck. Adjust the length of the neck strap so that the lowest part of the AN24™ is above the sternum and not touching the electrodes.

4.1.9 Secure Cables

If the ECG cable(s) are loose or hanging, secure them with hypoallergenic tape (not supplied) to the patient's abdomen to prevent the cables from pulling on or detaching from the ECG electrodes.

4.2 During monitoring

Self checks during a recording

During recording the AN24™ will regularly perform self-checks. The AN24™ can only be in one of the following four states:

MONITORING OK – GREEN LED FLASHES

The green signal quality LED (**5**) will continue to flash once every 2 seconds to indicate that the electrodes remain attached correctly and that the maternal ECG beat has been detected.

MATERNAL SIGNAL LOST – GREEN LED ON

The green signal quality LED (**13**) will remain constantly illuminated to indicate that the electrodes remain attached correctly but that the maternal heart beat cannot be located. This is not a cause for alarm and may be temporary and due to interference from other sources, for example the noise generated by maternal muscle/movement. Section 10 - Troubleshooting

ELECTRODE DETACHED – GREEN LED FLICKERS

The green signal quality LED (**5**) will flicker rapidly to indicate that one of the electrodes has become detached. The recording will not be stopped at this point, if suitably trained staff are available the electrodes should be re attached to resolve the problem, see Section 10 - Troubleshooting.

BATTERY LOW – YELLOW LED FLASHES

If the Yellow battery status LED (**6**) begins to flash, this indicates that the battery is running low. A short while after this occurs; the AN24™ will automatically turn off. If the device is in Mode 1 (recording mode) the recorded data will be retained until it is uploaded, see Mode 1 - USB upload later in this section.

NB: Monica VS monitors also provide on-screen device status feedback see the VS Reference Operating Manual for details.

4.3 Turn off

When the recording session is completed, turn the AN24™ off by pressing the on/off button (**3**) followed by the event button (**8**) followed by the event button (**8**) again.

This sequence of button presses must be completed within 4 seconds to turn the device off. When the AN24™ is switched off all three LED's (**4, 5** and **6**) will flash three times.

If using a Monica VS Monitor to end a real time recording (mode 2) the Monica AN24 can be switched off remotely by the VS Monitor.

Data Upload - If the AN24™ was used in Mode 1 (recording mode), the recorded data must be uploaded to a computer running the Monica VS Monitor, see 'USB Upload' later in this section.

Clean the AN24™ (**1**) and electrode lead connector (**2**) as described in Section 6 - Cleaning and Maintenance

Battery Charging - recharge the AN24™ (**1**) as described in 3.1 Battery Charging.

4.4 Connecting to a VS Monitor

Monica devices are an integral part of a diagnostic system. The user must adhere to warnings in order to ensure safe and reliable performance of the system.

- Monica VS Monitors complies with IEC 60601-1 the international product safety standard for electrical medical equipment
- Non-medical electrical equipment (e.g. Wireless remote printer) must be situated outside the patient environment (patient environment according to IEC 60601-1-1: = radius 1.5m around the patient).
- The Monica VS Monitors (PT-101-010, PT-101-015) fully comply with the above and are required when using the Monica AN24™ to monitor in real-time within the patient environment (as defined by IEC 60601-1-1).

When connecting to a VS Monitor in either Retrospective or Real-Time mode it is firstly necessary to ensure that the Monica VS Monitor is on and running.

To connect to a VS Monitor in **Retrospective mode**:

A. Disconnect the electrodes from the leads - Disconnect the electrode lead connector (**2**) from the AN24™ (**1**) as described in 3.1 Battery Charging.
B. Power up the VS Monitor, log in and wait until the system is fully loaded
C. Connect USB lead - Connect the AN24™-to-USB lead (**14**) into the socket inside the top of the AN24™ (**1**). Plug the USB end of the lead into a free USB port on the Monitor. The Monica AN24™ device will be automatically recognised by the monitor and will provide status information.

From this point the Monica VS software will know if there is data stored on the device ready for upload (Mode 1 operation). If there is data stored on the device the VS Monitor will guide you through the correct process to upload or delete the stored data.

To connect to a VS Monitor in **Real-Time mode**:

Place the electrodes on the patient as described in in the Getting Started Wizard (press the help icon on the VS screen) or Supplement 1; connect the Monica AN24 to the patient and turn it on.

Select the New Recording button from the Monica VS menu which will then take you through the set-up process.

Section 5 - Safety and Standards

5.1 General

This section describes safety precautions that may appear within the manual and those that appear as symbols labels on the AN24™ itself. Furthermore, this section describes a group of precautions that are applicable, in general, when using the AN24™.

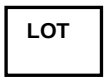
The Monica AN24™ is intended for trained medical personnel (including midwives, nurses, and physicians) who are familiar with obstetric procedures. Keep this operator's manual with the unit for use by the operator.

5.2 Symbols

Attention - Refer to manual

Class II Medical Device

Type BF



Batch number

Manufacture date

Bluetooth® approved device

ESD - Static sensitive device

CE approved

WEEE logo

5.3 Indications For Use

The Monica AN24 is a monitoring device for non-invasively measuring the Fetal Heart Rate (FHR) and Uterine Activity (UA). The Monica VS software, which accompanies the AN24, enables the measured parameters to be reviewed graphically using a PC, notebook computer or any compatible Series 50 format device, and to generate hard copy traces in a “standard” user defined format. This data is intended to aid in assessment of the wellbeing of the fetus and mother for laboring singleton pregnancies who are of gestation age ≥37 weeks. The AN24 device typically generates standard length FHR and UA traces from a single setup. Application of the device must be by trained personnel.

5.4 Standards

The Monica AN24™ complies with the following safety standards

Standard	Description
IEC EN 60601-1: 1990 UL60601-1:2003 CSA C22.2 No 60601.1	Medical Electrical Equipment Part 1: General requirements for safety
EN 60601-1-2: 2002 IEC 60601-1-2: 2001	Medical Electrical Equipment Part 1-2: General requirements for safety – Collateral Standard: Electromagnetic Compatibility – requirements and tests
Partial compliance of: EN 60601-2-47: 2001 IEC 60601-2-47: 2001	Medical Electrical Equipment Part 2-47: Particular requirements for the safety, including essential performance, of ambulatory electrocardiographic systems
IEC EN 60601-1-4: 1996	Medical electrical equipment Collateral standard: Programmable Electrical Medical Systems
EN 980: 1996	Graphical symbols for use in the labelling of medical devices
EN 1041: 1998	Information supplied by the manufacturer with medical devices

5.5 Interpreting Results

Monica Healthcare recommend that a repeat test is undertaken, using either the AN24™ or an alternative device to confirm the results from the initial test. The repeat test should be carried out in the case of either normal or abnormal results generated by the AN24™.

Good Practise:

When the MHR is high, or the signal quality is poor (section4.7 VS Operator manual), check the FHR using auscultation (Pinard) or hand held Doppler every 15min to confirm the FHR, and if in any doubt, ask the women to stop pushing during the second stage, until the FHR is confirmed.

5.6 Safety

WARNING: The Monica AN24™ is splash proof but is not designed for submersion in water. Patients must be warned not to immerse the AN24™ or any of its accessories in water, or to take a shower or bath whilst being monitored.

WARNING: The Monica AN24™ is not explosion-proof and must not be used in the presence of flammable anaesthetics.

WARNING: SHOCK HAZARD — Do not attempt to connect the battery charger with wet hands. Make certain that your hands are clean and dry before touching a power lead or plug.

WARNING: Use only the electrode lead cables supplied with the device. Use of any other cables may result in out-of-specification performance and possible safety hazards.

WARNING: Unplug the AN24™ from the AC power source (battery charger and detach all accessories before cleaning. Do not immerse the unit in water or allow liquids to enter the case.

WARNING: Examine the AN24™ and any accessories periodically to ensure that the leads, connectors and the device itself do not have visible evidence of damage that may affect patient safety or monitoring performance. The recommended inspection interval is once per week or less. Do not use the device if there is any visible sign of damage.

WARNING: The protective silicone rubber cover must be used during Labor and Delivery. Not using the protective silicone rubber cover could result in the ingress of contaminated blood and other fluids into the Monica AN24 case.

WARNING: Only the Battery Charger and mains plug supplied with the Monica AN24™, or its equivalent, is approved for use with the AN24™.

WARNING: Do not attempt to service the Monica AN24™. Only Monica approved and qualified service personnel should attempt any necessary internal servicing.

WARNING: The Monica AN24™ is not specified or intended for operation in conjunction with any other type of monitoring equipment except the specific devices that have been identified for use in this Operator's Manual.

WARNING: Since the Monica AN24™ detects the electrical signals generated from the fetal heart, if other equipment which introduces electrical energy in to the mother is used (e.g. TENS machine, diathermy, impedance meter), then the AN24™ will not be able to detect the fetal heart rate.

WARNING: Do not operate the Monica AN24™ if it fails to pass the power on self-test procedure, see Section 4.

WARNING: Any unexpected data generated by the Monica AN24™ must result in further examination of the mother and fetus in a hospital environment. The data generated by the AN24™ must be backed up by alternative monitoring technologies.

WARNING: For Electromagnetic Compatibility (EMC). Use of accessories, electrodes and leads other than those specified in this manual may result in increased EMC emissions and/or decreased immunity of the Monica AN24™ to other electrical equipment.

WARNING: For Electromagnetic Compatibility (EMC). The Monica AN24™ has been tested for to IEC EN 60601-1-2 for EMC. However, the Monica AN24™ picks up very small electrophysiological signals and so occasionally if other electrical equipment is in the immediate vicinity of monitoring the AN24™ may produce spurious results. The operator should ensure that any such

interfering electrical equipment is not in close proximity to the AN24™ during monitoring.

WARNING: The lithium polymer battery pack used within this device has the potential for fire or burning. Do not disassemble, crush, heat or burn.

WARNING: The lithium polymer battery pack cannot be replaced by the user. Replacement may only be made with the battery pack specified by Monica Healthcare, and replacement can only be carried out by Monica Healthcare. Fire or burning may occur if the customer uses a battery pack other than specified by Monica Healthcare.

CAUTION: Keep the operating environment free of dust, vibrations, corrosive, or flammable materials, and extremes of temperature and humidity. The AN24™ and all lead connectors should be kept clean and free of electrode gel and other substances.

CAUTION: Do not operate the unit if it is damp or wet because of condensation or spills. Avoid using the equipment immediately after moving it from a cold environment to a warm, humid location.

CAUTION: Never use sharp or pointed objects to operate the two front-panel membrane switches.

CAUTION: General-purpose personal computers and modems are not designed to meet the electrical safety requirements of medical devices.

CAUTION: Do not autoclave the AN24™ or any accessories. Follow cleaning and disinfection instructions in Section 6 - Cleaning and Maintenance

CAUTION: Do not immerse AN24™, connector or leads in liquid. When using solutions, use sterile/clean wipes to avoid pouring fluids directly on to the AN24™ and connector. Follow cleaning and disinfection instructions in Section 6 - Cleaning and Maintenance

CAUTION: The water temperature must not exceed 40℃ (104℉). Do not use chlorine bleach.

CAUTION: Take extra care when cleaning the membrane switches and LED surfaces, which are sensitive to rough handling.

CAUTION: Do not autoclave. Do not gas sterilize.

CAUTION: Only the Battery Charger supplied with the device is approved for use in recharging the internal batteries.

CAUTION: The Monica AN24™ is not specified or intended for operation during the use of defibrillators or during defibrillator discharge.

CAUTION: The Monica AN24™ is not specified or intended for operation in the presence of electrosurgical equipment.

CAUTION: There are minimum signal amplitudes under which the Monica AN24™ will not be able to measure physiological signals.

5.7 CE

CE The CE Mark on this product denotes conformity with the European Council Medical Device Directive 93/42/EEC.

0843

Section 6 - Cleaning and Maintenance

6.1 AN24™ Device

To avoid damage to the AN24™, connector and leads, clean and disinfect only according to the following instructions. Care MUST be taken to preserve both the AN24™ label and the connector label.

CAUTION**:** Do not remove, conceal or deface the labels.

CAUTION: Do not autoclave. Do not gas sterilize.

CAUTION: Do not immerse the device or any accessories in liquid and do not expose the connector pins to the cleaning solution. Do not apply oil at any point.

CAUTION: Do not use undiluted bleach or any other cleaning solution other than those recommended here because permanent damage to the AN24™ and leads could occur.

Clean - Wipe the AN24™ and leads with a soft non-abrasive cloth or disposable wipe soaked in aqueous detergent/ disinfectant or other solution such as 70% isopropyl alcohol. Do not use aerosol preparations since they might contain organic solvents. Do not pour fluids directly on the unit and its accessories. Wipe the exterior of the AN24™ and leads three times. Prepare the detergent according to the manufacturer's recommendations. If necessary scrub the AN24™, and leads with the solution using a soft bristled brush for five minutes.

Wash off & Dry - When using solutions, use sterile wipes or gauze to avoid pouring fluids directly on the unit and its accessories. Wipe the AN24™, and leads three times with sterile or distilled water to remove cleaning solution residue. Dry the AN24™, connector and leads thoroughly with a sterile soft towel or gauze surgical sponge.

Disinfect - If a low-level disinfection is required, use a 1:10 bleach solution after the AN24™ and leads have been cleaned following the same procedure described above. After the low level disinfections, wipe the AN24™ and leads three (3) times with sterile or distilled water to remove diluted bleach residue. Dry the AN24™, connector and leads thoroughly with a sterile soft towel or gauze surgical sponge.

Store the clean AN24™, connector, and leads in a clean bag, covered tray, or other suitable system when not in use.

Monica recommends the patient neck cord included with the Monica AN24 is washed thoroughly or replaced between patients.

6.2 Batteries

The 3.6V rechargeable lithium polymer battery pack should be stored at 0-35°C. Typically the batteries will last for two years or more with regular use. If you need to replace the battery, contact Monica Healthcare directly or your Monica healthcare representative.

6.3 Firmware version

AN24™ Firmware
VS Monitor update

Periodically there will be a need to release new versions of the Firmware and VS Monitor updates, please check with your local distributor to see if you have the latest version.

6.4 Calibration

Calibration of the Monica AN24™ is not required

6.5 Servicing

Maintenance of the AN24™ is carried out by Monica Healthcare. The only routine maintenance which is necessary is battery replacement when failing to hold charge and cleaning as outlined earlier in this Section. Further information is available from:

Monica Healthcare Ltd
BioCity
Pennyfoot Street
Nottingham NG1 1GF
UK
Tel: +44 1159124540
Email: info@monicahealthcare.com
Web: www.monicahealthcare.com

Section 7 - Monica Accessories

Part No.	Description
100-PT-100	Monica VS10 Monitor (Panasonic Toughbook CF-H1)
100-PT-101	Monica VS10 Monitor (Panasonic Toughbook CF-H1, upgrade for existing AN24 customers only)
100-PT-110	Monica VS15 Monitor (Arbor M1525)
100-PT-111	Monica VS15 Monitor (Arbor M1525 upgrade for existing AN24 customers only)
100-PT-001	Monica AN24

100-PT-130	Monica Cart (ITD PRO3OU)
100-PT-131	Monica Cart - printer shelf (ITD PRO3OU
100-PT-132	Monica Desktop Stand (Vesa desktop stand ARM 150 or equivalent)
100-PT-140	Monica Printer (Real-time) - Thermal Z-fold (Fetalgard Lite)
100-PT-160	Monica VS Network Viewer

100-PT-002	ECG Lead Assembly - Standard; ~28 weeks to term
100-PT-004	Battery Charger (UK\ EU\ USA please specify)
100-PT-005	AN24 – USB computer connection cable
100-PT-015	Soft silicon rubber protective boot (x5)
100-PT-016	3M red Dot 2236 skin prep tape (x5)
100-PT-017	Monica approved electrodes – 25 pouches x 10 electrodes (250 electrodes)
100-PT-018	Monica approved electrodes – 150 pouches x 10 electrodes (1500 electrodes)
100-PT-019	Monica AN24 Neck Cord (x5)
100-PT-020	Monica Healthcare glossy sales literature folder (x50)
100-PT-021	Sales Literature sheets
100-PT-022	Skin preparation pen
100-PT-141	Z-Fold paper printer (3 cm/min, 30 - 240 bpm) Analogic US
100-PT-142	Z-Fold paper printer (1 cm/min, 50 - 210 bpm) Analogic International
100-PT-143	Z-Fold paper printer (3 cm/min, 30 - 240 bpm) Philips US
100-PT-144	Z-Fold paper printer (1 cm/min, 50 - 210 bpm) Philips International

Section 8 - Monica VS Monitors

8.1 Overview

Monica VS series of monitors (VS15/VS10) allow the FHR, MHR[1], UA, maternal movement[1] and event annotation data to be viewed, stored and printed as a conventional CTG trace. It is also provides the Monica AN24™ set-up tools to configure the unit and label and store the monitoring sessions for easy identification and retrieval. The functionality of the Monica VS Monitors is explained in detail in the Monica VS Reference Operating Manual.

8.2 System Requirements

Monica devices are an integral part of a diagnostic system. The user must adhere to warnings in order to ensure safe and reliable performance of the system.

- Monica VS Monitors complies with IEC 60601-1 the international product safety standard for electrical medical equipment
- Non-medical electrical equipment (e.g. Wireless remote printer) **must be** situated outside the patient environment (patient environment according to IEC 60601-1-1: = radius 1.5m around the patient).
- The Monica VS Monitors (PT-101-010, PT-101-015) fully comply with the above and are required when using the Monica AN24™ to monitor in real-time within the patient environment (as defined by IEC 60601-1-1).

Section 9 - AN24 Specifications

9.1	**Measured**	Time	Real-Time clock
		Maternal Movement[1]	3 axis accelerometer
		Clinical Event Marker	Button
		Abdominal Electrophysiological Signal	3 different channels
9.2	**Calculated**	FHR	Range 60-240 beats per minute 2 second average or better
		MHR[1]	Range 40-240 beats per minute 2 second average
		Maternal Movement[1]	4 levels – (Inactive to very active)
		Uterine Activity	Range 0-500 microvolts (0-255 levels)
9.3	**Storage**	Internal Micro SD Card	
9.4	**Interfaces**	Download	USB – download stored data to computer Wireless – Real-Time data transfer using Bluetooth®
		User	LED indicator 1: Yellow – Battery status LED indicator 2: Green – Signal quality LED indicator 3: Orange – Memory status Button 1: On/Off Button Button 2: Event marker
9.5	**Data Format**	Series 50 Protocol via Bluetooth®	
9.6	**Battery**	Rechargeable lithium polymer 3.6V 2400mA-hours	
9.7	**Battery Charger**	Input	100-240V, 50-60Hz UK\EU\US adapter
		Output	DC 5V 1A USB PC connection
9.8	**Dimensions**	11.5 x 5.5 x 2.0 cm Including lead assembly	
9.9	**Weight**	105g excluding lead assembly	
9.10	**Operating Temperature**	0 to + 40℃	
9.11	**Storage Temperature**	0 to + 40℃	
9.12	**Approval**	CE approved (Directive 93/42/EEC) as amended by 2007/47/EEC	

Section 10 - Troubleshooting

10.1 Signal Quality (Green LED flickers)

Electrodes are not attached correctly.

If the green LED flickers, first check that the electrode lead connector cap is connected securely on both sides of the AN24™ (both buttons engaged). If this does not resolve the problem, put AN24™ into electrode check **'Phase 1'** by pressing event button twice within a 2-second period. (NB: this is not required if connected to a VS Monitor which will display the problem electrode(s) on screen without the need to touch the AN24).

x2

The system will then 'display' the electrode/skin impedance for the electrodes connected to the yellow, green and orange leads.

The electrode/skin impedance will be communicated to the user as follows:

- LED on continuously – the electrode connected to the lead defined by the LED colour has a good connection / low skin impedance
- LED flickers - the electrode connected to the lead defined by the LED colour has a bad connection / high skin impedance

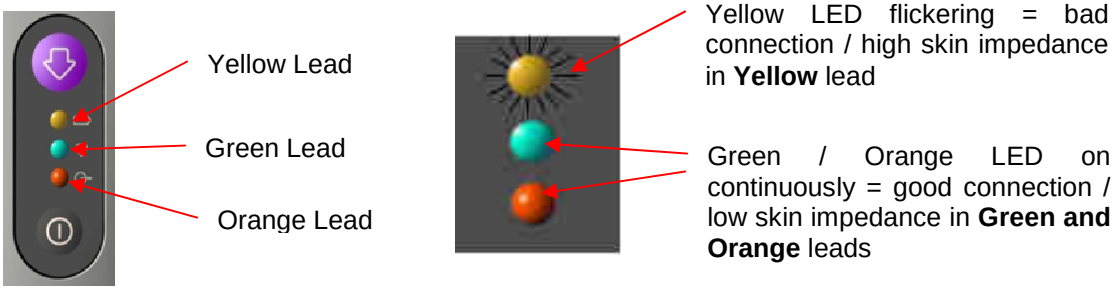


Figure 3 Phase 1 Lead check

If a bad connection is identified in the Yellow, Orange or Green leads, disconnect the lead from the electrode(s) that has a bad connection (leave AN24™ on), remove the electrode(s) and again prepare the skin as described in Supplement 1 – Electrode Placement. When all the electrode(s) have been replaced the leads should be reconnected.

If all the LED are on continuously (good connection), put the AN24™ into electrode check **'Phase 2'** by pressing event button twice within a 2 second period.

x2

In 'mode 2' the electrode/skin impedance will be communicated to the user for the remaining two electrodes as follows:

- Yellow LED on continuously – the electrode connected to the **White** lead has a good connection / low skin impedance
- Yellow LED flickers - the electrode connected to the **White** lead has a bad connection / high skin impedance
- Green LED on continuously – the electrode connected to the **Black** lead has a good connection / low skin impedance
- Green LED flickers - the electrode connected to the **Black** lead has a bad connection / high skin impedance

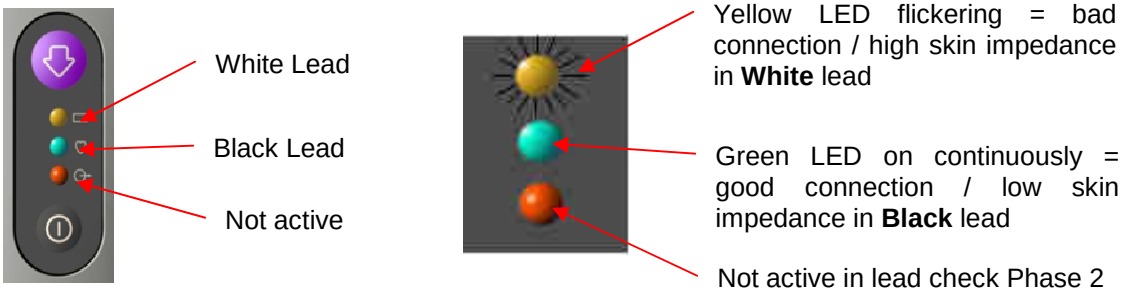


Figure 4 Phase 2 Lead check

If a bad connection is identified in the black or white leads, disconnect the lead from the electrode(s) that has a bad connection (leave AN24™ on), remove the electrode(s) and again prepare the skin as described in Supplement 1 – Electrode Placement. When all the electrode(s) have been replaced the leads should be reconnected.

If the Green and Yellow LED's are on the user should start their monitoring session by pressing the event button twice within a 2-second period

x2

In the unusual event that it is not possible with repeated skin preparation and correct electrode placement to bring the impedance down and gain a good connection; impedance check may be by-passed or can be halted and repeated at a later date.

To by-pass the impedance checks:

Press the following key sequence in succession:
Power On Button > Pink Event Button > Power Button

If after by passing the impedance check the green LED remains continuously on – Maternal ECG cannot be found – the monitoring session can be halted and repeated at a later date. This failure should be reported to Monica Healthcare Ltd. Please make a note of which electrode or electrodes failed to pass the impedance check. Monitoring the patient at a future time/date may still be possible.

To abort the electrode check phases (Phase1 or Phase2): switch off the AN24™ as usual (press ON button, then press pink Event button, then press pink Event button)

Alternatively, the lead may be broken. Turn the AN24™ off. Disconnect the lead from both the AN24™ and the electrodes. Attach a spare lead and retry.

If problem is not resolved, contact Monica Healthcare for advice.

Excessive vernix formation in the 26-34 week gestation period may result in a significant reduction in FHR detection in some patients.

10.2 Signal Quality (Green) LED constantly on

The maternal heartbeat cannot be picked up by the AN24™, though the electrodes are correctly connected. This is a common occurrence, which may be due to interference from other sources, for example the noise generated by maternal muscle/ movement. The mother should relax and remain in a supine position for as long as practicable during the recording for optimal results. If problem is not resolved, contact Monica Healthcare for advice.

10.3 Battery Status (Yellow) LED flashing when unit is not being charged

Battery is low. The AN24™ will shortly automatically turn off. Upload the data and recharge the batteries (see 3.1 Battery Charging). If problem is not resolved, contact Monica Healthcare for advice.

10.4 Memory Status (Orange) LED flashing

This indicator will only light just after the AN24™ has been turned on and indicates that there is > 1 minute of data on the device. Upload / delete the data currently stored on the device (see Section 4 -). Turn on the device and resume the monitoring session. If problem is not resolved, contact Monica Healthcare for advice.

10.5 AN24™ will not turn on

Recharge the AN24™ for at least an hour even if the AN24 battery does not flash. If after recharge the AN24™ still does not turn on, return to Monica Healthcare for service.

10.6 AN24™ will not turn off

Return to Monica Healthcare for service

10.7 AN24™ will not recharge

Disconnect AN24™, reconnect battery charger and check charger is connected at both the wall socket and the device. Leave the recorder connected to the charger for half an hour. Then disconnect the AN24™ from the charger and reconnect it again. If problem is not resolved, contact Monica Healthcare for advice.

10.8 AN24™ will not connect via USB

Disconnect USB lead from both the AN24™ and VS Monitor. Reconnect USB lead and retry. If problem is not resolved, connect the AN24™ to the charger for half an hour and try connecting the recorder to the VS Monitor again. If the problem is not solved, contact Monica Healthcare for advice.

10.9 AN24™ will not connect via USB and will not recharge

If the AN24™ does not charge and is not recognised by the VS Monitor, disconnect the AN24™, reconnect battery charger and check charger is connected at both the wall socket and the device. Leave the recorder connected to the charger for half an hour. Then disconnect the AN24™ from the charger and reconnect it again. If problem persists there may be an issue with the Bluetooth® module in the AN24™ - please contact Monica Healthcare for advice.

If the AN24™charges but is not recognised by the VS Monitor disconnect USB lead from both the AN24™ and computer. Reconnect USB lead and retry. If the problem persists there may be an issue with the USB cable – please contact Monica healthcare for advice

10.10 AN24™ will not connect via Bluetooth®

Bring the AN24™ physically close (i.e. within 2 metres) of the VS Monitor and retry. If problem is not resolved, contact Monica Healthcare for advice.

Section 11 - Returns Procedure

11.1 Maintenance

There are no user serviceable parts in the Monica AN24™ or accessories. In the event of device failure or the battery needs to be changed, please contact Monica Healthcare or your local representative.

11.2 Returns

To return a defective product to Monica, you will need to obtain a Return Goods Authorization (RGA) number from the Monica Healthcare Support Group. Please contact a Service Coordinator at:

Telephone: +44 1159124540
Email: support@monicahealthcare.com

You will need to supply the Service Coordinator with the following information:

- The Model number(s) and Serial number(s) of the product, this information can be found on the label on the rear of the AN24™.
- The quantity of items you wish to return.
- Your "Bill to" address for invoice purposes.
- Your "Ship to" address.
- Your Purchase Order number.
- Details of the reported failure.

The Service Coordinator at Monica Healthcare will then inform you of:

- The Return Goods Authorization (RGA) number.
- The warranty or non-warranty status of the units being returned.
- Any repair charge.

All returned material must be shipped “PREPAID” to the address below for both warranty and non-warranty repairs. Please reference your RGA number on both your purchase order and the shipping label:

RGA reference number:
Tioga
St Thomas House
St Mary’s Wharf
Mansfield Road
Derby
DE1 3TN
UK

Supplement 1 – Electrode Placement

I. Patient Posture

It is very important that the woman's stomach muscles are relaxed and she should be encouraged to 'relax' on a bed either on her back (recumbent or semi-recumbent) or on her side (left/right) for as long as practicable during the monitoring session. The patient should **avoid** whenever possible**:**

1. Any position or activity where the abdominal muscles are contracted e.g. sitting upright or lying down with her back raised from the hips at an angle of 45°. If this is unavoidable then using a cushion to support the back can help.
2. A tense stressful situation which will cause abdominal muscle tone to increase even though the patient is in a comfortable position e.g. When the room where the patient is being monitored is filled with Drs, Midwives, Family, Children and other onlookers. In this situation it is advisable to leave the Monica AN24 in place and return when the patient situation has changed.

The VS series of monitors provide a real-time indication of signal to noise in the signal quality indicator where the muscle noise (red-bar height) and the fetal ECG height (green bar) are displayed.

If the fetal ECG height is small and the muscle noise is high then FHR extraction may be compromised; ask the mother to get into a position that is comfortable for her and relax. In addition, changes in maternal posture like lying on the left or right can change the fetal position in relation to the abdomen and uterus and improve the ECG conducting pathway.

II. Electrode Location

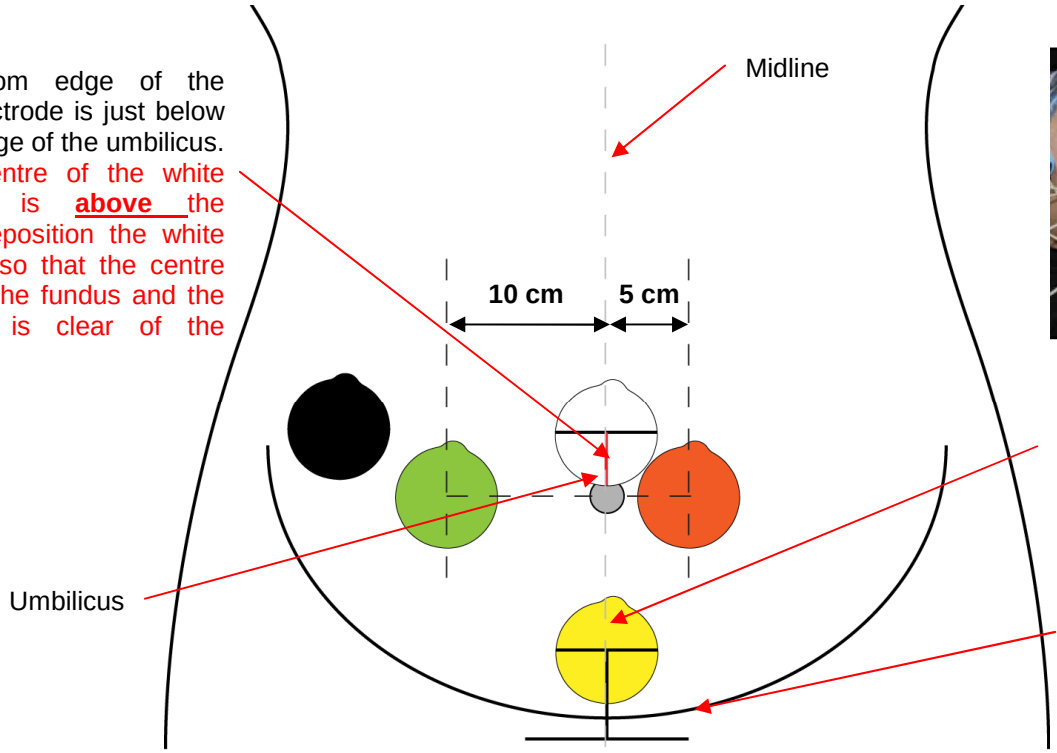
It is important to correctly prepare the skin before the application of the electrodes. You are advised to read all of this section before starting the procedure.

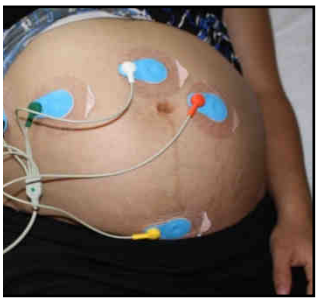
The instrument has three separate detection channel leads. The connectors on these leads are colour coded as **orange**, **white** and **green**. All three channels share a common connection point and this lead connector is coloured **yellow**. Finally, a ground lead with a **black** colour coded connector is also used. These leads are connected to 5 electrodes positioned on the maternal abdomen. Please refer to the table and figures below for guidance in positioning the electrodes.

Electrode / Connector	Position
Yellow	Place the yellow electrode on the mid-line 6cm above the symphysis pubis or as close to 6cm above the symphysis pubis as you can achieve without requiring removal of the pubic hair.
White	**For gestations < 27+6 weeks & > 33+0 weeks through to L&D** Place the white electrode on the mid-line so that the bottom edge of the electrode is just below the top edge of the umbilicus.
	For gestations 28+0 to 32+6 weeks Place the white electrode on the mid-line so that the centre is 7cm above the top edge of the umbilicus
	For ANY gestation *If the centre of the white electrode is **above** the fundus, reposition the white electrode so that the centre is **below** the fundus and the electrode is clear of the umbilicus*
Green and Orange	Place the centre of the green and orange electrodes either side of the umbilicus and on the same horizontal line as the umbilicus. The centre of the green electrode should be **10cm** from the **left hand edge** of the umbilicus and the centre of the orange electrode **5cm** from the **right hand edge** of the umbilicus.
Black	The black electrode is the reference electrode and is positioned towards the back behind the green electrode. Its exact position is not critical.

Gestation <28 weeks, >33 Weeks & through L&D

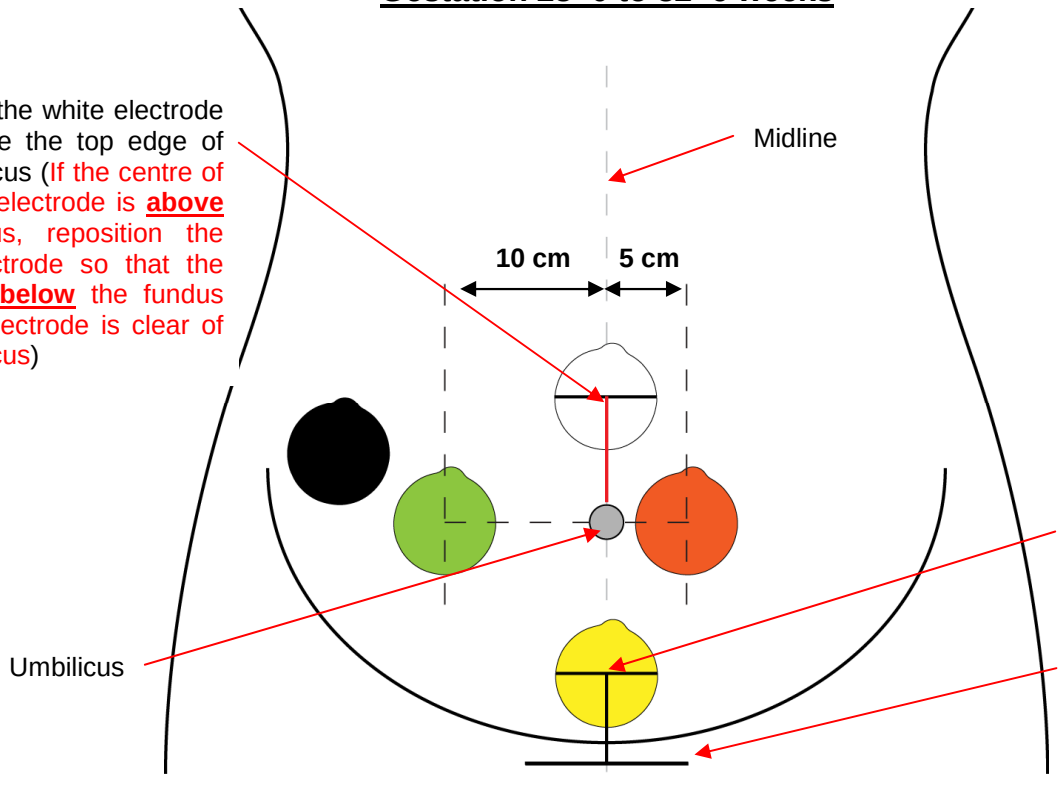
The bottom edge of the White electrode is just below the top edge of the umbilicus. (If the centre of the white electrode is **above** the fundus, reposition the white electrode so that the centre is **below** the fundus and the electrode is clear of the umbilicus)





Gestation 28+0 to 32+6 weeks

Centre of the white electrode 7cm above the top edge of the umbilicus (If the centre of the white electrode is **above** the fundus, reposition the white electrode so that the centre is **below** the fundus and the electrode is clear of the umbilicus)

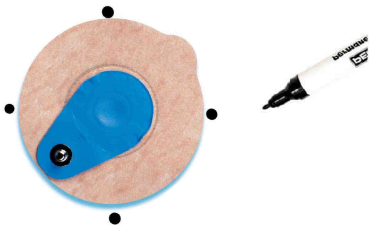


For patients with a large pannis (apron of fat) overhanging the symphysis pubis it is recommended that the yellow electrode be placed **on top** of the pannis on the mid-line such that the centre of the electrode is 6cm above the upper margin of the symphysis pubis or as close to 6cm above the upper margin of symphysis pubis without covering the yellow electrode with the pannis.

These instructions only apply to **Ambu VLC-00-S** electrodes.
Results may be impaired if any electrode is used other than those recommended by

III. Preparation of the skin and electrode application

1. Mark the electrode positions – using the electrode as a template and an alcohol based permanent marker pen.



Note: *If unable to use a pen to mark the site an alternative* ***MUST*** *be used to mark the site. Example: patient's fingers or a small piece of skin prep-tape*

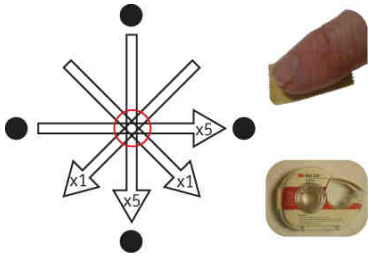
Caution: When using a marker pen ALWAYS follow local cross-contamination protocols.

Warning: DO NOT use a marker pen if the woman has any cuts or open sores on her abdomen

2. If the patient has been using skin care products wash the abdomen with a mild soap and water solution and **dry** first. On **<u>all women</u>** clean the electrode area vigorously with an alcohol swab and allow to dry.

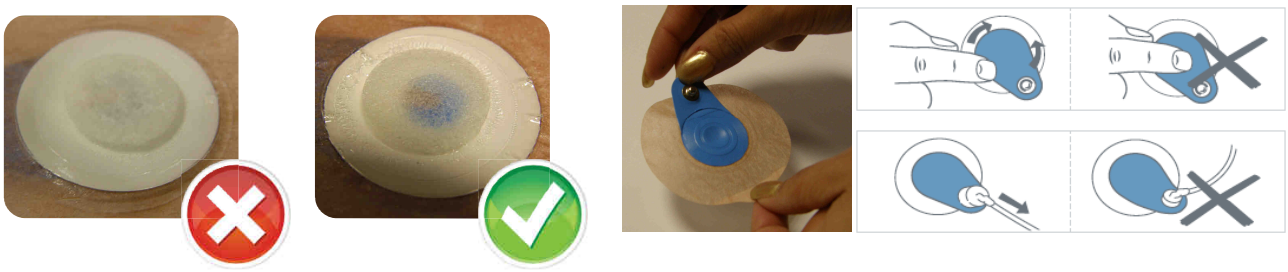
Caution: Using an alcohol wipe on abraded skin may cause patient discomfort and skin irritation.

3. Once the alcohol has dried off, abrade the area, using the supplied prep-tape, stroking the skin in one direction only (5 North to South, 5 East to West, 1 NW-SE, 1 SW- NE) as shown below



Caution: Use only moderate force since excessive use of prep tape may cause patient discomfort and skin irritation. In some patients local skin reactions to the electrode adhesive\gel may occur causing slight reddening of the skin.

4. Apply the electrodes (check the use by date and the gel on the electrode is still wet)



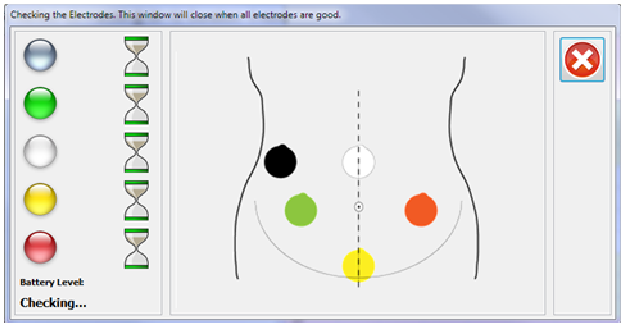
   a. Select one electrode and remove the plastic backing holding the electrode by the single strip of paper remaining so as not to touch the sticky part of the electrode.
   b. Place the electrode on the patient in the exact location that has been prepared. Do not press down in the middle of the electrode since the gel will be forced out. Only press the electrode around the outside and ensure that the material of the electrode does not crease.
   c. Remove the remaining strip of paper and stick down. When positioning the electrode ensure that the connection stud /tab is pointing to the right side of the patient, so that the cable be in the same direction in which the cables are being pulled

Repeat steps 1 – 4 (above) until all five electrodes have been placed.

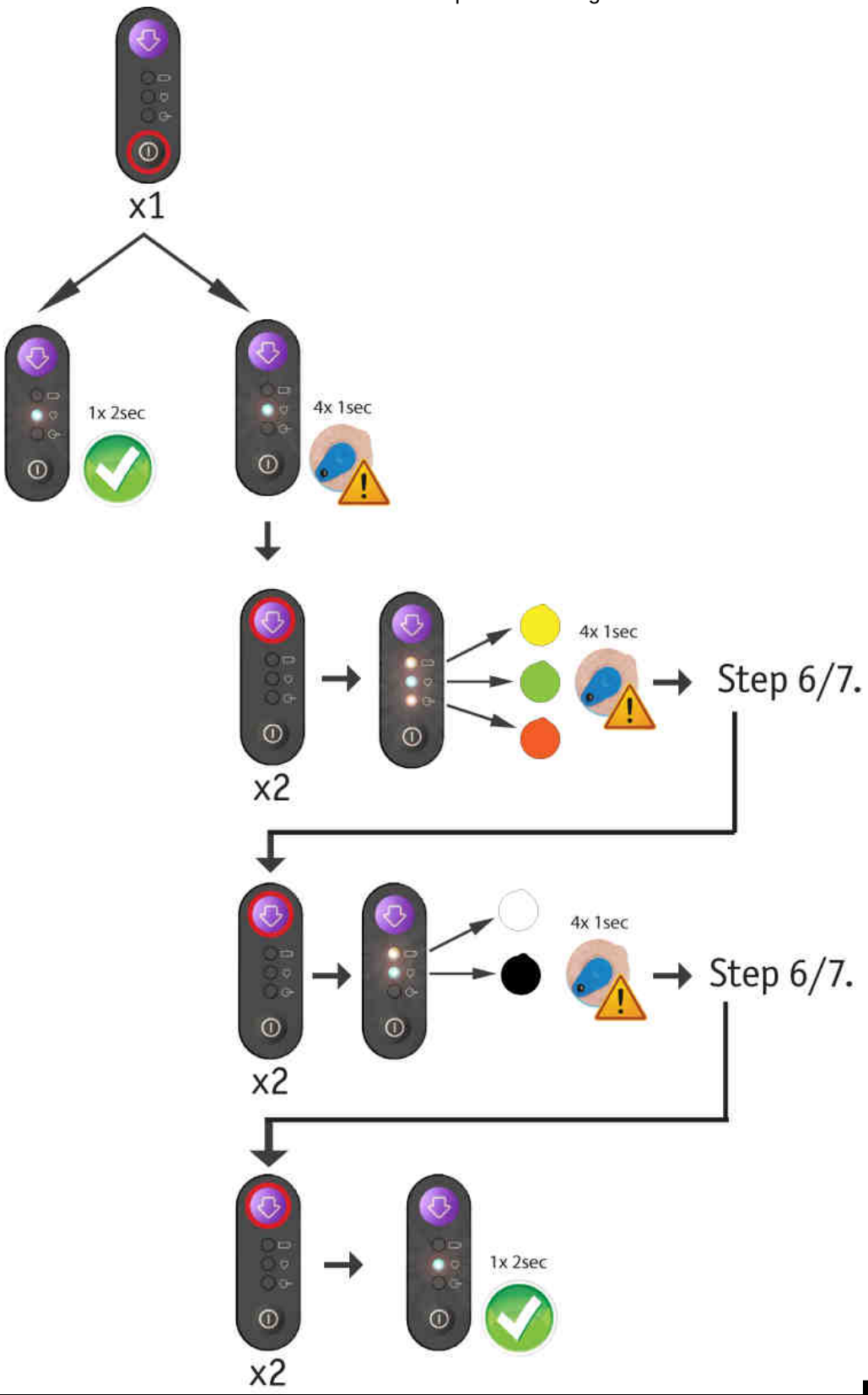
Caution: Do not use any electrodes which are dry or from a pack that has been opened by more than one week. When opening a fresh packet of electrodes, if all the electrodes are not used, write on the pack the date opened and make sure the pack is sealed to prevent the remaining electrodes from drying out.

Warning: Only use any electrodes specified by Monica healthcare. Failure to use the specified electrode could result in unacceptable noise levels resulting in poor FHR detection.

5. Check the electrode impedance (AN24 or VS Monitor – please refer to the Reference VS Operating Manual)
   a. Impedance Check using Monica VS Monitor



b. If the VS monitor is not available check the Impedance using the Monica AN24



6. If impedance check fails
    a. Peel back electrode
    b. Dry wipe the area to remove gel and moisture left by the electrode
    c. Re-abrade the same area of skin pressing firmly
    d. Re-attach the same electrode
    e. Wait 2-3 minutes for the electrode to settle
    f. Check the impedance again (Step 5)

7. If the impedance check fails a second time
    a. remove and discard the electrode
    b. Dry wipe the area to remove gel and moisture left by the electrode
    c. Re-abrade the same area of skin pressing firmly as long as the mother does not become uncomfortable
    d. attach a new electrode
    e. Wait 2-3 minutes for the electrode to settle
    f. Check the impedance again (Step 5)

8. If the impedance check fails a third time on one or more of the Green, White, black or Orange electrodes then the impedance check can be by-passed (see AN24 Reference Operating Manual – 10.1 Troubleshooting Guide). **This is not recommended**. Alternatively, leave the electrodes in place for 30 minutes and try the impedance check again (Step 5).

9. '**Do Not'** by-pass the impedance check if the impedance check for the yellow electrode fails – go to step 6 and repeat process as long as the mother does not become uncomfortable.

10. If it is still not possible to pass the yellow electrode impedance check,

    Option 1: go back to step 8 and by-pass the impedance check. The fetal abdominal ECG can be good in early and late gestation monitoring so noise introduced by high skin electrode impedance can be mitigated. However the quality of the signal cannot be confirmed until the recording commences by looking at the signal to noise bar graph on the VS display or on the Quick-View PDA.

    Option 2: halt the recording and try again at a future time/date.

Caution: Do not use water to remove the electrodes

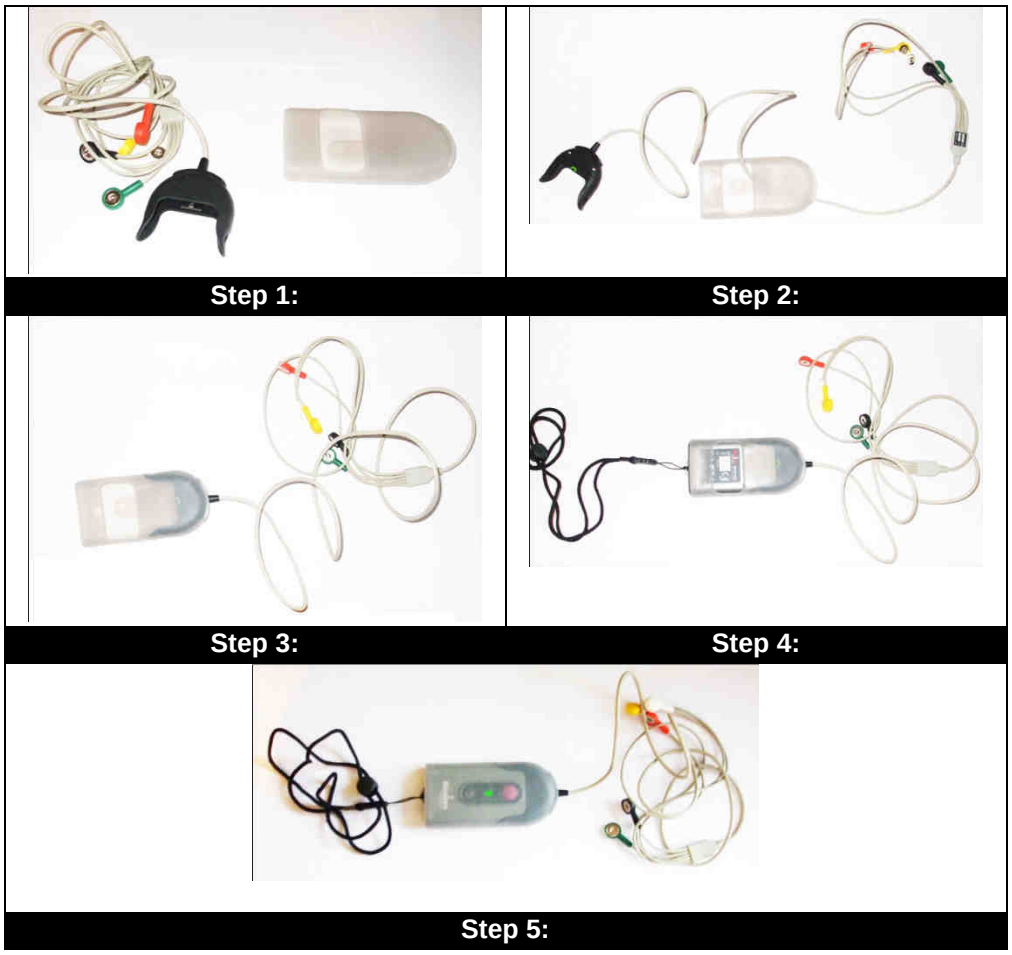
Before attaching the electrodes on to a patient, the user should prepare the skin and place five electrodes on themselves or a volunteer, connect the Monica AN24™ and switch on. The positioning of the electrodes is not important, but this will provide an insight into the skin preparation needed in order to obtain a steady green LED (**5**) indicating that all the electrodes have been correctly attached to the skin.

IV. Lead connection

The 'button' connector on the electrode is located on a 'flap' that is not stuck down. This means that, (a) the flap can be lifted and the correct colour coded lead connector can be pressed/snapped onto the button without pressing on the skin and disturbing the gel electrode contact with the skin and (b) no downward force is applied to the maternal abdomen.

V. Protective cover and neck strap

The protective silicone rubber cover is designed to protect the Monica AN24™ during use, keep it clean and to keep it dry and avoid the ingress of fluids. **It must be used on all L&D subjects.**



Warning: Not using the protective silicone rubber cover could result in the ingress of contaminated blood and other fluids into the Monica AN24 case.

VI. Lead security

It is important to secure and tidy the electrode leads to avoid lead or electrode detachment during operation. The electrode leads are of different lengths to aid in their correct placement and are fitted with two small plastic lead separators, which can be repositioned to avoid lead tangles and aid placement. The long single lead is fitted with a Velcro band so that it can be neatly coiled and secured when the patient is mobile.

VII. Electrostatic Discharge (ESD) precautions

Although precautions have been taken to ensure otherwise, static electricity could cause damage to the sensitive input circuits of the AN24™ and render the device inoperable. In the context of the AN24™, static is most likely to reach the AN24™ via a user\ patient touching static sensitive parts of the device.

ESD precautionary measures should be taken to minimise the risk of damage to the AN24™. More specifically:

- The connector which joins the AN24™ and lead connector together should not be touched by any part of the body, including the fingers
- The metallic (conducting) part of the electrode (press-stud) clips at the extremities of the electrode leads should not be touched by any part of the body, including the fingers

All staff that use the AN24™ should receive an explanation of the ESD warning symbol and receive the following basic training\ instruction in ESD precautions before use of the AN24™:

- How to fit the AN24™ to the patient, and;
- How to attach the electrodes to the AN24™, and;
- How to attach the electrodes to the patient.

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The Monica AN24™™ complies with the requirements of the European Council Directives: 93/42/EEC as amended by 2007/47/EEC, concerning medical devices
ISO 13485 Monica Healthcare Ltd operates Quality Management Systems that have been approved and audited to ISO 13485.

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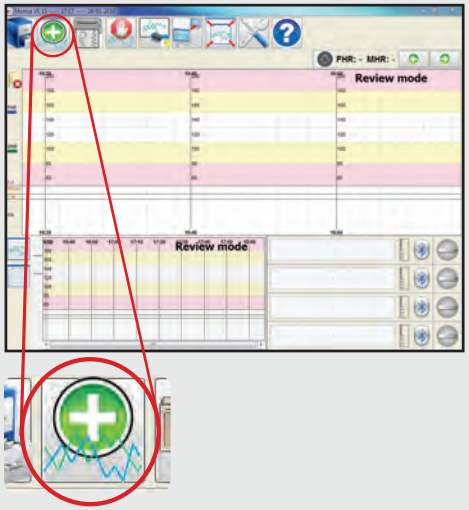

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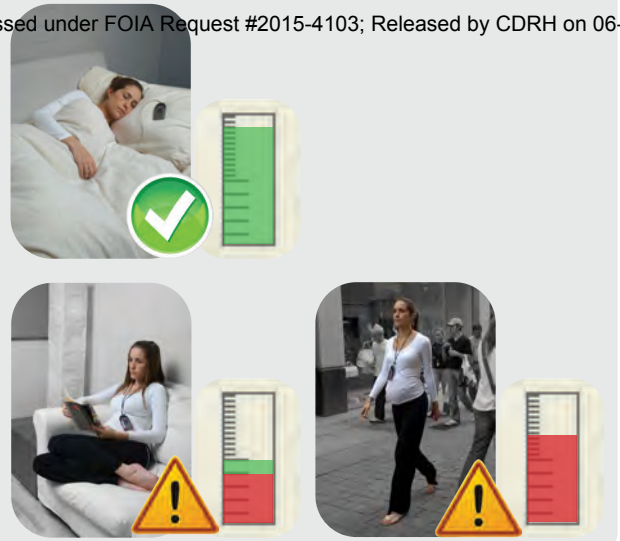

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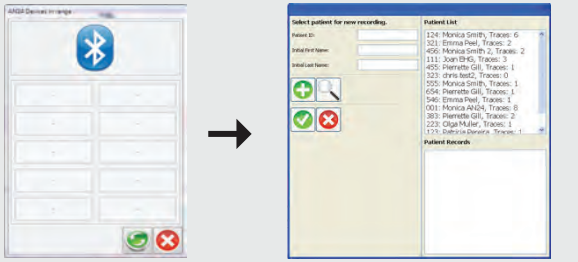

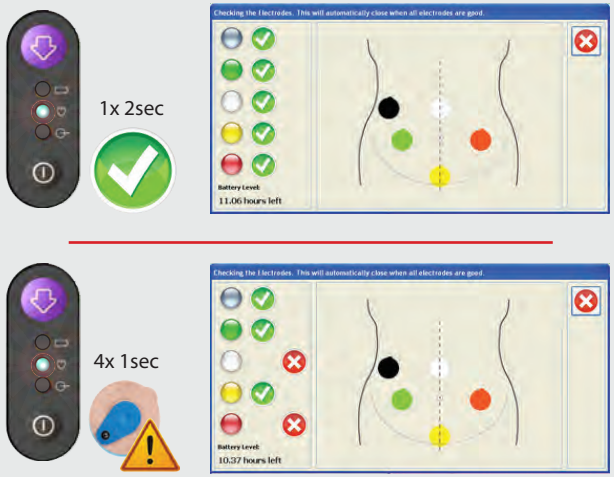

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Monica VS series

...the next generation CTG

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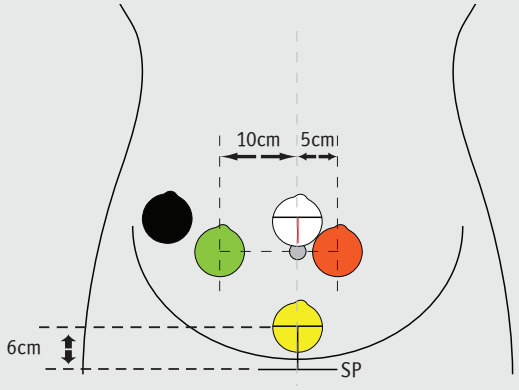
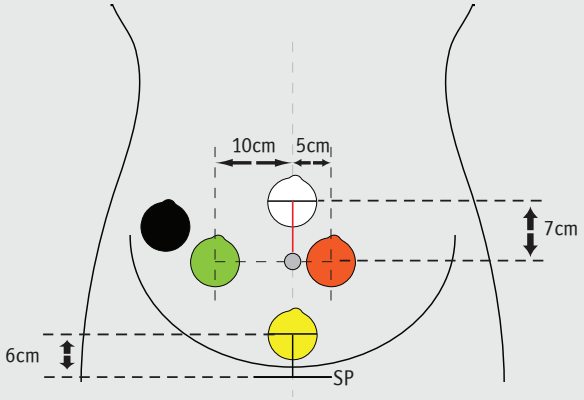
<28 & >32+6 Weeks



28 - 32+6 Weeks



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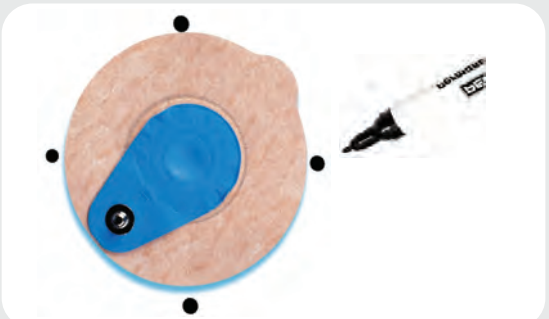

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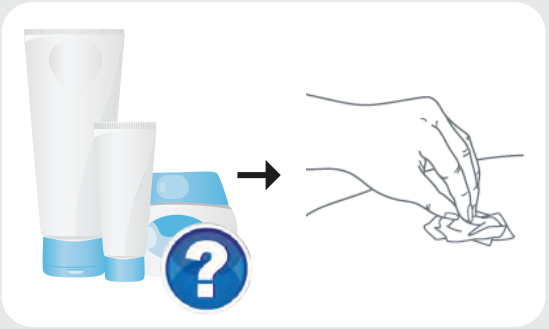

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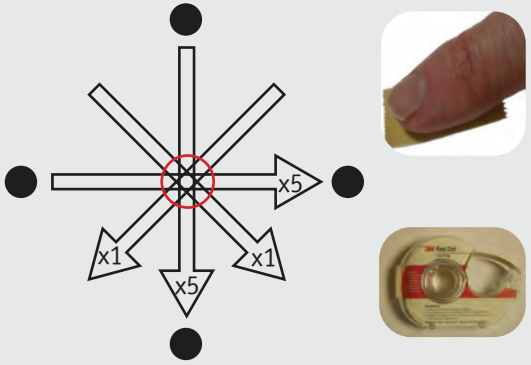
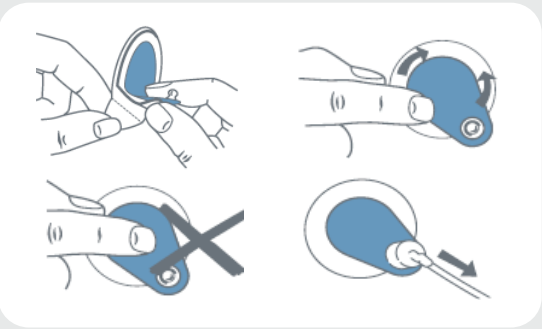
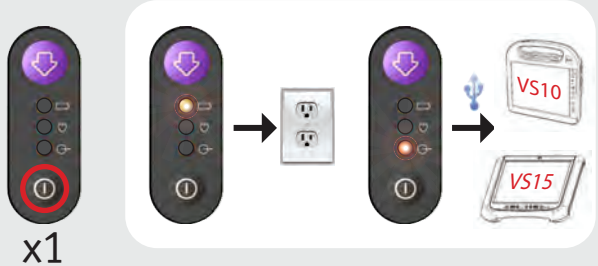


4. AMBU® Blue Sensor VLC-00-S

5.



6. AN24™



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Technical Report

- CONFIDENTIAL -

Study: 1857 Cleaning Evaluation Study of Fetal Monitor AN24 for Monica Healthcare

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Product	Monica AN24 Abdominal Fetal/Maternal Monitor
Document name	Clinical Investigation Protocol – Fetal Heart Rate and Uterine Activity during Labor and Delivery For Patients >37 Weeks gestation

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Product	AN24 Abdominal FECG recorder
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Product	AN24 Abdominal FECG recorder

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Product	AN24 Abdominal Fetal ECG recorder
Document name	System Requirements Specification
Document type	**SPECIFICATION**

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Product	AN24 Abdominal Fetal ECG recorder
Document name	Requirements Traceability
Document type	**SPECIFICATION**
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Product	AN24 Abdominal Fetal ECG recorder
Document name	Firmware: Software Requirements Specification (SRS)
Document type	**SPECIFICATION**

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Product	AN24 Abdominal Fetal ECG recorder
Document name	USB Link, Software Interface Control Document
Document type	**SPECIFICATION**
(b)(4) [redacted]	

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Product	AN24 Abdominal FECG recorder
Document name	Hardware Requirements Specification (HRS)
Document type	**SPECIFICATION**

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Product	AN24 Abdominal Fetal ECG recorder
Document name	VS software, Software Requirements Specification (SRS)
Document type	**SPECIFICATION**
(b)(4) [redacted]	

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Product	AN24 Abdominal Fetal ECG recorder
Document name	Wireless Link, Software Interface Control Document
Document type	**SPECIFICATION**
(b)(4) [redacted]	

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Product	AN24 Abdominal Fetal ECG recorder
Document name	Risk Assessment
Document type	**Technical File**
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Product	AN24 Abdominal FECG recorder
Document name	Hardware Design Document (HDD)
Document type	**TECHNICAL FILE**

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Product	AN24 Abdominal FECG recorder
Document name	Software Design Document (SDD)
Document type	**TECHNICAL FILE**
Abstract	This file describes how the Monica VS software is designed.

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5 REQUIREMENTS TRACEABILITY

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Product	AN24 Abdominal Fetal ECG recorder
Document name	Software Description
Document type	**Technical File**
Abstract	This document gives a summary overview of the features and software operating environment for the AN24 Fetal ECG recorder

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Product	AN24 Abdominal FECG recorder
Document name	Software Development Environment Description
Document type	**TECHNICAL FILE**
Abstract	This document gives a summary of the life cycle development plan for the AN24 FECG recorder firmware and Monica VS software.

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Product	AN24 Abdominal Fetal ECG recorder
Document name	(b)(4) [redacted]
Document type	
Abstract	

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Product	AN24 Abdominal FECG recorder
Document name	Revision Level History
Document type	**Technical File**
Abstract	This document defines the history of software revisions generated during the course of product development.

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Product	AN24 Abdominal FECG recorder
Document name	Firmware Design Document
Document type	**TECHNICAL FILE**
Abstract	This file describes how the firmware of the AN24 is designed.

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5 REQUIREMENTS TRACEABILITY

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Product	AN24 Abdominal Fetal ECG recorder
Document name	Off-The-Shelf Software
Document type	**Technical File**
Abstract	This document describes the OTS Software used in conjunction with the Abdominal FECG (b)(4) [redacted] The OTS software is the computer operating system. The OTS software, after risk analysis, (b)(4) [redacted]

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Product	AN24 Abdominal FECG recorder
Document name	System Validation
Document type	**TECHNICAL FILE**
	This file describes the tests for the validation of the AN24 system. It involves the combined test of the AN24 recorder and Monica VS software.

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Product	AN24 Abdominal FECG recorder
Document name	Firmware Validation
Document type	**TECHNICAL FILE**
(b)(4) [redacted]	This file describes the tests that validate the firmware of the AN24.

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Product	AN24 Abdominal FECG recorder
Document name	Hardware Validation
Document type	**TECHNICAL FILE**
(b)(4) [redacted]	This file describes the tests that validate the hardware of the AN24.

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Records processed under FOIA Request #2015-4103; Released by CDRH on 06-06-2016

Product	AN24 Abdominal FECG recorder
Document name	Monica VS software Validation
Document type	**TECHNICAL FILE**
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1 SCOPE

1.1 Document Identification

This document corresponds to the M validation of the Monica VS software. The document is identified as follows:

- ✓ Identification Number: 100-TP-006.
- ✓ Title: AN24 Abdominal FECG recorder – Monica VS Software Validation

1.2 Document Scope

This document first describes the tests that will be performed to validate the Monica VS Software. The document also holds the example test report sheets.

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1.3 System overview

The AN24 abdominal FECG recorder is designed as an ambulatory device for the monitoring of

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(b)(4) [redacted] a VS database if on the network.

The data can be viewed retrospectively or in real-time.

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2 RELATED DOCUMENTS

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3 GLOSSARY

BT	Bluetooth
ECG	Electro CardioGram
EHG	Electrohysterogram
FECG	Fetal ElectroCardioGram
FHR	Fetal Heart Rate
LED	Light Emitting Diode
MECG	Maternal ElectroCardioGram
MHR	Maternal Heart Rate
RTC	Real Time Clock
UA	Uterine Activity
USB	Universal Serial Bus

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4 Test Environment

Tests are performed on a test bench in Monica Healthcare premises during the planned validation phase. The tests results are reported in the validation report [11].

Depending upon the requirement to satisfy, the methods can be controlled by:

- ✓ Inspection (I),
- ✓ Analysis (A),
- ✓ Demonstration (D),
- ✓ Test (T).

4.1 Human resources and responsibilities

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5 Test Requirement Coverage

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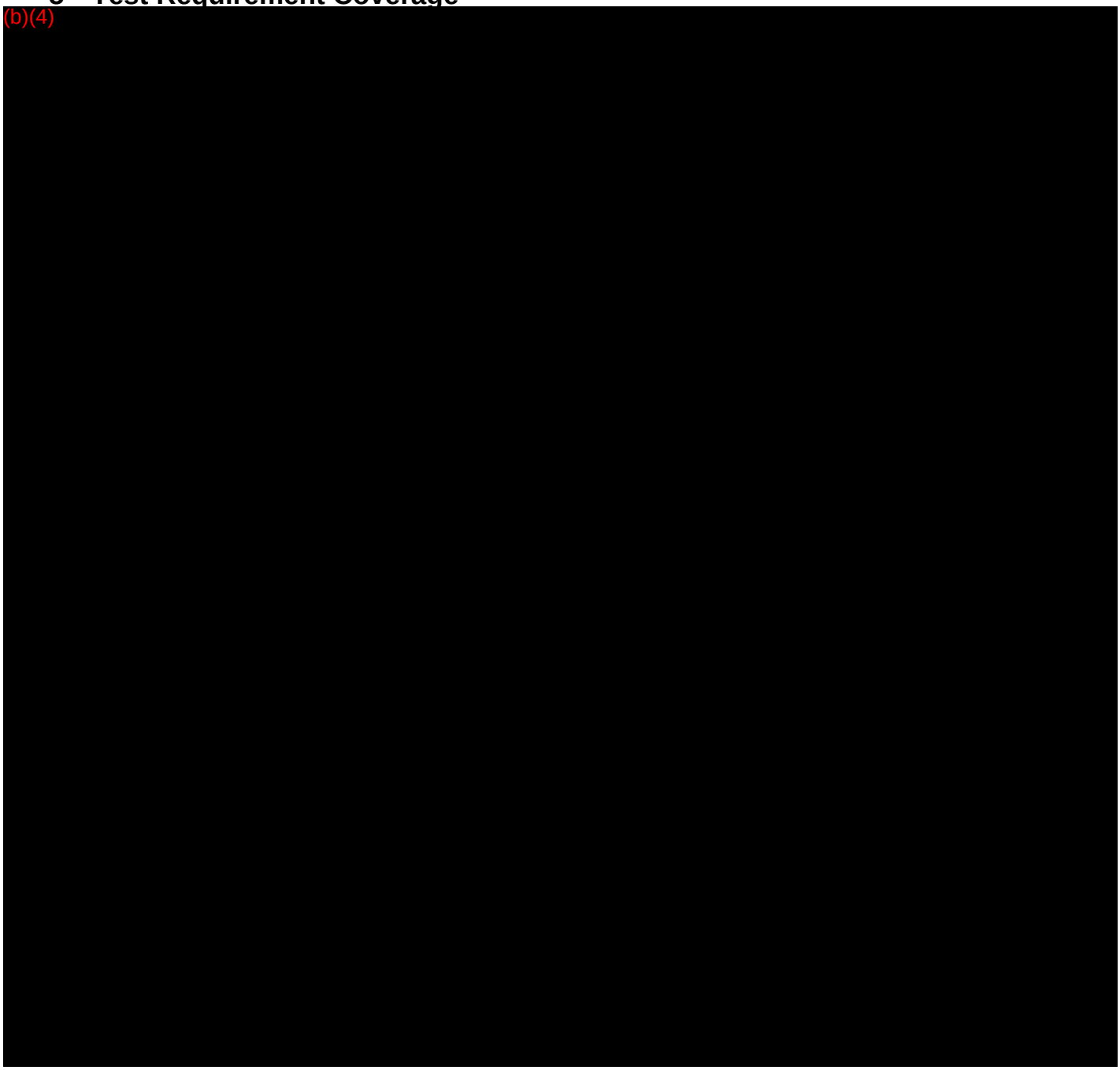

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6 Tests Sheets

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Product	AN24 Abdominal FECG recorder
Document name	System Validation Report
Document type	**TECHNICAL FILE**

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Product	AN24 Abdominal FECG recorder
Document name	Firmware Validation Report
Document type	**TECHNICAL FILE**

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Product	AN24 Abdominal FECG recorder
Document name	Hardware Validation
Document type	**TECHNICAL FILE**
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Product	AN24 Abdominal FECG recorder
Document name	Monica VS Software Validation Report
Document type	**TECHNICAL FILE**
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Purpose

To ensure that the correct documents are identified and available and are kept up to date.

Scope

- Quality Assurance Manual
- Operating Procedures
- Quality Forms
- Technical Files
- Drawings
- Instructions
- Parts Lists
- Software & Firmware

Procedure

(b)(4) Operating Procedures

[redacted]

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Product	Monica AN24 Abdominal Fetal/Maternal Monitor
Document name	Appendices to Clinical Investigation Report – Fetal Heart Rate and Uterine Activity during Labor and Delivery For Patients ≥37 Weeks gestation
Document type	**Appendices to Clinical Trial Report**
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Product	Monica AN24 Abdominal Fetal/Maternal Monitor
(b) (4) [redacted]	
Document type	**Clinical Trial Multi Reader Study Protocol**
(b) (4) [redacted]	

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Records processed under FOIA Request #2015-4103; Released by CDRH on 06-06-2016.

Food and Drug Administration
Office of Device Evaluation &
Office of In Vitro Diagnostics

COVER SHEET MEMORANDUM

From: Reviewer Name — Kathy Dau-Kopp

Subject: 510(k) Number — K101801 / S2

To: The Record

Please list CTS decision code SE

- ☐ Refused to accept (Note this is considered the first review cycle. See Screening Checklist http://eroom.fda.gov/eRoomReg/Files/CDRH3/CDRHPremarketNotification510kProgram/0_5631/Screening%20Checklist202%2007.doc)
- ☐ Hold (Additional Information or Telephone Hold).
- X Final Decision (SE, SE with Limitations, NSE, Withdrawn, etc.).

Please complete the following for a final clearance decision (i.e., SE, SE with Limitations, etc.):		YES	NO
Indications for Use Page	*Attach IFU*	✓	
510(k) Summary /510(k) Statement	*Attach Summary*		
Truthful and Accurate Statement.	*Must be present for a Final Decision*	✓	
Is the device Class III?			✓
If yes, does firm include Class III Summary?	*Must be present for a Final Decision*		
Does firm reference standards? (If yes, please attach form from http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3654.pdf)			✓
Is this a combination product? (Please specify category N, see http://eroom.fda.gov/eRoomReg/Files/CDRH3/CDRHPremarketNotification510kProgram/0_413b/COMBINATION%20PRODUCT%20ALGORITHM%20(REVISED%203-12-03).DOC			✓
Is this a reprocessed single use device? (Guidance for Industry and FDA Staff – MDUFMA - Validation Data in 510(k)s for Reprocessed Single-Use Medical Devices, http://www.fda.gov/cdrh/ode/guidance/1216.html)			✓
Is this device intended for pediatric use only?			✓
Is this a prescription device? (If both prescription & OTC, check both boxes.)		✓	
Did the application include a completed FORM FDA 3674, Certification with Requirements of ClinicalTrials.gov Data Bank?		✓	
Is clinical data necessary to support the review of this 510(k)? Did the application include a completed FORM FDA 3674, *Certification with Requirements of ClinicalTrials.gov Data Bank*? (If not, then applicant must be contacted to obtain completed form.)		✓	
Does this device include an Animal Tissue Source?			✓
All Pediatric Patients age<=21			✓
Neonate/Newborn (Birth to 28 days)			
Infant (29 days -< 2 years old)			
Child (2 years -< 12 years old)			
Adolescent (12 years -< 18 years old)			
Transitional Adolescent A (18 - <21 years old) Special considerations are being given to this group, different from adults age ≥ 21 (different device design or testing, different protocol procedures, etc.)			

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

Records processed under FOIA Request #2015-4103; Released by CDRH on 06-06-2016.

Transitional Adolescent B (18 -<= 21; No special considerations compared to adults => 21 years old)			
Nanotechnology			✓
Is this device subject to the Tracking Regulation? (Medical Device Tracking Guidance, http://www.fda.gov/cdrh/comp/guidance/169.html)	*Contact OC.*		✓

Regulation Number	**Class***	**Product Code**
21 CFR 884.2740	II	HGM

(*If unclassified, see 510(k) Staff)

Additional Product Codes: QSP

Review: Colleen M Pollard (Branch Chief) OGDB (Branch Code) 2/3/11 (Date)

Final Review: (Division Director) dp 2/3/11 (Date)

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

Records processed under FOIA Request #2015-4103; Released by CDRH on 06-06-2016.

DEPARTMENT OF HEALTH AND HUMAN SERVICES **MEMORANDUM**

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

Premarket Notification [510(k)] Review
Traditional/Abbreviated

K101801

Date: February 1, 2011
To: The Record
From: Kathryn S. Daws-Kopp

Office: ODE
Division: DRARD

510(k) Holder: Monica Healthcare Ltd
Device Name: Monica AN24
Contact: Ian How, Regulatory Affairs Manager
Phone: 44 (0)115 912 4540
Fax: 44 (0)115 912 4289
Email: ianhow@monicahealthcare.com

I. Purpose and Submission Summary

The 510(k) holder would like to introduce Monica AN24 into interstate commerce. The Monica AN24 is a device that is used by clinicians to record and display fetal and maternal data acquired from monitoring devices, making it a perinatal monitor. Perinatal monitors are pre-amendments devices. When reviewing a 510(k) for these devices, we look at the following characteristics of the device: labeling, intended use, physical characteristics, device features, and software development process and testing.

This particular monitor is different than other intrapartum perinatal monitors on the market, in that fetal heart rate and uterine activity signals are only acquired through electrodes placed on the abdomen. That is there are no scalp or IUP electrodes involved. This device was previously submitted for

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[redacted]

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

Records processed under FOIA Request #2015-4103; Released by CDRH on 06-06-2016.

Supplemental information provided in response to our requests including additional analyses and line data were provided as part of interactive review and satisfied these remaining concerns.

Review Team:

Julia Corrado, MD	Clinical
Ken Blank, MD	Clinical (K081435 and pre-IDEs)
Bipasa Biswas	Statistical
Ali Mehrabi, Ph.D.	Electrical Engineering (communications and electrical safety)
Michael Bailey, Ph.D.	Biocompatibility

II. Administrative Requirements

		Yes	No	N/A
Indications for Use page (Indicate if: Prescription or OTC)	email	✓		
Truthful and Accuracy Statement	page 11, sec 1	✓		
510(k) Summary or 510(k) Statement	revised, email	✓		
Standards Form			✓	

Form 3454, Financial Disclosure for Clinical studies (page 13, section 1) was revised as requested.

III. Device Description

	Yes	No	N/A
Is the device life-supporting or life sustaining?		✓	
Is the device an implant (implanted longer than 30 days)?		✓	
Does the device design use software?	✓		
Is the device sterile?	✓		
Is the device reusable (not reprocessed single use)? Are "cleaning" instructions included for the end user?	✓		

This device makes skin contact only via abdominal electrodes. This requires disinfection or sterilization to SAL of 10-3. Some components are reusable and some are disposable. See discussion under Sterilization/Reuse, below.

(b)(4)

[redacted]

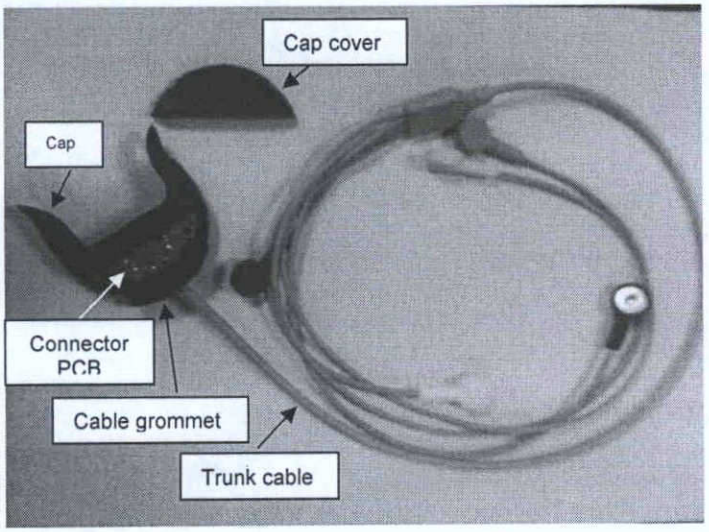
Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-4103; Released by CDRH on 06-06-2016.

- Battery charger and lead
- AN24 monitor connector/computer USB cable
- ECG Electrodes (K041026)
- AN24 protective cover
- Monica VS Software

AN24 body

The lead connector plugs into the top of the AN 24 body. The AN24 body has a neck strap (not shown) that keeps it with the patient. The controls on the front panel include (from bottom to top in picture): on/off, memory status LED (red), signal quality status LED (green), battery status LED (yellow), and event button. The neck strap attaches to what is the bottom end in the picture. The signal quality LED indicates different issues by flashing or flickering during both setup and monitoring, some of which do not apply to the US version. The main use of the event button is as an event marker, but it is also used in some additional minor functions. Some control of the device occurs by use of Monica VS software, including clearing of recorded data in memory and mode selection. Retrospective mode (default) allows viewing of stored data and real time mode allows for viewing and recording of new data.



Lead cable

(b)(4)

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

9

Records processed under FOIA Request #2015-4103; Released by CDRH on 06-06-2016.

of the three may be connected at a time, thus, you cannot charge the battery while collecting or transmitting data.

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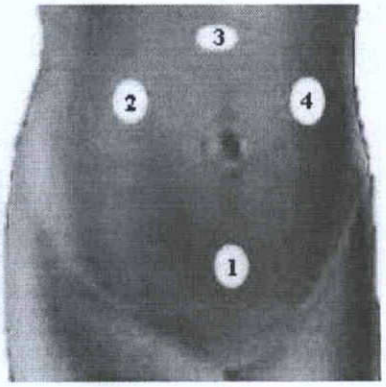
[redacted]

called the ground electrode, is positioned on the subject's back.



AN24 electrode locations

(b)(4)

[redacted]

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

10

Records processed under FOIA Request #2015-4103; Released by CDRH on 06-06-2016.

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[redacted]

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

(b)(4)

[redacted]

"The Monica AN24 is an intrapartum maternal-fetal monitor that non-invasively measures and displays fetal heart rate (FHR) and uterine activity (UA). The AN24 acquires and displays the FHR tracing from abdominal surface electrodes that pick up the fetal ECG (fECG) signal. Using the same surface electrodes, the AN24 also acquires and displays the UA tracing from the uterine electromyography (EMG) signal. The AN24 is indicated for use on women who are at term (>36 completed weeks), in labor, with singleton pregnancies, using surface electrodes on the maternal abdomen.

The AN24 maternal-fetal monitor is intended for use by healthcare professionals in a clinical setting."

V. Predicate Device Comparison

The predicate device is identified as the Philips series XM50 fetal/maternal monitors (K954351).

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[redacted]

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

12

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VI. Labeling

Labeling provided includes: Operating manual, Quick reference guide, Sales sheet, and specification for all device labels (label plus control button overlay, placement guide label, serial number label, etc.). The

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[redacted]

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

Records processed under FOIA Request #2015-4103; Released by CDRH on 06-06-2016.

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[redacted]

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

Records processed under FOIA Request #2015-4103; Released by CDRH on 06-06-2016.

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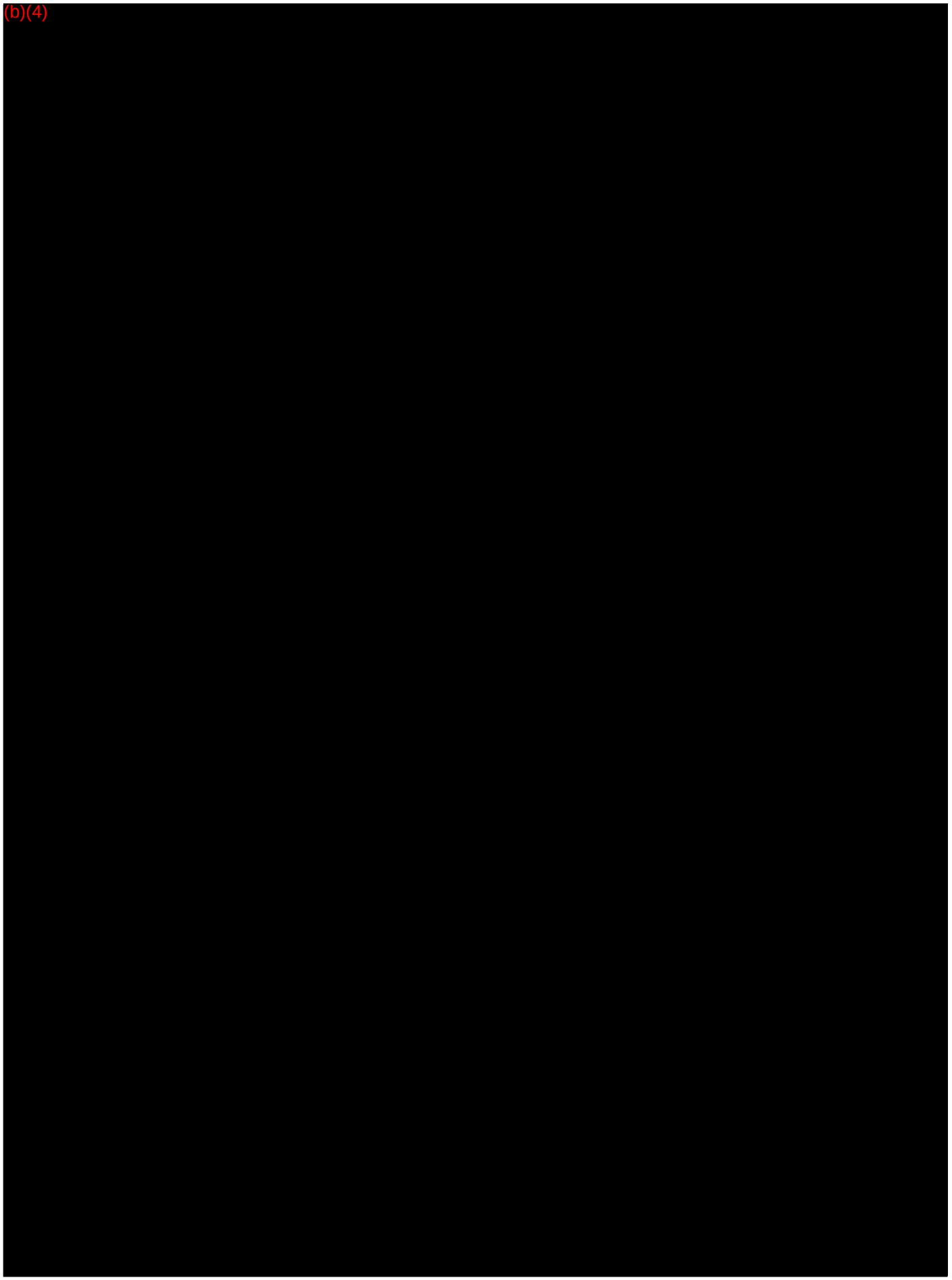

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-4103; Released by CDRH on 06-06-2016.

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[redacted]

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

Records processed under FOIA Request #2015-4103; Released by CDRH on 06-06-2016.

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[redacted]

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

Records processed under FOIA Request #2015-4103; Released by CDRH on 06-06-2016.

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[redacted]

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

Records processed under FOIA Request #2015-4103; Released by CDRH on 06-06-2016.

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[redacted]

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

Records processed under FOIA Request #2015-4103; Released by CDRH on 06-06-2016.

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[redacted]

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

20

Records processed under FOIA Request #2015-4103; Released by CDRH on 06-06-2016.

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[redacted]

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

Records processed under FOIA Request #2015-4103; Released by CDRH on 06-06-2016.

(b)(4)

[redacted]

Kathryn S. Drew-Kopp
Reviewer

2/1/11
Date

Coleen Pollard
Branch Chief

2/3/11
Date

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

(b)(4) Responses to Deficiencies

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Records processed under FOIA Request #2015-4103; Released by CDRH on 06-06-2016.

Monica Healthcare Intrapartum Labor Monitor
K101801
Clinical Review

MEMORANDUM FOR: Kathryn S. Daws-Kopp, Electrical Engineer
Obstetrics and Gynecology Devices Branch
Division of Reproductive, Gastrorenal and
Urological Devices

FROM: Julia Corrado, MD
Obstetrics and Gynecology Devices Branch
Division of Reproductive, Gastrorenal and
Urological Devices

SUBJECT: Clinical Review of Monica Healthcare's Monica AN24 Labor Monitor (K101801)

DATE: January 31, 2011

CC: Colin Pollard
Jill Brown, MD
Bipasa Biswas, PhD
Ali Mehrabi, PhD
Herb Lerner, MD

This is the clinical review of the above premarket notification for an intrapartum maternal fetal monitoring system that uses electrophysiology signals to display fetal heart rate (FHR) and uterine activity (UA). This review draws from prior clinical consulting reviews dated August 19, 2010, November 19, 2010 and December 20, 2010.

(b)(4)

[redacted]

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

30

Records processed under FOIA Request #2015-4103; Released by CDRH on 06-06-2016.

(b)(4)

[redacted]

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

Records processed under FOIA Request #2015-4103; Released by CDRH on 06-06-2016.

(b)(4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.
32

Records processed under FOIA Request #2015-4103; Released by CDRH on 06-06-2016.

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[redacted]

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

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[redacted]

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

Records processed under FOIA Request #2015-4103; Released by CDRH on 06-06-2016.

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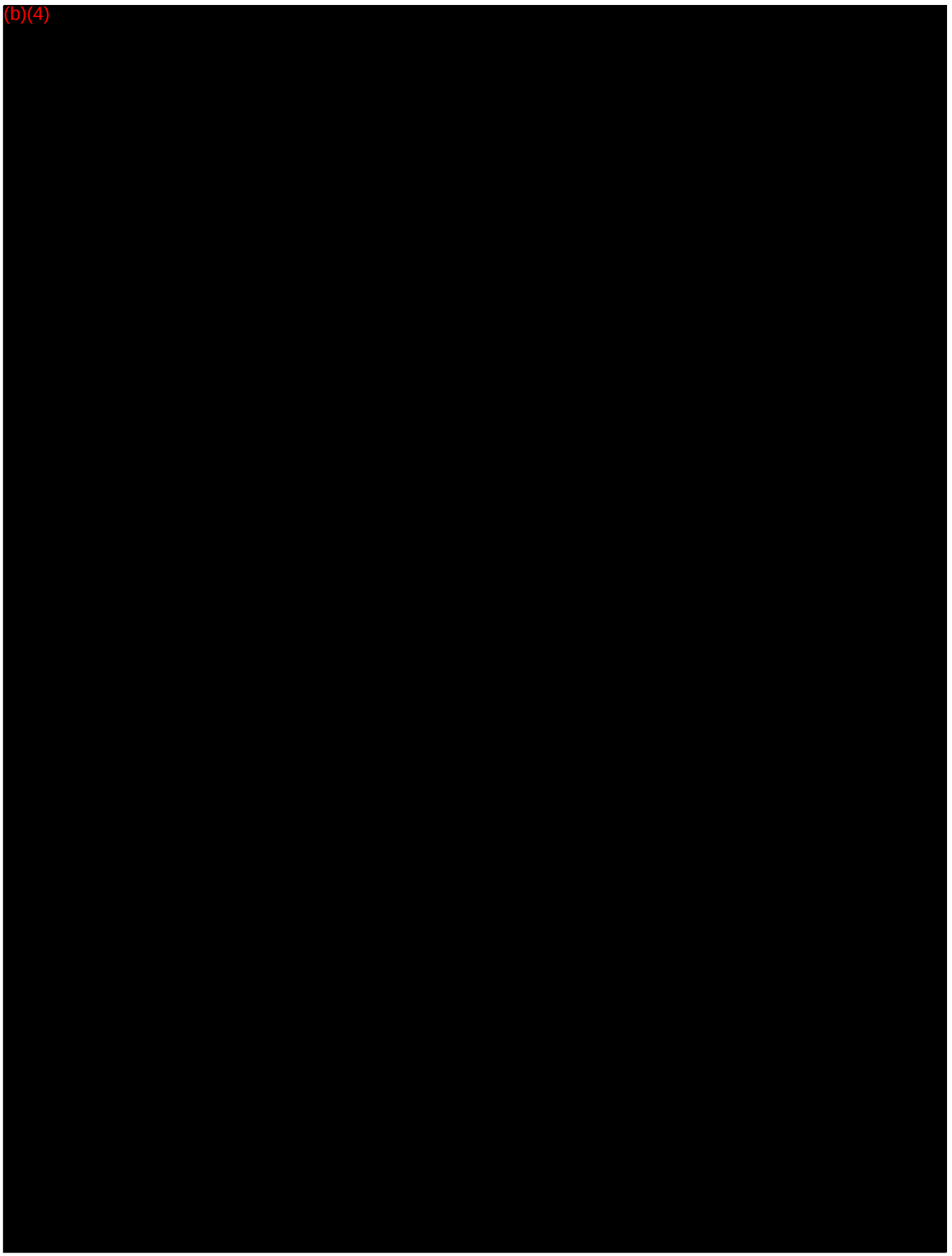

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

JS

Records processed under FOIA Request #2015-4103; Released by CDRH on 06-06-2016.

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[redacted]

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

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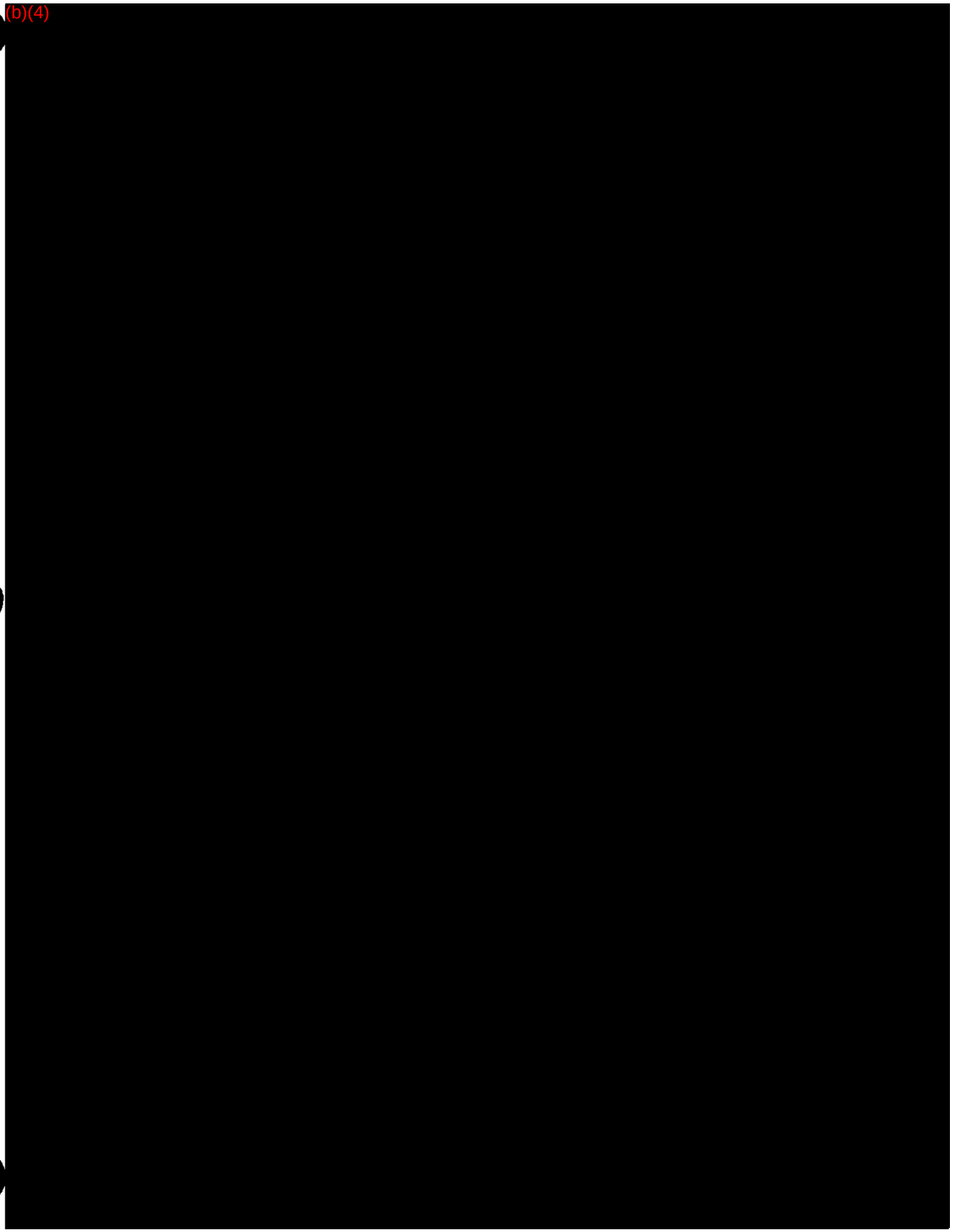

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Records processed under FOIA Request #2015-4103; Released by CDRH on 06-06-2016.

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[redacted]

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

Records processed under FOIA Request #2015-4103; Released by CDRH on 06-06-2016.

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

Records processed under FOIA Request #2015-4103; Released by CDRH on 06-06-2016.

(b)(4)

[redacted]

Julia Corrado, MD Date

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

40

Records processed under FOIA Request #2015-4103; Released by CDRH on 06-06-2016.

Daws-Kopp, Kathryn S.

From: Corrado, Julia A
Sent: Friday, November 19, 2010 6:16 PM
To: Daws-Kopp, Kathryn S.
Cc: Pollard, Colin M.
Subject: Clinical review of responses from Monica Healthcare Limited to FDA request for additional information on the Monica AN 24 intrapartum maternal fetal monitor (K101801/S001)

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[redacted]

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

41

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This issue is resolved.

(b)(4)

[redacted]

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

42

(b)(4)

[redacted]

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

(b)(4)

Julia

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

Records processed under FOIA Request #2015-4103; Released by CDRH on 06-06-2016.

Monica Healthcare Monica AN24 Maternal Fetal Monitor
K101801
Clinical Review

MEMORANDUM FOR: Kathryn S. Daws-Kopp, Electrical Engineer
Obstetrics and Gynecology Devices Branch
Division of Reproductive, Abdominal and Radiological Devices

FROM: Julia Corrado, MD
Obstetrics and Gynecology Devices Branch
Division of Reproductive, Abdominal and Radiological Devices

DATE: August 19, 2010

SUBJECT: Clinical Review of Monica Health Care's AN24 Maternal Fetal Monitor (K101801)

CC: Colin Pollard
Bipasa Biswas, PhD
Jill Brown, MD
Ken Blank, MD

This is the clinical review of the above premarket notification for an intrapartum maternal fetal monitoring system that uses electrophysiology signals to display fetal heart rate (FHR) and uterine activity (UA).

I. BACKGROUND

(b)(4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118. 45

Records processed under FOIA Request #2015-4103; Released by CDRH on 06-06-2016.

(b)(4)

[redacted]

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

96

Records processed under FOIA Request #2015-4103; Released by CDRH on 06-06-2016.

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[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.
47

Records processed under FOIA Request #2015-4103; Released by CDRH on 06-06-2016.

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[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.
48

Records processed under FOIA Request #2015-4103; Released by CDRH on 06-06-2016.

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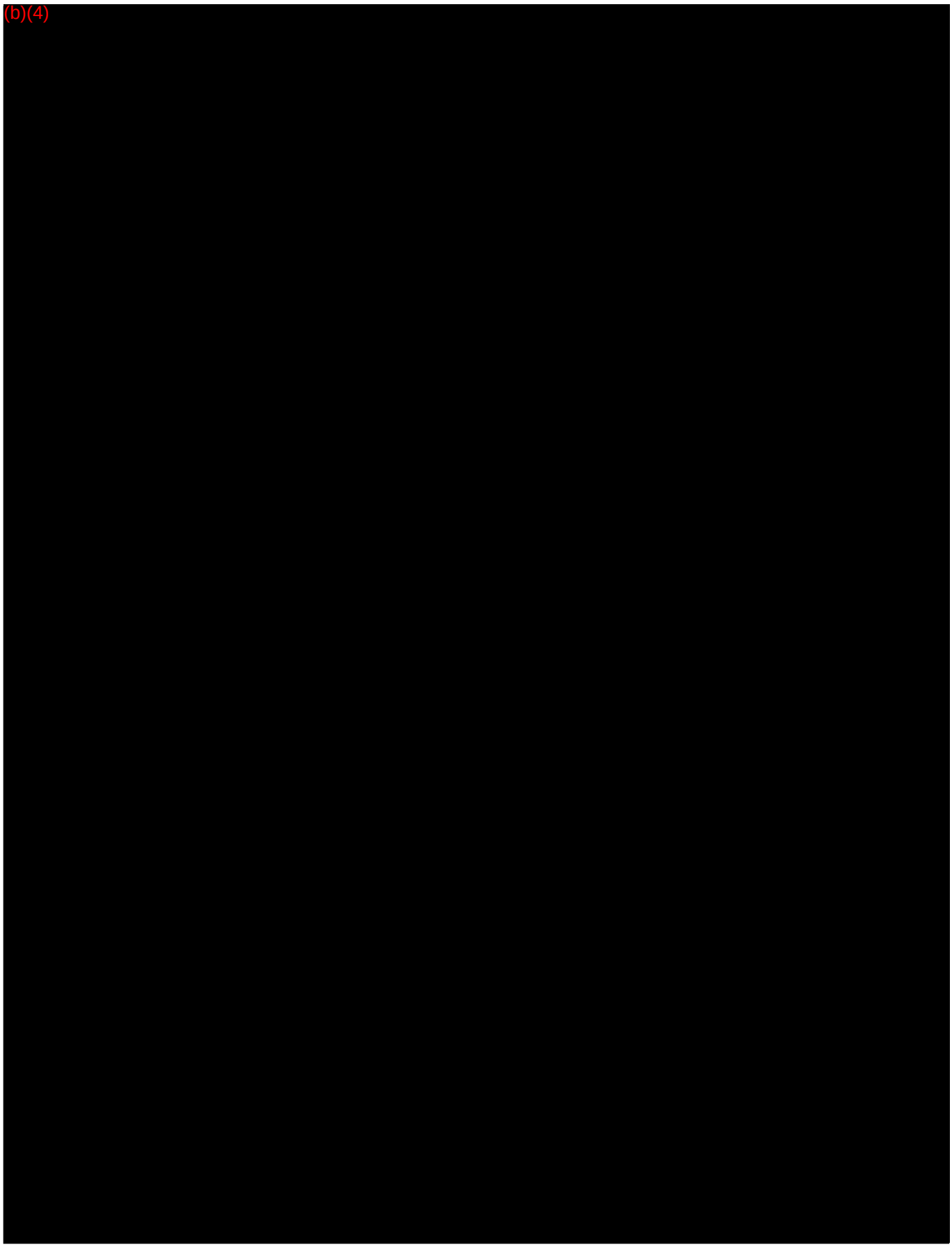

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[redacted]

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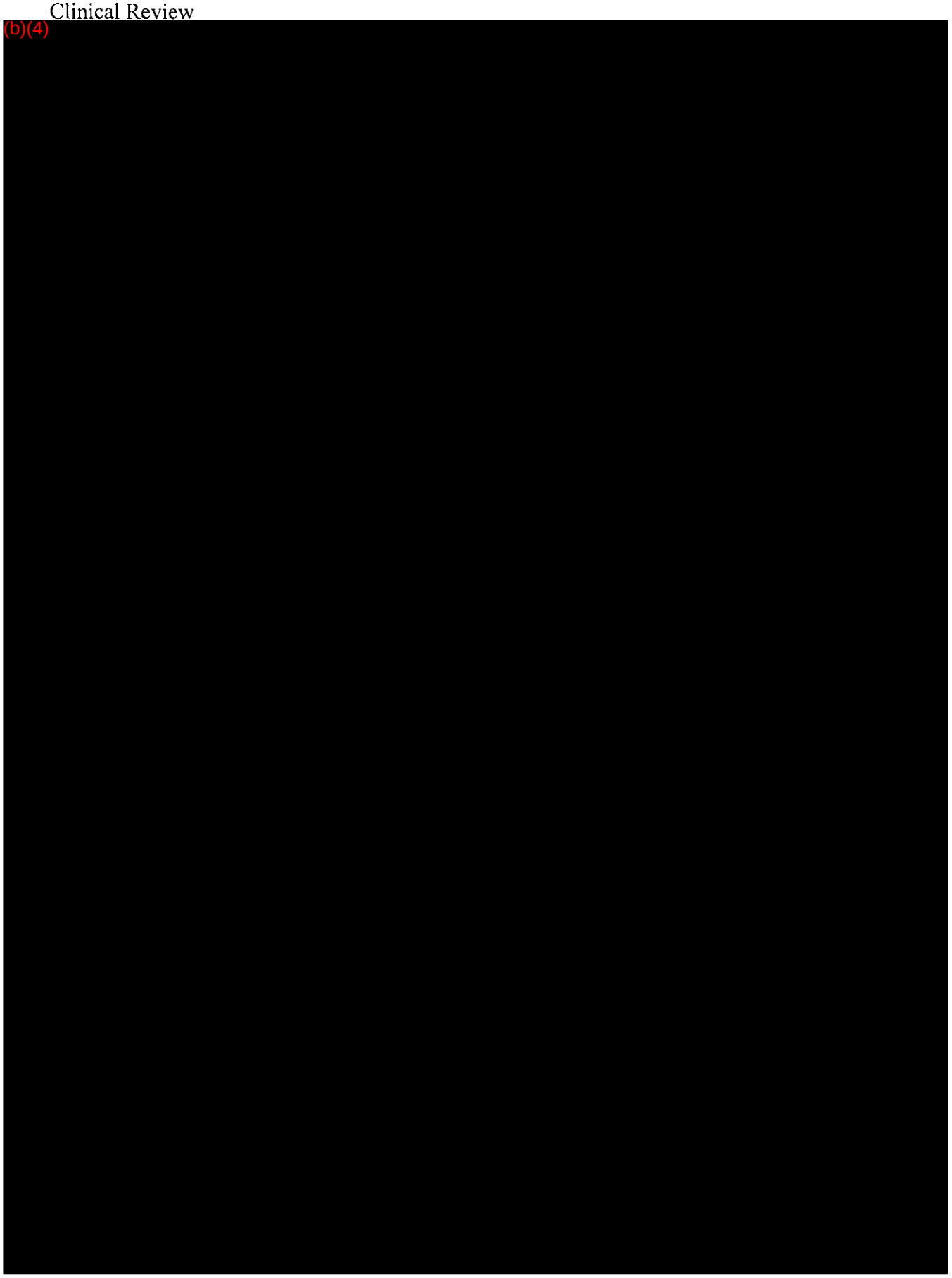

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Records processed under FOIA Request #2015-4103; Released by CDRH on 06-06-2016.

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[redacted]

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

Records processed under FOIA Request #2015-4103; Released by CDRH on 06-06-2016.

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

Records processed under FOIA Request #2015-4103; Released by CDRH on 06-06-2016.

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[redacted]

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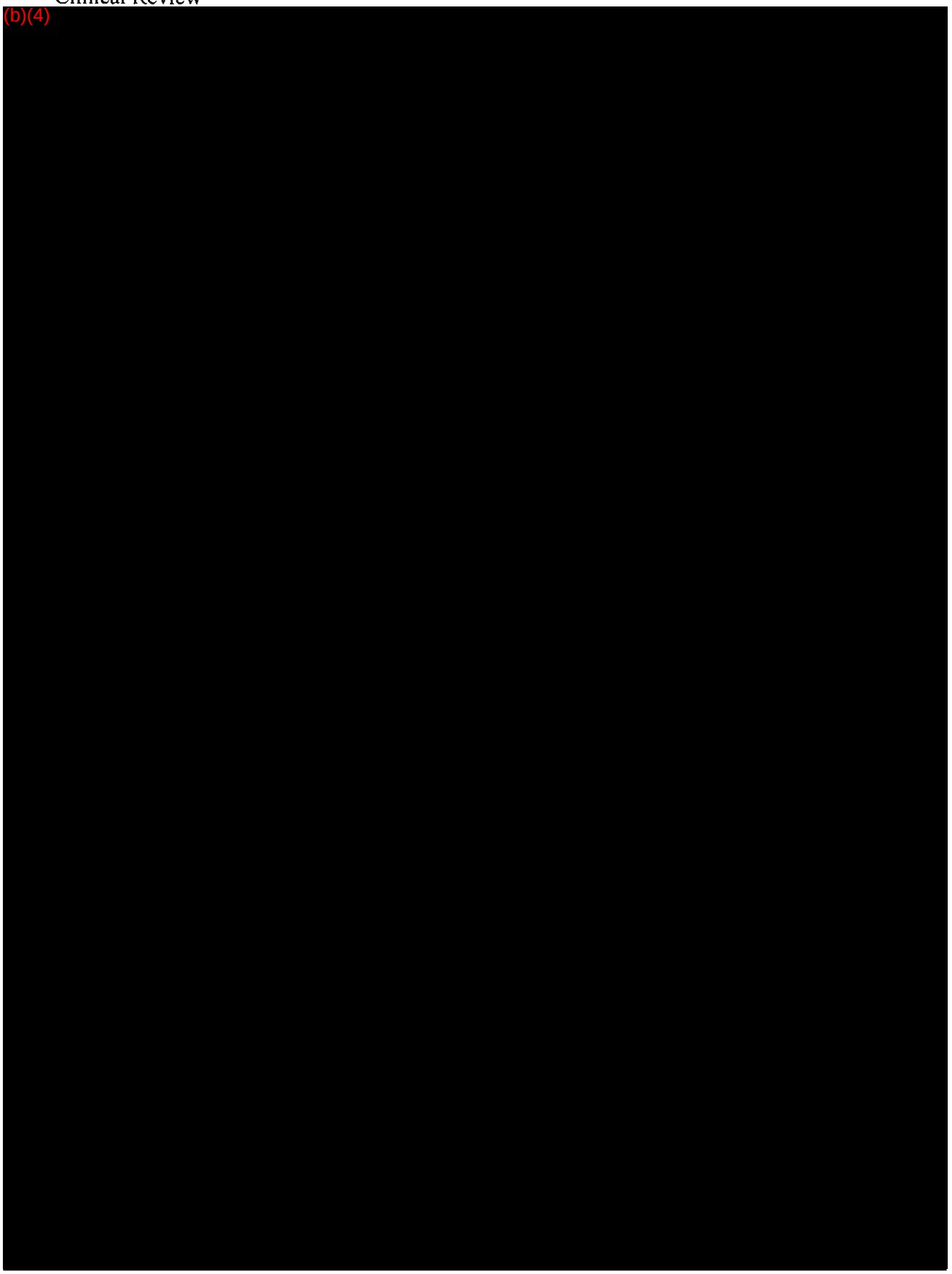

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59

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Records processed under FOIA Request #2015-4103; Released by CDRH on 06-06-2016.

(b)(4)

[redacted]

I have no additional comments at this time.

1-20-11

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

Records processed under FOIA Request #2015-4103; Released by CDRH on 06-06-2016.
Monica Healthcare Monica AN24 Maternal Fetal Monitor
K101801
Clinical Review
Julia Corrado, MD Date

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.
62

Records processed under FOIA Request #2015-4103; Released by CDRH on 06-06-2016.

(b)(4)

[redacted]

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

Records processed under FOIA Request #2015-4103; Released by CDRH on 06-06-2016.

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[redacted]

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

Records processed under FOIA Request #2015-4103; Released by CDRH on 06-06-2016.

Functional Components:
The AN24 is a portable, battery-powered device which connects to the patients using four electrodes. The device contains a rechargeable battery and is supplied with an international (multiple voltages) charger.

Thank you,
Ali Mehrabi
Thursday, January 27, 2011

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

Records processed under FOIA Request #2015-4103; Released by CDRH on 06-06-2016.

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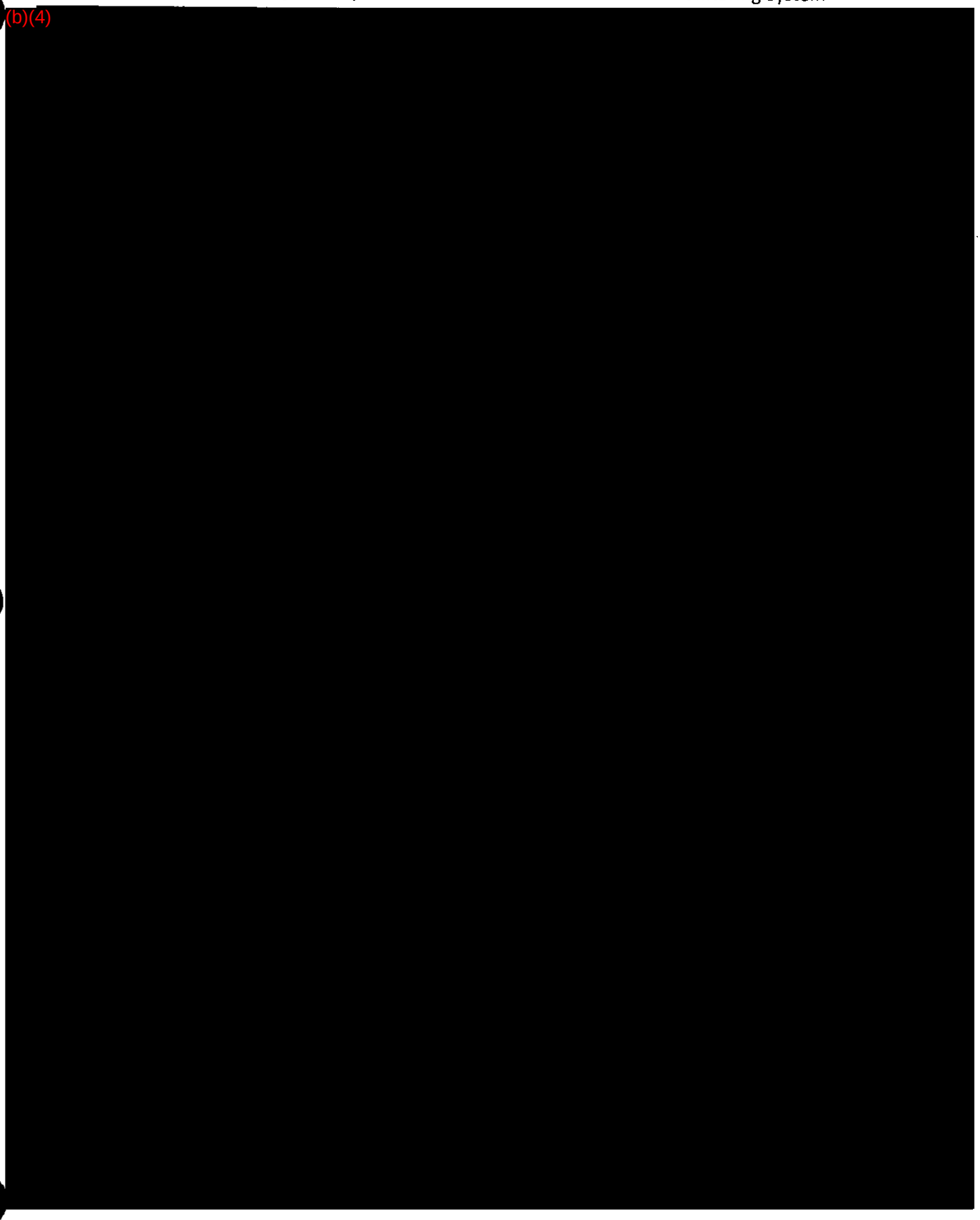

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Records processed under FOIA Request #2015-4103; Released by CDRH on 06-06-2016.

(b)(4)

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

Records processed under FOIA Request #2015-4103; Released by CDRH on 06-06-2016.

Daws-Kopp, Kathryn S.

From: Daws-Kopp, Kathryn S.
Sent: Monday, January 24, 2011 11:06 AM
To: Pollard, Colin M.; Mehrabi, Ali
Subject: Reviews and final review

(b)(4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.
63

Records processed under FOIA Request #2015-4103; Released by CDRH on 06-06-2016.

Daws-Kopp, Kathryn S.

From: Mehrabi, Ali
Sent: Tuesday, December 14, 2010 4:56 PM
To: Daws-Kopp, Kathryn S.
Subject: Monica Review
Attachments: Monica AN24 510(k)_Follow Up Questions.doc

Hi Kathy -

I have attached my formal review of the Monica fetal monitor. Please let me know if you have any questions.

Thank you,
Ali Mehrabi

Ali Mehrabi, Ph.D.
Senior Electronics Engineer
Medical Electronics Laboratory Leader
Division of Electrical and Software Engineering
Office of Science and Engineering Laboratories
U.S. Food and Drug Administration
Center for Devices and Radiological Health
Mailing Address:
WO62 - 4209
U.S. Food and Drug Administration
10903 New Hampshire Ave
Silver Spring MD 20993-0002

Office: (301) 796-2788
FAX : (301) 796-9931
Cell : (301) 461-1003
Ali.Mehrabi@FDA.HHS.GOV

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

Records processed under FOIA Request #2015-4103; Released by CDRH on 06-06-2016.

Daws-Kopp, Kathryn S.

From: Daws-Kopp, Kathryn S.
Sent: Friday, November 19, 2010 5:18 PM
To: Mehrabi, Ali
Subject: K101801.Dr.Mehrabi.doc

Attachments: K101801.Dr.Mehrabi.doc

(b)(4)

[redacted]

Kathy

Obstetrics and Gynecology Devices Branch
Division of Reproductive, Abdominal, and
[redacted]iological Devices
[redacted]DE/CDRH

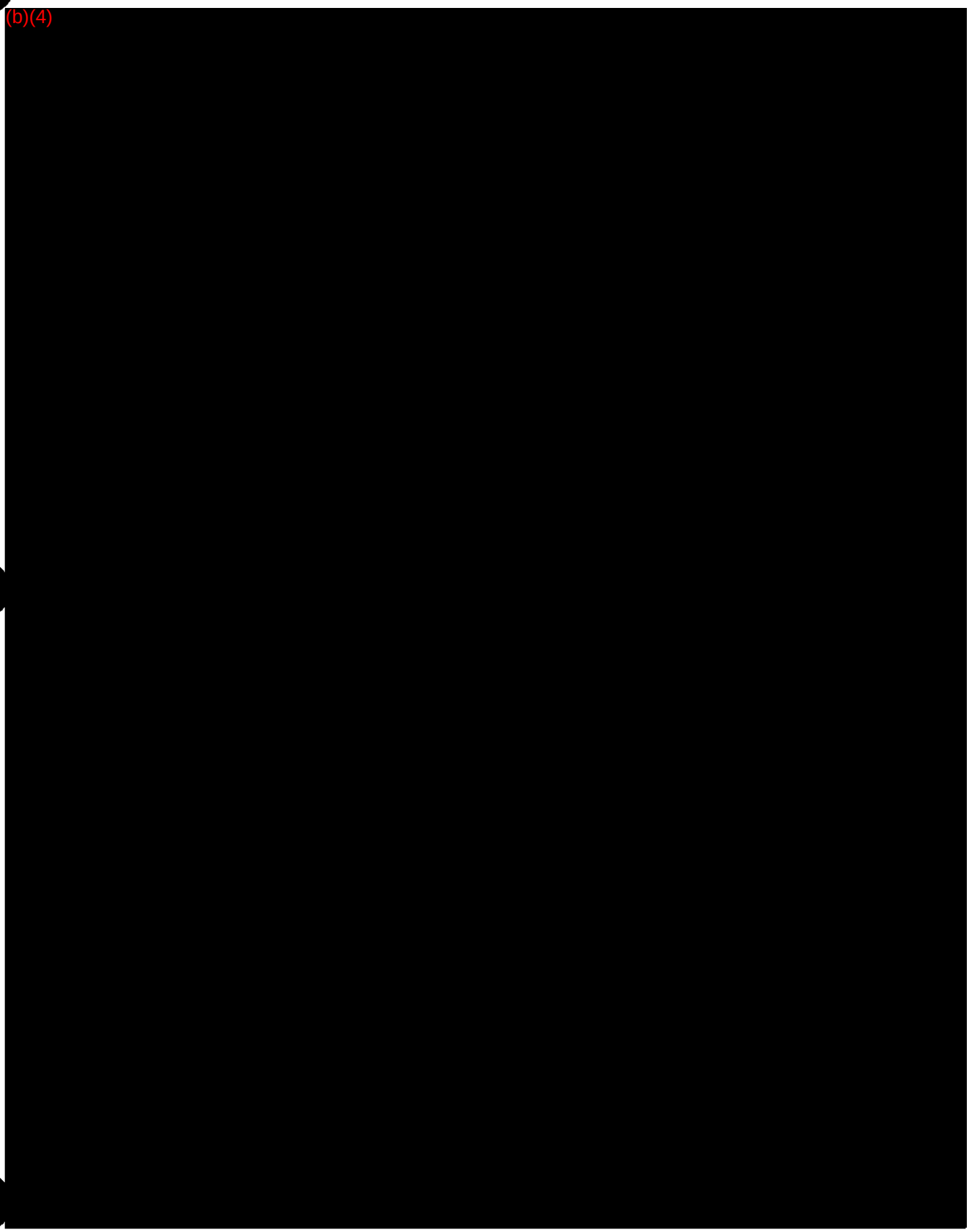
Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

10

Records processed under FOIA Request #2015-4103; Released by CDRH on 06-06-2016.

K101801/S001
Ali Mehrabi's questions

(b)(4)



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Records processed under FOIA Request #2015-4103; Released by CDRH on 06-06-2016.

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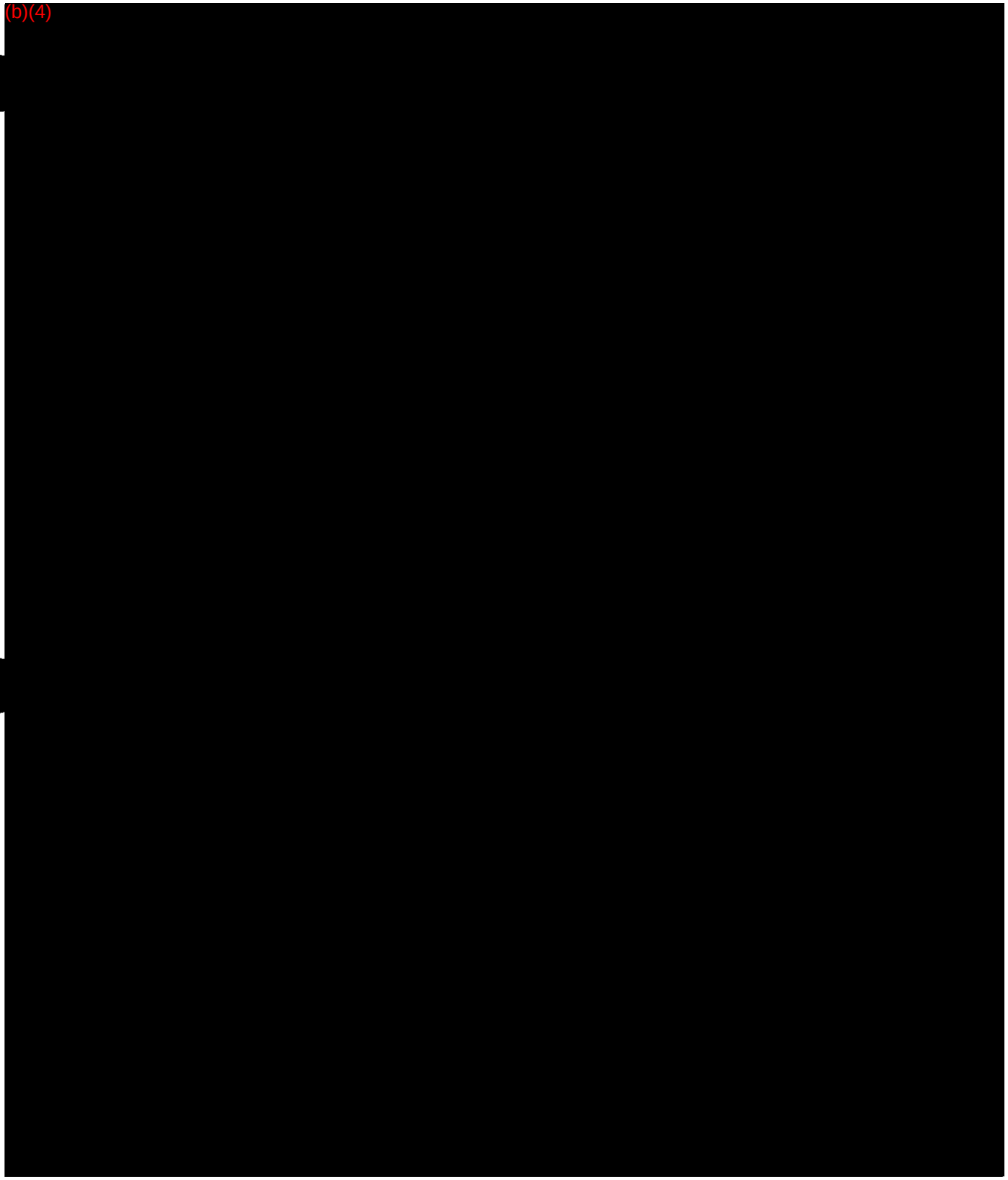

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-4103; Released by CDRH on 06-06-2016.

Daws-Kopp, Kathryn S.

From: Mehrabi, Ali
Sent: Friday, November 19, 2010 6:34 PM
To: Daws-Kopp, Kathryn S.
Subject: RE: FHR/MHR question for Monica

(b)(4)

[redacted]

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

Records processed under FOIA Request #2015-4103; Released by CDRH on 06-06-2016.

From: Daws-Kopp, Kathryn S.
Sent: Friday, November 19, 2010 4:49 PM
To: Mehrabi, Ali

(b)(4)

[redacted]

Kathy

Obstetrics and Gynecology Devices Branch
Division of Reproductive, Abdominal, and Radiological Devices
ODE/CDRH

New phone: 301-796-6535

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.
74

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Daws-Kopp, Kathryn S.

From: Daws-Kopp, Kathryn S.
Sent: Monday, November 22, 2010 3:02 PM
To: 'Ian How'
Subject: K101801

Attachments: K101801.S1 deficiencies.doc

To: Monica Healthcare Ltd
Ian How, Regulatory Affairs Manager
email: ianhow@monicahealthcare.com
Phone: 44 (0) 115 912 4540
Fax: 44 (0) 115 912 4289

(b)(4)

[redacted]

Kathy

Obstetrics and Gynecology Devices Branch
Division of Reproductive, Abdominal, and
Radiological Devices
ODE/CDRH

New phone: 301-796-6535

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

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K101801/S001 Deficiencies

(b)(4) Deficiencies

[redacted]

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Date: December 13, 2010

From: Bipasa Biswas (Mathematical Statistician)
Division of Biostatistics, OSB

(b)(4)

[redacted]

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

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Statistical Review

(b)(4)

[redacted]

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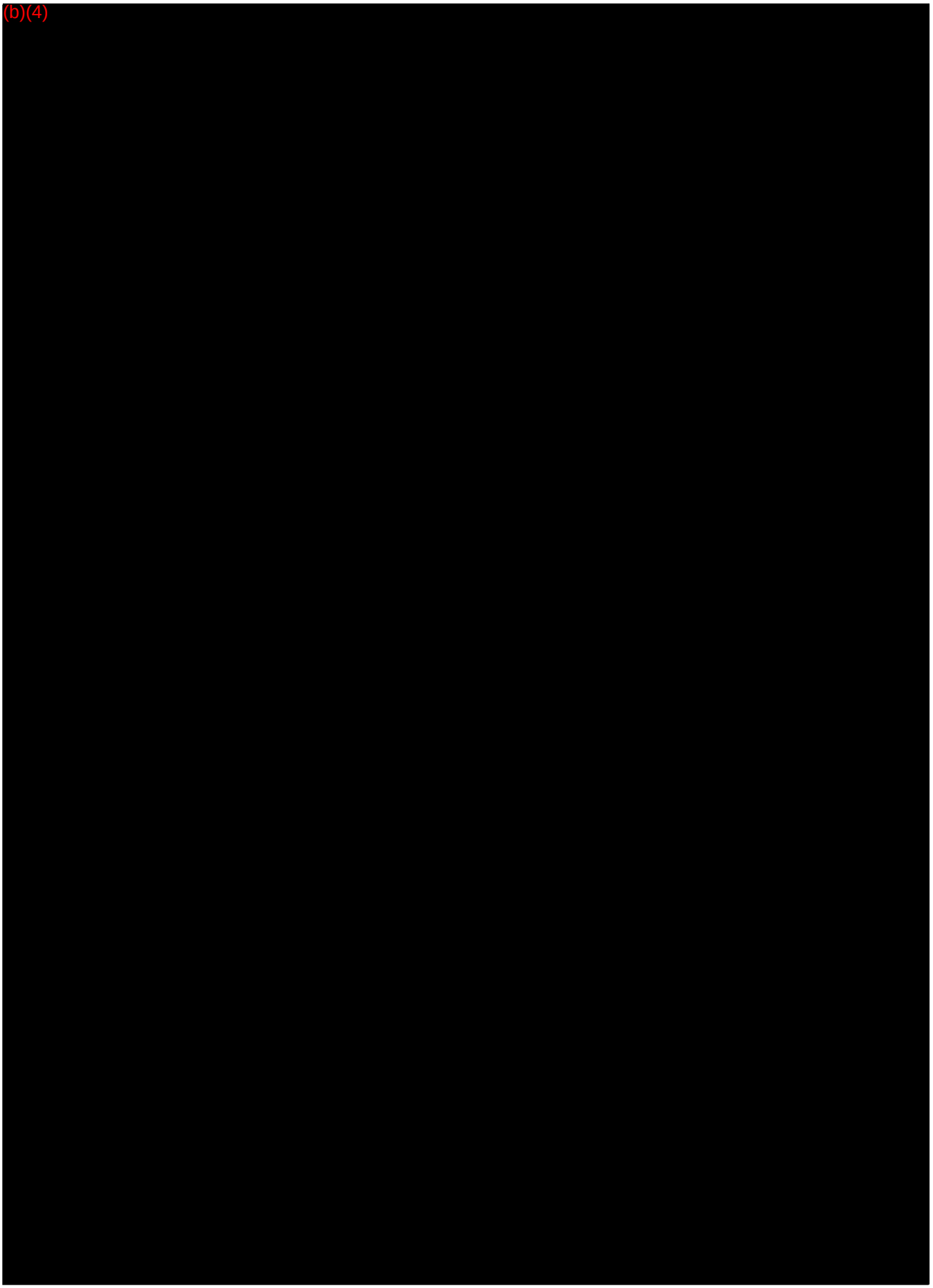
(b)(4)



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

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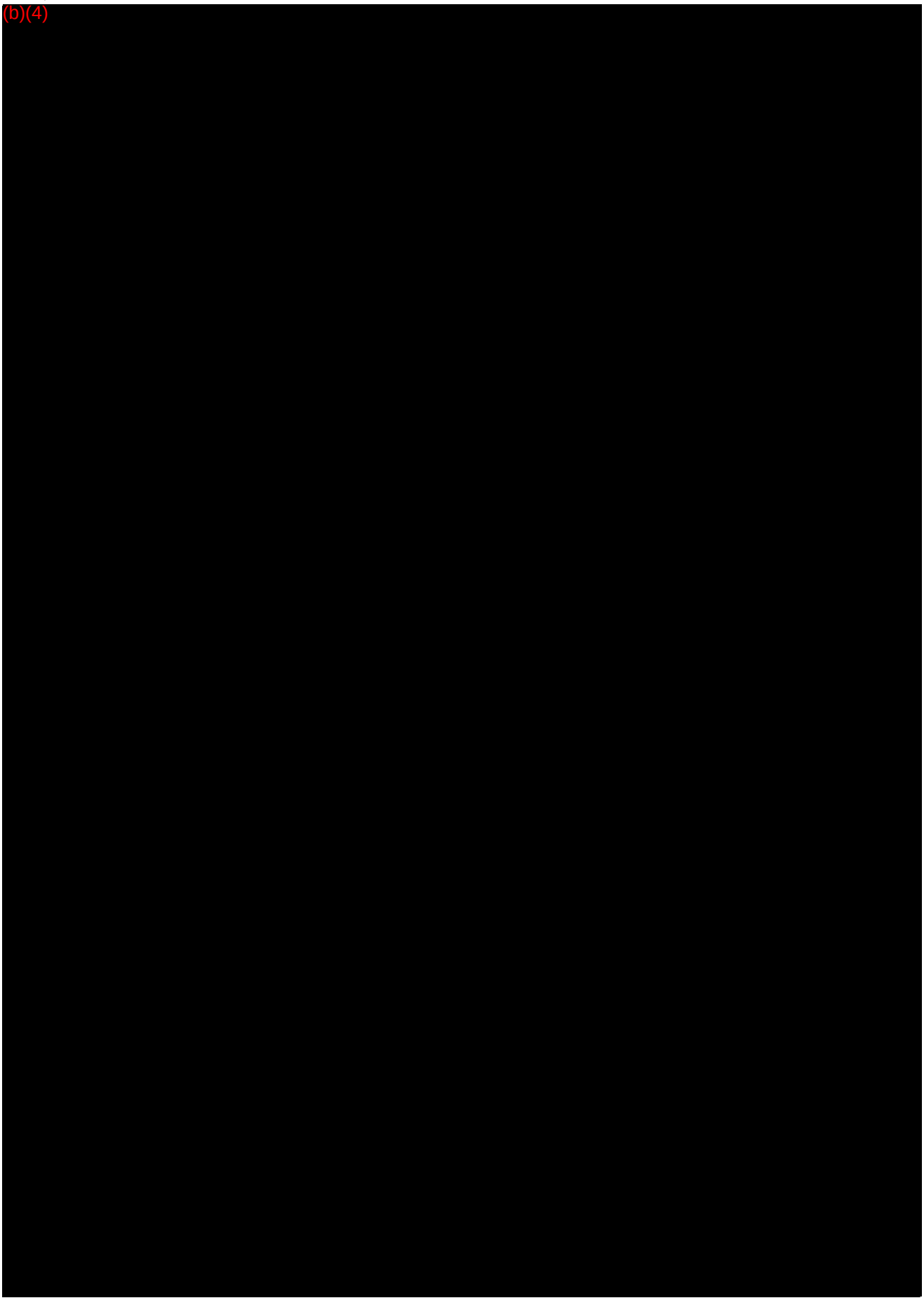
(b)(4)



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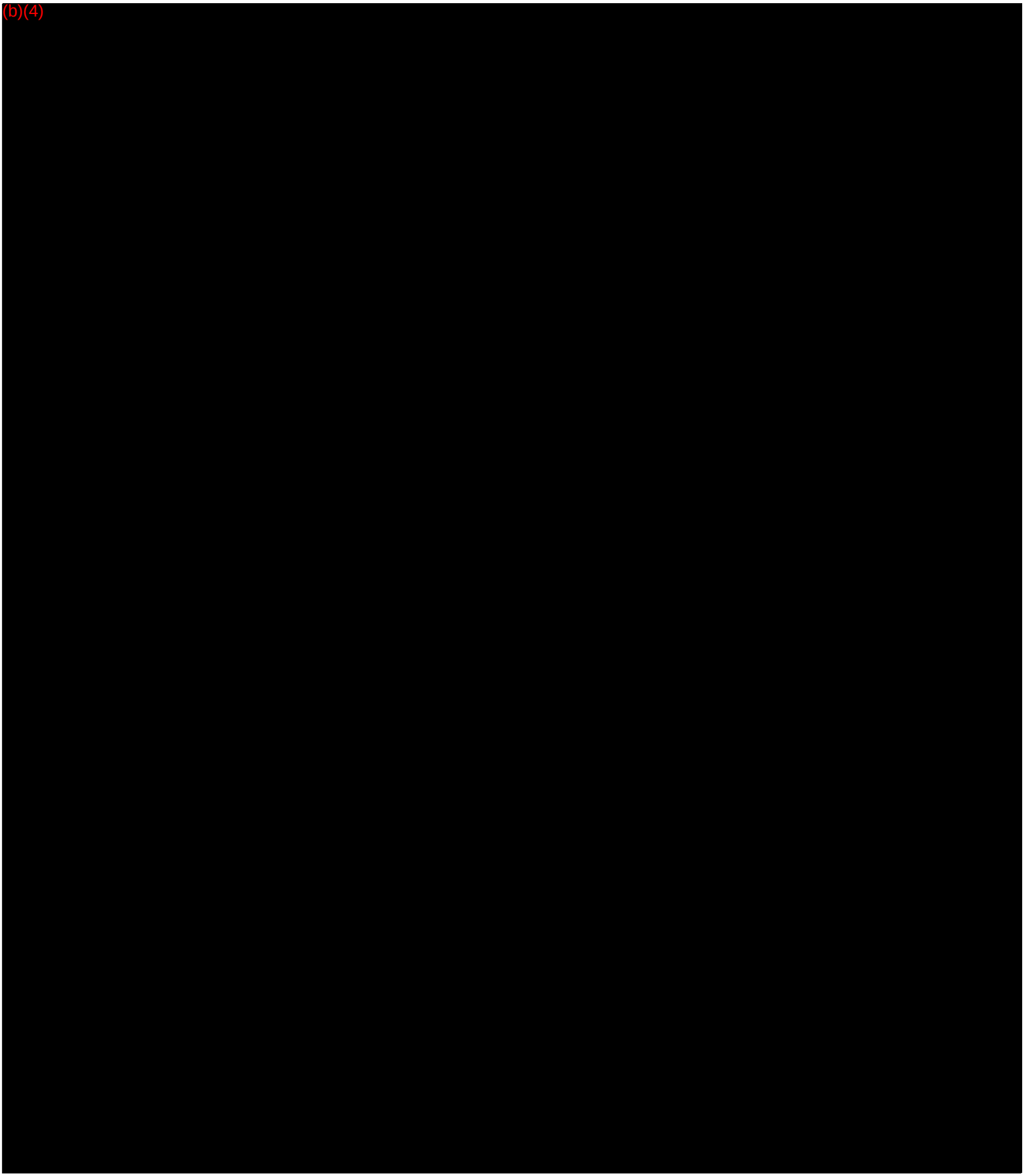

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(b)(4)

[redacted]

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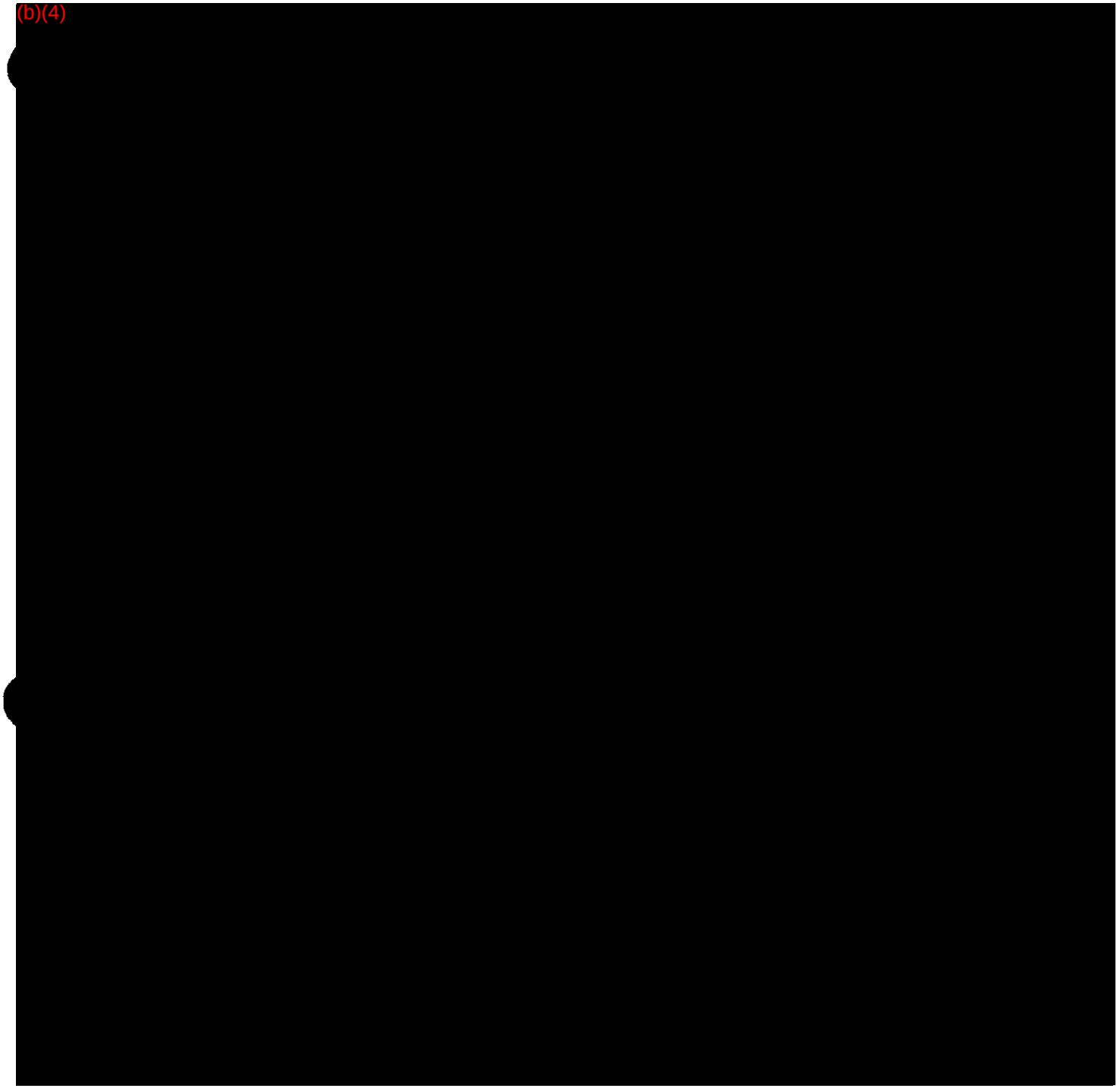
(b)(4)



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

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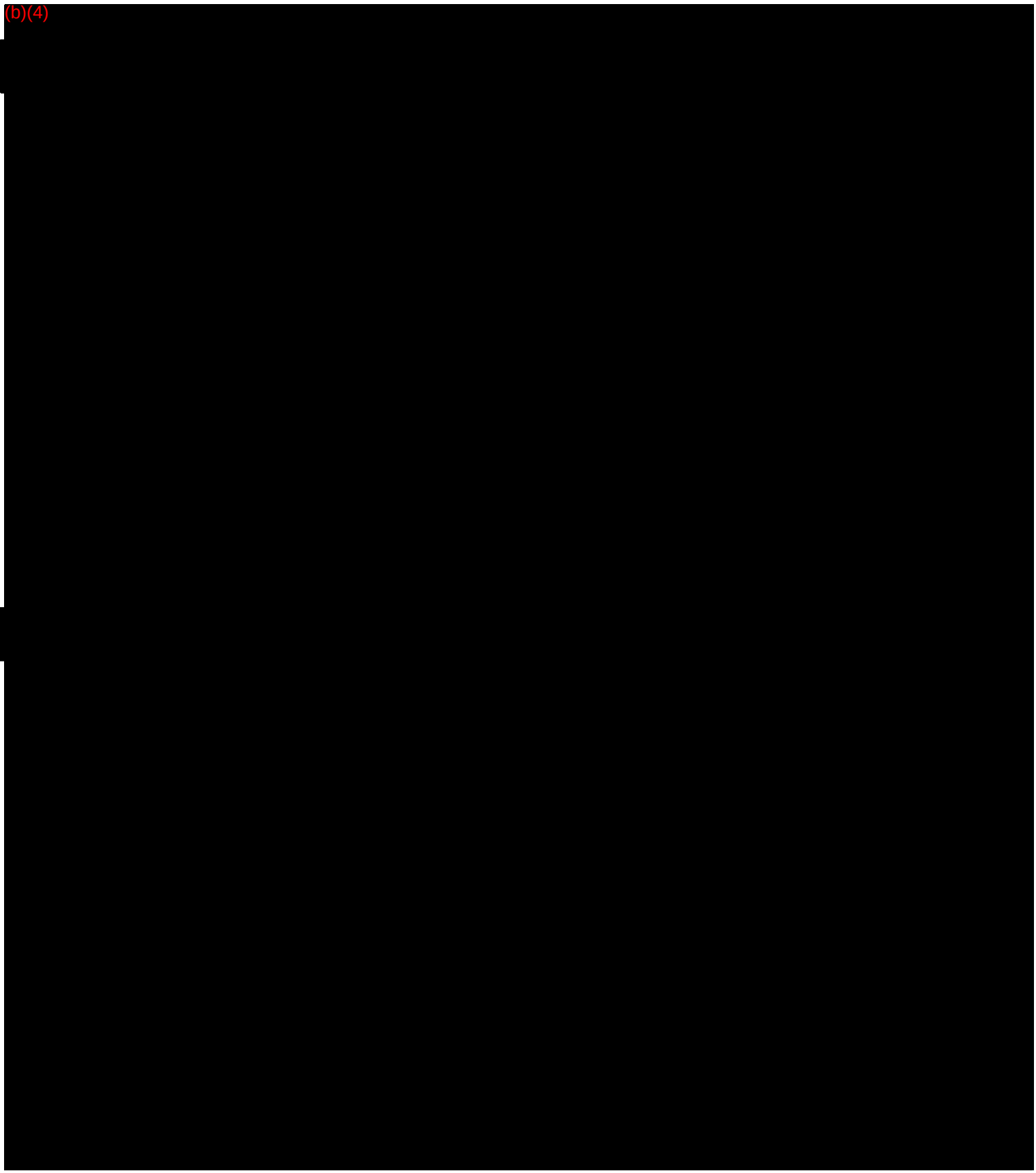

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(b)(4)

[redacted]

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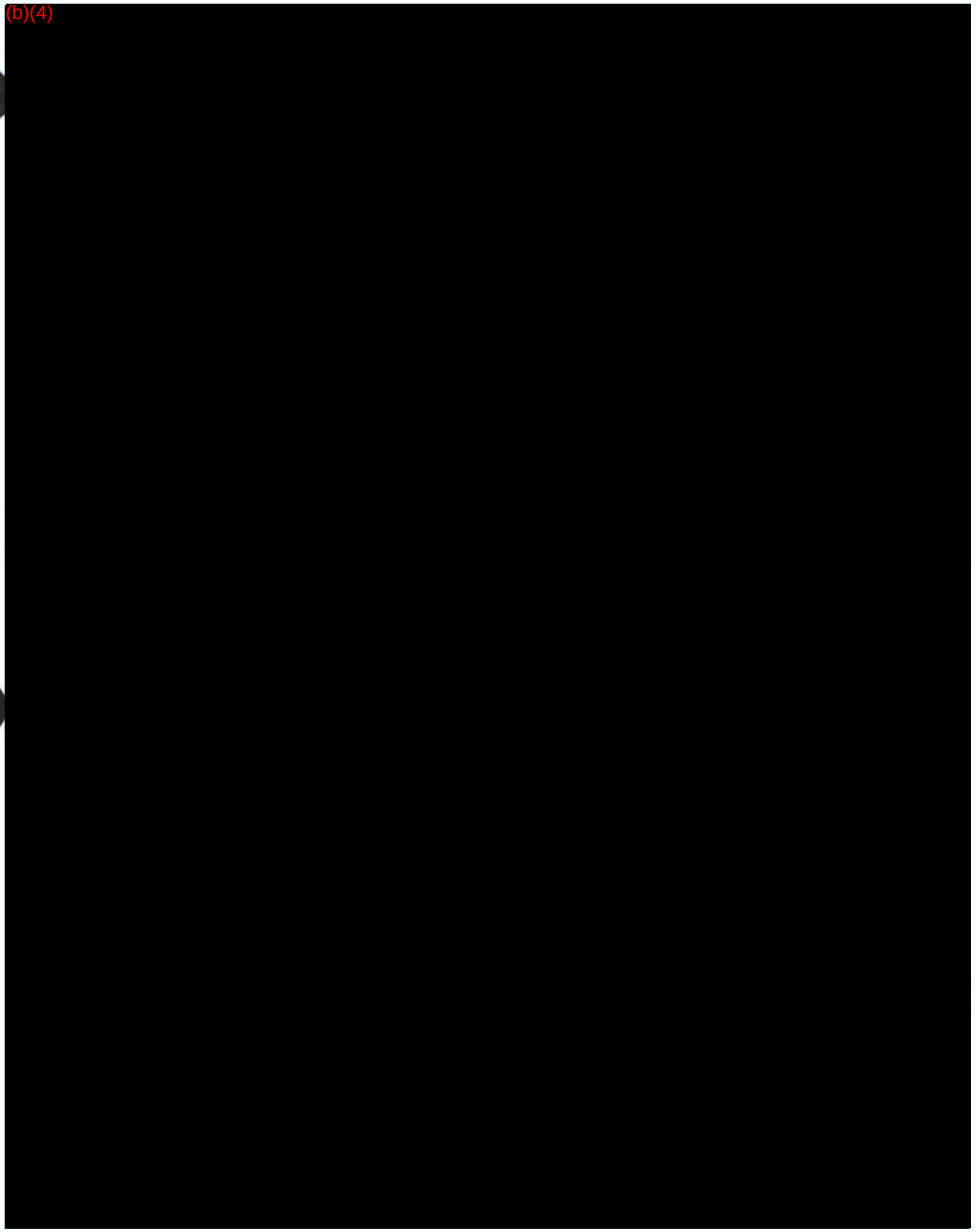
(b)(4)



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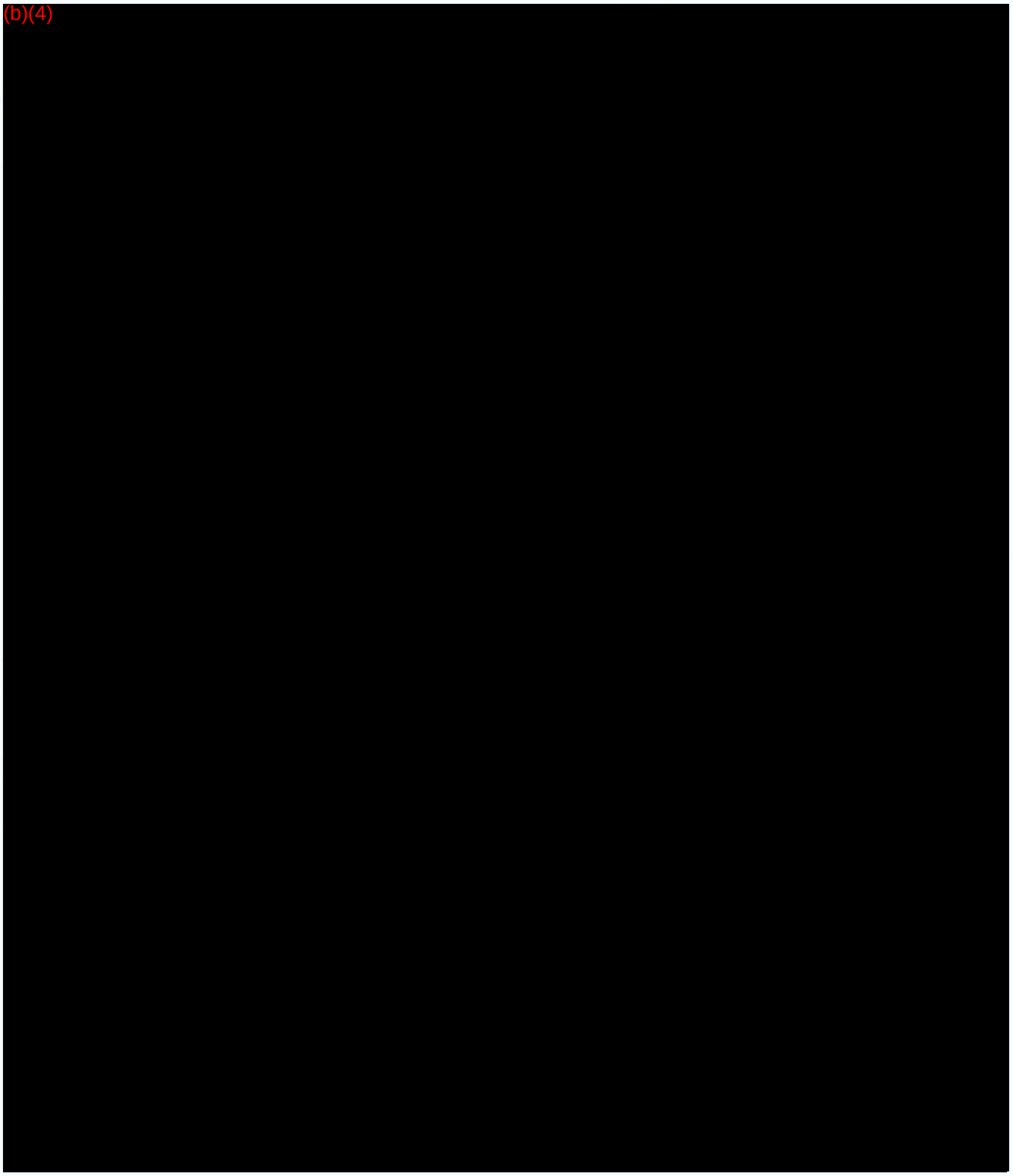

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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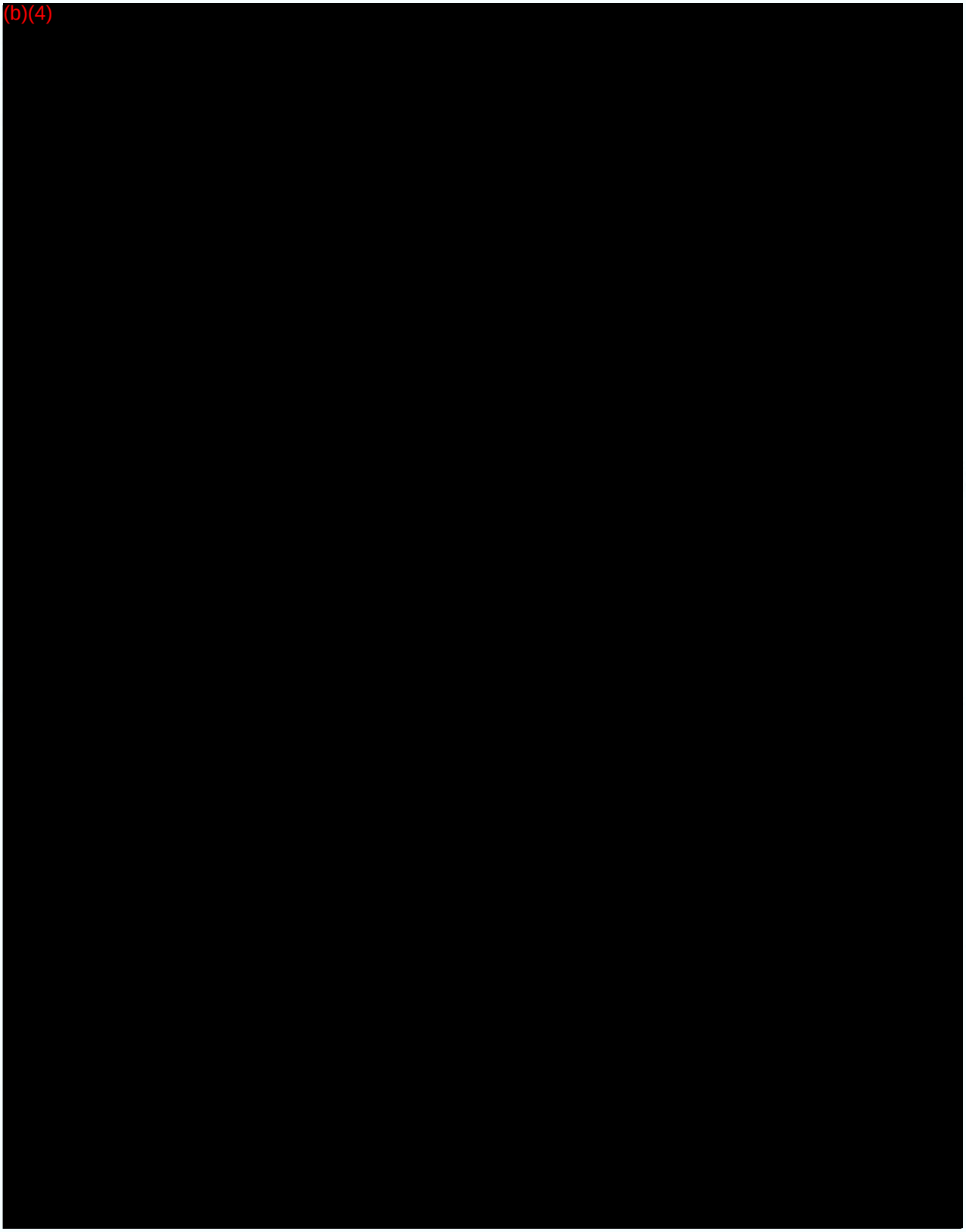
(b)(4)



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Conclusion

The sponsor has provided all requested analyses and answered all the statistical deficiencies. I have no further comments about the submission.

(b)(4)

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

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Daws-Kopp, Kathryn S

(b)(4)

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From: Daws-Kopp, Kathryn S. [mailto:Kathryn.Daws-Kopp@fda.hhs.gov]
Sent: 25 January 2011 15:40
To: 'ianhow@monicahealthcare.com'
Subject: Indications statement

(b)(4)

[redacted]

Kathy

Obstetrics and Gynecology Devices Branch
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ODE/CDRH

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New phone: 301-796-6535

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

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MONICA AN24 COMPARATIVE FETAL HEART RATE AND UTERINE ACTIVITY CLINICAL TRIAL

(b)(4) Clinical Trial

[redacted]

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(b)(4) Clinical Trial

(b)(4) Clinical Trial

(b)(4) Clinical Trial

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K101801 510(K) Summary

Monica AN24

Submitters Name:

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Monica Healthcare Ltd
Biocity
Pennyfoot Street
Nottingham NG1 1GF
UK

Tel: +44 (0)115 912 4541
Email: ianhow@monicahealthcare.com

Name of Device: Monica AN24

Manufactured by:

Monica Healthcare Ltd
Biocity
Pennyfoot Street
Nottingham NG1 1GF
UK

Date of Summary: 4th January 2011

Classification Name: 21 CFR 884.270 System Monitoring Perinatal

Predicate Device: Philips 50XM (K954351)

Device Description:
The Monica AN24™ is a small, battery-powered device for L&D surveillance of fetal well-being. The AN24™ is designed to passively monitor Fetal Heart Rate (FHR) from the fetal electrocardiogram (fECG) and Uterine Activity (UA) from the Electrohysterogram (EHG) during pregnancy and can be used at any time from > 36 completed weeks gestation in laboring patients. The AN24™ is suitable for singleton pregnancies only.

Intended Use:

The Monica AN24 is an intrapartum maternal-fetal monitor that non-invasively measures and displays fetal heart rate (FHR) and uterine activity (UA). The AN24 acquires and displays the FHR tracing from abdominal surface electrodes that pick up the fetal ECG (fECG) signal. Using the same surface electrodes, the AN24 also acquires and displays the UA tracing from the uterine electromyography (EMG) signal. The AN24 is indicated for use on women who are at term (>36 completed weeks), in labor, with singleton pregnancies, using surface electrodes on the maternal abdomen.

The AN24 maternal-fetal monitor is intended for use by healthcare professionals in a clinical setting.

Technology Characteristics:
The Monica AN24 is a small, battery powered electrophysiological monitor (specifically fetal ECG and uterine EMG). The electrical signals are passively monitored on three channels using five electrodes placed on the pregnant abdomen in specific locations. From these electrical signals the Fetal Heart Rate (FHR) and

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Uterine Activity (UA) are continuously extracted and displayed in **the same standard format** as the predicate device.

The detection technology of the Monica AN24 differs from the predicate device which uses Doppler ultrasound to measure Fetal Heart Rate (FHR) and a tocodynamometer (TOCO) to measure Uterine Activity (UA). The predicate device detects the mechanical RR interval of the fetal heart whilst the Monica AN24 detects the electrical RR interval. However, from this data both instruments produce the same output i.e. fetal heart rate (expressed as number of heart beats per minute).

Uterine activity in the Monica AN24 is derived from the electrohysterogram which is the electric signal of the contracting/moving uterine muscle. The uterine activity in the TOCO predicate is derived from an external strain gauge to measure the abdominal pressure of the contracting/moving uterine muscle. However from this data both instruments produce the same uterine activity output trace.

For the actual detection of both FHR and UA the Monica AN24 does not emit any energy into the patient and hence the above differences in detection technology do not raise any new type of safety and effectiveness questions. In addition for FHR and uterine activity both the AN24 and predicate device are external, skin contacting devices. Differences in materials in contact with the patient are resolved with biocompatibility testing and compliance with standards.

To ensure clinical effectiveness the clinical performance data was collected as described in the "Clinical Study" section below. This study demonstrates that the Monica AN24 device is at least as accurate and reliable as the predicate device for monitoring both FHR and UA.

In summary, the differences in technology between the AN24 and the predicate device do not affect safety or effectiveness.

Clinical Study

1. Introduction

This section summarizes the six-way clinical equivalence trial and subsequent Multi-Reader-Multi-Case (MRMC) studyI supporting the effectiveness of the Monica AN24. The study enrolled 60 women at term, in labor, at two clinical sites, of which 33 women contributed to the Fetal Heart rate (FHR) study and 30 to the Uterine activity (UA) study. Each study subject was instrumented with three technologies for measuring fetal heart rate (FHR) and with three technologies for measuring uterine activity (UA). These are:

Fetal Heart Rate (FHR):

1) Doppler ultrasound cardiotocograph (Philips Series 50XM) – predicate device
2) Monica AN24 abdominal fetal ECG – test device
3) Direct fetal Scalp ECG (second Phillips Series 50XM device) – gold standard (GS)

Uterine Activity (UA):

1) Tocodynamometry (Philips Series 50XM) – predicate device
2) Monica AN24 Electrohysterogram (EHG) - test device
3) Intrauterine Pressure Catheter (IUPC), Philips Series 50XM – gold standard (GS)

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Using fetal scalp electrode and IUPC as the "gold standards", this study methodology allowed a six-way comparison for evaluating how well the Monica AN24 performed vs. Doppler for FHR measurement and Monica AN24 versus tocodynamometry for uterine activity.

2. Study Design

2.1 Study Objective

The primary objective was to demonstrate that during the intrapartum period the Monica AN24 is equivalent to the Doppler FHR and tocodynamometer-derived uterine activity when both are compared simultaneously to direct scalp FHR and IUPC uterine activity, respectively.

Inclusion Criteria:

- Pregnant, age 15-40
- Term gestation (>36 completed weeks)
- Singleton fetus
- Active labor
- Vertex presentation
- Requiring internal monitoring

Exclusion Criteria:

- Clinical contraindication for IUPC
- Major fetal malformation

2.2 Study Methodology

Each study subject agreed to be simultaneously instrumented with three different technologies for measuring FHR and with three different technologies for measuring uterine activity (UA). Sensors and/or catheters were applied and removed as clinically indicated. For the UA comparison, three 30-minute segments of data were randomly selected from the entire monitored period for each subject, two 30-minute tracings from Stage 1 and one 30-minute trace from Stage 2 of labor. Therefore, 90 minutes of recording was analyzed for each subject for UA. For the FHR comparison, all the FHR data was analyzed for the entire monitoring period when the direct scalp FHR data was present.

2.3 Outcome Measures

Both the Monica AN24 (FHR and EHG) and the predicate devices (Doppler or TOCO) were compared with the gold standard (GS) device (i.e. direct scalp fetal ECG or IUPC). Monica AN24 was tested against the predicates using null hypotheses of inferiority and alternative hypotheses of non-inferiority, for the measurement of FHR and UA in terms of: Interpretability and *Accuracy* - resulting in four separate endpoints as follows:

Fetal Heart Rate

The data from all 3 FHR instruments was processed into synchronized 0.25 second epochs. The following primary end points were calculated for FHR:

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End Point 1: For *FHR* interpretability the Monica FHR (or the Doppler FHR) versus the GS was organized into a 2x2 table of interpretable and uninterpretable data, i.e., where uninterpretable data are defined as those where the device in question does not report a valid FHR reading. A positive percent agreement (PPA) with GS was generated for each patient giving two values per patient – one for Monica AN24 vs GS and one for Doppler vs GS. PPA is defined as the percent of epochs with valid GS figures that are interpretable by the device in question

End Point 2: For FHR *accuracy*, a single Bland Altman (BA) difference plot was generated for Monica FHR (or Doppler FHR) vs the GS for each patient and a root mean square (RMS) error was determined for each device comparison. A BA difference plot is a scatter plot of the difference between the device and GS measurements vs. the GS measurement. RMS error is the square root of the mean of the squared differences.

Uterine Activity

The uterine activity data were independently reviewed in a Multi-Reader Study by four Board Certified Obstetricians who independently indicated on randomized trace segments the following features: "*Interpretable or Un-interpretable*" data, and "*Individual Contractions*", with each individual contraction marked as "*Good Quality*" or "*Bad Quality*". The marking was blind with respect to the device that produced the tracing. The four sets of data were again processed in terms of interpretability and accuracy. The following primary end points were calculated for UA:

End Point 3: For *UA interpretability*, a 2x2 Table of interpretable/uninterpretable data of Monica EHG (or TOCO) vs GS (IUPC) was constructed and the PPA was determined in the same manner as for FHR.

End Point 4a: For UA sensitivity accuracy, a Table of individual contractions identified by both Monica AN24 (or TOCO) and GS (IUPC) and those detected only by GS (IUPC) was constructed. To determine sensitivity, the proportion of contractions as determined by GS that were detected within ± 30 seconds by the device in question were calculated

End Point 4b: A second UA accuracy parameter (UA timing accuracy) was calculated as the difference in timing of corresponding contractions between Monica AN24 (or TOCO) and the GS (IUPC).

3. Description of Study Population

Thirty-four of 60 subjects enrolled provided evaluable data. Mean gestational age was 39 weeks 3 days (37 w 2d to 42 w 0d). Mean age was 26 years (18 to 38). Mean body mass index (BMI) was 32 (19 to 54). Thirty-one subjects were successfully instrumented with all six technologies, two subjects were successfully instrumented with three FHR technologies and one subject was successfully instrumented with three uterine activity technologies.

4. Results

The following key statistical outcomes, all validated with 95% confidence limits, were:

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FHR compared to fetal scalp ECG

1. FHR Interpretability: The mean positive percent agreement (PPA) for interpretable data for Monica was 85% compared with 72% for Doppler
2. FHR Accuracy: The mean RMS error from Bland Altman was 5 bpm for Monica compared with 12 bpm for Doppler, indicating that the Monica AN24 FHR output is more similar to the gold standard fetal scalp electrode measurement compared to Doppler.

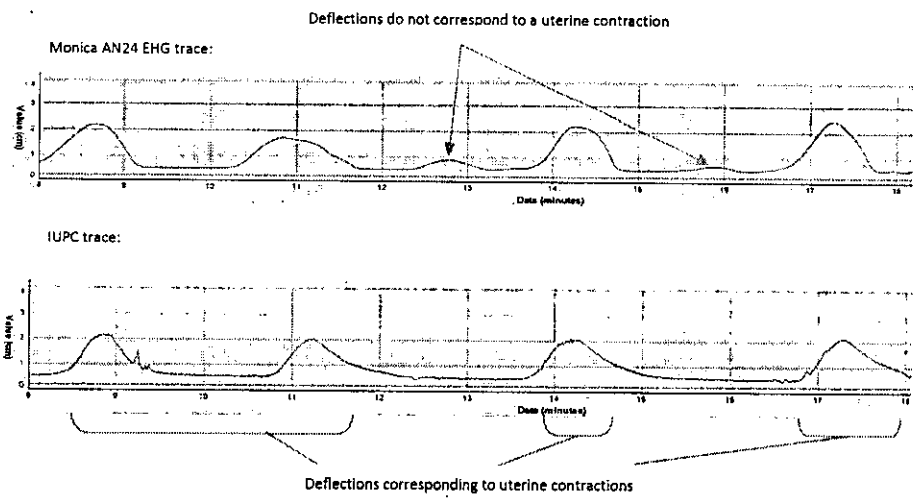
Uterine Activity compared to IUPC (average of 4 board certified obstetricians):

1. UA Interpretability: The mean PPA for UA trace interpretability of Monica was 97% compared with 67% for TOCO
2. UA Sensitivity Accuracy: The mean sensitivity for detecting individual contractions observed on IUPC, within ± 30 seconds, was 89% (84% to 91%) for Monica compared with 55% (48% to 62%) for TOCO.
3. UA Timing Accuracy: The mean timing difference of corresponding contractions was 2.5 seconds lag (2.06 to 2.94 seconds lag) when comparing Monica AN24 with IUPC and 3.3 seconds lag (2.92 to 3.69 seconds lag) when comparing TOCO with IUPC.

5. False Positives

When Monica AN24 or tocodynamometry tracings exhibit a deflection above baseline that does not have a corresponding deflection on the gold standard IUPC, that deflection may be considered a "False Positive" (FP). The Monica "Multi-Reader Study" evaluated the relative FP rate for Monica AN24 and tocodynamometry. The results of this analysis demonstrated that clinician judgement on individual deflections varied widely among the four clinical reviewers. Therefore, it is unclear whether comparison of the FP rate for Monica AN24 vs. tocodynamometry in the Multi-Reader Study is generalizable.

To illustrate how individual clinical judgment may vary, the following example displays a Monica AN24 tracing with two discernable deflections above baseline that do not correspond to deflections on the IUPC tracing:



If most or all of the types of Monica AN24 deflections above are counted as contractions, then the Monica AN24 may display more FP contractions compared to

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tocodynamometry. This difference, however, is unlikely to have an adverse impact on clinical outcomes in full term laboring patients.

5. Acknowledgements
Monica Healthcare Ltd, UK, would like to thank: the clinical teams at QHC, New York and Temple University, Philadelphia for undertaking this study and the USA mothers who kindly agreed to take part in the study.

Non Clinical Test Summary
The Monica AN24 and Accessories comply with voluntary standards. The standards were employed in the following areas:

- Electrical Safety
- EMC
- Material Safety
- Software Validation

Conclusion
The non clinical tests used voluntary standards employed at accredited independent test facilities to demonstrate that the Monica AN24 is as safe and effective in performance to the predicate device, the main standards employed were

- IEC60601-1 electrical safety
- IEC60601-1-2 EMC
- IEC 60601-1-2-47 Performance standard for electrocardiographs
- IEC60601-1-4 Software
- ISO10993 Biocompatibility
- ISO14385 QMS

To demonstrate that the Monica AN24 is as clinically safe and effective as the predicate device, the clinical study described above measured the clinical performance of the Monica AN24 and the predicate device against the gold standards fetal scalp ECG and IUPC. The outcomes showed that in a clinical setting the Monica AN24 achieved for FHR: a positive percent agreement (PPA) for interpretability of 85% compared to 72% for the predicate; whilst for accuracy a mean RMS error from Bland Altman of 5 bpm for Monica AN24 when compared with 12 bpm for the predicate. For Uterine Activity the Monica AN24 achieved: a mean PPA for interpretability of 97% compared with 67% for predicate (TOCO); whilst for accuracy the mean sensitivity for detecting individual contractions was 89% for Monica AN24 compared with 55% for the predicate (TOCO); further the mean timing difference of corresponding contractions was 2.5 seconds (lag) when comparing Monica AN24 with IUPC and 3.3 seconds (lag) when comparing TOCO with IUPC. The Monica AN24 had an increased false positive contraction count compared to the predicate however, this was not clinically significant.

The conclusions drawn from the nonclinical tests and clinical study demonstrate that the Monica AN24 is as safe, as effective and performs as safely and effectively as the legally marketed predicate device.

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Indications for Use Statement

510(k) Number (if known):

Device Name: AN24

Indications For Use:

The Monica AN24 is an intrapartum maternal-fetal monitor that non-invasively measures and displays fetal heart rate (FHR) and uterine activity (UA). The AN24 acquires and displays the FHR tracing from abdominal surface electrodes that pick up the fetal ECG (fECG) signal. Using the same surface electrodes, the AN24 also acquires and displays the UA tracing from the uterine electromyography (EMG) signal. The AN24 is indicated for use on women who are at term (>36 completed weeks), in labor, with singleton pregnancies, using surface electrodes on the maternal abdomen.

The AN24 maternal-fetal monitor is intended for use by healthcare professionals in a clinical setting.

Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

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Daws-Kopp, Kathryn S.

From: Ian How [ianhow@monicahealthcare.com]
Sent: Wednesday, January 19, 2011 2:09 PM
To: Daws-Kopp, Kathryn S.

(b)(4)

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From: Daws-Kopp, Kathryn S. [mailto:Kathryn.Daws-Kopp@fda.hhs.gov]
Sent: 18 January 2011 20:41
To: 'Ian How'

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From: Ian How [mailto:ianhow@monicahealthcare.com]
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To: Daws-Kopp, Kathryn S.

(b)(4) [redacted]

Regards

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From: Daws-Kopp, Kathryn S. [mailto:Kathryn.Daws-Kopp@fda.hhs.gov]

Records processed under FOIA Request #2015-4103; Released by CDRH on 06-06-2016.

See Data Statement on Reverse. Form Approved: OMB No. 0910-0616, Expiration Date: 10-31-2011

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Certification of Compliance, under 42 U.S.C. § 282(j)(5)(B), with Requirements of ClinicalTrials.gov Data Bank (42 U.S.C. § 282(j))

(For submission with an application/submission, including amendments, supplements, and resubmissions, under §§ 505, 515, 520(m), or 510(k) of the Federal Food, Drug, and Cosmetic Act or § 351 of the Public Health Service Act.)

SPONSOR / APPLICANT / SUBMITTER INFORMATION

1. NAME OF SPONSOR/APPLICANT/SUBMITTER
Monica Healthcare Ltd

2. DATE OF THE APPLICATION/SUBMISSION WHICH THIS CERTIFICATION ACCOMPANIES
28 JUNE 2010

3. ADDRESS *(Number, Street, State, and ZIP Code)*
Biocity
Pennyfoot Street
Nottingham NG1 1GF
UK

4. TELEPHONE AND FAX NUMBERS *(Include Area Code)*
(Tel.) +44 115 912 4540
(Fax) +44 115 912 4289

PRODUCT INFORMATION

5. FOR DRUGS/BIOLOGICS: Include Any/All Available Established, Proprietary and/or Chemical/Biochemical/Blood/Cellular/Gene Therapy Product Name(s)
FOR DEVICES: Include Any/All Common or Usual Name(s), Classification, Trade or Proprietary or Model Name(s) and/or Model Number(s)
(Attach extra pages as necessary)

Common Name: Fetal Heart Rate Monitor
Classification: Class II
Trade Name: Fetal Monitor
Model: AN24

APPLICATION / SUBMISSION INFORMATION

6. TYPE OF APPLICATION/SUBMISSION WHICH THIS CERTIFICATION ACCOMPANIES
☐ IND ☐ NDA ☐ ANDA ☐ BLA ☐ PMA ☐ HDE ☒ 510(k) ☐ PDP ☐ Other

7. INCLUDE IND/NDA/ANDA/BLA/PMA/HDE/510(k)/PDP/OTHER NUMBER *(If number previously assigned)*

8. SERIAL NUMBER ASSIGNED TO APPLICATION/SUBMISSION WHICH THIS CERTIFICATION ACCOMPANIES

CERTIFICATION STATEMENT / INFORMATION

9. CHECK ONLY ONE OF THE FOLLOWING BOXES *(See instructions for additional information and explanation)*

☐ A. I certify that the requirements of 42 U.S.C. § 282(j), Section 402(j) of the Public Health Service Act, enacted by 121 Stat. 823, Public Law 110-85, do not apply because the application/submission which this certification accompanies does not reference any clinical trial.

☐ B. I certify that the requirements of 42 U.S.C. § 282(j), Section 402(j) of the Public Health Service Act, enacted by 121 Stat. 823, Public Law 110-85, do not apply to any clinical trial referenced in the application/submission which this certification accompanies.

☒ C. I certify that the requirements of 42 U.S.C. § 282(j), Section 402(j) of the Public Health Service Act, enacted by 121 Stat. 823, Public Law 110-85, apply to one or more of the clinical trials referenced in the application/submission which this certification accompanies and that those requirements have been met.

10. IF YOU CHECKED BOX C, IN NUMBER 9, PROVIDE THE NATIONAL CLINICAL TRIAL (NCT) NUMBER(S) FOR ANY "APPLICABLE CLINICAL TRIAL(S)," UNDER 42 U.S.C. § 282(j)(1)(A)(i), SECTION 402(j)(1)(A)(i) OF THE PUBLIC HEALTH SERVICE ACT, REFERENCED IN THE APPLICATION/ SUBMISSION WHICH THIS CERTIFICATION ACCOMPANIES *(Attach extra pages as necessary)*
NCT Number(s): NCT01280357

The undersigned declares, to the best of her/his knowledge, that this is an accurate, true, and complete submission of information. I understand that the failure to submit the certification required by 42 U.S.C. § 282(j)(5)(B), section 402(j)(5)(B) of the Public Health Service Act, and the knowing submission of a false certification under such section are prohibited acts under 21 U.S.C. § 331, section 301 of the Federal Food, Drug, and Cosmetic Act.
Warning: A willfully and knowingly false statement is a criminal offense, U.S. Code, title 18, section 1001.

11. SIGNATURE OF SPONSOR/APPLICANT/SUBMITTER OR AN AUTHORIZED REPRESENTATIVE (Sign)

12. NAME AND TITLE OF THE PERSON WHO SIGNED IN NO. 11
(Name) Ian How
(Title) Regulatory Affairs Manager

13. ADDRESS *(Number, Street, State, and ZIP Code) (of person identified in Nos. 11 and 12)*
Biocity
Pennyfoot Street
Nottingham NG1 1GFUK

14. TELEPHONE AND FAX NUMBERS *(Include Area Code)*
(Tel.) +44 115 912 4540
(Fax) +44 115 912 4289

15. DATE OF CERTIFICATION
18 January 2011

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

Records processed under FOIA Request #2015-4103; Released by CDRH on 06-06-2016.

Instructions for Completion of Form FDA 3674

Certification of Compliance, under 42 U.S.C. § 282(j)(5)(B), with Requirements of ClinicalTrials.gov Data Bank (42 U.S.C. § 282(j))
Form 3674 must accompany an application/submission, including amendments, supplements, and resubmissions, submitted under §§ 505, 515, 520(m), or 510(k) of the Federal Food, Drug, and Cosmetic Act or § 351 of the Public Health Service Act.

1. **Name of Sponsor/Applicant/Submitter** - This is the name of the sponsor/applicant/submitter of the drug/biologic/device application/submission which the certification accompanies. The name must be identical to that listed on the application/submission.
2. **Date** - This is the date of the application/submission which the certification accompanies.
3. & 4. - Provide complete address, telephone number and fax number of the sponsor/applicant/submitter.
5. **Product Information** - For **Drugs/Biologics:** Provide the established, proprietary name, and/or chemical/biochemical/blood product/cellular/gene therapy name(s) for the product covered by the application/submission. Include all available names by which the product is known. For **Devices:** Provide the common or usual name, classification, trade or proprietary or model name(s), and/or model number(s). Include all available names/model numbers by which the product is known.
6. **Type of Application/Submission** - Identify the type of application/submission which the certification accompanies by checking the appropriate box. If the name of the type of application/submission is not identified, check the box labeled "Other."
7. **IND/NDA/ANDA/BLA/PMA/HDE/510(k)/PDP/Other Number** - If FDA has previously assigned a number associated with the application/submission which this certification accompanies, list that number in this field. For example, if the application/submission accompanied by this certification is an IND protocol amendment and the IND number has already been issued by FDA, that number should be provided in this field.
8. **Serial Number** - In some instances a sequential serial number is assigned to the application. If there is such a serial number, provide it in this field. If there is no such number, leave this field blank.
9. **Certification** - This section contains three different check-off boxes.

   Box A should be checked if the sponsor/applicant/submitter has concluded that the requirements of 42 U.S.C. § 282(j), section 402(j) of the Public Health Service Act, do not apply because no clinical trials are included, relied upon, or otherwise referred to, in the application/submission which the certification accompanies.

   Box B should be checked if the sponsor/applicant/submitter has concluded that the requirements of 42 U.S.C. § 282(j), section 402(j) of the Public Health Service Act, do not apply at the time of submission of the certification to any clinical trials that are included, relied upon, or otherwise referred to, in the application/submission which the certification accompanies. This means that, even though some or all of the clinical trials included, relied upon, or otherwise referred to in the application/submission may be "applicable clinical trials" under 42 U.S.C. § 282(j)(1)(A)(i), section 402(j)(1)(A)(i) of the Public Health Service Act, on the date the certification is signed, 42 U.S.C. § 282(j), section 402(j) of the Public Health Service Act, does not require that any information be submitted to the ClinicalTrials.gov Data Bank with respect to those clinical trials.

   Box C should be checked if the sponsor/applicant/submitter has concluded that the requirements of 42 U.S.C. § 282(j), section 402(j) of the Public Health Service Act, do apply, on the date the certification is signed, to some or all of the clinical trials that are included, relied upon, or otherwise referred to, in the application/submission which the certification accompanies. This means that, as of the date the certification is signed, the requirements of 42 U.S.C. § 282(j), section 402(j) of the Public Health Service Act, apply to one or more of the clinical trials included, relied upon, or otherwise referred to, in the application/submission which this certification accompanies.
10. **National Clinical Trial (NCT) Numbers** - If you have checked Box C in number 9 (Certification), provide the NCT Number obtained from www.ClinicalTrials.gov for each clinical trial that is an "applicable clinical trial" under 42 U.S.C. § 282(j)(1)(A)(i), section 402(j)(1)(A)(i) of the Public Health Service Act, and that is included, relied upon, or otherwise referred to, in the application/submission which the certification accompanies. Type only the number, as the term "NCT" will be added automatically before number. Include any and all NCT numbers that, as of the date the certification is signed, have been assigned to the clinical trials included, relied upon, or otherwise referred to, in the application/submission which this certification accompanies. Multiple NCT numbers may be required for a particular certification, depending on the number of "applicable clinical trials" included, relied upon, or otherwise referred to, in the application/submission which the certification accompanies. Leave this field blank if you have checked Box 9.C but, at the time the certification is completed, you have not yet received any NCT numbers for the "applicable clinical trial(s)" included, relied upon, or otherwise referred to in the application/submission.
11. **Signature of Sponsor/Applicant/Submitter or an Authorized Representative** - The person signing the certification must sign in this field.
12. **Name and Title of Person Who Signed In number 11** - Include the name and title of the person who is signing the certification. If the person signing the certification is not the sponsor/applicant/submitter of the application/submission, he or she must be an authorized representative of the sponsor/applicant/submitter.
13. & 14. - Provide the full address, telephone and fax numbers of the person who is identified in number 11 and signs the certification in number 11.
15. Provide the date the certification is signed. This date may be different from the date provided in number 2.

Paperwork Reduction Act Statement

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Department of Health and Human Services
Food and Drug Administration
Office of the Chief Information Officer (HFA-250)
5600 Fishers Lane
Rockville, MD 20857

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

Records processed under FOIA Request #2015-4103; Released by CDRH on 06-06-2016.

Daws-Kopp, Kathryn S.

From: Ian How [ianhow@monicahealthcare.com]
Sent: Tuesday, December 14, 2010 7:37 AM
To: Daws-Kopp, Kathryn S.

(b)(4) [redacted]

Regards

Ian How
Regulatory Affairs Manager
Monica Healthcare Ltd
Tel: +44 (0) 115 912 4541
Fax: +44 (0) 115 912 4289
Mob: +44 (0) 7984540013
Web: www.monicahealthcare.com
Email: ianhow@monicahealthcare.com

Corporate Name: Monica Healthcare Ltd
Registration: Companies House, Cardiff, UK
Reg Number: 5439443
Reg Office Address: Monica Healthcare Ltd
Biocity
Pennyfoot Street
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UK

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From: Daws-Kopp, Kathryn S. [mailto:Kathryn.Daws-Kopp@fda.hhs.gov]
Sent: 10 December 2010 23:44
To: 'Ian How'
(b)(4) [redacted]

Records processed under FOIA Request #2015-4103; Released by CDRH on 06-06-2016.

(b)(4)

[redacted]

Kathy

Obstetrics and Gynecology Devices Branch
Division of Reproductive, Abdominal, and
Radiological Devices
ODE/CDRH

New phone: 301-796-6535

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

Records processed under FOIA Request #2015-4103; Released by CDRH on 06-06-2016.

Daws-Kopp, Kathryn S.

From: Ian How [ianhow@monicahealthcare.com]
Sent: Wednesday, December 15, 2010 8:18 AM
To: Daws-Kopp, Kathryn S.
Subject: RE:
Attachments: 100-TF-006 - rev Ib - AN24 Reference Operating Manual _USA_.pdf

(b)(4) [redacted]

Regards

Ian How
Regulatory Affairs Manager
Monica Healthcare Ltd
Tel: +44 (0) 115 912 4541
Fax: +44 (0) 115 912 4289
Mob: +44 (0) 7984540013
Web: www.monicahealthcare.com
Email: ianhow@monicahealthcare.com

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From: Daws-Kopp, Kathryn S. [mailto:Kathryn.Daws-Kopp@fda.hhs.gov]
Sent: 14 December 2010 21:07
To: 'Ian How'
Subject:

(b)(4) [redacted]

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(b)(4) [redacted]

Kathy

Obstetrics and Gynecology Devices Branch
Division of Reproductive, Abdominal, and Radiological Devices
ODE/CDRH

New phone: 301-796-6535

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Daws-Kopp, Kathryn S.

From: Ian How [ianhow@monicahealthcare.com]
Sent: Wednesday, December 15, 2010 8:57 AM
To: Daws-Kopp, Kathryn S.
Subject: RE: K101801

(b)(4) [redacted]

Regards

Ian How
Regulatory Affairs Manager
Monica Healthcare Ltd
Tel: +44 (0) 115 912 4541
Fax: +44 (0) 115 912 4289
Mob: +44 (0) 7984540013
Web: www.monicahealthcare.com
Email: ianhow@monicahealthcare.com

Corporate Name: Monica Healthcare Ltd
Registration: Companies House, Cardiff, UK
Reg Number: 5439443
Reg Office Address: Monica Healthcare Ltd
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From: Daws-Kopp, Kathryn S. [mailto:Kathryn.Daws-Kopp@fda.hhs.gov]
Sent: 14 December 2010 20:19
To: 'Ian How'
Cc: Pollard, Colin M.; Biswas, Bipasa; Corrado, Julia A
Subject: RE: K101801

(b)(4) [redacted]

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

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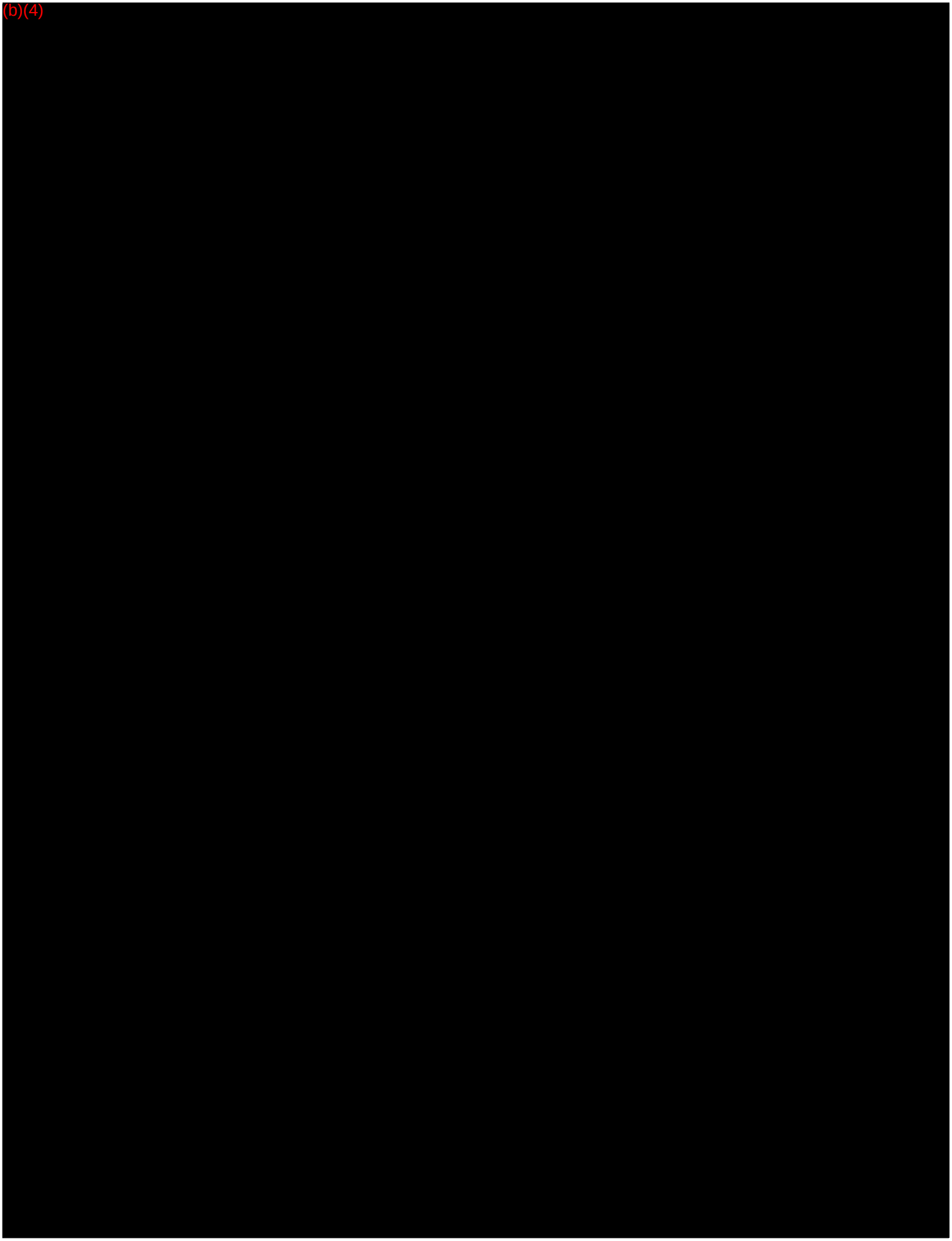
(b)(4)



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

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(b)(4)

[redacted]

Kathy

Obstetrics and Gynecology Devices Branch
Division of Reproductive, Abdominal, and
Radiological Devices
ODE/CDRH

New phone: 301-796-6535

From: Ian How [mailto:ianhow@monicahealthcare.com]
Sent: Tuesday, December 14, 2010 2:20 PM
To: Daws-Kopp, Kathryn S.
Subject: RE: K101801

Kathy
Please see attached

Regards

Ian How
Regulatory Affairs Manager
Monica Healthcare Ltd
Tel: +44 (0) 115 912 4541
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From: Daws-Kopp, Kathryn S. [mailto:Kathryn.Daws-Kopp@fda.hhs.gov]
Sent: 14 December 2010 19:01
To: 'Ian How'
Subject: RE: K101801

(b)(4)

[redacted]

Kathy

Obstetrics and Gynecology Devices Branch
Division of Reproductive, Abdominal, and
Radiological Devices
ODE/CDRH

New phone: 301-796-6535

From: Ian How [mailto:ianhow@monicahealthcare.com]
Sent: Tuesday, November 30, 2010 2:09 PM
To: Daws-Kopp, Kathryn S.
Subject: RE: K101801

(b)(4)

[redacted]

Records processed under FOIA Request #2015-4103; Released by CDRH on 06-06-2016.

Regards

[redacted]

Ian How
Regulatory Affairs Manager
Monica Healthcare Ltd
Tel: +44 (0) 115 912 4541
Fax: +44 (0) 115 912 4289
Mob: +44 (0) 7984540013
Web: www.monicahealthcare.com
Email: ianhow@monicahealthcare.com

Corporate Name: Monica Healthcare Ltd
Registration: Companies House, Cardiff, UK
Reg Number: 5439443
Reg Office Address: Monica Healthcare Ltd
Biocity
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From: Daws-Kopp, Kathryn S. [mailto:Kathryn.Daws-Kopp@fda.hhs.gov]
Sent: 22 November 2010 20:02
To: 'Ian How'
Subject: K101801

To: Monica Healthcare Ltd
Ian How, Regulatory Affairs Manager
email: ianhow@monicahealthcare.com
Phone: 44 (0) 115 912 4540
Fax: 44 (0) 115 912 4289

From: Kathryn S. Daws-Kopp
Electrical Engineer
OB/GYN Devices Branch (HFZ-470)

Date: November 22, 2010
Subject: K101801

(b)(4)

[redacted]

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

172

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(b)(4)

[redacted]

Kathy

Obstetrics and Gynecology Devices Branch
Division of Reproductive, Abdominal, and
Radiological Devices
ODE/CDRH

New phone: 301-796-6535

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

173

Records processed under FOIA Request #2015-4103; Released by CDRH on 06-06-2016.

Daws-Kopp, Kathryn S.

From: Ian How [ianhow@monicahealthcare.com]
Sent: Monday, December 13, 2010 7:59 AM
To: Daws-Kopp, Kathryn S.
Subject: RE: More questions--K101801

(b)(4) [redacted]

Regards

Ian How
Regulatory Affairs Manager
Monica Healthcare Ltd
Tel: +44 (0) 115 912 4541
Fax: +44 (0) 115 912 4289
Mob: +44 (0) 7984540013
Web: www.monicahealthcare.com
Email: ianhow@monicahealthcare.com

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Reg Office Address: Monica Healthcare Ltd
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From: Daws-Kopp, Kathryn S. [mailto:Kathryn.Daws-Kopp@fda.hhs.gov]
Sent: 10 December 2010 22:02
To: 'Ian How'
Subject: RE: More questions--K101801

(b)(4) [redacted]

Records processed under FOIA Request #2015-4103; Released by CDRH on 06-06-2016.

can't find where we ever got modified plots for fetal heart rate.

(b)(4)

[redacted]

Kathy

Obstetrics and Gynecology Devices Branch
Division of Reproductive, Abdominal, and
Radiological Devices
ODE/CDRH

New phone: 301-796-6535

From: Daws-Kopp, Kathryn S.
Sent: Friday, December 10, 2010 11:37 AM
To: 'Ian How'
Subject: RE: More questions--K101801

Monday is okay. thanks.

[redacted]

Kathy

Obstetrics and Gynecology Devices Branch
Division of Reproductive, Abdominal, and
Radiological Devices
ODE/CDRH

New phone: 301-796-6535

From: Ian How [mailto:ianhow@monicahealthcare.com]
Sent: Friday, December 10, 2010 6:43 AM
To: Daws-Kopp, Kathryn S.
Subject: RE: More questions--K101801

(b)(4)

[redacted]

Regards

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

INS

Records processed under FOIA Request #2015-4103; Released by CDRH on 06-06-2016.

Ian How
Regulatory Affairs Manager
Monica Healthcare Ltd
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Fax: +44 (0) 115 912 4289
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Web: www.monicahealthcare.com
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From: Daws-Kopp, Kathryn S. [mailto:Kathryn.Daws-Kopp@fda.hhs.gov]
Sent: 09 December 2010 22:48
To: 'Ian How'
Subject: FW: More questions--K101801

(b)(4) [redacted]

Kathy

Obstetrics and Gynecology Devices Branch
Division of Reproductive, Abdominal, and
Radiological Devices
ODE/CDRH

New phone: 301-796-6535

From: Biswas, Bipasa
Sent: Thursday, December 09, 2010 4:20 PM
To: Daws-Kopp, Kathryn S.
Subject: RE: More questions--K101801

Kathy,

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

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Records processed under FOIA Request #2015-4103; Released by CDRH on 06-06-2016.

(b)(4)

[redacted]

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

Records processed under FOIA Request #2015-4103; Released by CDRH on 06-06-2016.

Monica Healthcare Limited
Biocity, Pennyfoot Street, Nottingham, NG1 1GF, UK
T +44 (0)115 912 4540 / F +44 (0)115 912 4289 / E info@monicahealthcare.com
www.monicahealthcare.com

Ms Kathy Daws - Kopp
Food And Drug Administration
Centre for Devices and Radiological Health
Document Mail Centre – WO66 – G609
10903 New Hampshire Avenue
Silver Spring, Maryland USA 20993-0002

13th December 2010

Reference: K1010801
Trade Name : Monica AN24

Dear Kathy,

(b)(4) Deficiencies

[redacted]

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

18

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T +44 (0)115 912 4540 / F +44 (0)115 912 4289 / E info@monicahealthcare.com
www.monicahealthcare.com

(b)(4) Deficiencies

[redacted]

Yours sincerely,

Ian How
Regulatory Affairs Manager

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

(b)(4) Deficiencies

(b)(4) Deficiencies

(b)(4) Deficiencies

Records processed under FOIA Request #2015-4103; Released by CDRH on 06-06-2016.

Product	Monica AN24 Abdominal Fetal/Maternal Monitor
Document name	Clinical Investigation Report Supplement – Fetal Heart Rate Accuracy during Labor and Delivery For Patients ≥37 Weeks gestation
Document type	**Clinical Trial Report Supplement**

(b) (4) [redacted]

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Food and Drug Administration
Office of Device Evaluation &
Office of In Vitro Diagnostics

COVER SHEET MEMORANDUM

From: Reviewer Name Kathy Dow-Hoop

Subject: 510(k) Number K101801/S1

To: The Record

Please list CTS decision code TH

- ☐ Refused to accept (Note: this is considered the first review cycle, See Screening Checklist http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_5631/Screening%20Checklist%207%202%2007.doc)
- ☐ Hold (Additional Information or Telephone Hold).
- ☐ Final Decision (SE, SE with Limitations, NSE, Withdrawn, etc.).

Please complete the following for a final clearance decision (i.e., SE, SE with Limitations, etc.):		YES	NO
Indications for Use Page	*Attach IFU*		
510(k) Summary /510(k) Statement	*Attach Summary*		
Truthful and Accurate Statement.	*Must be present for a Final Decision*		
Is the device Class III? If yes, does firm include Class III Summary?	*Must be present for a Final Decision*		
Does firm reference standards? (If yes, please attach form from http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3654.pdf)			
Is this a combination product? (Please specify category _____, see http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_413b/COMBINATION%20PRODUCT%20ALGORITHM%20(REVISED%203-12-03).DOC			
Is this a reprocessed single use device? (Guidance for Industry and FDA Staff – MDUFMA - Validation Data in 510(k)s for Reprocessed Single-Use Medical Devices, http://www.fda.gov/cdrh/ode/guidance/1216.html)			
Is this device intended for pediatric use only?			
Is this a prescription device? (If both prescription & OTC, check both boxes.)			
Did the application include a completed FORM FDA 3674, Certification with Requirements of ClinicalTrials.gov Data Bank?			
Is clinical data necessary to support the review of this 510(k)? Did the application include a completed FORM FDA 3674, *Certification with Requirements of ClinicalTrials.gov Data Bank*? (If not, then applicant must be contacted to obtain completed form.)			
Does this device include an Animal Tissue Source?			
All Pediatric Patients age<=21			
Neonate/Newborn (Birth to 28 days)			
Infant (29 days -< 2 years old)			
Child (2 years -< 12 years old)			
Adolescent (12 years -< 18 years old)			
Transitional Adolescent A (18 - <21 years old) Special considerations are being given to this group, different from adults age ≥ 21 (different device design or testing, different protocol procedures, etc.)			

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Transitional Adolescent B (18 -<= 21; No special considerations compared to adults => 21 years old)	
Nanotechnology	
Is this device subject to the Tracking Regulation? (Medical Device Tracking Guidance, http://www.fda.gov/cdrh/comp/guidance/169.html)	*Contact OC.*

Regulation Number **Class*** **Product Code**

_____

(*If unclassified, see 510(k) Staff)

Additional Product Codes: _____

Review: _____

(Branch Chief) (Branch Code) (Date)

Final Review: _____

(Division Director) (Date)

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

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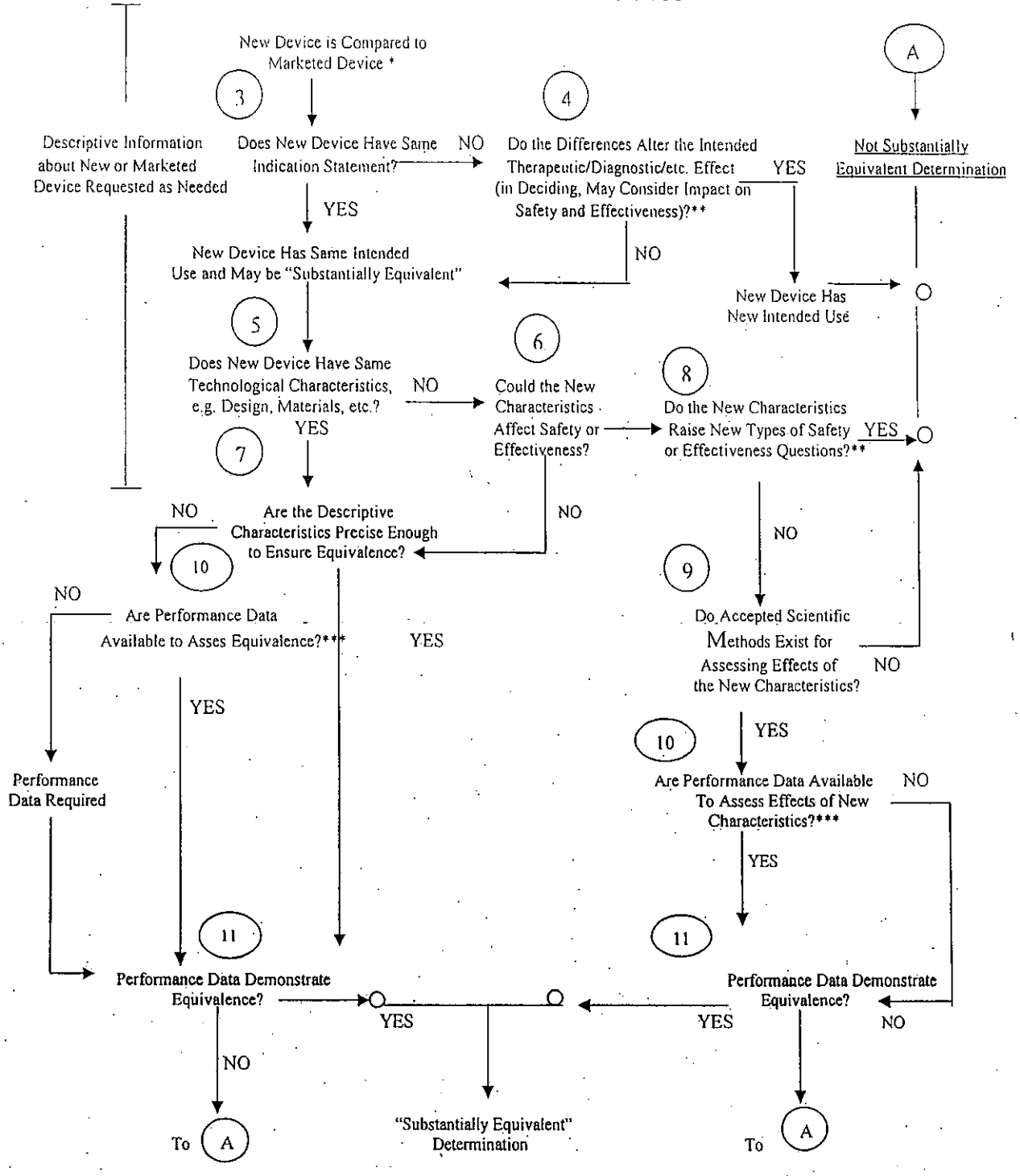
510(k) "SUBSTANTIAL EQUIVALENCE" DECISION-MAKING PROCESS



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Food and Drug Administration
Office of Device Evaluation &
Office of In Vitro Diagnostics

COVER SHEET MEMORANDUM

From: Reviewer Name — Kathy Dowt-Kopp

Subject: 510(k) Number — K101807

To: The Record

Please list CTS decision code AT

- ☐ Refused to accept (Note: this is considered the first review cycle, See Screening Checklist http://eroom.fda.gov/eRoomReg/Files/CDRH3/CDRHPremarketNotification510kProgram/0_5631/Screening%20Checklist%207%202%2007.doc)
- ☒ Hold (Additional Information or Telephone Hold).
- ☐ Final Decision (SE, SE with Limitations, NSE, Withdrawn, etc.).

Please complete the following for a final clearance decision (i.e., SE, SE with Limitations, etc.):		YES	NO
Indications for Use Page	*Attach IFU*	✓	
510(k) Summary /510(k) Statement	*Attach Summary*		
Truthful and Accurate Statement.	*Must be present for a Final Decision*		
Is the device Class III? If yes, does firm include Class III Summary?	*Must be present for a Final Decision*		
Does firm reference standards? (If yes, please attach form from http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3654.pdf)			
Is this a combination product? (Please specify category _____, see http://eroom.fda.gov/eRoomReg/Files/CDRH3/CDRHPremarketNotification510kProgram/0_413b/COMBINATION%20PRODUCT%20ALGORITHM%20(REVISED%203-12-03).DOC			
this a reprocessed single use device? (Guidance for Industry and FDA Staff – MDUFMA - Validation Data in 510(k)s for Reprocessed Single-Use Medical Devices, http://www.fda.gov/cdrh/ode/guidance/1216.html)			
Is this device intended for pediatric use only?			
Is this a prescription device? (If both prescription & OTC, check both boxes.)			
Did the application include a completed FORM FDA 3674, Certification with Requirements of ClinicalTrials.gov Data Bank?			
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All Pediatric Patients age<=21			
Neonate/Newborn (Birth to 28 days)			
Infant (29 days -< 2 years old)			
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Adolescent (12 years -< 18 years old)			
Transitional Adolescent A (18 - <21 years old) Special considerations are being given to this ...up, different from adults age ≥ 21 (different device design or testing, different protocol ...ures, etc.)			

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Transitional Adolescent B (18 -<= 21; No special considerations compared to adults => 21 years old)			
Nanotechnology			
Is this device subject to the Tracking Regulation? (Medical Device Tracking Guidance, http://www.fda.gov/cdrh/comp/guidance/169.html)	*Contact OC.*		

Regulation Number 21 CFR 884.2740 **Class*** II **Product Code** HGM

(*If unclassified, see 510(k) Staff)

Additional Product Codes:

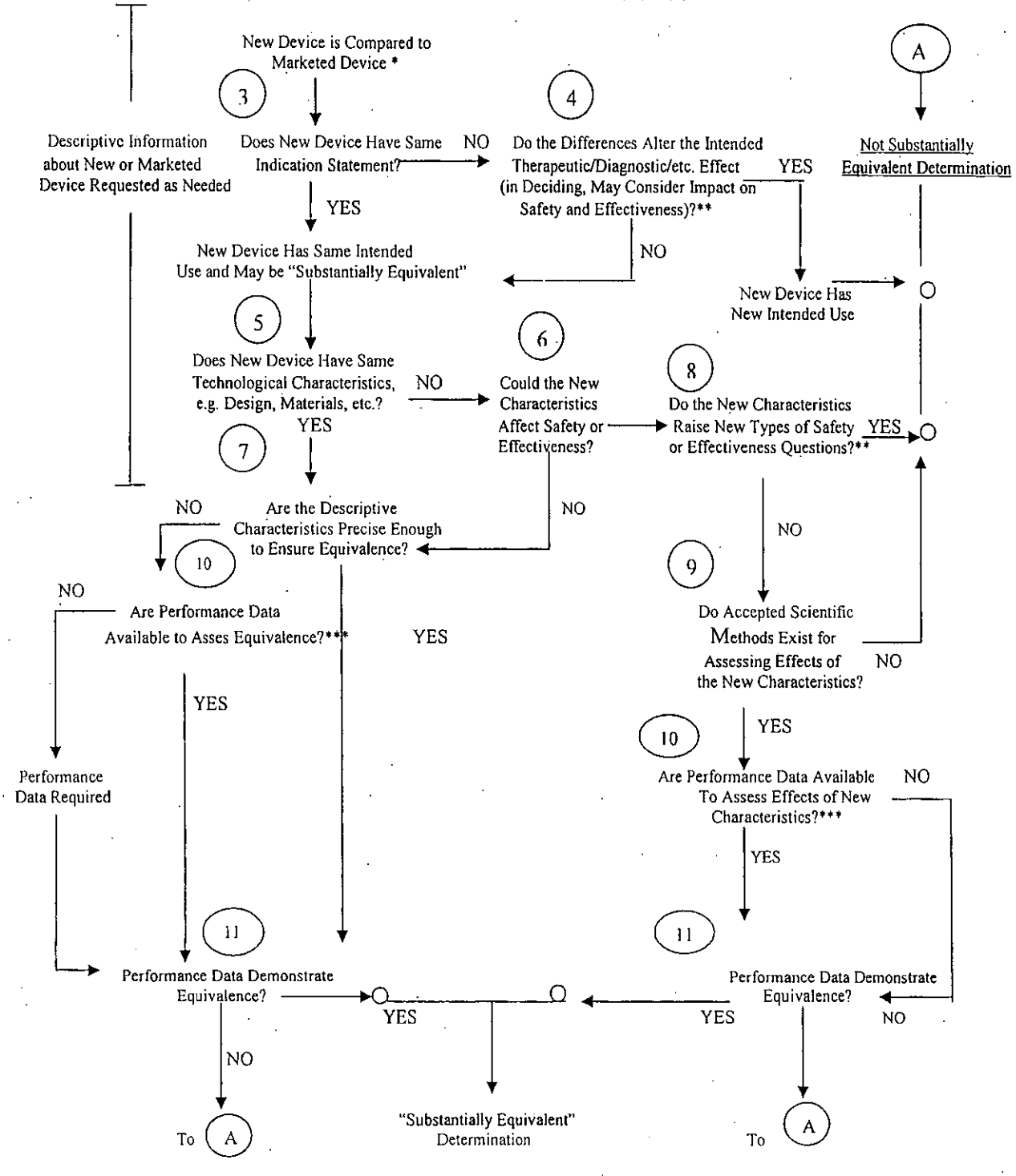
Review: Colin M Pollard (Branch Chief) OGDB (Branch Code) 8/20/10 (Date)

Final Review:

(Division Director) (Date)

Records processed under FOIA Request #2015-4103; Released by CDRH on 06-06-2016.

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



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DEPARTMENT OF HEALTH AND HUMAN SERVICES MEMORANDUM

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

Premarket Notification [510(k)] Review
Traditional/Abbreviated

(b)(4) and (b)(5) FDA Review

[redacted]

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

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Ambu

Ideas that work for life

Key Features

- Highly conductive wet gel
- Combination of instant and long-term adhesives
- Breathable microporous material
- Special soft sponge
- Unique offset concept
- High-quality Ag/AgCl sensor
- Available with preattached lead wire

Ambu® **Blue Sensor VLC**

The very large Ambu Blue Sensor VLC features highly conductive wet gel and a combination of instant and long-term adhesives for excellent contact and stable signals throughout the monitoring period. To avoid reactions on sensitive skin, a special soft sponge is used in the gel area. And thanks to the low-profile microporous material, skin is able to breathe so the electrode remains comfortable to wear over long periods. The VLC is also available with a pre-attached lead wire.

LIFETIME

Recommended application time (max.)	48 hours
In opened pouches	1 month
Unopened pouches*	12 months

* from date of production

X-RAY & MRI

X-ray-translucent	No
MRI-safe	No

DIMENSIONS

Electrode size (max. L x W or diameter in mm)	72 x 68
Skin contact size (max. L x W or diameter in mm)	68
Adhesive area (in mm²)	3377
Height excluding connector/wire (in mm)	1

SENSOR

Sensor material	Silver/silver chloride (Ag/AgCl)
Gel system	Wet gel
Sensor area* (in mm²)	20.8 / 22.4
Gel area/measuring area (in mm²)	254

*non-wire/wire

ELECTRICAL DATA (ANSI/AAMI)

AC impedance - typical	500 Ω
DC offset voltage - typical	0.2 mV
Defibrillation overload recovery - typical	7.4 mV
Rate of change of polarization potential- typical	0.2 mV/s
Combined offset instability and internal noise	<15 µV
Bias current tolerance (over 8 hours)	<5 mV

CARDIOLOGY

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

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Ambu

Ideas that work for life

ENVIRONMENT

PVC-free electrode	No
Latex-free electrode	Yes
PVC-free lead wire	No
Latex-free lead wire	Yes
PVC-free packaging	Yes

STANDARD PACKAGING

Quantity/liner	1
Quantity/pouch	4, 10, 25
Quantity/box	500/1000
Minimum sales	1000

OPTIONS

Connectors	S
Pre-wired	Yes
Pre-wired connectors	K

AVAILABLE CONFIGURATIONS*

Quantity/pouch	4	10	25
	Qty per inner/outer box		
VLC-00-S	500/1000	500/1000	500/1000
VLC-50-K			500/1000

* Some configurations may not be available worldwide.

VLC-00-S
- PRODUCT
- WIRE LENGTH
- CONNECTOR

PRECAUTION

Single patient use only

MATERIALS - ELECTRODE

Bio-compatible	Yes
Sensor	Silver/silver chloride (Ag/AgCl)
Sponge	Polyurethane foam/microporous (non woven rayon)
Outer carrier	Microporous tape (non woven rayon)
Outer adhesive	Acrylate
Inner carrier (if any)	Polyvinyl chloride film (PVC)
Inner adhesive (if any)	Acrylate
Upper part	Polyvinyl chloride film (PVC)
Fitting	Polypropylene
Connector (stud)	Nickel-plated brass
Lead-wire core	Copper
Lead-wire insulation	Polyvinyl chloride (PVC)
Lead-wire connector	Brass/polypropylene (PP)
Liner	Polyester/polyethylene film (PET/PE)

MATERIALS - PACKAGING

Pouches, inner layer	Polyethylene (PE)
Pouches, centre layer	Aluminium (Al)
Pouches, outer layer	Polyester (PET)
Boxes	Cardboard

CONNECTORS:

S = Stud

PRE-WIRED CONNECTORS:

K = 1.5 mm connector

Ambu A/S
Baltorpbakken 13
DK-2750 Ballerup
Denmark
T +45 72 25 20 00
F +45 72 25 20 50
www.ambu.com

CARDIOLOGY

CE US: Rx only

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

493 1021 01 - 05/2008 - Ambu A/S - Technical data may be modified without further notice.

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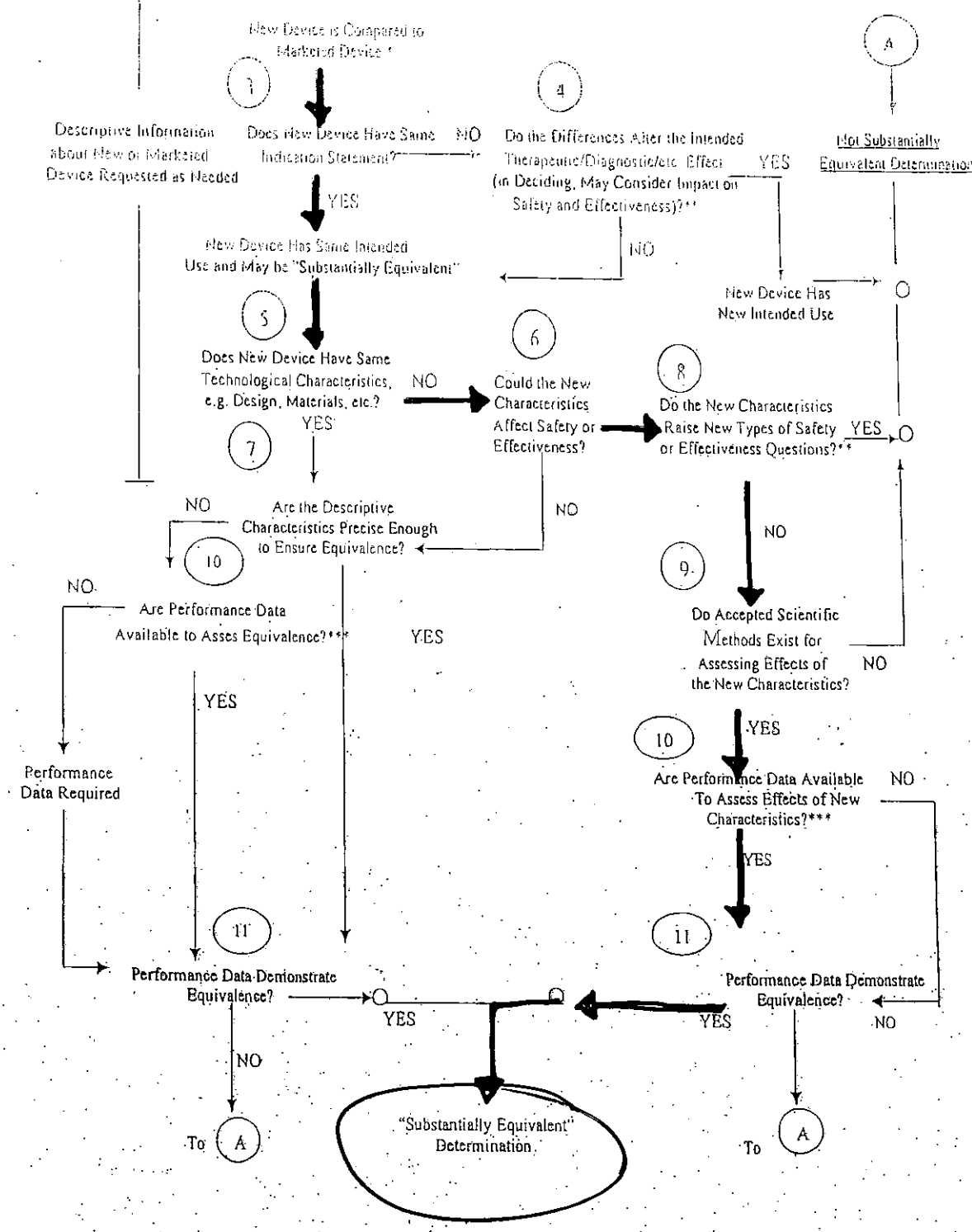
510(k) "SUBSTANTIAL EQUIVALENCE" DECISION-MAKING PROCESS



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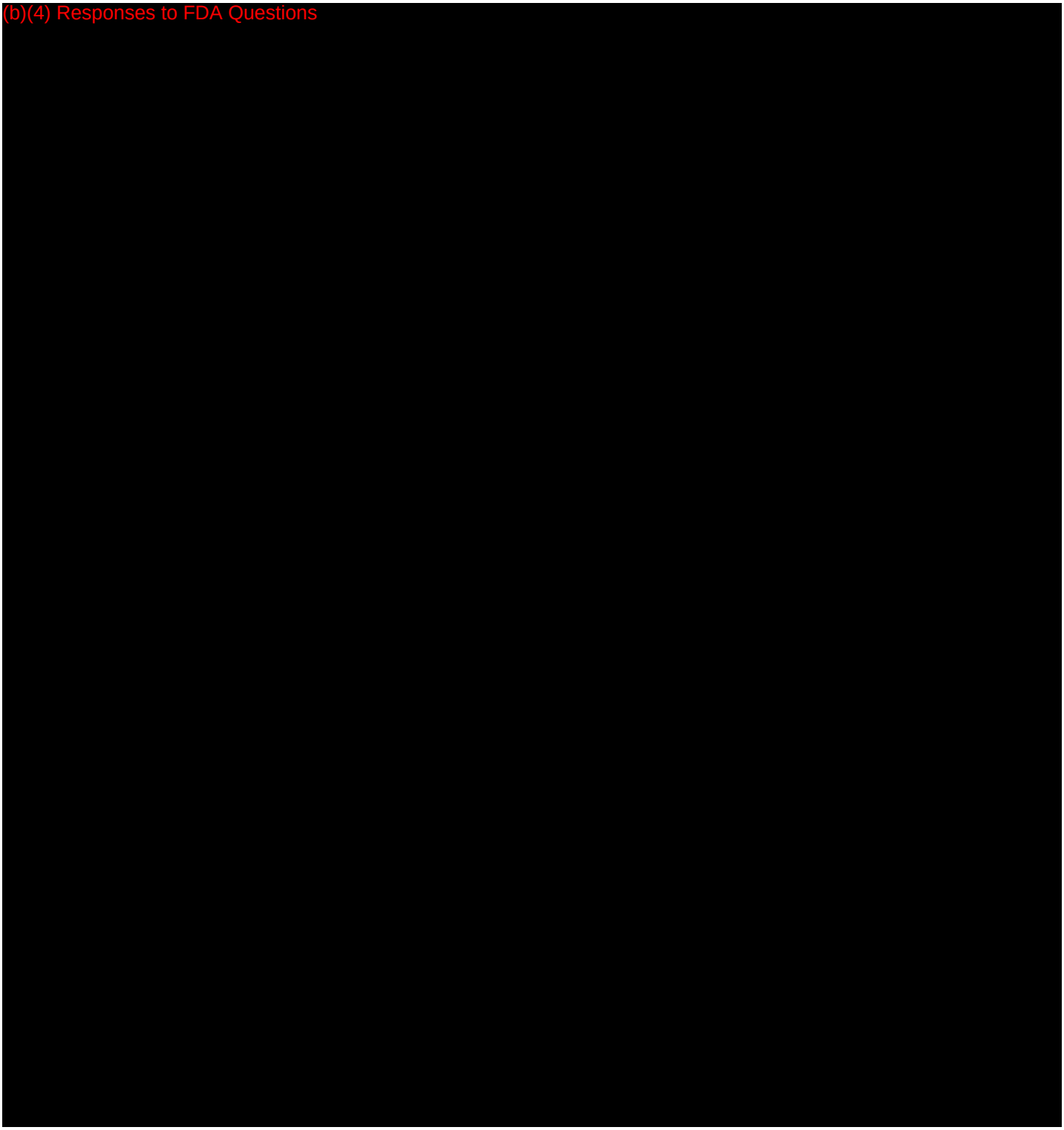
APPENDIX (regarding Q7)

(b)(4) Responses to FDA Questions



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Monica AN24™

Reference Operator Manual

100-TF-006 Revision I

CE
0843

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US law restricts this device to sale by, or on the order of, a physician.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.

Indications For Use

The Monica AN24 is a monitoring device for non-invasively measuring the Fetal Heart Rate (FHR) and Uterine Activity (UA). The Monica VS software, which accompanies the AN24, enables the measured parameters to be reviewed graphically using a PC, notebook computer or any compatible Series 50 format device, and to generate hard copy traces in a “standard” user defined format. This data is intended to aid in assessment of the wellbeing of the fetus and mother for laboring singleton pregnancies who are of gestation age ≥37 weeks. The AN24 device typically generates standard length FHR and UA traces from a single setup. Application of the device must be by trained personnel.

Declaration

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This Operator's Manual is intended for trained medical personnel (including obstetricians, midwives, nurses, and physicians) who are familiar with obstetric procedures. Keep this operator's manual with the unit for use by the operator.

Conventions Used in This Operator Manual

Warning: A warning alerts you to a potential serious outcome, adverse event, or safety hazard. Failure to observe a warning may result in death or serious injury to the user or patient.

Caution: A caution alerts you to situations where special care is necessary for the safe and effective use of the product. Failure to observe a caution may result in minor or moderate personal injury or damage to the product or other property, and possibly in a remote risk of more serious injury.

On your monitor, this sign indicates that there is detailed information in this book, which you must read before proceeding with your task.

Monica™ and AN24™ are registered trademarks of Monica Healthcare Ltd. Other brand names and product names are trademarks or registered trademarks of their respective holders.

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Numbers in brackets ( ) refer to the key number in Figure 1 or the index of Table 1

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Section 1 - Unpacking the AN24™

Table 1 - The Monica AN24™ case should contain the following items

	Description
10	Monica AN24™ Device [Item1, Figure 1]
11	Electrode lead connector [Item 2, Figure 1]
12	AN24™ neck strap
13	Battery Charger and lead
14	AN24™ monitor connector/computer USB cable
16	10 Electrodes
17	Roll of abrasive skin tape
18	AN24™ protective cover
20	Quick Start Guide
	Skin Preparation Pen

Please confirm that you can identify all the items in the case .

Figure 1 Monica AN24™ Controls and Indicators

Section 2 - Product Description

2.1 General description

The Monica AN24™ is a wearable, battery-powered device for L&D surveillance of fetal well-being. The AN24™ is designed to passively monitor Fetal Heart Rate (FHR) and Uterine Activity (UA) from the Electro Hysterogram (EHG) during pregnancy and can be used at any time from ≥ 37 weeks gestation to the end of second stage labour. The AN24™ is currently suitable for singleton pregnancies only. One AN24™ is suitable for extended monitoring sessions of up to 18 hours.

2.2 Patient attachment

The Monica AN24™ is attached via a detachable lead assembly that in turn attaches to 5 disposable ECG electrodes placed on the abdomen of a pregnant woman to generate 3 signal channels. The AN24™ then records the electrical signals present at these electrodes that contains information relating to the fetal heart and other sources of electrical energy inside the body.

(b) (4)

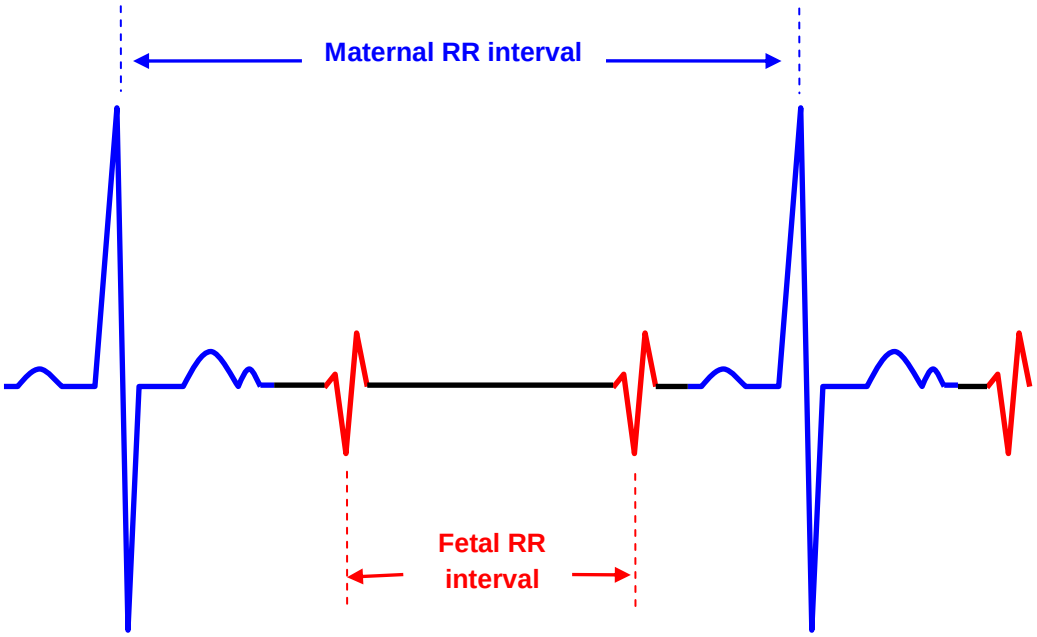


Figure 2 Calculation of FHR from ECG

(b) (4)

Section 3 - Installation

3.1 Battery Charging

The Monica AN24™ (Figure 1) is dispatched with a non-removable rechargeable battery which, for shipping, is not fully charged.

The battery must be fully charged prior to use as described below.

Please refer to Figure 1

A. Connect the lead on the supplied battery charger into the socket inside the top of the AN24™ body (**1**). Plug the battery charger into a mains outlet and switch on the mains outlet. The amber battery status LED (**6**) will flash if a connection has been made (this should be confirmed) until the device is charged, when it will be constantly lit. This should take no more than 2½ hrs.
B. When the electrode leads connector (**2**) is connected to the Monica AN24™ Recorder (**1**) disconnect the lead connector (**2**) from the AN24™ body (**1**) by pressing the two buttons (**7**) on either side of the recorder, and gently pulling apart the AN24™ body (**1**) from the lead connector (**2**).

3.2 Instructions

Please fully read these instructions before using the AN24™.

Section 4 - Operating the AN24™

4.1 Set-up procedure when not using the VS monitor

4.1.1 Select mode.

The Monica AN24™ can be operated in two modes, namely:

(b) (4)

[redacted]

4.1.2 Electrode attachment

Prior to applying the electrodes, the skin must be prepared correctly using an alcohol wipe and abrasive skin tape (**17**) as described in Supplement 1 – Electrode Placement.

Additionally, the electrodes (**16**) must be positioned correctly on the women's abdomen.

For skin preparation and electrode positions please refer to Supplement 1 – Electrode Placement

4.1.3 Lead connection

Attach the electrode leads connector (**2**) to the electrodes (**16**) following the colour code guide in Supplement 1 – Electrode Placement. Ensure that the electrode leads connector (**2**) is securely attached to the AN24™ (**1**), by pushing the two sections firmly together such that the two buttons (**7**) are engaged.

For monitoring in Labour and Delivery always use the AN24™ Protective cover (supplied). Please refer to Supplement 1 – Electrode Placement for instructions on fitting the protective cover.

4.1.4 Turn on

Turn the AN24™ on by pressing the on/off button (3). All three LEDs (4, 5 and 6) will flash 3 times to indicate that the AN24™ has been turned on.

4.1.5 Memory status self-check

If the Orange memory status LED (**4**) begins to flash when the AN24™ has been turned on, this indicates there is data from a previous patient stored in the memory of the AN24™.

The stored data can be a) downloaded using Monica VS Monitor via a USB cable or b) deleted remotely via Bluetooth® connection to the Monica VS monitor.

a) To download the data via USB, turn off the recorder (see 'Turn Off' section below), and connect the AN24™ to the VS Monitor with the USB cable provided (please refer to the Monica VS Reference Manual for detailed instructions). Once the data has been downloaded, the recorder can be used for a new recording.

b) To delete the data via Bluetooth®, use a Monica VS monitor to connect to the recorder. The VS monitor will automatically recognise that there is data stored on the AN24™ and offer to delete the data or allow the user to disconnect it from VS to download as per a) above (please refer to the Monica VS Reference Manual for detailed instructions). Once the data is deleted the recorder can be used for Real Time mode recording.

4.1.6 Battery status self-check

If the Yellow battery status LED (6) begins to flash when the AN24™ has been turned on, this means that the battery charge is too low for recording to begin. The LED will flash 10 times and then the AN24™ will be automatically turned off. See 'Recharging the batteries later in this section.

N.B. If there is data on the recorder, the Memory Status led will flash alongside the battery status LED.

4.1.7 Electrode attachment self-check

After turn on, the AN24™ will check the electrodes are attached correctly. The green signal quality LED (**5**) will go into one of three states:

- GREEN LED FLICKERS

The green LED flickers rapidly when the electrodes are not correctly attached. To solve this problem please refer to Section 10 - Troubleshooting. The AN24™ will continue this self-check until the problem has been resolved and recording will not begin until it has.

- GREEN LED ON

The green LED is constantly on to indicate that all electrodes are correctly attached to the skin. Once the AN24™ is satisfied that the electrodes are correctly attached the recording will begin. The AN24™ will then look for the signal.

- GREEN LED SLOWLY FLASHES

The green LED will flash (once every 2 seconds) when the AN24™ is satisfied that the electrodes are correctly attached and that monitoring has started (note – this may take up to 30 seconds once the correct electrode attachment has been confirmed). If the LED remains constantly on, please refer to Section 10 - Troubleshooting. If the problem persists please contact your distributor.

NB: Monica VS monitors provide an on-screen electrode attachment check during the setup of a new patient see the VS Reference Operating Manual for details.

4.1.8 Secure the AN24™

If the patient wishes to carry the AN24™ it can either be held in their clothing (e.g. a pocket) or carried around the neck using the supplied neck strap (12). If the patient wishes to use the neck strap, attach it to the AN24™ main body (1) using the neck strap connection (9) and hang the neck strap around the patient's neck. Adjust the length of the neck strap so that the lowest part of the AN24™ is above the sternum and not touching the electrodes.

4.1.9 Secure Cables

If the ECG cable(s) are loose or hanging, secure them with hypoallergenic tape (not supplied) to the patient's abdomen to prevent the cables from pulling on or detaching from the ECG electrodes.

4.2 During monitoring

Self checks during a recording

During recording the AN24™ will regularly perform self-checks. The AN24™ can only be in one of the following four states:

MONITORING OK – GREEN LED FLASHES
The green signal quality LED (**5**) will continue to flash once every 2 seconds to indicate that the electrodes remain attached correctly.

SIGNAL LOST – GREEN LED ON
The green signal quality LED (**13**) will remain constantly illuminated to indicate that the electrodes remain attached correctly but that the signal has been lost. This is not a cause for alarm and may be temporary and due to interference from other sources, for example the noise generated by maternal muscle/movement. Section 10 - Troubleshooting

ELECTRODE DETACHED – GREEN LED FLICKERS
The green signal quality LED (**5**) will flicker rapidly to indicate that one of the electrodes has become detached. The recording will not be stopped at this point, if suitably trained staff are available the electrodes should be re attached to resolve the problem, see Section 10 - Troubleshooting.

BATTERY LOW – YELLOW LED FLASHES
If the Yellow battery status LED (**6**) begins to flash, this indicates that the battery is running low. A short while after this occurs; the AN24™ will automatically turn off. If the device is in Mode 1 (recording mode) the recorded data will be retained until it is uploaded, see Mode 1 - USB upload later in this section.

NB: Monica VS monitors also provide on-screen device status feedback see the VS Reference Operating Manual for details.

4.3 Turn off

When the recording session is completed, turn the AN24™ off by pressing the on/off button (**3**) followed by the event button (**8**) followed by the event button (**8**) again.

This sequence of button presses must be completed within 4 seconds to turn the device off. When the AN24™ is switched off all three LED's (**4, 5** and **6**) will flash three times.

If using a Monica VS Monitor to end a real time recording (mode 2) the Monica AN24 can be switched off remotely by the VS Monitor.

Data Upload - If the AN24™ was used in Mode 1 (recording mode), the recorded data must be uploaded to a computer running the Monica VS Monitor, see 'USB Upload' later in this section.

Clean the AN24™ (**1**) and electrode lead connector (**2**) as described in Section 6 - Cleaning and Maintenance

Battery Charging - recharge the AN24™ (**1**) as described in 3.1 Battery Charging.

4.4 Connecting to a VS Monitor

Monica devices are an integral part of a diagnostic system. The user must adhere to warnings in order to ensure safe and reliable performance of the system.

- Monica VS Monitors complies with IEC 60601-1 the international product safety standard for electrical medical equipment
- Non-medical electrical equipment (e.g. Wireless remote printer) must be situated outside the patient environment (patient environment according to IEC 60601-1-1: = radius 1.5m around the patient).
- The Monica VS Monitors (PT-101-010, PT-101-015) fully comply with the above and are required when using the Monica AN24™ to monitor in real-time within the patient environment (as defined by IEC 60601-1-1).

When connecting to a VS Monitor in either Retrospective or Real-Time mode it is firstly necessary to ensure that the Monica VS Monitor is on and running.

To connect to a VS Monitor in **Retrospective mode**:

A. Disconnect the electrodes from the leads - Disconnect the electrode lead connector (**2**) from the AN24™ (**1**) as described in 3.1 Battery Charging.
B. Power up the VS Monitor, log in and wait until the system is fully loaded
C. Connect USB lead - Connect the AN24™-to-USB lead (**14**) into the socket inside the top of the AN24™ (**1**). Plug the USB end of the lead into a free USB port on the Monitor. The Monica AN24™ device will be automatically recognised by the monitor and will provide status information.

From this point the Monica VS software will know if there is data stored on the device ready for upload (Mode 1 operation). If there is data stored on the device the VS Monitor will guide you through the correct process to upload or delete the stored data.

To connect to a VS Monitor in **Real-Time mode**:

Place the electrodes on the patient as described in in the Getting Started Wizard (press the help icon on the VS screen) or Supplement 1; connect the Monica AN24 to the patient and turn it on.

Select the New Recording button from the Monica VS menu which will then take you through the set-up process.

Section 5 - Safety and Standards

5.1 General

This section describes safety precautions that may appear within the manual and those that appear as symbols labels on the AN24™ itself. Furthermore, this section describes a group of precautions that are applicable, in general, when using the AN24™.

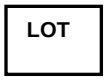
The Monica AN24™ is intended for trained medical personnel (including midwives, nurses, and physicians) who are familiar with obstetric procedures. Keep this operator's manual with the unit for use by the operator.

5.2 Symbols

Attention - Refer to manual

Class II Medical Device

Type BF



Batch number

Manufacture date

Bluetooth® approved device

ESD - Static sensitive device

CE approved

WEEE logo

5.3 Standards

The Monica AN24™ complies with the following safety standards

Standard	Description
IEC EN 60601-1: 1990 UL60601-1:2003 CSA C22.2 No 60601.1	Medical Electrical Equipment Part 1: General requirements for safety
EN 60601-1-2: 2002 IEC 60601-1-2: 2001	Medical Electrical Equipment Part 1-2: General requirements for safety – Collateral Standard: Electromagnetic Compatibility – requirements and tests
Partial compliance of: EN 60601-2-47: 2001 IEC 60601-2-47: 2001	Medical Electrical Equipment Part 2-47: Particular requirements for the safety, including essential performance, of ambulatory electrocardiographic systems
IEC EN 60601-1-4: 1996	Medical electrical equipment Collateral standard: Programmable Electrical Medical Systems
EN 980: 1996	Graphical symbols for use in the labelling of medical devices
EN 1041: 1998	Information supplied by the manufacturer with medical devices

5.4 Interpreting Results

Monica Healthcare recommend that a repeat test is undertaken, using either the AN24™ or an alternative device to confirm the results from the initial test. The repeat test should be carried out in the case of either normal or abnormal results generated by the AN24™.

Good Practise:

When the MHR is high, or the signal quality is poor (section 4.7 VS Operator manual), check the FHR using auscultation (Pinard) or hand held Doppler every 15min to confirm the FHR, and if in any doubt, ask the women to stop pushing during the second stage, until the FHR is confirmed.

5.5 Safety

WARNING: The Monica AN24™ is splash proof but is not designed for submersion in water. Patients must be warned not to immerse the AN24™ or any of its accessories in water, or to take a shower or bath whilst being monitored.

WARNING: The Monica AN24™ is not explosion-proof and must not be used in the presence of flammable anaesthetics.

WARNING: SHOCK HAZARD — Do not attempt to connect the battery charger with wet hands. Make certain that your hands are clean and dry before touching a power lead or plug.

WARNING: Use only the electrode lead cables supplied with the device. Use of any other cables may result in out-of-specification performance and possible safety hazards.

WARNING: Unplug the AN24™ from the AC power source (battery charger and detach all accessories before cleaning. Do not immerse the unit in water or allow liquids to enter the case.

WARNING: Examine the AN24™ and any accessories periodically to ensure that the leads, connectors and the device itself do not have visible evidence of damage that may affect patient safety or monitoring performance. The recommended inspection interval is once per week or less. Do not use the device if there is any visible sign of damage.

WARNING: The protective silicone rubber cover must be used during Labor and Delivery. Not using the protective silicone rubber cover could result in the ingress of contaminated blood and other fluids into the Monica AN24 case.

WARNING: Only the Battery Charger and mains plug supplied with the Monica AN24™, or its equivalent, is approved for use with the AN24™.

WARNING: Do not attempt to service the Monica AN24™. Only Monica approved and qualified service personnel should attempt any necessary internal servicing.

WARNING: The Monica AN24™ is not specified or intended for operation in conjunction with any other type of monitoring equipment except the specific devices that have been identified for use in this Operator's Manual.

WARNING: Since the Monica AN24™ detects the electrical signals generated from the fetal heart, if other equipment which introduces electrical energy in to the mother is used (e.g. TENS machine, diathermy, impedance meter), then the AN24™ will not be able to detect the fetal heart rate.

WARNING: Do not operate the Monica AN24™ if it fails to pass the power on self-test procedure, see Section 4.

WARNING: Any unexpected data generated by the Monica AN24™ must result in further examination of the mother and fetus in a hospital environment. The data generated by the AN24™ must be backed up by alternative monitoring technologies.

WARNING: For Electromagnetic Compatibility (EMC). Use of accessories, electrodes and leads other than those specified in this manual may result in increased EMC emissions and/or decreased immunity of the Monica AN24™ to other electrical equipment.

WARNING: For Electromagnetic Compatibility (EMC). The Monica AN24™ has been tested for to IEC EN 60601-1-2 for EMC. However, the Monica AN24™ picks up very small electrophysiological signals and so occasionally if other electrical equipment is in the immediate vicinity of monitoring the AN24™ may produce spurious results. The operator should ensure that any such interfering electrical equipment is not in close proximity to the AN24™ during monitoring.

WARNING: The lithium polymer battery pack used within this device has the potential for fire or burning. Do not disassemble, crush, heat or burn.

WARNING: The lithium polymer battery pack cannot be replaced by the user. Replacement may only be made with the battery pack specified by Monica Healthcare, and replacement can only be carried out by Monica Healthcare. Fire or burning may occur if the customer uses a battery pack other than specified by Monica Healthcare.

CAUTION: Keep the operating environment free of dust, vibrations, corrosive, or flammable materials, and extremes of temperature and humidity. The AN24™ and all lead connectors should be kept clean and free of electrode gel and other substances.

CAUTION: Do not operate the unit if it is damp or wet because of condensation or spills. Avoid using the equipment immediately after moving it from a cold environment to a warm, humid location.

CAUTION: Never use sharp or pointed objects to operate the two front-panel membrane switches.

CAUTION: General-purpose personal computers and modems are not designed to meet the electrical safety requirements of medical devices.

CAUTION: Do not autoclave the AN24™ or any accessories. Follow cleaning and disinfection instructions in Section 6 - Cleaning and Maintenance

CAUTION: Do not immerse AN24™, connector or leads in liquid. When using solutions, use sterile/clean wipes to avoid pouring fluids directly on to the AN24™ and connector. Follow cleaning and disinfection instructions in Section 6 - Cleaning and Maintenance

CAUTION: The water temperature must not exceed 40°C (104°F). Do not use chlorine bleach.

CAUTION: Take extra care when cleaning the membrane switches and LED surfaces, which are sensitive to rough handling.

CAUTION: Do not autoclave. Do not gas sterilize.

CAUTION: Only the Battery Charger supplied with the device is approved for use in recharging the internal batteries.

CAUTION: The Monica AN24™ is not specified or intended for operation during the use of defibrillators or during defibrillator discharge.

CAUTION: The Monica AN24™ is not specified or intended for operation in the presence of electrosurgical equipment.

CAUTION: There are minimum signal amplitudes under which the Monica AN24™ will not be able to measure physiological signals.

5.6 Clinical Warnings

WARNING: The AN24 utilizes electromyoghraphic (emg) signals to detect uterine activity. As a result, the AN24 occasionally displays deflections above the baseline that reflect electrical activity that may not have generated or correspond to an actual contraction. Such deflections are generally of lower amplitude compared to deflections characteristic of the overall contraction pattern.

WARNING: When assessing FHR decelarations as early, late or variable do not rely on a single deflection above baseline (especially an atypical appearing deflection) as rare “false” contractions may occur.

5.7 CE

CE The CE Mark on this product denotes conformity with the European Council Medical Device Directive 93/42/EEC.

0843

Section 6 - Cleaning and Maintenance

6.1 AN24™ Device

To avoid damage to the AN24™, connector and leads, clean and disinfect only according to the following instructions. Care MUST be taken to preserve both the AN24™ label and the connector label.

***CAUTION*:** Do not remove, conceal or deface the labels.

CAUTION: Do not autoclave. Do not gas sterilize.

CAUTION: Do not immerse the device or any accessories in liquid and do not expose the connector pins to the cleaning solution. Do not apply oil at any point.

CAUTION: Do not use undiluted bleach or any other cleaning solution other than those recommended here because permanent damage to the AN24™ and leads could occur.

Clean - Wipe the AN24™ and leads with a soft non-abrasive cloth or disposable wipe soaked in aqueous detergent/ disinfectant or other solution such as 70% isopropyl alcohol. Do not use aerosol preparations since they might contain organic solvents. Do not pour fluids directly on the unit and its accessories. Wipe the exterior of the AN24™ and leads three times. Prepare the detergent according to the manufacturer's recommendations. If necessary scrub the AN24™, and leads with the solution using a soft bristled brush for five minutes.

Wash off & Dry - When using solutions, use sterile wipes or gauze to avoid pouring fluids directly on the unit and its accessories. Wipe the AN24™, and leads three times with sterile or distilled water to remove cleaning solution residue. Dry the AN24™, connector and leads thoroughly with a sterile soft towel or gauze surgical sponge.

Disinfect - If a low-level disinfection is required, use a 1:10 bleach solution after the AN24™ and leads have been cleaned following the same procedure described above. After the low level disinfections, wipe the AN24™ and leads three (3) times with sterile or distilled water to remove diluted bleach residue. Dry the AN24™, connector and leads thoroughly with a sterile soft towel or gauze surgical sponge.

Store the clean AN24™, connector, and leads in a clean bag, covered tray, or other suitable system when not in use.

Monica recommends the patient neck cord included with the Monica AN24 is washed thoroughly or replaced between patients.

6.2 Batteries

The 3.6V rechargeable lithium polymer battery pack should be stored at 0-35°C. Typically the batteries will last for two years or more with regular use. If you need to replace the battery, contact Monica Healthcare directly or your Monica healthcare representative.

6.3 Firmware version

AN24™ Firmware
VS Monitor update

Periodically there will be a need to release new versions of the Firmware and VS Monitor updates, please check with your local distributor to see if you have the latest version.

6.4 Calibration

Calibration of the Monica AN24™ is not required

6.5 Servicing

Maintenance of the AN24™ is carried out by Monica Healthcare. The only routine maintenance which is necessary is battery replacement when failing to hold charge and cleaning as outlined earlier in this Section. Further information is available from:

Monica Healthcare Ltd
BioCity
Pennyfoot Street
Nottingham NG1 1GF
UK
Tel: +44 1159124540
Email: info@monicahealthcare.com
Web: www.monicahealthcare.com

Section 7 - Monica Accessories

Part No.	Description
100-PT-100	Monica VS10 Monitor (Panasonic Toughbook CF-H1)
100-PT-101	Monica VS10 Monitor (Panasonic Toughbook CF-H1, upgrade for existing AN24 customers only)
100-PT-110	Monica VS15 Monitor (Arbor M1525)
100-PT-111	Monica VS15 Monitor (Arbor M1525 upgrade for existing AN24 customers only)
100-PT-001	Monica AN24

100-PT-130	Monica Cart (ITD PRO3OU)
100-PT-131	Monica Cart - printer shelf (ITD PRO3OU
100-PT-132	Monica Desktop Stand (Vesa desktop stand ARM 150 or equivalent)
100-PT-140	Monica Printer (Real-time) - Thermal Z-fold (Fetalgard Lite)
100-PT-160	Monica VS Network Viewer

100-PT-002	ECG Lead Assembly - Standard; ~28 weeks to term
100-PT-004	Battery Charger (UK\ EU\ USA please specify)
100-PT-005	AN24 – USB computer connection cable
100-PT-015	Soft silicon rubber protective boot (x5)
100-PT-016	3M red Dot 2236 skin prep tape (x5)
100-PT-017	Monica approved electrodes – 25 pouches x 10 electrodes (250 electrodes)
100-PT-018	Monica approved electrodes – 150 pouches x 10 electrodes (1500 electrodes)
100-PT-019	Monica AN24 Neck Cord (x5)
100-PT-020	Monica Healthcare glossy sales literature folder (x50)
100-PT-021	Sales Literature sheets
100-PT-022	Skin preparation pen
100-PT-141	Z-Fold paper printer (3 cm/min, 30 - 240 bpm) Analogic US
100-PT-142	Z-Fold paper printer (1 cm/min, 50 - 210 bpm) Analogic International
100-PT-143	Z-Fold paper printer (3 cm/min, 30 - 240 bpm) Philips US
100-PT-144	Z-Fold paper printer (1 cm/min, 50 - 210 bpm) Philips International

Section 8 - Monica VS Monitors

8.1 Overview

Monica VS series of monitors (VS15/VS10) allow the FHR, UA and event annotation data to be viewed, stored and printed as a conventional CTG trace. It is also provides the Monica AN24™ set-up tools to configure the unit and label and store the monitoring sessions for easy identification and retrieval. The functionality of the Monica VS Monitors is explained in detail in the Monica VS Reference Operating Manual.

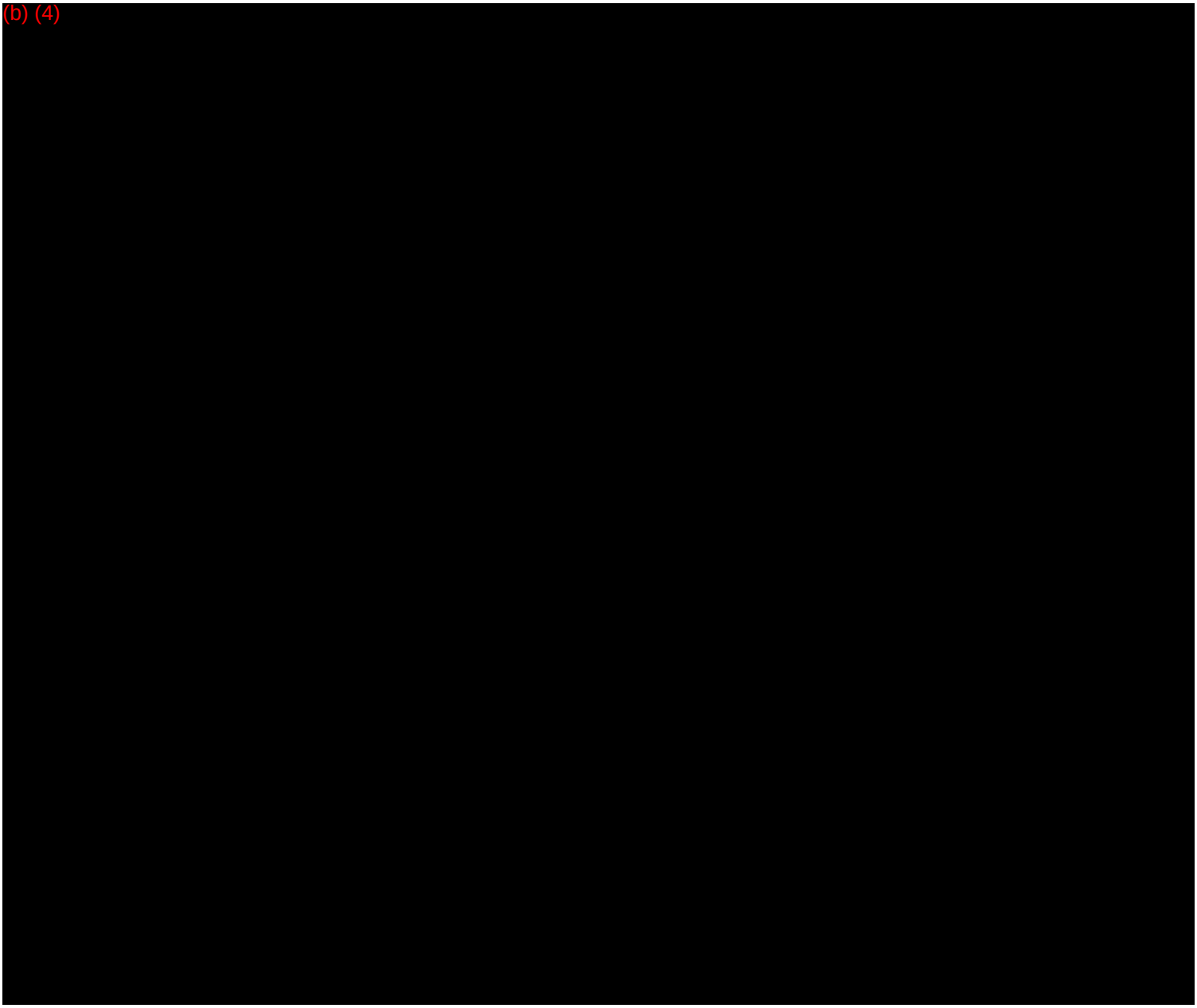
8.2 System Requirements

Monica devices are an integral part of a diagnostic system. The user must adhere to warnings in order to ensure safe and reliable performance of the system.

- Monica VS Monitors complies with IEC 60601-1 the international product safety standard for electrical medical equipment
- Non-medical electrical equipment (e.g. Wireless remote printer) **must be** situated outside the patient environment (patient environment according to IEC 60601-1-1: = radius 1.5m around the patient).
- The Monica VS Monitors (PT-101-010, PT-101-015) fully comply with the above and are required when using the Monica AN24™ to monitor in real-time within the patient environment (as defined by IEC 60601-1-1).

Section 9 - AN24 Specifications

(b) (4)

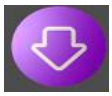


Section 10 - Troubleshooting

10.1 Signal Quality (Green LED flickers)

Electrodes are not attached correctly.

If the green LED flickers, first check that the electrode lead connector cap is connected securely on both sides of the AN24™ (both buttons engaged). If this does not resolve the problem, put AN24™ into electrode check **'Phase 1'** by pressing event button twice within a 2-second period. (NB: this is not required if connected to a VS Monitor which will display the problem electrode(s) on screen without the need to touch the AN24).

 x2

The system will then 'display' the electrode/skin impedance for the electrodes connected to the yellow, green and orange leads.

The electrode/skin impedance will be communicated to the user as follows:

- LED on continuously – the electrode connected to the lead defined by the LED colour has a good connection / low skin impedance
- LED flickers - the electrode connected to the lead defined by the LED colour has a bad connection / high skin impedance

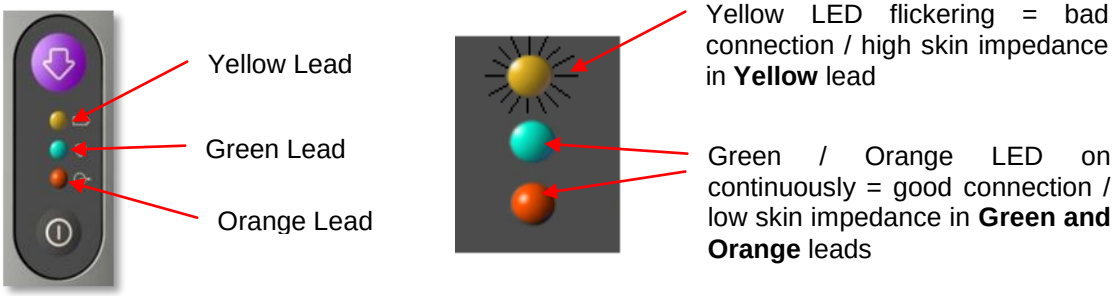
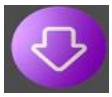


Figure 3 Phase 1 Lead check

If a bad connection is identified in the Yellow, Orange or Green leads, disconnect the lead from the electrode(s) that has a bad connection (leave AN24™ on), remove the electrode(s) and again prepare the skin as described in Supplement 1 – Electrode Placement. When all the electrode(s) have been replaced the leads should be reconnected.

If all the LED are on continuously (good connection), put the AN24™ into electrode check **'Phase 2'** by pressing event button twice within a 2 second period.

 x2

In 'mode 2' the electrode/skin impedance will be communicated to the user for the remaining two electrodes as follows:

- Yellow LED on continuously – the electrode connected to the **White** lead has a good connection / low skin impedance
- Yellow LED flickers - the electrode connected to the **White** lead has a bad connection / high skin impedance
- Green LED on continuously – the electrode connected to the **Black** lead has a good connection / low skin impedance
- Green LED flickers - the electrode connected to the **Black** lead has a bad connection / high skin impedance

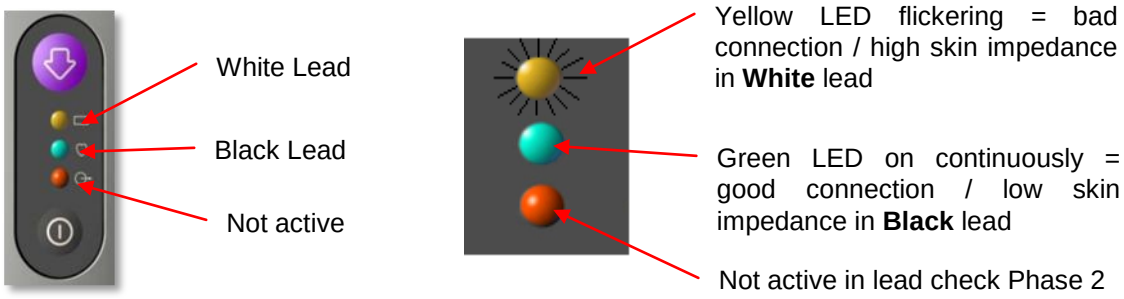
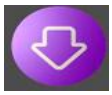


Figure 4 Phase 2 Lead check

If a bad connection is identified in the black or white leads, disconnect the lead from the electrode(s) that has a bad connection (leave AN24™ on), remove the electrode(s) and again prepare the skin as described in Supplement 1 – Electrode Placement. When all the electrode(s) have been replaced the leads should be reconnected.

If the Green and Yellow LED's are on the user should start their monitoring session by pressing the event button twice within a 2-second period

 x2

In the unusual event that it is not possible with repeated skin preparation and correct electrode placement to bring the impedance down and gain a good connection; impedance check may be by-passed or can be halted and repeated at a later date.

To by-pass the impedance checks:

Press the following key sequence in succession:
Power On Button > Pink Event Button > Power Button

If after by passing the impedance check the green LED remains continuously on – signal cannot be found – the monitoring session can be halted and repeated at a later date. This failure should be reported to Monica Healthcare Ltd. Please make a note of which electrode or electrodes failed to pass the impedance check. Monitoring the patient at a future time/date may still be possible.

To abort the electrode check phases (Phase1 or Phase2): switch off the AN24™ as usual (press ON button, then press pink Event button, then press pink Event button)

Alternatively, the lead may be broken. Turn the AN24™ off. Disconnect the lead from both the AN24™ and the electrodes. Attach a spare lead and retry.

If problem is not resolved, contact Monica Healthcare for advice.

10.2 Signal Quality (Green) LED constantly on

The signal cannot be picked up by the AN24™, though the electrodes are correctly connected. This is a common occurrence, which may be due to interference from other sources, for example the noise generated by maternal muscle/ movement. The mother should relax and remain in a supine position for as long as practicable during the recording for optimal results. If problem is not resolved, contact Monica Healthcare for advice.

10.3 Battery Status (Yellow) LED flashing when unit is not being charged

Battery is low. The AN24™ will shortly automatically turn off. Upload the data and recharge the batteries (see 3.1 Battery Charging). If problem is not resolved, contact Monica Healthcare for advice.

10.4 Memory Status (Orange) LED flashing

This indicator will only light just after the AN24™ has been turned on and indicates that there is > 1 minute of data on the device. Upload / delete the data currently stored on the device (see Section 4 -). Turn on the device and resume the monitoring session. If problem is not resolved, contact Monica Healthcare for advice.

10.5 AN24™ will not turn on

Recharge the AN24™ for at least an hour even if the AN24 battery does not flash. If after recharge the AN24™ still does not turn on, return to Monica Healthcare for service.

10.6 AN24™ will not turn off

Return to Monica Healthcare for service

10.7 AN24™ will not recharge

Disconnect AN24™, reconnect battery charger and check charger is connected at both the wall socket and the device. Leave the recorder connected to the charger for half an hour. Then disconnect the AN24™ from the charger and reconnect it again. If problem is not resolved, contact Monica Healthcare for advice.

10.8 AN24™ will not connect via USB

Disconnect USB lead from both the AN24™ and VS Monitor. Reconnect USB lead and retry. If problem is not resolved, connect the AN24™ to the charger for half an hour and try connecting the recorder to the VS Monitor again. If the problem is not solved, contact Monica Healthcare for advice.

10.9 AN24™ will not connect via USB and will not recharge

If the AN24™ does not charge and is not recognised by the VS Monitor, disconnect the AN24™, reconnect battery charger and check charger is connected at both the wall socket and the device. Leave the recorder connected to the charger for half an hour. Then disconnect the AN24™ from the charger and reconnect it again. If problem persists there may be an issue with the Bluetooth® module in the AN24™ - please contact Monica Healthcare for advice.

If the AN24™charges but is not recognised by the VS Monitor disconnect USB lead from both the AN24™ and computer. Reconnect USB lead and retry. If the problem persists there may be an issue with the USB cable – please contact Monica healthcare for advice

10.10 AN24™ will not connect via Bluetooth®

Bring the AN24™ physically close (i.e. within 2 metres) of the VS Monitor and retry. If problem is not resolved, contact Monica Healthcare for advice.

Section 11 - Returns Procedure

11.1 Maintenance

There are no user serviceable parts in the Monica AN24™ or accessories. In the event of device failure or the battery needs to be changed, please contact Monica Healthcare or your local representative.

11.2 Returns

To return a defective product to Monica, you will need to obtain a Return Goods Authorization (RGA) number from the Monica Healthcare Support Group. Please contact a Service Coordinator at:

Telephone: +44 1159124540
Email: support@monicahealthcare.com

You will need to supply the Service Coordinator with the following information:

- The Model number(s) and Serial number(s) of the product, this information can be found on the label on the rear of the AN24™.
- The quantity of items you wish to return.
- Your "Bill to" address for invoice purposes.
- Your "Ship to" address.
- Your Purchase Order number.
- Details of the reported failure.

The Service Coordinator at Monica Healthcare will then inform you of:

- The Return Goods Authorization (RGA) number.
- The warranty or non-warranty status of the units being returned.
- Any repair charge.

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Supplement 1 – Electrode Placement

I. Patient Posture

It is very important that the woman's stomach muscles are relaxed and she should be encouraged to 'relax' on a bed either on her back (recumbent or semi-recumbent) or on her side (left/right) for as long as practicable during the monitoring session. The patient should **avoid** whenever possible**:**

1. Any position or activity where the abdominal muscles are contracted e.g. sitting upright or lying down with her back raised from the hips at an angle of 45°. If this is unavoidable then using a cushion to support the back can help.
2. A tense stressful situation which will cause abdominal muscle tone to increase even though the patient is in a comfortable position e.g. When the room where the patient is being monitored is filled with Drs, Midwives, Family, Children and other onlookers. In this situation it is advisable to leave the Monica AN24 in place and return when the patient situation has changed.

The VS series of monitors provide a real-time indication of signal to noise in the signal quality indicator where the muscle noise (red-bar height) and the fetal ECG height (green bar) are displayed.

If the fetal ECG height is small and the muscle noise is high then FHR extraction may be compromised; ask the mother to get into a position that is comfortable for her and relax. In addition, changes in maternal posture like lying on the left or right can change the fetal position in relation to the abdomen and uterus and improve the ECG conducting pathway.

II. Electrode Location

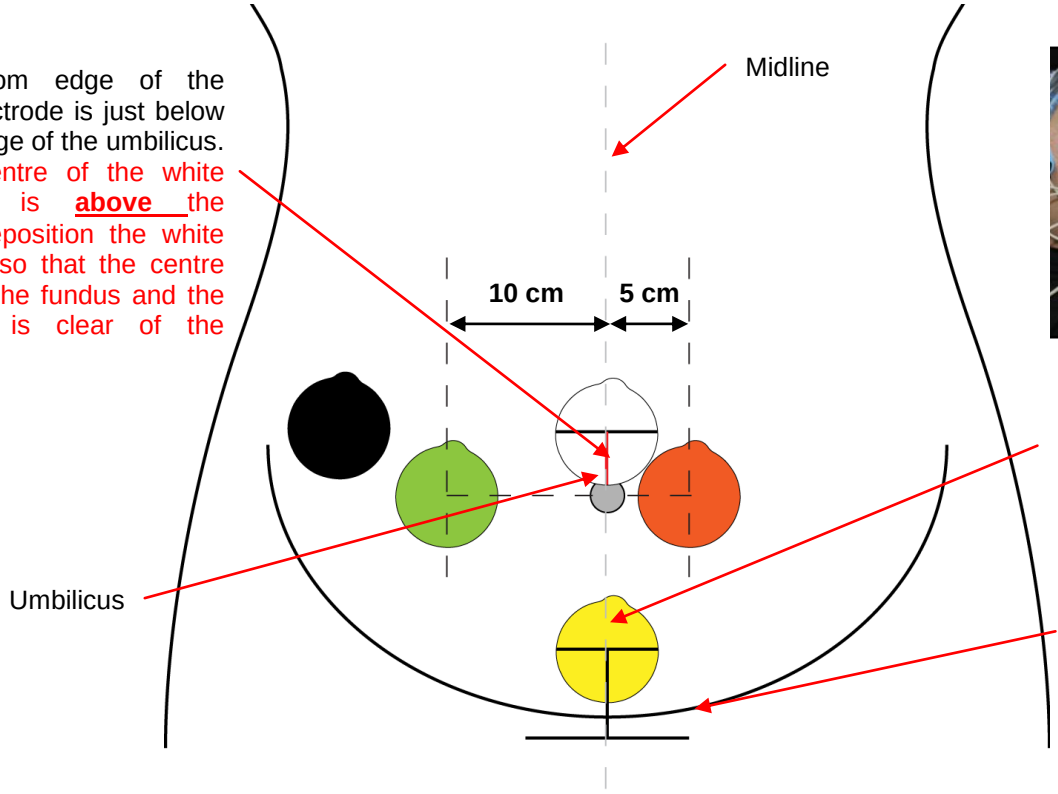
It is important to correctly prepare the skin before the application of the electrodes. You are advised to read all of this section before starting the procedure.

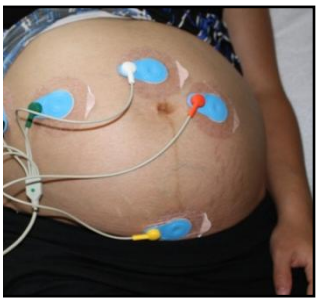
The instrument has three separate detection channel leads. The connectors on these leads are colour coded as **orange**, **white** and **green**. All three channels share a common connection point and this lead connector is coloured **yellow**. Finally, a ground lead with a **black** colour coded connector is also used. These leads are connected to 5 electrodes positioned on the maternal abdomen. Please refer to the table and figures below for guidance in positioning the electrodes.

Electrode / Connector	Position
Yellow	Place the yellow electrode on the mid-line 6cm above the symphysis pubis or as close to 6cm above the symphysis pubis as you can achieve without requiring removal of the pubic hair.
White	Place the white electrode on the mid-line so that the bottom edge of the electrode is just below the top edge of the umbilicus. *If the centre of the white electrode is **above** the fundus, reposition the white electrode so that the centre is **below** the fundus and the electrode is clear of the umbilicus*
Green and Orange	Place the centre of the green and orange electrodes either side of the umbilicus and on the same horizontal line as the umbilicus. The centre of the green electrode should be **10cm** from the **left hand edge** of the umbilicus and the centre of the orange electrode **5cm** from the **right hand edge** of the umbilicus.
Black	The black electrode is the reference electrode and is positioned towards the back behind the green electrode. Its exact position is not critical.

Electrode Positions

The bottom edge of the White electrode is just below the top edge of the umbilicus. (If the centre of the white electrode is **above** the fundus, reposition the white electrode so that the centre is **below** the fundus and the electrode is clear of the umbilicus)





For patients with a large pannis (apron of fat) overhanging the symphysis pubis it is recommended that the yellow electrode be placed **on top** of the pannis on the mid-line such that the centre of the electrode is 6cm above the upper margin of the symphysis pubis or as close to 6cm above the upper margin of symphysis pubis without covering the yellow electrode with the pannis.

These instructions only apply to **Ambu VLC-00-S** electrodes.
Results may be impaired if any electrode is used other than those recommended by

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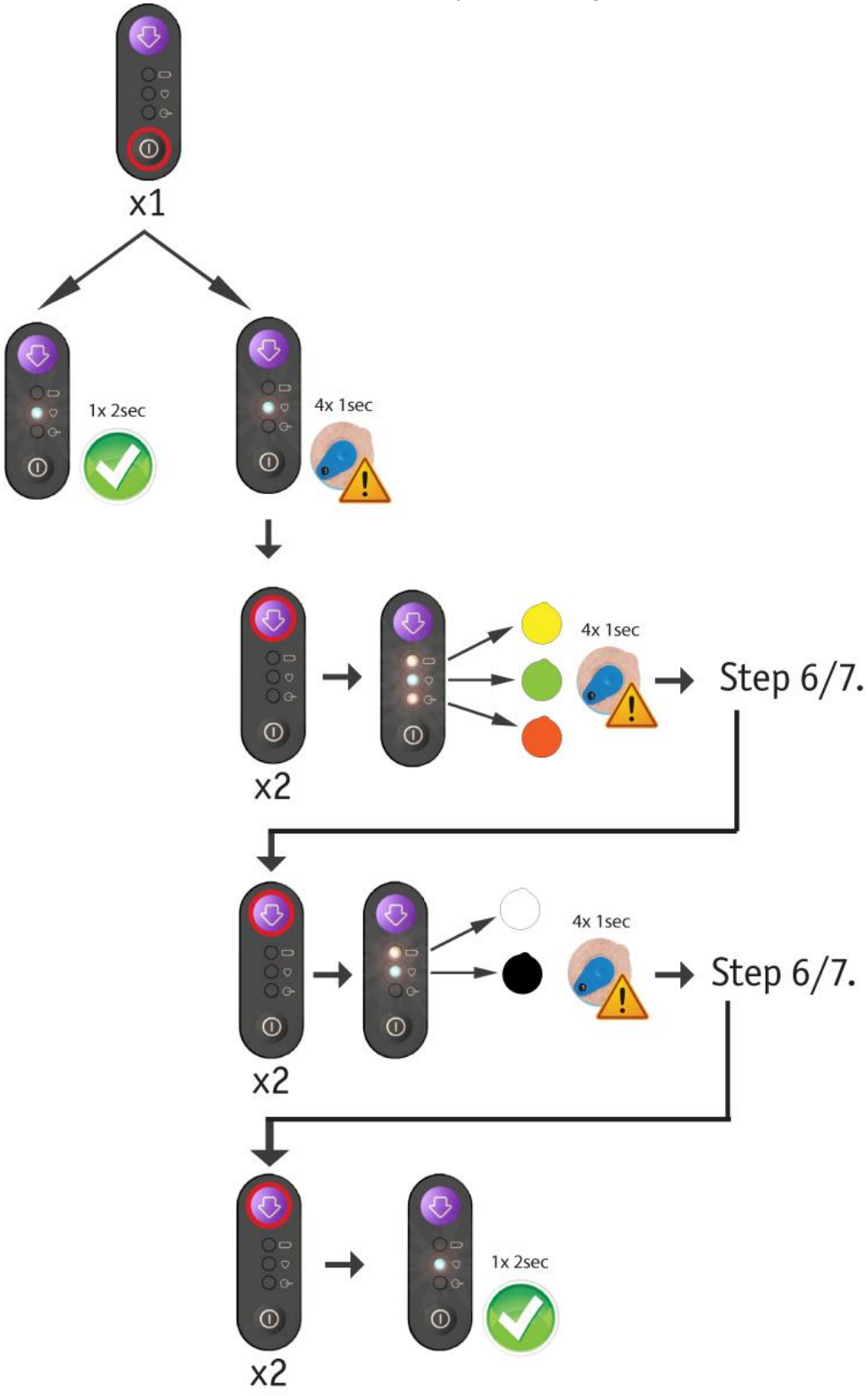
b. If the VS monitor is not available check the Impedance using the Monica AN24



6. If impedance check fails
    a. Peel back electrode
    b. Dry wipe the area to remove gel and moisture left by the electrode
    c. Re-abrade the same area of skin pressing firmly
    d. Re-attach the same electrode
    e. Wait 2-3 minutes for the electrode to settle
    f. Check the impedance again (Step 5)

7. If the impedance check fails a second time
    a. remove and discard the electrode
    b. Dry wipe the area to remove gel and moisture left by the electrode
    c. Re-abrade the same area of skin pressing firmly as long as the mother does not become uncomfortable
    d. attach a new electrode
    e. Wait 2-3 minutes for the electrode to settle
    f. Check the impedance again (Step 5)

8. If the impedance check fails a third time on one or more of the Green, White, black or Orange electrodes then the impedance check can be by-passed (see AN24 Reference Operating Manual – 10.1 Troubleshooting Guide). **This is not recommended**. Alternatively, leave the electrodes in place for 30 minutes and try the impedance check again (Step 5).

9. '**Do Not'** by-pass the impedance check if the impedance check for the yellow electrode fails – go to step 6 and repeat process as long as the mother does not become uncomfortable.

10. If it is still not possible to pass the yellow electrode impedance check,

    Option 1: go back to step 8 and by-pass the impedance check. The fetal abdominal ECG can be good in early and late gestation monitoring so noise introduced by high skin electrode impedance can be mitigated. However the quality of the signal cannot be confirmed until the recording commences by looking at the signal to noise bar graph on the VS display or on the Quick-View PDA (not available for sale in the USA).

    Option 2: halt the recording and try again at a future time/date.

Caution: Do not use water to remove the electrodes

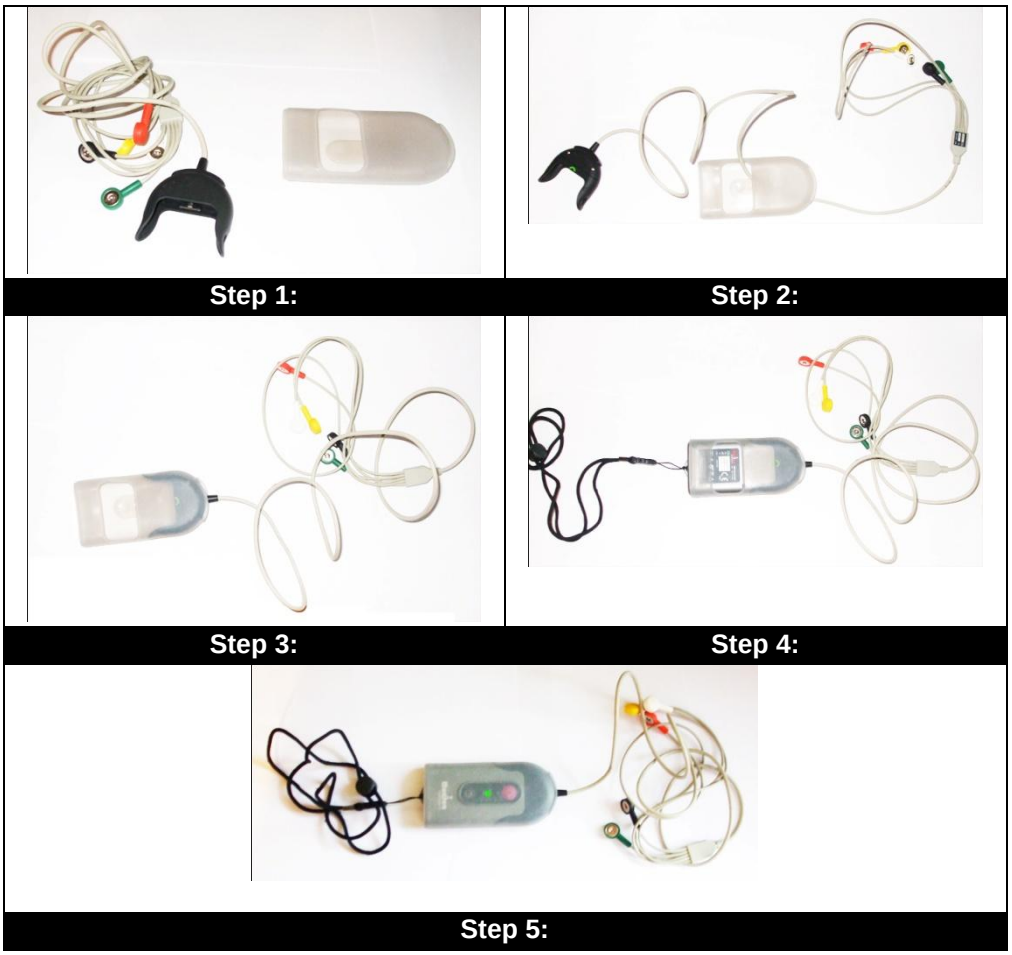
Before attaching the electrodes on to a patient, the user should prepare the skin and place five electrodes on themselves or a volunteer, connect the Monica AN24™ and switch on. The positioning of the electrodes is not important, but this will provide an insight into the skin preparation needed in order to obtain a steady green LED (**5**) indicating that all the electrodes have been correctly attached to the skin.

IV. Lead connection

The 'button' connector on the electrode is located on a 'flap' that is not stuck down. This means that, (a) the flap can be lifted and the correct colour coded lead connector can be pressed/snapped onto the button without pressing on the skin and disturbing the gel electrode contact with the skin and (b) no downward force is applied to the maternal abdomen.

V. Protective cover and neck strap

The protective silicone rubber cover is designed to protect the Monica AN24™ during use, keep it clean and to keep it dry and avoid the ingress of fluids. **It must be used on all L&D subjects.**



Warning: Not using the protective silicone rubber cover could result in the ingress of contaminated blood and other fluids into the Monica AN24 case.

VI. Lead security

It is important to secure and tidy the electrode leads to avoid lead or electrode detachment during operation. The electrode leads are of different lengths to aid in their correct placement and are fitted with two small plastic lead separators, which can be repositioned to avoid lead tangles and aid placement. The long single lead is fitted with a Velcro band so that it can be neatly coiled and secured when the patient is mobile.

VII. Electrostatic Discharge (ESD) precautions

Although precautions have been taken to ensure otherwise, static electricity could cause damage to the sensitive input circuits of the AN24™ and render the device inoperable. In the context of the AN24™, static is most likely to reach the AN24™ via a user\ patient touching static sensitive parts of the device.

ESD precautionary measures should be taken to minimise the risk of damage to the AN24™. More specifically:

- The connector which joins the AN24™ and lead connector together should not be touched by any part of the body, including the fingers
- The metallic (conducting) part of the electrode (press-stud) clips at the extremities of the electrode leads should not be touched by any part of the body, including the fingers

All staff that use the AN24™ should receive an explanation of the ESD warning symbol and receive the following basic training\ instruction in ESD precautions before use of the AN24™:

- How to fit the AN24™ to the patient, and;
- How to attach the electrodes to the AN24™, and;
- How to attach the electrodes to the patient.

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The Monica AN24™™ complies with the requirements of the European Council Directives: 93/42/EEC as amended by 2007/47/EEC, concerning medical devices
ISO 13485 Monica Healthcare Ltd operates Quality Management Systems that have been approved and audited to ISO 13485.

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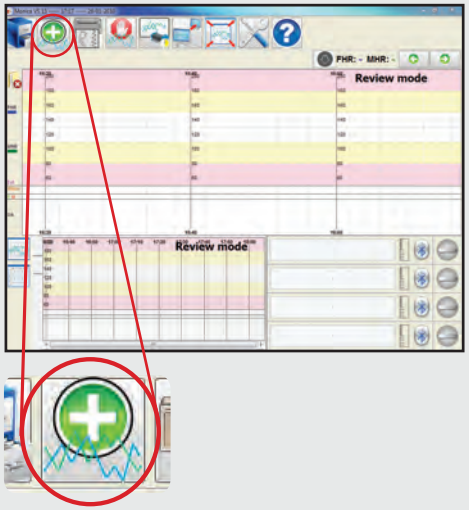

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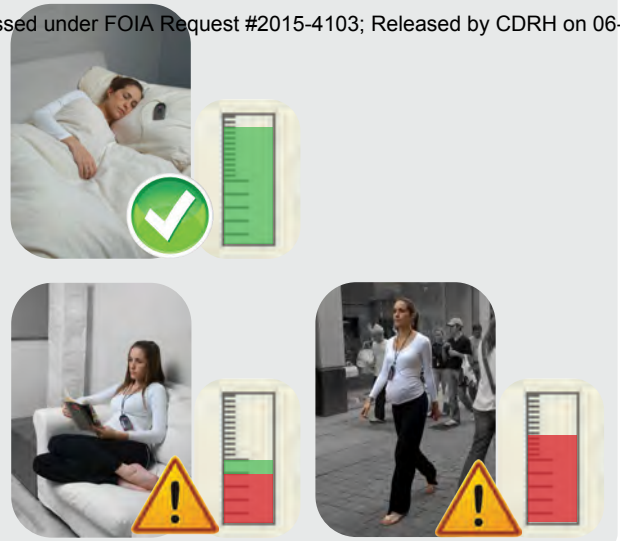

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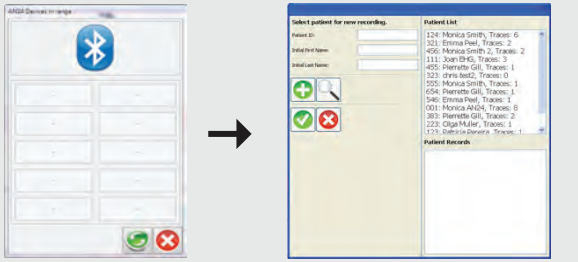

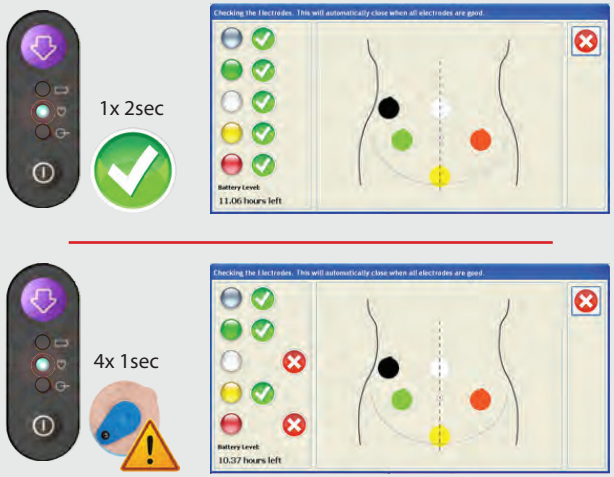

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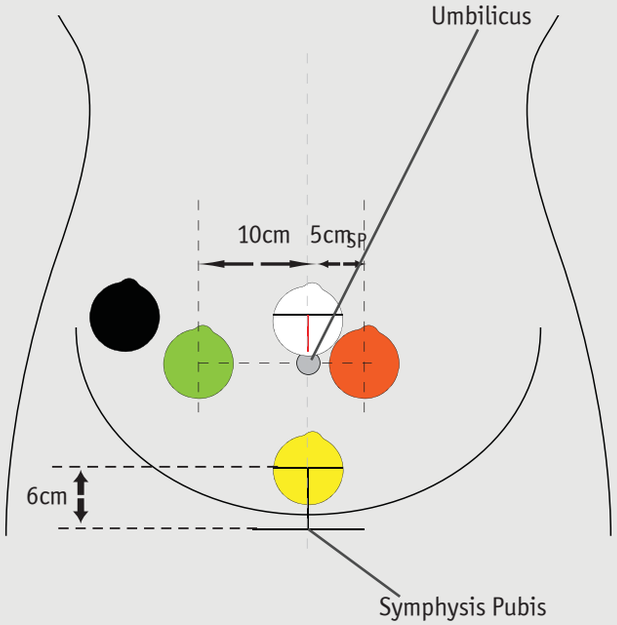
Electrode Positions



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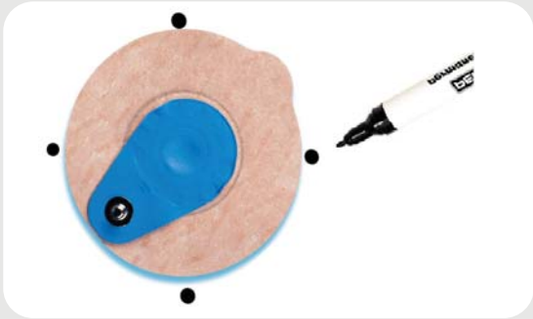

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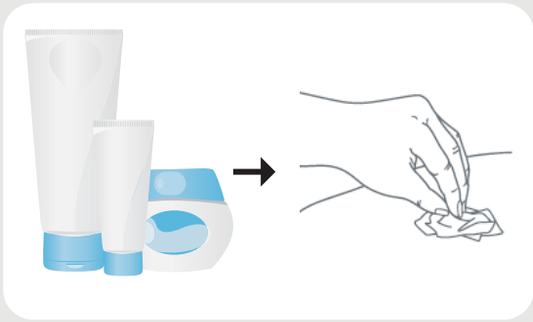

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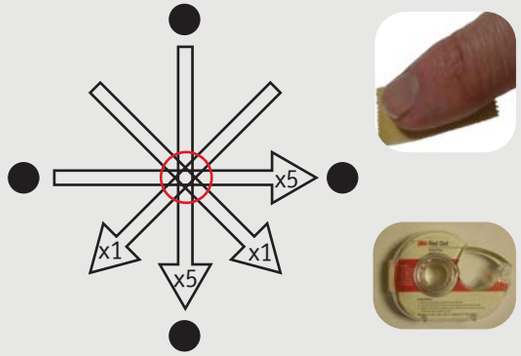

4. AMBU® Blue Sensor VLC-00-S

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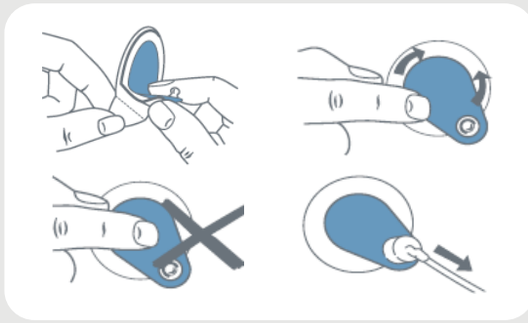
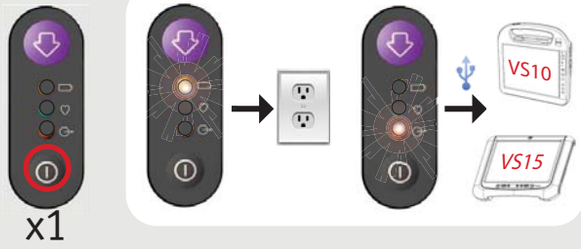


6. AN24™



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Records processed under FOIA Request #2015-4103; Released by CDRH on 06-06-2016

Product	AN24 Abdominal FECG recorder
Document name	System Validation Report
Document type	**TECHNICAL FILE**

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Product	AN24 Abdominal FECG recorder
Document name	Monica VS Software Validation Report

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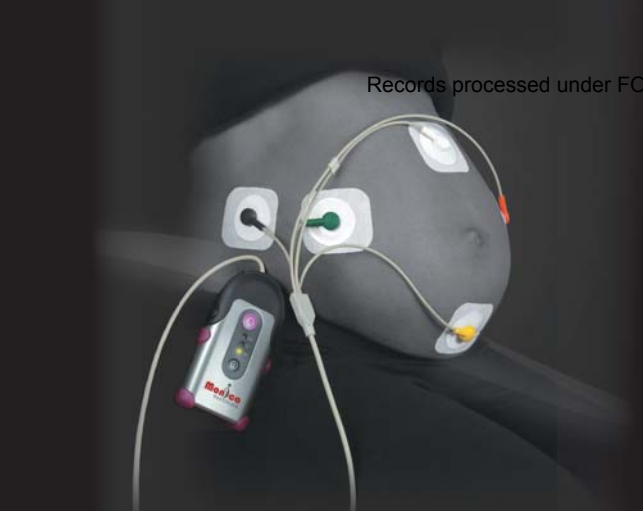


Monica Healthcare

Monica VS series

...the next generation CTG

60 BMI

Wireless Mobility
- Can reduce time in labour[1]
- Natural Birthing positions
- Patient Satisfaction

Beltless
- Patient Comfort
- Continuity of monitoring during procedures

Reduced User Intervention
- No repositioning of transducers
- Continuous monitoring for 20+ hours

Accurate Surveillance
- Direct FHR monitoring from fECG
- Uterine Activity validated against IUPC

Improved work flow
- Electronic storage / Paperless
- Remote viewing & Central Station connectivity
- Event annotation & decision support

Obesity
- Minimal performance loss with obese patients

45 BMI

1 Enabling patients to mobilise can reduce the time in labour
"Maternal positions and mobility during first stage labour" Lawrence et.al. 2009
2 Not Available in the US

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

Monica VS series

...the next generation CTG

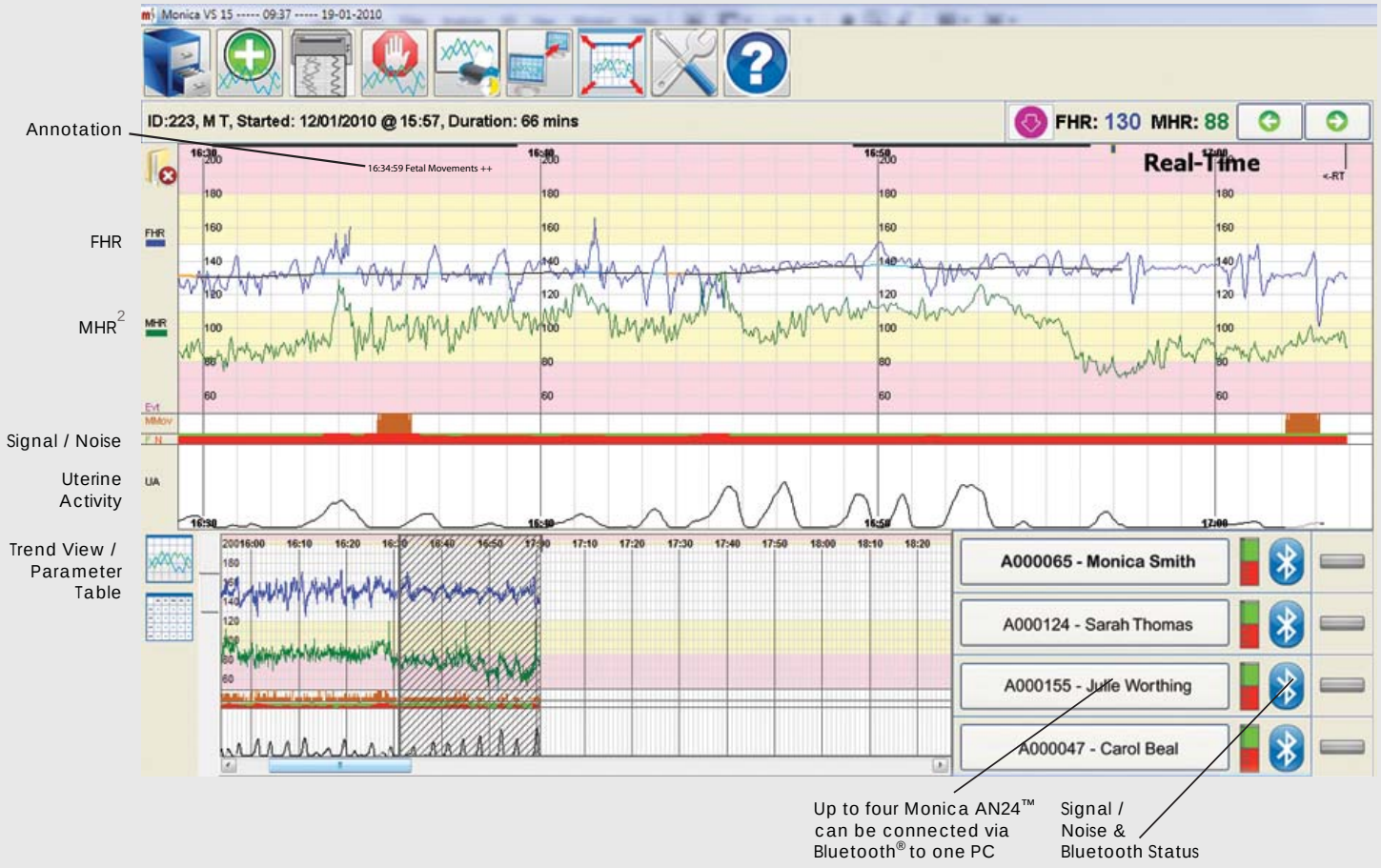
Monica's VS series of wireless fetal-maternal monitors opens up a whole new world of passive surveillance, flexible management, and patient comfort during pregnancy and labour in the hospital, clinic or home.

Using innovative abdominal fECG FHR and EHG UA technology the VS series provides a new solution for Labour and Delivery monitoring and performs well in women with a high BMI.

Featuring FHR, UA, and event annotation the Monica VS series of monitors offer simple set-up, minimal supervision and robust solutions for clinical use.

Available as a 15" monitor (VS15) mountable on a desk or cart with optional real-time 'Z-fold' thermal printer or as a 10" portable monitor (VS10). The Monica VS series provides a level of information and connectivity never before available to the clinician.

CTG display using the Monica VS15 or VS10 Monitor



Non-Invasive	✓	Late gestation	✓
Passive	✓	Throughout Induction & Labour	✓
Requires Minimal Supervision	✓		
Maternal Freedom	✓	High Maternal BMI	✓
FHR - based on accurate R-R interval	✓	Monitor Multiple Beds - from 1 VS Monitor (in range)	✓
Uterine Activity (EHG)	✓		
Event Marker	✓	Central Station Link	✓
		Remote Network Viewing	✓
Real-Time thermal print option	✓		
		High Level of data integrity	✓

For more information on the Monica VS series please contact your local Monica representative or visit www.monicahealthcare.com

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

100-PT-001 Monica AN24™

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Part No: 100-TF-005 Part a, rev N, January 2010
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Distributed by:

r call 301-796-8118.

Records processed under FOIA Request #2015-4103; Released by CDRH on 06-06-2016

Product	AN24 Abdominal Fetal ECG recorder
Document name	System Requirements Specification

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Records processed under FOIA Request #2015-4103; Released by CDRH on 06-06-2016

Product	AN24 Abdominal Fetal ECG recorder
Document name	Requirements Traceability
Document type	**SPECIFICATION**
(b)(4) [redacted]	

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Records processed under FOIA Request #2015-4103; Released by CDRH on 06-06-2016

Product	AN24 Abdominal Fetal ECG recorder
Document name	Risk Assessment

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Records processed under FOIA Request #2015-4103; Released by CDRH on 06-06-2016.

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Records processed under FOIA Request #2015-4103; Released by CDRH on 06-06-2016

Product	AN24 Abdominal FECG recorder
Document name	System Validation
Document type	**TECHNICAL FILE**
(b)(4) [redacted]	

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Records processed under FOIA Request #2015-4103; Released by CDRH on 06-06-2016

Product	AN24 Abdominal FECG recorder
Document name	Monica VS software Validation
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Records processed under FOIA Request #2015-4103; Released by CDRH on 06-06-2016.

Product	Monica AN24 Abdominal Fetal/Maternal Monitor
Document name	Clinical Investigation Report – Fetal Heart Rate and Uterine Activity during Labor and Delivery For Patients ≥37 Weeks gestation
Document type	**Clinical Trial Report**

(b)(4) [redacted]

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Records processed under FOIA Request #2015-4103; Released by CDRH on 06-06-2016.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

CERTIFICATION: FINANCIAL INTERESTS AND ARRANGEMENTS OF CLINICAL INVESTIGATORS

Form Approved: OMB No. 0910-0396
Expiration Date: August 31, 2012

TO BE COMPLETED BY APPLICANT

(b) (4), (b) (6)

[redacted]

Paperwork Reduction Act Statement

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. Public reporting burden for this collection of information is estimated to average 1 hour per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the necessary data, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information to the address to the right:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
1350 Piccard Drive, 420A
Rockville, MD 20850

PSC Graphics (301) 443-1090 EF

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

Records processed under FOIA Request #2015-4103; Released by CDRH on 06-06-2016

See OMB Statement on Reverse. Form Approved: OMB No. 0910-0616, Expiration Date: 10-31-2011

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Certification of Compliance, under 42 U.S.C. § 282(j)(5)(B), with Requirements of ClinicalTrials.gov Data Bank (42 U.S.C. § 282(j))

(For submission with an application/submission, including amendments, supplements, and resubmissions, under §§ 505, 515, 520(m), or 510(k) of the Federal Food, Drug, and Cosmetic Act or § 351 of the Public Health Service Act.)

SPONSOR / APPLICANT / SUBMITTER INFORMATION

1. NAME OF SPONSOR/APPLICANT/SUBMITTER
Monica Healthcare

2. DATE OF THE APPLICATION/SUBMISSION WHICH THIS CERTIFICATION ACCOMPANIES
28 June 2010

3. ADDRESS *(Number, Street, State, and ZIP Code)*
Biocity
Pennyfoot Street
Nottingham NG1 1GF
UK

4. TELEPHONE AND FAX NUMBERS *(Include Area Code)*
(Tel.) +44 (0)115 9124540
(Fax) +44 (0)115 9124289

PRODUCT INFORMATION

5. **FOR DRUGS/BIOLOGICS:** Include Any/All Available Established, Proprietary and/or Chemical/Biochemical/Blood/Cellular/Gene Therapy Product Name(s)
FOR DEVICES: Include Any/All Common or Usual Name(s), Classification, Trade or Proprietary or Model Name(s) and/or Model Number(s)
(Attach extra pages as necessary)

Common Name: Fetal Heart Rate Monitor
Classification: Class II
Trade Name: Monica Fetal Holter Recorder
Model: AN24

APPLICATION / SUBMISSION INFORMATION

6. TYPE OF APPLICATION/SUBMISSION WHICH THIS CERTIFICATION ACCOMPANIES

☐ IND ☐ NDA ☐ ANDA ☐ BLA ☐ PMA ☐ HDE ☒ 510(k) ☐ PDP ☐ Other

7. INCLUDE IND/NDA/ANDA/BLA/PMA/HDE/510(k)/PDP/OTHER NUMBER *(If number previously assigned)*

8. SERIAL NUMBER ASSIGNED TO APPLICATION/SUBMISSION WHICH THIS CERTIFICATION ACCOMPANIES

CERTIFICATION STATEMENT / INFORMATION

9. CHECK ONLY ONE OF THE FOLLOWING BOXES *(See instructions for additional information and explanation)*

☐ A. I certify that the requirements of 42 U.S.C. § 282(j), Section 402(j) of the Public Health Service Act, enacted by 121 Stat. 823, Public Law 110-85, do not apply because the application/submission which this certification accompanies does not reference any clinical trial.

☒ B. I certify that the requirements of 42 U.S.C. § 282(j), Section 402(j) of the Public Health Service Act, enacted by 121 Stat. 823, Public Law 110-85, do not apply to any clinical trial referenced in the application/submission which this certification accompanies.

☐ C. I certify that the requirements of 42 U.S.C. § 282(j), Section 402(j) of the Public Health Service Act, enacted by 121 Stat. 823, Public Law 110-85, apply to one or more of the clinical trials referenced in the application/submission which this certification accompanies and that those requirements have been met.

10. IF YOU CHECKED BOX C, IN NUMBER 9, PROVIDE THE NATIONAL CLINICAL TRIAL (NCT) NUMBER(S) FOR ANY "APPLICABLE CLINICAL TRIAL(S)," UNDER 42 U.S.C. § 282(j)(1)(A)(i), SECTION 402(j)(1)(A)(i) OF THE PUBLIC HEALTH SERVICE ACT, REFERENCED IN THE APPLICATION/ SUBMISSION WHICH THIS CERTIFICATION ACCOMPANIES *(Attach extra pages as necessary)*

NCT Number(s):

The undersigned declares, to the best of her/his knowledge, that this is an accurate, true, and complete submission of information. I understand that the failure to submit the certification required by 42 U.S.C. § 282(j)(5)(B), section 402(j)(5)(B) of the Public Health Service Act, and the knowing submission of a false certification under such section are prohibited acts under 21 U.S.C. § 331, section 301 of the Federal Food, Drug, and Cosmetic Act.
Warning: A willfully and knowingly false statement is a criminal offense, U.S. Code, title 18, section 1001.

11. SIGNATURE OF SPONSOR/APPLICANT/SUBMITTER OR AN AUTHORIZED REPRESENTATIVE (Sign)

12. NAME AND TITLE OF THE PERSON WHO SIGNED IN NO. 11
(Name) Dr Carl Barratt
(Title) Chief Executive Officer

13. ADDRESS *(Number, Street, State, and ZIP Code) (of person identified in Nos. 11 and 12)*
Monica Healthcare, BioCity, Pennyfoot Street
Nottingham, NG1 1GF
UK

14. TELEPHONE AND FAX NUMBERS *(Include Area Code)*
(Tel.) +(44) 115 9124540
(Fax) +(44) 115 9124289

15. DATE OF CERTIFICATION
August 2010

Form FDA 3674 (11/08) (FRONT)

PSC Graphics: (301) 443-1090 EF

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

Records processed under FOIA Request #2015-4103; Released by CDRH on 06-06-2016.

Instructions for Completion of Form FDA 3674

Certification of Compliance, under 42 U.S.C. § 282(j)(5)(B), with Requirements of ClinicalTrials.gov Data Bank (42 U.S.C. § 282(j))
Form 3674 must accompany an application/submission, including amendments, supplements, and resubmissions, submitted under §§ 505, 515, 520(m), or 510(k) of the Federal Food, Drug, and Cosmetic Act or § 351 of the Public Health Service Act.

1. **Name of Sponsor/Applicant/Submitter -** This is the name of the sponsor/applicant/submitter of the drug/biologic/device application/ submission which the certification accompanies. The name must be identical to that listed on the application/submission.
2. **Date -** This is the date of the application/submission which the certification accompanies.
3. **& 4. -** Provide complete address, telephone number and fax number of the sponsor/applicant/submitter.
5. **Product Information - For Drugs/Biologics:** Provide the established, proprietary name, and/or chemical/biochemical/blood product/ cellular/gene therapy name(s) for the product covered by the application/submission. Include all available names by which the product is known. **For Devices:** Provide the common or usual name, classification, trade or proprietary or model name(s), and/or model number(s). Include all available names/model numbers by which the product is known.
6. **Type of Application/Submission -** Identify the type of application/submission which the certification accompanies by checking the appropriate box. If the name of the type of application/submission is not identified, check the box labeled "Other."
7. **IND/NDA/ANDA/BLA/PMA/HDE/510(k)/PDP/Other Number -** If FDA has previously assigned a number associated with the application/ submission which this certification accompanies, list that number in this field. For example, if the application/submission accompanied by this certification is an IND protocol amendment and the IND number has already been issued by FDA, that number should be provided in this field.
8. **Serial Number -** In some instances a sequential serial number is assigned to the application. If there is such a serial number, provide it in this field. If there is no such number, leave this field blank.
9. **Certification -** This section contains three different check-off boxes.

   Box A should be checked if the sponsor/applicant/submitter has concluded that the requirements of 42 U.S.C. § 282(j), section 402(j) of the Public Health Service Act, do not apply because no clinical trials are included, relied upon, or otherwise referred to, in the application/ submission which the certification accompanies.

   Box B should be checked if the sponsor/applicant/submitter has concluded that the requirements of 42 U.S.C. § 282(j), section 402(j) of the Public Health Service Act, do not apply at the time of submission of the certification to any clinical trials that are included, relied upon, or otherwise referred to, in the application/submission which the certification accompanies. This means that, even though some or all of the clinical trials included, relied upon, or otherwise referred to in the application/submission may be "applicable clinical trials" under 42 U.S.C. § 282(j)(1)(A)(i), section 402(j)(1)(A)(i) of the Public Health Service Act, on the date the certification is signed, 42 U.S.C. § 282(j), section 402(j) of the Public Health Service Act, does not require that any information be submitted to the ClinicalTrials.gov Data Bank with respect to those clinical trials.

   Box C should be checked if the sponsor/applicant/submitter has concluded that the requirements of 42 U.S.C. § 282(j), section 402(j) of the Public Health Service Act, do apply, on the date the certification is signed, to some or all of the clinical trials that are included, relied upon, or otherwise referred to, in the application/submission which the certification accompanies. This means that, as of the date the certification is signed, the requirements of 42 U.S.C. § 282(j), section 402(j) of the Public Health Service Act, apply to one or more of the clinical trials included, relied upon, or otherwise referred to, in the application/submission which this certification accompanies.
10. **National Clinical Trial (NCT) Numbers -** If you have checked Box C in number 9 (Certification), provide the NCT Number obtained from www.ClinicalTrials.gov for each clinical trial that is an "applicable clinical trial" under 42 U.S.C. § 282(j)(1)(A)(i), section 402(j)(1)(A)(i) of the Public Health Service Act, and that is included, relied upon, or otherwise referred to, in the application/submission which the certification accompanies. Type only the number, as the term "NCT" will be added automatically before number. Include any and all NCT numbers that, as of the date the certification is signed, have been assigned to the clinical trials included, relied upon, or otherwise referred to, in the application/submission which this certification accompanies. Multiple NCT numbers may be required for a particular certification, depending on the number of "applicable clinical trials" included, relied upon, or otherwise referred to, in the application/submission which the certification accompanies. Leave this field blank if you have checked Box 9.C but, at the time the certification is completed, you have not yet received any NCT numbers for the "applicable clinical trial(s)" included, relied upon, or otherwise referred to in the application/ submission.
11. **Signature of Sponsor/Applicant/Submitter or an Authorized Representative -** The person signing the certification must sign in this field.
12. **Name and Title of Person Who Signed in number 11 -** Include the name and title of the person who is signing the certification. If the person signing the certification is not the sponsor/applicant/submitter of the application/submission, he or she must be an authorized representative of the sponsor/applicant/submitter.
13. **& 14. -** Provide the full address, telephone and fax numbers of the person who is identified in number 11 and signs the certification in number 11.
15. Provide the date the certification is signed. This date may be different from the date provided in number 2.

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Public reporting burden for this collection of information is estimated to average 15 minutes and 45 minutes (depending on the type of application/submission) per response, including time for reviewing instructions. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to the address below.

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Food and Drug Administration
Office of the Chief Information Officer (HFA-250)
5600 Fishers Lane
Rockville, MD 20857

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Form FDA 3674 (11/08) (BACK)

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Records processed under FOIA Request #2015-4103; Released by CDRH on 06-06-2016.

Indications for Use Statement

510(k) Number (if known):

Device Name: AN24

Indications For Use:

The Monica AN24 is a monitoring device for non-invasively measuring the Fetal Heart Rate (FHR) and Uterine Activity (UA). This data is intended to aid in assessment of the wellbeing of the fetus and mother for Intrapartum laboring singleton pregnancies who are of gestation age ≥37 weeks. The AN24 device typically generates standard length FHR and UA traces from a single setup. Application of the device must be by a clinician in a hospital, clinic, home or doctors office environment.

Prescription Use ✔ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

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www.monicahealthcare.com

Ms Kathy Daws - Kopp
Food And Drug Administration
Centre for Devices and Radiological Health
Document Mail Centre – WO66 – G609
10903 New Hampshire Avenue
Silver Spring, Maryland USA 20993-0002

26th October 2010

Reference: K1010801
Trade Name : Monica AN24

Dear Kathy,

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[redacted]

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

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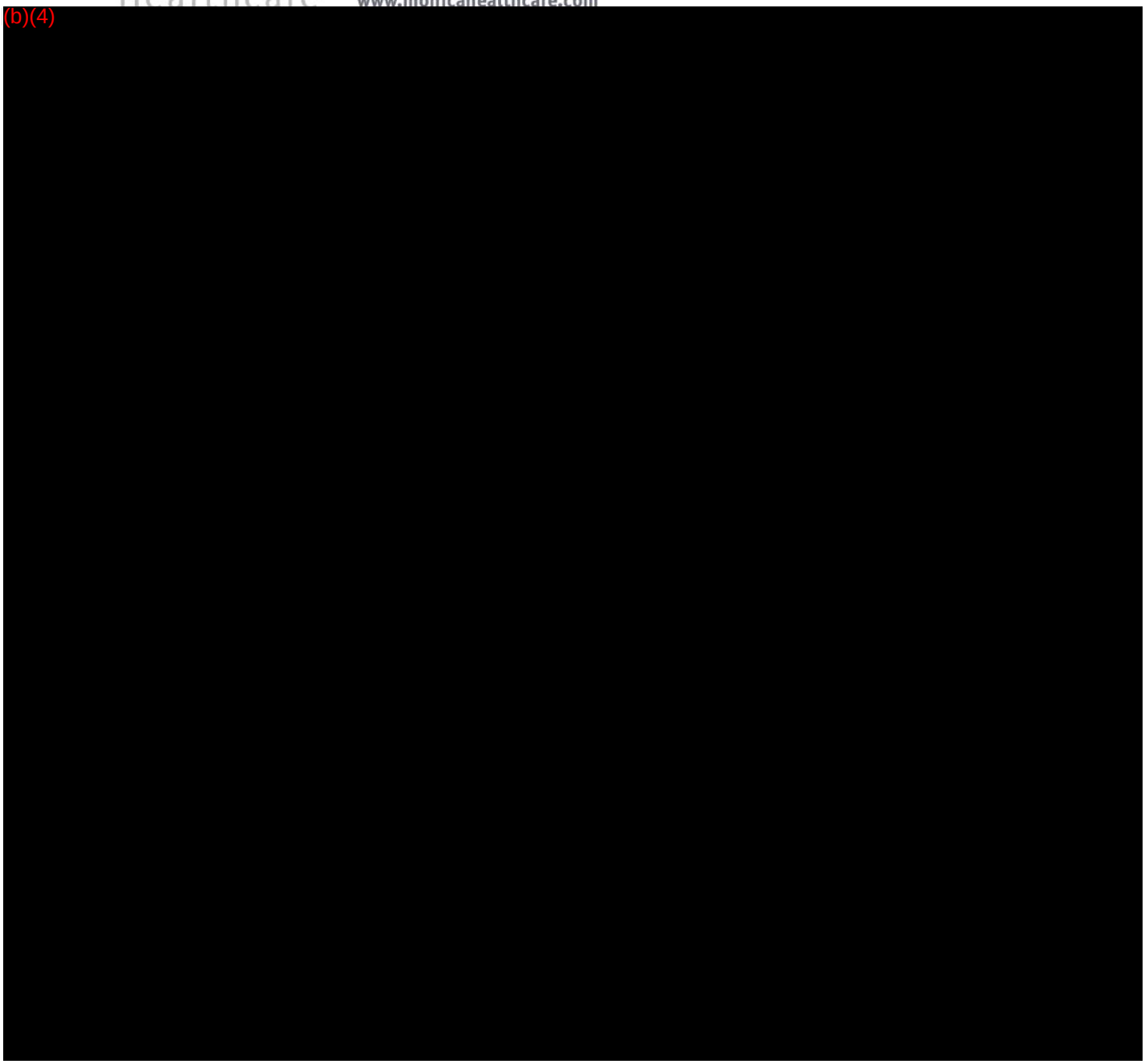

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Records processed under FOIA Request #2015-4103; Released by CDRH on 06-06-2016.

Product	Monica AN24 Abdominal Fetal/Maternal Monitor
Document name	Clinical Investigation Report Supplement – Fetal Heart Rate Accuracy during Labor and Delivery For Patients ≥37 Weeks gestation
Document type	**Clinical Trial Report Supplement**
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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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Indications for Use Statement

510(k) Number (if known):

Device Name: AN24

Indications For Use:

The Monica AN24 is a monitoring device for non-invasively measuring the Fetal Heart Rate (FHR) and Uterine Activity (UA). This data is intended to aid in assessment of the wellbeing of the fetus and mother for Intrapartum laboring singleton pregnancies who are of gestation age ≥37 weeks.

Prescription Use ✔ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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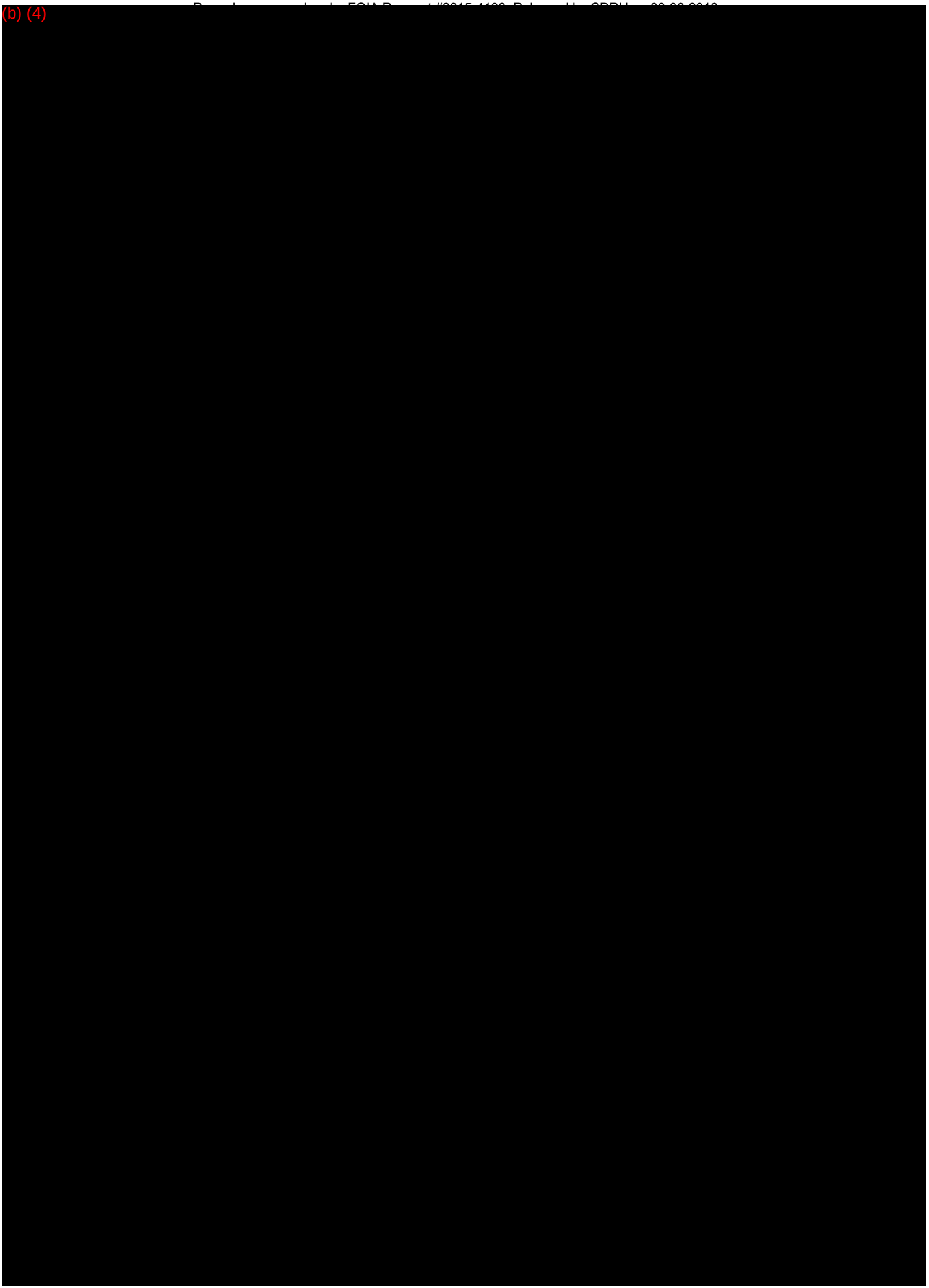

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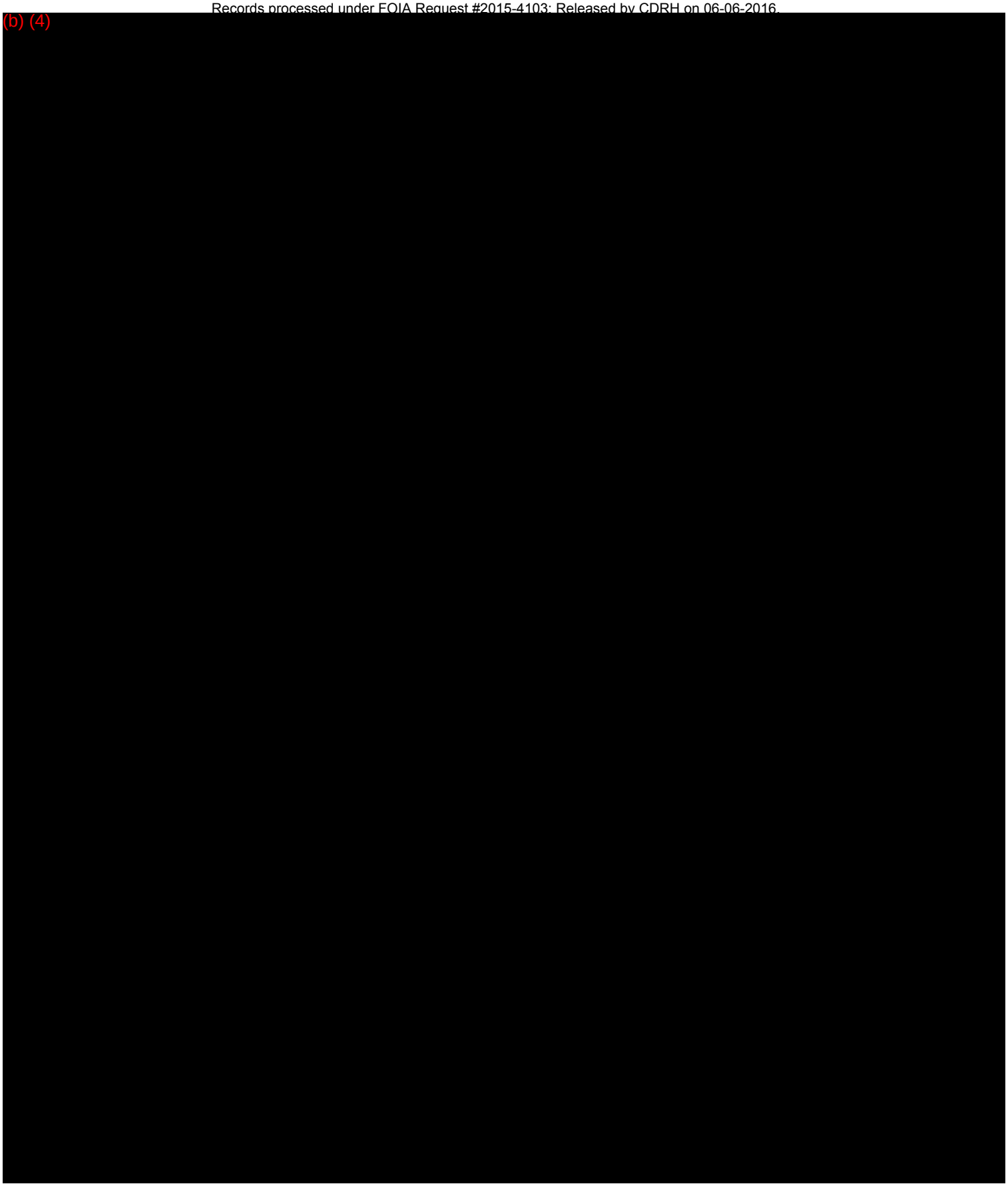

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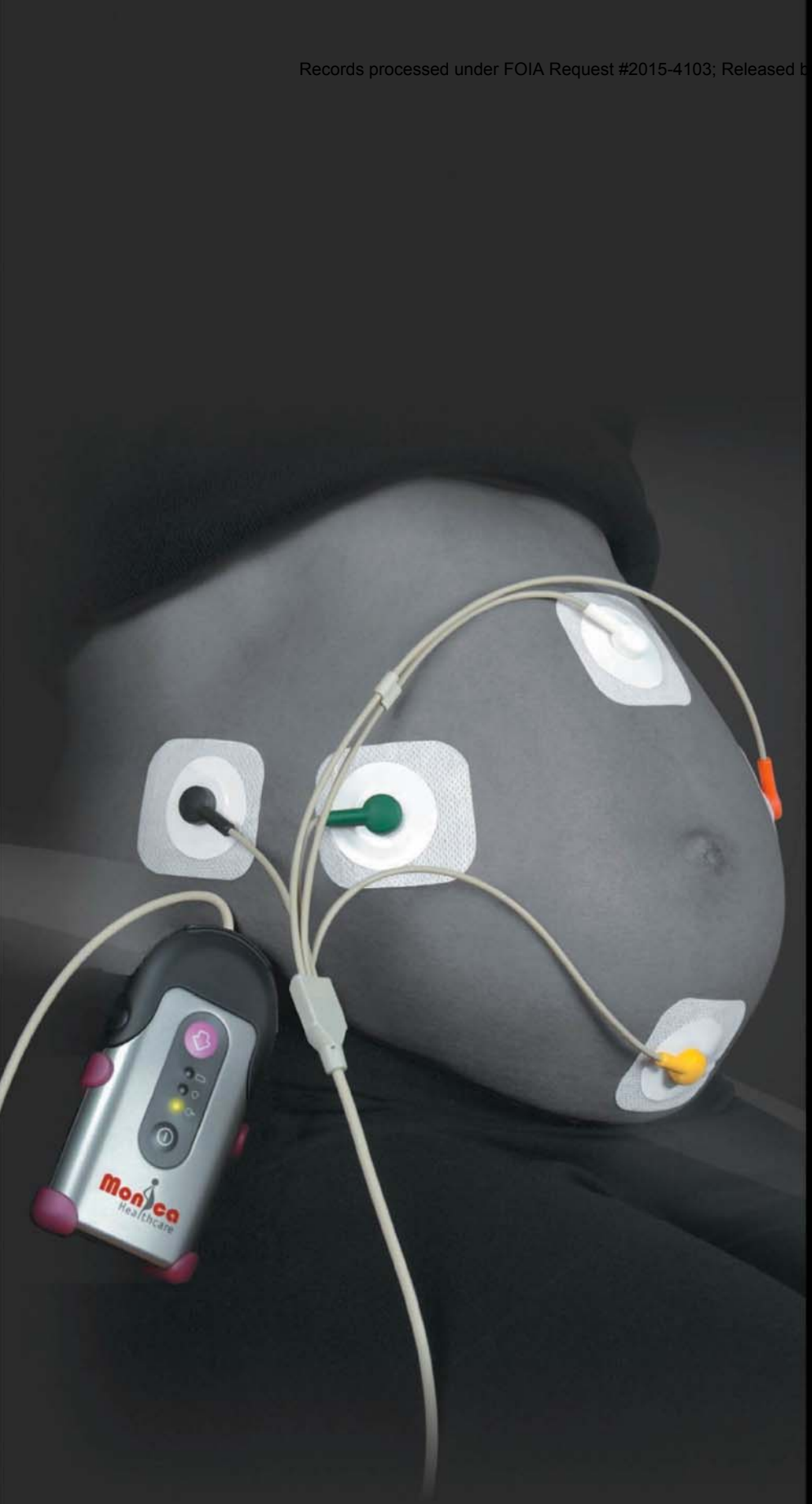

Monica AN24™

Reference Operator Manual

100-TF-006 Revision I

CE
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US law restricts this device to sale by, or on the order of, a physician.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.

Indications For Use

The Monica AN24 is a monitoring device for non-invasively measuring the Fetal Heart Rate (FHR) and Uterine Activity (UA). This data is intended to aid in assessment of the wellbeing of the fetus and mother for Intrapartum laboring singleton pregnancies who are of gestation age ≥37 weeks.

Safety

WARNING: The Monica AN24™ is splash proof but is not designed for submersion in water. Patients must be warned not to immerse the AN24™ or any of its accessories in water, or to take a shower or bath whilst being monitored.

WARNING: The Monica AN24™ is not explosion-proof and must not be used in the presence of flammable anaesthetics.

WARNING: SHOCK HAZARD — Do not attempt to connect the battery charger with wet hands. Make certain that your hands are clean and dry before touching a power lead or plug.

WARNING: Use only the electrode lead cables supplied with the device. Use of any other cables may result in out-of-specification performance and possible safety hazards.

WARNING: Unplug the AN24™ from the AC power source (battery charger) and detach all accessories before cleaning. Do not immerse the unit in water or allow liquids to enter the case.

WARNING: Examine the AN24™ and any accessories periodically to ensure that the leads, connectors and the device itself do not have visible evidence of damage that may affect patient safety or monitoring performance. The recommended inspection interval is once per week or less. Do not use the device if there is any visible sign of damage.

WARNING: The protective silicone rubber cover must be used during Labor and Delivery. Not using the protective silicone rubber cover could result in the ingress of contaminated blood and other fluids into the Monica AN24 case.

WARNING: Only the Battery Charger and mains plug supplied with the Monica AN24™, or its equivalent, is approved for use with the AN24™.

WARNING: Do not attempt to service the Monica AN24™. Only Monica approved and qualified service personnel should attempt any necessary internal servicing.

WARNING: The Monica AN24™ is not specified or intended for operation in conjunction with any other type of monitoring equipment except the specific devices that have been identified for use in this Operator's Manual.

WARNING: Since the Monica AN24™ detects the electrical signals generated from the fetal heart, if other equipment which introduces electrical energy in to the mother is used (e.g. TENS machine, diathermy, impedance meter), then the AN24™ will not be able to detect the fetal heart rate.

WARNING: Do not operate the Monica AN24™ if it fails to pass the power on self-test procedure, see Section 4.

WARNING: Any unexpected data generated by the Monica AN24™ must result in further examination of the mother and fetus in a hospital environment. The data generated by the AN24™ must be backed up by alternative monitoring technologies.

WARNING: For Electromagnetic Compatibility (EMC). Use of accessories, electrodes and leads other than those specified in this manual may result in increased EMC emissions and/or decreased immunity of the Monica AN24™ to other electrical equipment.

WARNING: For Electromagnetic Compatibility (EMC). The Monica AN24™ has been tested for to IEC EN 60601-1-2 for EMC. However, the Monica AN24™ picks up very small electrophysiological signals and so occasionally if other electrical equipment is in the immediate vicinity of monitoring the AN24™ may produce spurious results. The operator should ensure that any such interfering electrical equipment is not in close proximity to the AN24™ during monitoring.

WARNING: The lithium polymer battery pack used within this device has the potential for fire or burning. Do not disassemble, crush, heat or burn.

WARNING: The lithium polymer battery pack cannot be replaced by the user. Replacement may only be made with the battery pack specified by Monica Healthcare, and replacement can only be carried out by Monica Healthcare. Fire or burning may occur if the customer uses a battery pack other than specified by Monica Healthcare.

CAUTION: Keep the operating environment free of dust, vibrations, corrosive, or flammable materials, and extremes of temperature and humidity. The AN24™ and all lead connectors should be kept clean and free of electrode gel and other substances.

CAUTION: Do not operate the unit if it is damp or wet because of condensation or spills. Avoid using the equipment immediately after moving it from a cold environment to a warm, humid location.

CAUTION: Never use sharp or pointed objects to operate the two front-panel membrane switches.

CAUTION: General-purpose personal computers and modems are not designed to meet the electrical safety requirements of medical devices.

CAUTION: Do not autoclave the AN24™ or any accessories. Follow cleaning and disinfection instructions in Section 6 - Cleaning and Maintenance

CAUTION: Do not immerse AN24™, connector or leads in liquid. When using solutions, use sterile/clean wipes to avoid pouring fluids directly on to the AN24™ and connector. Follow cleaning and disinfection instructions in Section 6 - Cleaning and Maintenance

CAUTION: The water temperature must not exceed 40°C (104°F). Do not use chlorine bleach.

CAUTION: Take extra care when cleaning the membrane switches and LED surfaces, which are sensitive to rough handling.

CAUTION: Do not autoclave. Do not gas sterilize.

CAUTION: Only the Battery Charger supplied with the device is approved for use in recharging the internal batteries.

CAUTION: The Monica AN24™ is not specified or intended for operation during the use of defibrillators or during defibrillator discharge.

CAUTION: The Monica AN24™ is not specified or intended for operation in the presence of electrosurgical equipment.

CAUTION: There are minimum signal amplitudes under which the Monica AN24™ will not be able to measure physiological signals.

Clinical Warnings

WARNING: The AN24 utilizes electromyoghraphic (emg) signals to detect uterine activity. As a result, the AN24 occasionally displays deflections above the baseline that reflect electrical activity that may not have generated or correspond to an actual contraction. Such deflections are generally of lower amplitude compared to deflections characteristic of the overall contraction pattern.

WARNING: When assessing FHR decelarations as early, late or variable do not rely on a single deflection above baseline (especially an atypical appearing deflection) as rare “false” contractions may occur.

WARNING: The Monica AN24 does not replace observation and evaluation of the mother and fetus at regular intervals, by a qualified care provider, who will make diagnoses and decide on treatments and interventions. Clinical assessment of the monitor display must be combined with knowledge of patient history and risk factors to properly care for the mother and fetus.

WARNING: The safety and effectiveness of uterine electromyography for monitoring uterine activity have NOT been established for the following patient populations:

- Preterm gestation (i.e., < 36 weeks completed gestation)
- Antepartum (i.e., at term, but not in labor)
- Multiple gestations

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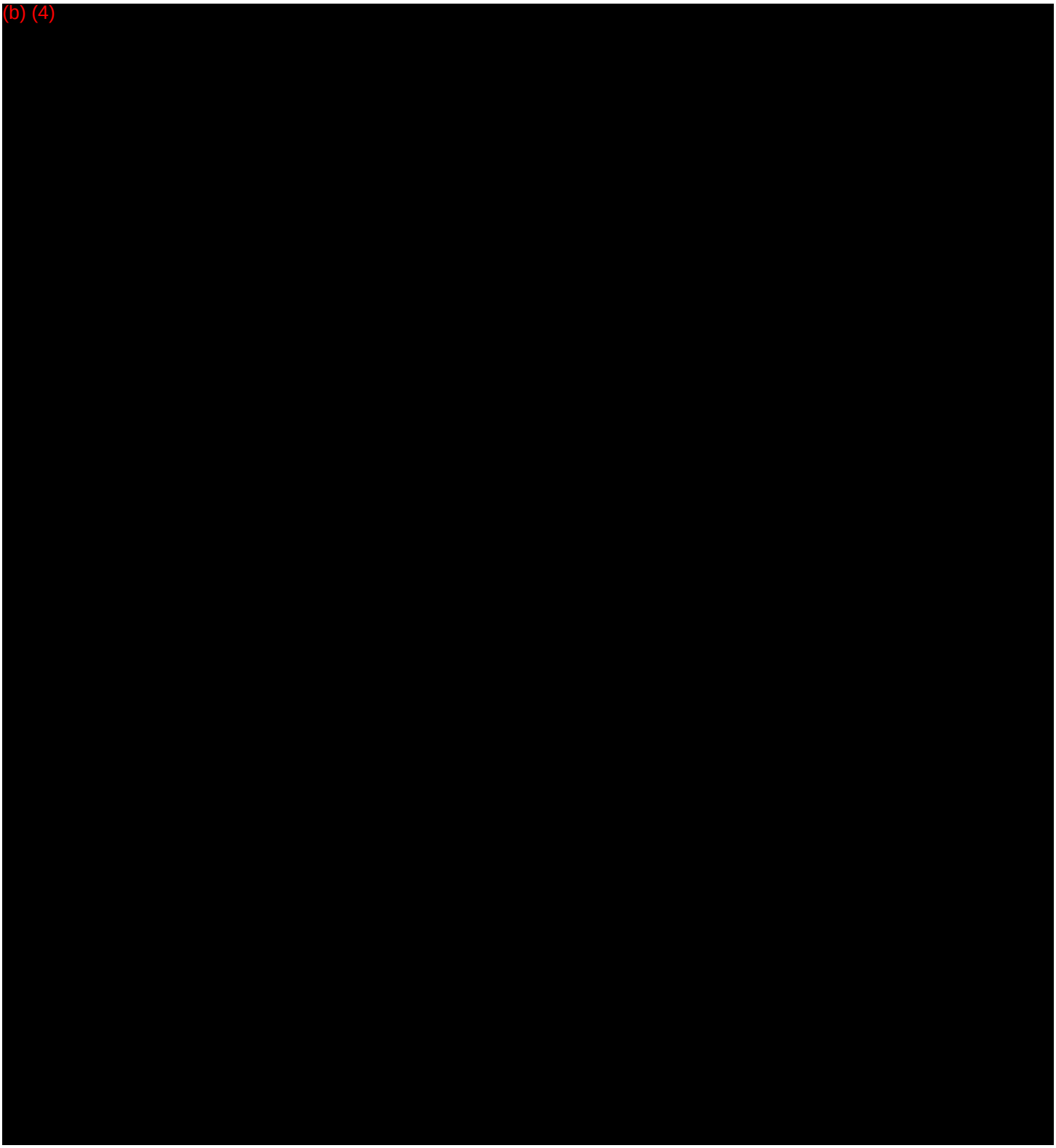

CONTRAINDICATIONS: The Monica AN24 is contraindicated for use in preterm gestation (≤36 completed weeks). The Monica AN 24 may display deflections from baseline that do not represent uterine contractions. These deflections from baseline may represent electrical activity in the myometrium that is not sufficiently organized to cause the uterine smooth muscle to contract. In the context of a preterm pregnancy, clinical misinterpretation of the uterine tracing may lead to unnecessary intervention, such as tocolysis, diagnostic procedures, and/or preterm delivery.

Declaration

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Information in this manual is believed to be accurate and reliable. However, Monica Healthcare Ltd assumes no responsibility for its use, or any infringements of patents or other rights of third parties that may result from its use. No license is granted by implication or otherwise under any patent or patent rights of Monica Healthcare.

This Operator's Manual is intended for trained medical personnel (including obstetricians, midwives, nurses, and physicians) who are familiar with obstetric procedures. Keep this operator's manual with the unit for use by the operator.

Conventions Used in This Operator Manual

Warning: A warning alerts you to a potential serious outcome, adverse event, or safety hazard. Failure to observe a warning may result in death or serious injury to the user or patient.

Caution: A caution alerts you to situations where special care is necessary for the safe and effective use of the product. Failure to observe a caution may result in minor or moderate personal injury or damage to the product or other property, and possibly in a remote risk of more serious injury.

On your monitor, this sign indicates that there is detailed information in this book, which you must read before proceeding with your task.

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Numbers in brackets ( ) refer to the key number in Figure 1 or the index of Table 1

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Section 1 - Unpacking the AN24™

Table 1 - The Monica AN24™ case should contain the following items

	Description
10	Monica AN24™ Device [Item1, Figure 1]
11	Electrode lead connector [Item 2, Figure 1]
12	AN24™ neck strap
13	Battery Charger and lead
14	AN24™ monitor connector/computer USB cable
16	10 Electrodes
17	Roll of abrasive skin tape
18	AN24™ protective cover
20	Quick Start Guide
	Skin Preparation Pen

Please confirm that you can identify all the items in the case.

Figure 1 Monica AN24™ Controls and Indicators

Section 2 - Product Description

2.1 General description

The Monica AN24™ is a wearable, battery-powered device for L&D surveillance of fetal well-being. The AN24™ is designed to passively monitor Fetal Heart Rate (FHR) and Uterine Activity (UA) from the Electro Hysterogram (EHG) during pregnancy and can be used at any time from ≥ 37 weeks gestation to the end of second stage labour. The AN24™ is currently suitable for singleton pregnancies only. One AN24™ is suitable for extended monitoring sessions of up to 18 hours.

2.2 Patient attachment

The Monica AN24™ is attached via a detachable lead assembly that in turn attaches to 5 disposable ECG electrodes placed on the abdomen of a pregnant woman to generate 3 signal channels. The AN24™ then records the electrical signals present at these electrodes that contains information relating to the fetal heart and other sources of electrical energy

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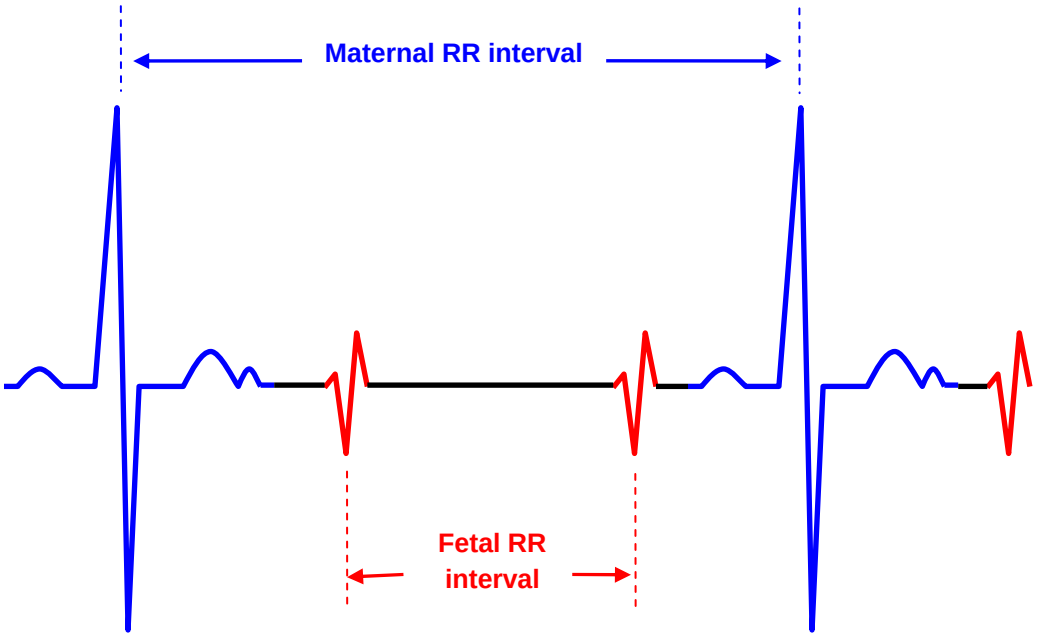

Figure 2 Calculation of FHR from ECG

The FHR is with a ¼ second rolling window update. The amount of averaging is dependant on the ratio of the fetal height to noise and the number of fECG complexes detected, but it

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Section 3 - Installation

3.1 Battery Charging

The Monica AN24™ (Figure 1) is dispatched with a non-removable rechargeable battery which, for shipping, is not fully charged.

The battery must be fully charged prior to use as described below.

Please refer to Figure 1

A. Connect the lead on the supplied battery charger into the socket inside the top of the AN24™ body (**1**). Plug the battery charger into a mains outlet and switch on the mains outlet. The amber battery status LED (**6**) will flash if a connection has been made (this should be confirmed) until the device is charged, when it will be constantly lit. This should take no more than 2½ hrs.
B. When the electrode leads connector (**2**) is connected to the Monica AN24™ Recorder (**1**) disconnect the lead connector (**2**) from the AN24™ body (**1**) by pressing the two buttons (**7**) on either side of the recorder, and gently pulling apart the AN24™ body (**1**) from the lead connector (**2**).

3.2 Instructions

Please fully read these instructions before using the AN24™.

Section 4 - Operating the AN24™

4.1 Set-up procedure when not using the VS monitor

4.1.1 Select mode.

The Monica AN24™ can be operated in two modes, namely:

Mode 1 - Retrospective mode
The Monica AN24™ records fetal heart rate (FHR) and Uterine Activity (UA) for retrospective upload and viewing on a Monica VS Monitor.

Mode 2 - Real time mode
The Monica AN24™ transfers FHR and UA using Bluetooth® wireless transmission in 'real-time' to a Monica VS Monitor for real-time viewing of the data.

The default mode when the Monica AN24™ is turned on for the first time is Mode 1 (Retrospective mode). Connection via USB to a VS Monitor is required to set the time for the first recording.

The AN24™ already running in Mode 1 can be set up to run in Mode 2 by making a wireless Bluetooth® connection using the Monica VS Monitor (see section 4.4).

4.1.2 Electrode attachment

Prior to applying the electrodes, the skin must be prepared correctly using an alcohol wipe and abrasive skin tape (**17**) as described in Supplement 1 – Electrode Placement.

Additionally, the electrodes (**16**) must be positioned correctly on the women's abdomen.

For skin preparation and electrode positions please refer to Supplement 1 – Electrode Placement

4.1.3 Lead connection

Attach the electrode leads connector (**2**) to the electrodes (**16**) following the colour code guide in Supplement 1 – Electrode Placement. Ensure that the electrode leads connector (**2**) is securely attached to the AN24™ (**1**), by pushing the two sections firmly together such that the two buttons (**7**) are engaged.

For monitoring in Labour and Delivery always use the AN24™ Protective cover (supplied). Please refer to Supplement 1 – Electrode Placement for instructions on fitting the protective cover.

4.1.4 Turn on

Turn the AN24™ on by pressing the on/off button (3). All three LEDs (4, 5 and 6) will flash 3 times to indicate that the AN24™ has been turned on.

4.1.5 Memory status self-check

If the Orange memory status LED (**4**) begins to flash when the AN24™ has been turned on, this indicates there is data from a previous patient stored in the memory of the AN24™.

The stored data can be a) downloaded using Monica VS Monitor via a USB cable or b) deleted remotely via Bluetooth® connection to the Monica VS monitor.

a) To download the data via USB, turn off the recorder (see 'Turn Off' section below), and connect the AN24™ to the VS Monitor with the USB cable provided (please refer to the Monica VS Reference Manual for detailed instructions). Once the data has been downloaded, the recorder can be used for a new recording.

b) To delete the data via Bluetooth®, use a Monica VS monitor to connect to the recorder. The VS monitor will automatically recognise that there is data stored on the AN24™ and offer to delete the data or allow the user to disconnect it from VS to download as per a) above (please refer to the Monica VS Reference Manual for detailed instructions). Once the data is deleted the recorder can be used for Real Time mode recording.

4.1.6 Battery status self-check

If the Yellow battery status LED (6) begins to flash when the AN24™ has been turned on, this means that the battery charge is too low for recording to begin. The LED will flash 10 times and then the AN24™ will be automatically turned off. See 'Recharging the batteries later in this section.

N.B. If there is data on the recorder, the Memory Status led will flash alongside the battery status LED.

4.1.7 Electrode attachment self-check

After turn on, the AN24™ will check the electrodes are attached correctly. The green signal quality LED (**5**) will go into one of three states:

- GREEN LED FLICKERS

The green LED flickers rapidly when the electrodes are not correctly attached. To solve this problem please refer to Section 10 - Troubleshooting. The AN24™ will continue this self-check until the problem has been resolved and recording will not begin until it has.

- GREEN LED ON

The green LED is constantly on to indicate that all electrodes are correctly attached to the skin. Once the AN24™ is satisfied that the electrodes are correctly attached the recording will begin. The AN24™ will then look for the signal.

- GREEN LED SLOWLY FLASHES

The green LED will flash (once every 2 seconds) when the AN24™ is satisfied that the electrodes are correctly attached and that monitoring has started (note – this may take up to 30 seconds once the correct electrode attachment has been confirmed). If the LED remains constantly on, please refer to Section 10 - Troubleshooting. If the problem persists please contact your distributor.

NB: Monica VS monitors provide an on-screen electrode attachment check during the setup of a new patient see the VS Reference Operating Manual for details.

4.1.8 Secure the AN24™

If the patient wishes to carry the AN24™ it can either be held in their clothing (e.g. a pocket) or carried around the neck using the supplied neck strap (12). If the patient wishes to use the neck strap, attach it to the AN24™ main body (1) using the neck strap connection (9) and hang the neck strap around the patient's neck. Adjust the length of the neck strap so that the lowest part of the AN24™ is above the sternum and not touching the electrodes.

4.1.9 Secure Cables

If the ECG cable(s) are loose or hanging, secure them with hypoallergenic tape (not supplied) to the patient's abdomen to prevent the cables from pulling on or detaching from the ECG electrodes.

4.2 During monitoring

Self checks during a recording

During recording the AN24™ will regularly perform self-checks. The AN24™ can only be in one of the following four states:

MONITORING OK – GREEN LED FLASHES
The green signal quality LED (**5**) will continue to flash once every 2 seconds to indicate that the electrodes remain attached correctly.

SIGNAL LOST – GREEN LED ON
The green signal quality LED (**13**) will remain constantly illuminated to indicate that the electrodes remain attached correctly but that the signal has been lost. This is not a cause for alarm and may be temporary and due to interference from other sources, for example the noise generated by maternal muscle/movement. Section 10 - Troubleshooting

ELECTRODE DETACHED – GREEN LED FLICKERS
The green signal quality LED (**5**) will flicker rapidly to indicate that one of the electrodes has become detached. The recording will not be stopped at this point, if suitably trained staff are available the electrodes should be re attached to resolve the problem, see Section 10 - Troubleshooting.

BATTERY LOW – YELLOW LED FLASHES
If the Yellow battery status LED (**6**) begins to flash, this indicates that the battery is running low. A short while after this occurs; the AN24™ will automatically turn off. If the device is in Mode 1 (recording mode) the recorded data will be retained until it is uploaded, see Mode 1 - USB upload later in this section.

NB: Monica VS monitors also provide on-screen device status feedback see the VS Reference Operating Manual for details.

4.3 Turn off

When the recording session is completed, turn the AN24™ off by pressing the on/off button (**3**) followed by the event button (**8**) followed by the event button (**8**) again.

This sequence of button presses must be completed within 4 seconds to turn the device off. When the AN24™ is switched off all three LED's (**4, 5** and **6**) will flash three times.

If using a Monica VS Monitor to end a real time recording (mode 2) the Monica AN24 can be switched off remotely by the VS Monitor.

Data Upload - If the AN24™ was used in Mode 1 (recording mode), the recorded data must be uploaded to a computer running the Monica VS Monitor, see 'USB Upload' later in this section.

Clean the AN24™ (**1**) and electrode lead connector (**2**) as described in Section 6 - Cleaning and Maintenance

Battery Charging - recharge the AN24™ (**1**) as described in 3.1 Battery Charging.

4.4 Connecting to a VS Monitor

Monica devices are an integral part of a diagnostic system. The user must adhere to warnings in order to ensure safe and reliable performance of the system.

- Monica VS Monitors complies with IEC 60601-1 the international product safety standard for electrical medical equipment
- Non-medical electrical equipment (e.g. Wireless remote printer) must be situated outside the patient environment (patient environment according to IEC 60601-1-1: = radius 1.5m around the patient).
- The Monica VS Monitors (PT-101-010, PT-101-015) fully comply with the above and are required when using the Monica AN24™ to monitor in real-time within the patient environment (as defined by IEC 60601-1-1).

When connecting to a VS Monitor in either Retrospective or Real-Time mode it is firstly necessary to ensure that the Monica VS Monitor is on and running.

To connect to a VS Monitor in **Retrospective mode**:

A. Disconnect the electrodes from the leads - Disconnect the electrode lead connector (**2**) from the AN24™ (**1**) as described in 3.1 Battery Charging.
B. Power up the VS Monitor, log in and wait until the system is fully loaded
C. Connect USB lead - Connect the AN24™-to-USB lead (**14**) into the socket inside the top of the AN24™ (**1**). Plug the USB end of the lead into a free USB port on the Monitor. The Monica AN24™ device will be automatically recognised by the monitor and will provide status information.

From this point the Monica VS software will know if there is data stored on the device ready for upload (Mode 1 operation). If there is data stored on the device the VS Monitor will guide you through the correct process to upload or delete the stored data.

To connect to a VS Monitor in **Real-Time mode**:

Place the electrodes on the patient as described in in the Getting Started Wizard (press the help icon on the VS screen) or Supplement 1; connect the Monica AN24 to the patient and turn it on.

Select the New Recording button from the Monica VS menu which will then take you through the set-up process.

Section 5 - Safety and Standards

5.1 General

This section describes safety precautions that may appear within the manual and those that appear as symbols labels on the AN24™ itself. Furthermore, this section describes a group of precautions that are applicable, in general, when using the AN24™.

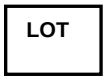
The Monica AN24™ is intended for trained medical personnel (including midwives, nurses, and physicians) who are familiar with obstetric procedures. Keep this operator's manual with the unit for use by the operator.

5.2 Symbols

Attention - Refer to manual

Class II Medical Device

Type BF



Batch number

Manufacture date

Bluetooth® approved device

ESD - Static sensitive device

CE approved

WEEE logo

5.3 Standards

The Monica AN24™ complies with the following safety standards

Standard	Description
IEC EN 60601-1: 1990 UL60601-1:2003 CSA C22.2 No 60601.1	Medical Electrical Equipment Part 1: General requirements for safety
EN 60601-1-2: 2002 IEC 60601-1-2: 2001	Medical Electrical Equipment Part 1-2: General requirements for safety – Collateral Standard: Electromagnetic Compatibility – requirements and tests
Partial compliance of: EN 60601-2-47: 2001 IEC 60601-2-47: 2001	Medical Electrical Equipment Part 2-47: Particular requirements for the safety, including essential performance, of ambulatory electrocardiographic systems
IEC EN 60601-1-4: 1996	Medical electrical equipment Collateral standard: Programmable Electrical Medical Systems
EN 980: 1996	Graphical symbols for use in the labelling of medical devices
EN 1041: 1998	Information supplied by the manufacturer with medical devices

5.4 Interpreting Results

Monica Healthcare recommend that a repeat test is undertaken, using either the AN24™ or an alternative device to confirm the results from the initial test. The repeat test should be carried out in the case of either normal or abnormal results generated by the AN24™.

Good Practise:

When the MHR is high, or the signal quality is poor (section 4.7 VS Operator manual), check the FHR using auscultation (Pinard) or hand held Doppler every 15min to confirm the FHR, and if in any doubt, ask the women to stop pushing during the second stage, until the FHR is confirmed.

5.5 CE

CE The CE Mark on this product denotes conformity with the European Council Medical Device Directive 93/42/EEC.

0843

Section 6 - Cleaning and Maintenance

6.1 AN24™ Device

To avoid damage to the AN24™, connector and leads, clean and disinfect only according to the following instructions. Care MUST be taken to preserve both the AN24™ label and the connector label.

***CAUTION*:** Do not remove, conceal or deface the labels.

CAUTION: Do not autoclave. Do not gas sterilize.

CAUTION: Do not immerse the device or any accessories in liquid and do not expose the connector pins to the cleaning solution. Do not apply oil at any point.

CAUTION: Do not use undiluted bleach or any other cleaning solution other than those recommended here because permanent damage to the AN24™ and leads could occur.

Clean - Wipe the AN24™ and leads with a soft non-abrasive cloth or disposable wipe soaked in a solution such as 70% isopropyl alcohol. Do not use aerosol preparations since they might contain organic solvents. Do not pour fluids directly on the unit and its accessories. Wipe the exterior of the AN24™ and leads three times. Prepare the detergent according to the manufacturer's recommendations. If necessary scrub the AN24™, and leads with the solution using a soft bristled brush for five minutes.

Wash off & Dry - When using solutions, use sterile wipes or gauze to avoid pouring fluids directly on the unit and its accessories. Wipe the AN24™, and leads three times with sterile or distilled water to remove cleaning solution residue. Dry the AN24™, connector and leads thoroughly with a sterile soft towel or gauze surgical sponge.

Disinfect - Use a 1:10 bleach solution after the AN24™ and leads have been cleaned following the same procedure described above. After the low level disinfections, wipe the AN24™ and leads three (3) times with sterile or distilled water to remove diluted bleach residue. Dry the AN24™, connector and leads thoroughly with a sterile soft towel or gauze surgical sponge.

Store the clean AN24™, connector, and leads in a clean bag, covered tray, or other suitable system when not in use.

Monica recommends the patient neck cord included with the Monica AN24 is washed thoroughly or replaced between patients.

6.2 Batteries

The 3.6V rechargeable lithium polymer battery pack should be stored at 0-35°C. Typically the batteries will last for two years or more with regular use. If you need to replace the battery, contact Monica Healthcare directly or your Monica healthcare representative.

6.3 Firmware version

AN24™ Firmware
VS Monitor update

Periodically there will be a need to release new versions of the Firmware and VS Monitor updates, please check with your local distributor to see if you have the latest version.

6.4 Calibration

Calibration of the Monica AN24™ is not required

6.5 Servicing

Maintenance of the AN24™ is carried out by Monica Healthcare. The only routine maintenance which is necessary is battery replacement when failing to hold charge and cleaning as outlined earlier in this Section. Further information is available from:

Monica Healthcare Ltd
BioCity
Pennyfoot Street
Nottingham NG1 1GF
UK
Tel: +44 1159124540
Email: info@monicahealthcare.com
Web: www.monicahealthcare.com

Section 7 - Monica Accessories

Part No.	Description
100-PT-100	Monica VS10 Monitor (Panasonic Toughbook CF-H1)
100-PT-101	Monica VS10 Monitor (Panasonic Toughbook CF-H1, upgrade for existing AN24 customers only)
100-PT-110	Monica VS15 Monitor (Arbor M1525)
100-PT-111	Monica VS15 Monitor (Arbor M1525 upgrade for existing AN24 customers only)
100-PT-001	Monica AN24

100-PT-130	Monica Cart (ITD PRO3OU)
100-PT-131	Monica Cart - printer shelf (ITD PRO3OU
100-PT-132	Monica Desktop Stand (Vesa desktop stand ARM 150 or equivalent)
100-PT-140	Monica Printer (Real-time) - Thermal Z-fold (Fetalgard Lite)
100-PT-160	Monica VS Network Viewer

100-PT-002	ECG Lead Assembly - Standard; ~28 weeks to term
100-PT-004	Battery Charger (UK\ EU\ USA please specify)
100-PT-005	AN24 – USB computer connection cable
100-PT-015	Soft silicon rubber protective boot (x5)
100-PT-016	3M red Dot 2236 skin prep tape (x5)
100-PT-017	Monica approved electrodes – 25 pouches x 10 electrodes (250 electrodes)
100-PT-018	Monica approved electrodes – 150 pouches x 10 electrodes (1500 electrodes)
100-PT-019	Monica AN24 Neck Cord (x5)
100-PT-020	Monica Healthcare glossy sales literature folder (x50)
100-PT-021	Sales Literature sheets
100-PT-022	Skin preparation pen
100-PT-141	Z-Fold paper printer (3 cm/min, 30 - 240 bpm) Analogic US
100-PT-142	Z-Fold paper printer (1 cm/min, 50 - 210 bpm) Analogic International
100-PT-143	Z-Fold paper printer (3 cm/min, 30 - 240 bpm) Philips US
100-PT-144	Z-Fold paper printer (1 cm/min, 50 - 210 bpm) Philips International

Section 8 - Monica VS Monitors

8.1 Overview

Monica VS series of monitors (VS15/VS10) allow the FHR, UA and event annotation data to be viewed, stored and printed as a conventional CTG trace. It is also provides the Monica AN24™ set-up tools to configure the unit and label and store the monitoring sessions for easy identification and retrieval. The functionality of the Monica VS Monitors is explained in detail in the Monica VS Reference Operating Manual.

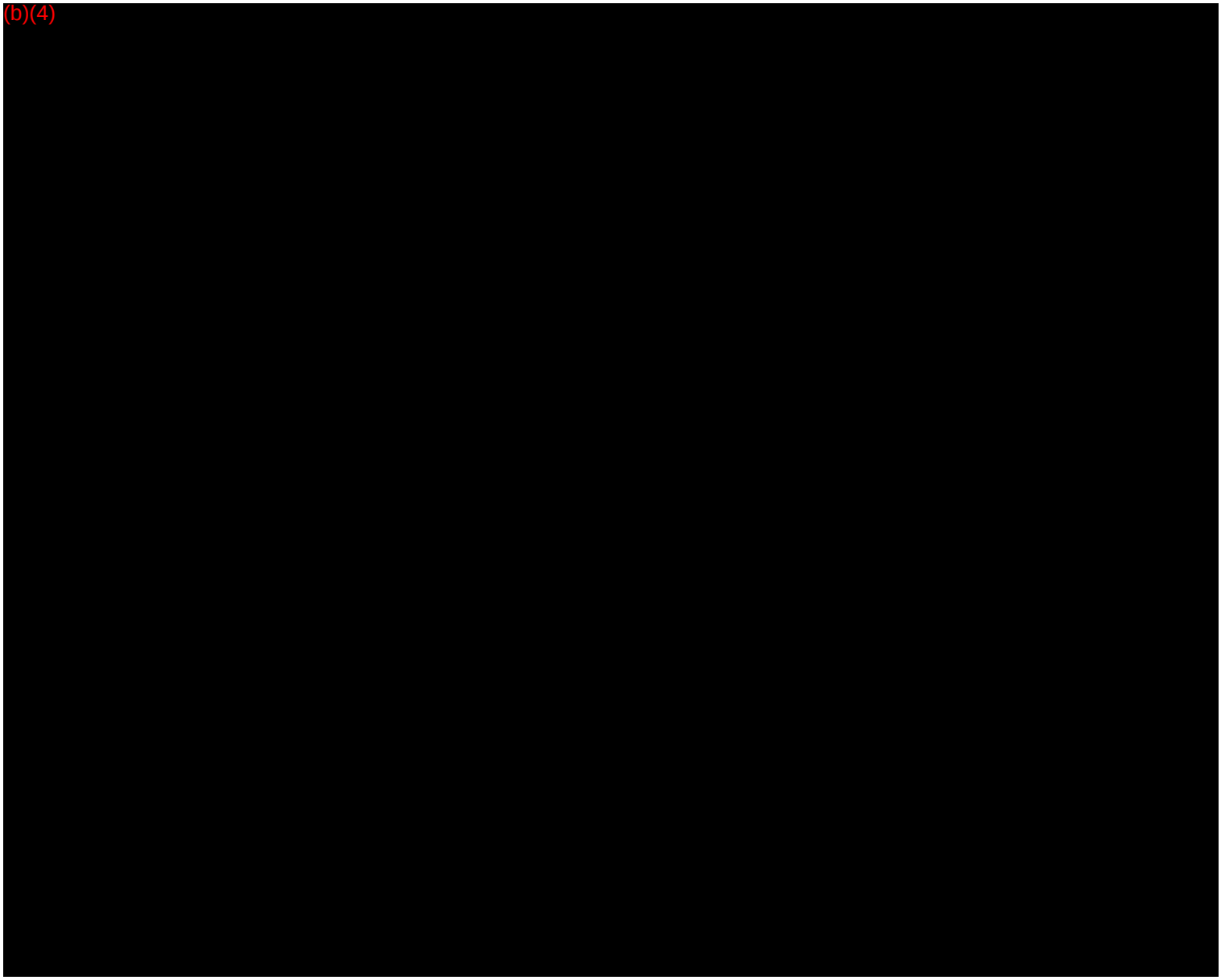
8.2 System Requirements

Monica devices are an integral part of a diagnostic system. The user must adhere to warnings in order to ensure safe and reliable performance of the system.

- Monica VS Monitors complies with IEC 60601-1 the international product safety standard for electrical medical equipment
- Non-medical electrical equipment (e.g. Wireless remote printer) **must be** situated outside the patient environment (patient environment according to IEC 60601-1-1: = radius 1.5m around the patient).
- The Monica VS Monitors (PT-101-010, PT-101-015) fully comply with the above and are required when using the Monica AN24™ to monitor in real-time within the patient environment (as defined by IEC 60601-1-1).

Section 9 - AN24 Specifications

(b)(4)

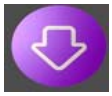


Section 10 - Troubleshooting

10.1 Signal Quality (Green LED flickers)

Electrodes are not attached correctly.

If the green LED flickers, first check that the electrode lead connector cap is connected securely on both sides of the AN24™ (both buttons engaged). If this does not resolve the problem, put AN24™ into electrode check **'Phase 1'** by pressing event button twice within a 2-second period. (NB: this is not required if connected to a VS Monitor which will display the problem electrode(s) on screen without the need to touch the AN24).

 x2

The system will then 'display' the electrode/skin impedance for the electrodes connected to the yellow, green and orange leads.

The electrode/skin impedance will be communicated to the user as follows:

- LED on continuously – the electrode connected to the lead defined by the LED colour has a good connection / low skin impedance
- LED flickers - the electrode connected to the lead defined by the LED colour has a bad connection / high skin impedance

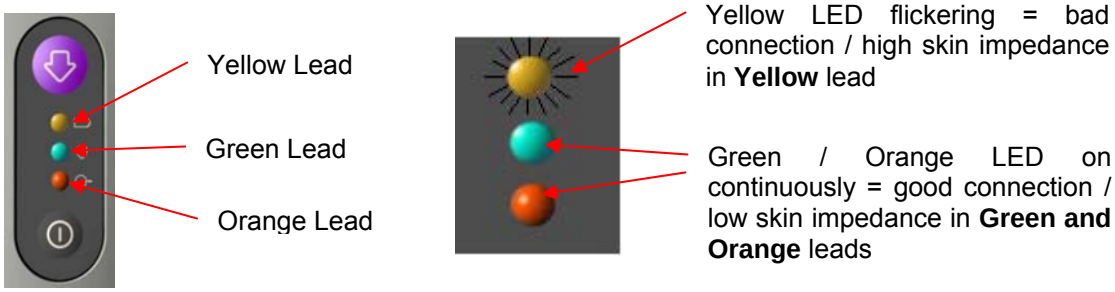
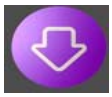


Figure 3 Phase 1 Lead check

If a bad connection is identified in the Yellow, Orange or Green leads, disconnect the lead from the electrode(s) that has a bad connection (leave AN24™ on), remove the electrode(s) and again prepare the skin as described in Supplement 1 – Electrode Placement. When all the electrode(s) have been replaced the leads should be reconnected.

If all the LED are on continuously (good connection), put the AN24™ into electrode check **'Phase 2'** by pressing event button twice within a 2 second period.

 x2

In 'mode 2' the electrode/skin impedance will be communicated to the user for the remaining two electrodes as follows:

- Yellow LED on continuously – the electrode connected to the **White** lead has a good connection / low skin impedance
- Yellow LED flickers - the electrode connected to the **White** lead has a bad connection / high skin impedance
- Green LED on continuously – the electrode connected to the **Black** lead has a good connection / low skin impedance
- Green LED flickers - the electrode connected to the **Black** lead has a bad connection / high skin impedance

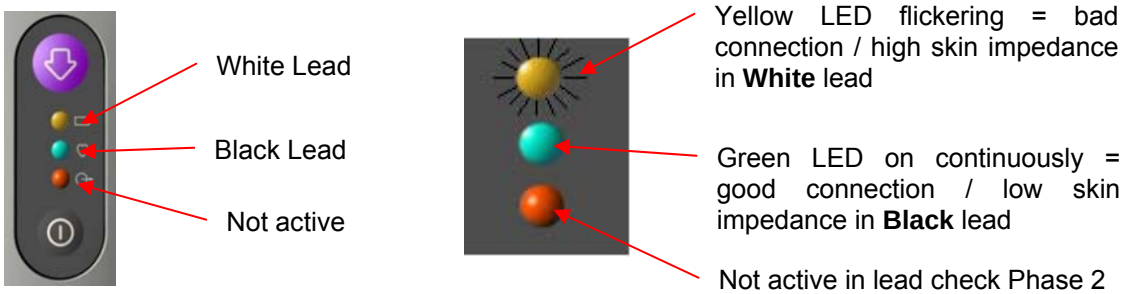
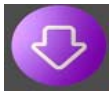


Figure 4 Phase 2 Lead check

If a bad connection is identified in the black or white leads, disconnect the lead from the electrode(s) that has a bad connection (leave AN24™ on), remove the electrode(s) and again prepare the skin as described in Supplement 1 – Electrode Placement. When all the electrode(s) have been replaced the leads should be reconnected.

If the Green and Yellow LED's are on the user should start their monitoring session by pressing the event button twice within a 2-second period

 x2

In the unusual event that it is not possible with repeated skin preparation and correct electrode placement to bring the impedance down and gain a good connection; impedance check may be by-passed or can be halted and repeated at a later date.

To by-pass the impedance checks:

Press the following key sequence in succession:
Power On Button > Pink Event Button > Power Button

If after by passing the impedance check the green LED remains continuously on – signal cannot be found – the monitoring session can be halted and repeated at a later date. This failure should be reported to Monica Healthcare Ltd. Please make a note of which electrode or electrodes failed to pass the impedance check. Monitoring the patient at a future time/date may still be possible.

To abort the electrode check phases (Phase1 or Phase2): switch off the AN24™ as usual (press ON button, then press pink Event button, then press pink Event button)

Alternatively, the lead may be broken. Turn the AN24™ off. Disconnect the lead from both the AN24™ and the electrodes. Attach a spare lead and retry.

If problem is not resolved, contact Monica Healthcare for advice.

10.2 Signal Quality (Green) LED constantly on

The signal cannot be picked up by the AN24™, though the electrodes are correctly connected. This is a common occurrence, which may be due to interference from other sources, for example the noise generated by maternal muscle/ movement. The mother should relax and remain in a supine position for as long as practicable during the recording for optimal results. If problem is not resolved, contact Monica Healthcare for advice.

10.3 Battery Status (Yellow) LED flashing when unit is not being charged

Battery is low. The AN24™ will shortly automatically turn off. Upload the data and recharge the batteries (see 3.1 Battery Charging). If problem is not resolved, contact Monica Healthcare for advice.

10.4 Memory Status (Orange) LED flashing

This indicator will only light just after the AN24™ has been turned on and indicates that there is > 1 minute of data on the device. Upload / delete the data currently stored on the device (see Section 4 -). Turn on the device and resume the monitoring session. If problem is not resolved, contact Monica Healthcare for advice.

10.5 AN24™ will not turn on

Recharge the AN24™ for at least an hour even if the AN24 battery does not flash. If after recharge the AN24™ still does not turn on, return to Monica Healthcare for service.

10.6 AN24™ will not turn off

Return to Monica Healthcare for service

10.7 AN24™ will not recharge

Disconnect AN24™, reconnect battery charger and check charger is connected at both the wall socket and the device. Leave the recorder connected to the charger for half an hour. Then disconnect the AN24™ from the charger and reconnect it again. If problem is not resolved, contact Monica Healthcare for advice.

10.8 AN24™ will not connect via USB

Disconnect USB lead from both the AN24™ and VS Monitor. Reconnect USB lead and retry. If problem is not resolved, connect the AN24™ to the charger for half an hour and try connecting the recorder to the VS Monitor again. If the problem is not solved, contact Monica Healthcare for advice.

10.9 AN24™ will not connect via USB and will not recharge

If the AN24™ does not charge and is not recognised by the VS Monitor, disconnect the AN24™, reconnect battery charger and check charger is connected at both the wall socket and the device. Leave the recorder connected to the charger for half an hour. Then disconnect the AN24™ from the charger and reconnect it again. If problem persists there may be an issue with the Bluetooth® module in the AN24™ - please contact Monica Healthcare for advice.

If the AN24™charges but is not recognised by the VS Monitor disconnect USB lead from both the AN24™ and computer. Reconnect USB lead and retry. If the problem persists there may be an issue with the USB cable – please contact Monica healthcare for advice

10.10 AN24™ will not connect via Bluetooth®

Bring the AN24™ physically close (i.e. within 2 metres) of the VS Monitor and retry. If problem is not resolved, contact Monica Healthcare for advice.

Section 11 - Returns Procedure

11.1 Maintenance

There are no user serviceable parts in the Monica AN24™ or accessories. In the event of device failure or the battery needs to be changed, please contact Monica Healthcare or your local representative.

11.2 Returns

To return a defective product to Monica, you will need to obtain a Return Goods Authorization (RGA) number from the Monica Healthcare Support Group. Please contact a Service Coordinator at:

Telephone: +44 1159124540
Email: support@monicahealthcare.com

You will need to supply the Service Coordinator with the following information:

- The Model number(s) and Serial number(s) of the product, this information can be found on the label on the rear of the AN24™.
- The quantity of items you wish to return.
- Your "Bill to" address for invoice purposes.
- Your "Ship to" address.
- Your Purchase Order number.
- Details of the reported failure.

The Service Coordinator at Monica Healthcare will then inform you of:

- The Return Goods Authorization (RGA) number.
- The warranty or non-warranty status of the units being returned.
- Any repair charge.

All returned material must be shipped “PREPAID” to the address below for both warranty and non-warranty repairs. Please reference your RGA number on both your purchase order and the shipping label:

RGA reference number:
Tioga
St Thomas House
St Mary’s Wharf
Mansfield Road
Derby
DE1 3TN
UK

Supplement 1 – Electrode Placement

I. Patient Posture

It is very important that the woman's stomach muscles are relaxed and she should be encouraged to 'relax' on a bed either on her back (recumbent or semi-recumbent) or on her side (left/right) for as long as practicable during the monitoring session. The patient should **avoid** whenever possible**:**

1. Any position or activity where the abdominal muscles are contracted e.g. sitting upright or lying down with her back raised from the hips at an angle of 45°. If this is unavoidable then using a cushion to support the back can help.
2. A tense stressful situation which will cause abdominal muscle tone to increase even though the patient is in a comfortable position e.g. When the room where the patient is being monitored is filled with Drs, Midwives, Family, Children and other onlookers. In this situation it is advisable to leave the Monica AN24 in place and return when the patient situation has changed.

The VS series of monitors provide a real-time indication of signal to noise in the signal quality indicator where the muscle noise (red-bar height) and the fetal ECG height (green bar) are displayed.

If the fetal ECG height is small and the muscle noise is high then FHR extraction may be compromised; ask the mother to get into a position that is comfortable for her and relax. In addition, changes in maternal posture like lying on the left or right can change the fetal position in relation to the abdomen and uterus and improve the ECG conducting pathway.

II. Electrode Location

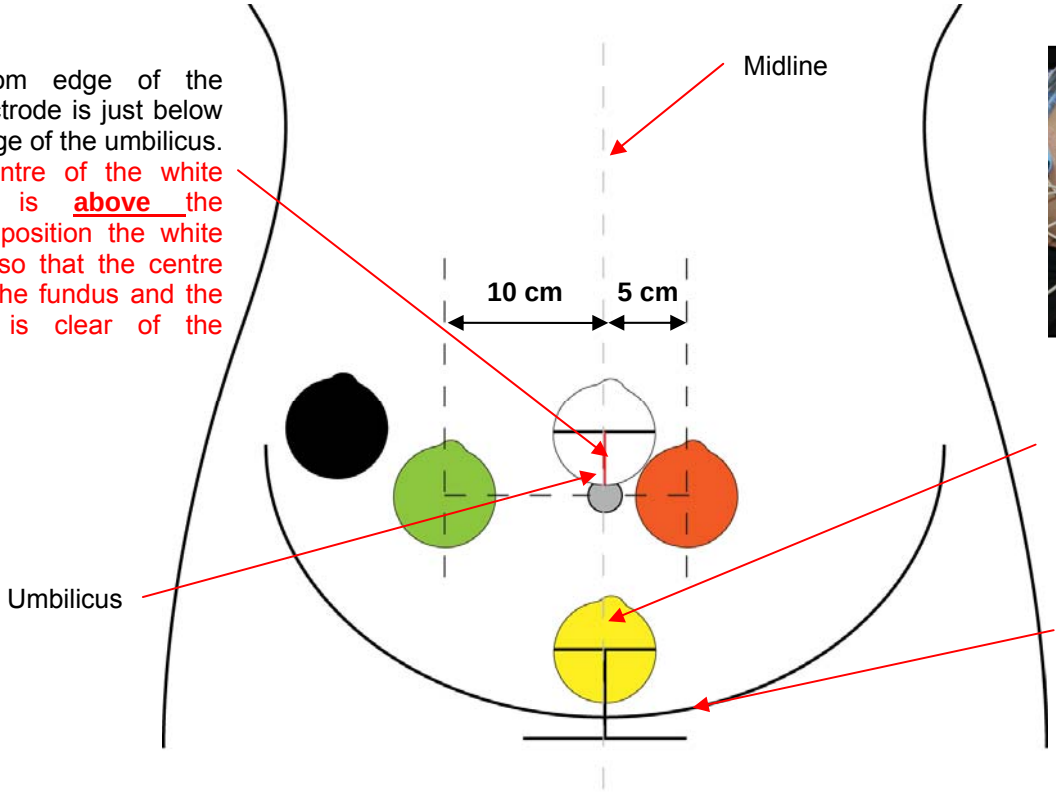
It is important to correctly prepare the skin before the application of the electrodes. You are advised to read all of this section before starting the procedure.

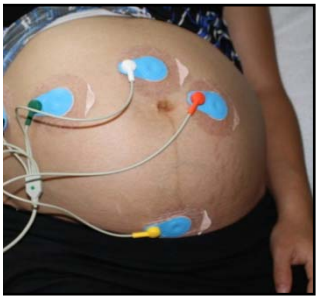
The instrument has three separate detection channel leads. The connectors on these leads are colour coded as **orange**, **white** and **green**. All three channels share a common connection point and this lead connector is coloured **yellow**. Finally, a ground lead with a **black** colour coded connector is also used. These leads are connected to 5 electrodes positioned on the maternal abdomen. Please refer to the table and figures below for guidance in positioning the electrodes.

Electrode / Connector	Position
Yellow	Place the yellow electrode on the mid-line 6cm above the symphysis pubis or as close to 6cm above the symphysis pubis as you can achieve without requiring removal of the pubic hair.
White	Place the white electrode on the mid-line so that the bottom edge of the electrode is just below the top edge of the umbilicus. *If the centre of the white electrode is **above** the fundus, reposition the white electrode so that the centre is **below** the fundus and the electrode is clear of the umbilicus*
Green and Orange	Place the centre of the green and orange electrodes either side of the umbilicus and on the same horizontal line as the umbilicus. The centre of the green electrode should be **10cm** from the **left hand edge** of the umbilicus and the centre of the orange electrode **5cm** from the **right hand edge** of the umbilicus.
Black	The black electrode is the reference electrode and is positioned towards the back behind the green electrode. Its exact position is not critical.

Electrode Positions

The bottom edge of the White electrode is just below the top edge of the umbilicus. (If the centre of the white electrode is **above** the fundus, reposition the white electrode so that the centre is **below** the fundus and the electrode is clear of the umbilicus)



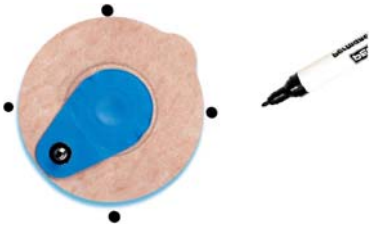


For patients with a large pannis (apron of fat) overhanging the symphysis pubis it is recommended that the yellow electrode be placed **on top** of the pannis on the mid-line such that the centre of the electrode is 6cm above the upper margin of the symphysis pubis or as close to 6cm above the upper margin of symphysis pubis without covering the yellow electrode with the pannis.

These instructions only apply to **Ambu VLC-00-S** electrodes.
Results may be impaired if any electrode is used other than those recommended by

III. Preparation of the skin and electrode application

1. Mark the electrode positions – using the electrode as a template and an alcohol based permanent marker pen.



Note: *If unable to use a pen to mark the site an alternative* ***MUST*** *be used to mark the site. Example: patient's fingers or a small piece of skin prep-tape*

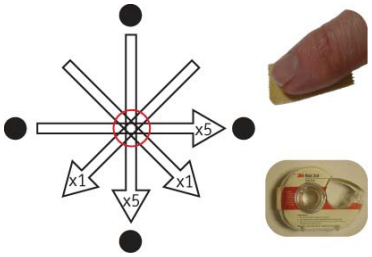
Caution: When using a marker pen ALWAYS follow local cross-contamination protocols.

Warning: DO NOT use a marker pen if the woman has any cuts or open sores on her abdomen

2. If the patient has been using skin care products wash the abdomen with a mild soap and water solution and **dry** first. On **<u>all women</u>** clean the electrode area vigorously with an alcohol swab and allow to dry.

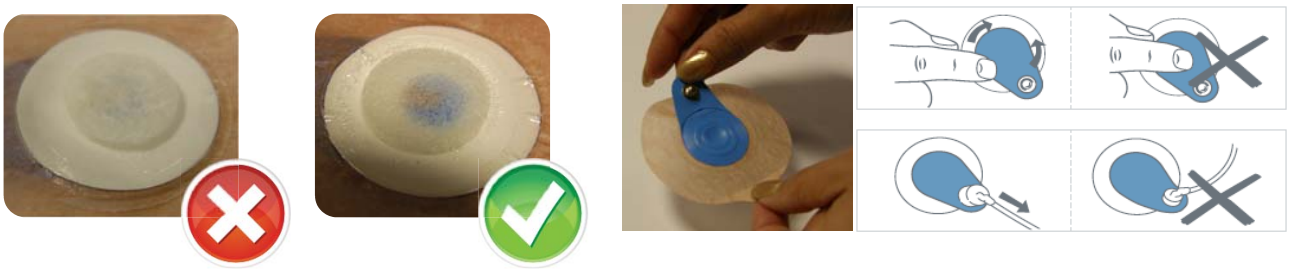
Caution: Using an alcohol wipe on abraded skin may cause patient discomfort and skin irritation.

3. Once the alcohol has dried off, abrade the area, using the supplied prep-tape, stroking the skin in one direction only (5 North to South, 5 East to West, 1 NW-SE, 1 SW- NE) as shown below



Caution: Use only moderate force since excessive use of prep tape may cause patient discomfort and skin irritation. In some patients local skin reactions to the electrode adhesive\gel may occur causing slight reddening of the skin.

4. Apply the electrodes (check the use by date and the gel on the electrode is still wet)



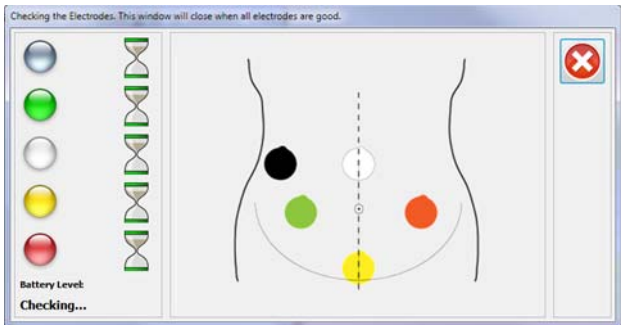
   a. Select one electrode and remove the plastic backing holding the electrode by the single strip of paper remaining so as not to touch the sticky part of the electrode.
   b. Place the electrode on the patient in the exact location that has been prepared. Do not press down in the middle of the electrode since the gel will be forced out. Only press the electrode around the outside and ensure that the material of the electrode does not crease.
   c. Remove the remaining strip of paper and stick down. When positioning the electrode ensure that the connection stud /tab is pointing to the right side of the patient, so that the cable be in the same direction in which the cables are being pulled

Repeat steps 1 – 4 (above) until all five electrodes have been placed.

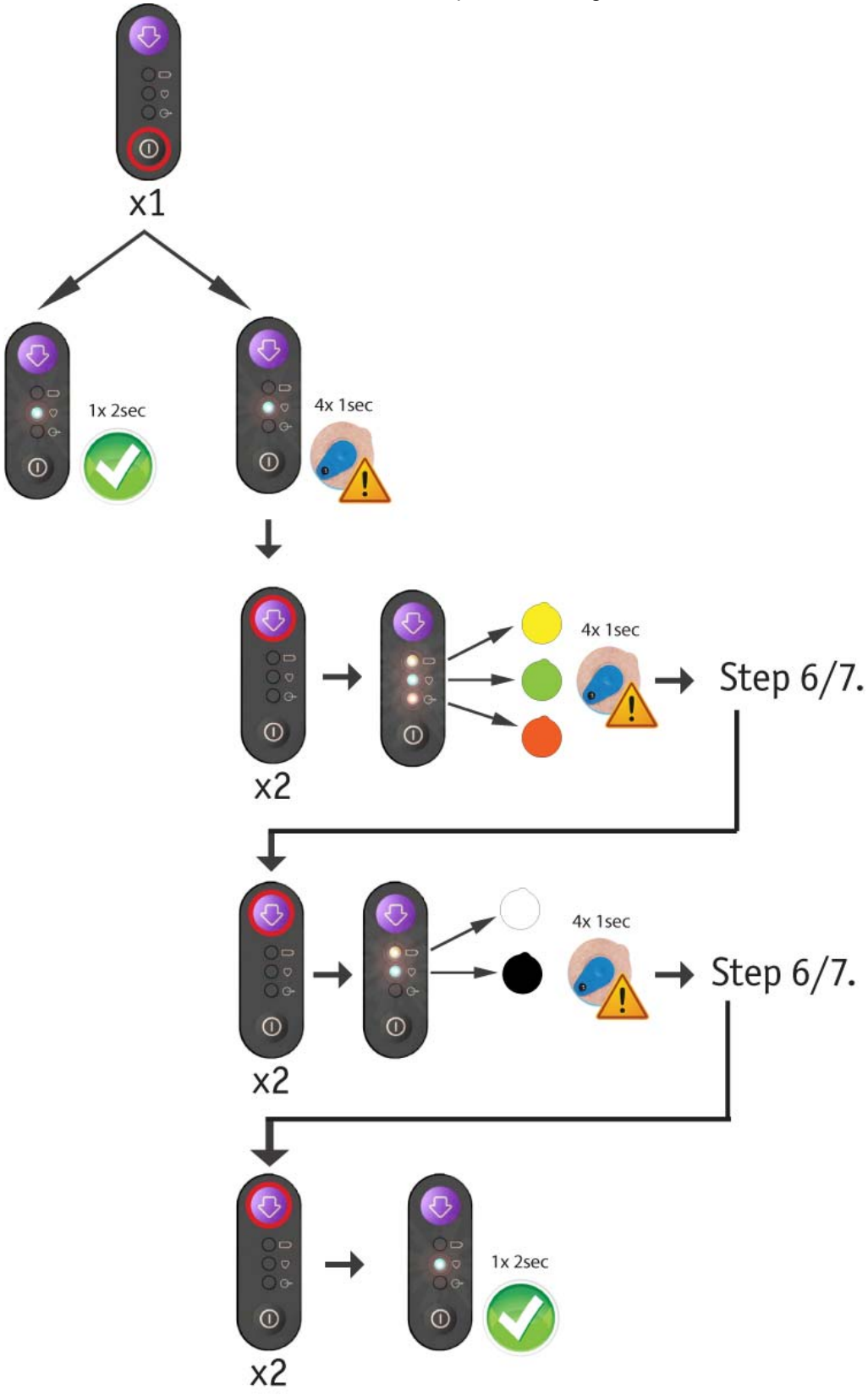
Caution: Do not use any electrodes which are dry or from a pack that has been opened by more than one week. When opening a fresh packet of electrodes, if all the electrodes are not used, write on the pack the date opened and make sure the pack is sealed to prevent the remaining electrodes from drying out.

Warning: Only use any electrodes specified by Monica healthcare. Failure to use the specified electrode could result in unacceptable noise levels resulting in poor FHR detection.

5. Check the electrode impedance (AN24 or VS Monitor – please refer to the Reference VS Operating Manual)
   a. Impedance Check using Monica VS Monitor



b. If the VS monitor is not available check the Impedance using the Monica AN24



6. If impedance check fails
    a. Peel back electrode
    b. Dry wipe the area to remove gel and moisture left by the electrode
    c. Re-abrade the same area of skin pressing firmly
    d. Re-attach the same electrode
    e. Wait 2-3 minutes for the electrode to settle
    f. Check the impedance again (Step 5)

7. If the impedance check fails a second time
    a. remove and discard the electrode
    b. Dry wipe the area to remove gel and moisture left by the electrode
    c. Re-abrade the same area of skin pressing firmly as long as the mother does not become uncomfortable
    d. attach a new electrode
    e. Wait 2-3 minutes for the electrode to settle
    f. Check the impedance again (Step 5)

8. If the impedance check fails a third time on one or more of the Green, White, black or Orange electrodes then the impedance check can be by-passed (see AN24 Reference Operating Manual – 10.1 Troubleshooting Guide). **This is not recommended**. Alternatively, leave the electrodes in place for 30 minutes and try the impedance check again (Step 5).

9. '**Do Not'** by-pass the impedance check if the impedance check for the yellow electrode fails – go to step 6 and repeat process as long as the mother does not become uncomfortable.

10. If it is still not possible to pass the yellow electrode impedance check,

    Option 1: go back to step 8 and by-pass the impedance check. The fetal abdominal ECG can be good in early and late gestation monitoring so noise introduced by high skin electrode impedance can be mitigated. However the quality of the signal cannot be confirmed until the recording commences by looking at the signal to noise bar graph on the VS display or on the Quick-View PDA (not available for sale in the USA).

    Option 2: halt the recording and try again at a future time/date.

Caution: Do not use water to remove the electrodes

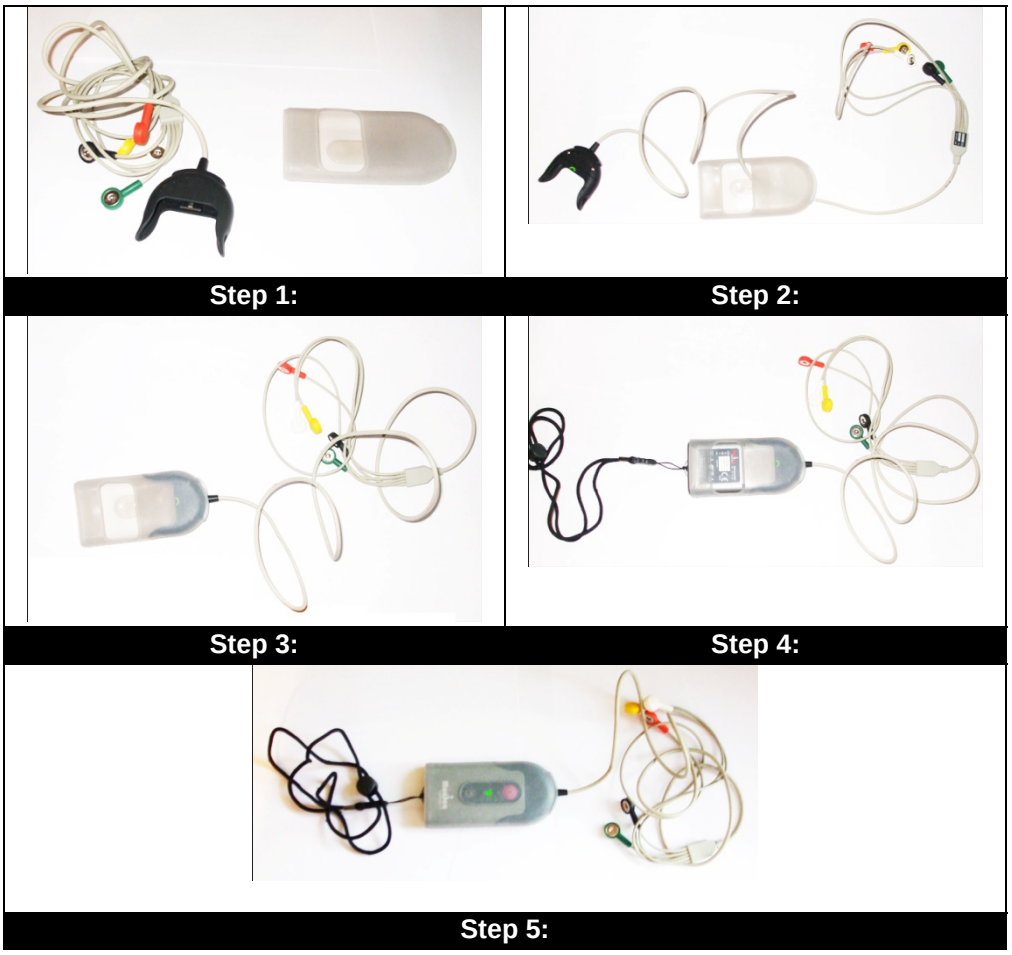
Before attaching the electrodes on to a patient, the user should prepare the skin and place five electrodes on themselves or a volunteer, connect the Monica AN24™ and switch on. The positioning of the electrodes is not important, but this will provide an insight into the skin preparation needed in order to obtain a steady green LED (**5**) indicating that all the electrodes have been correctly attached to the skin.

IV. Lead connection

The 'button' connector on the electrode is located on a 'flap' that is not stuck down. This means that, (a) the flap can be lifted and the correct colour coded lead connector can be pressed/snapped onto the button without pressing on the skin and disturbing the gel electrode contact with the skin and (b) no downward force is applied to the maternal abdomen.

V. Protective cover and neck strap

The protective silicone rubber cover is designed to protect the Monica AN24™ during use, keep it clean and to keep it dry and avoid the ingress of fluids. **It must be used on all L&D subjects.**



Warning: Not using the protective silicone rubber cover could result in the ingress of contaminated blood and other fluids into the Monica AN24 case.

VI. Lead security

It is important to secure and tidy the electrode leads to avoid lead or electrode detachment during operation. The electrode leads are of different lengths to aid in their correct placement and are fitted with two small plastic lead separators, which can be repositioned to avoid lead tangles and aid placement. The long single lead is fitted with a Velcro band so that it can be neatly coiled and secured when the patient is mobile.

VII. Electrostatic Discharge (ESD) precautions

Although precautions have been taken to ensure otherwise, static electricity could cause damage to the sensitive input circuits of the AN24™ and render the device inoperable. In the context of the AN24™, static is most likely to reach the AN24™ via a user\ patient touching static sensitive parts of the device.

ESD precautionary measures should be taken to minimise the risk of damage to the AN24™. More specifically:

- The connector which joins the AN24™ and lead connector together should not be touched by any part of the body, including the fingers
- The metallic (conducting) part of the electrode (press-stud) clips at the extremities of the electrode leads should not be touched by any part of the body, including the fingers

All staff that use the AN24™ should receive an explanation of the ESD warning symbol and receive the following basic training\ instruction in ESD precautions before use of the AN24™:

- How to fit the AN24™ to the patient, and;
- How to attach the electrodes to the AN24™, and;
- How to attach the electrodes to the patient.

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The Monica AN24™™ complies with the requirements of the European Council Directives: 93/42/EEC as amended by 2007/47/EEC, concerning medical devices
ISO 13485 Monica Healthcare Ltd operates Quality Management Systems that have been approved and audited to ISO 13485.

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Ms Kathy Daws - Kopp
Food And Drug Administration
Centre for Devices and Radiological Health
Document Mail Centre – WO66 – G609
10903 New Hampshire Avenue
Silver Spring, Maryland USA 20993-0002

1st December 2010

Reference: K1010801
Trade Name : Monica AN24

Dear Kathy,

(b)(4)

[redacted]

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

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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December 03, 2010

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BIOCITY
PENNYFOOT STREET
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ATTN: IAN HOW

510k Number: K101801

Product: MONICA AN24

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. Pleaseremember that all correspondence concerning your submission MUST be sent to the Document Mail Center 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 http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089402.htm. On August 12, 2005 CDRH issued the Guidance for Industry and FDA Staff: Format for Traditional and Abbreviated 510(k)s. This guidance can be found at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm084365.htm. Please refer to this guidance for assistance on how to format an original submission for a Traditional or Abbreviated 510(k).

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 in 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.

Please ensure that whether you submit a 510(k) Summary as per 21 CFR 807.92, or a 510(k) Statement as per 21 CFR 807.93, it meets the content and format regulatory requirements.

If you have procedural questions, please contact the Division of Small Manufacturers International and Consumer Assistance (DSMICA) at (301)796-7100 or at their toll-free number (800)638-2041, or contact the 510k staff at (301)796-5640.

Sincerely,

510(k) Staff

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

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Silver Spring, Maryland USA 20993-0002

K101801/S2

Received
DEC - 8 2010
FDA CDRH DMC

1st December 2010

Reference: K1010801
Trade Name : Monica AN24

Dear Kathy,

(b)(4) FDA Questions and Responses to FDA Questions

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(b)(4) FDA Questions and Responses to FDA Questions

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Indications for Use Statement

510(k) Number (if known):

Device Name: AN24

Indications For Use:

The Monica AN24 is a monitoring device for non-invasively measuring the Fetal Heart Rate (FHR) and Uterine Activity (UA). This data is intended to aid in assessment of the wellbeing of the fetus and mother for Intrapartum laboring singleton pregnancies who are of gestation age ≥37 weeks.

Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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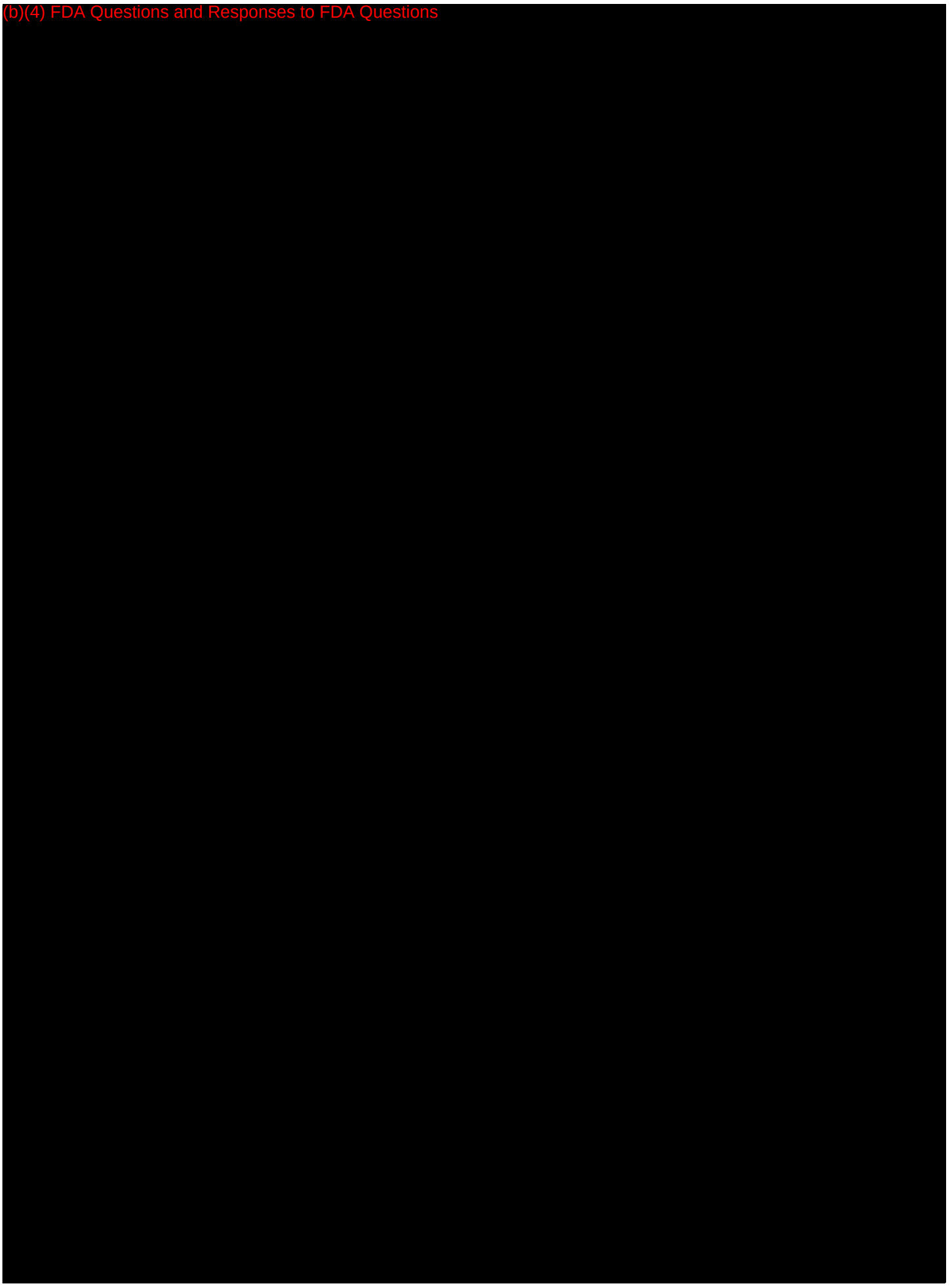

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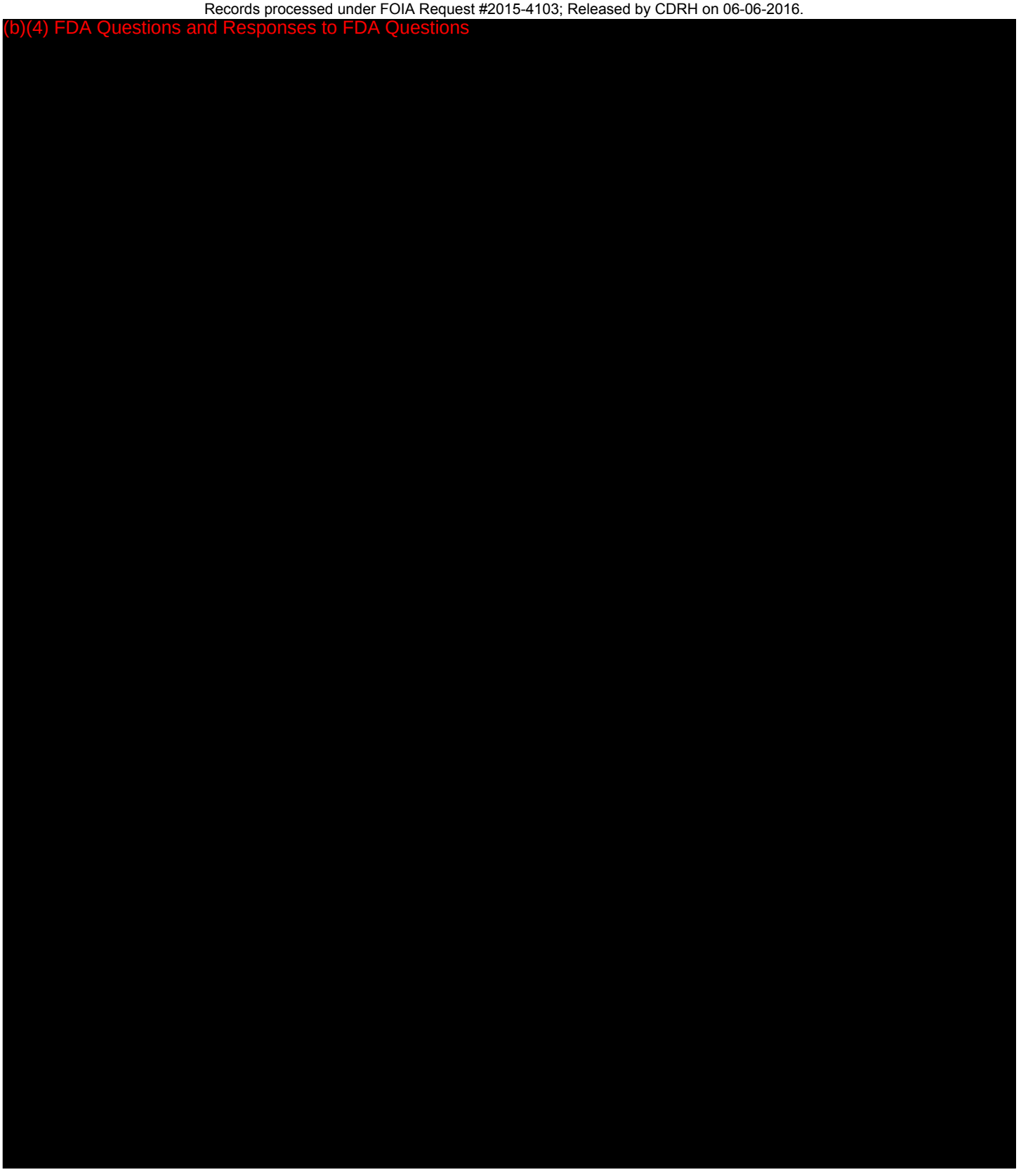

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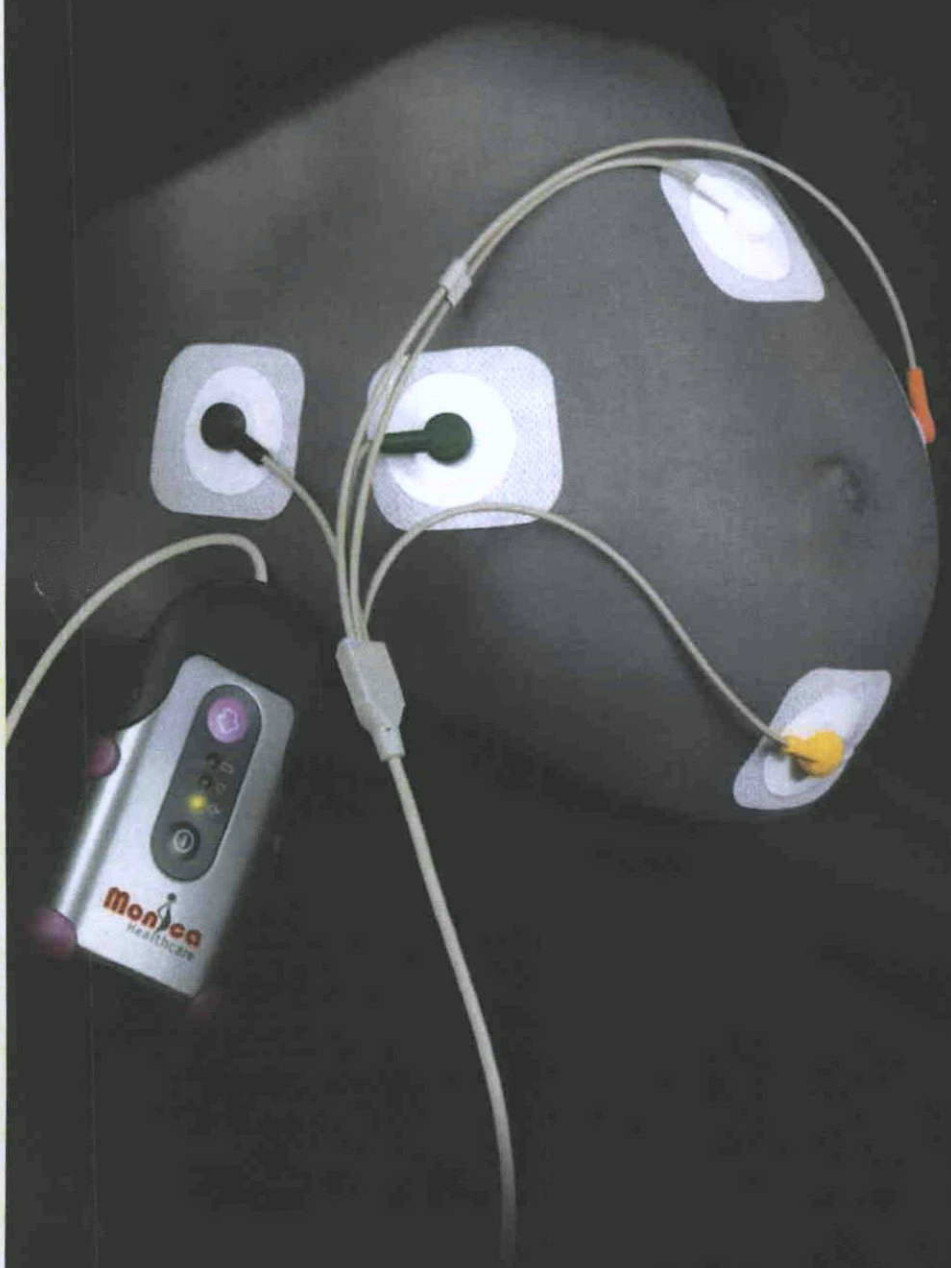

Monica AN24™

Reference Operator Manual

100-TF-006 Revision I

CE 0843

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US law restricts this device to sale by, or on the order of, a physician.

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Indications For Use

The Monica AN24 is a monitoring device for non-invasively measuring the Fetal Heart Rate (FHR) and Uterine Activity (UA). This data is intended to aid in assessment of the wellbeing of the fetus and mother for Intrapartum laboring singleton pregnancies who are of gestation age ≥37 weeks.

Safety

WARNING: The Monica AN24™ is splash proof but is not designed for submersion in water. Patients must be warned not to immerse the AN24™ or any of its accessories in water, or to take a shower or bath whilst being monitored.

WARNING: The Monica AN24™ is not explosion-proof and must not be used in the presence of flammable anaesthetics.

WARNING: SHOCK HAZARD — Do not attempt to connect the battery charger with wet hands. Make certain that your hands are clean and dry before touching a power lead or plug.

WARNING: Use only the electrode lead cables supplied with the device. Use of any other cables may result in out-of-specification performance and possible safety hazards.

WARNING: Unplug the AN24™ from the AC power source (battery charger) and detach all accessories before cleaning. Do not immerse the unit in water or allow liquids to enter the case.

WARNING: Examine the AN24™ and any accessories periodically to ensure that the leads, connectors and the device itself do not have visible evidence of damage that may affect patient safety or monitoring performance. The recommended inspection interval is once per week or less. Do not use the device if there is any visible sign of damage.

WARNING: The protective silicone rubber cover must be used during Labor and Delivery. Not using the protective silicone rubber cover could result in the ingress of contaminated blood and other fluids into the Monica AN24 case.

WARNING: Only the Battery Charger and mains plug supplied with the Monica AN24™, or its equivalent, is approved for use with the AN24™.

WARNING: Do not attempt to service the Monica AN24™. Only Monica approved and qualified service personnel should attempt any necessary internal servicing.

WARNING: The Monica AN24™ is not specified or intended for operation in conjunction with any other type of monitoring equipment except the specific devices that have been identified for use in this Operator's Manual.

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

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WARNING: Since the Monica AN24™ detects the electrical signals generated from the fetal heart, if other equipment which introduces electrical energy in to the mother is used (e.g. TENS machine, diathermy, impedance meter), then the AN24™ will not be able to detect the fetal heart rate.

WARNING: Do not operate the Monica AN24™ if it fails to pass the power on self-test procedure, see Section 4.

WARNING: Any unexpected data generated by the Monica AN24™ must result in further examination of the mother and fetus in a hospital environment. The data generated by the AN24™ must be backed up by alternative monitoring technologies.

WARNING: For Electromagnetic Compatibility (EMC). Use of accessories, electrodes and leads other than those specified in this manual may result in increased EMC emissions and/or decreased immunity of the Monica AN24™ to other electrical equipment.

WARNING: For Electromagnetic Compatibility (EMC). The Monica AN24™ has been tested for to IEC EN 60601-1-2 for EMC. However, the Monica AN24™ picks up very small electrophysiological signals and so occasionally if other electrical equipment is in the immediate vicinity of monitoring the AN24™ may produce spurious results. The operator should ensure that any such interfering electrical equipment is not in close proximity to the AN24™ during monitoring.

WARNING: The lithium polymer battery pack used within this device has the potential for fire or burning. Do not disassemble, crush, heat or burn.

WARNING: The lithium polymer battery pack cannot be replaced by the user. Replacement may only be made with the battery pack specified by Monica Healthcare, and replacement can only be carried out by Monica Healthcare. Fire or burning may occur if the customer uses a battery pack other than specified by Monica Healthcare.

CAUTION: Keep the operating environment free of dust, vibrations, corrosive, or flammable materials, and extremes of temperature and humidity. The AN24™ and all lead connectors should be kept clean and free of electrode gel and other substances.

CAUTION: Do not operate the unit if it is damp or wet because of condensation or spills. Avoid using the equipment immediately after moving it from a cold environment to a warm, humid location.

CAUTION: Never use sharp or pointed objects to operate the two front-panel membrane switches.

CAUTION: General-purpose personal computers and modems are not designed to meet the electrical safety requirements of medical devices.

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CAUTION: Do not autoclave the AN24™ or any accessories. Follow cleaning and disinfection instructions in Section 6 - Cleaning and Maintenance

CAUTION: Do not immerse AN24™, connector or leads in liquid. When using solutions, use sterile/clean wipes to avoid pouring fluids directly on to the AN24™ and connector. Follow cleaning and disinfection instructions in Section 6 - Cleaning and Maintenance

CAUTION: The water temperature must not exceed 40°C (104°F). Do not use chlorine bleach.

CAUTION: Take extra care when cleaning the membrane switches and LED surfaces, which are sensitive to rough handling.

CAUTION: Do not autoclave. Do not gas sterilize.

CAUTION: Only the Battery Charger supplied with the device is approved for use in recharging the internal batteries.

CAUTION: The Monica AN24™ is not specified or intended for operation during the use of defibrillators or during defibrillator discharge.

CAUTION: The Monica AN24™ is not specified or intended for operation in the presence of electrosurgical equipment.

CAUTION: There are minimum signal amplitudes under which the Monica AN24™ will not be able to measure physiological signals.

Clinical Warnings

WARNING: The AN24 utilizes electromyoghraphic (emg) signals to detect uterine activity. As a result, the AN24 occasionally displays deflections above the baseline that reflect electrical activity that may not have generated or correspond to an actual contraction. Such deflections are generally of lower amplitude compared to deflections characteristic of the overall contraction pattern.

WARNING: When assessing FHR decelarations as early, late or variable do not rely on a single deflection above baseline (especially an atypical appearing deflection) as rare "false" contractions may occur.

WARNING: The Monica AN24 does not replace observation and evaluation of the mother and fetus at regular intervals, by a qualified care provider, who will make diagnoses and decide on treatments and interventions. Clinical assessment of the monitor display must be combined with knowledge of patient history and risk factors to properly care for the mother and fetus.

WARNING: The safety and effectiveness of uterine electromyography for monitoring uterine activity have NOT been established for the following patient populations:

- Preterm gestation (i.e., < 36 weeks completed gestation)
- Antepartum (i.e., at term, but not in labor)
- Multiple gestations

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CONTRAINDICATIONS: The Monica AN24 is contraindicated for use in preterm gestation (≤36 completed weeks). The Monica AN 24 may display deflections from baseline that do not represent uterine contractions. These deflections from baseline may represent electrical activity in the myometrium that is not sufficiently organized to cause the uterine smooth muscle to contract. In the context of a preterm pregnancy, clinical misinterpretation of the uterine tracing may lead to unnecessary intervention, such as tocolysis, diagnostic procedures, and/or preterm delivery.

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Declaration

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This Operator's Manual is intended for trained medical personnel (including obstetricians, midwives, nurses, and physicians) who are familiar with obstetric procedures. Keep this operator's manual with the unit for use by the operator.

Conventions Used in This Operator Manual

Warning: A warning alerts you to a potential serious outcome, adverse event, or safety hazard. Failure to observe a warning may result in death or serious injury to the user or patient.

Caution: A caution alerts you to situations where special care is necessary for the safe and effective use of the product. Failure to observe a caution may result in minor or moderate personal injury or damage to the product or other property, and possibly in a remote risk of more serious injury.

On your monitor, this sign indicates that there is detailed information in this book, which you must read before proceeding with your task.

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Numbers in brackets ( ) refer to the key number in Figure 1 or the index of Table 1

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Section 1 - Unpacking the AN24™

Table 1 - The Monica AN24™ case should contain the following items

	Description
10	Monica AN24™ Device [Item1, Figure 1]
11	Electrode lead connector [Item 2, Figure 1]
12	AN24™ neck strap
13	Battery Charger and lead
14	AN24™ monitor connector/computer USB cable
16	10 Electrodes
17	Roll of abrasive skin tape
18	AN24™ protective cover
20	Quick Start Guide
	Skin Preparation Pen

Please confirm that you can identify all the items in the case.

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Figure 1 Monica AN24™ Controls and Indicators

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Section 2 - Product Description

2.1 General description

The Monica AN24™ is a wearable, battery-powered device for L&D surveillance of fetal well-being. The AN24™ is designed to passively monitor Fetal Heart Rate (FHR) and Uterine Activity (UA) from the Electro Hysterogram (EHG) during pregnancy and can be used at any time from ≥ 37 weeks gestation to the end of second stage labour. The AN24™ is currently suitable for singleton pregnancies only. One AN24™ is suitable for extended monitoring sessions of up to 18 hours.

2.2 Patient attachment

The Monica AN24™ is attached via a detachable lead assembly that in turn attaches to 5 disposable ECG electrodes placed on the abdomen of a pregnant woman to generate 3 signal channels. The AN24™ then records the electrical signals present at these electrodes that contains information relating to the fetal heart and other sources of electrical energy

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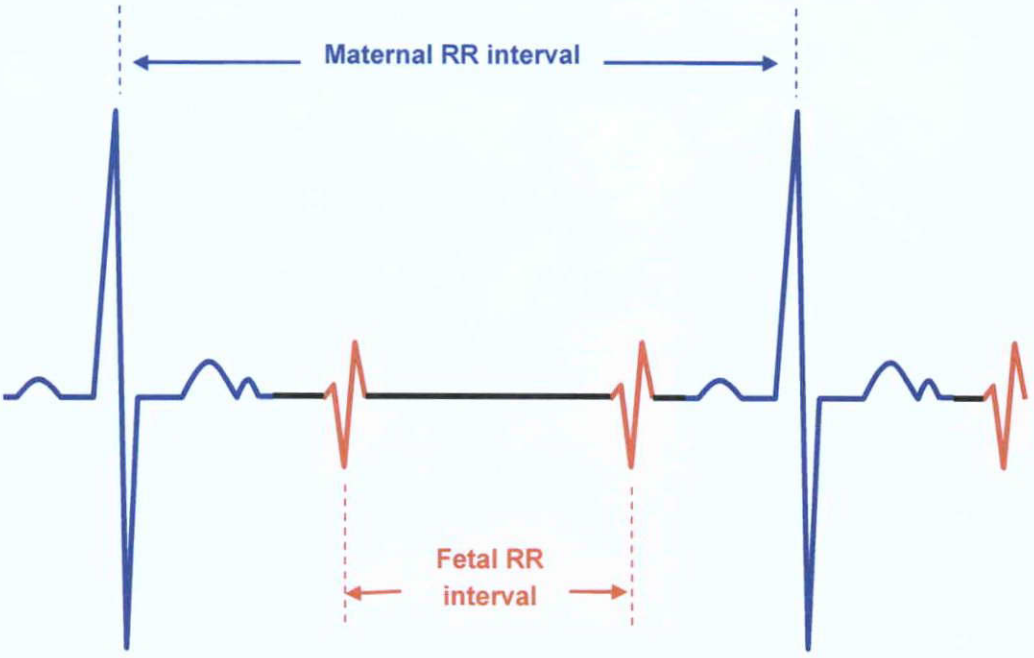

Figure 2 Calculation of FHR from ECG

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Section 3 - Installation

3.1 Battery Charging

The Monica AN24™ (Figure 1) is dispatched with a non-removable rechargeable battery which, for shipping, is not fully charged.

The battery must be fully charged prior to use as described below.

Please refer to Figure 1

A. Connect the lead on the supplied battery charger into the socket inside the top of the AN24™ body (**1**). Plug the battery charger into a mains outlet and switch on the mains outlet. The amber battery status LED (**6**) will flash if a connection has been made (this should be confirmed) until the device is charged, when it will be constantly lit. This should take no more than 2½ hrs.
B. When the electrode leads connector (**2**) is connected to the Monica AN24™ Recorder (**1**) disconnect the lead connector (**2**) from the AN24™ body (**1**) by pressing the two buttons (**7**) on either side of the recorder, and gently pulling apart the AN24™ body (**1**) from the lead connector (**2**).

3.2 Instructions

Please fully read these instructions before using the AN24™.

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Section 4 - Operating the AN24™

4.1 Set-up procedure when not using the VS monitor

4.1.1 Select mode.

The Monica AN24™ can be operated in two modes, namely:

Mode 1 - Retrospective mode
The Monica AN24™ records fetal heart rate (FHR) and Uterine Activity (UA) for retrospective upload and viewing on a Monica VS Monitor.

Mode 2 - Real time mode
The Monica AN24™ transfers FHR and UA using Bluetooth® wireless transmission in 'real-time' to a Monica VS Monitor for real-time viewing of the data.

The default mode when the Monica AN24™ is turned on for the first time is Mode 1 (Retrospective mode). Connection via USB to a VS Monitor is required to set the time for the first recording.

The AN24™ already running in Mode 1 can be set up to run in Mode 2 by making a wireless Bluetooth® connection using the Monica VS Monitor (see section 4.4).

4.1.2 Electrode attachment

Prior to applying the electrodes, the skin must be prepared correctly using an alcohol wipe and abrasive skin tape (**17**) as described in Supplement 1 – Electrode Placement.

Additionally, the electrodes (**16**) must be positioned correctly on the women's abdomen.

For skin preparation and electrode positions please refer to Supplement 1 – Electrode Placement

4.1.3 Lead connection

Attach the electrode leads connector (**2**) to the electrodes (**16**) following the colour code guide in Supplement 1 – Electrode Placement. Ensure that the electrode leads connector (**2**) is securely attached to the AN24™ (**1**), by pushing the two sections firmly together such that the two buttons (**7**) are engaged.

For monitoring in Labour and Delivery always use the AN24™ Protective cover (supplied). Please refer to Supplement 1 – Electrode Placement for instructions on fitting the protective cover.

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4.1.4 Turn on

Turn the AN24™ on by pressing the on/off button (3). All three LEDs (4, 5 and 6) will flash 3 times to indicate that the AN24™ has been turned on.

4.1.5 Memory status self-check

If the Orange memory status LED (**4**) begins to flash when the AN24™ has been turned on, this indicates there is data from a previous patient stored in the memory of the AN24™.

The stored data can be a) downloaded using Monica VS Monitor via a USB cable or b) deleted remotely via Bluetooth® connection to the Monica VS monitor.

a) To download the data via USB, turn off the recorder (see 'Turn Off' section below), and connect the AN24™ to the VS Monitor with the USB cable provided (please refer to the Monica VS Reference Manual for detailed instructions). Once the data has been downloaded, the recorder can be used for a new recording.

b) To delete the data via Bluetooth®, use a Monica VS monitor to connect to the recorder. The VS monitor will automatically recognise that there is data stored on the AN24™ and offer to delete the data or allow the user to disconnect it from VS to download as per a) above (please refer to the Monica VS Reference Manual for detailed instructions). Once the data is deleted the recorder can be used for Real Time mode recording.

4.1.6 Battery status self-check

If the Yellow battery status LED (6) begins to flash when the AN24™ has been turned on, this means that the battery charge is too low for recording to begin. The LED will flash 10 times and then the AN24™ will be automatically turned off. See 'Recharging the batteries later in this section.

N.B. If there is data on the recorder, the Memory Status led will flash alongside the battery status LED.

4.1.7 Electrode attachment self-check

After turn on, the AN24™ will check the electrodes are attached correctly. The green signal quality LED (**5**) will go into one of three states:

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- GREEN LED FLICKERS

The green LED flickers rapidly when the electrodes are not correctly attached. To solve this problem please refer to Section 10 - Troubleshooting. The AN24™ will continue this self-check until the problem has been resolved and recording will not begin until it has.

- GREEN LED ON

The green LED is constantly on to indicate that all electrodes are correctly attached to the skin. Once the AN24™ is satisfied that the electrodes are correctly attached the recording will begin. The AN24™ will then look for the signal.

- GREEN LED SLOWLY FLASHES

The green LED will flash (once every 2 seconds) when the AN24™ is satisfied that the electrodes are correctly attached and that monitoring has started (note – this may take up to 30 seconds once the correct electrode attachment has been confirmed). If the LED remains constantly on, please refer to Section 10 - Troubleshooting. If the problem persists please contact your distributor.

NB: Monica VS monitors provide an on-screen electrode attachment check during the setup of a new patient see the VS Reference Operating Manual for details.

4.1.8 Secure the AN24™

If the patient wishes to carry the AN24™ it can either be held in their clothing (e.g. a pocket) or carried around the neck using the supplied neck strap (12). If the patient wishes to use the neck strap, attach it to the AN24™ main body (1) using the neck strap connection (9) and hang the neck strap around the patient's neck. Adjust the length of the neck strap so that the lowest part of the AN24™ is above the sternum and not touching the electrodes.

4.1.9 Secure Cables

If the ECG cable(s) are loose or hanging, secure them with hypoallergenic tape (not supplied) to the patient's abdomen to prevent the cables from pulling on or detaching from the ECG electrodes.

4.2 During monitoring

Self checks during a recording

During recording the AN24™ will regularly perform self-checks. The AN24™ can only be in one of the following four states:

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MONITORING OK – GREEN LED FLASHES

The green signal quality LED (**5**) will continue to flash once every 2 seconds to indicate that the electrodes remain attached correctly.

SIGNAL LOST – GREEN LED ON

The green signal quality LED (**13**) will remain constantly illuminated to indicate that the electrodes remain attached correctly but that the signal has been lost. This is not a cause for alarm and may be temporary and due to interference from other sources, for example the noise generated by maternal muscle/movement. Section 10 - Troubleshooting

ELECTRODE DETACHED – GREEN LED FLICKERS

The green signal quality LED (**5**) will flicker rapidly to indicate that one of the electrodes has become detached. The recording will not be stopped at this point, if suitably trained staff are available the electrodes should be re attached to resolve the problem, see Section 10 - Troubleshooting.

BATTERY LOW – YELLOW LED FLASHES

If the Yellow battery status LED (**6**) begins to flash, this indicates that the battery is running low. A short while after this occurs; the AN24™ will automatically turn off. If the device is in Mode 1 (recording mode) the recorded data will be retained until it is uploaded, see Mode 1 - USB upload later in this section.

NB: Monica VS monitors also provide on-screen device status feedback see the VS Reference Operating Manual for details.

4.3 Turn off

When the recording session is completed, turn the AN24™ off by pressing the on/off button (**3**) followed by the event button (**8**) followed by the event button (**8**) again.

This sequence of button presses must be completed within 4 seconds to turn the device off. When the AN24™ is switched off all three LED's (**4, 5** and **6**) will flash three times.

If using a Monica VS Monitor to end a real time recording (mode 2) the Monica AN24 can be switched off remotely by the VS Monitor.

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Data Upload - If the AN24™ was used in Mode 1 (recording mode), the recorded data must be uploaded to a computer running the Monica VS Monitor, see 'USB Upload' later in this section.

Clean the AN24™ (**1**) and electrode lead connector (**2**) as described in Section 6 - Cleaning and Maintenance

Battery Charging - recharge the AN24™ (**1**) as described in 3.1 Battery Charging.

4.4 Connecting to a VS Monitor

Monica devices are an integral part of a diagnostic system. The user must adhere to warnings in order to ensure safe and reliable performance of the system.

- Monica VS Monitors complies with IEC 60601-1 the international product safety standard for electrical medical equipment
- Non-medical electrical equipment (e.g. Wireless remote printer) must be situated outside the patient environment (patient environment according to IEC 60601-1-1: = radius 1.5m around the patient).
- The Monica VS Monitors (PT-101-010, PT-101-015) fully comply with the above and are required when using the Monica AN24™ to monitor in real-time within the patient environment (as defined by IEC 60601-1-1).

When connecting to a VS Monitor in either Retrospective or Real-Time mode it is firstly necessary to ensure that the Monica VS Monitor is on and running.

To connect to a VS Monitor in **Retrospective mode**:

A. Disconnect the electrodes from the leads - Disconnect the electrode lead connector (**2**) from the AN24™ (**1**) as described in 3.1 Battery Charging.
B. Power up the VS Monitor, log in and wait until the system is fully loaded
C. Connect USB lead - Connect the AN24™-to-USB lead (**14**) into the socket inside the top of the AN24™ (**1**). Plug the USB end of the lead into a free USB port on the Monitor. The Monica AN24™ device will be automatically recognised by the monitor and will provide status information.

From this point the Monica VS software will know if there is data stored on the device ready for upload (Mode 1 operation). If there is data stored on the device the VS Monitor will guide you through the correct process to upload or delete the stored data.

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

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To connect to a VS Monitor in **Real-Time mode**:

Place the electrodes on the patient as described in in the Getting Started Wizard (press the help icon on the VS screen) or Supplement 1; connect the Monica AN24 to the patient and turn it on.

Select the New Recording button from the Monica VS menu which will then take you through the set-up process.

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

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Section 5 - Safety and Standards

5.1 General

This section describes safety precautions that may appear within the manual and those that appear as symbols labels on the AN24™ itself. Furthermore, this section describes a group of precautions that are applicable, in general, when using the AN24™.

The Monica AN24™ is intended for trained medical personnel (including midwives, nurses, and physicians) who are familiar with obstetric procedures. Keep this operator's manual with the unit for use by the operator.

5.2 Symbols

Attention - Refer to manual

Class II Medical Device

Type BF

Batch number

Manufacture date

Bluetooth® approved device

ESD - Static sensitive device

CE approved

WEEE logo

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5.3 Standards

The Monica AN24™ complies with the following safety standards

Standard	Description
IEC EN 60601-1: 1990 UL60601-1:2003 CSA C22.2 No 60601.1	Medical Electrical Equipment Part 1: General requirements for safety
EN 60601-1-2: 2002 IEC 60601-1-2: 2001	Medical Electrical Equipment Part 1-2: General requirements for safety – Collateral Standard: Electromagnetic Compatibility – requirements and tests
Partial compliance of: EN 60601-2-47: 2001 IEC 60601-2-47: 2001	Medical Electrical Equipment Part 2-47: Particular requirements for the safety, including essential performance, of ambulatory electrocardiographic systems
IEC EN 60601-1-4: 1996	Medical electrical equipment Collateral standard: Programmable Electrical Medical Systems
EN 980: 1996	Graphical symbols for use in the labelling of medical devices
EN 1041: 1998	Information supplied by the manufacturer with medical devices

5.4 Interpreting Results

Monica Healthcare recommend that a repeat test is undertaken, using either the AN24™ or an alternative device to confirm the results from the initial test. The repeat test should be carried out in the case of either normal or abnormal results generated by the AN24™.

Good Practise:

When the MHR is high, or the signal quality is poor (section 4.7 VS Operator manual), check the FHR using auscultation (Pinard) or hand held Doppler every 15min to confirm the FHR, and if in any doubt, ask the women to stop pushing during the second stage, until the FHR is confirmed.

5.5 CE

CE The CE Mark on this product denotes conformity with the European Council Medical Device Directive 93/42/EEC.

0843

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

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Section 6 - Cleaning and Maintenance

6.1 AN24™ Device

To avoid damage to the AN24™, connector and leads, clean and disinfect only according to the following instructions. Care MUST be taken to preserve both the AN24™ label and the connector label.

***CAUTION*:** Do not remove, conceal or deface the labels.

CAUTION: Do not autoclave. Do not gas sterilize.

CAUTION: Do not immerse the device or any accessories in liquid and do not expose the connector pins to the cleaning solution. Do not apply oil at any point.

CAUTION: Do not use undiluted bleach or any other cleaning solution other than those recommended here because permanent damage to the AN24™ and leads could occur.

Clean - Wipe the AN24™ and leads with a soft non-abrasive cloth or disposable wipe soaked in a solution such as 70% isopropyl alcohol. Do not use aerosol preparations since they might contain organic solvents. Do not pour fluids directly on the unit and its accessories. Wipe the exterior of the AN24™ and leads three times. Prepare the detergent according to the manufacturer's recommendations. If necessary scrub the AN24™, and leads with the solution using a soft bristled brush for five minutes.

Wash off & Dry - When using solutions, use sterile wipes or gauze to avoid pouring fluids directly on the unit and its accessories. Wipe the AN24™, and leads three times with sterile or distilled water to remove cleaning solution residue. Dry the AN24™, connector and leads thoroughly with a sterile soft towel or gauze surgical sponge.

Disinfect - Use a 1:10 bleach solution after the AN24™ and leads have been cleaned following the same procedure described above. After the low level disinfections, wipe the AN24™ and leads three (3) times with sterile or distilled water to remove diluted bleach residue. Dry the AN24™, connector and leads thoroughly with a sterile soft towel or gauze surgical sponge.

Store the clean AN24™, connector, and leads in a clean bag, covered tray, or other suitable system when not in use.

Monica recommends the patient neck cord included with the Monica AN24 is washed thoroughly or replaced between patients.

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

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6.2 Batteries

The 3.6V rechargeable lithium polymer battery pack should be stored at 0-35°C. Typically the batteries will last for two years or more with regular use. If you need to replace the battery, contact Monica Healthcare directly or your Monica healthcare representative.

6.3 Firmware version

AN24™ Firmware
VS Monitor update

Periodically there will be a need to release new versions of the Firmware and VS Monitor updates, please check with your local distributor to see if you have the latest version.

6.4 Calibration

Calibration of the Monica AN24™ is not required

6.5 Servicing

Maintenance of the AN24™ is carried out by Monica Healthcare. The only routine maintenance which is necessary is battery replacement when failing to hold charge and cleaning as outlined earlier in this Section. Further information is available from:

Monica Healthcare Ltd
BioCity
Pennyfoot Street
Nottingham NG1 1GF
UK
Tel: +44 1159124540
Email: info@monicahealthcare.com
Web: www.monicahealthcare.com

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

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Section 7 - Monica Accessories

Part No.	Description
100-PT-100	Monica VS10 Monitor (Panasonic Toughbook CF-H1)
100-PT-101	Monica VS10 Monitor (Panasonic Toughbook CF-H1, upgrade for existing AN24 customers only)
100-PT-110	Monica VS15 Monitor (Arbor M1525)
100-PT-111	Monica VS15 Monitor (Arbor M1525 upgrade for existing AN24 customers only)
100-PT-001	Monica AN24

100-PT-130	Monica Cart (ITD PRO3OU)
100-PT-131	Monica Cart - printer shelf (ITD PRO3OU
100-PT-132	Monica Desktop Stand (Vesa desktop stand ARM 150 or equivalent)
100-PT-140	Monica Printer (Real-time) - Thermal Z-fold (Fetalgard Lite)
100-PT-160	Monica VS Network Viewer

100-PT-002	ECG Lead Assembly - Standard; ~28 weeks to term
100-PT-004	Battery Charger (UK\ EU\ USA please specify)
100-PT-005	AN24 – USB computer connection cable
100-PT-015	Soft silicon rubber protective boot (x5)
100-PT-016	3M red Dot 2236 skin prep tape (x5)
100-PT-017	Monica approved electrodes – 25 pouches x 10 electrodes (250 electrodes)
100-PT-018	Monica approved electrodes – 150 pouches x 10 electrodes (1500 electrodes)
100-PT-019	Monica AN24 Neck Cord (x5)
100-PT-020	Monica Healthcare glossy sales literature folder (x50)
100-PT-021	Sales Literature sheets
100-PT-022	Skin preparation pen
100-PT-141	Z-Fold paper printer (3 cm/min, 30 - 240 bpm) Analogic US
100-PT-142	Z-Fold paper printer (1 cm/min, 50 - 210 bpm) Analogic International
100-PT-143	Z-Fold paper printer (3 cm/min, 30 - 240 bpm) Philips US
100-PT-144	Z-Fold paper printer (1 cm/min, 50 - 210 bpm) Philips International

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

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Section 8 - Monica VS Monitors

8.1 Overview

Monica VS series of monitors (VS15/VS10) allow the FHR, UA and event annotation data to be viewed, stored and printed as a conventional CTG trace. It is also provides the Monica AN24™ set-up tools to configure the unit and label and store the monitoring sessions for easy identification and retrieval. The functionality of the Monica VS Monitors is explained in detail in the Monica VS Reference Operating Manual.

8.2 System Requirements

Monica devices are an integral part of a diagnostic system. The user must adhere to warnings in order to ensure safe and reliable performance of the system.

- Monica VS Monitors complies with IEC 60601-1 the international product safety standard for electrical medical equipment
- Non-medical electrical equipment (e.g. Wireless remote printer) **must be** situated outside the patient environment (patient environment according to IEC 60601-1-1: = radius 1.5m around the patient).
- The Monica VS Monitors (PT-101-010, PT-101-015) fully comply with the above and are required when using the Monica AN24™ to monitor in real-time within the patient environment (as defined by IEC 60601-1-1).

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

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Section 9 - AN24 Specifications

(b) (4)

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Section 10 - Troubleshooting

10.1 Signal Quality (Green LED flickers)

Electrodes are not attached correctly.

If the green LED flickers, first check that the electrode lead connector cap is connected securely on both sides of the AN24™ (both buttons engaged). If this does not resolve the problem, put AN24™ into electrode check **'Phase 1'** by pressing event button twice within a 2-second period. (NB: this is not required if connected to a VS Monitor which will display the problem electrode(s) on screen without the need to touch the AN24).

x2

The system will then 'display' the electrode/skin impedance for the electrodes connected to the yellow, green and orange leads.

The electrode/skin impedance will be communicated to the user as follows:

- LED on continuously – the electrode connected to the lead defined by the LED colour has a good connection / low skin impedance
- LED flickers - the electrode connected to the lead defined by the LED colour has a bad connection / high skin impedance

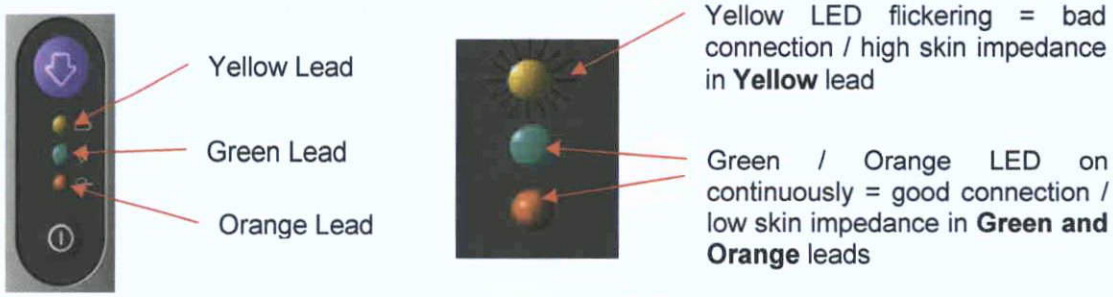

Figure 3 Phase 1 Lead check

If a bad connection is identified in the Yellow, Orange or Green leads, disconnect the lead from the electrode(s) that has a bad connection (leave AN24™ on), remove the electrode(s) and again prepare the skin as described in Supplement 1 – Electrode Placement. When all the electrode(s) have been replaced the leads should be reconnected.

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If all the LED are on continuously (good connection), put the AN24™ into electrode check **'Phase 2'** by pressing event button twice within a 2 second period.

x2

In 'mode 2' the electrode/skin impedance will be communicated to the user for the remaining two electrodes as follows:

- Yellow LED on continuously – the electrode connected to the **White** lead has a good connection / low skin impedance
- Yellow LED flickers - the electrode connected to the **White** lead has a bad connection / high skin impedance
- Green LED on continuously – the electrode connected to the **Black** lead has a good connection / low skin impedance
- Green LED flickers - the electrode connected to the **Black** lead has a bad connection / high skin impedance

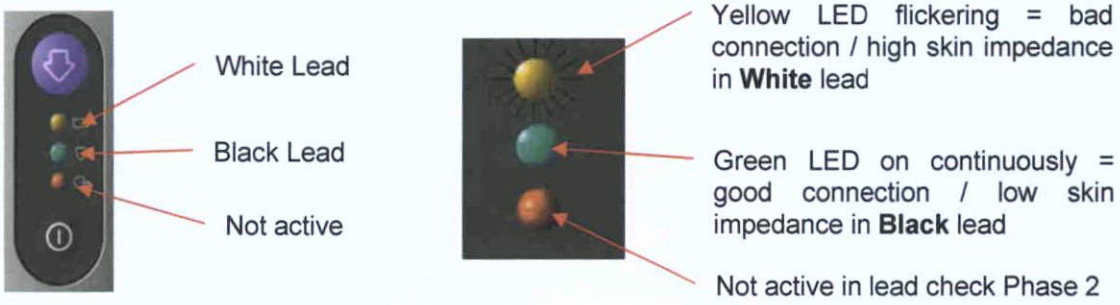

Figure 4 Phase 2 Lead check

If a bad connection is identified in the black or white leads, disconnect the lead from the electrode(s) that has a bad connection (leave AN24™ on), remove the electrode(s) and again prepare the skin as described in Supplement 1 – Electrode Placement. When all the electrode(s) have been replaced the leads should be reconnected.

If the Green and Yellow LED's are on the user should start their monitoring session by pressing the event button twice within a 2-second period

x2

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In the unusual event that it is not possible with repeated skin preparation and correct electrode placement to bring the impedance down and gain a good connection; impedance check may be by-passed or can be halted and repeated at a later date.

To by-pass the impedance checks:

Press the following key sequence in succession:
Power On Button > Pink Event Button > Power Button

If after by passing the impedance check the green LED remains continuously on – signal cannot be found – the monitoring session can be halted and repeated at a later date. This failure should be reported to Monica Healthcare Ltd. Please make a note of which electrode or electrodes failed to pass the impedance check. Monitoring the patient at a future time/date may still be possible.

To abort the electrode check phases (Phase1 or Phase2): switch off the AN24™ as usual (press ON button, then press pink Event button, then press pink Event button)

Alternatively, the lead may be broken. Turn the AN24™ off. Disconnect the lead from both the AN24™ and the electrodes. Attach a spare lead and retry.

If problem is not resolved, contact Monica Healthcare for advice.

10.2 Signal Quality (Green) LED constantly on

The signal cannot be picked up by the AN24™, though the electrodes are correctly connected. This is a common occurrence, which may be due to interference from other sources, for example the noise generated by maternal muscle/ movement. The mother should relax and remain in a supine position for as long as practicable during the recording for optimal results. If problem is not resolved, contact Monica Healthcare for advice.

10.3 Battery Status (Yellow) LED flashing when unit is not being charged

Battery is low. The AN24™ will shortly automatically turn off. Upload the data and recharge the batteries (see 3.1 Battery Charging). If problem is not resolved, contact Monica Healthcare for advice.

10.4 Memory Status (Orange) LED flashing

This indicator will only light just after the AN24™ has been turned on and indicates that there is > 1 minute of data on the device. Upload / delete the data currently stored on the device (see Section 4 -). Turn on the device and resume the monitoring session. If problem is not resolved, contact Monica Healthcare for advice.

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10.5 AN24™ will not turn on

Recharge the AN24™ for at least an hour even if the AN24 battery does not flash. If after recharge the AN24™ still does not turn on, return to Monica Healthcare for service.

10.6 AN24™ will not turn off

Return to Monica Healthcare for service

10.7 AN24™ will not recharge

Disconnect AN24™, reconnect battery charger and check charger is connected at both the wall socket and the device. Leave the recorder connected to the charger for half an hour. Then disconnect the AN24™ from the charger and reconnect it again. If problem is not resolved, contact Monica Healthcare for advice.

10.8 AN24™ will not connect via USB

Disconnect USB lead from both the AN24™ and VS Monitor. Reconnect USB lead and retry. If problem is not resolved, connect the AN24™ to the charger for half an hour and try connecting the recorder to the VS Monitor again. If the problem is not solved, contact Monica Healthcare for advice.

10.9 AN24™ will not connect via USB and will not recharge

If the AN24™ does not charge and is not recognised by the VS Monitor, disconnect the AN24™, reconnect battery charger and check charger is connected at both the wall socket and the device. Leave the recorder connected to the charger for half an hour. Then disconnect the AN24™ from the charger and reconnect it again. If problem persists there may be an issue with the Bluetooth® module in the AN24™ - please contact Monica Healthcare for advice.

If the AN24™charges but is not recognised by the VS Monitor disconnect USB lead from both the AN24™ and computer. Reconnect USB lead and retry. If the problem persists there may be an issue with the USB cable – please contact Monica healthcare for advice

10.10 AN24™ will not connect via Bluetooth®

Bring the AN24™ physically close (i.e. within 2 metres) of the VS Monitor and retry. If problem is not resolved, contact Monica Healthcare for advice.

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

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Section 11 - Returns Procedure

11.1 Maintenance

There are no user serviceable parts in the Monica AN24™ or accessories. In the event of device failure or the battery needs to be changed, please contact Monica Healthcare or your local representative.

11.2 Returns

To return a defective product to Monica, you will need to obtain a Return Goods Authorization (RGA) number from the Monica Healthcare Support Group. Please contact a Service Coordinator at:

Telephone: +44 1159124540
Email: support@monicahealthcare.com

You will need to supply the Service Coordinator with the following information:

- The Model number(s) and Serial number(s) of the product, this information can be found on the label on the rear of the AN24™.
- The quantity of items you wish to return.
- Your "Bill to" address for invoice purposes.
- Your "Ship to" address.
- Your Purchase Order number.
- Details of the reported failure.

The Service Coordinator at Monica Healthcare will then inform you of:

- The Return Goods Authorization (RGA) number.
- The warranty or non-warranty status of the units being returned.
- Any repair charge.

All returned material must be shipped "PREPAID" to the address below for both warranty and non-warranty repairs. Please reference your RGA number on both your purchase order and the shipping label:

RGA reference number:
Tioga
St Thomas House
St Mary's Wharf
Mansfield Road
Derby
DE1 3TN
UK

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

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Supplement 1 – Electrode Placement

I. Patient Posture

It is very important that the woman's stomach muscles are relaxed and she should be encouraged to 'relax' on a bed either on her back (recumbent or semi-recumbent) or on her side (left/right) for as long as practicable during the monitoring session. The patient should **avoid** whenever possible:

1. Any position or activity where the abdominal muscles are contracted e.g. sitting upright or lying down with her back raised from the hips at an angle of 45°. If this is unavoidable then using a cushion to support the back can help.
2. A tense stressful situation which will cause abdominal muscle tone to increase even though the patient is in a comfortable position e.g. When the room where the patient is being monitored is filled with Drs, Midwives, Family, Children and other onlookers. In this situation it is advisable to leave the Monica AN24 in place and return when the patient situation has changed.

The VS series of monitors provide a real-time indication of signal to noise in the signal quality indicator where the muscle noise (red-bar height) and the fetal ECG height (green bar) are displayed.

If the fetal ECG height is small and the muscle noise is high then FHR extraction may be compromised; ask the mother to get into a position that is comfortable for her and relax. In addition, changes in maternal posture like lying on the left or right can change the fetal position in relation to the abdomen and uterus and improve the ECG conducting pathway.

II. Electrode Location

It is important to correctly prepare the skin before the application of the electrodes. You are advised to read all of this section before starting the procedure.

The instrument has three separate detection channel leads. The connectors on these leads are colour coded as **orange**, **white** and **green**. All three channels share a common connection point and this lead connector is coloured **yellow**. Finally, a ground lead with a **black** colour coded connector is also used. These leads are connected to 5 electrodes positioned on the maternal abdomen. Please refer to the table and figures below for guidance in positioning the electrodes.

Electrode / Connector	Position
Yellow	Place the yellow electrode on the mid-line 6cm above the symphysis pubis or as close to 6cm above the symphysis pubis as you can achieve without requiring removal of the pubic hair.
White	Place the white electrode on the mid-line so that the bottom edge of the electrode is just below the top edge of the umbilicus. *If the centre of the white electrode is **above** the fundus, reposition the white electrode so that the centre is **below** the fundus and the electrode is clear of the umbilicus*
Green and Orange	Place the centre of the green and orange electrodes either side of the umbilicus and on the same horizontal line as the umbilicus. The centre of the green electrode should be **10cm** from the **left hand edge** of the umbilicus and the centre of the orange electrode **5cm** from the **right hand edge** of the umbilicus.
Black	The black electrode is the reference electrode and is positioned towards the back behind the green electrode. Its exact position is not critical.

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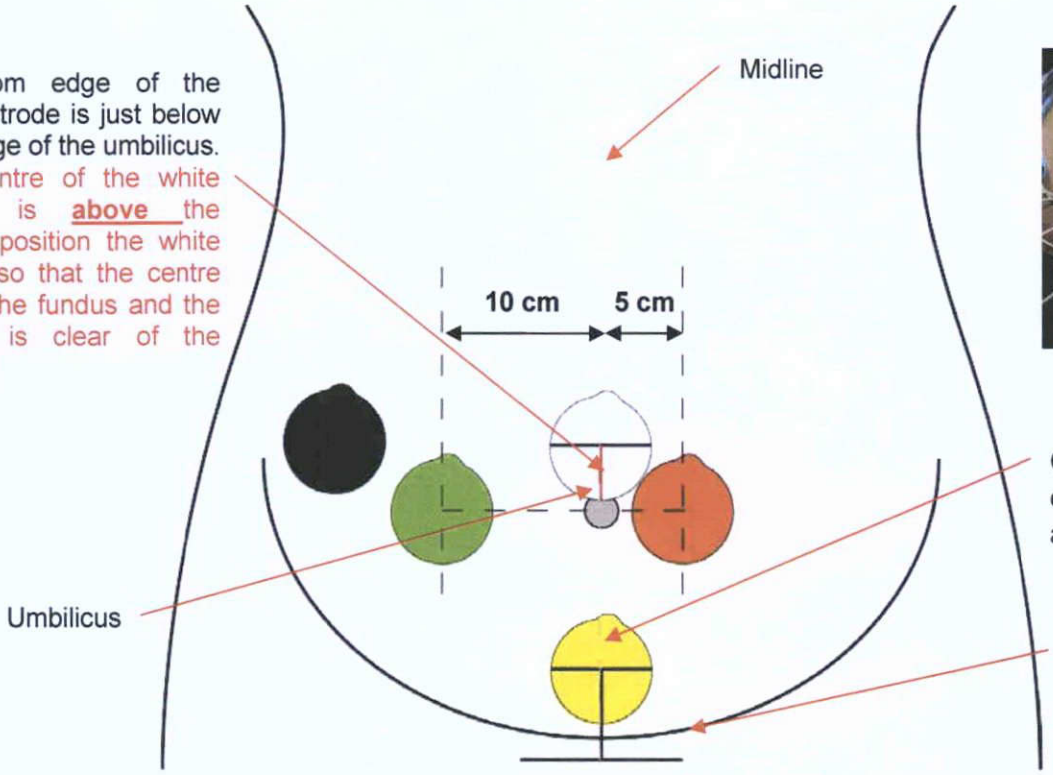
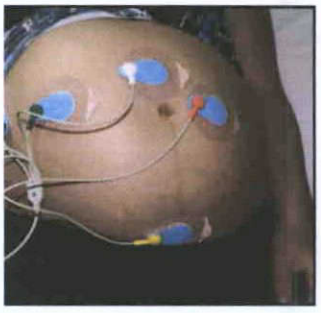
Electrode Positions

The bottom edge of the White electrode is just below the top edge of the umbilicus. (If the centre of the white electrode is **above** the fundus, reposition the white electrode so that the centre is **below** the fundus and the electrode is clear of the umbilicus)





For patients with a large pannis (apron of fat) overhanging the symphysis pubis it is recommended that the yellow electrode be placed **on top** of the pannis on the mid-line such that the centre of the electrode is 6cm above the upper margin of the symphysis pubis or as close to 6cm above the upper margin of symphysis pubis without covering the yellow electrode with the pannis.

These instructions only apply to **Ambu VLC-00-S** electrodes.
Results may be impaired if any electrode is used other than those recommended by

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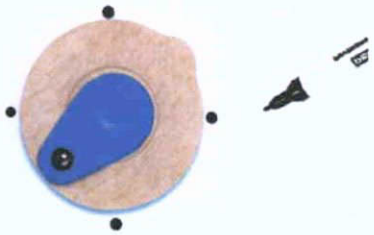
III. Preparation of the skin and electrode application

1. Mark the electrode positions – using the electrode as a template and an alcohol based permanent marker pen.

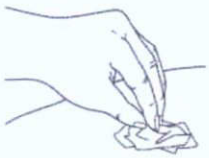


Note: *If unable to use a pen to mark the site an alternative* ***MUST*** *be used to mark the site. Example: patient's fingers or a small piece of skin prep-tape*

Caution: When using a marker pen ALWAYS follow local cross-contamination protocols.

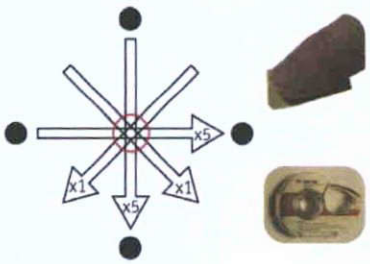
Warning: DO NOT use a marker pen if the woman has any cuts or open sores on her abdomen

2. If the patient has been using skin care products wash the abdomen with a mild soap and water solution and **dry** first. On **<u>all women</u>** clean the electrode area vigorously with an alcohol swab and allow to dry.



Caution: Using an alcohol wipe on abraded skin may cause patient discomfort and skin irritation.

3. Once the alcohol has dried off, abrade the area, using the supplied prep-tape, stroking the skin in one direction only (5 North to South, 5 East to West, 1 NW-SE, 1 SW- NE) as shown below



Caution: Use only moderate force since excessive use of prep tape may cause patient discomfort and skin irritation. In some patients local skin reactions to the electrode adhesive\gel may occur causing slight reddening of the skin.

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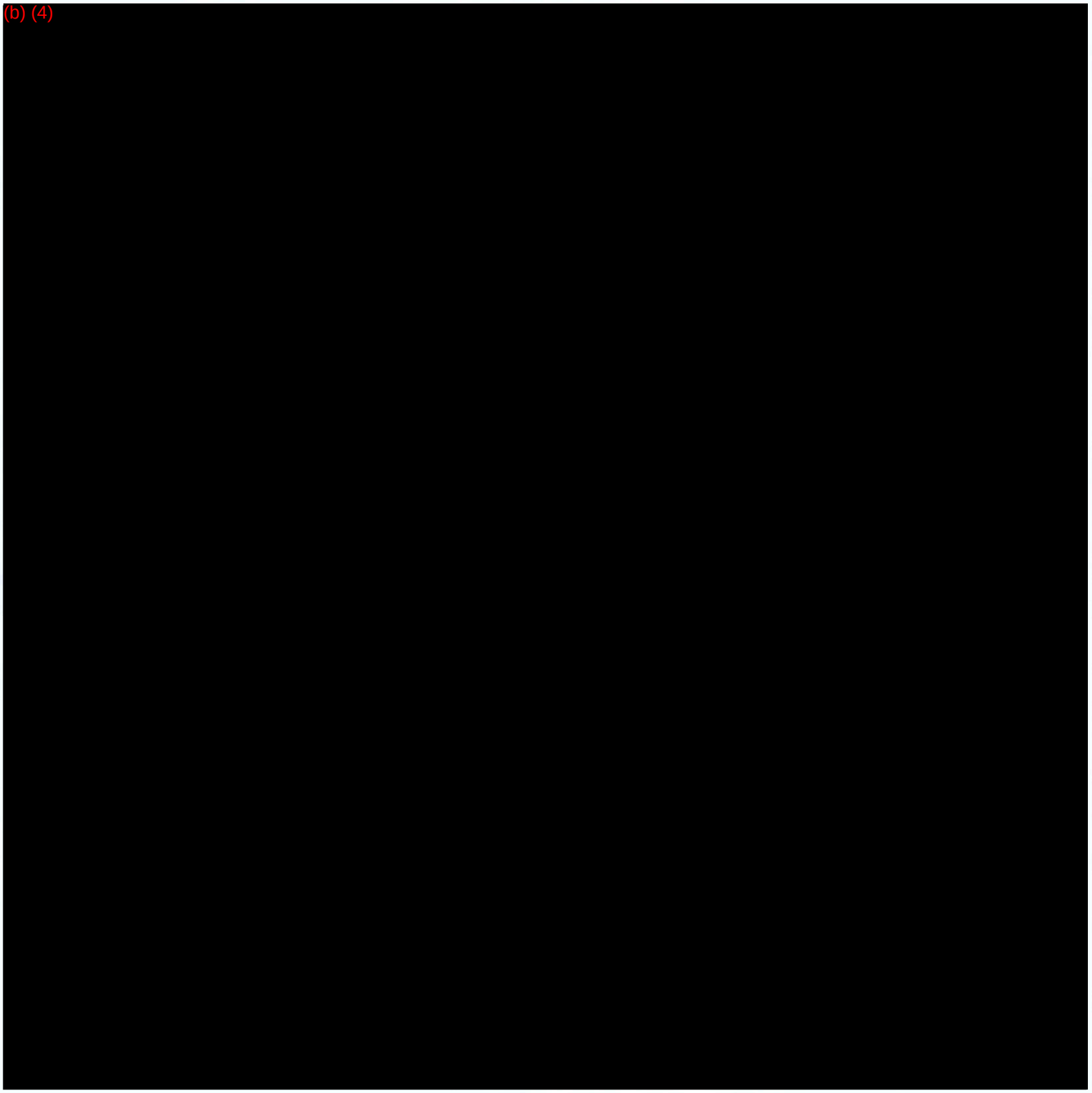

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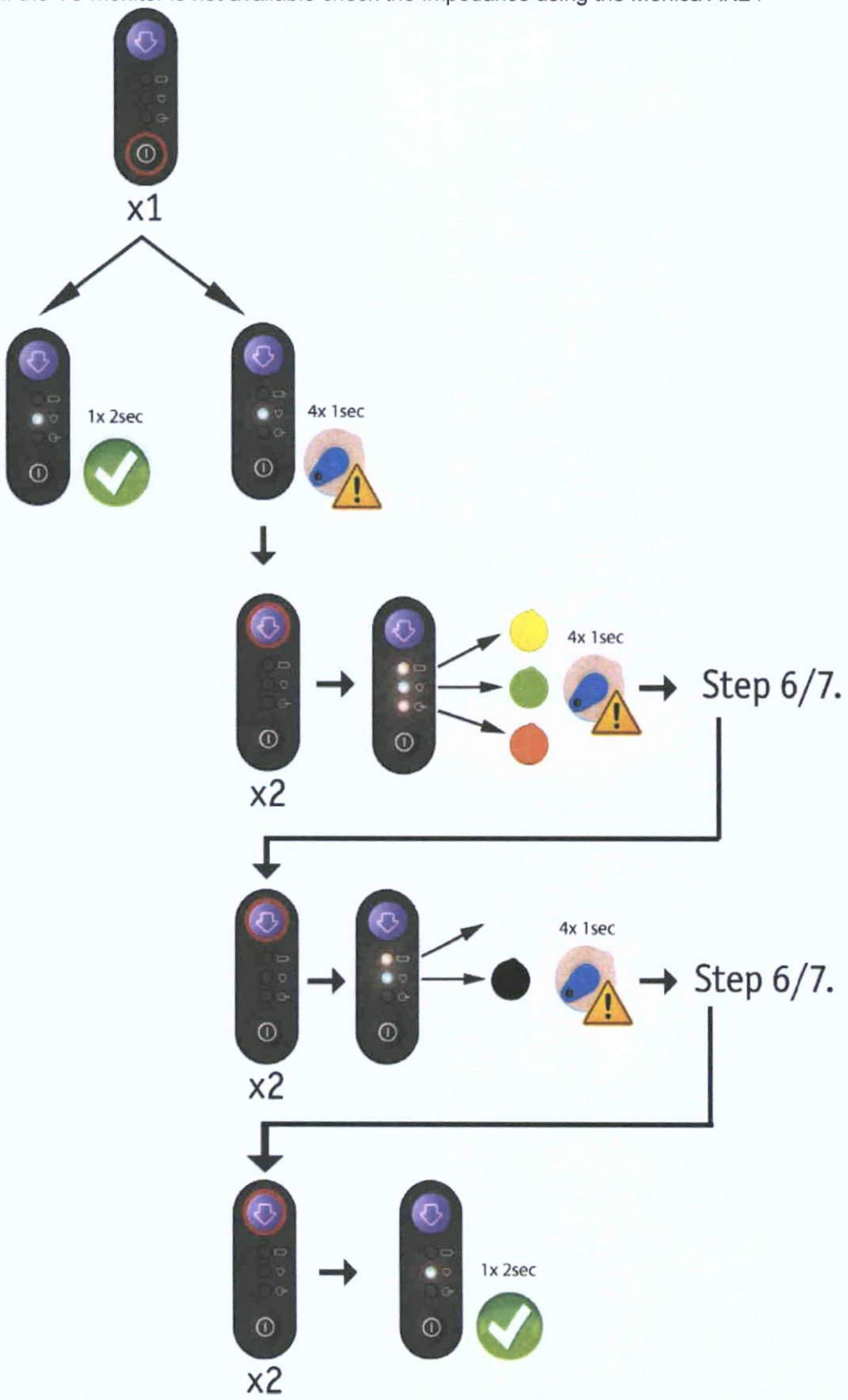
b. If the VS monitor is not available check the Impedance using the Monica AN24



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6. If impedance check fails
    a. Peel back electrode
    b. Dry wipe the area to remove gel and moisture left by the electrode
    c. Re-abrade the same area of skin pressing firmly
    d. Re-attach the same electrode
    e. Wait 2-3 minutes for the electrode to settle
    f. Check the impedance again (Step 5)

7. If the impedance check fails a second time
    a. remove and discard the electrode
    b. Dry wipe the area to remove gel and moisture left by the electrode
    c. Re-abrade the same area of skin pressing firmly as long as the mother does not become uncomfortable
    d. attach a new electrode
    e. Wait 2-3 minutes for the electrode to settle
    f. Check the impedance again (Step 5)

8. If the impedance check fails a third time on one or more of the Green, White, black or Orange electrodes then the impedance check can be by-passed (see AN24 Reference Operating Manual – 10.1 Troubleshooting Guide). **This is not recommended**. Alternatively, leave the electrodes in place for 30 minutes and try the impedance check again (Step 5).

9. '**Do Not**' by-pass the impedance check if the impedance check for the yellow electrode fails – go to step 6 and repeat process as long as the mother does not become uncomfortable.

10. If it is still not possible to pass the yellow electrode impedance check,

    Option 1: go back to step 8 and by-pass the impedance check. The fetal abdominal ECG can be good in early and late gestation monitoring so noise introduced by high skin electrode impedance can be mitigated. However the quality of the signal cannot be confirmed until the recording commences by looking at the signal to noise bar graph on the VS display or on the Quick-View PDA (not available for sale in the USA).

    Option 2: halt the recording and try again at a future time/date.

Caution: Do not use water to remove the electrodes

Before attaching the electrodes on to a patient, the user should prepare the skin and place five electrodes on themselves or a volunteer, connect the Monica AN24™ and switch on. The positioning of the electrodes is not important, but this will provide an insight into the skin preparation needed in order to obtain a steady green LED (**5**) indicating that all the electrodes have been correctly attached to the skin.

IV. Lead connection

The 'button' connector on the electrode is located on a 'flap' that is not stuck down. This means that, (a) the flap can be lifted and the correct colour coded lead connector can be pressed/snapped onto the button without pressing on the skin and disturbing the gel electrode contact with the skin and (b) no downward force is applied to the maternal abdomen.

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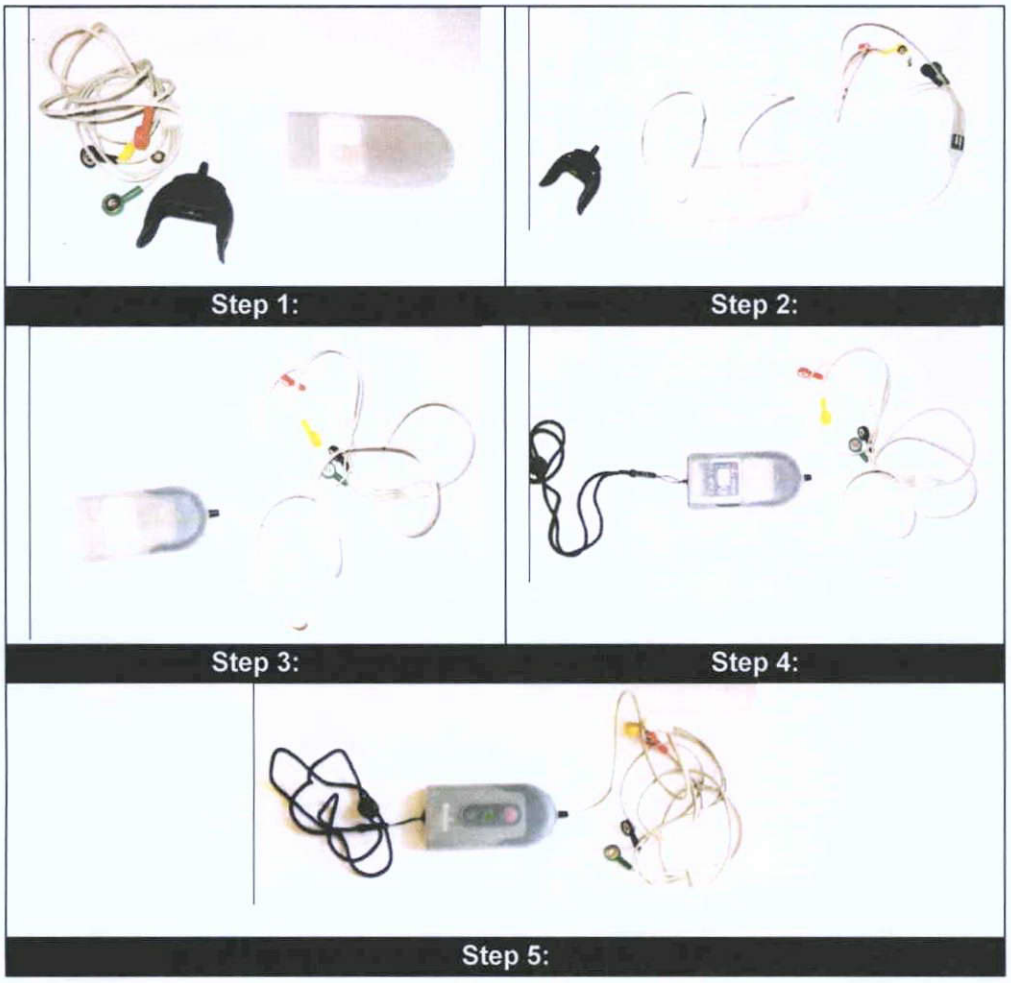
V. Protective cover and neck strap

The protective silicone rubber cover is designed to protect the Monica AN24™ during use, keep it clean and to keep it dry and avoid the ingress of fluids. **It must be used on all L&D subjects.**



Warning: Not using the protective silicone rubber cover could result in the ingress of contaminated blood and other fluids into the Monica AN24 case.

VI. Lead security

It is important to secure and tidy the electrode leads to avoid lead or electrode detachment during operation. The electrode leads are of different lengths to aid in their correct placement and are fitted with two small plastic lead separators, which can be repositioned to avoid lead tangles and aid placement. The long single lead is fitted with a Velcro band so that it can be neatly coiled and secured when the patient is mobile.

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VII. Electrostatic Discharge (ESD) precautions

Although precautions have been taken to ensure otherwise, static electricity could cause damage to the sensitive input circuits of the AN24™ and render the device inoperable. In the context of the AN24™, static is most likely to reach the AN24™ via a user\ patient touching static sensitive parts of the device.

ESD precautionary measures should be taken to minimise the risk of damage to the AN24™. More specifically:

- The connector which joins the AN24™ and lead connector together should not be touched by any part of the body, including the fingers
- The metallic (conducting) part of the electrode (press-stud) clips at the extremities of the electrode leads should not be touched by any part of the body, including the fingers

All staff that use the AN24™ should receive an explanation of the ESD warning symbol and receive the following basic training\ instruction in ESD precautions before use of the AN24™:

- How to fit the AN24™ to the patient, and;
- How to attach the electrodes to the AN24™, and;
- How to attach the electrodes to the patient.

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The Monica AN24™™ complies with the requirements of the European Council Directives: 93/42/EEC as amended by 2007/47/EEC, concerning medical devices

ISO 13485 Monica Healthcare Ltd operates Quality Management Systems that have been approved and audited to ISO 13485.

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