



# U.S. Department of Health & Human Services

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**Food and Drug Administration**

## SAVE REQUEST

**USER:** (jmr)  
**FOLDER:** K950944 - 317 pages  
**COMPANY:** BIOSENSOR CORP. (BIOSENSOR)  
**PRODUCT:** COMPUTER, DIAGNOSTIC, PROGRAMMABLE (DQK)  
**SUMMARY:** Product: AMBULATORY (HOLTER) RECORDING SYSTEM

**DATE REQUESTED:** Jul 17, 2014

**DATE PRINTED:** Jul 17, 2014

**Note:** Printed



K950944/A2



13755 First Avenue North  
Plymouth, MN 55441-9760  
612-449-9100  
612-449-8966 Fax

June 18, 1996

Charles S. C. Ho, Ph.D.  
Office of Device Evaluation  
Document Mail Center (HFZ-401)  
Food and Drug Administration  
9200 Corporate Blvd.  
Rockville, MD 20850

Fax: 301-480-4204  
RE: 510(k) K950944  
Request for additional information

RECEIVED  
19 JUN 96 10 46  
FDA/CDRH/ODE/DMC

Dear Dr. S. C. Ho:

In response to our telephone conversation the following information is submitted.

Biosensor will change the intended use number 1.2 as indicated on the next page.

Should you have further questions please don't hesitate to contact me at the telephone number above.

Sincerely,

Darren D. Dershem  
Quality Assurance

6/18/86  
DDD

8

interventions in individual patients or groups of patients.

*ST segment changes*

- 1.2) Evaluation of patients for ~~silent ischemia~~.
- 1.3) Evaluation of patients with pacemakers.
- 1.4) Evaluation of individual patient's response upon resuming occupational or recreational activities (e.g. after M.I., cardiac surgery).
- 1.5) Evaluation of clinical syndromes and situations where arrhythmias may increase risk of sudden death.
- 1.6) Clinical and epidemiological research studies.

7

**Warnings**

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

- **CAUTION:** This device has not been tested for compliance with AAMI specifications regarding defibrillation equipment. Use of defibrillators may result in damage to this device.

-----

**Statement of Intended Use**

The Full Disclosure Monitoring System is intended for patients requiring ambulatory (Holter) monitoring from 1 to 24 hours. Such monitoring is most frequently used in the indications listed below:

Current Uses of Ambulatory ECG Recording \*  
(\* Portions from Ambulatory Electrocardiographic Recording. Wenger NK, Mock MB, and Reingquist I, Year Book Medical Publishers, Copyright 1981.

- 1.0) Evaluation of symptoms suggesting arrhythmia or myocardial ischemia.
- 1.1) Evaluation of ECG documenting therapeutic



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

OCT 9 1996

Mr. Gary Hansen  
Director of Research and Development  
Biosensor Corporation  
13755 First Avenue North  
Plymouth, Minnesota 55441-9760

Re: K950944  
Ambulatory (Holter) Recording System  
Dated: September 4, 1996  
Received: September 10, 1996

Dear Mr. Hansen:

We have received the information in your letter dated September 4, 1996, regarding the 510(k) notification K950944 previously submitted for the device referenced above. Based solely on the information that you have provided, it appears that you have significantly changed or modified the design, components, method of manufacture, device labeling, or intended use of the device referenced above (see 21 CFR 807.81(a)(3)). You will need to submit a new 510(k) and receive Food and Drug Administration clearance prior to marketing your device with these changes. Your letter referenced above will be added to the original 510(k) file with a copy of this letter. If you have questions please contact Charles S. C. Ho, Ph.D., at (301) 443-8609 or the Division of Small Manufacturers Assistance at 1-800-638-2041 or (301) 443-6597.

Sincerely yours,

A handwritten signature in cursive script that reads "Richard N. Phillips, Ph.D.".

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

OCT 9 1996

Mr. Gary Hansen  
Director of Research and Development  
Biosensor Corporation  
13755 First Avenue North  
Plymouth, Minnesota 55441-9760

Re: K950944  
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Dated: September 4, 1996  
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Sincerely yours,

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

Page 2 - Mr. Gary Hansen

cc: HFZ-450 DCRND  
HFZ-401 DMC

Prepared by: CHO:att/9/20/96

FILE  
COPY

OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE
450	HO	9/20/96						
450	Phillips	9/20/96						

U.S. GPO 1969-169 009



## DEPARTMENT OF HEALTH &amp; HUMAN SERVICES

Public Health Service  
Food And Drug Administration

Memorandum

Date: 9-11-96

From: Document Mail Center (HFZ-401)

Subject: Premarket Notification Number(s) K950944/A<sup>3</sup>

To: Division Director, CV/DCRND

The attached information has been received by the 510(k) Document Mail Center (DMC), on the above referenced 510(k) submission. 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. Feel free to note any additional comments below.

Thank you for your cooperation.

Information does not change status of the 510(k); no other action required by the DMC; please add to the image file. [THE DIVISION SHOULD PREPARE A CONFIRMATION LETTER - AN EXAMPLE IS AVAILABLE ON THE LAN (K25). THIS DOES NOT APPLY 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 the company to submit a new 510(k). [THE DIVISION SHOULD PREPARE THE K30 LETTER ON THE LAN.]

Additional information requires a new 510(k); please process. [THIS INFORMATION WILL BE MADE INTO A NEW 510(K)].

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

COMMENTS:

*QT interval has not been cleaned previously. Hence this is a new ~~intention~~ intended use for this device.*

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

Reviewed by: Chal. C. H.

Date: Sept. 20, 1996



13755 First Avenue North  
Plymouth, MN 55441-9760  
612-449-9100  
612-449-8966 Fax

September 4, 1996

Office of Device Evaluation  
Document Mail Center (HFZ-401)  
Food and Drug Administration  
9200 Corporate Blvd.  
Rockville, MD 20850

FDA/CDRH/ODE/DMC

10 SEP 96 15 39

RECEIVED

Dear Sir or Madam:

This letter is formal notice that we intend to modify our Holter monitoring system to allow analysis of the QT duration of the ECG waveform. This system is already covered under a 510K (reference # K950944), and we consider that this change does not substantially affect the intended use of our product in any way.

While there are many possible ways to measure the QT interval, we propose to use the four most common variants. <sup>(b)(4)</sup>

(b)(4)

We would bin the data into <sup>(b)(4)</sup> second segments and report the average of the above parameters in tabular and graphical form. The standard report would offer mean QT, QT<sub>p</sub>, QT<sub>c</sub>, and QT<sub>pc</sub> at one hour intervals, but the user could select sub-intervals within the 24 hour data set for more specific analysis. The system would also provide a user-defined "QT threshold" highlighting any episodes of elongated QT interval that are found during that time.

Please note that QT analysis has been an accepted part of cardiological practice for many years, and the efficacy of the technique is well established in the medical literature. While there are many medical conditions that affect the repolarization of the heart, and thus the QT interval, we restrict the use of our product to the diagnosis of cardiac illness: the same clinical use as earlier versions of our product. As a result, the basic purpose of the system has not changed, it is not targeted at a different market, and there is no reduction in safety or efficacy.

As always, we wish to comply in good faith with FDA regulations. We are confident that the addition of QT analysis to our Holter system is a minor change, but we want to inform you of this change in case you have any questions or concerns. Please review this letter and add it to our file in reference to the 510K application mentioned above.

Sincerely,

Gary Hansen  
Director of Research and Development

K950944/A



13755 First Avenue North  
Plymouth, MN 55441-9760  
612-449-9100  
612-449-8966 Fax

June 17, 1996

Charles S. C. Ho, Ph.D.  
Office of Device Evaluation  
Document Mail Center (HFZ-401)  
Food and Drug Administration  
9200 Corporate Blvd.  
Rockville, MD 20850

Fax: 301-480-4204  
RE: 510(k) K950944  
Request for additional information

FDA/CDRH/OCE/DHC

18 JUN 96 09 01

RECEIVED

Dear Dr. S. C. Ho:

In response to our telephone conversation of this morning the following information is submitted.

(b)(4)

the next page. In addition, Biosensor states that the only HRV calculations provided by the system are the Mean and Standard Deviation.

Clarification of FDA question number 13 is as follows. As stated in the previous answer. A time slider bar feature allows time adjustments to be performed on any portion of the stored ECG data down to a four minute minimum interval. In addition to the original time selection, four additional graphs are provided. Each graph is a one quarter representation of the initial slider bar time selection. In the case of the provided example these graphs breakdown into one minute intervals. If the initial slider bar time is selected for the entire twenty four hour procedure these graphs would each represent a six hour period. If initial slider bar time is selected as eight hours the graphs would each represent a two hour period. These quarter graphs are used to supplement the initial main graph.

Should you have further questions please don't hesitate to contact me at the telephone number above.

Sincerely,

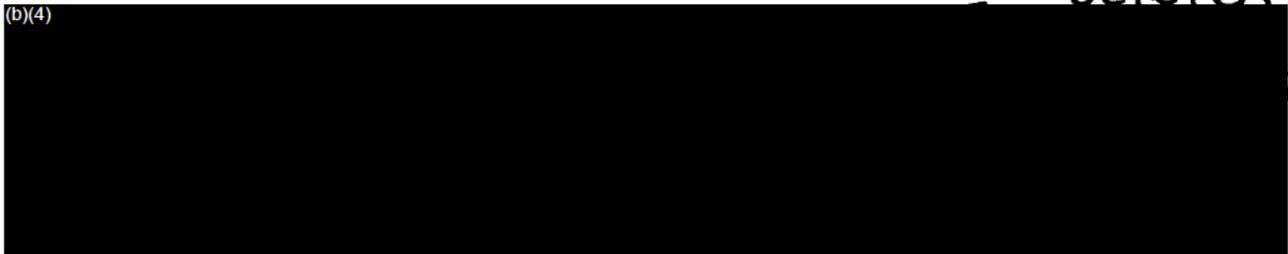
Darren D. Dershem  
Quality Assurance

10. FDA question number 10.

What is the intended use for the device's feature of HRV analysis in the time domain? List all the specific claims made for the feature of HRV.

Heart rate variability (HRV) analysis in the time domain is intended for quantification and graphic displays of heart rate changes over a specific monitoring period, and is to be used as an adjunct to other clinical diagnostic techniques.

(b)(4)



Deleted

6/17/96  
DDD

ed

Deleted

6/17/96  
DDD

(b)(4)





## DEPARTMENT OF HEALTH &amp; HUMAN SERVICES

Public Health Service

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

JUN 18 1996

Mr. Darren D. Dershem  
Biosensor Corporation  
13755 First Avenue North  
Plymouth, Minnesota 55441-9760

Re: K950944  
Ambulatory (Holter) Recording System  
Regulatory Class: II (two)  
Product Code: 74 DQK  
Dated: March 14, 1996  
Received: March 18, 1996

Dear Mr. Dershem:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

001

Page 2 - Mr. Darren D. Dershem

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

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4639. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597.

Sincerely yours,



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

002

510(K) ROUTE SLIP

510(k) NUMBER K950944 PANEL CV DIVISION DCRND BRANCH ADDG

TRADE NAME AMBULATORY (HOLTER) RECORDING SYSTEM

COMMON NAME \_\_\_\_\_

PRODUCT CODE \_\_\_\_\_

APPLICANT BIOSENSOR CORP.

SHORT NAME BIOSENSOR

CONTACT DARREN D DERSHEM

DIVISION \_\_\_\_\_

ADDRESS 13755 FIRST AVENUE NORTH

PLYMOUTH, MN 554419760

PHONE NO. (612) 449-9100

FAX NO. (612) 449-8966

MANUFACTURER BIOSENSOR CORP.

REGISTRATION NO. 2183509

DATE ON SUBMISSION 15-FEB-95

DATE DUE TO 510(K) STAFF 03-MAY-95

DATE RECEIVED IN ODE 17-FEB-95

DATE DECISION DUE 18-MAY-95

DECISION \_\_\_\_\_

DECISION DATE \_\_\_\_\_

SUPPLEMENTS	SUBMITTED	RECEIVED	DUE POS	DUE	OUT
<u>S001</u>	<u>11-MAY-95</u>	<u>12-MAY-95</u>	<u>26-JUL-95</u>	<u>10-AUG-95</u>	<u>21-AUG-95</u>
<u>S002</u>	<u>14-MAR-96</u>	<u>18-MAR-96</u>	<u>01-JUN-96</u>	<u>16-JUN-96</u>	

CORRESPONDENCE	SENT	DUE BACK	
<u>C001</u>	<u>10-MAY-95</u>	<u>09-JUN-95</u>	<u>HOLD LETTER</u>
<u>C002</u>	<u>21-AUG-95</u>	<u>20-MAR-96</u>	<u>HOLD LETTER</u>

Is this 510(k) identified as a Class III device \_\_\_\_\_ YES \_\_\_\_\_ NO

SE  
 JUN 18 1996



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service  
Food And Drug Administration

Memorandum

6/18/96

From: Reviewer(s) - Name(s) CHARLES HO

Subject: 510(k) Number K950944 / S<sup>2</sup>

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

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

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

This 510(k) contains:

- Truthful and Accurate Statement  Requested  Enclosed N/A, received on Feb. 17, '95  
(required for originals received 3-14-95 and after)
- A 510(k) summary OR  A 510(k) statement
- The required certification and summary for class III devices N/A
- The indication for use form (required for originals received 1-1-96 and after)

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

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

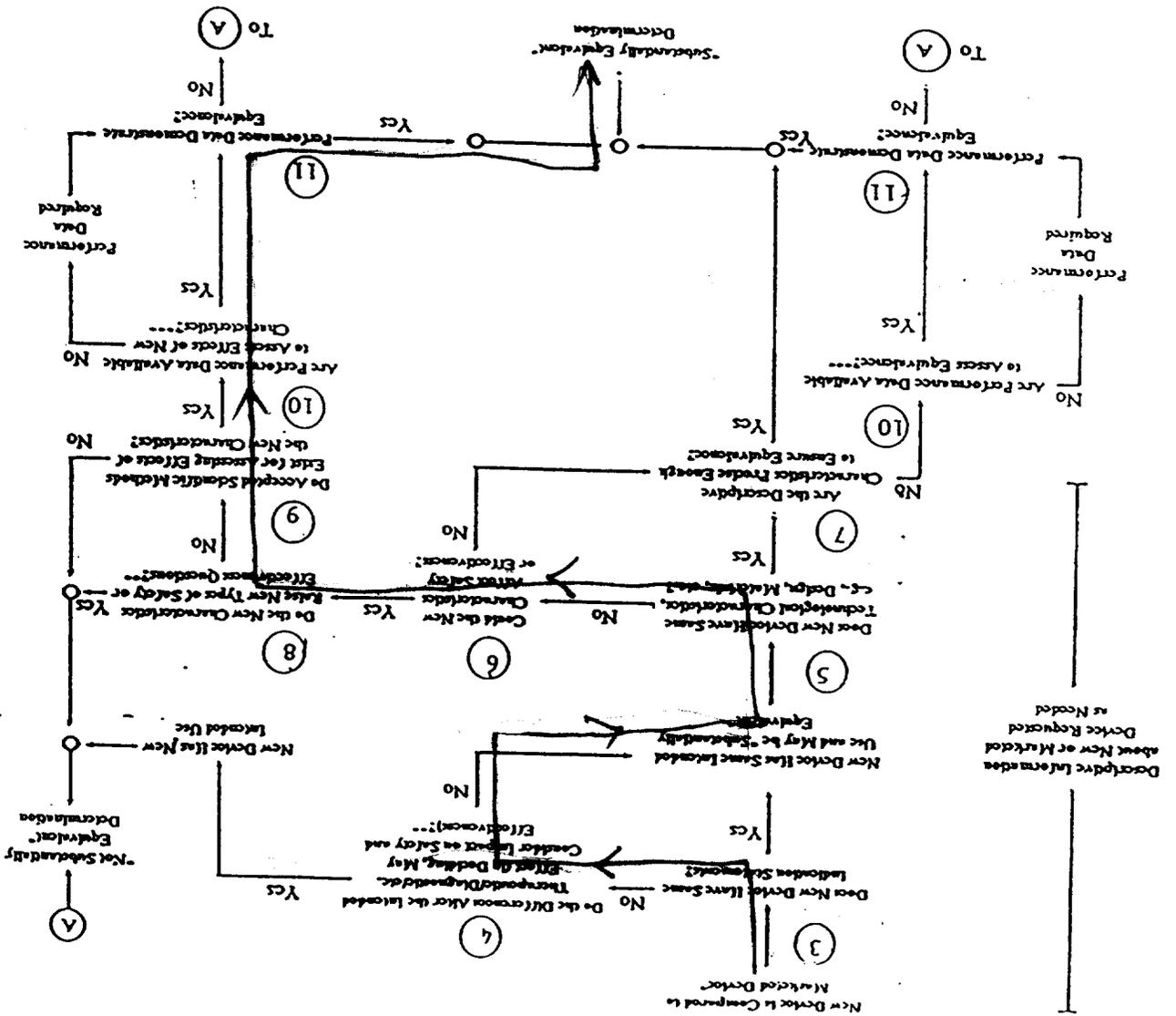
Predicate Product Code with panel and class: Additional Product Code(s) with panel (optional):

74 DQK / II (two)

Review: Mark Marx ADD6 6/18/96  
(Branch Chief) (Branch Code) (Date)

Final Review: Richard Phyllis 6/18/96  
(Division Director) (Date)

### 510(k) 'SUBSTANTIAL EQUIVALENCE' DECISION-MAKING PROCESS (DETAILED)



510(k) submissions compare new devices to marketed devices. FDA requests additional information if the relationship between marketed and 'predicate' (pre-Amendments or redassified post-Amendments) devices is unclear. This decision is normally based on descriptive information alone, but limited testing information is sometimes required. ... Data may be in the 510(k), other 510(k)s, the Center's classification files, or the literature.

005

Addendum, June 18, 1996

Telephone Contact

June 18, 1996, Mr. Mark Massi, acting as Signatory Reviewer, requested the removal of the indication of "Evaluation of patients for silent ischemia", since that particular indication is not supported by the ACC/AHA Task Force Report on ambulatory ECG, as published in JACC, Vol. 13, No. 1, January 1989: 249-58.

Later that day, I talked to Mr. Darren Dershem, and we agreed to change the indication to:

"Evaluation of patients for ST-segment changes"

The manufacturer's revised list of intended uses was FAXed to me, and is enclosed.

*Chad Cho*  
*June 18, 96*

*Mark Massi*  
*6/18/96*



13755 First Avenue North  
Plymouth, MN 55441-9700  
612-449-8100  
612 449 8866 Fax

*Page 1 of 2*

June 18, 1996

Charles S. C. Ho, Ph.D.  
Office of Device Evaluation  
Document Mail Center (HFZ 401)  
Food and Drug Administration  
9200 Corporate Blvd.  
Rockville, MD 20850

Fax: 301-480-4204  
RE: 510(k) K950944  
Request for additional information

Dear Dr. S. C. Ho:

In response to our telephone conversation the following information is submitted.

Biosensor will change the intended use number 1.2 as indicated on the next page.

Should you have further questions please don't hesitate to contact me at the telephone number above.

Sincerely,

Darren D. Darsham  
Quality Assurance

called  
DDD

Page 2 of 2

8

interventions in individual patients or groups of patients.

ST segment changes

- 1.2) Evaluation of patients for ~~silent ischemia~~
- 1.3) Evaluation of patients with pacemakers.
- 1.4) Evaluation of individual patient's response upon resuming occupational or recreational activities (e.g. after M.I., cardiac surgery).
- 1.5) Evaluation of clinical syndromes and situations where arrhythmias may increase risk of sudden death.
- 1.6) Clinical and epidemiological research studies.



7

Warnings

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

- CAUTION: This device has not been tested for compliance with AAMI specifications regarding defibrillation equipment. Use of defibrillators may result in damage to this device.

Statement of Intended Use

The Full Disclosure Monitoring System is intended for patients requiring ambulatory (Holter) monitoring from 1 to 24 hours. Such monitoring is most frequently used in the indications listed below.

Current Uses of Ambulatory ECG Recording \*

(\*) Portions from Ambulatory Electrocardiographic Recording. Wenger NK, Mack MB, and Reingquist J, Year Book Medical Publishers, Copyright 1961.

- 1.2) Evaluation of symptoms suggesting arrhythmia or myocardial ischemia.
- 1.1) Evaluation of ECG documenting therapeutic

MEMO TO THE RECORD  
510(K) REVIEW

K950944/S2

DATE: June 17, 1996 *Charles Ho* OFFICE: ODE  
FROM: Charles Shang Chan Ho, Ph.D. DIVISION: DCRND

COMPANY NAME: Biosensor Corporation  
DEVICE NAME: Ambulatory (Holter) Recording System

"SUBSTANTIAL EQUIVALENCE" (SE) DECISION-MAKING DOCUMENTATION

NARRATIVE DEVICE DESCRIPTION

1. REASON 510(k) WAS SUBMITTED:

This 510(k) notification covers the Ambulatory (Holter) Recording System manufactured by Biosensor Corporation. The reasons for the 510(k) notification are a) to add a dual channel pacemaker stimulus detector circuit, b) to increase memory size for better ECG resolution, and c) to add R-R interval statistics, for an original device with the same name that was cleared under K922027 on February 17, 1993. Note that Item c is in fact heart rate variability (HRV) analysis in the time domain. The present supplement is the manufacturer's response to our AI letter dated August 21, 1995.

2. INTENDED USE:

From an unnumbered page of notification, "The Full Disclosure Monitoring System is intended for patients requiring ambulatory (Holter) monitoring from 1 to 24 hours. Such monitoring is most frequently used in the indications listed below:

Evaluation of symptoms suggesting arrhythmia or myocardial ischemia.

Evaluation of ECG documenting therapeutic interventions in individual patients or groups of patients.

Evaluation of patients for silent ischemia.

Evaluation of patients with pacemakers.

Evaluation of individual patient's response upon resuming occupational or recreational activities (e.g., after M.I.,

cardiac surgery)

Evaluation of clinical syndromes and situations where arrhythmias may increase risk of sudden death.

Clinical and epidemiological research studies."

Further, the intended use for HRV is listed in a FAXed message on June 17, 1996, as follows:

"Heart rate variability (HRV) analysis in the time domain is intended for quantification and graphic displays of heart rate changes over a specific monitoring period, and is to be used as an adjunct to other clinical diagnostic techniques."

Note that except for the patients with pacemakers and the HRV part this list is similar to the predicate's list.

3. DEVICE DESCRIPTION:

- A. Life-supporting or life-sustaining: N
- B. Implant (short-term or long-term): N
- C. Is the device sterile? N  
If yes, is sterility information provided? N/A
- D. Is the device for single use? N
- E. Is the device for prescription use? Y  
If yes, is prescription labeling included? Y
- F. Is the device for home use or portable? Y (patient recorder is portable)  
Whether the answer is yes or no, is adequate environmental testing, including EMC, performed for the intended environment, and are results provided, including test protocols, data, and a summary? Y
- G. Does the device contain drug or biological product as a component? N
- H. Is this device a kit? N  
If yes, and some or all of the components are not new, does the submission include a certification that these components were either preamendment or found to be substantially equivalent? N/A
- I. Software-driven: Y  
Estimated level of concern: (Major, Moderate, Minor)?  
Moderate



of the articles must be provided as opposed to listing the author and titles, the significant areas of the articles must be highlighted, and a summary must be provided relating the information to the issue at hand, including a discussion of the study protocol, data, statistical analyses, and a summary of the results.

- b. If applicable, comparative in vitro testing including protocol, data, and a summary of the results should be provided.
  - c. Performance data including protocol, data, and summary explaining how testing and data demonstrate that the device performs as intended should be provided.
  - d. If applicable, animal testing including protocol, data, and a summary of the results should be provided.
  - e. If applicable, clinical testing, including the investigational plan, data, statistical analyses and a summary of results should be provided. If the study was performed under an investigational device exemption (IDE), the IDE number should be provided. If the device is nonsignificant risk, the study should be conducted under the auspices of the institutional review board (IRB) even though an IDE would not need to be filed with the FDA.
  - f. If applicable, biocompatibility testing, including the protocol for each test required as outlined in the Tripartite Biocompatibility Guidance, the pass/fail criteria, data, and a summary of results should be provided.
  - g. The firm should provide the labeling offered with the device, including adequate instruction (or prescription labeling), cautions and warnings, contraindications, package label, promotional literature, and claims to be made for the device.
- N. Provide a statement of how the device is either similar to and/or different from other marketed devices, plus data (if necessary) to support the statement. Provide a summary about the devices design, materials, physical properties and toxicology profile if important.

At this moment in time, the manufacturer has removed all my concerns on the device as follows:

- \* The device's ability to place a marker (simulated spike) in the ECG tracing to within +/- 4 msec of the real spike has been verified.

- \* The patient recorder has been tested for EMC immunity.
- \* The device's data compression scheme has been verified.
- \* Labeling has been revised to show the specification of 4 msec referred to above.
- \* Labeling has been revised to show that the device records only the temporal location (i.e., time of occurrence of the spikes), and not pulse width nor pulse height.
- \* The device's regulatory classification is clarified as Class II (two).
- \* The intended use of the new feature of HRV analysis in the time domain has been clarified.
- \* The device's HRV analysis capability in the time domain has been validated.

Hence, I am pleased to recommend SE.

EXPLANATIONS TO "YES" AND "NO" ANSWERS TO QUESTIONS ON PAGE 1 OF REVIEW FORM AS NEEDED (DELETE QUESTIONS WHICH ARE NOT APPLICABLE)

1. IF THE ANSWER TO QUESTION 1 IS NO, EXPLAIN WHY THE PRODUCT IS NOT A DEVICE. <>

2. IF THE ANSWER TO QUESTION 2 IS NO, EXPLAIN WHY THE DEVICE IS NOT SUBJECT TO 510(K). <>

3. IF THE ANSWER TO QUESTION 3 IS NO, EXPLAIN HOW THE NEW INDICATION DIFFERS FROM THE PREDICATE DEVICE'S INDICATION. The new indication involves heart rate variability (HRV) analysis in the time domain.

4. IF THE ANSWER TO QUESTION 4 IS YES OR NO, EXPLAIN WHY THERE IS/IS NOT A NEW EFFECT OR SAFETY OR EFFECTIVENESS ISSUE. HRV analysis in the time domain is similar to the R-R interval analysis that the medical profession has been doing manually for many years. The device only automates this analysis.

5. IF THE ANSWER TO QUESTION 5 IS NO, DESCRIBE THE NEW TECHNOLOGICAL CHARACTERISTICS. The new technological characteristic is the HRV analysis in the time domain.

6. IF THE ANSWER TO QUESTION 6 IS YES OR NO, EXPLAIN HOW THE NEW CHARACTERISTICS COULD/COULD NOT AFFECT

**SAFETY OR EFFECTIVENESS. HRV analysis is a new indication for use, and so can affect safety and effectiveness.**

**7. IF THE ANSWER TO QUESTION 7 IS NO, EXPLAIN HOW THE DESCRIPTIVE CHARACTERISTICS ARE NOT PRECISE ENOUGH. <>**

**8. IF THE ANSWER TO QUESTION 8 IS YES OR NO, EXPLAIN THE NEW TYPES OF SAFETY OR EFFECTIVENESS QUESTIONS RAISED OR WHY THE QUESTIONS ARE NOT NEW. HRV analysis in the time domain is similar to the R-R interval analysis that the medical profession has been doing mentally for many years. The device only automates this analysis.**

**9. IF THE ANSWER TO QUESTION 9 IS NO, EXPLAIN WHY THE EXISTING SCIENTIFIC METHODS CAN NOT BE USED. <>**

**10. IF THE ANSWER TO QUESTION 10 IS NO, EXPLAIN WHAT PERFORMANCE DATA IS NEEDED. <>**

**11. THE ANSWER TO QUESTION 11 IS YES OR NO, EXPLAIN HOW THE PERFORMANCE DATA DEMONSTRATES THAT THE DEVICE IS/IS NOT SUBSTANTIALLY EQUIVALENT. The manufacturer has presented a comparison of device vs human overreader in analyzing the HRV parameters of mean and standard deviation for 197 beats. The device's results are similar to the human results.**

- O. Does the submission include a summary of safety and effectiveness information upon which an equivalence determination is based? N**  
**If not, does the submission include a certification that such information will be made available to interested persons upon request? Y**

P. RECOMMENDATION:

I believe that this device is equivalent to: 74 DQK

Classification should be based on:

870.1425                      Class: II (two)

If the device is substantially equivalent to a class III device, does the submission include: (1) certification that a reasonable search of all information known, or otherwise available, about the generic type of device has been performed and (2) a summary description of the types of safety and effectiveness problems associated with the type of device and a citation to the literature, or other sources of information, upon which they have based the description?  
N/A

Charles Vdo <>

I believe that this device is not equivalent to any pre-enactment/predicate device:

\_\_\_\_\_ <>

I believe that additional information is required to determine equivalence (see attached):

\_\_\_\_\_ <>

**REVIEW MEMORANDUM**

*Charles Shang*  
**From:** Charles Shang Chan Ho, Ph.D.   **Date:** June 17, 1996  
**To:** The Record   **Office:** ODE  
**Subject:** K950944/S2   **Division:** DCRND

-----

Manufacturer Contact

Mr. Steve Springrose  
President  
Biosensor Corporation  
13755 First Avenue North  
Plymouth, Minnesota 55441-9760  
Phone: (612) 449-9100                      FAX: (612) 449-8966

Manufacturer Contact

Mr. Darren D. Dershem  
Quality Assurance  
Biosensor Corporation  
13755 First Avenue North  
Plymouth, Minnesota 55441-9760  
Phone: (612) 449-9100                      FAX: (612) 449-8966

Reason for Notification

This 510(k) notification covers the Ambulatory (Holter) Recording System manufactured by Biosensor Corporation. The reasons for the 510(k) notification are a) to add a dual channel pacemaker stimulus detector circuit, b) to increase memory size for better ECG resolution, and c) to add R-R interval statistics, for an original device with the same name that was cleared under K922027 on February 17, 1993. Note that Item c is in fact heart rate variability (HRV) analysis in the time domain. The present supplement is the manufacturer's response to our AI letter dated August 21, 1995.

Intended Use

From an unnumbered page of notification, "The Full Disclosure Monitoring System is intended for patients requiring ambulatory (Holter) monitoring from 1 to 24 hours. Such monitoring is most frequently used in the indications listed below:

Evaluation of symptoms suggesting arrhythmia or myocardial ischemia.

Evaluation of ECG documenting therapeutic interventions in individual patients or groups of patients.

Evaluation of patients for silent ischemia.

Evaluation of patients with pacemakers.

Evaluation of individual patient's response upon resuming occupational or recreational activities (e.g., after M..I., cardiac surgery)

Evaluation of clinical syndromes and situations where arrhythmias may increase risk of sudden death.

Clinical and epidemiological research studies."

Further, the intended use for HRV is listed in a FAXed message on June 17, 1996, as follows:

"Heart rate variability (HRV) analysis in the time domain is intended for quantification and graphic displays of heart rate changes over a specific monitoring period, and is to be used as an adjunct to other clinical diagnostic techniques."

Note that except for the patients with pacemakers and the HRV part this list is similar to the predicate's list.

Class II (TWO) Classification

I should point out that the manufacturer was not clear in his/her previous submittals on the device features of alarm and off-line analysis. Only after I specifically inquired about these features, does the manufacturer indicate in the present and previous submittals that the device has only off-line arrhythmia monitoring capabilities, with no real-time alarms. There is a mechanical blocking out arrangement so that the patient cable for ECG recording has to be removed before the computer cable can be connected for ECG analysis. Hence, I conclude that as the risk involved is small, the device should be placed in Class II (two), not III(three), which the manufacturer had initially indicated.

**Claimed Predicate Devices**

The Ambulatory (Holter) Recording System (same device name) manufactured by Biosensor Corporation (same manufacturer name). The predicate was cleared under K922027 on February 17, 1993.

Further, another device from the same manufacturer, with the same device name and identical functions except for HRV, has been cleared under K950723 on February 9, 1996.

Submittal Review

Since I was the reviewer of the file K950723 for a device identical to the present device except for the HRV function, I have re-used the eight questions from the K950723 file. As K950723 was found substantially equivalent on February 9, 1996, the manufacturer has chosen to present the same responses to the first seven questions, and slightly modified the eighth question.

Hence, the following are the same reviews for the first seven questions, copied from K950723, since they also apply to the present file:

Question 1 a and b:

The manufacturer has replied that the device can work on single and dual chamber pacemaker pulse generators. It can distinguish the atrial stimulus from the ventricular stimulus by their timing with reference to the paced beat. The answer is adequate.

Question 2a:

The manufacturer has replied that the two gains referred to different stages of the device. The answer is adequate.

Question 2b:

The manufacturer has replied that there was a typographical error in that the input voltage in Table 3 of page 86 of the initial submittal should have been 0.01 V p-p, not 0.1 V p-p. Now the dB calculations are correct. The answer is adequate.

Question 2c:

The manufacturer has provided a copy of the test procedure used to test the pacemaker stimulus detector during manufacturing. However, there is no test report to verify that the device detects the stimulus within a certain tolerance. This is important since the device samples the ECG at 250 samples/sec, and a pacemaker stimulus may or may not be recorded and later displayed in the ECG channel. There is an analog channel that detects the pacemaker stimulus and puts a simulated pacemaker stimulus at the detected location of the real pacemaker stimulus, within +/- 4 msec, according to the manufacturer on February 7, 1996. The proof of this 4 msec tolerance has been received on February 8, 1996. The answer is adequate.

Question 2d:

The manufacturer has provided the requested ECG tracings. They are reasonable. The answer is adequate.

**Question 3:**

The manufacturer has replied that the increase in memory size is market driven. There is a minor change in data compression scheme. The present scheme is as follows:

The Biosensor recorder initially reduces the data 2:1 from the 250 samples per second of raw data using the Turning Point Method with extremes retained. The first difference of the 125 Hz 8 bit data is then stored using a Huffman encoding method. The predicate (K922027) device uses the same compression scheme except it initially reduces the data 4:1 from the 250 samples per second raw data and retains only the top 6 bits of the samples before first difference and Huffman encoding.

The answer is adequate.

**Question 4:**

The manufacturer has provided a summary of over 200 test reports to verify that memory increase is implemented correctly and that ECG resolution has been improved. The answer is adequate.

**Question 5:**

The manufacturer has replied that the ECG cable and the computer cable are mutually exclusive via a mechanical blocking arrangement. (This is the same arrangement used in the predicate of K922027.) Hence, the patient cannot be connected to the PC while the PC is used to analyze arrhythmia. The answer is adequate.

**Question 6:**

February 8, 1996, I talked to Mr. Dershem again. He clarified that the two requested changes involve the patient recorder only. The other changes involve updating the operation manual and help screens to reflect the addition of pacemaker spike detection. Hence, I explained to him my rationale for requesting EMC immunity testing for only the patient recorder, and not the whole system including the PC-- the requested changes concern the patient recorder only. And the patient recorder should not generate any significant RF waves since it is battery-powered and is not an intentional radiator of RF energy. In the present supplement, the manufacturer has submitted a test report from Inchcape Testing Services showing that the patient recorder was immune to RF fields up to 3 V/m. The answer is adequate.

**Question 7 a to d:**

The manufacturer has provided all the requested labeling change. The answer is adequate.

**Question 8:**

The manufacturer has replied that the version number of the firmware used in the device is Rev A Version 9509.19. The answer is adequate.

The following questions concern the present file exclusively:

**Question 9:**

The manufacturer has replied that MIT 107 is a 30 minute database tape containing only two types of beat classifications, (2078 paced beats and 59 ventricular beats). In addition, the 59 ventricular beats are comprised of 2 varying morphological shapes. No other beat types are present in this tape. The absence of a normal beat morphology can have an adverse effect on the device's adaptive dynamic learning strategy. The short 30 minute tape length prevents the algorithm from having a reasonable chance of learning which morphology is the normal beat. The system attempts to identify a normal morphology but finds one of the different ventricular morphologies and labels it as normal. As this is a limitation common to many other devices, the answer is adequate.

**Question 10:**

The manufacturer has adopted our proposed intended use of HRV, namely,

"Heart rate variability (HRV) analysis in the time domain is intended for quantification and graphic displays of heart rate changes over a specific monitoring period, and is to be used as an adjunct to other clinical diagnostic techniques."

However, in the present supplement, he/she has added two other uses on alterations in autonomic tone and sympathetic and parasympathetic autonomic function... and risk stratification.

(b) (5)

these claims. In fact, my Question 11 has requested clinical [redacted] of HRV other than our proposed intended

(b)(4)

Darren Dershem on June 17, 1996, and Mr. Dershem agreed to [redacted]. A FAX to that effect has been received and attached to this memorandum. A hardcopy will be mailed by the manufacturer later.

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Question 11 and 12:

The manufacturer has provided the sections in the user manual concerning HRV. All of our previously recommended labeling changes are adopted. The answers are adequate, in view of the only remaining intended use of HRV.

Question 13:

The manufacturer has summarized two tests in order to validate his/her device:

- \* 200 data sets were input through two system versions, one with HRV and one without HRV. The manufacturer reported that the presence or absence of the mean and standard deviation calculation (used in HRV analysis) has not had an adverse effect on any other system features.

- \* For a four minute interval of ECG tracings, the device with HRV produced the following R-R statistics:

Mean of 1202 msec and standard deviation of 75 msec.

Then, the same interval was measured manually using calipers and generated the R-R statistics of:

Mean of 1203 msec and standard deviation of 76.2 msec.

Hence, I believe that the device's R-R analysis capability has been validated as these results are very similar.

Telephone Contact

June 17, 1996, I talked to Mr. Darren Dershem, a manufacturer representative, on the issue of intended uses for HRV. The manufacturer agreed to delete the two unsubstantiated intended uses, leaving only the intended use of "quantification and graphic displays of heart rate ... as an adjunct to other clinical diagnostic techniques".

In responding to Question 13, the manufacturer clarified that the minimum time span that the device can analyze in the HRV mode is 4 minutes. However, in presenting the HRV results, the device generates 5 graphs as follows:

- \* The first graph is for the total time span, 4 minutes in the example of the present supplement.
- \* Each of the remaining 4 graphs covers one quarter of the time span, making it look like that the device can analyze a minimum time span of 1 minute.

We also discussed the following issues:

- \* The device belongs to Class II (two), not III (three), since it is an off-line arrhythmia analysis system, and HRV analysis is considered Class II also.
- \* We clarified that the device does not generate any HRV parameter other than mean and standard deviation of R-R intervals.

Mr. Dershem has sent me a FAX to confirm these agreements. The FAX is attached. The hardcopy will come later.

Issue of Substantial Equivalence

At this moment in time, the manufacturer has removed all my concerns on the device as follows:

- \* The device's ability to place a marker (simulated spike) in the ECG tracing to within +/- 4 msec of the real spike has been verified.
- \* The patient recorder has been tested for EMC immunity.
- \* The device's data compression scheme has been verified.
- \* Labeling has been revised to show the specification of 4 msec referred to above.
- \* Labeling has been revised to show that the device records only the temporal location (i.e., time of occurrence of the spikes), and not pulse width nor pulse height.
- \* The device's regulatory classification is clarified as Class II (two).
- \* The intended use of the new feature of HRV analysis in the time domain has been clarified.
- \* The device's HRV analysis capability in the time domain has been validated.

Hence, I am pleased to recommend SE.

**RECOMMENDATION**

It is the recommendation of this reviewer that the Ambulatory (Holter) Recording System, filed under K950944, be found substantially equivalent to the device with same name from the same manufacturer of Biosensor, cleared under K922027.

Another predicate is the Ambulatory (Holter) Recording System (same device name) manufactured by Biosensor Corporation (same manufacturer), cleared under K950723 on February 9, 1996.

The regulatory classification should be II (two) since there is no real-time alarm and the arrhythmia analysis is done off-line.

*Concur  
Mark Mani  
6/18/96*



13755 First Avenue North  
Plymouth, MN 55441-0700  
612-449-9100  
612-449-8000 Fax



# FAX COVER SHEET

Date: June 17, 1996

To: Dr. S.C. Ho Fax 301-480-4704

Company: FDA

From: Darren Derstom

Number of Pages (including Cover Page): 3

**Message:**

Additional information K950944



13755 First Avenue North  
Plymouth, MN 55441-9760  
612-449-8100  
612-449-8966 Fax

June 17, 1996

Charles S. C. Ho, Ph.D.  
Office of Device Evaluation  
Document Mail Center (HFZ-401)  
Food and Drug Administration  
9200 Corporate Blvd.  
Rockville, MD 20850

Fax: 301-480-4204  
RE: 510(k) K950944  
Request for additional information

Dear Dr. S. C. Ho:

In response to our telephone conversation of this morning the following information is submitted.

(b)(4)

the next page. In addition, Biosensor states that the only HRV calculations provided by the system are the Mean and Standard Deviation.

Clarification of FDA question number 13 is as follows. As stated in the previous answer. A time slider bar feature allows time adjustments to be performed on any portion of the stored ECG data down to a four minute minimum interval. In addition to the original time selection, four additional graphs are provided. Each graph is a one quarter representation of the initial slider bar time selection. In the case of the provided example these graphs breakdown into one minute intervals. If the initial slider bar time is selected for the entire twenty four hour procedure these graphs would each represent a six hour period. If initial slider bar time is selected as eight hours the graphs would each represent a two hour period. These quarter graphs are used to supplement the initial main graph.

Should you have further questions please don't hesitate to contact me at the telephone number above.

Sincerely,

A handwritten signature in black ink that reads "Darren D. Dershem". The signature is written in a cursive, somewhat stylized script.

Darren D. Dershem  
Quality Assurance

027

**10. FDA question number 10.**

**What is the intended use for the device's feature of HRV analysis in the time domain? List all the specific claims made for the feature of HRV.**

Heart rate variability (HRV) analysis in the time domain is intended for quantification and graphic displays of heart rate changes over a specific monitoring period, and is to be used as an adjunct to other clinical diagnostic techniques.

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000*

**I N T E R O F F I C E   M E M O R A N D U M**

**Date:** 17-Jun-1996 03:18pm EDT  
**From:** Ho, Charles S.  
CBH  
**Dept:** ODE\_DCRND - HFZ-450  
**Tel No:** 443-8609

**TO:** Shulman, Marjorie ( MYS )  
**CC:** Phillips, Richard ( RNP )  
**CC:** Ho, Charles S. ( CBH )

**Subject:** K950944

Marjie:

Please be informed that I have placed the device in the above file, Ambulatory (Holter) Recording System, in regulatory class II (two) since the device cannot perform real-time analysis on ECG signals, and has no real-time alarms.

This classification is different from the initial classification of III (three) by the mfr (Biosensor Corp.) and our Document Mail Center.

Hence, please inform our Office of Compliance accordingly. The file will be recommended for SE today or tomorrow.

Thank you!

Charles Ho  
Reviewer of K950944

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

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

March 19, 1996

BIOSENSOR CORP.  
13755 FIRST AVENUE NORTH  
PLYMOUTH, MN 55441  
ATTN: MR. DARREN D. DERSHEM

510(k) Number: K950944  
Product: AMBULATORY  
(HOLTER)  
RECORDING SYSTEM

The additional information you have submitted has been received.

We will notify you when the processing of this submission has been completed or if any additional information is required. Please remember that all correspondence concerning your submission MUST be sent to the Document Mail Center (HFZ-401) at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification submission. Because of equipment and personnel limitations we cannot accept telefaxed material as part of your official premarket notification submission, unless specifically requested of you by an FDA official.

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

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

Sincerely yours,

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

030

K950944/S



13755 First Avenue North  
Plymouth, MN 55441-9760  
612-449-9100  
612-449-8966 Fax

March 14, 1996

Charles S. C. Ho, Ph.D.  
Office of Device Evaluation  
Document Mail Center (HFZ-401)  
Food and Drug Administration  
9200 Corporate Blvd.  
Rockville, MD 20850

FDA/CDRH/OCE/DMD  
18 Mar 96 14 48  
RECEIVED

RE: 510(k) K950944  
Request for additional information

Dear Dr. S. C. Ho:

In response to your request for additional information on 510(k) K950944. The following data is submitted. I believe it provides the information you have requested.

In addition, the data pertaining to FDA question number 1 through number 8 was previously provided in our 510k K950723. K950723 was reviewed and approved in February 1996. This proposed K950944 device has the same pacemaker stimulus detection design and function as the K950723 device. The only difference is the addition of the HRV feature. All data is provided again to facilitate your review.

Should you have further questions please don't hesitate to contact me at the telephone number above.

Sincerely,

Darren D. Dershem  
Quality Assurance

031

The FDA has requested information on the following technical items.

1. FDA question number 1.  
FDA has the following questions concerning the design of the pacemaker stimulus detector circuit in the device:

- 1a. Clarify whether the detector circuit can work on single chamber or dual chamber pacemaker pulse generators.

- 1b. If dual chamber, can the device distinguish the Atrial stimulus from the ventricular stimulus? If yes, how?

1a. The Biosensor Holter system is capable of both single chambered and dual chambered pacemaker detection and reporting. The system detects pacemaker stimuli in a separate channel specifically designed to detect and locate the pacemaker, whether unipolar, bipolar, Atrial pacing or ventricular pacing. In the event a single stimulus is in the programmed capture range of a detected QRS, single chambered pacing is called. In the event two stimuli are in the programmable A-V range of a resultant paced QRS (preset at 200 msec), dual chambered A-V pacing is called. Therefore, the system is able to distinguish between single chambered and dual chambered pacing by the number of pacemaker stimuli that precede and are proximal to the resultant paced QRS.

1b. The Biosensor system is able to distinguish the Atrial stimulus from the ventricular stimulus. In DVI operation the Atrial stimulus are separated into separate clusters from the ventricular beats as a result of the dual pulses proximal to the resultant paced beats. In AAI operation, the system is programmed to the expected PR interval, and the Atrial pulses are linked with the resultant paced QRS. However, in DDD pacing, the AAI and VVI beats will be clustered together using this system. VDI and VVI pacing do not have Atrial stimulus, and therefore are not relevant to this question.

**2. FDA question number 2.**

FDA has the following questions concerning the verification testing of the pacemaker stimulus detector circuit, reported in the initial submittal.

2a. The detector circuit seems to respond differently for the same 100 Hz frequency input. Specifically, the signal was magnified on page 85 while it was decreased on page 86.

2b. Are the dB calculations on page 86 correct? Specifically, for the 100 Hz signal, the -12.0 dB result should have been -32 dB. Other values under the same column have similar difficulties. Please explain how they were arrived at.

The verification testing of the pacemaker stimulus circuit reported in the initial submittal did have some typing errors. The corrected tables have been reinserted here to help clarify the concerns you may have. The necessary corrections have been made.

The initial submittal page 85, (provided as Table 2 below), shows the gain performance of the device from its input to the output of the instrumentation amplifier, (Gain=35 at 100 Hz). The initial submittal page 86, (provided as Table 3 below), shows the response of the Bandpass filter plus the gain stage in the pacemaker detection circuit. The expected response at 100 Hz for this portion of the circuit is  $-12.8 \text{ dB} = -40 \text{ dB} + 27.2 \text{ dB}$ , ( $-40 \text{ dB} : 20 \text{ dB per pole per decade}$ ,  $27.2 \text{ dB} : \text{gain of 23 stage}$ ). The response at 100 Hz was measured at -12 dB. The difference is within the tolerance of the parts used in the circuit.

Biosensor tested the system design in three phases. In the first, the basic design was tested. During this phase, circuit thresholds were tested using a computer model for ranges, limits and tolerances. In phase two, the major circuit sub-sections were tested and analyzed to determine that the overall system was functioning as expected and designed. Finally, the overall system was then tested to verify that it was functioning as expected and designed.

A summary of the system circuit sub-section tests and the overall system tests with results is described below:

1. Low-Pass Front End Analog Filter Tests.

A function generator was used to input a sine wave into the low pass filter. The frequency of the input signal was varied over the entire test range. The input amplitude remained constant during this test. The output of the filter was measured to determine the performance of the circuit. Table 1 below is a summary of these test results.

Table 1

<u>Frequency</u>	<u>Voltage In</u>	<u>Voltage Out</u>	<u>db</u>
(b)(4)			

2.0 The Gain vs. Frequency of the pacer detect circuitry instrumentation amplifiers with voltage limits were tested. A function generator was used to vary the frequency of the input signal over the entire test range. The input amplitude remained constant during this test. The output of the instrumentation amplifiers were measured and compared to expected results. Table 2 below is a summary of test results.

Table 2

<u>Frequency</u>	<u>Voltage In</u>	<u>Voltage Out</u>	<u>Gain</u>
(b)(4)			

3.0 The bandwidth response of the Bandpass filter with gain was also tested. A function generator was used to vary the frequency and of the input signal over the entire test range. The input amplitude remained constant during this test. The output of the filter was measured and compared to expected results. Table 3 below is a summary of the test results.

**Table 3**

<u>Frequency</u>	<u>Voltage In</u>	<u>Voltage Out</u>	<u>Measured db</u>
(b)(4)			

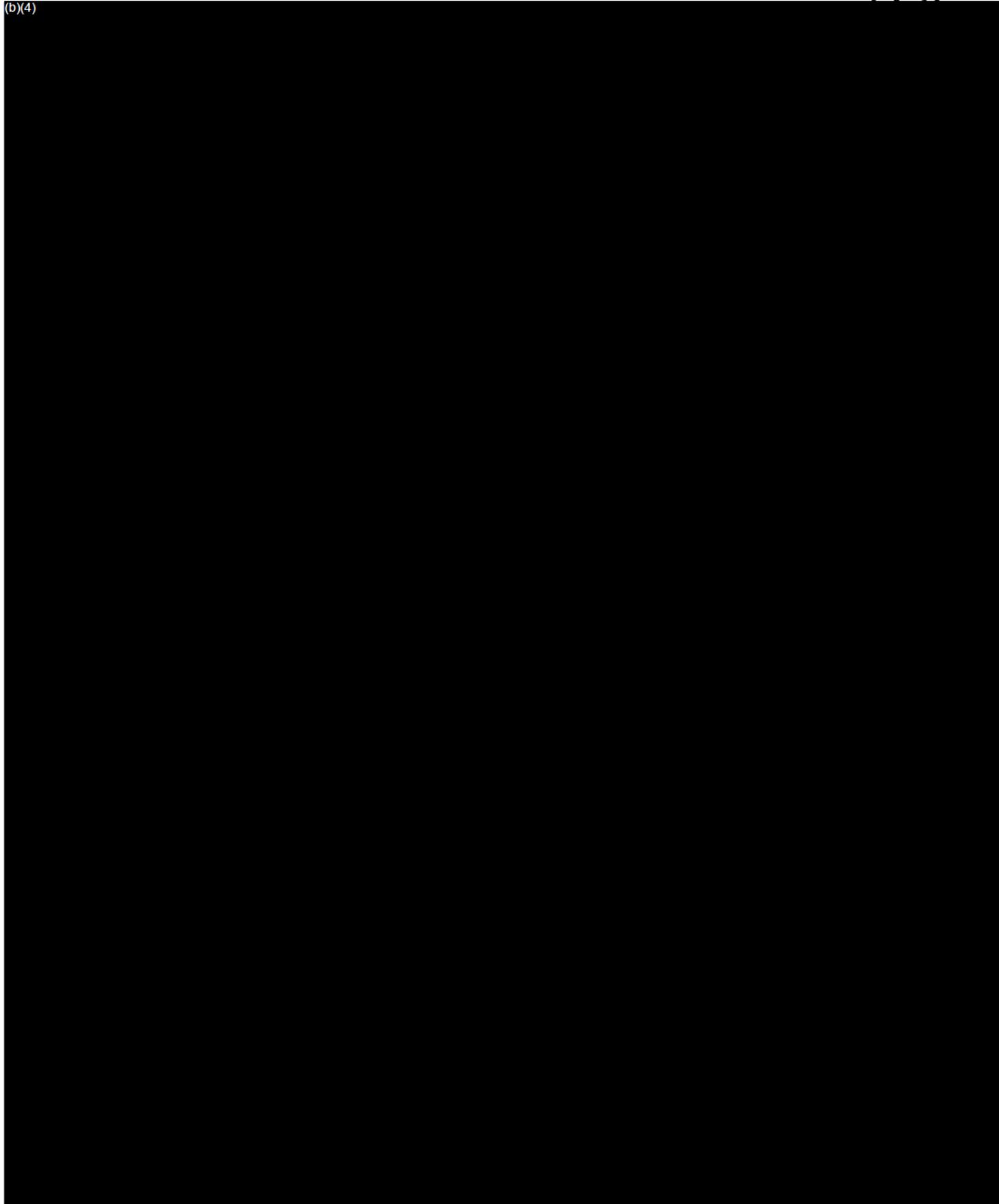
**2c. Please provide test report(s) to verify that the pacemaker stimulus detector is designed and manufactured according to your specifications. Please include the test protocol with pass/fail criteria and test results.**

**The following information is submitted to satisfy this request. 100 % of manufactured pace stimulus detector circuits are tested. The following pages contain the test protocol along with pass/fail criteria. The pages have been taken directly out of the manufacturing test procedure Biosensor intends to use and has used to verify correct circuit operations. The steps described below are designed to determine if the High Pass Filter (1kHz), Low Pass Filter (8kHz), and the pace stimulus detection thresholds are functioning as designed.**

(2C)  
Biosensor Corporation

PACEMAKER DETECTION CIRCUIT TESTS

(b)(4)

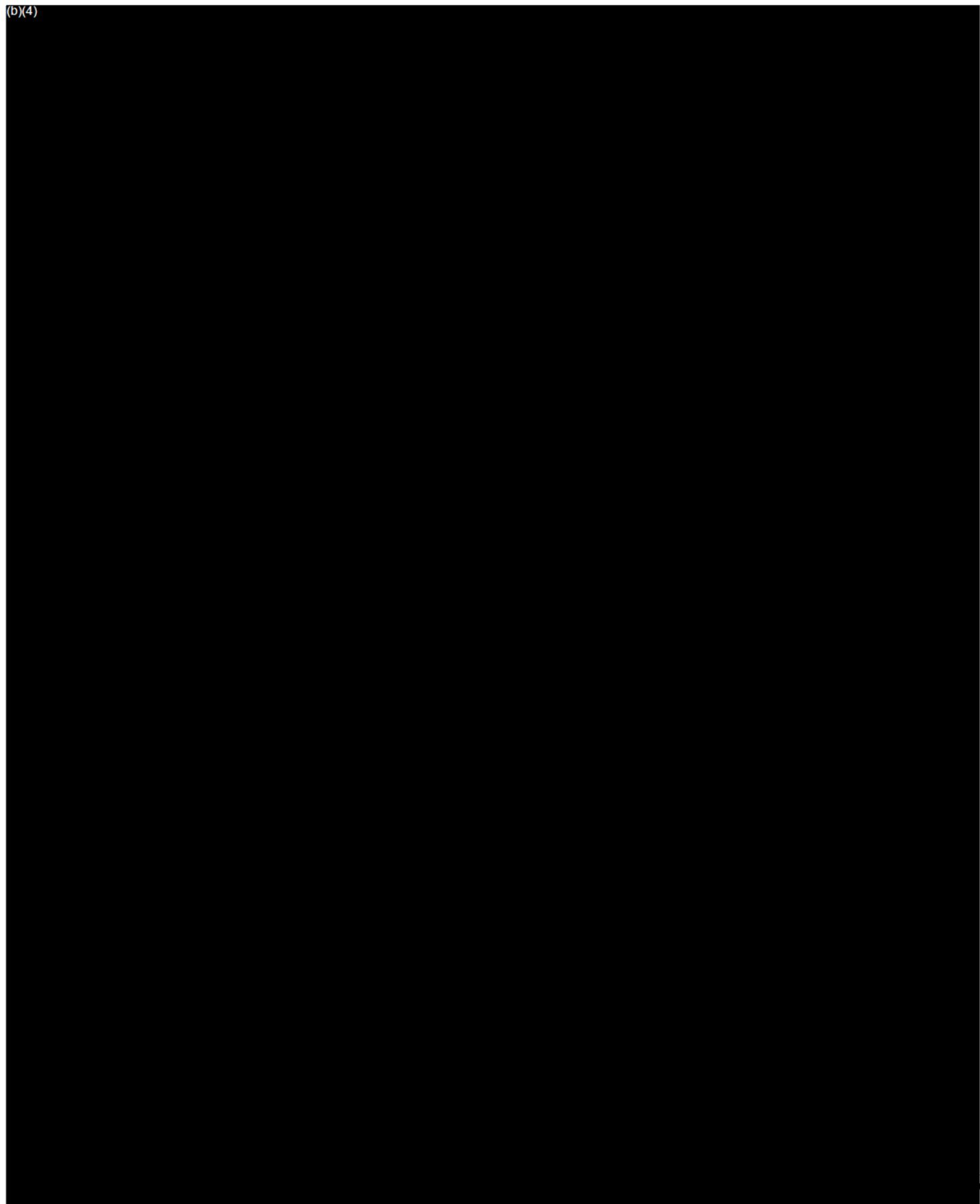


038

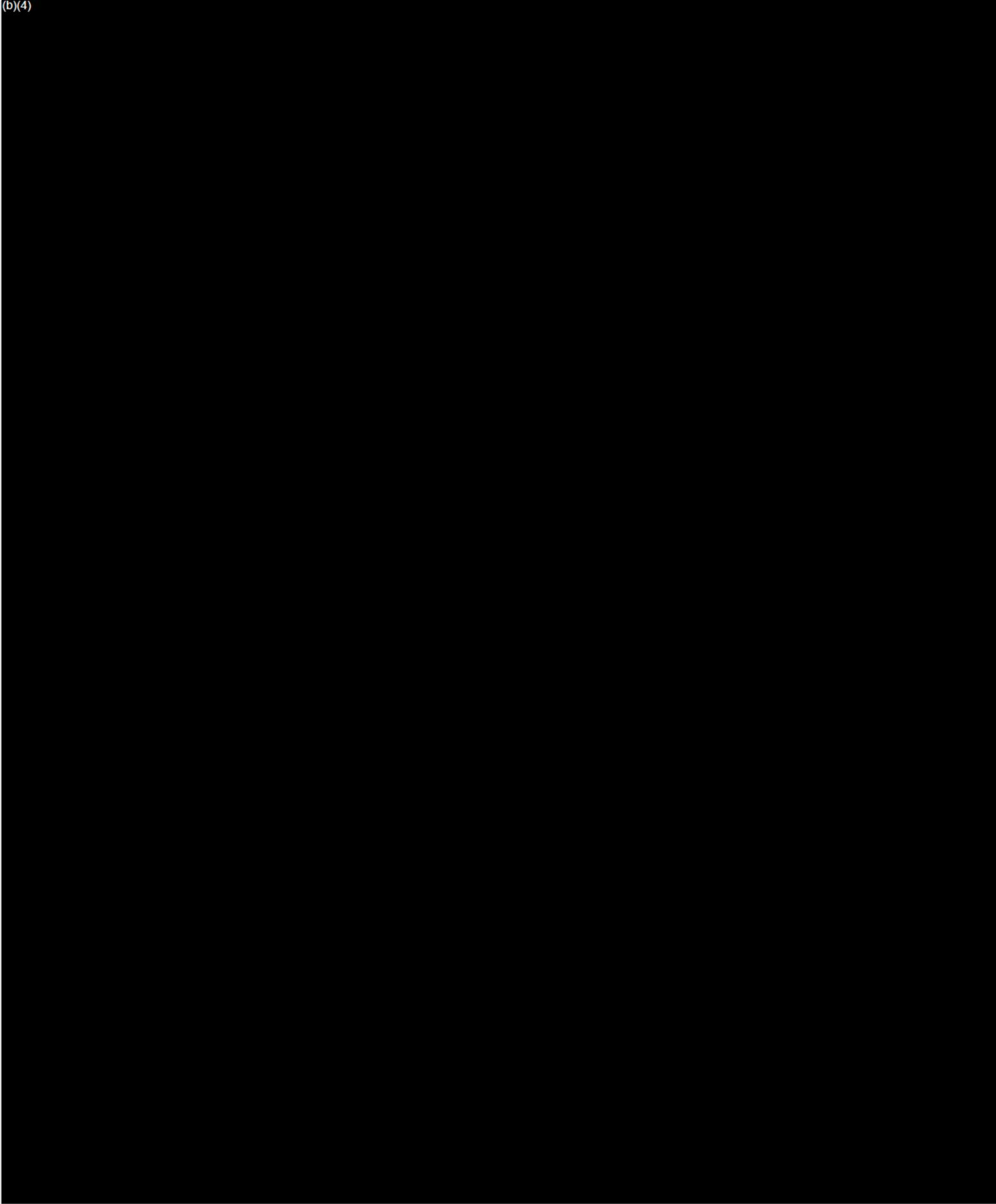
Biosensor Corporation

4A800.I1A Page 10 of 11

PACEMAKER LOW PASS FILTER TEST



(b)(4)



**Test Conclusions:**

**Biosensor has used the above pace stimulus detection circuit test procedure to verify the correct operations of 25 systems used in product development and pre-production testing. Each system passed the test protocol.**

**The following two pages contain a technical explanation of the systems pacemaker stimulus Time-Stamping technique along with supporting test data.**

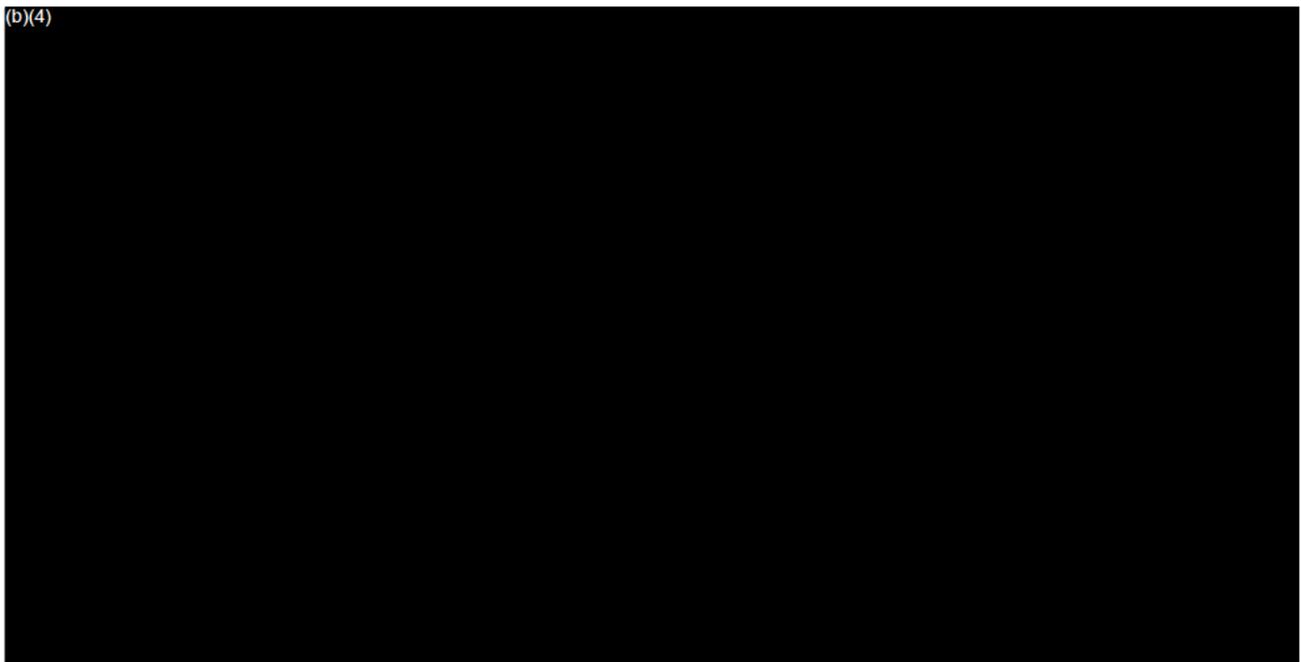
**Pacemaker Stimulus Measurement Accuracy**

(b)(4)



**Verification Testing**

(b)(4)



Simulated Pace Pulse Example  
RECORDER: 14005

ECG STRIPS

7.Mar.1995  
Page: 1



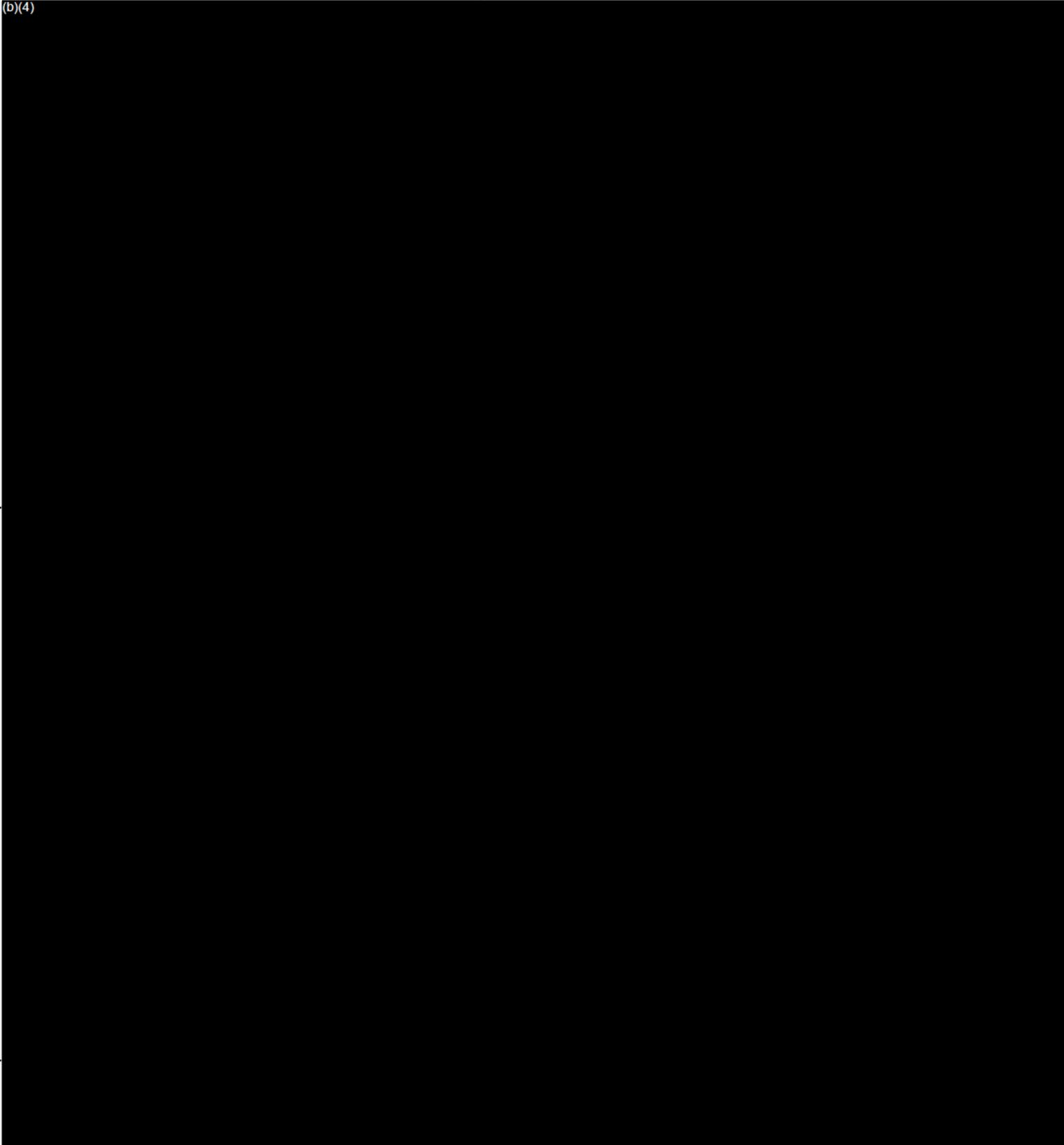
Figure 1.0

\*\*\* Calibration: 25 mm = 1 sec, 10 mm = 1 mV (all channels)

RECORDER: 14005

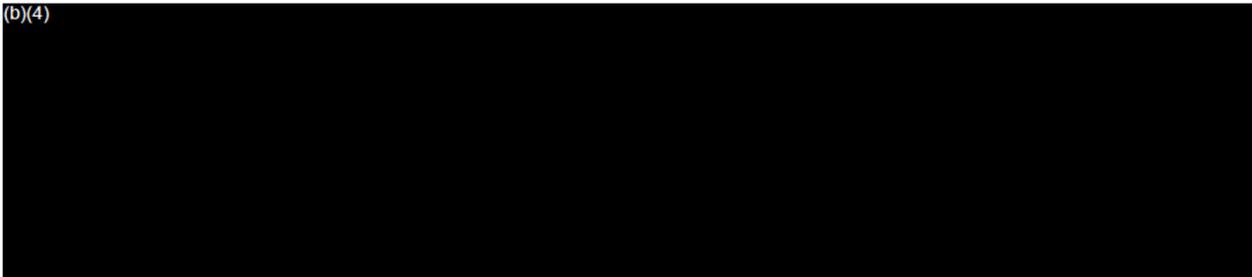
**CALIPER STRIPS**

(b)(4)



**2d. Please provide at least 10 ECG tracings with pacemaker stimuli (both chambers if applicable) to demonstrate the stimulus detection capability.**

(b)(4)

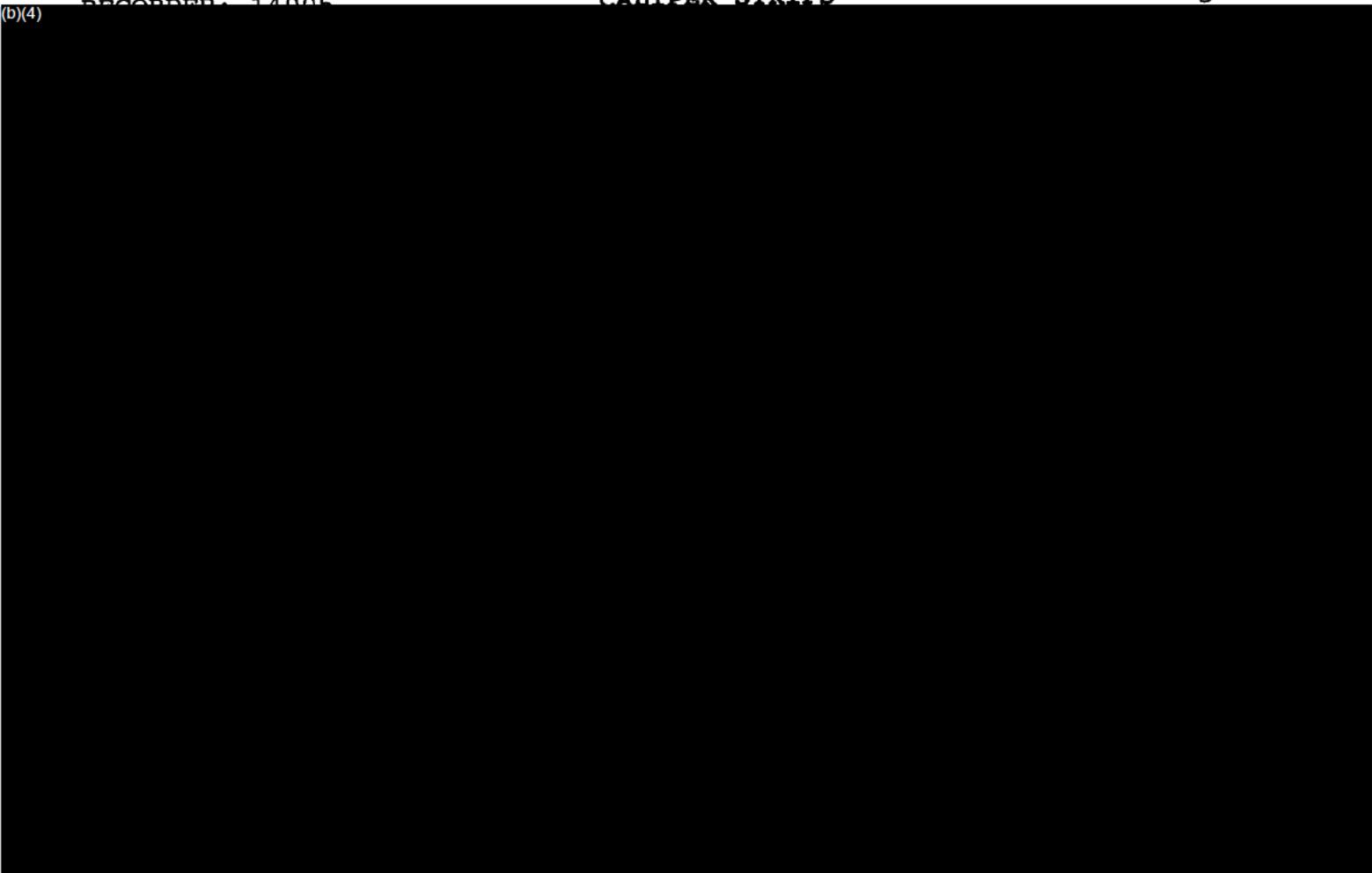


ECG Tracing #1  
RECORDED: 14005

**CALIPER STRIPS**

Feb 13, 1995  
Page: 1

(b)(4)



\*\*\* Calibration: 25 mm = 1 sec, 10 mm = 1 mV (all channels)

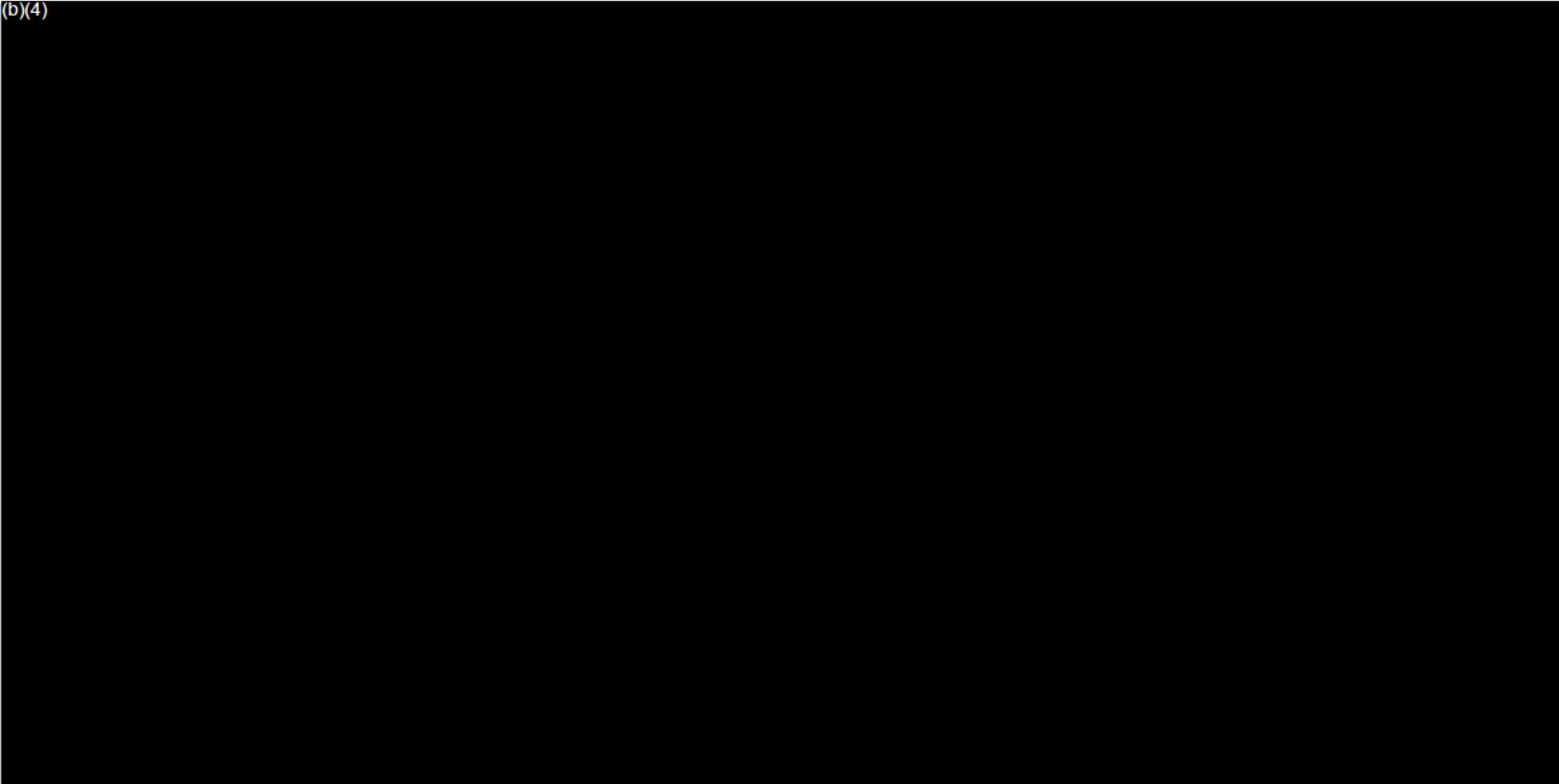
**045**

ECG Tracing #2  
RECORDER: 14005

CALIPER STRIPS

Feb 10, 1995  
Page: 1

(b)(4)



\*\*\* Calibration: 25 mm = 1 sec, 10 mm = 1 mV (all channels)

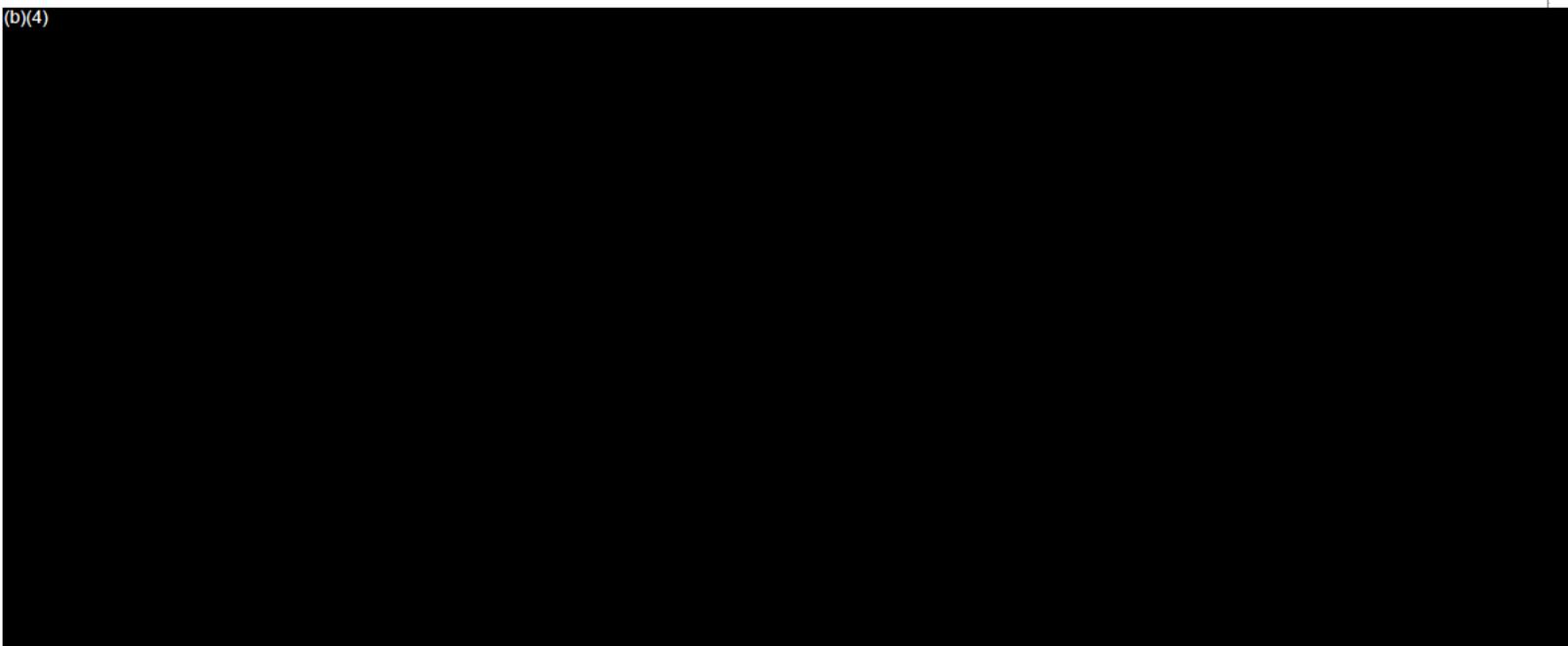
046

ECG Tracing #3  
RECORDER: 14002

CALIPER STRIPS

Mar 7, 1995  
Page: 1

(b)(4)



\*\*\* Calibration: 25 mm = 1 sec, 10 mm = 1 mV (all channels)

047

ECG Tracing #4  
RECORDER: 14005

CALIPER STRIPS

Feb 14, 1995  
Page: 1



\*\*\* Calibration: 25 mm = 1 sec, 10 mm = 1 mV (all channels)

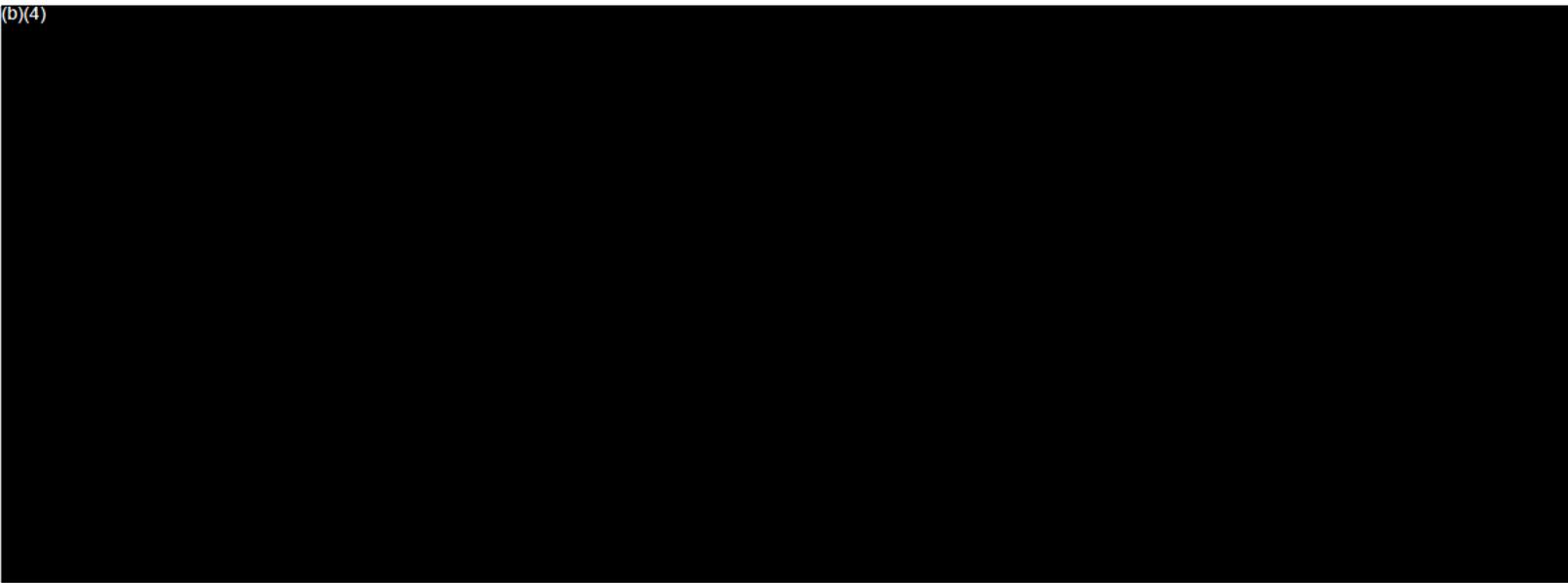
048

ECG Tracing #5  
RECORDER: 14002

CALIPER STRIPS

Mar 8, 1995  
Page: 1

(b)(4)



\*\*\* Calibration: 25 mm = 1 sec, 10 mm = 1 mV (all channels)

049

ECG Tracing #6  
RECORDER: 14002

CALIPER STRIPS

Feb 14, 1995  
Page: 1

(b)(4)



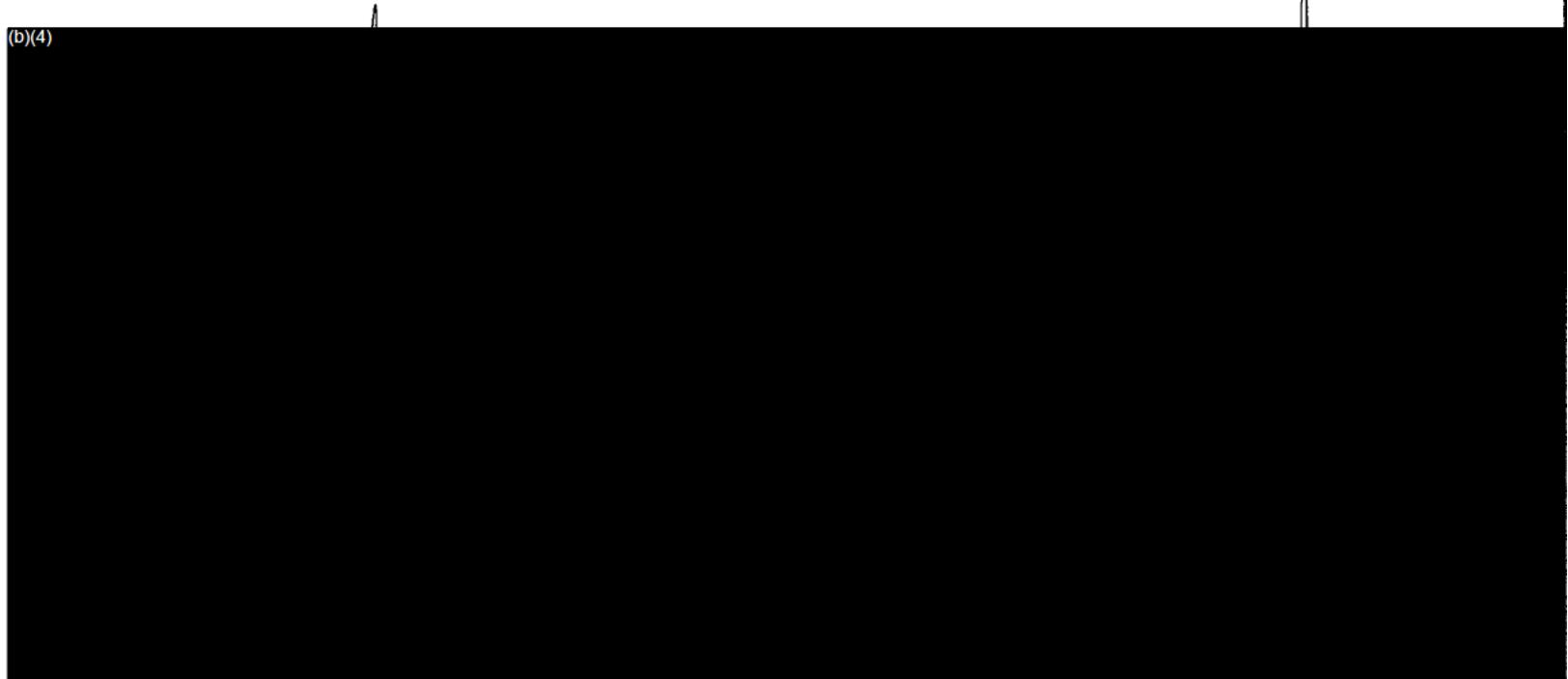
\*\*\* Calibration: 25 mm = 1 sec, 10 mm = 1 mV (all channels)

050

ECG Tracing #7  
RECORDER: 14005

CALIPER STRIPS

Mar 7, 1995  
Page: 1



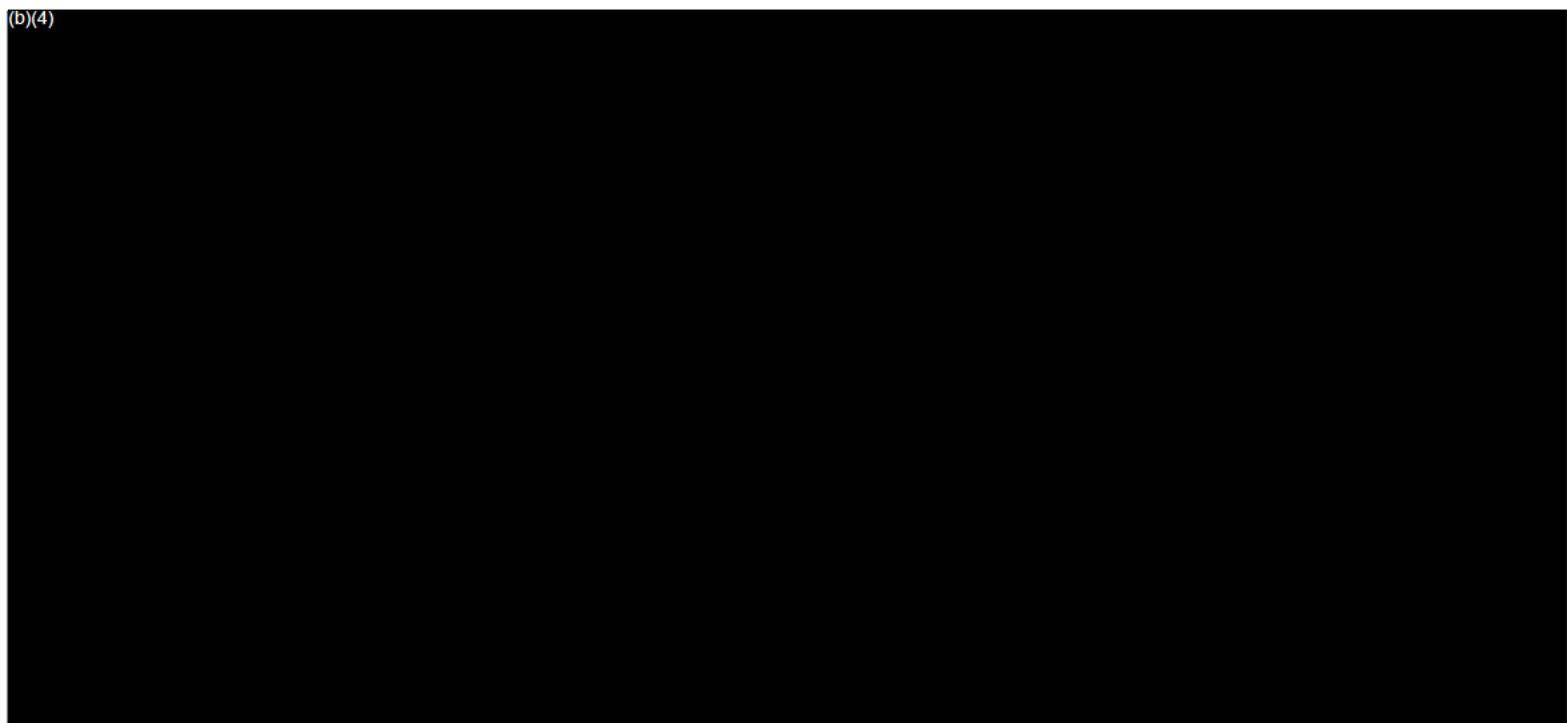
\*\*\* Calibration: 25 mm = 1 sec, 10 mm = 1 mV (all channels)

051

ECG Tracing #8  
RECORDER: 14005

CALIPER STRIPS

Apr 3, 1995  
Page: 1



\*\*\* Calibration: 25 mm = 1 sec, 10 mm = 1 mV (all channels)

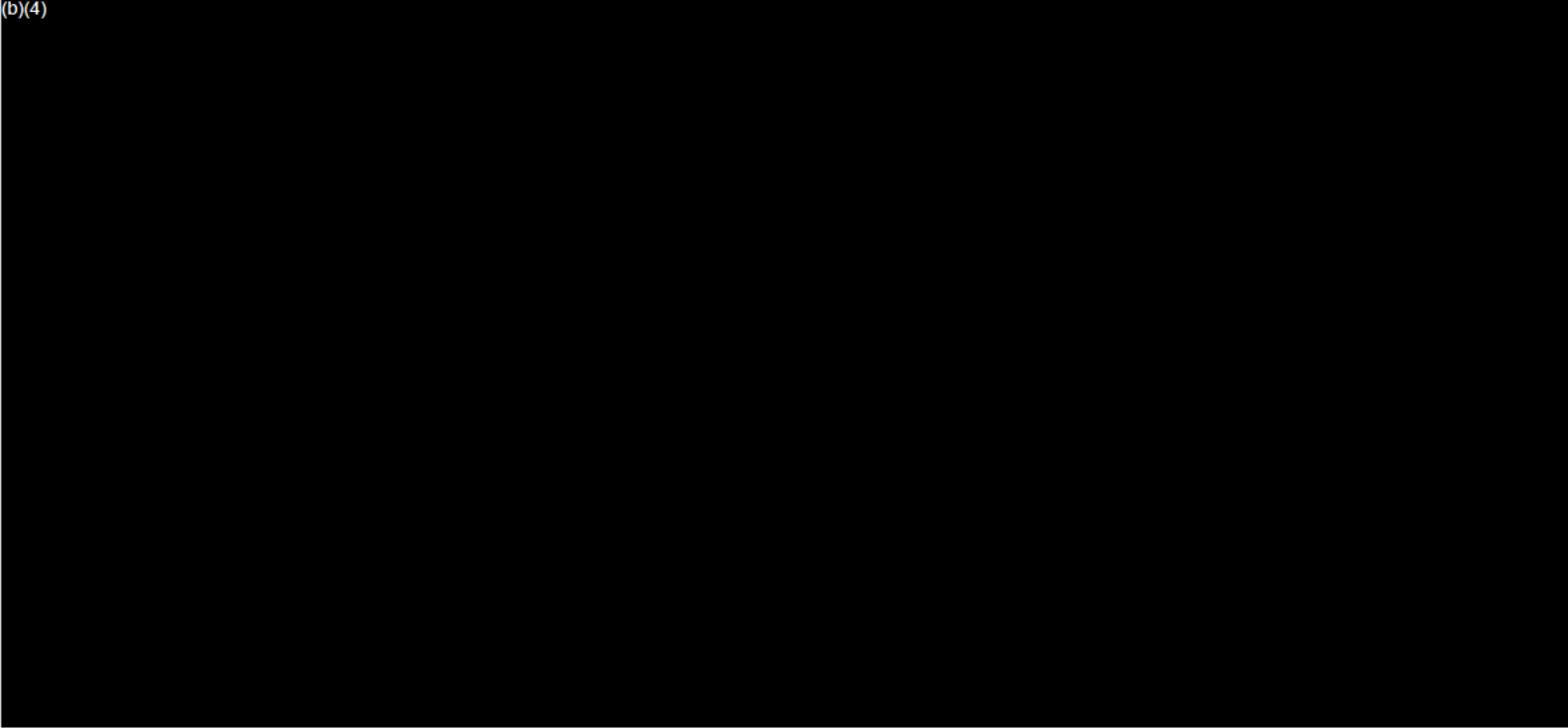
052

ECG Tracing #9  
RECORDER: 14005

**CALIPER STRIPS**

Mar 9, 1995  
Page: 1

(b)(4)



\*\*\* Calibration: 25 mm = 1 sec, 10 mm = 1 mV (all channels)

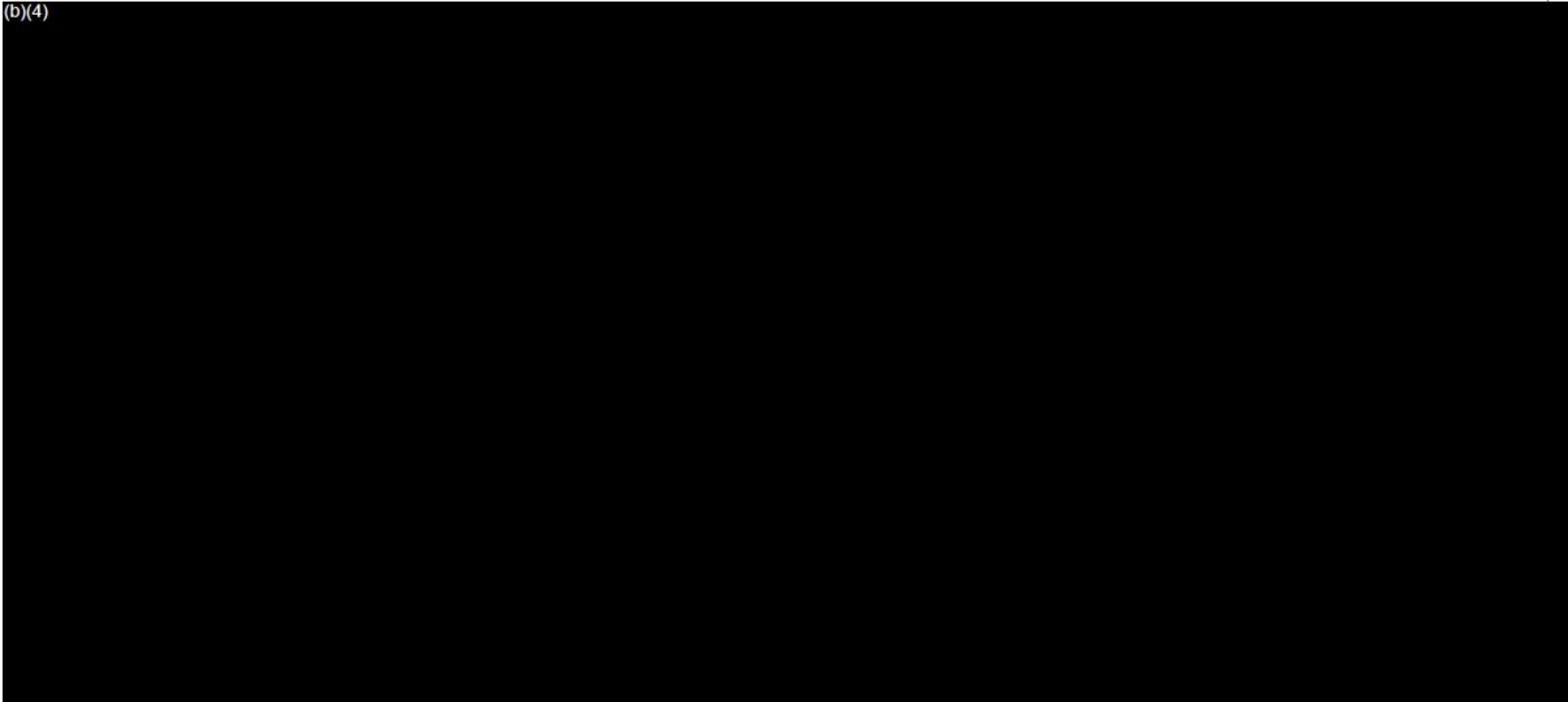
**053**

ECG Tracing #10  
RECORDER: 14002

CALIPER STRIPS

Feb 10, 1995  
Page: 1

(b)(4)



\*\*\* Calibration: 25 mm = 1 sec, 10 mm = 1 mV (all channels)

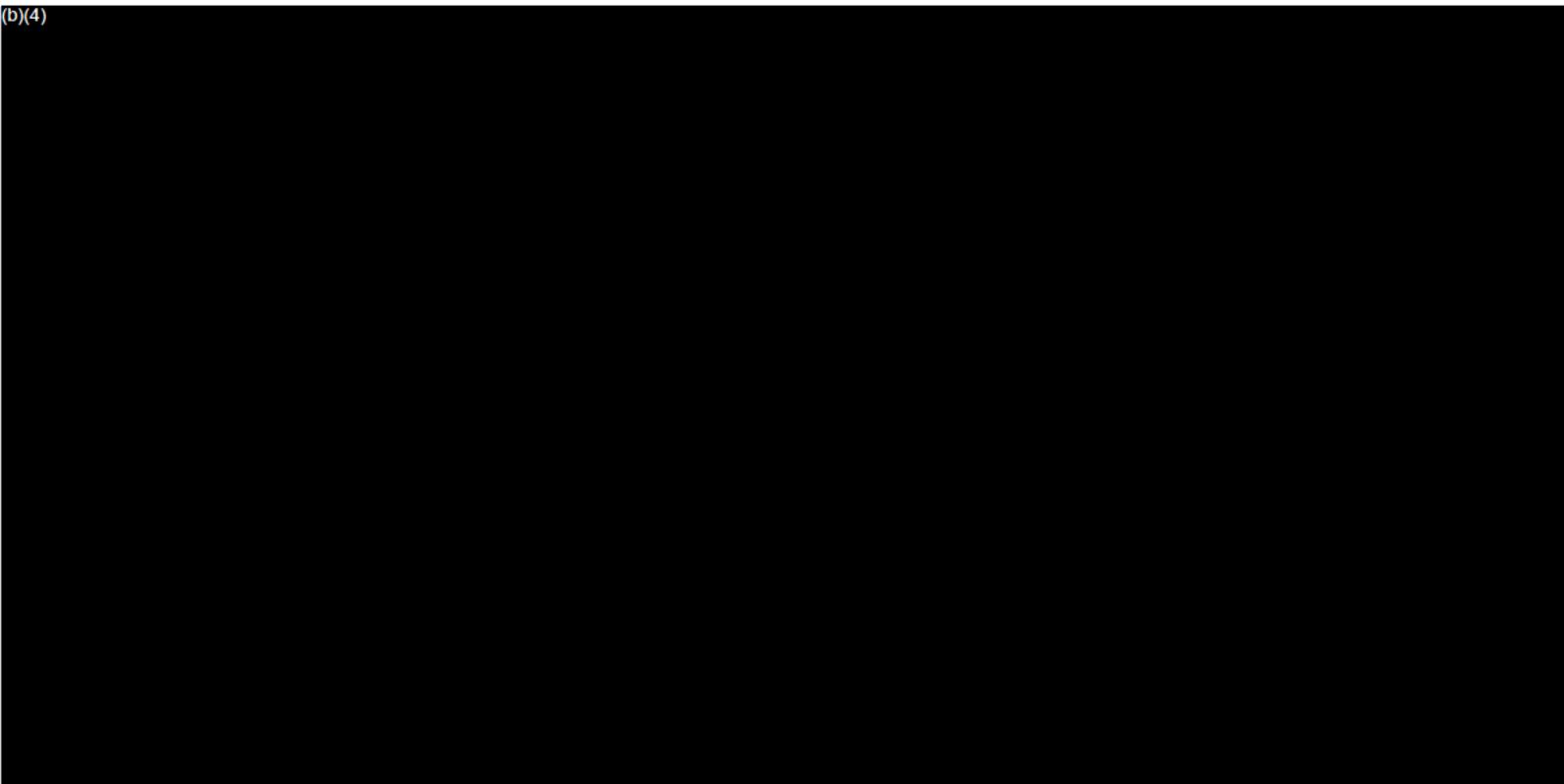
054

ECG Tracing #11  
RECORDER: 14002

CALIPER STRIPS

Mar 7, 1995  
Page: 1

(b)(4)



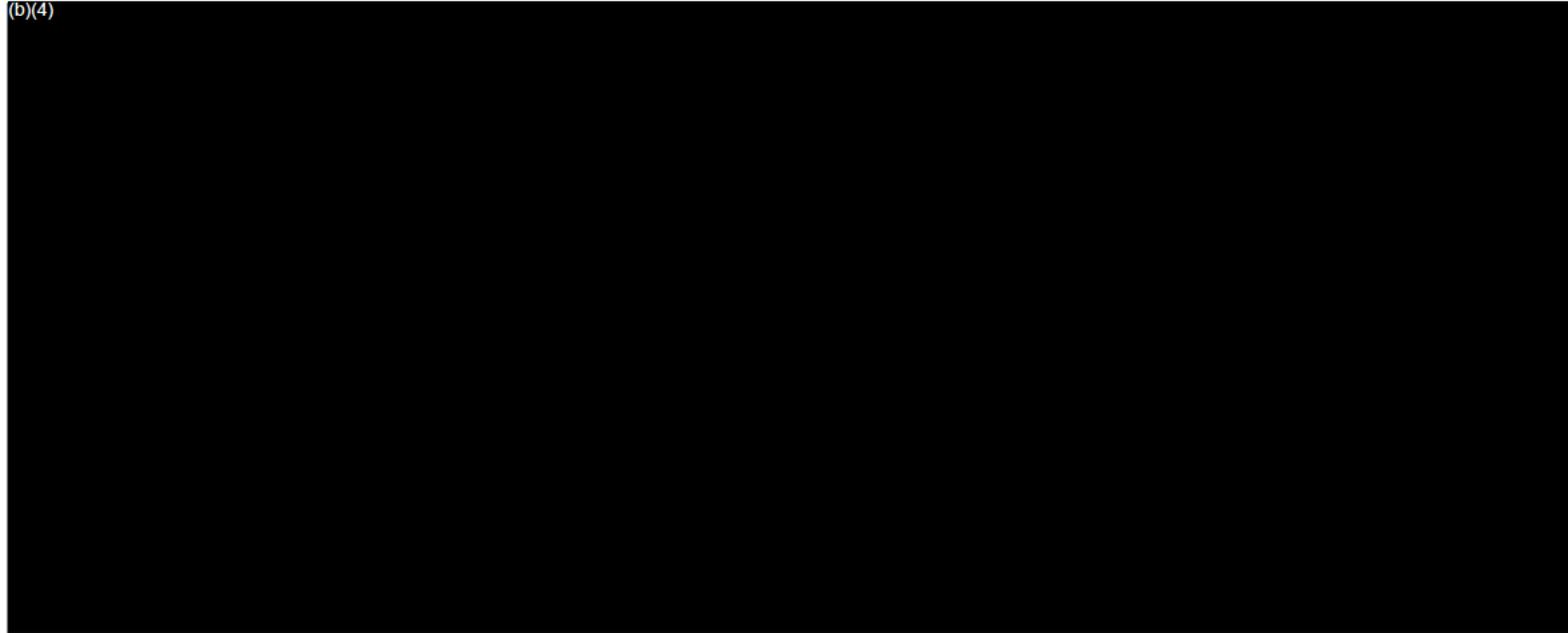
\*\*\* Calibration: 25 mm = 1 sec, 10 mm = 1 mV (all channels)

055

ECG Tracing #12  
RECORDER: 14002

CALIPER STRIPS

Mar 7, 1995  
Page: 1



\*\*\* Calibration: 25 mm = 1 sec, 10 mm = 1 mV (all channels)

056

3. **FDA question number 3.**

**We have indicated that the increase in memory size, from 6-8MBytes to 16-32 MBytes, is needed to allow the device to store higher resolution ECG data. Please describe the implementation procedures for this increase. Is there any change in the signal compression scheme? What is the intended use of the memory increase when the predicate can already store 24 hours of ECG records?**

**The memory increase has been performed because of market and customer requests. Demands for higher resolution of ECG signals permits Biosensor's digital systems a resolution equivalent to the 125 - 128 sample per second advertised by most tape processing manufacturers. 125 sample per second resolution is sometimes requested by customers due to competitive pressure. The increase in memory will remove any relative disadvantage perceived by some centers between digital storage and tape ECG data storage. A description for the increase in memory is as follows:**

**The proposed device uses a data compression scheme that uses similar methods as found in the predicate. The modifications actually simplify calculations, but requires more memory storage.**

**Biosensor samples EKG data at 250 samples per second for automated data analysis purposes. The proposed Biosensor recorder initially reduces the data 2:1 from the 250 samples per second of raw data using the Turning Point Method with extremes retained. This gives improved ECG fidelity over randomly sampled 125 Hz signals. All storage of the 125 Hz signal is lossless. The first difference of the 125 Hz 8 bit data is then stored using a Huffman encoding method. The predicate (K922027) device uses the same compression scheme except it initially reduces the data 4:1 from the 250 sample per second raw data and retains only the top 6 bits of the samples before first difference and Huffman encoding.**

**Biosensor has reviewed 200 patient data sets simultaneously input into the proposed and predicate device (K922027) using a Y-cable test fixture to verify that the memory increase is functioning as expected per the design. Sample strips are attached.**

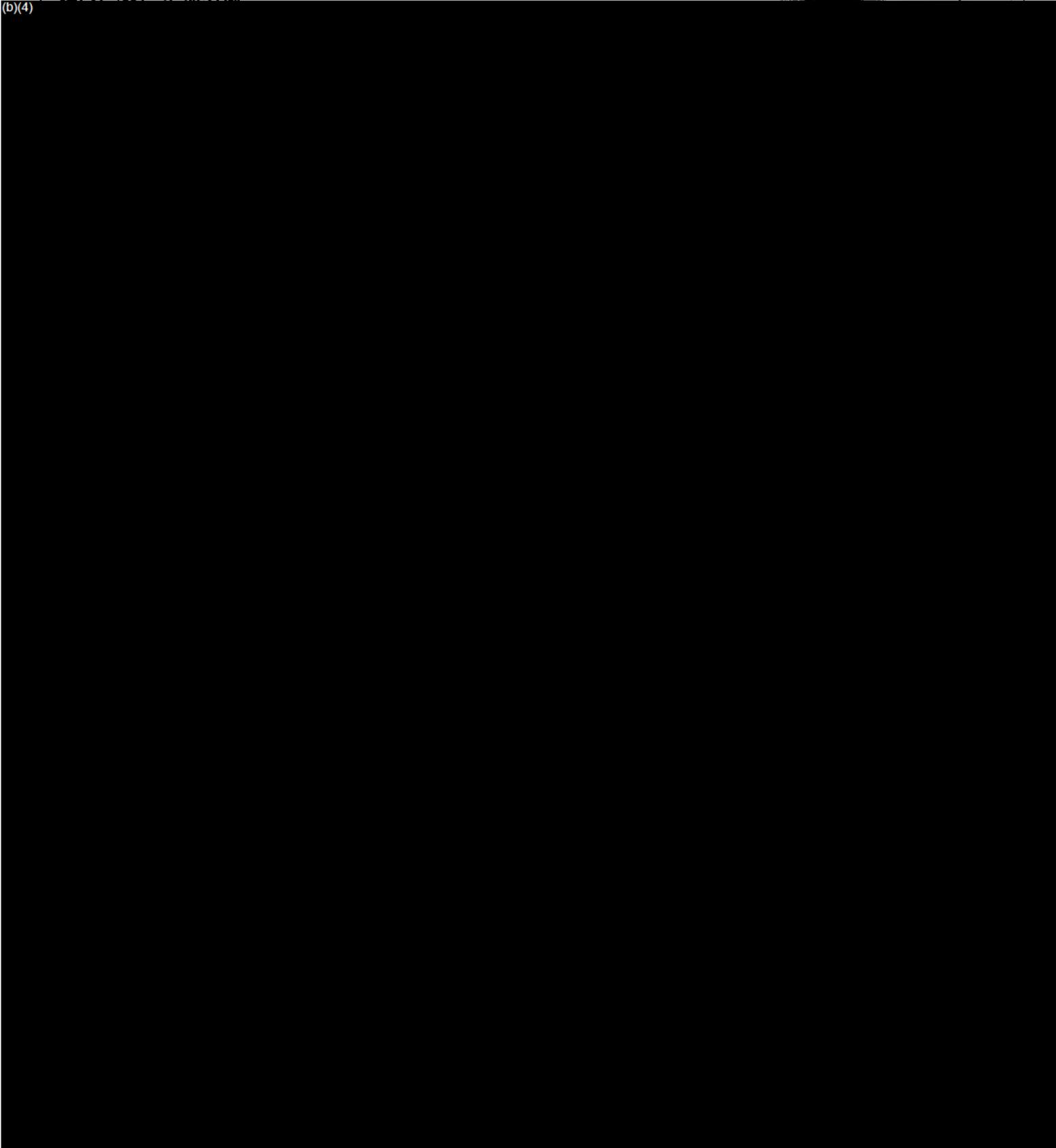
**Note: Biosensor wishes to make a minor correction to the initial file. The lower memory limit can be 8MBytes and not 16MBytes as previously reported. Biosensor considers this change insignificant and is only noted here as a technicality. The lower memory limit was incorrectly reported previously.**

108  
RECORDER: 14013

CALIPER STRIPS

Sep 27, 1995  
Page: 1

(b)(4) / Sep 27 1995 12:00:22am



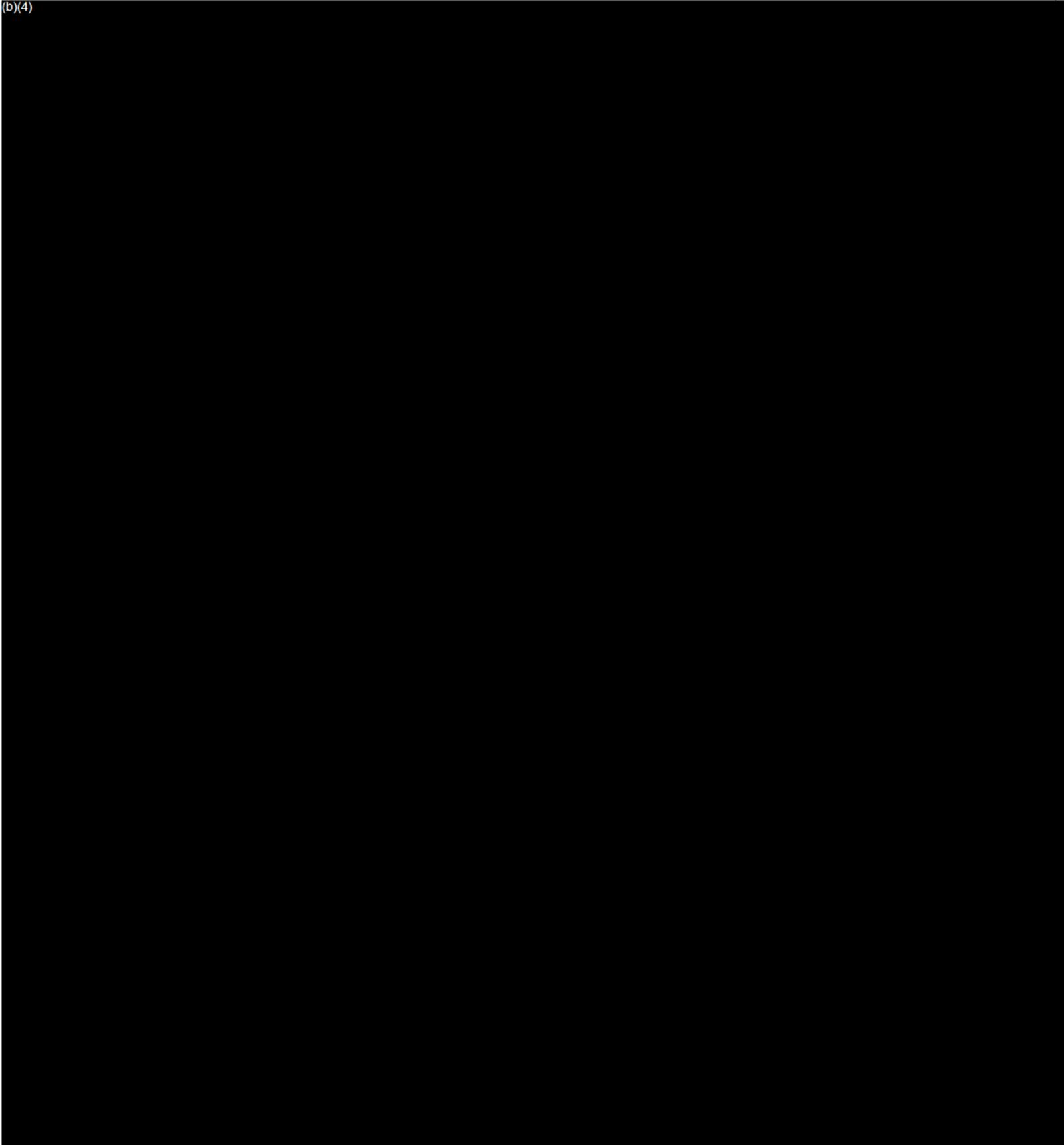
\*\*\* Calibration: 25 mm = 1 sec, 10 mm = 1 mV (all channels)

058

108  
RECORDER: 65535

CALIPER STRIPS

(b)(4)



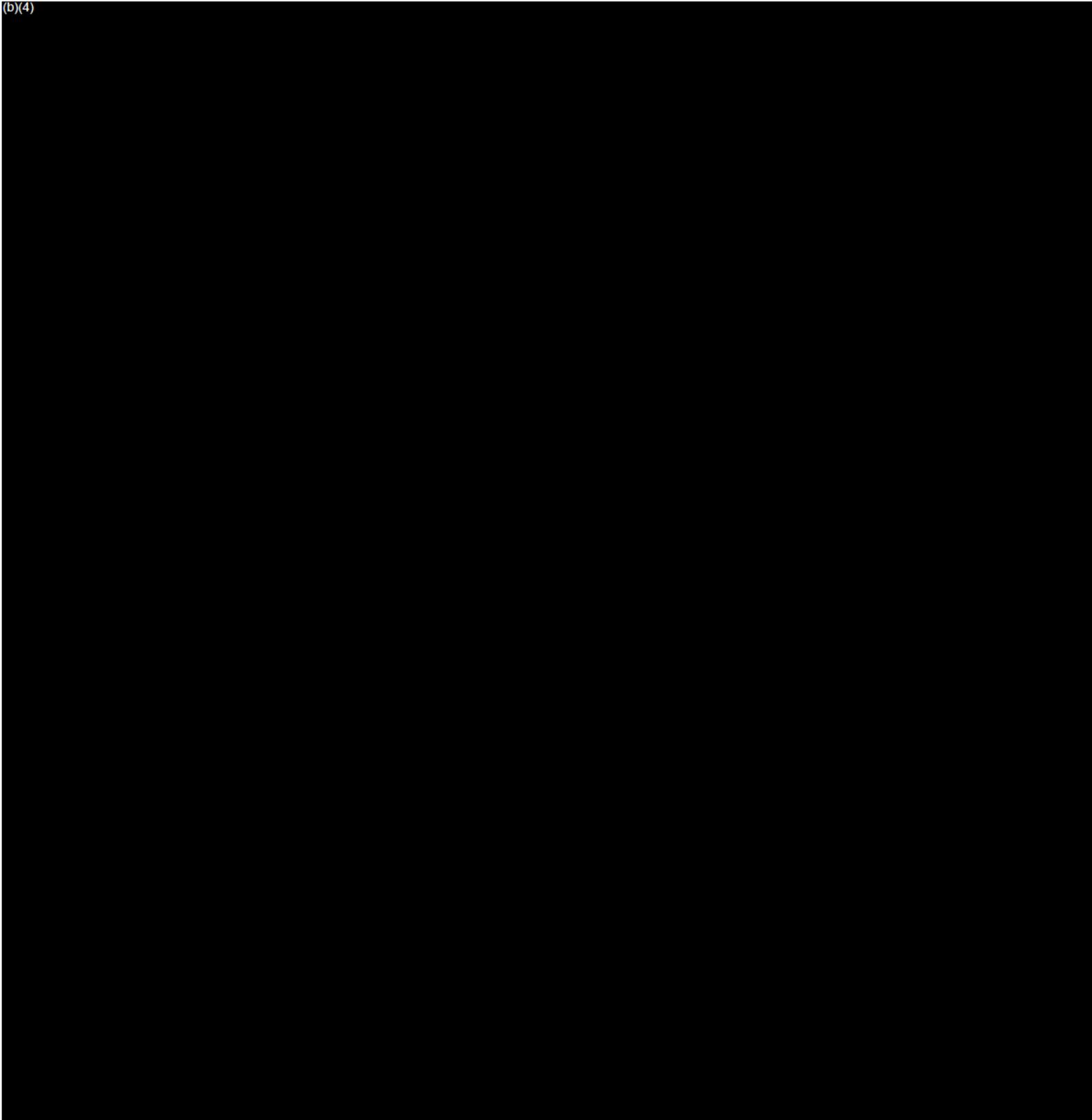
\*\*\* Calibration: 25 mm = 1 sec, 10 mm = 1 mV (all channels)

6007  
RECORDER: 14013

CALIPER STRIPS

Sep 27, 1995  
Page: 1

(b)(4)



\*\*\* Calibration: 25 mm = 1 sec, 10 mm = 1 mV (all channels)

060

6007

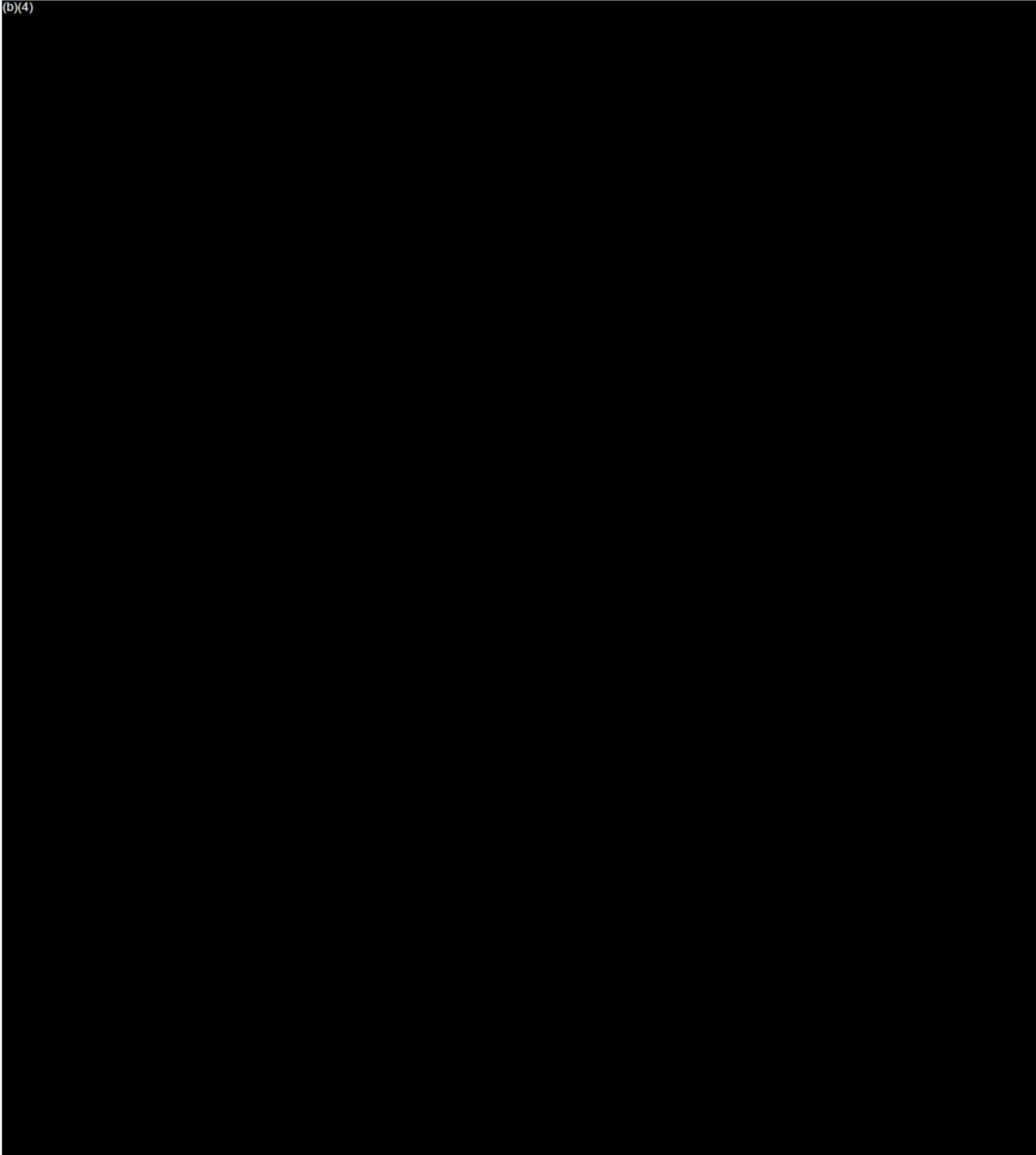
RECORDER: 65535

CALIPER STRIPS

Sep 27, 1995

Page: 1

(b)(4)



\*\*\* Calibration: 25 mm = 1 sec, 10 mm = 1 mV (all channels)

061

4. **FDA question number 4.**  
**Please provide test report(s) to verify that the memory increase is implemented correctly, and that ECG resolution has been improved.**

**In addition to the 200 test reports collected and compared as reported in question 3, Biosensor performed the following tests. Biosensor has simultaneously input a sine wave signal into the proposed device and the predicate device (K922027) using a Y-cable test fixture. The sine wave input was varied from 5 Hz to 40 Hz. A cycle frequency below 5 Hz was not input. Below 5 Hz differences in the resolution of signals by either system are unrecognizable. Data demonstrates improved signal resolution in the 5 - 40 Hz ECG range, and proper storage and reporting of the test waveforms.**

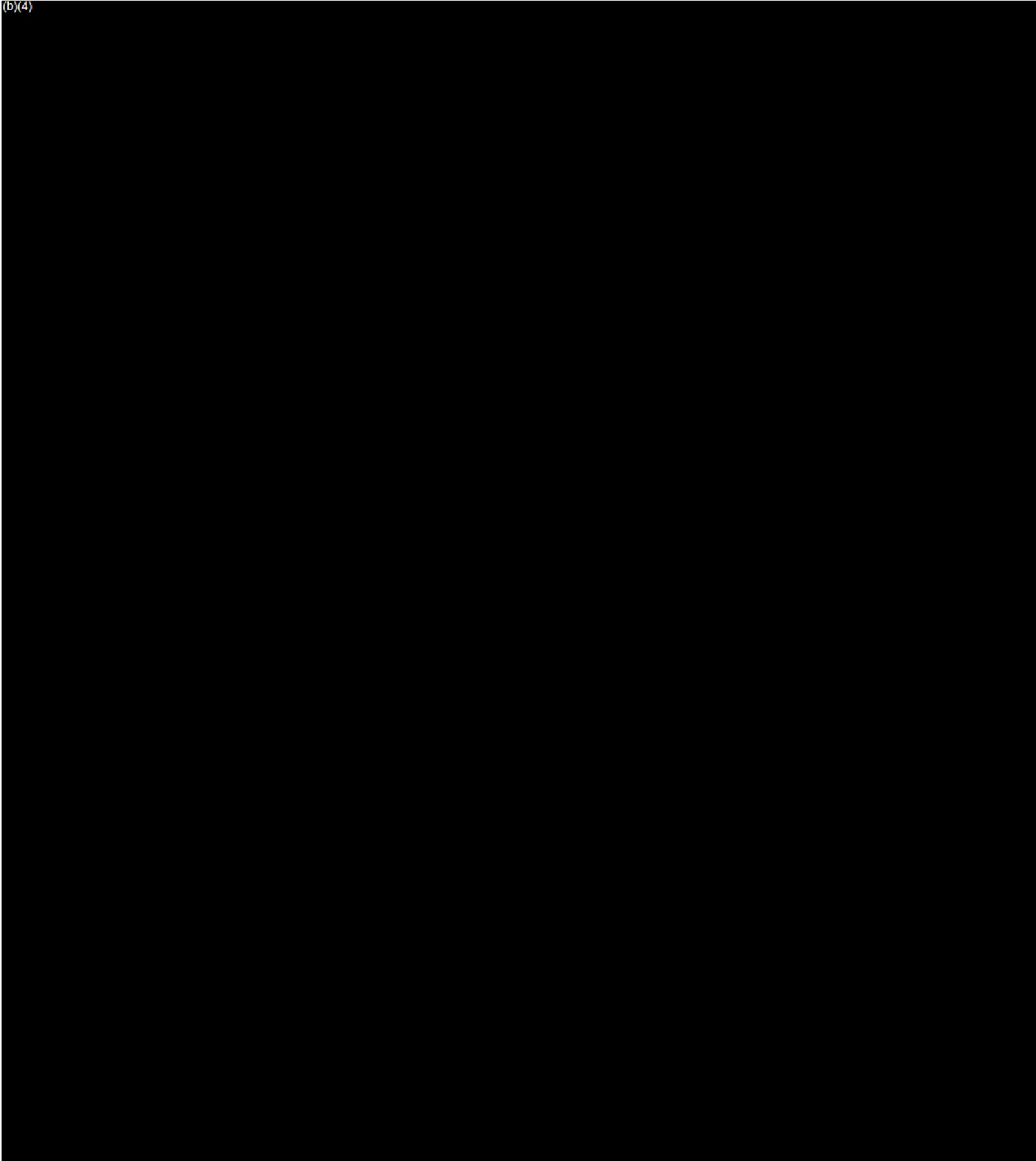
PROPOSED DEVICE

**Resolution Test**  
**RECORDER: 14013**

**ECG STRIPS**

**Oct 23, 1995**  
**Page: 1**

(b)(4)



\*\*\* Calibration: 25 mm = 1 sec, 10 mm = 1 mV (all channels)

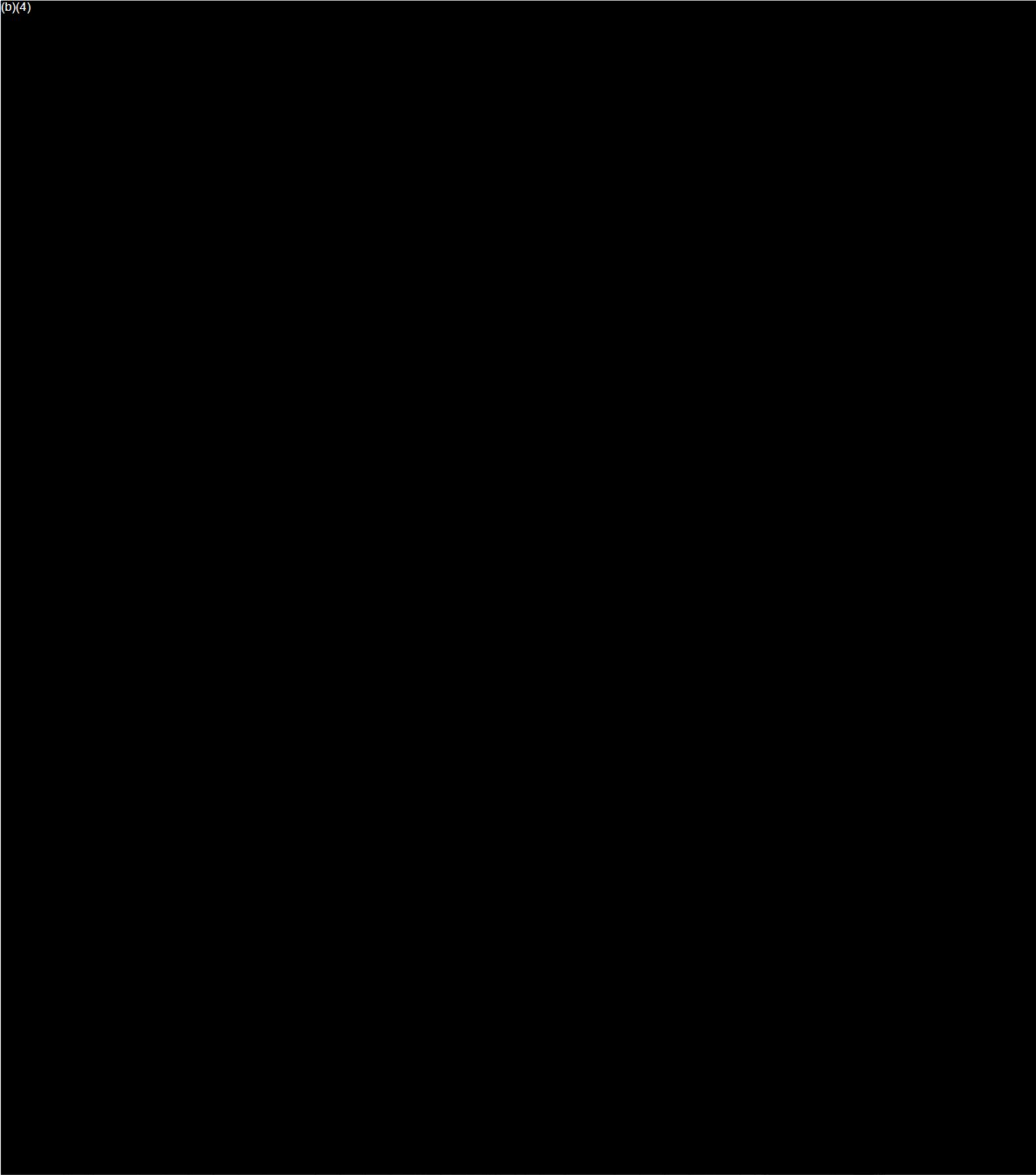
063

**Resolution Test**  
**RECORDER: 14013**

**ECG STRIPS**

**Oct 23, 1995**  
**Page: 2**

(b)(4)



\*\*\* Calibration: 25 mm = 1 sec, 10 mm = 1 mV (all channels)

Questions? Contact FDA/CDRH/OCE/DID at [CDRH-FOISTATUS@fda.hhs.gov](mailto:CDRH-FOISTATUS@fda.hhs.gov) or 301-796-8118

**064**

**Resolution Test**

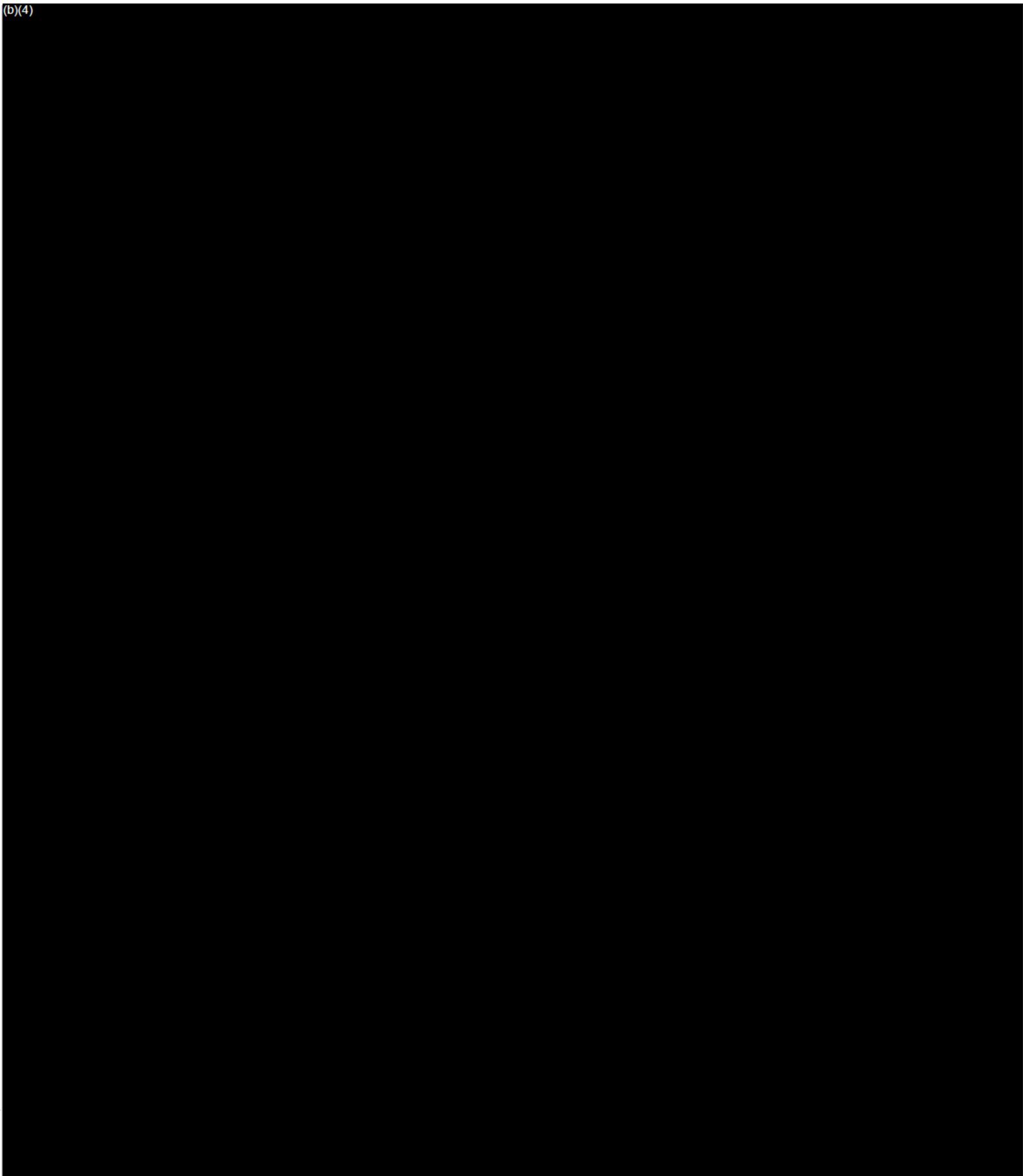
**RECORDER: 10212**

**ECG STRIPS**

**Oct 23, 1995**

**Page: 1**

(b)(4)



\*\*\* Calibration: 25 mm = 1 sec, 10 mm = 1 mV (all channels)

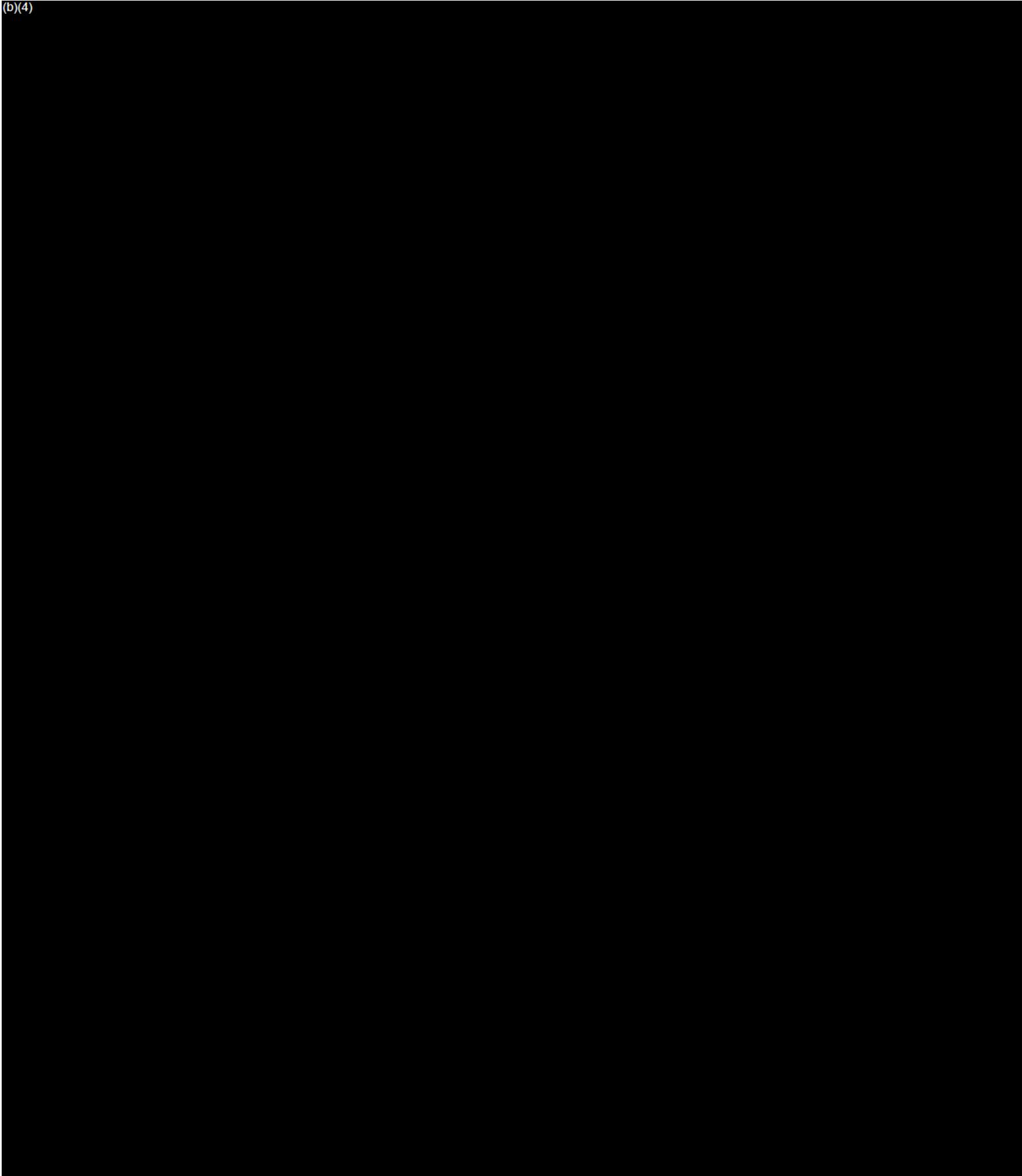
065

**Resolution Test**  
**RECORDER: 10212**

**ECG STRIPS**

**Oct 23, 1995**  
**Page: 2**

(b)(4)



\*\*\* Calibration: 25 mm = 1 sec, 10 mm = 1 mV (all channels)

**066**

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

5. **FDA question number 5.**

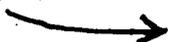
**Your device can detect arrhythmia's while the patient is still connected to the patient recorder, and the patient recorder connected to the personal computer. Hence, there is a chance that risk current can flow from the PC through the patient recorder.**

**It is NOT possible to connect the Holter device to a patient and the PC at the same time. The proposed device and the predicate device (K922027) uses the SAME mechanical defeat design which does not allow for the connections you have assumed. The patient is 'OFF LINE' during data transfer from the device to a PC. Real time data acquisition and real time data display are not possible with this system. The PC in principle is a host computer that allows for graphical display and printing of previously analyzed recorder data.**

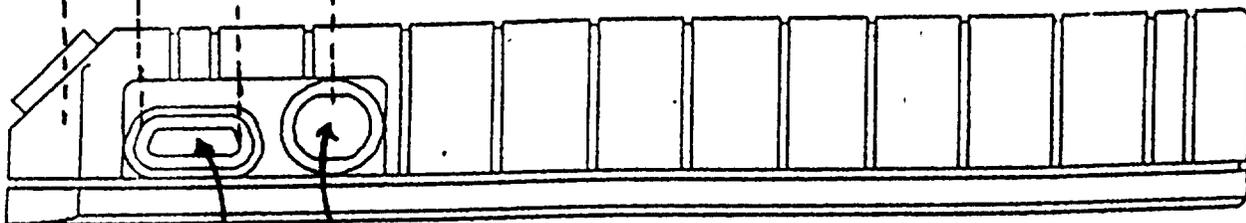
**A diagram of the mechanical interlock is attached.**

Communication cable from PC covers patient cable connection port

Top View of  
Communication  
Cable (PC)



Side View of  
Holter



Communication Port (PC)

Patient Cable Connection Port

**6. FDA question number 6.**

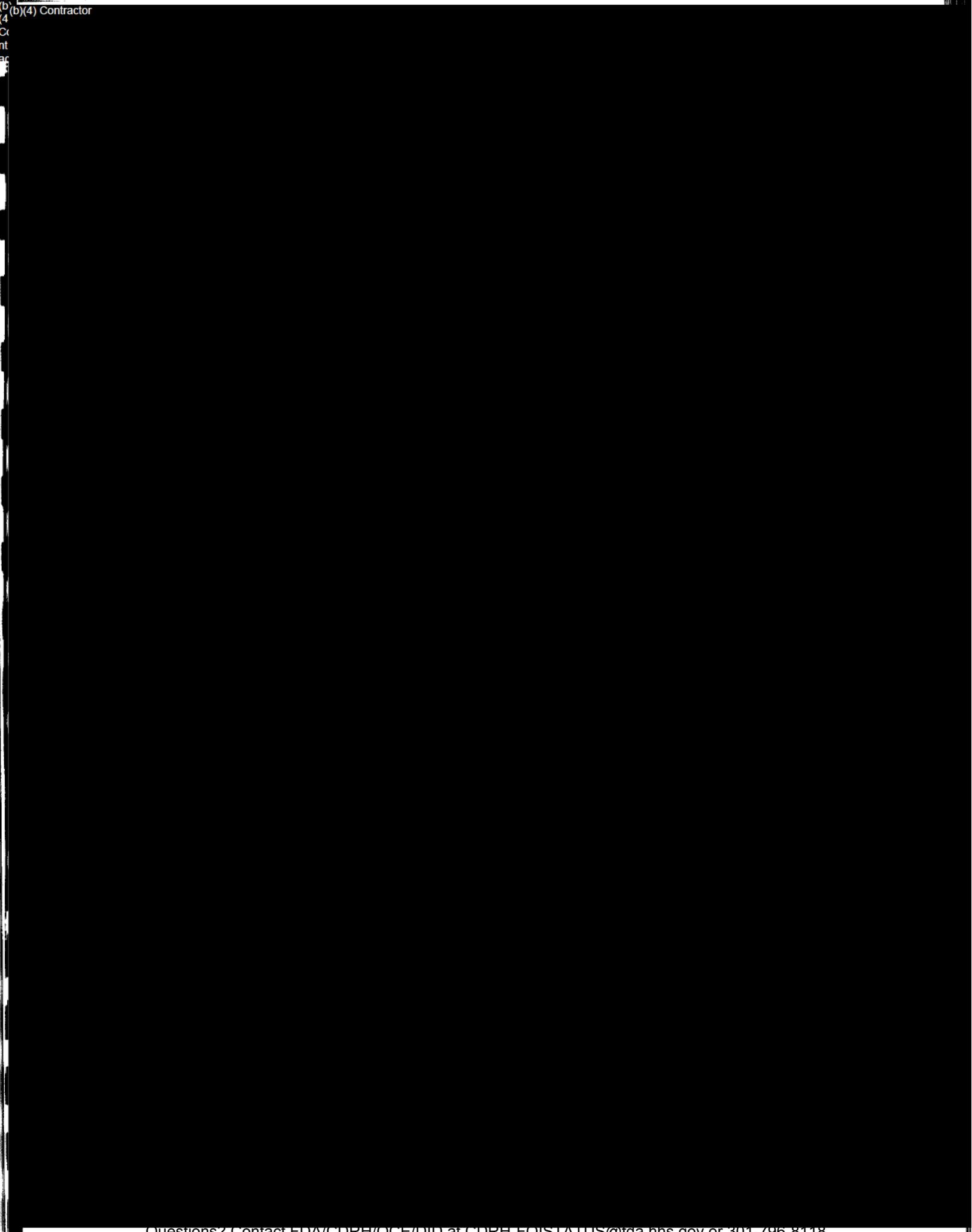
**Your device includes battery powered as well as AC powered components -- PC used to analyze the Holter recorder. Hence, please provide a valid reason why electromagnetic compatibility/interference (EMC/EMI) testing is not needed. Otherwise, EMC/EMI testing is needed.**

**As explained in question 5 above the PC is used with the patient 'OFF-LINE' from the recorder. Direct connection is not possible with the recorder. On August 29th we spoke to the reviewer, Dr. S. C. Ho to clarify our understanding of this question and EMC/EMI testing issues. During that conversation Biosensor was instructed to provide data for AAMI section 3.2.10.2.1, Immunity to Electromagnetic Fields in response to this question. Due to the complete physical isolation of the PC when used with this system, and given that the actual device runs on battery power, Biosensor was instructed that this EMC/EMI test was the only requirement needing fulfillment.**

**On September 29, 1995 Biosensor contracted with Inchcape Testing Services to perform the requested EMC/EMI test. The device was subjected to the electromagnetic fields as outlined in the AAMI specification. The certification and a brief explanation of the tests performed are included on the following pages.**



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**7. FDA question number 7.**

**We have the following questions concerning the submitted user manual:**

**7a. The labeling should include specifications on the incoming pacemaker stimuli such as duration, pulse width, pulse height, etc.**

**7b. The labeling should indicate that the device only records the time of occurrence of the stimulus. Hence, information on other characteristics, such as pulse width and pulse height, is not available to the user.**

**7c. Please provide a prescription labeling in your manual, as requested by 21 CFR 801.109.**

**7d. Please provide the label change to indicate non-compliance with defibrillation shock requirements, as indicated in the section labeled AAMI in the initial submittal.**

**The following user manual modifications are submitted to satisfy this request. All Requested changes 7a-7d have been made in the user manual to help clarify these issues. The associated pages are included here to help facilitate your review. Biosensor is enclosing the pages associated with your requests below. Inclusion of the entire help manual copy would add redundancy to this filing. The location in which items 7a-7d are handled are marked in the margin with the corresponding alphanumeric identifier.**

7a Pacemaker Analysis Parameters

This popup displays the current state of the pacemaker analysis options. The options include:

(NO PACEMAKER)

Select this to disable pacemaker analysis.

(PACEMAKER)

Select this to enable pacemaker analysis (see notes below).

(AV INTERVAL)

Edit the interval field to program the recorder to be aware of the expected AV delay between dual chambered pacemaker pulses. The default interval is 200 msec.

It is highly recommended that you program the recorder with these parameters during a baseline (see Setup Patient Recorder). Attempting to enable pacemaker analysis after the procedure has finished will not work (the opportunity to detect the high-frequency pulses has already passed).

Pacemaker Specifications

7b The pacemaker detection circuit in the Biosensor Holter recorder is separate from the ECG channels and is designed to trigger on pacemaker stimulus signals with a spectral component between 1 and 8 KHz, the range of pacemaker signals.

The pacemaker signal detector requires a minimum pulse amplitude of 1.5mV at the skin. Pulsewidths above 0.10 msec are detectable by the system. A minimum interval of 12 milliseconds between pulses is also enforced by the recorder. When the pacemaker detection circuit is triggered, the recorder annotates the time of the pulse: no other information is kept regarding the pulse. High-frequency signals can be filtered out of the 250 sample per second ECG signal, but are not processed by ECG analysis. Higher amplitude pacemaker pulses are often present on the stored ECG signal. Some filtered pacemaker stimulus residue can be seen after filtering due to ringing. Please keep in mind the filtered pulse residues are not stored at their original high frequency content. Later, the PC program simulates the high-frequency pacemaker pulses in the ECG display with CYAN or MAGENTA spikes. During the analysis stage, the pulse times are correlated to beat times and are appropriately labeled (according to user-specified interval). These simulated pace pulses are between +/- 4 msec on the printed ECG strip of the original pace stimulus occurrence.

The Biosensor Holter system is capable of both single chambered and dual chambered pacemaker detection and re-  
porting. The system detects pacemaker stimuli in a separate channel specifically designed to detect and locate the pacemaker, whether unipolar, bipolar, atrial pacing or ventricular pacing. In the event two stimuli are in the programmable range of a resultant paced QRS. (preset at 200 msec), dual chambered A-V pacing is called. Therefore, the system is able to distinguish between single chambered and dual chambered pacing by the number of pacemaker stimuli that proceed the resultant paced QRS.

7c- CAUTION: Federal Law restricts this device to sale by or on the order of a physician.

7d CAUTION: This device has not been tested for compliance with AAMI specifications regarding defibrillation equipment. Use of defibrillators may result in damage to this device.

**8. FDA question number 8.**

**What is the version number of the software used in the device?**

The version number of the firmware used in the device is : Rev A Version 9509.19.

**9. FDA question number 9.**

**Explain the reasons for the low Ventricular Sensitivity results for the MIT 107 tape in the section entitled AAMI.**

MIT 107 is a 30 minute database tape containing only two types of beat classifications, (2078 paced beats and 59 ventricular beats). In addition, the 59 ventricular beats are comprised of 2 varying morphological shapes. No other beat types are present in this tape. The absence of a normal beat morphology can have an adverse effect on the Biosensor adaptive dynamic learning strategy. The short 30 minute tape length prevents the algorithm from having a reasonable chance of learning which morphology is the normal beat. The system attempts to identify a normal morphology but finds one of the different ventricular morphologies and labels it as normal.

**10. FDA question number 10.**

**What is the intended use for the device's feature of HRV analysis in the time domain? List all the specific claims made for the feature of HRV.**

Heart rate variability (HRV) analysis in the time domain is intended for quantification and graphic displays of heart rate changes over a specific monitoring period, and is to be used as an adjunct to other clinical diagnostic techniques.

Heart rate variability may be clinically useful in evaluating cardiovascular responsiveness to alterations in autonomic tone.<sup>1</sup>

Heart rate variability may offer information about sympathetic and parasympathetic autonomic function and could serve as a measure of risk stratification for serious cardiac arrhythmia's and possible sudden cardiac death.<sup>2</sup>

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<sup>1</sup> Stephen, Pieper J, M.D., Stephen, Hammill C, M.D. Heart Rate Variability: Technique and Investigation Applications in Cardiovascular Medicine. Mayo Clin Proc 1995; 70:955-964

<sup>2</sup> American College of Cardiology Cardiovascular Technology Committee. Heart Rate Variability for Risk Stratification of Life-Threatening Arrhythmia's. JACC Vol. 22. No. 3, September 1993:948-950

**11 and 12. FDA questions number 11 and 12.**

**Please provide a copy of the devices revised labeling and describe how the HRV information is collected from the incoming ECG signal in the users manual.**

**These two questions have been grouped together since they are so closely related. Biosensor does not make any other specific claims for HRV than the one outlined in number 10 above. Revised labeling and a description of the HRV feature has been added to the user manual. The following user manual modifications are submitted to satisfy these requests. All Requested changes 10-11 have been made in the user manual to help clarify these issues. The associated pages are included here to help facilitate your review. Inclusion of the entire help manual copy would add redundancy to this filing.**

7

**Warnings**

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

- **CAUTION:** This device has not been tested for compliance with AAMI specifications regarding defibrillation equipment. Use of defibrillators may result in damage to this device.

- **CAUTION:** The use of Heart rate variability (HRV) analysis for the diagnosis or prognosis of a particular disease or condition has not been established, and is therefore considered investigational.

**Statement of Intended Use**

The Full Disclosure Monitoring System is intended for patients requiring ambulatory (Holter) monitoring from 1 to 24 hours. Such monitoring is most frequently used in the indications listed below:

**Current Uses of Ambulatory ECG Recording \***

(\*) Portions from Ambulatory Electrocardiographic Recording. Wenger NK, Mook MB, and Reingquist J, Year Book Medical Publishers, Copyright 1981.

8

1.0) Evaluation of symptoms suggesting arrhythmia or myocardial ischemia.

1.1) Evaluation of ECG documenting therapeutic interventions in individual patients or groups of patients.

1.2) Evaluation of patients for ~~silent~~ ~~arrhythmias~~.

1.3) Evaluation of patients with pacemakers.

1.4) Evaluation of individual patient's response upon resuming occupational or recreational activities (e.g. after M.I., cardiac surgery).

1.5) Evaluation of clinical syndromes and situations where arrhythmias may increase risk of sudden death.

1.6) Clinical and epidemiological research studies.

1.7) Heart rate variability (HRV) analysis in the time domain is intended for quantification and graphic displays of heart rate changes over a specific monitoring period, and is to used as an adjunct to other clinical diagnostic techniques.

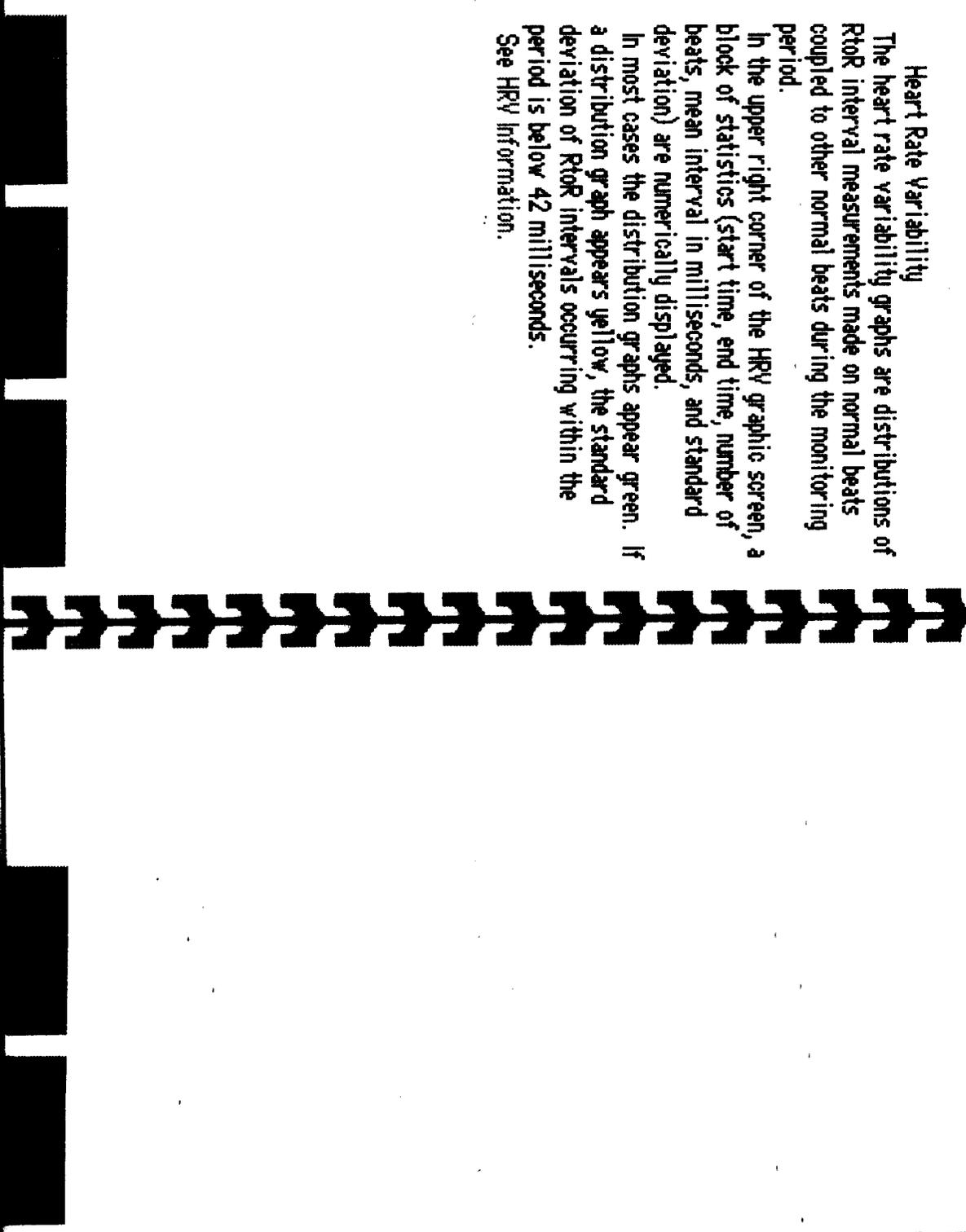
### Heart Rate Variability

The heart rate variability graphs are distributions of RtoR interval measurements made on normal beats coupled to other normal beats during the monitoring period.

In the upper right corner of the HRV graphic screen, a block of statistics (start time, end time, number of beats, mean interval in milliseconds, and standard deviation) are numerically displayed.

In most cases the distribution graphs appear green. If a distribution graph appears yellow, the standard deviation of RtoR intervals occurring within the period is below 42 milliseconds.

See HRV Information.



#### HRV Information

##### Technical Information:

The HRV graph is essentially a distribution of normal beat intervals. Given a user-selected time range, the time interval between all normal beats coupled to other normal beats are collected. Supraventricular, paced, and ventricular ectopic beats (on either side of the candidate interval) are not used in the creation of this distribution.

The distribution is presented as a series of interval frequencies. Each interval frequency represents the number of normal-to-normal intervals within ~~the~~ range.

The program displays the time range represented by the graph, the number of normal-to-normal intervals found in that time range, the average normal-to-normal interval in that time range, and the standard deviation of those intervals.

##### Precautions:

Since various neural, respiratory, and humoral influences are generally known to affect heart rate, the significance of the data must be determined by the clinician.

HRV measurements are not valid in patients with sinus node dysfunction, second or third degree

atrioventricular block, or temporary or permanent pacemakers, or who experience atrial or ventricular dysrhythmia during the analysis period.

Some HRV parameters are highly dependent on mean heart rate. Certain consideration should be given to the interpretation of results between and within specific patient populations.

HRV analysis results may differ among devices from different manufacturers since the methods, such as treatment of premature supraventricular, missed, and ventricular ectopic beats, are not standardized. Therefore, caution should be used in applying conclusions drawn from studies with other devices.

**13. FDA question number 13**

**Provide the test plan, results and discussion to validate the HRV feature in the device. Describe the procedures for ensuring that other features of the device have not been adversely affected by the addition of HRV.**

HRV is simply the standard deviation calculation of normal beat R-R intervals over a given time period. The R-R intervals for all beat classes is already stored in the devices memory. These R-R intervals have always been used to calculate such useful numbers as heart rate. The HRV calculation uses the R-R interval values of the normal to normal beat morphology to determine the statistical mean and standard deviation of those intervals. The same R-R interval storage method used in the predecessor K922027 device is used in this device.

Biosensor has input 200 data sets through two system versions, one with HRV and one without HRV and verified that the presence or absence of the mean and standard deviation calculation has not had an adverse effect on any other system features.

In addition, a time slider bar feature allows time adjustments to be performed on any portion of the stored ECG data down to a [REDACTED] interval. The following page contains an HRV graph printout for a [REDACTED] interval. The next nine pages contains the data from hand caliper measurements for the same time period. The devices HRV calculation produced a mean of 1202 msec and a standard deviation of 75 msec. Hand caliper measurements over the same time period produced a mean of 1203 msec and a standard deviation of 76.2 msec. The small difference is probably a result of human measurement variation.

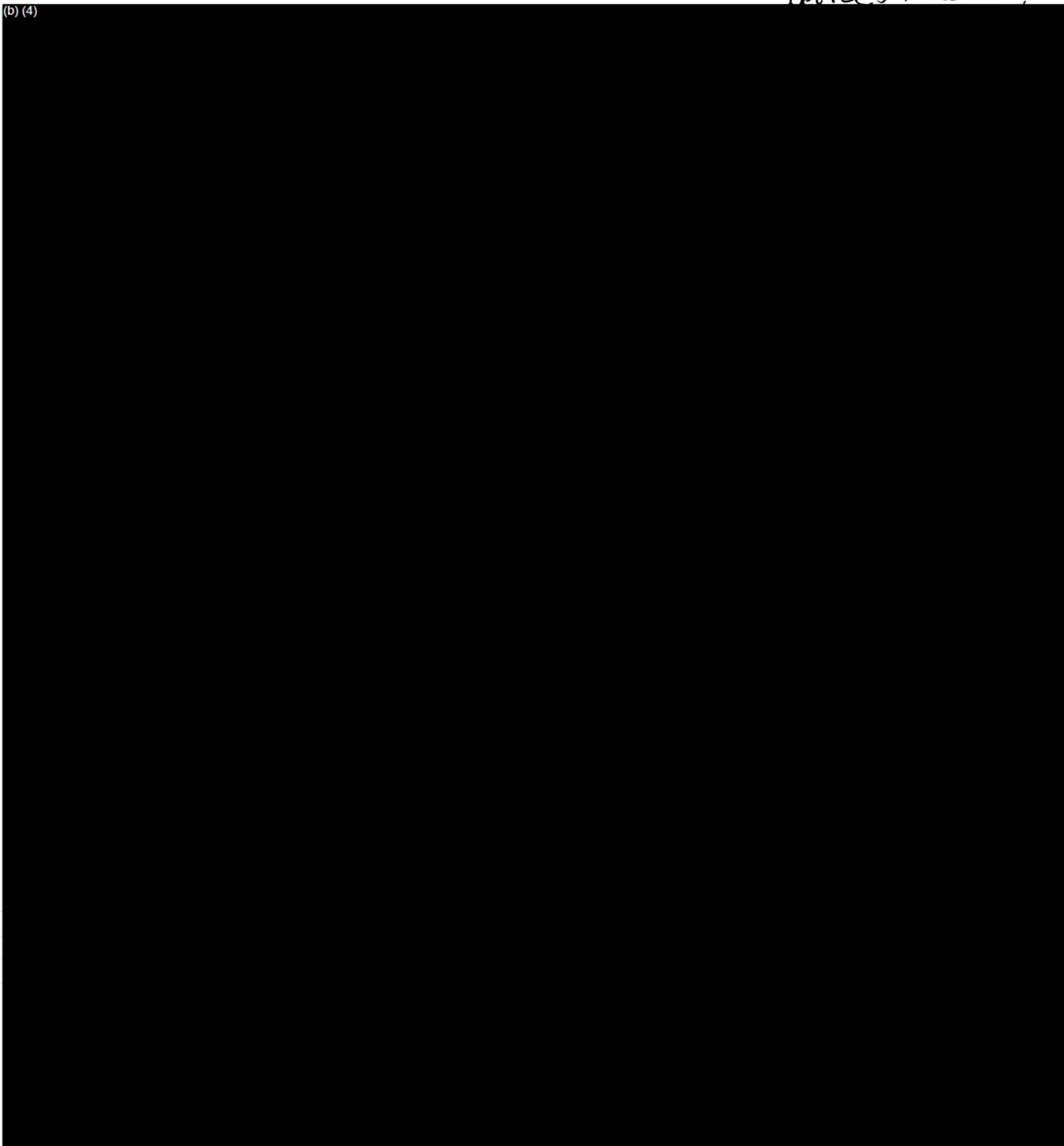
HRV TEST EXAMPLE  
RECORDER: 14071

GRAPHS

Jan 30, 1996  
Page: 1

*Device's Measurement*

(b) (4)



KEY :  0 > 42 msec  0 < 42 msec

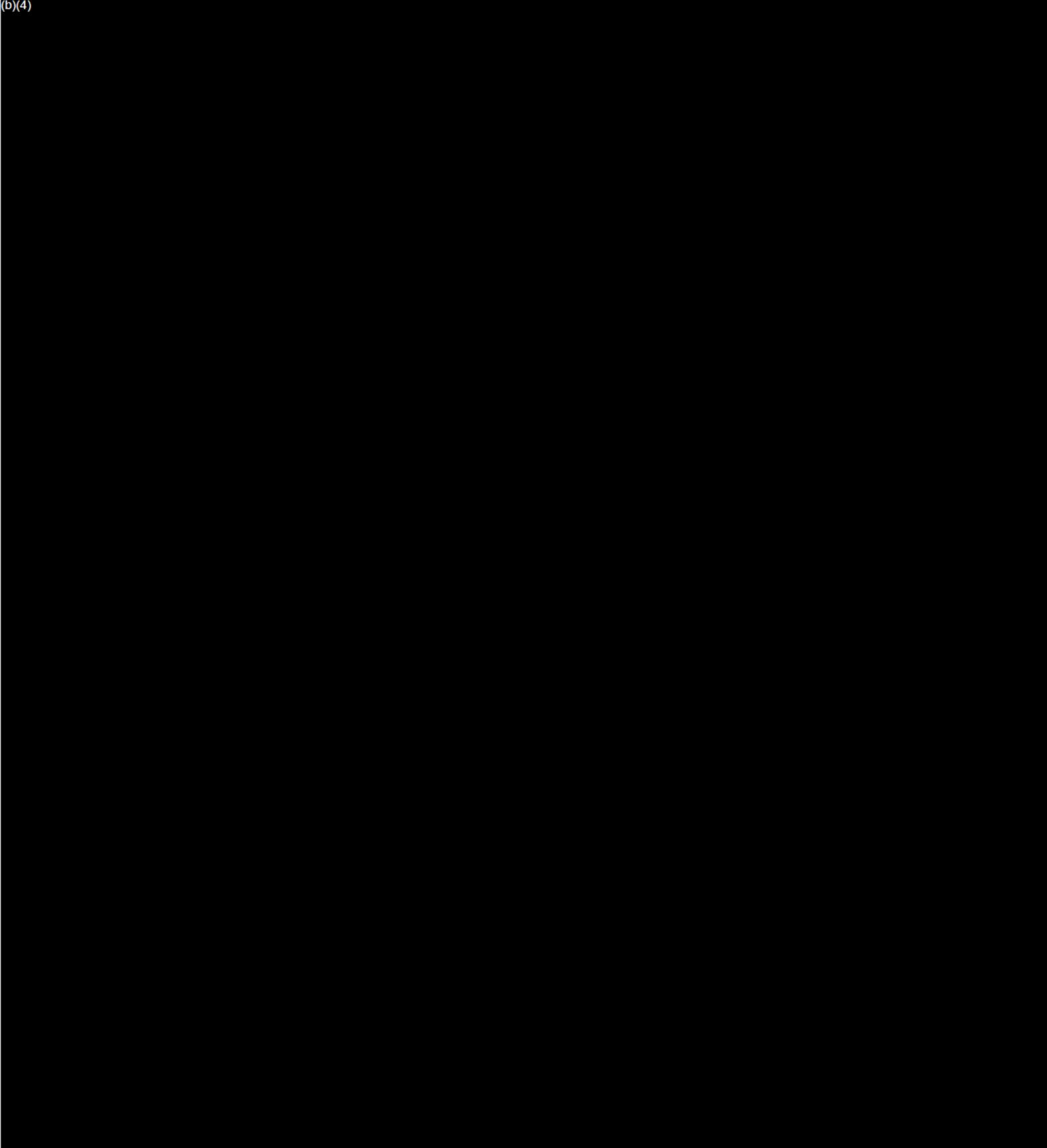
090

HRV TEST EXAMPLE  
RECORDER: 14071

*Hand Measurements*

CALIPER STRIPS

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\*\*\* Calibration: 25 mm = 1 sec, 10 mm = 1 mV (all channels)

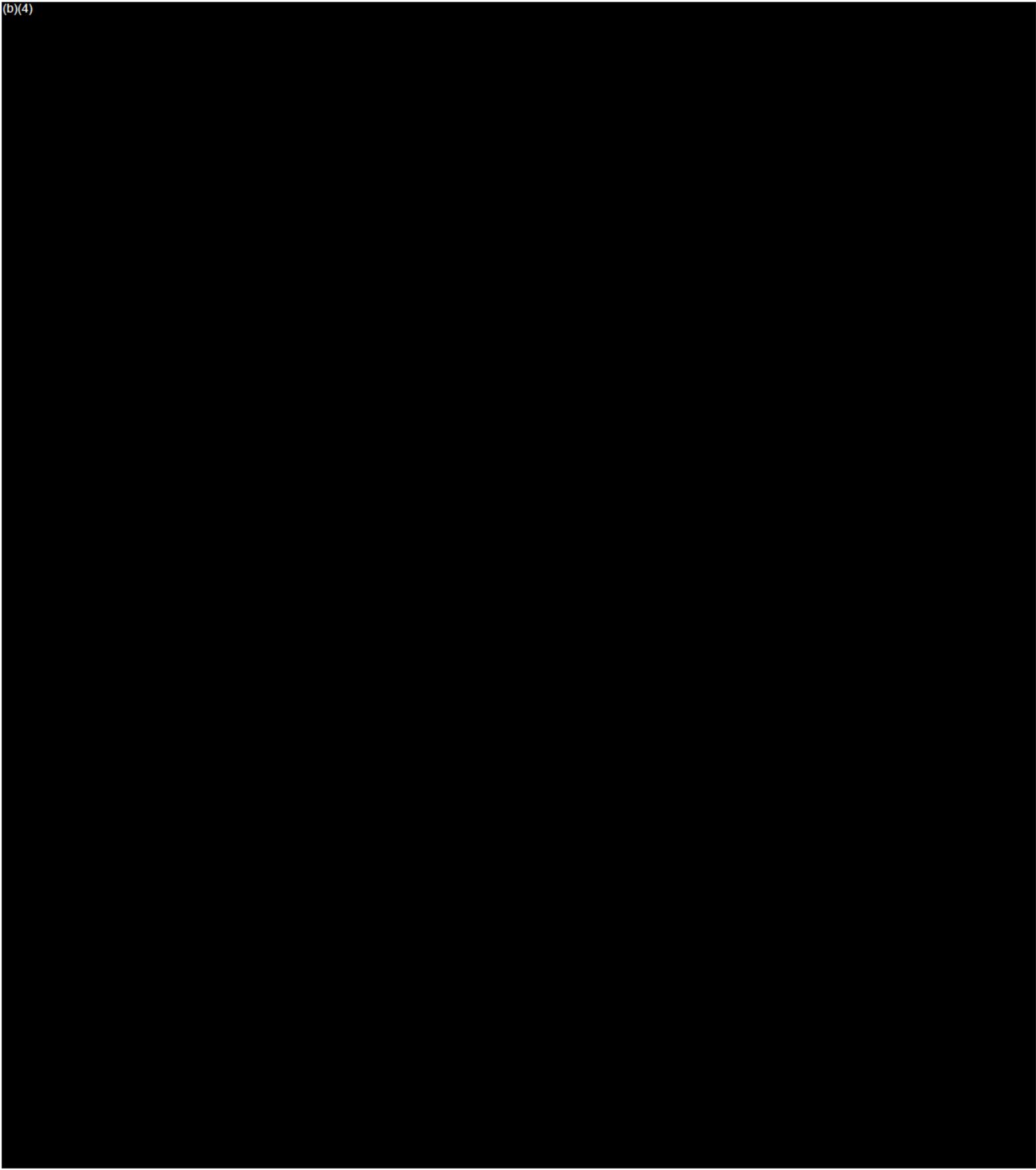
091

HRV TEST EXAMPLE  
RECORDER: 14071

CALIPER STRIPS

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(b)(4)



\*\*\* Calibration: 25 mm = 1 sec, 10 mm = 1 mV (all channels)

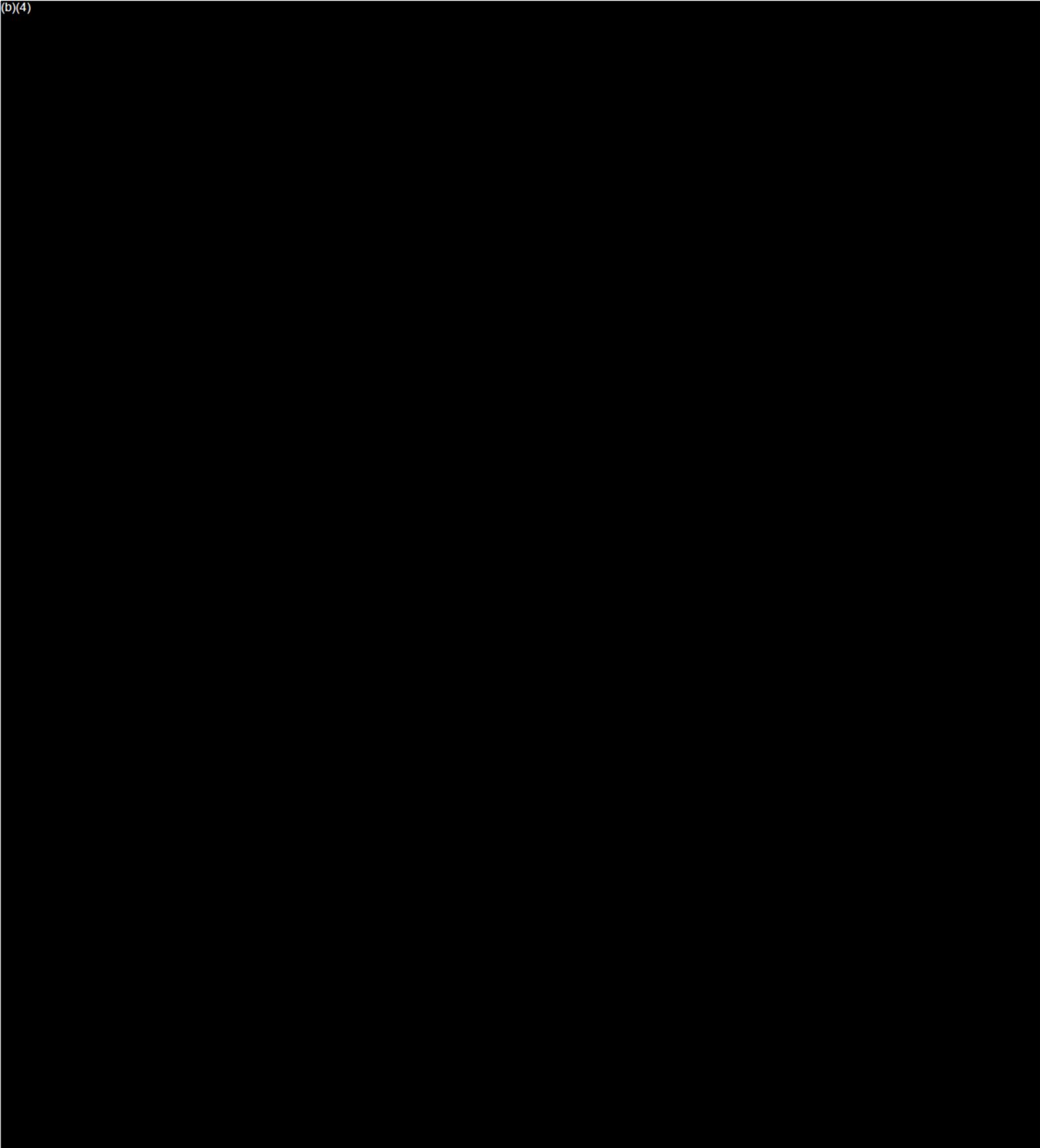
032

HRV TEST EXAMPLE  
RECORDER: 14071

CALIPER STRIPS

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(b)(4)



\*\*\* Calibration: 25 mm = 1 sec, 10 mm = 1 mV (all channels)

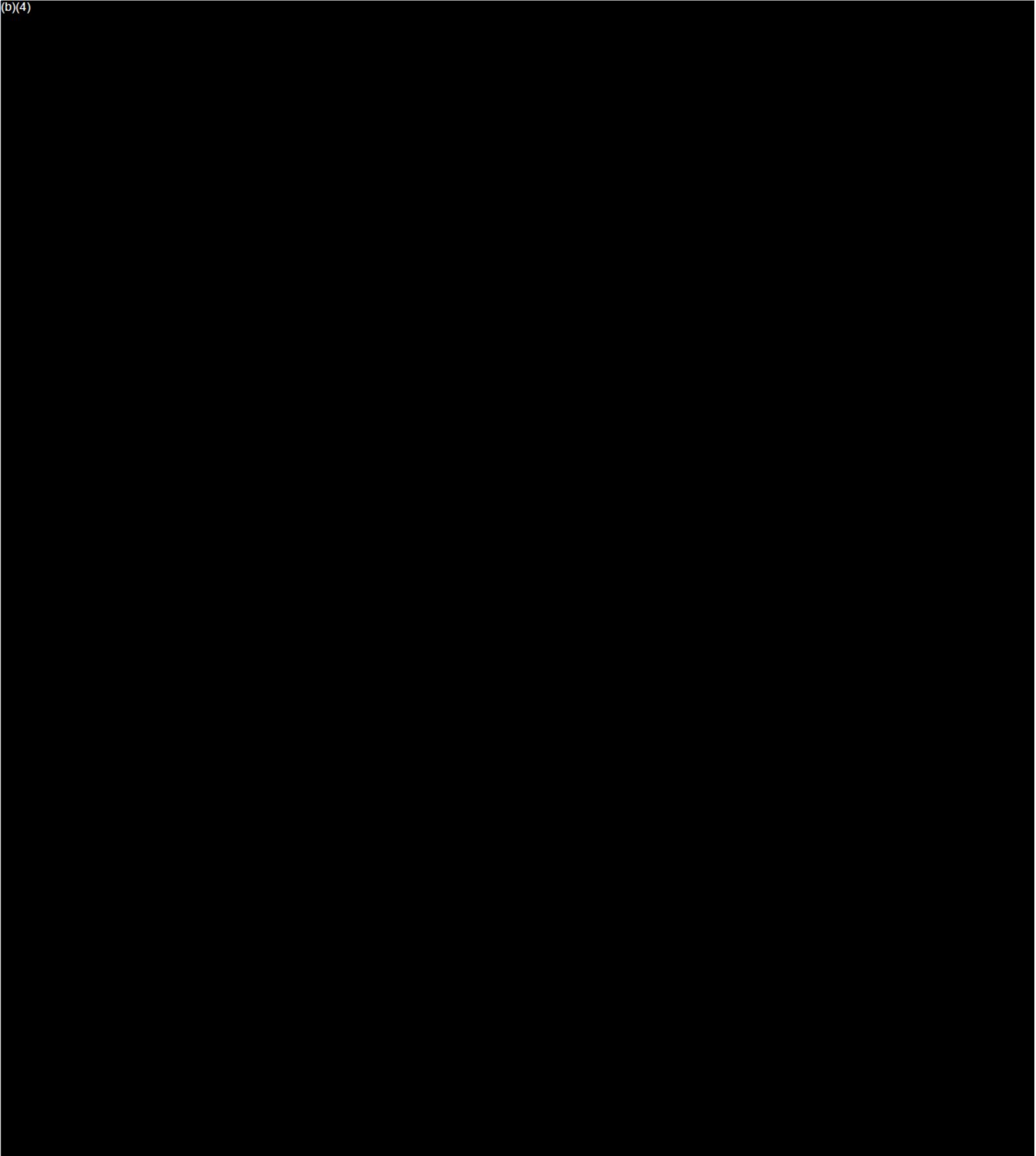
093

HRV TEST EXAMPLE  
RECORDER: 14071

CALIPER STRIPS

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(b)(4)



\*\*\* Calibration: 25 mm = 1 sec, 10 mm = 1 mV (all channels)

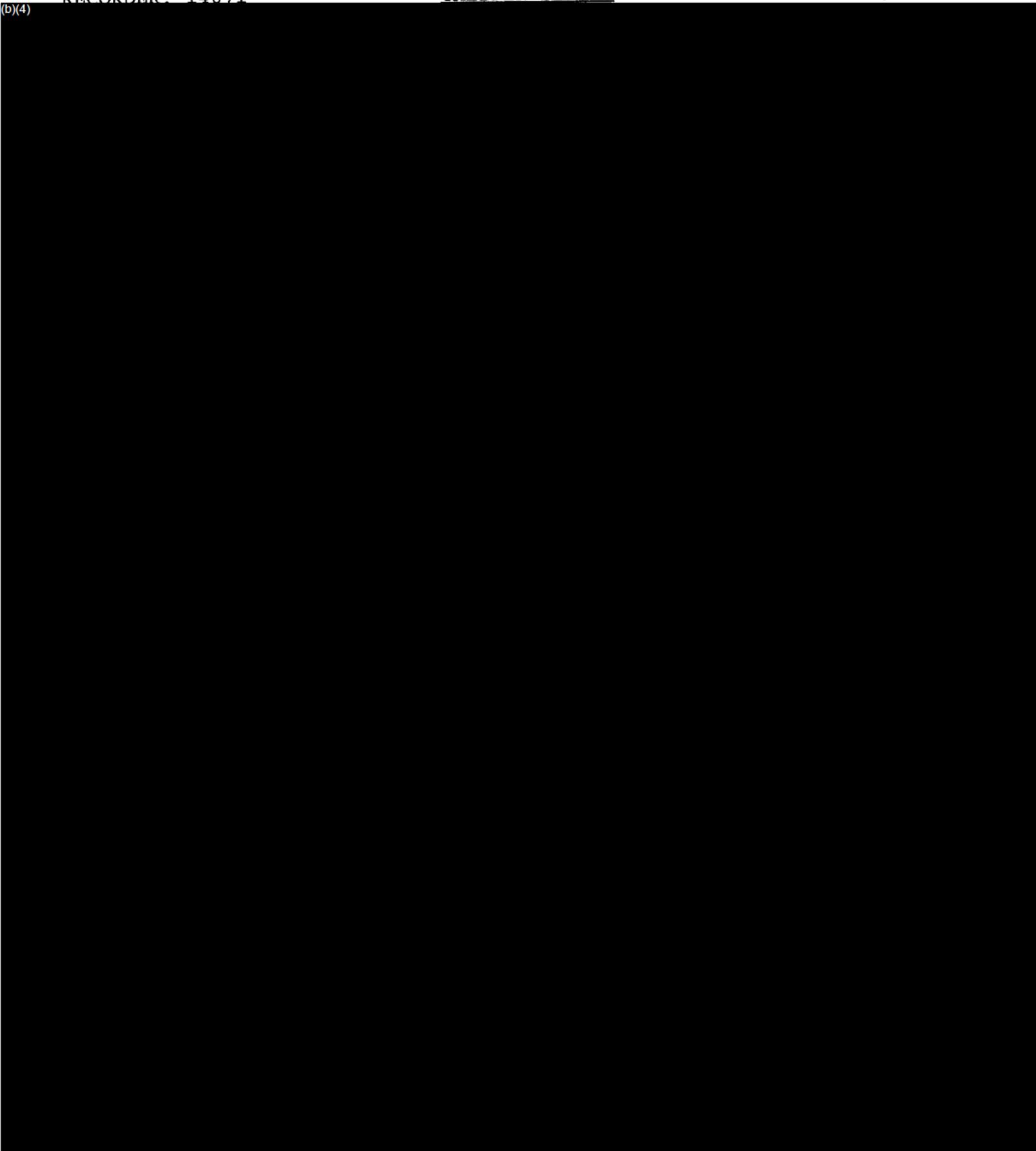
091

HRV TEST EXAMPLE  
RECORDER: 14071

**CALIPER STRIPS**

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\*\*\* Calibration: 25 mm = 1 sec, 10 mm = 1 mV (all channels)

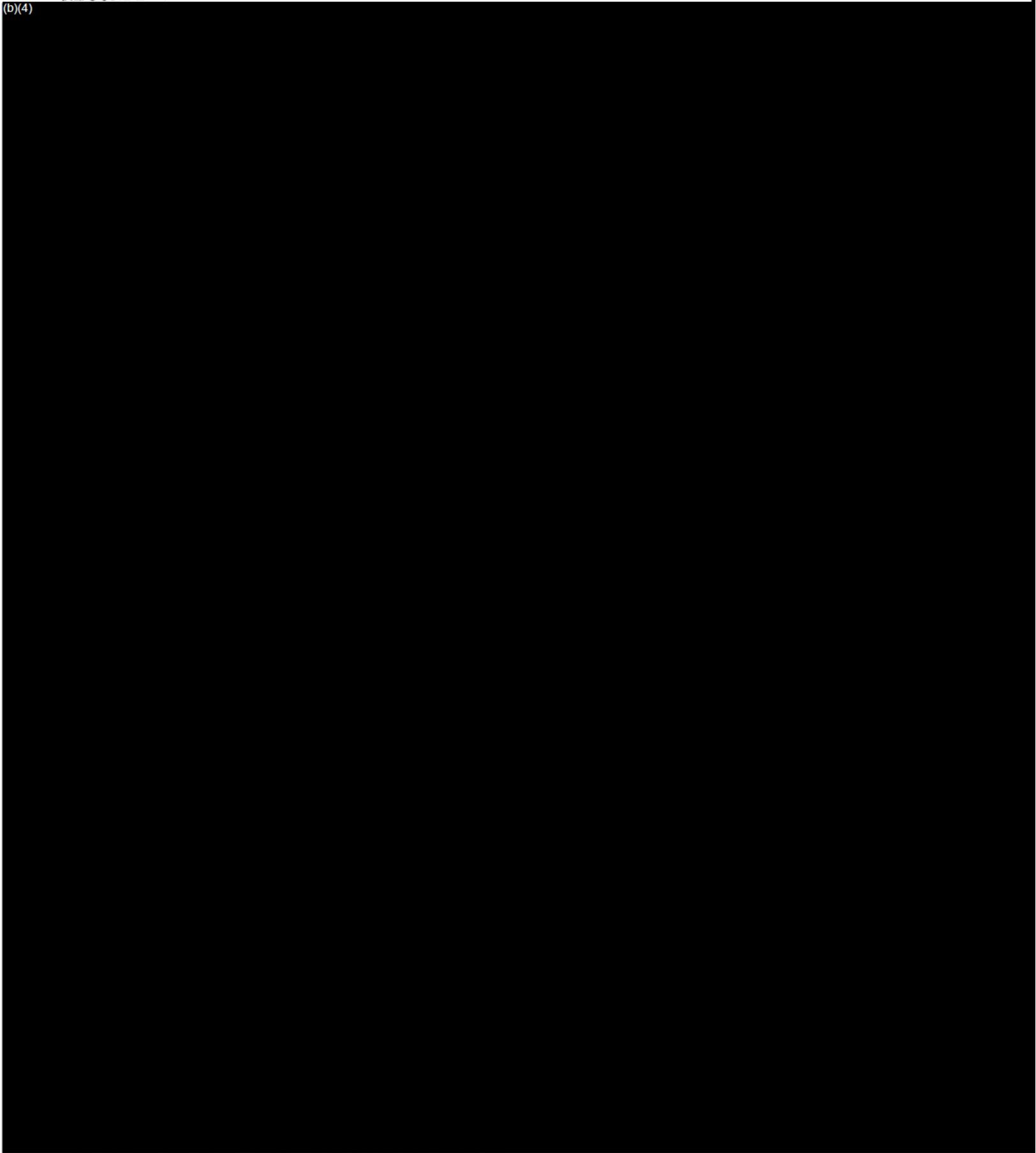
**095**

HRV TEST EXAMPLE  
RECORDER: 14071

CALIPER STRIPS

Jan 30, 1996  
Page: 6

(b)(4)



\*\*\* Calibration: 25 mm = 1 sec, 10 mm = 1 mV (all channels)

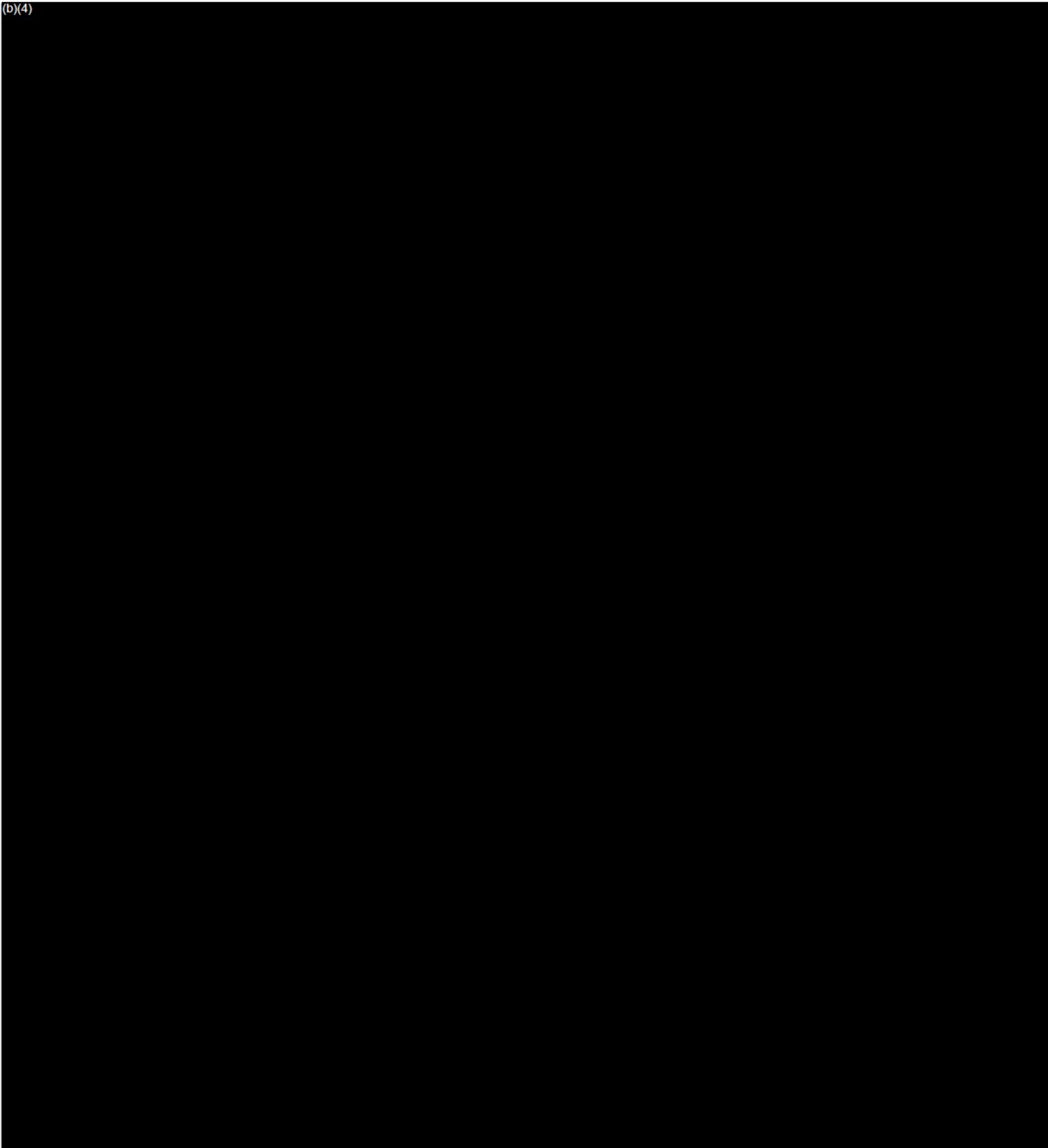
096

HRV TEST EXAMPLE  
RECORDER: 14071

CALIPER STRIPS

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Page: 7

(b)(4)



\*\*\* Calibration: 25 mm = 1 sec, 10 mm = 1 mV (all channels)

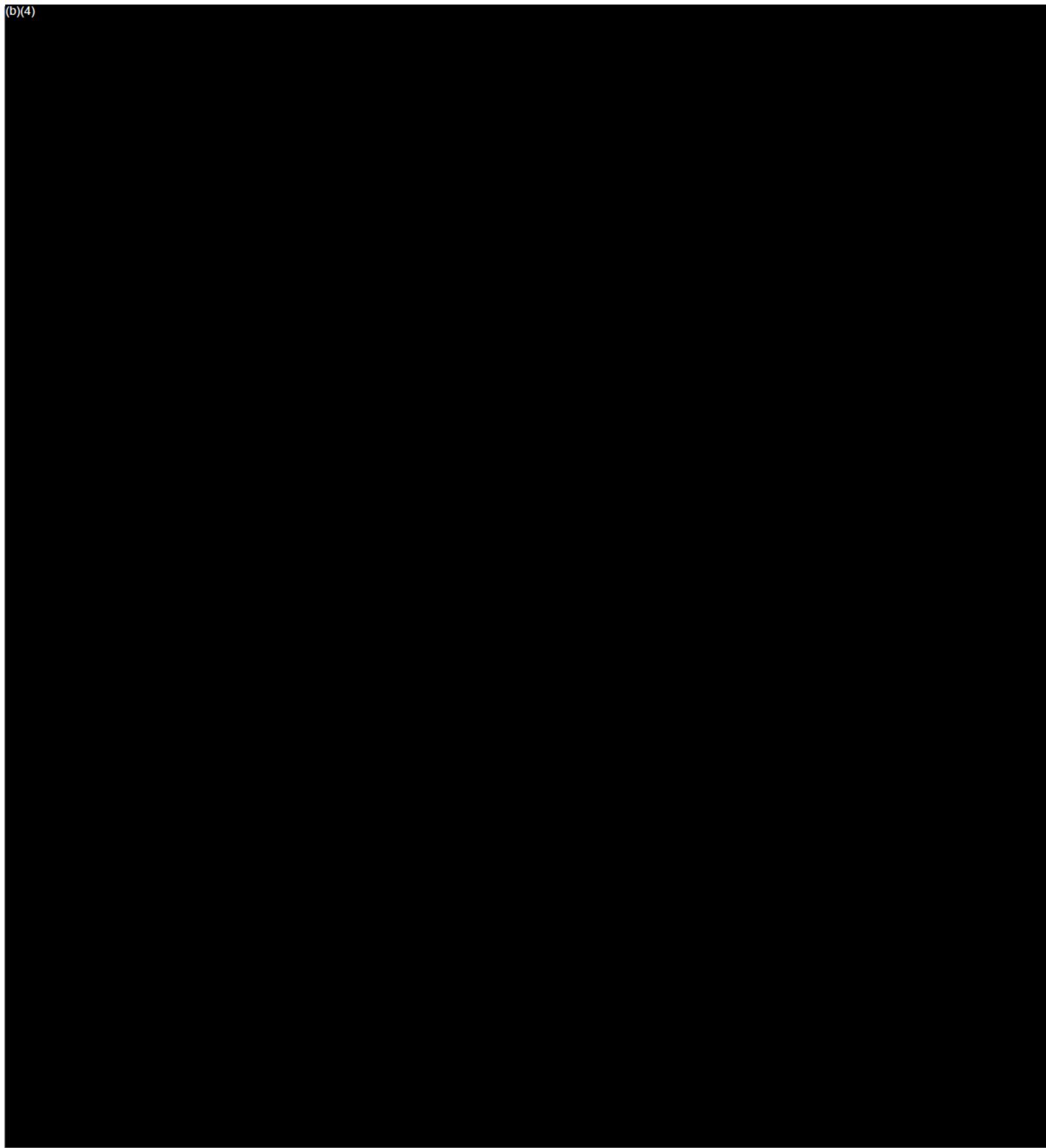
097

HRV TEST EXAMPLE  
RECORDER: 14071

CALIPER STRIPS

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Page: 8

(b)(4)



\*\*\* Calibration: 25 mm = 1 sec, 10 mm = 1 mV (all channels)

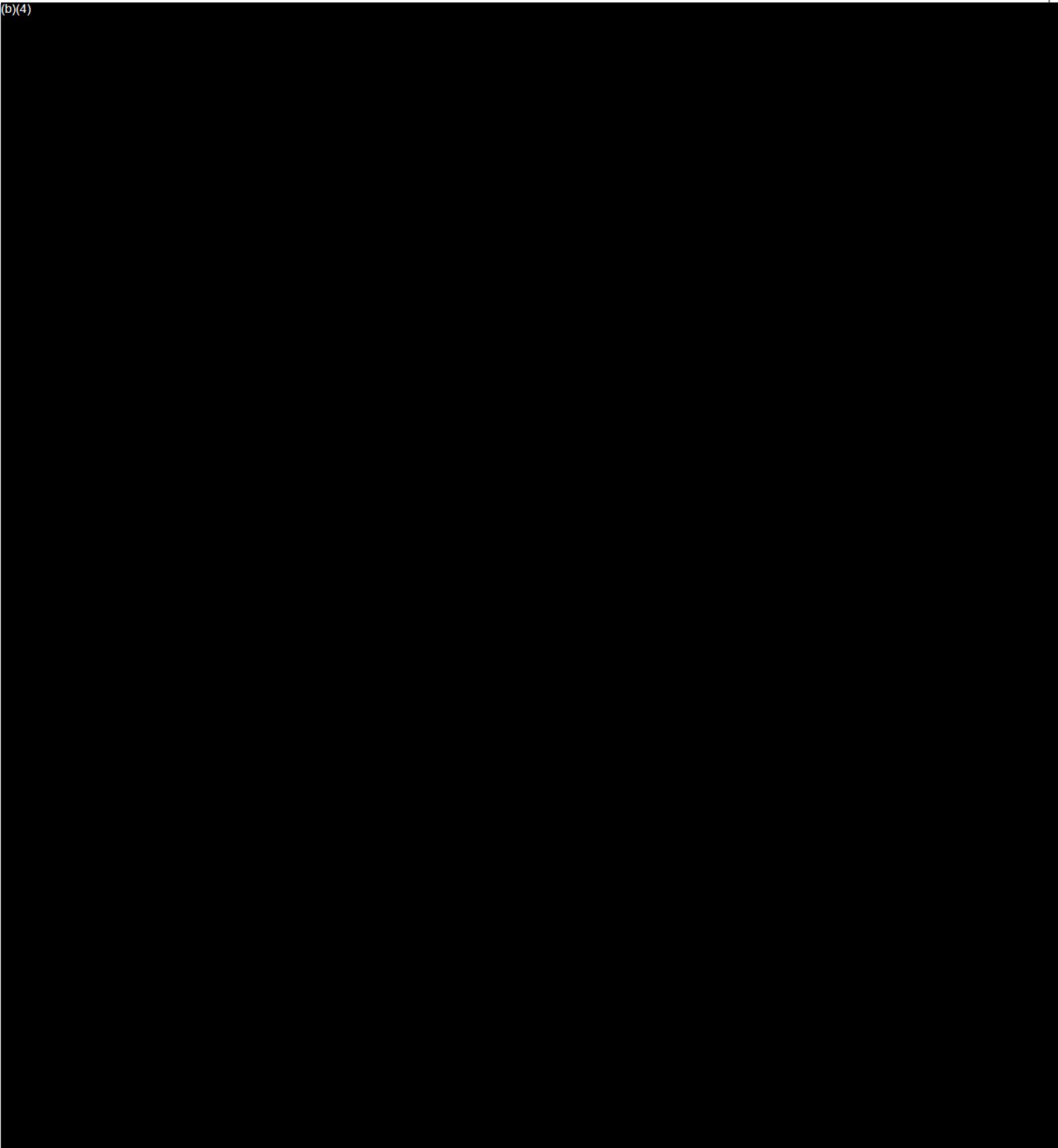
038

HRV TEST EXAMPLE  
RECORDER: 14071

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

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

December 18, 1995

BIOSENSOR CORP.  
13755 FIRST AVENUE NORTH  
PLYMOUTH, MN 55441  
ATTN: MR. DARREN D. DERSHEM

510(k) Number: K950944  
Product: AMBULATORY  
(HOLTER)  
RECORDING SYSTEM

Extended Until: 20-MAR-96

Based on your recent request, an extension of time has been granted for you to submit the additional information we requested.

If the additional information is not received by the "Extended Until" date shown above your premarket notification will be considered withdrawn.

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

Sincerely yours,

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



13755 First Avenue North  
Plymouth, MN 55441-9760  
612-449-9100  
612-449-8966 Fax

FDA/CDRH/OCE/DMC

December 12, 1995

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

RE: 510(k) K950944

Dear Sirs:

Biosensor Corporation hereby requests an extension on its 510(k) submission until **March 1, 1996** in order to allow sufficient time to gather additional data requested by the reviewer.

Thank you for your attention to this request.

Sincerely,

A handwritten signature in cursive script that reads "DD Dershem".

Darren D. Dershem  
Quality Assurance

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

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

September 14, 1995

BIOSENSOR CORP.  
13755 FIRST AVENUE NORTH  
PLYMOUTH, MN 55441  
ATTN: MR. DARREN D. DERSHEM

510(k) Number: K950944  
Product: AMBULATORY  
(HOLTER)  
RECORDING SYSTEM

Extended Until: 20-DEC-95

Based on your recent request, an extension of time has been granted for you to submit the additional information we requested.

If the additional information is not received by the "Extended Until" date shown above your premarket notification will be considered withdrawn.

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

Sincerely yours,

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



13755 First Avenue North  
Plymouth, MN 55441-9760  
612-449-9100  
612-449-8966 Fax

September 13, 1995

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

RE: 510(k) K950944

Dear Sirs:

Biosensor Corporation hereby requests an extension on its 510(k) submission until ~~December~~ 31, 1995 in order to allow sufficient time to gather additional data requested by the reviewer.

Thank you for your attention to this request.

Sincerely,

A handwritten signature in cursive script that reads "D. Dershem".

Darren D. Dershem  
Quality Assurance

RECEIVED  
14 SEP 95 08 56  
FDA/CDRH/OCE/DWG

103



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

AUG 21 1995

Mr. Steve Springrose  
President  
Biosensor Corporation  
13755 First Avenue North  
Plymouth, Minnesota 55441-9760

Re: K950944  
Ambulatory (Holter) Recording System  
Dated: May 11, 1995  
Received: May 12, 1995

Dear Mr. Springrose:

We have reviewed your Section 510(k) notification of intent to market the device referenced above. We cannot determine if the device is substantially equivalent to a device marketed prior to May 28, 1976, the enactment date of the Medical Device Amendments, based solely on the information you provided. In order for us to complete the review of your submission, we require the following:

1. We have the following questions concerning the design of the pacemaker stimulus detector circuit in your device:
  - a. Please clarify whether the detector circuit can work on single chamber or dual chamber pacemaker pulse generators.
  - b. If dual chamber, can the device distinguish the atrial stimulus from the ventricular stimulus? If yes, how?
2. We have the following questions concerning the verification testing of the pacemaker stimulus detector circuit, reported in the initial submittal:
  - a. The detector circuit seems to respond differently for the same 100 Hz frequency input. Specifically, the signal was magnified on page 85 while it was decreased on page 86. Please explain.
  - b. Are the dB calculations on page 86 correct? Specifically, for the 100 Hz signal, the -12.0 dB result should have been -32 dB. Other values under the same column of dB have similar difficulties. Please explain how they were arrived at.

Page 2 - Mr. Steve Springrose

- c. Please provide test report(s) to verify that the pacemaker stimulus detector is designed and manufactured according to your specifications. Please include the test protocol with pass/fail criteria and test results.
  - d. Please provide at least 10 ECG tracings with pacemaker stimuli (both chambers if applicable) to demonstrate the stimulus detection capability.
3. You have indicated that the increase in memory size, from 6-8 Mbytes to 16-32 Mbytes, is needed to allow the device to store higher resolution ECG data. Please describe the implementation procedures for this increase. Is there any change in the signal compression scheme? What is the intended use of the memory increase when the predicate can already store 24 hours of ECG records?
4. Please provide test report(s) to verify that the memory increase is implemented correctly, and that ECG resolution has been improved.
5. Your device can detect arrhythmias while the patient is still connected to the patient recorder, and the patient recorder connected to the personal computer (PC). Hence, there is a chance that risk current can flow from the PC through the patient recorder to the patient. Please explain your safeguards for limiting the risk current to an amount smaller than that recommended by the Association for the Advancement of Medical Instrumentation (AAMI) ES1-1993 standard?
6. Your device includes battery powered as well as AC powered components-- the PC used to analyze the Holter records. Hence, please provide a valid reason why electromagnetic compatibility/interference (EMC/EMI) testing is not needed. Otherwise, EMC/EMI testing is needed.
7. We have the following questions concerning the submitted user manual:
  - a. The labeling should include specifications on the incoming pacemaker stimuli such as duration, pulse width, pulse height, etc. Please change the labeling accordingly.
  - b. The labeling should indicate that the device only records the time of occurrence of the stimulus. Hence, information on other characteristics of the stimulus, such as pulse width and pulse height, is not available to the user. Please change the labeling accordingly.
  - c. Please provide a prescription label on your device, as stated in 21 CFR 801.109.

Page 3 - Mr. Steve Springrose

- d. Please provide the labeling change to indicate non-compliance with defibrillation shock requirements, as indicated in the section labeled AAMI in the initial submittal.
8. What is the version number of the software (or firmware) used in your device?
9. Please explain the reasons for the exceptionally low Ventricular Sensitivity result of 30.56 percent reported for the MIT 107 tape in the section entitled AAMI.
10. What is the intended use for your device's feature of heart rate variability (HRV) analysis in the time domain? Please list all the specific claims made for the feature of HRV.
11. We have enclosed our draft of recommended labeling for HRV devices. If your claims in response to Question 10 above differ from the statement in our draft, additional supporting data, including clinical data, may be required. Please provide a copy of your revised labeling.
12. There is no instruction in the user manual to describe how the HRV information is collected from the incoming ECG signal. How are the graphs and parameters on page 7 of Enclosure D generated? Please add such instruction to your user manual.
13. Please provide your test plan, results and discussion to validate the HRV feature in your device. Please further describe your procedures for ensuring that other features of your device have not been adversely affected by the addition of HRV.

We believe that this information is necessary for us to determine whether or not this device is substantially equivalent to a legally marketed predicate device with regard to its safety and effectiveness.

You may not market this device until you have provided adequate information described above and required by 21 CFR 807.87(f) and (h), 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 Federal Food, Drug, and Cosmetic Act (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.

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); therefore, all information previously submitted must be resubmitted so that your new 510(k) is complete.

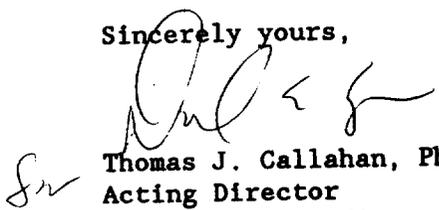
Page 4 - Mr. Steve Springrose

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

If you have questions concerning the contents of this letter, please contact Charles S.C. Ho, Ph.D., at (301) 443-8609. If you need information or assistance concerning the IDE regulations, please contact the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597.

Sincerely yours,

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

Enclosure

Mr. Steve Springrose  
President  
Biosensor Corporation  
13755 First Avenue North  
Plymouth, Minnesota 55441-9760

Re: K950944  
Ambulatory (Holter) Recording System  
Dated: May 11, 1995  
Received: May 12, 1995

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Page 2 - Mr. Steve Springrose

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Page 3 - Mr. Steve Springrose

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11. We have enclosed our draft of recommended labeling for HRV devices. If your claims in response to Question 10 above differ from the statement in our draft, additional supporting data, including clinical data, may be required. Please provide a copy of your revised labeling.
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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Page 4 - Mr. Steve Springrose

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:

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

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Sincerely yours,

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

Enclosure

Prepared by: CHO:att/8/18/95

FILE  
COPY

OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE
450	HO	8/18/95						
450	M...	8/18/95						
450	Z...	8/18/95						



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

PASSED SCREENING

Memorandum

Date:
From: REVIEWER(S) - NAME(S) CHARLES HO
Subject: 510(k) NUMBER K950944/S'

To: THE RECORD -- It is my recommendation that the subject 510(k) Notification:

- Is substantially equivalent to marketed devices.
Requires premarket approval. NOT substantially equivalent to marketed devices.
Requires more data. WMM 8/18/95
Other (e.g., exempt by regulation, not a device, duplicate, etc.)

Is this device subject to Postmarket Surveillance? YES NO
Is this device subject to the Tracking Regulation? YES NO
Was clinical data necessary to support the review of this 510(k)? YES NO

This 510(k) contains: Truthful and Accurate Statement Requested Enclosed
(required for originals received 3-14-95 and after)

A 510(k) summary OR A 510(k) statement
The required certification and summary for class III devices

The submitter requests under 21 CFR 807.95: No Confidentiality
Confidentiality for 90 days Continued Confidentiality exceeding 90 days

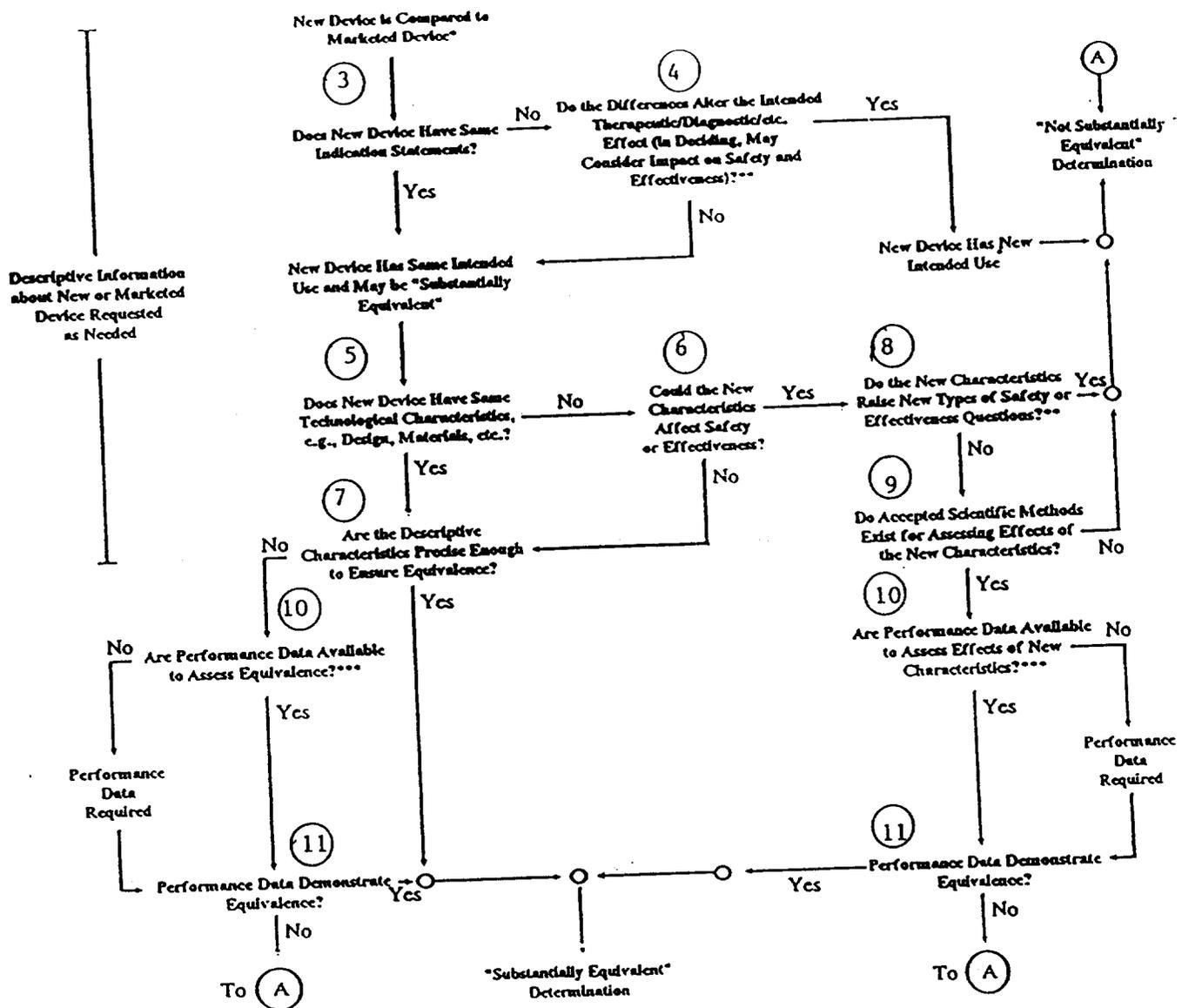
Predicate Product Code with panel and class: 74 DSI / III (THREE)
Additional Product Code(s) with panel (optional):

REVIEW: (BRANCH CHIEF) (BRANCH CODE) (DATE)

FINAL REVIEW: (DIVISION DIRECTOR) (DATE)

Revised 3/8/95

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



- 510(k) submissions compare new devices to marketed devices. FDA requests additional information if the relationship between marketed and "predicate" (pre-Amendments or reclassified post-Amendments) devices is unclear.
- This decision is normally based on descriptive information alone, but limited testing information is sometimes required.
- Data may be in the 510(k), other 510(k)s, the Center's classification files, or the literature.

**MEMO TO THE RECORD**  
**510(K) REVIEW**

**K950944/S1**

**DATE:** August 15, 1995  
**FROM:** Charles Shang Chan Ho, Ph.D. *Charles Ho* **OFFICE:** HFZ-450  
**DIVISION:** DCRND/ADRDG

**COMPANY NAME:** Biosensor Corporation  
**DEVICE NAME:** Ambulatory (Holter) Recording System

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

**NARRATIVE DEVICE DESCRIPTION**

**1. REASON 510(k) WAS SUBMITTED:**

This 510(k) notification covers the Ambulatory (Holter) Recording System manufactured by Biosensor Corporation. The reasons for the 510(k) notification are a) to add a dual channel pacemaker stimulus detector circuit, b) to increase memory size for better ECG resolution, and c) to add R-R interval statistics, for an original device with the same name that was cleared under K922027 on February 17, 1993. Note that Item c is in fact heart rate variability (HRV) analysis in the time domain.

The initial submittal, which was received at FDA on February 17, 1995, failed 510(k) screening by Ms. Senora Smallwood. The present supplement is the manufacturer's response to the deficiencies listed on her checklist.

**2. INTENDED USE:**

From an unnumbered page of notification, "The Full Disclosure Monitoring System is intended for patients requiring ambulatory (Holter) monitoring from 1 to 24 hours. Such monitoring is most frequently used in the indications listed below:

Evaluation of symptoms suggesting arrhythmia or myocardial ischemia.

Evaluation of ECG documenting therapeutic interventions in individual patients or groups of patients.

Evaluation of patients for silent ischemia.

Evaluation of patients with pacemakers.

Evaluation of individual patient's response upon resuming occupational or recreational activities (e.g., after M.I., cardiac surgery)

Evaluation of clinical syndromes and situations where arrhythmias may increase risk of sudden death.

Clinical and epidemiological research studies."

Note that except for the patients with pacemakers and the HRV parts this list is similar to the predicate's list. The missing intended use of HRV will be referred to in my Question 9.

I should point out further that the device has real-time arrhythmia monitoring capabilities.

3. DEVICE DESCRIPTION:

- A. Life-supporting or life-sustaining: N
- B. Implant (short-term or long-term): N
- C. Is the device sterile? N  
If yes, is sterility information provided? N/A
- D. Is the device for single use? N
- E. Is the device for prescription use? Y  
If yes, is prescription labeling included? N, to be requested.
- F. Is the device for home use or portable? N (partly)  
Whether the answer is yes or no, is adequate environmental testing, including EMC, performed for the intended environment, and are results provided, including test protocols, data, and a summary? No, to be requested
- G. Does the device contain drug or biological product as a component? N
- H. Is this device a kit? N  
If yes, and some or all of the components are not new, does the submission include a certification that these components were either preamendment or found to be substantially equivalent? <>
- I. Software-driven: Y  
Estimated level of concern: (Major, Moderate, Minor)?  
Major  
Has the firm provided a hazard analysis, software

requirements and design information, adequate test plans/protocols with appropriate data and test reports, documentation of the software development process including quality assurance activities, configuration management plan, and verification activities and summaries, commensurate with the level of concern, as discussed in the Reviewer Guidance for Computer Controlled Medical Devices? Y  
Software version: N, to be requested

J. Electrically Operated: Y  
If yes, are AAMI or IEC leakage currents met and is the test protocol, data, and results provided? No, to be requested

K. Applicable standards to which conformance has been demonstrated (e.g., IEC, ANSI, ASTM, etc.): AAMI EC38-1994  
If applicable, has test data been provided to demonstrate conformance (protocol, data, and results) Not enough

L. Device(s) to which equivalence is claimed, manufacturer, and 510(k) number or preamendment status:

Ambulatory (Holter) Recording System (same device name) manufactured by Biosensor Corporation (same manufacturer), cleared under K922027 on February 17, 1993.

M. Submission provides comparative specifications Y  
comparative in in vitro data N/A (upgrade of predicate)

performance data	Y
animal testing	N/A
clinical testing	N
biocompatibility testing	N/A
labeling/promotional lit	Y

a. A comparison of similarities and differences (features, specifications, intended use, materials, design, theory of operation, accessories, etc.) in tabular form should be included. Differences should be explained with supporting rationale and/or data. If differences include new intended use or new technological characteristics, clinical data would be needed to demonstrate that no new issues of safety and effectiveness are raised. If reference literature is accepted by the FDA to support any differences, copies of the articles must be provided as opposed to listing the author and titles, the significant areas of the articles must be highlighted, and a summary must be provided relating

the information to the issue at hand, including a discussion of the study protocol, data, statistical analyses, and a summary of the results.

- b. If applicable, comparative in vitro testing including protocol, data, and a summary of the results should be provided.
  - c. Performance data including protocol, data, and summary explaining how testing and data demonstrate that the device performs as intended should be provided.
  - d. If applicable, animal testing including protocol, data, and a summary of the results should be provided.
  - e. If applicable, clinical testing, including the investigational plan, data, statistical analyses and a summary of results should be provided. If the study was performed under an investigational device exemption (IDE), the IDE number should be provided. If the device is nonsignificant risk, the study should be conducted under the auspices of the institutional review board (IRB) even though an IDE would not need to be filed with the FDA.
  - f. If applicable, biocompatibility testing, including the protocol for each test required as outlined in the Tripartite Biocompatibility Guidance, the pass/fail criteria, data, and a summary of results should be provided.
  - g. The firm should provide the labeling offered with the device, including adequate instruction (or prescription labeling), cautions and warnings, contraindications, package label, promotional literature, and claims to be made for the device.
- N. Provide a statement of how the device is either similar to and/or different from other marketed devices, plus data (if necessary) to support the statement. Provide a summary about the devices design, materials, physical properties and toxicology profile if important.

<>

EXPLANATIONS TO "YES" AND "NO" ANSWERS TO QUESTIONS ON PAGE 1 OF REVIEW FORM AS NEEDED (DELETE QUESTIONS WHICH ARE NOT APPLICABLE)

1. IF THE ANSWER TO QUESTION 1 IS NO, EXPLAIN WHY THE

PRODUCT IS NOT A DEVICE. <>

2. IF THE ANSWER TO QUESTION 2 IS NO, EXPLAIN WHY THE DEVICE IS NOT SUBJECT TO 510(K). <>

3. IF THE ANSWER TO QUESTION 3 IS NO, EXPLAIN HOW THE NEW INDICATION DIFFERS FROM THE PREDICATE DEVICE'S INDICATION. <>

4. IF THE ANSWER TO QUESTION 4 IS YES OR NO, EXPLAIN WHY THERE IS/IS NOT A NEW EFFECT OR SAFETY OR EFFECTIVENESS ISSUE. <>

5. IF THE ANSWER TO QUESTION 5 IS NO, DESCRIBE THE NEW TECHNOLOGICAL CHARACTERISTICS. <>

6. IF THE ANSWER TO QUESTION 6 IS YES OR NO, EXPLAIN HOW THE NEW CHARACTERISTICS COULD/COULD NOT AFFECT SAFETY OR EFFECTIVENESS. <>

7. IF THE ANSWER TO QUESTION 7 IS NO, EXPLAIN HOW THE DESCRIPTIVE CHARACTERISTICS ARE NOT PRECISE ENOUGH. <>

8. IF THE ANSWER TO QUESTION 8 IS YES OR NO, EXPLAIN THE NEW TYPES OF SAFETY OR EFFECTIVENESS QUESTIONS RAISED OR WHY THE QUESTIONS ARE NOT NEW. <>

9. IF THE ANSWER TO QUESTION 9 IS NO, EXPLAIN WHY THE EXISTING SCIENTIFIC METHODS CAN NOT BE USED. <>

10. IF THE ANSWER TO QUESTION 10 IS NO, EXPLAIN WHAT PERFORMANCE DATA IS NEEDED. <>

11. THE ANSWER TO QUESTION 11 IS YES OR NO, EXPLAIN HOW THE PERFORMANCE DATA DEMONSTRATES THAT THE DEVICE IS/IS NOT SUBSTANTIALLY EQUIVALENT. <>

O. Does the submission include a summary of safety and effectiveness information upon which an equivalence determination is based? N  
If not, does the submission include a certification that such information will be made available to interested persons upon request? Y

P. RECOMMENDATION:

I believe that this device is equivalent to: 74 DSI

Classification should be based on:

870.1025 Class: III (THREE)

If the device is substantially equivalent to a class III device, does the submission include: (1) certification that a reasonable search of all information known, or otherwise available, about the generic type of device has been performed and (2) a summary description of the types of safety and effectiveness problems associated with the type of device and a citation to the literature, or other sources of information, upon which they have based the description? <>

\_\_\_\_\_ <>

I believe that this device is not equivalent to any pre-enactment/predicate device:

\_\_\_\_\_ <>

I believe that additional information is required to determine equivalence (see attached):

Charles Mo <>

**REVIEW MEMORANDUM**

*Charles Ho*  
**From:** Charles Shang Chan Ho, Ph.D.      **Date:** Aug. 15, 1995  
**To:** The Record      **Office:** ODE  
**Subj:** K950944/S1      **Division:** DCRND

-----

**Manufacturer Contact**

Mr. Steve Springrose  
President  
Biosensor Corporation  
13755 First Avenue North  
Plymouth, Minnesota 55441-9760  
Phone: (612) 449-9100      FAX: (612) 449-8966

**Reason for Notification**

This 510(k) notification covers the Ambulatory (Holter) Recording System manufactured by Biosensor Corporation. The reasons for the 510(k) notification are a) to add a dual channel pacemaker stimulus detector circuit, b) to increase memory size for better ECG resolution, and c) to add R-R interval statistics, for an original device with the same name that was cleared under K922027 on February 17, 1993. Note that Item c is in fact heart rate variability (HRV) analysis in the time domain.

The initial submittal, which was received at FDA on February 17, 1995, failed 510(k) screening by Ms. Senora Smallwood. The present supplement is the manufacturer's response to the deficiencies listed on her checklist.

Note that the manufacturer has previously submitted a 510(k) notification for a similar device in addition to heart rate variability (HRV) analysis capability. That file, K943953, was found Not Substantially Equivalent on December 5, 1994 due to the HRV issue. Now, the manufacturer was told that we are re-thinking our position on HRV.

Intended Use

From an unnumbered page of notification, "The Full Disclosure Monitoring System is intended for patients requiring ambulatory (Holter) monitoring from 1 to 24 hours. Such monitoring is most frequently used in the indications listed below:

Evaluation of symptoms suggesting arrhythmia or myocardial ischemia.

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Note that except for the patients with pacemakers and the HRV parts this list is similar to the predicate's list. The missing intended use of HRV will be referred to in my Question 9.

I should point out further that the device has real-time arrhythmia monitoring capabilities.

Claimed Predicate Devices

The Ambulatory (Holter) Recording System (same device name) manufactured by Biosensor Corporation (same manufacturer name). The predicate was cleared under K922027 on February 17, 1993.

Device Description

The device consists of a (user-supplied) IBM-compatible personal computer (PC) with the firmware and a computer card, and one or more digital patient recorders (similar to Holter monitors). The device has the capability to monitor the arrhythmias of the patient in real-time, i.e., while the patient is still connected to the patient recorder, and the patient recorder connected to the PC. Hence, I agree with the manufacturer that the device should be classified as Class III (THREE) with a product code of DSI for its real-time arrhythmia monitoring capabilities.

The PC has the following specifications:

IBM PC compatible (80386 or higher speed recommended)  
Hard disk: 20 megabytes or greater  
Floppy drive: 3-1/2 inch or 5-1/4 inch high density  
RAM: 2 Mbyte or greater  
Parallel port for printer  
EGA or higher graphics capability  
Open slot for Holter communication card, supplied with system software.

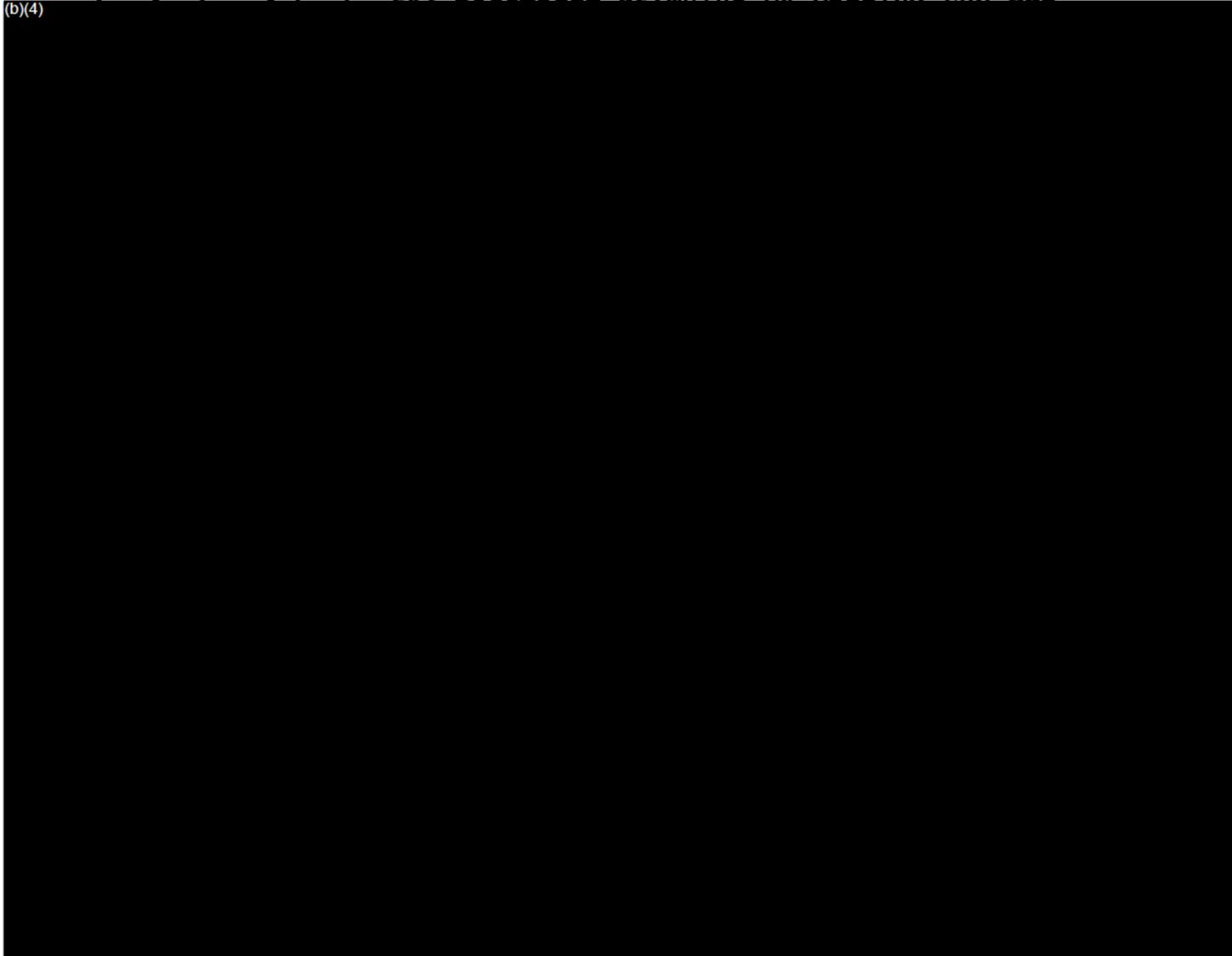
The patient recorder has the following specifications:

Power supply: 4x AA Duracell alkaline/2.4 Ah  
Patient event marker  
Data storage: digital  
Frequency response: 0.05 - 40 Hz at 3 dB points  
Programmability: Tachycardia rates, bradycardia rates,  
pause intervals, ST analysis, SV  
prematurity  
Algorithm: 2 channel Argus ECG Diagnostic Method

The manufacturer has indicated that the only changes requested by the present notification are a) to add a dual channel pacemaker stimulus detector circuit, b) to increase memory size for better ECG resolution, and c) to add R-R interval statistics, for an original device with the same name that was cleared under K922027 on February 17, 1993. Hence, my review will concentrate on these three issues.

Pacemaker Stimulus Detector Circuit

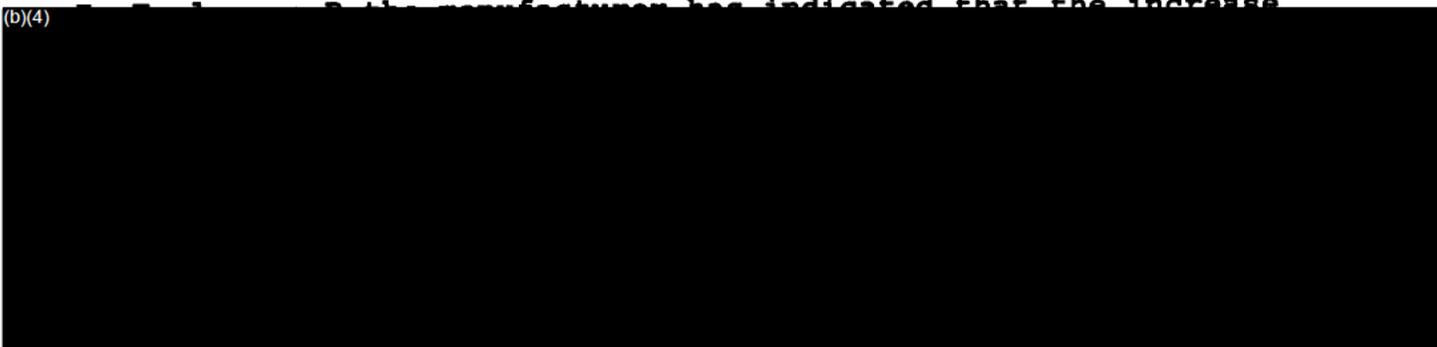
(b)(4)



Increase in Memory Size

(b)(4)

The manufacturer has indicated that the increase



Heart Rate Variability

(b)(4)



**Software**

(b)(4)

[Redacted content]

**EMC/EMI Testing**

(b)(4)

[Redacted content]

Labeling

The manufacturer has submitted a 510(k) statement.

The manufacturer has submitted a Class III summary and certification.

There is a reasonable user manual. (The manufacturer has not clarified the correct name of this manual.) However, there is no specific mention of the pacemaker stimulus detection in the manual. The labeling should include specifications on the incoming pacemaker stimulus pulses, such as duration, pulse width, etc. Then, the fact that the device only records the time of occurrence of the stimulus should be made known to the user.

Further, the prescription labeling is missing from the user manual, although it is provided in the supplemental information requested by Ms. Smallwood.

And, there is the need for a label change to indicate non-compliance with defibrillation shock requirements, as indicated in the section labeled AAMI in the initial submittal.

The above issues will be referred to in my Question 7, together with prescription labeling requirement.

Other

A new issue seems to have come up on the ventricular sensitivity; it is only 30.56%. Hence, my Question 11 will request an explanation, as follows:

11. Please explain the reasons for the exceptionally low Ventricular Sensitivity result of 30.56 percent reported for the MIT 107 tape in the section entitled AAMI.

**RECOMMENDATION**

It is the recommendation of this reviewer that the application be placed on hold pending the manufacturer's reply to the question referenced in my review memorandum.

*Concur  
Mark Mani  
8/18/15*

WMM  
8/16/95

Questions:

1. We have the following questions concerning the design of the pacemaker stimulus detector circuit in your device:
  - a. Please clarify whether the detector circuit can work on single chamber or dual chamber pacemaker pulse generators.
  - b. If dual chamber, can the device distinguish the atrial stimulus from the ventricular stimulus? If yes, how?
2. We have the following questions concerning the verification testing of the pacemaker stimulus detector circuit, reported in the initial submittal:
  - a. The detector circuit seems to respond differently for the same 100 Hz frequency input. Specifically, the signal was magnified on page 85 while it was decreased on page 86.
  - b. Are the dB calculations on page 86 correct? Specifically, for the 100 Hz signal, the -12.0 dB result should have been -32 dB. Other values under the same column of dB have similar difficulties. Please explain how they were arrived at.
  - c. Please provide test report(s) to verify that the pacemaker stimulus detector is designed and manufactured according to your specifications. Please include the test protocol with pass/fail criteria and test results.
  - d. Please provide at least 10 ECG tracings with pacemaker stimuli (both chambers if applicable) to demonstrate the stimulus detection capability.
3. You have indicated that the increase in memory size, from 6-8 Mbytes to 16-32 Mbytes, is needed to allow the device to store higher resolution ECG data. Please describe the implementation procedures for this increase. Is there any change in the signal compression scheme? What is the intended use of the memory increase when the predicate can already store 24 hours of ECG records?
4. Please provide test report(s) to verify that the memory increase is implemented correctly, and that ECG resolution has been improved.
5. Your device can detect arrhythmias while the patient is

still connected to the patient recorder, and the patient recorder connected to the personal computer (PC). Hence, there is a chance that risk current can flow from the PC through the patient recorder to the patient. Please explain your safeguards for limiting the risk current to an amount smaller than that recommended by the Association for the Advancement of Medical Instrumentation (AAMI) ES1-1993 standard?

6. Your device includes battery powered as well as AC powered components-- the PC used to analyze the Holter records. Hence, please provide a valid reason why electromagnetic compatibility/interference (EMC/EMI) testing is not needed. Otherwise, EMC/EMI testing is needed.
7. We have the following questions concerning the submitted user manual:
  - a. The labeling should include specifications on the incoming pacemaker stimuli such as duration, pulse width, pulse height, etc. Please change the labeling accordingly.
  - b. The labeling should indicate that the device only records the time of occurrence of the stimulus. Hence, information on other characteristics of the stimulus, such as pulse width and pulse height, is not available to the user. Please change the labeling accordingly.
  - c. Please provide a prescription label on your device, as stated in 21 CFR 801.109.
  - d. Please provide the labeling change to indicate non-compliance with defibrillation shock requirements, as indicated in the section labeled AAMI in the initial submittal.
8. What is the version number of the software (or firmware) used in your device?
9. Please explain the reasons for the exceptionally low Ventricular Sensitivity result of 30.56 percent reported for the MIT 107 tape in the section entitled AAMI.
10. What is the intended use for your device's feature of heart rate variability (HRV) analysis in the time domain? Please list all the specific claims made for the feature of HRV.
11. We have enclosed our draft of recommended labeling for

HRV devices. If your claims in response to Question 10 above differ from the statement in our draft, additional supporting data, including clinical data, may be required. Please provide a copy of your revised labeling.

12. There is no instruction in the user manual to describe how the HRV information is collected from the incoming ECG signal. How are the graphs and parameters on page 7 of Enclosure D generated? Please add such instruction to your user manual.
13. Please provide your test plan, results and discussion to validate the HRV feature in your device. Please further describe your procedures for ensuring that other features of your device have not been adversely affected by the addition of HRV.

Mr. Steve Springrose  
President  
Biosensor Corporation  
13755 First Avenue North  
Plymouth, Minnesota 55441-9760

Re: K950944  
Ambulatory (Holter) Recording System  
Dated: May 11, 1995  
Received: May 12, 1995

Dear Mr. Springrose:

We have reviewed your Section 510(k) notification of intent to market the device referenced above. We cannot determine if the device is substantially equivalent to a device marketed prior to May 28, 1976, the enactment date of the Medical Device Amendments, based solely on the information you provided. In order for us to complete the review of your submission, we require the following:

1. We have the following questions concerning the design of the pacemaker stimulus detector circuit in your device:
  - a. Please clarify whether the detector circuit can work on single chamber or dual chamber pacemaker pulse generators.
  - b. If dual chamber, can the device distinguish the atrial stimulus from the ventricular stimulus? If yes, how?
2. We have the following questions concerning the verification testing of the pacemaker stimulus detector circuit, reported in the initial submittal:
  - a. The detector circuit seems to respond differently for the same 100 Hz frequency input. Specifically, the signal was magnified on page 85 while it was decreased on page 86. Please explain.
  - b. Are the dB calculations on page 86 correct? Specifically, for the 100 Hz signal, the -12.0 dB result should have been -32 dB. Other values under the same column of dB have similar difficulties. Please explain how they were arrived at.

- c. Please provide test report(s) to verify that the pacemaker stimulus detector is designed and manufactured according to your specifications. Please include the test protocol with pass/fail criteria and test results.
  - d. Please provide at least 10 ECG tracings with pacemaker stimuli (both chambers if applicable) to demonstrate the stimulus detection capability.
3. You have indicated that the increase in memory size, from 6-8 Mbytes to 16-32 Mbytes, is needed to allow the device to store higher resolution ECG data. Please describe the implementation procedures for this increase. Is there any change in the signal compression scheme? What is the intended use of the memory increase when the predicate can already store 24 hours of ECG records?
  4. Please provide test report(s) to verify that the memory increase is implemented correctly, and that ECG resolution has been improved.
  5. Your device can detect arrhythmias while the patient is still connected to the patient recorder, and the patient recorder connected to the personal computer (PC). Hence, there is a chance that risk current can flow from the PC through the patient recorder to the patient. Please explain your safeguards for limiting the risk current to an amount smaller than that recommended by the Association for the Advancement of Medical Instrumentation (AAMI) ES1-1993 standard?
  6. Your device includes battery powered as well as AC powered components-- the PC used to analyze the Holter records. Hence, please provide a valid reason why electromagnetic compatibility/interference (EMC/EMI) testing is not needed. Otherwise, EMC/EMI testing is needed.
  7. We have the following questions concerning the submitted user manual:
    - a. The labeling should include specifications on the incoming pacemaker stimuli such as duration, pulse width, pulse height, etc. Please change the labeling accordingly.
    - b. The labeling should indicate that the device only records the time of occurrence of the stimulus. Hence, information on other characteristics of the stimulus, such as pulse width and pulse height, is not available to the user. Please change the

labeling accordingly.

- c. Please provide a prescription label on your device, as stated in 21 CFR 801.109.
  - d. Please provide the labeling change to indicate non-compliance with defibrillation shock requirements, as indicated in the section labeled AAMI in the initial submittal.
8. What is the version number of the software (or firmware) used in your device?
  9. Please explain the reasons for the exceptionally low Ventricular Sensitivity result of 30.56 percent reported for the MIT 107 tape in the section entitled AAMI.
  10. What is the intended use for your device's feature of heart rate variability (HRV) analysis in the time domain? Please list all the specific claims made for the feature of HRV.
  11. We have enclosed our draft of recommended labeling for HRV devices. If your claims in response to Question 10 above differ from the statement in our draft, additional supporting data, including clinical data, may be required. Please provide a copy of your revised labeling.
  12. There is no instruction in the user manual to describe how the HRV information is collected from the incoming ECG signal. How are the graphs and parameters on page 7 of Enclosure D generated? Please add such instruction to your user manual.
  13. Please provide your test plan, results and discussion to validate the HRV feature in your device. Please further describe your procedures for ensuring that other features of your device have not been adversely affected by the addition of HRV.

We believe that this information is necessary for us to determine whether or not this device is substantially equivalent to a legally marketed predicate device with regard to its safety and effectiveness.

You may not market this device until you have provided adequate information described above and required by 21 CFR 807.87(f) and (h), 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 Federal Food, Drug, and Cosmetic Act (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.

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); therefore, all information previously submitted must be resubmitted so that your new 510(k) is complete.

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:

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

If you have any questions concerning the contents of this letter, please contact Charles S.C. Ho, Ph.D., at (301) 443-8609. If you need information or assistance concerning the IDE regulations, please contact the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597.

Sincerely yours,

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

Enclosure

**bcc:**           **HFZ-401 DMC**  
                  **HFZ-404 510(k) Staff**  
                  **HFZ-       Division**  
                  **D.O.**

## **Operator's Manual**

### Description

[Provide a brief description of the software and the device on which it is implemented.]

### Indications for Use

The [device name] is indicated for... Heart rate variability (HRV) analysis in the time domain is intended for quantification and graphic displays of heart rate changes over a specific monitoring period, and is to be used as an adjunct to other clinical diagnostic techniques.

### Contraindications

[There are no contraindications associated with the use of the device.]

### Warnings

[There are no warnings associated with the use of the device.]

### Precautions

Since various neural, respiratory, and humoral influences are generally known to affect heart rate, the significance of the data must be determined by the clinician.

HRV measurements are not valid in patients with sinus node dysfunction, second or third degree atrioventricular block, or temporary or permanent pacemakers, or who experience atrial or ventricular dysrhythmia during the analysis period.

Some HRV parameters are highly dependent on mean heart rate. Careful consideration should be given to the interpretation of results between and within specific patient populations.

HRV analysis results may differ among devices from different manufacturers since the methods, such as treatment of premature supraventricular, missed, and ventricular ectopic beats, are not standardized. Therefore, caution should be used in applying conclusions drawn from studies with other devices.

### Directions for Use

[Thoroughly describe the use of the software.]

### Technical Information

[Disclose all definitions of parameters.]

### **Other Labeling Requirements**

The label to the device on which the HRV analysis software is implemented, or the operator's manual if the submission is for the software option only, must bear the following statements:

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

**Caution:** The use of HRV analysis for the diagnosis or prognosis of a particular disease or condition has not been established, and is therefore considered investigational.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

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

May 16, 1995

BIOSENSOR CORP.  
13755 FIRST AVENUE NORTH  
PLYMOUTH, MN 55441  
ATTN: MR. DARREN D. DERSHEM

510(k) Number: K950944  
Product: AMBULATORY  
(HOLTER)  
RECORDING SYSTEM

The additional information you have submitted has been received.

We will notify you when the processing of this submission has been completed or if any additional information is required. Please remember that all correspondence concerning your submission MUST be sent to the Document Mail Center (HFZ-401) at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification submission. Because of equipment and personnel limitations we cannot accept telefaxed material as part of your official premarket notification submission, unless specifically requested of you by an FDA official.

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

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

Sincerely yours,

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

140

**For DCRND Use Only**

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

Device: <u>Amblulatory (Walker) Recording System</u>		<u>K950944</u>
Submitter:		
Date received: Original 510(k): <u>2-17-95</u>	This submission: <u>5-12-95</u>	Review cycle <u>(2)</u>
Review Tier (circle one): I, II, III <i>(for Tier I, complete items 1-5 on the Screening Checklist)</i>		
Question	Yes	No
A. Is the product a device?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
B. Is the device exempt from 510(k) by regulation or policy?	<input type="checkbox"/>	<input checked="" type="checkbox"/>
C. Expedited Review Status: Requested by sponsor	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Identified by DCRND	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Granted by DCRND	<input type="checkbox"/>	<input checked="" type="checkbox"/>
D. Has this device has been the subject of a previous NSE decision?	<input type="checkbox"/>	<input type="checkbox"/>
If yes, does this new 510(k) address the NSE Issues(s), e.g., performance data?	<input type="checkbox"/>	<input type="checkbox"/>
E. Has the sponsor been the subject of an integrity investigation?	<input type="checkbox"/>	<input type="checkbox"/>
If yes, has the ODE Integrity Officer given permission to proceed with the review?	<input type="checkbox"/>	<input type="checkbox"/>

Administrative Reviewer Signature: Bill Sutton Date: JUN 7 1995  
Bill Sutton

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

Device: <u>Ambulatory (HOLTER) Recording SYSTEM K950944</u>			
Submitter: <u>BIOSENSOR CORP.</u>			
Items which should be Included <i>(circle missing &amp; needed information)</i>	✓		✓ if Item Needed & MISSING
	Yes	No	
1. General information: a) trade name, b) common name, c) establishment registration #, d) address of manufacturer, e) device class, f) new or modification, g) predicate device identified, h) 513/514 compliance (none yet available)	✓		
2. SMDA requirements: 510(k) summary or statement (any Class device)	✓		
Class III Certification & Summary (if Class III)	✓		
3. Proposed Labeling: a) package labels, b) statement of intended use, c) advertisements or promotional materials, d) MRI compatibility (if claimed)	✓		
4. Description of device (or modification) including diagrams, engineering drawings, photographs, service manuals	✓		
5. Comparison Information (similarities and differences) to named legally marketed equivalent device (table preferred) should include: a) labeling, b) intended use, c) physical characteristics, d) anatomical sites, f) performance (bench, animal, clinical) testing, g) safety characteristics	✓		
6. Biocompatibility data for all patient-contacting materials, OR, certification of identical material/formulation: a) component & material, b) identify patient-contacting materials, c) biocompatibility of final sterilized product	✓		
7. Sterilization and expiration dating information: a) sterilization method, b) SAL, c) packaging, d) specify pyrogen free, e) ETO residues, f) radiation dose	N/A		
8. Software validation & verification: a) hazard analysis, b) level of concern, c) development documentation, d) certification	✓		
9. Meets current DCRND guidelines and applicable standards for this device: a) specify guidance, b) comply with content			

Items shaded under "No" are necessary for all submissions.  
Any checks in the last (Needed & MISSING) column requires resubmission.

Passed 510(k) Screen: Yes No

Signature: Bin Sam

Date: JUN 7 1995

K950944 / S1



13755 First Avenue North  
Plymouth, MN 55441-9760  
612-449-9100  
612-449-8966 Fax  
MAY 13 10 32

FDA/CDRH/OCE/DMC

May 11, 1995

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

RE: Request for additional information on 510(k) K950944

In response to your request for additional information on our 510(k) submission (K950723), the following data is submitted.

Biosensor has received a DCRND Premarket Notification 510(k) Screening Checklist requesting additional information on the following items.

- #3. Proposed Labeling: b) statement of intended use, c) advertisements or promotional materials.
- #4. Description of device (or modification) including diagrams, engineering drawings, or photographs.
- #5. Comparison Information: a) labeling, b) intended use, d) anatomical sites, g) safety characteristics.
- #8. Software validation & verification:

The following pages contain additional information to fulfill your request and accompany the original 510(k) information. Biosensor believes it provides the information you have requested.

Sincerely,

Darren D. Dershem  
Quality Assurance

**Additional Proposed Labeling**

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

### Statement of Intended Use

The Full Disclosure Monitoring System is intended for patients requiring ambulatory (Holter ) monitoring from 1 to 24 hours. Such monitoring is most frequently used in the indications listed below:

#### Current Uses of Ambulatory ECG Recording<sup>1</sup>

- 1.0 Evaluation of symptoms suggesting arrhythmia or myocardial ischemia.
- 1.1 Evaluation of ECG documenting therapeutic interventions in individual patients or groups of patients.
- 1.2 Evaluation of patients for silent ischemia.
- 1.3 Evaluation of patients with pacemakers.
- 1.4 Evaluation of individual patient's response upon resuming occupational or recreational activities (e.g. after M.I., cardiac surgery).
- 1.5 Evaluation of clinical syndromes and situations where arrhythmia's may increase risk of sudden death.
- 1.6 Clinical and epidemiological research studies.

---

<sup>1</sup>Portions from Ambulatory Electrocardiographic Recording. Wenger NK, Mock MB, and Reingquist I, Year Book Medical Publishers, Copyright 1981.

### **Precautions and Contraindications**

Precautions as follows:

1. **Good incoming ECG signals are essential to quality computerized ECG analysis. Skin site preparation is important, as it is directly related to ECG signal quality.**
2. **System equipment is not waterproof. Do not allow moisture to penetrate equipment openings such as the desktop computer's keyboard or the patient recorder's battery compartment.**
3. **Patients should avoid heavy manufacturing equipment and malfunctioning electrical equipment. Such equipment may effect the functioning of the patient recorder.**
4. **Patients should avoid soaking skin electrodes. Too much moisture can cause air pockets resulting in poor electrical connection.**
5. **Do not start the patient recorder erase procedure until the previous patients data has been thoroughly transferred. Once the erase procedure has been started in the patient recorder all data is lost.**
6. **Use 4 AA good quality alkaline batteries for one 24-hour procedure. We recommend using new batteries for each procedure. For best performance do not use rechargeable batteries.**

**Contraindications: None known.**

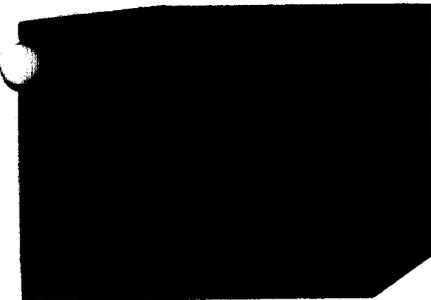
**Biosensor certifies that the above caution, Statement of Intended Uses and Precautions and Contraindications labeling will be added to the final printed help manual.**

The following five pages contain a copy of a brochure for the advertisements or promotional materials request.

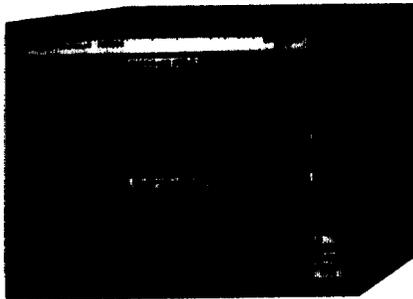
**Biosensor**   
CORPORATION



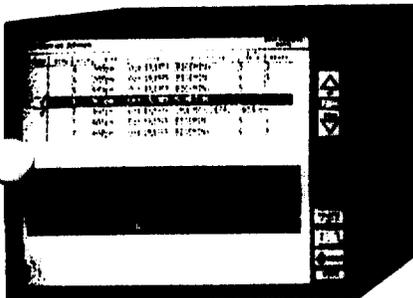
**HOLTER MONITORING SYSTEMS**



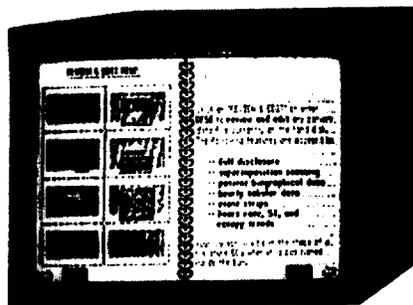
Rapid Access To Any Minute Of The Day.



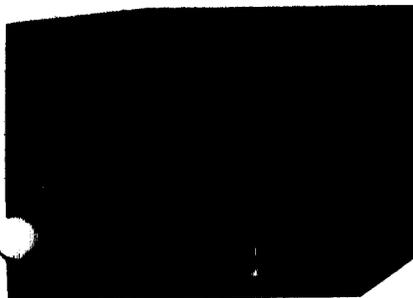
Bar Charts, Graphs, And Tabulations To Quickly Spot Trends.



Computer Generated ECG Summary, With Unique Event Chronology Listing.



Built-in Help, Whenever Needed.



Optional High Speed Superimposition.

### ***Simplicity and Speed***

■ Holter monitoring has never been easier. Biosensor's Holter system has outstanding on-screen graphics that use the latest video command technology for ease of learning. An on-screen help manual is always available, and automatically opens to the right page for answers to any questions. Your whole staff will quickly be using the Biosensor system with confidence.

■ The remarkable speed of Biosensor's Holter system means that summary reports are prepared in minutes. Fast backup records are made for up to 24 hours, on a dot-matrix or laser printer. If a rapid full-disclosure printout is a priority, the laser printer gives you a 24-hour printout in just 20 minutes. And 24-hour backup data can also be archived on a floppy diskette.

### ***Maximum Patient Comfort***

■ The small size of Biosensor's patient recorder does away with bulky recorders and noisy tape drives. The 140-gram recorder fits easily under clothing or in a shirt pocket. It's so small, patients won't even know they're wearing it.

### ***Cost-Effective and Reliable, Now And For The Future***

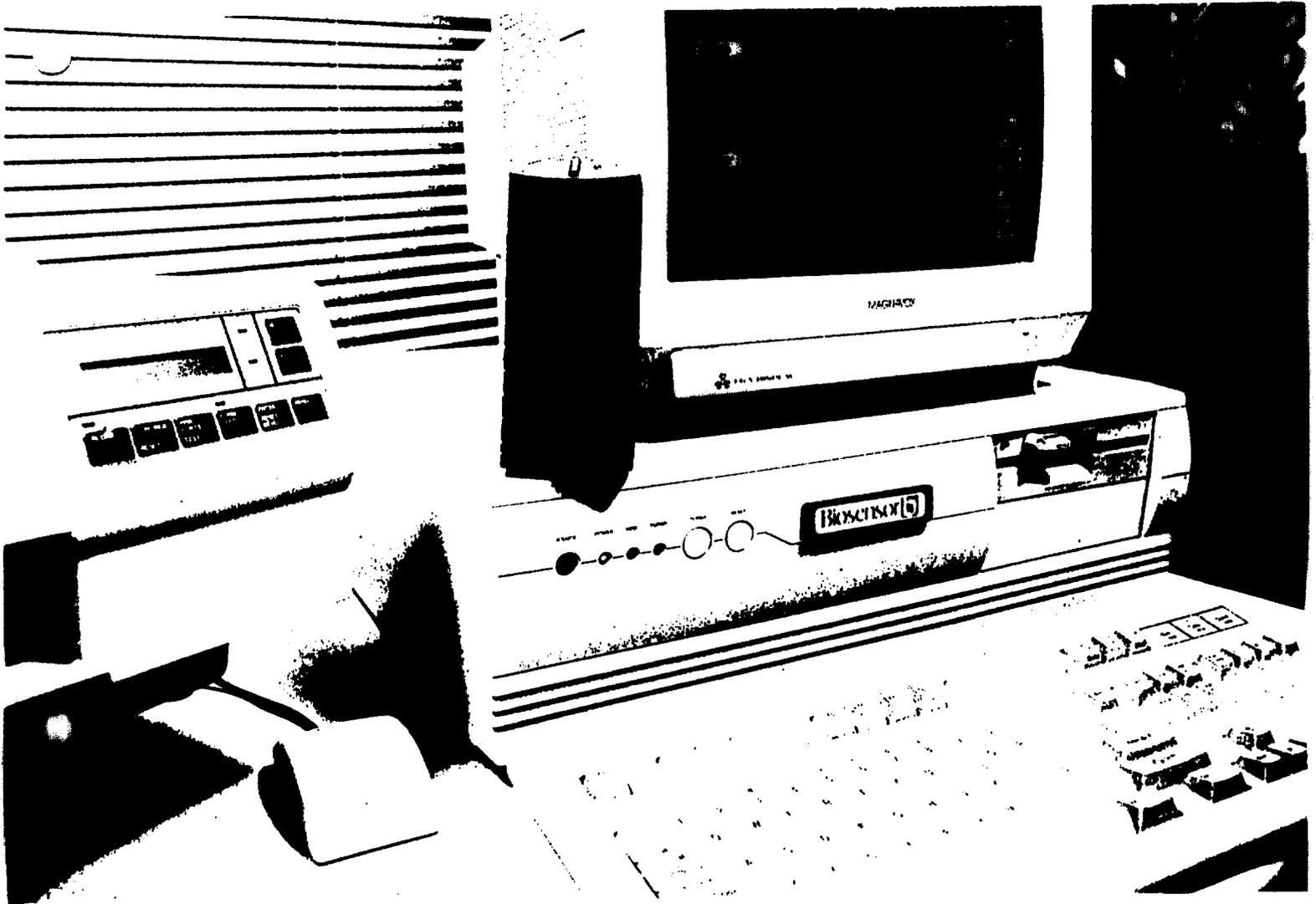
■ The Biosensor Holter system, based on the economy and reliability of IBM-PC design, is the most cost-effective system available. It gives you performance superior to systems that cost much more, with a full range of products to suit any budget.

■ The software-based construction of Biosensor's Holter system means that the



computer base station is available for other applications, including ambulatory blood pressure and spirometry. And new techniques and procedures can be instantly implemented with new software—there's no more risk that your system will become obsolete.

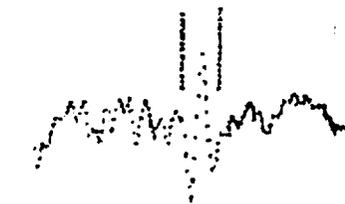
■ Within the patient recorder, Biosensor's solid state digital components are unsurpassed for mechanical reliability, and eliminate the frequent, costly and inconvenient breakdowns of tape drives. Solid state patient recorders can also be updated with new software, making them the cost-effective alternative.



## Superior Performance With Comprehensive Capabilities

■ Biosensor's extensive system capabilities give you a comprehensive Holter report you can depend on. ARGUS has the advantage of two decades of proven superior performance, recognized by more than 25 publications and one-on-one comparisons with high-priced scanners. For more information, ask for our easy-to-read tech note, *The ARGUS Algorithm*.

■ The development of digital storage technology means that tape storage of ECG data is becoming obsolete. Because Biosensor stores ECG data digitally, tape stretch and distortions of tape readers are eliminated. Low-frequency episodes like ST segment depressions are reliably stored, providing the highest quality recordings available.



Optimize Report Quality Using The "Argus" Digital Analysis Algorithm.

## Optional Superimposition

■ Biosensor software gives you the additional capability for true 60X superimposition scanning, a valuable addition to Holter practice. High-speed visual review of 24-hour ECG data is used to:

- Verify and update the summary report
- Check for p-wave abnormalities, including first-degree heart block
- Watch for shifts in ST segments

Quickly-moving displays of all ECG data, R-R intervals, rates, histograms and stop/start/expand capabilities make Biosensor's superimposition complete.

## **SYSTEM SPECIFICATIONS**

### **COMPUTER SYSTEM REQUIREMENTS:**

IBM PC Compatible (80386 or Higher Speed Recommended)  
Hard Disk, 20 Megabytes or Greater  
Floppy Drive, 3-1/2" or 5-1/4" High Density  
RAM: 2 MByte or Greater  
Parallel Port for Printer  
EGA or Higher Graphics Capability  
Open Slot for Holter Communication Card, Supplied with System Software

### **OPERATING SYSTEM:**

DOS 3.1 or Higher

### **MONITOR REQUIREMENTS**

EGA or Higher Graphics Capability  
Color or Monochrome

### **PRINTER OPTIONS:**

Laser (HP Laserjet Compatible) or Dot Matrix (LQ 1500 Graphics Compatible)  
The following Printers Are Recommended: HP Laser Series IIP,  
HP Laser Series IIIP, HP4, EPSON Action 1500, Panasonic 24 pin

### **OPTIONAL MOUSE:**

Bus or Serial Architecture/Graphical User Interface.

### **PATIENT RECORDER:**

Size: 15 x 6 x 2 cm (5.9" x 2.5" x 0.8")  
Weight: 140g (5oz.)  
Power Supply: 4x AA Duracell Alkaline/2.4 Ah  
Patient Event Marker  
Data Storage: Digital  
Frequency Response: 0.05-40 Hz at 3dB Points  
Data Transfer: Bi-Directional Parallel  
Programmability: Tachycardia Rates, Bradycardia Rates, Pause Intervals, ST  
Analysis, SV Prematurity  
Algorithm: 2 channel Argus ECG Diagnostic Method

**SOFTWARE:**

Multicolor, High Resolution, High Speed Graphical Interface

Built-in Help Manual

Morphologic Scanning

Summary Report Printout

Operator Overrides For Report Printout Revisions

Full Disclosure Printouts:

1, 2 or 3 Channel

15, 30, or 60 Minutes Per Page

Selection of Time Desired

Full Size Printout For Any Time Entry

Optional superimposition Scanning

Diskette Backup For Permanent Storage

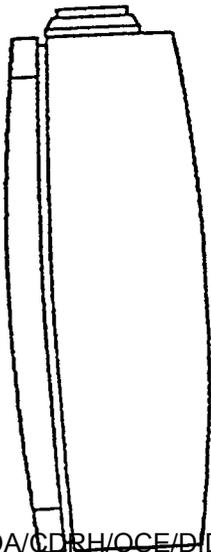
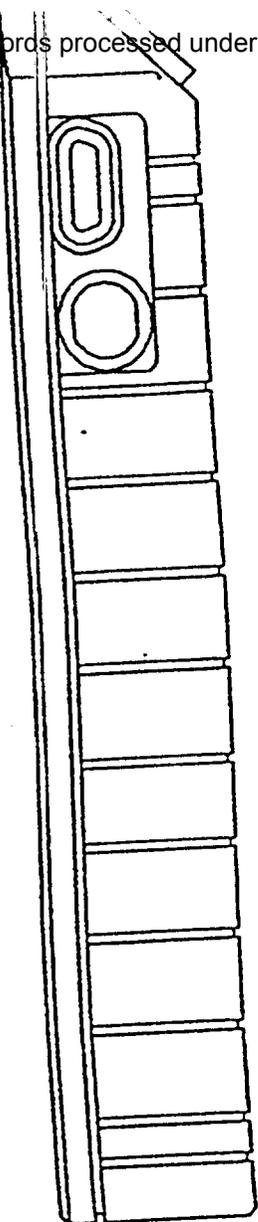
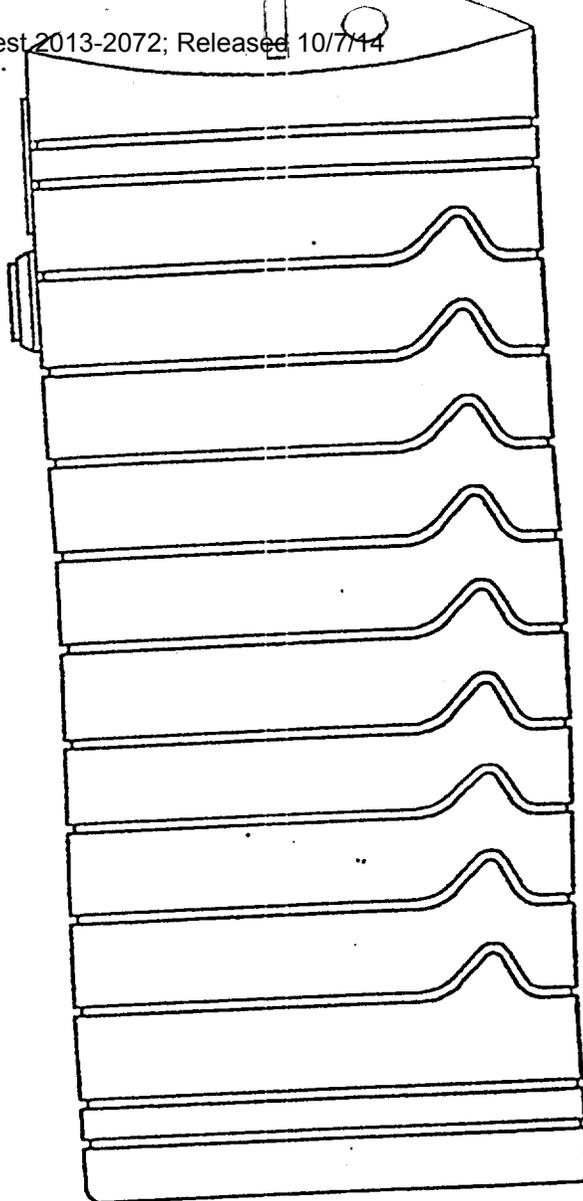
**Description of device (or modification) including diagrams, engineering drawings and a copy of a device photograph.**

**The following seven pages contain the requested device diagrams. The physical characteristics of the device are shown on the diagrams. A summary of the devices physical characteristics are as follows:**

**Size: 15 x 6 x 2 cm (5.9" x 2.5" x 0.8")**

**Weight: 140g (5 oz)**

**Power Supply: 4 x AA Alkaline batteries/ 2.4 Ah**



APPROVAL	DATE	TITLE	
DRAWN M. MUESING	8-8-89	Biosensor CORPORATION	
ENG'G		HOLTER RECORDER -	
ENG.MGR.		FINAL ASSY DRAWING	
TOLERANCE: UNLESS OTHERWISE SPECIFIED		SIZE	FSCM NO.
.XX = ±0.010 .XXX = ±0.005		B	
ANGLE = ±0.5°		SCALE	DWG NO.
DIMENSIC IN INCHES		1=1	4G200.E1
		WT.	HEET 1 OF













**Additional comparison information of proposed Holter device  
with existing K922027 Holter Device**

**Labeling Comparisons:**

A copy of the devices label is shown on the next page. The same type of label used on the K922027 device will be used on the proposed device. The proposed device serial numbers will start with a unique number sequence. The device changes as indicated on the original 510(k) are changes to the internal components and their function. The outside molded case will have the same general appearance and functionality. Product literature contains the same claims, except that the system literature may in the future note the presence of high resolution ECG strips, pacemaker analysis and HRV capabilities.



**Intended Use Comparisons:**

**Proposed Device**

The Full Disclosure Monitoring System is intended for patients requiring ambulatory (Holter) monitoring from 1 to 24 hours. Such monitoring is most frequently used in the indications listed below:

Evaluation of symptoms suggesting arrhythmia or myocardial ischemia.

Evaluation of ECG documenting therapeutic interventions in individual patients or groups of patients.

Evaluation of patients for silent ischemia.

Evaluation of patients with pacemakers.

Evaluation of individual patient's response upon resuming occupational or recreational activities (e.g. after M.I., cardiac surgery).

Evaluation of clinical syndromes and situations where arrhythmia's may increase risk of sudden death.

Clinical and epidemiological research studies.

**K922027 Device**

The Full Disclosure Monitoring System is intended for patients requiring ambulatory (Holter) monitoring from 1 to 24 hours. Such monitoring is most frequently used in the indications listed below.

Evaluation of symptoms suggesting arrhythmia or myocardial ischemia.

Evaluation of ECG documenting therapeutic interventions in individual patients or groups of patients.

Evaluation of patients for silent ischemia.

Does Not provide pacemaker evaluation.

Evaluation of individual patient's response upon resuming occupational or recreational activities (e.g. after M.I., cardiac surgery).

Evaluation of clinical syndromes and situations where arrhythmia may increase risk of sudden death.

Clinical and epidemiological research studies.

**Anatomical Site Comparisons:**

**Proposed Device**

Device is applied the same as the K992027 device.

**K922027 Device**

Device is applied the same as the proposed device.

**Safety Characteristics Comparisons**

**Proposed Device**

Safety characteristics are the same as the K922027 device.

**K922027 Device**

Safety characteristics are the same as the proposed device.

**510(k) Software Documentation Matrix**

### **Hazard Analysis**

Biosensor believes that the risk to the patient from the device is minimal. The device is battery powered and does not provide any direct power connections to the patient. Patient isolation is provided. The skin electrodes applied to the patients skin may cause some minor discomfort and medical professionals are experienced at electrode placement techniques and applications. The degree of the devices influence depends on the physicians review and interpretation of the raw full disclosure ECG data.

Biosensor has designated this software with a minor concern level. Although this software does provide a preliminary Summary report, user experience in the field of ECG is necessary to interpret the test information and raw ECG waveforms, and in optional editing of the final report. This device is principally used as a screening tool and physician review of the raw full disclosure data is necessary to determine the presence of any significantly important ECG activity. This original 510(k) described the device changes to be primarily associated with the addition of a pacemaker detection circuit and increase in memory, which are principally hardware changes.

### **Functional Requirements & System Specifications**

The software changes associated with the additional hardware changes are separate modules with specific purposes and functions. The pacemaker detection hardware does produce a hardware interrupt that enables software to simply position the occurrence of the pace stimulus in the overall stream of raw data. The software controls of this interrupt are considered to be extremely insignificant in comparison to the source code transferred from the approved K922027 device. The same source code used in the approved K922027 can be used in the proposed device because the devices use the same microprocessor families. The memory increase allows Biosensor Holter systems to store higher resolution ECG data compared to the predecessor product. The result is a higher resolution ECG tracing, similar to when the memory capacity was increased and approved in the K922027 device. The HRV statistical calculation is simply the mean and standard deviation calculations on the R-R interval data. Biosensor is approved for R-R interval reporting in the K922027 device.

Biosensor has implemented specific revision control techniques, revision histories, and a revision control system with ckeekin/checkout controls to assure proper revision handling. In addition design reviews are implemented to review requested changes as a result of ongoing continuous improvement techniques. Internal source code asserts are used in test systems to identify unexpected errors. In addition install checks and checksums are used for functional minimums.

### **Software Design & Development Techniques**

The software development process used is as follows.

1. A specification concept and requirements phase has been performed.
2. Data flow and data context diagrams have been completed and documented.
3. Module hierarchy of software sections has been performed.
4. Code has been designed and implemented according to specifications, module flow charts and design review. Top down design and bottom up development of software source code has been followed.
5. Code modules have been integrated to produce the expected results.
6. Design reviews have been performed to assure development progress.

### **Verification & Validation**

During the development process source code modules have been tested and results validated by white box testing techniques. Module integration testing has been performed on the various software features and components.

### **Test Results and Analysis**

Biosensor believes that test results and analysis demonstrates that the intended software performance has been met.

### **Certification**

Biosensor confirms that standard software development techniques were used and that good quality assurance procedures were adhered to during this software development phase. Biosensor believes that test results demonstrate that the system specifications and functional requirements were met.

**Biosensor certifies that all the information provided in this 510(k) to be true and accurate.**



## DEPARTMENT OF HEALTH &amp; HUMAN SERVICES

Public Health Service

MAY 10 1995

Re: K950944

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20856

Mr. Steve Springrose  
Biosensor Corporation  
13755 First Avenue North  
Plymouth, Minnesota 55441-9760

Ambulatory (Holter) Recording System

Dated: February 15, 1995

Received: February 17, 1995

Dear Mr. Springrose:

We have completed an administrative review of your section 510(k) Premarket Notification (510(k)) of intent to market the device referenced above. This administrative review is part of the Refuse to Accept procedure. Our review indicates that your 510(k) is administratively incomplete; therefore, we are holding your 510(k), pending receipt of additional data. We believe that basic information is necessary for us to begin our substantive review and to determine whether or not this device is substantially equivalent to devices marketed prior to May 28, 1976, the enactment date of the Medical Device Amendments to the Federal Food, Drug, and Cosmetic Act (act). Therefore, in order for us to begin the substantive review of your 510(k) submission we require the information indicated on the enclosed "DCRND Screening Checklist."

If you adopt the format outlined in the enclosed "Draft DCRND Guidance", you will greatly facilitate our review. The additional information should be submitted in duplicate, referencing the 510(k) number above to:

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

Please note that since your 510(k) submission has not been substantively reviewed, additional information may be required during the review process and the file may again be placed on hold. You may not market this device until you have provided adequate information as required by 21 CFR 807.87(f) and (h), and you have received a letter from the Food and Drug Administration (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 exemptions (IDE) regulations (21 CFR part 812).

If the requested information 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); therefore, all information previously submitted must be resubmitted so that your new 510(k) is complete. FDA cannot accept telefaxed material as part of your official submission responsive to this letter, unless specifically requested of you by an FDA official.

If you have any questions pertaining to the scientific requirements necessary to process your application, please contact Michael Gluck, D.Sc., at (301) 443-8609. If you have questions that pertain to the administrative requirements, please contact Senora Smallwood or William Sutton at (301) 443-8320. If you need copies of regulations or guidance documents, please contact the Division of Small Manufacturers Assistance at their toll free number (800) 628-2041 or at (301) 443-6597.

Sincerely yours,



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

Enclosures



# Memorandum

Date \_\_\_\_\_

From REVIEWER(S) - NAME(S) Bill Sutton

Subject 510(k) NOTIFICATION K950944

To THE RECORD

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

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

*mm*  
*5/10/15*

Additional Comments:

Is this device subject to Postmarket Surveillance? Yes  No

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

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

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Does the submitter request under 21 CFR ~~312.63~~ 312.65:\*

Predicate Product Code w/panel and class: \_\_\_\_\_

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

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

REVIEW: \_\_\_\_\_

(BRANCH CHIEF) BRANCH CODE (DATE)

FINAL REVIEW: \_\_\_\_\_

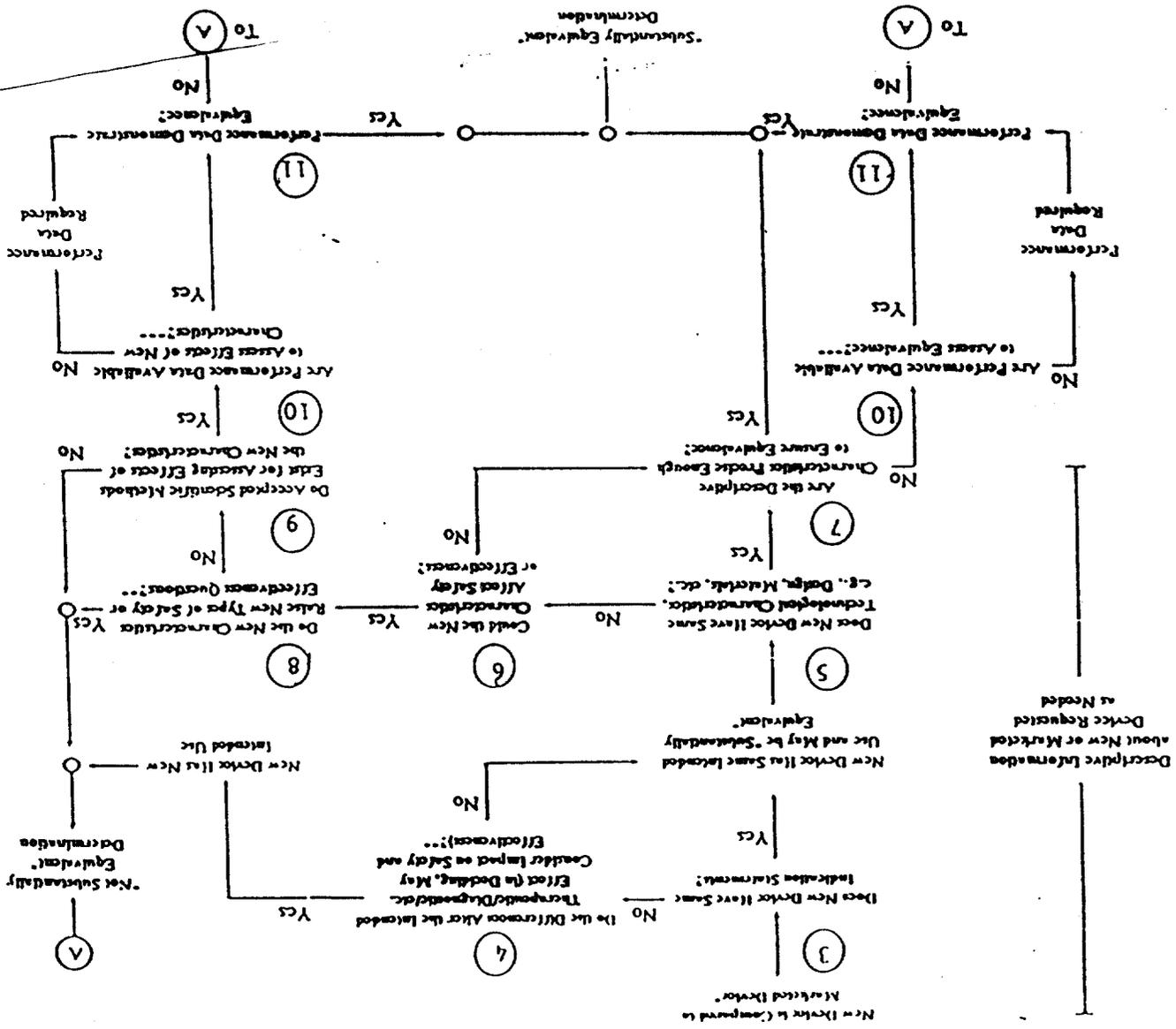
(DIVISION DIRECTOR) (DATE)

\*DOES NOT APPLY TO ANY "SE" DECISIONS

Revised 11/18/91

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### 510(k) 'SUBSTANTIAL EQUIVALENCE' DECISION-MAKING PROCESS (DETAILED)



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

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

... compare new device to marketed device. FDA requests additional information if the relationship between marketed and "predicate" (pre-amendments or reclassified post-amendments) devices is unclear.

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**For DCRND Use Only**

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

*\* With HEART Rate Variability*

Device: <i>Embolyx (Filter) Recording System</i>		<i>16950944</i>
Submitter: <i>Biosensor Corporation</i>		
Date received: Original 510(k): <i>2-17-95</i>	This submission: <i>2-17-95</i>	Review cycle <i>(1)</i>
Review Tier (circle one): I, II, III  <i>(for Tier I, complete items 1-5 on the Screening Checklist)</i>		
Question	Yes	No
A. Is the product a device?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
B. Is the device exempt from 510(k) by regulation or policy?	<input type="checkbox"/>	<input checked="" type="checkbox"/>
C. Expedited Review Status: Requested by sponsor	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Identified by DCRND	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Granted by DCRND	<input type="checkbox"/>	<input checked="" type="checkbox"/>
D. Has this device has been the subject of a previous NSE decision?	<input type="checkbox"/>	<input type="checkbox"/>
If yes, does this new 510(k) address the NSE Issues(s), e.g., performance data?	<input type="checkbox"/>	<input type="checkbox"/>
E. Has the sponsor been the subject of an integrity investigation?	<input type="checkbox"/>	<input type="checkbox"/>
If yes, has the ODE Integrity Officer given permission to proceed with the review?	<input type="checkbox"/>	<input type="checkbox"/>

Administrative Reviewer Signature: *Bill Sutton* Date: MAY 3 1995  
Bill Sutton

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

\* With HEART RATE Variability

Device: <u>ambulatory (Holter) Recording System K950944</u>			
Submitter: <u>Biosensor Corporation</u>			
Items which should be Included <i>(circle missing &amp; needed information)</i>	✓		✓ if Item Needed & MISSING
	Yes	No	
1. General information: a) trade name, b) common name, c) establishment registration #, d) address of manufacturer, e) device class, f) new or modification, g) predicate device identified, h) 513/514 compliance (none yet available)	✓		
2. SMDA requirements: 510(k) summary or statement (any Class device)	✓		
Class III Certification & Summary (if Class III)	✓		
3. Proposed Labeling: a) package labels, b) statement of intended use, c) advertisements or promotional materials, d) MRI compatibility (if claimed)			✓
4. Description of device (or modification) including diagrams, engineering drawings, photographs, service manuals			✓
5. Comparison Information (similarities and differences) to named legally marketed equivalent device (table preferred) should include: a) labeling, b) intended use, c) physical characteristics, d) anatomical sites, f) performance (bench, animal, clinical) testing, g) safety characteristics			✓
6. Biocompatibility data for all patient-contacting materials, OR, certification of identical material/formulation: a) component & material, b) identify patient-contacting materials, c) biocompatibility of final sterilized product		✓	
7. Sterilization and expiration dating information: a) sterilization method, b) SAL, c) packaging, d) specify pyrogen free, e) ETO residues, f) radiation dose	N/A		
8. Software validation & verification: a) hazard analysis, b) level of concern, c) development documentation, d) certification			✓
9. Meets current DCRND guidelines and applicable standards for this device: a) specify guidance, b) comply with content			

Items shaded under "No" are necessary for all submissions.  
Any checks in the last (Needed & MISSING) column requires resubmission.

Passed 510(k) Screen: Yes No

Signature: Bill Swan Date: MAY 3 1995

510(K) ROUTE SLIP

510(k) NUMBER K950944 PANEL CV DIVISION DCRND BRANCH PEDB

TRADE NAME AMBULATORY (HOLTER) RECORDING SYSTEM

COMMON NAME \_\_\_\_\_

PRODUCT CODE \_\_\_\_\_

APPLICANT BIOSENSOR CORP.

SHORT NAME BIOSENSOR

CONTACT DARREN D DERSHEM

DIVISION \_\_\_\_\_

ADDRESS 13755 FIRST AVENUE NORTH

PLYMOUTH, MN 554419760

PHONE NO. (612) 449-9100

FAX NO. (612) 449-8966

MANUFACTURER BIOSENSOR CORP.

REGISTRATION NO. 2183509

DATE ON SUBMISSION 15-FEB-95

DATE DUE TO 510(K) STAFF 03-MAY-95

DATE RECEIVED IN ODE 17-FEB-95

DATE DECISION DUE 18-MAY-95

DECISION \_\_\_\_\_

DECISION DATE \_\_\_\_\_

*Delete - Duplicate of K950723  
4/10/95  
CLASS III*

K \_\_\_\_\_ "SUBSTANTIAL EQUIVALENCE" (SE) DECISION MAKING DOCUMENTATION

REVIEWER: \_\_\_\_\_ DIVISION/BRANCH: \_\_\_\_\_

TRADE NAME: \_\_\_\_\_ COMMON NAME: \_\_\_\_\_

PRODUCT TO WHICH COMPARED: \_\_\_\_\_  
(510(k) NUMBER IF KNOWN)

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

1. IS PRODUCT A DEVICE? 

--	--

 - IF NO STOP

2. DEVICE SUBJECT TO 510(k)? 

--	--

 - IF NO STOP

3. SAME INDICATION STATEMENT? 

--	--

 - IF YES GO TO 5

4. DO DIFFERENCES ALTER THE EFFECT OR RAISE NEW ISSUES OF SAFETY OR EFFECTIVENESS? 

--	--

 - IF YES STOP - 

5. SAME TECHNOLOGICAL CHARACTERISTICS? 

--	--

 - IF YES GO TO 7

6. COULD THE NEW CHARACTERISTICS AFFECT SAFETY OR EFFECTIVENESS? 

--	--

 - IF YES GO TO 8

7. DESCRIPTIVE CHARACTERISTICS PRECISE ENOUGH? 

--	--

 - IF NO GO TO 10  
- IF YES STOP - 

8. NEW TYPES OF SAFETY OR EFFECTIVENESS QUESTIONS? 

--	--

 - IF YES STOP - 

9. ACCEPTED SCIENTIFIC METHODS EXIST? 

--	--

 - IF NO STOP - 

10. PERFORMANCE DATA AVAILABLE? 

--	--

 - IF NO REQUEST DATA

11. DATA DEMONSTRATE EQUIVALENCE? 

--	--



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

**NARRATIVE DEVICE DESCRIPTION**

1. INTENDED USE: \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

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

SUMMARY: \_\_\_\_\_  
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**EXPLANATIONS TO "YES" AND "NO" ANSWERS TO QUESTIONS ON PAGE 1 AS NEEDED**

1. **EXPLAIN WHY NOT A DEVICE:** \_\_\_\_\_

\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

2. **EXPLAIN WHY NOT SUBJECT TO 510(k):** \_\_\_\_\_

\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

3. **HOW DOES THE NEW INDICATION DIFFER FROM THE PREDICATE DEVICE'S INDICATION:** \_\_\_\_\_

\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

4. **EXPLAIN WHY THERE IS OR IS NOT A NEW EFFECT OR SAFETY OR EFFECTIVENESS ISSUE:** \_\_\_\_\_

\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

5. **DESCRIBE THE NEW TECHNOLOGICAL CHARACTERISTICS:** \_\_\_\_\_

\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

6. **EXPLAIN HOW NEW CHARACTERISTICS COULD OR COULD NOT AFFECT SAFETY OR EFFECTIVENESS:** \_\_\_\_\_

\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

7. EXPLAIN HOW DESCRIPTIVE CHARACTERISTICS ARE NOT PRECISE ENOUGH: \_\_\_\_\_

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

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

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10. EXPLAIN WHAT PERFORMANCE DATA IS NEEDED: \_\_\_\_\_

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

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ATTACH ADDITIONAL SUPPORTING INFORMATION



Yes Present Omission Justified  
 No Inadequate Omitted

Critical Elements:		
A. Is the product a device?	<input type="checkbox"/>	<input type="checkbox"/>
B. Is the device exempt from 510(k) by regulation or policy?	<input type="checkbox"/>	<input type="checkbox"/>
C. Is device subject to review by CDRH?	<input type="checkbox"/>	<input type="checkbox"/>
D. (i) Are you aware that this device has been the subject of a previous NSE decision?  (ii) If yes, does this new 510(k) address the NSE issue(s) (e.g., performance data)?	<input type="checkbox"/>	<input type="checkbox"/>
E. (i) Are you aware of the submitter being the subject of an integrity investigation?  If yes, consult the ODE Integrity Officer.  (ii) Has the ODE Integrity Officer given permission to proceed with the review? (Blue Book Memo #I91-2 and Federal Register 90N-0332, September 10, 1991.)	<input type="checkbox"/>	<input type="checkbox"/>

Yes  
 Present  
 Omission Justified

No  
 Inadequate  
 Omitted

<p>F. Does the submission contain the information required under sections 510(k), 513(f), and 513(i) of the Federal Food, Drug, and Cosmetic Act (Act) and Subpart E of Part 807 in Title 21 of the Code of Federal Regulations?:</p>		
<p>1. Device trade or proprietary name</p>	<input type="checkbox"/>	<input type="checkbox"/>
<p>2. Device common or usual name or classification name</p>	<input type="checkbox"/>	<input type="checkbox"/>
<p>3. Establishment registration number (only applies if establishment is registered)</p>	<input type="checkbox"/>	<input type="checkbox"/>
<p>4. Class into which the device is classified under (21 CFR Parts 862 to 892)</p>	<input type="checkbox"/>	<input type="checkbox"/>
<p>5. Classification Panel</p>	<input type="checkbox"/>	<input type="checkbox"/>
<p>6. Action taken to comply with Section 514 of the Act</p>	<input type="checkbox"/>	<input type="checkbox"/>
<p>7. Proposed labels, labeling and advertisements (if available) that describe the device, its intended use, and directions for use (Blue Book Memo #G91-1)</p>	<input type="checkbox"/>	<input type="checkbox"/>

Yes  
 Present  
 Omission Justified

No  
 Inadequate  
 Omitted

8. A 510(k) summary of safety and effectiveness or a 510(k) statement that safety and effectiveness information will be made available to any person upon request	<input type="checkbox"/>	<input type="checkbox"/>
9. For class III devices only, a class III certification and a class III summary	<input type="checkbox"/>	<input type="checkbox"/>
10. Photographs of the device	<input type="checkbox"/>	<input type="checkbox"/>
11. Engineering drawings for the device with dimensions and tolerances	<input type="checkbox"/>	<input type="checkbox"/>
12. The marketed device(s) to which equivalence is claimed including labeling and description of the device	<input type="checkbox"/>	<input type="checkbox"/>
13. Statement of similarities and/or differences with marketed device(s)	<input type="checkbox"/>	<input type="checkbox"/>
14. Data to show consequences and effects of a modified device(s)	<input type="checkbox"/>	<input type="checkbox"/>
II. Additional Information that is necessary under 21 CFR 807.87(h):		
A. Submitter's name and address	<input type="checkbox"/>	<input type="checkbox"/>

Yes Present Omission Justified  
 No Inadequate Omitted

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

Yes  
Present  
Omission Justified

No  
Inadequate  
Omitted

new device		
bench testing	<input type="checkbox"/>	<input type="checkbox"/>
animal testing	<input type="checkbox"/>	<input type="checkbox"/>
clinical data	<input type="checkbox"/>	<input type="checkbox"/>
D. Sterilization information	<input type="checkbox"/>	<input type="checkbox"/>
E. Software information	<input type="checkbox"/>	<input type="checkbox"/>
F. Hardware information	<input type="checkbox"/>	<input type="checkbox"/>
G. If this 510(k) is for a kit, has the kit certification statement been provided?	<input type="checkbox"/>	<input type="checkbox"/>
H. Is this device subject to issues that have been addressed in specific guidance document(s)? If yes, continue review with checklist from any appropriate guidance documents. If no, is 510(k) sufficiently complete to allow substantive review?	<input type="checkbox"/>	<input type="checkbox"/>

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

## Public Health Service

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

March 06, 1995

BIOSENSOR CORP.  
 13755 FIRST AVENUE NORTH  
 PLYMOUTH, MN 55441  
 ATTN: DARREN D. DERSHEM

510(k) Number: K950944  
 Received: 17-FEB-95  
 Product: AMBULATORY  
 (HOLTER)  
 RECORDING SYSTEM

The Center for Devices and Radiological Health (CDRH), Office of Device Evaluation (ODE), has received the Premarket Notification you submitted in accordance with Section 510(k) of the Federal Food, Drug, and Cosmetic Act (Act) for the above referenced product. We have assigned your submission a unique 510(k) number that is cited above. Please refer prominently to this 510(k) number in any future correspondence that relates to this submission. We will notify you when the processing of your premarket notification has been completed or if any additional information is required.

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

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

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

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

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

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

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

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

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

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

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

Furthermore, the new legislation, section 522(a)(1), of the Act, states that if your device is a permanent implant the failure of which may cause death, you may be subject to required postmarket surveillance. If the premarket notification for your device was originally received on or after November 8, 1991, is subsequently found to be substantially equivalent to an Aneurysm Clip, Annuloplasty Ring, Artificial Embolization Device, Automatic Implanted Cardioverter Defibrillator System, Cardiovascular Intravascular Filter, Cardiovascular Permanent Pacemaker Electrode (Lead), Central Nervous System Fluid Shunt, Coronary Vascular Stent, Implantable Pacemaker Pulse Generator, Implanted Diaphragmatic/ Phrenic Nerve Stimulator, Intracardiac Patch or Pledget, Intravascular Occluding Catheter, Replacement Heart Valve, Total Artificial Heart, Tracheal Prosthesis, Vascular Graft Prosthesis (less than 6 mm diameter), Vascular Graft Prosthesis (6 mm or greater diameter), Vena Cava Clip, or Ventricular Assist Device - Implant, you will be subject to the required postmarket surveillance and so notified of this determination in your substantially equivalent letter. (Some of the above listed types of devices may require a premarket approval application). This list is subject to change without notification. If you have any questions as to whether or not your device may be subject to postmarket surveillance or about this program, please contact the Postmarket Surveillance Studies Branch at (301) 594-0639.

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

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

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

Sincerely yours,

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

**PREMARKET NOTIFICATION (510(k)) STATUS REQUEST**

**TO:** 510(k) Status Coordinator  
Division of Small Manufacturers Assistance (HFZ-220)  
Center for Devices and Radiological Health, FDA  
5600 Fishers Lane  
Rockville, MD 20857  
USA  
Fax Number: (301) 443-8818

Please provide the status of the 510(k) identified below. Please send the information to the requester identified in section B by (check one):

\_\_\_\_\_ fax  
\_\_\_\_\_ mail

**A. Sponsor Information:**

- 1. Name of 510(k) sponsor: \_\_\_\_\_
- 2. Sponsor's mailing address: \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

**B. Requester information:**

- 1. Request name: \_\_\_\_\_
- Requester affiliation with sponsor: \_\_\_\_\_
- 3. Requester mailing address: \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_
- 4. Request fax number (if applicable): \_\_\_\_\_
- 5. Requester telephone number: \_\_\_\_\_

**C. 510(k) information:**

- 1. Product name: \_\_\_\_\_
- 2. 510(k) number: \_\_\_\_\_
- 3. Date logged in by Office of Device Evaluation (ODE) (as identified in acknowledgment letter from ODE): \_\_\_\_\_

Name of contact person identified on firm's 510(k) submission: \_\_\_\_\_

.....  
I certify that the above information is accurate and truthful to the  
of my knowledge.

(Rev:2)

\_\_\_\_\_  
Requester signature

2  
CV  
TIT

K950944



13755 First Avenue North  
Plymouth, MN 55441-9760  
612-449-8100  
612-449-8986 Fax

February 15, 1995

Food and Drug Administration  
Bureau of Medical Devices  
Document Mail Center (HFZ-401)  
1390 Piccard Drive  
Rockville, MD 20850

RE: Section 510(k) Premarket Notification

Ladies and Gentlemen:

The enclosed 510(k) submission is to be treated as a NEW 510(k) submission. It contains an exact photocopy of a previous 510(k) submission. The file is being re-submitted in accordance with the recommendation of Mr. Bob Chissler and Ms. Heather Rosecrans because the FDA has been re-thinking its position on heart rate variability (HRV).

This new 510(k) submission also contains a tab. Information behind the tab is responsive to questions asked of us over the telephone in December, 1994. It provided to help make this filing more complete.

Please review this new file and the information enclosed herewith. Thank you for your attention to this matter.

Sincerely,

Steve Springrose  
President  
FDA@HRV.SS

same as  
K950723

RECEIVED  
17 FEB 1995 09 18  
FDA/CDRH/OCE/DMD



13755 First Avenue North  
Plymouth, MN 55441-9760  
612-449-9100  
612-449-8966 Fax

July 25, 1994

Food and Drug Administration  
Bureau of Medical Devices  
Document Mail Center (HFZ-401)  
1390 Piccard Drive  
Rockville, MD 20850

RE: Section 510(k) Premarket Notification  
Modified Class III Device

Biosensor Corporation hereby submits this original and two copies notifying of its intention to modify our Ambulatory Holter recording system.

**Device:** Ambulatory (Holter) Recording System

**Regulatory Class:** Class III

**Establishment Registration Number:** 2183509

**Performance Standard:** No performance standards have been established under Section 514.

Biosensor Corporation is testing and plans to release an updated version of its ambulatory cardiac monitoring system. The prior system was found to be equivalent to a device under 510(k) file number K922027. With this submission Biosensor Corporation is reporting a device change involving a pacemaker spike detector and a patient recorder memory increase. In addition the Company requests release of its software which computes statistics on the R-R interval history.

Sincerely,

A handwritten signature in cursive script, appearing to read "D. Dershem".

Darren D. Dershem  
Quality Assurance

**TABLE OF CONTENTS****510(k) Modified Ambulatory (Holter) Recording System**

<b><u>Enclosure</u></b>	<b><u>Pages</u></b>	<b><u>Description</u></b>
A	1 - 3	Comparison of modified Holter device and existing K922027 device.
B	4 - 5	Overview of the modified ambulatory (Holter) system.
C	6 - 60	Labeling and promotional material
D	61 - 83	Examples of summary report printouts
E	84 - 87	Summary of System Tests.
F	88 - 91	Class III Summaries and Class III Certifications Document.
G	92	Statement of Safety and Effectiveness.

**Enclosure A**  
**Comparison of proposed Holter device with existing**  
**K922027 Holter Device**

	<u>Proposed Device</u>	<u>K922027 Device</u>
<u>Product Name</u>	Biosensor Holter System	Biosensor Holter System
Product Sub-Categories:	Real Time (RT) Full Disclosure (FD) Superimposition (SI)	Real Time (RT) Full Disclosure (FD) Superimposition (SI)
ECG Analysis:	Argus	Argus
Data Storage:	Digital	Digital
Days of Storage:	1-3	1-3
<u>Patient Recorder</u>		
Size:	5.8"x2.5"x.8"	5.8"x2.5"x.8"
Weight:	6-8 oz. approx.	6-8 oz. approx.
Power Supply:	4-AA batteries	4-AA batteries
Patient Isolation:	Yes	Yes
Microprocessor Code:	80C51 Family	80C51 Family
Hardware Pacer Detect Circuitry and reporting:	Yes	No
Data Storage Capacity:	16-32MBytes	6-8MBytes
Storage of 24 Hours Data:	Yes	Yes
Channels of ECG:	2 or 3	2 or 3
Analog Front End Circuitry:	Adjustable Digital Bandpass Filter	Discrete Analog Bandpass Filter
Symptom Switch:	Yes	Yes
Patient Cable Connectors:	Yes	Yes

**System Software Requirements**

Computer:	IBM-PC Compatible	IBM-PC Compatible
Printer:	24 pin dot matrix or laser	24 pin dot matrix or laser
Program Installation:	Hard Drive	Hard Drive
Ram Required:	2MByte	2MByte
Video Graphics:	EGA, VGA, or SVGA	EGA, VGA, or SVGA
Ports:	Parallel (2)	Parallel (2)

**System Software Features**

"Real Time" Summary Report Based on Argus ECG Analysis:	Yes	Yes
Morphology Scanning:	Yes	Yes
Ischemia/ST Analysis:	4 measurement points	4 measurement points
Full 24 Hour with Digital Storage of ECG:	10:1 compression	10:1 compression
Full 24 Hour ECG Printout Capability:	Optional	Optional
Superimposition Scanning at 60/sec	Optional	Optional
Color Screen Display:	Optional	Optional
Data Transfer Method:	Parallel	Parallel

Permanent  
Data storage  
methods:

Floppy Diskette or  
other computer  
storage media

Floppy Diskette or  
other computer  
storage media

R-R Interval  
reporting:

Heart Rates,  
Arrhythmia gram  
Bar Graph,  
Atrial fibrillation  
R-R trends including  
standard deviation  
and mean.

Heart Rates,  
Arrhythmia gram  
Bar Graph  
Atrial fibrillation  
R-R trends not  
including standard  
deviation or mean.

**Enclosure B**  
**Overview of the Modified Ambulatory (Holter) System**

The following summarizes changes to the Biosensor Holter system covered under this modification notice:

#### **Pacemaker Stimulus Detector Circuit**

Biosensor has implemented an elegant dual channel pacemaker stimulus detector circuit to be used in conjunction with its Holter analysis software. The new hardware design can be summarized as follows:

A bandpass filter tuned to pacemaker signals with a frequency response from 1kHz - 8kHz and with a gain of 23 is used to filter out the rising and falling edges of the pacemaker stimulus from the background ECG. The detection of a rising or falling edge of a stimulus spike is used to identify the location of the various pacemaker impulses.

The bandpass filter output goes to a threshold detector. The edge detector passes through either an upper or lower voltage threshold setting to determine whether or not a pacemaker stimulus has occurred. The sensitivity to both rising and falling edges allows for a more accurate assessment of the presence of pacemaker stimulus spikes.

When the detector circuitry finds a pacemaker edge, a digital output pulse is sent to the system's microprocessor to trigger and generate an interrupt. This interrupt is used to report the locus of the pacemaker stimulus within 4msec. The interrupt time stamps are stored in a memory buffer and later used by the processing algorithm to identify the pacemaker impulses in the overall arrhythmia and rate classification stream.

#### **Memory Increase**

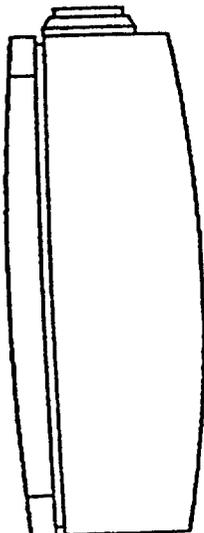
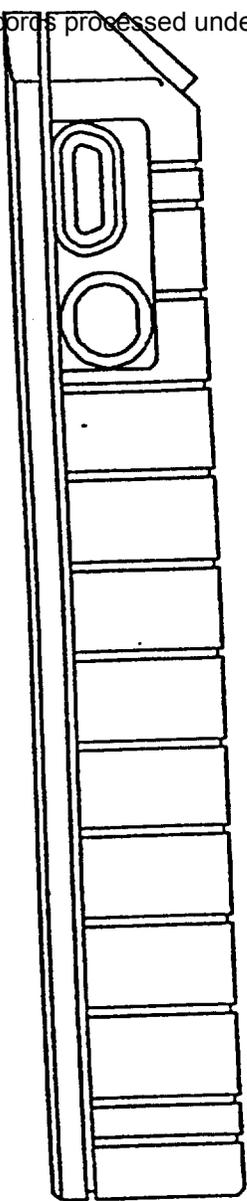
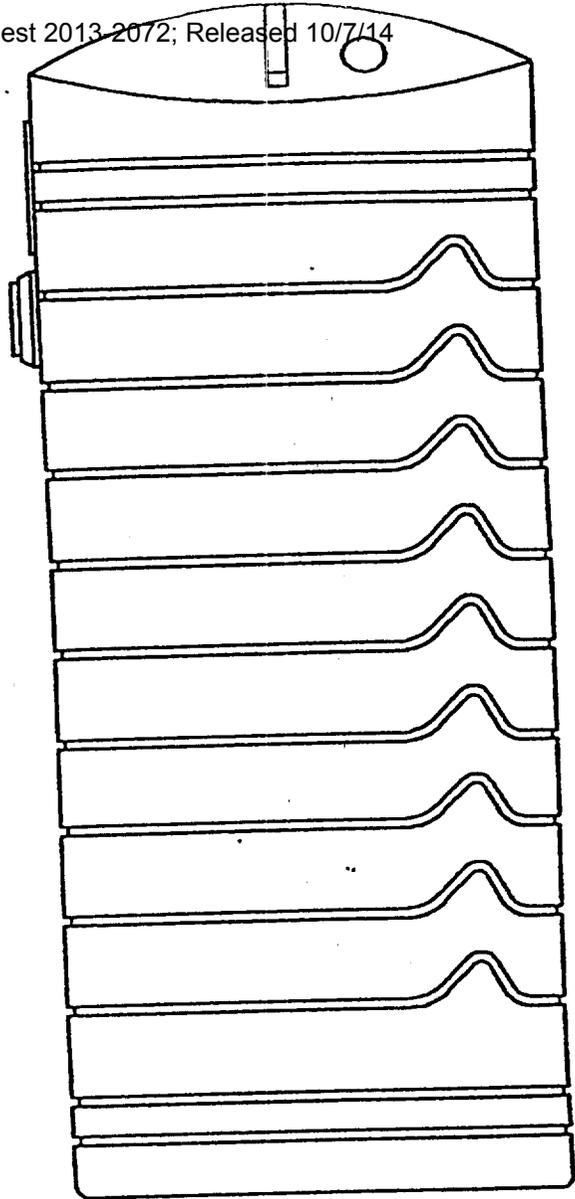
Advances in electronic memory densities have allowed Biosensor to increase the amount of ECG storage memory in the Holter system without changing the Holter package size. The current configuration allows up to 32MByte of patient information to be stored.

The memory increase allows Biosensor Holter systems to store higher resolution ECG data compared to the processor product. The result is a higher resolution ECG tracing, similar to when the memory capacity was increased and approved in the K922027 device.

**R-R Interval History**

The Company will include the R-R interval mean and standard deviation calculations along with the original R-R interval history.

**ENCLOSURE C**  
**Labeling and Promotional Material**



APPROVAL	DATE	TITLE	
DRAWN M. MUESING	8-8-89	<b>Biosensor</b> CORPORATION HOLTZER RECORDER - FINAL ASSY DRAWING	
ENG'G		SIZE	DWG NO.
ENG'GR.		B	4G200.E1
TOLERANCE: UNLESS OTHERWISE SPECIFIED .XX = ±0.010 .XXX = ±0.005 AN' = ±0.5" IN INCHES DIMEN'		SCALE	1 = 1
		WT.	1 OF 1



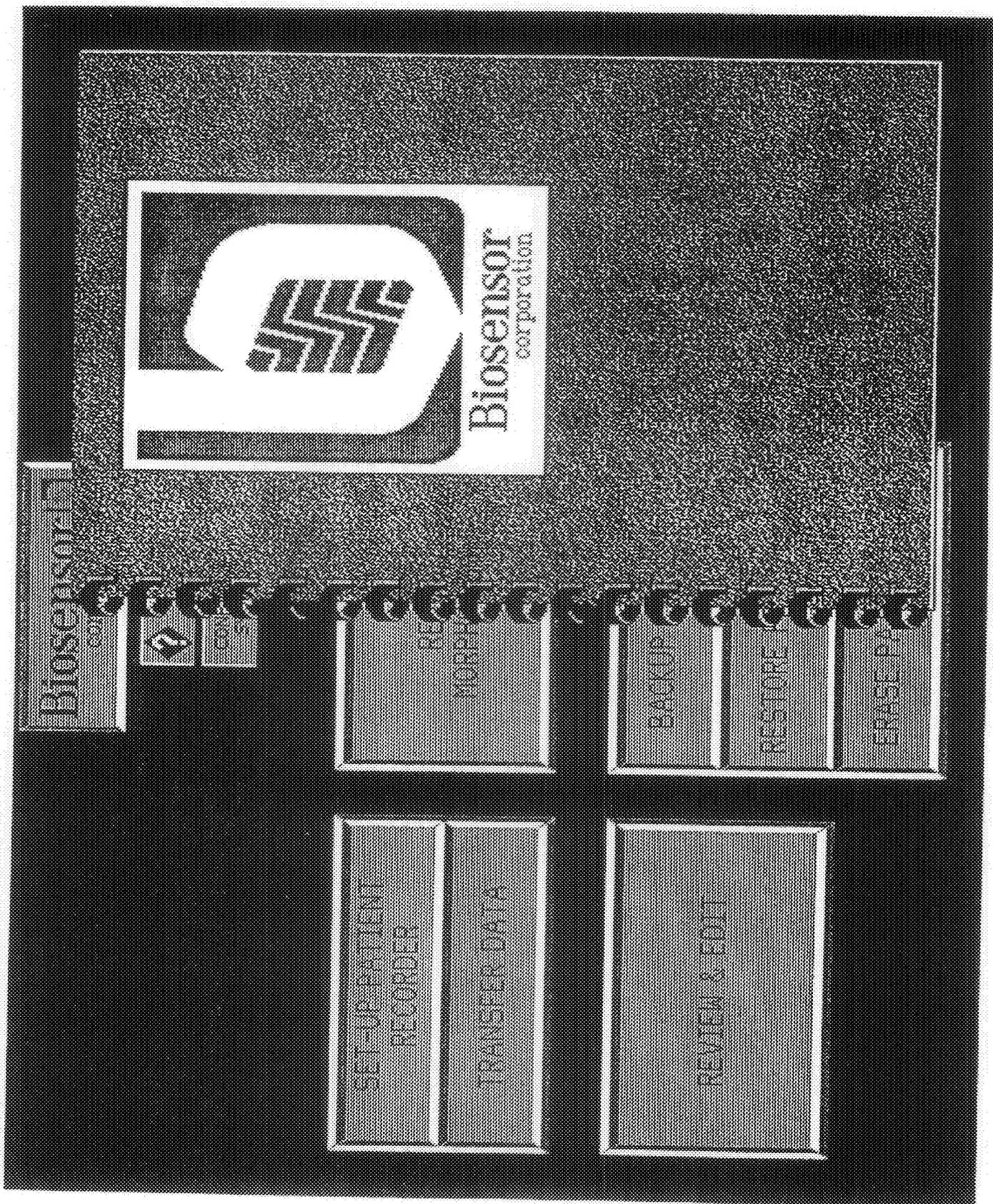


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Help on Help  
 Navigating the system  
 Main Screen  
 Selecting a Patient  
 Configuration Dialog  
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 Backing up and Restoring Data  
 Patient Hook-up  
 Setting up Patient Recorder  
 Patient Recorder Batteries  
 Baseline Display  
 ST Point Adjustment  
 Transfer Data  
 Analysis Parameters Dialog  
 Edit Patient Data Screen  
 Edit Fields  
 Review and Edit Screen  
 Beat Markers  
 Episode Markers  
 Review and Edit Display Options  
 Using the Calipers  
 Creating an Episode with Calipers  
 Review/Edit Morphologies

Review/Edit Beats  
 Other Classifications  
 Using the Morphology screen  
 Episodes Screen  
 Reclassifying Episodes  
 Relabeling Episodes  
 Selecting Episode Types  
 Trend Graph Screens  
 Tabular Data  
 Superimposition Screen  
 Narrative Summary  
 Printing Dialog  
 Selecting a Time Range  
 Notes Concerning Heart Rates  
 Normalization of ST Values  
 Using a Mouse  
 Using the Keyboard  
 Using a Slider  
 Formatting a disk  
 GLOSSARY



**Help on Help**

The help system is context sensitive. This means that the help manual will automatically "open" to the topic where you asked for help. However, you may read any help topic by pressing [TABLE OF CONTENTS], then clicking on the help topic.

You may click on hot words to "open" the manual to the section which provides more detail to the word or topic in RED.

**[TABLE OF CONTENTS]**

This button will display the table of contents for all available topics. This button is not available if you are currently viewing the table of contents.

**[BACKTRACK]**

Pressing this button will return you to the two pages you just looked at. Each time this button is pressed, the pages that were visible before the current pages will be shown. This button is available only after you changed pages in the help system.

**[NEXT PAGE]**

This button will turn the page in the manual (i.e., if you are on pages 7 and 8, you will move to pages 9

and 10). This button is not available if you are currently viewing the last pages.

**[PREVIOUS PAGE]**

This button will turn to the preceding pages in the manual (i.e., if you are on pages 7 and 8, you will move to pages 5 and 6). This button is not available if you are currently viewing the first pages.

**[EXIT]**

Exits the help dialog and returns to where the help system was invoked from.



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5 Navigating the system

The following outline shows the hierarchy of screens within the Biosensor Holter program. Some of the screens show up in multiple places because they can be reached in more than one way.

Main Screen

- Help
- Configuration Dialog
- Setup Patient Recorder
  - Baseline Display & ST Point Adjustment
  - Transfer Data \*
- Analysis Parameters
- Review/Edit Morphologies \*
- Review/Edit Beats \*
- Print Morphologies
- Summary Report
- Review and Edit \*
- Review/Edit Morphologies \*
- Review/Edit Beats \*
- Print Morphologies
- Episodes \*
- Analysis Parameters
- Relabeling Episodes
- Reclassifying Episodes
- Printing Episodes

Graphs

- Heart Rate + ST CH.1 Graphs \*
- Heart Rate + ST CH.2 Graphs \*
- Heart Rate + Ecotopy Graphs \*
- Ecotopy + Coupling Graphs \*
- R to R Distribution Graphs \*
- Printing Graphs
- Hourly Tabular Data
  - Rate + SVE Tabular Data \*
  - VE Episodes/Beat Counts Tabular Data \*
  - ST Tabular Data \*
- Printing Tabular Data
- Superimposition Scanning
- Narrative Summary \*
- Printing Reports (including full disclosure)
- Printing Strips & 1-12 minutes of ECG
- Caliper Tool
  - Creating user-defined episode strips
- Display Options
- Backup To Floppy
- Restore From Floppy
- Erase Patient File
- Exit to DOS

\* indicates that Edit Patient Data is available from this screen.





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Selecting a Patient  
This dialog is used to select a patient data set for all Main Screen functions.

After selecting a main screen function, this dialog will display all patient data sets available for that function. Available data sets are displayed in white. Data sets displayed in black are not available for the current main screen function. (The numbers following the procedure time correspond to the subdirectories of the BIO system.)

[CTL\_A] - [CTL\_J]  
Selects the patient set/subdirectory.

[CANCEL]  
Exits back to the main screen without selecting a patient set.



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for new patients.  
[EXIT TO DOS]  
Exits the BIO program and returns you to the DOS prompt.

← PREVIOUS PAGE

TABLE OF CONTENTS

SEARCH

EXIT PAGE

→ NEXT PAGE

by the holster system. Typically, this should be changed only when installing the system or upgrading to a different transfer card.

Card Address:

This number represents the hexadecimal I/O address of the transfer card. Again, this should be changed only when installing or upgrading the system. The default values should be used except when there is a conflict with another interface card such as a network card. If this value is changed, the transfer card must also be changed to match the new address. See the following descriptions on how to do this.

**Configuration Dialog**  
This dialog permits you to "personalize" the software. See also Report Cover Page for instructions on creating a cover page for reports.

User level

[BEGINNER]

receives all verification dialogs such as- "Are you sure you wish to leave the program?", "You are about to remove the current morphology edits, are you sure this is what you want to do?".

[ADVANCED]

Bypasses most verification dialogs for faster interaction. You should not select this level until you have experience using the system.

[CONFIGURE PRINTER]

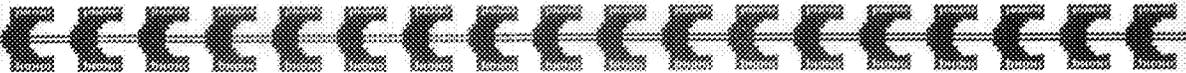
Selects the desired printer and parallel port. The printer can also be configured whenever any printing is requested. See Printers and Ports.

Transfer Card

[25-9 pin, P/N 4A121]

[37 pin, P/N 4A114]

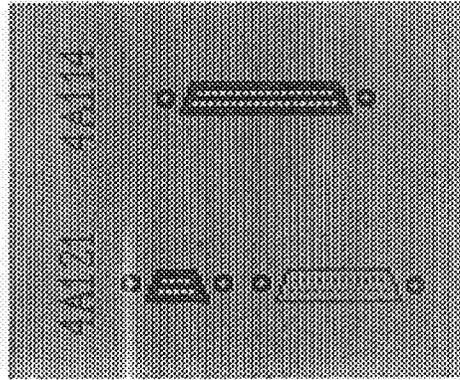
These are the two types of transfer cards supported



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**Recognizing transfer cards:**

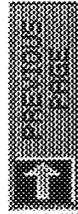
If you are not sure which transfer card is installed on your computer, look at the back of your computer and try to find one of the following cards in one of your expansion slots:



The 4A121 card is characterized by a 25-pin female parallel connector and a 9-pin male serial connector. The 4A114 card is characterized by a single 37-pin male connector.

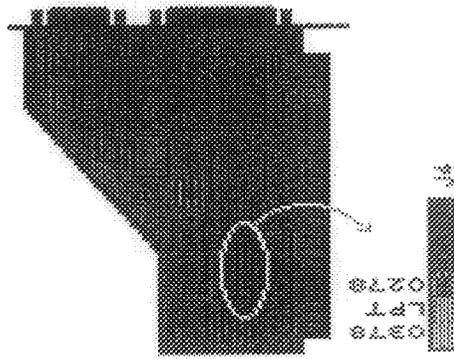
**I/O Addresses of transfer cards:**

The 4A121 card has a factory default address of 0278. Its valid addresses include 0278 and 0378



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only. To change the card address of a 4A121 card, move jumper J4 on the card according to the following diagram:



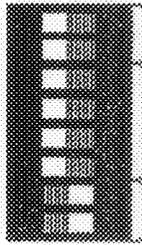
Pins 1 & 2 represent address 0378 and pins 2 & 3 represent address 0278.

The 4A114 card has a factory default address of 0300. It has a range of valid addresses from 0200 to 03FC. To change the card address, set the S1 dip switches on the card according to the following diagram:



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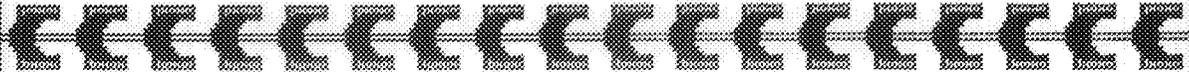
BASE ADDRESS  
9 8 7 6 5 4 3 2



00??|??|??|??|??|00

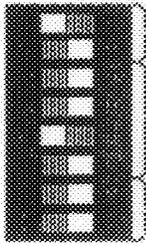
BaseAddress lines 9 & 8 (dip switch toggles 1 & 2) indicate the low 2 bits of the most significant hex digit (the high 2 bits are assumed to be 0). BaseAddress lines 7, 6, 5, & 4 (dip switch toggles 3, 4, 5, & 6) indicate the 4 bits of the middle hex digit. BaseAddress lines 3 & 2 (dip switch toggles 7 & 8) indicate the high 2 bits of the least significant hex digit (the low 2 bits are assumed to be 0). Please realize that not every address is valid (depending on your hardware). If an address doesn't work, try a different address.

PROCESSED



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Example:



0011|1011|1000

3 B 8

See the Binary to Hexidecimal Conversion table provided on the next page.



Report Cover Page

It is possible to create a cover page that will be printed as the first page of any report consisting of multiple sections. Create a text file named BIO\_COVR.PG in the BIO directory that consists of the text desired on the cover page. This text will be centered both horizontally and vertically on the first page of the report.

To create the text file, you may use any text editor. DOS 5.0 comes with an excellent editor called EDIT; Previous versions of DOS provide EDLIN (see your DOS manual for how to use EDIT or EDLIN). If you don't have a text editor, you may create the file (from the DOS prompt, i.e. C:\BIO) using the following commands:

```
COPY CON BIO_COVR.PG
text to be included on the cover page
this text may be multiple lines
when all lines have been typed...
<F6>
```

Binary to Hexadecimal Conversion:

binary hexadecimal

0000	0
0001	1
0010	2
0011	3
0100	4
0101	5
0110	6
0111	7
1000	8
1001	9
1010	A
1011	B
1100	C
1101	D
1110	E
1111	F



Navigation and utility buttons:

- PREVIOUS PAGE (left arrow)
- THIS IS THE CONTENTS (document icon)
- BACKSPACE (left arrow)
- END HELP (right arrow)
- HELP (right arrow)

### Printers and Ports

Whenever printed output is requested, a dialog box requests that the printer be set up. The set up consists of verifying that the printer is on-line (i.e., powered on and connected to the computer) and has a supply of paper. This dialog box also gives you the option to change the type of printer and which parallel port it is connected to. Three major types of printers are supported:

- 24-pin Epson compatible dot matrix printers  
resolutions: 180 DPI
- HP LaserJet compatible laser printers  
resolutions: 150 DPI, 300 DPI \*
- HP DeskJet compatible printers  
resolutions: 150 DPI, 300 DPI

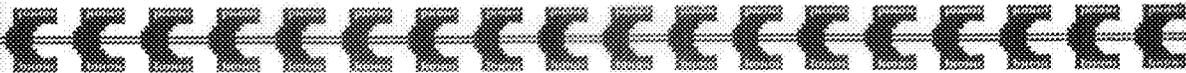
\* 300 DPI printing requires a 1 Megabyte memory expansion in the printer unit.

Specify the printer by clicking on the appropriate box. This will become the default printer for future printing operations.

You may configure any of these printers for any available parallel port. Select the parallel port by clicking on the boxes labeled LPT1 through LPT3.

Note these boxes only appear if the program determines that these ports are available on your machine.

After printing has commenced but before it's completed, you may cancel the printout by pressing the space bar. This should return control to you very soon but the printer will still print out whatever is in its buffer.



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**Backing up and Restoring Data**

After a patient data set has been transferred from the patient recorder, analyzed, and printed, you may want to backup the data on floppy disk for permanent storage.

Backups come in two varieties: FULL BACKUPS and REPORT-ONLY BACKUPS. FULL backups store everything about the patient, enough to do a total re-edit if necessary. REPORT-ONLY backups store just what is needed to print the report again. REPORT-ONLY backups are NOT EDITABLE after they have been restored, but they typically require only one high-density disk to store them. FULL backups require more backup disks, depending on the specific patient data. A patient with very many episodes will require more disks. The following numbers are estimates for FULL backups of 24 hour procedures (assuming that the target disks contain no other data).

**DISK TYPE : ESTIMATED # OF DISKS PER PATIENT**

- 5 1/4" low density : 13
- 5 1/4" high density : 4
- 3 1/2" low density : 7
- 3 1/2" high density : 4

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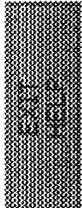
The disks must be formatted (see Formatting a disk) before attempting to backup patient data onto the disks.

You will be prompted by number for each floppy disk when backing up.

You may not backup more than one patient data set to the same disk. If you attempt to backup a second patient's data onto a disk that already contains patient data, you will be prompted to provide a different disk or overwrite the existing patient data on the floppy disk.

If you wish to review data from a patient's data set after it has been erased from the hard disk, you will need to restore the data to the hard disk. If there is not enough room on the hard disk to contain the data, the restore will not be done (you must delete some other data from the hard disk, then attempt the restore again).

You will be prompted by number for each floppy disk when restoring.



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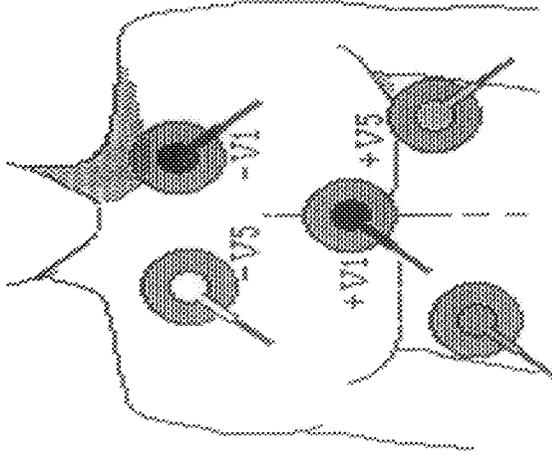
**Patient Hook-up**

It is important that the patient is properly prepared for electrode placement to avoid problems such as loosened electrodes, inadequate signal amplitude, and irritated skin and patients.

**Skin Preparation**

- (1) Locate a bony prominence, such as the right and left clavicle, the manubrium, or the ribs. The electrodes will be placed on a bony prominence to eliminate artifact signals caused by excessive body movement.
- (2) Mark the areas on the patient's chest prior to applying the electrodes. A water-soluble marking pen can be used. For patients with normal cardiac configuration, the placement of the electrodes marks are shown in the figure.
- (3) Shave the body hair around the electrode mark in an area measuring about twice the diameter of the electrode.
- (4) Carefully wipe the exposed skin clean with alcohol to remove soap, oil, or solvent residue. Allow the skin to dry thoroughly.

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- (5) **IMPORTANT:** Go over the area again, rubbing with Omni Prep to remove the top epidermal layer. If Omni Prep is not available, a Scotch Pad (3M) or a light grade of sandpaper (200\*) can be used. This greatly helps to lower skin impedance, which is the resistance to the ECG signal. When using sandpaper, lightly pull the paper toward you in short, quick strokes. Using a forward and backward or circular stroke can damage skin unnecessarily (and REALLY irritate the biker whose chest you just shaved).



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(6) Attach the electrodes to the electrode wires.

Lead	Typical	Color
Ch.1	V5+	Red
Ch.1	V5-	White
Ch.2	V1+	Black
Ch.2	V1-	Brown
	Ground	Green

(7) Place the color coded connector end of each

electrode wire into the appropriately colored

receptacle of the patient cable yoke, making certain

they are secure.

(8) Remove five pregelled silver/silver chloride

electrodes from their packages and snap one onto each

color coded wire receptacle.

(9) Before applying the electrodes to the patient's

skin, be sure that the skin has been properly prepared.

Any alcohol or other solvents left under the electrode

can cause skin irritations. Use the electrodes at room

temperature.

(10) Carefully remove all of the backing paper from

the electrode. Be sure that the gel is moist, but don't

touch the adhesive surface. Place the gelled center of

each electrode over the marked areas of the chest.

First smooth one adhesive side down, then the other,

pressing lightly. Do not stretch the electrode tightly.

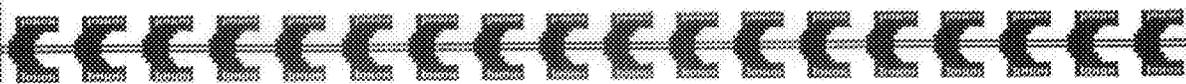
This may cause discomfort. Finally, firmly press the

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electrode to ensure good adhesion.

(11) Make a stress-loop in each electrode wire and

tape the loop to the skin.



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Pressing the symptom button will stop the 'OK' flash message.

These sequences will continue for about 10 minutes, giving you time to recognize and fix the problem.

Poor signal quality in channel 1:



Poor signal quality in channel 2:



Poor signal quality in both channels:



Low Battery Warning:



5) Disconnect the patient cable from the recorder and connect the communication cable to the recorder.

6) From the main menu, click on [SET-UP PATIENT RECORDER].

7) Verify that the baseline strip shows that the ECG

### Setting up Patient Recorder

1) Insert batteries into the recorder. **MAKE SURE ALL 4 BATTERIES ARE IN CORRECTLY!** Use alkaline batteries only. The small LED on the recorder should flash once, indicating it has power. Approximately 50 seconds later, the recorder will flash 3 times, indicating that it has passed it's memory self-test. See Patient Recorder Batteries.

2) Connect electrodes to the lead wires on the patient cable and then place electrodes onto the patient. See Patient Hook-up.

3) Connect the patient cable to the recorder. The patient cable only fits one way into the recorder. The light on the recorder will flash twice to signify the connection of the patient cable. **DO NOT TWIST THE CABLE!**

4) Wait approximately 3 minutes for GAINSET. The patient should remain sedentary during this phase. When GAINSET completes, the recorder will begin a flashing sequence to represent the quality of the hookup.

GAINSET is OK:



**Gainset**





### Baseline Display

The baseline signal is used to verify that the signal being received by the patient recorder is adequate (strong and noise-free). Therefore, the baseline should be taken at the beginning of the procedure.

While viewing the ECG Baseline on the screen, you may see a dialog warning of poor signal quality in one or both channels. If so, remove the batteries from the patient recorder and start over again. See Setting up Patient Recorder.

The first baseline taken during a procedure is automatically saved in the patient recorder for inclusion as an episode strip. If multiple baselines are taken, you are asked if you want to save the most recent one, overwriting the one currently saved on the patient recorder. Overwriting the initial baseline on the patient recorder is NOT recommended. Only one baseline may be saved on the patient recorder.

[PRINT]

Prints the baseline as a strip.

[EXIT]

Saves the baseline data to the patient recorder and

while leaving the new bottom batteries in place. Please note that this is a last resort option because there is still a chance of losing the patient data while replacing the batteries. If you have any questions about how or whether to do this, you should contact Biosensor technical support.



returns to the main screen.

See Setting up Patient Recorder  
See ST Point Adjustment

### ST Point Adjustment

ST Point Adjustment is used to override the computer selected points at which ST measurements will be made. ST Point Adjustment may only be done if the baseline was taken during the first 15 minutes of the procedure (called learn time), and the ST points haven't been previously adjusted in this procedure. If these conditions are met, the screen will initially show the points that the computer has chosen. If these conditions are not met, the ST Point Adjustment portion of the screen will be blank and the buttons applicable to ST Point Adjustment are not available.

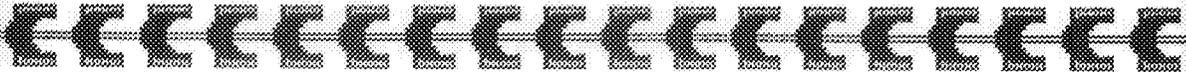
If the computer has selected less than ideal points, an adjustment may be made to improve where the ST measurements are taken, thus improving the ST data and ST reporting. ST level is measured as the difference between the value at the isoelectric point and the value at the ST point. ST slope is measured as the difference between the J+12ms point and ST point.

Isoelectric point and ST Points buttons select which line to move. The <- and -> buttons move the selected line.



changes have been made to the ST points.

See also:  
Setting up Patient Recorder  
Baseline Display and  
Normalization of ST Values.



[ISOELECTRIC POINT]

Selects the isoelectric point as the point to be moved. Use the (<- and ->) buttons to move the point. You should select the point preceding the QRS onset that best identifies the isoelectric point.

[ST POINT]

Selects the ST point as the point to be moved. Use the (<- and ->) buttons to move the point. You should select the point following the QRS termination that best identifies the ST point.

[ <- ]

Moves the selected point left 1/250 second (1 tick).

[ -> ]

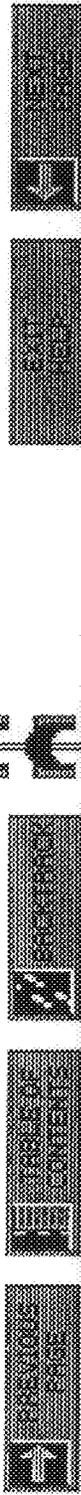
Moves the selected point right 1/250 second (1 tick).

[UNDO CHANGES]

Undoes all changes since this screen was entered.

[EXIT]

Returns to the baseline screen, saves the baseline to the patient recorder, and sets the patient recorder ST parameters to the currently displayed values if any



# Pinpoint

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## Transfer Data

- 1) Disconnect the patient cable from the recorder and connect the communication cable to the recorder.
- 2) From the main menu, click on [TRANSFER DATA].
- 3) The analysis parameters dialog will appear. Adjust the parameters as desired. See Analysis Parameters Dialog.
- 4) Enter patient information into the PATIENT INFO page. You must enter at least a name into the patient data screen.
- 5) Data transfer commences. This may take up to 5 minutes.
- 6) After the initial data has been transferred successfully, a dialog will appear reminding you not to disconnect the patient recorder until all data has been transferred and another dialog appears stating it is safe to disconnect the patient recorder.

**DO NOT** disconnect the patient recorder from the PC until a dialog has appeared stating that it is safe to do so. Data transfer will continue in the background





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until all data has been transferred. However, it is safe to start reviewing and/or editing the patient data immediately after the patient info edit screen has appeared, even though the transfer process is still happening in the background.




**Analysis Parameters Dialog**

The values that appear when this dialog is first displayed are the values that were used in the most recent analysis of this patient data set or the system default values if this dialog was entered from the Main Screen [TRANSFER PATIENT DATA].

**VE Tachy HR:**

Specifies in BPM the heart rate above which a VE Run episode will be called a VE Tachy episode. Factory setting is 100 BPM.

**SV Tachy HR:**

Specifies in BPM the minimum heart rate for a paroxysmal SV Tachy episode. Factory setting is 100 BPM.

**SV Prematurity:**

Specifies how early a beat must be to be classified as SVE. Furthermore, the beat must represent an R to R interval above 100 BPM. Factory setting is 25%.

**Brady HR:**

Specifies the maximum heart rate a Bradycardia episode may have. All potential Brady episodes with higher rates are not annotated. Factory setting is 50

**BPM.**

**Pause Duration:**

Specifies in seconds how long a pause must be before it will be labeled as an episode. Factory setting is 2.5 seconds.

**ST Episode Deviation:**

Specifies the deviation (from isoelectric point) necessary for ST episodes to be called. Factory setting is 1.0 mm. See Normalization of ST Values.

**ST measurements:**

Specifies which method to use when selecting the baseline value for ST values in each channel. The choices are:

[ABSOLUTE]

All ST values are relative to 0.0 mm in each channel

[RELATIVE TO MEDIAN]

All ST values are relative to the median ST value in each channel. If these median values have been calculated for this patient, they will appear in the boxes on the right side of the dialog box.

[RELATIVE TO OTHER]

All ST values are relative to a user-specified baseline value in each channel. These user-specified



This page intentionally left blank.

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values can be entered into the boxes on the right side of the dialog box.

**[LOAD DEFAULTS]**

Loads the default values for use in analysis.

**[SAVE AS DEFAULTS]**

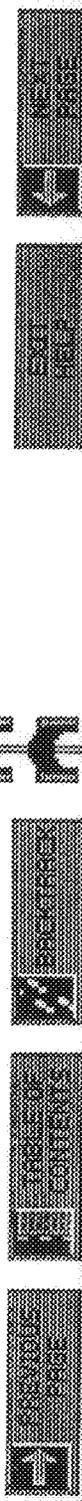
Saves the current settings as the defaults to be used for future patients and to be loaded when load defaults is selected. Clicking here causes immediate changes; selecting [CANCEL] will not undo this operation.

**[CANCEL]**

Leave the dialog but do not save changes or re-analyze the patient data. Cancel will not undo the effects of clicking on [SAVE AS DEFAULTS].

**[OK]**

Leave the dialog and if there were any changes in parameters, re-analyze the patient data.



**Edit Patient Data Screen**

Patient data is readily available throughout the review and edit subsystem. Simply click on the patient name bar at the top of the screen to retrieve and edit the patient biographical data, as well as indications for the test, current medications, and interpretation.

The only field that must have data entered into it is the patient name field. All other fields may be left blank if desired. Note that the data entered here will be printed on the patient data report section.

The interpretation field is on a separate screen that is accessed by clicking on [INTERP. PAGE]. When on the interpretation screen, you may return to the other data by clicking on [BIOGRAPHICAL PAGE].

**Edit Fields**

Edit fields may be single- (SL) or multi-line (ML). The following keypresses are available to you:

<ENTER>

SL: finished with this field

ML: line feed, go to next line

<ESC>

SL: abort this edit

ML: finished, return to mouse control

<TAB>

<Shift-TAB>

ML: next/previous field

<UP>

<DOWN>

ML: next/previous line

<BACKSPACE>

<DEL>

<LEFT>

<RIGHT>

<HOME>

<END>

SL,ML: cursor movement



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### Review and Edit Screen

Click on [REVIEW & EDIT] to review and edit any patient data file currently on the hard disk. The following features are accessible:

- Full Disclosure
- Edit Patient Data
- Morphology Editing
- Episode strips
- Heart rate, ectopy, and ST trend graphs
- Hourly Tabular Data
- Superimposition Scanning
- Narrative Summary
- Printing Reports
- Callipers
- Display Options

The slider bar may be used to choose the time to display. See Using a Slider.

### Beat Markers

Individual beats are annotated on the full disclosure portion of the screen, directly below the onset of the beat. Typically, these markers are color-coded as follows:

GREEN	normal beat
RED	ventricular beat
GRAY	unclassified beat (see glossary).
YELLOW	other beat

### Episode Markers

Episodes are marked on the full disclosure portion of the screen with red brackets. These brackets appear as [ and ] to signify the onset and offset of each episode. Single-beat episodes are not bracketed, but simply use a single red line to mark the beat. Each episode marked in this fashion corresponds directly to the episodes found on the episode screen (see Episodes Screen).

Whenever the recorder has marked a portion of the full disclosure as 'too noisy to analyze', that portion will appear with a gray background.

To magnify the full disclosure, move the cursor onto the QRS complex or area of interest with the mouse, and click. A 7.5 second strip is displayed in the viewing area in strip mode. Any episode markers now also appear with a number at the top. This number directly corresponds with episode numbers found on the episode screen. Click again to return to the miniaturized full disclosure display. When in strip

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Superimposition Screen.

[VIEW SUMMARY]

Displays the narrative summary. See Narrative Summary.

[PRINT REPORT]

Accesses the printing dialog. Any section of the printed report may be requested in the printing dialog. See Printing Dialog.

[PRINT PAGE]

Prints the page or strip that is currently displayed.

Notes concerning printed strips:

Beats are annotated on most strip printouts with identifying letters:

- N normal beat
- V ventricular beat
- U unclassified beat

When printing strips, the strips are sized to fit four on a page. It may seem that nothing was printed; however, the program is simply buffering the strips until it has enough to fill a page. Exiting the current screen or sending other data to the printer (graphs, for instance) will cause the buffered strips to print.

mode, both channels are displayed regardless of the channel display mode. Sliding is also possible in strip mode.

[PATIENT NAME BAR]

Allows patient data to be reviewed and edited. See Edit Patient Data Screen.

[EDIT MORPHS]

Permits confirmation or reclassification of morphologies. If any morphology types are changed in the morphology editing screen, the patient data will be re-analyzed. See Review/Edit Morphologies.

[EPISODES]

Displays episodes screen. See Episodes Screen.

[GRAPHS]

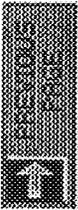
Displays trend graphs. See Trend Graph Screens.

[TABULAR DATA]

Displays hourly tabular data screens. See Tabular Data.

[SUPER.]

Displays superimposition screen. See



**[CALIPERS]**

A caliper tool is provided to permit you to  
1) Determine the heart rate over any range of  
beats.

2) Define the beginning and end of a user defined  
episode.  
See Using the Calipers.

**[DISPLAY OPTIONS]**

Callis up a dialog box that permits you to designate  
which channels to display and at what density (minutes  
per page). It allows you to choose whether you want to  
display beat markers. It also allows you to choose  
whether you want to display episode markers. See  
Review and Edit Display Options.

**[EXIT]**

Returns to the main menu screen.

**Review and Edit Display Options**

This dialog box allows you to configure the display  
for the Review and Edit screen.

**[CHANNEL 1]  
[CHANNEL 2]**

Select which channel(s) you want to display. At least  
one of the channels must remain selected.

**MINUTES PER SCREEN**

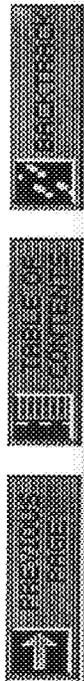
This determines the density of the full disclosure on  
the screen.

**[DISPLAY BEAT MARKERS]**

This toggles the beat markers at the bottom of each  
row of full disclosure (see Beat Markers).

**[DISPLAY EPISODE MARKERS]**

This toggles the episode markers that appear on the  
full disclosure page (see Episode Markers).



**Using the Calipers**

To enter caliper mode, click on [CALIPERS]. When the button is dark, click on it again to leave caliper mode and return to Review and Edit Screen.

To use the calipers, click on the beginning of the ECG to be measured, then click on the end of the ECG to be measured. (The computer will automatically reverse the two points if the second point is before the first.) A dialog box will appear showing the:

- 1) amount of time between the selected points,
- 2) number of beats between the selected points, and
- 3) heart rate (if 2 or more beats exist) between the selected points. See notes Concerning Heart Rates.

**[USER-DEFD STRIP]**

Provides a dialog to create an episode with this data. See Creating an Episode with Calipers.

**[OK]**

Returns to Review and Edit Screen.

**Creating an Episode with Calipers**

User-defined episodes can be created with the caliper tool (Review and Edit Screen). These episodes will not affect tabular data, but will provide a strip that you can print.

To label the new episode, either select a pre-defined label from the boxes provided, or just type the label into the edit field.

**[CANCEL]**

Exits without creating the user-defined episode strip.

**[OK]**

Saves the user-defined episode strip and returns to Review and Edit Screen.



**Review/Edit Morphologies**

Select morphology edit from the main screen by clicking on [REVIEW MORPHOLOGIES] or from the review and edit screen by clicking on [EDIT MORPHS].

Morphology Edit is used to confirm or reclassify computer generated VE morphologies, relabel morphologies with custom labels, and merge morphologies with similar appearance. For more information on using this screen effectively, see Using the Morphology screen.

Only 9 morphologies can be displayed at once; if there are more, a slider bar will be available to review additional morphologies on the screen (see Using a Slider). The morphologies are displayed in boxes with the following colored borders:

- Red - confirmed VE
- Blue - ARTIFACT
- Green - NORMAL
- Yellow - OTHER (see Other Classifications)

**[EDIT FAMILY]**

This is the default mode when first entering this screen. This mode signifies that edits will affect



whole families of beats.

**[EDIT BEATS]**

This mode permits you to review and edit individual beats within a family of beats. See Review/Edit Beats.

**[MERGE FAMILIES]**

This edit function permits grouping of similar morphologies into one family. Clicking here darkens the button to signify this as the new edit mode. Merging families is a three-step procedure:

- 1) Click on the SOURCE morphology. The cursor changes from ECG with up arrow to ECG with down arrow. The SOURCE morphology now has a BLACK surrounding box.
- 2) Click on the DESTINATION morphology. The cursor changes from ECG with down arrow to the word MERGE and the SOURCE morphology is overlaid onto the DESTINATION.
- 3) Confirm the edit by clicking again on the DESTINATION; or click on the SOURCE again to cancel the merge.

**[VE]  
[ARTIFACT]**



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[NORMAL]  
[OTHER] (See Other Classifications)  
Confirm or reclassify a morphology. First, select the morphology label desired by clicking on the appropriate button (which then becomes highlighted). Then, simply click on any of the displayed morphologies to confirm or reclassify it. That morphology's surrounding box is then highlighted with the corresponding edit color.

[UNDO...]  
These functions permit you remove or 'undo' any or all of the edits that have been performed on this data set. When you click here, a dialog box will pop up with one or more of the following options:

[ALL EDITS]  
[NEW EDITS]  
[LAST EDIT]

Clicking on [ALL EDITS] will reset the patient data to the pristine state it was in when it was first transferred from the recorder.

Clicking on [NEW EDITS] will remove any edits that have been performed since you last entered the morphology screen.

Clicking of [LAST EDIT] will remove last edit you have just performed. For instance, if you just

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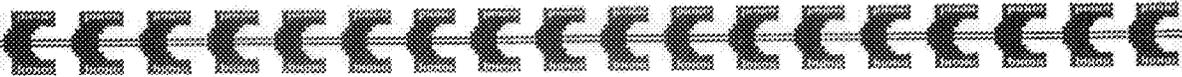
performed a merge and you want to 'undo' that merge without undoing everything else you've done in this session, the [LAST EDIT] button can be very handy. Clicking here again will 'un-undo' the last edit by putting it back.

[PRINT]  
Prints all morphologies (including normals).

[DISPLAY OPTIONS]  
Clicking here will pop up a dialog box which will allow you to select which classes of morphologies you wish the view. These classes include:

[Ventricular]  
[Normal]  
[Paced]  
[Artifact]  
[Unclassified]

[EXIT]  
Returns to parent screen and re-analyzes the patient data if there was any morphology type change.



**Review/Edit Beats**

This is available only from the Review/Edit Morphologies screen. This permits you to confirm or reclassify on a beat-by-beat level. It is also especially handy for editing beats the recorder was unable to classify. For more information on using this screen effectively, see Using the Morphology screen.

When in this mode, the cursor will appear as a magnifying glass over morphologies that can be viewed beat-by-beat. When you click on one of these morphologies, a slider bar will appear to the right of that morphology, allowing you to scroll up and down to view the beats in that morphology (see Using a Slider). The letter 'R' will also appear on the beat, signifying that this beat is the representative beat for this morphology.

This screen is very much like the Review/Edit Morphologies screen with the following exceptions:

**[MOVE BEAT]**

This function allows you to remove a beat from one morphology and place it into another. The mechanics of this function are very similar to [MERGE FAMILIES] on the Review/Edit Morphologies screen.

**[REPRESENTATIVE]**

Clicking here will mark the currently visible beat as the 'representative' beat of this morphology. From now on, whenever you see this morphology, whether on the screen or on a printed report, this beat will be shown. As mentioned above, the letter 'R' appear within the box to signify that this is the representative beat.

**[VE]**

**[ARTIFACT]**

**[NORMAL]**

**[OTHER]** (See Other Classifications)

Confirm or reclassify a beat. This function is slightly different from the similar function regarding morphologies. When reclassifying a single beat, that beat must be removed from its current family and placed into a new family with the desired classification. From then on, any beats edited in this fashion are placed into this new family.

The quickest method of editing a beat is to not use the mouse. A single-beat edit can be accomplished with a single keystroke, making keyboard use the easiest method of editing beats. The keypad definitions are:

V - Ventricular beat



- N - Normal beat
- A - Artifact
- 1-4 - Other Classifications

**Other Classifications**  
 You can create 4 user-defined labels and classifications using this feature. When the [OTHER] button is clicked on, a dialog box will pop up with the current labels and classifications for these 4 types. Click on the the names provided in the boxes to enter a user-defined label and classification.

**System Defaults:**

- [SAVE]
- [LOAD]

You can save the current values as system default. This means that every time you analyze a new patient, these OTHER values will come up as default.

Morphologies (and single beats) that are edited to one of these OTHER classifications are tabulated in an OTHER BEATS column in the Tabular Data.



Navigation and control buttons:

- [Previous Page]
- [Next Page]
- [Home]
- [Back]
- [Forward]
- [Print]
- [Exit]
- [Help]
- [Close]

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5) If an 'Unclassified' family exists, review this morphology using the method described in step 3.  
 6) Perform ALL desired edits before exiting. Since pressing EXIT will cause the data set to be re-analyzed, you should try to minimize the number of times this analysis occurs.

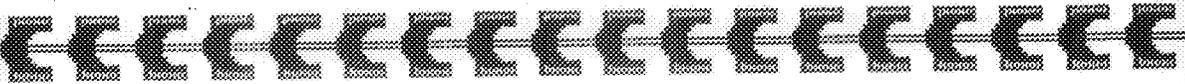
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Using the Morphology screen

This is probably the most significant edit function you can perform on the data. Recognize that no **holter device correctly classifies all beats.** But these edit features permit you to fix any incorrectly classified beat, thereby removing false-positive episodes and inserting missed episodes. There is no single correct or incorrect way to use this edit screen, but a few simple tips can speed up this important process:

- 1) Merge similar morphologies first. This will minimize the clutter on the screen and simplify the remaining tasks.
- 2) Reclassify any morphology that has been incorrectly classified by the recorder.
- 3) When editing beats in a particular morphology, it can be helpful to first determine which is the most common type of beat in this family and remove the exceptions. For instance, if a morphology consists of mostly ventricular beats, edit out the normal beats. The remaining ventricular beats can then be merged as whole family, minimizing the time required to perform this edit function.
- 4) If a 'Marginal V' family exists, review this morphology using the method described in step 3.

MUSELSON



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### Episodes Screen

From the Review & Edit screen, click on [EPISODES] to view the episode strips. A listing of all the episodes during the monitoring period is provided as an overview. Episodes may also be (un)deleted, (de)selected for printing, relabeled, or reclassified on the episodes screen.

For each episode, the sequence number, the time of occurrence (onset), the type of episode, the number of beats, the duration in seconds, and (for episodes of more than 1 beat) the heart rate are displayed. See Notes Concerning Heart Rates. A checkmark to the left of the data indicates that this episode has been selected for inclusion in the printed summary report.

You may delete an episode from the summary report by clicking on the highlighted episode. If the episode has been deleted, you may un-delete the episode by clicking on the highlighted episode. The cursor will indicate whether the episode will be deleted or undeleted. Episodes deleted in this fashion are labeled as Deleted by user.

You may select or de-select an episode from being printed in the episode strip section by clicking on the

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far left of the highlighted episode (correct cursor positioning is indicated by a checkmark cursor). A checkmark to the left of the data indicates that this episode has been selected for inclusion in the printed summary report.

To highlight a different episode, click on that episode.

### [EPISODE PARAMS]

Allows adjustment of the episode parameters (pause length, SV Tachy rate, VE Tachy rate, and ST level). If the parameters are changed in this dialog, the patient data will be re-analyzed. See Analysis Parameters Dialog.

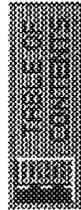
### [RELABEL STRIP]

Allows you to change the text associated with a specific strip. It does NOT change any other information (e.g., tabular data).

### [RECLASSIFY EPISODE]

Allows you to change the episode type of an episode. See Reclassifying Episodes.

### [DISPLAY OPTIONS]



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Calls up a dialog box that allows you to determine which episode types to display in the list. See Selecting Episode Types.

[PRINT]

Allows you to print individual strips or a textual listing of episodes. You may print the episode chronology, all "checked" strips, or a single strip. For more information concerning printed strips, see Notes concerning printed strips.

[EXIT]

Returns to the review and edit screen.

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### Reclassifying Episodes

Episodes may be reclassified from Episodes Screen. To select a new episode classification, click on the new episode class.

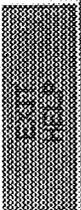
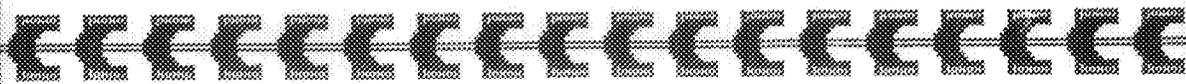
For some reclassifications, tabular data and trend graphs are fully updated to reflect the change. This only occurs when editing single beat episodes to other single beat episodes, pairs to pairs, or runs to runs. For all other conversions, the tabular data is updated to reflect the removal of the original episode but is not updated to reflect an addition of the new episode type; not all of the needed information is available to fully update the tabular data.

When performing a reclassification, the episode types that will allow a complete edit will appear with BLACK text. All remaining episode types will appear with GRAY text, signifying that selecting these types will result in only a partial reclassification. A warning message will also appear if you are attempting a partial reclassification.

[CANCEL]

Returns to episodes screen without making any changes to the episode.

## Episodes



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[OK]

Returns to episodes screen and changes the episode classification.

### Phonetic

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#### Relabeling Episodes

Episodes may be relabeled from Episodes Screen. Relabeling episodes will not change the tabular data, but will only change the label of the episode.

To get the original label back, backspace over the edit field until the label is completely blank, then press <ENTER>. The BIO program will recognize this and return to the original episode label.

To make the arrow cursor active again after editing the label, press <ENTER> to accept editing changes or <ESC> to abort editing changes.

[CANCEL]

Returns to episodes screen without making any changes to the episode.

[OK]

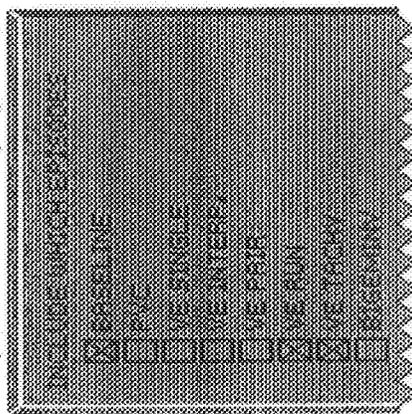
Returns to episodes screen and changes the episode label.



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**Selecting Episode Types**

A "filter" dialog box is provided to allow selection of the type of episodes to be displayed or printed.



Checked episode types will be displayed while unchecked types will not be displayed.

Note about checkboxes: It is not necessary to click within the box to turn on or off the checkbox, you may also click on the word next to the checkbox.

The [DELETED] type is somewhat special. If [DELETED] is the only box checked, all types of deleted episodes will be displayed. However, if [DELETED] is not the only box checked, only episodes



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of the checked type(s) will be displayed (including deleted episodes of that type(s)).

If [PRINTED STRIPS ONLY] is checked, only strips that are selected for printing (Summary Strips) will be displayed.

[NONE]

Removes check marks from all episode types. You may then turn on individual episode types manually.

[ALL]

Adds check marks to all episode types. You may then turn off individual episode types manually.

[CANCEL]

Leave the dialog but do not save changes to the episode types selections.

[OK]

Activates changes to the episode types selections.



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**Trend Graph Screens**

Click on [GRAPHS] to view the graphs.

Six graphs describe the data:

**Heart Rate Trend**

The heart rate graph displays the minimum, maximum, and average heart rate during the monitoring period. The center of each bar denotes the average heart rate for that time while the top edge of each bar denotes the maximum heart rate and the bottom edge denotes the minimum heart rate. See Notes Concerning Heart Rates.

**ST Values - Channel 1****ST Values - Channel 2**

The ST graphs indicate the average, minimum, and maximum ST values. See Normalization of ST Values.

**Total Ventricular Ectopy**

The ventricular ectopy bar graph displays a histogram of ectopic occurrences.

**Ectopic Coupling Intervals**

The ectopic coupling intervals graph is a frequency

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distribution. The intervals are expressed in milliseconds.

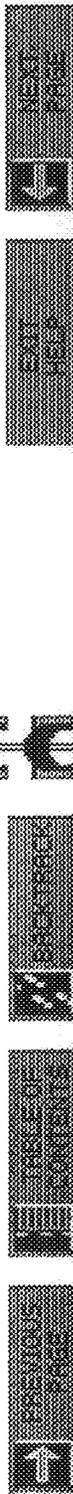
**R to R Distribution**

These graphs are distributions of RtoR interval measurements made on normal beats coupled to other normal beats during the monitoring period.

**General Info**

The amount of time represented by each bar in the bar graphs is dependent on how much time is displayed. Of course there is an exception. When data has been manually edited in the hourly tabular data fields, the bar will represent a full hour. This bar is displayed in a lighter green to indicate that it represents manually edited data.

When this screen is first entered, the full time range is displayed. If a finer resolution is desired in the graphs, you can place the cursor on the hour you want to enlarge (notice the cursor appears as a magnifying glass). When you click on the graph, the time range is changed to a resolution of 1 hour. If you desire to jump from the graph directly to full disclosure at a specific time, simply click again on the fine resolution graph at the exact time you desire (notice the cursor appears as a heartbeat).



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[HEART RATE & ST CH.1]

Displays the heart rate and ST channel 1 graphs.

[HEART RATE & ST CH.2]

Displays the heart rate and ST channel 2 graphs.

[HEART RATE & ECTOPY]

Displays the heart rate and ventricular ectopy graphs.

[ECTOPY & COUPLING]

Displays the ventricular ectopy and ectopic coupling interval graphs.

[R-TO-R DISTRIBUTION]

Displays the R to R distribution graph.

[SELECT TIME RANGE]

Brings up a dialog box where you are allowed to set the time range to be displayed on the graphs. Any time range may be selected down to a minimum time range of 4 minutes. See Selecting a Time Range.

[ZOOM OUT]

Sets the displayed time range to the full time range of the procedure.

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[PRINT]

Prints the graphs. If the full time range is currently displayed, the graphs printed will represent the full time range. If the full time range is not currently displayed, graphs representing the full time range and graphs for the currently displayed time range will be printed. (Note that graphs of the entire monitoring period may be printed with the summary report.)

[EXIT]

Returns to the review and edit screen.

Blindscan



[RATE + SVE DATA]

Displays the rate and supraventricular data. See Notes Concerning Heart Rates.

[EPISODE/VE COUNTS]

Displays the ventricular and other beat data.

[ST DATA]

Displays the ST level and slope data for each channel. See Normalization of ST Values.

[PRINT]

Prints all the tabular data (not just the currently displayed table(s) as might be assumed).

[EXIT]

Returns to the review and edit screen.

Tabular Data

Click on [TABULAR DATA] to access hourly tabular data. The hourly tabular data may be edited if desired.

To edit any cell entry, either click on the cell or move onto the cell using the left and right arrow keys and press <ENTER>. (While the cursor is in the table proper, the up and down arrow keys will also move the cursor).

The cell will darken, signifying that you are in edit mode. Only numerical data entries are accepted. Use the <BACKSPACE> or <DELETE> keys to edit entries into the cell. To save an edited value in a cell, press <ENTER>.

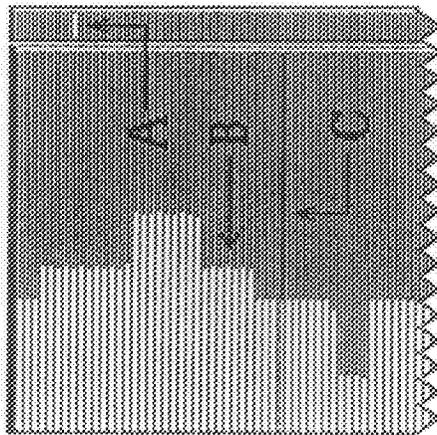
Important Note: Once a cell has been edited, the new value overrides all changes that could affect the value in the cell (i.e. editing morphologies, deleting episodes, etc.). Until edited again, the cell will not change value. To restore a cell to its original value, erase the value using the <BACKSPACE> or <DELETE> keys and press <ENTER> when the cell is empty. A cell that contains edited data is indicated by a white border.



**Superimposition Screen**

Click on [SUPERIMP.] to access superimposition scanning and horizontal scrolling.

High-speed superimposition of successive QRS waveforms allows quick screening of an ECG record for variations in R-R interval.



A small tick mark is provided to show the current position in the data set (A).

The instantaneous R-R interval is plotted vertically on the left side of the viewing area (B). Short lines indicate short R-R intervals (high heart rate) while

PREVIOUS SCREEN

TABLE OF CONTENTS

ECG TRACK

long lines indicate long R-R intervals (low heart rate).

A moving guide is superimposed on this graph to orient the user (C).

To interrupt superimposition at any time, press the spacebar or press either the left or right arrow key to begin scrolling to the left or to the right, respectively.

Superimposition may also be accomplished in the backwards direction by pressing the up-arrow key.

To return to full-disclosure (review and edit screen) at the minute beginning with the current beat, press <ESC>.

The numbers 0 through 9 move n/10ths through the procedure. For example, pressing 3 moves to the 3/10ths position.

Note that the mouse is not active while in the Superimposition screen. All interaction takes place through the keyboard.

EXIT HELP

NEW PAGE



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A quick report has been predefined for ease of use. It consists of Patient Data, Hourly Tabular Data, and a quick list version of Episode Strips. Click on [QUICK] to select the quick report sections.

A standard report has also been predefined. It consists of every section except Episode Chronology and Full Disclosure. The standard version of Episode Strips will be included in the standard report. Click on [STANDARD] to select the standard report sections.

When accessing printing from the main menu, the standard report sections are selected by default. When accessing printing from the review and edit screen, no sections are selected by default.

A user-defined report may also be defined by selecting the desired sections, then clicking on [SAVE]. This saves the currently defined sections of the report as a user-defined report. The user-defined report can be selected by clicking on [CUSTOM]. Please note that the episode types to be included in the Episode Chronology are not saved as part of the user-defined report type. If Episode Chronology is selected as part of a user-defined report, all episode types are

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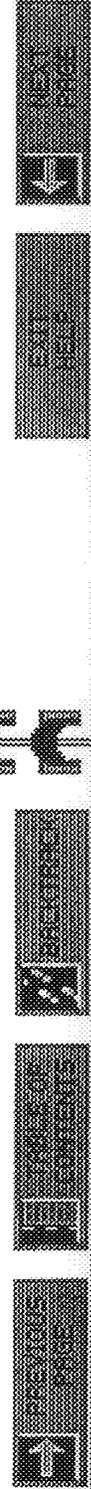
included in the user-defined report. Similarly, the time range on Full Disclosure is not saved as part of the user-defined report type. If Full Disclosure is selected, the full time range will be included.

To select or un-select any of the report sections, click on the appropriate box. Clicking on [EPISODE CHRONOLOGY] provides another dialog box where you are allowed to select the type of episodes to print in the list (see Selecting Episode Types). When selecting Episode Strips, one of three subcategories (Quick, Summary, All) must be selected. A subcategory will be selected for you if you click on [EPISODE STRIPS] or you may click on any subcategory.

#### [FULL DISCLOSURE...]

If you select the full disclosure section, you will get a dialog box allowing you to specify a start and stop time, the number of minutes per page, and the channel configuration. Use the sliders to adjust the start and stop times. You may select either 30 or 60 minutes per page if only printing a single channel or 15 or 30 minutes per page if printing both channels. See Selecting a Time Range.

Some episode types are marked on the resulting printout. These episode types are: SV tachy, VE run,



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VE tachy, Pauses, Brady episodes, Symptom strips, and user-defined strips. These episodes are marked with simple brackets and a number corresponding to the numbers found on the episode screen (see Episodes Screen).

Whenever the recorder has marked a portion of the full disclosure as 'too noisy to analyze', that portion will appear with a gray background.

There is an indication on this dialog box of the approximate number of pages that the currently selected printout will take. Please pay attention to this number to avoid printing out more than is necessary. Selecting [EPISODE CHRONOLOGY] with all types or [EPISODE STRIPS] with all strips can create a massive printout for some patients.

Selecting a Time Range

This dialog box is used in 2 places: selecting a time range for graphs (See Trend Time Range) and selecting a range of full disclosure to print (See Printing Full Disclosure).

Two slider bars will appear in this dialog. The start and end times may be adjusted by moving the sliders.

- [15 MIN. PER PAGE]
- [30 MIN. PER PAGE]
- [60 MIN. PER PAGE]

Selects how much ECG to print on each page. This is only available on the full disclosure dialog.

- [INCLUDE CHANNEL 1]
- [INCLUDE CHANNEL 2]

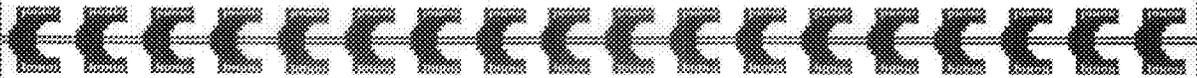
Selects which channel(s) to print out. If only one channel is selected, the print density (see above) is doubled. This is only available on the full disclosure dialog.

[CANCEL]

Leave the dialog with no time range selected.

[OK]

Activates the selected time range (and print options).



Notes Concerning Heart Rates

Heart rates can be calculated in many ways. This program uses a 16-beat running average for most of the data (i.e. trend graphs, tabular data, episode rates, and summary report). However, the caliper only uses the selected beats to determine a rate. As a result, it is possible for the caliper to report a rate that is outside the minimum or maximum rates reported in the tabular data.

For instance, if you select a 4-beat SV tachy episode using the calipers, the calipers might report a rate of 220 BPM; while the summary report says that the maximum rate for the entire procedure was only 200 BPM. This is because the 200 BPM rate was based on the 16-beat running average while the 220 BPM rate was based on only 4 beats.

Normalization of ST Values

All ST data has been normalized in each channel. This means that all ST values reported throughout the system are relative to an ST normal. This normal defaults to the MEDIAN of the data in each channel. If an absolute ST value is desired, set the ST measurement parameter to ABSOLUTE. See Analysis Parameters Dialog.

NOTE: Remember, the MEDIAN is the center value; such that half the values are less than the median and half are greater. This can be different from the MEAN (or average) value.



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### Using a Mouse

If you have never used a mouse before, a short familiarization period will be necessary.

Reserve some flat space in front of or to either side of your terminal. You will need an area of at least 36 square inches to begin with. As you become more familiar with your mouse, this space requirement will become smaller. Make sure the surface is hard and free of dust or dirt.

You don't have to keep the mouse 'anchored' to your desk at all times. In fact, you will be picking it up frequently in a brushing, or scooting motion to move the cursor across the screen.

Imagine your mouse work surface is covered with long-haired carpet and you are brushing or smoothing the hair in the direction you want your cursor to move on the screen.

Example: the cursor is in the upper left corner of your screen and you need to move it to the lower right corner. Slide the mouse from the upper left to the lower right corner of your mouse work surface, pick up the mouse and slide again, repeating as necessary.

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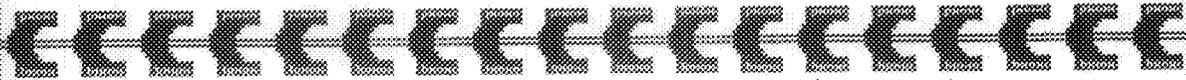
If you have two mouse buttons, it doesn't matter which button is used. If you have three mouse buttons, either the left or right button may be used but the center button is always ignored.

There are two ways to use the mouse buttons. Clicking occurs when you depress and immediately release the button. Dragging occurs when you depress the button and hold it down while moving the mouse.

Clicking is used to choose or select an icon, beat, or program option. First move your cursor onto the icon or box you would like to select. Your cursor may change in appearance or color in the vicinity of the icon or box. This area, where the cursor takes on a new appearance or color, is called a 'hot spot'. It is your signal to click the mouse button.

Dragging, on the other hand, is used to pick something up off the screen and move it to another location on the screen.

BRUSHING



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### Using the Keyboard

If you suffer from a fear of rodents, or you simply don't have one, we have provided a method of using the keyboard to simulate using the mouse:

<ENTER>

This button simulates a button click on the mouse.

<LEFT>

<RIGHT>

<TAB>

<Shift-TAB>

These buttons will move the cursor, in succession, to every hot-spot currently accessible. When the cursor is over the desired hot-spot, press <ENTER>.

<Ctrl-LEFT>

<Ctrl-RIGHT>

<Ctrl-UP>

<Ctrl-DOWN>

Press and hold these buttons down to 'slide' the cursor around the screen.

Most hot-spots have a keypress associated with them. For instance, the help button you clicked to open this help system uses <F1> as it's hot-key.

<Ctrl-F1>

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This keypress will identify the keypresses for all hot spots currently on the screen. Go ahead and press it now. Those hot-key labels will remain on the screen until you press a key or move the mouse.

When you press a hot-key, the cursor will slide over to the hot-spot. The action associated with that hot-spot is then performed.

<Print Screen>

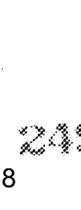
Press this key (some keyboards also require the Shift key to be depressed) to print a snapshot of the screen on the printer. This comes in handy for training new users and in tracking down problems when dealing with technical support.

<SysReq>

This special key will provide a revision dialog from anywhere in the BIO system. This revision dialog will tell you which version of the software you are currently running. This special key is active everywhere in the BIO system except for superimposition.

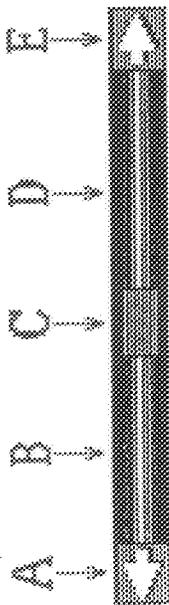
To use a slider without using the mouse, position the cursor over the slider (the cursor is a yellow double

Pinpointers



### Using a Slider

Slider bars are provided when there is more data than will fit on the screen (e.g., full disclosure or episode screens) or to adjust a time value (e.g., start and stop times for graphs).



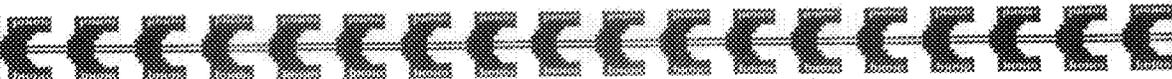
To move the slider by the smallest possible amount (e.g., one minute in full disclosure), you would click on one of the arrows at the end of the slider (A or E). The slider will move in the direction that the arrow points.

To move the slider by a larger amount (e.g., one screen which may be up to 12 minutes in full disclosure), you would click on the slider bar (B or D) between the slider and the arrow. The cursor will be shaped like an arrow with a bar when positioned correctly.

To move the slider to a specific spot, drag the slider with the mouse to the desired spot. This is the

arrow when positioned correctly), press (ENTER) then press the left and right arrow keys (for a horizontal slider) or the up and down arrow keys (for a vertical slider) to move slider to the desired position. After a couple seconds of not pressing an arrow key, the cursor returns so that the arrow keys will move the cursor to other hot-spots. Note that when moving the slider box, the longer the arrow key remains depressed, the faster the box will move.

PinpointView



### Formatting a disk

Floppy disks need to be formatted before they may be used by the backup process. Disks may be purchased pre-formatted or they may be formatted by the DOS format command. The typical command (at the DOS prompt) to format a disk is:

format a: (if using drive a)

-or-

format b: (if using drive b)

You will be prompted for the volume name. However, volume names are not required.

Please be aware that formatting a disk destroys any previously existing data on that disk.

Diskettes generally come in 2 sizes, each with 2 different densities:

- 3-1/2" ... 720K (low density)
- 3-1/2" ... 1.44Mg (high density)
- 5-1/4" ... 360K (low density)
- 5-1/4" ... 1.2Mg (high density)

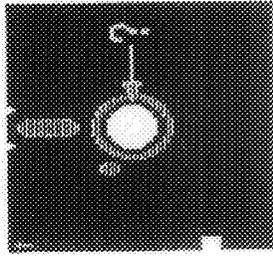
### IMPORTANT:

Do not attempt to format a low density disk as high

quickest way to move the slider a large distance. To drag the slider, move the cursor onto the slider (C) (it will be in the shape of a yellow double arrow when it is properly positioned), then click and hold the mouse button and slide it to the desired position, then release the mouse button.

The size of the slider indicates how much of the data is currently displayed. In the grapho, approximately 1/8 of the data is displayed as indicated by the slider covering approximately 1/8 of the slider bar.





5-1/4" DISKS:

LOW DENSITY:

There is a shiny black ring on the disk media visible through the center hole.

HIGH DENSITY:

There is no shiny black ring.

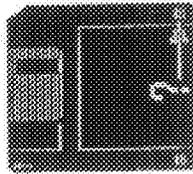
For more information concerning formatting floppy disks of different densities, consult your DOS manual.

Procedures



density. Sometimes the format will succeed, but the data integrity is poor at best. At any time the disk can fail and you'll be stuck with a backup that is unretrievable.

To avoid this, it is vital to be able to recognize the differences between the types and densities of diskettes:



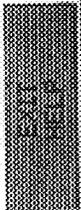
3-1/2" DISKS:

HIGH DENSITY:

There is a hole punched through the diskette where you see the yellow "7".

LOW DENSITY:

There is no hole there.



icons.

cursor

This is what moves on the screen in response to mouse movements. It can take on a number of forms, depending on the application.

dialog box

A dialog box is a graphic box that is displayed when something requires your immediate attention. You may enter information into the box (if appropriate), then click on [OK] or [CANCEL] to continue processing. Please note that even though other hot-spots may be visible around the periphery of the dialog box, only the buttons inside the box are active.

DOS

Disk Operating System.

DPI

Dots Per Inch -- a measure of the maximum resolution of the printer. Printing at the higher resolution provides a nicer appearance but printing will be slightly slower.

drag

GLOSSARY

[ ]

Symbols that indicate a clickable box.

<>

Symbols that indicate a key to be typed.

back-up

A copy of a patient's data file on floppy diskettes.

bar graph

A graph using vertically arranged rectangles or 'bars'. For example, the number of ectopic beats per hour is expressed as a bar graph.

click

Depress the mouse button and immediately release it. When instructed to 'click on an icon', make sure the cursor is properly placed on the icon; in most cases, the cursor will change appearance or color to signify proper placement.

control panel

The gray area at the right edge of the screen where all program options are listed in the form of boxes or



monitoring period. This record can be printed out in miniaturized form.

**hot-key**

This refers to the keypress associated with a hot-spot.

**hot-spot**

This refers to the area in and around an icon or box in which the cursor changes appearance or color, and on which you may click with the mouse to access the corresponding option or feature.

**icon**

A pictorial representation or symbol used to describe program features or options.

**isolated ectopic beat**

A single ectopic beat.

**paging**

Moving forward or backward through the full-disclosure ECG one screen at a time. When one minute of data is displayed per screen, paging forward or backward moves the record in one-minute increments.

Some fixtures on the screen can be 'picked up' and 'dragged' across the screen to another location. To accomplish this, position the cursor on the fixture with the mouse. When the cursor changes appearance or color, depress the mouse button. With the button depressed, move the mouse to 'drag' the fixture to the desired location. Once there, release the button to anchor the fixture.

**edit**

This feature allows the user to change patient and set up data and add comments to the Holter report.

**episodes**

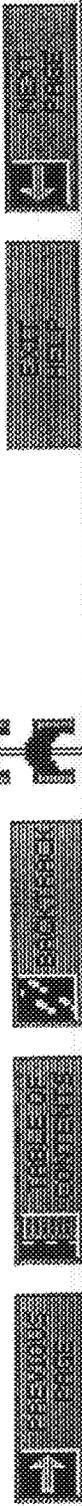
These are strips of importance which were 1) detected by the analysis software, 2) marked by the patient pressing the symptom button, or 3) marked by the user with the calipers.

**family**

Another word commonly used to refer to a morphological collection of similar beats.

**full-disclosure**

This refers to the beat-by-beat recording and presentation of the ECG recording for the entire



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position, and the rail that the slider moves along. Clicking on the rail will move the slider in larger "steps" than clicking on the arrows.

superimposition

Individual QRS complexes are superimposed at high speed to aid in the detection of differences in R-R interval, indicative of rate disturbances or ectopic beats. When a shortened or lengthened R-R interval occurs, the QRS complex in the center of the screen flashes momentarily. R-R intervals are presented graphically at the left edge of the screen. A 'spike' corresponds to an abnormally long interval, a very short horizontal line corresponds to an abnormally short interval.

technical support

Biosensor technical support may be reached at 1-800-727-6665 or 612-449-9100.

toggle

A box or icon which is alternately selected and deselected by consecutive mouse clicks.

trend

A graph which displays the fluctuations of a quantity

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parallel port

Typically, an output device on your computer used to communicate with a printer. This program can also use special input/output parallel ports to perform the data transfer from the recorder. See the User's Manual that came with your computer for more information regarding parallel ports.

P.R.

Patient Recorder

restore

To transfer a patient's data file from floppy diskettes to the hard disk for viewing.

review

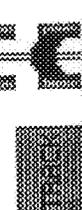
A feature allowing the user to view the full-disclosure and all graphs, tables, and patient data.

scrolling

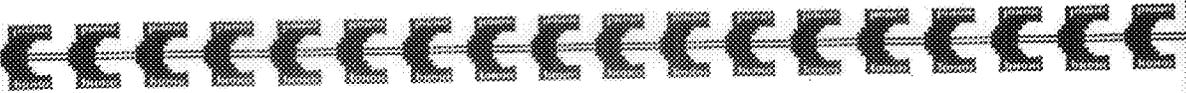
Moving forward or backward through the full-disclosure ECG one line at a time.

slider bar

The vertical or horizontal bar consisting of an arrow at each end, a slider that represents the relative



This page intentionally left blank.



or parameter over time. Examples are the heart rate, ST, and VE minute trends.

unclassified beats

These beats could not be successfully correlated as a normal or a ventricular beat, although they are most likely aberrant. Typically, there are treated as normals with the following exceptions: they will not initiate an SV episode and will not terminate a VE run episode.

validation

Confirmation of the recorder's analysis by viewing the full-disclosure and captured episode strips.

viewing area

The central and largest portion of the screen. When reviewing the ECG, this area is the blue area in which the the ECG is displayed.



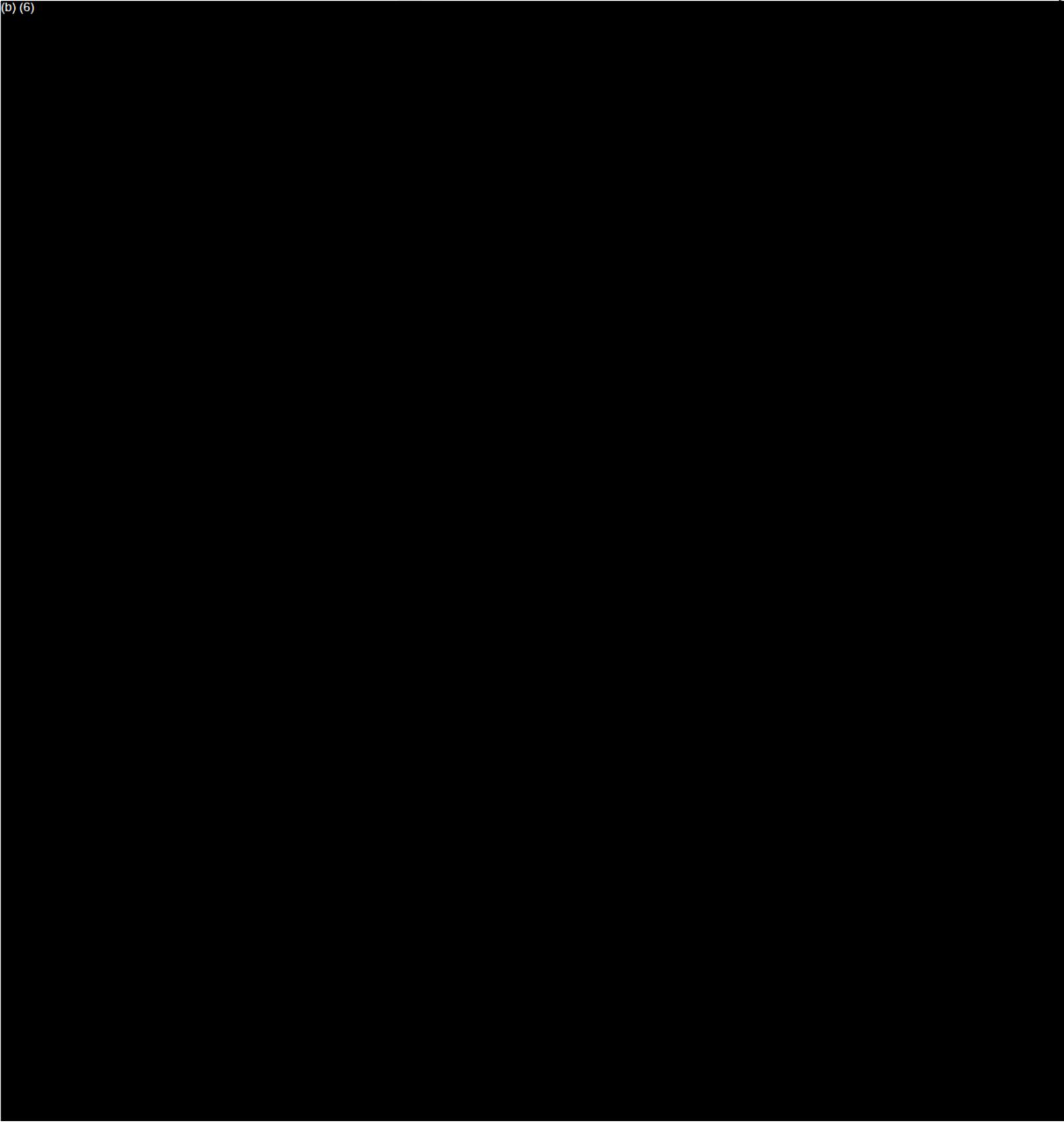
**ENCLOSURE D**  
Example of a Summary Report printout

Bio Demo Patient (v7.03)  
RECORDER: 8267

Oct 7, 1992  
Page: 1

PATIENT DATA SUMMARY

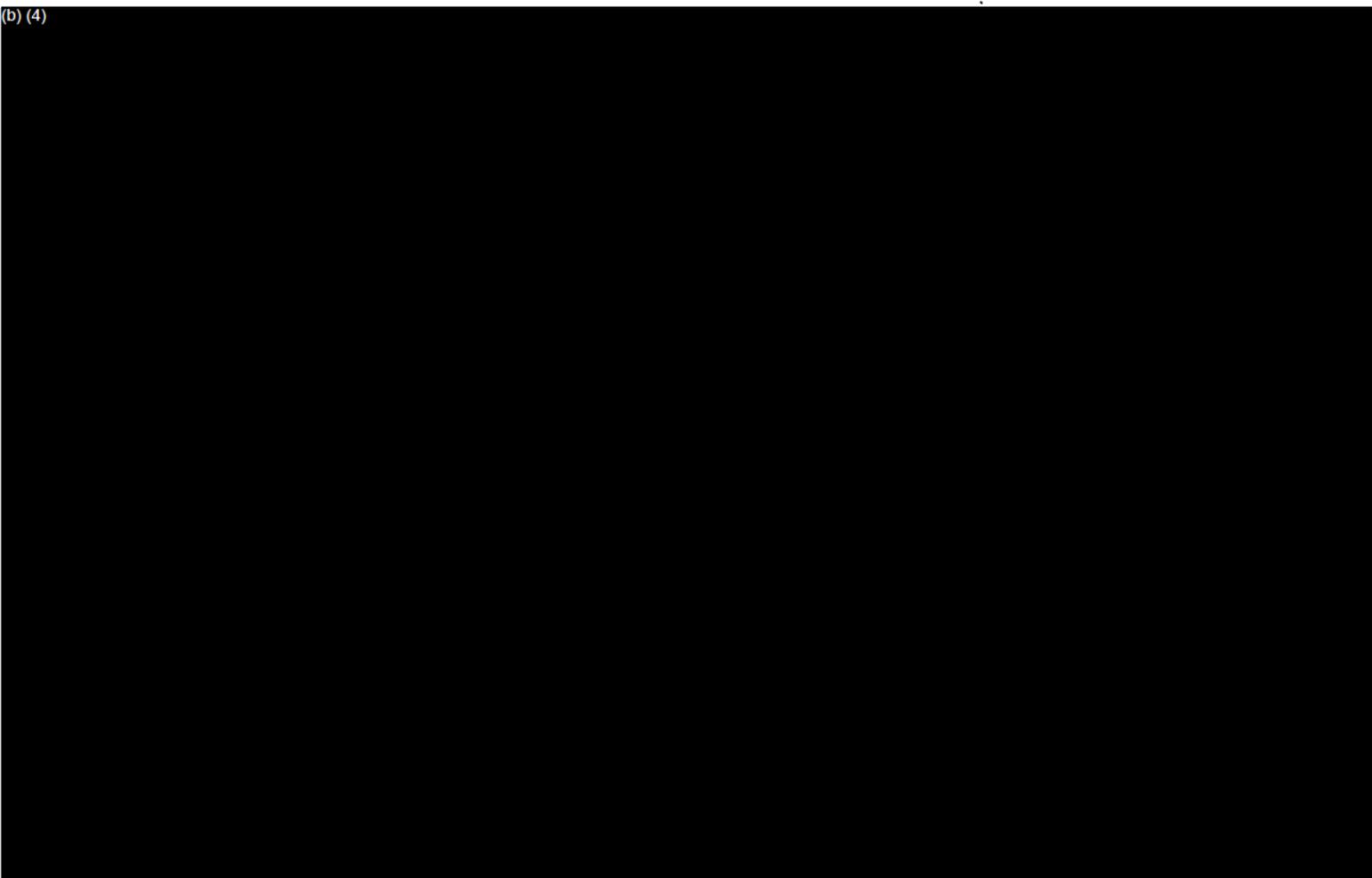
(b) (6)



Bio Demo Patient (v7.03)  
RECORDER: 8267

Oct 7, 1992  
Page: 2

HOURLY TABULAR DATA :



Bio Demo Patient (v7.03)  
RECORDER: 8267

Oct 7, 1992  
Page: 3

HOURLY TABULAR DATA

(b) (4)

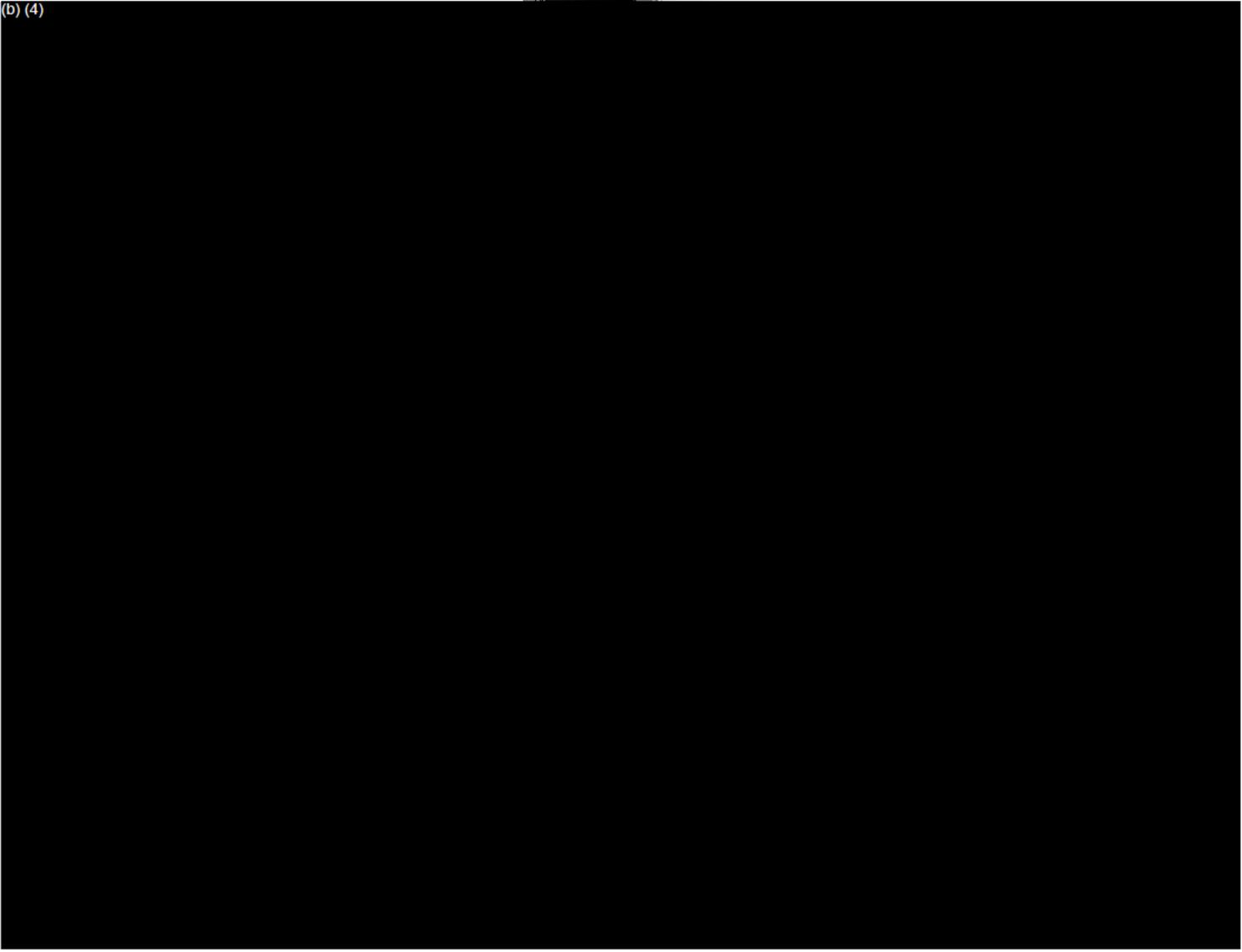


Bio Demo Patient (v7.03)  
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Page: 4

HOURLY TABULAR DATA

(b) (4)

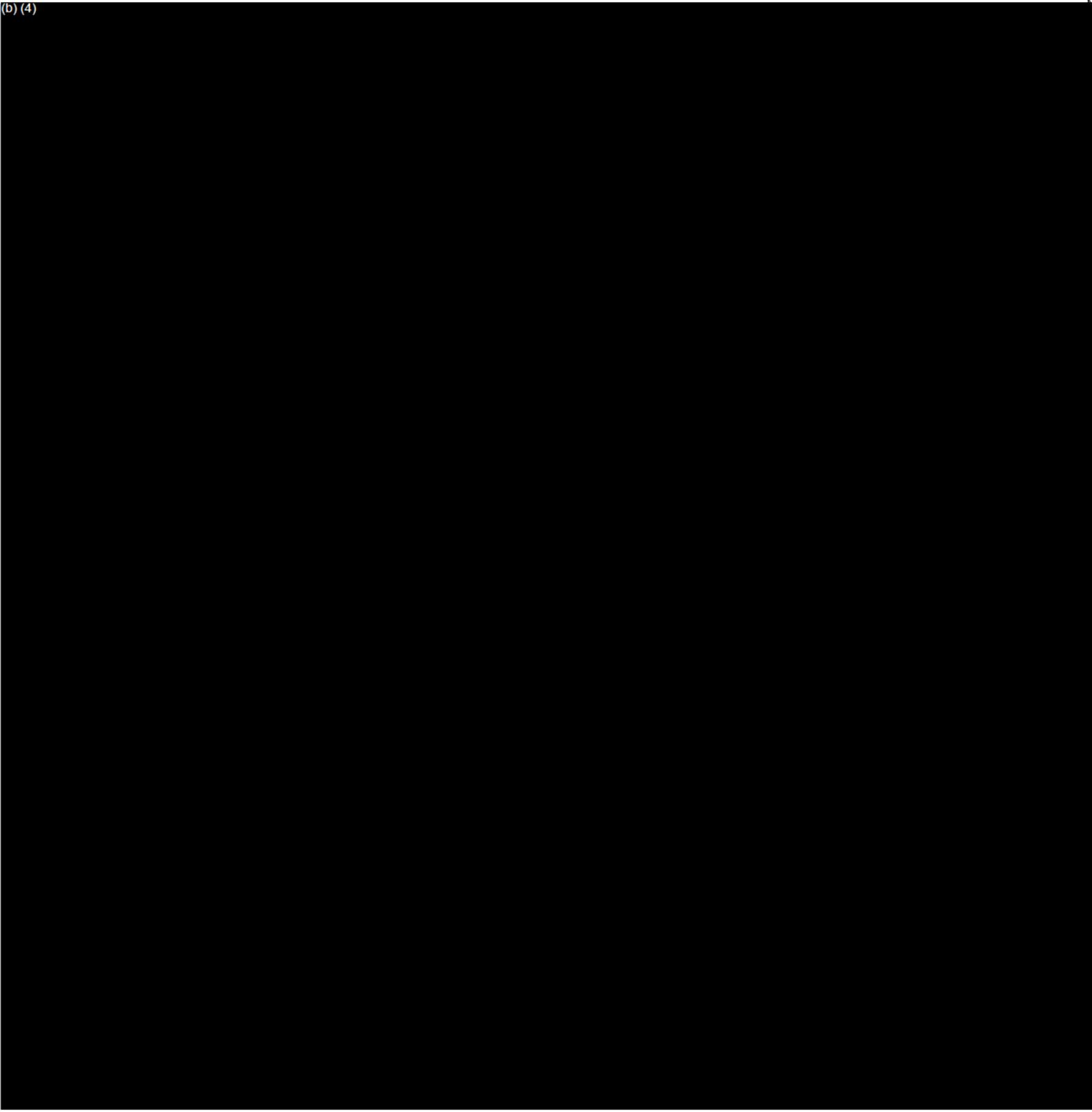


Bio Demo Patient (v7.03)  
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GRAPHS

(b) (4)



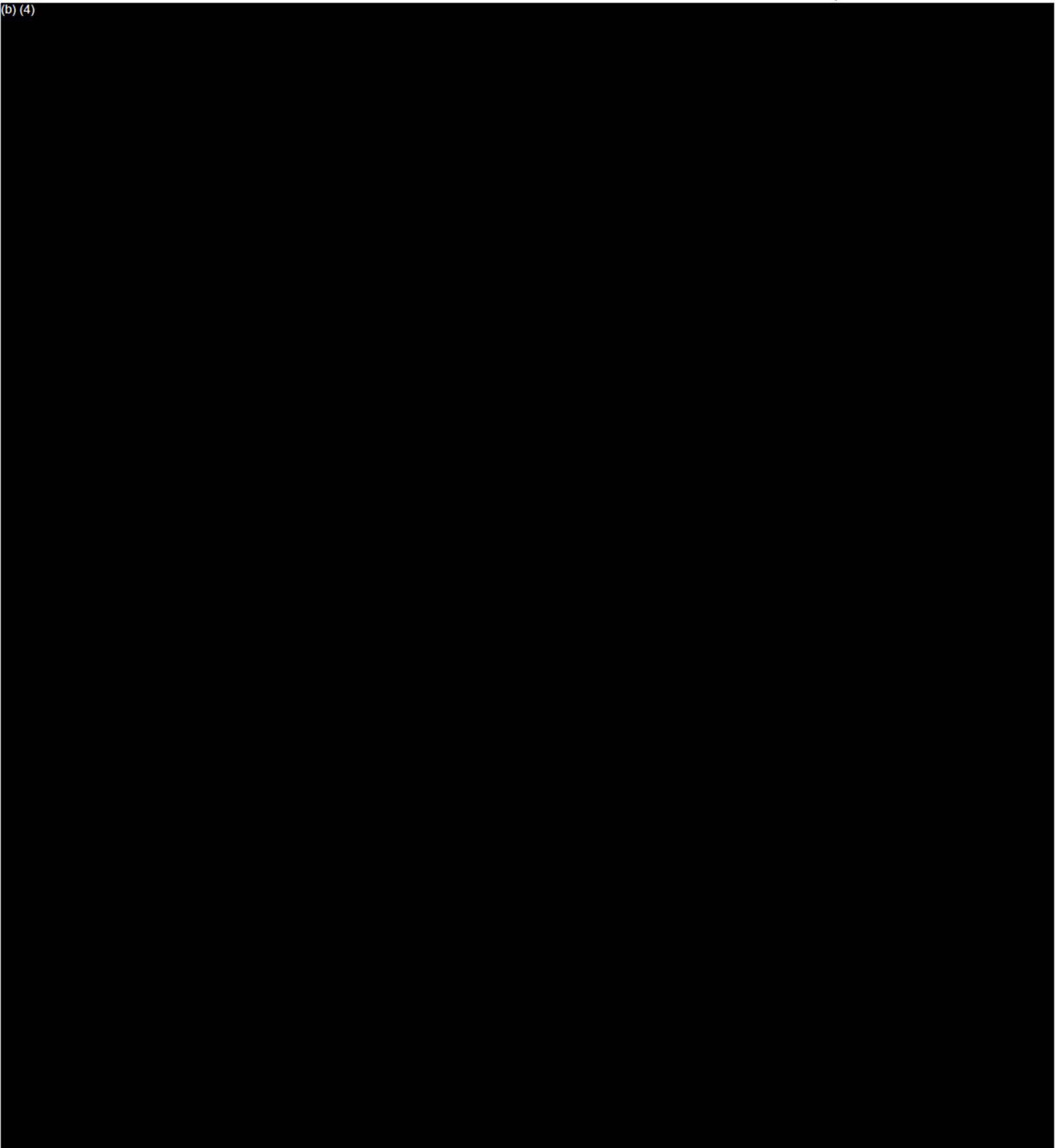
KEY :  Original values  Edited values

Bio Demo Patient (v7.03)  
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GRAPHS

(b) (4)



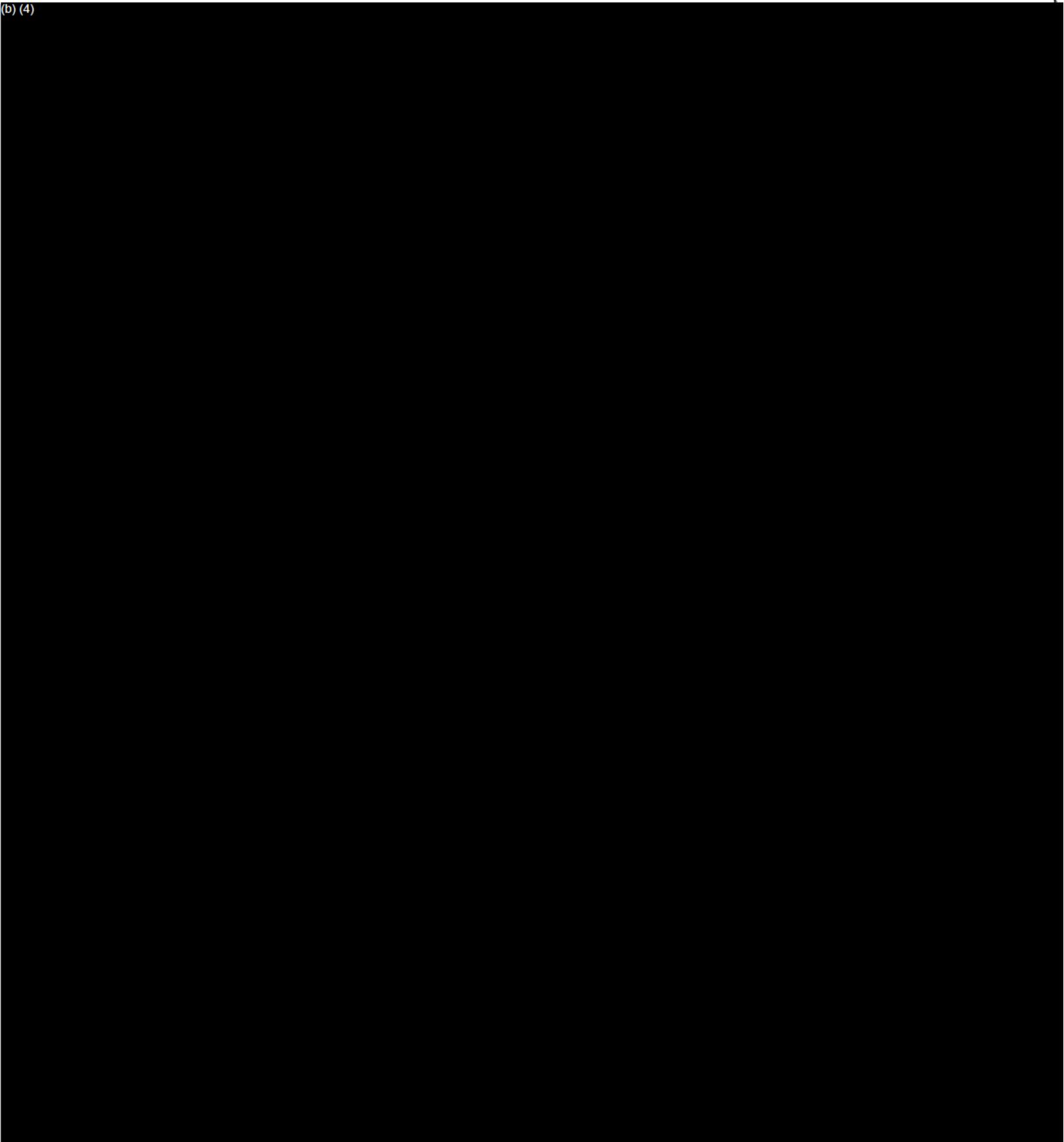
KEY :  Original values  Edited values

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GRAPHS

(b) (4)



0 200 400 600

TIME (MICROSECONDS)

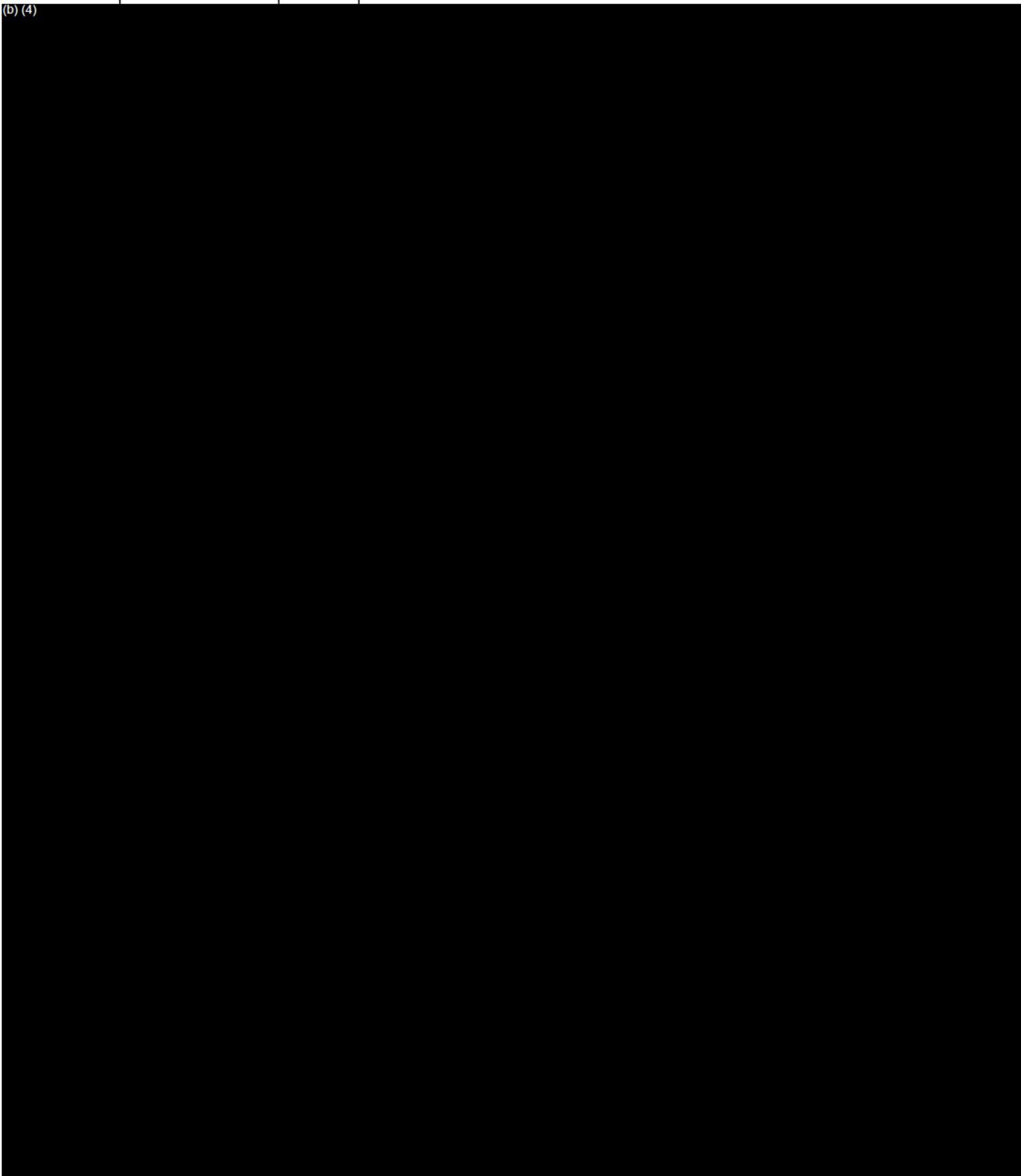
KEY :   $\sigma > 42$  msec   $\sigma < 42$  msec

264

Bio Demo Patient (v7.03)  
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Oct 7, 1992  
Page: 8

MORPHOLOGIES



\*\*\* Calibration: 10 mm = 1 mV \*\*\*

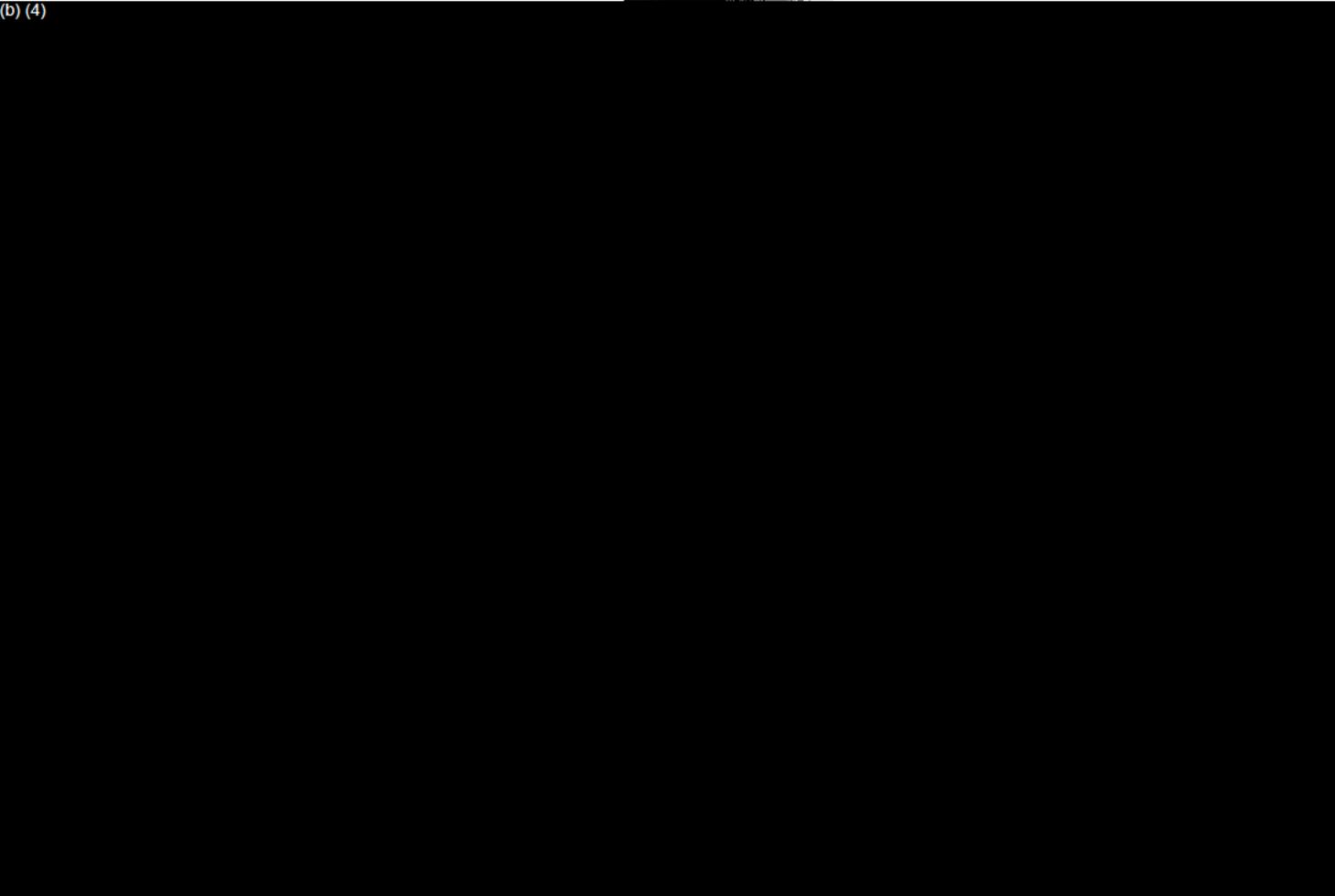
265

Bio Demo Patient (v7.03)  
RECORDER: 8267

Oct 7, 1992  
Page: 9

MORPHOLOGIES

(b) (4)



\*\*\* Calibration: 10 mm = 1 mV \*\*\*





























**Enclosure E**  
**Summary of System Tests**

2.0 The Gain vs. Frequency of the pacer detect circuitry instrumentation amplifiers with voltage limits were tested. A function generator was used to vary the frequency of the input signal over the entire test range. The input amplitude remained constant during this test. The output of the instrumentation amplifiers were measured and compared to expected results. Table 2 below is a summary of test results.

**Table 2**

<u>Frequency</u>	<u>Voltage In</u>	<u>Voltage Out</u>	<u>Gain</u>
(b)(4) testing graphs			

3.0 The bandwidth of the bandpass filter was also tested. A function generator was used to vary the frequency and of the input signal over the entire test range. The input amplitude remained constant during this test. The output of the filter was measured and compared to expected results. Table 3 below is a summary of the test results.

**Table 3**

<u>Frequency</u>	<u>Voltage In</u>	<u>Voltage Out</u>	<u>db</u>
(b)(4) testing graphs			

4. Integrated pacemaker circuitry testing was also performed. A pacemaker stimulus generator was used to verify the circuits operation. Seamed<sup>1</sup> is a registered pacemaker stimulus generator used as a temporary pacemaker by various manufacturers. The one used in these tests was built and labeled for Cardiac Pacemakers, Inc. (CPI).

Output from the pacemaker stimulus generator was input into the front end analog circuitry of the device under test. The generators output was varied from a minimum voltage of 0.75 mv to the point of saturation. The generators pulse width was also varied from 100 usec to 2 msec. Tests were conducted using pacemaker stimuli only as well as pacemaker stimuli in combination with ECG. Timing relationships between the pacemaker stimulus and QRS complex of the ECG were controlled assuring that the pacemaker stimulus properly preceded the resultant QRS wave form. Pacemaker testing and arrhythmia processing were verified as normal. The device under test was observed to trigger the necessary interrupt pulse to indicate the presence of the pacemaker stimulus.

### Conclusions

Test results demonstrate that the pacemaker stimulus detection circuitry is functioning as expected and intended. The results indicated that the system does operate as originally designed and specified.

Biosensor believes that the integrated circuit test is the most relevant indication of the systems proper performance. The circuit sub-sections tests support this final verification and validation test step. Biosensor's standard quality assurance practices were followed throughout the entire design, development and testing process of this development project.

---

<sup>1</sup>Seamed Corporation, Seattle Washington

**Enclosure F**  
**Class III Summaries and Class III Certifications Document**

**PREMARKET NOTIFICATION  
CERTIFICATION AND SUMMARY**

I certify that I have conducted a reasonable search of all information known or otherwise available to me about the types and causes of safety and/or effectiveness problems that have been reported for Holter monitoring systems. I further certify that I am aware of the types of problems to which Holter monitoring systems are susceptible and that the following summary of the types and causes of safety and/or effectiveness problems about the Holter monitoring system is complete and accurate:

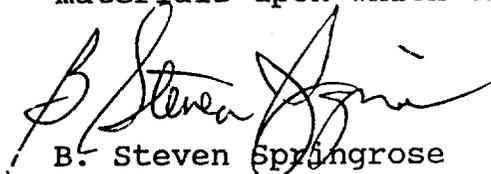
1. Errors in Automated ECG Analysis:

Computerized ECG analysis systems can make errors, both false positive where the error produces an incorrect abnormal and false negative, where the error causes an abnormal event to be missed. Since false positive errors are more easily reviewed and detected by users of Holter monitoring systems than false negatives, efforts should especially target false negative errors. The "sensitivity" statistics give an indication of the level of false negative errors.

2. Data Compression and ECG Resolution.

Digital systems using different techniques of data storage are able to reproduce the fidelity of the ECG signal at varying levels. In general, the larger the amount of data storage space available the higher the fidelity of the signal.

Attached is a bibliography, or other citation, of the materials upon which the above summary is based.



B. Steven Springrose  
President

Biosensor Corporation  
July 25, 1994

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C.N. Mead, H.R. Pull, K.W. Clark, and L.J. Thomas, Jr.: Expanded frequency-domain ECG waveform processing: integration into a new version of Argus/2H. IEEE Proc. Computers in Cardiology, pp. 205-208. 1982 (Seattle, Washington).

F.M. Nolle: ARGUS, a clinical computer system for monitoring electrocardiographic rhythms. Washington University, Sever Institute (D.Sc. dissertation). 1972.

C.N. Mead, H.R. Pull, J-S Cheng, K.W. Clark, L.J. Thomas, Jr.: A frequency-domain-based QRS classification algorithm. IEEE Proc. Computers in Cardiology, pp. 351-354, 1981 (Florence, Italy).

C.N. Mead, K.W. Clark, S.J. Potter, S.M. Moore, L.J. Thomas, Jr.: Development and evaluation of a new QRS detector/delineator. IEEE Proc. Computers in Cardiology, pp. 251-254, 1979 (Geneva, Switzerland).

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Arithmetic Coding for ECG Data Compression. G Passariello, L Gavidia, F Rodriguez, J Condado, V Ruesta, C Roux, F Mora, 1992 IEEE.

ST-Segment Analysis with Ambulatory ECG Monitoring: Are Solid State Recorders better than Tape Cassette? Thomas Brueggemann, Dietrich Andresen, Rolf Schroeder, 1991 IEEE.

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Diagnostic Errors in Automatic ECG Analysis of Signals Reconstructed by Irreversible Compressors. R R Bendini, D Franchi, G Palagi, CNR Institute of Clinical Physiology, Pisa, Institute of Pathology, University of Pisa, Pisa, ITALY, 1992 IEEE.

Compression and Encoding of ECG Data within the European Standard Communications Protocol. C Zywietz, G Joseph, R. Fischer, R Degani JL Willems, Medical School Hannover, GERMANY, CNR Padova, ITALY;; Katholieke Universiteit, Leuven, BELGUIM, 1992 IEEE.

Ambulatory ECG Monitors. September 1989 - Vol. 18, No. 9.

Evaluation of Algorithms for Real-Time ECG Data Compression. C. Lamberti, M. Zagnoni, R. Degani, G. Bortolan, D.E.I.S. Universita di Bologna. Bologna, Italy, LADSEB-CNR. Padova, Italy, 1991 IEEE.

Compression of Diagnostic Resting Electrocardiograms. Chr. Zywietz, G. Joseph, R. Fischer, Biosignalverarbeitung, Medizinische Hochschule Hannover, FRG, 1991 IEEE.

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Performance Evaluation and Choice Criteria of Data Compression Algorithms by extensive test of CSE Data Base. NO ARTICLE!!!!!!

**ENCLOSURE G**  
Statement of Safety and Effectiveness

Re: 510k Statement of Safety and Effectiveness

Biosensor hereby certifies that the Company will make available all information included in this 510(k) submission on safety and effectiveness that supports a finding of substantial equivalence within 30 days of request by any person. The information the Company agrees to make available does not include confidential patient identifiers.

**AAAI**

The following information is provided in response to questions asked in December 1994, for compliance with the Association for the Advancement of Medical Instrumentation, (AAMI), requirement. Questions from the 510(k) reviewer have directed Biosensor to provide the following information on the AAMI Section 3.2 Performance requirement. Biosensor has provided data and answers to questions relevant to the current design.

## Section 3.2 Performance

### 3.2.1.1 Stationary Equipment

#### Not Applicable

Biosensor Holter systems use an IBM compatible PC architecture which is not appropriately controller by this specification. A variety of computers may be used with the medical device, which includes computer software and battery powered patient recorders, described below.

### 3.2.1.2 Portable equipment

Biosensor Holter systems meet the portable equipment requirements of:

Power: Power supplied by 4 'AA' Alkaline brand batteries.

Temperature: 0 degree C to 45 degree C

Relative Humidity: 10% to 95%, non condensing.

Ambient Air Pressure: 700-1600 millibars.

Biosensor Holter systems exceed the shock and vibration specifications outlined under this requirement.

### 3.2.2.1 Number of leads

Biosensor Holter systems are capable of simultaneously recording and/or analyzing a minimum of two and up to three independent ECG channels. The system uses four to six patient electrode connection wires and a separate 'ground' reference lead wire arrangement as specified under this requirement. The loss of 1 channel of ECG does not effect the loss of recording of all ECG signals.

### 3.2.2.2 Verification of electrode placement

Verification of electrode placement is performed at the time of initial patient and recorder set up. A clear and effective method is described and outlined in the user manual.

### 3.2.2.3 Safe electrode lead wire connectors

Electrode wire connections meet the safety standard EC12-1991. The electrode wires use a locking mechanism and polarity protection design that prohibits incorrect and adverse electrical connections.

### 3.2.3 ECG input channels

#### 3.2.3.1 Input dynamic range

The Biosensor device has an analog reset function implemented and meets the requirements of this section. When a DC offset is applied the device momentarily changes the front-end high pass filter from 0.05 Hz to 8 Hz until the DC offset has disappeared. The device then returns to its normal operating condition.

#### 3.2.3.2 Input Impedance

The Biosensor device has an input impedance of 10 gigaohms and suffers insignificant distortion. The system meets the input impedance requirement specified.

#### 3.2.3.3 Direct currents in patient electrode connections

Biosensor estimates the DC leakage values are below the micro amp specification and meets the requirements of this section.

#### 3.2.3.4 Common mode rejection

The instrumentation amplifier has a CMRR greater than 60 db from DC to 60 Hz and meets the requirements of this section.

#### 3.2.5.1 AC Voltage

Meets requirement.

The range of the instrumentation amplifier is +/- 5V, coupled with an analog restore circuit, the voltage would not be seen 30 seconds later.

#### 3.2.5.2 Defibrillator energy shunting

Voltage limiters are incorporated. While defibrillator energy is expected to open the circuit, no guarantees of defibrillation protection can be made without statistical sampling. Product labeling indicates that the system does not meet this requirement.

### 3.2.6.1 Gain accuracy

The gain error for the instrumentation amplifier is less than 0.3% and the non linearity is less than 95 ppm.

### 3.2.6.2 Gain stability

The high precision instrumentation amplifier and A/D have excellent gain versus temperature and time characteristics. The system meets this specification.

### 3.2.6.3 Amplitude calibration

Not applicable for digital systems. The digital system is calibrated and contains a calibration pulse.

### 3.2.7.1 System noise

Meets specification. The output noise (display or printout) does not exceed 25 uv over any 60 second period.

### 3.2.7.2 Multichannel crosstalk

Meets specification. System A/D hardware has low channel to channel crosstalk. Operates less than 5 %.

### 3.2.7.3 Frequency response

Meets specification.

- a) The amplitude response of the device is 0.05 Hz to 73 Hz.
- b) The response to all pulses of a 1.5 mv, 20 ms triangular pulse train are within 0 to 110 % of the response to a train of 1.5 mv, 200 ms triangular pulses, while the repetition rate of the pulses is slowly varied from 60 bpm to 70 bpm over a 2 minute period.
- c) Meets all three criteria for a 3 mv, 100 ms rectangular pulse.
- d) Not applicable to this device.

#### 3.2.7.4 Hysteresis and minimum feature size

Meets specification. The hysteresis does not exceed 50 uv after a deflection of 1.5 mv in either direction from baseline has been applied to the device. In addition, a 10 Hz 50 uv p-p sinusoidal signal yields a visible recorded deflection at a time base of 25 mm/s and a gain setting of 10 mm/mv.

#### 3.2.7.5 Overall system error

Overall system error operates within +/- 20 % or +/- 100 uv.

#### 3.2.7.6 Special considerations for high speed superimposition display (optional)

Meets requirement.

Biosensor superimposition scanning can display 2 or 3 simultaneous ECG channels. Biosensor superimposition visual display scans at 60 times real time with start, stop, reverse and resume scanning options. Biosensor superimposition scanning uses color differentiation for various beat classifications.

#### 3.2.7.7 Baseline stability

The Biosensor device meets requirement and offers further corrective action if necessary, by momentarily changing and pulling down the high pass filter. The signal is maintained within the digitized window, resulting in corrective action.

#### 3.2.7.8 Pacemaker pulse tolerance capability

The device records ECG signal in the presence of pacemakers with pulses over the stated range of amplitude, rates, and pulse widths.

#### 3.2.7.9 Special infant requirements

Not applicable. Product labeling indicates that the system does not meet this requirement.

#### 3.2.7.10 Patient event marks

Meets requirement.

Biosensor Holter systems provide a patient event symptom button that allows for patient activated marking.

### 3.2.8 Time base selection, accuracy, and stability

#### 3.2.8.1 Timing accuracy

Meets requirement.

Biosensor Holter systems have a cumulative error over a 24 hour period of not more than +/- 60 seconds.

#### 3.2.8.2 Hard copy time base

Meets requirement.

Time base strip printouts of 25 mm/s are available. Time base accuracy meets the +/- 5 % of +/- 10 % requirement.

#### 3.2.8.3 Hard copy grid standard

Meets requirement.

Printed grids are available on the recognized standard of 25 mm/s at 10 mm/mv. Strip scaling factors are printed at the bottom of each strip page printout.

#### 3.2.8.4 Full disclosure (miniature displays)

Meets requirement.

A hard copy record of all recorded data is available for printing. Gaps in recorded data are indicated by square wave calibration pulses corresponding to real time ECG. The compressed time and voltage scales are not less than 1 mm/mv and 2.5 mm/s. Total printing time is not more than 2 hours. Patient identification, date and time of day are present on each page of the printed record.

#### 3.2.8.5 Gain settings and switching

Meets requirement.

Biosensor Holter systems support the three required gain settings of 20 mm/mv, 10 mm/mv and 5 mm/mv. The gain setting of 10 mm/mv is the default setting for each procedure. Other user selected gain settings are provided for the users convenience.

### 3.2.9 Temporal alignment

Meets requirement.

The Biosensor device provide channel to channel temporal alignment of the ECG signals. The channel to channel skew is estimated to be less than +/- 20 ms collectively

### 3.2.10 Electromagnetic compatibility requirements

Not Tested. These evaluations are felt unnecessary and unduly burdensome for a battery powered device. There are no FCC requirements as well. A company our size finds the prescribed test impractical and asserts there is no patient safety issue associated with the operation of its battery powered device or any other component of the Holter system. In the presence of electromagnetic fields, the system may experience periods of noise. Special detection circuitry is in place to report such environmental noise, whether from motion, muscle, environmental emissions or other sources.

#### 3.2.10.2.5 Power line transients

Biosensor Holter recorder devices are not designed to be operated directly from line power, and are mechanically locked to prevent such interactions.

### 3.2.11 Auxiliary output

Not applicable.

This specification does not apply to this AECG device. The device does not have an auxiliary output.

### 3.2.12 Monitoring time and battery capacity

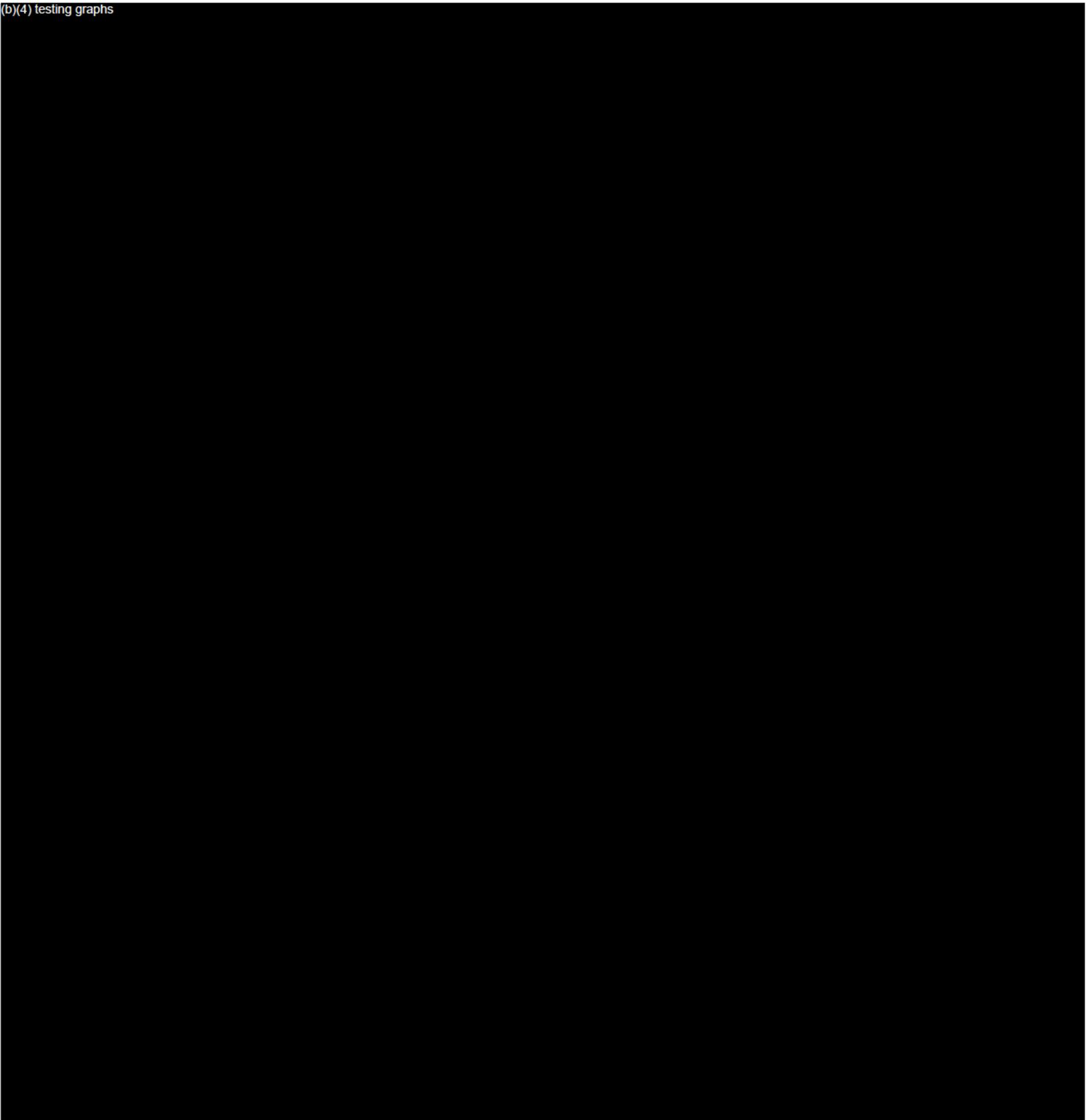
Biosensor Holter devices are capable of monitoring for at least 24 hours continuously. The data is stored in nonvolatile memory and will be retained under the clinician removes the data from the recorder. A safe power fail technique has been implemented to assure proper data removal.

#### 3.2.14.3.1 Record-by record database results

The following pages contain test information for database testing performed on the Biosensor analysis algorithm. Testing was performed using standard database tapes as outlined in official documents. Records from the AHA DB, MIT DB and ESC DB were used to test the device. Programs supplied with the MIT-DB were used to perform comparisons between the device test files and the reference annotation files. Statistical outputs from these programs have been left in standard format for easy review. A record by record result is provided for each tape tested. A page for the overall QRS beat classification, VE pairs/runs, SV pairs/runs and pacemaker performance testing are provided. Summary statistics are provided at the end of each page. Biosensor believes the data provided meets the testing requirements.

QRS Classification

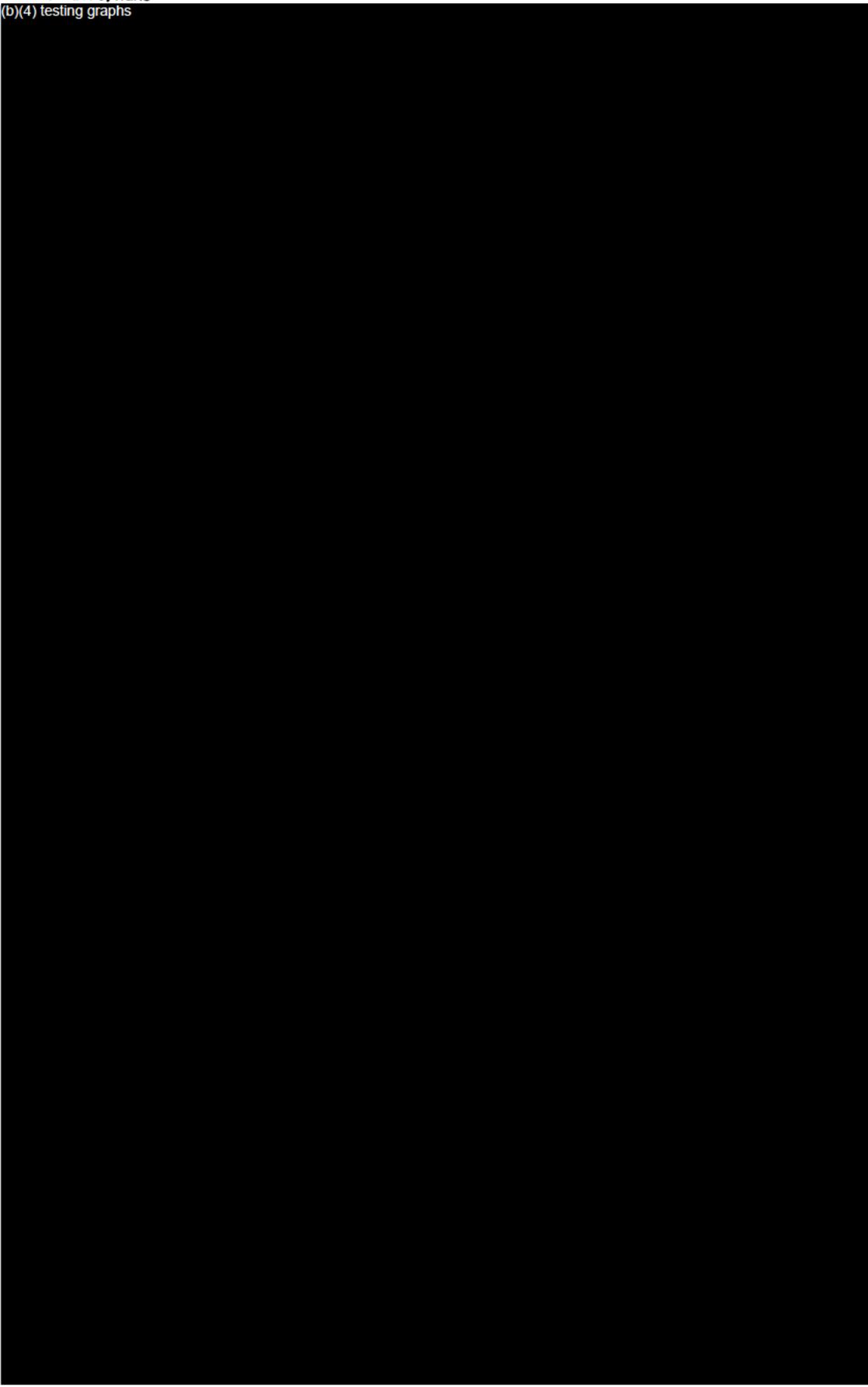
(b)(4) testing graphs



Summary of results from 55 records

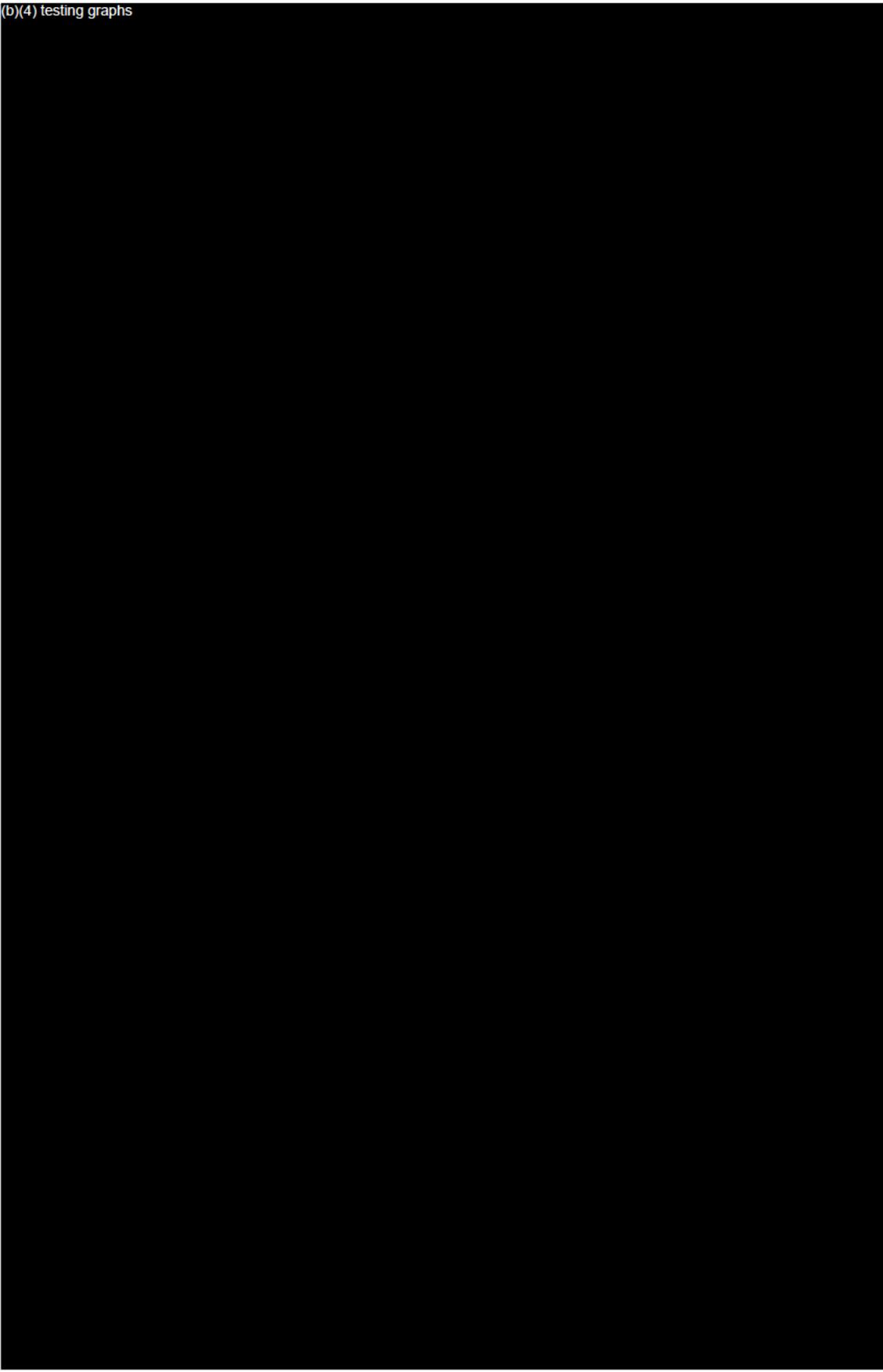
VE Pairs/Runs

(b)(4) testing graphs



SV Pairs/Runs

(b)(4) testing graphs



Pacemaker DB testing. The following summary information is provided for database testing on MIT DB records containing paced beats.

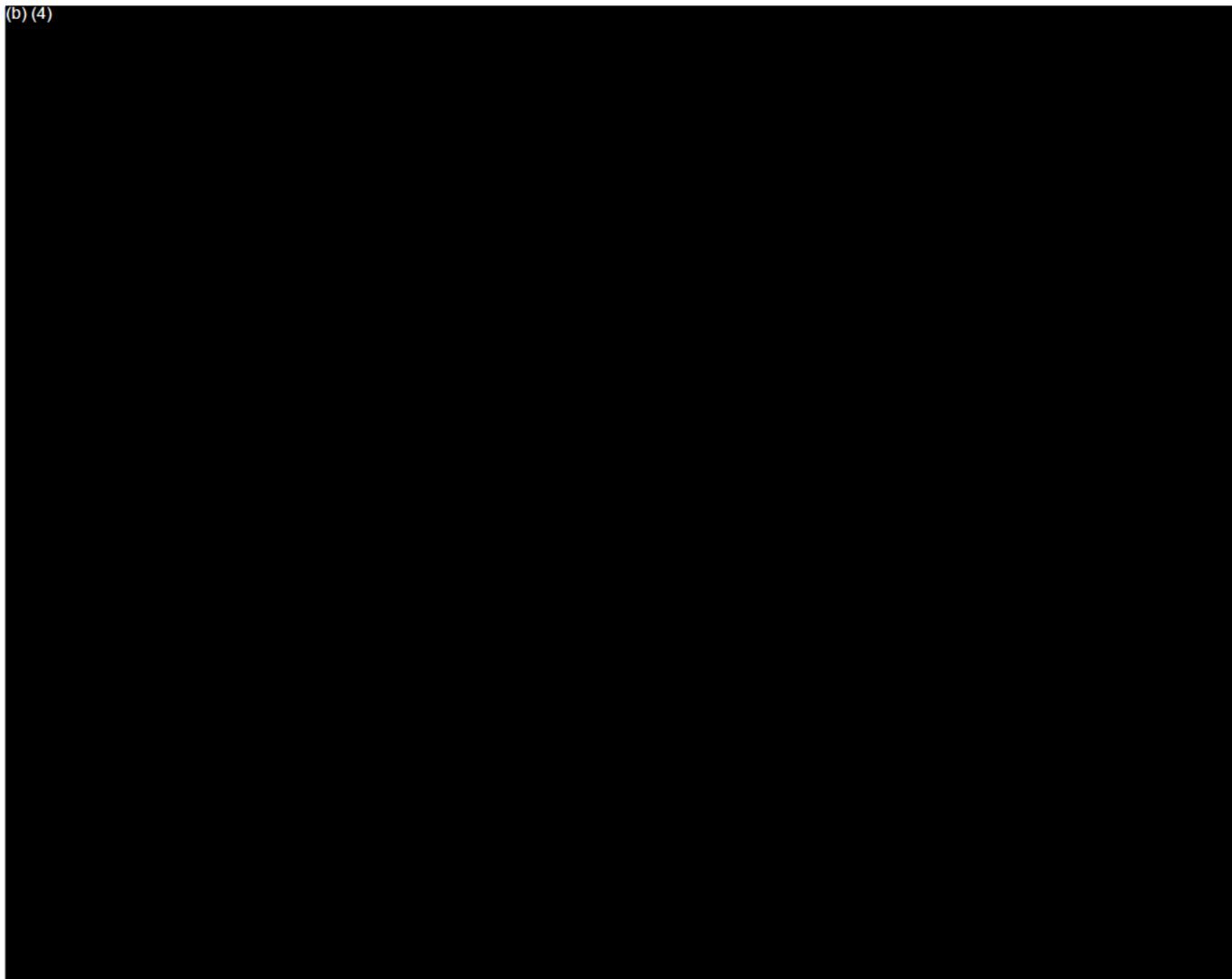
Record	Q Se	Q +p	Pace Se	Pace +p	V Se	V +p
(b)(4) testing graphs						

The following data is provided for testing of the ST algorithm. The ST algorithm used in the Biosensor device has not changed from its previous design. Biosensor has tested and is providing ST algorithm data as requested in the ST Segment Monitor Preliminary Guidance document. The following pages contain record by record ST reporting for European ST database tapes. In addition, ST segment measurement data is provided from Biosensor's proprietary database testing as outlined in the guidance document.

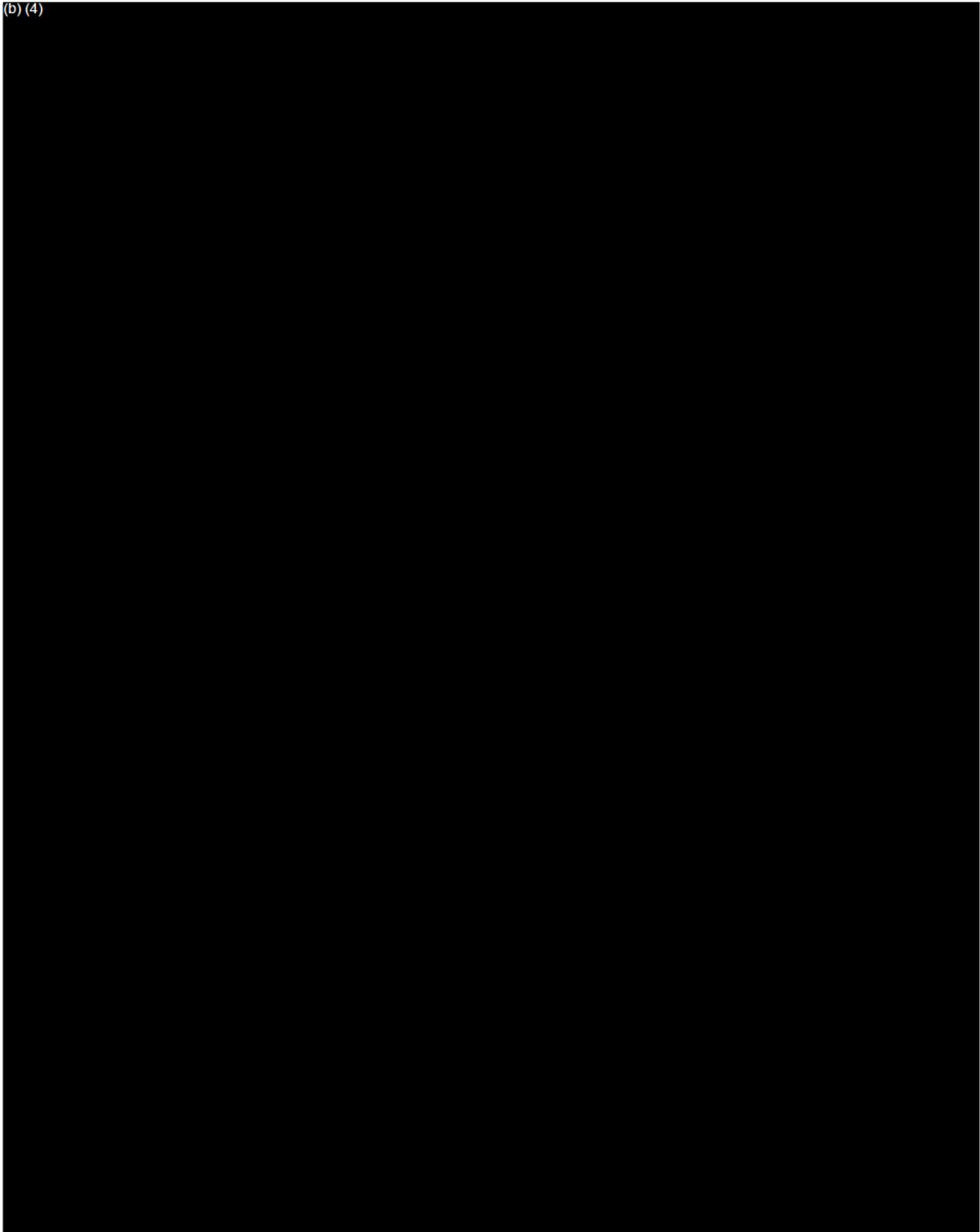
European ST database tapes containing ST episodes with deviations of at least 2mm and lasting at least 1 min.

Record	Annotated Number of Episodes	Annotated ST Episode Peak Measurement	Device Detected Episode	Device 32 beat Average Peak Measurements
--------	------------------------------------	---	-------------------------------	--

(b)(4)



(b) (4)



Summary of the European database testing:

55 annotated episodes, 53 detected by device, 96% Sensitivity

Conclusions:

ST values found in the Biosensor system are found to be only slightly below those found by the European ST database records. This is because the European database selects the single peak beat in its reporting of the maximal ST deviation, while the Biosensor ST software selects the peak 32 beat average. Biosensor believes the 32 beat averaging method is more appropriate due to its strengths in artifact rejection. Other averaging methods are reported in the medical literature.

A measurement ratio of the Biosensor 32 beat peak average to the annotated single peak ST values was also provided in the above table. The Biosensor system shows a measurement ratio of 0.78 when compared to the European single peak annotation values. The small discrepancy noted is caused by the difference in measurement techniques.

The following data is provided from proprietary database testing as outlined in the guidance document. Biosensor has selected ST patients from data sets collected in the past. The data has been replayed on the Biosensor test platform. Six minute two lead records for an ST baseline normal, ST segment elevation, and ST segment depression were input into the new device as outlined in the guidance document. A one minute test episode has been hand annotated from each record and averaged. Corresponding device measurements have also been taken. The table below provides the necessary data comparisons.

Segment Type	Averaged Hand Annotated Values	Upper Confidence Bound for Absolute Error Hand Annotated	Averaged Device Values	Upper Confidence Bound for Absolute Error Device
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(b)(4) testing graphs



**Conclusions:**

The averaged ST segment values for the device are similar to the hand annotated values. The upper confidence bound for the absolute error of the device values are less than the upper confidence bound for the absolute error of the hand annotated measurements. The variation in ST segment measurements of the device are less than those obtained by hand annotation.

### 3.2.15 Minimum reporting requirements

#### Meets requirement.

Biosensor Holter reports list all user-selected parameters. The report summarizes each item once per hour. The item procedure total is also provided for the entire procedure.

#### 3.2.15.1 Heart Rate

#### Meets requirement.

Biosensor Holter reports provides the low, mean and high heart rates per hour. The report also provides the heart rate totals at the end of the procedure. The report also provides the total number of heart beats detected during the procedure.

#### 3.2.15.2 Supraventricular ectopy

#### Meets requirement.

Totals for single SVPBs, paired SVPBs, runs of SVT, and run duration are provided in the summary report. Summary information is provided for total supraventricular ectopy per hour. Supraventricular ectopy information is also provided for the entire procedure.

#### 3.2.15.3 Ventricular ectopy

#### Meets requirement.

Totals for single VEBs, paired VEBs, runs of three or more VEBs, and run duration are provided in the summary report. Summary information is provided for total ventricular ectopy per hour. Ventricular ectopy information is also provided for the entire procedure. The number of minutes and seconds analyzed per hour is also provided on the summary report.

#### 3.2.15.4 Bradycardia data

#### Meets requirement.

Hourly totals for bradycardia episodes are provided in the summary report. A programmable heart rate threshold of 50 bpm/min or less is provided.

#### 3.2.15.5 Pauses

#### Meets requirement.

The total number of pauses based on a user defined threshold are provided in the summary report.

### 3.2.15.6 ST Segment shifts

Meets requirement.

ST analysis is provided on all leads. User defined criteria can be used to adjust ST Segment thresholds. ST Segment deviations along with ST Segment slope information is provided on the summary report.

### 3.2.15.7 ECG hard copy

Meets requirement.

25 mm/s, multichannel ECG strips are available for all meaningful conclusions. Lead configuration is part of the procedure settings information. ECG strips provide time of strip, heart rate of strip, and strip annotation. Each page of ECG strips contain the patient identification and channel calibration reference.