

K962928

Premarket Notification - Camino NeuroCare™

DEC - 2 0 1996

**PREMARKET NOTIFICATION
510(k) SUMMARY**

1. SUBMITTER:

Camino NeuroCare,™ Inc.
5955 Pacific Center Blvd.
San Diego, CA 92121

Donna L. Free (Contact Person)
Phone: 619-455-1115
Fax: 619-455-8298

2. DEVICE NAME:

- Trade Name:
- a. Micro-Ventricular Pressure-Temperature Monitoring Kit (110-4HMT)
Parenchymal Pressure-Temperature Monitoring Kit (110-4BT)
 - b. Multi-Parameter Monitor (MPM)
- Common Name:
- a. Intracranial Pressure and Temperature Monitoring Kit
 - b. Multi-Parameter Monitor
- Classification Name:
- a. Intracranial Pressure Monitoring System
 - b. Intracranial Pressure Monitoring System

3. PREDICATE DEVICE:

Camino NeuroCare™ Intracranial Pressure-Temperature Monitoring Kit:

Model 110-4BT is equivalent to:

Camino, Intracranial Pressure Monitoring Kit, Model 070, 853864C
Electromedics, Inc., Esophageal, Rectal, Nasopharyngeal Probe, Model 2403, K813459A.

Model 110-4HMT is equivalent to:

Camino, Micro Ventricular Pressure Monitoring Kit, Model 110-HM, K914735
Electromedics, Inc., Esophageal, Rectal, Nasopharyngeal Probe, Model 2403, K813459A.

000006

Premarket Notification - Camino NeuroCare™

3. PREDICATE DEVICE:

Camino NeuroCare™ Multi Parameter Monitor:

Model MPM is equivalent to:

Camino, Direct Pressure Monitor, Model V420, K893232
SpaceLabs, Patient Monitor, Model Alpha PC Patient Computer,
K842616.

4. DEVICE DESCRIPTION:

The Intracranial Pressure-Temperature Monitoring System consists of a catheter and monitor. The catheter is a sterile transducer-tipped pressure monitoring catheter with thermistor and accessory items to be used as a diagnostic tool for rapidly determining and continuously monitoring intracranial pressure and temperature. The Camino catheter has a miniature transducer and thermistor at the distal tip. The pressure transducer is identical to the Camino predicate device. The design eliminates the need for a "fluid-filled system" to carry pressure waves to an external transducer. The transducer is 4F, fiber optic with a pressure measurement range of -10 to 250 mmHg and a temperature measurement range of 30°C -40°C.

The Multi-Parameter Monitor (MPM) is a compact, portable device for use with Camino Pressure-Temperature catheters. The MPM measures Intracranial Pressure (ICP), Intracranial Temperature (ICT) and calculates Cerebral Perfusion Pressure (CPP). The MPM provides a continuous display of the pressure waveform, as well as mean ICP, CPP, temperature or systolic and diastolic values. A continuous record of mean pressure and temperature values over the most recent 24-hour period is stored in memory, and can be displayed on command as a TREND either as the most recent 8 or 24 hour period. An analog output accessory provides a continuous ICP waveform for hard copy documentation or data acquisition. Although the MPM is intended to be a stand alone system, it also conveniently connects to any hospital bedside monitoring system. A built-in rechargeable battery permits monitoring during patient transport. The monitor is equipped with an high ICP alarm. The dimensions are 274 mm x 216 mm x 89 mm and weighs 4.3 Kg.

5. INTENDED USE:

Model 110-4BT:

Use by a qualified neurosurgeon for direct measurement of intracranial pressure and temperature in the parenchyma.

Model 110-4HMT:

Use by a qualified neurosurgeon for direct measurement of intracranial pressure and temperature in the ventricles and cerebrospinal fluid drainage.

000007

Premarket Notification - Camino NeuroCare™

Intended to be used with an external drainage system as indicated by individual manufacturers.

6. SUBSTANTIAL EQUIVALENCE:

Pressure:

The ICP/T catheter and monitor have the same indication statements for monitoring pressure as Camino's predicate devices.

Temperature:

Predicate temperature-sensing devices include the Electromedics, Model 2403, Temperature Probe, K813459A. The predicate probes are used to measure the temperature of a target organ or tissue. Camino's temperature probe has the same use.

Nevertheless, the ICP/T has a difference in the indication statements in regard to temperature. The difference refers to the tissue in which the temperature is taken. For example, the Electromedics predicate catheter is labeled for general temperature use. Other indications include general surgery, cardiovascular surgery, anesthesiology, critical care, newborn care, and neonatal care. The Camino probes have similar labeling in that they are for general uses that may include surgery, critical care, pediatric care and head injured patients. The Electromedics probe is labeled to take a patient's temperature in the esophagus, on the skin surface, in cardioplegia systems and in the myocardium. The Camino pressure-temperature probe is labeled to be used in the brain, with either parenchyma or ventricular placement.

Monitor:

The ICP/T monitor and both predicate monitors display pressure.

The ICP/T monitor and SpaceLabs monitor display temperature.

The ICP/T monitor and SpaceLabs monitor display Cerebral Perfusion Pressure (CPP).

The ICP/T monitor and both predicate monitors display a waveform.

The ICP/T monitor and both predicate monitors display trends.

The ICP/T monitor and both predicate monitors comply with UL Medical Equipment standards.

The ICP/T monitor and the predicate monitors comply with AAMI/ANSI Safe Current Limits standards.

7. PERFORMANCE TESTING:

Camino NeuroCare conducted animal studies to support substantial equivalence. We conducted a comparative study of the subject (test) device measuring intracranial temperature compared with a predicate device, located along side the test device, also measuring intracranial temperature over a varied temperature range. The temperature measurements were $\pm 0.4^{\circ}\text{C}$ between the test device and predicate device in the 10 animals tested. These data support the claim of substantial equivalence.

000008

Premarket Notification - Camino NeuroCare™

8. CONCLUSIONS

The contact area of the Camino probe is of the same design, has the same materials, and it is inserted into the body in the same manner as predicate Camino probes. Thus, the questions of safety are the same. The diagnostic effect of temperature probes for general use is to provide temperature information to a physician for whatever use he or she may choose, based on the user's training and experience. The effectiveness of a temperature probe for diagnostic or monitoring use is determined by its ability to deliver an accurate temperature reading. This is the same standard that was used for predicate devices, some of which were cleared for organs and tissues which may have been different from those for which existing predicate devices were cleared.

Based on the above information Camino NeuroCare™ Inc., concludes that the ICP/T Monitoring system demonstrates substantial equivalence to the predicate devices.

000009



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 20 1996

Mr. Gary S. Mocnik
Camino NeuroCare,™ Inc.
5955 Pacific Center Boulevard
San Diego, California 92121

Re: K962928
Trade Name: Combined Intracranial Pressure-Temperature Sensing
Regulatory Class: II
Product Code: 84GWM
Dated: November 15, 1996
Received: November 18, 1996

Dear Mr. Mocnik:

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 (for the indications for use stated in the enclosure) 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.

Page 2 - Mr. Gary S Mocnik

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) 594-4648. 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 (301) 443-6597 or at its internet address "dsma@fdadr.cdrh.fda.gov".

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

Enclosure

Premarket Notification - Camino NeuroCare™

510(k) number (if known) K962928

Device Name: Intracranial Pressure-Temperature Monitoring Device

Indications For Use:

Model 110-4BT:

Use by a qualified neurosurgeon for direct measurement of intracranial pressure and temperature in the parenchyma.

Model 110-4HMT:

Use by a qualified neurosurgeon for direct measurement of intracranial pressure and temperature in the ventricles and cerebrospinal fluid drainage.

Intended to be used with an external drainage system as indicated by individual manufacturers.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Samuel Kams 12/17/96
(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K962928

Prescription Use
(Per 21 CFR 801.109)

OR

Over-The-Counter Use

510(K) ROUTE SLIP

510(k) NUMBER K962928 PANEL NE DIVISION DCRND BRANCH PNDG
 TRADE NAME COMBINED INTRACRANIAL PRESSURE-TEMPERATURE SENSING SYSTEM
 COMMON NAME INTRACRANIAL PRESSURE MONITORING DEVICE
 PRODUCT CODE _____

APPLICANT CAMINO NEUROCARE
 SHORT NAME CAMINEUR
 CONTACT DONNA L FREE
 DIVISION _____
 ADDRESS 5955 PACIFIC CENTER BLVD.
SAN DIEGO, CA 92121
 PHONE NO. (619) 455-1115 FAX NO. (619) 455-8298
 MANUFACTURER CAMINO NEUROCARE REGISTRATION NO. 2023988

DATE ON SUBMISSION 26-JUL-96 DATE DUE TO 510(K) STAFF 12-OCT-96
 DATE RECEIVED IN ODE 29-JUL-96 DATE DECISION DUE 27-OCT-96
 DECISION _____ DECISION DATE _____

SUPPLEMENTS	SUBMITTED	RECEIVED	DUE POS	DUE	OUT
<u>S001</u>	<u>15-NOV-96</u>	<u>18-NOV-96</u>	<u>01-FEB-97</u>	<u>16-FEB-97</u>	

CORRESPONDENCE	SENT	DUE BACK
<u>C001</u>	<u>24-OCT-96</u>	<u>23-NOV-96</u> <u>HOLD LETTER</u>

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

SE

DEC 19 1996

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration



Memorandum

Date: December 17, 1996

From: Robert F. Munzner, Ph.D., Division of Cardiovascular, Respiratory and Neurological Devices (DCRND), Office of Device Evaluation (ODE), HFZ-450

To: Tom Callahan, Director, DCRND, HFZ-450

Through: Acting Group Leader, Pacing and Neurological Devices, DCRND, HFZ-450
Attn: Janine Morris

Thomas J. Callahan 12/18/96
Janine Morris 12/17/96

Subject: Intracranial Temperature Monitor (K962928)

Summary: This equivalence determination will set a precedent in that it is the first intracranial temperature monitoring device. As you may recall from our earlier discussions that there was some concern that this device would have a new intended use such for administering hypothermia or hyperthermia, or for some special diagnostic purpose.

It is my understanding that our finding of equivalence is based^{on} our considering the temperature measurement solely as an adjunctive feature to the intracranial pressure monitoring device and that it will be used for same indications that other ICP monitoring devices are used. This modification of the ICP device may provide some additional information to the surgeon and it does not to any degree diminish the safety and effectiveness of the primary device.

This is to confirm that you agree with the equivalence determination on this basis, and that this determination cannot be cited as evidence for the effectiveness of hypothermia therapy or any other new intended use.

Considering that this action is setting a precedent, I recommend that the Division Director personally endorse the decision.

RFM
Robert F. Munzner, Ph.D.

cc: RFM/Chron
LKeely
HFZ-401(K962928)

S



Memorandum

From: Reviewer(s) - Name(s) L Keeley

Subject: 510(k) Number K962928/S1

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.
- Accepted for review _____
(date)
- 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
Was this 510(k) reviewed by a Third Party?	<input type="checkbox"/> YES	<input checked="" type="checkbox"/> 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 N/A

The indication for use form (required for originals received 1-1-96 and after) yes

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: 882.1620 Class II Additional Product Code(s) with panel (optional):

84 GWM Intraocular Pressure Monitor (with temperature thermometer)

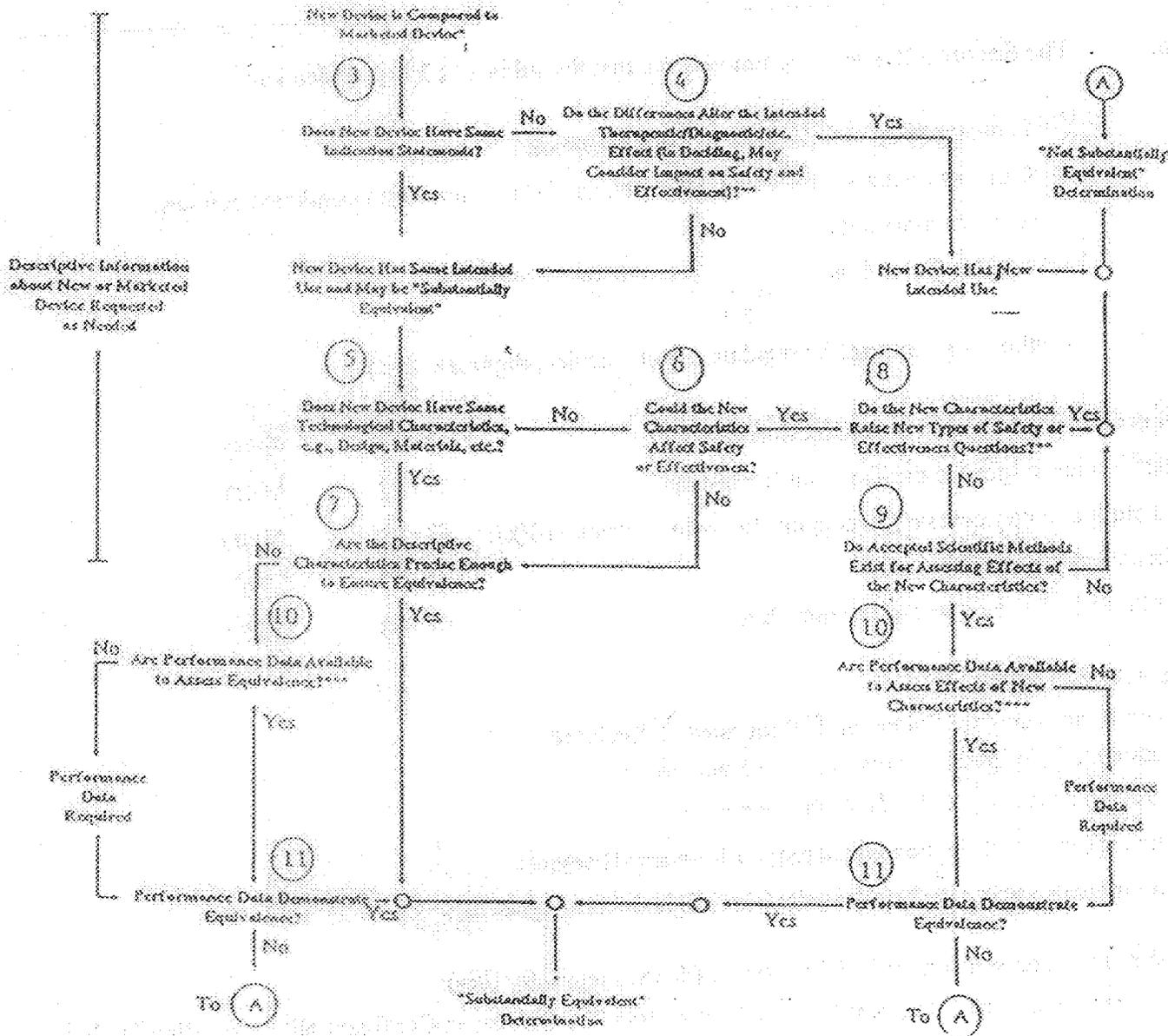
Review: Robert Mangner, Ph.D. NEDB 12/17/96
(Branch Chief) (Branch Code) (Date)

SEE MEMO 2/17/96 R

Final Review: Thomas J. Callahan 12/18/96
(Division Director) (Date)

Revised: 7-1-96

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.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

Memorandum

Date: December 17, 1996

From: Robert F. Munzner, Ph.D., Division of Cardiovascular, Respiratory and Neurological Devices (DCRND), Office of Device Evaluation (ODE), HFZ-450

To: Tom Callahan, Director, DCRND, HFZ-450

Through: Acting Group Leader, Pacing and Neurological Devices,
DCRND, HFZ-450 Attn: Janine Morris _____

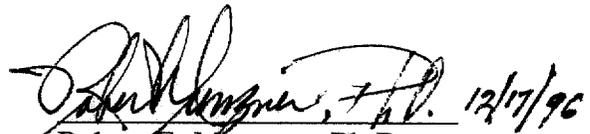
Subject: Intracranial Temperature Monitor (K962928)

Summary: This equivalence determination will set a precedent in that it is the first intracranial temperature monitoring device. As you may recall from our earlier discussions that there was some concern that this device would have a new intended use such for administering hypothermia or hyperthermia, or for some special diagnostic purpose.

It is my understanding that our finding of equivalence is based ^{on} our considering the temperature measurement solely as an adjunctive feature to the intracranial pressure monitoring device and that it will be used for same indications that other ICP monitoring devices are used. This modification of the ICP device may provide some additional information to the surgeon and it does not to any degree diminish the safety and effectiveness of the primary device.

This is to confirm that you agree with the equivalence determination on this basis, and that this determination cannot be cited as evidence for the effectiveness of hypothermia therapy or any other new intended use.

Considering that this action is setting a precedent, I recommend that the Division Director personally endorse the decision.


Robert F. Munzner, Ph.D. 12/17/96

cc: RFM/Chron
LKeely
HFZ-401(K962928)

REVISED: 3/14/95

THE 510(K) DOCUMENTATION FORMS ARE AVAILABLE ON THE LAN UNDER 510(K) BOILERPLATES TITLED "DOCUMENTATION" AND MUST BE FILLED OUT WITH EVERY FINAL DECISION (SE, NSE, NOT A DEVICE, ETC.).

"SUBSTANTIAL EQUIVALENCE" (SE) DECISION MAKING DOCUMENTATION

Reviewer: K 962928
L Beely

Division/Branch: DCRND / PNDG

Device Name: Intracranial Pressure - Temperature Sensor.

Product To Which Compared (510(K) Number If Known): Model 110-~~421~~ HM K914231
Electrodes Temperature Probe K813459 Model 11

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

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

1. Intended Use: *For direct measurement of intracranial pressure and temperature in the brain parenchyma*
2. Device Description: Provide a statement of how the device is either similar to and/or different from other marketed devices, plus data (if necessary) to support the statement. Is the device life-supporting or life sustaining? Is the device implanted (short-term or long-term)? Does the device design use software? Is the device sterile? Is the device for single use? Is the device product as a component? Is this device a kit? 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 AS NEEDED

1. Explain why not a device: *Is a device*
2. Explain why not subject to 510(k): *Is subj. to 510(k)*
3. How does the new indication differ from the predicate device's indication: *Some as separate comparison devices but this combines pressure with direct brain parenchyma temperature*
4. Explain why there is or is not a new effect or safety or effectiveness issue: *Doesn't affect S+E. New use of directly measuring temperature of the brain does not impact on safety and effectiveness of thermal measures is not changed.*
5. Describe the new technological characteristics: *They are similar to other Pressure Temp. measuring devices.*
6. Explain how new characteristics could or could not affect safety or effectiveness: *Interpretation of thermal measure by the clinician is the only concern but there is no reason to suspect that this does not measure pressure/temperature safely*
7. Explain how descriptive characteristics are not precise enough: *They are precise enough i. S+E + accurately*
8. Explain new types of safety or effectiveness questions raised or why the questions are not new:
9. Explain why existing scientific methods can not be used:
10. Explain what performance data is needed:
11. Explain how the performance data demonstrates that the device is or is not substantially equivalent:

ATTACH ADDITIONAL SUPPORTING INFORMATION

510(K) REVIEW K962928

Company Name: Camino Neurocare, Inc.
Device Name: Multiparameter Waveform Display
ICP Temperature monitoring Kit

Model 110-4BT catheter for direct measurement of ICP and temperature in the parenchyma
Model 110-4HMT catheter for direct measurement of ICP and temperature in the ventricles and CSF. Also used for access and sampling of CSF.

Model MPM-1 multi-parameter monitor

- | | |
|---|-----|
| 1. Life supporting or life sustaining? | no |
| 2. Implant (short-term or long-term)? | Yes |
| 3. Software-driven? | Yes |

The firm does certify that all system requirements are fulfilled with a software version that has been documented and the results demonstrate that the system specifications and functional requirements have been met.

The firm has provided the software validation, and has performed a hazard analysis. The software requirement specifications have been provided and the development plan has been submitted.

The software validation protocol was provided and the "Reviewer Guidance for Computer Controlled Devices issued by the FDA was utilized in the review of the software.

What is the estimated level of concern has been broken down into systems in assessing Major, Moderate or Minor concern?

The overall concern is minor to moderate. This device does not control any other processes or devices. Failure of the device would either provide no data or would provide inaccurate data to the physician which would result in the clinician having to perform more testing to determine the correctness of the data displayed. This device controls no other device or processes.

4. Device(s) to which equivalence is claimed and manufacturer:

- Camino ICP monitoring Kit, Model 070 (k853864)
- Electromedica Inc., Esophageal, rectal, nasopharyngeal probe (K813459)
- Camino Micro Ventricular Pressure Monitoring Kit Model 110-HM (K914735)
- Camino direct pressure Monitor, Monitor V420, K893232
- Spacelabs Patient Monitor, PC Computer, K842616

5. Submission provides

- | | |
|-------------------------------------|-------------------------------|
| comparative specifications | Yes, Camino and Electromedics |
| comparative in vitro data | Yes |
| summary of animal testing | Yes |
| summary of clinical testing | No |
| refer to industry standards? | Yes |

UL-544 Medical Electrical Equipment

AAMI/ANSI Safe Current Limits

6. Description of device and differences between device and pre-enactment/predicate device(s), including indication for use, new technology and new kinds of safety issues:

**MEMO
k962928**

CAMINO, ICP pressure/temperature device

December 16, 1996

**"SUBSTANTIAL EQUIVALENCE" (SE) DECISION-MAKING DOCUMENTATION
NARRATIVE DEVICE DESCRIPTION**

INTENDED USE: For direct measurement of intracranial pressure and temperature in the parenchyma, ventricles and spinal fluid and for external drainage.

DEVICE DESCRIPTION:

Is the device sterile? The intracranial components of the system are sterile and single use devices. They are sterilized in accordance with FDA guideline FR 43, June 23, 1978 for EtO sterilization and allowable residuals. The monitor itself is a multiple use device which does not require sterilization but needs to be cleaned per routine hospital procedures.

Is the device for single use? The catheters are intended for single use. The monitor is intended for multiple patient use.

Is the device for home use or prescription use? NO

Does the device contain drug or biological product as a component? NO

Is this device a kit? The catheter is included in a sterile procedure kit which consists of previously cleared products for the same use including a ventricular access device, ventricular catheter bolt, female luer lock and stylet, twist drill with safety stop, luer port to connect drainage system, thermistor connector cover.

SUMMARY:

This device is a modification to a presently existing intracranial pressure monitoring kit. The modification includes the addition of a temperature sensing device (thermistor) to the tip of the catheter.

This system consists of a catheter and monitor.

The catheter is a sterile transducer tipped pressure monitoring catheter with thermistor used as a diagnostic tool for continuously monitoring ICP and temperature. The miniature transducer is identical to the Camino predicate device and eliminates the need for a fluid filled system to carry pressure to an external transducer. The transducer is 4F and has a pressure measurement range of -10 to 250 mmHg. and a temperature range of 30°C to 40°C, $\pm 0.3^\circ\text{C}$. The length of the catheter is 110 cm

The Multi-Parameter Monitor measures ICP, Intracranial Temperature and calculates the Cerebral perfusion pressure (CPP) from the ICP and Mean arterial pressure (MAP) and displays these values continuously. It provides a trend over the most recent 24 hours. An analog output provides a continuous ICP waveform for hard copy documentation or data acquisition

Model 110-4BT allows for pressure and temperature measurement.

Model 110 4HMT allows for pressure and temperature measurement and CSF fluid sampling.

Biocompatibility data was provided.

ANIMAL TESTING

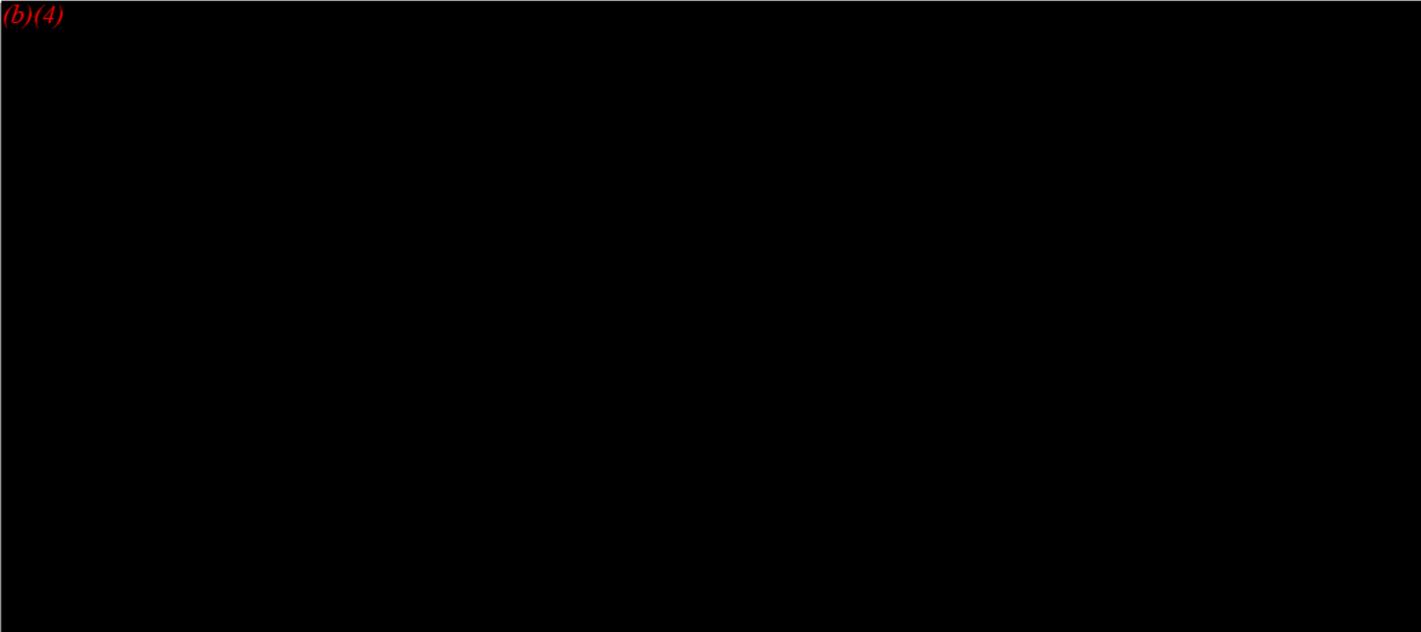
(b)(4)

MEMO
k962928

CAMINO, ICP pressure/temperature device

December 16, 1996

(b)(4)



Labeling states that temperature measurement accuracy is $\pm 0.3^{\circ}\text{C}$ (30°C to 40°C)

This device will be promoted only for "*use by qualified neurosurgeons for measurement of intracranial pressure and temperature*".

EXPLANATIONS TO "YES" AND "NO" ANSWERS TO QUESTIONS ON PAGE 1 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. **This is a device.**
2. IF THE ANSWER TO QUESTION 2 IS NO, EXPLAIN WHY THE DEVICE IS NOT SUBJECT TO 510(K). **This device is 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 indication is for "*use by qualified neurosurgeons for measurement of intracranial pressure and temperature*". The predicate devices were intended for use in measuring the intracranial pressure and drainage of the cerebral spinal fluid. The other device, a temperature thermister, was used to measure temperature in other areas of the body including rectally, orally and in the esophagus. This device is intended to measure temperature intracranially also.
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. **There are no claims other than those of measuring pressure and temperature intracranially.**

**MEMO
k962928**

CAMINO, ICP pressure/temperature device

December 16, 1996

5. IF THE ANSWER TO QUESTION 5 IS NO, DESCRIBE THE NEW TECHNOLOGICAL CHARACTERISTICS. **Technological characteristics are similar.**

6. IF THE ANSWER TO QUESTION 6 IS YES OR NO, EXPLAIN HOW THE NEW CHARACTERISTICS COULD/COULD NOT AFFECT SAFETY OR EFFECTIVENESS. **The only safety and effectiveness question is one related to the interpretation of the intracranial temperature measurement by the clinician. Interpretation is not however stated nor implied in this submission.**

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

The descriptive characteristics are precise enough to demonstrate that this device relatively accurately measures the intracranial pressure and temperature, therefore I recommend that this device be found equivalent to the two predicate devices which the sponsor identified. This device combines the functions of the two predicate devices, measurement of pressure and the measurement of temperature in a single device. Although the measurement of temperature has not been marketed in a predicate device in the brain, the technology of such measurement is not significantly different from that of temperature measurement in other areas of the body. There are no new issues of safety identified over those already present in the predicate intracranial pressure monitoring devices presently on the market. The monitoring of the temperature is an added feature. The effectiveness of monitoring temperature is not in question since the technology of such measurement is the same as in other devices. The only issue is that of interpretation of the temperature measurements by the clinician. The sponsor of this device is not making any claims of the use of this aspect of the device and leaves this up to the clinician to assess.

I believe this device is equivalent to device:

84 GWM Intracranial Pressure monitor

Classification should be based on:

Subsection: 882.1620 Intracranial Pressure monitor Presently Class II


G. Levering Keely

Date: Dec 16, 1996

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

Date: 26-Nov-1996 05:08pm EST
From: Dawson, John M.
JMD
Dept: OSB_DBS - HFZ-542
Tel No: 827-0201

TO: Keely Jr., G. Levering (LZK)

CC: Morris, Janine M. (JZM)

Subject: Camino UD response

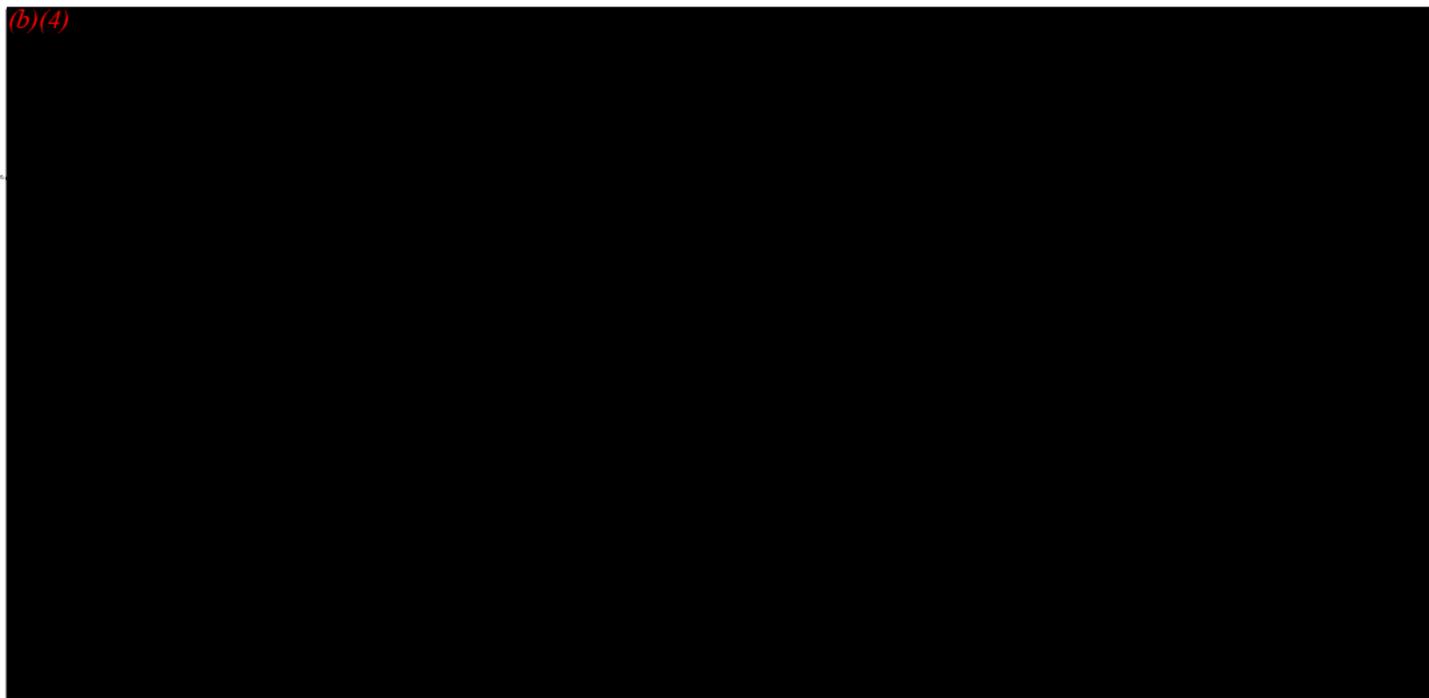
MEMORANDUM FOR G. LEVERING KEELY, JR.,
SCIENTIFIC REVIEWER

November 26, 1996

FROM: John Dawson

SUBJECT: Camino NeuroCare's November 15, 1996, response to UD
letter on Intracranial Temperature Measurement (K962928)

(b)(4)



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

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

November 18, 1996

CAMINO NEUROCARE
5955 PACIFIC CENTER BLVD.
SAN DIEGO, CA 92121
ATTN: DONNA L. FREE

510(k) Number: K962928
Product: COMBINED
INTRACRANIAL
PRESSURE-TEMPERA
TURE SENSING

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



CAMINO
NeuroCareTM, Inc.
Saba Medical Group, L.P.

RECEIVED
18 NOV 96 09 36
FDA/CDRH/OCE/DHC

November 15, 1996

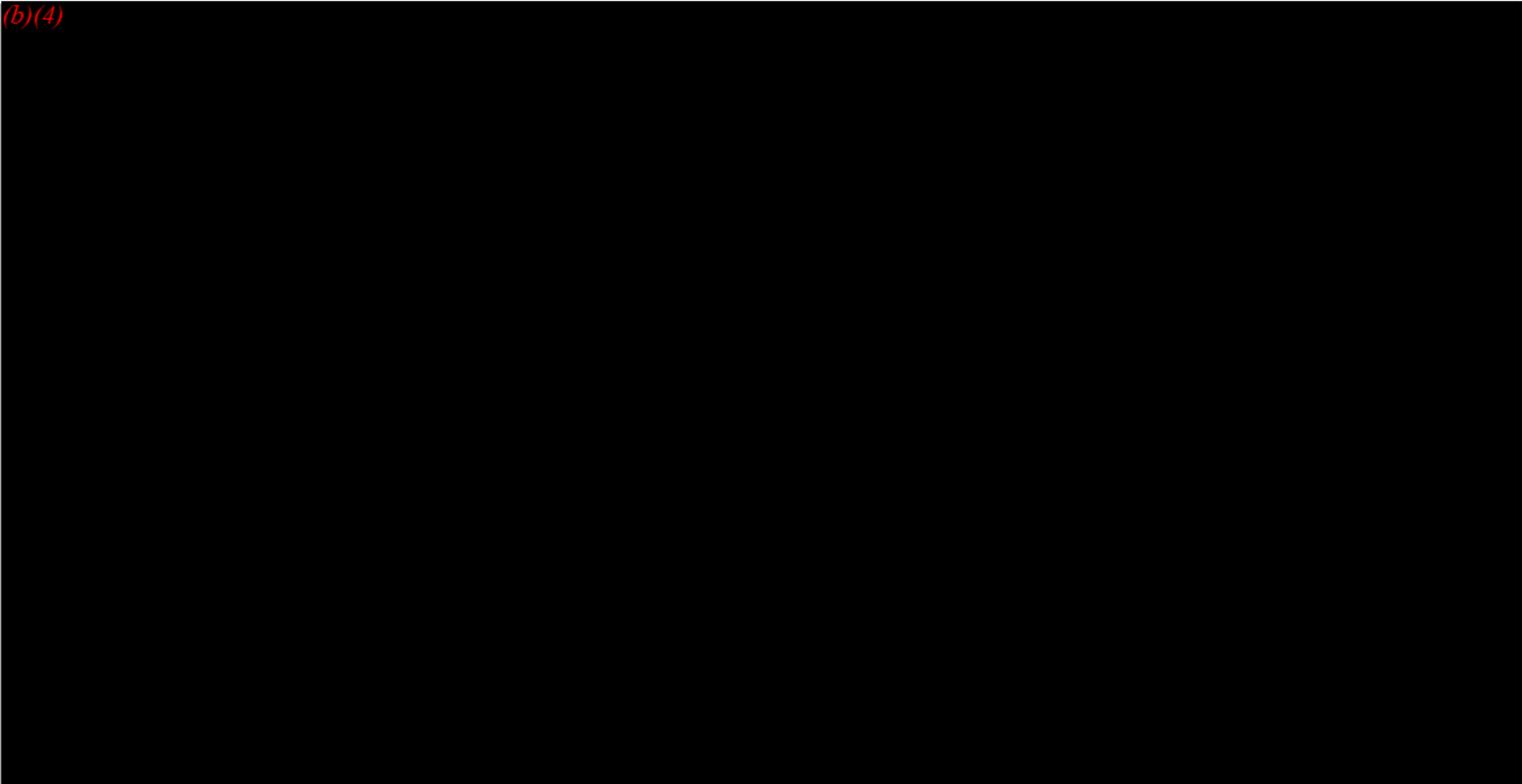
Document Mail Center (HFZ-401)
Center for Devices and Radiological Health
Food and Drug Administration
9200 Corporate Blvd.
Rockville, MD 20850

Attention : Mr. Levering Keely

Subject: Premarket Notification K962928
Intracranial Pressure-Temperature Monitoring Catheter
(Models: 110-4BT and 110-4HMT) and
Multi-Parameter Monitor (Model: MPM)
Dated: July 26, 1996

Dear Mr. Keely,

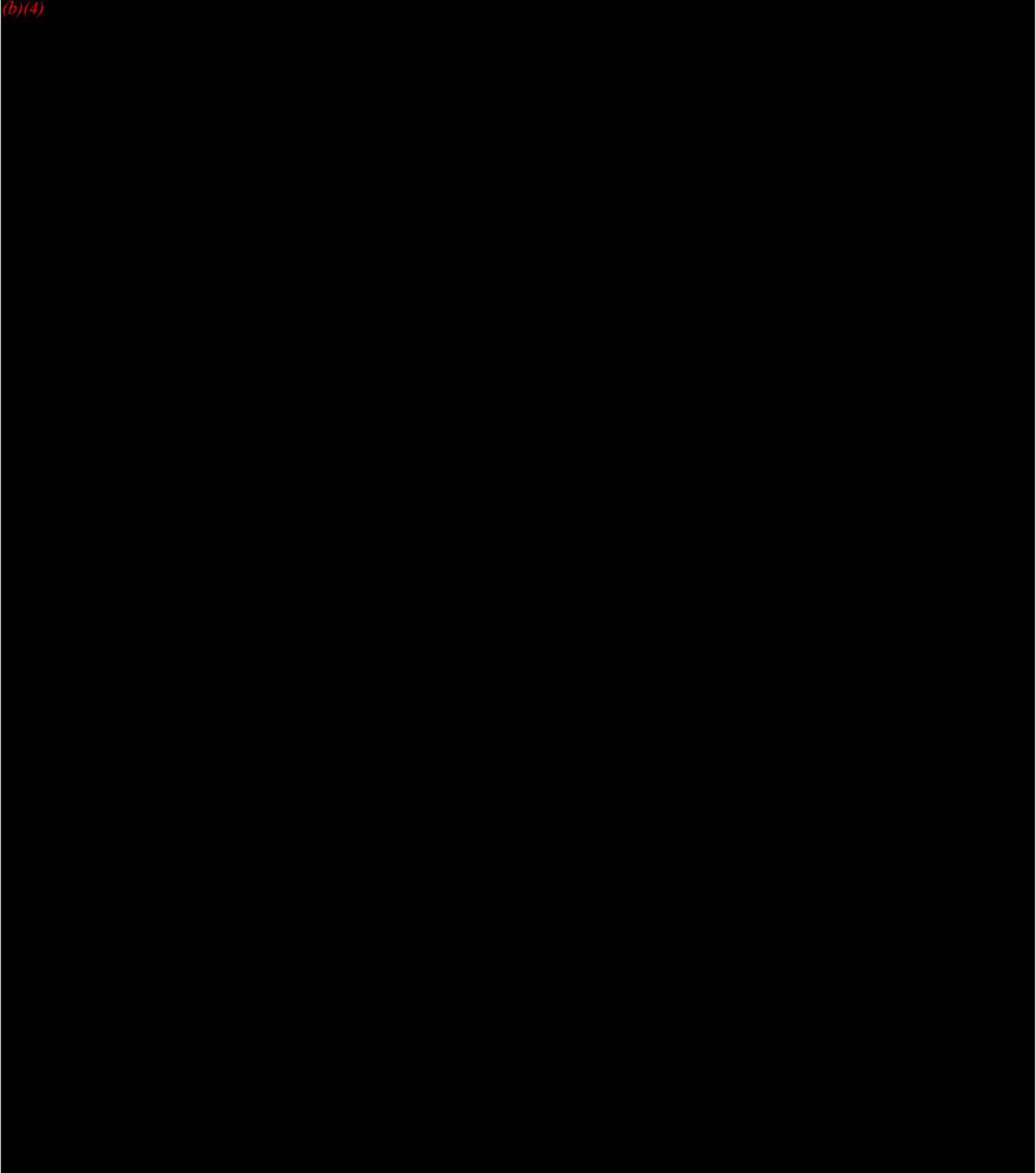
This is in response to the Food and Drug Administration (FDA) request for additional information, dated October 24, 1996, regarding Premarket Notification K962928. We will repeat the questions below and provide responses.



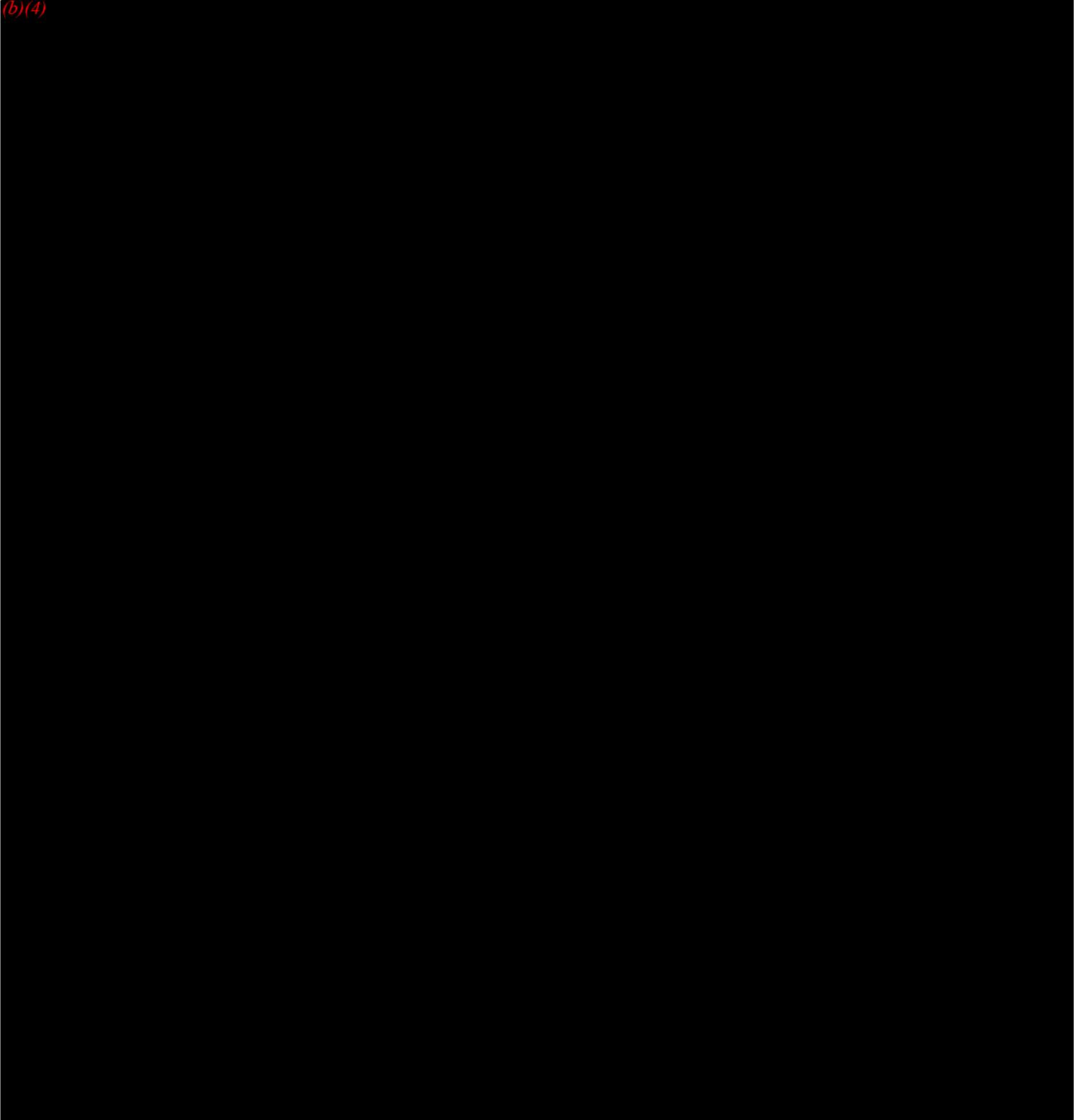
(b)(4)

17

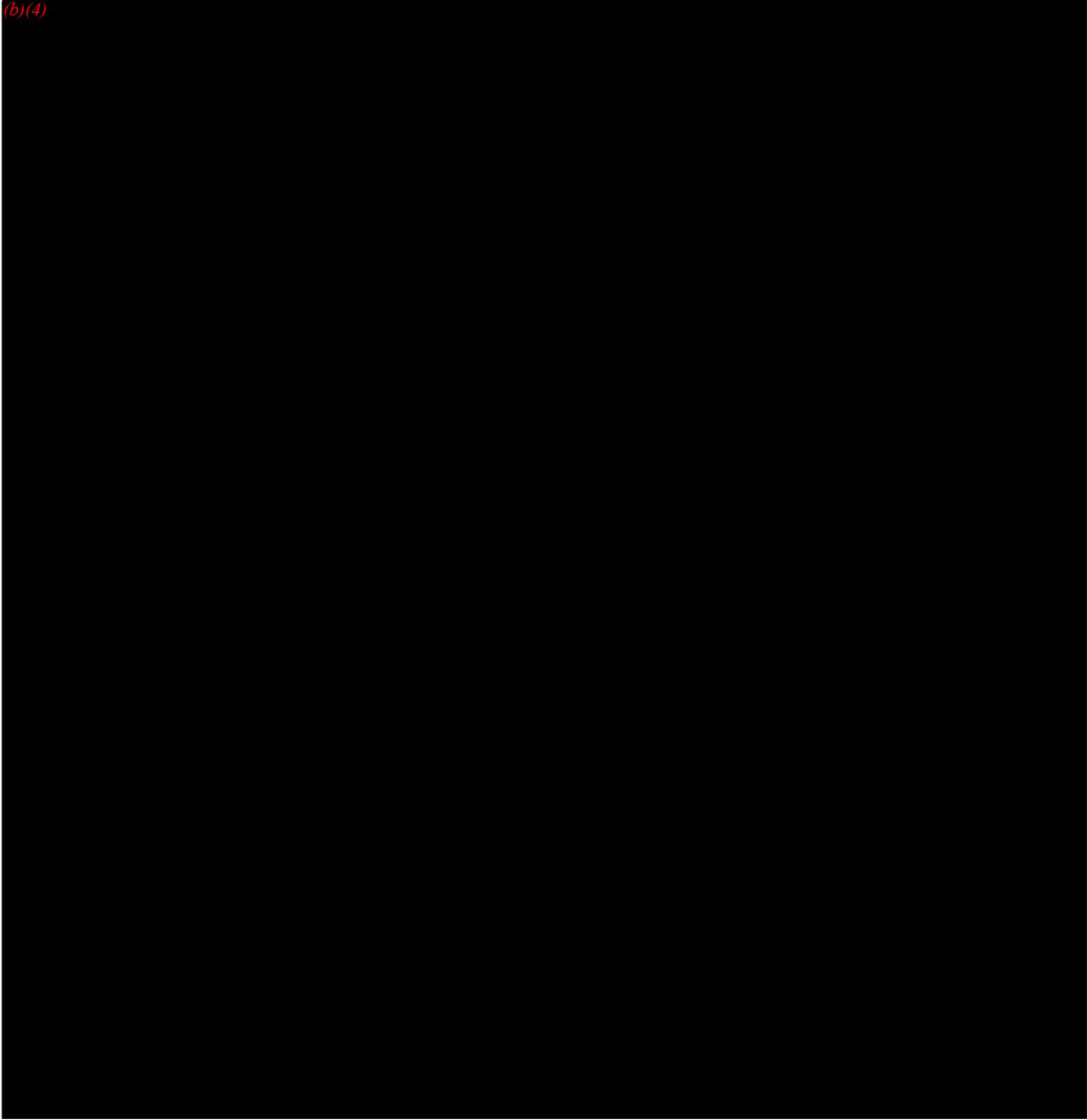
(b)(4)



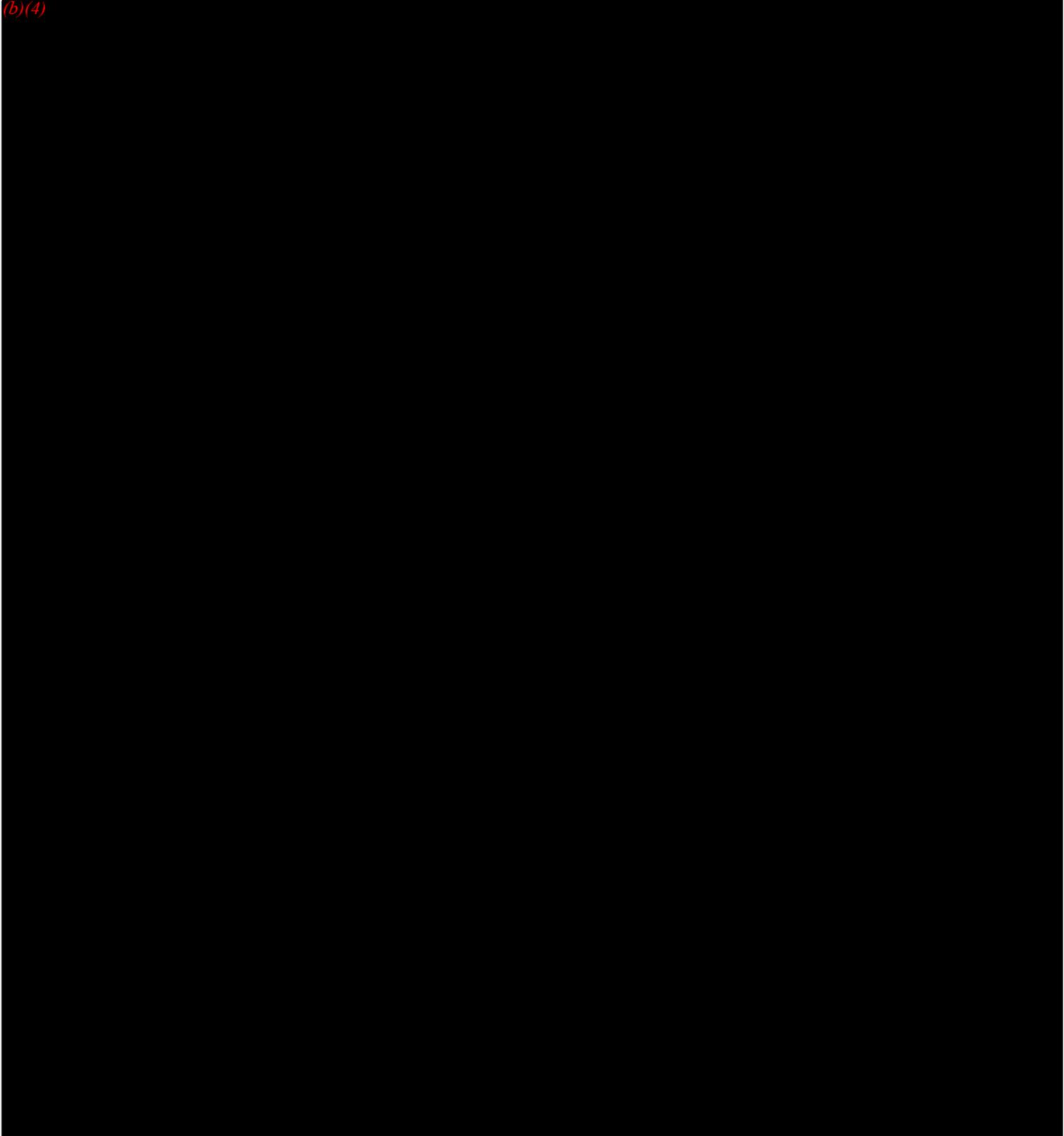
(b)(4)



(b)(4)



(b)(4)



I. Monitor**A. Predicate for Pressure Display****Camino Model V420 - K893232:**

The Camino Monitor provides continuous display of the pressure waveform, as well as mean, systolic, and diastolic values.

B. Predicate for Temperature Display**Spacelabs Model 9030 Monitor with Model 90403 Pressure/Dual Temperature Module - K842616:**

Model 90403 is the Pressure/Dual Temperature module which provides invasive pressure and temperature signal acquisition and processing. It acquires the temperature data through Yellow Spring Instruments Series 400 or 700 temperature probes (or their equivalent, including the Electromedics 2403).

C. Combined Device**MPM-1 Multi-parameter Monitor - Proposed Device :**

The MPM-1 provides a continuous display of the pressure waveform, as well as mean ICP, CPP, temperature, systolic and diastolic values.

A detailed comparison of the characteristics of the proposed device and the predicate is included in the original submission under Section 6 (Comparative Information) of the July 29, 1996 submission and is repeated below:

<u>ATTRIBUTE</u>	<u>DEVICE</u>	<u>PREDICATE DEVICES</u>	
	CAMINO	CAMINO	SPACELABS
	Multi-Parameter Monitor	Direct Pressure Monitor	Host Monitor
Model	Model MPM-1	Model V420	Model 9030/90403 press/temp module
K Number	TBD	K893232	K842616
INDICATIONS FOR USE	Monitor pressure and temperature Calculate cerebral perfusion pressure	Monitor pressure Not Same- ICP only	Monitor pressure and temperature Same
TARGET POPULATION	Adult, child, pediatric	Same	Same
ENVIRONMENT USED	OR, Intensive Care Unit, Trauma Center, Emergency Room	Same	Same
DESIGN	Displays ICP, CPP, Temperature Displays ICP and CPP waveform Displays 8 and 24 hour trend	Displays ICP Displays ICP waveform 8 hour trend	Displays ICP, CPP, Temp, MAP, etc Displays ICP, CPP, MAP, ECG waveform 1 2 hour trend
ALARMS	ICP Alarm	No alarm	Alarms for all measurements
PERFORMANCE STANDARDS	UL 544 Medical Equipment AAMI/ANSI Safe Current Limits	Same Same	Same Same

II. Catheter

Predicate for Pressure Sensing, Biocompatibility, and Safety

Camino Model 110-4HM Catheter - K853684 and Model 110-4B Catheter - K853864

The Camino Micro Ventricular Bolt Pressure Monitoring Kit (110-4HM) is indicated for direct intracranial pressure measurement along with cerebrospinal fluid drainage. The Camino Intracranial Pressure Monitoring Kit (110-4B) is indicated for direct intracranial pressure measurement without cerebral spinal fluid drainage.

Predicate for Temperature Sensing

Electromedics Model 2403 - K813459

Esophageal and Rectal thermistor temperature probe for measurement of temperature.

Combined Device

Camino Model 110-4BT and 110-4HMT Catheter

For use by qualified neurosurgeons for measurement of intracranial pressure and temperature. The Camino 110-4BT and the 110-4HMT use the same materials and design in the contact area and are inserted in the same manner as the Camino 110-4B and 110-4HM and therefore there are no new questions of safety or effectiveness.

A detailed comparison of the characteristics of the proposed device and the predicate is included in the original submission under Section 6 (Comparative Information) of the July 29, 1996 submission and is repeated below:

<u>ATTRIBUTE</u>	<u>DEVICE</u>	<u>PREDICATE DEVICES</u>	
	CAMINO	CAMINO	ELECTROMEDICS
Model	Intracranial Pressure-Temperature Monitoring Kit, Model i1048T and Model i104HMT	Intracranial Pressure Monitoring Kit, Model 110-4B and Model 110-HM	Esophageol, Rectal, Nasopharyngeal Temperature Probe Model 2403
K Number	TBD	K853684C	K813459A
INDICATIONS FOR USE	Measure pressure Measure temperature Parencymal placement (I 10-4BT) Subarachnoid placement (I 10-4BT) Ventricular Placement (I 10-4HMT) CSF drainage (II 0-HMT)	Same Not Same-no temp Same (OM) Same (OM) Same (I 10-4HM) Same (I 10-HM)	Not Same-doesn't measure pressure Same General Use General Use General Use Not Same-no CSF drainage
TARGET POPULATION	Adult, child, pediatric	Same	Same
ENVIRONMENT USED	OR, Intensive Care Unit, Trauma Center Emergency Room	Same	General Use
DESIGN	Sterile catheter Thermistor Pressure sensor Pressure Range -10 to 250 mmHg Temperature Range 30-40 C Contains introducer accessory items	Same No thermistor Same Same No temperature Same	Same Thermistor No pressure sensor No pressure Temp Range 0-50 C Not Same-Catheter only
STERILITY	Sterile	Sterile	Sterile
BIOCOMPATIBILITY	Per ISO-10993	Same	Same

These devices incorporate the same technological characteristics as the predicates and as summarized below, have the same intended use as the predicates

Proposed device	Predicate Device	Intended use	Differenc
MPM-1 Pressure display Temperature display	Camino Model V420 Spacelabs Model 9030/90403	Display pressure and temperature measurement Display pressure measurement Display temperature and pressure measurement	none none
110-4BT/110-4HMT Pressure sensing Temperature sensing	Camino Model 110-4B Electromedics Model 2403	Sense temp. and press. in tissue in which placed Sense press. in tissue in which placed Sense temp. in the tissue in which placed	none none

Question 6: It appears that you have numerous accessories to be included in the kits with this catheter and monitoring system. If this device is to be marketed as a kit, identify all components and provide the certification stated below: ...

Response to Question 6: Each catheter model of the proposed device (110-4BT - "Intracranial Pressure-Temperature Monitoring Kit" and 110-4HMT - "Micro Ventricular Bolt Pressure-Temperature Monitoring Kit") is packaged in the identical packaging configuration (Tyvek lidded thermoformed tray) as the previously cleared predicate devices (110-4B - "Intracranial Pressure Monitoring Kit" and 110-4HM - "Micro Ventricular Bolt Pressure Monitoring Kit"). The package configuration for the 110-4BT and 110-4HMT are identical to the predicate kits other than the identity of the catheter contained in the package. These accessories are listed and compared to the predicates below:

110-4B (Predicate)	110-4BT (Proposed)
Compression Cap	same
Bolt	same
Drill Bit	same
Zero Adjustment Tool	same
Stylet	same
Allen Wrench	same

110-4HM (Predicate)	110-4HMT (Proposed)
Luer Cap	same
Drill Bit	same
Safety Stop	same
Zero Adjustment Tool	same
Ventricular Access Device	same
Allen Wrench	same

Labeling for the predicate kits was included in the original submission and is also included in Attachment 2 for reference. Figure 1 in the labeling graphically shows the items listed above for each device. The proposed devices (110-4BT and 110-4HMT) will be packaged with the identical accessories as the previously cleared predicate devices (110-4B and 110-4HM).

The predicate devices (110-4B and 110-4HM) and the proposed devices (110-4BT and 110-4HMT) both also refer in their labeling to a Model 070 "Disposable Twist Drill Procedure Kit" and a Model H-ITH "Cranial Access Kit". These kits have been previously cleared by the FDA and have their own 510(k) numbers. The components for the Model 070 kit are identified in the predicate device labeling (Figure 1A) included in Attachment 2. The components for the H-ITH kit are identical to the Model 070 kit except for the addition of a 7mm Drill Bit (identical to drill bit included in 110-4B and 110-4HM) for cranial access. The H-ITH kit and the Model 070 kit are separate packages from the 110-4B/T and 110-4HM/T package configurations.

The certification statement requested is included in Attachment 3.

In summary, we believe that the above information along with the original submission provides the necessary information for determining that these devices are substantially equivalent to legally marketed predicate devices

Please note that the contact person for this submission has changed and all further communications regarding this submission should be directed to the undersigned.

If you have any additional questions regarding the information in this letter, or the original 510(k) submission, or if you need further information on any matter, please call, fax, or e-mail us and we will provide any needed information as quickly as possible. If you need such additional information we would appreciate being contacted in such a way as to preserve the submissions place in queue, if possible.

Sincerely,



Gary S. Mocnik

Director of Regulatory Affairs and Quality Assurance

voice 619.455.1115 x116 fax 619.455.8298 e-Mail GMocnik@AOL.Com

Attachment 1

MICRO-VENTRICULAR BOLT PRESSURE-TEMPERATURE MONITORING KIT

MODEL 110-4HMT

SYSTEM DESCRIPTION

The Camino Micro-Ventricular Pressure-Temperature Monitoring Kit consists of a sterile transducer-tipped pressure monitoring catheter with thermistor and accessory items which provide a means of access to the cerebral ventricles for CSF sampling and drainage, fluid injection and continuously monitoring intracranial pressure and temperature. Since its method of measuring pressure is unique, please read this section carefully.

Unlike ordinary pressure monitoring systems, the Camino Catheter has a miniature transducer and thermistor at the distal tip. This unique design eliminates the need for a "fluid-filled system" to carry pressure waves to an external transducer. Thus, the problems inherent in such fluid-filled systems are eliminated. The result is a precise pressure measurement and an artifact free, high-fidelity waveform trace.

The Micro-Ventricular Pressure-Temperature Monitoring Kit contains the following accessory items for use with the Camino Catheter:

- Camino Ventricular Access Device with Ventricular Catheter, Bolt, Female Luer Lock and Stylet,
- Twist Drill Bit with Safety Stop,
- Additional Luer Lock Port to connect drainage system,
- Thermistor Connector Cover

Note: A hand drill and various standard surgical instruments and supplies are required to place the ICP/CT monitoring system.

A complete set of instruments and supplies is available from Camino NeuroCare as the H-HH Series Cranial Access Kits or the 110-4HMT Kit.

PRECAUTIONS

- Extreme bending and/or kinks can impair the performance of the Fiber Optic Pressure Transducer. Exercise caution when handling the catheter.
- The catheter is designed for **SINGLE USE ONLY. DO NOT RESTERILIZE OR REUSE.**
- Use aseptic technique throughout procedures.

- Maintain the insertion site with regular meticulous redressing using aseptic technique.
- Do not attach anything to transducer air vent. Vent must remain open for proper operation.

CAUTION

- Federal law (U.S.A.) restricts this device to sale by or on the order of a physician.
- Connect the thermistor connector only to Host Monitors marked "Patient connection electrically isolated", or "BF" or "CF", or marked with the international symbols:



- When connecting the thermistor connector to a Host Monitor, refer to the Host Monitor's operations manual for complete instructions.
- Verify proper operation of the combined Host Monitor-110-4HMT System before clinical use.
- The combined leakage currents of devices interconnected with the 110-4HMT can lead to a potentially hazardous condition. Ensure that the combined system leakage current does not exceed 0.1 mA.

INSTRUCTIONS FOR USE INSERTION METHOD FOR THE CAMINO MICRO-VENTRICULAR BOLT

- The recommended frontal placement is 3-4 cm off the midline, just anterior to the coronal suture. After the site has been chosen, the craniotomy and prepped in a sterile manner with a betadine solution, the shaver and prepared area is then draped. The area of the incision is infiltrated subcutaneously with 1% lidocaine. An approximately three centimeter linear incision is made and carried to the bone. A self-retaining retractor is then inserted to provide good bone exposure and hemostasis of the skin edges.

- Adjust the safety stop on the drill bit to the estimated skull thickness and secure firmly with the allen wrench.
- Secure the drill bit to a twist drill and in a standard fashion drill a hole through the outer and inner tables of the skull, taking care to minimize any potential for parenchymal injury. Penetrate the dura under direct vision with a #11 blade, securing hemostasis as necessary.
- Using the stylet, insert the ventricular catheter into the ventricle. When the CSF is obtained, hold the catheter securely, remove the stylet, slide the bolt down and screw in, using bone wax to insure a tight seal. Do not over tighten, as stripping of the threads may cause loss of seal.
- Continue to hold the catheter securely, and turn the compression cap clockwise to lock the catheter in place. Slide the strain relief down and attach to the compression cap. Cap the catheter with luer cap to prevent CSF loss.

CAMINO PRESSURE-TEMPERATURE MONITORING CATHETER PREPARATION

(prior to insertion into ventricular catheter):

- The Camino Catheter can be used only in conjunction with the Camino 420, M420 or V420 Pressure Monitor. For Camino Monitor set-up and use, refer to the Camino Monitor User Information.
- Remove the Camino Catheter from its sterile package and firmly attach the transducer connector to the pre-amp connector. If the Camino display does not read zero after a short system self-check delay, use the tool from the catheter until the Camino display reads zero.
- Remove cover from the thermistor connector of the Camino Catheter. To interface with host monitor cardiac output module, connect cardiac output monitor cable connector to Camino Thermistor Connector. Verify that a temperature is displayed on the Host Monitor.

INSERTION OF CAMINO CATHETER

- Remove the Luer cap from the ventricular catheter, insert the Camino transducer-tipped Catheter and secure Luer lock. Holding the ventricular catheter straight will facilitate passage.
- Prepare an external ventricular drainage system according to its manufacturer's directions and attach to the side port of the Y-connector. Note that the CSF may be drained without interrupting pressure/temperature monitoring.

- When monitoring is to be discontinued, detach the strain relief from the compression cap. Loosen compression cap and remove ventricular catheter prior to the removal of the bolt from the skull.

CONTINUOUS PRESSURE AND TEMPERATURE MONITORING

Since the Camino Catheter has a miniaturized transducer at the distal tip, it requires no fluid-filled system. Thus, the need for an external transducer, pressure dome, and pressure tubing is eliminated. As a result, temperature and pressure may be monitored continuously without flushing or re-calibration.

INDICATIONS

The Camino Micro-Ventricular Bolt Pressure-Temperature Monitoring Kit is indicated for use by qualified neurosurgeons for measurement of intracranial pressure and temperature and for cerebrospinal fluid drainage. The Camino Micro-Ventricular Bolt Pressure-Temperature Monitoring Kit is intended to be used with an external drainage system as indicated by individual manufacturers.

CONTRAINDICATIONS

This device is not intended for any use other than that indicated. This device is contraindicated for use in the MRI field.

RISK AND COMPLICATIONS

Maintenance of sterility during placement and subsequent handling of the Camino Micro-Ventricular Bolt Pressure-Temperature Monitoring Kit is essential. Sterile technique should be used at all times when inserting, adjusting, and securing the Camino Catheter.

Infection, subcutaneous leakage of CSF, neurological sequelae, and blockage by intraventricular debris (including bloody and/or highly proteinic CSF) have occurred during the use of ventricular catheters.

Placement of the tip opening within the reach of choroid plexus has resulted in blockage of ventricular catheters.

The craniotomy must be carried out by a qualified neurosurgeon using standard surgical procedures and skill. Hemorrhage from the dura or cortical surface at the bolt insertion site may occur. Patients should be tested for normal blood clotting function prior to bolt placement. Appropriate measures to avoid infections and complications are the sole responsibility of the neurosurgeon in charge.

INTRACRANIAL PRESSURE-TEMPERATURE MONITORING KIT

MODEL 110-4BT

SYSTEM DESCRIPTION

The Intracranial Pressure-Temperature Monitoring Kit consists of a sterile transducer-tipped pressure monitoring catheter with thermistor and accessory items to be used as a diagnostic tool for rapidly determining and continuously monitoring intracranial pressure and temperature. Since its method of measuring pressure is unique, please read this section carefully.

Unlike ordinary pressure monitoring systems, the Camino Catheter has a miniature transducer and thermistor at the distal tip. This unique design eliminates the need for a "fluid-filled system" to carry pressure waves to an external transducer. Thus, the problems inherent in such fluid-filled systems are eliminated. The result is a precise pressure measurement and an artifact free, high fidelity waveform trace.

The Intracranial Pressure-Temperature Monitoring Kit contains the following accessory items for use with the Camino Catheter:

- Camino Bolt with Compression Cap and Tensioning Wings.
- 1/8 inch (2.7 mm) diameter No. 36 Drill Bit with Safety Stop.
- Spacer to adjust seating depth of the bolt.
- Strain Relief-Protective Sheath.
- .050 inches (1.3 mm) diameter Stylet.
- Thermistor Connector Cover.

Note: A hand drill and various standard surgical instruments and supplies are required to place the ICP/ICT monitoring system.

A complete set of Instruments and supplies is available from Camino NeuroCare as the HHTH Series Cranial Access Kit, or the 110-4BTC Kit.

PRECAUTIONS

- Extreme bending and/or kinks can impair the performance of the Fiber Optic Pressure Transducer. Exercise caution when handling the catheter.
- The catheter is designed for **SINGLE USE ONLY. DO NOT RESTERILIZE OR REUSE.**
- Use aseptic technique throughout procedures.
- Maintain the insertion site with regular meticulous redressing using aseptic technique.
- Do not attach anything to transducer air vent. Vent must remain open for proper operation.

CAUTION

- Federal law (U.S.A.) restricts this device to sale by or on the order of a physician.
- Connect the thermistor connector only to Host Monitors marked "Patient connection electrically isolated", or "BF" or "CF", or marked with the international symbols:



- When connecting the thermistor connector to a Host Monitor, refer to the Host Monitor's operations manual for complete instructions.
- Verify proper operation of the combined Host Monitor-110-4BT System before clinical use.
- The combined leakage currents of devices interconnected with the 110-4BT can lead to a potentially hazardous condition. Ensure that the combined system leakage current does not exceed 0.1 mA.

INSTRUCTIONS FOR USE

INSERTION METHOD FOR THE CAMINO BOLT

- Area of insertion: The standard right and left prefrontal areas are the primary areas of insertion. This region allows the patient to have his head rotated from side to side and still remain in a supine position without interference with the monitoring function. In addition, the incision will be carried behind the hairline in the majority of patients and therefore be cosmetically acceptable.
- After the insertion site has been chosen, the area is shaved and prepped in a sterile fashion, usually with a betadine solution. The shaved and prepared area is then draped with sterile towels. The area of the incision, which usually lies two to three centimeters anterior to the coronal suture in the mid-pupillary line is infiltrated subcutaneously with 1% Lidocaine. An approximately half centimeter linear incision is made ~~into the~~ ^{into} the bone. A small mastoid type of retractor is then inserted to provide a good bone exposure and hemostasis of the skin edges.
- The safety stop on the drill bit provided in the kit can be positioned as desired by loosening the setscrew with the allen wrench, sliding the stop into position, and retightening the setscrew.

- The drill bit is then secured to a twist drill and in a standard fashion, a twist drill hole is made through the outer and inner tables of the skull. The surgeon needs to be careful when penetrating the inner table to minimize any potential for parenchymal injury.
- After penetration of the inner table, the drill is removed and the hole is irrigated with sterile saline. An 18G spinal needle is then used to open the dura in a cruciate fashion. The stylet can be inserted to ensure adequate opening of the dura.
- Following opening of the dura, the Camino Bolt is screwed manually into the skull. The seating depth of the Camino Bolt will be at the surgeon's discretion pending the thickness of the skull. This will be approximately 2-3 mm for the neonatal age group, 3-5 mm for the pediatric age group and 5 mm to 1 cm for adults. If desired, the spacer can be used as a guide, otherwise the spacer can be removed and discarded.
- The stylet provided in the kit is inserted through the Camino Bolt and the dura to clear the passage for the Camino Transducer-Tipped Catheter.
- The Camino Bolt is irrigated with non-bacteriostatic sterile saline.

CAMINO PRESSURE-TEMPERATURE MONITORING CATHETER PREPARATION PRIOR TO INSERTION

- The Camino Catheter can be used only in combination with the Camino 420 or V420 Pressure Monitor. For Camino Monitor set up and use, refer to the Camino Monitor User Information.
- Remove the Camino Catheter from its sterile package and firmly attach the transducer connector to the preamp connector. If the Camino display does not read zero after a short system self-check delay, use the tool from the catheter kit to turn the zero adjustment on the bottom side of the transducer connector until the Camino display reads zero.
- Remove cover from the thermistor connector of the Camino Catheter. To interface with host monitor cardiac output module, connect cardiac output monitor cable connector to Camino Thermistor Connector. Verify that a temperature is displayed on the Host Monitor.

INSERTION OF CAMINO CATHETER

- To measure intracranial pressure and temperature, insert the Camino Catheter into the Camino Bolt, using the 5 cm markings on the catheter to gauge insertion depth. The thermistor is placed approximately 1 cm from the tip of the catheter. If the surgeon places his fingers between the



6 and 7 cm marks (double dot at the 5 cm mark), then inserts the catheter until his fingers touch the top of the bolt, the tip of the catheter will be 2 cm beyond the end of the bolt, into the parenchyma. He should pull the catheter back slightly, then turn the compression cap on the Camino Bolt clockwise to secure the catheter in place. If using a Host Monitor and/or V420, verify pressure waveform. If necessary, loosen the compression cap, reposition the Camino Catheter, and retighten the compression cap. While holding the catheter from above, slide the strain relief sheath down and secure it onto the compression cap.

CONTINUOUS PRESSURE AND TEMPERATURE MONITORING

Since the Camino Catheter has a miniaturized transducer at the distal tip, it requires no fluid-filled system. Thus, the need for an external transducer, pressure dome and pressure tubing is eliminated. As a result, pressure and temperature may be monitored continuously without recalibration.

INDICATIONS

The Camino Intracranial Pressure-Temperature Monitoring Kit is indicated for use by qualified neurosurgeons for measurement of intracranial pressure and temperature.

CONTRAINDICATIONS

This device is not intended for any use other than that indicated. This device is contraindicated for use in the MRI field.

RISK AND COMPLICATIONS

Maintenance of sterility during placement and subsequent handling of the Camino Pressure-Temperature Monitoring Kit is essential. Sterile technique should be used at all times when inserting, adjusting and securing the Camino Bolt and the Camino Catheter.

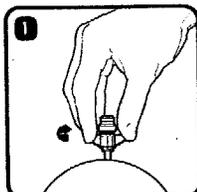
If monitoring is continued for more than 5 days, placement of a new system under sterile conditions is recommended. Placement of the Camino Bolt must be carried out by a qualified neurosurgeon to avoid penetration of the cerebral cortical surface during the drilling process, which requires standard surgical procedure and skill.

Hemorrhage from the dura or cortical surface at the bolt insertion site may occur. Patients should be tested for normal blood clotting function prior to bolt placement. Determination of possible extracerebral, subarachnoid, or intracerebral hemorrhage at the bolt insertion site will be the responsibility solely of the operating neurosurgeon. Appropriate steps and proceedings to control such hemorrhage should be taken when indicated by the neurosurgeon in charge.

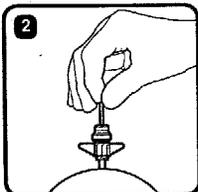
Attachment 2

**RECOMMENDED
INSERTION
PROCEDURE
SUMMARY**

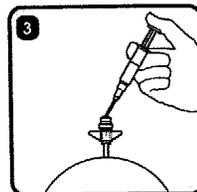
After drilling hole in skull and nicking the dura,



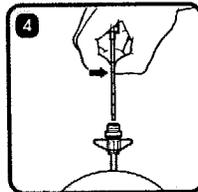
1. Screw in bolt.



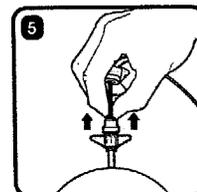
2. Clear path with stylet.



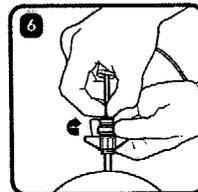
3. Irrigate.



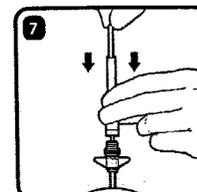
4. Zero the transducer, then place fingers at 5 cm and insert catheter until fingers touch top of bolt.



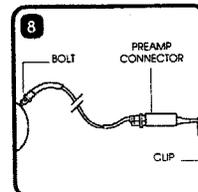
5. Pull back slightly.



6. Secure by tightening compression cap. Verify waveform, reposition if necessary.



7. Hold catheter from above, pull strain relief down and attach to bolt.



7. To protect fiber optics, position as shown, and secure preamp connector with clip.

SPECIFICATIONS

Transducer Size	4F
Transducer Type	Fiber optic
Frequency response (system)	120Hz (-3dB) 33Hz (-3dB)
Measurement Range (system)	-10 to +250 mmHg
Zero Drift (system)	0 ± 2 mmHg First 24 hours (maximum) 5 days (typical)
Temperature Coefficient	Max of 3 mmHg over temperature range of 22°C to 38°C (70°F-100°F)
Linearity and Hysteresis (system)	
Pressure range:	
-10 to 50 mmHg	± 2 mmHg or better
51 to 200 mmHg	± 6% of reading or better
201 to 250 mmHg	± 7% of reading or better
Reference Pressure	Atmosphere
Overpressure	-700 to 1250 mmHg

Manufactured under one or more of:
U.S. Patent Nos. 4,446,715; 4,705,047; 4,931,049; 4,903,707; 5,107,847 and Des. 285,112; 283,053;
EPO Patent No. 0127476;
Other U.S. and foreign patents issued and pending.



5955 PACIFIC CENTER BLVD., SAN DIEGO, CALIFORNIA 92121 (619)455-1115 (800) 663-8787 FAX: (619)455-8298
300261 REV M

**OLM INTRACRANIAL
PRESSURE MONITORING KIT
MODEL 110-4B**

DIRECTIONS FOR USE

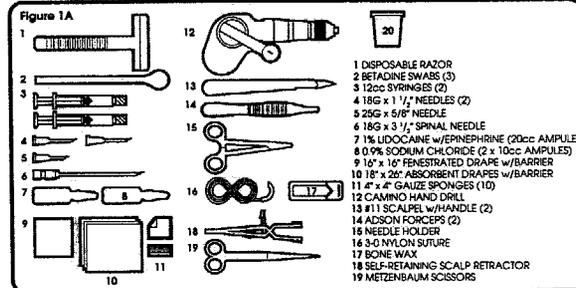
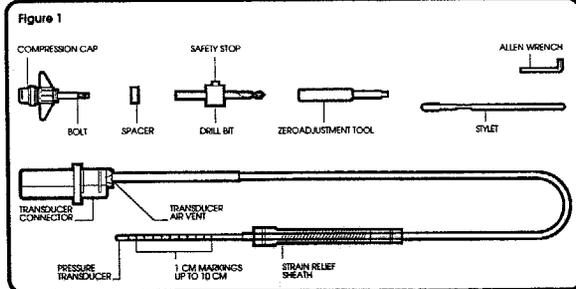
READ CAREFULLY PRIOR TO USE



OLM INTRACRANIAL PRESSURE MONITORING KIT

MODEL: 110-4B

* The OLM ICP Kit was developed in cooperation with Richard C. Ostrup, M.D., Thomas G. Luessen, M.D. and Lawrence F. Marshall, M.D. (San Diego, California)



SYSTEM DESCRIPTION

The OLM[®] Intracranial Pressure Monitoring Kit consists of a sterile transducer-tipped pressure monitoring catheter with accessory items to be used as a diagnostic tool for rapidly determining and continuously monitoring intracranial pressure. Since its method of measuring pressure is unique, please read this section carefully.

Unlike ordinary pressure monitoring systems, the Camino Catheter has a miniature transducer at the distal tip. This unique design eliminates the need for a "fluid-filled system" to carry pressure waves to an external transducer. Thus, the problems inherent in such fluid-filled

systems are eliminated. The result is a precise pressure measurement and an artifact free, high fidelity waveform trace.

The OLM[®] Intracranial Pressure Monitoring Kit contains the following accessory items for use with the Camino Catheter (Figure 1):

- Camino Bolt with Compression Cap and Turning Wings.
- 1.06 inches (2.71 mm) diameter No. 36 Drill Bit with Safety Stop.
- Spacer to adjust seating depth of the bolt.
- Strain Relief—protective Sheath.
- .050 inches (1.3 mm) diameter Stylet

Note: A hand drill and various standard surgical instruments and supplies are required to place the ICP monitoring system.

A complete set of instruments and supplies is available from Camino NeuroCare as Model 070 Disposable Twist Drill Procedure Kit (Figure 1A), or the H-TH Series Cranial Access Kits.

PRECAUTIONS

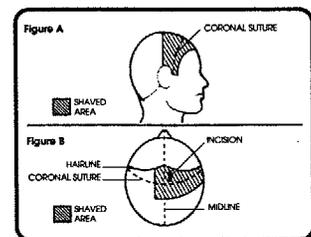
• Extreme bending and/or kinks can impair the performance of the Fiber Optic Pressure Transducer. Exercise caution when handling the catheter.

- The catheter is designed for **SINGLE USE ONLY. DO NOT RESTERILIZE OR REUSE.**
- Use aseptic technique throughout procedures.
- Maintain the insertion site with regular meticulous redressing using aseptic technique.
- Do not attach anything to transducer air vent. Vent must remain open for proper operation (Figure 1).

CAUTION

- Federal law (U.S.A.) restricts this device to sale by or on the order of a physician.

INSTRUCTIONS FOR USE INSERTION METHOD FOR THE CAMINO ICP BOLT



- Area of insertion: The standard right and left prefrontal areas are the primary areas of insertion. This region allows the patient to have his head rotated from side to side and still remain in a supine position without interference with the intracranial pressure monitoring function. In addition, the incision will be carried behind the hairline in the majority of patients and therefore be cosmetically acceptable (Figures A and B).
- After the insertion site has been chosen, the area is shaved and prepped in a sterile fashion, usually with a betadine solution. The shaved and prepared area is then draped with sterile towels. The area of the incision, which usually lies two to three centimeters anterior to the coronal suture in the mid-pupillary line is infiltrated subcutaneously with 1% Xylocaine. An approximately half

centimeter linear incision is made and carried to the bone. A small mastoid type of retractor is then inserted to provide a good bone exposure and hemostasis of the skin edges.

- The safety stop on the drill bit provided in the kit can be positioned as desired by loosening the setscrew with the allen wrench, sliding the stop into position, and retightening the setscrew.
- The drill bit is then secured to a twist drill and, in a standard fashion, a twist drill hole is made through the outer and inner tables of the skull. The surgeon needs to be careful when penetrating the inner table to minimize any potential for parenchymal injury.
- After penetration of the inner table, the drill is removed and the hole is irrigated with sterile saline. An 18G spinal needle is then used to open the dura in a cruciate fashion. The stylet can be inserted to ensure adequate opening of the dura.

- Following opening of the dura, the Camino Bolt is screwed manually into the skull. The seating depth of the Camino Bolt will be at the surgeon's discretion pending the thickness of the skull. This will be approximately 2-3 mm for the neonatal age group, 3-5 mm for the pediatric age group and 5 mm to 1 cm for adults. If desired, the spacer can be used as a guide, otherwise the spacer can be removed and discarded.

- The stylet provided in the kit is inserted through the Camino Bolt and the dura to clear the passage for the Camino Transducer-Tipped Catheter.

- The Camino Bolt is irrigated with non-bacteriostatic sterile saline.

Camino Transducer-Tipped Pressure Monitoring Catheter preparation prior to insertion:

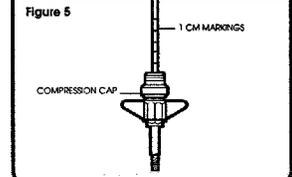
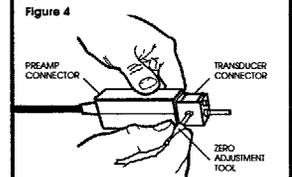
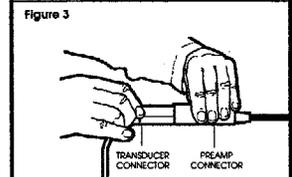
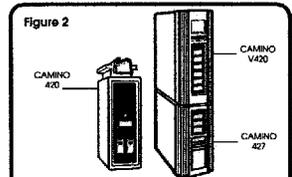
- The Camino Catheter can be used only in combination with the Camino 420 or V420 Pressure Monitor (Figure 2). For Camino set-up and use, refer to the Camino Monitor User Information.

- Remove the Camino Catheter from its sterile package and firmly attach the transducer connector to the preamp connector (Figure 3). If the Camino display does not read zero after a short system self-check delay, use the tool from the catheter kit to turn the zero adjustment on the bottom side of the transducer connector until the Camino display reads zero (Figure 4).

- To measure intracranial pressure, insert the Camino Catheter into the Camino Bolt, using the cm markings on the catheter to gauge insertion depth (Figure 5). If the surgeon places his fingers at the 5 cm mark (double dot), then inserts the

catheter until his fingers touch the top of the bolt, the tip of the catheter will be 0.5 cm beyond the end of the bolt, approximately in the subarachnoid space. He should pull the catheter back slightly, then turn the compression cap on the Camino Bolt clockwise to secure the catheter in place. If using a bedside monitor, verify waveform. If necessary, loosen the Catheter, and retighten the compression cap.

- The surgeon may easily vary the insertion depth by locating his fingers at the proper cm mark



before performing the above step. For example, placing the fingers at 5.5 cm will locate the tip of the catheter 1 cm beyond the end of the bolt, into the parenchyma.

• While holding the catheter from above, slide the strain relief sheath down and secure it onto the compression cap.

IT IS RECOMMENDED THAT THE CATHETER BE DISCONNECTED FROM THE PRE-AMP CONNECTOR WHEN THE PATIENT IS MOVED. THIS WILL NOT AFFECT CALIBRATION.

CONTINUOUS PRESSURE MONITORING

Since the Camino Catheter has a miniaturized transducer at the distal tip, it requires no fluid-filled system. Thus, the need for an external transducer, pressure dome and pressure tubing is eliminated. As a result, pressure may be monitored continuously without recalibration.

INDICATIONS

The use of the OLM[®] Intracranial Pressure Monitoring Kit by a qualified neurosurgeon is indicated when direct measurement of intracranial pressure in the parenchyma or the subarachnoid space, is clinically important.

CONTRAINDICATIONS

This device is not intended for any use other than that indicated.

RISK AND COMPLICATIONS

Maintenance of sterility during placement and subsequent handling of the Camino Bolt is essential. Sterile technique should be used at all times when inserting, correcting or adjusting the Camino Bolt and the Camino Transducer-Tipped Pressure Monitoring Catheter.

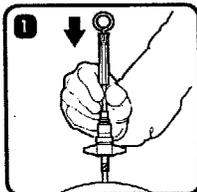
If monitoring is continued for more than 5 days, placement of a new system under sterile conditions is recommended.

Placement of the Camino Bolt must be carried out by a qualified neurosurgeon to avoid penetration of the cerebral cortical surface during the drilling process, which requires standard surgical procedure and skill.

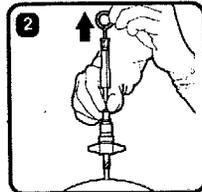
Hemorrhage from the dura or cortical surface at the bolt insertion site may occur. Patients should be tested for normal blood clotting function prior to bolt placement. Determination of possible extracerebral, subarachnoid, or intracerebral hemorrhage at the bolt insertion site will be the responsibility solely of the operating neurosurgeon. Appropriate steps and proceedings to control such hemorrhage should be taken when indicated by the neurosurgeon in charge.

**RECOMMENDED
INSERTION
PROCEDURE
SUMMARY**

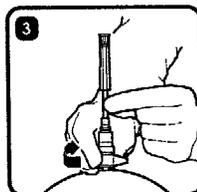
After drilling hole in skull and nicking the dura.



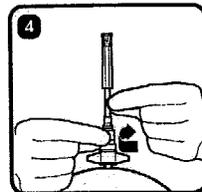
1. Pass ventricular catheter assembly into ventricle.



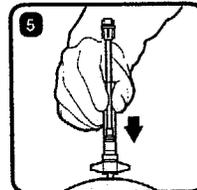
2. Remove stylet.



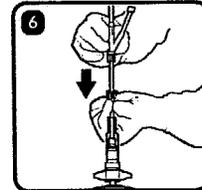
3. Slide ball down and screw in.



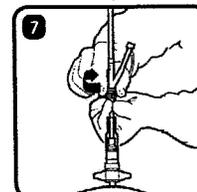
4. Secure compression cap.



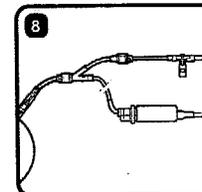
5. Slide strain relief sheath down and attach to compression cap.



6. Zero the transducer, then insert transducer-tipped catheter into ventricular catheter.



7. Secure luer lock.



8. Connect drainage system to y-site.

SPECIFICATIONS

Ventricular Catheter:	
Outside Diameter	3.7 mm
Inside Diameter	2.2 mm
Length	6-8 cm
Transducer Size	
	4F
Transducer Type	
	Fiber optic
Frequency Response (system)	
Model V420/M420/420XP	120Hz (-3dB)
Model 420	33Hz (-3dB)
Measurement Range (system)	
	-10 to +250 mmHg
Zero Drift (system)	
First 24 hours (maximum)	0 ± 2 mmHg
5 days (typical)	less than ± 1 mmHg per day
Temperature Coefficient	
	Max. of 3 mmHg over temperature range of 22°C to 38°C (70°F - 100°F)
Linearity and Hysteresis (system)	
Pressure Range:	
-10 to 50 mmHg	±2 mmHg or better
51 to 200 mmHg	±6% of reading or better
201 to 250 mmHg	±7% of reading or better
Reference Pressure	
	Atmosphere
Overpressure	
	-700 to 1250 mmHg

Manufactured under one or more of:
 U.S. Patent Nos. 4,446,715; 4,705,047; 4,931,049; 4,903,707; 5,107,847 and Des. 285,112; 283,053;
 EPO Patent No. 0127476;
 Other U.S. and foreign patents issued and pending



5955 PACIFIC CENTER BLVD., SAN DIEGO, CALIFORNIA 92121 (619) 455-1116 (800) 663-8767 FAX: (619) 455-8298
 300698 REV E

**MICRO VENTRICULAR BOLT
PRESSURE MONITORING KIT
MODEL 110-4HM**

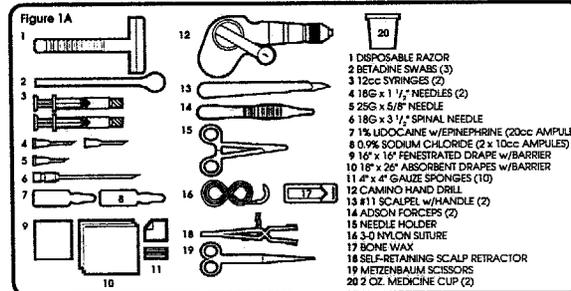
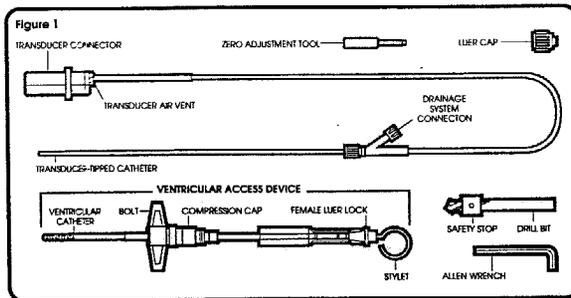
DIRECTIONS FOR USE

READ CAREFULLY PRIOR TO USE



MICRO VENTRICULAR BOLT PRESSURE MONITORING KIT

MODEL: 110-4HM



SYSTEM DESCRIPTION

The Camino Micro Ventricular Bolt Pressure Monitoring Kit consists of a sterile transducer-tipped pressure monitoring catheter with accessory items which provide a means of access to the cerebral ventricles for CSF sampling and drainage, fluid injection and intracranial pressure monitoring. Since its method of measuring pressure is unique, please read this section carefully.

Unlike ordinary pressure monitoring systems, the Camino Catheter has a miniature transducer at the distal tip. This unique design

eliminates the need for a "fluid-filled system" to carry pressure waves to an external transducer. Thus, the problems inherent in such fluid-filled systems are eliminated. The result is a precise pressure measurement and an artifact free, high fidelity waveform trace.

The Camino Micro Ventricular Bolt Monitoring Kit contains the following accessory items for use with the Camino Catheter (Figure 1):

- Camino Ventricular Access Device, with ventricular catheter, bolt, female Luer lock and stylet.

- Twist drill bit with safety stop.
- Spacer to adjust seating depth of the bolt.
- Additional Luer lock port to connect drainage system,

The indwelling portion of the ventricular catheter assembly is fabricated of barium-impregnated silicone elastomer, having an OD of 3.7 mm and ID of 2.2 mm. Its length is adjustable from 6-8 cm. Designed for directing fluid from the ventricles through a series of drainage holes, it can be inserted into the ventricular cavity with the supplied stainless steel stylet.

Note: A hand drill and various standard surgical instruments and supplies are required to place the ICP monitoring system.

A complete set of instruments and supplies is available from Camino NeuroCare in Model 070 Disposable Twist Drill Procedure Kit (Figure 1A), or the H-TH Series Cranial Access Kits.

PRECAUTIONS

- Extreme bending and/or kinks can impair the performance of the Fiber Optic Pressure Transducer. Exercise caution when handling the catheter.
- The catheter is designed for SINGLE USE ONLY. DO NOT RESTERILIZE OR REUSE.
- It is imperative that the ventricular catheter not be handled with bare fingers or come into contact with linty surfaces. Silicone elastomers are very electrostatic and therefore susceptible to contamination by airborne or surface particles. The presence of these contaminants could cause adverse tissue reaction. Rubber-rod clamps or washed, gloved hands are the best means of handling implantable silicone devices.
- Use aseptic technique throughout procedures.
- Maintain the insertion site with regular meticulous redressing using aseptic technique.
- Do not attach anything to transducer air vent. Vent must remain open for proper operation (Figure 1).

CAUTION

- Federal law (U.S.A.) restricts this device to sale by or on the order of a physician.

INSTRUCTIONS FOR USE

The recommended frontal placement is 3-4 cm off the midline, just anterior to the coronal suture.

After the site has been chosen, the area is shaved and prepped in a sterile fashion, usually with a betadine solution. The shaved and prepared area is then draped. The area of the incision is infiltrated subcutaneously with 1% lidocaine. An approximately three centimeter linear incision is made and carried to the bone. A self-retaining retractor is then inserted to provide good bone exposure and hemostasis of the skin edges.

- Adjust the safety stop on the drill bit to the estimated skull thickness and secure firmly with the allen wrench.

- Drill a hole through the outer and inner tables of the skull, taking care to minimize any potential for parenchymal injury. Penetrate the dura under direct vision with a #11 blade, securing hemostasis as necessary.

- Using the stylet, insert the ventricular catheter into the ventricle. When the CSF is obtained, hold the catheter securely, remove the stylet, slide the bolt down and screw in, using bone wax to insure a tight seal. Do not over tighten, as stripping of the threads may cause loss of seal.

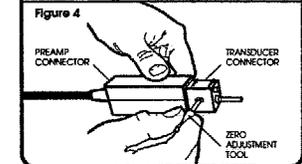
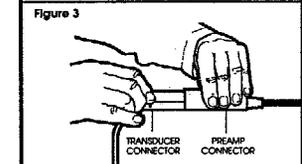
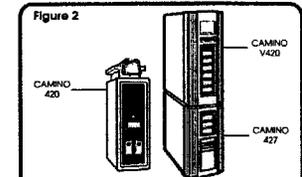
- Continue to hold the catheter securely, and turn the compression cap clockwise to lock the catheter in place. Slide the strain relief down and attach to the compression cap. Cap the catheter with Luer cap to prevent CSF loss.

Camino transducer-tipped pressure monitoring catheter preparation (prior to insertion into ventricular catheter):

- The Camino catheter can be used only in conjunction with the Camino 420, M420 or V420 Pressure Monitor (Figure 2). For Camino Monitor set-up and use, refer to the Camino Monitor User Information. Remove the Camino catheter from its sterile package and firmly attach the transducer connector to the preamp connector (Figure 3). If the Camino display does not read zero after a short system self-check delay, use the tool from the catheter kit to turn the zero adjustment on the bottom side of the transducer connector until the Camino display reads zero (Figure 4).

- Remove the Luer cap from the ventricular catheter, insert the Camino transducer-tipped catheter and secure the Luer lock. Holding the ventricular catheter straight will facilitate passage.

- Prepare an external ventricular drainage system according to its manufacturer's directions and attach to the side part of the Y-connector. Note that the CSF may be drained without interrupting pressure/temperature monitoring.



- When monitoring is to be discontinued, detach the strain relief from the compression cap. Loosen compression cap and remove ventricular catheter prior to the removal of the bolt from the skull.

IT IS RECOMMENDED THAT THE CATHETER BE DISCONNECTED FROM THE PRE-AMP CONNECTOR WHEN THE PATIENT IS MOVED. THIS WILL NOT AFFECT CALIBRATION.

CONTINUOUS PRESSURE MONITORING

Since the Camino catheter has a miniaturized transducer at the distal tip. It requires no fluid-filled system. Thus, the need for an external transducer, pressure dome, and pressure tubing is eliminated. As a result, temperature and pressure may be monitored continuously without flushing or recalibration.

INDICATIONS

The use of the Camino Micro Ventricular Pressure Monitoring Kit by a qualified neurosurgeon is indicated when direct pressure measurement and cerebrospinal fluid drainage is clinically important. The Camino Micro Ventricular Pressure Monitoring Kit is intended to be used with an external drainage system as indicated by individual manufacturers.

CONTRAINDICATIONS

This device is not intended for any use other than that indicated.

RISK AND COMPLICATIONS

Maintenance of sterility during placement and subsequent handling of the Camino Micro Ventricular Pressure Monitoring Kit is essential. Sterile technique should be used at all times when inserting, adjusting, and securing the Camino catheter. Infection, subcutaneous leakage of CSF, neurological sequelae, and blockage by intraventricular debris (including bloody and/or highly proteinic CSF) have occurred during the use of ventricular catheters.

Placement of the tip openings within the reach of choroid plexus has resulted in blockage of ventricular catheters.

The ventriculostomy must be carried out by a qualified neurosurgeon using standard surgical procedure and skill. Hemorrhage from the dura or cortical surface at the bolt insertion site may occur. Patients should be tested for normal blood clotting function prior to bolt placement. Appropriate measures to avoid infections and complications are the sole responsibility of the neurosurgeon in charge.

Attachment 3



CAMINO
NeuroCare, Inc.
Saba Medical Group, L.P.

**PREMARKET NOTIFICATION
Kit Component Certification**

I certify that the following components of Camino NeuroCare's (Camino) kit are either (1) legally marketed preamendment devices, (2) general-purpose articles whose use is generally known by persons trained in their use per 21 C.F.R 807.65 (c), (3) exempt from premarket notification (consistent with the exemption criteria described in the classification regulation (s) and the limitations of exemptions from Section 510(k) of the Act (e.g. 21 C.F.R. 862.9), or (4) have been found to be substantially equivalent through the premarket notification process for the use (s) for which the kit is to be intended (i.e. I am not claiming or causing a new use for the component(s)).

I further certify that these components are not purchased in "bulk", but are purchased in finished form, i.e., they are packaged, labeled, etc., consistent with their preamendments, general purpose, exemption, or premarket notification criteria and status. For example, although some items, such as allen wrenches and others, may be purchased in large lots (i.e. "in bulk") and incorporated into kits, they are bought in their finished form.

Components in 110-4B and 110-4HM - K853684 (to be included in proposed device)

- Compression Cap
- Bolt
- Drill Bit
- Safety Stop
- Zero Adjustment Tool
- Stylet
- Allen Wrench
- Ventricular Access Device

Model 070 - ICP Monitoring Kit - K853864

Model H-TH Cranial Access Kit - K860161

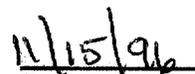
From time to time, Camino may make changes to the kits, and the components may change, but these changes will be made so as to be consistent with the first two paragraphs of this statement and Camino's policies for submission of Section 510(k) Premarket Notifications for changes or modifications to devices.



Signature



Printed Name



Date



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 24 1996

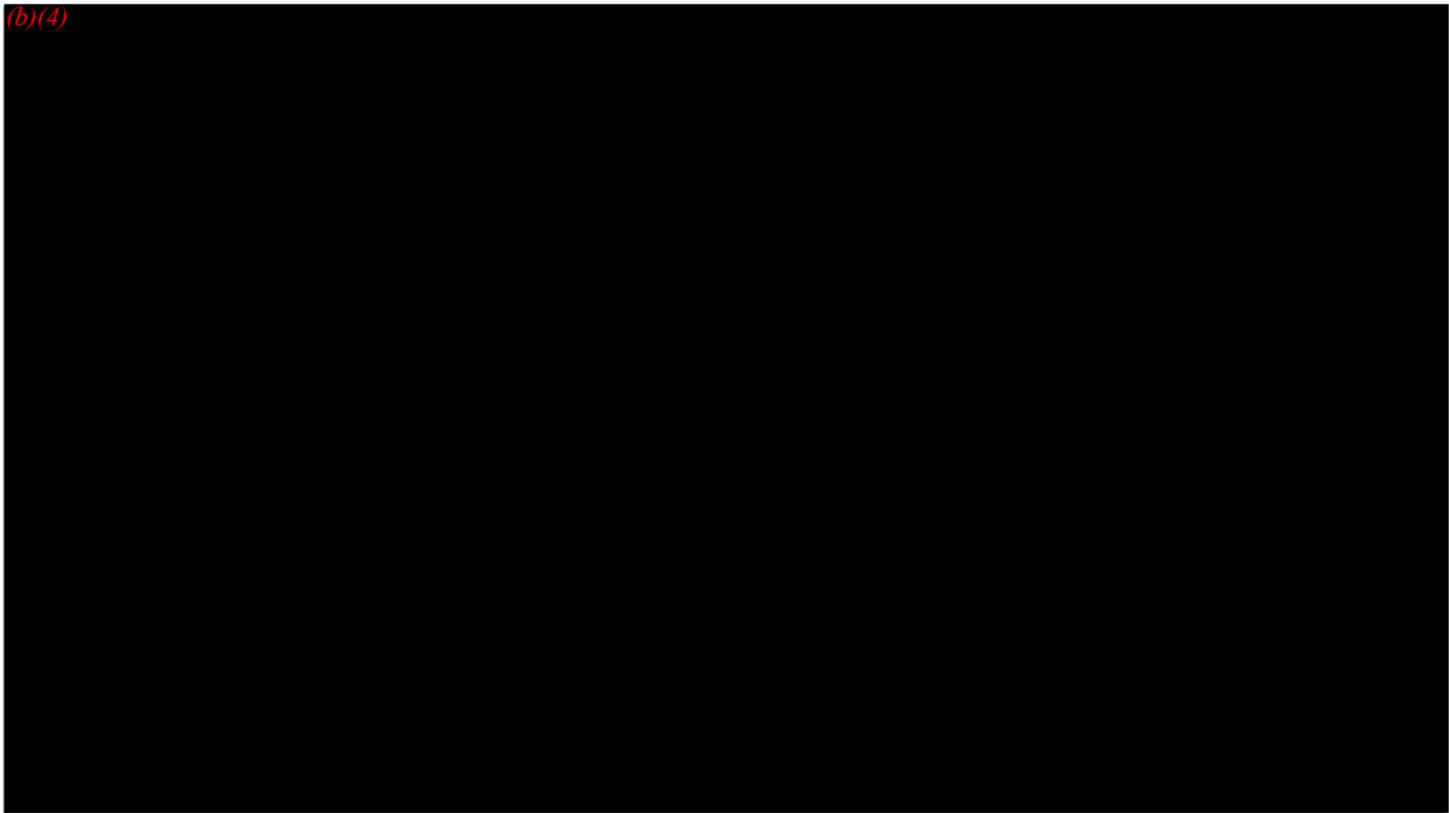
Ms. Donna L. Free
Director, Regulatory and Clinical Affairs
Camino NeuroCare™, Inc.
5955 Pacific Center Boulevard
San Diego, California 92121

Re: K962928
Intracranial Pressure-Temperature Monitoring Catheter
(Models: 110-4BT and 110-4HMT) and
Multi-Parameter Monitor (Model: MPM)
Dated: July 26, 1996
Received: July 29, 1996

Dear Ms. Free:

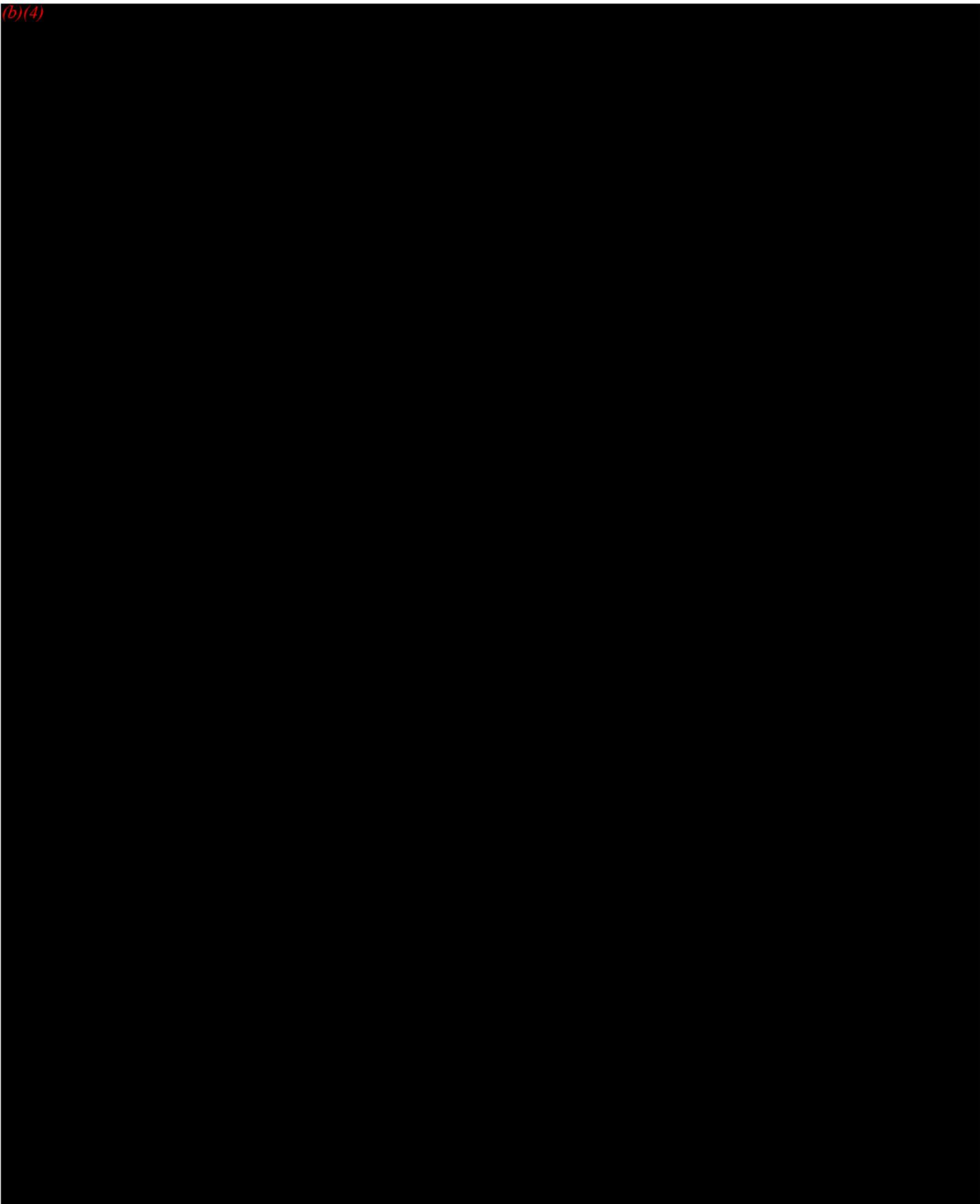
We have reviewed your Section 510(k) notification of intent to market the device referenced above. We cannot determine if the device is substantially equivalent to a legally marketed predicate device based solely on the information you provided. To complete the review of your submission, we require the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

(b)(4)



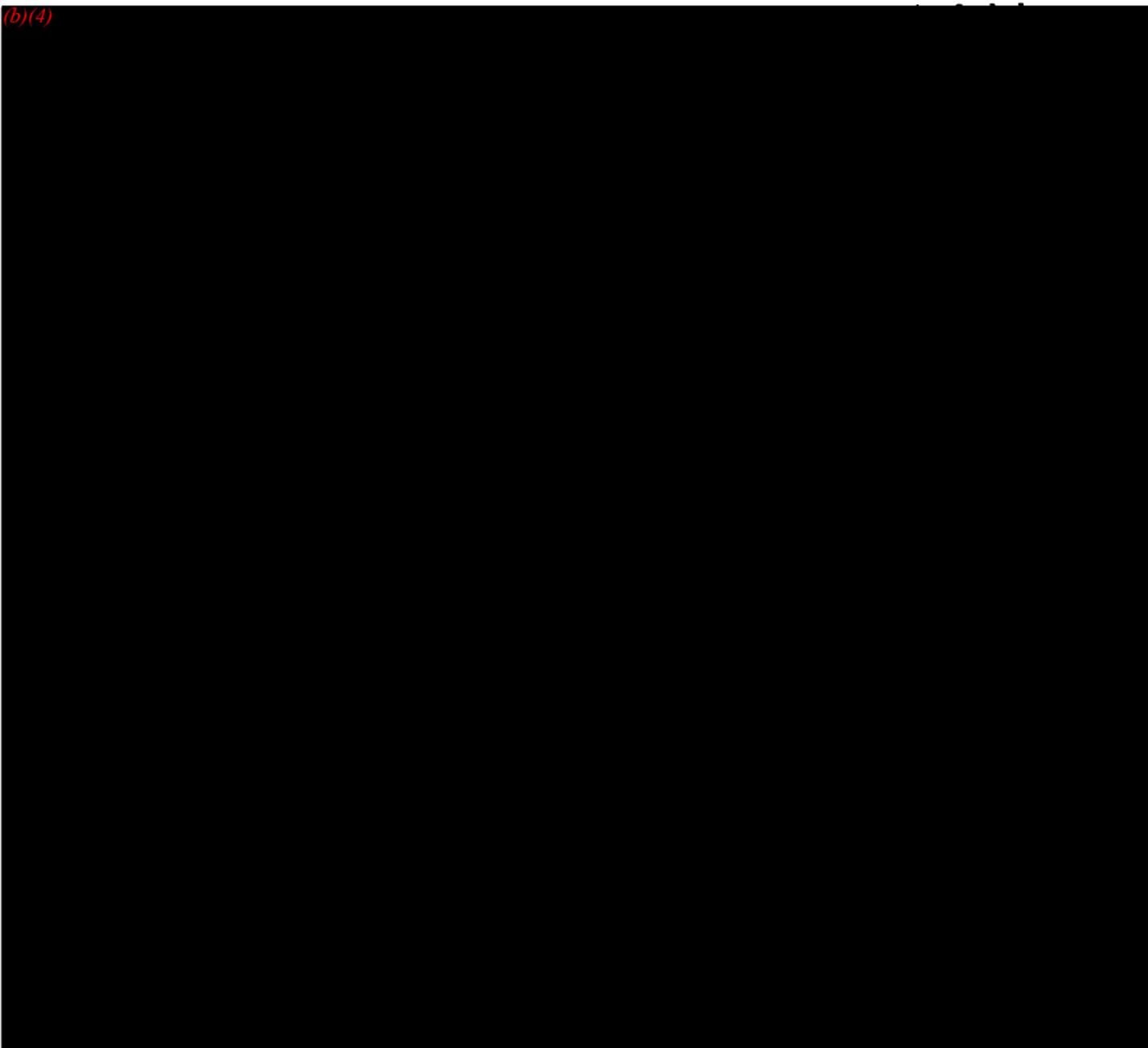
Page 2 - Ms. Donna L. Free

(b)(4)



Page 3 - Ms. Donna L. Free

(b)(4)



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(k), 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.

38

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

Page 4 - Ms. Donna L. Free

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 questions concerning the contents of this letter, please contact Levering Keely at (301) 443-8517. 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,

Woj Sepulveda M.D.

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

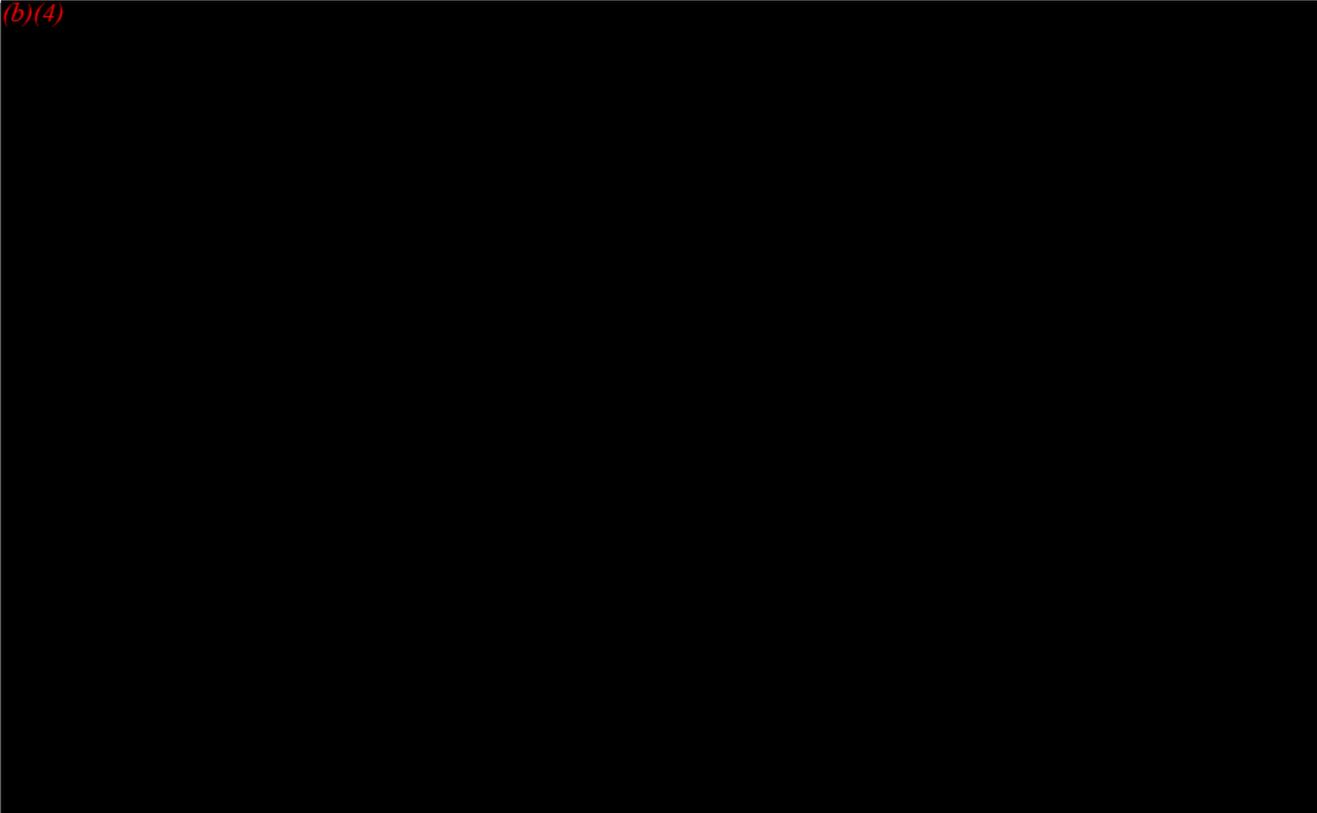
Ms. Donna L. Free
Director, Regulatory and Clinical Affairs
Camino NeuroCare™, Inc.
5955 Pacific Center Boulevard
San Diego, California 92121

Re: K962928
Intracranial Pressure-Temperature Monitoring Catheter
(Models: 110-4BT and 110-4HMT) and
Multi-Parameter Monitor (Model: MPM)
Dated: July 26, 1996
Received: July 29, 1996

Dear Ms. Free:

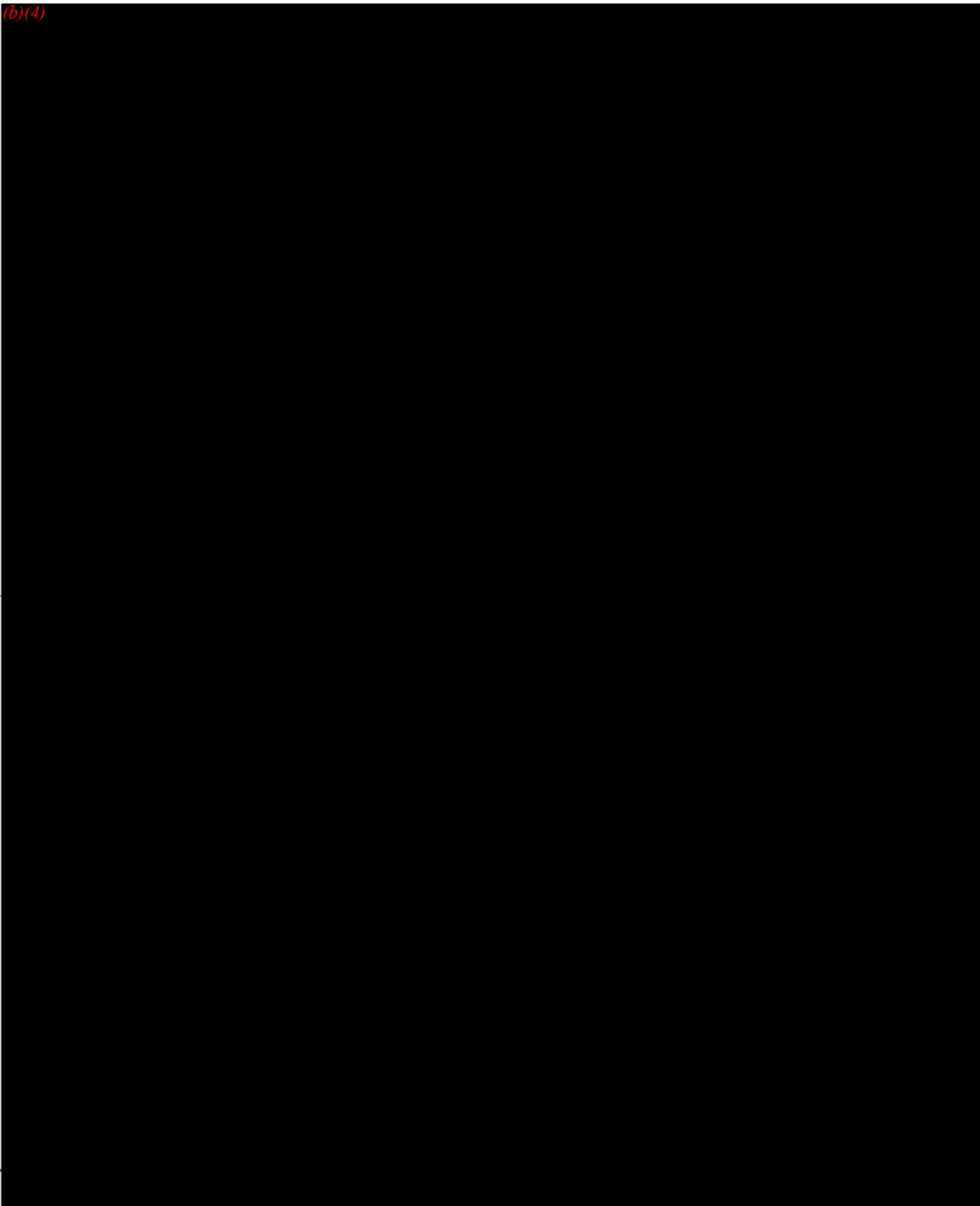
We have reviewed your Section 510(k) notification of intent to market the device referenced above. We cannot determine if the device is substantially equivalent to a legally marketed predicate device based solely on the information you provided. To complete the review of your submission, we require the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

(b)(4)



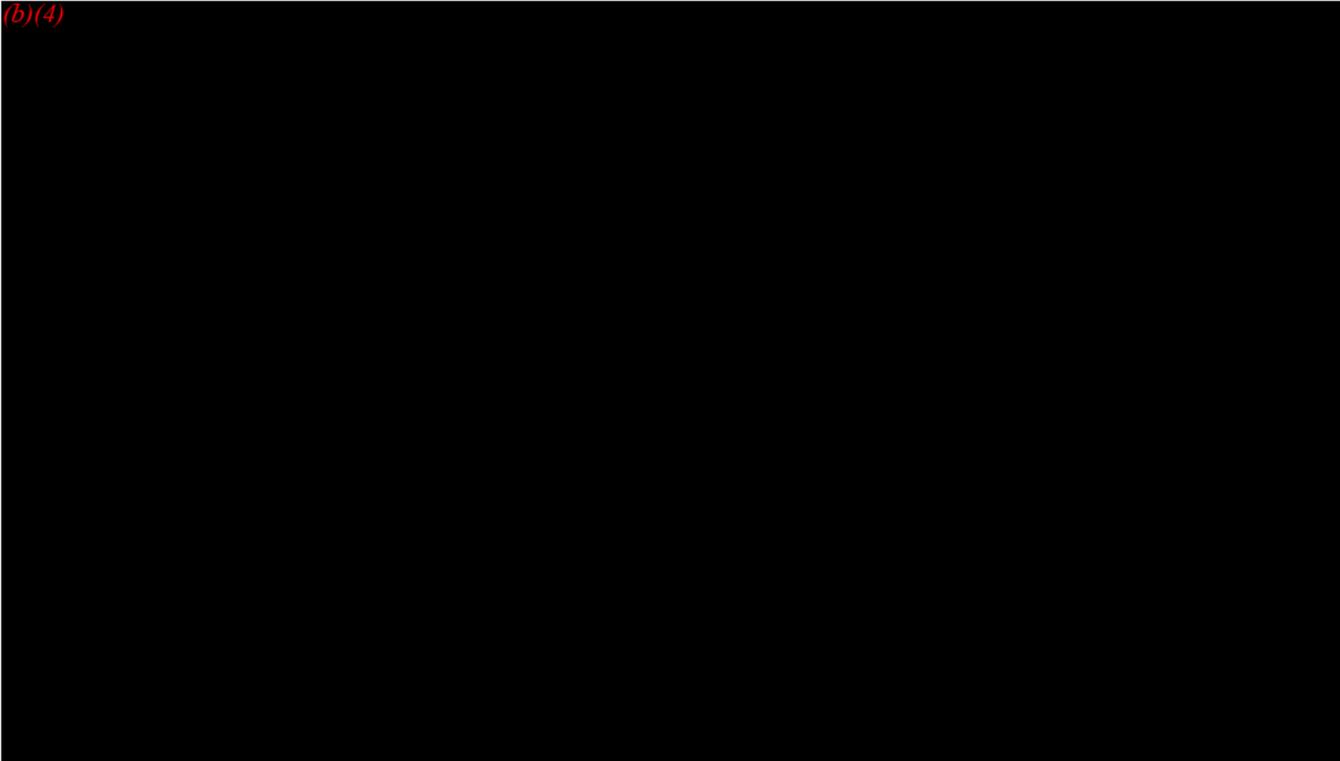
Page 2 - Ms. Donna L. Free

(b)(4)

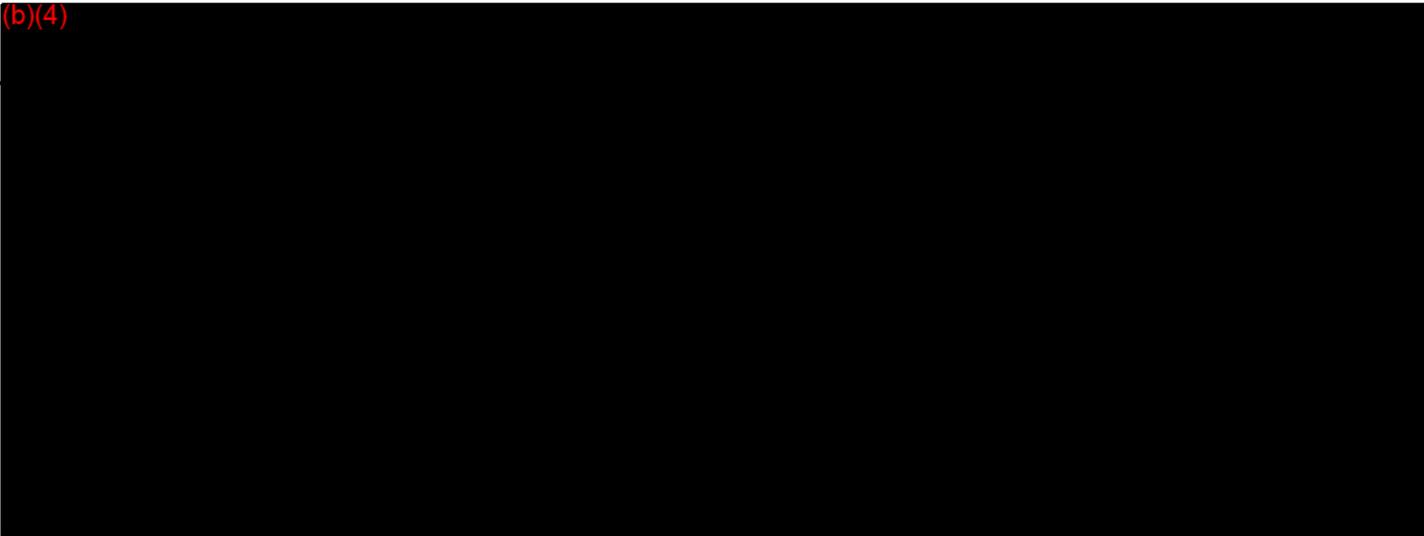


Page 3 - Ms. Donna L. Free

(b)(4)



(b)(4)



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(k), 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.

Page 4 - Ms. Donna L. Free

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 questions concerning the contents of this letter, please contact Levering Keely at (301) 443-8517. 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.
Director
Division of Cardiovascular, Respiratory,
and Neurological Devices
Office of Device Evaluation
Center for Devices
and Radiological Health

Page 5 - Ms. Donna L. Free

Prepared by:LZKeely:jsy:10/18/96
Revised:LZKeely:jsy:10/22/96

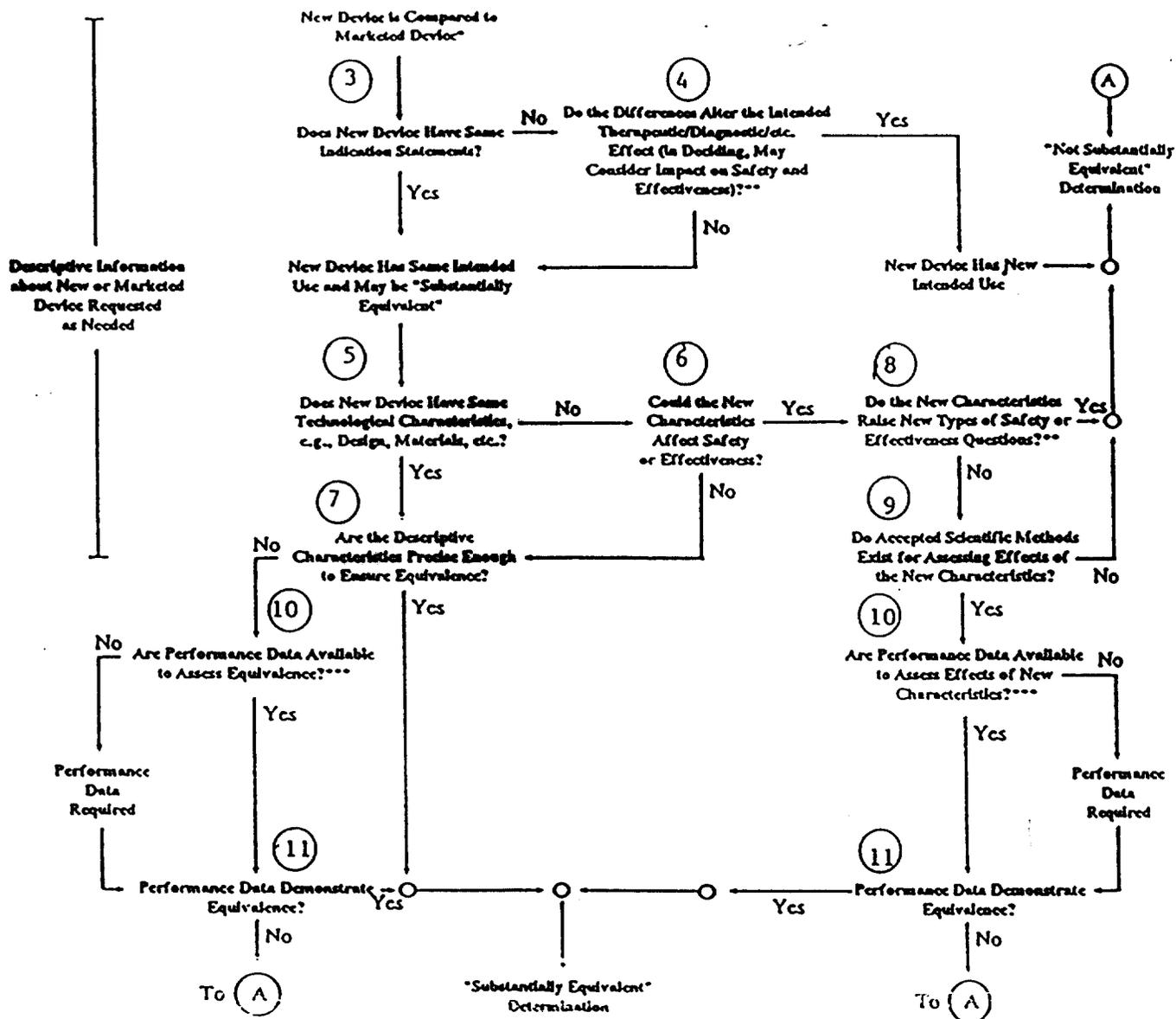
cc: HFZ-401 DMC
HFZ-404 510(k) Staff
HFZ-450 Division
D.O.

FILE
COPY

OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE
2450	L. Keely	10/22						
450	Thompson	10/22						
450	Stevens	10/23						

U.S. GPO 190G-169 069

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.

MEMORANDUM

Page 1 of 3

DATE: October 18, 1996

FROM: G. Levering Keely, Neurological Devices Branch, HFZ-450
Office of Device Evaluation, DCRND

SUBJECT: K962928, Camino Neurocare, Inc.
Device Name: Multiparameter Waveform Display
ICP Temperature monitoring Kit

TO: File

This device is a modification to a presently existing intracranial pressure monitoring kit. The modification includes (b)(4)

(b)(4)

NOTE: There is an IDE (b)(4) for the use of this device in (b)(4) institutions, for (b)(4) subjects comparing

(b)(4)

(b)(4)

No data has yet been reported for that study.

Previous reviews of this device under other 510(k) submissions are attached and have recommended that this device be found NSE. If this device makes no additional claims other than that it measures temperature, I do not see any reason that this may not be found SE to an ICP monitor with an additional feature of measuring temperature.

I have a few outstanding questions, however, which need to be answered before a decision regarding the equivalency of this device can be established.

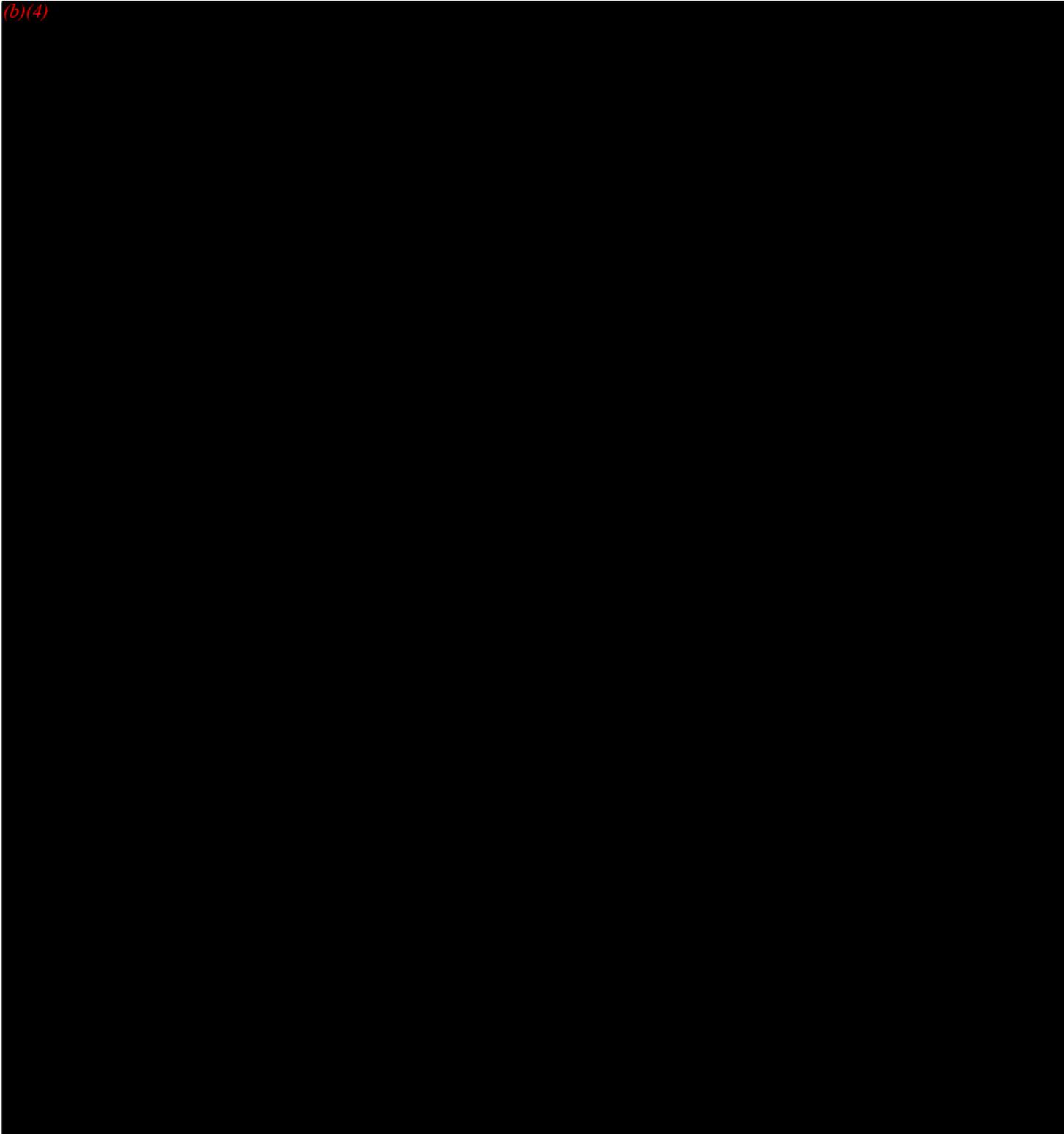
(b)(4)

Page 1 of 3

MEMORANDUM
K962928
Camino ICP monitor

October 22, 1996

(b)(4)



MEMORANDUM
K962928
Camino ICP monitor

October 22, 1996

(b)(4)



If you cannot make the above referenced certification statement (first paragraph) for each component of your kit, you must itemize the components without a pre-amendments, exemption, or premarket notification status. In this case we will continue our premarket notification review of these components of your kit.

If you cannot make the above referenced certification statement (second paragraph) for each component of your kit, you must itemize these components, state whether they are pre-amendments, exempt, or have been found substantially equivalent through the premarket notification process, and describe how you further process them (e.g., sterilize, package/repackage, label/relabel, etc.).

RECOMMENDATION

I recommend that before any determination of equivalence can be made, this submission be placed on hold pending a response to the above questions..


G. Levering Keely

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

Date: 21-Oct-1996 04:59pm EDT
From: Dawson, John M.
JMD
Dept: OSB DBS - HFZ-542
Tel No: 827-0201

TO: Keely Jr., G. Levering

(LZK)

CC: Morris, Janine M.

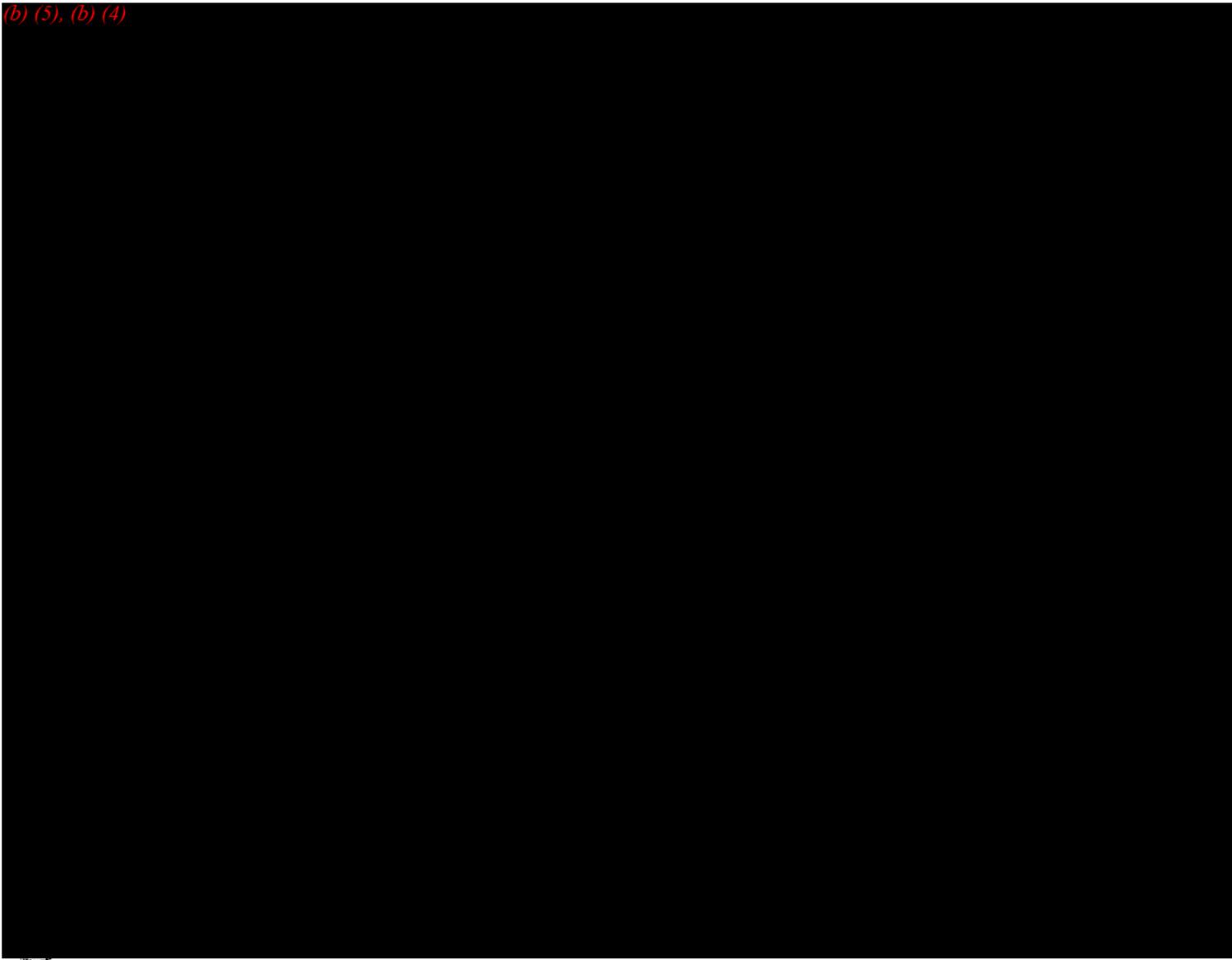
(JZM)

Subject: Camino temp probe

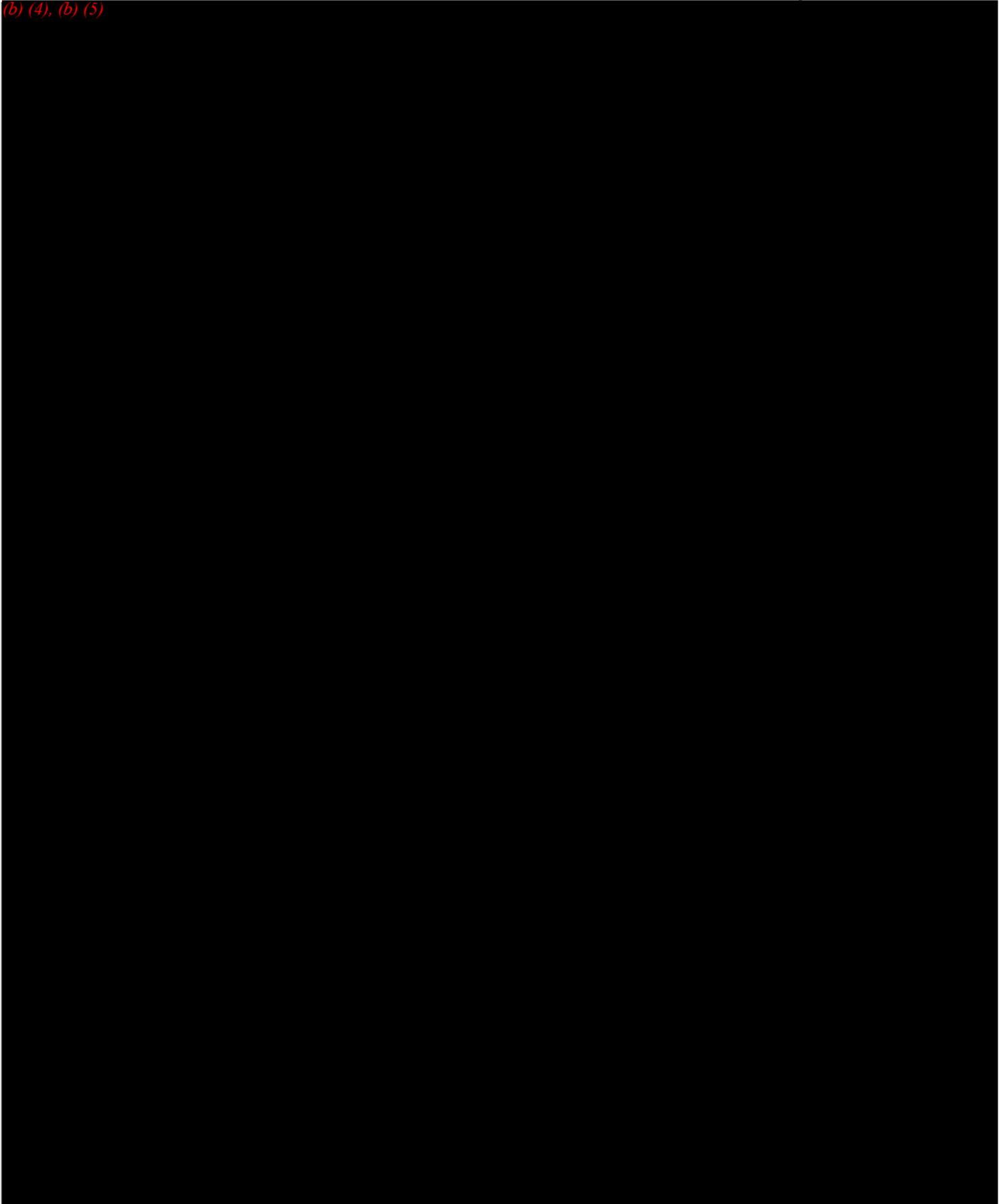
MEMORANDUM FOR G. LEVERING KEELY, JR.,
SCIENTIFIC REVIEWER

October 21, 1996

(b) (5), (b) (4)



(b) (4), (b) (5)



**510k REVIEW
SUPPLEMENTAL SUMMARY SHEET**

510K NUMBER: K953679
MANUFACTURER: Camino NeuroCare
DEVICE NAME: Micro-Ventricular Pressure-Temperature Monitoring Kit, Model 110-4HMT
 Parenchymal Pressure-Temperature Monitoring Kit, Model 110-4BT

SUMMARY:

This 510k premarket notification represents a modification of two devices which are intended to monitor intracranial pressure (ICP) or monitor ventricular pressure. The modification is the addition of temperature monitoring capabilities by incorporating a thermistor in the former designs. The predicate devices are Camino's ICP Monitoring Kit, Model 070 (K853864) and Ventricular Pressure Monitoring Kit, Model 110-4HM (K914735).

The proposed labeling, i.e., Instructions for Use, for these devices do not specify how temperature is to be used and when measurement of brain tissue temperature is clinically meaningful. No other promotional material was provided. However, in the firm's cover letter dated August 4, 1995, the firm states, "An IDE for these devices was submitted January 31, 1995. The IDE (b)(4) clinical study is for determining the (b)(4) I am aware of no other use for measuring brain tissue temperature or cerebral ventricular pressure other than its use in the investigational treatment of hypothermia for head trauma victims.

Two other premarket notifications for a intracranial temperature monitoring catheter were submitted by PMT Corporation:

<u>510k No.</u>	<u>Device Name</u>	<u>Status</u>	<u>Letter Date</u>
K903922	Temperature Monitoring Catheter	DELETED	November 27, 1990
K915294	Model 1110 Catheter with Thermistor	NSE	March 16, 1993

The first PMT submission (K903922), we issued a special letter stating, "...Although the intended use of your temperature monitoring catheter is to function as a component of a system used in administering hypothermia, you have provided no data concerning equivalent hypothermia devices, nor have you provided any data to show hypothermia is a safe and effective therapy. In order for us to complete our review, you must provide data to show that the use of hypothermia devices is substantially equivalent to the use of other preamendment devices." The firm never responded and the file was deleted from the system.

The second PMT submission (K915294) was another attempt by PMT to market their device

9

as a ventricular catheter. We issued a "not substantially equivalent" letter based on the fact that "your implied indication (profound hypothermia and circulatory arrest for aneurysm surgery) alters the intended therapeutic and diagnostic effect, impacting safety and effectiveness and is therefore a new intended use."

The device labeling, i.e., Instructions for Use, for both these premarket notifications did not indicate the use of the device for hypothermia treatment. Additional information provided with the submission was what gave the association with hypothermia treatment as the intended use.

Based on the precedent decisions made on the PMT premarket notifications, the existing IDE for this device for hypothermia treatment, and no known use for monitoring brain temperature over core body temperature it is my recommendation that this premarket notification for both pressure and temperature monitoring kits be found **not substantially equivalent** based on the fact that the implied indication of hypothermia treatment alters the intended therapeutic and diagnostic effect, impacting safety and effectiveness and is therefore a new intended use.

Janine M. Morris, Mechanical Engineer
Division of Cardiovascular, Respiratory,
and Neurological Devices



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 15 1995

Mr. Greg Holland
Consultant to
Camino NeuroCare, Inc.
5955 Pacific Center Boulevard
San Diego, California 92121

Re: K954141
Camino NeuroCare,™ Inc. MPM-1, Multi-Parameter
Monitor
Regulatory Class: III
Dated: August 31, 1995
Received: September 1, 1995

Dear Mr. Holland:

We have reviewed your Section 510(k) notification of intent to market the device referenced above. We have determined the device is not substantially equivalent to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to any device which has been reclassified into class I (General Controls) or class II (Special Controls). This decision is based on the fact that your indication of measuring intracranial temperature which implies its use with hypothermia therapy alters the intended therapeutic effect, impacting safety and effectiveness and is therefore a new intended use.

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

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

Any commercial distribution of this device prior to approval of a PMA, or the effective date of any order by the Food and Drug Administration re-classifying this device into class I or II, would be a violation of the Act. Clinical investigations of this device must be conducted in accordance with the investigational device exemptions (IDE) regulations.

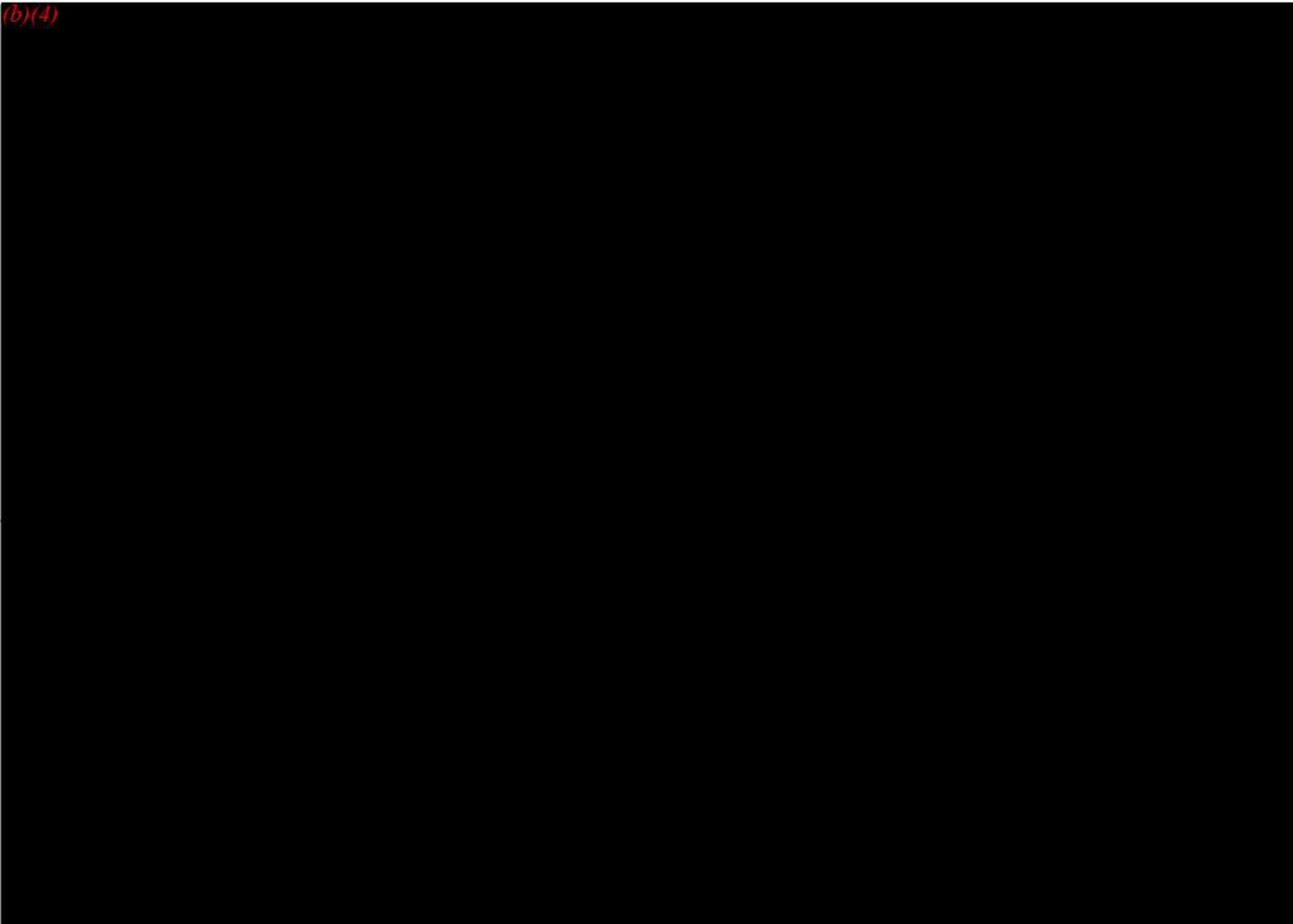
If you wish to pursue the marketing of this device and need information or assistance for preparing PMA, IDE, or

Page 3 - Mr. Greg Holland

Prepared By: JMorris:mlg:11/27/95

cc: HFZ-401
HFZ-404 510(K) Staff
HFZ-450 Division
HFZ-300
D.O.

Reasons for Not Substantially Equivalent Decisions



FILE
COPY

OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE
2450	MORRIS	11/27	404	Rowe	11/15			
2450	GRANT	11/28						
400	Callan	11/28						

U.S. GPO 1906-169-089

4

**510k REVIEW
SUPPLEMENTAL SUMMARY SHEET**

510K NUMBER: K954141
MANUFACTURER: Camino NeuroCare™ Inc.
DEVICE NAME: Multi-Parameter Monitor, MPM-1

SUMMARY:

Device Description and Intended Use

This premarket notification represents a modification to the firm's current ICP monitor. The modification involves accomodating multiple parameters in addition to intracranial pressure. The firm intends to expand this capability in the future but this current model is intended to measure intracranial temperature (ICT) as well as intracranial pressure (ICP) and calculate cerebral perfusion pressure (CPP).

A few months prior to this submission Camino NeuroCare™ submitted a premarket notification for their Micro-Ventricular Pressure-Temperature Monitoring Kit and Parenchymal Pressure-Temperature Monitoring Kit (K953679). This file was found **not substantially equivalent** based on their implied intended use with hypothermia therapy which alters the therapeutic/diagnostic effect, impacting the safety and effectiveness, and is therefore a new intended use. This device was modified to accomodate the devices described in the former 510k (K953679) and seems to have no other function other than used with the monitoring catheters provided with the kits under K953679.

It is my recommendation that this device be found **not substantially equivalent** based on the the same reasons (b)(4)

(b)(4)

Janine M. Morris, Mechanical Engineer
Division of Cardiovascular, Respiratory,
and Neurological Devices

DCRND Screening Checklist for Premarket Notification 510(k)

Device: <u>Micro-Ventricular Bolt Pressure-Temp. Monit. Kit (110-4HMT) + Intracranial Pres.-Temp. Monit. Kit K962928</u>			
Submitter: <u>Camino Neurocare</u>			
Items which should be Included <i>(circle missing & needed information)</i>	Yes	No	✓ if Item Needed & MISSING
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), i) Truth and Accuracy Statement, j) Indications for Use Statement (separate page)	✓		
2. SMDA requirements: 510(k) summary or statement (any Class device)	✓		
Class III Certification & Summary (if Class III)	N/A		
3. Proposed Labeling: a) package labels, b) statement of intended use, c) <u>advertisements or promotional materials</u> , d) MRI compatibility (if claimed)	✓		
4. Description of device (or modification) including <u>diagrams</u> , engineering drawings, <u>photographs</u> , 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, <u>performance</u> (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, <u>N/A</u> e) ETO residues, f) radiation dose	✓		
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. Circled items and items with checks in the "Needed & MISSING" column must be submitted before acceptance of the document.

Screening: Yes No Reviewer: Senora Smallwood Date: 7/31/96

For DCRND Use Only

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

Device: <i>Macro-Ventricular Bolt Press-Temp Mont Kit (110-4HMT) Intracranial Press-Temp Mont, kit K962928</i>		
Submitter: <i>Camino Neurocare</i>		
Date received: Original 510(k): <i>29 Jul-96</i> This submission: <i>29 Jul-96</i>	Review cycle 1	
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?	X	
B. Is the device exempt from 510(k) by regulation or policy?		X
C. Expedited Review Status: Requested by sponsor		X
Identified by DCRND		X
Granted by DCRND		
D. Has this device has been the subject of a previous NSE decision?		
If yes, does this new 510(k) address the NSE Issues(s), e.g., performance data?		
E. Has the sponsor been the subject of an integrity investigation?		
If yes, has the ODE Integrity Officer given permission to proceed with the review?		

Administrative Reviewer Signature: *Senora Smallwood* Date: *7/31/96*

REVISED: 01/22/96

PREMARKET NOTIFICATION (510(K)) CHECKLIST FOR ACCEPTANCE DECISION

Device Name _____

Division/Branch _____

Administrative Reviewer Signature _____ Date _____

Supervisory Signature _____ Date _____

Did the firm request expedited review? _____ Yes _____ No

Did we grant expedited review? _____ Yes _____ No

Truthful and accurate statement enclosed? _____ Yes _____ No

(If Not Enclosed, Must Be A Refuse To Accept Letter)

Required For Originals Received 3/14/95 And After

Is the Indication for Use Form enclosed? _____ YES _____ No

(Required for Original 510(k)s received 1/1/96 and after --

must be submitted on a separate sheet of paper)

Without reviewing this 510(k), do you believe this device type may be a preamendments class III device? _____ Yes _____ No (IF YES, NOTIFY POS IMMEDIATELY IF THE OUTSIDE OF THE 510(k) HAS NOT BEEN STAMPED CLASS III SO THAT THE GMP INSPECTION CAN BE SCHEDULED AS SOON AS POSSIBLE). Class III devices can not receive a determination of substantial equivalence until the GMP inspection process has been completed.

this a file that was determined to be substantially equivalent by ODE, but placed on hold due to GMP violations and deleted after 12 months on hold? -- If so, a new ODE review is not required, please forward to POS.

_____ Yes _____ No

Accepted

Refuse To
Accept

I. CRITICAL ELEMENTS:	YES PRESENT OMISSION JUSTIFIED	NO INADEQUATE OMITTED
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"/>	<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"/>	<input type="checkbox"/> <input type="checkbox"/>
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?:	<input type="checkbox"/>	<input type="checkbox"/>
1. Device Trade Or Proprietary Name	<input type="checkbox"/>	<input type="checkbox"/>
2. Device Common Or Usual Name Or Classification Name	<input type="checkbox"/>	<input type="checkbox"/>
3. Establishment Registration Number (Only Applies If Establishment Is Registered)	<input type="checkbox"/>	<input type="checkbox"/>
4. Class Into Which The Device Is Classified Under (21 CFR Parts 862 to 892)	<input type="checkbox"/>	<input type="checkbox"/>
5. Classification Panel	<input type="checkbox"/>	<input type="checkbox"/>
6. Action Taken To Comply With Section 514 Of The Act	<input type="checkbox"/>	<input type="checkbox"/>
7. Proposed Labels, Labeling And Advertisements (If Available) That Describe The Device, Its Intended Use, And Directions For Use (Blue Book Memo #G91-1)	<input type="checkbox"/>	<input type="checkbox"/>

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"/>
15. Truthful And Accurate Statement	<input type="checkbox"/>	<input type="checkbox"/>
II. Additional Information That <u>Is</u> Necessary Under 21 CFR 807.87(h):	<input type="checkbox"/>	<input type="checkbox"/>
A. Submitter's Name And Address	<input type="checkbox"/>	<input type="checkbox"/>
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 <u>May Be</u> Necessary Under 21 CFR 807.87(h):	<input type="checkbox"/>	<input type="checkbox"/>
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	<input type="checkbox"/>	<input type="checkbox"/>
MARKETED DEVICE:	<input type="checkbox"/>	<input type="checkbox"/>
Bench Testing	<input type="checkbox"/>	<input type="checkbox"/>
Animal Testing	<input type="checkbox"/>	<input type="checkbox"/>
Clinical Data	<input type="checkbox"/>	<input type="checkbox"/>
NEW DEVICE:	<input type="checkbox"/>	<input type="checkbox"/>
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)?	<input type="checkbox"/>	<input type="checkbox"/>
If Yes, Continue Review With Checklist From Any Appropriate Guidance Documents.	<input type="checkbox"/>	<input type="checkbox"/>
If No, Is 510(k) Sufficiently Complete To Allow Substantive Review?	<input type="checkbox"/>	<input type="checkbox"/>
I. Other (Specify)	<input type="checkbox"/>	<input type="checkbox"/>

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

July 29, 1996

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

CAMINO NEUROGARE
 5955 PACIFIC CENTER BLVD.
 SAN DIEGO, CA 92121
 ATTN: DONNA L. FREE

510(k) Number: K962928
 Received: 29-JUL-96
 Product: COMBINED
 INTRACRANIAL
 PRESSURE-TEMPERATURE
 SENSING 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. YOU MAY NOT PLACE THIS DEVICE INTO COMMERCIAL DISTRIBUTION UNTIL YOU RECEIVE A LETTER FROM FDA ALLOWING YOU TO DO SO.

On January 1, 1996, FDA began requiring that all 510(k) submitters provide on a separate page and clearly marked "Indication For Use" the indication for use of their device. If you have not included this information on a separate page in your submission, please complete the attached and amend your 510(k) as soon as possible. Also if you have not included your 510(k) Summary or 510(k) Statement, or your Truthful and Accurate Statement, please do so as soon as possible. There may be other regulations or requirements affecting your device such as Postmarket Surveillance (Section 522 (a) (1) of the Act) and the Device Tracking regulation (21 CFR Part 821). Please contact the Division of Small Manufacturers Assistance at the number below for more information.

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. Any telefaxed material must be followed by a hard copy to the Document Mail Center (HFZ-401).

If you have procedural or policy questions, or want information on how to check on the status of your submission (after 90 days from the receipt date), please contact the Division of Small Manufacturers Assistance at (301) 443-6597 or their toll-free number (800) 638-2041, or call me at (301) 594-1190.

Sincerely yours,

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

K962928



camino
NeuroCare™, Inc.
Saba Medical Group, L.P.

RECEIVED

29 Jul 96 09 32

FDA/CDRH/OCE/DMC

July 26, 1996

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

Subject: Premarket Notification

Camino NeuroCare™, Inc. Intracranial Pressure-Temperature Monitoring Catheter
(Models: 110-4BT and 110-4HMT) and
Camino NeuroCare™, Inc. Multi-Parameter Monitor (Model: MPM)

Attention: Document Mail Clerk

Camino NeuroCare™, Inc. (Camino) is submitting this Premarket Notification pursuant to section 510(k) of the Federal Food, Drug and Cosmetic Act and 21 CFR 807.87. This premarket notification comprises Camino NeuroCare's Combined Intracranial Pressure-Temperature Sensing System (ICP/T), which includes disposable pressure-temperature sensing catheters and a multi-parameter monitor.

Camino's ICP/T probes are a modification of the company's existing intracranial pressure probes (b)(4) [redacted]. The predicate probes were cleared for marketing via K853864C and K914735. The ICP/T will be offered as "a diagnostic tool for rapidly determining and continuously monitoring intracranial pressure and temperature," and it will be indicated for use by physicians whenever they view direct measurement of intracranial pressure and temperature as being parameters that are clinically important, see labeling in Tab 4. The company intends the ICP/T probe to be a general purpose device to provide physicians with direct measurements of the brain pressure and temperature in use situations similar to those of Camino's existing general purpose intracranial pressure monitors.

Camino submitted previous separate premarket notifications for the ICP/T catheters (K953679) and MPM monitor (K954141) on August 4, 1995 and August 31, 1995 respectively. FDA responded by letters dated November 20, 1995 and December 15, 1995 respectively, stating that, in the agency's view, the Intracranial Pressure-Temperature Monitoring devices were not substantially equivalent to predicate devices. Camino believes the ICP/T system, labeled as proposed, is substantially equivalent to predicate temperature and intracranial pressure monitoring systems because the intended use of determining and monitoring intracranial temperature does not alter the intended diagnostic effect of predicate devices in determining the temperature of tissue. The technology does not raise questions of safety or effectiveness that are different from those raised by predicate devices.

The issues were discussed with FDA subsequent to November 20, 1995, and the agency recommended that Camino perform animal testing to provide data that the new device accurately measures temperature compared to a known legally marketed device. Camino's letter to the agency memorializing the discussions is attached. The animal testing now has been completed and it is included in this premarket notification in Appendix A. The premarket notification also contains bench testing data to demonstrate equivalence to the predicate devices.

604

5955 Pacific Center Blvd., San Diego, CA 92121 U.S.A.
Telephone: (619) 455-1115 Facsimile: (619) 455-8298

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

NE
TL

Included in this submission is information regarding the Multi-Parameter Monitor, Model MPM. The name "Genesis" is also used in this submission, particularly in reports. Genesis is the name used for the MPM device during the developmental phase. Also please note that Camino NeuroCare is formerly Camino Laboratories.

Since our original submission of the ICP/T devices was almost one year ago, and we are submitting additional testing requested by FDA in this new premarket notification, we would greatly appreciate an expedited review of this submission. Should you require additional information, please contact me at 619-455-1115.

Sincerely,



Donna L. Free
Director, Regulatory and Clinical Affairs



Camino
NeuroCare™, Inc.
Saba Medical Group, L.P.

RECEIVED

29 Jun 96 09 32

FDA/CDRH/OCE/DMC

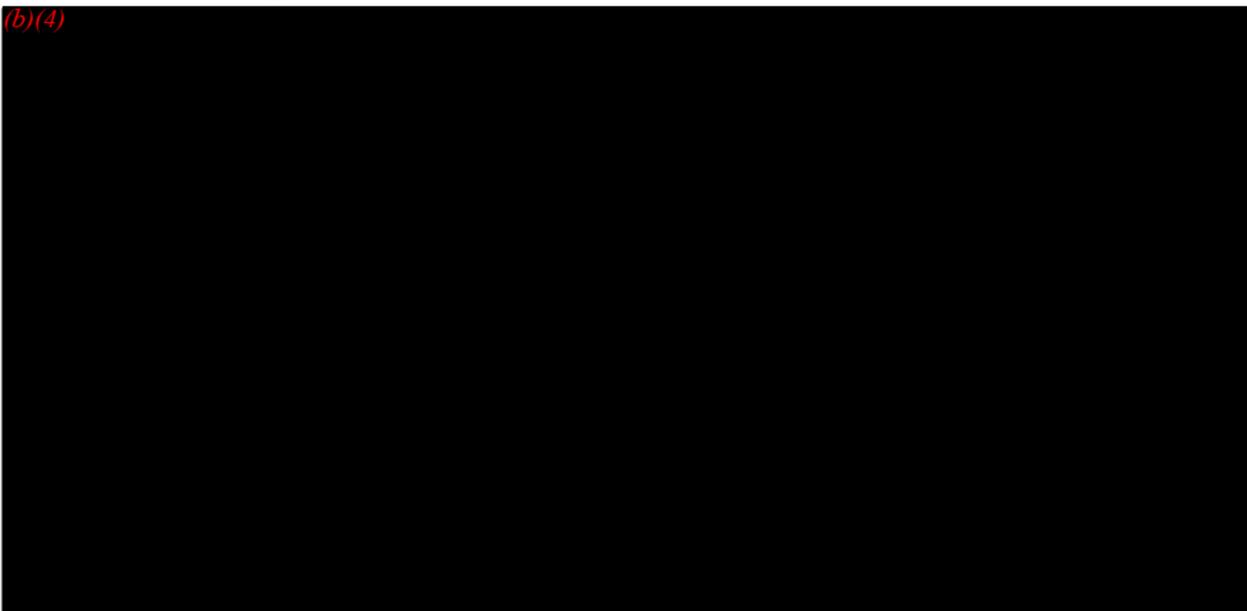
February 13, 1996

Thomas J. Callahan, Ph.D.
Acting Director
Division of Cardiovascular, Respiratory and Neurological Devices
Office of Device Evaluation
Department of Health & Human Services
Food and Drug Administration
9200 Corporate Boulevard
Rockville, MD 20850

Re: Intracranial Pressure - Temperature Monitoring Catheter (ICP/T) device
included in kit model numbers 110-4 BT and 110-4 HMT
and
Camino NeuroCare,™ Inc. MPM-1, Multi-Parameter Monitor

Dear Dr. Callahan:

Thank you very much for taking the time to talk to us regarding the two
above referenced product's 510(k) submissions. This is to summarize the plan
of action we agreed upon in the telephone conference call.



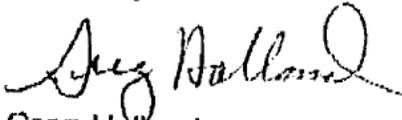
5955 Pacific Center Blvd., San Diego, CA 92121 U.S.A.
Telephone: (619) 455-1115 Facsimile: (619) 455-8298

608

(b) (6)
- 2 -

As expressed, the addition of temperature monitoring to the current system could be of significant benefit to the medical community. Accordingly, we would appreciate an expedited review for the 510(k) notifications, as the devices they describe will have specific public health benefits.

Sincerely,



Greg Holland
Consultant to Camino NeuroCare,™ Inc.

cc: Guy L. Clifton, M.D. (University of Texas, Houston)
Janine Morris (FDA)
Donna Free (Camino)
Steve Lawrence (Hogan & Hartson)

TABLE OF CONTENTS

TAB	SECTION	PAGE
1	Cover Sheet	
2	General Information	1
	Device Name	2
	Establishment Registration Number	2
	Classification	2
	Reason For Premarket Notification	3
	Equivalent Legally Marketed Device	4
	Performance Standards	4
3	Summary & Certification	5
	510(k) Summary	6
	Premarket Notification	10
	Indications for Use	11
4	Labeling	13
	Proposed Instructions for Use - Model 110-4HMT	15
	Proposed Instructions for Use - Model 110-4BT	19
	Proposed Instructions for Use - Multi Parameter Monitor	23
	Predicate Instructions for Use - Camino 110-4HM	37
	Predicate Instructions for Use - Camino 070	43
	Predicate Instructions for Use - Electromedics Probe	47
	Predicate Instructions for Use - Camino V420 Monitor	55
	Predicate Instructions for Use - SpaceLabs, PC Bedside Patient Monitor (90302/90303)	62
5	Device Description	105
6	Comparative Information	112
7	Biocompatibility Assessment	119
8	Sterilization Information	122
9	Software Validation and Verification	124
	Hazard Analysis	127
	Requirements Specification	150
	Software Development	183
	Verification and Verification	196
	Executive Summary	262
	Certification	272
10	Specific Standards and Guidance	274
11	Attachments	276
	Attachment A - Animal Study	277
	Attachment B - Biocompatibility Data	318
	Attachment C - Temperature Stabilization & Accuracy	366

Premarket Notification - Camino NeuroCare™

TAB 1

PREMARKET SUBMISSION COVER SHEET

CENTER FOR DEVICES AND RADIOLOGICAL HEALTH			
Premarket Submission Cover Sheet			
Date of Submission: July 19, 1996		FDA Document Number:	
SECTION A		Type of Submission	
<input checked="" type="checkbox"/> 510(k)	<input type="checkbox"/> IDE	<input type="checkbox"/> PMA	<input type="checkbox"/> PMA Amendment
<input type="checkbox"/> 510(k) Add'l Information	<input type="checkbox"/> IDE Amendment	<input type="checkbox"/> PMA Amendment	<input type="checkbox"/> PMA Amendment
	<input type="checkbox"/> IDE Supplement	<input type="checkbox"/> PMA Report	<input type="checkbox"/> PMA Amendment
	<input type="checkbox"/> IDE Report		<input type="checkbox"/> PMA Amendment
SECTION B1		Reason for Submission - 510(k)s Only	
<input checked="" type="checkbox"/> New Device	<input type="checkbox"/> Additional or expanded indications	<input type="checkbox"/> Change in technology, design, materials or manufacturing process	
SECTION B2		Reason for Submission - PMAs Only	
<input type="checkbox"/> New Device	<input type="checkbox"/> Change in design, component or specifications	<input type="checkbox"/> Location Change	
<input type="checkbox"/> Withdrawal	<input type="checkbox"/> Software	<input type="checkbox"/> Manufacturer	
<input type="checkbox"/> Add'l or expanded indications	<input type="checkbox"/> Color Additive	<input type="checkbox"/> Sterilizer	
<input type="checkbox"/> Licensing agreement	<input type="checkbox"/> Other (specify below)	<input type="checkbox"/> Packager	
<input type="checkbox"/> Labeling change:	<input type="checkbox"/> Process change	<input type="checkbox"/> Report submission:	
<input type="checkbox"/> Indications	<input type="checkbox"/> Manufacturer	<input type="checkbox"/> Annual or periodic	
<input type="checkbox"/> Instructions	<input type="checkbox"/> Sterilizer	<input type="checkbox"/> Post-approval	
<input type="checkbox"/> Performance Characteristics	<input type="checkbox"/> Packager	<input type="checkbox"/> Adverse Reaction	
<input type="checkbox"/> Shelf Life		<input type="checkbox"/> Device Defect	
<input type="checkbox"/> Trade Name		<input type="checkbox"/> Amendment	
<input type="checkbox"/> Other (specify below)	<input type="checkbox"/> Response to FDA correspondence (specify)		
	<input type="checkbox"/> Request for applicant hold		
	<input type="checkbox"/> Request for removal of applicant hold		
<input type="checkbox"/> Change in ownership	<input type="checkbox"/> Request for extension		
<input type="checkbox"/> Change in correspondent	<input type="checkbox"/> Request to remove or add manufacturing site		
<input type="checkbox"/> Other (specify):			
SECTION B3		Reason for Submission - IDEs Only	
<input type="checkbox"/> New Device	<input type="checkbox"/> Change in:	<input type="checkbox"/> Response to FDA letter concerning:	
<input type="checkbox"/> Addition of institution	<input type="checkbox"/> Correspondent	<input type="checkbox"/> Conditional approval	
<input type="checkbox"/> Expansion/extension of study	<input type="checkbox"/> Design	<input type="checkbox"/> Deemed approved	
<input type="checkbox"/> IRB certification	<input type="checkbox"/> Informed Consent	<input type="checkbox"/> Deficient final report	
<input type="checkbox"/> Request hearing	<input type="checkbox"/> Manufacturer	<input type="checkbox"/> Deficient progress report	
<input type="checkbox"/> Request waiver	<input type="checkbox"/> Manufacturing	<input type="checkbox"/> Deficient investigator report	
<input type="checkbox"/> Termination of study	<input type="checkbox"/> Protocol -feasibility	<input type="checkbox"/> Disapproval	
<input type="checkbox"/> Withdrawal of application	<input type="checkbox"/> Protocol -other	<input type="checkbox"/> Request extension of time to respond to FDA	
<input type="checkbox"/> Unanticipated adverse effect	<input type="checkbox"/> Sponsor	<input type="checkbox"/> Request meeting	
<input type="checkbox"/> Emergency use:	<input type="checkbox"/> Report submission:	<input type="checkbox"/> IOL submission only:	
<input type="checkbox"/> Notification of emergency use	<input type="checkbox"/> Current investigator	<input type="checkbox"/> Change in IOL style	
<input type="checkbox"/> Additional information	<input type="checkbox"/> Annual progress	<input type="checkbox"/> Request for protocol waiver	
	<input type="checkbox"/> Site waiver		
	<input type="checkbox"/> Final		
<input type="checkbox"/> Other reason (specify):			

FDA Document Number:			
SECTION C Product Classification			
Product Code:	GWM	CFR Section:	21 CFR 882.1620 Device Class:
Classification Panel:	84	<input type="checkbox"/> Class I	<input checked="" type="checkbox"/> Class II
		<input type="checkbox"/> Class III	<input type="checkbox"/> Unclassified
SECTION D Information on 510(k) Submission			
Product Codes of devices to which substantial equivalence is claimed:			Summary of, or statment concerning safety and effectiveness data:
1	2	3	4
5	6	7	8
			<input type="checkbox"/> 510(k) summary attached
			<input checked="" type="checkbox"/> 510(k) statement
Information on devices to which substantial equivalence is claimed:			
510(k) Number	Trade or proprietary or model name		Manufacturer
1 K853864C	1	Model 070	1 Camino Laboratories
2 K914735	2	Model 110-4HM	2 Camino Laboratories
3 K813459A	3	Model 2403	3 Electomedics
4 K893232	4	Model V420	4 Camino Laboratories
5 K842616	5	Model Alpha PC Patient Bedside Monitor	5 SpaceLabs
6	6		6
SECTION E Product Information - Applicable to All Applications			
Common or usual name or classification name:			
Intracranial Pressure Monitoring Device			
	Trade or proprietary or model name		Model Number
1	Micro-Ventricular Pressure-Temperature Monitoring Kit		1 110-4HMT
2	Parenchymal Pressure-Temperature Monitoring Kit		2 110-4BT
3	Multi-Parameter Monitor		3 MPM
4			4
5			5
6			6
FDA document numbers of all prior related submissions (regardless of outcome):			
1 K953679	2 K954141	3	4
7	8	9	10
			11
			12
Data included in submission:	<input checked="" type="checkbox"/> Laboratory testing	<input checked="" type="checkbox"/> Animal trials	<input type="checkbox"/> Human trials
Indications (from labeling):			
Patients with severe head injury,			
Continuous monitoring of intracranial pressure and temperature - Model 110-4BT			
Continuous monitoring of intracranial pressure and temperature with drainage of CSF - Model 110-4HMT			

2

7/

FDA Document Number:			
SECTION F Manufacturing/Packaging/Sterilization Sites			
<input checked="" type="checkbox"/> Original FDA establishment registration number:		<input checked="" type="checkbox"/> Manufacturer <input type="checkbox"/> Contract sterilizer	
<input type="checkbox"/> Add <input type="checkbox"/> Delete 2023988		<input type="checkbox"/> Contract Manufacturer <input type="checkbox"/> Repackager/relabeler	
Company/Institution name: Camino NeuroCare™ Inc.			
Division name (if applicable): Not Applicable		Phone number (including area code): 619-455-1115	
Street address: 5955 Pacific Center Blvd		FAX number (including area code): 619-455-8298	
City: San Diego	State/Province: California	Country: USA	ZIP/Postal Code: 92121
Contact name: Donna L. Free			
Contact title: Director, Regulatory and Clinical Affairs			
<input type="checkbox"/> Original FDA establishment registration number:		<input type="checkbox"/> Manufacturer <input type="checkbox"/> Contract sterilizer	
<input type="checkbox"/> Add <input type="checkbox"/> Delete		<input type="checkbox"/> Contract Manufacturer <input type="checkbox"/> Repackager/relabeler	
Company/Institution name:			
Division name (if applicable):		Phone number (including area code):	
Street address:		FAX number (including area code):	
City:	State/Province:	Country:	ZIP/Postal Code:
Contact name:			
Contact title:			
<input type="checkbox"/> Original FDA establishment registration number:		<input type="checkbox"/> Manufacturer <input type="checkbox"/> Contract sterilizer	
<input type="checkbox"/> Add <input type="checkbox"/> Delete		<input type="checkbox"/> Contract Manufacturer <input type="checkbox"/> Repackager/relabeler	
Company/Institution name:			
Division name (if applicable):		Phone number (including area code):	
Street address:		FAX number (including area code):	
City:	State/Province:	Country:	ZIP/Postal Code:
Contact name:			
Contact title:			

FDA Document Number:			
SECTION G		Applicant or Sponsor	
Company/Institution name: Camino NeuroCare™ Inc		FDA establishment registration number: 2023988	
Division name (if applicable): Not Applicable		Phone number (including area code): 619-455-1115	
Street address: 5955 Pacific Center Blvd.		FAX number (including area code): 619-455-8298	
City: San Diego	State/Province: California	Country: USA	ZIP/Postal Code: 92121
Signature:			
Name: Donna L. Free			
Title: Director, Regulatory and Clinical Affairs			
SECTION H		Submission correspondent (if different from above)	
Company/Institution name:			
Division name (if applicable): Not Applicable		Phone number (including area code):	
Street address:		FAX number (including area code):	
City:	State/Province:	Country:	ZIP/Postal Code:
Contact Name:			
Contact Title:			

72

Premarket Notification - Camino NeuroCare™

TAB 2

GENERAL INFORMATION

000001

Premarket Notification - Camino NeuroCare™

REASON FOR PREMARKET NOTIFICATION:

This premarket notification represents a modification to existing legally marketed and manufactured products by Camino NeuroCare™ Inc. The products involved comprise a system including a single use, disposable intracranial catheter and a patient monitor. Two types of catheters, depending on the anatomical site targeted, are being modified in this notification. One catheter is the Intracranial Pressure Monitoring Kit (Model 070), used for parenchymal application and the other is the Ventricular Pressure Monitoring Kit (Model 110-4HM), used for ventricular application. The monitor being modified is the Direct Pressure Monitor (Model V420). The change to these products is the additional capability of measuring temperature to have a combined pressure-temperature measuring capability.

The modification of the catheters is the addition of a temperature sensing device (thermistor) to the tip of the intracranial pressure monitoring catheters. These catheters are used to monitor pressure in the parenchyma or cerebral ventricles. This allows the specialist to measure brain pressure and temperature simultaneously. There is no direct contact with any of the temperature measurement sensors in either model and there is no change in materials from the predicate devices which have direct patient contact.

The Direct Pressure Monitor (Model V420) measures and displays intracranial pressure (ICP). The modification to the monitor is that the newer product, MPM adds the capability of measuring and displaying temperature and calculating and displaying cerebral perfusion pressure (CPP). CPP measurement is based on the calculation of subtracting the ICP from the mean arterial pressure. The mean arterial pressure measurement is transmitted from the bedside patient monitor. The MPM line of products are instruments for monitoring and displaying intracranial pressure and other related neurological parameters, e.g., cerebral perfusion pressure, temperature, cerebral blood flow, oxygen, pH and carbon dioxide. These parameters, and other physiological parameters, are routinely displayed on a stationary bedside patient monitor, e.g., SpaceLabs. The MPM will allow the clinician to have the neurological parameters displayed on a single portable monitor. The version of the MPM product, subject of this submission, will measure intracranial pressure (ICP) and intracranial temperature (ICT) and calculate cerebral perfusion pressure (CPP). These parameters may be displayed on a graphics screen and output for hard copy. The MPM monitor will accept catheters designed for use on the present Camino NeuroCare™, Inc. monitors (Models 420, V420 and M420), as well as the intracranial pressure-temperature catheters (Models 110-4HMT and 110-4BT) subject of this premarket notification. The MPM monitor is also compatible with the existing Camino catheters that only measure pressure, e.g., Model 110-4HM.

Please note that Camino NeuroCare™, Inc. was formerly Camino Laboratories. Included in this submission is information regarding the Multi-Parameter Monitor, Model MPM. The name Genesis is also used in this submission. Genesis is the name used for the MPM device during the development phase.

000003

Premarket Notification - Camino NeuroCare™

EQUIVALENT LEGALLY MARKETED DEVICE

Camino NeuroCare™ Intracranial Pressure-Temperature Monitoring Kit:

Model 110-4BT is equivalent to:

Camino, Intracranial Pressure Monitoring Kit, Model 070,
853864C ✓
Electromedics, Inc., Esophageal, Rectal, Nasopharyngeal Probe,
Model 2403, K813459A. ✓

Model 110-4HMT is equivalent to:

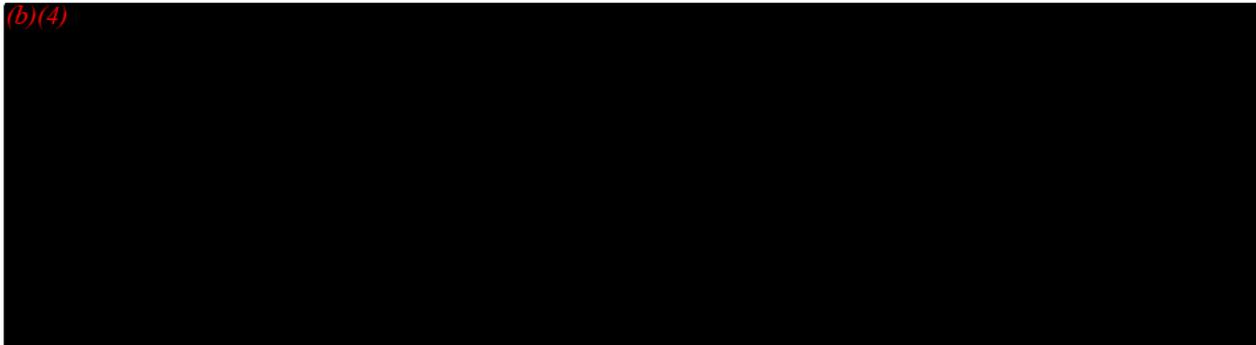
Camino, Micro Ventricular Pressure Monitoring Kit,
Model 110-HM, K914735 ✓
Electromedics, Inc., Esophageal, Rectal, Nasopharyngeal Probe,
Model 2403, K813459A. ✓

Camino NeuroCare™ Multi Parameter Monitor:

Model MPM is equivalent to:

Camino, Direct Pressure Monitor, Model V420, K893232 ✓
SpaceLabs, Patient Monitor, Model Alpha PC Patient Computer,
K842616. ✓

(b)(4)



PERFORMANCE STANDARDS

Not Applicable

000004

Premarket Notification - Camino NeuroCare™

TAB 3

SUMMARY & CERTIFICATION

K9162 2x8

Premarket Notification - Camino NeuroCare™

**PREMARKET NOTIFICATION
510(k) SUMMARY**

1. SUBMITTER:

Camino NeuroCare,™ Inc.
5955 Pacific Center Blvd.
San Diego, CA 92121

Donna L. Free (Contact Person)
Phone: 619-455-1115
Fax: 619-455-8298

2. DEVICE NAME:

- Trade Name:
 - a Micro-Ventricular Pressure-Temperature Monitoring Kit (110-4HMT)
 - Parenchymal Pressure-Temperature Monitoring Kit (110-4BT)
 - b Multi-Parameter Monitor (MPM)
- Common Name:
 - a Intracranial Pressure and Temperature Monitoring Kit
 - b Multi-Parameter Monitor
- Classification Name:
 - a Intracranial Pressure Monitoring System
 - b Intracranial Pressure Monitoring System

3. PREDICATE DEVICE:

Camino NeuroCare™ Intracranial Pressure-Temperature Monitoring Kit:

Model 110-4BT is equivalent to:
Camino, Intracranial Pressure Monitoring Kit, Model 070, 853864C
Electromedics, Inc., Esophageal, Rectal, Nasopharyngeal Probe, Model 2403, K813459A.

Model 110-4HMT is equivalent to:
Camino, Micro Ventricular Pressure Monitoring Kit, Model 110-HM, K914735
Electromedics, Inc., Esophageal, Rectal, Nasopharyngeal Probe, Model 2403, K813459A.

000000

3. PREDICATE DEVICE:

Camino NeuroCare™ Multi Parameter Monitor:

Model MPM is equivalent to:

Camino, Direct Pressure Monitor, Model V420, K893232
SpaceLabs, Patient Monitor, Model Alpha PC Patient Computer,
K842616.

4. DEVICE DESCRIPTION:

The Intracranial Pressure-Temperature Monitoring System consists of a catheter and monitor. The catheter is a sterile transducer-tipped pressure monitoring catheter with thermistor and accessory items to be used as a diagnostic tool for rapidly determining and continuously monitoring intracranial pressure and temperature. The Camino catheter has a miniature transducer and thermistor at the distal tip. The pressure transducer is identical to the Camino predicate device. The design eliminates the need for a "fluid-filled system" to carry pressure waves to an external transducer. The transducer is 4F, fiber optic with a pressure measurement range of -10 to 250 mmHg and a temperature measurement range of 30°C -40°C.

The Multi-Parameter Monitor (MPM) is a compact, portable device for use with Camino Pressure-Temperature catheters. The MPM measures Intracranial Pressure (ICP), Intracranial Temperature (ICT) and calculates Cerebral Perfusion Pressure (CPP). The MPM provides a continuous display of the pressure waveform, as well as mean ICP, CPP, temperature or systolic and diastolic values. A continuous record of mean pressure and temperature values over the most recent 24-hour period is stored in memory, and can be displayed on command as a TREND either as the most recent 8 or 24 hour period. An analog output accessory provides a continuous ICP waveform for hard copy documentation or data acquisition. Although the MPM is intended to be a stand alone system, it also conveniently connects to any hospital bedside monitoring system. A built-in rechargeable battery permits monitoring during patient transport. The monitor is equipped with an high ICP alarm. The dimensions are 274 mm x 216 mm x 89 mm and weighs 4.3 Kg.

5. INTENDED USE:

Model 110-4BT

Use by a qualified neurosurgeon for direct measurement of intracranial pressure and temperature in the parenchyma.

Model 110-4HMT:

Use by a qualified neurosurgeon for direct measurement of intracranial pressure and temperature in the ventricles and cerebrospinal fluid drainage.

000007

Premarket Notification - Camino NeuroCare™

Intended to be used with an external drainage system as indicated by individual manufacturers.

6. SUBSTANTIAL EQUIVALENCE:

Pressure:

The ICP/T catheter and monitor have the same indication statements for monitoring pressure as Camino's predicate devices.

Temperature:

Predicate temperature-sensing devices include the Electromedics, Model 2403, Temperature Probe, K813459A. The predicate probes are used to measure the temperature of a target organ or tissue. Camino's temperature probe has the same use.

Nevertheless, the ICP/T has a difference in the indication statements in regard to temperature. The difference refers to the tissue in which the temperature is taken. For example, the Electromedics predicate catheter is labeled for general temperature use. Other indications include general surgery, cardiovascular surgery, anesthesiology, critical care, newborn care, and neonatal care. The Camino probes have similar labeling in that they are for general uses that may include surgery, critical care, pediatric care and head injured patients. The Electromedics probe is labeled to take a patient's temperature in the esophagus, on the skin surface, in cardioplegia systems and in the myocardium. The Camino pressure-temperature probe is labeled to be used in the brain, with either parenchyma or ventricular placement.

Monitor:

The ICP/T monitor and both predicate monitors display pressure.

The ICP/T monitor and SpaceLabs monitor display temperature.

The ICP/T monitor and SpaceLabs monitor display Cerebral Perfusion Pressure (CPP).

The ICP/T monitor and both predicate monitors display a waveform.

The ICP/T monitor and both predicate monitors display trends.

The ICP/T monitor and both predicate monitors comply with UL Medical Equipment standards.

The ICP/T monitor and the predicate monitors comply with AAMI/ANSI Safe Current Limits standards

7. PERFORMANCE TESTING:

Camino NeuroCare conducted animal studies to support substantial equivalence. We conducted a comparative study of the subject (test) device measuring intracranial temperature compared with a predicate device, located along side the test device, also measuring intracranial temperature over a varied temperature range. The temperature measurements were $\pm 0.4^{\circ}\text{C}$ between the test device and predicate device in the 10 animals tested. These data support the claim of substantial equivalence.

000008

Premarket Notification - Camino NeuroCare™

8. CONCLUSIONS

The contact area of the Camino probe is of the same design, has the same materials, and it is inserted into the body in the same manner as predicate Camino probes. Thus, the questions of safety are the same. The diagnostic effect of temperature probes for general use is to provide temperature information to a physician for whatever use he or she may choose, based on the user's training and experience. The effectiveness of a temperature probe for diagnostic or monitoring use is determined by its ability to deliver an accurate temperature reading. This is the same standard that was used for predicate devices, some of which were cleared for organs and tissues which may have been different from those for which existing predicate devices were cleared.

Based on the above information Camino NeuroCare™ Inc., concludes that the ICP/T Monitoring system demonstrates substantial equivalence to the predicate devices.

Premarket Notification - Camino Neuro



camino
NeuroCare™, Inc.
Saba Medical Group, L.P.

**PREMARKET NOTIFICATION
TRUTHFUL AND ACCURATE STATEMENT**

(As required by 21 CFR 807.87(j))

I certify that, in my capacity as Director, Regulatory and Clinical Affairs of Camino NeuroCare™, Inc., I believe this statement is based on my review of the material in this submission. In reviewing the material, I have relied on the truthfulness and accuracy of the documents presented to me and of the representations of persons who provided me with information. Nothing in this statement is intended to suggest that I have undertaken any independent investigation of the truthfulness or accuracy of those documents or representation or of whether or not they omit any material fact.

Donna L Free

Signature

Donna L. Free

Typed Name

July 26, 1996

Date

BEING APPLIED FOR

PreMarket Notification 510(k) Number

000010

Premarket Notification - Camino NeuroCare™

INDICATIONS FOR USE STATEMENT

Premarket Notification - Camino NeuroCare™

510(k) number (if known): K962928

Device Name: Intracranial Pressure-Temperature Monitoring Device

Indications For Use:

Model 110-4BT:

Use by a qualified neurosurgeon for direct measurement of intracranial pressure and temperature in the parenchyma.

Model 110-4HMT:

Use by a qualified neurosurgeon for direct measurement of intracranial pressure and temperature in the ventricles and cerebrospinal fluid drainage.

Intended to be used with an external drainage system as indicated by individual manufacturers.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K962928

Prescription Use _____
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____

Premarket Notification - Camino NeuroCare™

TAB 4

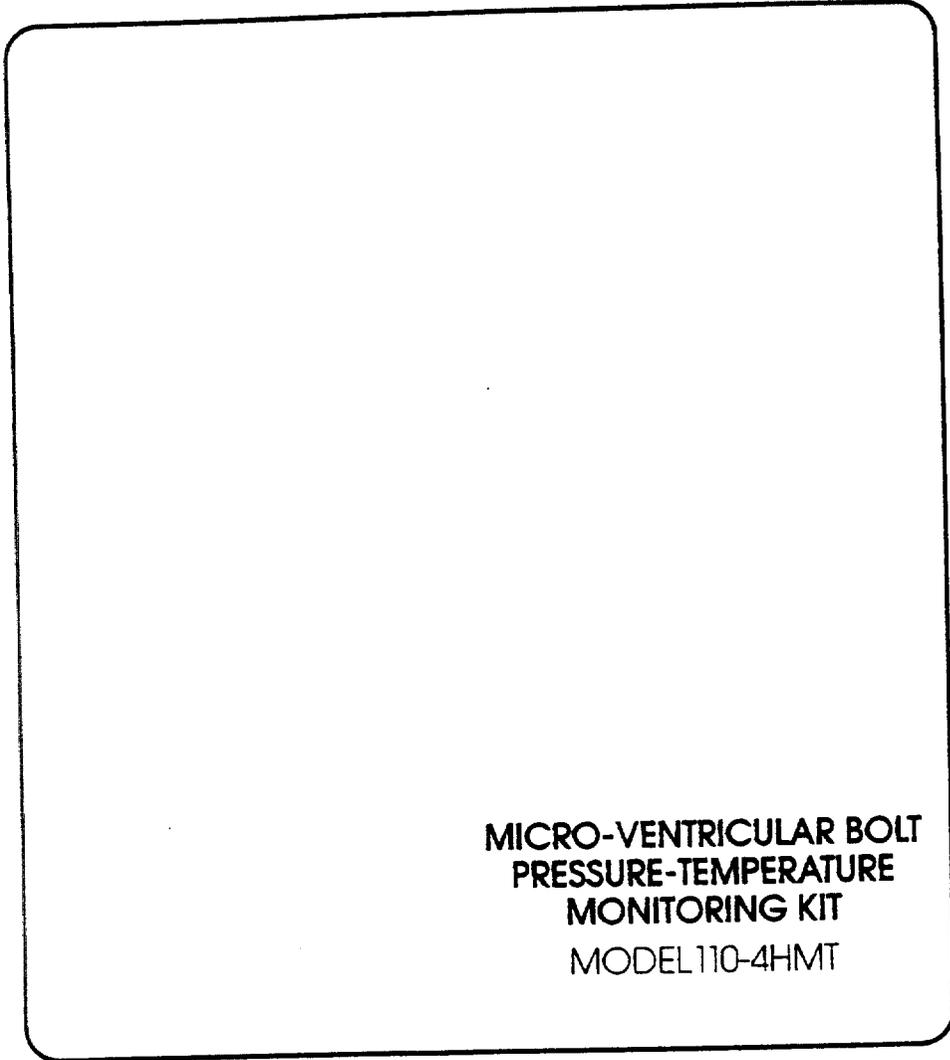
LABELING

000013

Premarket Notification - Camino NeuroCare™

PROPOSED LABELING CATHETER

000014



**MICRO-VENTRICULAR BOLT
PRESSURE-TEMPERATURE
MONITORING KIT
MODEL 110-4HMT**

INSTRUCTIONS FOR USE

Read carefully prior to use



camino
NeuroCare, inc.
Saba Medical Group, L.P.

000015

MICRO-VENTRICULAR BOLT PRESSURE-TEMPERATURE MONITORING KIT

MODEL 110-4HMT

SYSTEM DESCRIPTION

The Camino Micro-Ventricular Pressure-Temperature Monitoring Kit consists of a sterile transducer-tipped pressure monitoring catheter with thermistor and accessory items which provide a means of access to the cerebral ventricles for CSF sampling and drainage, fluid injection and continuously monitoring intracranial pressure and temperature. Since its method of measuring pressure is unique, please read this section carefully.

Unlike ordinary pressure monitoring systems, the Camino Catheter has a miniature transducer and thermistor at the distal tip. This unique design eliminates the need for a "fluid-filled system" to carry pressure waves to an external transducer. Thus, the problems inherent in such fluid-filled systems are eliminated. The result is a precise pressure measurement and an artifact free, high fidelity waveform trace.

The Micro-Ventricular Pressure-Temperature Monitoring Kit contains the following accessory items for use with the Camino Catheter:

- Camino Ventricular Access Device with Ventricular Catheter, Bolt, Female Luer Lock and Stylet,
- Twist Drill Bit with Safety Stop,
- Additional Luer Lock Port to connect drainage system,
- Thermistor Connector Cover

Note: A hand drill and various standard surgical instruments and supplies are required to place the ICP/ICT monitoring system.

A complete set of instruments and supplies is available from Camino NeuroCare as the H-ITH Series Cranial Access Kits or the 110-4HMT Kit.

PRECAUTIONS

- Extreme bending and/or kinks can impair the performance of the Fiber Optic Pressure Transducer. Exercise caution when handling the catheter.
- The catheter is designed for **SINGLE USE ONLY. DO NOT RESTERILIZE OR REUSE.**
- Use aseptic technique throughout procedures.

- Maintain the insertion site with regular meticulous redressing using aseptic technique.
- Do not attach anything to transducer air vent. Vent must remain open for proper operation.

CAUTION

- Federal law (U.S.A.) restricts this device to sale by or on the order of a physician.
- Connect the thermistor connector only to Host Monitors marked "Patient connection electrically isolated", or "BF" or "CF", or marked with the international symbols:



- When connecting the thermistor connector to a Host Monitor, refer to the Host Monitor's operations manual for complete instructions.
- Verify proper operation of the combined Host Monitor-110-4HMT System before clinical use.
- The combined leakage currents of devices interconnected with the 110-4HMT can lead to a potentially hazardous condition. Ensure that the combined system leakage current does not exceed 0.1 mA.

INSTRUCTIONS FOR USE

INSERTION METHOD FOR THE CAMINO MICRO-VENTRICULAR BOLT

- The recommended frontal placement is 3-4 cm off the midline, just anterior to the coronal suture. After the site has been chosen, the area is shaved and prepped in a sterile fashion, usually with a betadine solution. The shaved and prepared area is then draped. The area of the incision is infiltrated subcutaneously with 1% lidocaine. An approximately three centimeter linear incision is made and carried to the bone. A self-retaining retractor is then inserted to provide good bone exposure and hemostasis of the skin edges.

- Adjust the safety stop on the drill bit to the estimated skull thickness and secure firmly with the allen wrench.
- Secure the drill bit to a twist drill and in a standard fashion drill a hole through the outer and inner tables of the skull, taking care to minimize any potential for parenchymal injury. Penetrate the dura under direct vision with a #11 blade, securing hemostasis as necessary.
- Using the stylet, insert the ventricular catheter into the ventricle. When the CSF is obtained, hold the catheter securely, remove the stylet, slide the bolt down and screw in, using bone wax to insure a tight seal. Do not over tighten, as stripping of the threads may cause loss of seal.
- Continue to hold the catheter securely, and turn the compression cap clockwise to lock the catheter in place. Slide the strain relief down and attach to the compression cap. Cap the catheter with Luer cap to prevent CSF loss.

CAMINO PRESSURE-TEMPERATURE MONITORING CATHETER PREPARATION

(prior to insertion into ventricular catheter):

- The Camino Catheter can be used only in conjunction with the Camino 420, M420, V420, or MPM-1 Pressure Monitor. For Camino Monitor set-up and use, refer to the Camino Monitor User Information.
- Remove the Camino Catheter from its sterile package and firmly attach the transducer connector to the pre-amp connector. If the Camino display does not read zero after a short system self-check delay, use the tool from the catheter until the Camino display reads zero.
- Remove cover from the thermistor connector of the Camino Catheter. To interface with host monitor cardiac output module, connect cardiac output monitor cable connector to Camino Thermistor Connector. Verify that a temperature is displayed on the Host Monitor.

INSERTION OF CAMINO CATHETER

- Remove the Luer cap from the ventricular catheter, insert the Camino Transducer-tipped Catheter and secure Luer lock. Holding the ventricular catheter straight will facilitate passage.
- Prepare an external ventricular drainage system according to its manufacturer's directions and attach to the side port of the Y-connector. Note that the CSF may be drained without interrupting pressure/temperature monitoring.

- When monitoring is to be discontinued, detach the strain relief from the compression cap. Loosen compression cap and remove ventricular catheter prior to the removal of the bolt from the skull.

CONTINUOUS PRESSURE AND TEMPERATURE MONITORING

Since the Camino Catheter has a miniaturized transducer at the distal tip, it requires no fluid-filled system. Thus, the need for an external transducer, pressure dome, and pressure tubing is eliminated. As a result, temperature and pressure may be monitored continuously without flushing or re-calibration.

INDICATIONS

The use of the Camino Micro-Ventricular Bolt Pressure-Temperature Monitoring Kit by a qualified neurosurgeon is indicated when direct pressure and temperature measurement and cerebrospinal fluid drainage is clinically important. The Camino Micro-Ventricular Bolt Pressure-Temperature Monitoring Kit is intended to be used with an external drainage system as indicated by individual manufacturers.

CONTRAINDICATIONS

This device is not intended for any use other than that indicated. This device is contraindicated for use in the MRI field.

RISK AND COMPLICATIONS

Maintenance of sterility during placement and subsequent handling of the Camino Micro-Ventricular Bolt Pressure-Temperature Monitoring Kit is essential. Sterile technique should be used at all times when inserting, adjusting, and securing the Camino Catheter.

Infection, subcutaneous leakage of CSF, neurological sequelae, and blockage by intraventricular debris (including bloody and/or highly proteinic CSF) have occurred during the use of ventricular catheters.

Placement of the tip opening within the reach of choroid plexus has resulted in blockage of ventricular catheters.

The ventriculostomy must be carried out by a qualified neurosurgeon using standard surgical procedures and skill. Hemorrhage from the dura or cortical surface at the bolt insertion site may occur. Patients should be tested for normal blood clotting function prior to bolt placement. Appropriate measures to avoid infections and complications are the sole responsibility of the neurosurgeon in charge.

000017

INTERNATIONAL MARKINGS



CATHETER EXTENSION CABLE CONNECTIONS

Symbol also signifies:

TYPE BF EQUIPMENT: Protected against electric shock, having an F-type isolated (floating) applied part.



TYPE CF EQUIPMENT: Provided with a degree of protection against electric shock higher than Type BF equipment, having an F-type isolated (floating) applied part; intended for direct cardiac application.

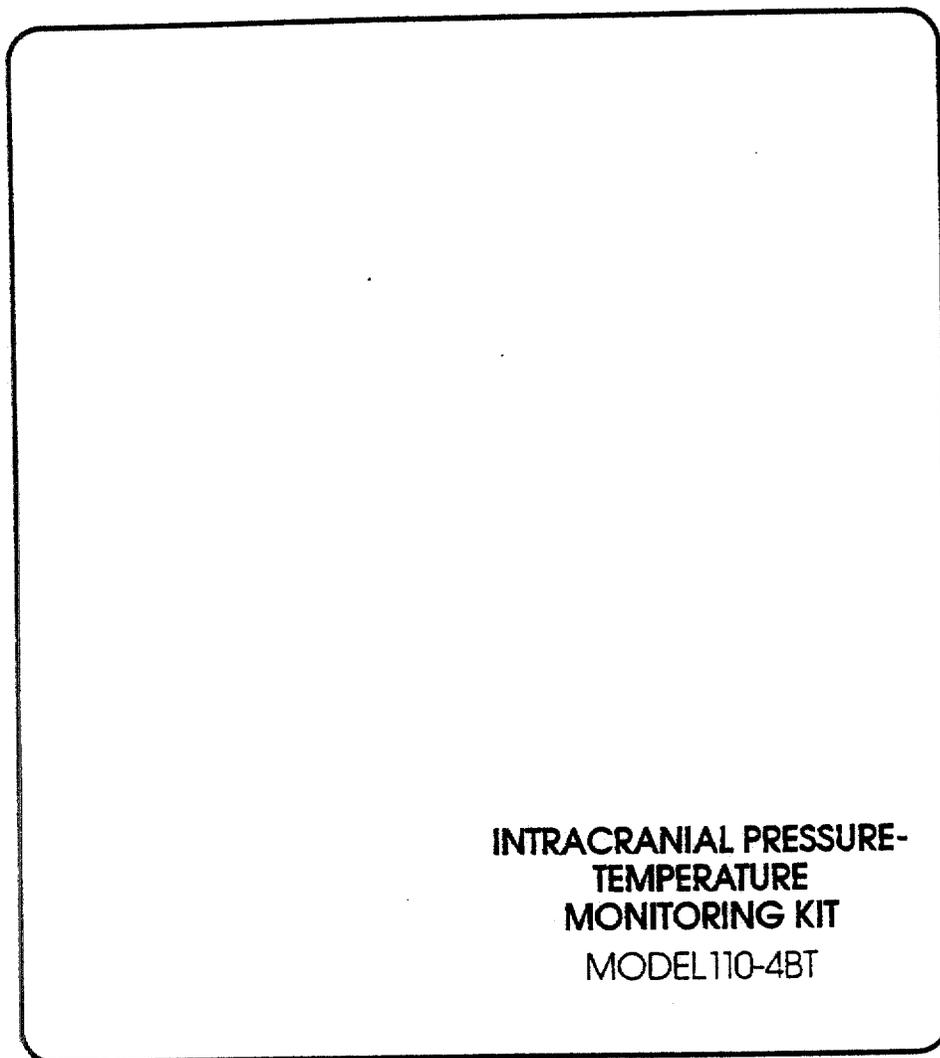
SPECIFICATIONS

Transducer size	4F
Transducer type	Fiber optic
Frequency response (system) Model V420/M420/420XP Model 420	120Hz (-3dB) 33Hz (-3dB)
Measurement range (system)	-10 to +250 mmHg
Zero drift (system) First 24 hours (maximum) 5 days (typical)	0 ± 2 mmHg less than ± 1 mmHg per day
Reference pressure	Atmosphere
Overpressure	-700 to 1250 mmHg
Temperature coefficient	Max of 3 mmHg over temperature range of 22°C to 38°C (70°F-100°F)
Linearity and hysteresis (system) Pressure range: -10 to 50 mmHg 51 to 200 mmHg 201 to 250 mmHg	± 2 mmHg or better ± 6% of reading or better ± 7% of reading or better
Temperature Measurement Temperature Measurement Resolution Temperature Measurement Range Temperature Measurement Accuracy	0.1°C 30°C - 40°C ± 0.3°C (30°C - 40°C)

Manufactured under one or more of:
 U.S.— Patent Nos. 4,446,715; 4,705,047; 4,931,049; 4,903,707; 5,107,847 and Des. 285,112; 283,053;
 EPO — Patent No. 0127476;
 Other U.S. and foreign patents issued and pending.



5855 PACIFIC CENTER BLVD., SAN DIEGO, CALIFORNIA 92121 (619)455-1115 FAX: (619)455-8298
 300864 REV C



**INTRACRANIAL PRESSURE-
TEMPERATURE
MONITORING KIT**
MODEL 110-4BT

INSTRUCTIONS FOR USE

Read carefully prior to use



92

INTRACRANIAL PRESSURE-TEMPERATURE MONITORING KIT

MODEL 110-4BT

SYSTEM DESCRIPTION

The Intracranial Pressure-Temperature Monitoring Kit consists of a sterile transducer-tipped pressure monitoring catheter with thermistor and accessory items to be used as a diagnostic tool for rapidly determining and continuously monitoring intracranial pressure and temperature. Since its method of measuring pressure is unique, please read this section carefully.

Unlike ordinary pressure monitoring systems, the Camino Catheter has a miniature transducer and thermistor at the distal tip. This unique design eliminates the need for a "fluid-filled system" to carry pressure waves to an external transducer. Thus, the problems inherent in such fluid-filled systems are eliminated. The result is a precise pressure measurement and an artifact free, high fidelity waveform trace.

The Intracranial Pressure-Temperature Monitoring Kit contains the following accessory items for use with the Camino Catheter:

- Camino Bolt with Compression Cap and Turning Wings,
- .106 inches (2.71 mm) diameter No. 36 Drill Bit with Safety Stop,
- Spacer to adjust seating depth of the bolt,
- Strain Relief—Protective Sheath,
- .050 inches (1.3 mm) diameter Stylet
- Thermistor Connector Cover

Note: A hand drill and various standard surgical instruments and supplies are required to place the ICP/ICT monitoring system.

A complete set of instruments and supplies is available from Camino NeuroCare as the H-ITH Series Cranial Access Kit, or the 110-4BTC Kit.

PRECAUTIONS

- Extreme bending and/or kinks can impair the performance of the Fiber Optic Pressure Transducer. Exercise caution when handling the catheter.
- The catheter is designed for **SINGLE USE ONLY. DO NOT RESTERILIZE OR REUSE.**
- Use aseptic technique throughout procedures.
- Maintain the insertion site with regular meticulous redressing using aseptic technique.
- Do not attach anything to transducer air vent. Vent must remain open for proper operation.

CAUTION

- Federal law (U.S.A.) restricts this device to sale by or on the order of a physician.
- Connect the thermistor connector only to Host Monitors marked "Patient connection electrically isolated", or "BF" or "CF", or marked with the international symbols:



- When connecting the thermistor connector to a Host Monitor, refer to the Host Monitor's operations manual for complete instructions.
- Verify proper operation of the combined Host Monitor-110-4BT System before clinical use.
- The combined leakage currents of devices interconnected with the 110-4BT can lead to a potentially hazardous condition. Ensure that the combined system leakage current does not exceed 0.1 mA.

INSTRUCTIONS FOR USE

INSERTION METHOD FOR THE CAMINO BOLT

- Area of insertion: The standard right and left prefrontal areas are the primary areas of insertion. This region allows the patient to have his head rotated from side to side and still remain in a supine position without interference with the monitoring function. In addition, the incision will be carried behind the hairline in the majority of patients and therefore be cosmetically acceptable.
- After the insertion site has been chosen, the area is shaved and prepped in a sterile fashion, usually with a betadine solution. The shaved and prepared area is then draped with sterile towels. The area of the incision, which usually lies two to three centimeters anterior to the coronal suture in the mid-pupillary line is infiltrated subcutaneously with 1% Lidocaine. An approximately half centimeter linear incision is made and carried to the bone. A small mastoid type of retractor is then inserted to provide a good bone exposure and hemostasis of the skin edges.
- The safety stop on the drill bit provided in the kit can be positioned as desired by loosening the setscrew with the allen wrench, sliding the stop into position, and retightening the setscrew.

000020

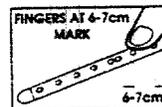
- The drill bit is then secured to a twist drill and in a standard fashion, a twist drill hole is made through the outer and inner tables of the skull. The surgeon needs to be careful when penetrating the inner table to minimize any potential for parenchymal injury.
- After penetration of the inner table, the drill is removed and the hole is irrigated with sterile saline. An 18G spinal needle is then used to open the dura in a cruciate fashion. The stylet can be inserted to ensure adequate opening of the dura.
- Following opening of the dura, the Camino Bolt is screwed manually into the skull. The seating depth of the Camino Bolt will be at the surgeon's discretion pending the thickness of the skull. This will be approximately 2-3 mm for the neonatal age group, 3-5 mm for the pediatric age group and 5 mm to 1 cm for adults. If desired, the spacer can be used as a guide, otherwise the spacer can be removed and discarded.
- The stylet provided in the kit is inserted through the Camino Bolt and the dura to clear the passage for the Camino Transducer-Tipped Catheter.
- The Camino Bolt is irrigated with non-bacteriostatic sterile saline.

CAMINO PRESSURE-TEMPERATURE MONITORING CATHETER PREPARATION PRIOR TO INSERTION:

- The Camino Catheter can be used only in conjunction with the Camino 420, M420, V420, or MPM-1 Pressure Monitor. For Camino Monitor set-up and use, refer to the Camino Monitor User Information.
- Remove the Camino Catheter from its sterile package and firmly attach the transducer connector to the preamp connector. If the Camino display does not read zero after a short system self-check delay, use the tool from the catheter kit to turn the zero adjustment on the bottom side of the transducer connector until the Camino display reads zero.
- Remove cover from the thermistor connector of the Camino Catheter. To interface with host monitor cardiac output module, connect cardiac output monitor cable connector to Camino Thermistor Connector. Verify that a temperature is displayed on the Host Monitor.

INSERTION OF CAMINO CATHETER

- To measure intracranial pressure and temperature, insert the Camino Catheter into the Camino Bolt, using the cm markings on the catheter to gauge insertion depth. The thermistor is placed approximately 1 cm from the tip of the catheter. If the surgeon places his fingers between the



6 and 7 cm marks (double dot at the 5 cm mark), then inserts the catheter until his fingers touch the top of the bolt, the tip of the catheter will be 2 cm beyond the end of the bolt, into the parenchyma. He should pull the catheter back slightly, then turn the compression cap on the Camino Bolt clockwise to secure the catheter in place. If using a Host Monitor and/or V420, verify pressure waveform. If necessary, loosen the compression cap, reposition the Camino Catheter, and retighten the compression cap. While holding the catheter from above, slide the strain relief sheath down and secure it onto the compression cap.

CONTINUOUS PRESSURE AND TEMPERATURE MONITORING

Since the Camino Catheter has a miniaturized transducer at the distal tip, it requires no fluid-filled system. Thus, the need for an external transducer, pressure dome and pressure tubing is eliminated. As a result, pressure and temperature may be monitored continuously without recalibration.

INDICATIONS

The use of the intracranial Pressure-Temperature Monitoring Kit by a qualified neurosurgeon is indicated when direct measurement of intracranial pressure and temperature in the parenchyma is clinically important.

CONTRAINDICATIONS

This device is not intended for any use other than that indicated. This device is contraindicated for use in the MRI field.

RISK AND COMPLICATIONS

Maintenance of sterility during placement and subsequent handling of the Camino Pressure-Temperature Monitoring Kit is essential. Sterile technique should be used at all times when inserting, adjusting and securing the Camino Bolt and the Camino Catheter.

If monitoring is continued for more than 5 days, placement of a new system under sterile conditions is recommended. Placement of the Camino Bolt must be carried out by a qualified neurosurgeon to avoid penetration of the cerebral cortical surface during the drilling process, which requires standard surgical procedure and skill.

Hemorrhage from the dura or cortical surface at the bolt insertion site may occur. Patients should be tested for normal blood clotting function prior to bolt placement. Determination of possible extracerebral, subarachnoid, or intracerebral hemorrhage at the bolt insertion site will be the responsibility solely of the operating neurosurgeon. Appropriate steps and proceedings to control such hemorrhage should be taken when indicated by the neurosurgeon in charge.

000021

INTERNATIONAL MARKINGS



CATHETER EXTENSION CABLE CONNECTIONS

Symbol also signifies:

TYPE BF EQUIPMENT: Protected against electric shock, having an F-type isolated (floating) applied part.



TYPE CF EQUIPMENT: Provided with a degree of protection against electric shock higher than Type BF equipment, having an F-type isolated (floating) applied part; intended for direct cardiac application.

SPECIFICATIONS

Transducer size	4F
Transducer type	Fiber optic
Frequency response (system) Model V420/M420/420XP Model 420	120Hz (-3dB) 33Hz (-3dB)
Measurement range (system)	-10 to +250 mmHg
Zero drift (system) First 24 hours (maximum) 5 days (typical)	0 ± 2 mmHg less than ± 1 mmHg per day
Reference pressure	Atmosphere
Overpressure	-700 to 1250 mmHg
Temperature coefficient	Max of 3 mmHg over temperature range of 22°C to 38°C (70°F-100°F)
Linearity and hysteresis (system) Pressure range: -10 to 50 mmHg 51 to 200 mmHg 201 to 250 mmHg	± 2 mmHg or better ± 5% of reading or better ± 7% of reading or better
Temperature Measurement Temperature Measurement Resolution Temperature Measurement Range Temperature Measurement Accuracy	0.1°C 30°C - 40°C ± 0.3°C (30°C - 40°C)

Manufactured under one or more of:
 U.S. — Patent Nos. 4,446,715; 4,705,047; 4,931,049; 4,903,707; 5,107,847 and Des. 285,112; 283,053;
 EPO — Patent No. 0127476;
 Other U.S. and foreign patents issued and pending.



Camino
 NeuroCare, Inc.

Saba Medical Group, L.P.

5955 PACIFIC CENTER BLVD., SAN DIEGO, CALIFORNIA 92121 (619)455-1115 FAX: (619)455-8298

300863 REV C

000022

Premarket Notification - Camino NeuroCare™

PROPOSED LABELING MONITOR

000023

Camino NeuroCare™, Inc.

MULTI-PARAMETER MONITOR WITH WAVEFORM DISPLAY

Model MPM-1

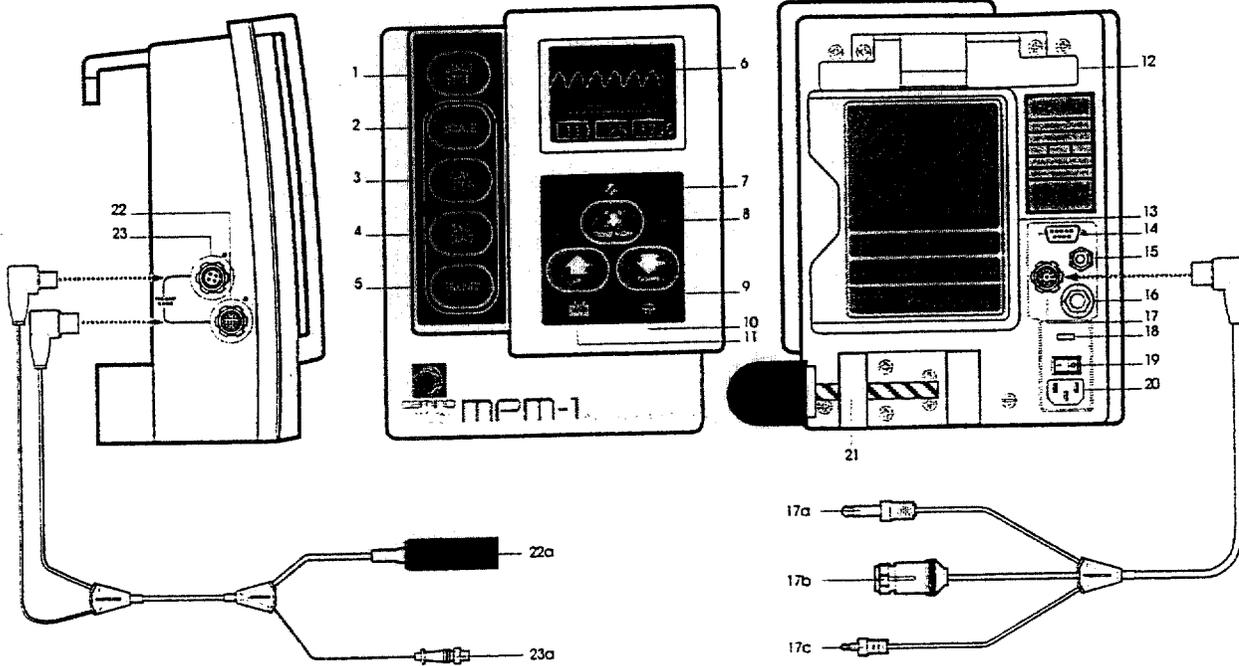
INSTRUCTIONS FOR USE

000024

FIGURE 3

FIGURE 1

FIGURE 2



FRONT PANEL (See Figure 1)

1. **START/STOP** - Press to turn MPM-1 on or off.
2. **SCALE** - Press to change scale of pressure waveform on MPM-1 Display. Each press of **SCALE** button advances to the next mmHg range in the following series: 10, 20, 50, 100, 200 and back to 0.
3. **CAL STEP** - Used to calibrate or check correlation of external bedside monitor. Press and hold to momentarily interrupt normal pressure display and substitute an artificially-generated pressure signal, which will appear on both the MPM-1 Display and on the external bedside monitor. Each press advances to the next mmHg value in the following series: 0, 20, 40, 100, 200 and back to 0.
4. **SYS/DIAS** - Press to toggle between the CPP-ICP-TEMP display and the SYSTOLIC-ICP-DIASTOLIC display
5. **TREND** - Press to graphically display the last 8 hours of ICP pressure values on the MPM-1 Display. Press again to display the last 24 hours of ICP pressure values. Press again to return to the pressure display.
6. **MPM-1 Display** - Displays ICP pressure waveform, cerebral perfusion pressure (CPP), mean intracranial pressure (ICP), intracranial temperature (ICT), systolic and diastolic values, trend data, and various "Help" messages.
7. **ALARMS DISABLED Indicator** - Illuminates whenever the ICP alarm limit is set to OFF.
8. **SILENCE ALARM** - Press to silence the alarm sound for 3 minutes.
9. **UP and DOWN** - Press the **UP** or **DOWN** button(s) to set the desired ICP alarm limit value. Press the **DOWN** button until OFF is displayed to disable the ICP alarm limit function.
10. **AC Power Indicator** - Illuminates when MPM-1 is connected to -AC power. The battery will charge whenever this indicator is illuminated.
11. **Low BATT Indicator** - Illuminates when MPM-1 is operating on Battery power, and less than fifteen minutes battery life remains. Connect to -AC power as soon as possible to prevent loss of trend data and to maintain battery charge. An audible cyclic indication will also be given to alert the user to the low battery condition.

BACK PANEL (See Figure 2)

12. **COMBINATION CORD WRAP, HANDLE, and BED RAIL MOUNT**
13. **MANUAL POCKET** - Storage location for the Instructions For Use booklet.
14. **RS232 CONNECTOR** - Used for data acquisition needs. Please contact Camino NeuroCare™, Inc. for details on use of this connector.
15. **ICP ISOLATED ANALOG CONNECTOR** - Used for data acquisition needs. Please contact Camino NeuroCare™, Inc. for details on use of this connector.
16. **EQUIPOTENTIAL CONNECTOR** - Used as the connection point for equipotential systems.
17. **BEDSIDE MONITOR CONNECTOR** - Used for connection to the bedside monitor.
 - 17a. ICT Temperature data to Bedside Monitor. Standard Phone Plug
 - 17b. ICP Pressure Waveform to Bedside Monitor. 6-Pin Cannon Connector
 - 17c. Arterial Pressure Data to MPM-1. Miniature Phone Plug
18. **VOLTAGE SELECTION SWITCH** - Used to select input -AC voltage of 115 or 220 Volts.
19. **MAINS ON/OFF SWITCH** - Applies -AC voltage to the MPM-1. Should be in the ON position during normal operation and whenever it is desired to maintain a charge on the internal battery.
20. **AC CONNECTOR** - Attachment point for the -AC power cord.
21. **POLE CLAMP** - Used to secure the MPM-1 to an equipment pole.

SIDE PANEL (See Figure 3)

22. **ICP CATHETER CONNECTION** - Attachment point for the Preamp Cable Connector.
 - 22a. ICP Catheter to Preamp connection.
23. **TEMPERATURE CONNECTION** - Attachment point for the Temperature Cable Connector.
 - 23a. ICT Catheter temperature connection.

SYSTEM DESCRIPTION

The Camino NeuroCare™, Inc. Multi-Parameter Monitor with Waveform Display MPM-1 is a compact, portable device for use with Camino NeuroCare™, Inc. Pressure/Temperature and Pressure Transducer-Tipped Catheters. Pressure and/or temperature are measured at the Catheter tip, eliminating the need for external transducers, fluid, pressure tubing, and flush devices. The MPM-1 measures Intracranial Pressure (ICP), Intracranial Temperature (ICT), and calculates Cerebral Perfusion Pressure (CPP).

This system saves time and eliminates the cause of most artifacts, such as bubbles, leveling, clogged tubing, and noise due to patient movement. It provides a high fidelity, linear pressure response over its entire range.

The MPM-1 provides a continuous display of the pressure waveform, as well as mean ICP, CPP, temperature, or systolic and diastolic values. A continuous record of mean pressure and temperature values over the most recent 24-hour period is stored in memory, and can be displayed on command as a TREND either as the most recent 8 or 24 hour period. An analog output accessory provides a continuous ICP waveform for hard copy documentation or data acquisition. Although the MPM-1 is intended to be a stand alone system, it also conveniently connects to any hospital bedside monitoring system. A built-in rechargeable battery permits monitoring during patient transport.

SET-UP

1. Carefully unpack the MPM-1, Power Cord, and Cables. Check to be sure each item is undamaged.
2. If desired, mount the MPM-1 on an equipment pole and tighten POLE CLAMP (Figure 2).

NOTE: The MPM-1 POLE CLAMP can accommodate equipment poles from 1/2" to 1 1/2" O.D. Make sure MPM-1 is properly attached to equipment pole and securely tightened.

3. If desired, connect the MPM-1 to an external bedside monitor system, using connectors 17a, 17b, 17c as required (Figure 2).
4. Verify that the --AC voltage selector is set to the proper voltage (Figure 2).
5. Insert the Power Cord into the AC CONNECTOR on the back panel of the MPM-1 (Figure 2). Then insert the Plug into a grounded --AC outlet.
6. Turn on the power by moving the MAINS ON/OFF switch to its ON position (Figure 2).

MPM-1 OPERATION

1. Turn on the MPM-1 by pressing the START/STOP button on the front panel. The MPM-1 will display the "Camino" logo (Figure 4). If the logo does not appear, verify that the MAINS ON/OFF switch on the back panel (Figure 2) is in the ON position.
2. Connect the Preamp Cable to the MPM-1 by inserting the two cable connectors in the appropriate receptacle. (Figure 3).
3. Select the desired Camino Pressure Monitoring Kit. Specific directions for use may be found in the User Information Insert provided with each Pressure Monitoring Kit.
4. Remove the Catheter from the Kit tray, and firmly connect the Transducer Connector(s) into the Preamp Connector(s) (Figure 5). After a short system test, the MPM-1 Display will change to the ICP/ICT display (Figure 6).
5. Before inserting the Catheter into the patient, ensure that the MPM-1 Display indicates an ICP Pressure of "0 mmHg". If not, use the tool from the Catheter Kit to turn the zero adjustment on the bottom side of the Transducer Connector until the ICP Pressure indicates "0 mmHg" (Figure 7). Also ensure that the temperature is a reasonable value, such as room temperature, before insertion of the Catheter into patient.

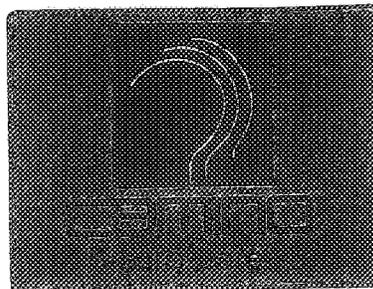


Figure 4

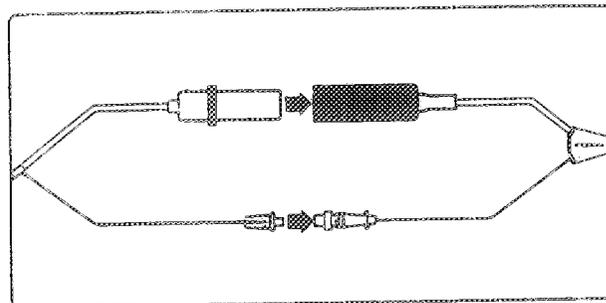


Figure 5

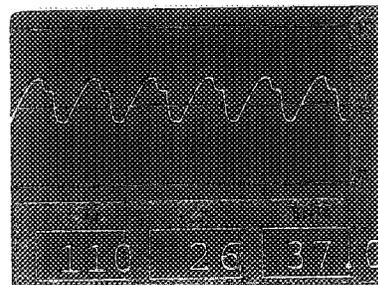


Figure 6

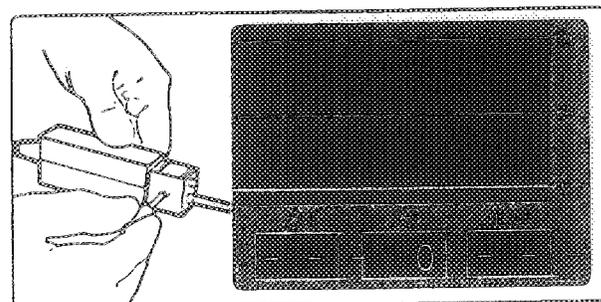


Figure 7

6. After the Catheter has been inserted into the patient, select the appropriate scale by repeatedly pressing the SCALE button on the MPM-1 front panel (Figure 8).
7. If the MPM-1 is connected to an external bedside monitor, the CAL STEP button (Figure 9) may be used to calibrate or balance the bedside monitor. Each press advances to the next mmHg value in the following series: 0, 20, 40, 100, 200 and back to 0. The CAL STEP momentarily interrupts normal pressure display and substitutes a calibration pressure signal on both the MPM-1 and on the external bedside monitor. Press the CAL STEP button repeatedly until 0 mmHg is displayed on the MPM-1. While keeping the button depressed to maintain 0, simultaneously zero the bedside monitor, then release the CAL STEP button. Within a few seconds the MPM-1 will return to the pressure display. Note that the CAL STEP button may be used at any time, and does not affect the transducer calibration.
8. Press the SYS/DIAS button to toggle between CPP, ICP, ICT and SYS, ICP, DIAS displays.
9. Press the TREND button (Figure 10) to display the mean ICP, ICT, and CPP values recorded during the preceding 8 hours. With the next press of the trend button, the mean ICP, ICT and CPP for the preceding 24 hours will be displayed. Press again to return to the pressure display. To clear trend, turn MPM-1 off momentarily.

NOTE: The trend information will be lost if the MPM-1 is turned off or if the battery discharges completely and the MPM-1 turns itself off.

NOTE: ICT and CPP values will ONLY be displayed when using the appropriate Catheter and/or bedside monitor input connections.

NOTE: When not in use, the MPM-1 must be connected to -AC power to maintain battery charge.

ALARMS

1. The HIGH ICP alarm value may be adjusted by pressing the UP or DOWN alarm adjustment buttons. The alarm value may be adjusted between 1 and 250 mmHg in 1 mmHg increments. The HIGH ICP alarm function may be disabled by pressing the DOWN button until OFF appears in the display. The ALARMS DISABLED indicator will be illuminated whenever the alarm limit is set to OFF. The MPM-1 returns to the previous display screen after 3 seconds of button inactivity. (Figure 11).

High ICP conditions will be detected and an alarm sounded when the ICP exceeds the user selected HIGH ICP alarm limit. This alarm may be silenced temporarily for 3 minutes by pressing the ALARM SILENCE button. The alarm may also be silenced by changing the actual HIGH ICP alarm limit to a higher value or turned off by pressing the DOWN button until OFF appears in the display.

2. The CHECK CATHETER CONNECTION alarm is initiated when the MPM-1 detects the absence of a Catheter for any reason. Correcting the Catheter/connection problem will remove the alarm condition.

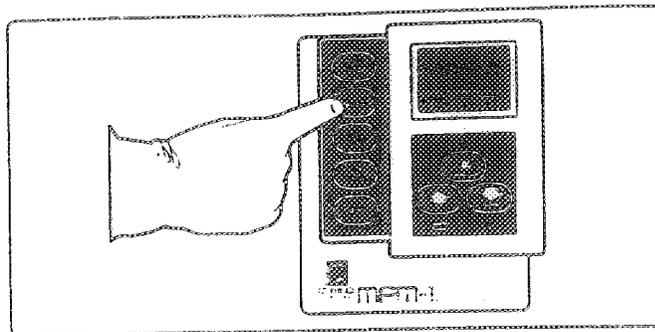


Figure 8

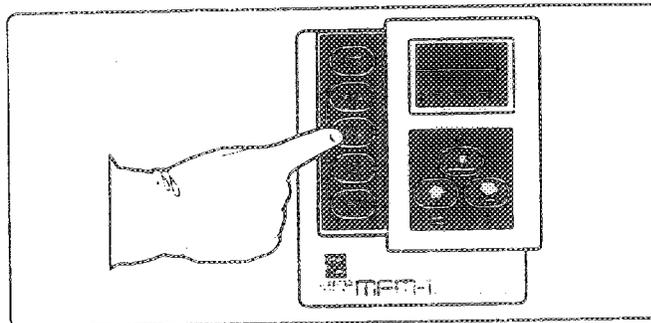


Figure 9

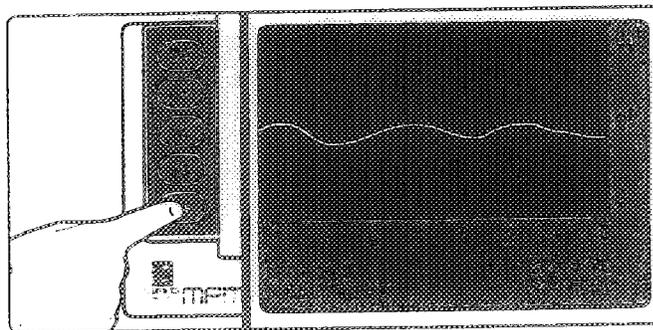


Figure 10

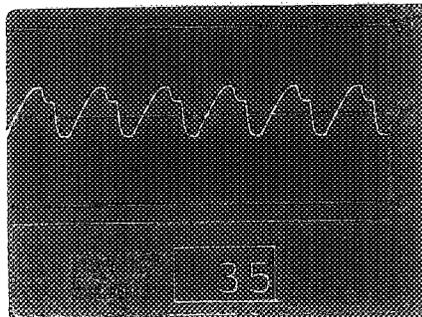


Figure 11

MPM-1 TROUBLESHOOTING

SYMPTOM	REMEDY
Display will not turn on.	<ul style="list-style-type: none"> • Verify MAINS ON/OFF -AC power switch is in the ON position. • Verify power cord is plugged into a live -AC power source.
Will not operate on battery. Low BATT Indicator illuminated.	<ul style="list-style-type: none"> • Connect to -AC power for approximately 8 to 10 hours to fully charge battery. • The MPM-1 may be used on -AC power while charging.
Waveform off screen or too small	<ul style="list-style-type: none"> • Press SCALE button to change scale.
MPM-1 Display reads: • CHECK CATHETER CONNECTION • -99	<ul style="list-style-type: none"> • Check connection between Catheter, Preamp Cable and MPM-1. • Replace Preamp Cable. • Replace MPM-1 • Replace Catheter
ICP, Systolic or Diastolic reads: " _ _ _ "	<p>Value outside operating range of MPM-1 — (-50 mmHg to 300 mmHg)</p> <ul style="list-style-type: none"> • Check connection between Catheter and Preamp Cable • Check connection between Preamp Cable and MPM-1 • Replace Preamp Cable • Replace MPM-1 • Replace Catheter
CPP reading " _ _ _ "	<p>Value outside operating range of MPM-1 — (0 mmHg to 210 mmHg)</p> <ul style="list-style-type: none"> • Check connection between Catheter, Preamp Cable and MPM-1 • Check connection between Bedside Monitor and MPM-1 • Replace Monitor Cable • Replace Preamp Cable • Replace MPM-1 • Replace Bedside Monitor • Replace Catheter
CPP reading missing	<ul style="list-style-type: none"> • Check connection between Catheter, Preamp Cable and MPM-1 • Check connection between Bedside Monitor and MPM-1 • Replace Monitor Cable • Replace Preamp Cable • Replace Bedside Monitor • Replace MPM-1 • Replace Catheter

<p>ICT reads: "----"</p>	<p>Value outside operating range of MPM-1 — (15°C to 45°C)</p> <ul style="list-style-type: none"> • Check connection between Catheter Temperature Connector, Preamp Cable and MPM-1 • Replace Preamp Cable. • Replace MPM-1 • Replace Catheter.
<p>ICT reading missing</p>	<ul style="list-style-type: none"> • Check connection between Catheter Temperature Connector, Preamp Cable and MPM-1 • Replace Preamp Cable. • Replace MPM-1 • Replace Catheter with a new ICP/ICT Catheter.

CLEANING AND STERILIZING

The MPM-1 Preamp Cable can be sterilized with ethylene-oxide.

It is a good practice to periodically clean the MPM-1 outer surfaces by wiping with a soft, clean cloth that has been dampened with warm water, or a general non-staining chemical disinfectant. Refer to the Housekeeping, Central Services, or Infection Control departments in your facility for further information.

CAUTIONS

Do not autoclave or immerse the MPM-1 as damage may occur.

Do not use solvents or cleaning agents as they could damage the plastic exterior of the MPM-1.

Camino Catheters are for single use only. Do not attempt to resterilize. Camino NeuroCare™, Inc. cannot assume any responsibility for damage caused by reesterilized Catheters.

PRECAUTIONS

- DANGER - Risk of explosion if used in the presence of flammable anesthetics.
- CAUTION - To reduce the risk of electric shock do not remove cover. Refer servicing to qualified service personnel.
- CAUTION - Read Instructions For Use before connecting to bedside patient monitors.
- CAUTION - Grounding reliability can only be achieved when connected to a receptacle marked "Hospital Only" or "Hospital Grade".

SERVICE

Periodic preventive maintenance is necessary to ensure proper functioning and calibration of Model MPM-1. The date on which the next maintenance is due can be found on the back panel of the unit. Contact Camino NeuroCare™, Inc. or our local distributor for details.

If the MPM-1 fails to perform as specified, and the cause cannot be determined, do not use it. Refer it to qualified service personnel. Additional user and service information can be obtained by writing:

Camino NeuroCare™, Inc.
5955 Pacific Center Boulevard
San Diego, CA 92121-4309
Attn.: Customer Service

Please include a description of the type of information desired, and details, of any difficulties you may have experienced.

You may also call us at (800)-354-5650 or (619) 455-1115.

For technical assistance and user information, ask for Technical Support.

For MPM-1 and accessory exchanges, contract information, and other ordering information, ask for Customer Service.

RETURNS

Should it be necessary to return your MPM-1 to a Camino Service Facility, contact Customer Service at (800)-354-5650 or (619) 455-1115 for return authorization and instructions. Camino NeuroCare™, Inc. cannot assume responsibility for loss or damage to returned equipment while in transit.



Camino NeuroCare™, Inc. LIMITED WARRANTY

CAMINO warrants that each new CAMINO product is free from defects in material and workmanship under normal use and service for a period of two (2) years (except as otherwise expressly provided as to accessory items—see Camino price list) from the date of delivery by CAMINO to the first purchaser but not beyond the "Use Before" date stated on any product labeling. Any covered product which is placed by CAMINO under a lease, rental or installment purchase agreement and which requires repair services during the terms of such placement agreement shall be repaired on an exchange basis. If any such defect occurs during the warranty period of term of such placement agreement, the purchaser should communicate directly with the CAMINO home office (San Diego, CA) if returned to CAMINO at its home office, repair or replacement will be carried out at CAMINO's expense, subject to the terms of this warranty and the applicable agreement. The defective product should be returned promptly, properly packaged and postage prepaid. Loss or damage in return shipment to CAMINO shall be at CUSTOMER's risk.

IN NO EVENT SHALL CAMINO BE LIABLE FOR ANY INCIDENTAL, INDIRECT OR CONSEQUENTIAL DAMAGES IN CONNECTION WITH THE ACQUISITION OR USE OF ANY CAMINO PRODUCT. Further, this warranty shall not apply to, and CAMINO shall not be responsible for, any loss arising in connection with the purchase or use of any CAMINO product which has been repaired by anyone other than an authorized CAMINO service representative or altered in any way so as, in CAMINO's judgment, to affect its stability or reliability, or which has been subject to misuse, negligence or accident, or which has been used otherwise than in accordance with the instructions furnished by CAMINO. This limited warranty is exclusive and in lieu of all other obligations or liabilities on CAMINO's part and CAMINO neither assumes nor authorizes any representative or other person to assume for it any other liability in connection with CAMINO products.

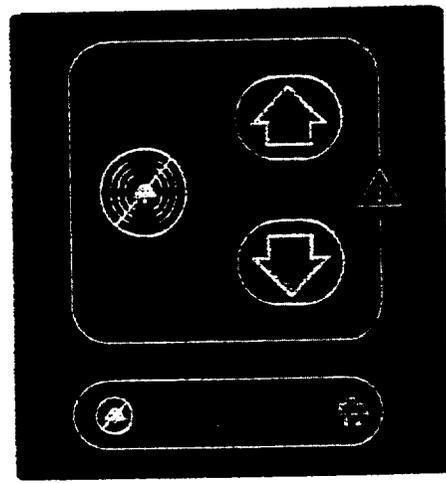
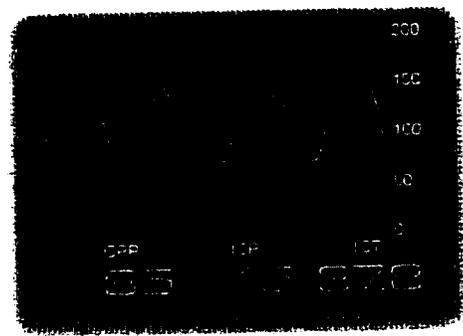
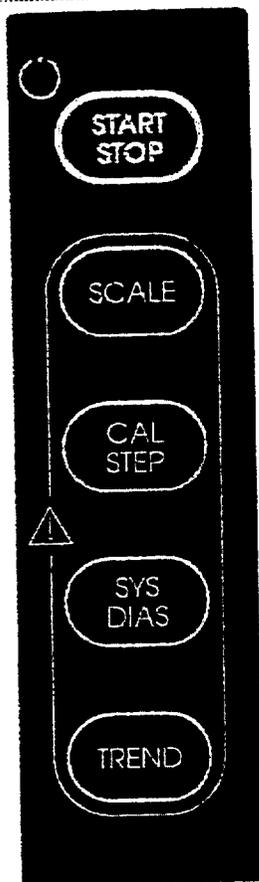
CAMINO DISCLAIMS ALL OTHER WARRANTIES, EXPRESS OR IMPLIED, INCLUDING ANY IMPLIED WARRANTY OF MERCHANTABILITY OR OF FITNESS FOR A PARTICULAR PURPOSE OR APPLICATION OR WARRANTY OF QUALITY, OTHER THAN THOSE EXPRESSLY SET FORTH IN THE PRODUCT LABELING, INCLUDING THE APPLICABLE USER INFORMATION.

The foregoing shall not relieve CAMINO from strict tort liability, if otherwise applicable under governing law, for damages of personal injury caused by a product defect that made the product unreasonably dangerous at the time it was sold or placed.

SPECIFICATIONS**Camino NeuroCare™, Inc. MULTI-PARAMETER MONITOR WITH WAVEFORM DISPLAY, Model MPM-1**

Pressure Sensor Type	Fiberoptic pressure transducer
Pressure Measurement Range (ICP)	-10 to +250 mmHg pressure, Resolution of 1 mmHg
High ICP Alarm	0 - 250 mmHg, 1 mmHg increments
Temperature Sensor Type	Thermistor transducer
Temperature Measurement Range	16.7°C to 42.2°C (65°F to 108°F), Accuracy of ±0.3° C (0.5°F)
Mean Cerebral Perfusion Pressure (CPP) Range	0 to 200 mmHg, Resolution of 1 mmHg
Linearity and Hysteresis	See individual Catheter specifications
Reference Pressure	Atmospheric
Display	Backlit TFT active matrix LCD panel display of pressure waveform, numeric pressure, cerebral perfusion pressure, temperature, systolic and diastolic values
Analog Output	For details contact Camino NeuroCare™, Inc.
RS232	For details contact Camino NeuroCare™, Inc.
External Monitor Output	5 µV/V/ mmHg
Battery Type	Rechargeable, sealed lead acid
Charge Time	8-10 hours to full charge
Operation Time	1-2 hour from full charge
Power Requirement	100/115/220 VAC, 0.45/0.4/0.3A, 50/60 Hz
Dimensions	274 mm H x 216 mm W x 89 mm D (10.8" x 8.5" x 3.5")
Weight	4.3 kg (9.6 lbs.)

DRAFT



INSTRUCTIONS
(For Detailed Information Refer to Camino MPM-1 User Information)

BEFORE CATHETER IS PLACED:

1. Connect to AC power. AC power indicator on front panel will illuminate.
2. Press START/STOP. A message will be displayed on the LCD screen.
3. Attach connector end of Camino Catheter to preamp cable.
4. Set ICP display to 0 (-1) by turning the zero adjust on the catheter connector.
5. System is now ready for Catheter placement. Follow specific directions on the User Information for each Pressure Monitoring kit.
6. If external bedside monitor is used, calibrate the bedside monitor according to Camino MPM-1 User Information.

Rechargeable Battery - Camino MPM-1 has a built-in rechargeable battery for patient transport. When not in use monitor must be connected to AC power to maintain battery charge.

DANGER - Possible explosion hazard if used in the presence of flammable anesthetics.

OUTPUT ELECTRICALLY ISOLATED
Grounding reliability can only be achieved by connection to replaceable marked Hospital Use or Hospital Grade. 300-1 PE, INC.

camino
NeuroCare
Camino Medical Group, Inc.
Camino Catheters, 11701

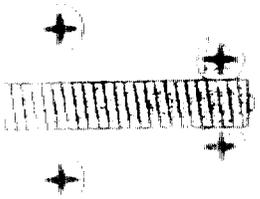
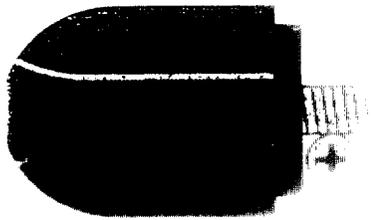
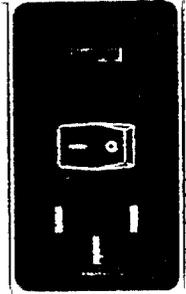
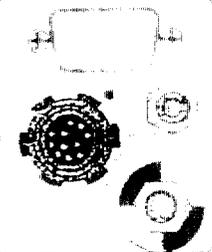
MPM-1

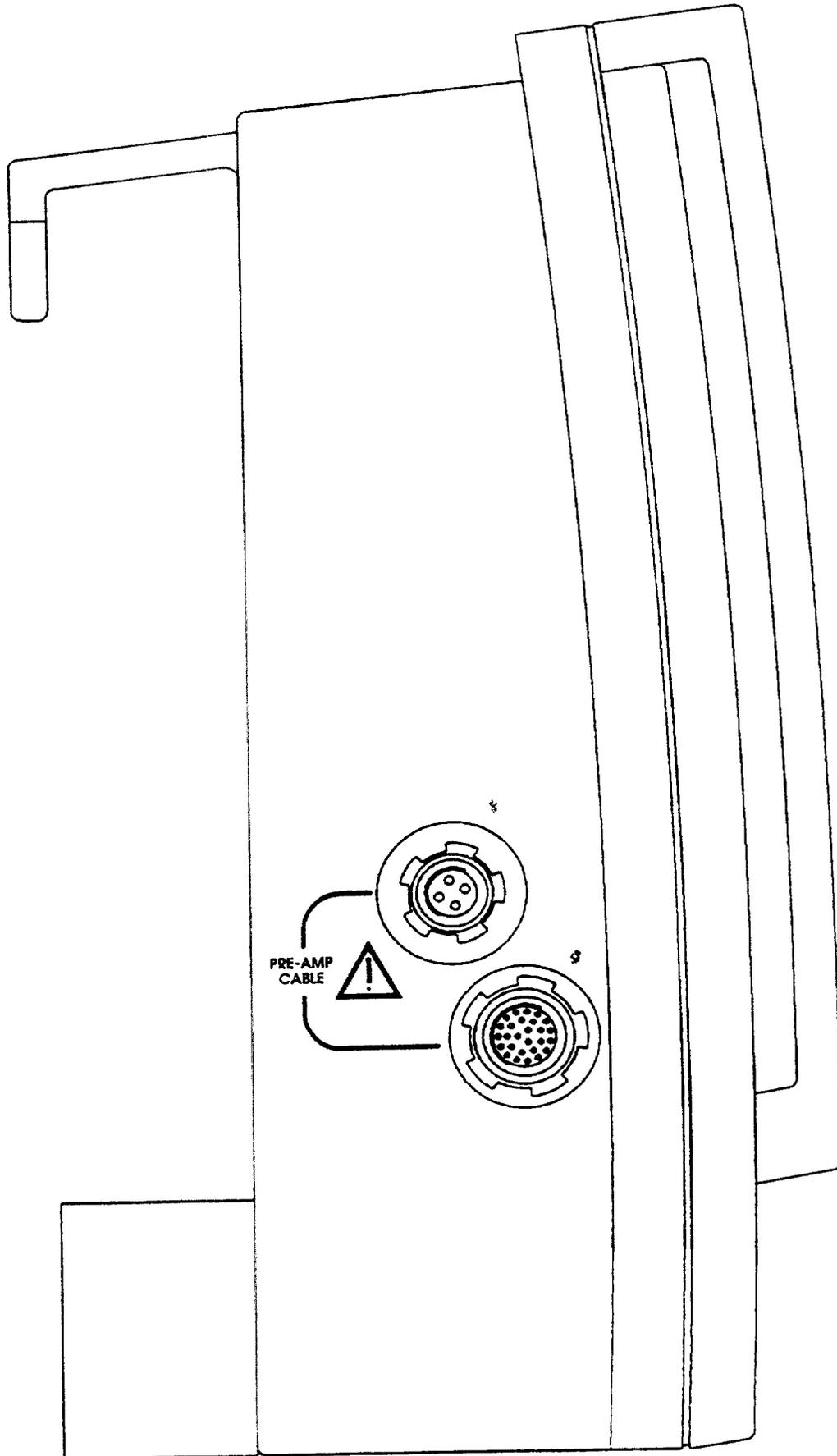
ICP

30-0/1 Hz	2.0 AMP	100-240 VAC
-----------	---------	-------------

MADE IN U.S.A.

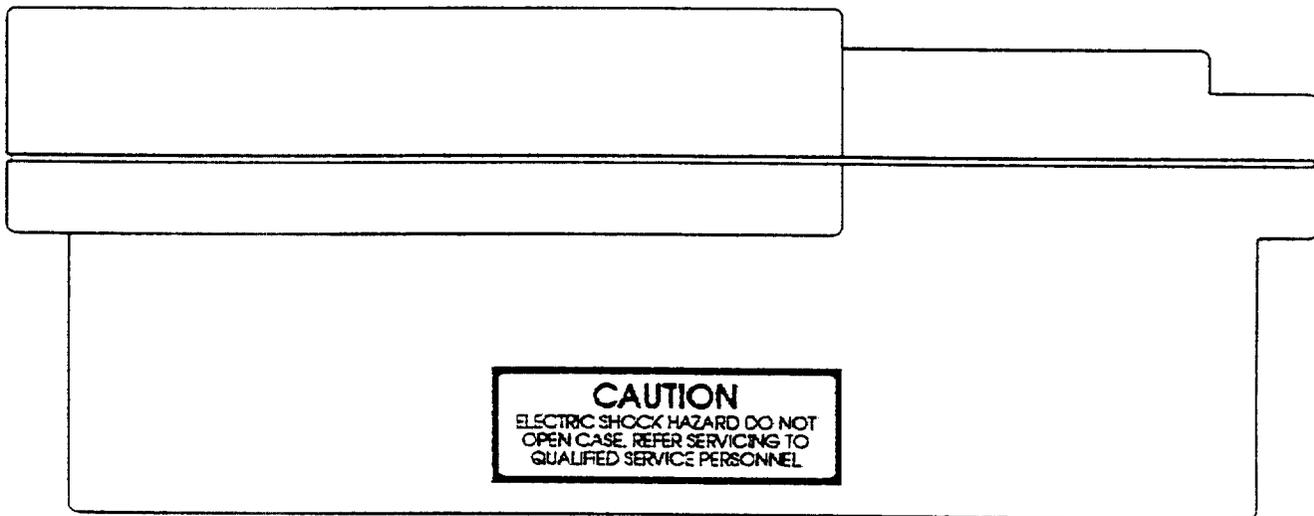
U.S. AND FOREIGN PATENTS
ISSUED AND PENDING



000034

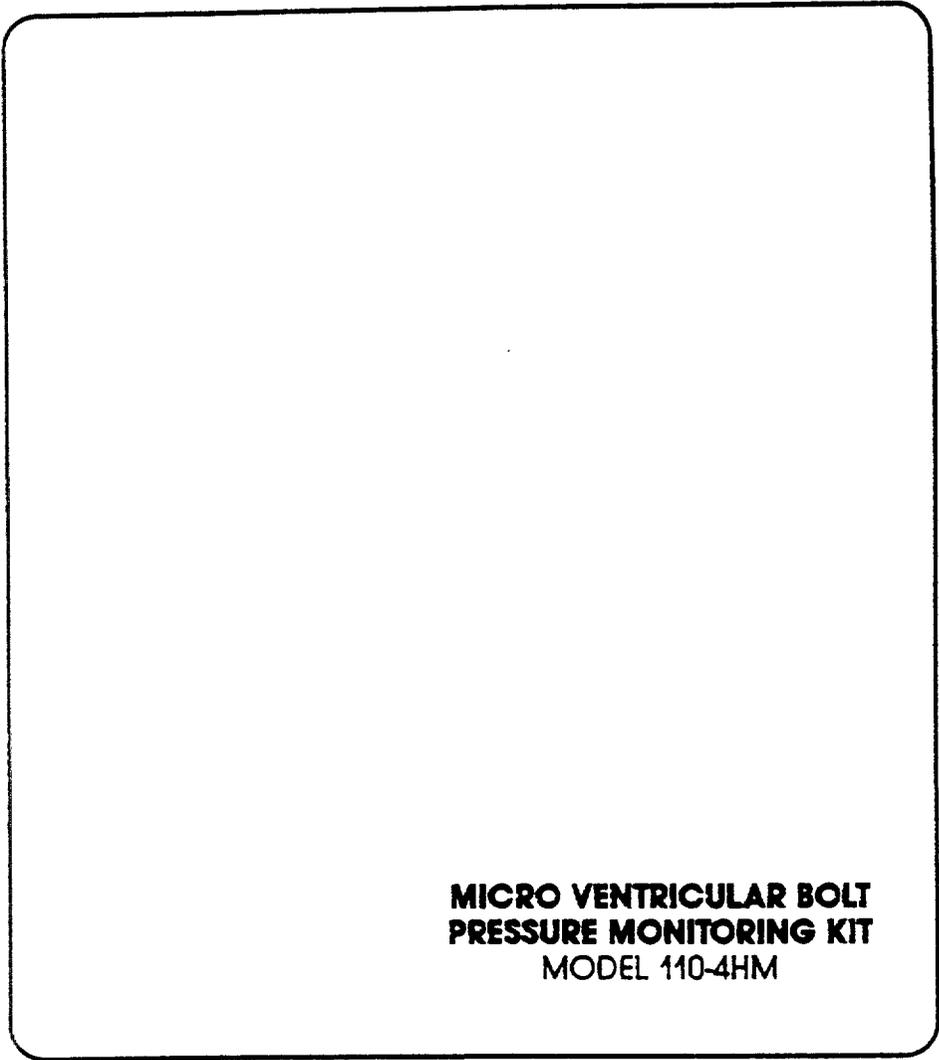
DRAFT



Premarket Notification - Camino NeuroCare™

PREDICATE LABELING CATHETER

000036



**MICRO VENTRICULAR BOLT
PRESSURE MONITORING KIT
MODEL 110-4HM**

USER INFORMATION

camino
Laboratories

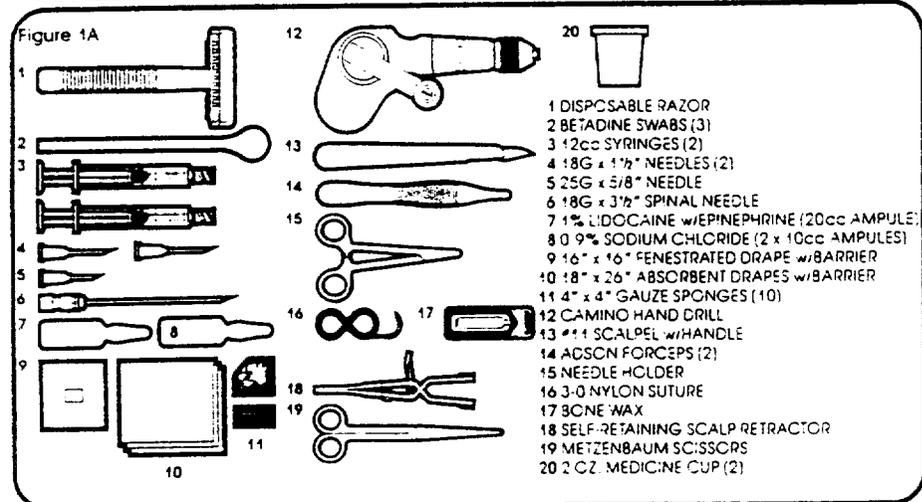
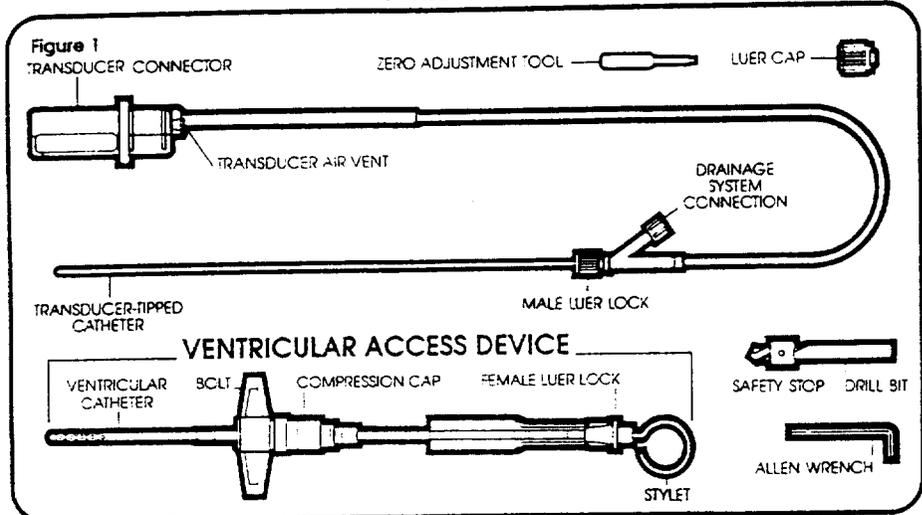
000037

CAMINO

USER INFORMATION

Read carefully prior to use

MICRO VENTRICULAR BOLT PRESSURE MONITORING KIT MODEL 110-4HM



SYSTEM DESCRIPTION

The Camino Micro Ventricular Bolt Pressure Monitoring Kit consists of a sterile transducer-tipped pressure monitoring catheter with accessory items which provide a means of access to the cerebral ventricles for CSF sampling and drainage, fluid injection and intracranial pressure monitoring. Since its method of measuring pressure is unique, please read the following section carefully:

Unlike ordinary pressure monitoring systems, the Camino catheter has a miniature transducer at the distal tip. This unique design eliminates the need for a "fluid-filled system" to carry pressure waves to an external transducer. Thus, the problems inherent in such fluid-filled systems are eliminated. The result is a precise pressure measurement and an artifact free, high fidelity waveform trace.

000038

The Camino Micro Ventricular Bolt Pressure Monitoring Kit contains the following accessory items for use with the Camino catheter (Figure 1):

- Camino Ventricular Access Device, with ventricular catheter, bolt, female Luer lock and stylet.
- Twist drill bit with safety stop.
- Additional Luer lock port to connect drainage system.

The indwelling portion of the ventricular catheter assembly is fabricated of barium-impregnated silicone elastomer, having an OD of 3.7mm and ID of 2.2mm. Its length is adjustable from 6–8 cm. Designed for directing fluid from the ventricles through a series of drainage holes, it can be inserted into the ventricular cavity with the supplied stainless steel stylet.

Note: A hand drill and various standard surgical instruments and supplies are required to place the ICP monitoring system.

A complete set of instruments and supplies is available from Camino Laboratories in Model 070 Disposable Twist Drill Procedure Kit (Figure 1A), or the H-ITH Series Cranial Access Kits.

PRECAUTIONS

- Extreme bending and/or kinks can impair the performance of the Fiber Optic Pressure Transducer. Exercise caution when handling the catheter.
- The catheter is designed for **SINGLE USE ONLY. DO NOT RESTERILIZE OR REUSE.**
- It is imperative that the ventricular catheter not be handled with bare fingers or come into contact with linty surfaces. Silicone elastomers are very electrostatic and therefore susceptible to contamination by airborne or surface particles. The presence of these contaminants could cause adverse tissue reaction. Rubber-shod clamps or washed, gloved hands are the best means of handling implantable silicone devices.
- Use aseptic technique throughout procedures.
- Maintain the insertion site with regular, meticulous redressing using aseptic technique.

- Do not attach anything to transducer air vent. Vent must remain open for proper operation (Figure 1).

CAUTION

- Federal law (U.S.A.) restricts this device to sale by or on the order of a physician.

INSTRUCTIONS FOR USE

- The recommended frontal placement is 3–4 cm off the midline, just anterior to the coronal suture. After the site has been chosen, the area is shaved and prepped in a sterile fashion, usually with a betadine solution. The shaved and prepared area is then draped. The area of the incision is infiltrated subcutaneously with 1% lidocaine. An approximately three centimeter linear incision is made and carried to the bone. A self-retaining retractor is then inserted to provide good bone exposure and hemostasis of the skin edges.
- Adjust the safety stop on the drill bit to the estimated skull thickness and secure firmly with the allen wrench.
- Drill a hole through the outer and inner tables of the skull, taking care to minimize any potential for parenchymal injury. Penetrate the dura under direct vision with a #11 blade, securing hemostasis as necessary.
- Using the stylet, insert the ventricular catheter into the ventricle. When CSF is obtained, hold the catheter securely, remove the stylet, slide the bolt down and screw in, using bone wax to insure a tight seal. Do not over tighten, as stripping of the threads may cause loss of seal.
- Continue to hold the catheter securely, and turn the compression cap clockwise to lock the catheter in place. Slide the strain relief down and attach to the compression cap. Cap the catheter with the Luer cap to prevent CSF loss.

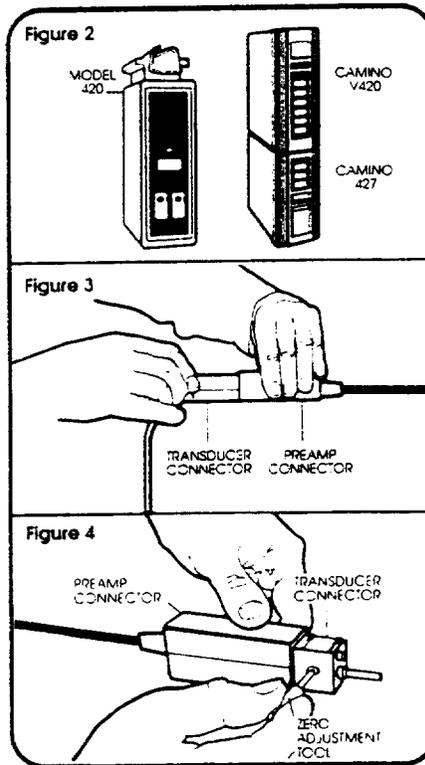
Camino transducer-tipped pressure monitoring catheter preparation (prior to insertion into ventricular catheter):

The Camino catheter can be used only in conjunction with the Camino 420 or V420 Pressure Monitor (Figure 2). For Camino Monitor set-up and use, refer to the Camino Monitor User information.

000039

Remove the Camino catheter from its sterile package and firmly attach the transducer connector to the preamp connector (Figure 3). If the Camino display does not read zero after a short system self-check delay, use the tool from the catheter kit to turn the zero adjustment on the bottom side of the transducer connector until the Camino display reads zero (Figure 4).

- Remove the Luer cap from the ventricular catheter, insert the Camino transducer-tipped catheter and secure the Luer lock. Holding the ventricular catheter straight will facilitate passage.



- Prepare an external ventricular drainage system according to its manufacturer's directions and attach to the side port of the Y-connector. Note that CSF may be drained without interrupting pressure monitoring.
- When monitoring is to be discontinued, detach the strain relief from the compression cap. Loosen compression cap and remove ventricular catheter prior to the removal of the bolt from the skull.

CONTINUOUS PRESSURE MONITORING

Since the Camino catheter has a miniaturized transducer at the distal tip, it requires no fluid-filled system. Thus, the need for an external transducer, pressure dome, and pressure tubing is eliminated. As a result, pressure may be monitored continuously without flushing or recalibration.

INDICATIONS

The use of the Camino Micro Ventricular Bolt Pressure Monitoring Kit by a qualified neurosurgeon is indicated when direct pressure measurement and cerebrospinal fluid drainage is clinically important. The Camino Micro Ventricular Bolt Pressure Monitoring Kit is intended to be used with an external drainage system as indicated by individual manufacturers.

CONTRAINDICATIONS

This device is not intended for any use other than that indicated.

RISK AND COMPLICATIONS

Maintenance of sterility during placement and subsequent handling of the Camino Micro Ventricular Bolt Pressure Monitoring Kit is essential. Sterile technique should be used at all times when inserting, adjusting, and securing the Camino catheter.

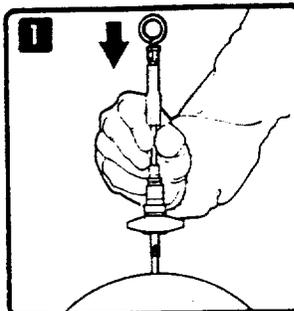
Infection, subcutaneous leakage of CSF, neurological sequelae, and blockage by intraventricular debris (including bloody and/or highly proteinic CSF) have occurred during the use of ventricular catheters.

Placement of the tip openings within the reach of choroid plexus has resulted in blockage of ventricular catheters.

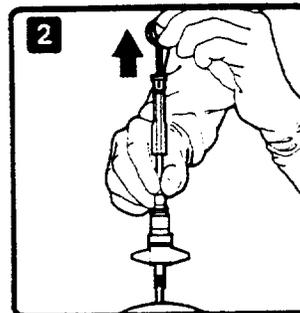
The ventriculostomy must be carried out by a qualified neurosurgeon using standard surgical procedure and skill. Hemorrhage from the dura or cortical surface at the bolt insertion site may occur. Patients should be tested for normal blood clotting function prior to bolt placement. Appropriate measures to avoid infections and complications are the sole responsibility of the neurosurgeon in charge.

**RECOMMENDED
INSERTION
PROCEDURE
SUMMARY**

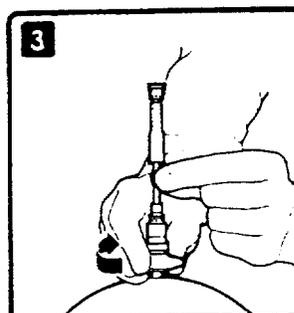
After drilling hole in skull and penetrating the dura.



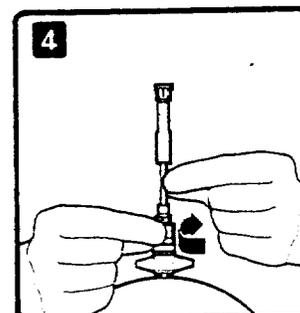
1. Pass ventricular catheter assembly into ventricle.



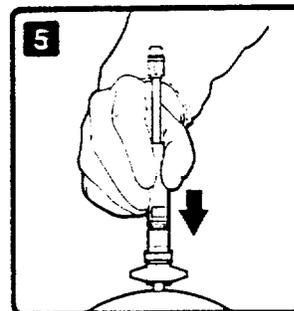
2. Remove stylet.



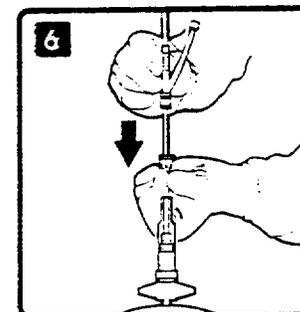
3. Slide bolt down and screw in.



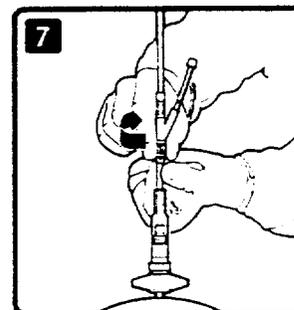
4. Secure compression cap.



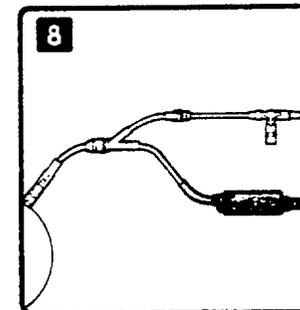
5. Slide strain relief sheath down and attach to compression cap.



6. Zero the transducer, then insert transducer-tipped catheter into ventricular catheter.



7. Secure luer lock.



8. Connect drainage system to valve.

000041

SPECIFICATIONS

Ventricular catheter:	
Outside diameter	3.7 mm
Inside diameter	2.2 mm
Length	6-8 cm (adjustable)
Transducer size	4F
Transducer type	Fiber optic
Frequency response (system)	
Model V420/M420/420XP	120Hz (-3dB)
Model 420	33Hz (-3dB)
Measurement range (system)	-10 to +250 mmHg
Zero drift (system)	
First 24 hours (maximum)	0 ± 2 mmHg
5 days (typical)	less than ± 1 mmHg per day
Temperature coefficient	Max of 3 mmHg over temperature range of 22°C to 38°C (70°F-100°F)
Linearity and hysteresis (system)	
Pressure range:	
-10 to 50 mmHg	± 2 mmHg or better
51 to 200 mmHg	± 6% of reading or better
201 to 250 mmHg	± 7% of reading or better
Reference pressure	Atmosphere
Overpressure	-700 to 1250 mmHg

Manufactured under one or more of:
 U.S.—Patent Nos. 4,446,715, 4,705,047; 4,931,049; 4,903,707; 5,107,847 and Des. 285,112; 283,053;
 EPO— Patent No. 0127476;
 Other U.S. and foreign patents issued and pending.

Camino
Laboratories

5955 PACIFIC CENTER BLVD., SAN DIEGO, CALIFORNIA 92121 (619)455-1115 FAX: (619)455-8298 300698 0

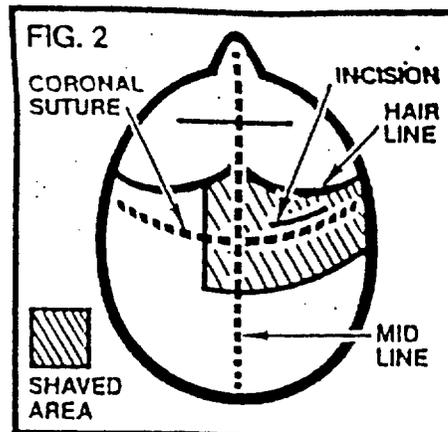
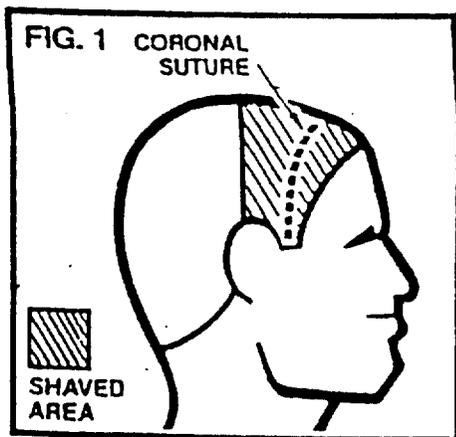
USER INFORMATION

MODEL 070 INTRACRANIAL PRESSURE MONITORING KIT

1. Area of insertion: The right and left prefrontal areas are the primary areas of insertion. This region allows the patient to have his head rotated from side to side and still remain in a supine position without interference of the intracranial pressure monitor function. In addition, the incision will be carried behind the hairline in the majority of patients and therefore cosmetically acceptable. (Figures 1 and 2)
2. After deciding whether to use either the right or left prefrontal region, the area is then shaven and prepped in a sterile fashion usually with a betadine solution. The shaved and prepped area is then draped with sterile towels. The area of the incision, which usually lies either one to two centimeters anterior to the coronal suture in the mid-pupillary line, is infiltrated subcutaneously with 1% Zylocaine. An approximate half centimeter linear incision is made and this is carried to the bone. A small mastoid type of retractor will then be inserted to provide good bone exposure. In addition, this provides hemostasis of the skin edges.
3. The drill bit provided in the kit, is then secured to a twist drill and in a standard fashion a twist drill hole is made through the outer and inner table of the skull. The surgeon needs to be careful when penetrating the inner table so that he minimizes any potential for brain parenchymal injury.

4. After penetration of the inner table, the drill is removed and the hole is irrigated with saline. A No. 15 needle is then used to open the dura in a cruciate fashion.
5. Following opening of the dura, the Camino Bolt will be screwed on manually into the skull. The seating depth of the Camino Bolt will be at the surgeon's discretion pending the thickness of the skull. The protective spacer on the Camino Bolt can be adjusted to match the seating depth of the Camino Bolt. For neonatal age group, the seating depth of the Camino Bolt would be approximately 2-3 mm, the pediatric age group would require 3-5 mm and the adults about 5 mm to 1 cm.
6. The Camino Bolt will then be irrigated with a sterile non-bacterial static saline with a 2.0 inch 22 gauge angio catheter.
7. Camino 110-4 Transducer-Tipped Pressure Monitoring Catheter preparation prior to insertion:
 - 7.1 The Camino Catheter can be used only in combination with the Camino 420 Digital Pressure Monitor. For Camino 420 set up and use, refer to the Camino 420 User Information.
 - 7.2 Remove the Camino Catheter from its sterile package and firmly attach the transducer connector to the pre-amp connector. If the Camino 420 display does not read zero after a short system self check delay, use the tool from the catheter kit to turn the zero adjustment on the bottom side of the transducer connector until the Camino 420 display reads zero. Refer to Camino User Information for Model 110-4 Transducer-Tipped Pressure Monitoring Catheter for set up and use.

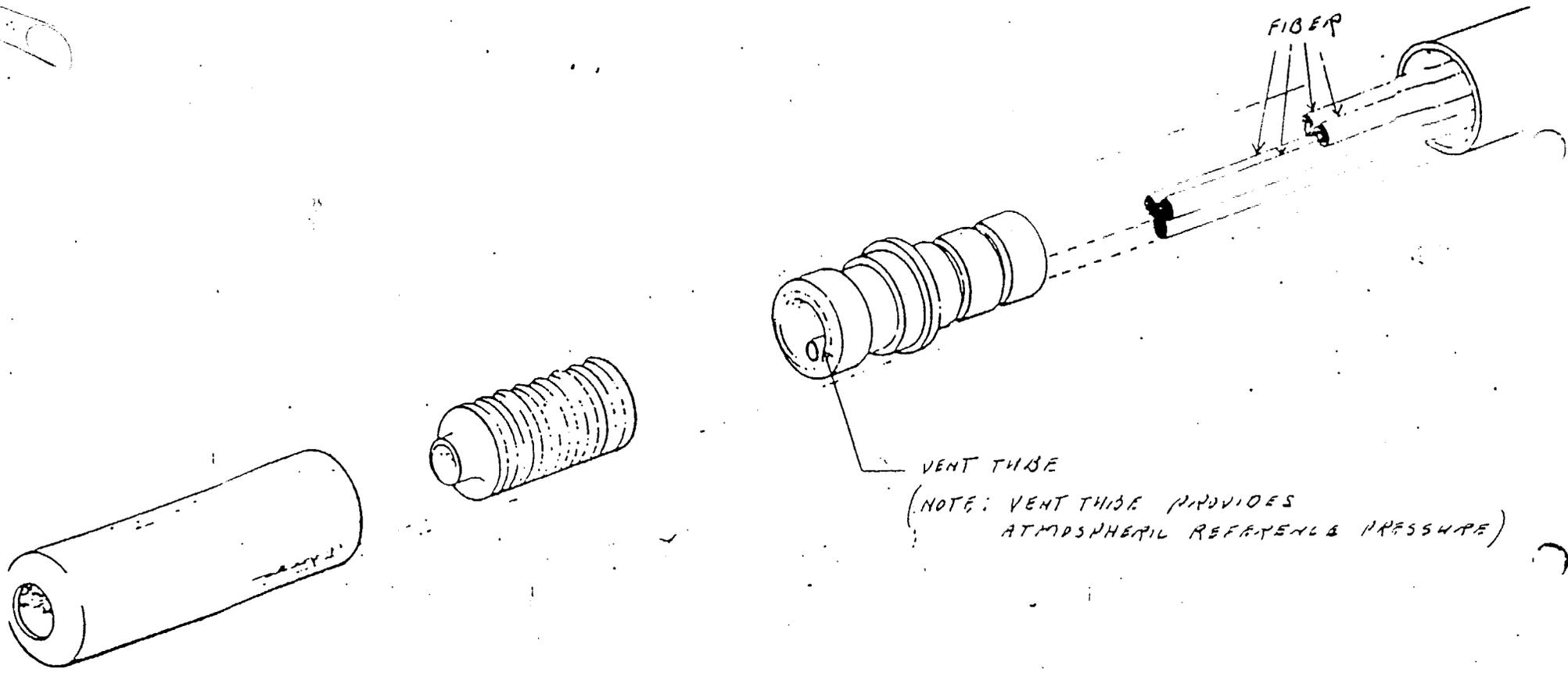
8. Sleeve the catheter contamination shield over the Camino Catheter.
9. To measure interparenchymal pressure, insert the Camino 110-4 Catheter 3 to 5 mm into the brain parenchyma through the Camino Bolt. Use the cm markings on the catheter to verify insertion depth. Turn the compression cap on the Camino Bolt clockwise to secure the catheter in place. To ensure sterility, adjust the contamination shield into place and secure it onto the compression cap on the Camino Bolt.
10. To measure subarachnoid pressure, insert the Camino 110-4 Catheter approximately 5 cm into the Camino Bolt. Use the cm markings on the catheter to verify insertion depth. Turn the compression cap on the Camino Bolt clockwise to secure the catheter in place. To ensure sterility, adjust the contamination shield into place and secure it onto the compression cap on the Camino Bolt.



9/4/85

000045

B1

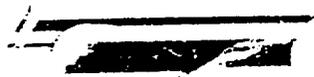


VENT TUBE
(NOTE: VENT TUBE PROVIDES
ATMOSPHERIC REFERENCE PRESSURE)

000046



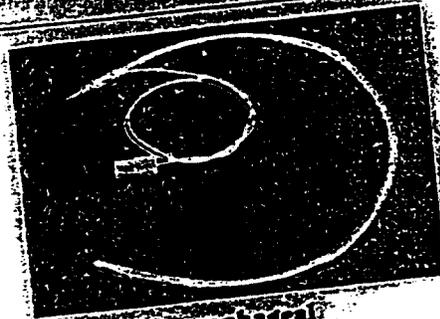
ELECTROMEDICS



Disposable Temperature Probes

Disposable Temperature Probes

Product



Disposable esophageal stethoscope/temperature probe

Features

This sterile probe combines the unique features of an esophageal stethoscope and thermistor temperature probe in one unit. As more and more surgical procedures monitor distinct heart sound plus esophageal temperature, this probe offers the advantages of being sterile, convenient, accurate and—disposable! The design features advanced thermistor technology and compatibility with other electronic temperature monitors.

Specifications

Size: 12, 18 and 24 French
 Length: 18 in. (45.7 cm); with wire, 36 in. (91 cm)
 Accuracy: $\pm 0.4^{\circ}\text{F}$ ($\pm 0.2^{\circ}\text{C}$)
 Range: 94°F to 106°F (34.5°C to 41.1°C)
 Packaging: Sterile. Case of 50 (5 boxes of 10)

Catalog Numbers

Series 2100: for use with Electro-medics temperature monitors
 2101 - 12 French
 2102 - 18 French
 2106 - 24 French
 Series 2400: for use with monitors accepting YSI 400 series temperature probes
 2401 - 12 French
 2402 - 18 French
 2406 - 24 French
 Series 2700: for use with monitors accepting YSI 700 series temperature probes
 2701 - 12 French
 2702 - 18 French
 2706 - 24 French
 6376 - 12 French esophageal stethoscope only
 6379 - 18 French esophageal stethoscope only
 6380 - 24 French esophageal stethoscope only

Electromedics Disposable Temperature Probes are cost efficient, convenient and designed to fit all major thermistor temperature monitors.

Today's modern medical facilities are vitally interested in money-saving, easy-to-use disposable temperature probes. Especially in the areas of general surgery, cardiovascular surgery, anesthesiology, critical care, newborn care and neonatal care. The basic reasons for this trend toward disposable temperature probes relate to costs and patient protection.

Only Electromedics offers disposable temperature probes for other thermistor temperature monitors.

Electromedics disposable temperature probes were designed for use with Electromedics equipment and most other electronic temperature monitors in the hospitals. Our specially designed extension adapter cables make Electromedics disposable temperature probes completely compatible with thermometry systems such as:

- Air Shields
- Bennett
- Data Scope
- General Electric
- Hewlett-Packard
- Tektronix
- Yellow Springs Instruments-YSI

Cost containment has high priority. Costs are going up everywhere. But in the areas of health services, the increases forced upon hospitals and medical care centers are astronomical!

Disposable probes cost less in the long run. A permanent, or re-usable, temperature probe can cost many times more than Electromedics disposable temperature probes. But initial cost is only the



beginning. After each use, the permanent temperature probe must be re-sterilized. This requires costly equipment, sterilizers, time and trained personnel.

And from the time it's used once, processed through sterilization, re-packaged and returned to its place of distribution, many things can happen to end its life-span abruptly. The truth is, re-usable temperature probes usually get thrown away before they've been fully amortized.

Even cost is second to safety.

The very act of sterilizing a permanent probe can be a potential threat to patient protection.

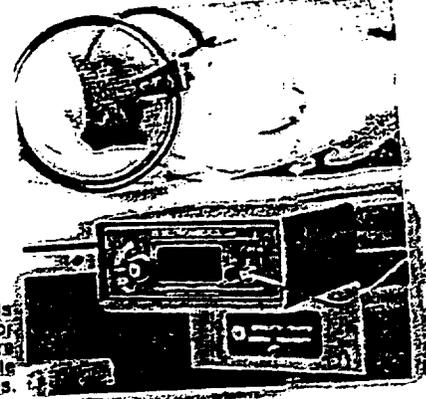
High-temperature steam sterilization methods can deteriorate the dependability of a probe in a relatively short time. Sterilization with ethylene-oxide gas may cause less deterioration to the temperature probe, but it can be tougher on the patient. With gas sterilization, the temperature probe wire must be aerated up to 12 hours. Or the gas residue can result in potential accidental chemical burns to the patient.

Electromedics disposable temperature probes are packed sterile and stay sterile up to the time the package is opened for use. And when you're done with them you throw them away. No re-infection. No contamination.

A telephone call will answer your specific questions. Electromedics wants to make sure you get all the details on its new disposable temperature probes. So don't hesitate to ask questions of our authorized representative in your area, or call our headquarters and talk directly to our product manager or customer service department.



Anesthesiologists are switching to disposable temperature probes because of convenience, safety and savings. Cardiovascular operations get fast and accurate temperature information with the TM-210 and its disposable temperature probes.



Neonatal Care finds many applications for thermistor temperature monitors and disposable temperature probes.

TEMPERATURE MONITORING PRODUCTS

CATALOG NO.	DESCRIPTION	PRICE EACH
TM-210 CONSTANT TEMPERATURE MONITOR - TWO CHANNEL		
TM-210	Temperature Monitor with Charger #9021 and 2 each #9012 Adapter Cables NOTE: The TM-210 uses 2100 Series Disposable Temperature Probes	\$280.00
9095	Pole Mount Bracket	28.00
9021	Replacement Charger (Grounded 110 VAC) for TM-210	15.00

The TM-210 has two channel inputs; thus it may be used to monitor two separate critical temperature sites.

The TM-210 is ideal for patient temperature monitoring in surgery suites. The rechargeable batteries allow up to 15 hours of continuous temperature monitoring when not used with recharger.

Disposable temperature probes assure ease of handling, set-up, convenience, accuracy and economy during surgery and recovery.

An optional adjustable mounting bracket (Catalog #9095) holds the TM-210 above 5-foot level on I.V. poles, anesthesia carts, etc. The mounting bracket allows easy removal of the TM-210 for recharging outside the surgery suites.

Temperature display: Celsius or Fahrenheit
 Display: 4-digit LED; 5" high (127 mm)
 Range: 32°F to 230°F or 0°C to 110°C
 Accuracy: ± 0.1°C in the biomedical range with reusable probes; (96°F to 106°F or 35.5°C to 41°C); ± 5% over the entire range
 Size: 2 1/4" x 6" x 6 1/4" (6.5 cm x 15 cm x 15.8 cm)
 Weight: 1.5 lbs. (680 grams)
 Temperature sensor: Thermistor - 2100 Series Disposables
 Probe Inputs: 2 each - two channel
 Power: 110 VAC Grounded or 220 VAC - Export
 Battery Operation: Rechargeable nicad battery allows up to 15 hours of continuous monitoring.

ADAPTER CABLES FOR MOST BRANDS OF TEMPERATURE MONITORS

NOTE: ADAPTER CABLES ARE REQUIRED IN ORDER TO USE THE DISPOSABLE TEMPERATURE PROBES

9003	Adapter FOR BENNETT CASCADE II (USE #2316 PROBE)	16.00
9004	Adapter FOR MONITORS USING YSI 400 (USE #2400 SERIES PROBES)	12.00
90041	Adapter FOR 3D/KDC/CAVITRON (USE #2400 SERIES PROBES)	18.00
90042	Adapter FOR HEWLETT-PACKARD "RIFLE SHOT" (USE #2400 SERIES PROBES)	12.00
90043	Adapter FOR GORMAN RUPP/HAMILTON (USE #2403 PROBE)	16.00
90046	Adapter FOR COROMETRICS (USE #2400 SERIES PROBES)	12.00
9007	Adapter FOR DATASCOPE & TEKTRONIX (USE #2700 SERIES PROBES)	12.00
90071	Adapter FOR SPACELABS "ALPHA SERIES" (USE #2700 SERIES PROBES)	16.00
90077	Adapter FOR SPACELABS "700 SERIES" (USE #2700 SERIES PROBES)	16.00
9009	Adapter FOR AIRSHIELDS/NARCO (USE #2904 PROBE)	12.00
9010	Adapter, EXTENSION 10' FOR USE WITH 9012 CABLE	12.00
9012	Adapter FOR ELECTROMEDICS, INC. (USE #2100 SERIES PROBES)	12.00

TERMS: All orders are subject to acceptance by Electromedics, Inc. Material furnished by Electromedics can be returned for repair or replacement if faulty. Before returning any material for credit, faulty or otherwise, written permission must be obtained. Any merchandise returned without written permission will be refused.

RESTOCKING CHARGE: 20% on returns with prior written authorization and returned freight prepaid.
PRICES: Prices do not include sales or excise taxes, and are subject to change without notice. All shipments will be made at price in effect at time of shipment.
MINIMUM ORDER ACCEPTED \$200.00

FREIGHT: F.O.B. DENVER, COLORADO: Prepaid and added to invoice.
TERMS OF PAYMENT: NET 30 DAYS.
PAST DUE ACCOUNTS: 1 1/2% (18% annual percentage rate) will be added each month to accounts unpaid for 30 days after net terms of the invoice.
 Prices, specifications, and terms are subject to change without notice.



ELECTROMEDICS, Inc.
 MEDICAL DIVISION

P.O. Box 3314, 109 Jcverness Dr. East, Englewood, CO 80155
 Phone: 303-770-6300 Western Union Telex: (D) 50495
 Telex: 900 525 7055 Int. (24) (24) (24) (24) (24) (24) (24) (24) (24) (24)

DISPOSABLE THERMISTOR PROBES

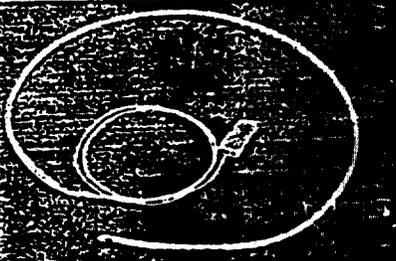
Quality and Accuracy in Temperature Measurement

CATALOG NO.	DESCRIPTION	PRICE EACH
ELECTROMEDICS 2100 SERIES DISPOSABLE TEMPERATURE PROBES are for use ONLY with Electromedics Thermistor Temperature Monitors.		
2101	Esophageal Stethoscope #12 French	\$430.00 per 50
2102	Esophageal Stethoscope # 18 French	435.00 per 50
2103	Esophageal or Rectal #9 French	322.50 per 50
2104	Skin Surface	270.00 per 50
2106	Esophageal Stethoscope #24 French	435.00 per 50
2111	In-Line Male Luer (Cardioplegia)	290.00 per 50
2112	In-Line Male Luer Tuohy-Borst	480.00 per 50
2115	Gas Flow 15mm male/female	295.00 per 50
2116	Gas Flow 22mm male/female	295.00 per 50
2124	Myocardium Needle 22 gauge 1/4"	240.00 per 10
2125	Myocardium Needle 22 gauge 1/4"	240.00 per 10
ELECTROMEDICS #2316 DISPOSABLE TEMPERATURE PROBES are for use ONLY with Bennett Cascade II Temperature Monitor/Controller.		
2316	Gas Flow 22mm for Bennett	295.00 per 50
ELECTROMEDICS 2400 SERIES DISPOSABLE TEMPERATURE PROBES are 3 feet long. Temperature probe interchangeability with Y.S.I. 400 series $\pm 2^{\circ}\text{C}$ in Biomedical Range.		
2401	Esophageal Stethoscope #12 French	430.00 per 50
2402	Esophageal Stethoscope #18 French	435.00 per 50
2403	Esophageal or Rectal #9 French	322.50 per 50
2404	Skin Surface	270.00 per 50
2406	Esophageal Stethoscope #24 French	435.00 per 50
2411	In-Line Male Luer (Cardioplegia)	290.00 per 50
2412	In-Line Male Luer Tuohy-Borst	480.00 per 50
2415	Gas Flow 15mm male/female	295.00 per 50
2416	Gas Flow 22mm male/female	295.00 per 50
ELECTROMEDICS 2700 SERIES DISPOSABLE TEMPERATURE PROBES are 3 feet long. Temperature probe interchangeability with Y.S.I. 700 Series $\pm 2^{\circ}\text{C}$ in Biomedical Range.		
2701	Esophageal Stethoscope #12 French	705.00 per 50
2702	Esophageal Stethoscope # 18 French	710.00 per 50
2703	Esophageal or Rectal #12 French	597.50 per 50
2704	Skin Surface	545.00 per 50
2706	Esophageal Stethoscope #24 French	710.00 per 50
2711	In-Line Male Luer (Cardioplegia)	565.00 per 50
2712	In-Line Male Luer Tuohy-Borst	647.50 per 50
2715	Gas Flow 15mm male/female	575.00 per 50
2716	Gas Flow 22mm male/female	575.00 per 50
ELECTROMEDICS #2904 DISPOSABLE TEMPERATURE PROBES are for use ONLY with Airshields/Narco Equipment using Airshields #17-575-14 Temperature Probes.		
2904	Skin Surface	290.00 per 50
DISPOSABLE ESOPHAGEAL STETHOSCOPE (W/O TEMPERATURE) for Monitoring of Heart, Lung and Breath sounds without electrical interference. Universal earpiece connector with soft PVC for patient comfort.		
6376	Esophageal Stethoscope #12 French 4mm O.D.	217.50 per 50
6379	Esophageal Stethoscope #18 French 6 mm O.D.	220.00 per 50
6380	Esophageal Stethoscope #24 French 8mm O.D.	220.00 per 50

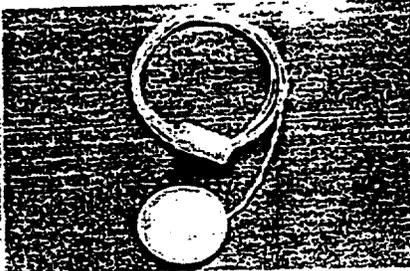


ELECTROMEDICS, Inc.
MEDICAL DIVISION

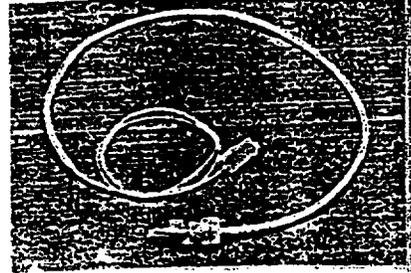
P.O. Box 3315, 109 Inverness Dr., East Englewood, CO 80155
Phone: 303-770-8794 Western Union Telex: DPMEDIC 45-0496
Telex: 890-527-0552 (International) 432-201-1375



Disposable esophageal/rectal temperature probe



Disposable skin surface temperature probe



Disposable fixed length male luer and adjustable Tuohy-Borst temperature probe

The ideal temperature sensing probe to use during surgery when you want a fast, accurate indication of subtle temperature changes. This probe is easy to use, inexpensive compared to permanent probes, and much safer to use. The medical-grade PVC sheathing provides excellent thermal sensitivity which allows for softening after placement and assures patient comfort. The small diameter reduces trauma, especially with children.

This temperature probe was designed to satisfy the most demanding medical staff's need for accurate skin temperature monitoring, especially in surgical and newborn care environments. In addition, it is cost efficient compared to permanent temperature probes that must be re-sterilized after each use. The surface skin probe adheres to the skin. Ideal for recovery rooms, labor and delivery rooms, critical care centers and neonatal nurseries. The backside of the adhesive foam pad is reflective mylar.

Designed to accommodate the increasing demand for accurate measurement of fluid and gas temperatures in line, the male luer model provides a universal connector that may be fitted to a female luer fitting. NOTE: The male luer was designed expressly for low temperature cardioplegia administration temperature monitoring only, do not use for temperature monitoring above 20°C. The Tuohy-Borst luerlock model permits the sensing probe length to be adjusted for optimum placement in the mainstream of the medium to be measured. The Tuohy-Borst is the ideal disposable temperature probe for deep shell oxygenator blood temperature measuring. Both style probes are made of medical-grade PVC plastics, these temperature probes have the advantages of being disposable, thus eliminating the need for re-sterilization.

Length: 18 in. (45.7 cm);
with wire, 36 in. (91 cm)
Accuracy: $\pm 0.4^{\circ}\text{F}$ ($\pm 0.2^{\circ}\text{C}$)
Range: 94°F to 106°F (34.5°C to 41.1°C)
Packaging: Sterile. Case of 50 (5 boxes of 10 probes each)

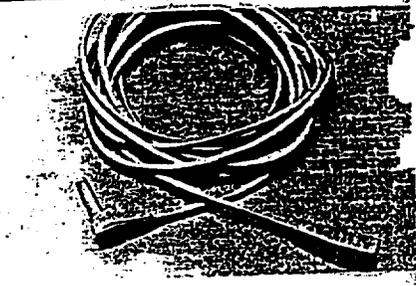
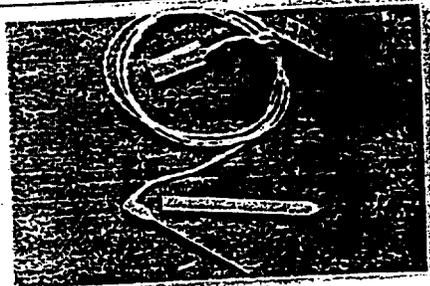
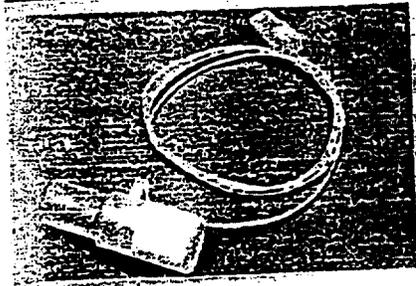
Length: Overall, with wire, 36 in. (91 cm)
Diameter: 1.0 in. (2.5 cm)
Accuracy: $\pm 0.4^{\circ}\text{F}$ ($\pm 0.2^{\circ}\text{C}$)
Range: 94°F to 106°F (34.5°C to 41.1°C)
Packaging: Sterile case of 50 (5 boxes of 10)

Length: Overall, with wire, 36 in. (91 cm)
Thermistor
Accuracy: 2111, 2411, 2711 $\pm .5^{\circ}\text{C}$
2112, 2412, 2712 $\pm .2^{\circ}\text{C}$
Range: 2111, 2411, 2711: 0°C to 20°C or 32°F to 68°F
2112, 2412, 2712: 0°C to 40°C or 32°F to 104°F
Packaging: Sterile. Case of 50 (5 boxes of 10)

Series 2103: for use with Electro-medics temperature monitors
Series 2403: for use with monitors accepting YSI series 400 temperature probes
Series 2703: for use with monitors accepting YSI series 700 temperature probes

2104: for use with Electro-medics temperature monitors
2404: for use with monitors accepting YSI 400 series temperature probes
2704: for use with monitors accepting YSI 700 series temperature probes
2904: for use with Airshields Infant Care Products

2111: Fixed length male luer
2112: Tuohy-Borst (adjustable) male luer
2111 and 2112 - for use with Electro-medics Temperature Monitors
2411: Fixed length male luer
2412: Tuohy-Borst (adjustable) male luer
2411 and 2412 - for use with monitors accepting YSI 400 series temperature probes
2711: Fixed length male luer
2712: Tuohy-Borst (adjustable) male luer
2711 and 2712 - for use with monitors accepting YSI 700 series temperature probes



Flow temperature probe

Disposable myocardial temperature probe

Extension adapter cables for disposable temperature probes

The flow temperature probe is a necessity where gases are administered by respirators, anesthesia gas and Intermittent Positive Pressure Apparatus. Electromedics feature male-to-female connection in 5 mm and 22 mm sizes that connect easily to most tubing circuits. Packaged sterile, they are ready for use, then disposed of without need to re-sterilize and re-package.

This disposable myocardial needle probe provides accurate temperature measurement of the myocardium during cardiovascular surgery. The small handle is designed to direct the wire at a right angle from the needle. This minimizes accidental removal of the needle because of pull from the weight of the wire. A drape clip is provided on the wire to relieve the weight of the wire and connector.

A re-usable extension adapter cable is required to connect an Electromedics Disposable Probe to the temperature monitor. The extension cable permits ample distance between the temperature monitoring unit and the disposable probe attached to the patient.

Adapter cables are available to accommodate a variety of major thermistor-based monitors. Designed to be re-usable, the cables are made of high-quality materials to insure positive connections.

Overall, with wire, 36 in. (91 cm)	Length: Overall, with wire, 60 in. (152.4 cm)	Length: 8 ft. - 9003
Accuracy: $\pm 0.4^{\circ}\text{F}$ ($\pm 0.2^{\circ}\text{C}$)	Needle: 22 gauge stainless steel with usable length of 1-3/4 in. (4.4 cm)	12 ft. - 9004, 9007, 9012
Range: 68°F to 106°F (20°C to 41.1°C)	Accuracy: $\pm 0.2^{\circ}\text{C}$ at 25°C	3 ft. - 9009
Packaging: Sterile. Case of 50	Range: 0° to 50°C	Packaging: One per package
	Packaging: Sterile. Boxes of 10	

115: for use with Electromedics temperature monitors	2125: for use only with Electromedics Temperature Monitors	9003: for use with Bennett MA-1 and MA-2 Cascade Controllers
2115-15 mm		9004: for use with monitors requiring YSI 400 series temperature probes or Electromedics 2400 series disposable temperature probes
2116-22 mm		9007: for use with monitors requiring YSI 700 series temperature probes or Electromedics 2700 series disposable temperature probes
315: 22mm for use only with Bennett MA-1 and MA-2 IPPB Cascade Temperature Controller		9009: for series 2900 disposable temperature probes (airshields)
5: for use with monitors accepting YSI 400 series temperature probes		9012: for use with Electromedics temperature monitors and Electromedics 2100 series disposable temperature probes
116: YSI 400 series temperature probes		
2415-15 mm		
2416-22 mm		
715: for use with monitors accepting YSI 700 series temperature probes		
2715-15 mm		
2716-22 mm		

Premarket Notification - Camino NeuroCare™

PREDICATE LABELING MONITOR

**SPECIFICATIONS
V420 DIRECT PRESSURE MONITOR**

Sensor Type	Fiberoptic pressure transducer
Measurement Range	-10 to +250 mmHg
Linearity and Hysteresis	See individual catheter specifications
Reference Pressure	Atmospheric
Display	Continuous CRT display of pressure waveform, mean, systolic and diastolic values
Frequency Response	120 Hz (-3 dB) at outputs 20 Hz (-3 dB) at CRT display
External Monitor Output	5 μ V/V/mmHg
Battery Type	Lead-acid
Charge Time	12 hours to full charge
Operation Time	1 hour from full charge
Power Requirement	100/115/220 VAC, .45/.4/.3A, 50/60 Hz
Dimensions	3 ³ / ₄ " x 10 ³ / ₈ " x 10 ³ / ₄ "
Weight	10 lb.

**SPECIFICATIONS
427 WAVEFORM/TREND RECORDER**

Recording Mechanism	Thermal array
Chart Speeds	50 mm/hr 25 mm/sec
Input	Digital, from V420 Monitor
Frequency Response	120 Hz (-3 dB)
Power Requirement	100/115/220 VAC, .45/.4/.3A, 50/60Hz
Dimensions	3 ³ / ₄ " x 8 ³ / ₈ " x 7 ³ / ₈ "
Weight	8 lb

Manufactured under one or more of: U.S.—Patent Nos 4,446,715, 4,705,047, 4,931,049, 4,903,707, 5,107,847 and Des. 285,112, 283,053, EPO—Patent No. 0127476.

Other U.S. and foreign patents issued and pending

camino
Laboratories

5955 PACIFIC CENTER BLVD. SAN DIEGO, CALIFORNIA 92121 (619)455-1115 FAX (619)455-8298 200496 REV E

**DIRECT PRESSURE
MONITOR WITH
WAVEFORM DISPLAY
MODEL V420**

**WAVEFORM/TREND
RECORDER
MODEL 427**

USER INFORMATION

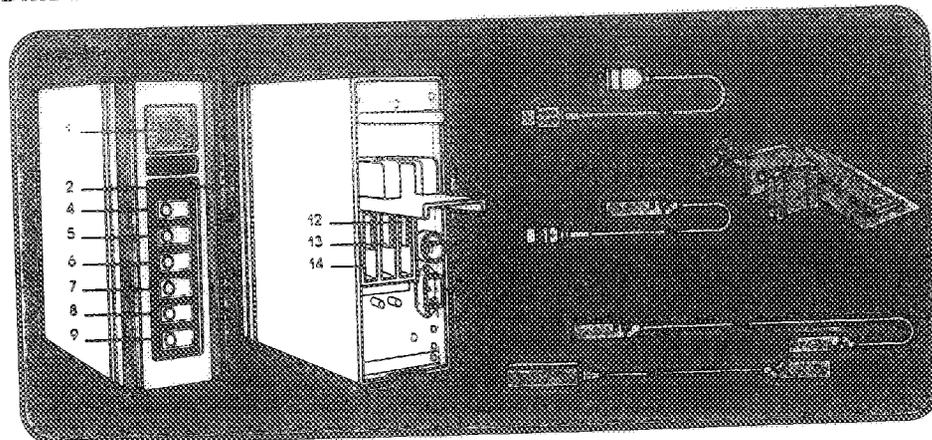
camino
Laboratories

000055

CAMINO V420

USER INFORMATION

DIRECT PRESSURE MONITOR WITH WAVEFORM DISPLAY — MODEL V420



FRONT PANEL

1. **CRT**— Displays pressure waveform, mean, systolic and diastolic values, trend data, and various "Help" messages.
2. **Low BATT Indicator**—Illuminates when V420 is operating on Battery power, and less than fifteen minutes battery life remains. Connect to AC power as soon as possible to prevent loss of trend data and to maintain battery charge.
3. **AC Power Indicator**—Illuminates when V420 is connected to AC power. Unit will charge battery whenever this indicator is illuminated.
4. **START/STOP Button**—Press to turn V420 on or off.
5. **SCALE**—Press to change scale of pressure waveform on CRT screen. Each press of SCALE button advances to the next range in the following series: 10, 20, 50, 100, 200 mmHg.
6. **CAL STEPS**—Used to calibrate or check correlation of external bedside monitor. Press and hold to momentarily interrupt normal pressure display and substitute an artificially-generated pressure signal, which will appear on both the V420 CRT screen and on the external bedside

- monitor. Each press advances to the next "cal step" in the following series: 0, 20, 40, 100, 200 mmHg.
7. **SYSTOLIC/DIASTOLIC**—Press to change V420 CRT display from MEAN ONLY to SYSTOLIC—MEAN—DIASTOLIC. Press again to return to MEAN ONLY.
8. **FREEZE**—Press and hold to momentarily freeze the waveform display. Mean, systolic, and diastolic values will continue to be updated.
9. **TREND DISPLAY**—Press to graphically display the last 8 hours of mean pressure values on the CRT screen. Press again to return to normal pressure display.

BACK PANEL

10. Power cord receptacle.
11. Circuit breaker switch.
12. Preamp extension cable receptacle.
13. External bedside monitor receptacle.
14. Accessory receptacle.

100

000056

SYSTEM DESCRIPTION

The Camino Direct Pressure Monitor is a compact, portable device for use with Camino Pressure Transducer-Tipped Catheters. Pressure is measured at the catheter tip, eliminating the need for external transducers, fluid, pressure tubing, and flush devices.

This system saves time and eliminates the cause of most artifacts, such as bubbles, leveling, clogged tubing, catheter whip, and noise due to patient movement. It provides a high fidelity, linear pressure response over its entire range.

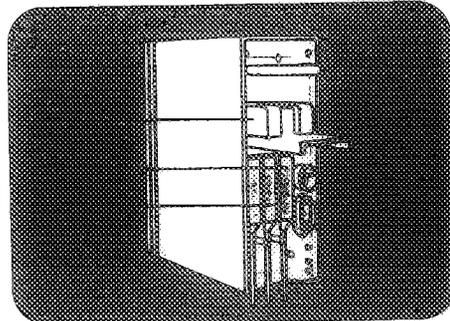
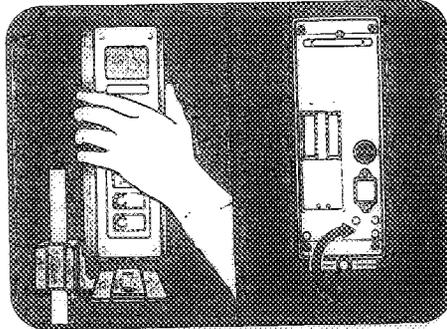
The Camino Monitor provides a continuous display of the pressure waveform, as well as mean, systolic, and diastolic values. A continuous record of mean pressure values over the most recent 8-hour period is stored in memory, and can be displayed on command as a "TREND". An optional stripchart accessory provides hard-copy output, including continuous trend recording. Although the Camino Monitor is intended to be a stand-alone system, it also conveniently connects to any hospital monitoring system. A built-in rechargeable battery permits monitoring during patient transport.

SET-UP

1. Carefully unpack the V420 Monitor, power cord, pole mount, and cables (Figure 1). Check to be sure each item is undamaged.
2. After attaching pole mount to pole, mount the V420 Monitor on pole mount and tighten locking bolt as shown (Figure 2).

NOTE: Pole mount may be attached to pole stand with $\frac{7}{8}$ " to $1 \frac{1}{8}$ " O.D. Make sure pole mount is properly attached to pole stand and locking bolts are securely tightened.

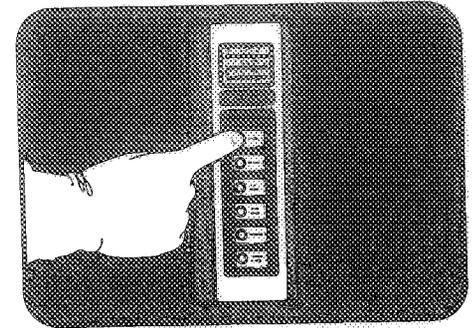
3. Connect the preamp extension cable as shown (Figure 3).
4. If connecting the V420 to an external bedside monitor system, connect the external bedside monitor cable as shown (Figure 3).
5. Insert the power cord into its receptacle on the back of the V420 Monitor (Figure 3). Then insert the plug into a grounded AC outlet.



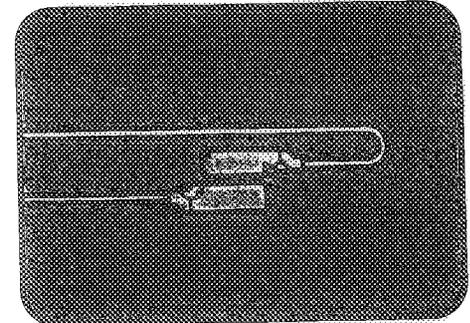
6. Turn on the power by moving the circuit breaker switch to its "up" position (Figure 3).

V420 OPERATION

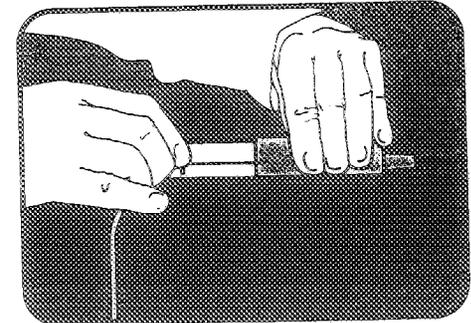
1. Turn on the V420 by pressing the START/STOP button on the front panel (Figure 4). The CRT screen will display a message. If no message appears, check that the circuit breaker switch on the back panel (Figure 3) is in the "up" position.



2. Connect the preamp cable to the V420 monitor by joining the two preamp cable couplers (Figure 5).
3. Select the desired Camino Pressure Monitoring Kit. Specific directions for use may be found in the User Information Insert provided with each Pressure Monitoring Kit.



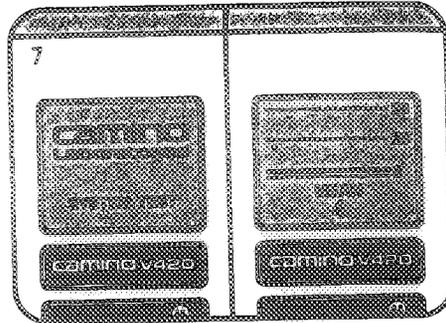
4. Remove the Transducer-Tipped Catheter from the Pressure Monitoring Kit tray, and firmly connect the transducer connector to the preamp connector (Figure 6).



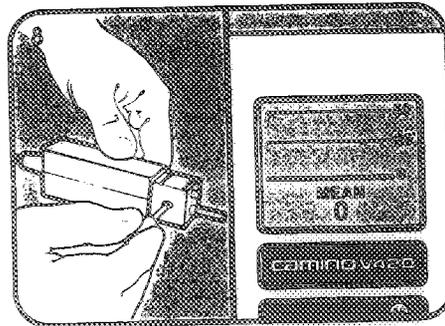
000057

V420 OPERATION, STEP 4, Continued

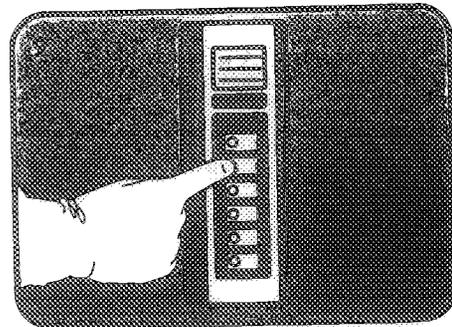
After a short system test, the CRT will change to pressure display (Figure 7).



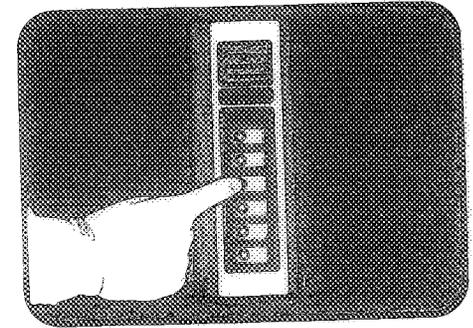
- Before insertion of catheter into patient, ensure that the Mean Pressure indicates "0". If not, use the tool from the catheter kit to turn the zero adjustment on the bottom side of the transducer connector until the Mean Pressure indicates "0" (Figure 8).



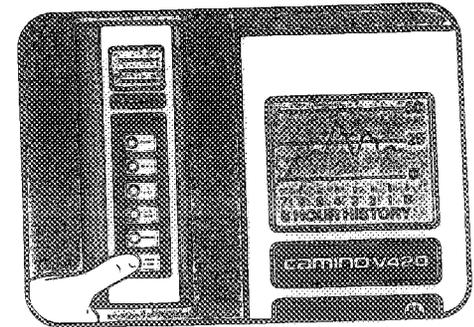
- After catheter has been inserted into patient, select the appropriate scale by repeatedly pressing the SCALE button on the V420 front panel (Figure 9).



- If the V420 is connected to an external bedside monitor, the CAL STEP button (Figure 10) may be used to calibrate or balance the bedside monitor. Each press advances to the next "CAL STEP" in the following series: 0, 20, 40, 100, 200 mmHg. The CAL STEP momentarily interrupts normal pressure display and substitutes a calibration pressure signal, which will appear on both the V420 CRT display and on the external bedside monitor. Press the CAL STEP button repeatedly until 0 is displayed on the V420. While keeping the button depressed to maintain 0, simultaneously zero the bedside monitor, then release the CAL STEP button. Within a few seconds the V420 display will return to the pressure display. Note that the CAL STEP button may be used at any time, and does not affect the transducer calibration.



- Press the trend button (Figure 11) to display the Mean Pressure values recorded during the preceding 8 hours. Press again to return to normal pressure and waveform display. To clear trend turn V420 Monitor off momentarily. NOTE: The trend information will be lost if the V420 is turned off.

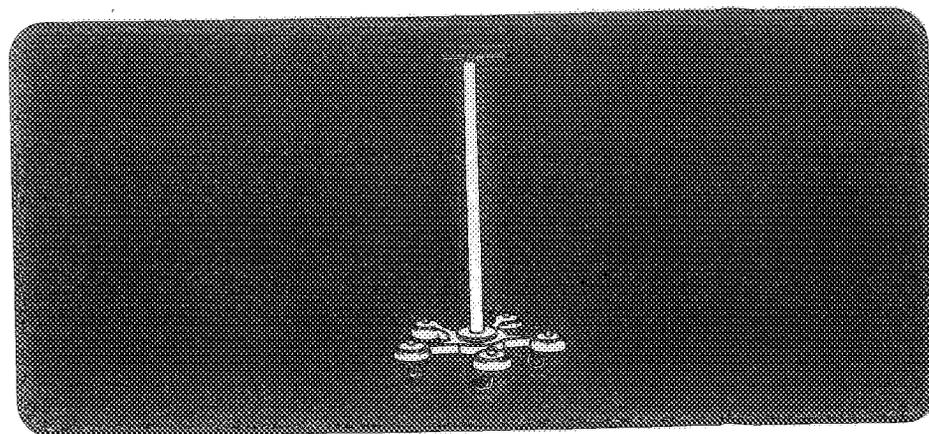


NOTE: When not in use, monitor must be connected to AC power to maintain battery charge.

000058

CAMINO POLE STAND

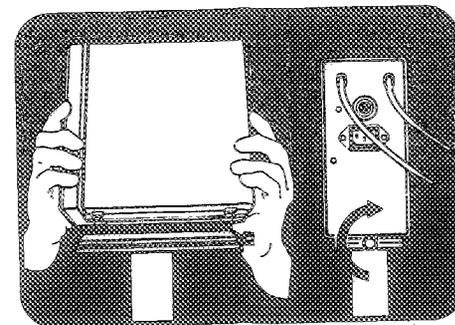
USER INFORMATION



As an option, the Camino V420 Monitor and 427 Recorder may be mounted on the Camino 428 Pole Stand.

SET-UP

1. Mount the 427 Recorder on the stand and tighten the locking bolt as shown (Figure 2).

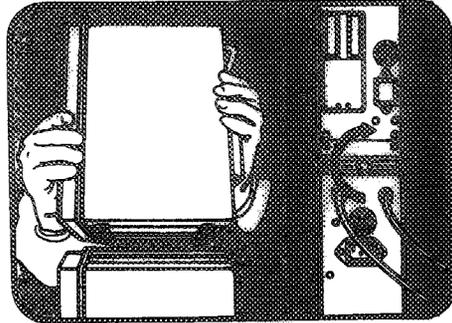


000059

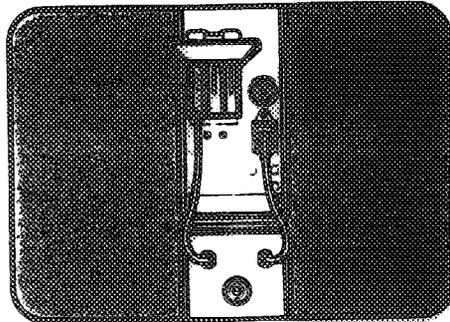
13

428 SET-UP Continued

2. Mount the V420 Monitor on top of 427 Recorder and tighten its locking bolt as shown (Figure 3).

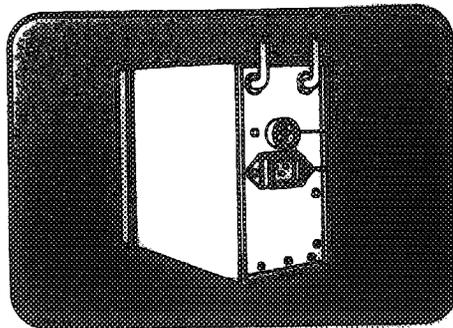


3. Connect the V420 interface cable to the V420 Monitor accessory receptacle (Figure 4).



4. Insert the short V420 power cable into the V420 power cord receptacle (Figure 4).

5. Insert the power cord into its receptacle on the back of the 427 Recorder (Figure 5). Then insert the plug into a grounded AC outlet.



NOTE: See V420/427 User Information for use of Direct Pressure Monitor, Waveform/Trend Recorder and Camino Transducer-Tipped Catheters.

V420 MONITOR TROUBLESHOOTING

Display won't turn on.	Verify circuit breaker switch in "up" position. If operating on battery, verify battery charged.
LOW BATT indicator illuminated.	Connect to AC power approximately 12 hours for full charge. Verify circuit breaker switch in "up" position.
Won't operate on battery.	Recharge for approximately 12 hours for full charge. When not in use connect to AC power.
Display reads: Check catheter connection, +350 or more, -99.	Check connection between catheter and preamp cable. Check connection between preamp cable and preamp extension cable. Check connection between preamp extension cable and V420 preamp extension cable receptacle. Replace preamp cable. Replace preamp extension cable. Replace V420 Monitor. Replace catheter.
Waveform off screen or too small.	Press SCALE button to change scale.

000060

CLEANING AND STERILIZING

Do not autoclave or immerse the Camino Direct Pressure Monitor, as damage may occur.

The Camino preamp cable can be sterilized with ethylene-oxide. It is a good practice to periodically clean the Camino Monitor outer surfaces by wiping with a soft, clean cloth that has been dampened with alcohol, warm water, or a general non-staining chemical disinfectant. Prepackaged alcohol wipes may also be used. Refer to the Housekeeping, Central Services, or Infection Control departments in your facility for further information.

Do not use solvents or cleaning agents as they could damage the plastic exterior of the monitor.

Camino Transducer-Tipped Catheters are for single use only. Do not attempt to resterilize. Camino Laboratories cannot assume any responsibility for damage caused by reesterilized catheters.

PRECAUTIONS

1. **DANGER** —Risk of explosion if used in the presence of flammable anesthetics.
2. **CAUTION** —To reduce the risk of electric shock do not remove cover. Refer servicing to qualified service personnel.
3. **CAUTION** —Read directions for use before connecting to patient monitors.
4. **CAUTION** —Grounding reliability can only be achieved when connected to a receptacle marked "Hospital Only" or "Hospital Grade".

SERVICE

Periodic preventive maintenance is necessary to ensure proper functioning and calibration of Model V420. The date on which the next maintenance is due can be found on the back panel of the unit. Contact Camino Laboratories or your local distributor for details.

If the Camino Monitor fails to perform as specified, and the cause cannot be determined, do not use it. Refer it to qualified service personnel. Additional user and service information can be obtained by writing:

CAMINO LABORATORIES, INC. 5955 Pacific Center Boulevard, San Diego, CA 92121-4309
Attn: Customer Service.

Please include a description of the type of information desired, and details of any difficulties you may have experienced.

You may also call us at (619)455-1115.

For technical assistance and user information, ask for Technical Support.

For monitor and accessory exchanges, contract information, and other ordering information, ask for Customer Service.

RETURNS

Should it be necessary to return a monitor to Camino Service Facility, contact Customer Service at the above address for return authorization and instructions. Camino Laboratories cannot assume any responsibility for loss or damage to returned equipment while in transit.



CAMINO LABORATORIES LIMITED WARRANTY

CAMINO warrants that each new CAMINO product is free from defects in material and workmanship under normal use and service for a period of two (2) years (except as otherwise expressly provided as to accessory items—see Camino price list) from the date of delivery by CAMINO to the first purchaser but not beyond the "Use Before" date stated on any product labeling. Any covered product which is placed by CAMINO under a lease, rental or installment purchase agreement and which requires repair service during the terms of such placement agreement shall be repaired on an exchange basis. If any such defect occurs during the warranty period of term of such placement agreement, the purchaser should communicate directly with the CAMINO home office (San Diego, CA). If returned to CAMINO at its home office, repair or replacement will be carried out at CAMINO's expense, subject to the terms of this warranty and the applicable agreement. The defective product should be returned promptly, properly packaged and postage prepaid. Loss or damage in return shipment to CAMINO shall be at CUSTOMER's risk.

IN NO EVENT SHALL CAMINO BE LIABLE FOR ANY INCIDENTAL, INDIRECT OR CONSEQUENTIAL DAMAGES IN CONNECTION WITH THE ACQUISITION OR USE OF ANY CAMINO PRODUCT. Further, this warranty shall not apply to, and CAMINO shall not be responsible for, any loss arising in connection with the purchase or use of any CAMINO product which has been repaired by anyone other than an authorized CAMINO service representative or altered in any way so as, in CAMINO's judgement, to affect its stability or reliability, or which has been subject to misuse, negligence or accident, or which has been used otherwise than in accordance with the instructions furnished by CAMINO. This limited warranty is exclusive and in lieu of all other obligations or liabilities on CAMINO's part and CAMINO neither assumes nor authorizes any representative or other person to assume for it any other liability in connection with CAMINO products.

CAMINO DISCLAIMS ALL OTHER WARRANTIES, EXPRESS OR IMPLIED, INCLUDING ANY IMPLIED WARRANTY OF MERCHANTABILITY OR OF FITNESS FOR A PARTICULAR PURPOSE OR APPLICATION OR WARRANTY OF QUALITY, OTHER THAN THOSE EXPRESSLY SET FORTH IN THE PRODUCT LABELING, INCLUDING THE APPLICABLE USER INFORMATION.

The foregoing shall not relieve CAMINO from strict tort liability, if otherwise applicable under governing law, for damages of personal injury caused by a product defect that made the product unreasonably dangerous at the time it was sold or placed.



SpaceLabs
A Squibb Company

**OPERATIONS
MANUAL**

90302/90303
PC BEDSIDE
PATIENT
MONITOR



Copyright © April 1986 SpaceLabs, Inc
No part of this document may be copied or transmitted in
any form without written permission of SpaceLabs, Inc.

000063

Table of Contents

Introduction

Purpose	vi
Scope	vi

Section 1: Getting Started

Overview	1-1
Front Panel Keys	1-2
Menu Keys	1-2
Physical	1-2
Interconnecting To Auxiliary Equipment	1-5
Environmental Considerations	1-5
Temperature	1-5
Leakage	1-5
Electrode Placement	1-5

Section 2: Operation

HELP Key	2-1
MONITOR SETUP Key	2-1
ALARM TONE Key	2-2
KEY TONE	2-3
BRIGHTNESS Key	2-3

Table of Contents

TIME/DATE Key	2-3
PATIENT NAME Key	2-4
SPECIAL FUNCTIONS Key	2-4
REMOTE VIEW Key	2-5
ALARM WATCH Key	2-5
RV/AW OFF	2-5
GRAPHIC TRENDS Key	2-6
TONE RESET/ALM SUSPEND Key	2-7
RECORD Key	2-7
PREVIOUS MENU Key	2-8
NORMAL SCREEN Key	2-8
Vertical Parameter Label Keys	2-8

Section 3: Monitoring ECG

ECG Module	3-1
Trending	3-1
ECG Key	3-2
ALARM LIMITS Key	3-2
SIZE Key	3-2
SWEEP SPEED Key	3-2
QRS TONE Key	3-3
LEAD SELECT Key	3-3
MORE Key	3-3

000065

Table of Contents

Section 4: Monitoring Pressure

Dual Pressure Module	4-1
LABEL SELECT Key	4-3
ZERO Key	4-3
ALARM LIMITS Key	4-3
SIZE Key	4-4
LABEL CHANGE Key	4-4
SCALES Key	4-4
SCALES/ON/OFF	4-5
ART Menu	4-5
ALARM LIMITS Key	4-5
SIZE Key	4-5
LABEL CHANGE Key	4-5
SCALES Key	4-6
FREEZE/ON/OFF	4-7
SIZE/CURSOR Key	4-7
ZERO Key	4-7

Section 5: Monitoring Pressure and Temperature

Pressure/Dual Temperature Module	5-1
TEMP Key	5-2
ALARMS/ON/OFF	5-2

Table of Contents

Section 6: Equipment Care

Unit Reliability	6-1
Visual Inspection	6-1
Cleaning	6-1
Preventive Measures	6-2
Corrective Measures	6-2

Section 7: Problem Solving

Diagnostics	7-1
-------------	-----

Section 8: Supplies and Accessories

Medical Supplies	8-1
------------------	-----

000067

Table of Contents

List of Figures

Figure No.	Title	
1-1	Front Panel	1-2
1-2	Rear Panel	1-4
1-3	Lead Placement	1-6
1-4	Electrode Application	1-7
2-1	Graphic Trends	2-6
3-1	EKG Module	3-4
4-1	Dual Pressure Module	4-1
4-2	Pressure Menu Display	4-2
4-3	Scaled Pressure	4-6
5-1	Pressure/Dual Temperature Module	5-1
5-2	Temperature Menu	5-2

000068

000069

142 vi

Introduction

Purpose

The purpose of this manual is to provide setup and operating procedures for the PC Bedside Monitor as manufactured by SpaceLabs, Inc.

Scope

Section 1 provides specifications, setup and installation procedures. Section 3 covers the operation of each of the front panel and touchscreen keys.

Monitoring ECG is discussed in Section 3. Section 4 covers monitoring pressure. Monitoring temperature is covered in Section 5.

Section 6 contains equipment care procedures, followed by Section 7, which provides problem solving guidelines.

Information on ordering additional parts is contained in Section 8.

Section 1: Getting Started

Overview

The PC Bedside Patient Monitor is a powerful microcomputer which provides multi-parameter monitoring and processing of information at the patient's bedside.

The monitor is controlled through the use of front panel keys and touchscreen keys. The touchscreen keys are referred to as "soft keys". They are software-generated control keys which are displayed on the screen of the monitor. The operator makes selections by touching the center of the key. The front panel keys are referred to as "hard keys" because they are not software-dependent.

The PC accepts up to four PC Input Modules which supply the necessary information for displaying touchscreen key labels, waveforms, and numerics for specific applications. The modules can be inserted and removed without interrupting the bedside operation of the monitor. The program modules process patient information for all monitor functions.

In order for Model 90302 to function properly, certain slot designations for modules must be followed. The ECG Module must be placed in the slot position of lower left (see Figure 1-1, #4). The lower right slot position is used for either Dual Pressure or Pressure/Dual Temperature. The top positions may be used for Dual Pressure or Pressure/Dual Temperature. When connected to the Alphas Interface, only one temperature will be displayed from the Pressure/Dual Temperature module.

An interchangeable program pack on the rear panel of the monitor (see Figure 1-2) contains programming for all functions.

Through its ability to communicate on SpaceLabs' Alphas Network (Model 90302), or an Ethernet local area network (Model 90303), the Bedside Patient Monitor can communicate with other bedside and central station devices.

This monitor runs on a powerful state-of-the-art processing system, based on a 16-bit microprocessor. It contains 512K bytes of Random Access Memory (RAM) and 256K bytes of Read Only Memory (ROM). It also displays up to five waveforms with their associated numerics and graphic symbols, plus all the necessary touchscreen key labels (specific to the input modules which are placed in the unit).

000071

90302/90303 PC Bedside Patient Monitor

**Front Panel
Keys**

The Bedside Monitor has been designed to accommodate add-on options such as a module expansion housing to hold additional PC Modules. The front panel keys (shown in Figure 1-1) are used to initiate actions such as strip-chart recordings, setting alarms, alarm tone suspension, reviewing previously displayed menus, modifying monitor setup, and also for accessing help messages.

Menu Keys

Menus are associated with certain front panel keys and with certain soft keys. Menus consist of a series of soft keys which are labeled according to their functions.

Physical

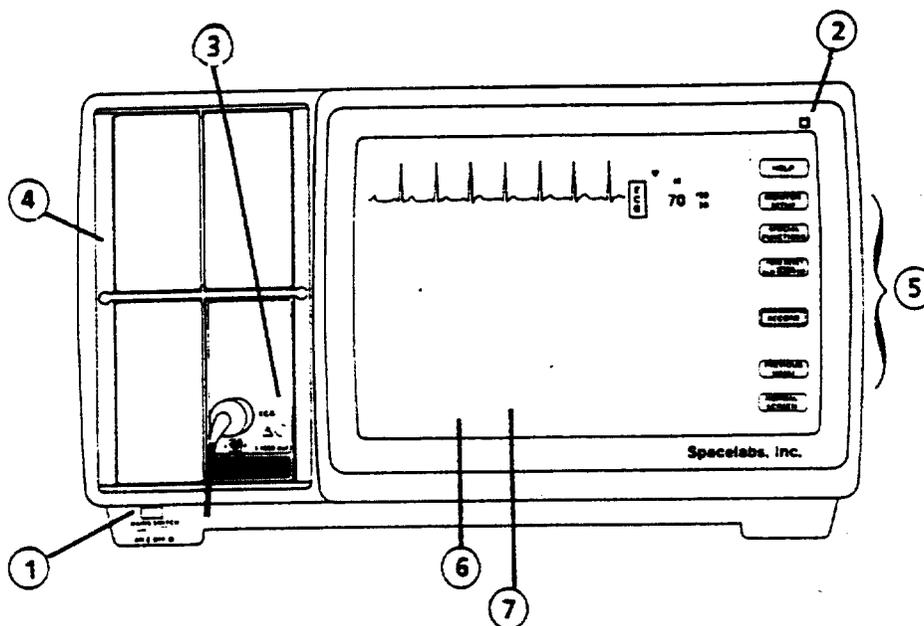
The physical size of the monitor is as follows:

Height	11.5" (29.2 cm)
Width	19.77" (50.2 cm)
Depth	17.0" (43.2 cm)
Weight	65 lbs. (29.5 kg)
Screen Size	12.0" (measured diagonally)

Display trace height = 4 cm dynamic range.

90302/90303 PC Bedside Patient Monitor

Figure 1-1.
PC Bedside Monitor
Front Panel

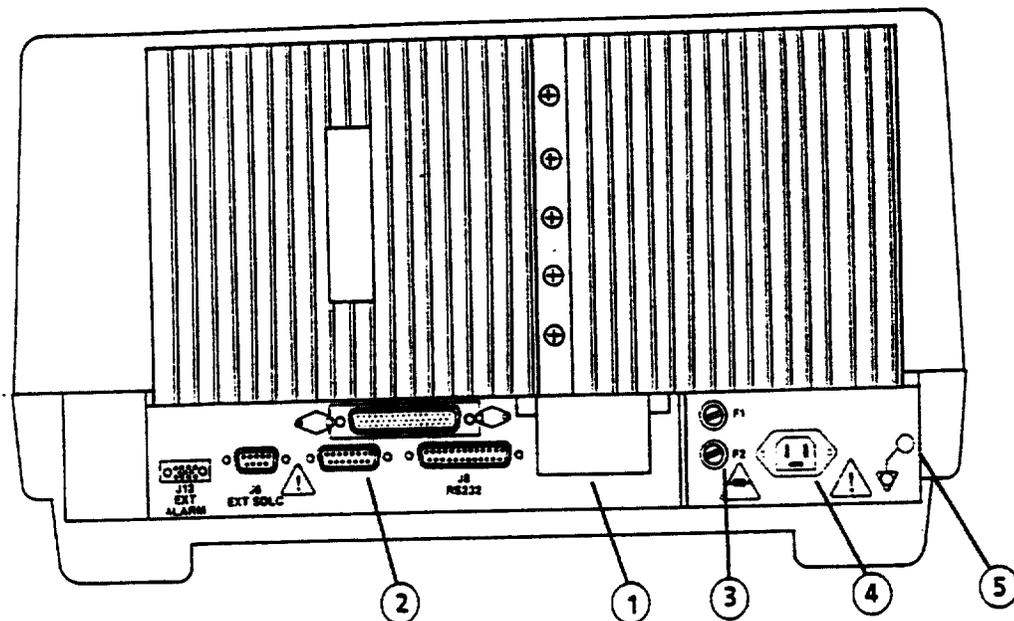


- ① Power Switch - Turns the monitor ON and OFF.
- ② Light Sensor - Senses ambient light and automatically adjusts the brightness of the display.
- ③ Access Indicators - Illuminate when the PC Monitor accesses module keys.
- ④ Program Module Areas - Four compartments for insertion of the Program modules.
- ⑤ Front Panel Keys (Hard Keys).
- ⑥ Menu Display Area - Where soft key menus are display.
- ⑦ Message Display Area - Where help and other messages are displayed.

000073

90302/90303 PC Bedside Patient Monitor

Figure 1-2.
PC Bedside Monitor
Rear Panel



- ① Interchangeable ROM Program Pack - Contains software for bedside operation.
- ② Communication Connectors - for SpaceLabs peripheral devices.
- ③ Fuses - Refer the replacement of fuses to the hospital biomedical engineer or to a SpaceLabs Customer Service Representative.
- ④ Power Cord Receptacle - Use only the power cord supplied with the PC. Connect to grounded AC Mains. Do not defeat the grounding system of Mains or the PC.
- ⑤ Mainframe Ground - Used as a secondary ground or to ground connected equipment.

147

90302/90303 PC Bedside Patient Monitor

Interconnecting To Auxiliary Equipment

Initial installations involving the connection of auxiliary equipment should be done by a hospital biomedical engineer or a SpaceLabs Customer Service Representative.

Environmental Considerations

Temperature

The monitor can be operated in ambient temperatures between 50-104° F (10-40° C).

This product has been designed to meet AAMI and UL Standards.

Leakage

Meets UL544 Standards for Electrical Safety.

Electrode Placement

Caution

Use high quality silver/silver chloride electrodes. Application of other electrodes may cause problems such as motion artifact and excessive recovery time. Do not use stainless steel electrodes.

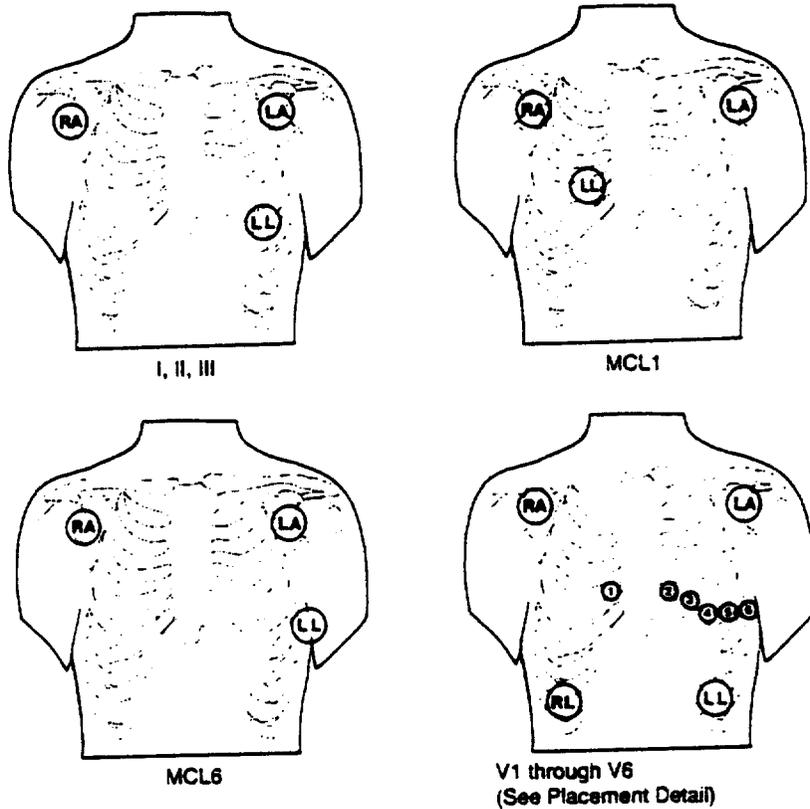
Attach the lead wires to the electrodes before you apply them to the patient. If you attach the lead wires after applying the electrodes, you may displace some of the conductive gel, resulting in signal degradation.

Match the electrode lead wire abbreviations to the corresponding limb abbreviations, as shown in Figure 1-3. For example, RA refers to the right arm. Place electrodes over bony areas of the body to minimize muscle artifact.

000075

90302/90303 PC Bedside Patient Monitor

Figure 1-3.
Lead Placement



Placement Detail: AVR, AVL, AVF(c) to be placed in positions 1-6 to correspond to V1 through V6. AVR, AVL, AVF may be obtained with or without (c).

If a lead failure occurs, the operator is notified. If possible, the failing lead is identified and another appropriate lead is automatically selected to continue monitoring.

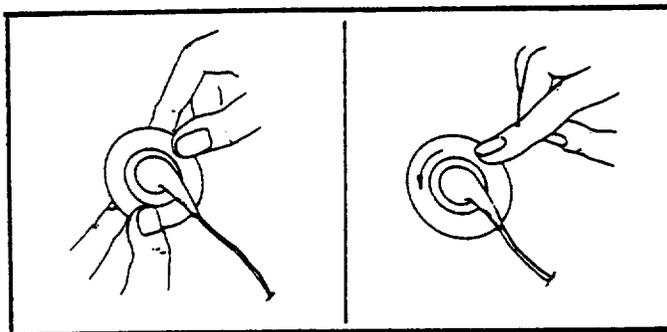
149

Prepare the patient for electrodes placement as follows:

1. Shave the area where electrodes are to be positioned.
2. Clean the skin with alcohol.
3. Dry thoroughly.

Electrodes are attached to the patient by pressing firmly around the entire edge of the adhesive surface, as shown in Figure 1-4.

Figure 1-4.
Electrode Application



APPLY OVER MINIMUM
MUSCLE AREA.

SMOOTH ELECTRODE
ADHESIVE AREA TO THE
SKIN WITH A CIRCULAR
MOTION.

000077

Section 2: Operation

This section will describe the functions of the various keys and menus associated with the PC Bedside Monitor. Hard keys (front panel) are activated by pressing them, as you would normally press a button. Soft keys (on the touchscreen) are activated by touching the center of the key, preferably with your finger. The use of the sharp objects may damage the screen.

When pressed, some keys activate soft keys (displayed on the screen), providing further options.

For specific information on Monitoring ECG, see Section 3. For Monitoring Pressure, see Section 4. For Monitoring Pressure and Temperature, see Section 5.

The first front panel key is the HELP key.



HELP must be used in conjunction with another key, whether it be a hard key from the front panel or a soft key from one of the menus.

The purpose of the HELP key is to provide information about the function of another key. For example, if you press HELP and then press the MONITOR SETUP key, the following message will be displayed in the message area of the screen:

"HELP: MONITOR SETUP - Accesses functions that pertain to the monitor itself. Example, setting alarm tone, screen brightness, etc."

The HELP messages will be displayed in the message area of the screen, located directly above the menu display area.

000078

90302/90303 PC Bedside Patient Monitor

MONITOR SETUP MENU

MONITOR SETUP Displays the following menu:

ALARM TONE	KEY TONE	BRIGHTNESS	TIME / DATE	PATIENT NAME
------------	----------	------------	-------------	--------------

For Model 90302 (Alphabus), only the first three keys shown on this menu apply.

MONITOR SETUP - ALARM TONE

ALARM TONE Displays the following menu:

TONE		VOLUME ↑	VOLUME ↓
ON	OFF		

This allows you to set the volume of the tone which sounds during alarm conditions. The tone must be set to the ON position before the VOLUME ↑ ↓ keys can be used. If OFF is highlighted, touch the key and ON will then be highlighted. The items on the screen which are highlighted (or appear in inverse video) are the currently selected items.

Inverse video means that the item appears with black characters on a green background, instead of the normal screen display of green characters on a black background.

Caution

It is not advisable to have the alarm tone set to OFF unless there is an alternate device available to provide alarm notification.

Use the VOLUME ↑ key to increase the volume and the VOLUME ↓ key to decrease the volume.

Notice that the borders of the VOLUME ↑ ↓ keys appear as solid lines until the maximum or minimum volume has been reached. At that point, the borders become dotted. This will happen with all ↑ ↓ keys within the various menus.

Note

If an alarm condition occurs, the tone will sound and the violated parameter's alarm menu will automatically be displayed (provided that no other menu is displayed at that time).

After the volume has been adjusted to the desired level, press the PREVIOUS MENU key (on the front panel) to continue with the setup procedure.

000079

90302/90303 PC Bedside Patient Monitor

MONITOR SETUP - KEY TONE

**KEY
TONE**

Displays the following menu:

TONE		VOLUME ↑	VOLUME ↓
ON	OFF		

This allows you to select a volume setting for the touch-sensitive menu keys which are displayed on the screen. Each time you touch the screen to make a selection, you will hear this tone. Use the VOLUME ↑ ↓ keys to adjust the volume.

Press the PREVIOUS MENU key on the front panel.

The next adjustment you may want to make is to the brightness of the display screen. This may not be necessary since the screen has ambient light sensors which automatically adjust it to the correct setting. If this automatic setting is satisfactory, proceed to the TIME/DATE key. To adjust the brightness, touch the BRIGHTNESS key.

MONITOR SETUP - DISPLAY BRIGHTNESS

**BRIGHT-
NESS**

Displays the following menu:

↑	↓
---	---

Use the ↑ ↓ keys to adjust the brightness until it reaches the desired level.

Press the PREVIOUS MENU key to proceed to the TIME/DATE settings.

MONITOR SETUP - TIME/DATE

**TIME /
DATE**

Displays the following menu:

TIME	24	AM	HOURS	MINUTES	↑	↓	ENTER
DATE	HOURS	PM					

In this menu you may select either a 24 hour mode or AM/PM settings for time. Note that this menu has an ENTER key. You must touch the ENTER key after all changes have been made in order to establish the new settings. Otherwise, the time will remain at the previous setting.

Note

On the Ethernet network (Model 90303), setting the time at any one Bedside Monitor or Central Display unit will set it for the entire system.

000080

90302/90303 PC Bedside Patient Monitor

Now touch the TIME/DATE key to set the DATE.

When DATE is highlighted, the menu keys will reflect date settings, as follows:

MONITOR SETUP - TIME/DATE

TIME	MONTH	DAY	YEAR
DATE			

↑	↓	ENTER
---	---	-------

When DATE is selected, MONTH will also be highlighted. Use the ↑ ↓ keys to adjust the setting for month. Now touch the DAY key. Note that MONTH is no longer highlighted. Set the day using the arrow keys and then touch the YEAR key. Use the arrow keys to set the year and then touch ENTER.

PATIENT NAME

Displays the following menu:

↑	↓	←	→	ENTER	START OVER
---	---	---	---	-------	------------

When this menu is displayed, the cursor will be positioned on the first letter of the first name. The ← → arrow keys are used to move forward/backward within the name, and the ↑ ↓ arrow keys are used to scroll through the letters of the alphabet. The sequence for the ↑ ↓ keys is A-Z, followed by a blank space, special characters, and numerics. Use the ↑ ↓ keys to scroll through the alphabet until you come to the correct letter for the first letter of the patient's first name. Use the → key to advance to the second letter of the name. Continue this procedure until the entire name is correct, then press ENTER. The maximum length allowed for PATIENT NAME is 15 characters.

Press the PREVIOUS MENU key (front panel) to return to the main MONITOR SETUP menu, or press the NORMAL SCREEN key to remove the currently displayed menu.

SPECIAL FUNCTIONS MENU

SPECIAL FUNCTIONS

Displays the following menu:

ALARM WATCH	SCREEN FORMAT	RV / AW OFF	GRAPHIC TRENDS
-------------	---------------	-------------	----------------

On Model 90302 (Connected to the Alphas Interface), GRAPHIC TRENDS will be the only soft key displayed under SPECIAL FUNCTIONS.

154

90302/90303 PC Bedside Patient Monitor

REMOTE VIEW MENU

REMOTE VIEW

Displays the following menu:

BED#	BED#	BED#	BED#	BED#
------	------	------	------	------

Up to nine channels can be displayed on this menu. If more than nine BED#'s are on the system, the first seven BED#'s will be displayed with a MORE key. Touching the MORE key will display the remaining BED#'s.

When a BED# is selected from this menu, the parameters for that patient are displayed. After one of these parameters has been selected for viewing, the parameter label key appears in the fifth waveform zone, along with the selected patient's BED# and the waveform for that parameter.

SPECIAL FUNCTIONS - ALARM WATCH MENU

ALARM WATCH

BED#	BED#	BED#	BED#	REC#
ON OFF				

ALARM WATCH allows you to determine which beds are watched for alarm conditions, where BED# will be the actual room number of each bed connected to the system. Up to nine channels can be displayed. If more than nine beds are connected on the system, the first seven BED#'s and a MORE key will be displayed. Touching the MORE key will display the remaining BED#'s. A CENT# will be displayed for each Central Display unit on the system. A REC# key will be displayed (a dotted key) for each PC Central Recorder on the system.

When ALARM WATCH is invoked, the following message is displayed in the 5th waveform zone:

"Area reserved for ALARM WATCH.
To turn off function, touch OFF key".

OFF

Press the PREVIOUS MENU key to return to the SPECIAL FUNCTIONS menu.

**RV / AW
OFF**

Allows you to turn the functions REMOTE VIEW and ALARM WATCH OFF.

000082

155

90302/90303 PC Bedside Patient Monitor

GRAPHIC TRENDS MENU

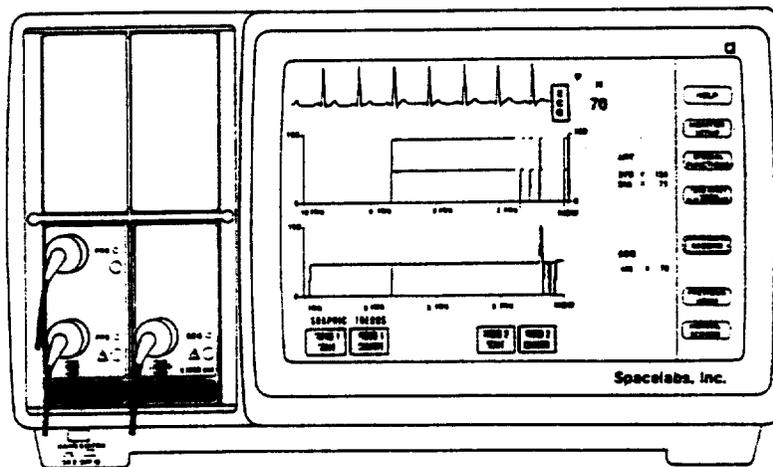


The CLEAR TRENDS key is not displayed on Model 90302 (Alphabus).

The CLEAR TRENDS key will erase the trend information from memory.

Figure 2-1 shows a GRAPHIC TRENDS display.

Figure 2-1.
Graphic Trends



GRAPHIC TRENDS displays information in the form of a line graph, covering a twelve hour period. In the GRAPHIC TRENDS menu, the SCALES keys adjust the vertical scale of the trend graph. The available scales are dependent upon the selected parameter type. The CHANNEL keys are used to select the parameter trend for display. Each time a CHANNEL key is touched, the display advances to the next parameter.

The GRAPHIC TRENDS Scales are as follows:

<u>Parameter</u>	<u>Default Scale</u>	<u>Range/Units</u>
ECG	0-150 bpm	1/bpm
ART	0-150 mmHg	1/mmHg
PA	0-150 mmHg	1/mmHg
CVP, ICP	0- 40 mmHg	1/mmHg
PRS (other)	0- 40 mmHg	1/mmHg

Temperature: 36.0 - 42.0°C.

Delta Temp: 0-35.0°C.

Available Scales: 0-10, 0-20, 0-40, 0-80, 0-150, 0-300

Available Scales - TEMP: 0-50.0, 15.0-40.0, 36.0-46.0, 36.0-42.0°C.

Available Scales - DELTA TEMP: 0-35.0, 0-10.0°C.

000083

**TONE RESET
ALM SUSPEND**

When an alarm condition occurs, pressing this key will silence the alarm tone for a period of 45 seconds. The ALM SUSPEND function of this key is activated with a second press of the key. It disables all alarms for a period of three minutes. A third press of the key reenables alarm detection.

If this key is pressed when no alarms are occurring, alarms are suspended for three minutes (alarms are automatically reenabled after three minutes have lapsed). Pressing the key a second time before three minutes elapse will reactivate alarm detection.

RECORD

Pressing the RECORD key activates the recorder and allows the operator to select any waveform parameter to be recorded.

When the RECORD key is pressed, all waveform parameter keys displayed on the screen will flash to indicate that they are eligible to be recorded. Touching one of these flashing parameter keys will result in that parameter being recorded.

Up to three of the flashing parameters may be selected to record from any one PC Bedside or Central Display at a time. If more than three recording requests are sent from any one bedside or central unit, the first three requests will be recorded and the remaining requests will be ignored. The order in which they are selected determines the order in which they are recorded. The queue of the recorder can store up to four requests at a time.

The selected parameters are placed in the recorder's memory prior to the time the recorder actually begins printing. In other words, the recorded information is that which was present at the time of selection. This is useful in recording alarm conditions as they occur.

The parameter being recorded will be recorded for a duration of twenty seconds. However, an alarm initiated recording will continue to be recorded until the alarm condition no longer exists. Subsequent alarm initiated recordings awaiting their turn in the queue of the recorder will be converted to twenty second recordings.

Alarm initiated recordings take precedence over manual recordings that are waiting in the queue of the recorder, but will not interrupt a recording that is already in progress.

000084

90302/90303 PC Bedside Patient Monitor

**PREVIOUS
MENU**

The purpose of this key is to take the operator one step back in the menu hierarchy (to whichever menu was displayed immediately before the currently displayed menu).

**NORMAL
SCREEN**

The purpose of this key is to clear all menus from the screen, returning the screen to a normal display of patient information.

**Vertical Parameter
Label Keys**

The parameter labels displayed on the screen of the PC Bedside Monitor are dependent on the input modules which are inserted in the front panel of the monitor. The following sections provide menu information and the functions of each of the modules.

000085

Section 3: Monitoring ECG

ECG Module

The ECG Module (Model 90401) can be inserted into either of the two bottom slot positions for Model 90303. Model 90302, using the Alphas Interface, requires the bottom left position for proper operation.

The module uses a standard AAMI connector.

Indicator lights on the modules will illuminate whenever the PC accesses the module controls.

The module (shown in Figure 3-1) provides ECG signal acquisition and processing. It acquires ECG signal data using disposable electrodes. The data is processed by microcircuitry within the module to determine lead configuration options and to calculate heart rate. This information is then transmitted to the PC Bedside Monitor for display on the screen. The module has the ability to automatically detect pacemaker spikes. It enhances pacer spikes for display, while rejecting the spike from the heart rate counter.

The ECG Module supplies data for the ECG waveform display, heart rate, lead selection, QRS, and alarm indicators. The key labels and data are transferred between the module and the bedside unit via a high speed data link.

The module triggers alarms on occurrences of heart rate violation and asystole. When the heart rate alarms are turned to the ON position, the module automatically sets preliminary alarm limits based upon the patient's heart rate at that time. These limits are easily modified by the operator.

The module recognizes a lead failure and will notify the operator. When possible, the module will identify the faulty lead and will switch to another appropriate lead configuration to continue monitoring.

Trending

Trending is done on all measured parameters with a trend time span of 12 hours.

When the ECG Module is inserted into one of the compartments on the front panel of the PC and a patient is connected, the message "IN LEARN" is displayed in the first waveform zone for approximately 30 seconds. A

90302/90303 PC Bedside Patient Monitor

vertical soft key labeled ECG will then be displayed to the right of the first waveform zone and a blinking heart light will be displayed next to the key.

ECG MENU

E
C
G

ALARM LIMITS	SIZE	SWEEP SPEED	QRS TONE	LEAD SELECT
--------------	------	-------------	----------	-------------

ECG MENU - ALARM LIMITS

ALARM
LIMITS

ALARMS		HI =	LO =	↑	↓
ON	OFF				

ALARMS must be ON in order for the other menu keys to be valid. You must select either HI = or LO = before the ↑ ↓ keys will be valid. The values shown in the HI = and LO = keys are the current settings for alarm limits. Touch the ↑ key to increase the value or the ↓ key to decrease the value. The displayed values will be increased or decreased (in increments of five) with each touch of an arrow key. Once the maximum or minimum allowable value has been reached, the border of the arrow key becomes a dotted line to indicate that the key is no longer functional.

Press the PREVIOUS MENU key to return to the main ECG menu.

ECG - SIZE

SIZE

SIZE ↑	SIZE ↓
--------	--------

This allows you to change the size of the waveform display for ECG. Touch the SIZE ↑ to increase the waveform size or touch the SIZE ↓ to decrease it.

Press the PREVIOUS MENU key.

ECG - SWEEP SPEED

SWEEP
SPEED

50 mm/sec	25 mm/sec
--------------	--------------

The currently select sweep speed is highlighted. To change it, simply touch the desired key.

Press the PREVIOUS MENU key.

000087

90302/90303 PC Bedside Patient Monitor

ECG - QRS TONE

QRS
TONE

TONE		VOLUME ↑	VOLUME ↓
ON	OFF		

If the TONE is set to OFF, the VOLUME keys are invalid. To modify the tone, set the TONE key to the ON position by touching the TONE/ON/OFF key. Use the VOLUME ↑ ↓ keys to adjust the volume of the tone. The QRS tone is audible when the tone is ON. The tone will sound with the detection of each "R" wave, in synchronization with the blinking heart symbol.

Press the PREVIOUS MENU key.

ECG - LEAD SELECT

LEAD
SELECT

I	II	III	V1	V6
---	----	-----	----	----

MORE

The currently selected lead configuration will be highlighted. When configurations requiring accurate placement of the chest electrode (C) are selected, a message is displayed on the screen with relation that selection. For example, if V6 is selected, this message is displayed:

"(C) 5th intercostal space, left midaxillary line."

This will not occur when standard lead selections are chosen, such as I, II, III, or augmented lead configurations.

MORE

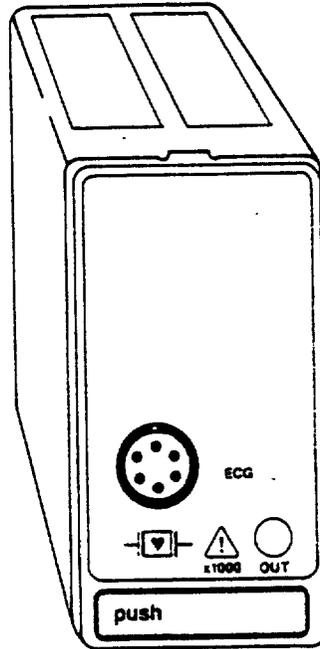
AVR	AVL	AVF	V2	V3	V4	V5
-----	-----	-----	----	----	----	----

Press the NORMAL SCREEN key to remove the menu display and return to the normal display screen.

000088

90302/90303 PC Bedside Patient Monitor

Figure 3-1.
ECG Module
Model 90401

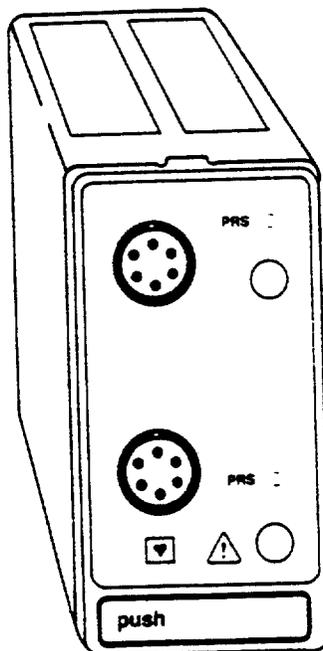


Section 4: Monitoring Pressure

Dual Pressure Module

The Dual Pressure Module provides invasive pressure signal acquisition and processing. This module receives pressure signals from a strain-gage transducer. The module then processes, stores, and transmits the data to the Bedside Monitor for display on the screen. The signal data is processed to derive systolic, diastolic, and mean pressure values (where applicable). When the module is installed, it performs a self-test on its internal circuitry.

Figure 4-1.
PC Dual
Pressure Module
Model 90402



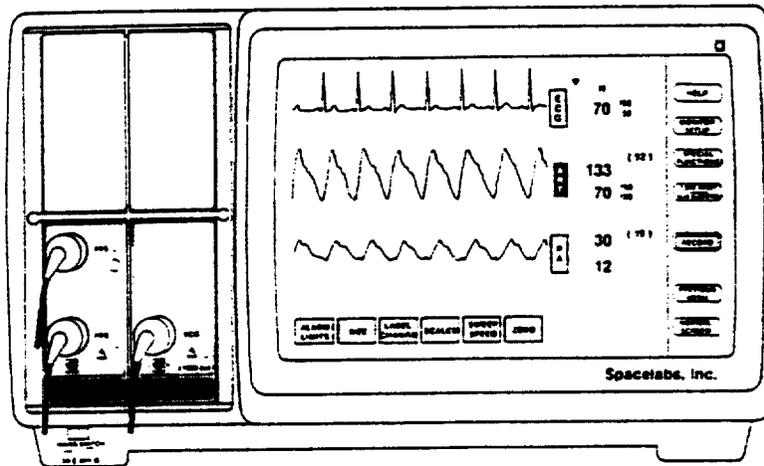
000090

90302/90303 PC Bedside Patient Monitor

A pressure channel automatically becomes active when a transducer is connected to the channel. The pressure channel is automatically removed when a transducer is disconnected from the channel.

When a transducer is connected to one of the channels, the operator is prompted through an initialization and setup procedure which includes selection of a pressure label of ART, PA, CVP, RAP, LAP, ICP, or PRS to identify the measurement site as Arterial, Pulmonary Artery, Central Venous, Left or Right Atrium, Intracranial, or generic pressure. The selected label will be displayed on the screen next to the waveform display for that channel. The operator must also zero the channel, as discussed in the following paragraphs.

Figure 4-2.
Pressure Menu
Display



164

90302/90303 PC Bedside Patient Monitor

When the PC Bedside requests data from the module, it is transferred through a high-speed data link.



When a transducer is first connected, the vertical parameter label key will be blank. Touch the key and it changes to inverse video.

Touch the LABEL SELECT key to select a pressure type.

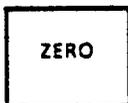


Displays the following menu:

ART	PA	CVP	RAP	LAP	ICP	PRS (others)
-----	----	-----	-----	-----	-----	-----------------

Zeroing a Channel

After a label is selected, it is displayed in the parameter label key. The message "NOT ZEROED" will be displayed to the right of the key.



Touch the ZERO key to start the zeroing process. The message "ZEROING..." will be displayed.

After successful completion of the zeroing process, the actual pressure values and the following message will be displayed:

"ZEROING COMPLETED. (offset = XX mmHg)."

The main PRESSURE menu will now be displayed. The menu for pressures labeled ART, PA, CVP, RAP, and LAP is as follows:

ALARM LIMITS	SIZE	LABEL CHANGE	SCALES	ZERO
-----------------	------	-----------------	--------	------

The menu for pressures labeled ICP and PRS is the same as the above, with the addition of a SWEEP SPEED key.



Displays the following menu:

ALARMS		HI =	LO =	↑	↓	SYS	DIA	MEAN
ON	OFF							

The ALARMS/ON/OFF key turns ALARMS for pressure ON/OFF. The default setting is OFF. When ALARMS are ON, high and low default limits are set, based on the current pressure value. After selecting either HI = or LO =, the limit can be set using the ↑ ↓ keys.

1105

90302/90303 PC Bedside Patient Monitor

Between -50 to +30, the ALARM limits are incremented/decremented in steps of one (47, 48, 49, etc.), and from 30 to 300, they are incremented/decremented in steps of five (35, 40, 45, etc.). The HI = limit cannot be set lower than the LO = limit and the LO = limit cannot be set higher than the HI = limit. If this is attempted, an error message will be displayed.

The SYS, DIA, and MEAN keys are displayed for pressures having systolic, diastolic, and mean values. Their purpose is to identify which pressure parameter is associated with the ALARM LIMITS menu. Only one of these can be selected at a time.

When the ALARM LIMITS option is selected from the main menu and limits have been set for more than one pressure value, systolic will be selected by default. If limits have only been set for one pressure value, that value will be selected.

If the menu display area is not available when an alarm condition occurs, the following message will be displayed.

"XX ALARM - Select NORMAL SCREEN key to view limits menu".

If an alarm condition occurs when the menu display area is empty and ALARMS are ON, an ALARM menu for that pressure is displayed. Either HI = or LO = will be flashing to indicate that it is the violated limit.

Alarms can be silenced by pressing the TONE RESET/ALM SUSPEND key on the front panel of the monitor.

SIZE MENU

SIZE

Displays the following menu:

SIZE ↑	SIZE ↓
--------	--------

The SIZE ↑ ↓ keys are used to increase/decrease the size of the pressure waveform.

LABEL CHANGE MENU

LABEL CHANGE

Displays the following menu:

ART	PA	CVP	RAP	LAP	ICP	PRS (others)
-----	----	-----	-----	-----	-----	--------------

Only one pressure label can be selected at a time. Stored data for each pressure label is retained under that label. Changing a label will not cause the data from the formerly selected label to be lost.

000093

90302/90303 PC Bedside Patient Monitor

SCALES MENU

SCALES

Displays the following menu:

SCALES		FREEZE		SIZE		
ON	OFF	ON	OFF	CURSOR	↑	↓

ZERO

Any pressure can be placed in scaled mode, but a maximum of two pressures can be scaled at the same time. In scaled mode, the screen assumes a five waveform display, with ECG displayed in the top zone. If a second (unscaled) waveform is displayed, it will be in zone 2.

SCALES	
ON	OFF

The SCALES/ON/OFF key gives the operator the option of retaining (or not retaining) scaled information when the NORMAL SCREEN key is pressed. The default position is ON. When SCALES are ON, the scales will remain ON when NORMAL SCREEN is pressed.

The vertical parameter label keys will display menus which are specific to their use. For example, the menu for ART is as follows.

ART MENU

**A
R
T**

Displays the following menu:

ALARM LIMITS	SIZE	LABEL CHANGE	SCALES	ZERO
--------------	------	--------------	--------	------

ART - ALARM LIMITS

ALARM LIMITS

Displays the following menu:

TONE								
ON	OFF	HI =	LO =	↑	↓	SYS	DIA	MEAN

When ALARMS are set to OFF, the remaining keys appear as dotted boxes, showing they are invalid. Set ALARMS to ON by touching the ALARMS/ON/OFF key. The current high and low alarm limit settings will be displayed in the HI = and LO = keys. After selecting HI = or LO =, use the ↑ ↓ keys to raise or lower the limit. The selected Systolic (SYS), Diastolic (DIA) or Mean (MEAN) pressure will be highlighted.

SYS, DIA, and MEAN are menu options for ART, PA, and PRS. All other pressures have only the MEAN pressure displayed.

SIZE MENU

SIZE

Displays the following menu:

↑	↓
---	---

The SIZE key allows you to select the size of the selected pressure waveform. Touching this key displays the following:

000094

90302/90303 PC Bedside Patient Monitor

LABEL CHANGE MENU

LABEL CHANGE

Displays the following menu:

ART	PA	CVP	RAP	LAP	ICP	PRS (others)
-----	----	-----	-----	-----	-----	--------------

The currently selected pressure type will be highlighted. If another pressure type is selected from this menu, a menu specific to that pressure will be displayed.

The same main menu used for ART is also used for PA, CVP, RAP, and LAP. For pressures labeled ICP and PRS, a SWEEP SPEED key is added.

SCALES MENU

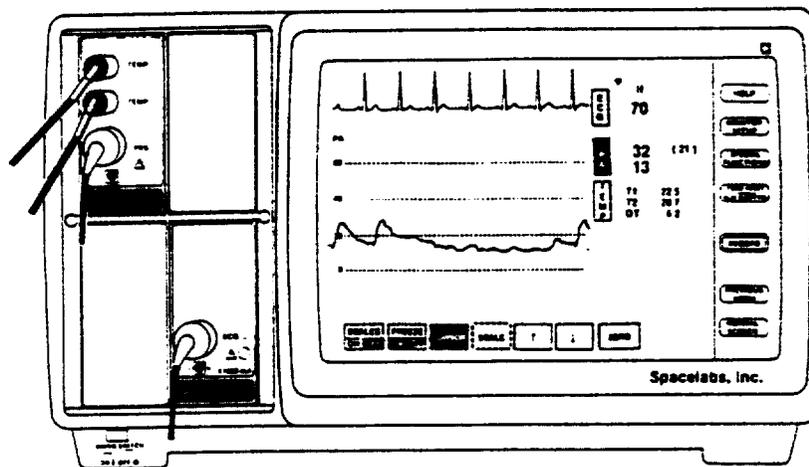
SCALES

Displays the following menu:

SCALES		FREEZE		SIZE	ZERO
ON	OFF	ON	OFF	CURSOR	

Where cursor = X refers to the position of the cursor. Any pressure can be in scaled mode, but a maximum of two pressures can be scaled at the same time. When SCALES are OFF and the NORMAL SCREEN key is pressed, SCALES remain OFF. If SCALES are ON when the NORMAL SCREEN key is pressed, the SCALES will remain ON.

Figure 4-3.
Scaled Pressure Menu



000095

1108

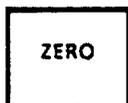
90302/90303 PC Bedside Patient Monitor



The **FREEZE** option is used to freeze/unfreeze the trace which was placed in scaled mode. To unfreeze the screen, either touch the **FREEZE/ON/OFF** key so that **OFF** is highlighted, or simply exit this menu by pressing the **PREVIOUS MENU** key or the **NORMAL SCREEN** key.



The **SIZE/CURSOR** key is used to toggle between the functions of **SIZE** and **CURSOR**. When **SIZE** is selected (highlighted) the arrow keys can be used to increase or decrease the size of the pressure waveform. When **cursor** is selected, the cursor may be moved up and down in the scale to give precise measurements of various points in the waveform.



The **ZERO** key is used to balance the transducer.

000096

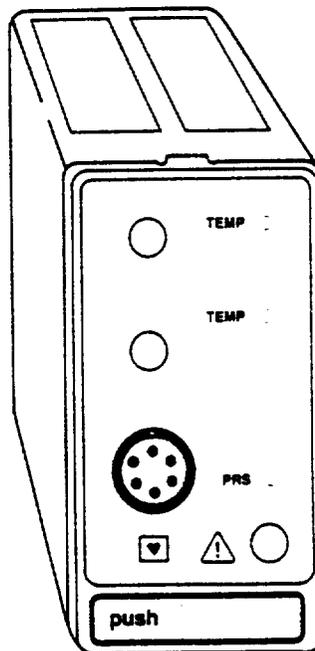
Section 5: Monitoring Pressure and Temperature

Pressure/Dual Temperature Module

Model 90403 is the PC Pressure/Dual Temperature Module which provides invasive pressure and temperature signal acquisition and processing. The module receives pressure signal data through a strain-gage transducer. It acquires the temperature data through Yellow Springs Instrument Company's Series-400 or Series-700 temperature probes (or their equivalent). The module senses which series of temperature probe is being used and processes the data accordingly. Temperature is displayed in large, easy to read numerics for each temperature. Alarm limits may be set for these values.

The function of the pressure channel for this module is the same as that of the Dual Pressure Module, as explained in Section 4.

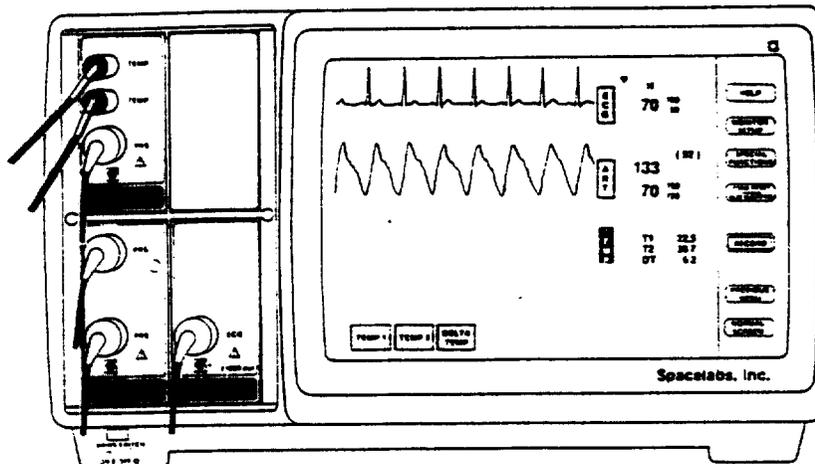
Figure 5-1.
PC Pressure/Dual
Temperature Module
Model 90403



000097

90302/90303 PC Bedside Patient Monitor

Figure 5-2.
Temperature Menu



When the TEMP label key is selected and two temperatures are being monitored from the same module, the following menu is displayed:

TEMP MENU

T
E
M
P

Displays the following menu:

TEMP1	TEMP2	DELTA T
-------	-------	---------

After a temperature type is selected, the following menu is displayed:

ALARMS		HI =	LO =	↑	↓
ON	OFF				

ALARMS/ON/OFF turns the ALARMS for temperature ON/OFF. Either ON or OFF will be highlighted to indicate the present setting. When ALARMS are ON, default limits are set, based upon the current temperature. The default limits are: LOW = 0.5° C below the current temperature, HIGH = 0.5° C above the current temperature.

The current temperature limits for high and low are displayed in the HI = and LO = keys when ALARMS are ON. When ALARMS are OFF, the word OFF is displayed in place of the limits.

The limits are increased or decreased by 0.1° C (from 0-50° C). The HI = limit cannot be set to a temperature that is lower than the setting for LO =. If this is attempted, an error message will be displayed on the screen. Likewise, the LO = limit cannot be set to a temperature that is higher than the setting for HI =. After selecting either HI = or LO =, use the ↑ ↓ keys to raise or lower the limits.

000098

90302/90303 PC Bedside Patient Monitor

When an alarm is violated, the following menu is displayed (provided that the menu display area is empty):

ALARMS		HI =	LO =	↑	↓
ON	OFF				

TEMP X ALARM IN VIOLATION

If the menu display area is occupied when an alarm is violated, the following message is displayed:

"TEMP X ALARM IN VIOLATION - Select NORMAL SCREEN key to view limits menu."

When the TEMP ALARM menu is displayed and ALARMS are ON, either the HI = or LO = key will be flashing to indicate that it is the violated limit.

000099

Section 6: Equipment Care

Unit Reliability

Each time the PC Bedside Monitor is powered up, it performs self-tests on its internal circuitry.

The monitor has been designed to be easy to use and to maintain. By following the procedures outlined in this section, you can ensure the continued reliability of the monitor.

Visual Inspection

Inspect all external cables and accessories each time the unit is used. Check for worn or damaged insulation, frayed or broken wires, cracked plastic enclosures, or any other signs of damage.

If the monitor has been damaged in any way, report it to your local SpaceLabs Customer Service Representative or to a hospital biomedical engineer. Have the unit checked for proper operation and to verify the accuracy of its measurements.

Cleaning

Clean the exterior of the PC as necessary. Use a cloth or swab that has been dampened in a solution of warm water and a mild detergent. Wring the cloth out thoroughly before use.

Clean the cables and accessories according to the manufacturer's instruction.

Clean the display screen with a cloth that has been dampened with water only. Wring excess moisture from the cloth before using.

Note

The screen may be cleaned during normal monitoring. Due to the design of the touchscreen, keys will not be activated during this process.

000100

90302/90303 PC Bedside Patient Monitor

Preventive Measures

Preventive maintenance checks should be performed at least every 180 days. These checks include verification of acceptable equipment performance as well as electrical safety testing. These procedures should be performed by a hospital biomedical engineer or a SpaceLabs Customer Service Representative.

Corrective Measures

Corrective maintenance procedures must be done by a qualified service person. See your hospital biomedical engineer or contact your local SpaceLabs Customer Service Representative. For other service information, contact SpaceLabs Service Department in Redmond, Washington at the number listed on the back cover of this manual.

000101

Section 7: Problem Solving

The SpaceLabs PC Bedside Patient Monitor was designed to be easily maintained and repaired. Should a problem occur, follow the guidelines covered in this section to verify that the problem is in instrument itself.

Diagnostics

When the monitor is switched ON, a series of self-tests are performed to check for internal operational faults. Observe the display screen to see if any self-test error codes or messages are displayed. Write down any error code numbers or messages to give to the maintenance personnel when you call for service.

If the monitor fails to start up, a screen message will appear. Turn the Mains power switch OFF, then ON again. If the monitor still fails to start, write down the code number appearing on the screen and contact a qualified service person.

000102

Section 8: Supplies and Accessories

Medical Supplies

A complete SpaceLabs Catalog is available. To order supplies, or a copy of the catalog, call toll free from anywhere in the Continental U.S. at the 800 number listed on the back cover of this manual.

Telex orders may be placed by dialing 910-494-4773/SpaceLabs Chats.

<u>Description</u>	<u>Part Number</u>
5-Lead Patient Cable	T012-0945-01
Snap Lead Wires A 5 Lead Configuration which Includes: One each Red & Green One each Black & White One each Brown	T012-0580-01
Probe, Temp, General Purpose	T118-0256-00
Probe, Temp, Surface	T118-002-00A

000103

90302/90303 PC Bedside Patient Monitor

The following manuals may be ordered from Service Parts at the 800 number listed on the back cover of this manual for locations outside of Washington State (or at the local number for locations within Washington).

<u>Description</u>	<u>Part Number</u>
Operator's Manual, PC Central Display	890311-002
PC Bedside Service Manual	890302-001
PC Mainframe Service Manual, ECG Module	890401-001
Service Manual, Dual Pressure Module, Model 90402	890402-001
Service Manual, Pressure/Dual Temperature Module	890403-001

000104

TAB 5

DEVICE DESCRIPTION

000105

Premarket Notification - Camino NeuroCare™

The Intracranial Pressure-Temperature Monitoring System consists of a catheter and monitor. The catheter is a sterile transducer-tipped pressure monitoring catheter with thermistor and accessory items to be used as a diagnostic tool for rapidly determining and continuously monitoring intracranial pressure and temperature. The Camino catheter has a miniature transducer and thermistor at the distal tip. The pressure transducer is identical to the Camino predicate device. The design eliminates the need for a "fluid-filled system" to carry pressure waves to an external transducer. The transducer is 4F, fiber optic with a pressure measurement range of -10 to 250 mmHg and a temperature measurement range of 30°C -40°C.

The Multi-Parameter Monitor (MPM) is a compact, portable device for use with Camino Pressure-Temperature catheters. The MPM measures Intracranial Pressure (ICP), Intracranial Temperature (ICT) and calculates Cerebral Perfusion Pressure (CPP). The MPM provides a continuous display of the pressure waveform, as well as mean ICP, CPP, temperature or systolic and diastolic values. A continuous record of mean pressure and temperature values over the most recent 24-hour period is stored in memory, and can be displayed on command as a TREND either as the most recent 8 or 24 hour period. An analog output accessory provides a continuous ICP waveform for hard copy documentation or data acquisition. Although the MPM is intended to be a stand alone system, it also conveniently connects to any hospital bedside monitoring system. A built-in rechargeable battery permits monitoring during patient transport. The monitor is equipped with an high ICP alarm. The dimensions are 274 mm x 216 mm x 89 mm and weighs 4.3 Kg.

ICP/T Probe:

The ICP/T probes are sterile, single use devices.

The ICP/T probes contain pressure-sensors at the tip of the probe.

The ICP/T probes contain a thermistor at the tip of the probe.

The ICP/T probes measure pressure and/or temperature in a target tissue..

The ICP/T probes measure pressure in a range of -10 to 250 mmHg.

The ICP/T probes measure temperature in the range of 30° C - 40° C.

Monitor:

The ICP/T monitor displays pressure.

The ICP/T monitor displays temperature.

The ICP/T monitor displays Cerebral Perfusion Pressure (CPP).

The ICP/T monitor displays waveforms.

The ICP/T monitor display trends.

The ICP/T monitor complies with UL Medical Equipment standards.

The ICP/T monitor complies with AAMI/ANSI Safe Current Limits standards.

000106

Premarket Notification - Camino NeuroCare™

The materials which come in direct contact with the patient are identical to the Camino NeuroCare substantially equivalent predicate probes.

Bill of Materials for both Model 110-4BT and Model 110-4HMT

Common to both models:

- *Transducer Assembly
- Optical Module Assembly
- Code Board Assembly
- 2 Connector Shell Halves
- Fiber Cover
- 4 Glass Optical Fibers coated w/urethane acrylate - 110 cm in length
- *Teflon FEP Marked Tubing
- *Fiber Holder
- *Epoxy Glues
- 1" Teflon Sleeve
- PVC Strain Reliefs
- Stainless Steel Vent Tube
- Thermistor Assembly

Unique components to each model:

Model 110-4BT:

- *PVC Female Luer
- PVC Male Luer Cap
- *PVC Tube
- Y Connector
- *Silicone Tube
- Compression Fitting
- *Introducer Assembly
- *Bolt Assembly

Model 110-4HMT:

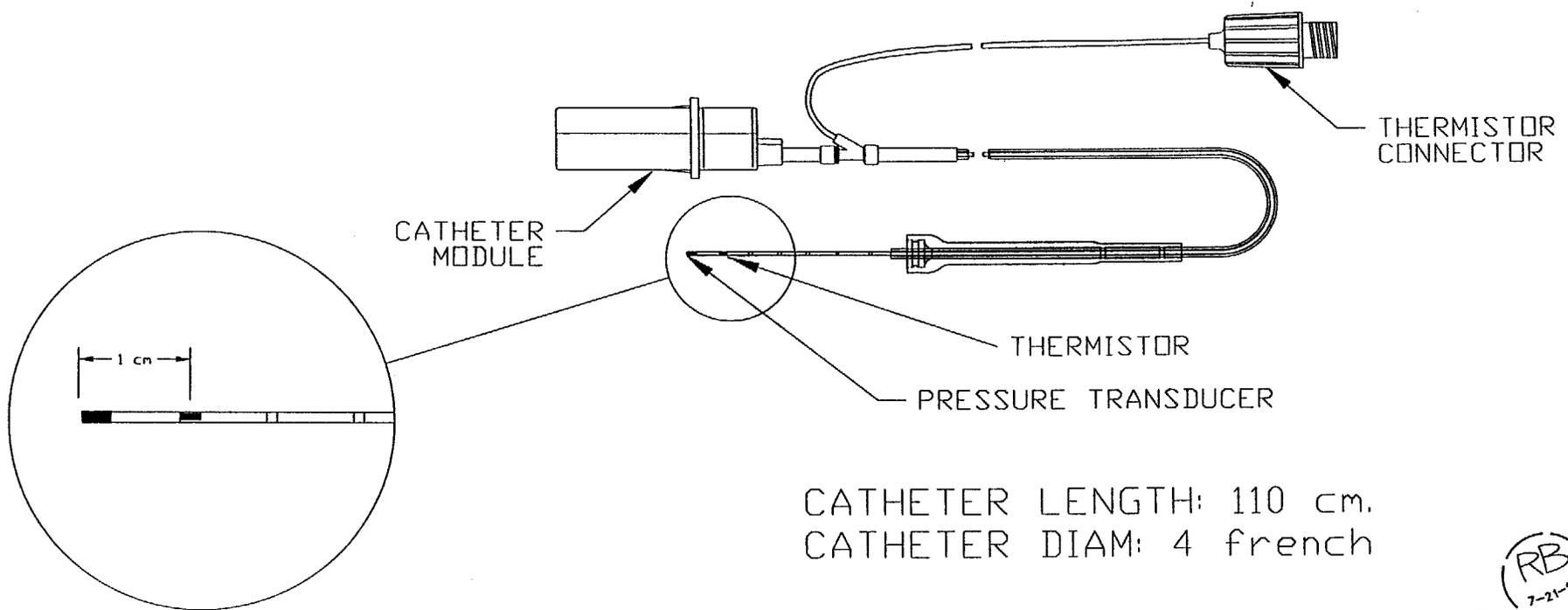
- PVC Tube
- Strain Relief (distal)

*Note: Direct patient contacting components included in biocompatibility testing.
Refer to Attachment B.

000107

181

INTRACRANIAL PRESSURE/TEMP MEASUREMENT PARENCHYMAL PLACEMENT (110-4BT)



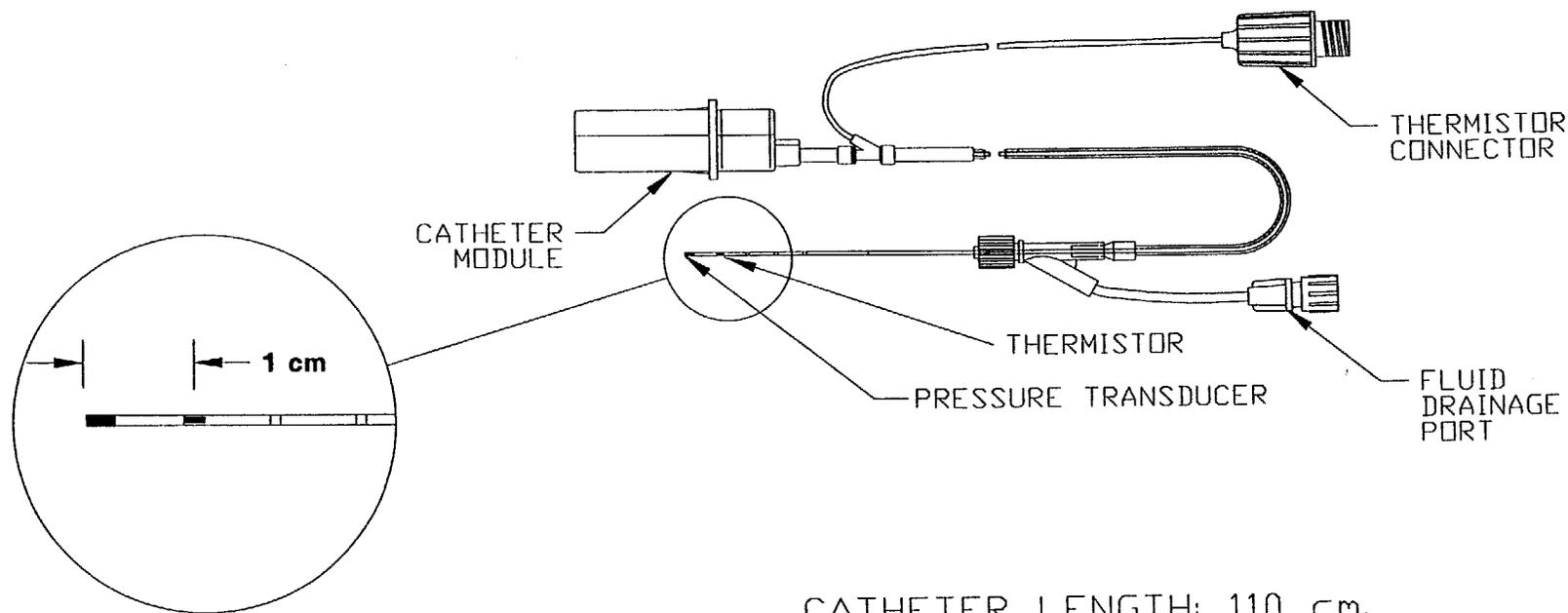
CATHETER LENGTH: 110 cm.
CATHETER DIAM: 4 french

110-4BT3.DWG



000108

INTRACRANIAL PRESSURE/TEMP MEASUREMENT VENTRICULAR PLACEMENT (110-4HMT)

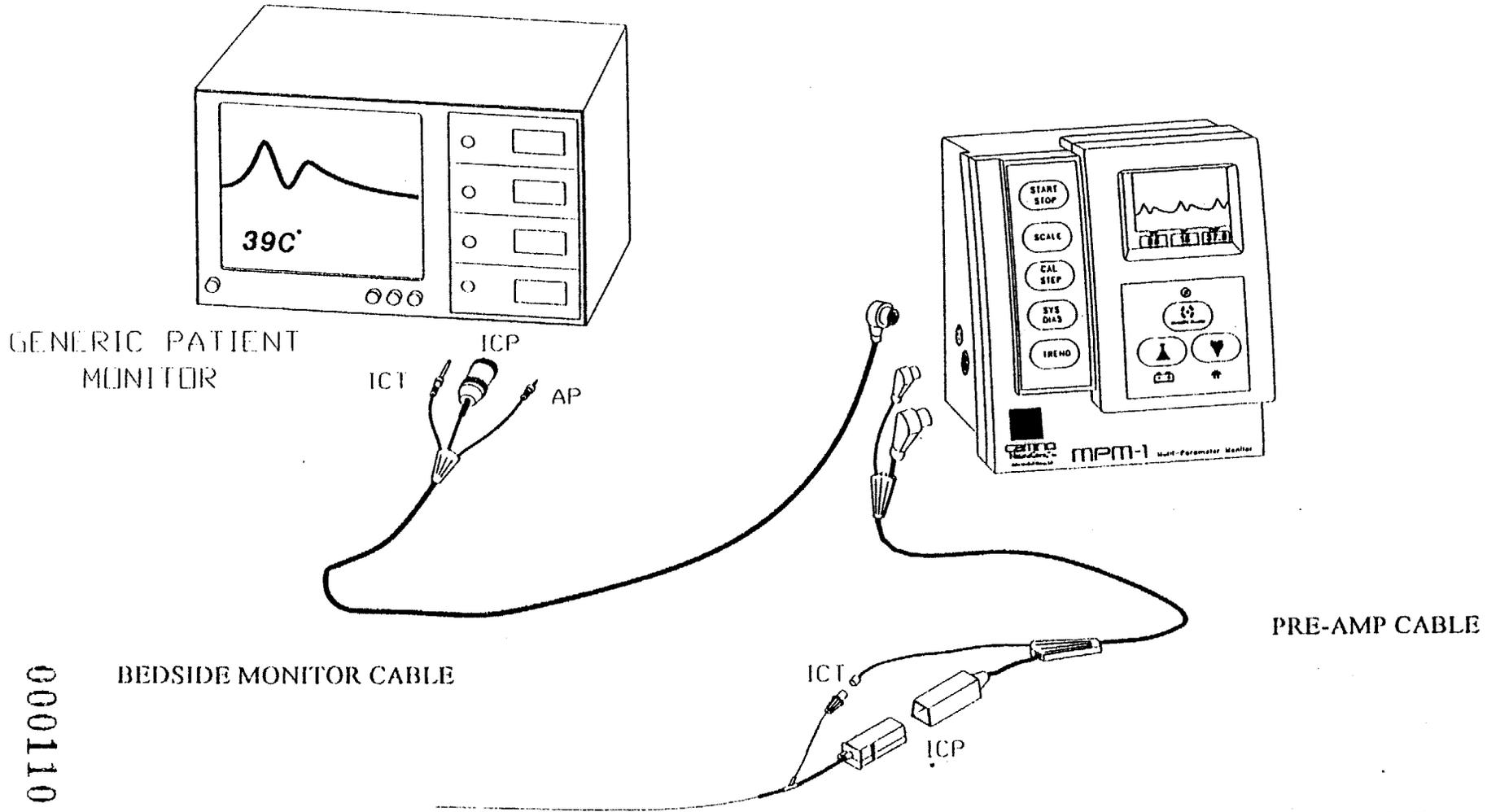


CATHETER LENGTH: 110 cm.
CATHETER DIAM: 4 french



000109

MPM-1 SYSTEM DIAGRAM



000110

CABLES DWG
RB 8-8-95

camino
NeuroCareno surprises
Continuous ImprovementGENESIS UNIT
BILL OF MATERIAL

DESCRIPTION	PART NO.	QTY
Pole Clamp	62001011	1
Bed Hook	62001012	1
Cover, Front	62001004	1
Panel, LCD	62001013	1
Membrane, Control Panel	62001014	1
Membrane, Alarm	62001015	1
Cover, Rear	62001005	1
Gasket, Side and Rear	62001019, 62001020	1
Chassis	62001003	1
PC, Analog	62001001	1
Shield, ANA/DIGI PC's	62001007	2
PC, Digital	62001016	1
Mount, LCD Power	62001009	1
Crossbeam, Chassis	62001022	1
RGB Video, 4"	LQ4RA01	1
Piezo Alarm (Mallory)	MSR320	1
Connector, 4-Pin	DG-104	1
Connector, 11-Pin	DG-104	1
Connector, 27-Pin	DG-105	1
Power Entry Module	PS0SXDH60B	1
Battery, 12V, 2Ah	NP2-12-2	1
Mount, Battery	62001006	1
Connector, Sub DB-9	747190-1	1
Phone Jack	41 TINI-JAX	1
PC & Daughter PC, Power Supply	62001002, 62001017	1
Shield, Power Supply	62001008	1
Access Plate	62001010	2
Knob, Clamp	SIGMA-20	1
Pocket, Manual	62001018	1
Misc. Hardware		
Cable, PMIO/Isolated Analog	62001024	1
Cable, RS232 / Speaker	62001025	1
Cable, Pre-Amp / Thermistor	62001026	1
Cable, LCD Display	TBD	1
Cable, LCD Power Supply	TBD	1
Cable, LCD Backlight	TBD	2
Power Cord		
TOTAL		

00011133

Premarket Notification - Camino NeuroCare™

TAB 6

COMPARATIVE INFORMATION

Premarket Notification - Camino NeuroCare™

In presenting this discussion of substantial equivalence, Camino is relying on FDA's Bluebook Memorandum dated June 30, 1986, entitled Guidance on the Center for Devices and Radiological Health's Premarket Notification Review Program (hereinafter "Bluebook Memorandum"). This section follows the flowchart included in the Bluebook Memorandum as Attachment II and included with this premarket notification at the end of this Tab 6.

The Bluebook Memorandum indicates that the first inquiry is whether the new device has the same intended use as the predicate devices. The memorandum states that intended use of the new device is to be determined by reference to labeling or promotional claims and that only in rare cases is it necessary to infer intended use from other types of information. A new device that has the same indication statements is substantially equivalent in regard to intended use. If a new device does not have the same indication statements, it still may be substantially equivalent if the differences do not alter the intended therapeutic or diagnostic effect. The key to whether a device has a substantial equivalent therapeutic or diagnostic effect is whether the labeling indications introduce questions about safety and effectiveness are different from those that were posed by the predicated devices intended use. If not, the device has the same intended use and may be substantially equivalent.

Indication Statements and Predicate Devices

The ICP/T is indicated as a diagnostic tool for rapidly determining and continuously monitoring intracranial pressure and temperature. It is labeled for use by qualified neurosurgeons when direct measurement of intracranial pressure and temperature is clinically important.

Pressure:

The ICP/T catheter and monitor have the same indication statements for monitoring pressure as Camino's predicate devices. (See Substantial Equivalence Comparison Chart, Tab 6; Predicate Device Labeling, Tab 4). Accordingly, the intended use for pressure is substantially equivalent.

Temperature:

Predicate temperature-sensing devices include the Electromedics, Model 2403, Temperature Probe, K813459A. Other predicate temperature probes include the following:

Clinical Technology Corp., Urinary Bladder Temperature Sensor, K823077.

Tissue Temperature Probe issued to Pat O. Daily, K850083.

Shiley Inc., Shiley Disposable Temperature Probes, K821244.

000113

Premarket Notification - Camino NeuroCare™

DeRoyal Industries, "Exact-Temp" and Clini-Temp" Tympanic and Myocardial Probes, K925792

Respiratory Support Products Inc., Myocardial Temperature Sensor, K920469.

Yellow Springs Instruments Co., YSI Temperature Probes

Mon-a-term, Inc., Mon-a-therm disposable temperature sensors for esophageal/rectal, catheterization, skin, EST, nasopharyngeal, tympanic or in-line solution temperature use.

This is only a partial list and, for ease of reference, this discussion and the accompanying comparison chart list only the Electromedics probe. All the predicate probes are used to measure the temperature of a target organ or tissue. Camino's temperature probe has the same use.

Nevertheless, the ICP/T has a difference in the indication statements in regard to temperature. The difference refers to the tissue in which the temperature is taken. For example, the Electromedics predicate catheter is labeled for general temperature use. Other indications include general surgery, cardiovascular surgery, anesthesiology, critical care, newborn care, and neonatal care. The Camino probes have similar labeling in that they are for general uses that may include surgery, critical care, pediatric care and head injured patients. The Electromedics probe is labeled to take a patient's temperature in the esophagus, on the skin surface, in cardioplegia systems and in the myocardium. The Camino pressure-temperature probe is labeled to be used in the brain, with either parenchyma or ventricular placement.

Diagnostic Effect:

Both the Camino and predicate temperature probes are intended to determine the temperature of the tissue in which they are placed. Thus, they have an intended diagnostic effect, which is to provide a piece of patient monitoring information to a physician. There is no intended therapeutic effect. The intended diagnostic effects of Camino and predicate probes are the same as those of predicate devices; to monitor the temperature of the tissue in which they are placed.

Safety and Effectiveness:

Safety:

In regard to safety, the contact area of the Camino probe is of the same design, has the same materials, and it is inserted into the body in the same manner as predicate Camino probes. Thus, the questions of safety are the same. Biocompatibility is addressed in Tab 7, sterility is addressed in Tab 8, monitor software is addressed in Tab 9 and instructions

Premarket Notification - Camino NeuroCare™

for use and warnings are included with the labeling for the ICP/T probes and monitor and the predicate Camino probes and monitor in Tab 4. Both new and predicate monitors meet UL standards for Medical Equipment and AAMI/ANSI standards for Safe Current Limits.

Effectiveness:

The diagnostic effect of temperature probes for general use is to provide temperature information to a physician for whatever use he or she may choose, based on the user's training and experience. Thus, the questions of effectiveness are not new: effectiveness of a temperature probe for diagnostic or monitoring use is determined by its ability to deliver an accurate temperature reading. This is the same standard that was used for predicate devices, some of which were cleared for organs and tissues which may have been different from those for which existing predicate devices were cleared.

The premarket notification contains both bench testing and animal testing showing the substantial equivalence of the Camino and Electromedics temperature probes in regard to accuracy and stability. The animal testing measures accuracy and stability in brain tissue over a range of temperatures, as requested by FDA.

Technological Characteristics:

Probe:

- The ICP/T probes and both predicate probes are sterile, single use devices.
- The ICP/T probes and Camino predicate probe contain the identical pressure-sensors.
- The ICP/T probes and the Electromedics probe contain the identical thermistor.
- The ICP/T probes and both predicate probes measure pressure and/or temperature in a target tissue or organ.
- The ICP/T probes and the Camino predicate probes measure pressure in a range of -10 to 250 mmHg.
- The ICP/T probes and the Electromedics probe measure temperature up to 50° C.

Monitor:

- The ICP/T monitor and both predicate monitors display pressure.
- The ICP/T monitor and both predicate monitors comply with UL Medical Equipment standards.
- The ICP/T monitor and the predicate monitors comply with AAMI/ANSI Safe Current Limits standards.
- The ICP/T monitor and SpaceLabs monitor display temperature.
- The ICP/T monitor and SpaceLabs monitor display Cerebral Perfusion Pressure (CPP).
- The ICP/T monitor and SpaceLabs monitor display temperature.
- The ICP/T monitor and both predicate monitors display a waveform.
- The ICP/T monitor and both predicate monitors display trends.

000115

Premarket Notification - Camino NeuroCare™

Thus, the ICP/T devices meet the Bluebook Memorandum requirements for substantial equivalence.

189

000116

199

SUBSTANTIAL EQUIVALENCE COMPARISON

INSTRUMENT

<u>ATTRIBUTE</u>	<u>DEVICE</u>	<u>PREDICATE DEVICES</u>	
	CAMINO	CAMINO	SPACELABS
	Multi-Parameter Monitor	Direct Pressure Monitor	Host Monitor
Model	Model MPM-1	Model V420	Model 9030
K Number	TBD	K893232	K842616
INDICATIONS FOR USE	Monitor pressure and temperature Calculate cerebral perfusion pressure	Monitor pressure Not Same- ICP only	Monitor pressure and temperature Same
TARGET POPULATION	Adult, child, pediatric	Same	Same
ENVIRONMENT USED	OR, Intensive Care Unit, Trauma Center, Emergency Room	Same	Same
DESIGN	Displays ICP, CPP, Temperature Displays ICP and CPP waveform Displays 8 and 24 hour trend	Displays ICP Displays ICP waveform 8 hour trend	Displays ICP, CPP, Temp, MAP, etc Displays ICP, CPP, MAP, ECG waveform 12 hour trend
ALARMS	ICP Alarm	No alarm	Alarms for all measurements
PERFORMANCE STANDARDS	UL 544 Medical Equipment AAMI/ANSI Safe Current Limits	Same Same	Same Same

000117

191

**SUBSTANTIAL EQUIVALENCE COMPARISON
DISPOSABLE CATHETER**

<u>ATTRIBUTE</u>	<u>DEVICE</u>	<u>PREDICATE DEVICES</u>	
		<u>CAMINO</u>	<u>ELECTROMEDICS</u>
Model	Intracranial Pressure-Temperature Monitoring Kit, Model 110-4BT and Model 110-4HMT	Intracranial Pressure Monitoring Kit, Model 070 and Model 110-HM	Esophageal, Rectal, Nasopharyngeal Temperature Probe Model 2403
K Number	TBD	K853684C	K813459A
INDICATIONS FOR USE	Measure pressure Measure temperature Parencymal placement (110-4BT) Subarachnoid placement (110-4BT) Ventricular Placement (110-4HMT) CSF drainage (110-HMT)	Same Not Same-no temp Same (070) Same (070) Same (110-4HM) Same (110-HM)	Not Same-doesn't measure pressure Same General Use* General Use* General Use* Not Same-no CSF drainage
TARGET POPULATION	Adult, child, pediatric	Same	Same
ENVIRONMENT USED	OR, Intensive Care Unit, Trauma Center, Emergency Room	Same	General Use*
DESIGN	Sterile catheter Thermistor Pressure sensor Pressure Range -10 to 250 mmHg Temperature Range 30-40 C Contains introducer accessory items	Same No thermistor Same Same No temperature Same	Same Thermistor No pressure sensor No pressure Temp Range 0-50 C Not Same-Catheter only
STERILITY	Sterile	Sterile	Sterile
BIOCOMPATIBILITY	Per ISO-10993	Same	Same

* General surgery, cardiovascular surgery, anesthesiology, critical care, neonatal care; use in e.g., esophagus, skin surface, myocardium, in-line (e.g., cardioplegia, oxygenator blood temperature, anesthesia gas)

000118

TAB 7

BIOCOMPATIBILITY ASSESSMENT

192

000119

Premarket Notification - Camino NeuroCare™

BIOCOMPATIBILITY INFORMATION

(b)(4)

A large black rectangular redaction box covering the entire section of biocompatibility information.

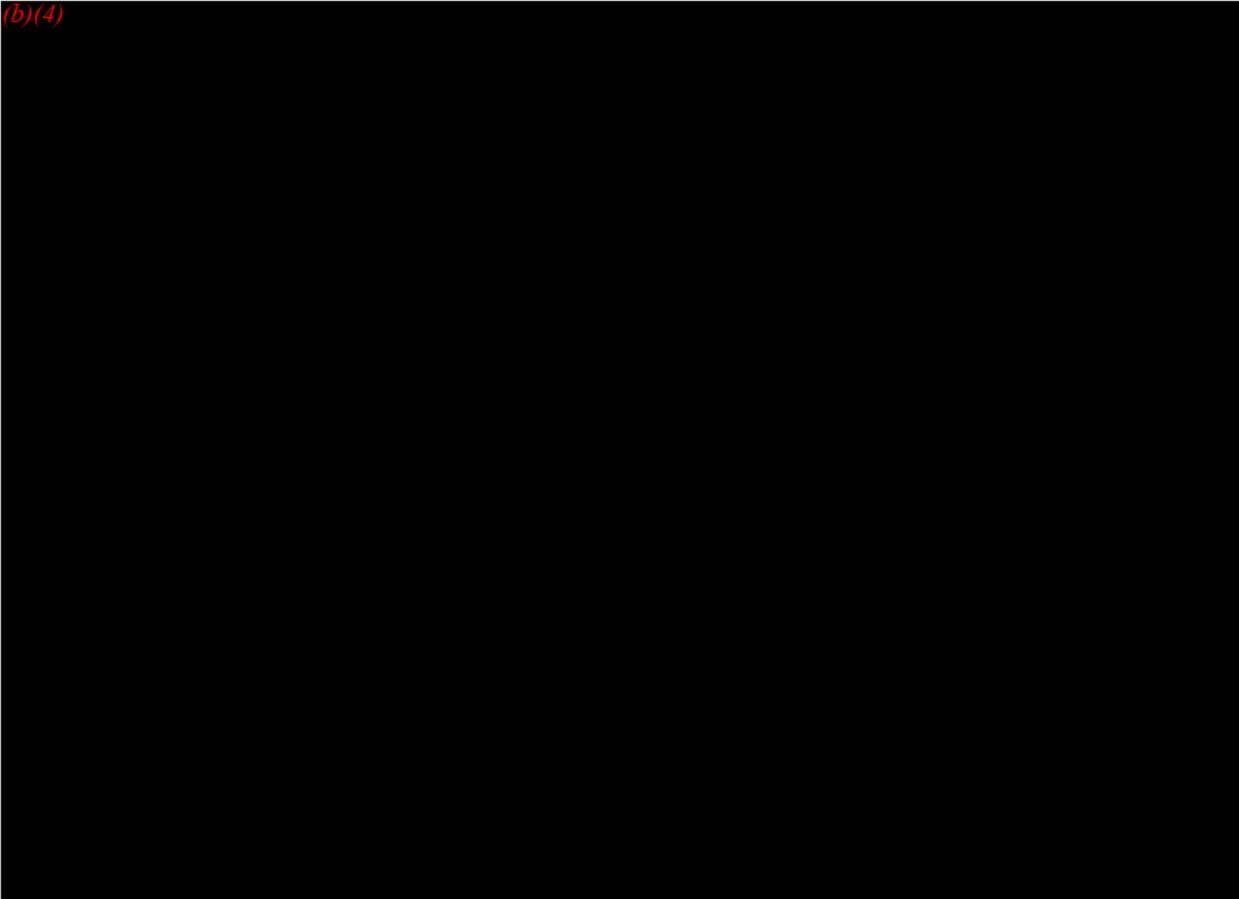
SUMMARY OF RESULTS

MATERIAL

TEST METHOD

RESULTS

(b)(4)

A large black rectangular redaction box covering the entire table of summary results.

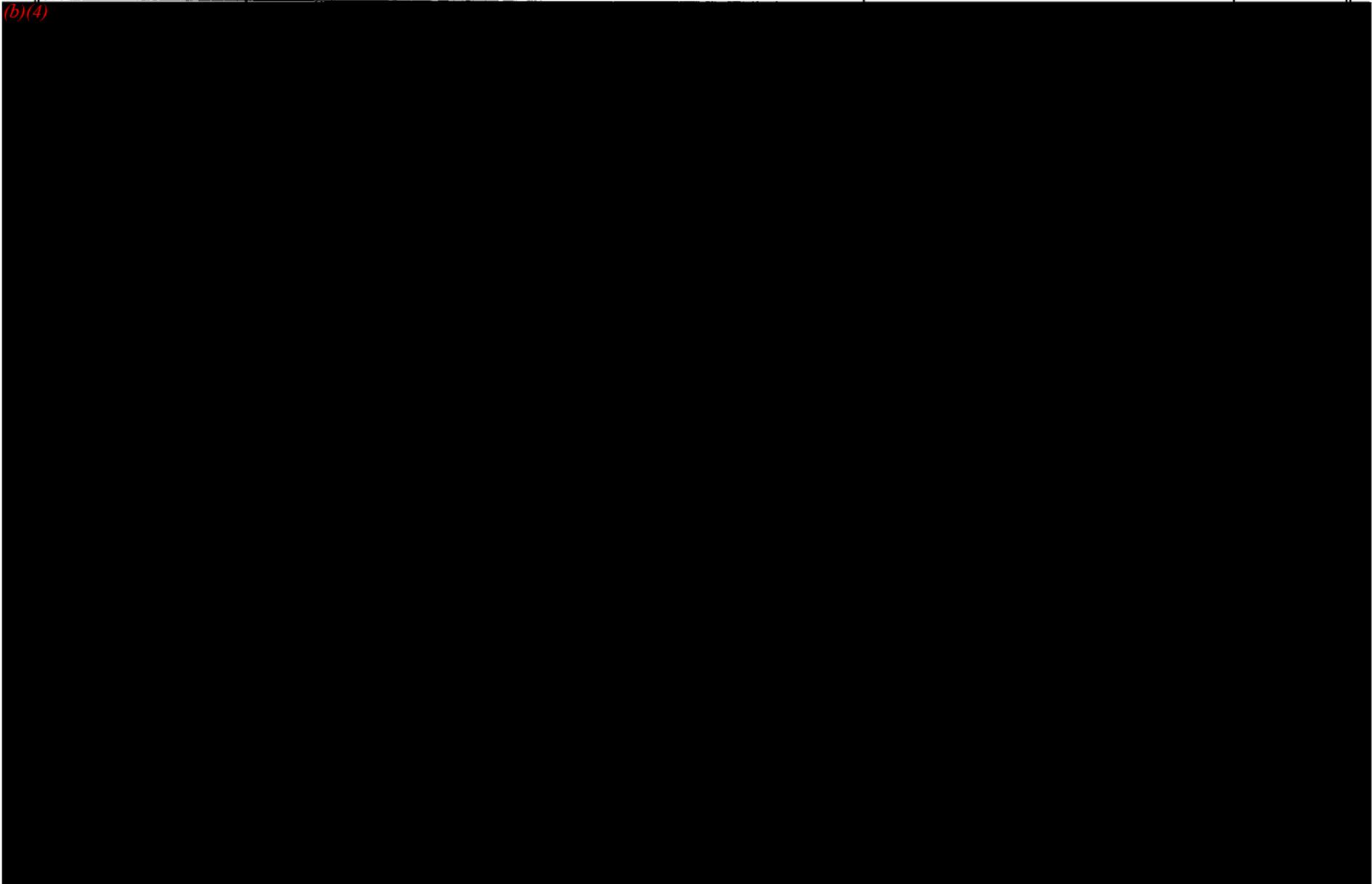
196

BIOCOMPATIBILITY TEST RESULTS

Performed per (b)(4)



Test	Test Description	Sample Description	Results
------	------------------	--------------------	---------



(b)(4)

000121

TAB 8

STERILIZATION INFORMATION

195

000128

Premarket Notification - Camino NeuroCare™

STERILIZATION METHOD

(b)(4)

VALIDATION METHOD

(b)(4)

STERILIZATION ASSURANCE LEVEL (SAL)

(b)(4)

PACKAGING USED TO MAINTAIN DEVICE'S STERILITY

(b)(4)

EXPIRATION DATE

The expiration data on the subject catheters is equivalent to the Camino predicate catheters.

MAXIMUM ALLOWABLE RESIDUAL LEVELS

(b)(4)

19/10

000123

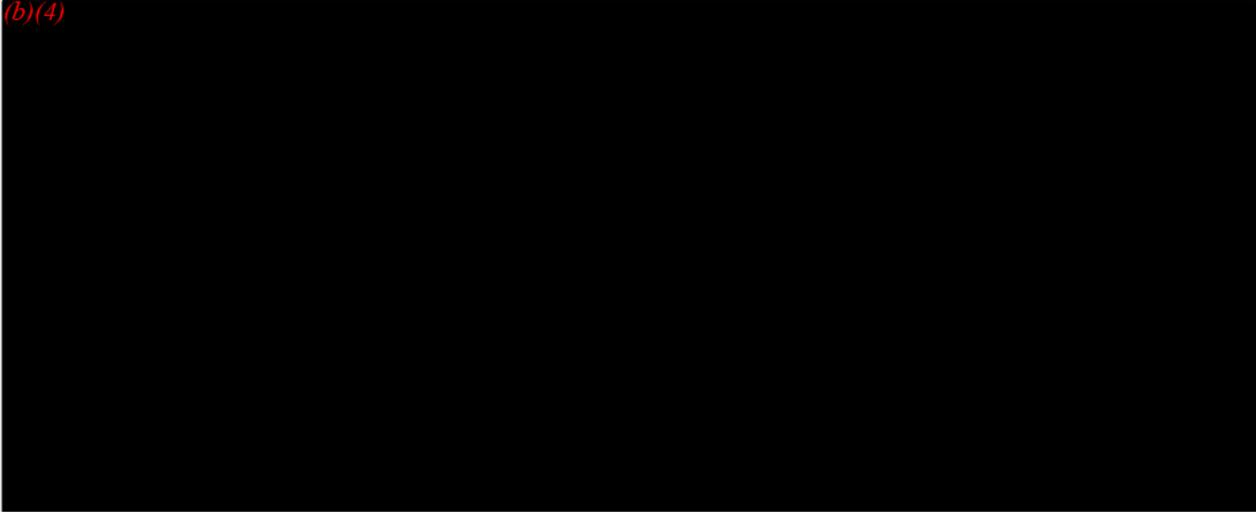
TAB 9

SOFTWARE VALIDATION & VERIFICATION

197

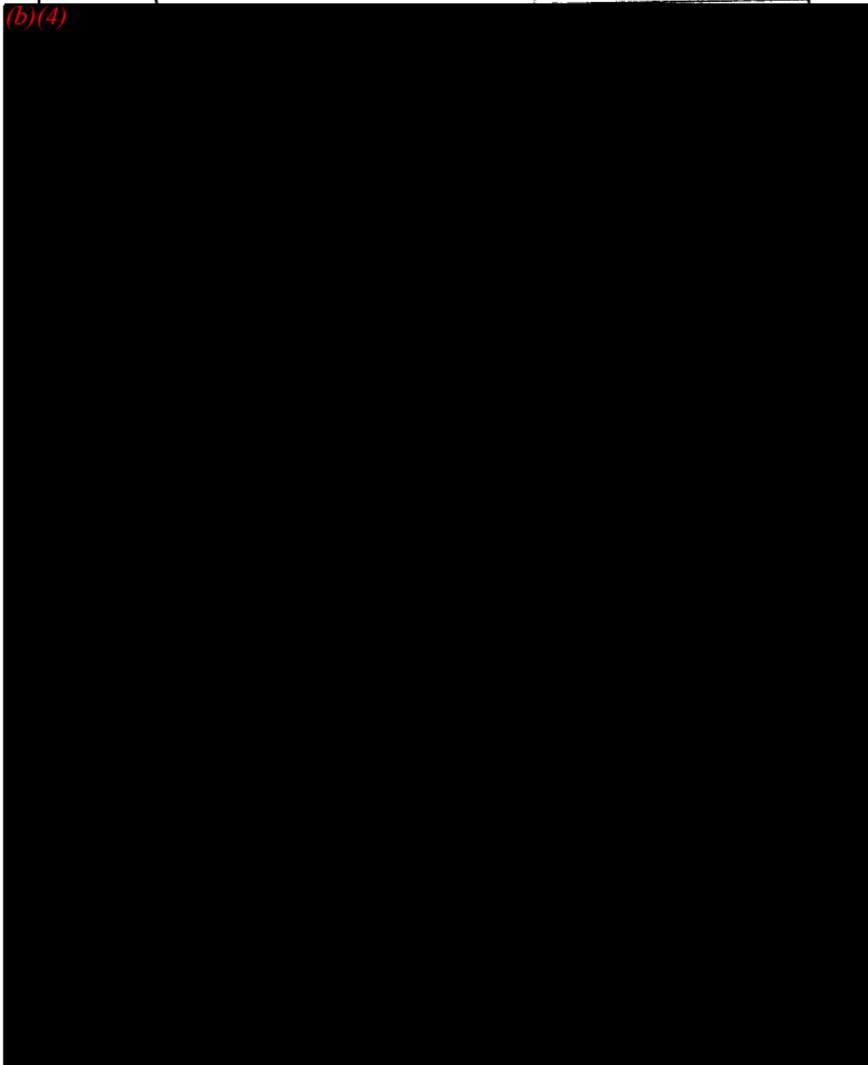
Premarket Notification - Camino NeuroCare™

(b)(4)



000125

Table 1 List of System Hazards

ID No.	System Hazard	Level of Concern
<p>(b)(4)</p> 		

Premarket Notification - Camino NeuroCare™

HAZARD ANALYSIS

000127



Premarket Notification - Camino NeuroCare™

SOFTWARE REQUIREMENTS SPECIFICATION

000150

Premarket Notification - Camino NeuroCare™

SOFTWARE DEVELOPMENT PLAN

**SOFTWARE
VERIFICATION & VALIDATION
PROTOCOL AND TESTING
RESULTS**

000196

Premarket Notification - Camino NeuroCare™

EXECUTIVE SUMMARY

Document Number	Document Revision	Date	Pages
TBD	Rev. C	8/25/95	7

Camino NeuroCare
5955 Pacific Center Blvd.
San Diego, CA 92121
(619) 455-8298

GENESIS (MPM-1) Executive Summary

Created By:



ReleSYS International, Inc.
 2 Venture Suite 400
 Irvine, CA 92718
 (714) 453-1715

Approved By:	Name	Title	Signature	Date
	Patrick J. Rimbert	VP of R&D	<i>Patrick J. Rimbert</i>	8/26/95

Release Notes:

Rev A (08/16/95) - Original
 Rev B (08/21/95) - Added Issue #2
 Rev C (08/25/95) - Added dispositions for Issues #1 and #2

kn:genesisiv&v:genexe.c

Project Code: 3001

359

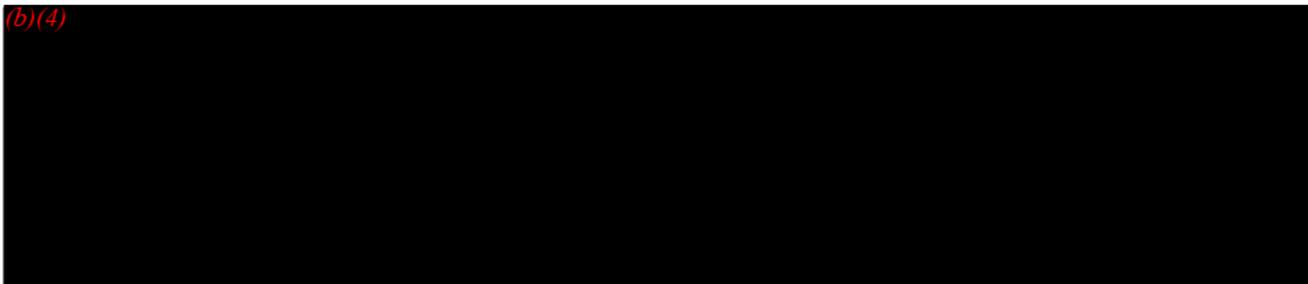
TABLE OF CONTENTS

1. INTRODUCTION 1
1.1 PURPOSE..... 1
1.2 REFERENCES..... 1
1.3 EXECUTIVE SUMMARY OVERVIEW 2
1.4 SQA GOALS 2
2. SQA APPROACH 3
3. FINDINGS..... 4
3.1 SAFETY RELATED PROBLEMS 5
3.2 TECHNICAL PROBLEMS 5
3.3 DOCUMENTATION AND DESIGN ISSUES 5
3.4 RECOMMENDATIONS AND OTHER FINDINGS..... 5
4. SOFTWARE VALIDATION PROTOCOL EXECUTION RESULTS 6

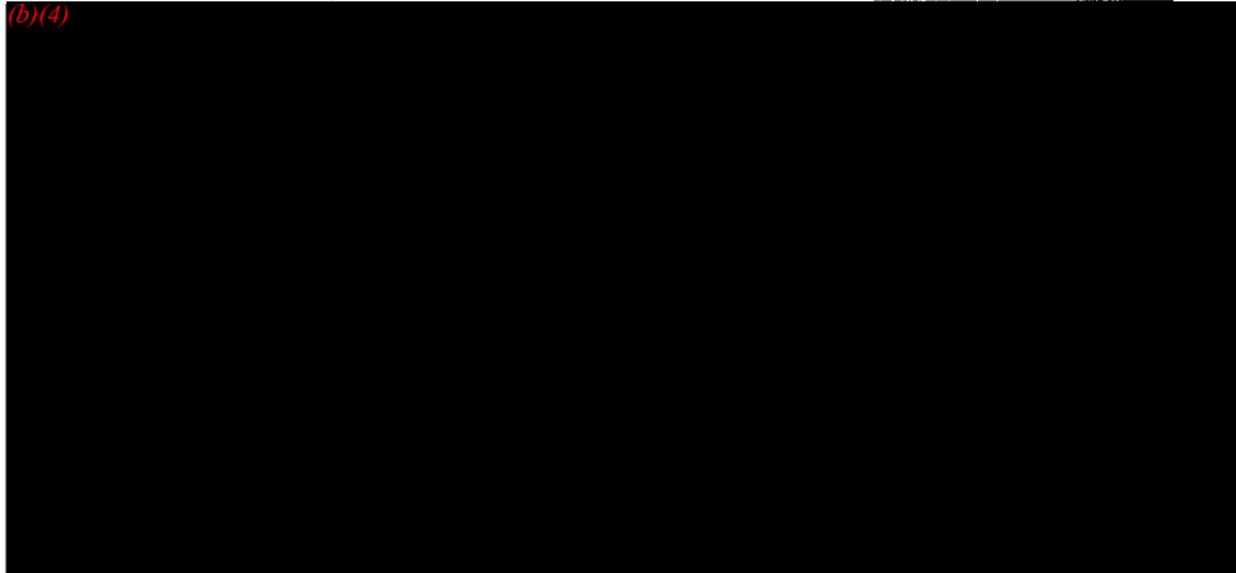
1. Introduction

1.1 Purpose

(b)(4)



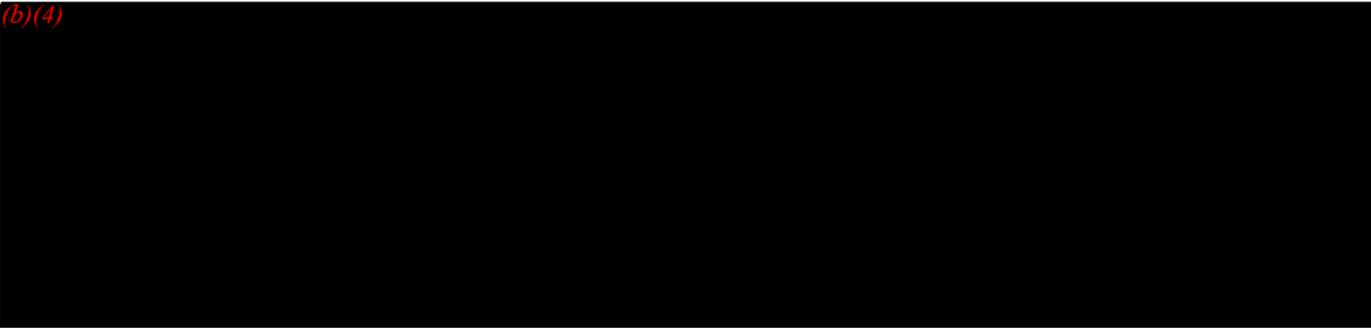
1.2 References

#	Document Description	Identification Date
(b)(4)		

339

1.3 Executive Summary Overview

(b)(4)



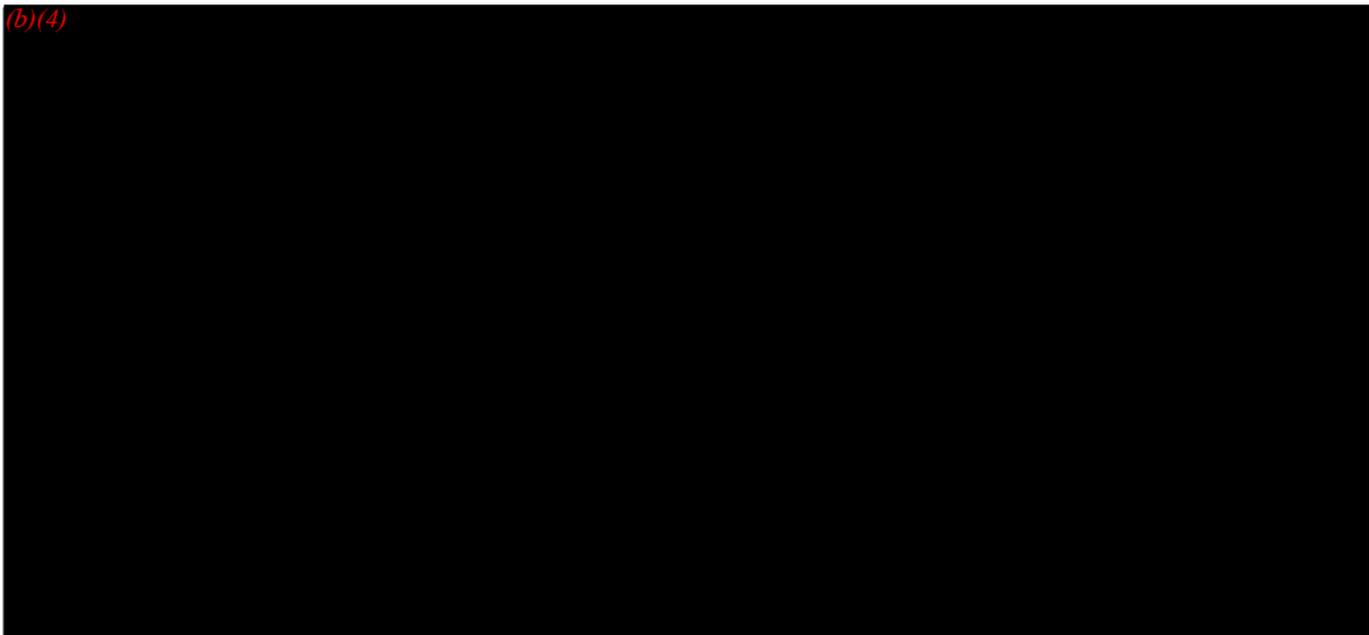
1.4 SQA Goals

(b)(4)



2. SQA Approach

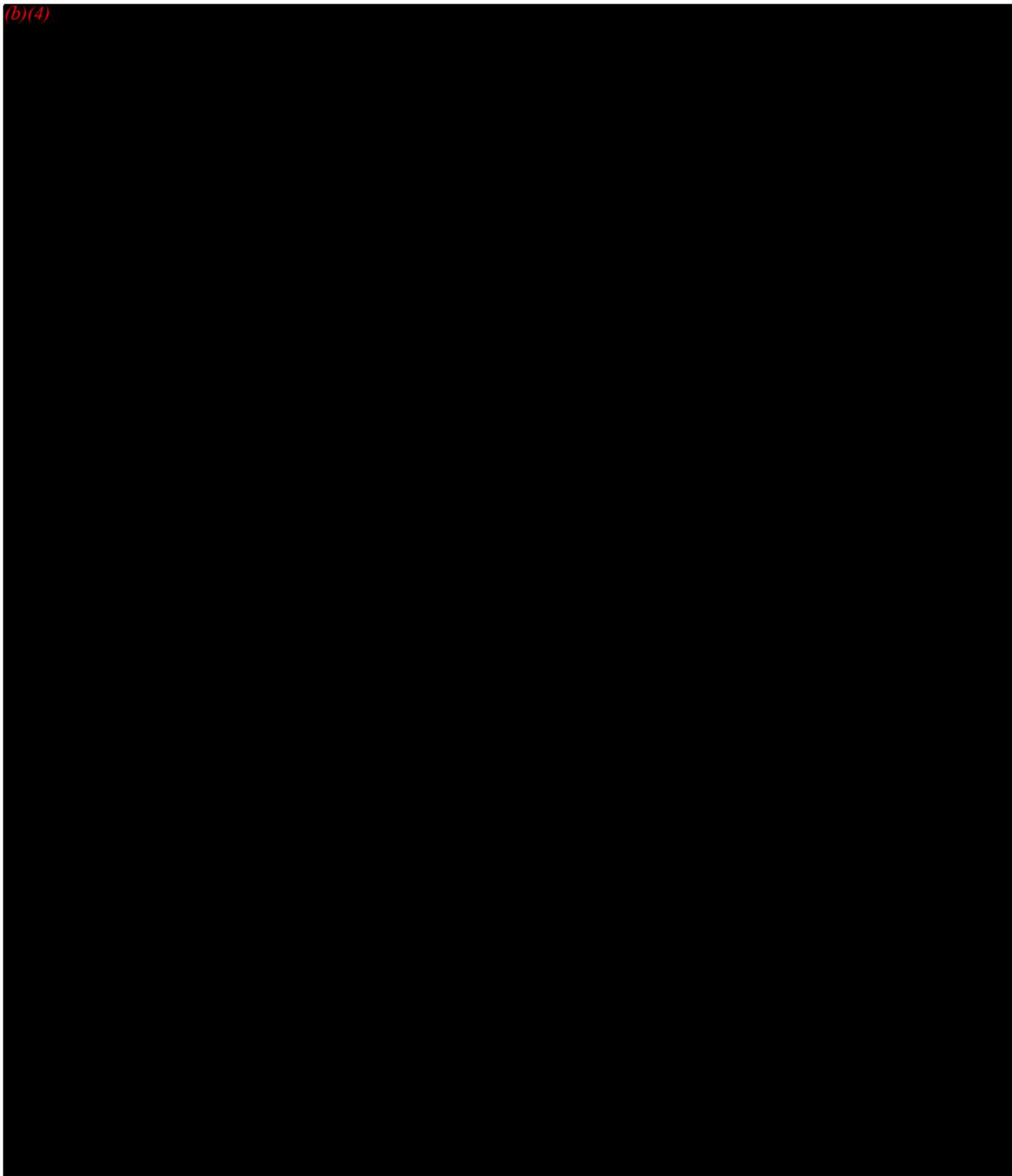
(b)(4)



000287

3. Findings

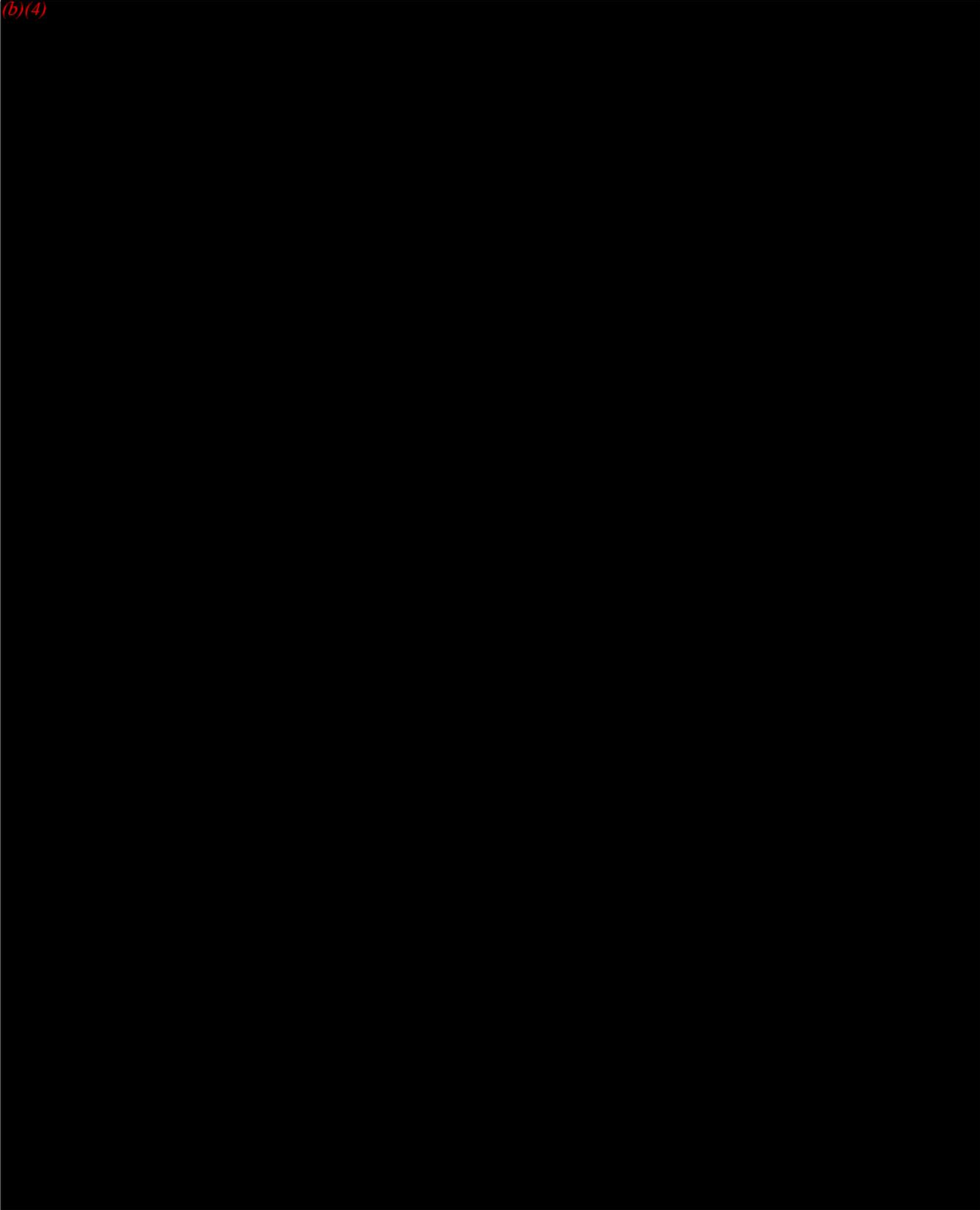
(b)(4)



Revision C

Page 5 of 7

(b)(4)



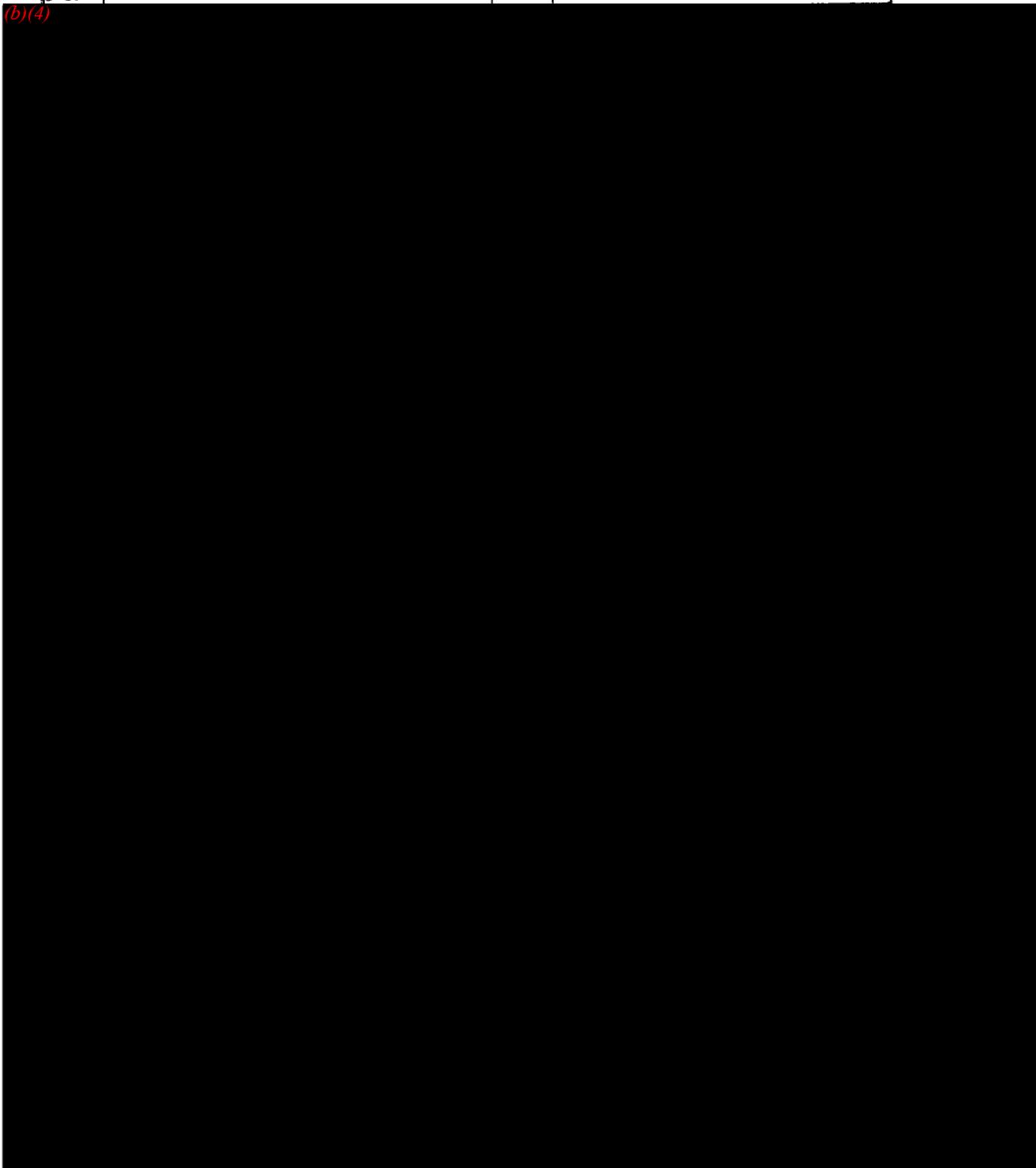
000269

343

4. Software Validation Protocol Execution Results¹

Test No.	Description	Pass/ Fail	Comments
----------	-------------	---------------	----------

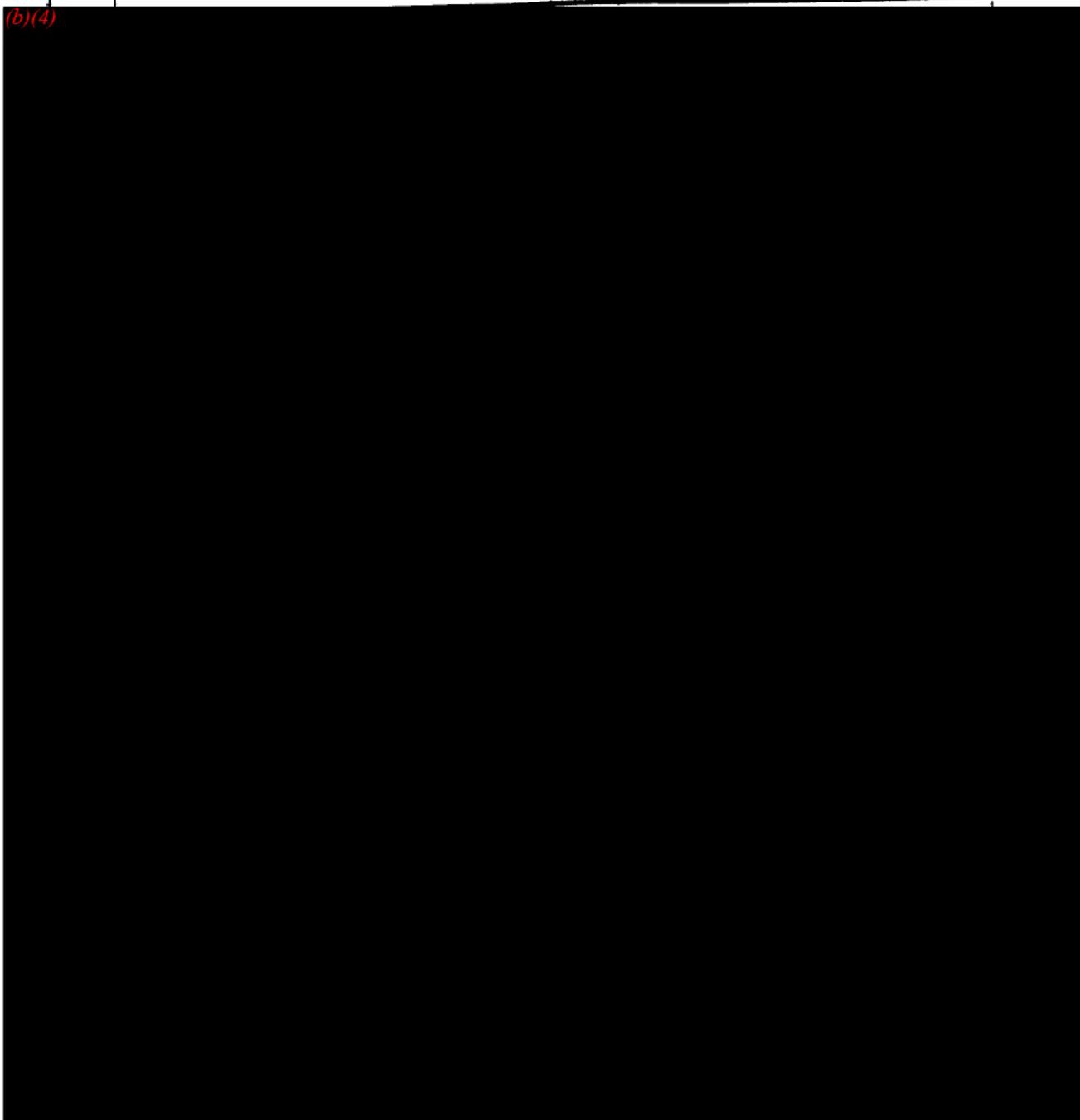
(b)(4)



Revision C

Page 7 of 7

Test No.	Description	Pass/ Fail	Comments
----------	-------------	---------------	----------



345

Premarket Notification - Camino NeuroCare™

CERTIFICATION

000273



Premarket Notification - Camino Neuro



camino
NeuroCare™, Inc.
Saba Medical Group, L.P.

**PREMARKET NOTIFICATION
SOFTWARE VALIDATION & VERIFICATION STATEMENT**

I certify that, in my capacity as Director, Regulatory and Clinical Affairs of Camino NeuroCare™, Inc., and to the best of my ability, that the software for Camino NeuroCare™, Inc's., Multi Parameter Monitor, Model MPM, has been developed in adherence with Camino NeuroCare's quality assurance procedures. The results demonstrate that the system specifications and functional requirements have been met.

Donna L Free

Signature

Donna L. Free

Typed Name

July 26, 1996

Date

BEING APPLIED FOR

PreMarket Notification 510(k) Number

SLP

TAB 10

SPECIFIC STANDARDS & GUIDANCES

000274

Premarket Notification - Camino NeuroCare™

There are no known specific standards and guidances for this type of medical device. The following are criteria for standards and guidances which were developed internally by Camino NeuroCare™ Inc. for the catheters.

Acceptance Criteria for Thermistor Temperature Stabilization Time

The 95% confidence bound on mean thermistor temperature stabilization time must be less than or equal to 60 seconds. Please refer to Attachment C for protocol and test report.

Acceptance Criteria for Temperature Accuracy

The 95% confidence bound on mean thermistor temperature measurement error must be less than or equal to $\pm 0.3^{\circ}\text{C}$. Please refer to Attachment C for protocol and test report

The following are criteria for standards and guidances which were used by Camino NeuroCare™ Inc. for the monitor.

FDA - Reviewer Guidance for Computer Controlled Medical Devices

000275

Premarket Notification - Camino NeuroCare™

TAB 11

ATTACHMENTS

000276

Premarket Notification - Camino NeuroCare™

ATTACHMENT A

ANIMAL TEST DATA

351

000277

Premarket Notification - Camino NeuroCare™

ATTACHMENT B

BIOCOMPATIBILITY

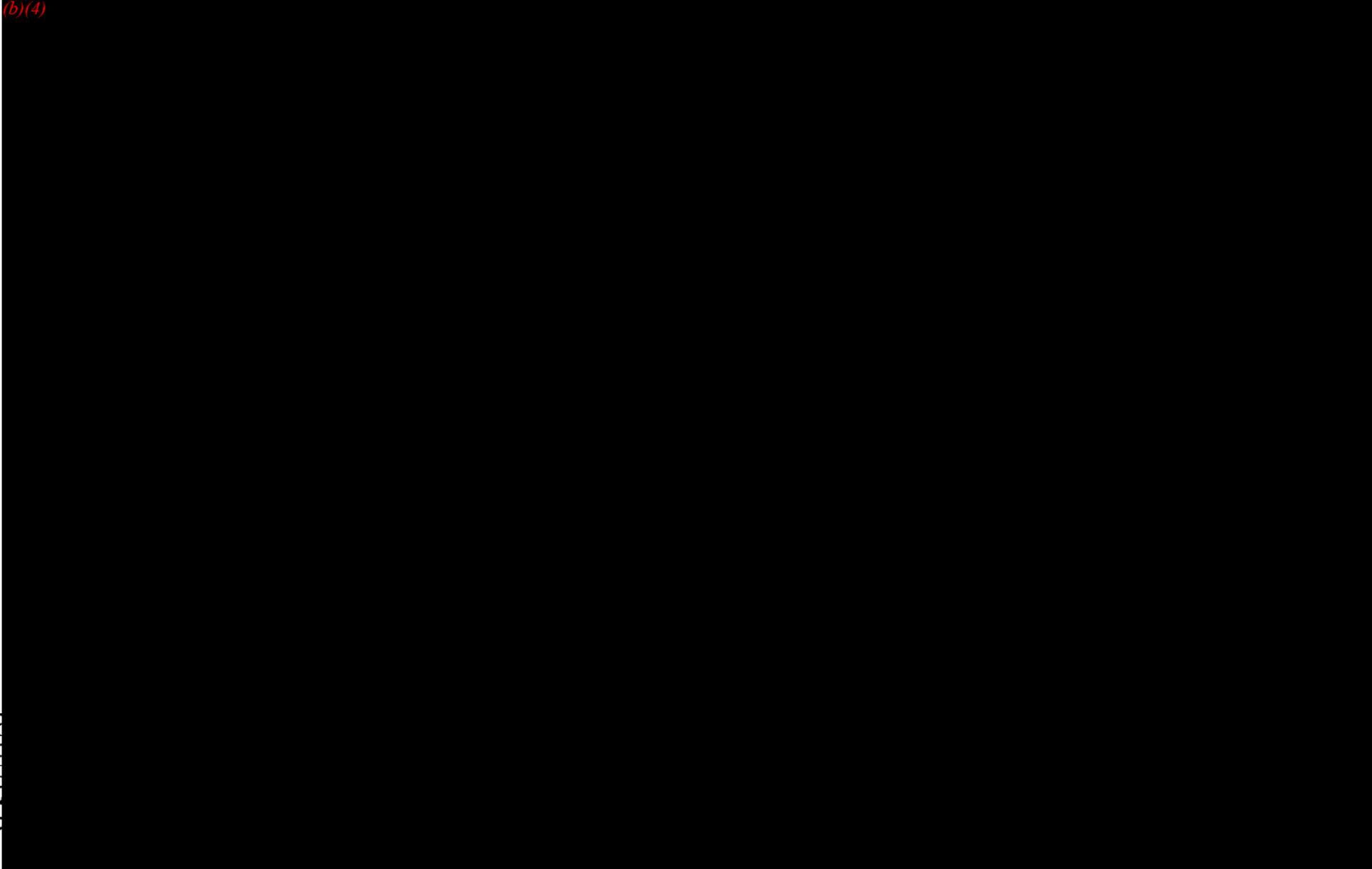
TEST DATA

BIOCOMPATIBILITY TEST RESULTS

Performed per (b)(4)

Handwritten scribbles

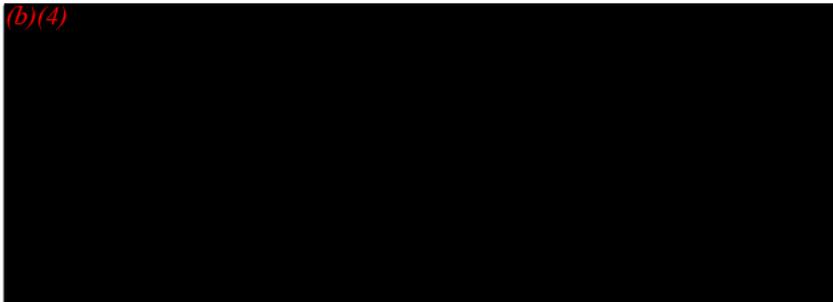
Test	Test Description	Sample Description	Results
------	------------------	--------------------	---------



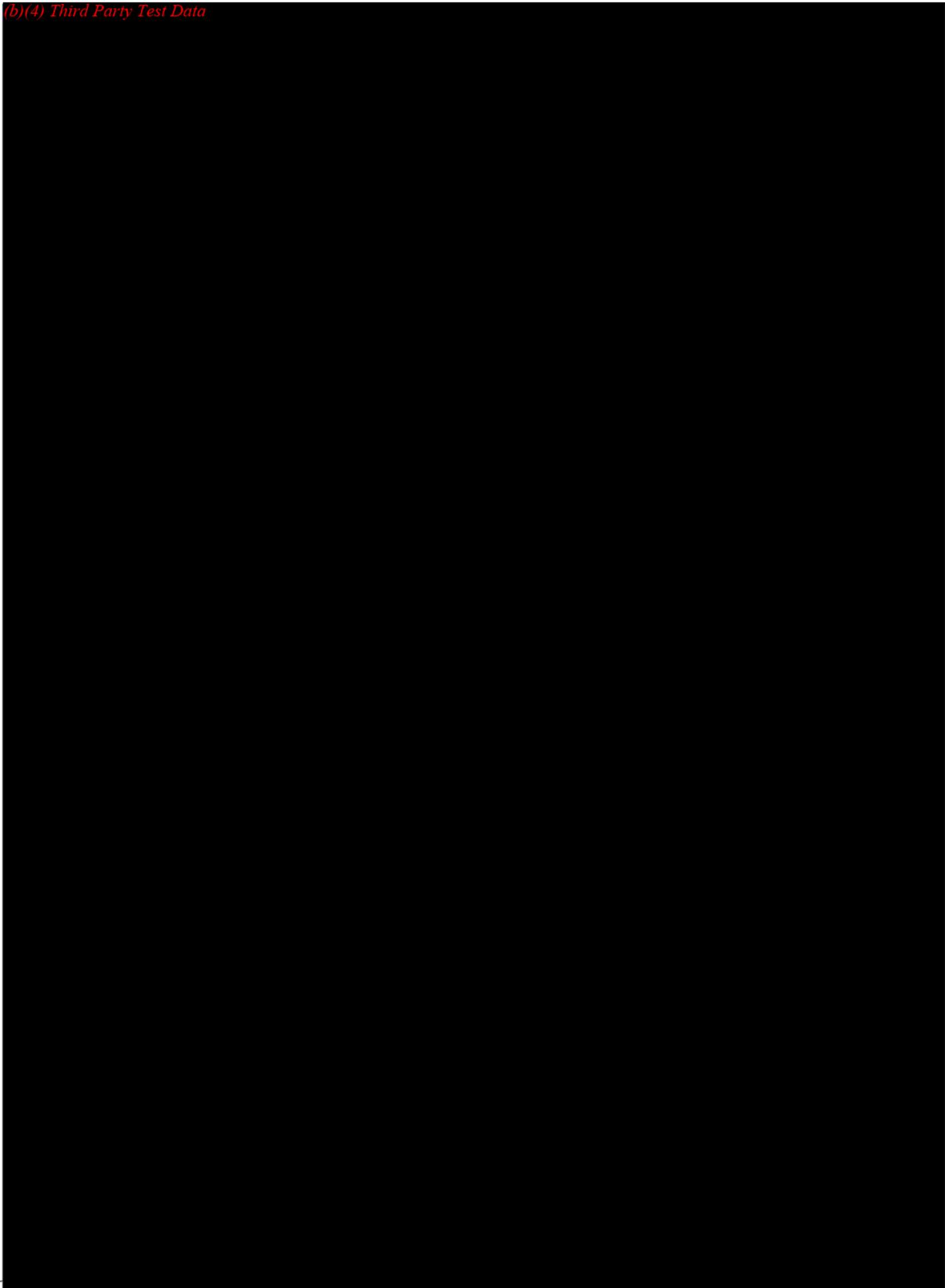
618000

BIOCOMPATIBILITY TEST DATA

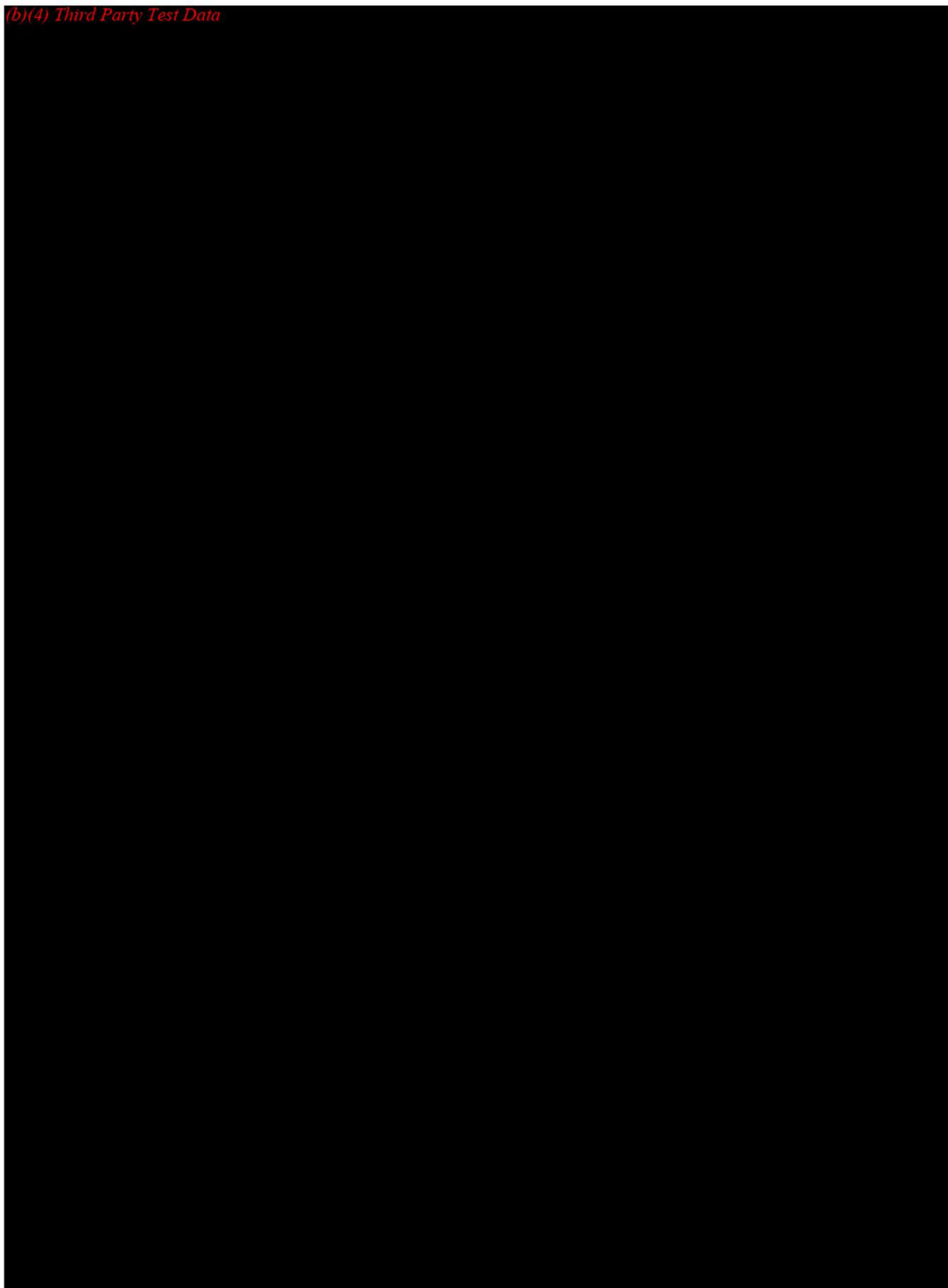
(b)(4)



(b)(4) Third Party Test Data

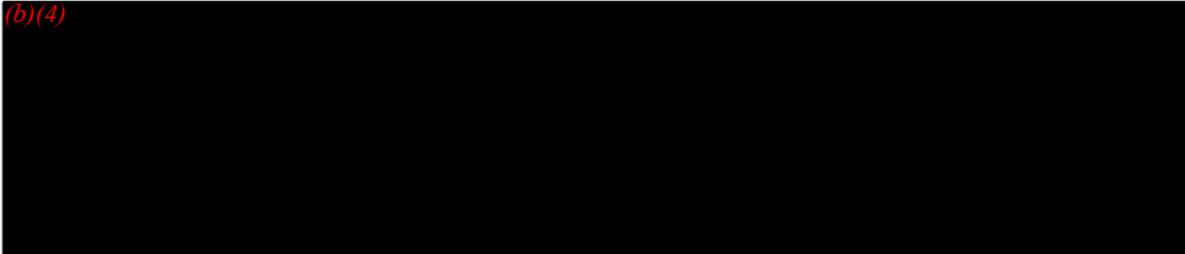


(b)(4) Third Party Test Data

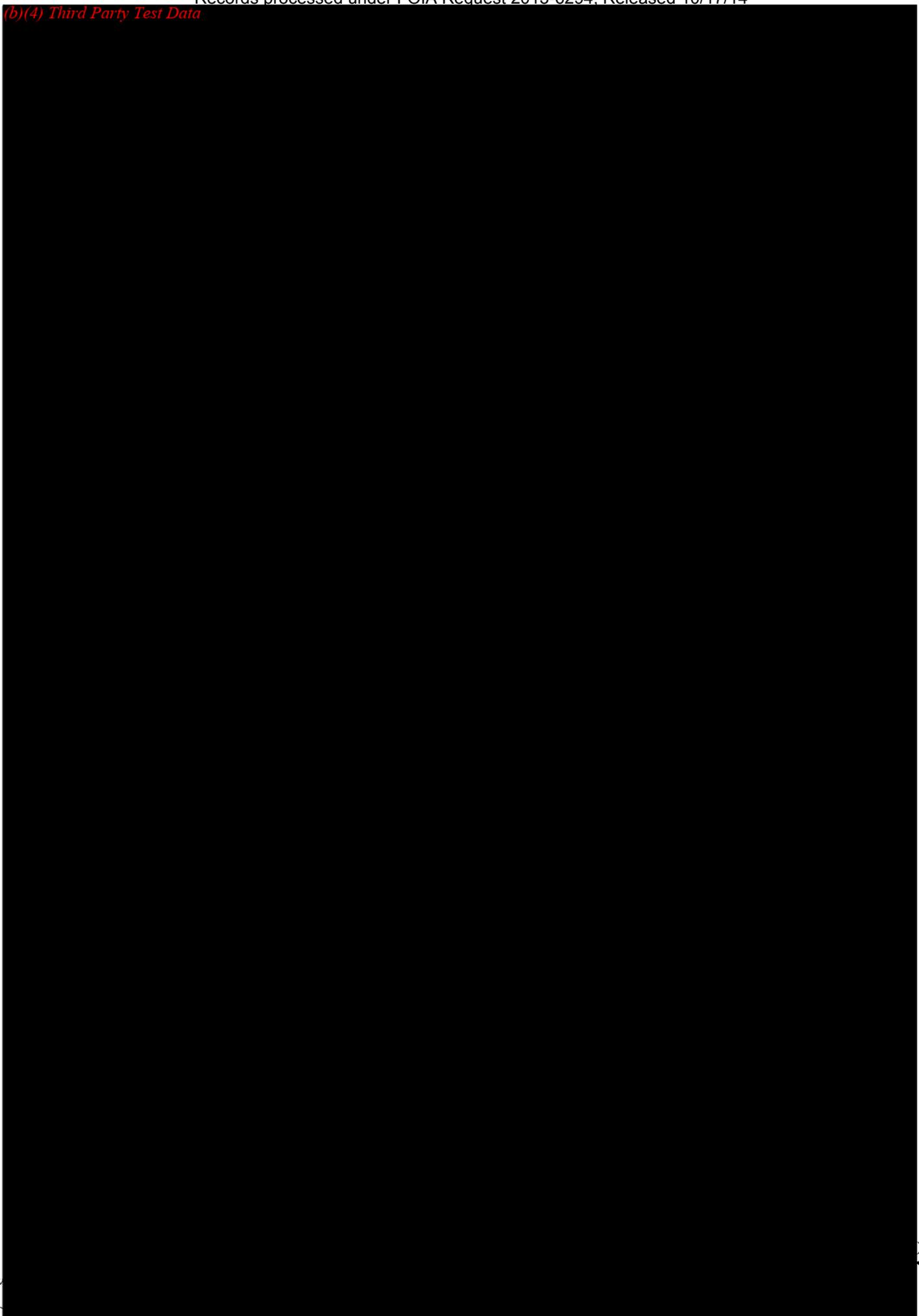


BIOCOMPATIBILITY TEST DATA

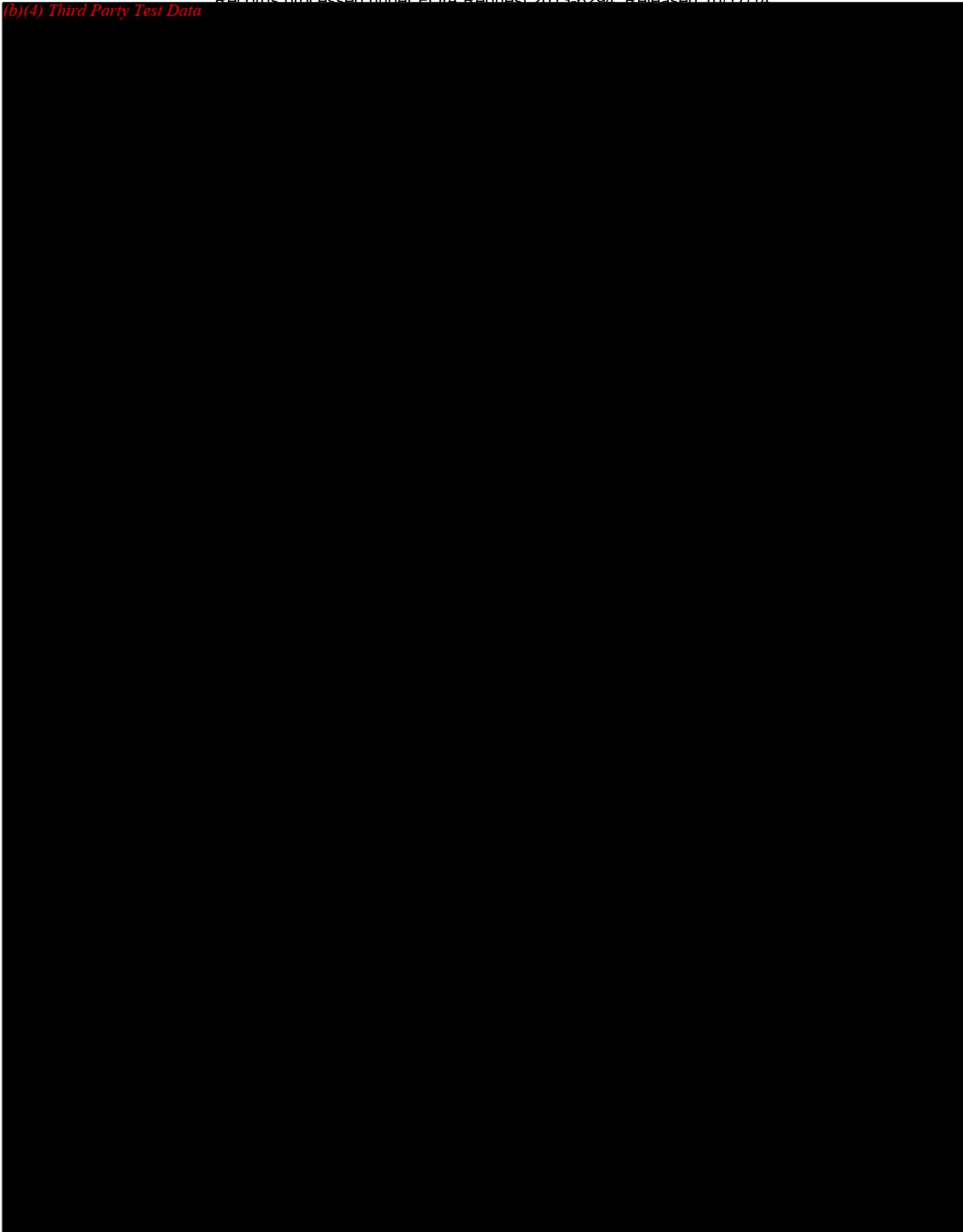
(b)(4)



(b)(4) Third Party Test Data

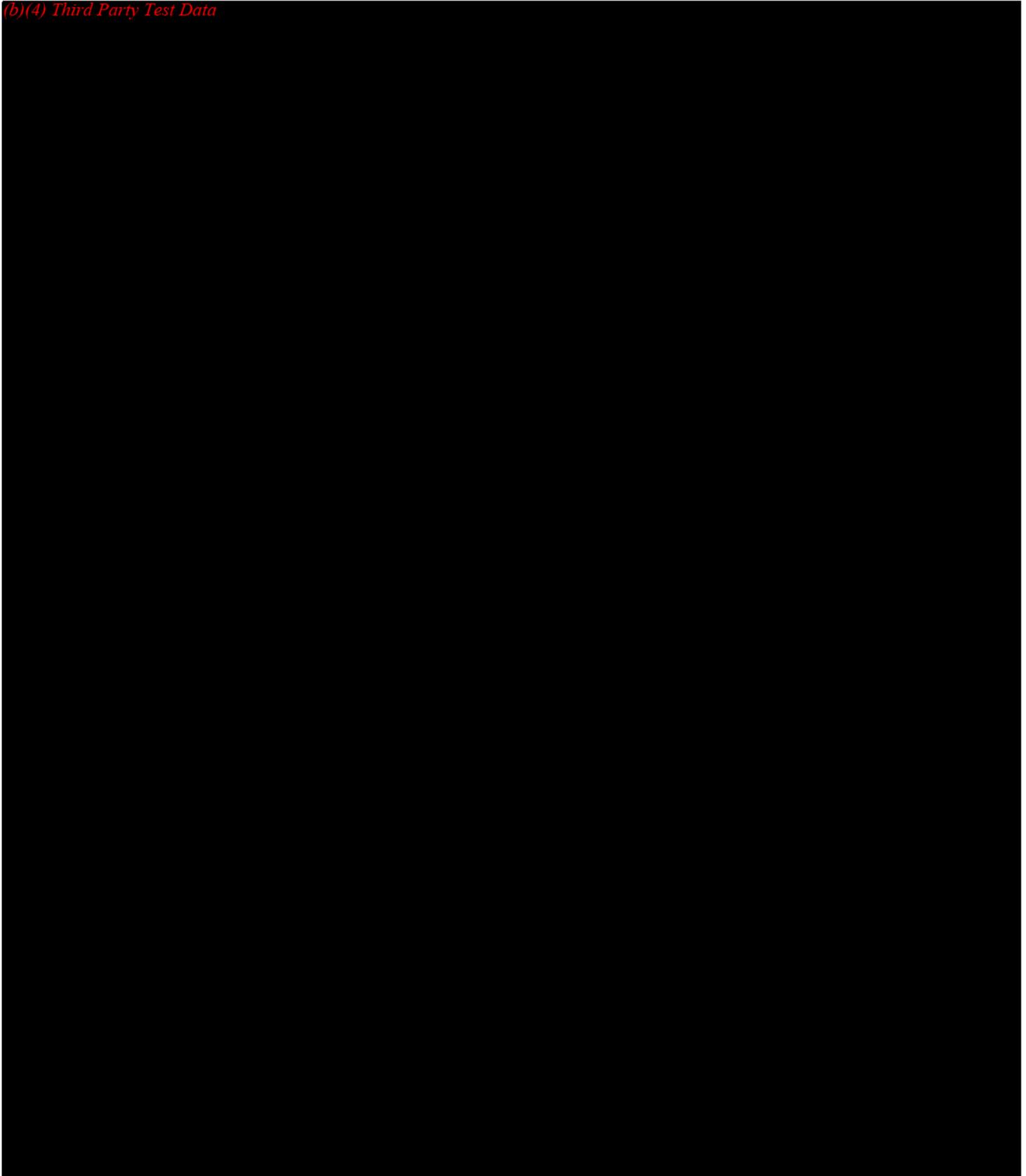


(b)(4) Third Party Test Data



309

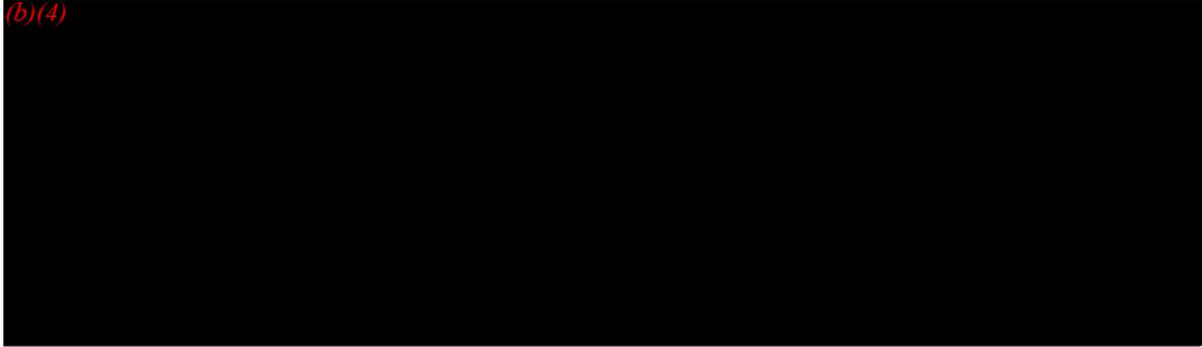
(b)(4) Third Party Test Data



000326

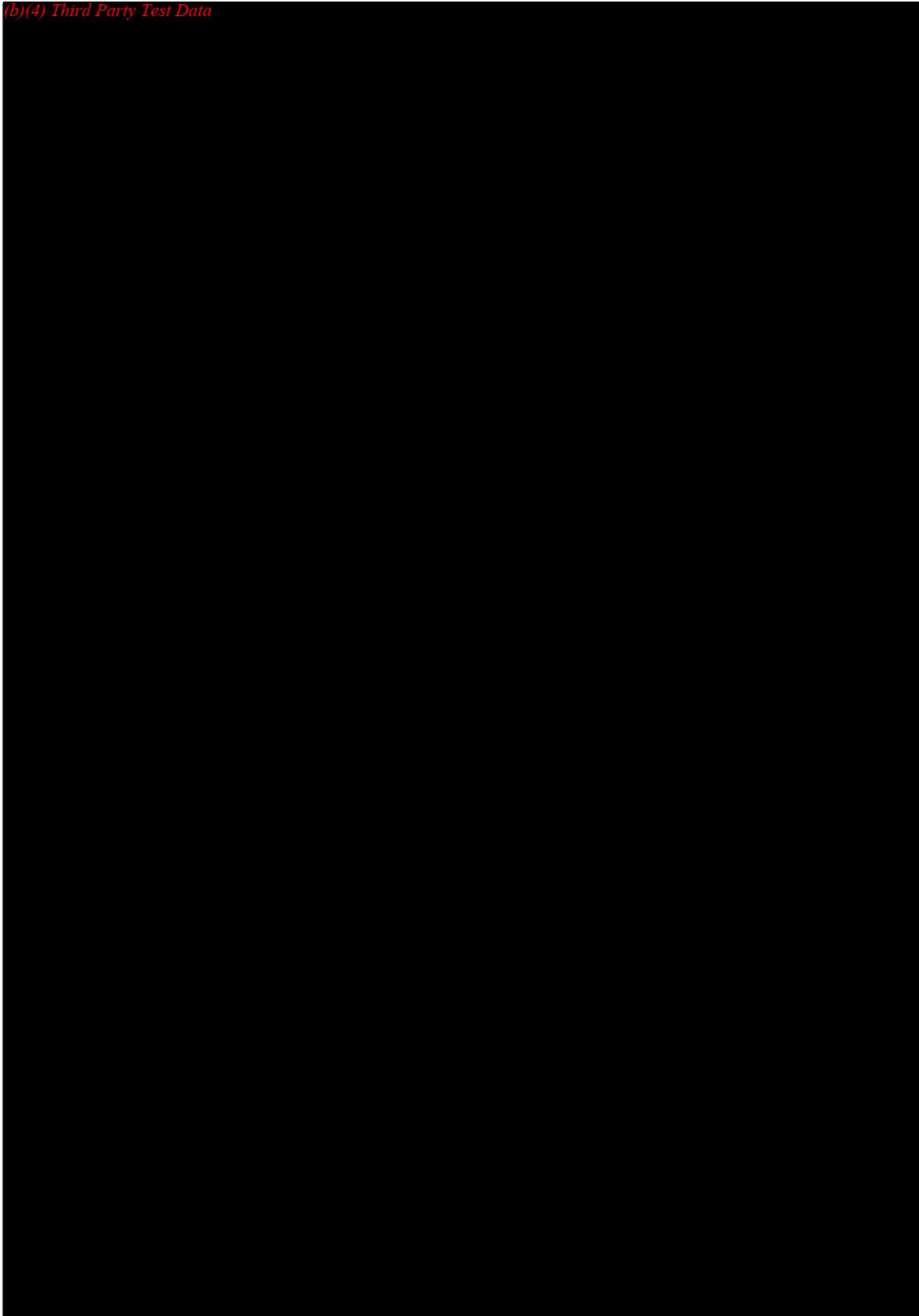
BIOCOMPATIBILITY TEST DATA

(b)(4)

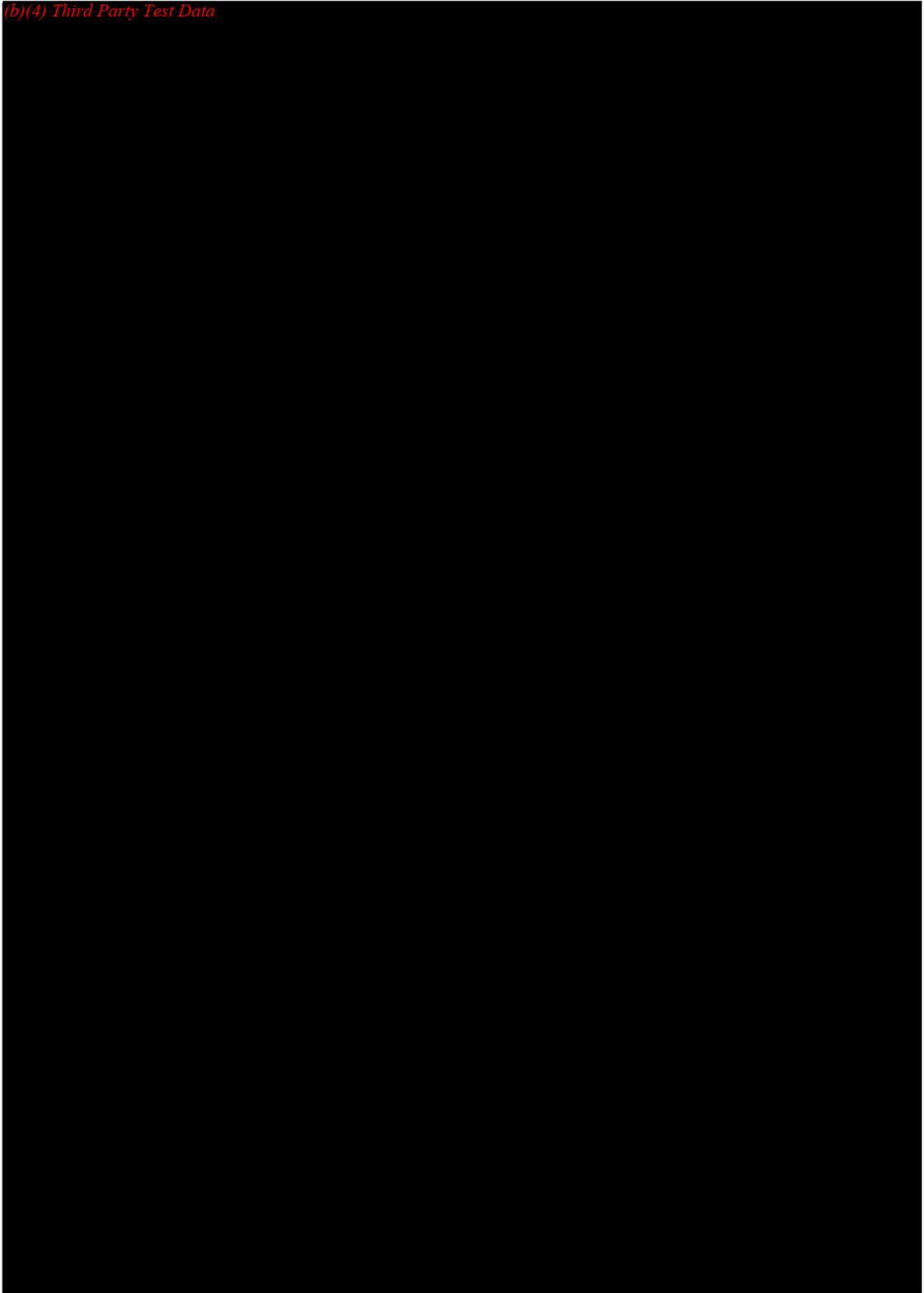


000327

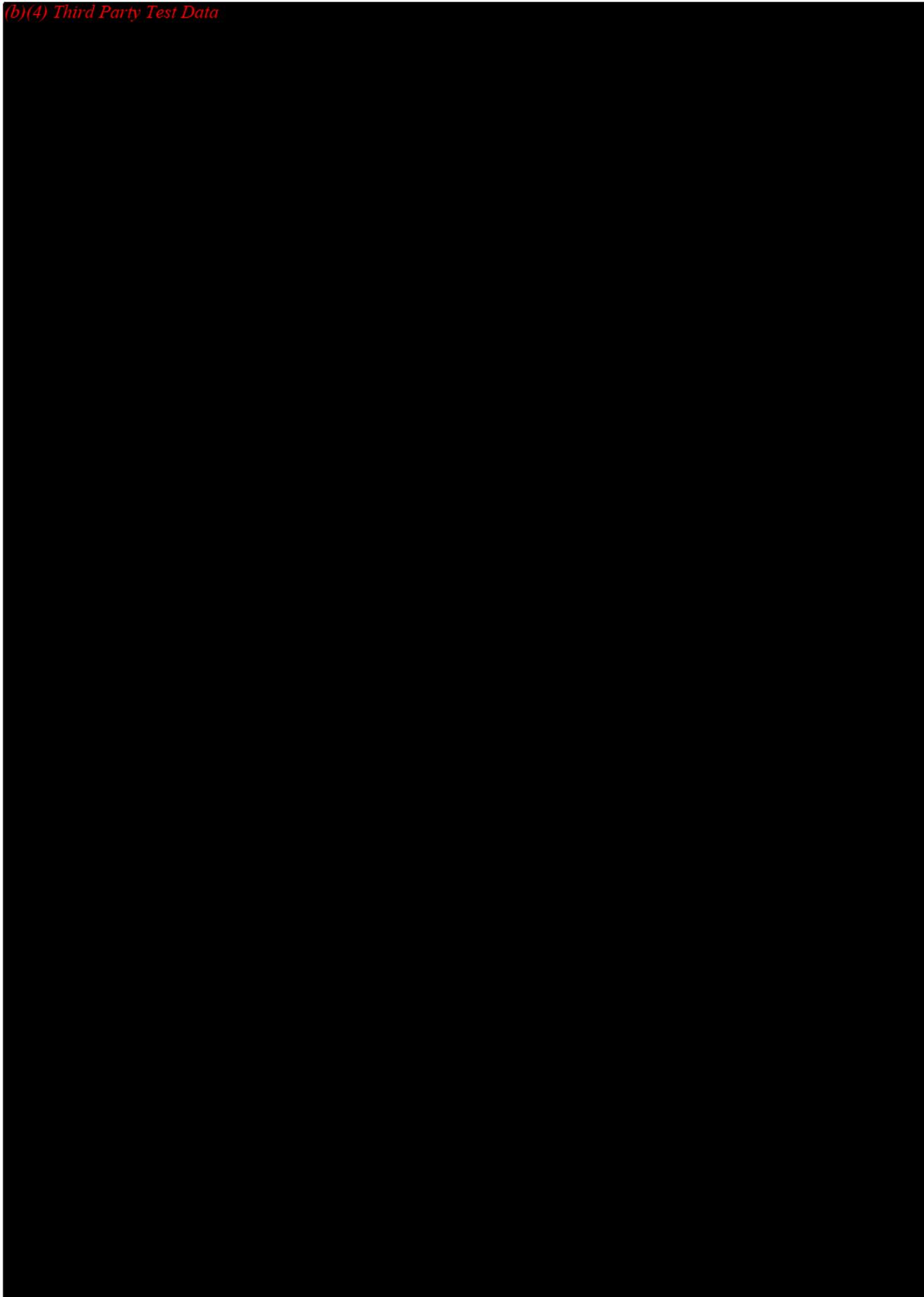
(b)(4) Third Party Test Data



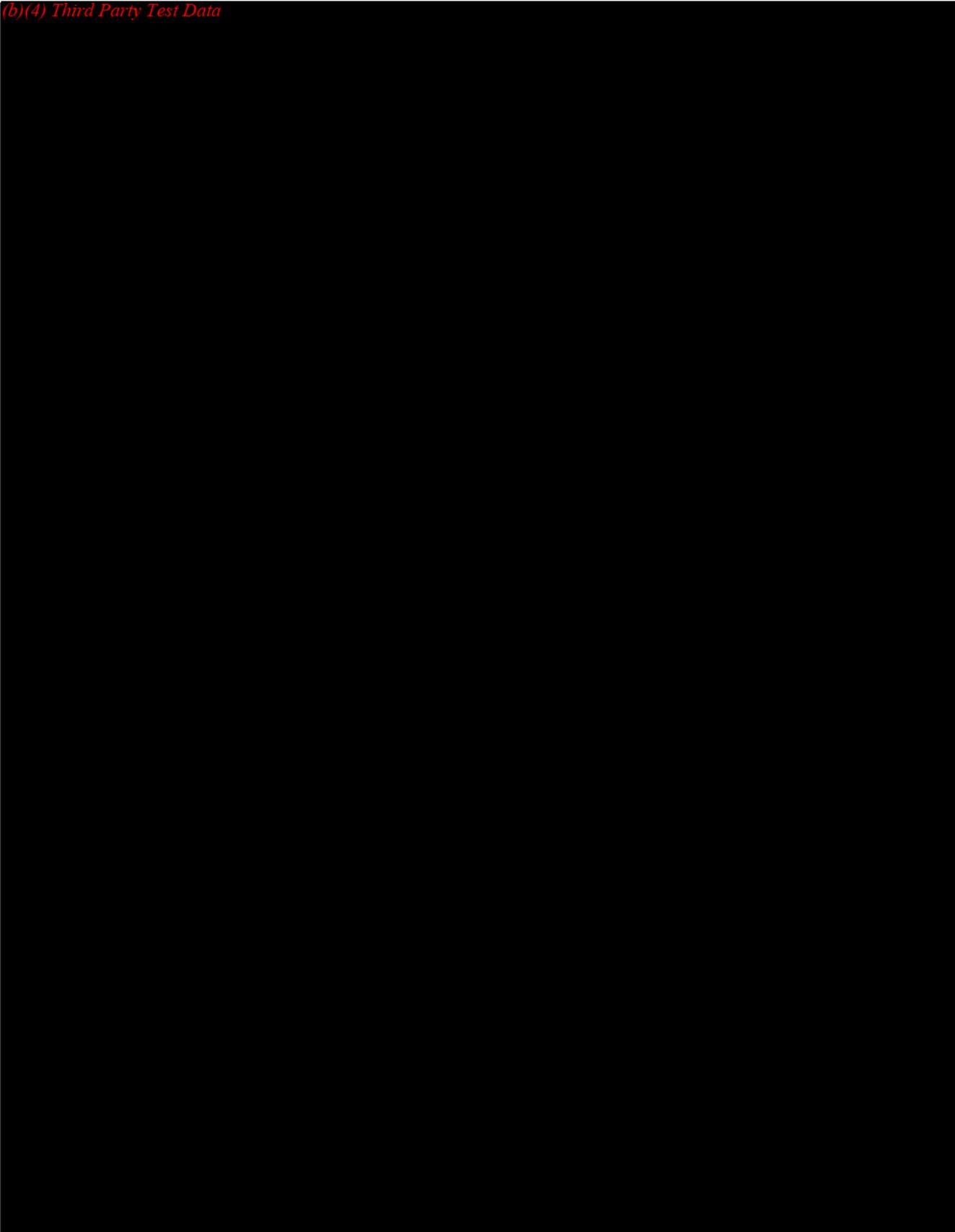
(b)(4) Third Party Test Data



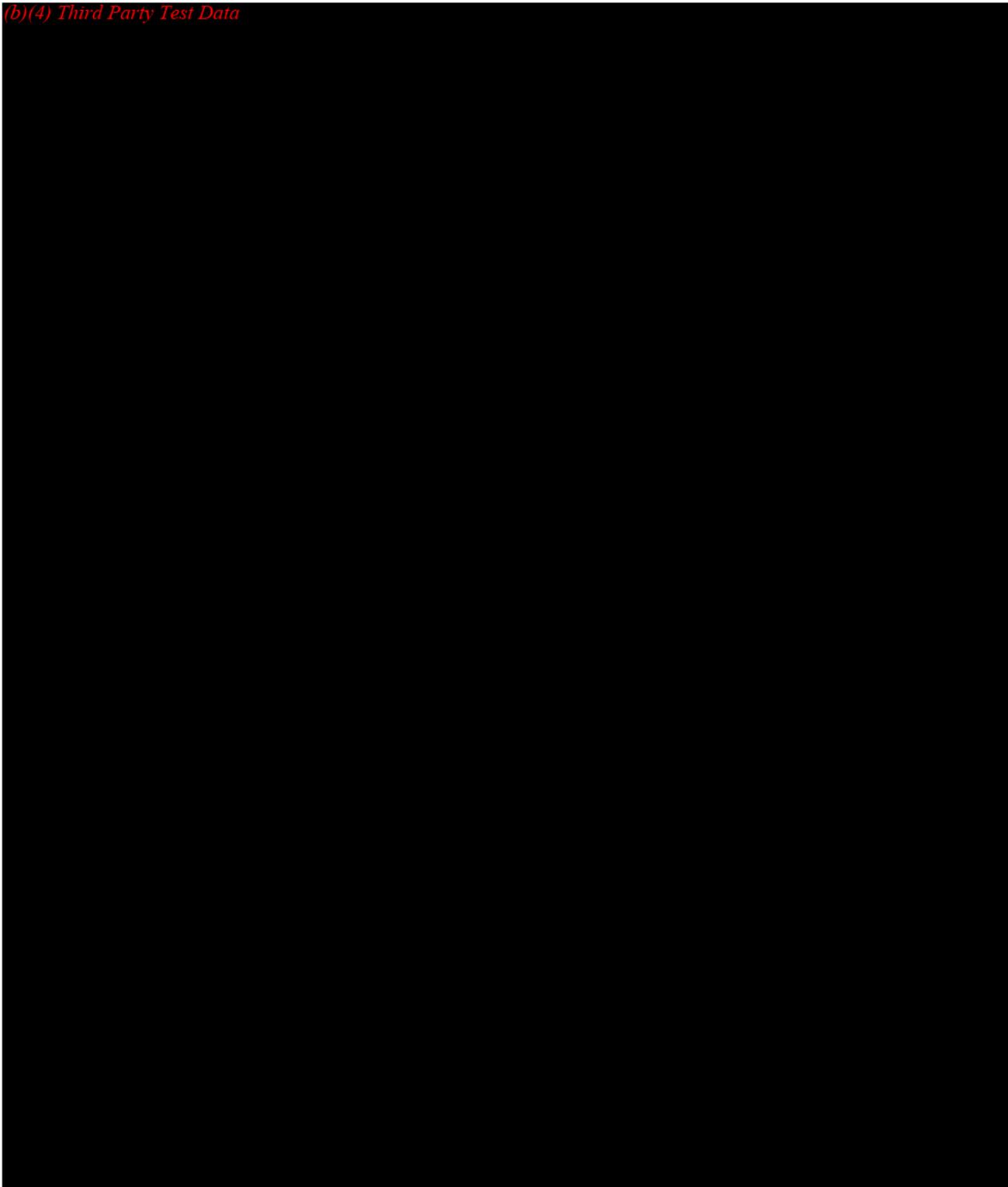
(b)(4) Third Party Test Data



(b)(4) Third Party Test Data

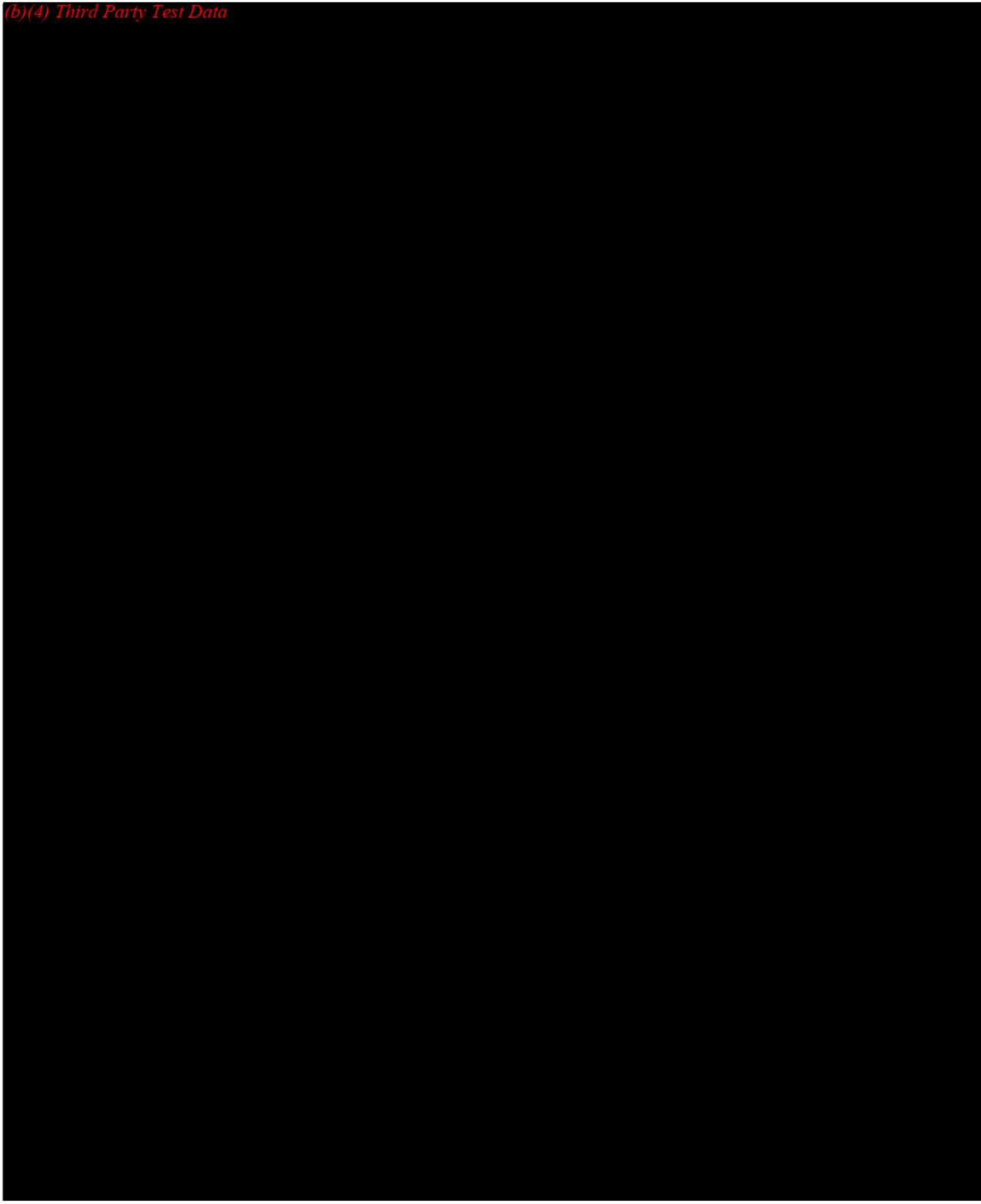


(b)(4) Third Party Test Data

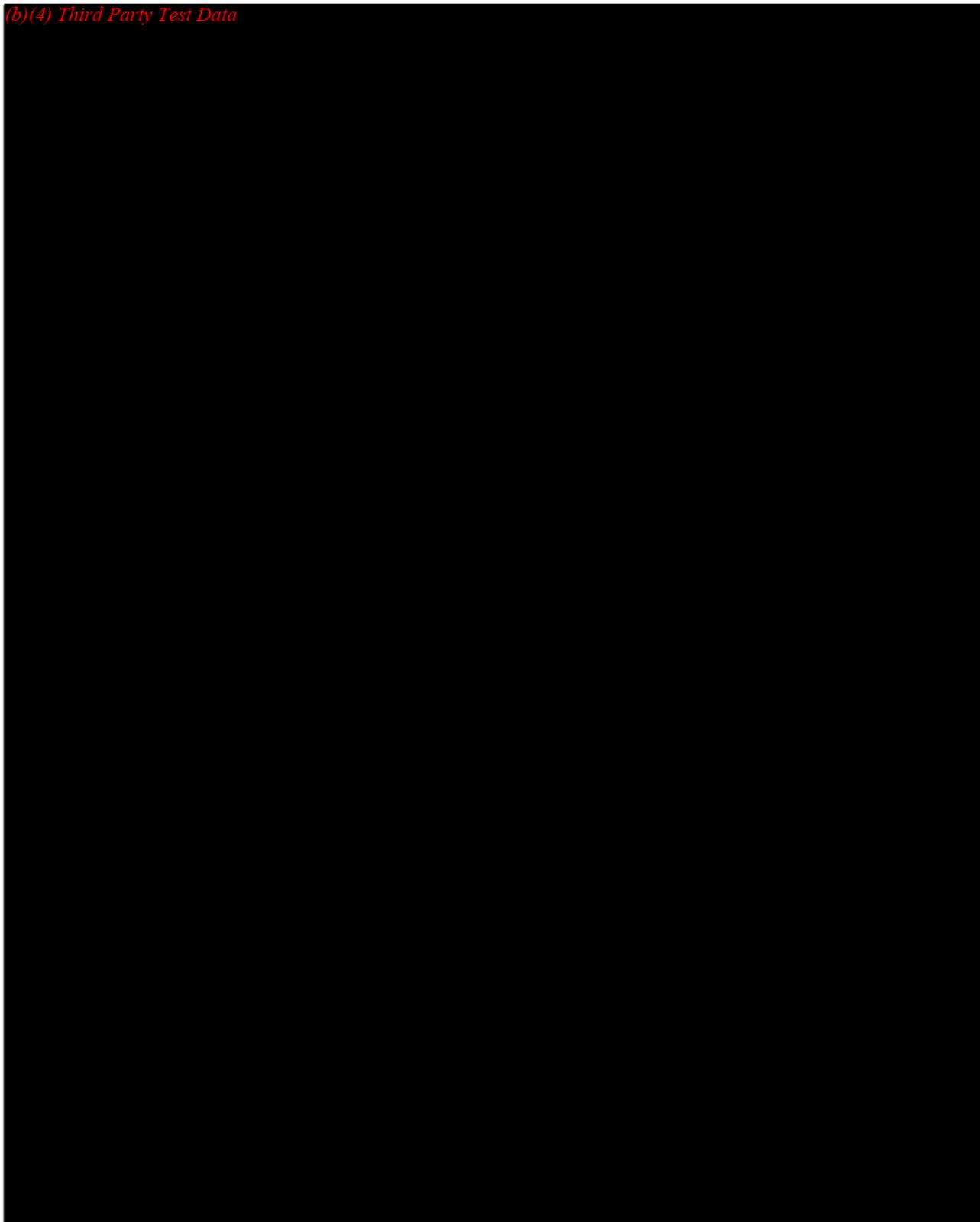


400

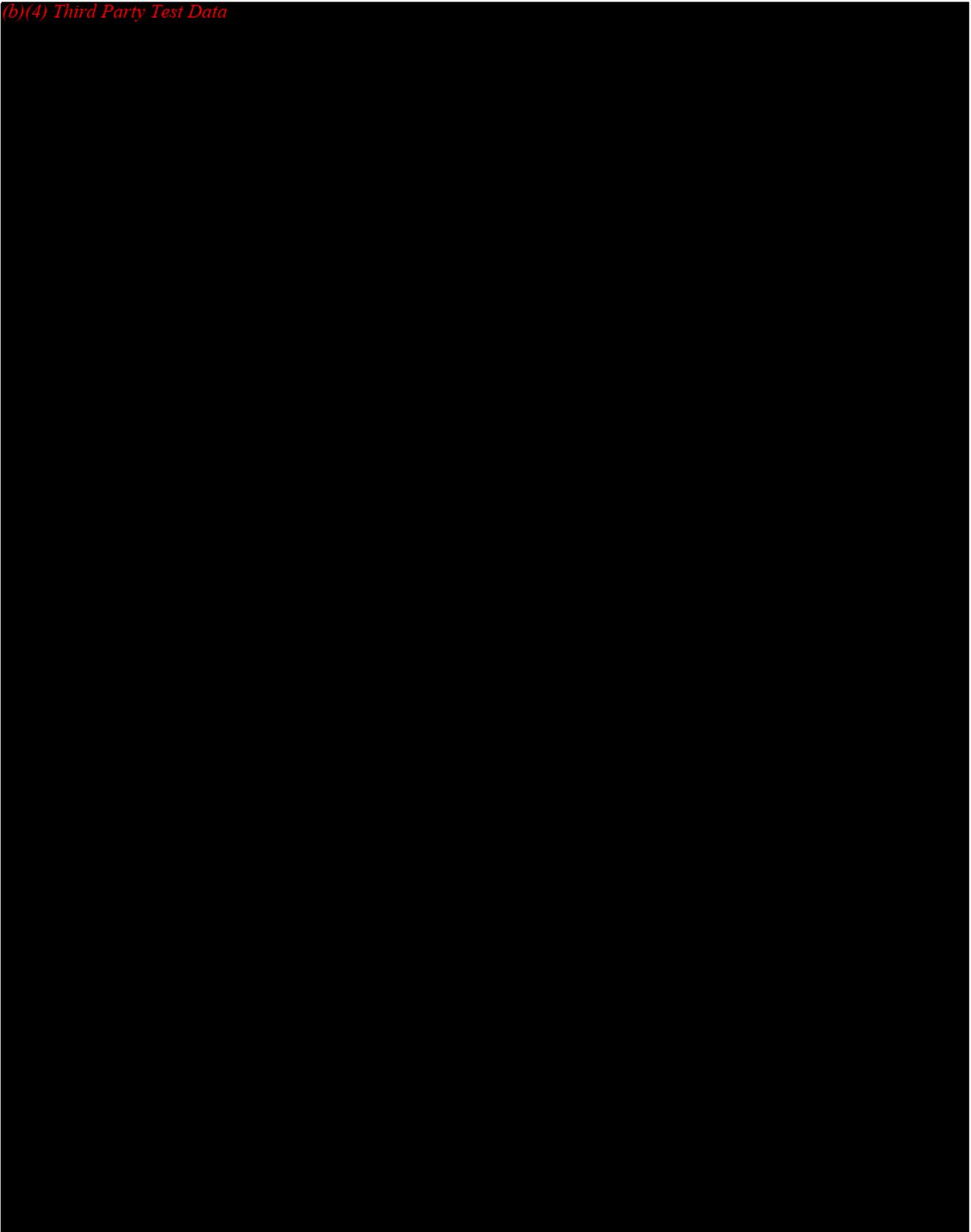
(b)(4) Third Party Test Data



(b)(4) Third Party Test Data

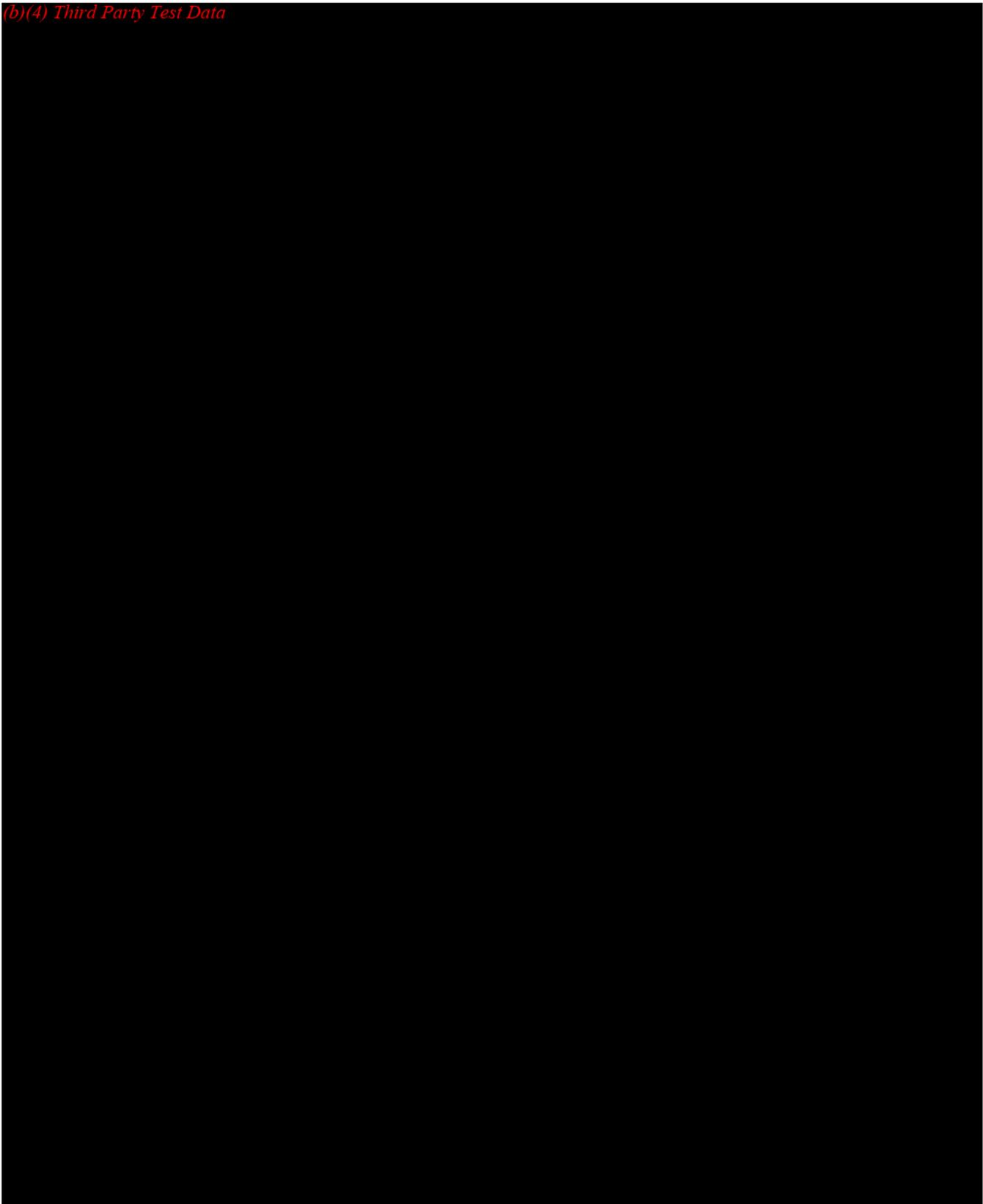


(b)(4) Third Party Test Data

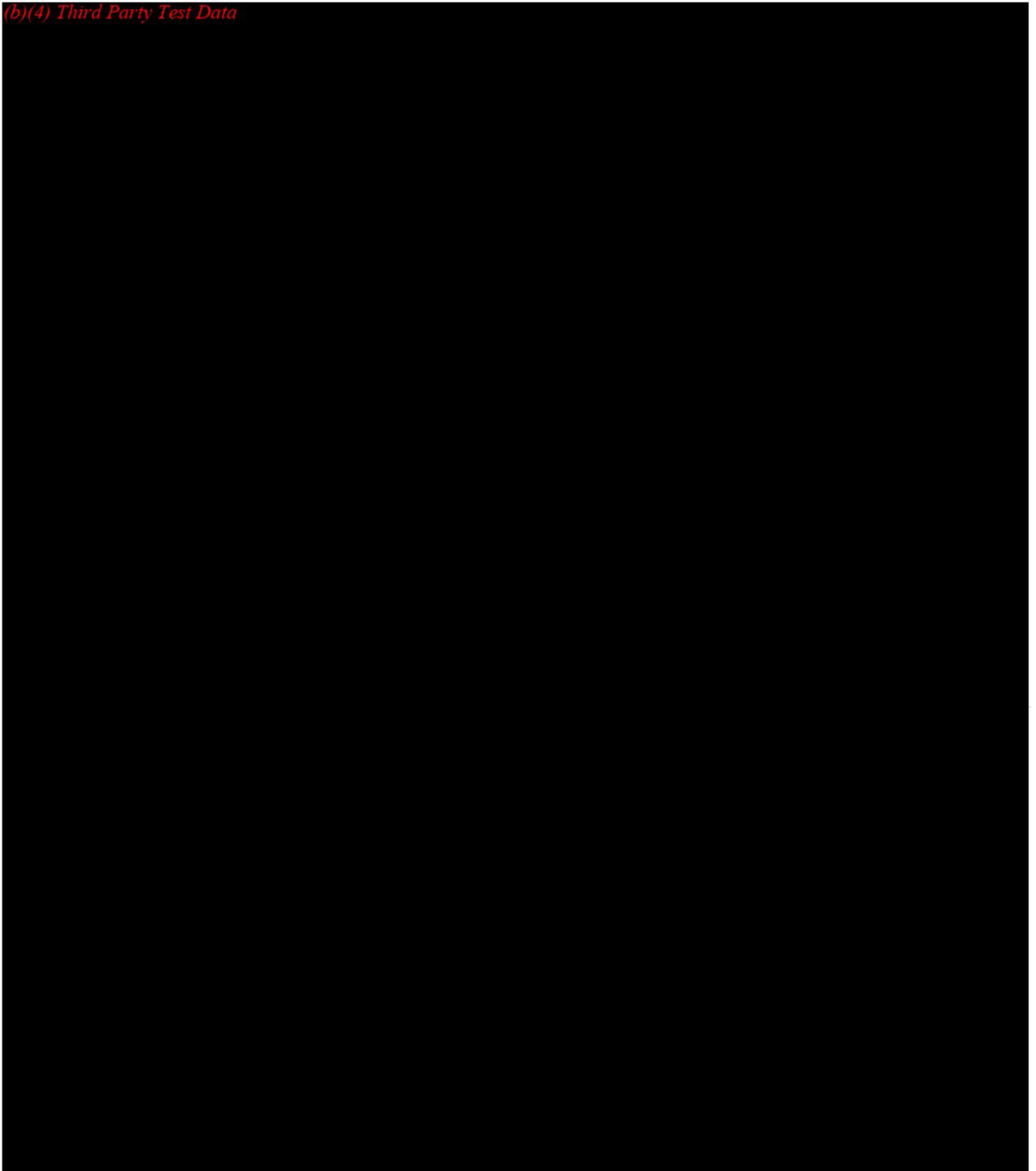


000335

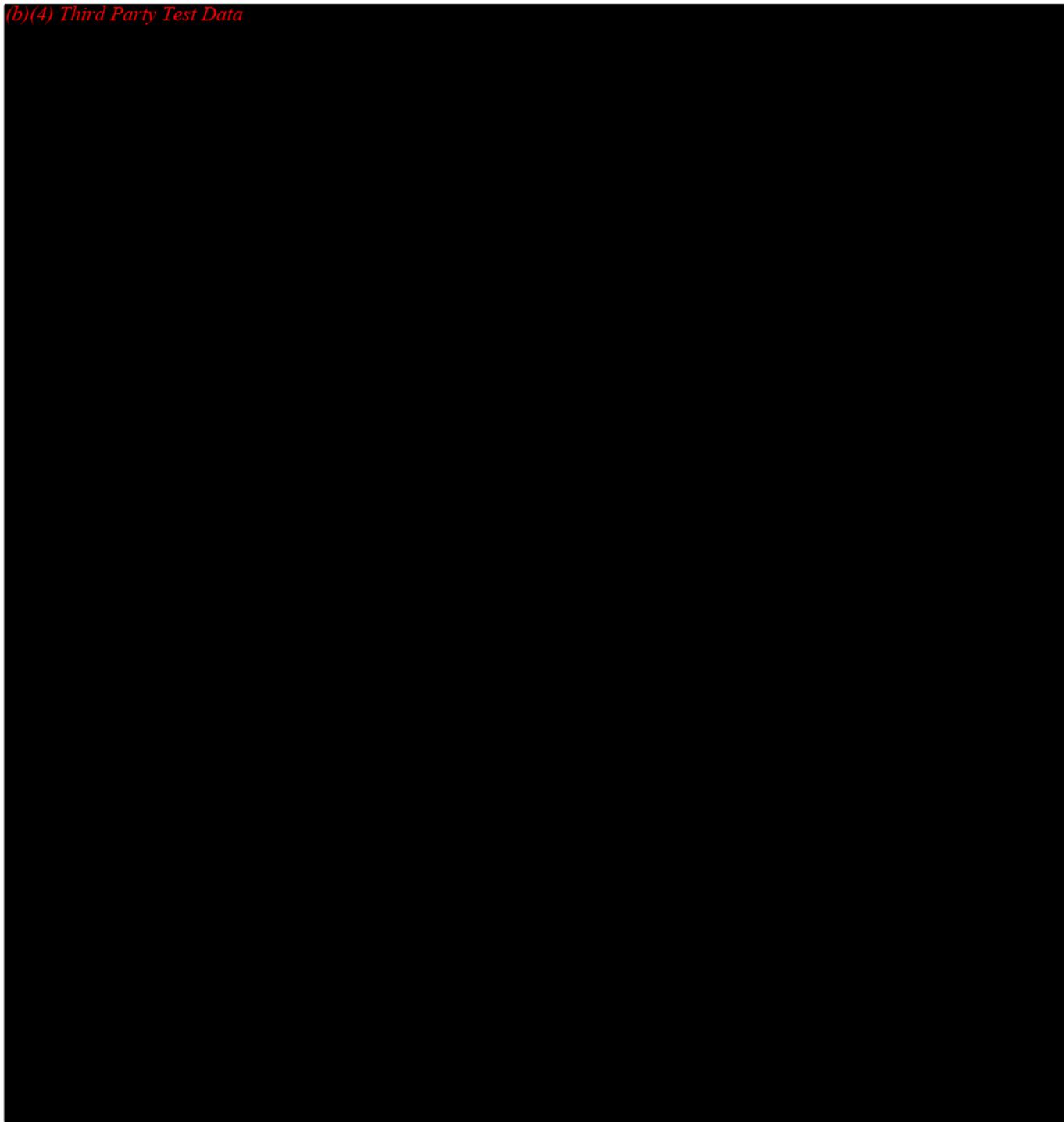
(b)(4) Third Party Test Data



(b)(4) Third Party Test Data

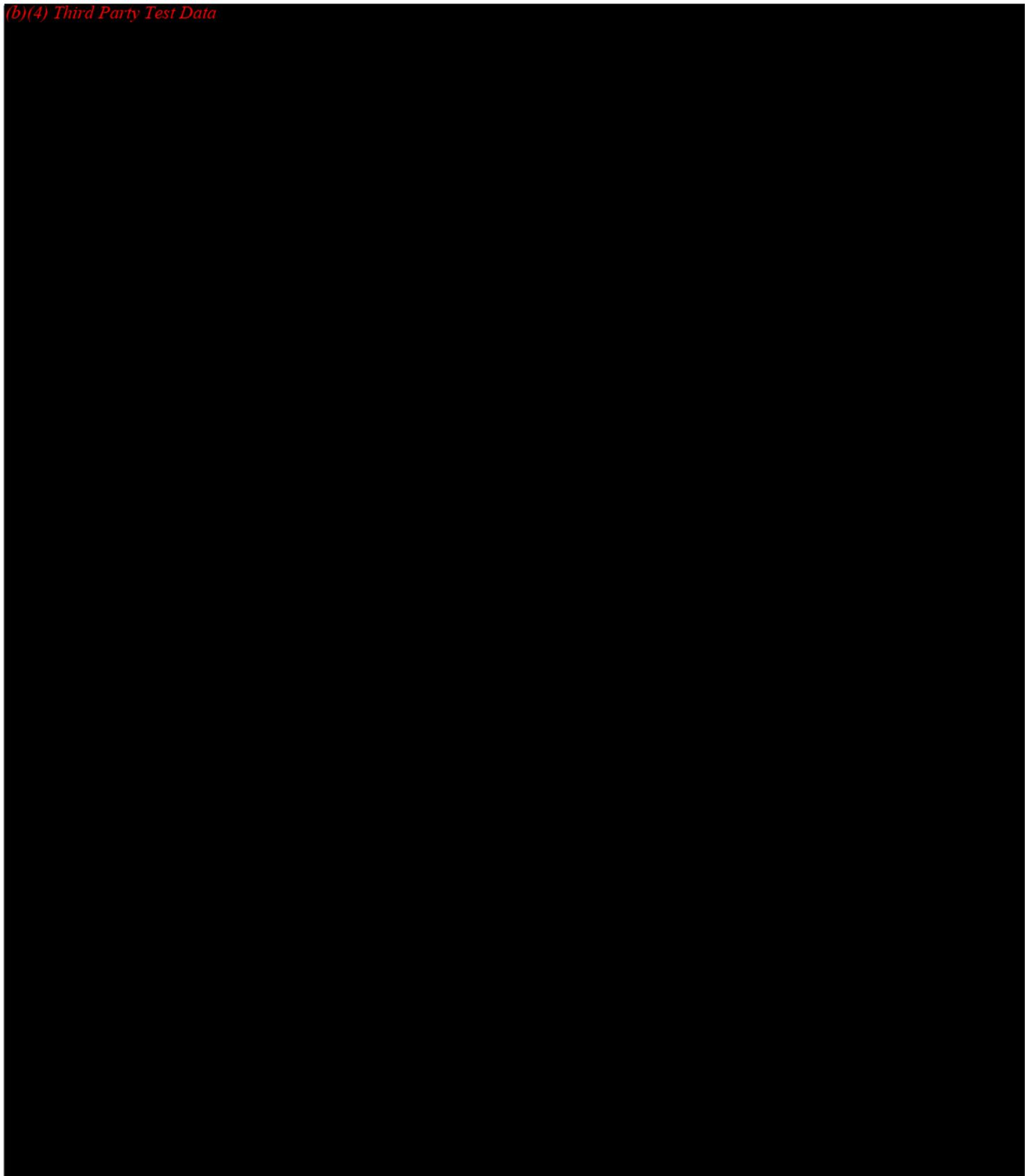


(b)(4) Third Party Test Data



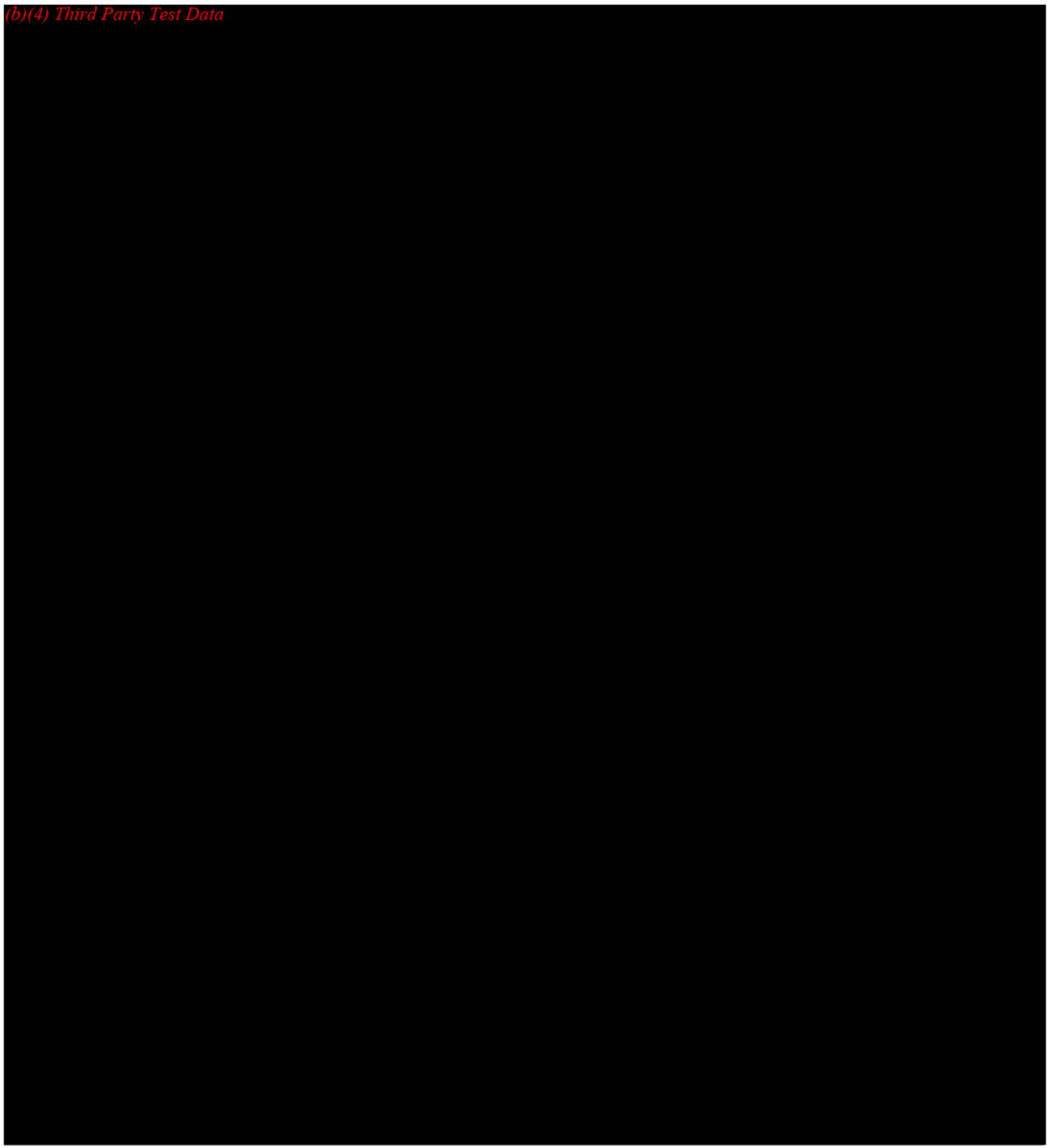
000335

(b)(4) Third Party Test Data



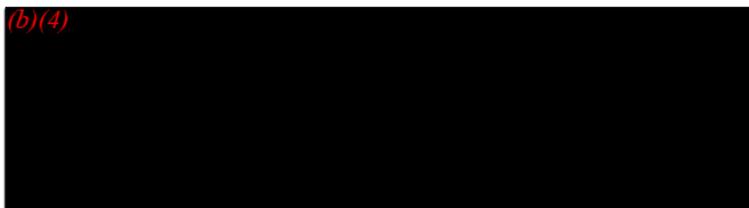
000330

(b)(4) Third Party Test Data



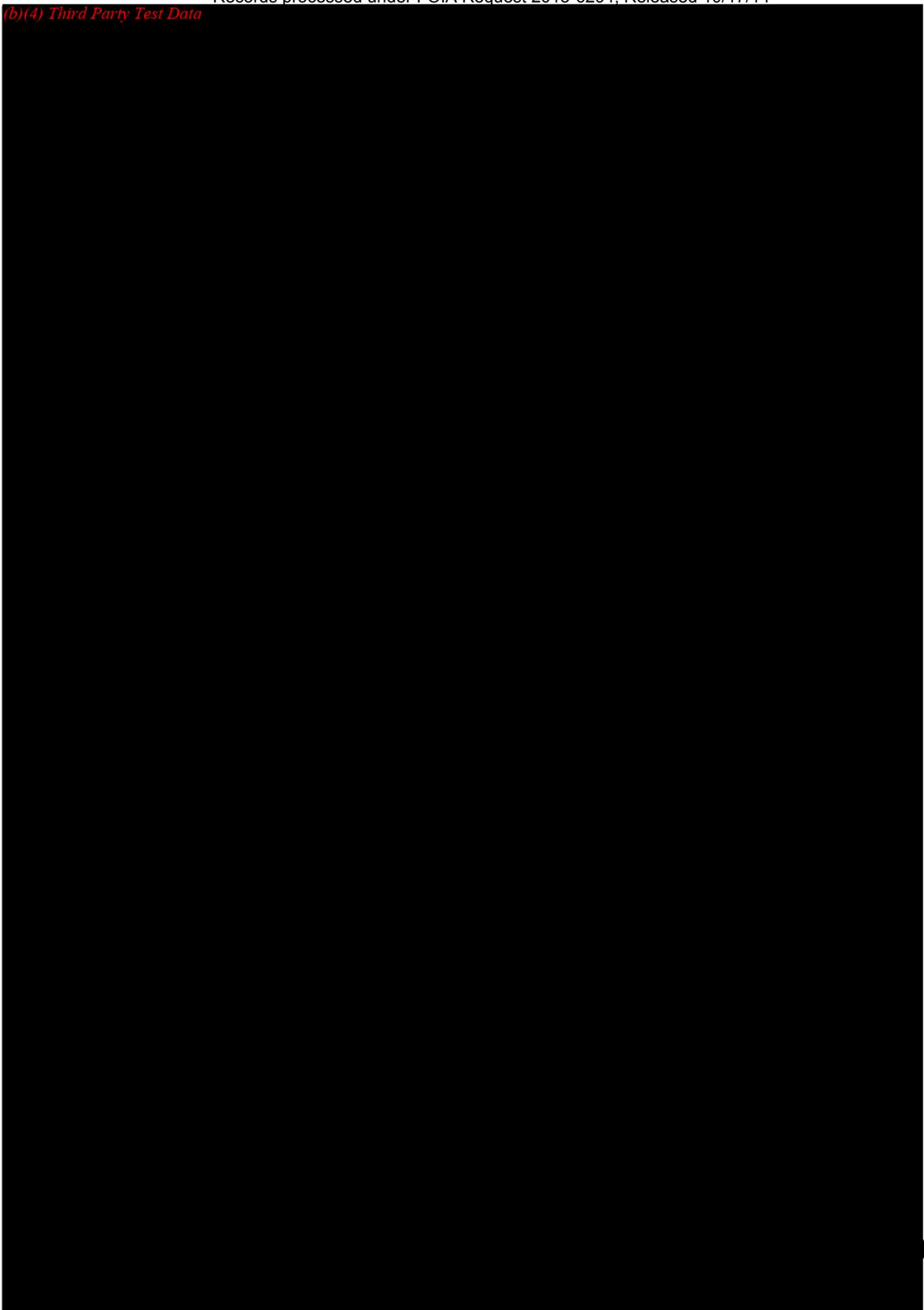
000340

BIOCOMPATIBILITY TEST DATA

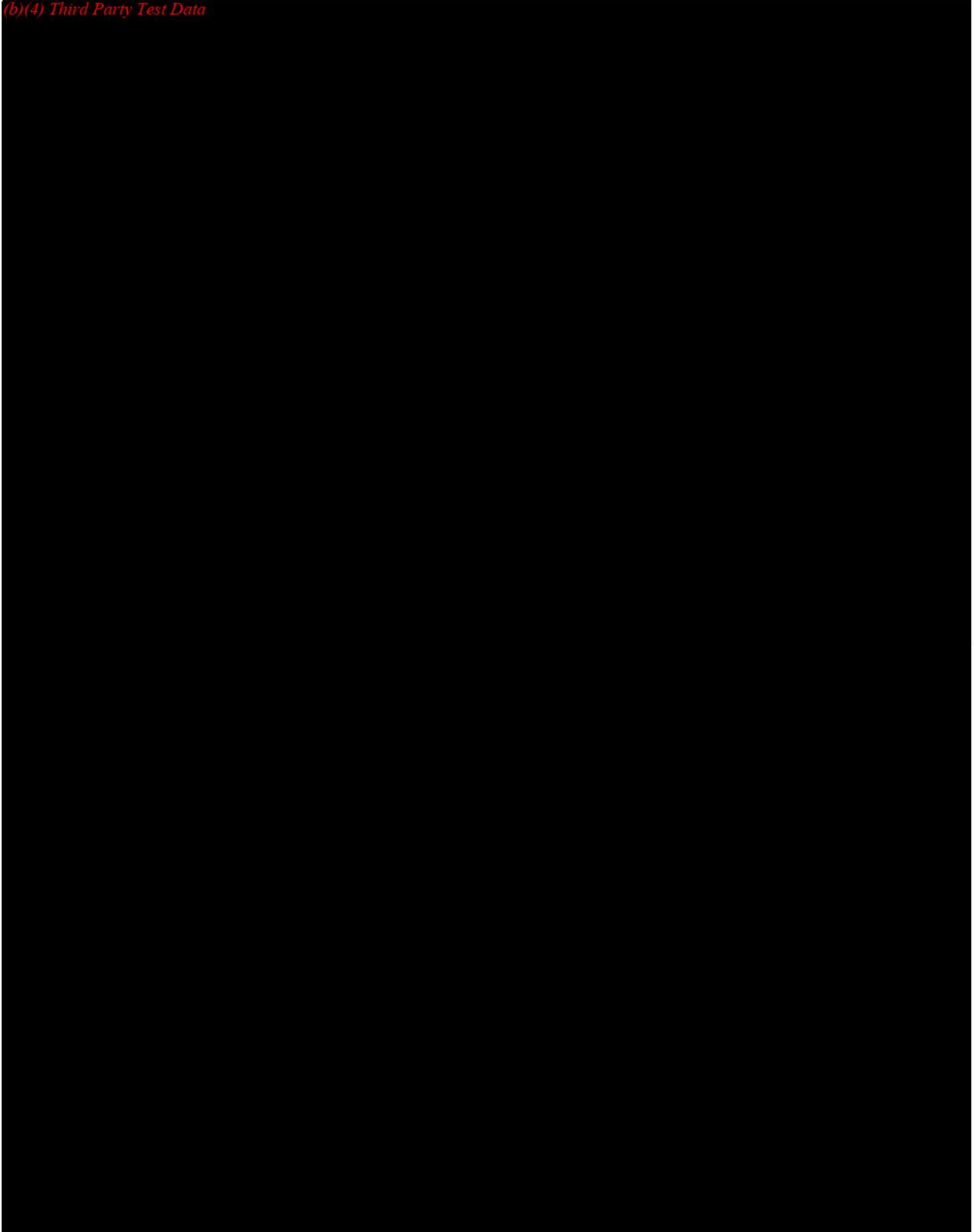


000341

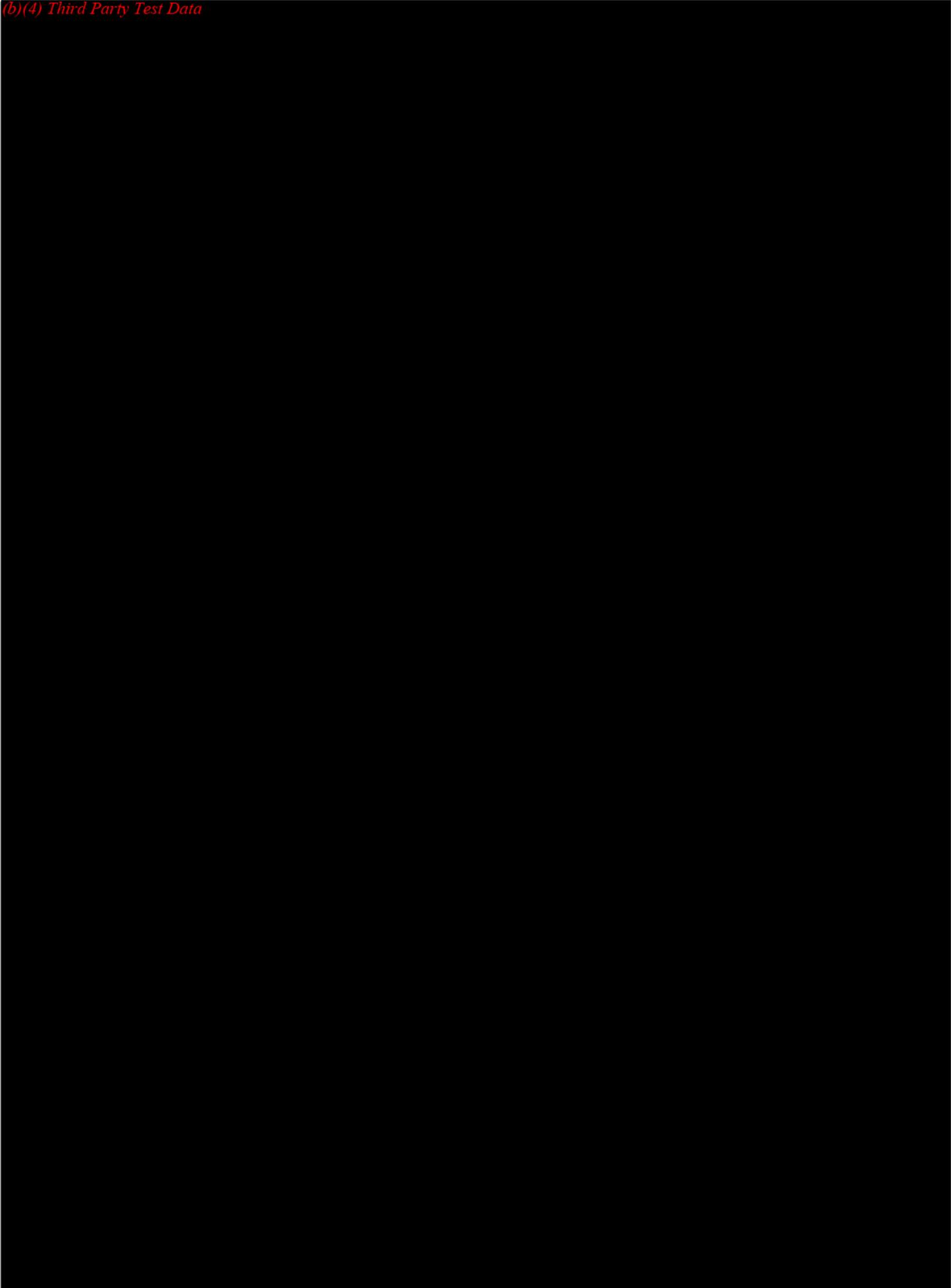
(b)(4) Third Party Test Data



(b)(4) Third Party Test Data



(b)(4) Third Party Test Data



Premarket Notification - Camino NeuroCare™

BIOCOMPATIBILITY TEST DATA

(b)(4)

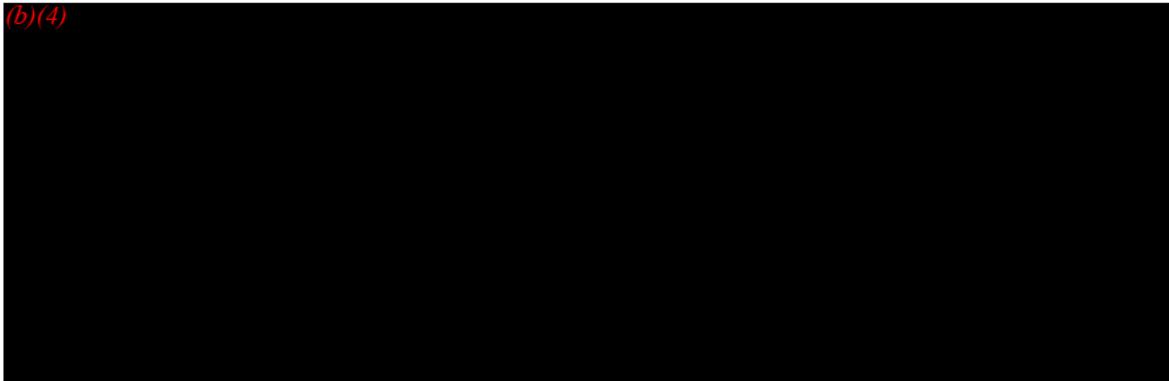


000345

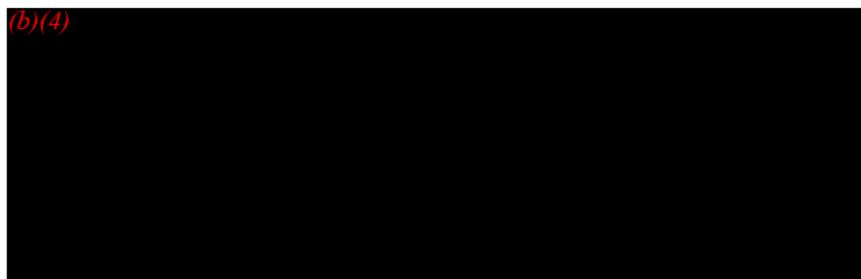
Premarket Notification - Camino NeuroCare™

BIOCOMPATIBILITY TEST DATA

(b)(4)

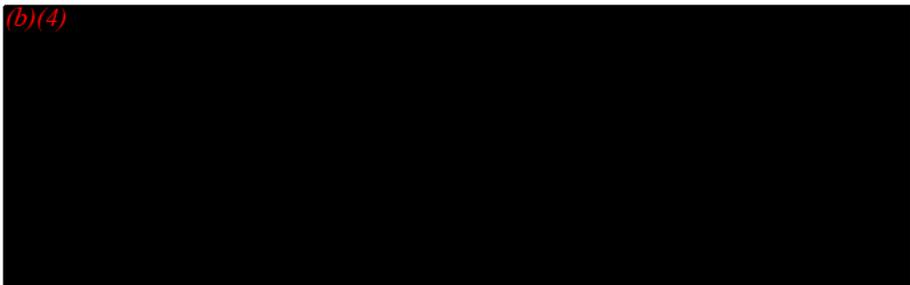


BIOCOMPATIBILITY TEST DATA



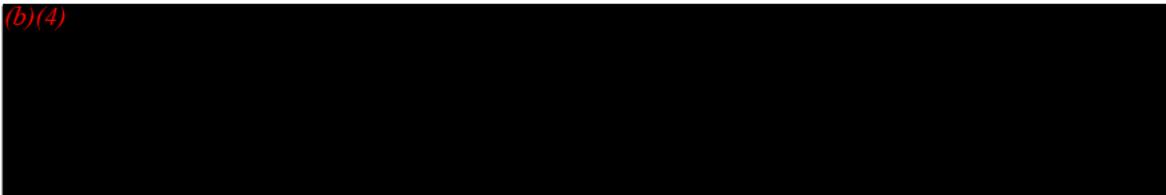
BIOCOMPATIBILITY TEST DATA

(b)(4)



BIOCOMPATIBILITY TEST DATA

(b)(4)

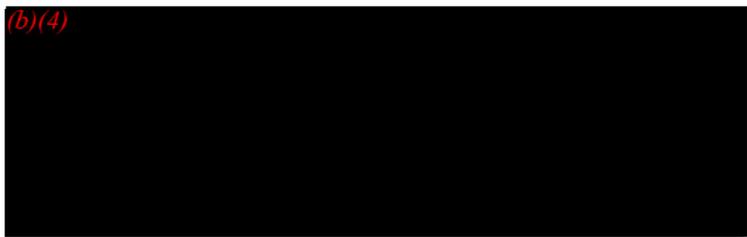


000360

Premarket Notification - Camino NeuroCare™

BIOCOMPATIBILITY TEST DATA

(b)(4)



Premarket Notification - Camino NeuroCare™

ATTACHMENT C

**TEMPERATURE
STABILIZATION AND
ACCURACY DATA**

