

JUL 12 2001

K011291

510(k) Summary

Submitter's Name: Exergen Corporation

Address: 51 Water Street
Watertown, MA 02172

Phone: (617) 923-9900
(800) 422-3006

Fax: (617) 923-9911

Contact: Gerald A. Clay

Date of Summary: April 27,2001

Trade Name: TemporalScanner Thermometer, formerly known as SensorTouch

Classification: Thermometer, Clinical, Electronic
Product Code: FLL
Regulation No. 880.2910
Class: II
Panel: 80 (General Hospital)

Predicate Device(s): Exergen Surface Temperature Scanner (K 873010) (Exergen Predicate)

Braun Thermoscan IRT 3020/3520 (K983295)(Braun Predicate)

Device Description: The TemporalScanner is a hand held, battery operated device that measures the skin temperature of the skin over the temporal artery. Operation is based on measuring the natural thermal infrared radiation emitted from the surface of the skin over the temporal artery.

Intended Use: The TemporalScanner Thermometer is an infrared thermometer intended for the intermittent measurement of human body temperature of people of all ages.

Technological

Characteristics: The TemporalScanner Thermometer and the predicate devices are all used to measure the temperature of a human by means of a thermopile

infrared sensor transducer coupled with electronic signal amplification, conditioning, and display unit.

The Exergen Predicate employed solid-state electronic signal amplification which is technology similar to the electronic surface mount technology used by the TemporalScanner Thermometer and the Braun Predicate. The Braun Predicate's signal conditioning consists of making mathematical adjustments to display the familiar oral range. Similarly, the TemporalScanner Thermometer's signal conditioning consists of making mathematical adjustments to the temperature measured at the skin surface over the temporal artery to display the familiar rectal range. All display units are solid-state displays, with the Exergen Predicate using an LED display while the TemporalScanner Thermometer and the Braun Predicate employ an LCD display.

All of the devices meet ASTM E1965-98 *Standard for Infrared Thermometers for Intermittent Determination of Patient Temperature, to the extent that this standard applies to them.*

The primary difference between the TemporalScanner Thermometer and the Braun Predicate is that the Braun Predicate measures the temperature of the auditory canal and mathematically converts and displays a familiar oral temperature, while the TemporalScanner measures surface skin temperature over the temporal artery and mathematically converts and displays a familiar rectal temperature.

Summary of non-clinical Performance Testing:

Performance test	Results
Accuracy tests	Pass
(b)(4) tests	Pass
(b)(4) tests	Pass
(b)(4) range tests	Pass
(b)(4) tests	Pass
(b)(4) test	Pass
EMC tests	Pass
(b)(4) test	Pass
(b)(4) evaluation	Pass

Conclusion:

Since performance testing confirms conformance to the same standard as both predicate devices, we conclude the device is substantially equivalent to those devices.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 12 2001

Exergen Corporation
C/O Mr. William Hare
Associate
Fish and Richardson, PC
601 13th Street, NW
Washington, DC 20005

Re: K011291
Trade/Device Name: TemporalScanner Thermometer,
SensorTouch
Regulation Number: 880.2910
Regulatory Class: II
Product Code: FLL
Dated: April 27, 2001
Received: April 27, 2001

Dear Mr. Hare:

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 legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). 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 (Pre-market 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 Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory

Page 2 - Mr. Hare

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.

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) 594-4692. 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" (21CFR 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 "<http://www.fda.gov/cdrh/dsma/dsmamain.html>".

Sincerely yours,



to

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K011291
Device Name: TemporalScanner Thermometer

Indications For Use: The TemporalScanner Thermometer is an infrared thermometer intended for the intermittent measurement of human body temperature of people of all ages.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____
Per 21 CFR 801.109)

OR

Over-The-Counter Use

(Optional Format 1-2-96)

90428.W11

Susan Remy

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K011291



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 12 2001

Exergen Corporation
C/O Mr. William Hare
Associate
Fish and Richardson, PC
601 13th Street, NW
Washington, DC 20005

Re: K011291
Trade/Device Name: TemporalScanner Thermometer,
SensorTouch
Regulation Number: 880.2910
Regulatory Class: II
Product Code: FLL
Dated: April 27, 2001
Received: April 27, 2001

Dear Mr. Hare:

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 legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). 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 Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory

Page 2 - Mr. Hare

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.

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) 594-4692. 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" (21CFR 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 "<http://www.fda.gov/cdrh/dsma/dsmamain.html>".

Sincerely yours,



to Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K011291
Device Name: TemporalScanner Thermometer

Indications For Use: The TemporalScanner Thermometer is an infrared thermometer intended for the intermittent measurement of human body temperature of people of all ages.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____
Per 21 CFR 801.109)

OR

Over-The-Counter Use

(Optional Format 1-2-96)

90428.W11

Susan Remy

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices

510(k) Number K011291

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

3

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

Memorandum

From: Reviewer(s) - Name(s) William M. Burdick

Subject: 510(k) Number K 011291

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

- Refused to accept.
- Requires additional information (other than refuse to accept).
- Is substantially equivalent to marketed devices.
- NOT substantially equivalent to marketed devices.

De Novo Classification Candidate? YES NO

Other (e.g., exempt by regulation, not a device, duplicate, etc.)

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

This 510(k) contains:

- Truthful and Accurate Statement Requested Enclosed
(required for originals received 3-14-95 and after)
- A 510(k) summary OR A 510(k) statement
- The required certification and summary for class III devices *N/A*
- The indication for use form (required for originals received 1-1-96 and after)
- Material of Biological Origin YES NO

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

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

Predicate Product Code with class:

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

80 FLL - Class II

800-29102 Electronic Thermometer (Infrared)

Review: Patricia Cuervo
(Branch Chief)

CD/DB
(Branch Code)

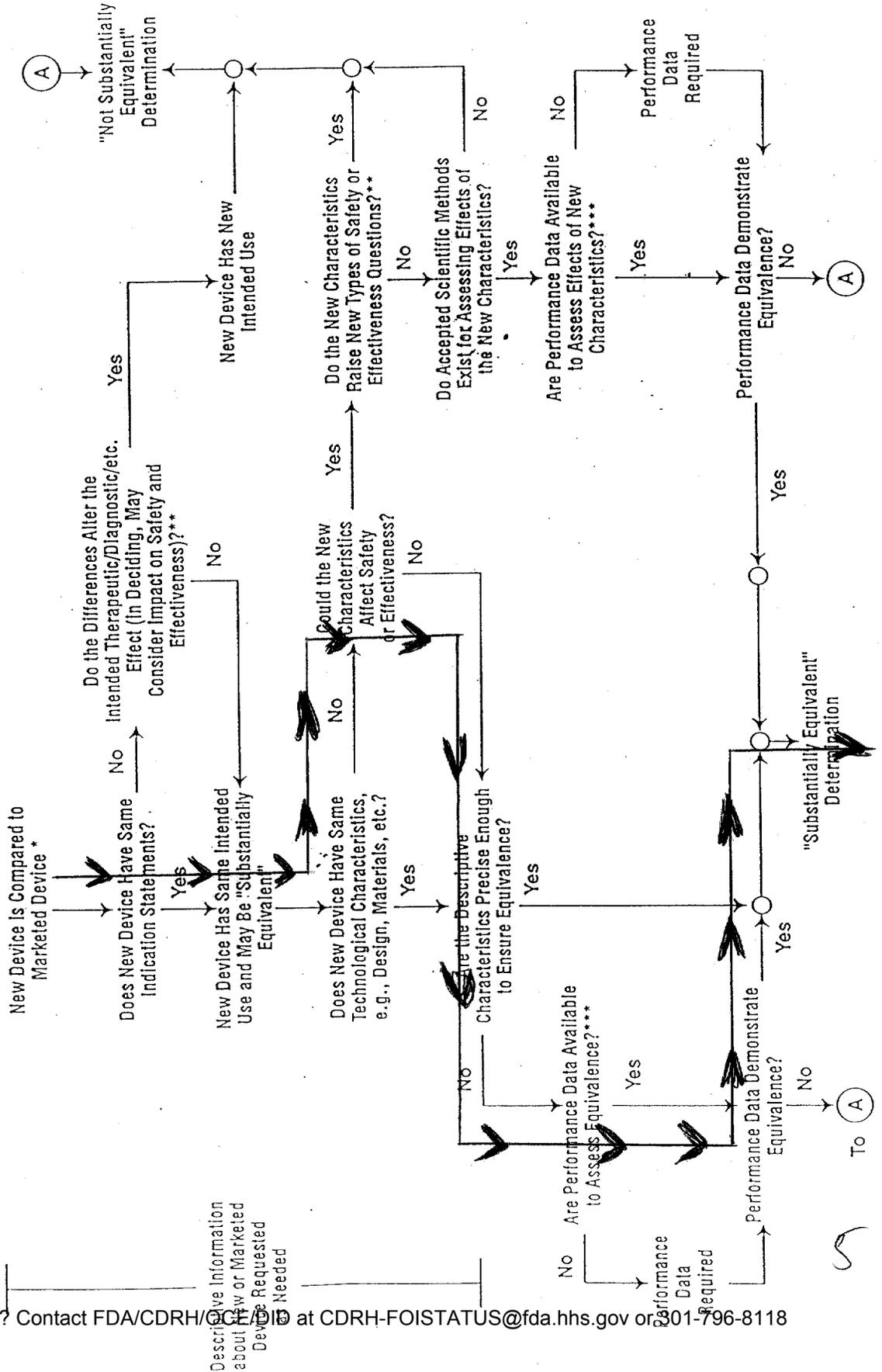
7/12/01
(Date)

Final Review: Susan Punon
(Division Director)

7/12/01
(Date)

Revised: 8/17/99

510(k) "Substantial Equivalence" Decision-Making Process (Detailed)



Questions? Contact FDA/CDRH/OCE/DTP at CDRH-FOISTATUS@fda.hhs.gov or 201-796-8118

* 510(k) Submissions Compare New Devices to Marketed Devices. FDA Requests Additional Information on the Relationship Between Marketed and "Predicate" (Pre-Amendment or Reclassified Post-Amendments) Devices is Unclear.
 ** This Decision is Normally Based on Descriptive Information Alone, But Information is Sometimes Required.
 *** Data May be Limited To the 510(k), Other 510(k)s, The Center's Classification Files, or the Literature.

"SUBSTANTIAL EQUIVALENCE" (SE) DECISION MAKING DOCUMENTATION

K011291

Reviewer: William M. Burdick

Division/Branch: DDIGD/GHDB

Device Name: Exergen TemporalScanner Infrared Thermometer

Product To Which Compared (510(K) Number If Known): Please refer to 3L of attached "510(k) REVIEW".

		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?		X	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?	X		If NO = Request Data
11.	Data Demonstrate Equivalence?	X		Final Decision: SE

(Continued on Next Page.)

1. Intended Use: Please refer to #2 of attached "510(k) REVIEW".
2. Device Description: Provide a statement of how the device is either similar to and/or different from other marketed devices, plus data (if necessary) to support the statement. Is the device life-supporting or life sustaining? Is the device implanted (short-term or long-term)? Does the device design use software? Is the device sterile? Is the device for single use? Is the device for home use or prescription use? Does the device contain drug or biological product as a component? Is this device a kit? Provide a summary about the devices design, materials, physical properties and toxicology profile if important.

Please refer to #1 of attached "510(k) REVIEW".

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

1. Explain why not a device: N/A
2. Explain why not subject to 510(k): N/A
3. How does the new indication differ from the predicate device's indication: N/A
4. Explain why there is or is not a new effect or safety or effectiveness issue: N/A
5. Describe the new technological characteristics: Please refer to 3N of attached "510(k) REVIEW".
6. Explain how new characteristics could or could not affect safety or effectiveness: The new characteristics are design, component, and software changes which are characteristics of legally marketed predicate devices.
7. Explain how descriptive characteristics are not precise enough: Clinical testing was necessary to assure that the thermometer would provide accurate measurements over the range of possible body temperatures for all patient ages from neonatal to geriatric.
8. Explain new types of safety or effectiveness questions raised or why the questions are not new: N/A
9. Explain why existing scientific methods can not be used: N/A
10. Explain what performance data is needed: N/A
11. Explain how the performance data demonstrates that the device is or is not substantially equivalent: The clinical results supported the clinical accuracy of the thermometer.

ATTACH ADDITIONAL SUPPORTING INFORMATION

Please refer to the attached "510(k) REVIEW".

Page 1 of 510(k) review

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

K011291

DATE: July 6, 2001

FROM: William M. Burdick

DIVISION:DDIGD/GHDB

COMPANY NAME: Exergen Corporation

DEVICE NAME: Exergen TemporalScanner Infrared Thermometer

"SUBSTANTIAL EQUIVALENCE" (SE) DECISION-MAKING DOCUMENTATION

NARRATIVE DEVICE DESCRIPTION

1. SUMMARY DESCRIPTION OF THE DEVICE UNDER REVIEW:

This submission is for a hand-held, battery-operated, infrared forehead thermometer designed to measure the temperature of the surface of the skin over the temporal artery. This device, as with all infrared thermometers, measures the infrared radiation emitted by the patient and converts the measurement to a temperature according to the Stefan-Boltzman Law. IR sensing is based on thermopile instead of pyroelectric technology for this device. The structure of the sensor is based on conventional semiconductor technology and includes a housing in which a layer of (b)(4) material is covered with a thermocouple film. When the thermocouple film is struck by infrared radiation, the temperature of the thermocouple film changes. Voltages are generated that are indicative of the amount of infrared radiation received and the ambient temperature as measured by a thermistor. These outputs are amplified and conditioned, and the resulting signals are sent to a microprocessor within the unit. In the microprocessor, algorithms are used to convert the amplified and conditioned signals to a body temperature measurement. For additional technical information, please refer to ATTACHMENT A.

Clinical testing was performed in order to assure the accuracy of the subject thermometer. The clinical test results appeared to be satisfactory (please refer to consult memorandum from Dr. Joy Samuels-Reid). Dr. Samuels-Reid stated that, "The sponsor will need to provide explicit instructions for placement of the device during temperature taking." It appears that the sponsor has provided adequate instructions in the Directions for Use (DFU).

Bench test data was not provided in this submission, but the sponsor did claim conformance to the FDA consensus standard for infrared thermometers. ASTM E 1965-98.

2. INTENDED USE:

This device is an infrared thermometer intended for the intermittent measurement of human body temperature of people of all ages.

DEVICE DESCRIPTION:

- A. Life-supporting or life-sustaining: No
- B. Implant (short-term or long-term): No

Page 2 of 510(k) review

- C. Is the device sterile? No
If yes, is sterility information provided? No
- D. Is the device for single use? No
- E. Is the device for prescription use? No
- F. Is the device for home use or portable? Yes
Whether the answer is yes or no, is adequate environmental testing, including EMC, performed for the intended environment, and are results provided, including test protocols, data, and a summary? Yes
- G. Does the device contain drug or biological product as a component?
No
- H. Is this device a kit? No
- I. Software-driven: Yes
Estimated level of concern: (Major, Moderate, Minor)? Moderate
Has the firm provided a hazard analysis, software requirements and design information, adequate test plans/protocols with appropriate data and test reports, documentation of the software development process including quality assurance activities, configuration management plan, and verification activities and summaries, commensurate with the level of concern, as discussed in the Reviewer Guidance for Computer Controlled Medical Devices? Yes
Software version: N/A
- J. Electrically Operated: Yes (battery-operated)
If yes, are AAMI or IEC leakage currents met and is the test protocol, data, and results provided? Yes, EN 60601-1
- K. Applicable standards to which conformance has been demonstrated (e.g., IEC, ANSI, ASTM, etc.):
- ASTM E 1965-98: Standard Specification for Infrared Thermometers for Intermittent Determination of Patient Temperature.
 - EN 60601-1:1990 - Medical Electrical Equipment Part 1: General Requirements for Safety.
 - EN 60601-1-2:1993 - Medical Electrical Equipment Part 1: General Requirements for Safety; 2. Collateral standard: Electromagnetic Compatibility - Requirements and Tests.
 - EN 55011 - EMC.
- L. Device(s) to which equivalence is claimed, manufacturer, and 510(k) number or preamendment status:
- Thermoscan Clinical Electronic Thermometer, Model IRT 3020/3520 (K983295), mfred. by Braun.
- M. Submission provides comparative specifications? Yes
comparative in in vitro data? No
performance data? No
animal testing? No
clinical testing? Yes
biocompatibility testing? No

Page 3 of 510(k) review

- N. Provide a statement of how the device is either similar to and/or different from other marketed devices, plus data (if necessary) to support the statement. Provide a summary about the devices design, materials, physical properties and toxicology profile if important.

Please refer to ATTACHMENT B for a comparison of the relative similarities and differences between the two devices.

No new issues of safety or effectiveness exist for this device.

- O. Does the submission include a summary of safety and effectiveness information upon which an equivalence determination is based? Yes

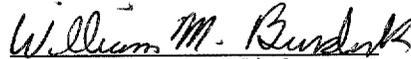
P. RECOMMENDATION:

I believe that this device is equivalent to: 80 FLL

Classification should be based on:

880.2910 - Clinical Electronic Thermometer (Infrared Thermometer)

Class: II


William M. Burdick
Biomedical Engineer

- Attachments: ATTACHMENT A - Technical Specifications
ATTACHMENT B - SE Comparison

cc.: K011291
Burdick/CHRON

ARTHERMINT 13

Substantial Equivalence Table

Item	Exergen TemporalScanner Thermometer (TemporalScanner) [†]	Exergen Surface Temperature Scanner K873010 (Dermatemp) (Exergen Predicate)	Braun Thermoscan IRT 3020/3520 Thermometer K983295 (Braun Predicate)
Intended Use	The TemporalScanner Thermometer is an infrared thermometer intended for the intermittent measurement of human body temperature of people of all ages.	The Surface Temperature Scanner is intended for the intermittent determination of surface temperature anywhere on the skin surface of a patient	The Braun predicate is intended for the intermittent measurement and monitoring of human body temperature in the home for use on people of all ages.
Where used	Skin surface of the forehead	Anywhere on the skin surface	Skin surface of the auditory canal
Technology Used	Arterial Heat Balance	Arterial Heat Balance	Arterial Heat Balance [‡]
Performance Specifications:			
Measurement range (max accuracy)	60 °F to 107.6 °F (15.5 °C to 42 °C)	96 °F to 102 °F (35 °C to 39 °C)	68 °F to 108 °F (20 °C to 42.2 °C)
Total range (min accuracy)	60 °F to 107.6 °F (15.5 °C to 42 °C)	60 °F to 110 °F (15 °C to 43 °C)	68 °F to 108 °F (20 °C to 42.2 °C)
Accuracy (max)	+/- 0.4 °F (0.2 °C)	+/- 0.2 °F (0.1 °C)	+/- 0.4 °F (0.2 °C)
Operating Ambient Range:			
Temperature	60 to 104 °F (15.5 to 40 °C)	65 °F to 95 °F (18 °C to 35 °C)	50 °F to 104 °F
Humidity	Per ASTM 1965-98, up to 95% noncondensing	Per ASTM 1965-98, up to 95% noncondensing	Per ASTM 1965-98, up to 95% noncondensing
Display resolution	0.1 °F or °C	0.1 °F or °C	0.1 °F or °C
Temperature scales	degrees F or C (factory selectable)	degrees F or C (user selectable)	degrees F or C (user selectable)
Storage:			
Temperature	-4° to 122 °F (-20 to 50 °C)	-4° to 122 °F (-20 to 50 °C)	-4° to 122 °F (-20° to 50 °C)

[†] Formerly the SensorTouch

[‡] Patented by Exergen and licensed to Braun Thermoscan

humidity (max)	up to 95% noncondensing	up to 95% noncondensing	up to 95% noncondensing
Electromagnetic compatible	Yes per EN 60601-1-2	Yes per EN 60601-1-2	Yes per EN 60601-1-2
Item	SensorTouch and Exergen TemporalScanner Thermometer	Exergen Surface Temperature Scanner K873010	Braun ThermoScan IRT 3020/3520 Thermometer K983295
Display modes	Displayed temperature is the actual temperature of the temple artery plus a mathematical adjustment to approximate the familiar rectal range	Displayed temperature is the actual temperature of the surface of the skin at the point of measurement.	Displayed temperature is the actual ear temperature plus a mathematical adjustment to approximate the familiar oral range
Power source	9 volt Alkaline	9 volt Alkaline	2 lithium batteries CR2032/DL 2032
display	LCD	LED	LCD
IR transducer	Thermopile	Thermopile	Thermopile
Indicators			
Battery low warning	Yes, audible and visual	Yes, audible	Yes
User error	Yes	no	Yes
Instrument Malfunction	Yes	no	Yes
Disposable covers	not required	not required	Yes
Case material	(b)(4)	(b)(4)(b)(4)	unknown
memory function	No	no	Yes
Auto off	Yes	yes	Yes
Standards met	ASTM E1965-98	ASTM E1965-98	ASTM E1965-98
UL listed	Yes	no	Yes
CE mark	Yes	Yes	Yes

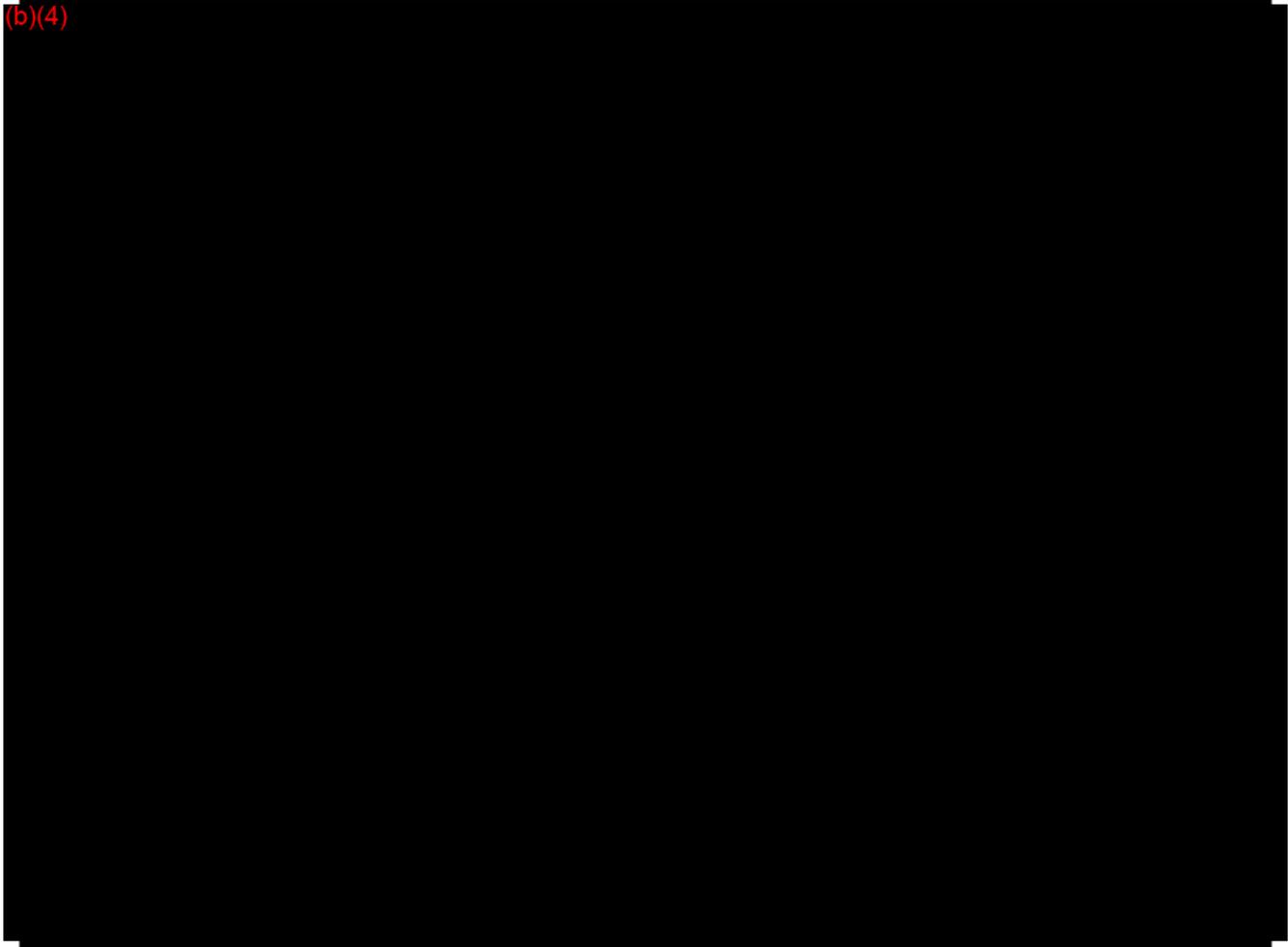
Discussion of Table

Similarities:

1. Same intended use demonstrates equivalence.
2. All units meet the same standard; therefore, the three devices should perform the same.
3. All units are battery operated.
4. All units use solid-state displays, minimizing battery drain.
5. All units have warning displays, such as battery low.
6. All units are CE marked, showing an independent third party assessment of the safety of the devices.
7. The SensorTouch, (renamed TheTemporalScanner), and the Thermoscan are UL listed, another independent third party assessment of the safety of the devices.
8. Consumer Report evaluation on the SensorTouch and the Thermoscan shows an independent third party assessment of the performance of the two devices.

Differences:

(b)(4)



ATTACHMENT A

Product Specifications

Clinical Accuracy	Meets ASTM E1965-98 and MDD 93142/EEC standards for electronic and radiation thermometers to the extent applicable to thermometers which measure the surface of the skin over the temporal artery.
Regulatory Approvals	CE Mark to -0197, TUV, Declaration of Conformity-ISO 9003/08.94, NIST certifiable traceable calibrations.
EMI/ RFI Protection	Error message displayed
Calibration Protection	Error message displayed
Temperature Range	15.5 to 42°C (60 to 107.5°F)
Operating Environment	15.5 to 40°C (60 to 104°F)
Resolution	0.1°C or °F
Response Time	Approximately 0.004 seconds
Time Displayed on Screen	30 seconds before automatic shutdown
Battery Life	Approximately 7,500 readings
Size	7.0 in x 1.75 in x 1.25 in(17.8 cm x 4.45 cm x 3.18 cm)
Weight	4.16 oz (120 grams) incl batt
Display Type	High contrast LCD
Construction Method	Impact resistant casing, Hermetically sealed sensing system
Warranty	1 Year
Laboratory Error:	+/- 4°F (+/- 0.2°C)
Storage Range:	-4°F - 122°F (-20°C-50°C)

14

Date: June 12, 2001

From: Joy H. Samuels-Reid, M.D., Medical Officer, CDRH/DDIGD

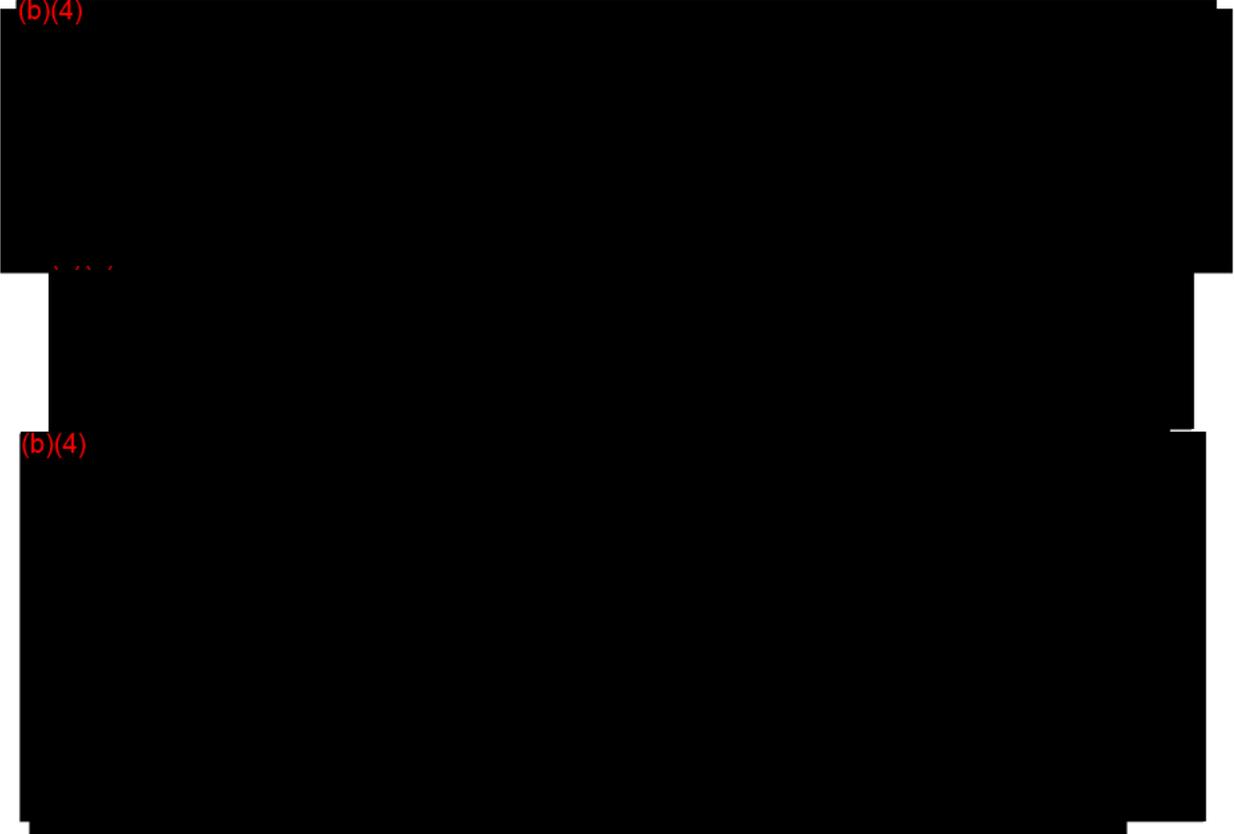
To: William M. Burdick, Biomedical Engineer, CDRH/ ODE/DDIGD/GHDB

Device: Exergen Temporal Scanner Infrared Thermometer -K011291

Sponsor: Exergen Corporation

Re: Clinical Trials

(b)(4)



(b)(4)

The supporting data, taken together, provide adequate documentation for the temporal artery thermometer as an adjunct in assessing temperature. The sponsor will need to provide explicit instructions for placement of the device during temperature taking. It will be necessary to specify site or technique differences due to age.



Joy H. Samuels-Reid, M.D.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

MEMORANDUM

Food and Drug Administration
Office of Device Evaluation
9200 Corporate Avenue
Rockville, MD 20850

REQUEST FOR CONSULTING REVIEW

Date: June 4, 2001

From: William M. Burdick, Biomedical Engineer, CDRH/ODE/DDIGD/GHDB (HFZ-480)

To: Joy Samuels-Reid, M.D., Medical Officer, CDRH/ODE/DDIGD (HFZ-480)

PMA/IDE/510(k)#: K011291

Device Name: Exergen TemporalScanner Infrared Thermometer

Sponsor Name: Exergen Corporation

REASON FOR REQUEST

- New Submission[] Response to Deficiency Letter
- Protocol Change[] Design Change
- New Material(s)[] Labeling
- Indication(s)
- Other: _____

TYPE OF REVIEW REQUESTED

- Engineering[] Materials
- Sterility[] Toxicology
- Clinical[] Statistical
- Labeling[] Regulatory Status Determination
- Jurisdiction Determination
- Other: _____

COMMENTS: Joy,

I need an assessment from you that their clinical trials are okay for this thermometer. Sorry I didn't get it to you, sooner. Please be aware that this is a **forehead IR thermometer**. Their site of placement of the thermometer IR sensor must be stated in a very specific manner. Any questions, I will be in on Wednesday.

Bill

Please Respond By: July 11, 2001

Signature of Requester: William M. Burdick

16

Screening Checklist

For all Premarket Notification 510(k) Submissions

3-30-01

Device Name: <i>Temperalscanner Thermometer</i>						K 011291						
Submitter (Company): <i>Exergen Corp.</i>												
Items which should be included (circle missing & needed information)						S P E C I A L	A B B R E V I A T E D	T R A D I T I O N A L	✓ IF ITEM IS NEEDED AND IS MISSING			
YES		NO		YES		NO		YES		NO		
1. Cover Letter clearly identifies Submission as:												
a) "Special 510(k): Device Modification"										✓		
b) "Abbreviated 510(k)"												
c) Traditional 510(k)												
						GO TO # 2,3			GO TO # 2,4,5			
2. GENERAL INFORMATION: REQUIRED IN ALL 510(K) SUBMISSIONS						✓ IF ITEM IS NEEDED						
Financial Certification or Disclosure Statement for 510(k)s with a Clinical Study 807.87(i) including forms 3454 and/or 3455						NA		YES		NO		AND IS MISSING
						SPECIALS		ABBREVIATED		TRADITIONAL		
YES		NO		YES		NO		YES		NO		
a) trade name, classification name, establishment registration number, device class										✓		
b) OR a statement that the device is not yet classified						FDA-may be a classification request; see coordinator						
c) identification of legally marketed equivalent device						NA				✓		
d) compliance with Section 514 - performance standards						NA				✓		
e) address of manufacturer										✓		
f) Truthful and Accurate Statement										✓		
g) Indications for Use enclosure										✓		
h) SMDA Summary or Statement (FOR ALL DEVICE CLASSES)										✓		
i) Class III Certification & Summary (FOR ALL CLASS III DEVICES)										✓		
j) Description of device (or modification) including diagrams, engineering drawings, photographs, service manuals										✓		
k) Proposed Labeling:										✓		
i) package labeling (user info)										✓		
ii) statement of intended use										✓		
iii) advertisements or promotional materials										✓		
i) MRI compatibility (if claimed)										✓		
l) Comparison Information (similarities and differences) to named legally marketed equivalent device (table preferred) should include:										✓		
i) Labeling										✓		
ii) intended use										✓		
iii) physical characteristics										✓		
iv) anatomical sites of use										✓		
v) performance (bench, animal, clinical) testing						NA						
vi) safety characteristics						NA						
m) If kit, kit certification												
3. "SPECIALS" - ONLY FOR MODIFICATIONS TO MANUFACTURER'S OWN CLASS II, III OR RESERVED CLASS I DEVICE												
a) Name & 510(k) number of legally marketed (unmodified) predicate device												
b) STATEMENT - INTENDED USE AND INDICATIONS FOR USE OF MODIFIED DEVICE AS DESCRIBED IN ITS										* if no - STOP not a special		

m

LABELING HAVE NOT CHANGED*				
c)	STATEMENT - FUNDAMENTAL SCIENTIFIC TECHNOLOGY OF THE MODIFIED DEVICE HAS NOT CHANGED*			* If no - STOP not a special
d)	Design Control Activities Summary			
i)	Identification of Risk Analysis method(s) used to assess the impact of the modification on the device and its components, and the results of the analysis			
ii)	Based on the Risk Analysis, an identification of the verification and/or validation activities required, including methods or tests used and acceptance criteria to be applied			
iii)	A declaration of conformity with design controls. The declaration of conformity should include:			
	1) A statement signed by the individual responsible, that, as required by the risk analysis, all verification and validation activities were performed by the designated individual(s) and the results demonstrated that the predetermined acceptance criteria were met			
	2) A statement signed by the individual responsible, that manufacturing facility is in conformance with design control procedure Requirements as specified in 21 CFR 820.30 and the records are available for review.			

	SPECIALS		ABBREVIATED		TRADITIONAL		✓ IF ITEM IS NEEDED AND IS MISSING
	YES	NO	YES	NO	YES	NO	
4. ABBREVIATED 510(K): SPECIAL CONTROLS/CONFORMANCE TO RECOGNIZED STANDARDS - PLEASE FILL OUT THE STANDARDS ABBREVIATED FORM ON THE H DRIVE							
a)	For a submission, which relies on a guidance document and/or special control(s), a summary report that describes how the guidance and/or special control(s) was used to address the risks associated with the particular device type						
b)	If a manufacturer elects to use an alternate approach to address a particular risk, sufficient detail should be provided to justify that approach.						
c)	For a submission, which relies on a recognized standard, a declaration of conformity to the standard. The declaration should include the following:						
	i) An identification of the applicable recognized consensus standards that were met						
	ii) A specification, for each consensus standard, that all requirements were met, except for inapplicable requirements or deviations noted below						
	iii) An identification, for each consensus standard, of						

18

any way(s) in which the standard may have been adapted for application to the device under review, e.g., an identification of an alternative series of tests that were performed			
iv) An identification, for each consensus standard, of any requirements that were not applicable to the device			
v) A specification of any deviations from each applicable standard that were applied			
vi) A specification of the differences that may exist, if any, between the tested device and the device to be marketed and a justification of the test results in these areas of difference			
vii) Name/address of test laboratory/certification body involved in determining the conformance of the device with applicable consensus standards and a reference to any accreditations for those organizations			
d) Data/information to address issues not covered by guidance documents, special controls, and/or recognized standards			

5. Additional Considerations: (may be covered by Design Controls)									
a) Biocompatibility data for all patient-contacting materials, OR certification of identical material/formulation:									
i) component & material									
ii) identify patient-contacting materials									
iii) biocompatibility of final sterilized product									
b) Sterilization and expiration dating information:									
i) sterilization method									
ii) SAL									
iii) packaging									
iv) specify pyrogen free									
v) ETO residues									
vi) radiation dose									
c) Software validation & verification:									
i) hazard analysis									
ii) level of concern									
iii) development documentation									
iv) certification									

Items shaded under "NO" are necessary for that type of submission. Circled items and items with checks in the "Needed & Missing" column must be submitted before acceptance of the document.

Passed Screening Yes No

Reviewer: William M. Burdick
 Concurrence by Review Branch: 6/4/01

Date: MAY - 2 2001

Internal Administrative Form

	YES	NO
1. Did the firm request expedited review?		✓
2. Did we grant expedited review?		✓
3. Have you verified that the Document is labeled Class III for GMP purposes?		✓
4. If, not, has POS been notified?		✓
5. Is the product a device?	✓	
6. Is the device exempt from 510(k) by regulation or policy?	✓	✓
7. Is the device subject to review by CDRH?		
8. Are you aware that this device has been the subject of a previous NSE decision?		✓
9. If yes, does this new 510(k) address the NSE issue(s), (e.g., performance data)?		✓
10. Are you aware of the submitter being the subject of an integrity investigation?		✓
11. If, yes, consult the ODE Integrity Officer.		
12. Has the ODE Integrity Officer given permission to proceed with the review? (Blue Book Memo #191-2 and Federal Register 90N0332, September 10, 1991.		✓

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

April 30, 2001

EXERGEN CORP.
C/O FISH AND RICHARDSON, PC
601 13TH STREET, NW
WASHINGTON, DC 20005
ATTN: WILLIAM HARE

510(k) Number: K011291
Received: 27-APR-2001
Product: TEMPORALSCANNER
THERMOMETER,
SENSORTOUCH

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 (DSMA) at the telephone or web site below for more information.

Please remember that all correspondence concerning your submission MUST be sent to the Document Mail Center (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).

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

Sincerely yours,

Marjorie Shulman
Consumer Safety Officer
Premarket Notification Staff
Office of Device Evaluation

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

21



MAY 4 2001

Food and Drug Administration
Center for Devices and
Radiological Health
2098 Gaither Road
Rockville, MD 20850

Ms. Jill B. Deal
Fish & Richardson P.C.
601 Thirteenth Street, NW
Washington, DC 20005

Re: Sensor Touch Temporal Thermometer

Dear Ms. Deal:

Thank you for your March 14 correspondence responding to our February 21 letter. We acknowledge that you plan to submit a premarket notification [510(k)] for the modified Sensor Touch Temporal Thermometer, and that when you do so, you will submit labeling complying with the terms in our April 3 letter.

We appreciate your cooperation in this matter. If you have any questions regarding the submission of your 510(k), you may contact Ms. Patricia Cricenti, Chief, General Hospital Devices Branch, Office of Device Evaluation at 301.443.8879. If you have any questions regarding this letter, please do not hesitate to call me at 301.594.4618.

Sincerely yours,

Leslie E. Dorsey
Consumer Safety Officer
General Hospital Devices Branch
Division of Enforcement II
Office of Compliance
Center for Devices and Radiological Health

cc:

HFA-224

HFZ-330

HFZ-333

HFZ-480(PCricenti)

Draft: LEDorsey/5-3-01 *350 5-4-01*

Final: JWMilto: 5/4/01

OC Track #86724

Disk #32, *Exergen 3 Ltr*



Food and Drug Administration
Center for Devices and
Radiological Health
2098 Gaither Road
Rockville, MD 20850

FEB 21 2001

Ms. Jill B. Deal
Fish & Richardson P.C.
601 Thirteenth Street, NW
Washington, DC 20005

Re: Sensor Touch Temporal Thermometer

Dear Ms. Deal:

This correspondence is in reference to your August 2, 2000 letter. While you have satisfactorily addressed our labeling concerns regarding the Sensor Touch Temporal Thermometer, the (b)(4) which was not discussed in our July 31, 2000 telephone conversation, still remains unaddressed. Please refer to our April 3, 2000 letter, item #5 (enclosed) for further explanation of our concerns with the (b)(4) As stated in this letter, (b)(4)

(b)(4)

In addition to the above, the medical device listing regulations (21 CFR Part 807) (enclosed) require certain establishments to list their devices with the FDA and to maintain a historical file of labels, labeling, and promotional material for those devices. Paragraph 807.31(e) of the regulations requires the owner or operator of establishments upon request, to provide FDA with information on these files.

In order to confirm your labeling modifications, we request that you provide us with a (b)(4)

Please provide a response within fifteen (15) working days of receipt of this letter to me at the letterhead address. The response should include both the materials mentioned above and a statement informing us when you plan on submitting your new 510(k).

29

Page 2 - Ms. Jill B. Deal

If you have any questions regarding the submission of a new 510(k), you may contact Ms. Patricia Cricenti, Chief, General Hospital Devices Branch, Office of Device Evaluation at 301.443.8879. If you have any questions regarding this letter, please do not hesitate to call me at 301.594.4618.

Sincerely yours,



Leslie E. Dorsey
Consumer Safety Officer
General Hospital Devices Branch
Division of Enforcement II
Office of Compliance
Center for Devices and Radiological Health

Enclosures

28

cc:

HFA-224

HFR-NE250

HFZ-330

HFZ-333

HFZ-480(PCricenti)

Draft: LEDorsey/2-15-01 *J209-21-01*

Reviewed: CBNiebauer/2-15-01

Final: JWMilto: 2/21/01

OC Track #84275

Disk #32, *Exergen 2 Ltr*

FISH & RICHARDSON P.C.

601 Thirteenth Street N.W.
Washington, DC 20005

Telephone
202 783-5070

Facsimile
202 783-2331

Web Site
www.fr.com

Frederick P. Fish
1855-1930

W.K. Richardson
1859-1951

BY HAND DELIVERY

April 27, 2001

510(k) Document Mail Center (HFZ-401)
Room 42ON
Center for Devices and Radiological Health
Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

RECEIVED
APR 27 3 59 PM '01
FDA/CDRH/OCE/DMD

Re: Exergen TemporalScanner Infrared Thermometer (formerly, SensorTouch)
Section 510(k) Premarket Notification (Traditional)

Dear Sir or Madam:

We attach as Exhibits A-C to this letter correspondence from staff in the CDRH Office of Compliance that relates to an infrared temporal thermometer manufactured by our client, Exergen Corporation (Exergen). The SensorTouch Temporal Thermometer (SensorTouch) was formerly distributed by Phillips Electronics North America (Phillips), which owns the SensorTouch trademark. The commercial agreement between Phillips and Exergen ended on February 19, 2000. Under the circumstances, Exergen decided that, in the future, the former SensorTouch manufactured by Exergen should be sold under another name, specifically, the TemporalScanner thermometer (TemporalScanner).

As you will see, in a letter from Steven E. Budabin, M.S., Consumer Officer, Office of Compliance, CDRH attached as Exhibit A, Mr. Budabin did not take issue with the then-SensorTouch's legal status as a cleared device under section 510(k) of the Federal Food, Drug and Cosmetic Act. Rather, his concerns focused primarily on

(b)(4) [Redacted]

At the end of his letter, he also inquired about possible

(b)(4) [Redacted]

Further correspondence between attorneys representing Philips or Exergen and the Office of Compliance resulted in either Philips (b)(b)(4) [Redacted]

Despite detailed written descriptions of the minor modifications of the device supplied, a letter from Leslie Dorsey, Consumer Safety Officer, Office of Compliance, CDRH dated February 21, 2001 to me (February 21 Letter) (Exhibit B to this letter) requested that

(b)(4) [Redacted]

- BOSTON
- DALLAS
- DELAWARE
- NEW YORK
- SAN DIEGO
- SILICON VALLEY
- TWIN CITIES
- WASHINGTON, DC

JK-38

27

FISH & RICHARDSON P.C.

510(k) Document Mail Center (HFZ-401)

April 27, 2001

Page 2

(b)(4) [REDACTED] The April 3 Letter is attached as Exhibit C to this letter.

We believe that a new 510(k) premarket notification is not required because the TemporalScanner is merely an update to the original, cleared version of the SensorTouch device, the Exergen Surface Temperature Scanner (Dermatemp) (K873010)(Exergen Predicate) to include technologically current components. Nevertheless, in accordance with Ms. Dorsey's request, Fish & Richardson is submitting a "catch-up" 510(k) pre-market notification on behalf of Exergen.

The TemporalScanner is an infrared thermometer intended for the intermittent measurement of human body temperature of people of all ages. As explained in greater detail in the attached premarket notification, the TemporalScanner is substantially equivalent to the Exergen Predicate and the Braun Thermoscan IRT 3020/3520 Thermometer (Braun Predicate) (K983295) because they have the same intended use and the same technological characteristics.

As you will see, Item 5 of the February 26 Letter posed three questions. Information responding to all of these questions can be found in Part 8 of this 510(k). Information relating to the (b)(4) [REDACTED] can be found at page 8-3; information relating to substitution of (b)(4) [REDACTED] used in the Exergen Predicate can be found at page 8-4 and information relating to (b)(4) [REDACTED] of the TemporalScanner from the Exergen Predicate can be found at page 8-2.

We understand from conversations with a reviewer that clinical data is required for all 510(k) premarket notifications for infrared thermometers. This data can be found at Part 11, beginning at page 9-30. The requisite certification regarding financial interests can be found at Part 12. With respect to (b)(4) [REDACTED], these can be found at Part 9, beginning at page 9-3.

We are aware that on April 19, 2001, CDRH issued its Guidance on Medical Device Patient Labeling; Final Guidance for Industry and FDA Reviewers (Guidance). Labeling materials for the device appear at Part 4, including draft directions for use. Final labeling materials have not been prepared. When labeling materials have been agreed with FDA, Exergen will consult the Guidance in preparing the final version of the labeling materials.

We trust that the information contained in the attached premarket notification will be sufficient to enable FDA to find the TemporalScanner substantially equivalent to the predicate device for the listed intended use and indications. Please direct any additional questions or requests for information to me or to William Hare of this office or to me at 202-783-5070.

28

FISH & RICHARDSON P.C.

510(k) Document Mail Center (HFZ-401)

April 27, 2001

Page 3

We also request that FDA notify the company of a finding of substantial equivalence by sending a facsimile to me at Fish & Richardson at 202-783 2331.

Very truly yours,

A handwritten signature in cursive script that reads "Jill B. Deal".

Jill B. Deal

cc: Leslie Dorsey (without attachments)

40053493.doc

ja

Food and Drug Administration
2088 Galter Road
Rockville MD 20860

APR 13 1999

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Letter Exhibit A

• Mr. Patrick J. Dinley
President
Philips Electronics North America Corporation
P.O. Box 120015
Stamford, Connecticut 06912-0015

Re: Sensor Touch Thermometer,
K873010

Dear Mr. Dinley:

The Food and Drug Administration (FDA) has reviewed promotional materials for the Sensor Touch Temporal Thermometer (Sensor Touch). This product is manufactured by Exergen Corporation (Exergen), distributed by Philips Electronics North America (Philips) and is a device as defined within the meaning of section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act).

The Sensor Touch has been cleared under section 510(k) of the Act and is intended to measure the body temperature of patients by means of a transducer coupled with an electronic signal amplification, conditioning, and display unit. The transducer may be in a detachable probe with or without a disposable cover.

We have reviewed a Philips press release titled, Philips Introduces a Revolutionary, Non-Invasive Way To Take Temperature, dated January 10, 1999, which makes claims for the Sensor Touch that have not been cleared by the agency. Specifically, the press release states that the Sensor Touch can measure core body temperatures.

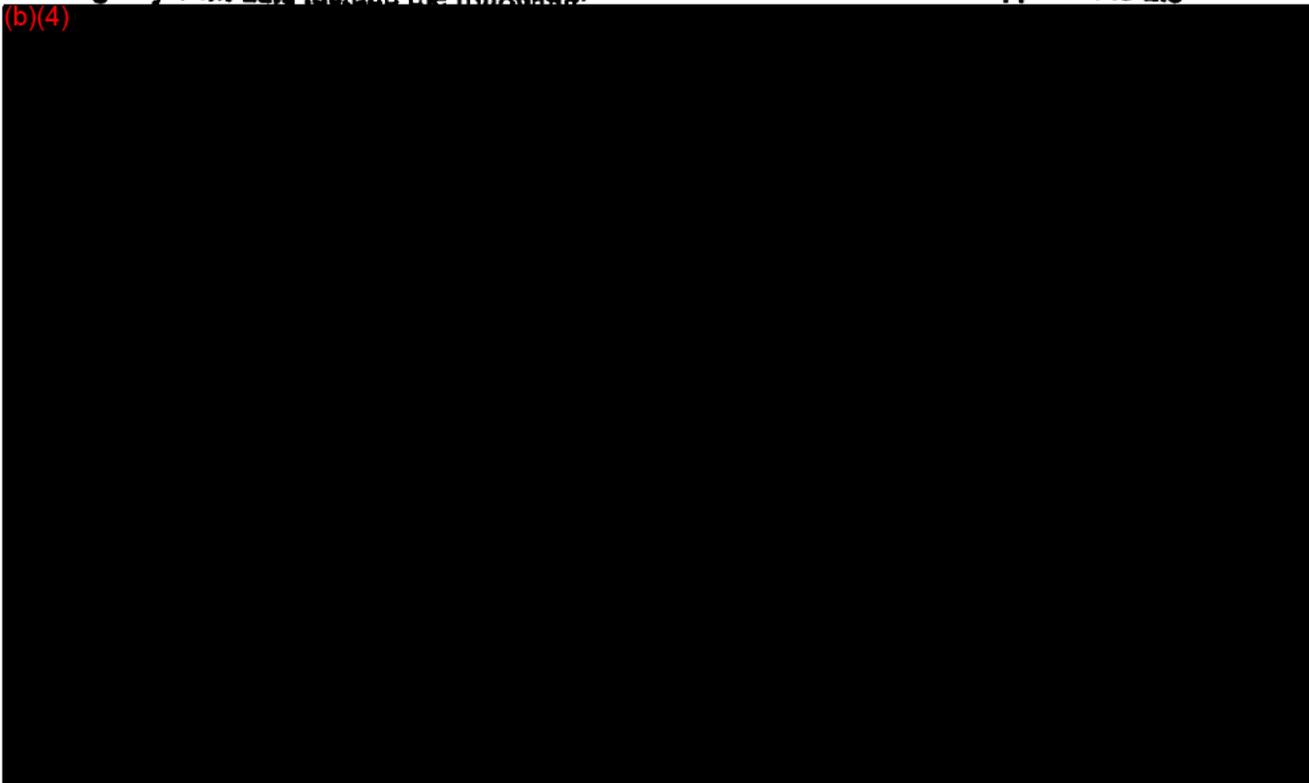
Such a claim represents a major modification in the intended use of the device as described under 21 CFR 807.81(a)(3)(ii) and requires the submission of a new 510(k) prior to marketing the Sensor Touch with that claim.

Continued promotion of the Sensor Touch for claims of measuring core body temperature causes your device to be misbranded and adulterated under sections 502(o) and 501(f)(B) of the Act, respectively.

We have also reviewed additional promotional materials that make claims for the Sensor Touch which have not been supported with data. The materials reviewed include: a Philips brochure titled, Philips Sensor Touch. Non-Invasive. Gentle. Easy. and Fast. Accurate (brochure dated 12/98- 5K); an article titled, Philips Unveils Sensor Touch from HFN dated January 18, 1999; and the press release.

Statements made in these promotional materials which have not been supported to the agency with data include the following:

(b)(4)



(b)(4)



Please submit a prompt response to this office in writing regarding Philips plans for corrective action and for removing the misleading information from the marketplace. You may submit your response to me at the letterhead address.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Steven E. Budabin". The signature is written in a cursive style.

Steven E. Budabin, M.S.
Consumer Safety Officer
Promotion and Advertising
Policy Staff
Office of Compliance
Center for Devices and
Radiological Health



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Center for Devices and
Radiological Health
2098 Gaither Road
Rockville, MD 20850

FEB 21 2001

RECEIVED

Letter Exhibit B

Ms. Jill B. Deal
Fish & Richardson P.C.
601 Thirteenth Street, NW
Washington, DC 20005

FEB 26 2001

FISH and RICHARDSON, P.C.
WASHINGTON, DC

Re: Sensor Touch Temporal Thermometer

Dear Ms. Deal:

This correspondence is in reference to your August 2, 2000 letter. While you have satisfactorily addressed our labeling concerns regarding the Sensor Touch Temporal Thermometer, the (b)(4) which was not discussed in our July 31, 2000 telephone conversation, still remains unaddressed. Please refer to our April 3, 2000 letter, item #5 (enclosed) for further explanation of our concerns with the (b)(4) As stated in this letter, (b)(4) (b)(4)

(b)(4) (b)(4) (b)(4) (b)(4)

In addition to the above, the medical device listing regulations (21 CFR Part 807) (enclosed) require certain establishments to list their devices with the FDA and to maintain a historical file of labels, labeling, and promotional material for those devices. Paragraph 807.31(e) of the regulations requires the owner or operator of establishments upon request, to provide FDA with information on these files.

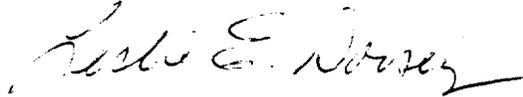
In order to confirm your labeling modifications, we request that you provide us with a (b)(4) (b)(4) (b)(4) (b)(4)

Please provide a response within fifteen (15) working days of receipt of this letter to me at the letterhead address. The response should include both the materials mentioned above and a statement informing us when you plan on submitting your new 510(k).

Page 2 - Ms. Jill B. Deal

If you have any questions regarding the submission of a new 510(k), you may contact Ms. Patricia Cricenti, Chief, General Hospital Devices Branch, Office of Device Evaluation at 301.443.8879. If you have any questions regarding this letter, please do not hesitate to call me at 301.594.4618.

Sincerely yours,



Leslie E. Dorsey
Consumer Safety Officer
General Hospital Devices Branch
Division of Enforcement II
Office of Compliance
Center for Devices and Radiological Health

Enclosures

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

APR 3 2000

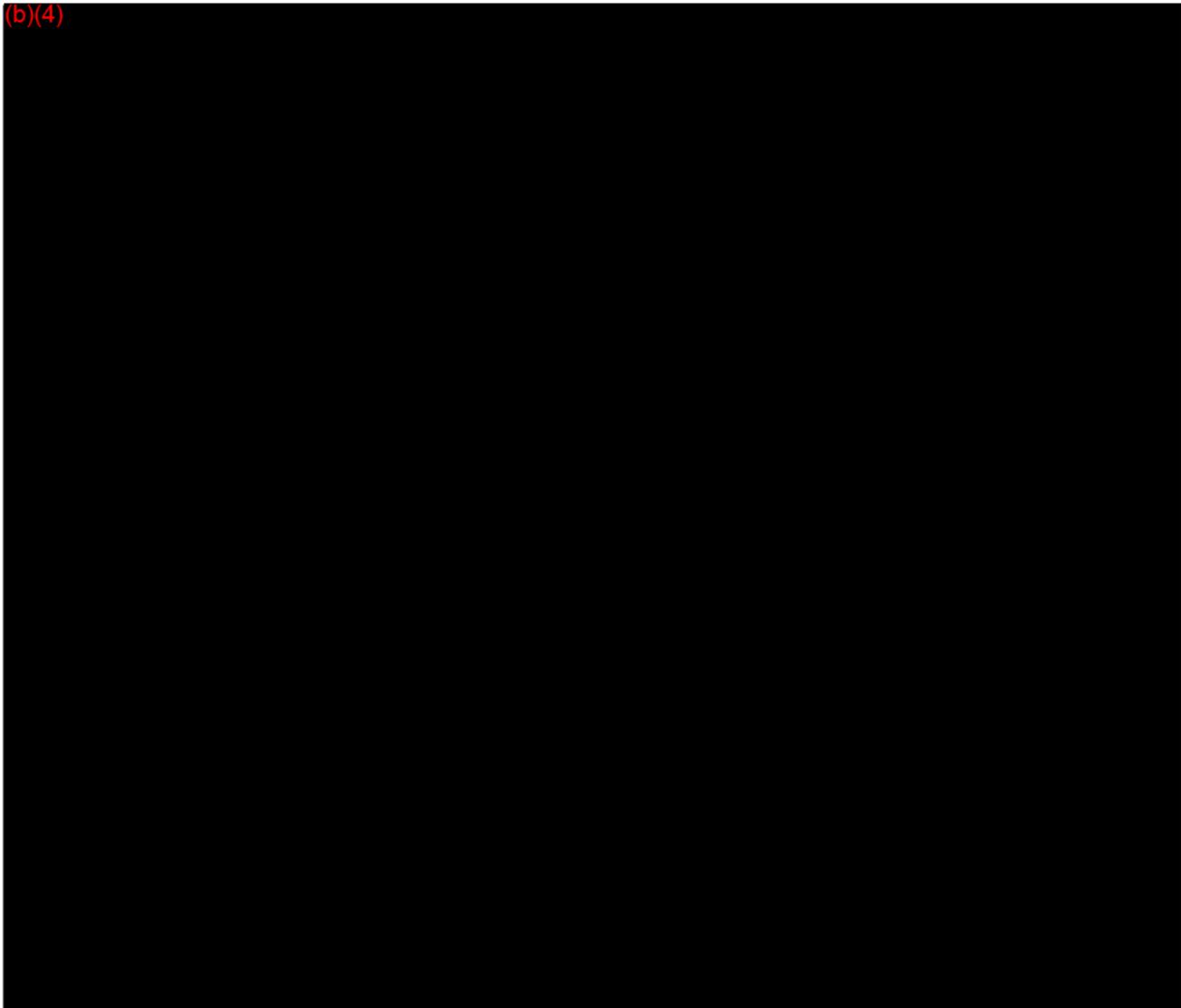
Letter Exhibit C

Mr. Howard M. Holstein
Hogan & Hartson
Columbia Square
555 Thirteenth Street, NW
Washington, DC 20004-1109

Dear Mr. Holstein:

We acknowledge receipt of your July 14, 1999 response to our April 13, 1999 correspondence to Mr. Patrick J. Dinley of Philips Electronics North America Corporation. We apologize for our delay in responding. Below I have outlined our concerns and followed them with our comments to your response to these concerns:

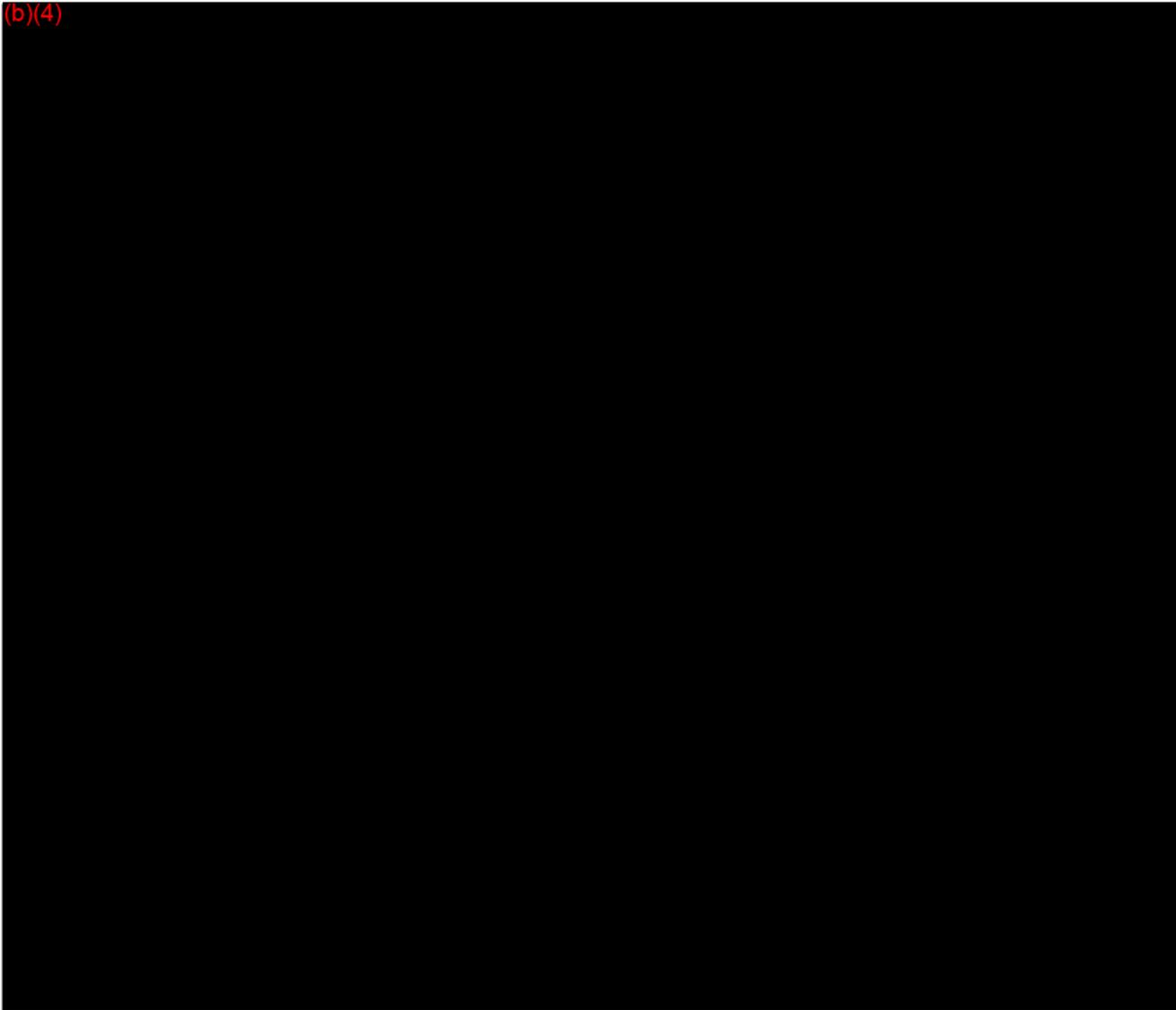
(b)(4)



38

Page 2 - Mr. Howard M. Holstein

(b)(4)



It appears, that given the history of communication between Philips Electronics and the FDA regarding the Sensor Touch, (b)(4)

(b)(4)

(b)(4)

(b)(4)

with its new labeling claims. Please provide a response within 15 days of receipt of this letter stating when you plan on submitting your new 510(k). If you choose to not submit a new 510(k), provide us with the specific steps you have taken to correct the noted labeling violations for which you have not adequately responded to. Include in your response information on what is being done with the labeling that is currently in distribution.

35

Page 3 - Mr. Howard M. Holstein

If you have any questions, please do not hesitate to contact me at 301.594.4618, ext. 115.

Sincerely yours,



Leslie E. Dorsey
Consumer Safety Officer
General Hospital Devices Branch
Division of Enforcement II
Office of Compliance
Center for Devices and Radiological Health

cc:
HFA-224
HFZ-330
HFZ-333
HFZ-480(HTrinh)

Draft: LEDorsey/3-30-00 *for 4-3-00*
Review: MSheldon for CBNiebauer/3-31-00
Final: JMIlto:4/3/00

OC Track #80864
Disk #32, *Philips.ltr*

34

**Table of Contents to Section 510(k) Premarket
Notification of the TemporalScanner Thermometer
by Exergen Corporation**

Section	Title	Page
1	FDA Cover Sheet	1-1
2	Truthful and Accurate Statement	2-1
3	Performance Standards	3-1
4	Labeling	4-1
	Proposed TemporalScanner DFU	4-2
	Draft Device Labels for TemporalScanner Thermometer	4-13
	Exergen Predicate Device Labeling	4-16
	Braun Predicate Device Labeling	
5	Statement of Indications for Use	5-1
6	Substantial Equivalence Table	6-1
	Table	6-2
	Discussion of SE Table	6-3
7	Summary	7-1
8	Description	8-1
	Operational Block Diagram of Typical IR Thermometer	8-6
	Temporal Scanner Pictures	8-7
	Exergen Predicate Pictures	8-12
	Braun Predicate Pictures	8-20
	Flowchart for Algorithm	8-24
9	Performance Data	9-1
	Performance Data for Product Acceptance	9-2
	Phillips Declaration of Conformity to Directive 93/42/EEC	9-6
	EMC Testing Conducted By Phillips	9-9
	Safety Testing Conducted on Behalf of Exergen	9-11
	(b)(4) Testing Conducted By Exergen	9-15
	Consumer Reports Testing	9-18
	Results of Clinical Trials in the (b)(4)	9-20

b

	Reports of Clinical Trials in (b)(4)	9-24
	Summary	9-25
	Clinical Study No. 1	9-30
	Clinical Study No. 2	9-37
	Clinical Study No. 3	9-87
	Clinical Study No. 4	9-99
	Clinical Study No. 5	9-101
10	Biocompatibility Data	10-1
11	Software	11-1
12	Clinical Trial Financial Certification	12-1

**Table of Contents to Section 510(k) Premarket
Notification of the TemporalScanner Thermometer
by Exergen Corporation**

Section	Title	Page
1	FDA Cover Sheet	1-1
2	Truthful and Accurate Statement	2-1
3	Performance Standards	3-1
4	Labeling	4-1
	Proposed TemporalScanner DFU	4-2
	Draft Device Labels for TemporalScanner Thermometer	4-15
	Exergen Predicate Device Labeling	4-18
	Braun Predicate Device Labeling	4-38
5	Statement of Indications for Use	5-1
6	Substantial Equivalence Table	6-1
	Table	6-2
	Discussion of SE Table	6-3
7	Summary	7-1
8	Description	8-1
	Operational Block Diagram of Typical IR Thermometer	8-6
	Temporal Scanner Pictures	8-7
	Exergen Predicate Pictures	8-12
	Braun Predicate Pictures	8-20
	Flowchart for Algorithm	8-24
9	Performance Data	9-1
	Performance Data for Product Acceptance	9-2
	Phillips Declaration of Conformity to Directive 93/42/EEC	9-6
	(b)(4) Testing Conducted By Phillips	9-9
	Safety Testing Conducted on Behalf of Exergen	9-11
	(b)(4) Testing Conducted By Exergen	9-15
	Consumer Reports Testing	9-18
	Results of Clinical Trials in the (b)(4)	9-20

	Reports of Clinical Trials in (b)(4)	9-24
	Summary	9-25
	Clinical Study No. 1	9-30
	Clinical Study No. 2	9-37
	Clinical Study No. 3	9-87
	Clinical Study No. 4	9-99
	Clinical Study No. 5	9-101
10	Biocompatibility Data	10-1
11	Software	11-1
12	Clinical Trial Financial Certification	12-1

11

Section 1

FDA Cover Sheet

42

CDRH SUBMISSION COVER SHEET

Date of Submission:

FDA Document Number:

Section A Type of Submission

PMA	PMA Supplement	PDP	510(k)	Meeting
<input type="checkbox"/> Original submission <input type="checkbox"/> Modular submission <input type="checkbox"/> Amendment <input type="checkbox"/> Report <input type="checkbox"/> Report Amendment	<input type="checkbox"/> Regular <input type="checkbox"/> Special <input type="checkbox"/> Panel Track <input type="checkbox"/> 30-day Supplement <input type="checkbox"/> 30-day Notice <input type="checkbox"/> 135-day Supplement <input type="checkbox"/> Real-time Review <input type="checkbox"/> Amendment to PMA Supplement	<input type="checkbox"/> Presubmission summary <input type="checkbox"/> Original PDP <input type="checkbox"/> Notice of intent to start clinical trials <input type="checkbox"/> Intention to submit Notice of Completion <input type="checkbox"/> Notice of Completion <input type="checkbox"/> Amendment to PDP <input type="checkbox"/> Report	<input type="checkbox"/> Original submission: <input type="checkbox"/> Traditional <input type="checkbox"/> Special <input type="checkbox"/> Abbreviated <input checked="" type="checkbox"/> Additional information: <input type="checkbox"/> Traditional <input type="checkbox"/> Special <input type="checkbox"/> Abbreviated	<input type="checkbox"/> Pre-IDE meeting <input type="checkbox"/> Pre-PMA meeting <input type="checkbox"/> Pre-PDP meeting <input type="checkbox"/> 180-day meeting <input type="checkbox"/> Other (specify):
IDE	Humanitarian Device Exemption	Class II Exemption	Evaluation of Automatic Class III Designation	Other Submission
<input type="checkbox"/> Original submission <input type="checkbox"/> Amendment <input type="checkbox"/> Supplement	<input type="checkbox"/> Original submission <input type="checkbox"/> Amendment <input type="checkbox"/> Supplement <input type="checkbox"/> Report	<input type="checkbox"/> Original submission <input type="checkbox"/> Additional information	<input type="checkbox"/> Original submission <input type="checkbox"/> Additional information	Describe submission:

Section B Applicant or Sponsor

Company / Institution name: Exergen Corporation	Establishment registration number: 1221195	
Division name (if applicable):	Phone number (include area code): (617) 923-9900	
Street address: 51 Water Street	FAX number (include area code): (617) 923-9911	
City: Watertown	State / Province: MA 02172	Country: USA
Contact name: Gerald A. Clay		
Contact title: Director, Regulatory Affairs	Contact e-mail address: gclay@exergen.com	

Section C Submission correspondent (if different from above)

Company / Institution name: Fish & Richardson, PC	Establishment registration number: NA	
Division name (if applicable):	Phone number (include area code): (202) 783-5070	
Street address: 601 13th Street, NW	FAX number (include area code): (202) 783-2331	
City: Washington	State / Province: DC	Country: USA 20005
Contact name: William Hare (Associate) or Jill B. Deal (Partner)		
Contact title:	Contact e-mail address: hare@fr.com deal@fr.com	

Section D1	Reason for Submission — PMA, PDP, or HDE	
<input type="checkbox"/> New device <input type="checkbox"/> Withdrawal <input type="checkbox"/> Additional or expanded indications <input type="checkbox"/> Licensing agreement <input type="checkbox"/> Process change <input type="checkbox"/> Manufacturing <input type="checkbox"/> Sterilization <input type="checkbox"/> Packaging <input type="checkbox"/> Other (specify below) <input type="checkbox"/> Response to FDA correspondence: <input type="checkbox"/> Request for applicant hold <input type="checkbox"/> Request for removal of applicant hold <input type="checkbox"/> Request for extension <input type="checkbox"/> Request to remove or add manufacturing site <input type="checkbox"/> Other reason (specify):	<input type="checkbox"/> Change in design, component, or specification: <input type="checkbox"/> Software <input type="checkbox"/> Color Additive <input type="checkbox"/> Material <input type="checkbox"/> Specifications <input type="checkbox"/> Other (specify below) <input type="checkbox"/> Labeling change: <input type="checkbox"/> Indications <input type="checkbox"/> Instructions <input type="checkbox"/> Performance Characteristics <input type="checkbox"/> Shelf life <input type="checkbox"/> Trade name <input type="checkbox"/> Other (specify below)	<input type="checkbox"/> Location change: <input type="checkbox"/> Manufacturer <input type="checkbox"/> Sterilizer <input type="checkbox"/> Packager <input type="checkbox"/> Distributor <input type="checkbox"/> Report submission: <input type="checkbox"/> Annual or periodic <input type="checkbox"/> Post-approval study <input type="checkbox"/> Adverse reaction <input type="checkbox"/> Device defect <input type="checkbox"/> Amendment <input type="checkbox"/> Change in ownership <input type="checkbox"/> Change in correspondent
Section D2	Reason for Submission — IDE	
<input type="checkbox"/> New device <input type="checkbox"/> Addition of institution <input type="checkbox"/> Expansion / extension of study <input type="checkbox"/> IRB certification <input type="checkbox"/> Request hearing <input type="checkbox"/> Request waiver <input type="checkbox"/> Termination of study <input type="checkbox"/> Withdrawal of application <input type="checkbox"/> Unanticipated adverse effect <input type="checkbox"/> Notification of emergency use <input type="checkbox"/> Compassionate use request <input type="checkbox"/> Treatment IDE <input type="checkbox"/> Continuing availability request <input type="checkbox"/> Other reason (specify):	<input type="checkbox"/> Change in: <input type="checkbox"/> Correspondent <input type="checkbox"/> Design <input type="checkbox"/> Informed consent <input type="checkbox"/> Manufacturer <input type="checkbox"/> Manufacturing process <input type="checkbox"/> Protocol - feasibility <input type="checkbox"/> Protocol - other <input type="checkbox"/> Sponsor <input type="checkbox"/> Report submission: <input type="checkbox"/> Current investigator <input type="checkbox"/> Annual progress <input type="checkbox"/> Site waiver limit reached <input type="checkbox"/> Final	<input type="checkbox"/> Response to FDA letter concerning: <input type="checkbox"/> Conditional approval <input type="checkbox"/> Deemed approved <input type="checkbox"/> Deficient final report <input type="checkbox"/> Deficient progress report <input type="checkbox"/> Deficient investigator report <input type="checkbox"/> Disapproval <input type="checkbox"/> Request extension of time to respond to FDA <input type="checkbox"/> Request meeting
Section D3	Reason for Submission — 510(k)	
<input type="checkbox"/> New device <input type="checkbox"/> Additional or expanded indications <input checked="" type="checkbox"/> Other reason (specify):	<input type="checkbox"/> Change in technology <input type="checkbox"/> Change in design	<input type="checkbox"/> Change in materials <input type="checkbox"/> Change in manufacturing process
<p>Requested by FDA. See letter from Leslie Dorsey, Consumer Safety Officer, General Hospital Services Branch. Division of Enforcement II, Office of Compliance, CDRH, FDA to Jill B. Deal, Fish & Richardson, P.C., dated Feb, 21, 2001. (Exhibit B to cover letter)</p>		

YH

Section E Additional Information on 510(k) Submissions							
Product codes of devices to which substantial equivalence is claimed:						Summary of, or statement concerning, safety and effectiveness data: <input type="checkbox"/> 510(k) summary attached <input type="checkbox"/> 510(k) statement	
1880FLL	2	3	4	5	6	7	8
Information on devices to which substantial equivalence is claimed:							
510(k) Number	Trade or proprietary or model name					Manufacturer	
1 K873010	1 Surface Temperature Scanner					1 Exergen Corporation	
2 K983295	2 Thermoscan JRT 30201/3520					2 Braun Thermoscan	
3	3					3	
4	4					4	
5	5					5	
6	6					6	
Section F Product Information — Applicable to All Applications							
Common or usual name or classification name:							
Trade or proprietary or model name						Model number	
1 TemporalScanner Thermometer, SensorTouch						1 not known at this time	
2						2	
3						3	
4						4	
5						5	
FDA document numbers of all prior related submissions (regardless of outcome):							
1	2	3	4	5	6	7	8
9	10	11	12	13	14	15	16
Data included in submission: <input type="checkbox"/> Laboratory testing <input type="checkbox"/> Animal trials <input type="checkbox"/> Human trials							
Section G Product Classification — Applicable to All Applications							
Product code: 80FL	C.F.R. Section: 880.2910					Device class: <input type="checkbox"/> Class I <input checked="" type="checkbox"/> Class II <input type="checkbox"/> Class III <input type="checkbox"/> Unclassified	
Classification panel: General Hospital & Personal Use Device							
Indications (from labeling): The TemporalScanner Thermometer is an infrared thermometer intended for the intermittent measurement of human body temperature of subjects of all ages							

Note: Submission of this information does not affect the need to submit a 2891 or 2891a Device Establishment Registration form.		FDA Document Number:	
Section H Manufacturing / Packaging / Sterilization Sites Relating to a Submission			
<input checked="" type="checkbox"/> Original <input type="checkbox"/> Add <input type="checkbox"/> Delete	FDA establishment registration number:		<input checked="" type="checkbox"/> Manufacturer <input type="checkbox"/> Contract manufacturer
Company / Institution name: Exergen Corporation		<input type="checkbox"/> Contract sterilizer <input type="checkbox"/> Repackager / relabeler	
Division name (if applicable):		Establishment registration number: 1221195	
Street address: 51 Water St.		Phone number (include area code): (617) 923-9900	
City: Watertown		State / Province: MA 02172	FAX number (include area code): (617) 923-9911
Country: USA		Contact name: Gerald A. Clay	
Contact title: Director, Regulatory Affairs		Contact e-mail address: gclay@exergen.com	
<input type="checkbox"/> Original <input type="checkbox"/> Add <input type="checkbox"/> Delete	FDA establishment registration number:		<input type="checkbox"/> Manufacturer <input type="checkbox"/> Contract manufacturer
Company / Institution name:		<input type="checkbox"/> Contract sterilizer <input type="checkbox"/> Repackager / relabeler	
Division name (if applicable):		Establishment registration number:	
Street address:		Phone number (include area code): ()	
City:		State / Province:	FAX number (include area code): ()
Country:		Contact name:	
Contact title:		Contact e-mail address:	
<input type="checkbox"/> Original <input type="checkbox"/> Add <input type="checkbox"/> Delete	FDA establishment registration number:		<input type="checkbox"/> Manufacturer <input type="checkbox"/> Contract manufacturer
Company / Institution name:		<input type="checkbox"/> Contract sterilizer <input type="checkbox"/> Repackager / relabeler	
Division name (if applicable):		Establishment registration number:	
Street address:		Phone number (include area code): ()	
City:		State / Province:	FAX number (include area code): ()
Country:		Contact name:	
Contact title:		Contact e-mail address:	

Section 2

Truthful and Accurate Statement

Section 3

Performance Standards

Performance Standards

The TemporalScanner Thermometer (formerly called the SensorTouch) has been tested to and found to comply with the following National or International voluntary standards:

1. ASTM E1965-98, and a working document (WD 124370-5) for EN 12470-5, the European Standard which is the European counterpart of ASTM E1965-98, to the extent these standards apply to an infrared thermometer which measures the temperature of the surface of the skin over the temporal artery.
2. EN 60601-1-2 - EMC
3. EN 55011 - EMC
4. EN60601-1 - Safety

Section 4 Labeling

Contents of Section 4 Labeling

Topic	Exhibit
Draft Instructions for Use for TemporalScanner Thermometer	4 -A
Draft Device Labels for TemporalScanner Thermometer	4 -B
Exergen Predicate Surface Temperature Scanner (Dermatemp) Labeling	4 - C
Braun Predicate (ThermoScan) Labeling	4 -D

Proposed Directions for Use for TemporalScanner

JS

Introduction

Congratulations and thank you for purchasing the Exergen TemporalScanner Thermometer for consumer use.

Your new TemporalScanner Thermometer is a totally non-invasive system with advanced infrared technology providing maximum ease of use with quick, consistently accurate measurements. Advanced, patented technology measures temperatures with a gentle stroke across the forehead.

The TemporalScanner Thermometer has been clinically tested for accuracy compared to rectal thermometers and accepted for use in major hospitals, making it the ideal thermometer for use with newborns, infants, children or adults.*

The TemporalScanner Thermometer has patented software, providing arterial heat balance. This unique process determines temperature by accurately measuring the balance between the tissues warming from arterial blood and tissues cooling caused by heat loss (gain) to the environment.

Why take temperature measurements at the skin surface over the temporal artery?

The best place to measure temperature is the center of the heart, but this can be done only under a doctor's supervision. Doctors know that measurement of the blood temperature in a major artery accurately reflects true body temperature. The TemporalScanner Thermometer is designed to measure the temperature of the skin surface over the temporal artery, a major artery.

The temporal artery is connected to the heart via the carotid artery, directly leading from the aorta, the main trunk of the arterial system. It offers constant blood flow. It is the only such artery positioned close enough to the skin surface to provide access needed to take an accurate measurement. It is easy to use because it is ideally located at the front portion of the forehead. The TemporalScanner is easier to use than other types of measurements devices such as oral, rectal, underarm and in-ear because it is non-invasive.

How does the TemporalScanner Thermometer work?

As you gently stroke the thermometer across the forehead crossing over the temporal artery, the sensor in its head performs two processes:

First, it scans like a video camera, capturing naturally emitted infrared heat from the arterial blood supply locking in the highest temperature it senses and;

* Comparison of Temperature Assessment of Infants and Toddlers via the Temporal Artery of Infants and Toddlers via the Temporal Artery and Rectum [where published or presented]; Comparison of New Temporal Artery Thermometer for Home Use with Rectal Thermometer in Two Pediatric Emergency Departments [where published or presented]. Available on Exergen's website: www.Exergen.com

Second, at the same time, a patented system measures the temperature of the site where the temperature is being taken. The patented “arterial heat balance” (AHB) software then synthesizes the two separate readings to accurately determine and display peak temperature.

As with any thermometer, taking temperatures properly is critical to obtaining accurate temperatures, so please read all instructions carefully and thoroughly before using this product.

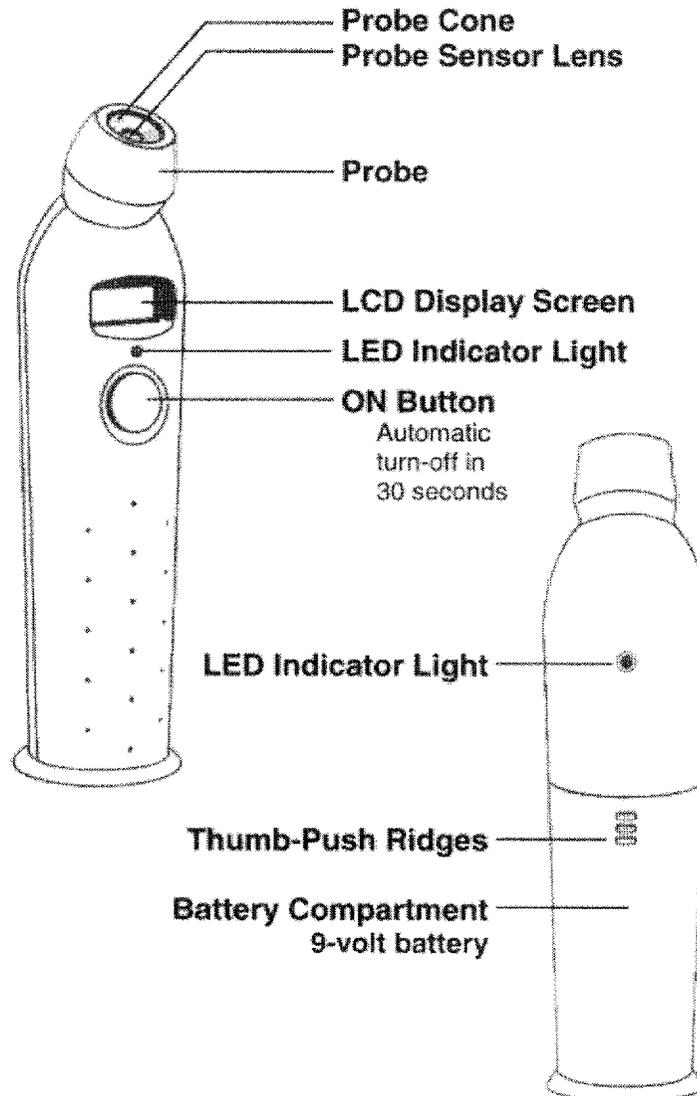
IMPORTANT

- Keep out of reach of children.
- Do not let children put the thermometer or its cap in their mouths.
- Do not take temperatures with this thermometer in places where the temperature is less than 60 °F or greater than 104 °F (105.5°C to 40°C).
- Do not expose this thermometer to a place where the temperature is below -4°F or exceeds 122°F (-20°/50°C) or to a place where it is excessively humid (95% RH non-condensing).
- Do not take temperatures with this thermometer near places that are very hot, such as fireplaces and stoves.
- Do not use this thermometer outdoors.
- Do not take temperatures over scar tissue, open sores or abrasions.
- Do not take temperatures on skin surfaces that are broken out or inflamed, e.g. pimples, dermatitis.
- Always store this thermometer in a clean, dry place in its travel case, protective cover or plastic case in a place where it will not become excessively cold (-4°F) or excessively hot (over 122°F).
- Always take basic safety precautions, especially when using the thermometer on or near children or disabled persons.
- Do not use this thermometer as a substitute for contacting your doctor; it is not meant for this purpose.
- This thermometer is not waterproof, so do not use it while bathing or place or store it where it might fall into water.
- The thermometer is not shock proof. Do not drop it or expose it to electrical shocks.
- This thermometer is not intended to be sterile. Do not try to sterilize it. Follow the cleaning instructions after each use.
- Use this product only for the uses as described in this manual. Do not use attachments which have not been recommended by Exergen Corporation
- Don't operate this thermometer if it is not working properly, if it has been dropped, exposed to temperature extremes, damaged, been subject to electrical shocks or immersed in water.
- There are no parts that you can service yourself except for the battery, which you should replace when low following the instructions in this manual. For service, examination, repair or adjustments, return your thermometer to Exergen.

- Do not operate where aerosol (spray) products are being used or where oxygen is being administered.
- Never drop or insert any object into any opening.
- Use this thermometer only to measure the temperature of the surface of the skin over the temporal artery.
- If your thermometer will not be used regularly, remove the battery to prevent possible damage due to chemical leakage. If battery leaks, remove carefully. Do not allow bare skin to touch leaking fluid.
- Dispose of used batteries properly. Do not wrap them in metal or aluminum foil. Wrap them in newspaper before disposing of them. Do not burn them. Battery may explode if overheated.

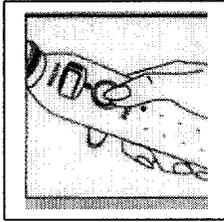
SAVE THESE INSTRUCTIONS !

Features



86

How to Take a Temperature

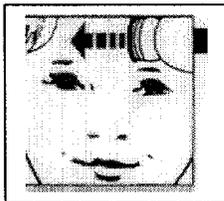


1

Remove protective cap before use. Be sure lens is clean. If not, clean with a cotton swab dipped in alcohol and let dry. Place the thermometer in your hand as shown with your thumb on the button.



Do not press the button yet

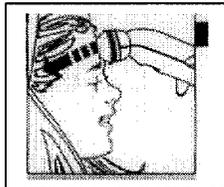


2

Gently position the sensor flush (flat) on the center of the forehead, midway between the eyebrow and the hairline. Press and hold the ON/OFF button.



Wait until the sensor is flush (flat) against the forehead before pressing the button.



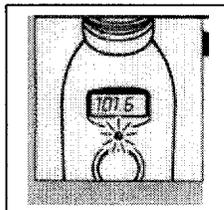
3

Slowly slide the thermometer across the forehead, keeping the sensor flat and in contact with the skin until you have reached the area at the top of the ear.



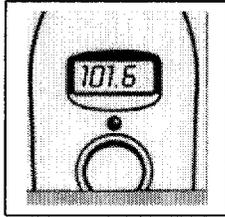
You will hear a beeping and the red light will blink to indicate a measurement is taking place.

Be careful not to keep the sensor on one spot too long. Otherwise, the thermometer will indicate the measurement is complete before you have reached the surface of the skin over the temporal artery.



4

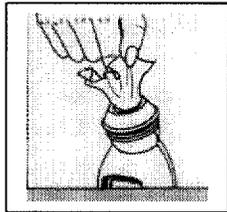
After the long beep when the red light remains on, the measurement is complete. Release the ON/OFF button and remove the thermometer from the head.



5

Read the temperature on the display. Press and release the button to turn the thermometer off.

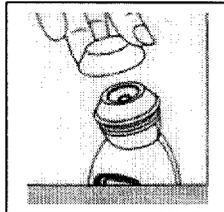
→ The thermometer will automatically turn off in 30 seconds if you forget.



6

To clean the thermometer, point the sensor downwards and gently wipe with a cotton swab or soft cloth dampened with rubbing alcohol or water.

→ Do not use a paper towel or abrasive cleaners



7

Place the protective cap on the thermometer to protect the sensor when not in use

58

Factors that may affect measurement accuracy



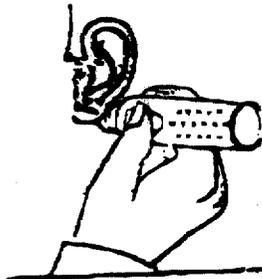
The patented AHB technology in your TemporalScanner actually makes two separate measurements: (1) the temperature of the skin over the temporal artery and (2) the temperature of the room. To determine the most accurate reading, it measures both temperatures some 2,000 times a second as you sweep the TemporalScanner across the forehead. The AHB system then calculates how much the blood has cooled down during its journey from the heart to the skin over the temporal artery and makes allowance for this in the temperature it displays. The result is a highly accurate reading - delivered extremely fast and with no discomfort.

To ensure that the reading always reflects the body temperature accurately, you need to take account of the following factors which may affect an accurate reading:

Sweating

When you develop a fever, your body tries to quickly bring its temperature down by sweating. TemporalScanner detects this reduction in temperature immediately - long before a rectal thermometer can do so. However, sweating also causes extra cooling of the skin. As a result, the reading given by the TemporalScanner may be low. You should therefore either wait until the sweating has stopped or use the following method, which has been clinically proven to provide an accurate result:

- Take the temperature on the forehead, as normal.
- Then also take the temperature behind the ear lobe, as shown in the figure.
- Gently nestle TemporalScanner, on head, directly behind ear lobe.
- Press the on/off button, maintaining skin contact until you hear the long beep.
- The higher of the two readings is the accurate one.



Note: Normally, the artery behind the ear lobe does not provide a sufficiently accurate reading. However, this area is less affected by sweating than the forehead. In addition, during sweating the increased blood flow and higher skin temperature result here in a good reflection of the body temperature. That is why on such occasions taking the temperature behind the ear may give a better result.

Environmental effects

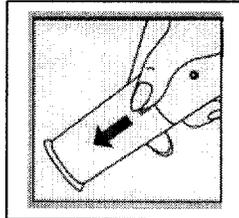
As part of its AHB system, TemporalScanner measures the temperature of the surrounding environment. For this measurement to be accurate, it needs to have become acclimatised to the temperature of the room in which it is to be used. If it is taken from a cold room into a hot room, or vice versa, allow it to acclimatise for at least 30 minutes before using it. Avoid holding the TemporalScanner by the head, as it will mistake the temperature of your hand for that of the room.

59

Tips on Using Your TemporalScanner Thermometer

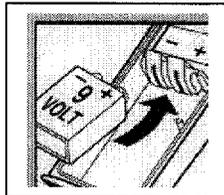
- Measure only the side of the head exposed. Anything covering the area, such as hair, hats, bandages and the like, will insulate the area and may give you readings that are falsely high.
- Slide the thermometer straight ACROSS the forehead NOT down the side of the face.
- When taking a temperature behind the ear lobe, first push away any hair, exposing the area.
- Infants frequently have blankets and clothing covering the neck. Unless your infant is visibly sweating, one measurement is usually enough to get an accurate temperature. However, if you feel the reading is too low, push aside any blankets or clothing covering the neck for 30 seconds and repeat the measurement.

Battery Installation / Replacement



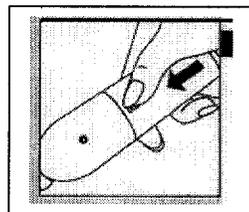
1

Slide the battery cover down as shown to open.



2

Insert the new 9 Volt battery as indicated. Make sure that the (+) and (-) leads are positioned correctly.



3

Close the battery cover.

Product Specifications

Clinical Accuracy	Meets ASTM E1965-98 and MDD 93142/EEC standards for electronic and radiation thermometers to the extent applicable to thermometers which measure the surface of the skin over the temporal artery.
Regulatory Approvals	CE Mark to -0197, TUV, Declaration of Conformity-ISO 9003/08.94, NIST certifiable traceable calibrations.
EMI/ RFI Protection	Error message displayed
Calibration Protection	Error message displayed
Temperature Range	15.5 to 42°C (60 to 107.5°F)
Operating Environment	15.5 to 40°C (60 to 104°F)
Resolution	0.1°C or °F
Response Time	Approximately 0.004 seconds
Time Displayed on Screen	30 seconds before automatic shutdown
Battery Life	Approximately 7,500 readings
Size	7.0 in x 1.75 in x 1.25 in(17.8 cm x 4.45 cm x 3.18 cm)
Weight	4.16 oz (120 grams) incl batt
Display Type	High contrast LCD
Construction Method	Impact resistant casing, Hermetically sealed sensing system
Warranty	1 Year
Laboratory Error:	+/- 4°F (+/- 0.2°C)
Storage Range:	-4°F - 122°F (-20°C-50°C)

Clinical accuracy characteristics and procedures are available from Exergen

Patents

Protected by one or more of the following US patents: 6056435, 6047205, 6045257, 5893833, 5874736, 5653238, 5628323, 5445158, 5381796, 5325863, 5199436, 5017019, 5012813, 4993419, 4874253, 4636091, RE035554, D03708. Other US and foreign patents pending.

Normal body temperature is not a single temperature, but a range of temperatures influenced by age, time of day and measurement site. You can establish your family's normal ranges by taking a number of temperatures from each member during a day and keeping records of them. Many people may not have an elevated temperature even if they are ill. These include, but are not limited to, infants under 90 days old, people on steroids, antibiotics or antipyretics (acetamenaphin, ibuprofen, aspirin), people with compromised immune systems (including the elderly and those having HIV/AIDS). Consult your doctor if you feel someone is ill even if their temperature is not elevated.

An elevated temperature or fever is often viewed as a danger sign. In fact, fever can be beneficial. It should be evaluated in the light of other physical symptoms. A doctor should be consulted in the following situations where fever is present: vomiting, diarrhea, changes in appetite, activity or breathing, or with children who are irritable, lethargic or unusually sleepy.

Normal Human Body Temperature Ranges At Various Measurement Sites

Oronasal (nose)

96. 6 - 99. 0° F
(35.9 - 37.2° C)

Axillary (under the arm)

95. 5 - 98. 8° F
(35.3 - 37.1° C)

Rectal

97.7 - 100.3° F
(36.5 - 37.9° C)

Arterial

97.4 -100. 1° F
(36.3 - 37.8° C)

Oral (mouth)

96. 6 - 99. 5° F

63

(35.9 - 37.5° C)

ASTM laboratory accuracy requirements in the display range of 37° to 39°C (98-102°F) for IR thermometers is $\pm 0.2^{\circ}\text{C}$ ($\pm 0.4^{\circ}\text{F}$) whereas for mercury-in-glass and electronic thermometers, the requirement per ASTM standards E667-86 and E1112 is $\pm 0.1^{\circ}\text{C}$ ($\pm 0.2^{\circ}\text{F}$)

Insert A Draft Instructions for Use – Section 4

This infrared thermometer meets requirements established in ASTM standard E1965-98 to the extent they are applicable to thermometers that measure the temperature of the surface of the skin over the temporal artery. Full responsibility for this product meeting applicable portions of this standard is assumed by Exergen Corporation, Watertown MA 02172.

68

Proposed TemporalScanner Labels

B.F. CONNECTIONS LLC D-15044 3RD PROOF

Device P/N TAT2000

Labeling

ACTUAL SIZE

EXERAEN \

Temp scanner / infrared thermometer

The following two pages describe the proposed

device labeling. The labels are like the labels

Probe lens and cone should be shiny clean, if not, wipe with an alcohol prep.

for other models so they are shown here with the model number taken out.

1. With probe flush on center of forehead, depress button, *keep depressed*.
2. Slowly slide probe across forehead into hairline.
3. Lift probe from forehead, touch on neck just behind ear lobe.

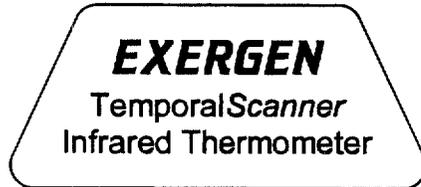
CUT LINE WILL NOT PRINT

ENLARGED FOR PROOFREADING

INSET BORDER

4. Release button, read, record temperature.

Model TAT-2000
EXERGEN Corporation
 Watertown, MA 617-923-9900
www.exergen.com



T
 MINIMUM AMOUNT OF SPACE BETWEEN BORDER & CUT LINE FOR DIE-CUTTING TOLERANCE

Probe lens and cone should be shiny clean, if not, wipe with an alcohol prep.

REV 1 SHEET

SIZE: 1 @ 1.08" X .48" OVERALL, .06" RADIUS CORNERS CUSTOM SHAPE
 1 @ 1.41" X .36", .06" RADIUS CORNERS
 1 @ 1.41" X 2" OVERALL, .06" RADIUS CORNERS CUSTOM SHAPE
 (NO CORNER RADIUS WAS SPECIFIED FOR THIS LABEL. HAS BEEN MADE AT .06" AS OTHERS)

COLOR: BLACK TEXT, COLOR MATCH 954 BLUE INSET BORDERS COLOR MATCH 953 OFF-WHITE BKGD.

MATERIAL: .006" TEXTURED PVC, 3M 467(2-MIL) YNDHE

1-18
 N
[Handwritten signature]

1. With probe flush on center of forehead, depress button, *keep depressed*.
 2. Slowly slide probe across forehead into hairline.
 3. Lift probe from forehead, touch on neck just behind ear lobe.
 4. Release button, read, record temperature.
- Model**
EXERGEN Corporation
 Watertown, MA 617-923-9900
www.exergen.com

4-16

67

200%

MAC#769906

TAT models are protected by one or more of the following US patents: 6056435, 6047205, 6045257, 5893833, 5874736, 5653238, 5628323, 5445158, 5381796, 5325863, 5199436, 5017019, 5012813, 4993419, 4874253, 4636001, RE035554, D03708

68

Exergen Predicate Device Labeling

69

I·N·S·T·R·U·C·T·I·O·N·S

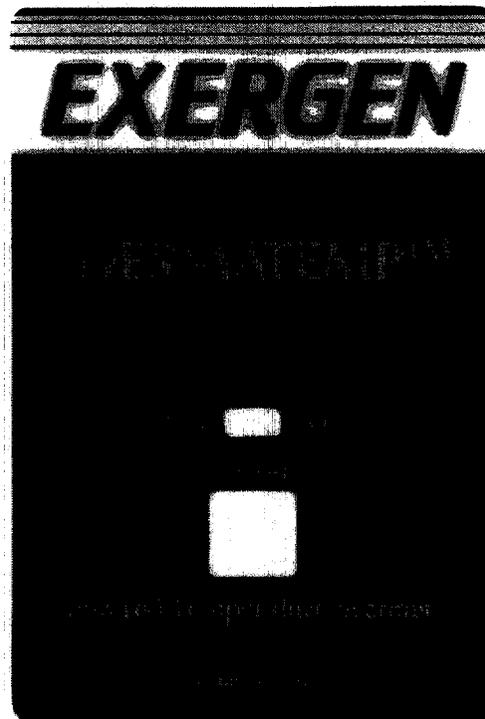
- 1** **Make sure lens is clean.**
If not, clean with a cotton swab dipped in alcohol and let dry.

- 2** **Select SCAN, MAX, or MIN mode.**
 - SCAN mode: Reads continuously.
 - MAX mode: Reads highest reading.
 - MIN mode: Reads lowest reading.

- 3** **Press red ON button and hold it down while scanning the surface. Release button to lock reading.**
For best accuracy bring the probe to within 1 mm of the surface being measured.

Patent Nos.: 4,636,091 and 4,993,419

Model DT-1001 Serial No. 3385
EXERGEN Corporation • Watertown, MA



BACK

FRONT

20

Five Year Warranty

Exergen Corporation warrants each new Exergen DermaTemp (except battery) against defects in materials or workmanship for a period of five years from the date of purchase, and agrees to repair or replace any defective product without charge.

IMPORTANT: This warranty does not cover damage resulting from accident, misuse or abuse, lack of reasonable care, the affixing of any attachment not provided with the product or loss of parts or subjecting the product to any but the specified battery.* Use of unauthorized replacement parts will void this warranty.

Exergen Corporation will not pay for warranty service performed by a non-authorized repair service and will not reimburse the customer for damage resulting from warranty service performed by a non-authorized repair service. No responsibility is assumed for any special, incidental or consequential damages.

In order to obtain warranty service, simply call Exergen Corporation Customer Service, 617-923-9900, for an Return Material Authorization number (RMA). Then send the product, postage or shipping prepaid, to Exergen in accordance with the instructions given with the RMA number. It is suggested that for your protection, you ship the product, insurance prepaid. Damage occurring during shipment is not covered by this warranty.

NOTE: No other warranty, written or verbal, is authorized by Exergen Corporation. This warranty gives you specific legal rights and you may also have other rights which vary from state to state. Some states do not allow the exclusion or limitation of incidental or consequential damages, so the above exclusion and limitations may not apply to you.



EXERGEN CORPORATION . 51 WATER STREET . WATERTOWN, MA, 02472
PHONE: 617.923.9900 . FAX: 617.923.9911
WWW.EXERGEN.COM

P/N: 818511 Rev 1

EXERGEN

USER'S MANUAL AND REFERENCE BOOK

DermaTemp 1001 Infrared Thermographic Scanner



Unparalleled Accuracy
... at the Speed of Light

V. Product Specifications

<i>Clinical Accuracy</i>	± 0.2°F or 0.1°C
<i>Temperature Range</i>	65 to 110°F (18 to 43°C)
<i>Operating Environment</i>	60 to 110°F (16 to 43°C)
<i>Resolution</i>	0.1°F or °C
<i>Response Time</i>	Approximately 0.1 second
<i>Emissivity Compensation</i>	Automatic
<i>Time Displayed on Screen</i>	10 Seconds
<i>Battery Life</i>	Approximately 5,000 readings
<i>Case Dimensions</i>	3.5" x 7" x 0.75" (9 cm x 18 cm x 2 cm)
<i>Weight</i>	9 oz (255 gm)
<i>Case Shielding</i>	Complete copper coating for EMI and RFI protection
<i>Display Type and Size</i>	Large, bright red LED's, easily readable in any lighting
<i>Construction</i>	Industrial duty, impact resistant casing, hermetically sealed sensing system
<i>NIST</i>	Certifiable traceable calibrations
<i>ASTM</i>	Meets or exceeds standards for electronic and radiation thermometers.
<i>Patents</i>	Protected by one or more of the following US patents: 6056435, 6047205, 6045257, 5893833, 5874736, 5653238, 5628323, 5445158, 5381796, 5325863, 5199436, 5017019, 5012813, 4993419, 4874253, 4636091, RE035554, D03708. Other US and foreign patents pending.

ell

²¹ Most RS, Simcock P. The epidemiology of lower extremity amputations in diabetic individuals. *Diabetes Care*. 6:87-91, 1983.

²² Bertholdt HT. Thermography on insensitive limbs. *Medical Thermography, Theory and Clinical Applications* 69-79, ed Uematsu S, Brentwood Publishing Co., Los Angeles, 1976.

²³ Dorgan MB, Birke JA, Moretto JA, Patour CA, Rehm BD. Performing foot screening for diabetic patients. *AJN* 32:37, Nov 1995.

²⁴ Uematsu S. Thermographic imaging of cutaneous sensory segment in patients with peripheral nerve injury. *J Neurosurg* 62:716-720, 1985.

²⁵ Rasmussen TB, Freedman H. Treatment of causalgia: analysis of 100 cases. *J Neurosurg* 3:165-173, 1946.

²⁶ Uematsu S, Shendler N, Hungerford D, et al: Thermography and electromyography in the differential diagnosis of chronic pain syndromes and reflex sympathetic dystrophy.

²⁷ Wexler CE, Small RB: Thermographic demonstration of a sensory nerve deficit. *J Neuro Orthoped Surg* 3:73-75, 1981.

²⁸ Ackerman RH, Noninvasive diagnosis of carotid disease in the era of digital subtraction angiography. *Neurool. Clin*:1:70-85, 1983.

²⁹ Abernathy M, Nichols R, Robinson C, Brandt M. Noninvasive testing for carotid stenosis: Thermography's place in the diagnostic profile. *Thermology*:1:61-66, 1985.

³⁰ Abernathy M, Chang L, et al. Cerebrovascular thermography: technique and quality control. *Am Acad of Thermology Ann Mtg*. Georgetown University Medical Center, 1985.

³¹ Perlestein P. Future directions for device design and infant management. *Medical Instrumentation* 21:1:36-41, Feb, 1987.

³² Robicsek F, et al. The value of thermography in the early diagnosis of postoperative sternal wound infections. *Thorac. Cardiovasc. Surg.* 32, 260-65, 1984.

³³ Warshaw TG, Lopez F. Thermoregulatory function in skin: an aspect of psoriasis. *Acta Thermographica* 5:22, 1980.

³⁴ Stuttgart G. Thermographic evaluation of the benign diseases and reactive changes of the skin. *Biomedical Thermology*, ed Gautherie M, Albert E. 397-411, Alan R. Liss, Inc., NY, 1982.

³⁵ Boycke E, Well MH. Toe temperature as an indication of blood flow in the critically ill. *Biology and Medicine*, Ch 190, 2073-2078.

³⁶ Kroloussy AM, Surfan S, Pavlides C, Matsumoto T. Central peripheral temperature: its value and limitations in the management of critically ill surgical patients. *Am J of Surgery*, Vol 140:609-612, Nov, 1980.

³⁷ Tsuji T. Patient monitoring during and after open heart surgery by an improved deep body thermometer. *Medical Progress Through Technology* 12, 25-38, Martinus Nijhoff Publishers, Boston, 1987.

³⁸ Benzinger TH. Heat regulation: Homeostasis of central temperature in man. *Physiol Rev* 49:671-759, 1969.

³⁹ Bassel LW, Gold RH, Clements PJ, Furst D. Hand thermography in normal subjects and scleroderma. *Acta Thermographica*:5:19-22, 1980.

⁴⁰ Haberman JD, Ethlich GE, Levenson C. Thermography in rheumatic diseases. *Arch. Phys. Med and Rehab* 48:187-191, 1968.

Table of Contents

I. The Instruments..... 1

The Instruments' Features..... 2

Optional Disposable Covers..... 2

Instructions for Applying Disposable Covers..... 3

Contact vs. Non-Contact Measurements..... 3

Operation and Controls..... 4

ON/OFF..... 4

To Lock Reading..... 4

To Restart..... 4

Operating Modes..... 5

Non-Contact Scanning..... 5

Changing the Battery..... 5

Fahrenheit or Celsius Conversion..... 6

Care and Maintenance..... 6

Self-Diagnostics..... 7

Customer Service..... 8

II. Body Surface Temperature..... 9

History and Introduction..... 9

Body Surface Temperature..... 10

Infrared Thermometry..... 11

The Dermal Temp Infrared Thermographic Scanner..... 13

Method Impedimenta..... 13

Ambient Effect on Body Surface Temperature..... 14

Solving the Problems..... 14

Emissivity..... 15

Alice's Quest for Emissivity..... 17

Correcting for Emissivity Automatically..... 18

Detection by Exception..... 18

III. Clinical Applications..... 20

Regional Blocks..... 20

Epidural Catheter Positioning..... 21

Joint Inflammation..... 21

Digital Perfusion Assessment..... 22

Reconstructive Surgery..... 22

Lower Back Pain..... 23

Diabetic Foot Screening..... 23

Peripheral Nerve Injury..... 24

Cerebrovascular Disorders..... 24

Neonatal Skin Temperature..... 25

Wound Management..... 25

Thermal Assessment of Skin Diseases and Allergy..... 26

Skin Temperature in Prognosis of the Critically Ill..... 26

Temperature Gradients in Detection of Shock..... 27

Raynaud's Syndrome..... 27

Other Areas or Applications of Interest..... 28

IV. References..... 29

V. Product Specifications..... 31

73

IV. References

- ¹ Chambliss J. Case of traumatic femoral aneurism (sic) treated by digital compression-ligation afterwards of the external iliac artery. *Confederate States Med Surg J*, 1:97-99, 1864.
- ² Coar T. The Aphorisms of Hippocrates with a Translation into Latin and English 88 (AJ Valpy, London 1822).
- ³ Robertson T. Clinical Temperature Measurement - Survey. CEC/Bell & Howell.
- ⁴ Uematsu S. Thermographic imaging of cutaneous sensory segment in patients with peripheral nerve injury. *J Neurosurg*, Vol 62, 717-720, May 1985.
- ⁵ Chamberlain DP, Chamberlain BDL. Changes in the skin temperature of the trunk and their relationship to sympathetic blockade during spinal anesthesia. *Anesthesiology* 65:139-143, 1986.
- ⁶ Shin Y, Pearson L, Burnett M. *Anesthesiology* V77, No 3A, Sep 1992.
- ⁷ Guadagni DN, Dreith F, Smyth CJ, Bartholomew BA. Skin temperature as an indicator of joint inflammation. *ISA BM* 74321 (105-110), 1974.
- ⁸ Levinsohn G, Gordon L, Sessler DI: Comparison of four objective methods of monitoring digital venous congestion; *J Hand Surgery*, Vol 16, No 6, 1056-1062, Nov 1991.
- ⁹ Bloomenstein RB. Viability prediction in pedicle flaps by infrared thermography: *Plast Reconstr. Surg.* 421:452-461, 1968.
- ¹⁰ Sirrat CR, Seaber AV, Urbaniak JR, Bright DS. Temperature monitoring in digital replantation. *J of Hand Surg*, Am Soc Surg of the Hand, 1978.
- ¹¹ Weinstein SA, Weinstein G. Thermography, EMG, CT Scan, Myelography and Surgery in 800 Patients: Georgetown University Medical Center, 14th Ann Meeting, Am Acad of Thermology.
- ¹² Barkan I. Thermography: A useful adjunct to differential diagnosis: lumbar radiculopathy versus plexopathy in 10 cases. Georgetown University Medical Center, 14th Ann Meeting, Am Acad of Thermology
- ¹³ Albert SM, Glickman M, Kailish M: Thermography in orthopedics, *Ann NY Academy of Science* 121, 157-170, 1964.
- ¹⁴ Heinz ER, Goldberg HI, Taveras JM: Experiences with thermography in neurologic patients. *Annual NY academy of Science* 121:177-189, 1964.
- ¹⁵ Raskin M, Martinez-Lopez M, Sheldon JJ: Lumbar thermography in discogenic disease. *Radiology*:119:149-152, 1976.
- ¹⁶ Tischauer IR: The objective corroboration of back pain through thermography. *J Occup Med*:19:727-731, 1977.
- ¹⁷ Ching C, Wexler CE: Peripheral thermographic manifestations of lumbar disc disease. *Appl Rad*:100:53-58, 1978.
- ¹⁸ Levin ME: Pathophysiology of diabetic foot lesions. In Davidson JK (ed): *Clinical Diabetes Mellitus: A Problem-Oriented Approach*, p504. Thieme Medical, NY, 1991.
- ¹⁹ Gibbons G, Eilopoulos GM. Infection of the diabetic foot. In: Kozak GP, Hoar CS, Rowbotham JL, (eds). *Management of Diabetic Foot problems*. 97-102, WB Saunders, 1984.
- ²⁰ Pliskin MA, Todd WF, Edelson GW. Presentations of Diabetic Feet. *Arch Fam Med*, 3:273-279, 1994.

phenomenon, particularly those with sclerodérama and progressive systemic sclerosis where it is the first symptom in 90% of cases, and may precede other manifestations by many years.^{3,4}

Other Areas or Applications of Interest

- Bone Fractures
- Diabetic Neuropathy
- Oncology
- Stress Fractures
- Breast Cancer Screening
- Diseases of Scrotum and/or Testicles
- Orthopedic Surgery
- Trigger Points
- Burn Injury
- Hansen's Disease
- Pagets Disease
- Tumor Screening
- Carpal Tunnel Syndrome
- Headache Clinic
- Pain Management
- Varicocoele Detection
- Cerebral Vascular Disease
- Joint Trauma
- Peripheral Nerve Injury
- Vascular Obstruction
- Nerve Root Compression
- Soft Tissue Injuries
- Dentistry
- Neuromuscular Injury
- Sports Medicine

I. The Instruments

The DermaTemp is a high precision hand-held infrared thermographic scanner designed to detect the subtle skin temperature variations caused by underlying perfusion variations.

These instruments feature a patented automatic emissivity compensation system for absolute accuracy regardless of skin type or color, and provide an instant temperature measurement on any surface location on the human body without the need for tissue contact.

In those applications where tissue contact is desirable or cross-contamination is an issue, the use of disposable wraps or sheaths allows even moist or wet tissue to be measured with precision accuracy.

The models include:

DT-1001

the standard model



DT-1001 LT

has a conveniently angled stainless steel probe, and can be used with or without disposable probe wraps



DT-1001 LN

has a longer probe than the DT-1001, and can be used with or without a disposable sheath. The sheath encases the entire instrument.



DT-1001 RS

has a remote stainless steel sensor attached to the instrument by cable, convenient for those especially hard to reach areas.



All instruments can be cleaned with any hospital approved disinfectant, including bleach, and can be gas or plasma sterilized.

The DermaTemp is recommended for use in such areas as plastic and vascular surgery, anesthesiology, pain management, rheumatology, neurology, oncology, and wound management.

The Instruments Feature:

- Full range resolution to 0.1°F/C
- SCAN, MAX and/or MIN modes of operation, model specific
- Fahrenheit/Celsius conversion
- A 10-second display lock
- An audible beeper to signal functional or conditional changes
- Hermetically sealed sensing system to withstand gas and plasma sterilization, and cleaning with any hospital approved disinfectant including bleach and alcohol.
- Pencil-like stainless steel sensor on the RS version.
- Optional disposable cover usage:
 - Complete encasement with disposable sheaths for the LN version.
 - Full probe covering with disposable wraps for the LT version.

Optional Disposable Covers

The use of disposable covers with the DT-1001 LT is optional, depending on the requirements of the application. Recommended guidelines are as follows:

Use With Disposable Cover

For absolute accuracy, minimizing the effects of emissivity and evaporative cooling, contact with the measurement site is recommended. Accordingly, when direct contact is employed, use of a disposable probe cover is recommended.

When touching moist tissue, use of a disposable cover is required specifically to avoid a lower temperature from the effects of evaporative cooling, and to protect against the risk of cross contamination.

Use Without Disposable Cover

If the measurement site is dry, direct contact can confidently be made without the use of a disposable cover. When the site is dry and the precise temperature is not a prerequisite, the measurement can be made without even contacting the skin. The probe can be cleaned with any hospital approved disinfectant, even bleach solution.

Temperature Gradients In Detection of Shock

Temperature monitoring of the gradient between forehead and sole temperatures has been demonstrated to provide early detection of masked symptoms during and after surgery. The effect of treatment and the prognosis for the patient are predictable according to the trends of the two temperatures as divergent or convergent. The dissociation when the two temperatures are more than 7°C apart from each other suggests that the hemodynamical condition is worse than in the convergence when they remain within 2°C.¹

The blood flow in finger skin is known to be very susceptible to sympathetic nervous activity. Palm tissue temperature varies more with the emotional stress than does sole tissue temperature. Assuming forehead and abdominal readings correspond to core temperature,² and sole and palm readings to shell temperature, the hemodynamical condition in convergence is usually better than in dissociation. If dissociation is observed in a post-op patient, the hemodynamical parameters have to be checked. When the arterial systolic pressure is less than 90 mmHg and the urine output less than 1ml/min/mg, a state of shock can be diagnosed based on the dissociation (difference >7°C).

A chilling sensation or shivering is common in dissociation, however, the symptoms can be overlooked in the patient just after surgery because an intubated patient cannot complain of a chilling sensation, and shivering does not occur in patients whose muscles are flaccid owing to residual pharmacological effects of anesthesia. Monitoring of the patient's body surface temperature allows for early detection of shock in postoperative patients with minimum discomfort and maximum safety to the patient.

Raynaud's Syndrome

Temperature monitoring of patients with Raynaud's Syndrome provides a useful, non-invasive method of quantifying temperature and heat patterns in determining the underlying pathogenesis of Raynaud's attacks, and in the evaluation of any subsequent therapy. Temperature monitoring may also be useful diagnostic tool in differentiating primary from secondary Raynaud's. Preliminary research data suggest Raynaud's may be a common denominator in certain sleep disorders. Many patients with connective tissue diseases present with Raynaud's



Evidence of Raynaud's Syndrome

26

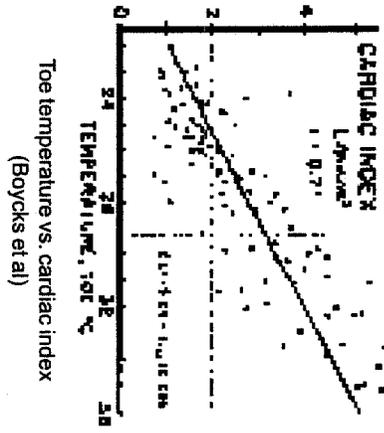
Thermal Assessment of Skin Diseases and Allergy

Temperature monitoring provides an objective assessment of skin diseases² as well as allergy and vasomotor tests³ since most of the skin diseases, or the percutaneous injection of pharmacodynamic substances used for testing, generate significant changes in the thermal pattern of the skin.

Skin Temperature in Prognosis of the Critically Ill

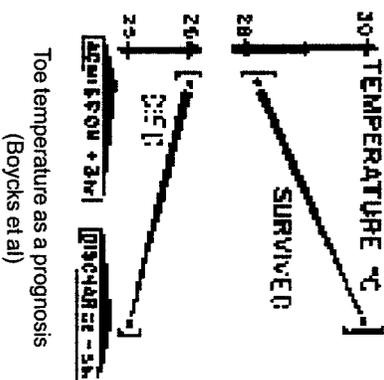
Skin temperature has been the subject of several studies monitoring blood flow in the critically ill.

Data from these studies indicate increases in the temperature of skin, especially the big toe, were accompanied by improvement in the clinical status of the patient, and significantly greater survival. Boycks and Weill⁴ concluded toe temperature provided the best correlation with cardiac index and prognosis of survival compared to arm, finger, thigh, or rectal temperatures.



Toe temperature vs. cardiac index (Boycks et al)

Kholoussy et al (1980)⁵ demonstrated attainment of normal rectal-toe temperature gradient consistently coincided with hemodynamic stabilization of the patient as indicated by other simultaneously measured parameters and by the clinical condition. In all the patients that died, rectal-toe temperature gradient gradually and progressively increased as the patient's condition became terminal.



Monitoring central peripheral temperature gradient was determined can accurately reflect the state of peripheral circulation, though may be limited by peripheral vascular disease, central hyperthermia, and the use of vasoactive drugs.

Instructions for Applying Disposable Covers

Model 1001 LT Only

- 1  Start with film perforation at edge of box tongue. Pinch bottom of white ring, push ring over peg.
- 2  Release pinch, gently pull box away from probe to release film from box. Pinch just below next ring, before perforation.
- 3  Rotate instrument into film until probe faces opposite direction, push ring on peg.
- 4  Release pinch. Pull box slightly away until next white ring is visible. Pinch ring, break film apart at perforation.

Contact vs. Non-Contact Measurements

In using any infrared temperature device, closer is always better, as the field of view increases proportionately to the distance from the surface. Accordingly, for maximum accuracy the probe must contact the surface at the point of interest. It does not need to be tightly pressed to the surface; a gentle touch is all that is required.

When contact with the surface is not an option, position the probe within 1/2 inch from the surface of interest. If using a non-contact protocol, the relative temperature indication of the instrument will be accurate.

2

Operation and Controls

The DermaTemp infrared thermographic scanner models 1001, 1001 LN, LT and RS are all identical in performance and specifications. All are maximized for ease of use. The remote sensor on the RS version can either be left attached to the instrument for one-handed operation, or separated for use in hard-to-reach areas of interest. The LN and LT models can be used with or without disposable covers

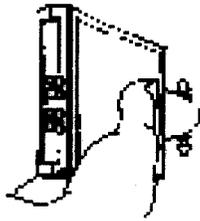
Using the DermaTemp

The DermaTemp is equipped with an ON/OFF power button and a mode selector switch, model specific. The mode selector switch allows you to choose one of the three modes of operation, SCAN, MAX, or MIN. The LT model is designed in a peak select mode, and automatically selects and locks the highest reading when the ON/OFF button is released.

ON/OFF:

To turn the instrument on, depress the red ON/OFF power push button. The single beep will audibly indicate that the instrument is on.

The display will momentarily read 8888, an indication that the microprocessor is performing a self-diagnostic check. After the test, the unit will measure and display temperature in the selected operating mode for as long as the power button is depressed.



To Lock Reading:

Release the red ON/OFF button to lock reading on display. The single beep will audibly indicate that the display is locked. The DermaTemp will hold the last reading on the display for 10 seconds before it automatically turns off.

If you are using a DermaTemp 1001 LT, the highest temperature measured will be retained before automatic turn off.

To Restart:

Depress the button anytime to restart. It is not necessary to wait until the display is clear. The DermaTemp automatically recalibrates each time the button is depressed.

Neonatal Skin Temperature

The goal of neonatal thermal management is to establish an environment of thermoneutrality in which the metabolic heat production requirement is minimal. Perstein¹⁴ indicates that both the core and surface temperature of the neonate are required to quantify the rate of heat loss. The greater the difference between core and surface temperatures, the greater the heat loss from the infant. (This holds only if vasomotor activity is absent, as is the case for a neonate.) A typical surface temperature for minimum heat loss is indicated as 36.0-36.5°C (96.8-97.7°F).

Conventional thermal sensor systems are sensitive to the thermal contact resistance between the surface of the patient and the surface mounted device. A large thermal resistance will result in inaccurate surface temperature readings, tending to be on the low side of the actual surface temperature. This technique requires time for the sensor to equilibrate and great care in the surface mounting methodology for accurate measurements. As a consequence, conventional surface detectors are usually used to monitor one location on the neonate and multiple site readings are rarely taken.

Infrared thermometry provides a method for accurate surface temperature measurements on multiple skin surface locations. The infrared technology has a short one-second time interval between readings, is essentially independent of user technique, and has no variable thermal contact resistance problem. The capability of rapid and accurate multi-surface temperature measurements provides the clinician a new and expanded method for the assessment of heat loss from the body surface of the neonate.



Wound Management

Increased skin temperature has long been associated with infection, thus measuring the changes in skin temperature in the area of incision or trauma when compared to the surrounding tissue provide the necessary quantifiable information for early recognition of such infections, well before the process has caused any visible skin changes.

Temperature measurement is especially useful for early diagnosis of postoperative wound infections¹⁵, those at the IV site, and decubitus ulcers, for example, and provides for routine quantification of the infection and subsequent monitoring of the healing process in an objective manner by the clinical staff.

Temperature is an early indicator of foot problems in diabetic patients⁵. Long before any clinical manifestations, heat can be detected, and the more sensitive the detection instrument, the earlier the warning. As a key indicator of complications from the disease, temperature has been incorporated into routine diabetic foot screening protocols.⁶

Two foot problems of major concern are foot ulcers and neuropathic fractures. Because of peripheral neuropathy, diabetic patients may not feel pain, and can continue walking on the foot. If the problem is not identified and treated in a timely fashion, they are at high risk for ulceration, infection, and deformities, with amputation of a lower limb always a real and devastating complication.

Using the DermaTemp for temperature monitoring in diabetic foot screening can immediately determine the thermal geography of the area of concern, identify hot spots, and locate cool areas. As a diagnostic tool, it is objective and quantifiable. Because it is relatively insensitive to user technique, many physicians have recommended their patients monitor their own foot and leg temperatures with the DermaTemp as part of their patient's self-care program.

Peripheral Nerve Injury

Temperature monitoring can be used in the quantification of peripheral nerve injury, differentiating among organic nerve damage, psychogenic factors, or even malingering.⁷ Skin temperature is altered in the field of an impaired peripheral nerve due to sympathetic vasomotor disturbance. Skin temperature in a normal individual differs between sides of the body only $0.24 \pm 0.073^{\circ}\text{C}$. In patients with peripheral nerve injury, the temperature of the skin innervated by the damaged nerve deviates an average of 1.55°C .^{8, 9, 10}

Temperature monitoring has been found to be highly successful in identifying the difficult pain problems e.g., diabetic or ischemic radiculopathy, facial pain syndrome, carpal tunnel, whiplash injuries of neck and upper back, and the phantom limb pain seen in amputees.

Cerebrovascular Disorders

Temperature monitoring is a useful method for screening for cerebrovascular disease before subjecting the patient to the risk of invasive procedures. In the evaluation of extracranial carotid complex, temperature monitoring demonstrates a high degree of sensitivity in detection of hemodynamically significant stenosis of the internal carotid artery.^{11, 12} Early detection allows the physician to institute appropriate therapy before a stroke occurs.¹³

Operating Modes (*Model Specific*)

- **SCAN:** In the SCAN mode, the target's instantaneous temperature is continuously displayed and updated 10 times per second for as long as you keep the button depressed. After the power button is released, the display will lock on the last temperature measured and hold that reading for 10 seconds.
- **MAX:** In the MAX (peak hold) mode, the display will lock on the highest temperature measured for as long as you hold the power button down. Each time a new peak temperature is measured or repeated, an audible beep will sound. After you release the power button, the display will lock on the maximum recorded temperature and hold that reading for 10 seconds.

- **MIN:** In the MIN (valley hold) mode, the display will lock on the lowest temperature measured as long as the power button is depressed. Each time a new low temperature is measured, a beep will sound. After the power button is released, the display will lock on the minimum recorded temperature and hold that reading for 10 seconds.

Non-Contact Scanning

For situations where even light contact is contraindicated, bring the instrument nose as close to the measuring site as safely possible, keeping the following in mind:

The instrument's field-of-view, also referred to as the distance-to-spot ratio, is 1:1. A 1:1 field-of-view means that the sensor sees a circular area with a diameter equal to the distance between the sensor and the target area.

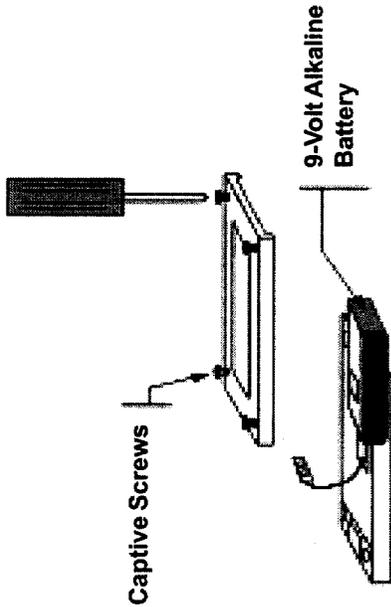
For example, at a distance of 2 inches (5 cm), the sensor sees a 2 inch (5 cm) diameter spot. The minimum spot size is approximately 1/4 inch (6 mm) when touching.

The DermaTemp averages the temperature of everything in its field-of-view.

A small hot spot may get lost in a large viewing area. The closer you hold the instrument to a surface, the sharper its target resolution.

Changing the Battery

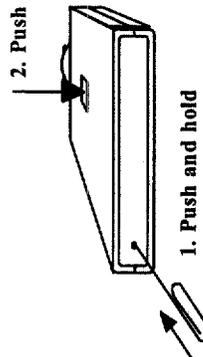
A standard 9-Volt alkaline battery will require replacement only once or twice per year under normal use. To replace, loosen the four captive screws and remove the cover. Disconnect the old battery and replace with a new one in the same location. Replace the cover and tighten the four screws. Use only high quality alkaline batteries or their equivalent.



Fahrenheit or Celsius Conversion

The DermaTemp can be used in either °F or °C. The only tool necessary to convert from one scale to the other is a paper clip.

- Find the small hole on the left side of the red display filter.
- Straighten the paper clip.
- Insert the end of the paper clip into the hole and push to activate the small switch underneath.
- While holding the paper clip pressed into the switch, turn the instrument on by pressing the red button.
- Remove the paper clip.
- To return to the original setting, repeat the process.



tized or ecchymotic digits, calling the physician for significant changes. The technique is atraumatic, and avoids patient anxiety which produces unwanted peripheral vasoconstriction. Temperature monitoring is also inexpensive and readily available.

Lower Back Pain

Lower back pain is one of the most common complaints of patients seeing a physician. Many complaints originate from work related accidents and contribute to a tremendously large number of hours lost from work. A study of 800 patients presenting with lumbar complaints and radicular asymptomatology by Weinstein et al³ compared the relative value of five diagnostic modalities and confirmed the accuracy of temperature as a method of confirming the presence or absence of root syndrome in low back pathology to be well above the 90th percentile.



Barkan demonstrated that lumbar radiculopathy can be detected by temperature measurement with accuracy equal to CT Scan or myelogram.⁴ These studies support the findings of many other similar studies,^{5, 6, 7, 8, 9} and clearly support the use of temperature measurement as a non-invasive technique without radiation, capable of reducing the number of invasive and uncomfortable myelograms and expensive CT scans of the lumbar spine.

Diabetic Foot Screening

Pedal infection is the most common cause of hospital admissions for diabetic patients in the United States and Great Britain^{1, 2, 3}, with more than 50% of the 125,000 amputations performed in the United States each year directly attributable to their disease.⁴ The American Diabetes Association estimates the costs of treating lower extremity amputations approaches \$10 billion annually, but interestingly, data from the Centers for Disease Control demonstrate up to 85% of diabetic foot and leg amputations can be prevented.

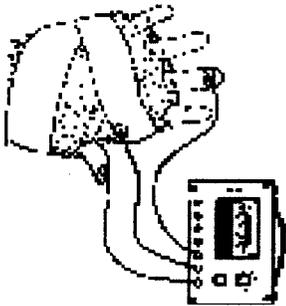


Digital Perfusion Assessment

Levinsohn et al (1991)¹ demonstrated that the infrared method of assessing perfusion was as reliable as Doppler methods, but far less expensive, much faster, and easier to use.

- A: Venous congestion was induced by placing a 28 mm wide cuff on the proximal phalanx of the long finger and then inflating the cuff to 5 mm Hg above resting diastolic pressure. With the aid of a nitrogen pressure regulator, cuff pressure was maintained for 60 minutes and assessment of digital perfusion was performed at 10 minute intervals using:
 - B: Laser Doppler Flowmetry
 - C: Pulse Oximetry
 - D: Skin Surface Fluorescence
 - E: Skin Surface Temperature Measurement via a DermaTemp (Levinsohn et al 1991).

Evaluation of methods of detecting perfusion impairment



Stirrat et al (1978) study on the effect of temperature on digital replantation

A study by Stirrat et al (1978)² on the effect of temperature monitoring in digital replantation demonstrated a decline in perfusion may be recognized earlier via temperature monitoring and improvement gained by clinical measures before the need for reoperation occurs. The objective temperature measurements allow a nurse or nurses aide to follow condition, especially where skin color cannot be followed easily, e.g. dark-skinned patients or with severely trauma-

Care and Maintenance

Handling

Your DermaTemp is designed and built to industrial durability standards in order to provide long and trouble-free service. However, it is also a high precision optical instrument, and should be accorded the same degree of care in handling as you would provide other precision optical instruments, such as cameras or otoscopes.

Calibration

Factory calibration data is installed via a computer through an optical link with the microprocessor. The instrument automatically self-calibrates each time it is turned on using this data, and will never require recalibration. If readings are not correct, the instrument should be returned for repair.

Cleaning

The DermaTemp can be gas or plasma sterilized, or wiped down with any hospital approved disinfectant, even bleach. With normal use, the only maintenance required is to keep the lens on the end of the probe clean. It is made of special mirror-like, infrared-transmitting material called Germanium.

Dirt, greasy films or moisture on the lens will interfere with the passage of infrared heat and affect the accuracy of the instrument. If necessary, clean the lens with an alcohol prep or a cotton swab dipped in alcohol. Periodic cleaning is a good practice.

Self Diagnostics

Continuous Single Beeping

The high performance DermaTemp continuously monitors its ability to produce accurate temperature readings. If either the target's temperature or the unit's ambient temperature exceeds the operational limits, the beeper will sound once per second and the LED display will default to a display message.

When the target temperature is outside of the instrument's operating range, the unit will display either HI or LO and will beep continuously at one beep per second. When the instrument's own temperature is outside operating limits for ambient temperature, the display will show either HI A or LO A, and will beep continuously at one beep per second.

Handwritten mark resembling a stylized 'S' or '2'.

Continuous Double Beeping

The battery voltage is also monitored. A low battery is indicated by a continuous double beep per second. Temperatures will continue to be displayed as long as accuracy can be assured. If the battery drops below 5.7 volts, it is considered "dead" and the display defaults to (---).

Customer Service

If repair is required:

- Contact Exergen for a Return Materials Authorization Number (RMA).
- Mark the RMA number on the outside of your package and packing slips.
- Include a description of the fault if possible.
- Send the instrument freight/postage prepaid to

Exergen Corporation
 51 Water Street
 Watertown, MA 02172
 Attention: RMA _____

- The instrument will be returned freight/postage prepaid.

Questions:

Should you have any clinical or technical questions, please contact a customer service representative in the medical division at Exergen Corporation. They may be contacted either by phone (617-923-9900), fax (617-923-9911) or email to medical@exergen.com.

sia, concluding skin temperature increase to be a useful indicator of sympathetic blockade, demonstrating that temperature elevation always preceded the upper limits of sensory blockade, and had a similar pattern of onset.

Epidural Catheter Positioning in Labor and Delivery

Foot temperature has successfully been demonstrated as an indicator in the functional positioning of an epidural catheter. In a recent study conducted at Georgetown University Medical Center involving 70 patients, Shin et al¹ confirmed the associated temperature changes provided better and objective evidence compared to the sensory pinprick test or subjective pain scales. The rapid and differential rise of foot temperature allowed early positioning of the patient with the unblocked cooler side down.

Joint Inflammation

Thermographic techniques have generally been used to demonstrate that surface temperature variations are an effective means to assess joint inflammation due to trauma and disease. Although the technique is effective it is not readily available in most clinical situations. In almost any clinical environment, infrared thermometry can provide the same basic data rapidly and at low cost.

In a paper on skin temperature as an indicator of joint inflammation, Guadagni et al (1974)² describe the surface temperature elevation over arthritic joints and the correlation of this measurement with the more conventional inflammatory index. They concluded averaged joint skin temperature not only offers quantitative but as reliable and reproducible information about the degree of joint inflammation as conventionally used parameters such as inflammatory index, grip strength, and joint size. Recorded temperature data provides an objective means for the evaluation of the joint and its treatment modality over time. Both the magnitude of the temperature elevation and its profile across the joint may be used in the evaluation.



Evidence of connective tissue disease

88

A striking example of perfusion effects can be demonstrated by compromise of circulation to the arm. A complete or partial occlusion of the artery in the upper arm will result in an immediate drop in hand temperature, and detectable in less than 30 seconds from the time of occlusion. The rapid response and the simplicity of infrared measurements make the technique effective in the hospital environment.

III. Clinical Applications

The following is a brief synopsis of a number of clinical applications for surface temperature measurements. These subjects are not covered in sufficient detail to be used for clinical protocols and are intended to be general indications for the use of infrared temperature measurements for clinical purposes. Because of the sensitivity of surface temperatures to the environment, it is important that certain precautions be followed in making surface temperature measurements. They are:

1. Provide for adequate equilibration time in the room environment at which the measurements will take place.
2. Protect the patient from drafts and exposure to cold surfaces (windows in winter).
3. Consider the use of a skin surface marker to ensure the measurement sites are repeatable.

Regional Blocks

The effectiveness of regional blocks can be monitored using the change in surface temperature due to sympathetic vasodilation of the tissue in the blocked area, eliminating the subjective pin prick assessment method. Depending on the type and location of the block, one can expect to see a temperature increase in the order of 1 to 1.5°C on the skin surface of the blocked area in 10 to 30 minutes after the injection of the blockade drug.



Using the DermaTemp to verify the geography of the block

In a recent study on sympathetic blockade, Chamberlain et al (1986)¹ measured the dynamic pattern of skin changes during spinal anes-

II. Body Surface Temperature

History and Introduction

As early as 2800 BC, the Egyptians, using the scanning sensitivity of the fingers over the surface of the body, recognized that the body produces heat, and that heat increases with disease. Further recognizing the distinction between local inflammation and fever, the Egyptians set the foundation for monitoring body surface temperature as a separate and distinct diagnostic methodology from the monitoring of core body temperature.

But the ancient diagnostic technique of feeling for heat is highly subjective, and only as sensitive as the hand of the feeler. The test of temperature is relative to the detector. A cold hand will indicate a warm body surface that a warm hand will indicate as cold. Certainly, the hand of an experienced physician laid upon the skin could provide much useful information about the temperature of the patient and the course of an illness, but eventually a more objective assessment was possible with the introduction of the clinical thermometer developed during the last century.



Typical 19th Century Thermometer

One of the earliest references to actually quantifying body surface temperature as a clinical diagnostic was in 1864 during the Civil War. Dr. Jackson Chambliss, a surgeon in the Confederate Army, used a thermometer to diagnose a traumatic femoral aneurysm by showing that surface temperature was decreased distally in the affected leg.¹

In more recent times, the measurement of the surface temperature of the human body has not been routinely undertaken in many clinical environments - not because the measurement lacks clinical significance, but because it has been difficult to acquire. Conventional mercury or electronic thermometers have generally been ineffective for surface temperature measurements for three reasons: 1) they are difficult to properly attach to the body surface, 2) they require a significant amount of time for the sensor portion of the device to equilibrate to the body



Electronic Thermometer

temperature measurements for three reasons: 1) they are difficult to properly attach to the body surface, 2) they require a significant amount of time for the sensor portion of the device to equilibrate to the body

surface temperature and 3) they are prone to low readings because it is not always evident that the surface thermal connection is adequate.

Body Surface Temperature

Heat signatures vary considerably over the surface of the human body, and physicians have long appreciated the relationship between heat and disease. In fact as early as 400 BC, Hippocrates wrote "*In whatever part of the body excess of heat or cold is felt, the disease is there to be discovered.*" Undoubtedly the earliest use of clinical thermography, Hippocrates found when he covered his patient's body with wet clay, the mud dried quicker on the diseased area, thus presenting a crude but dramatic demonstration of the heat signatures.



Thermographic scan of the patient with clay on his body. (Dorex, Inc. CA)

It is impossible to define the surface temperature by any single normal value, since it is the result of a thermal balance between energy supplied from the core via perfusion and energy lost to the environment via radiation, conduction, convection, and evaporation. All objects, whether animate or inanimate, homeothermic or poikilothermic, radiate electromagnetic energy (radiation) to the surroundings at a rate dependent on its temperature. In accordance with a basic law of physics, this invisible radiation is constantly emitted, absorbed, and re-emitted by everything in our surroundings so that thermal equilibrium can be maintained. A simple example: left in normal room temperature, a cup of hot coffee quickly cools and a glass of iced tea quickly warms to the temperature of the room.

If the human eye had the optical power to see the emitted radiation, which has all the same properties as a beam of light, but differing in wavelength, all mankind would have an incandescent glow. Because the temperature over the surface of the human body changes at a rapid rate in response either to its external environment or to its internal control mechanism, the incandescence would be quite bright over some areas and quite dark over others. This variability of the temperature pattern gives question as to its significance, and yet it is a remarkable indication of the underlying body physiology.

All biological tissue generates energy in proportion to the metabolic activity occurring within the cells. About 80% of the energy developed by

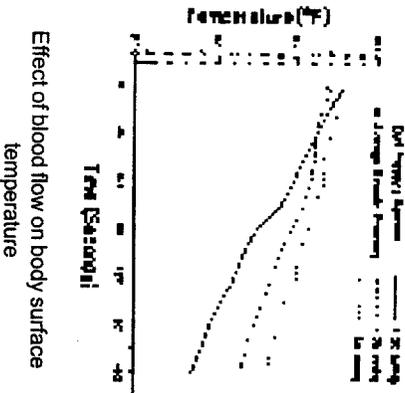
bilateral symmetry. Skin temperature differences from one side of the body compared to the other are not only extremely small, but also very stable, and unaffected by the age of the patient. Data show differences between sides at the forehead to be 0.12°C at the forehead, and 0.25°C at the lumbar region of the back. This symmetry forms the foundation for clinical interpretation of the varying surface temperature data.

In general, it is the relative readings between the body surface temperatures that are of interest. Hence, the general principle is *all detection is by exception*. Accordingly, the temperature data from the normal or reference area can then be used to adjust for the circadian variations and for variations in the ambient temperature.

The change in body surface temperature with compromised blood flow is profound. A recent study was undertaken to mimic both partial and complete occlusion of blood flow to an extremity. The results indicate changes in skin surface temperature of an extremity reflect blood flow interruption or alteration in blood flow to that extremity.

A baseline for systolic blood pressure was determined for each subject and the manometer cuff inflated to three levels, 30 mmHg above systolic, 25 mmHg below systolic and 50 mmHg below systolic, with temperature readings taken on the inside wrist at 15 second intervals. Even at the lowest cuff pressure, there is a clear indication at the end of three minutes of the surface temperature change due to the lowered tissue perfusion caused by the reduction in arterial blood flow. The data also indicate the time between occlusion or partial occlusion and a measurable temperature drop is very short, well under one minute.

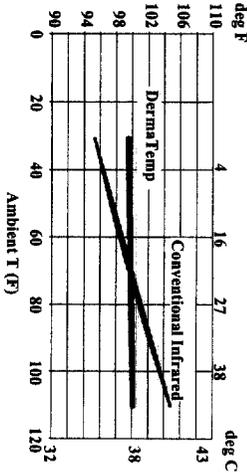
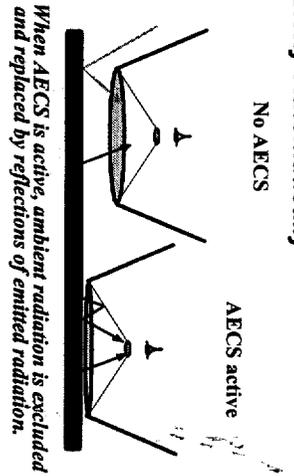
The surface temperature readings of the human body tend to be quite close between the bilaterally symmetric surfaces of region because of perfusion symmetry, but vary by several degrees on different body locations because of perfusion differences. Both the hands and the feet can be substantially colder than the rest of the body surface due to vasomotor constriction of arteriovenous shunts as a thermoregulatory response.



Handwritten mark

Correcting for Emissivity Automatically

Biological tissue has high emissivity, i.e. ~0.95. Accordingly, the reflected component will be about 5% of the energy measured by the DermaTemp, which translates to an absolute error of ~1°F (0.5°C). In addition, skin emissivity varies due to color, texture, etc. over the approximate range of 0.92 to 0.98. An uncertainty of approximately ±1°F (0.5°C) results from this emissivity variation, which can appreciably influence the assessment of a subtle perfusion issue.



Effect of ambient temperature on infrared device readings for a surface at 38°C (100°F) with emissivity 0.9.

A more significant error is due to the reflected energy, which can vary considerably if the ambient radiation includes sunlight, radiant warmers, etc. To solve this problem the DermaTemp is equipped with a unique patented feature called Automatic Emissivity Compensation System (AECS). The reflective cup on the end of the probe automatically compensates for emissivity when it is touching, or brought to within approximately 1mm of the surface. By excluding ambient radiation, and replacing it with reflections of emitted radiation, the emissivity is corrected, and the accurate temperature indicated.

Detection by Exception

The distribution of the temperature on the body surface varies appreciably. For example, on a normal individual, the highest average skin temperature is the forehead at 34.5°C (±0.73°C) and the lowest average temperature is the toes at 27.1°C (±2.72°C).¹ Considering the temperature of the skin is highly influenced by ambient temperature, one could wonder what diagnostic role, if any, temperature would play. The answer is that it plays a significant role, and the reason is the

the human body is converted into heat, with the balance converted into external work or into tissue growth. The circulatory system, in addition to circulating blood for its metabolic characteristics also distributes heat, thus replacing the heat energy lost to the environment, as well as nourishing the tissue. The resultant increase in heat energy delivered by the blood causes the temperature to rise until the heat energy lost to the environment again balances with the heat delivered.

It has long been recognized that where there is injury or infection, there is inflammation, but injury or infection of itself does not create heat energy. When there is trauma, whether an injury or abnormal stimulation caused by a physical, chemical, or biologic agent, a pathologic process of reactions occurs in the blood vessels and adjacent tissues in response to the perturbation. The natural defense mechanism triggered immediately increases the flow of blood to the area of concern, causing the temperature to rise in proportion to the increase in blood flow. However, the maximum temperature can be no higher than that of the core arterial supply to the trauma tissue.

Consider as a simple analogy, the action of washing your hands in a sink. If the water from the hot faucet were to be trickling in a small stream, it is likely it would feel only lukewarm. However, if you were to open that tap full force, the rushing water would feel quite hot. But, no matter how intense the rush, the water could never be hotter than the water from its source of heat, the furnace.

The ancient diagnostic technique of feeling for heat over the body is a longtime indicator of inflammation. While localized temperature elevations may be felt merely by the touch of the hand, the technique is highly subjective, and not sufficiently sensitive to detect the subtle temperature rises indicative of increased cellular or metabolic activity. With the introduction of infrared techniques, accurate surface temperature patterns are immediately quantifiable and any changes easily detected. It is this knowledge that enables us to study any disease process resulting in a change in heat generation or thermal properties of the tissue.

Infrared Thermometry

Temperature is a fundamental property of all matter related to its energy content, and can be described by a numeric value expressed on a scale of temperature. A human's touch produces an instinctive sense of hot or cold to judge the relative temperature of two objects. However, as a practical matter, clinicians must have a temperature scale that is independent of the observer, by which unknown temperatures

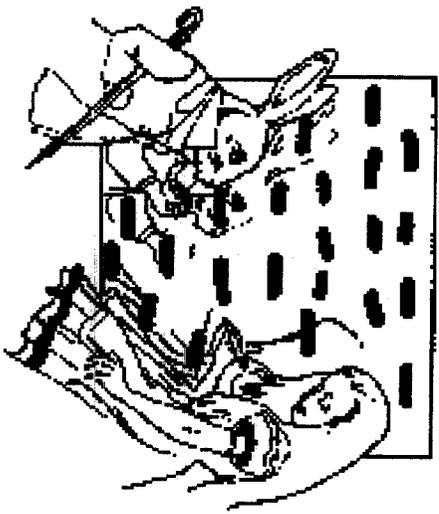
can be evaluated. With a proper temperature scale, measurements taken at different times or places can be compared. Without a thermometer, it would be impossible to measure the temperature of a human with respect to a fixed scale of reference. Remember, the human test of temperature is relative to the detector. A cold hand will indicate a warm body surface that a warm hand will indicate as cold.

Numerous techniques and devices are employed in the measurement of temperature. Many of these techniques, such as the use of glass mercury thermometers or electronic display devices using thermocouples or thermistors, are generally understood and as a result well accepted in clinical medical practice. All three of the devices have one very important characteristic: they measure their own temperature, not the temperature of the object being measured, except in an indirect way. In order to make an accurate temperature determination using one of these measurement techniques, it is necessary for the device to have intimate contact with the subject for sufficient time to raise the temperature of the thermometer to the same, or close to the same, temperature as that of the subject. Thermal contact thermometers require too much time to equilibrate, are sensitive to variations in contact pressure resulting in changes in the thermal resistance between the skin and the temperature detector, and tend to have too great a variation from reading to reading. If these devices are not properly located, properly attached, or left in place for enough time to equilibrate, they all will give incorrect readings.

The infrared method is fundamentally different from the other methods in that there is no temperature device to heat. Like an eye, the infrared instrument simply looks at the heat radiation naturally emitted from the body surface. Since there is nothing to heat, the measurement can be made very fast, orders of magnitude faster than the probe devices.

Historically, most of the published clinical data on body surface temperature measurements are based on the use of infrared thermography. Infrared thermography has long been recognized as a reliable, highly technical diagnostic tool, and refers to the process of recording and interpreting variations in temperature of the surface of the skin in color or shades of gray. The clinical information is contained in the relative temperature profiles. The technique is effective, but the equipment is complex and expensive.

Decades ago, the common image of a computer was that of an enormous, very expensive piece of equipment, something requiring an environmentally controlled room and complex installation. Today's computers have been reduced to hand held units. Infrared thermography



Alice's Quest for Emissivity

Is it possible to see a mirror?

When the mirror is looked at, all other objects in the room are seen.

Is it invisible?

No, if it were, the wall would show behind it.

So how can it be seen?

If crayon spots are painted on the mirror, then the mirror can be seen.

Of course, it can only be seen where there are spots.

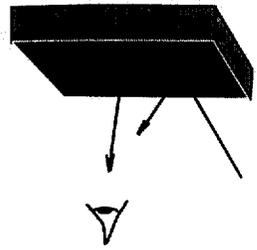
Everywhere else still reflects.

Thus, light is emitted from the spots and reflected from the non-spots.

(Full reprint available from Exergen)

86

ample, we saw 90% of the mirror as a perfect reflector and 10% as imperfections, 90% of the mirror would reflect; the remaining 10% would emit. Therefore, the emissivity equals 0.1.



Good Emitter
Emissivity = 0.9
Reflectivity = 0.1

1.0

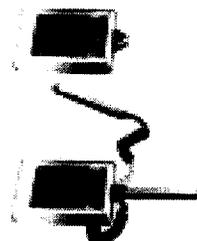
Consider for a moment the exact opposite of a perfect mirror, which is a perfect emitter. The eye looks at a perfect emitter and sees no reflection at all, only the emitting surface. Since 100% of the surface emits, and 0% reflects, the emissivity equals 1.0. This type of object is called a blackbody.

And finally, consider a good emitter. The eye sees a small amount of reflection interspersed with the large amount emitting. If, for example, 10% of the surface did not emit, and instead reflected, then we would have 10% reflecting and the remaining 90% emitting. Therefore, the emissivity equals 0.9. Accordingly, we can state the following rule of emissivity: **The emissivity of the surface is simply the percentage of the surface that emits. The remaining percentage of the surface reflects.**

was not a lot different: large and expensive, requiring environmentally controlled rooms, trained technicians, and exotic gases. Today's advanced technology makes it possible to put the power of infrared thermography in the palm of your hand, at a fraction of the cost of all previous techniques. While there are a variety of infrared thermometers available, only one is designed specifically to meet the stringent clinical requirements, the DermaTemp Infrared Thermographic Scanner.

The DermaTemp Infrared Thermographic Scanner

The DermaTemp is a high precision handheld infrared thermographic scanner designed to detect the subtle skin temperature variations caused by underlying perfusion variations. These instruments instantly measure temperature on any surface location on the human body without the need for tissue contact.



DermaTemp DT 1001 and DT 1001-RS

The DermaTemp is highly recommended for use in plastic and vascular surgery, anesthesiology, pain management, rheumatology, neurology, oncology, and wound management. Other applications follow this section.

Infrared thermometry is fast, stable, repeatable, and is relatively insensitive to user technique. Skin temperature measurements with infrared thermometry are attractive because they are objective, low cost, and cause absolutely no trauma or discomfort to the patient. The versatility of the products allows for absolute temperature measurement, surface scanning, and comparative methods of temperature differential.

Method Impedimenta

Despite the tremendous benefits of using infrared technology for clinical applications, there are several impediments which should cause pause, such as variable skin characteristics, wet skin, and environmental influences. Since the process of measuring temperature by viewing the infrared radiation of the surface is significantly faster than the other techniques mentioned earlier, the user needs to be aware of several important considerations. The surface temperature of the human body is sensitive to the external environment and can vary by several degrees in a short period of time. Drafts will lower the surface temperature. A cold room environment will lower the surface temperature. Any surface moisture will lower the surface temperature. Exercise will raise the surface temperature due to increased perfusion as a ther-

more regulatory response. Exposure to the sun or any other warm surface will raise the surface temperature. The user needs to be aware of these concepts and not be surprised in the event the temperature readings are not as expected.

Ambient Effect on Body Surface Temperature

The cardinal rule of interpretation of skin temperature is that the same environment will produce the same temperature if perfusion is the same. If the environment is the same and the temperature is different, then perfusion must be different. But body surface temperature can be significantly influenced by the temperature of the surrounding environment as evidenced in the table.

Effect of Ambient Temperature on Skin¹

Ambient	Hand	Forehead
4°C	8.9°C	13.7°C
23°C	26.9°C	29.2°C
27°C	33.2°C	33.2°C

Therefore, absolute temperature readings must be interpreted in relation to the environment, and the practitioner should be careful to protect the patient from drafts or exposure to large cold surfaces, to position the extremities to minimize pooling, and to allow time for the surface temperature to equilibrate to its environment.

The distribution of the temperature on the body surface is generally bilaterally symmetric. This symmetry can form the basis for clinical interpretation of the surface temperature data. The temperature data from the normal or reference area can also be used to adjust for the circadian variations and for variations in the temperature environment. In general, it is the relative readings between the body surface temperatures that is of interest.

Solving the Problems

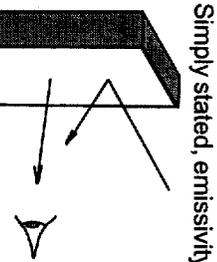
The DermaTemp is the result of many years of active scientific research in both the technology and clinical requirements. The patented reflective cup on the probe of the DermaTemp provides accuracy heretofore unavailable for clinical use. The instrument is completely unaffected by conditions prohibiting the use of other infrared devices. Because of its unique design, the classical problems in producing accurate temperatures have been solved.



Reflective cup on probe tip

Emissivity

An important concept needed to understand how temperature is measured using infrared radiation is the one of emissivity. Emissivity is a surface property which determines just how well an object's temperature can be measured by an infrared device. Emissivity (along with background thermal radiation) is the primary source of errors in infrared temperature measurement. Emissivity can be more easily understood if it is realized that infrared has similar properties to visible light.

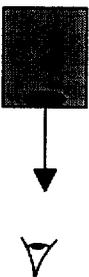


Poor Emitter
Emissivity = 0.1
Reflectivity = 0.9

1.0

Simply stated, emissivity is the opposite of reflectivity. A perfect mirror has a reflectivity of unity and an emissivity of zero. A perfect black body has an emissivity of unity and a reflectivity of zero. In actuality, all real bodies (including human ones) have an emissivity between these two limits.

It is not possible to accurately measure the surface temperature of any body with an emissivity of less than 1.0 without making a correction for this source of error. Human skin is near but not equal to 1.0 and, if not accounted for, can introduce errors in the order of one to two degrees. The cup-like mirror used in the nosepiece of the DermaTemp scanner removes this source of error by trapping all of the radiation from the skin surface and in effect causing the skin surface to act like a black body with an emissivity of 1.0.



Blackbody
Emissivity = 1.0
Reflectivity = 0.0

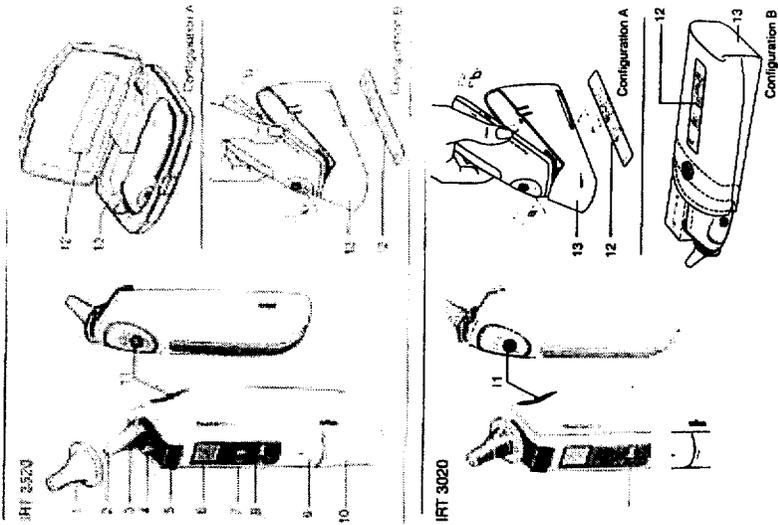
1.0

Mirrors figure prominently in the discussion of heat radiation and emissivity. Since heat and light radiation behave the same way, we can use what we see with our eyes as examples of what the DermaTemp sees. When you look in the mirror, you see only reflections, nothing of the mirror itself. If the mirror is perfect, it has 100% reflectivity. Because it reflects everything, it emits nothing. For this condition, the emissivity is zero.

If we consider an imperfect mirror, the eye then sees mostly reflection, but also some of the imperfections on the mirror surface. If, for ex-

Braun Predicate Device Labeling

89



English

The Braun ThermoScan thermometer has been carefully developed for accurate, safe and fast human body temperature measurements in the ear. The shape of the thermometer prevents it from being inserted too far into the ear canal to damage the eardrum.

However, as with any thermometer, proper technique is critical to obtaining accurate temperatures. Therefore, please read all instructions carefully and thoroughly before using this product.

Important

- The operating ambient temperature range for this thermometer is 50 °F to 104 °F (10 °C to 40 °C).
- Do not expose the thermometer to temperature extremes below - 4 °F or over 122 °F (- 20 / 50 °C) or excessive humidity (> 95 % RH non-condensing).
- This thermometer must only be used with genuine Braun ThermoScan Lens Filters (LF 40). Never use this thermometer without a new, clean lens filter attached.
- If the thermometer is ever accidentally used without a lens filter attached, clean the lens (see Care and Cleaning).
- Always store thermometer in travel case, protective cover or plastic case.
- Basic safety precautions should always be observed, especially when using the thermometer on or near children and disabled persons.
- Keep lens filters out of reach of children.
- Use of this thermometer is intended for home use only.
- This thermometer is not intended as a substitute for consultation with your physician.
- Do not leave thermometer or lens filters with infants or children at any time.

How does Braun ThermoScan work ?

The Braun ThermoScan thermometer measures the infrared heat generated by the eardrum and surrounding tissue. To help ensure accuracy, the thermometer - scans - by taking 8 measurements in just one second and displaying the highest temperature. The displayed ThermoScan temperature is the actual measured ear canal temperature plus a mathematical adjustment to approximate the familiar oral range. However, this is not necessarily the same as an oral temperature measured at the same time.



Why measure in the ear ?

The goal of thermometry is to measure core body temperature, which is the temperature of the vital organs. Clinical studies have shown that the ear is an excellent site to measure body temperature, since ear temperatures reflect core body temperature. The eardrum shares blood supply with the temperature control center in the brain, the hypothalamus, allowing changes in body temperature to be reflected sooner in the ear than at other sites.



- Axillary temperatures reflect skin temperature which may not indicate core body temperature.
- Oral temperatures are influenced by drinking, eating and breathing through the mouth.
- Rectal temperatures often lag behind changes in core body temperature and there is a risk of cross-contamination.

Body temperature

Normal body temperature is a range. The following table shows that ranges of normal also vary by site. Therefore, readings from different sites, even if taken at the same time, should not be directly compared.

Axillary:	94.5 °F - 98.1 °F	34.7 °C - 37.3 °C
Oral:	95.9 °F - 98.5 °F	35.5 °C - 37.5 °C
Rectal:	97.9 °F - 100.4 °F	36.6 °C - 38.0 °C
ThermoScan [®] :	96.4 °F - 100.4 °F	35.8 °C - 38.0 °C

Also, a person's normal temperature range tends to decrease with age. The following table shows normal ThermoScan ranges by age.

Normal ThermoScan temperature ranges¹

0 - 2 years	97.5 °F - 100.4 °F	36.4 °C - 38.0 °C
3 - 10 years	97.0 °F - 100.0 °F	36.1 °C - 37.8 °C
11 - 65 years	96.6 °F - 98.7 °F	35.9 °C - 37.6 °C
> 65 years	96.4 °F - 98.5 °F	35.8 °C - 37.5 °C

However, the range of normal also varies from person to person and fluctuates throughout the day. It is therefore important to determine your and your family members' normal temperature ranges. This is easily done using Braun ThermoScan. Practice taking temperatures on yourself and healthy family members to determine their normal temperature ranges.

Note: When consulting your physician, communicate that the ThermoScan temperature is a temperature measured in the ear and if possible, note the individual's normal ThermoScan temperature range as additional reference.

1. Chamberlain, J.M., Tenopus, T.E., New Light on Ear Thermometer Readings, Contemporary Pediatrics, March 1994, 114, 41. 2. Chamberlain, J.M., et al. Determination of Normal Ear Temperature with an Infrared Emission Detection Thermometer, Annals of Emergency Medicine, January 1992.

90

Memory mode

The last temperature taken before the thermometer powers down is stored in memory. To enter the memory mode, press the \odot /mem button.

Even in memory mode, a new temperature can be taken provided that the ready symbol is shown.

IRT 3020

The last stored temperature is displayed along with the MEM symbol. To quit the memory mode, press the \odot /mem button again.

IRT 3520

This model allows you to store up to 8 temperatures.

When pressing the \odot /mem button, the display shows the memory cell number (e.g. MEM 1). When releasing the \odot /mem button, the stored temperature is displayed.

Each time the \odot /mem button is pressed, a new memory cell is displayed (up to MEM 8).

An empty memory cell shows " - - °F". Only the first empty memory cell will be displayed.

To quit the memory mode, press the \odot /mem button again after reaching MEM 8 or " - - °F".

Memory clear

Press the \odot /mem button for 5 seconds to clear the temperatures stored in memory. Release the \odot /mem button to return to the ready symbol.

LCD light (model IRT 3520 only) for easy nighttime reading

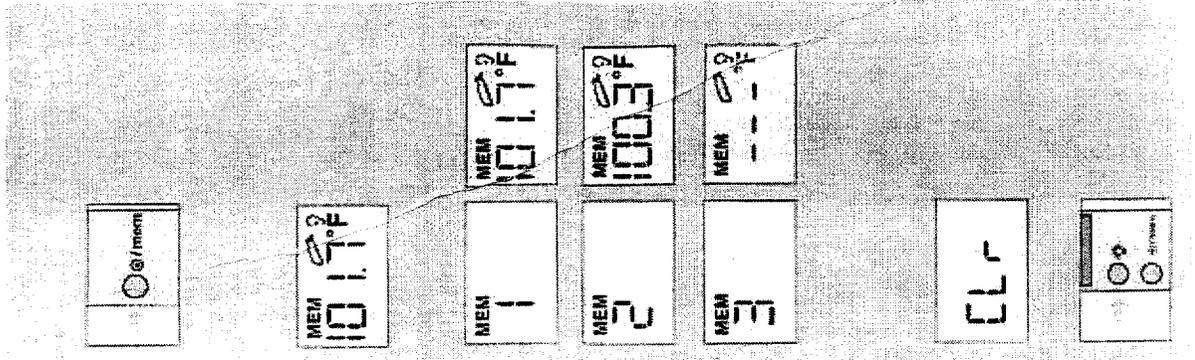
Note: In the following situations, it is recommended that you take three temperatures in the same ear. If they differ, use the highest reading.

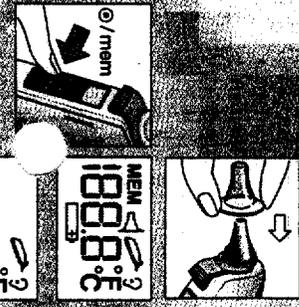
- Infants in the first 90 days of life.
- Children under three years of age who have a condition such as a compromised immune system and for whom the presence or absence of fever is critical.
- When you are first learning to use the ear thermometer until you are comfortable with the technique and are obtaining consistent readings.

Important: As with any type of thermometer, slight temperature variations ($\pm 0.3 - 0.5^\circ\text{F}$ / $\pm 0.2 - 0.3^\circ\text{C}$) can occur, if consecutive measurements are taken.

Temperature taking hints

- The right ear reading may differ from the reading taken at the left ear. Therefore, always take the temperature in the same ear.
- The ear must be free from obstructions or excess earwax build-up to take an accurate reading.
- External factors may influence ear temperatures, including when an individual has:
 - been lying on one ear or the other
 - had their ears covered
 - been exposed to very hot or very cold temperatures, or
 - been recently swimming or bathing.
 In these cases, remove the individual from the situation and wait 20 minutes prior to taking a temperature.





Product description

1. Lens filter
2. Probe tip
3. Probe
4. Lens filter detector
5. Lens filter ejector
6. Display (LCD)
7. LCD light button * (IRT 3520 only)
8. @ /mem button (On / memory function)
9. Battery door lock
10. Battery door
11. Activation button
12. Label
13. Travel case/protective cover/storage pouch (depending on configuration)

Package components

- Braun ThermoScan thermometer
- Use and Care manual
- Quick Reference Guide
- Lens filters (20, plus one on the thermometer)
- Owner registration / warranty card
- Additional items may be included as noted on outer packaging
- Label

The first time you use the thermometer, please make sure to apply the special label included in the package, in the language of your choice (item 12 on page 3).

How to use Braun ThermoScan

1. Always make sure a new, clean lens filter is in place to help ensure an accurate reading. The thermometer will not function without a lens filter attached (see Changing the lens filter).
2. Press the @ /mem button. The LCD (liquid crystal display) is activated, showing all segments.

When the ready symbol  is displayed the thermometer is ready for use.

To help ensure an accurate temperature reading, use the following technique: If you are right handed, hold the thermometer in the right hand and take the temperature in the right ear. If you are left handed, hold it in the left hand and use the left ear.

3. Perform an ear tug to straighten the ear canal. This gives the thermometer a clear view of the eardrum.

Children under 1 year:
Pull the ear straight back.

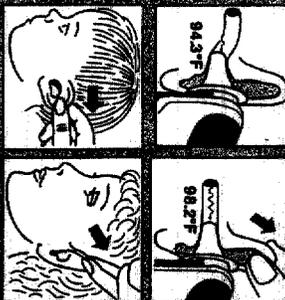
Children aged 1 year to adult:
Pull the ear up and back.

An ear tug is best performed by using your free hand to grasp the outer edge of the top half of the ear. To take your own temperature, wrap your free hand around the back of your head and grab your ear from behind.

4. While tugging the ear, fit the probe snugly into the ear canal as far as possible and press the activation button. Release it when you hear a beep. This is the Temp Beep that confirms the end of measurement.

5. Remove the thermometer from the ear canal. The LCD displays the temperature measured.

6. Replace the lens filter after each measurement: press the ejector button and put on a new, clean lens filter.



92

Changing the temperature scale

This thermometer is shipped with the Fahrenheit temperature scale activated. If you wish to switch to Celsius (°C), proceed as follows:

- Turn on the thermometer.
- (If it is already turned on, make sure it is not in memory mode.) Press the \odot /mem button and keep it pressed. Then press and release the activation button to switch over to the «change temperature scale» mode.
- By pressing the activation button again, the Celsius scale is activated, «C» is displayed on the LCD. Each further pressing of the activation button toggles the scale between °C and °F.
- Release the \odot /mem button to return to the ready symbol \odot .

All temperatures stored in memory will automatically be converted to the selected scale when displayed on the LCD.

Changing the lens filter

The thermometer is supplied with a lens filter in place. To assure accuracy and sanitary practice, Braun recommends replacing the lens filter after each use. To install a new lens filter, first remove the one in place by pressing the lens filter ejector. Check the lens for any damage. Then take a new lens filter from the box, and holding it by its edges, slide it onto the probe until it snaps in place.

Caution: Do not touch the tip of the probe or lens filters when installing. Fingerprints, ear wax, dust and other soiling compounds reduce the transparency, resulting in lower temperature readings (see also Care and cleaning).

Should you run out of lens filters and need to take a temperature, you may use the following lens filter cleaning procedure:

- Clean the lens filter without removing it from the thermometer with a soft cloth or cotton swab moistened with alcohol.
- Do not use hot or boiling water.
- Dry completely with a soft cloth before reusing.
- Replace lens filter as soon as possible with a new one (LF 40).
- Additional lens filters (LF 40) are available at most stores

carrying Braun ThermoScan thermometers or at Braun Service Centers.

- If you have accidentally placed the thermometer in your ear without a lens filter in place, be sure and clean the probe (see Care and cleaning) and then apply a clean lens filter.

Care and cleaning

The probe tip is the most delicate part of the thermometer. It has to be clean and intact to ensure accurate readings.

If the thermometer is ever accidentally used without a lens filter, clean the lens as follows:

- Hold the appliance with the probe tip facing down to prevent liquid from entering the probe tip area. Very gently wipe the surface with a cotton swab or soft cloth moistened with alcohol.
- After cleaning, allow at least 45 minutes drying time before reattaching a new, clean lens filter and taking a temperature. If the probe tip is damaged, contact Braun.

Use a soft, dry cloth to clean the thermometer display and exterior. Do not use abrasive cleaners. Never submerge the thermometer in water or any other liquid.

Store thermometer and lens filters in a dry location free from dust and contamination and away from direct sunlight. The ambient temperature at the storage location should remain fairly constant and within the range of 50 °F to 104°F (10 °C - 40 °C).

Always keep cleaning solutions and rubbing alcohol away from children.

Replacing the batteries

The thermometer is supplied with two 3 V lithium batteries (CR 2032/DL 2032). Insert new batteries when the battery symbol \square appears on the display.

Using the tip of a ball-point pen, press the battery door lock to open the battery compartment. Remove the batteries and replace with new batteries, making sure the poles are in the right direction. Slide battery door back in until it snaps in place.



Troubleshooting

Situation	Solution
No lens filter is attached.	Attach new, clean lens filter
No lens filter is attached and activation button was pressed while probe was in the ear.	Make sure probe tip is clean; refer to section "Care and cleaning" if necessary. Attach new, clean lens filter to stop error beeps.
Ambient temperature is not within the allowed operating range 50 °F to 104 °F (10 °C - 40 °C) or changing too rapidly.	Allow the thermometer to remain in a room for 30 minutes where the temperature is between 50 °F to 104 °F (10 °C - 40°C)
Temperature taken is not within typical human temperature range (93.2 °F - 108 °F / 34 °C - 42.2°C).	Make sure new, clean lens filter is attached and thermometer is properly inserted. Then, take a new temperature.
HI = too high LO = too low	
Battery is low, but thermometer will still operate correctly. (No light function on IRT 3020 models.)	Insert new batteries
Battery is too low to take correct temperature readings.	Insert new batteries
System error	Wait 2 minutes until thermometer powers down, then turn on again. ... reset the thermometer by removing the batteries and putting them back in. ... call Braun ThermoScan Customer Services at 1-800-327-7226.
• If error persists	
• If error still persists	

Special situations

The Braun ThermoScan thermometer has been shown in clinical studies to obtain accurate temperatures on persons of all ages. However, there are certain situations when the ear thermometer should not be used. These include but may not be limited to the following situations:

- If there is blood or drainage in the external ear canal.
 - For persons who have deformities of the face and ear canal where the probe of the thermometer cannot be inserted fully into the ear canal.
 - For persons wearing hearing aids or ear plugs, remove the device and wait 20 minutes prior to taking a temperature.
 - Use the untreated ear if prescription ear drops or other ear medications have been placed in the ear canal.
- Never attempt to clean inside ears. You could damage the ear drum or surrounding tissues. You should remove excess ear wax only when you can reach it with a wash cloth. If you suspect that you or your child has excess ear wax, consult your physician.

Fever facts

Many persons may not have an elevated temperature even when they are ill. These include, but are not limited to infants under 90 days of age, persons taking steroids, antibiotics or antipyretics (acetaminophen, ibuprofen, aspirin), persons with compromised immune systems, including the elderly or persons with some chronic illnesses. Consult your physician if you feel an illness is present even if there may not be an elevated temperature.

Fever is described as an elevation of body temperature over an individual's "normal" temperature.

An elevated temperature or fever is often viewed as a danger sign. In fact, a fever can be very beneficial, and helps our immune system work more effectively. A fever should be evaluated in the light of other physical symptoms. With the exception of newborn infants, the presence of fever, without any other symptoms of illness, or in a child who is behaving normally may not be cause for concern. On the other hand, a physician should be consulted in the following situations:

- vomiting
- diarrhea
- changes in appetite, activity or breathing, or
- with children who are irritable, lethargic or unusually sleepy.

Some people, like the elderly, infants under 90 days of age, those with compromised immune systems, or persons who take steroids, for example are often unable to build a response to illness or environmental conditions. These individuals may not be lower than expected for the severity of their illness. Other medications such as anti-inflammatory and some analgesics may also mask fever.

The presence or absence of fever should rarely be used as the only measurement of the significance of illness. Your physician should be contacted whenever there is a question about your family's health.

Antipyretics, like acetaminophen or ibuprofen, are usually recommended to relieve the aches and associated symptoms of fever, not the fever itself. Febrile seizures, or convulsions, which usually occur in children six months to six years of age, are thought to occur not because a fever is present, but because of the rate of rise of the child's temperature. Call your physician if your child has a febrile seizure or you desire further information.

Use of the Braun ThermoScan thermometer is not intended as a substitute for consultation with your physician.

Product specifications

Displayed temperature range 93.2 °F -108 °F (34°C - 42.2 °C)
 Operating ambient temperature range 50 °F -104 °F (10°C - 40 °C)
 Display resolution 0.1 °F or °C

Accuracy for patient temperature range

Maximum Laboratory Error
 96.8 °F -102.2 °F (36 °C - 39 °C): ± 0.4 °F ± 0.2 °C
 outside this range: ± 0.5 °F ± 0.3 °C

Long term storage ranges

Temperature: -4 °F to 122 °F (- 20 °C to 50 °C)
 Humidity: 95 % non-condensing

Battery life: 2 years / 1000 measurements.

This infrared thermometer meets requirements established in ASTM Standard E 1965-98. Full responsibility for the conformance of the product to the standard is assumed by Braun GmbH, 61476 Kronberg, Germany.

ASTM laboratory accuracy requirements in the display range of 98.8°F to 102.2°F (36°C to 39°C) for infrared thermometers is ± 0.4°F (± 0.2°C), whereas for mercury-in-glass and electronic thermometers, the requirement per ASTM Standards E 667-86 and E 1112-86 is ± 0.2 °F (± 0.1°C).

The Braun ThermoScan thermometer has been proven to be safe. To ensure the best results, please take the time to read this manual completely and keep it handy for future reference.

In the unlikely event you experience any difficulty using the Braun ThermoScan thermometer, simply call us toll free at : 1 (800) 327-7226.



TYPE BF EQUIPMENT
 ACCOMPANYING DOCUMENTS

Attention, consult DOCUMENTS

MEDICAL ELECTRICAL EQUIPMENT
 CLASSIFIED BY UNDERWRITERS LABORATORIES, INC.®
 WITH RESPECT TO ELECTRIC SHOCK, FIRE AND MECHANICAL HAZARDS ONLY
 IN ACCORDANCE WITH UL 2801-1 / CAN CSA C22.2 No.601.1 104K

Internally Powered Equipment
 Continuous Operation
 Not Protected against Ingress of Water
 U.S. Patent No. 5,088,834 Other Patents Pending

25

Section 5 Indications for Use

510(k) Number (if known): K011291
Device Name: TemporalScanner Thermometer

Indications For Use: The TemporalScanner Thermometer is an infrared thermometer intended for the intermittent measurement of human body temperature of people of all ages.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____
Per 21 CFR 801.109)

OR

Over-The-Counter Use

(Optional Format 1-2-96)

90428.W11

91

Section 6 Substantial Equivalence Comparison Table

Substantial Equivalence Table

Item	Exergen TemporalScanner Thermometer (TemporalScanner) [†]	Exergen Surface Temperature Scanner K873010 (Dermatemp) (Exergen Predicate)	Braun ThermoScan IRT 3020/3520 Thermometer K983295 (Braun Predicate)
Intended Use	The TemporalScanner Thermometer is an infrared thermometer intended for the intermittent measurement of human body temperature of people of all ages.	The Surface Temperature Scanner is intended for the intermittent determination of surface temperature anywhere on the skin surface of a patient	The Braun predicate is intended for the intermittent measurement and monitoring of human body temperature in the home for use on people of all ages.
Where used	Skin surface of the forehead	Anywhere on the skin surface	Skin surface of the auditory canal
Technology Used	Arterial Heat Balance	Arterial Heat Balance	Arterial Heat Balance [†]
Performance Specifications:			
Measurement range (max accuracy)	60 °F to 107.6 °F (15.5 °C to 42 °C)	96 °F to 102 °F (35 °C to 39 °C)	68 °F to 108 °F (20 °C to 42.2 °C)
Total range (min accuracy)	60 °F to 107.6 °F (15.5 °C to 42 °C)	60 °F to 110 °F (15 °C to 43 °C)	68 °F to 108 °F (20 °C to 42.2 °C)
Accuracy (max)	+/- 0.4 °F (0.2 °C)	+/- 0.2 °F (0.1 °C)	+/- 0.4 °F (0.2 °C)
Operating Ambient Range:			
Temperature	60 to 104 °F (15.5 to 40 °C)	65 °F to 95 °F (18 °C to 35 °C)	50 °F to 104 °F
Humidity	Per ASTM 1965-98, up to 95% noncondensing	Per ASTM 1965-98, up to 95% noncondensing	Per ASTM 1965-98, up to 95% noncondensing
Display resolution	0.1 °F or °C	0.1 °F or °C	0.1 °F or °C
Temperature scales	degrees F or C (factory selectable)	degrees F or C (user selectable)	degrees F or C (user selectable)
Storage:			
Temperature	-4° to 122 °F (-20 to 50 °C)	-4° to 122 °F (-20 to 50 °C)	-4° to 122 °F (-20° to 50 °C)

[†] Formerly the SensorTouch

[‡] Patented by Exergen and licensed to Braun ThermoScan

99

humidity (max)	up to 95% noncondensing	up to 95% noncondensing	95% noncondensing
Electromagnetic compatible	Yes per EN 60601-1-2	Yes per EN 60601-1-2	Yes per EN 60601-1-2
Item	SensorTouch and Exergen TemporalScanner Thermometer	Exergen Surface Temperature Scanner K873010	Braun Thermoscan IRT 3020/3520 Thermometer K983295
	(TemporalScanner)*	(Exergen Predicate)	(Braun Predicate)
Display modes	Displayed temperature is the actual temperature of the temple artery plus a mathematical adjustment to approximate the familiar rectal range	Displayed temperature is the actual temperature of the surface of the skin at the point of measurement.	Displayed temperature is the actual ear temperature plus a mathematical adjustment to approximate the familiar oral range
Power source	9 volt Alkaline	9 volt Alkaline	2 lithium batteries CR/2032/DL 2032
display	LCD	LED	LCD
IR transducer	Thermopile	Thermopile	Thermopile
Indicators			
Battery low warning	yes, audible and visual	yes, audible	yes
User error	Yes	no	yes
Instrument Malfunction	Yes	no	yes
Disposable covers	not required	not required	yes
Case material	(b)(4)	(b)(4)	unknown
memory function	No	no	yes
Auto off	Yes	yes	yes
Standards met	ASTM E1965-98	ASTM E1965-98	ASTM E1965-98
UL listed	Yes	no	yes
CE mark	Yes	Yes	yes

100

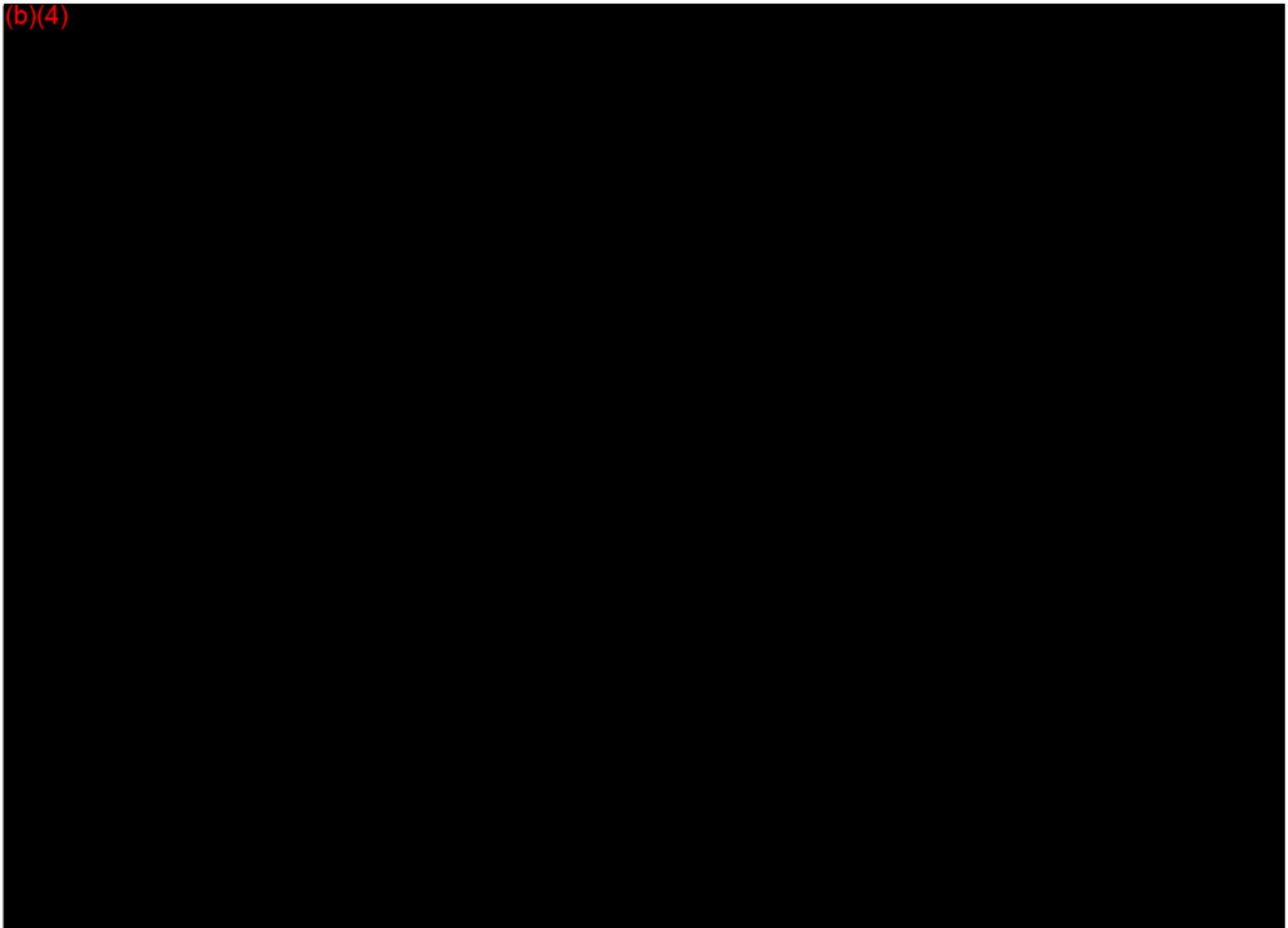
Discussion of Table

Similarities:

1. Same intended use demonstrates equivalence.
2. All units meet the same standard; therefore, the three devices should perform the same.
3. All units are battery operated.
4. All units use solid-state displays, minimizing battery drain.
5. All units have warning displays, such as battery low.
6. All units are CE marked, showing an independent third party assessment of the safety of the devices.
7. The SensorTouch, (renamed TheTemporalScanner), and the Thermoscan are UL listed, another independent third party assessment of the safety of the devices.
8. Consumer Report evaluation on the SensorTouch and the Thermoscan shows an independent third party assessment of the performance of the two devices.

Differences:

(b)(4)



101

Section 7 Summary

510(k) Summary

Submitter's Name: Exergen Corporation

Address: 51 Water Street
Watertown, MA 02172

Phone: (617) 923-9900
(800) 422-3006

Fax: (617) 923-9911

Contact: Gerald A. Clay

Date of Summary: April 27,2001

Trade Name: TemporalScanner Thermometer, formerly known as SensorTouch

Classification: Thermometer, Clinical, Electronic
Product Code: FLL
Regulation No. 880.2910
Class: II
Panel: 80 (General Hospital)

Predicate Device(s): Exergen Surface Temperature Scanner (K 873010) (Exergen Predicate)

Braun Thermoscan IRT 3020/3520 (K983295)(Braun Predicate)

Device Description: The TemporalScanner is a hand held, battery operated device that measures the skin temperature of the skin over the temporal artery. Operation is based on measuring the natural thermal infrared radiation emitted from the surface of the skin over the temporal artery.

Intended Use: The TemporalScanner Thermometer is an infrared thermometer intended for the intermittent measurement of human body temperature of people of all ages.

Technological

Characteristics: The TemporalScanner Thermometer and the predicate devices are all used to measure the temperature of a human by means of a thermopile

infrared sensor transducer coupled with electronic signal amplification, conditioning, and display unit.

The Exergen Predicate employed solid-state electronic signal amplification which is technology similar to the electronic surface mount technology used by the TemporalScanner Thermometer and the Braun Predicate. The Braun Predicate's signal conditioning consists of making mathematical adjustments to display the familiar oral range. Similarly, the TemporalScanner Thermometer's signal conditioning consists of making mathematical adjustments to the temperature measured at the skin surface over the temporal artery to display the familiar rectal range. All display units are solid-state displays, with the Exergen Predicate using an LED display while the TemporalScanner Thermometer and the Braun Predicate employ an LCD display.

All of the devices meet ASTM E1965-98 *Standard for Infrared Thermometers for Intermittent Determination of Patient Temperature, to the extent that this standard applies to them.*

The primary difference between the TemporalScanner Thermometer and the Braun Predicate is that the Braun Predicate measures the temperature of the auditory canal and mathematically converts and displays a familiar oral temperature, while the TemporalScanner measures surface skin temperature over the temporal artery and mathematically converts and displays a familiar rectal temperature.

Summary of non-clinical Performance Testing:

Performance test	Results
Accuracy tests	Pass
(b)(4) tests	Pass
(b)(4) tests	Pass
(b)(4) tests	Pass
(b)(4) tests	Pass
(b)(4) test	Pass
EMC tests	Pass
(b)(4) test	Pass
(b)(4)	Pass

104

Conclusion:

Since performance testing confirms conformance to the same standard as both predicate devices, we conclude the device is substantially equivalent to those devices.

W5

Section 8 Description

106

The TemporalScanner (formerly known as the SensorTouch) is a hand held, battery operated device that measures the temperature of the surface of the skin over the temporal artery. The TemporalScanner is an upgraded modification of the Exergen Predicate to include a more advanced infrared transducer and modern electronic components. The TemporalScanner operates by measuring the natural thermal infrared radiation emitted from the surface of the skin over the temporal artery. The Predicate devices also are hand held, battery operated devices that measure the temperature of the surface of the skin by measuring infrared radiation emitted from the surface of the skin. The Exergen Predicate, like the TemporalScanner, measures the infrared radiation emitted from the skin, although it is not explicitly indicated for measurement over the temporal artery. The Braun Predicate measures the infrared radiation emitted from the surface of the skin in the ear canal.

The TemporalScanner, the Exergen Predicate, and the Braun Predicate are all used to take intermittent measurements of the body temperature of a patient by means of an infrared transducer coupled with electronic signal amplification and conditioning, and to display the patient's temperature on a conventional display unit. The flowchart in Exhibit 8A shows how both the TemporalScanner and the Braun Predicate are operated to make these measurements. (Although firmware would also permit the Exergen Predicate to make these measurements, this feature has not been activated in the current model of this device.)

Pictures showing exterior views of the TemporalScanner, the Exergen Predicate, and the Braun Predicate are attached as Exhibits 8B, 8C, and 8D, respectively. As shown in these exhibits, each of these devices includes an ergonomic handle in which the operating batteries are stored, an On Button, a display screen, and an infrared probe. The dimensions of these devices are very similar. The TemporalScanner is 7.0 in x 1.75 in x 1.25 in and weighs 4.16 oz (120 grams) including battery. It is made from nontoxic, impact-resistant exterior parts.

The TemporalScanner is substantially equivalent to the Exergen Predicate and the Braun Predicate because they have the same intended use and very similar technological characteristics. The primary technological differences between the TemporalScanner and the Predicate devices are: (1) (b)(4)

and (2) (b)(4)

As described below in greater detail, these minor differences in technological characteristics between the TemporalScanner and the Predicate devices do not raise any new issues of safety or effectiveness.

The flowchart in Exhibit 8A illustrates the operation of the TemporalScanner as well as the Predicate devices. When either device is initially activated, the unit performs a rapid

107

self-test and a rapid self-calibration. For example, pressing the On button of the TemporalScanner activates the device and causes it to perform a self-test and a self-calibration. With the button depressed, the probe portion of the device is placed against the skin surface. Each unit then reads the output of a thermopile infrared sensor and the output of a thermister that measures ambient temperature on the housing of the thermopile infrared sensor. In the TemporalScanner and the Predicates, the infrared detector is a thermopile infrared sensor that measures infrared radiation from a surface. Likewise, the devices use a thermister to measure ambient temperature on the housing of the thermopile infrared sensor. The output of the thermopile infrared sensor and the thermister is in the form of electronic signals representing an amount of measured infrared radiation and the ambient temperature, respectively. These outputs then are amplified and conditioned, and the resulting signals are sent to a microprocessor within each unit. In the microprocessor, the calculations described below, including the arterial heat balance (AHB), are used to convert the measured and conditioned signals to a body temperature. When the user releases the button on the unit, the display shows the body temperature.

Exhibits 8 B-2, 8B-3 and 8B-4 depict the components of the TemporalScanner. One of the components is an off-the-shelf thermopile infrared sensor. The structure of the sensor is based on conventional semiconductor technology and includes a housing in which a layer of a (b)(4) material is covered with a thermocouple film. When the thermocouple film is struck by infrared radiation, the temperature of the thermocouple film changes. The change in temperature of the thermocouple film caused by the infrared radiation generates a voltage across the thermocouple film that is indicative of the amount of infrared radiation received. Because the temperature of the sensor is a factor in the voltage generated by the thermocouple film, a thermister is placed in contact with the housing to measure the ambient temperature at the housing. This is the same structure used in the Predicate devices. As described below, using the (b)(4)

(b)(4)

In addition to the sensor described above, the devices each include signal amplification circuitry. Both the TemporalScanner and the Predicate devices use conventional solid-state technology for electronic signal amplification. Signal amplification is necessary because of the low voltages generated by thermopile infrared sensors. As is to be expected, the amount by which the signal is amplified may vary depending primarily on the characteristics of the thermopile infrared sensor being used. Varying the amount of amplification is not new technology and raises no new issues of safety or effectiveness.

The diagrams in Exhibits 8 B-4, 8-C-3 and 8-D-2 provide interior views, respectively, of the TemporalScanner, the Braun Predicate, and the Exergen Predicate. Although the sealing of the TemporalScanner and the Exergen Predicate are the same, the components and layout used in the TemporalScanner and the Exergen Predicate are not. The layout has been modified to use some new components, primarily to use more technologically advanced components than were used with the Exergen Predicate when it was designed

108

and cleared 13 years ago. In fact, some of the original components are now difficult or impossible to obtain and have been replaced with currently available components.

Although, the TemporalScanner's circuit layout (b)(4)

(b)

(b)(4)

(b)

(b)(4)

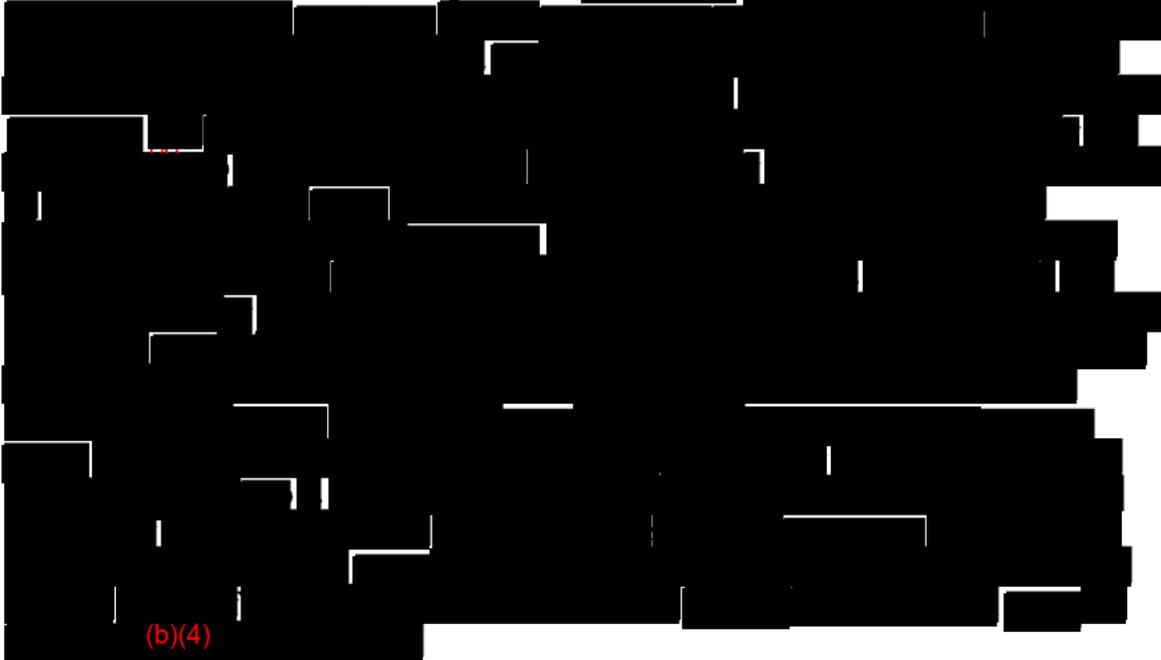
(b)

These changes do not raise new issues of safety or effectiveness because they are the same issues raised when the Exergen Predicate was designed. Thus, the testing and the validation used to design the Exergen Predicate also were used to develop the TemporalScanner.

Signal conditioning is used to obtain a signal representing body temperature. In the TemporalScanner and the Predicate devices, signal conditioning involves mathematically separating the variables and providing a digital signal to the display that represents the body temperature of the patient. Signal conditioning is accomplished in all three devices by means of the same mathematical method, namely, an "Arterial Heat Balance" (AHB), for compensating for the cooling effect of ambient temperatures. In fact, this method is patented by Exergen and licensed to Braun Thermoscan, the manufacturer of the Braun Predicate. The signal conditioning is performed in the microprocessor that is present in each device.

A chart setting forth the algorithm used for signal conditioning in all three devices appears as Exhibit 8E. Because the algorithm is the same for the devices, only one flowchart is necessary to describe the algorithm. (Exergen has confirmed this conclusion by testing the Braun Predicate to verify that it is using the AHB algorithm.)

As illustrated in Exhibit 8E, the algorithm is (b)(4)



(b)(4)

109

(b) (4) are not the same. This difference results from the (b)(4)

Thus, no new issues of safety and effectiveness are raised because they are the same issues of safety and effectiveness, which are addressed by determining the curve fit equation and testing to ensure that the equation is accurate.

In the display temperature equation, K is a constant that is related to the heat loss rate from the skin and the ambient surroundings. The constant K will vary with body site and is theoretically estimated and then experimentally refined. As indicated above, (b)(4)

This minor difference results from the change in body site of measurement but does not raise any new issues of safety or effectiveness. The Exergen Predicate relied on a constant K having a value of 1.00 to be accurate and was tested and validated to ensure that the correct constant K was theoretically derived and experimentally refined. Similarly, the TemporalScanner relies on a constant K to be accurate and was tested and validated to ensure that the correct constant was theoretically derived and experimentally refined. The software that implements the algorithm has been tested and validated. A report of this validation can be found in Section 11. This report demonstrates that the software passed all validation tests.

The transducer used in both the TemporalScanner, as described above, and the Braun Predicate is a thermopile infrared sensor mounted on a (b)(4) substrate. The sensor in the Exergen Predicate is also a thermopile infrared sensor but it is (b)(4) (b)(4)

when the Exergen Predicate was designed and cleared. However, as exemplified by the cleared Braun Predicate, in the intervening years technology has advanced and (b)(4) (b)(4) (b)(4)

The use of a (b)(4) substrate in place of a (b)(4) substrate does not raise new issues of safety or effectiveness. First, the thermopile infrared sensor does not measure temperature, it measures infrared emissions from skin. Thus, because a temperature is not actually measured, the heat distribution characteristics of either the (b)(4) or the (b)(4) do not influence the ability of the sensor to measure infrared emissions. Nonetheless, even if heat distribution were to be a concern, the TemporalScanner and the predicate devices have extensive thermal isolation around the probe, which prevents any non-uniformity in heat distribution at the probe. However, because thermopile infrared

100

sensors are affected by the ambient temperature, a thermister is placed in contact with the thermopile infrared sensor housing. As explained with respect to the calculations described above, the calculated body temperature is a function of the ambient temperature and the infrared emissions. Possible non-uniform heating of the thermopile is avoided on both the Exergen Predicate and TemporalScanner by locating the thermister, which generates a small amount of self heating, outside the housing instead of on the (b)(4) substrate.

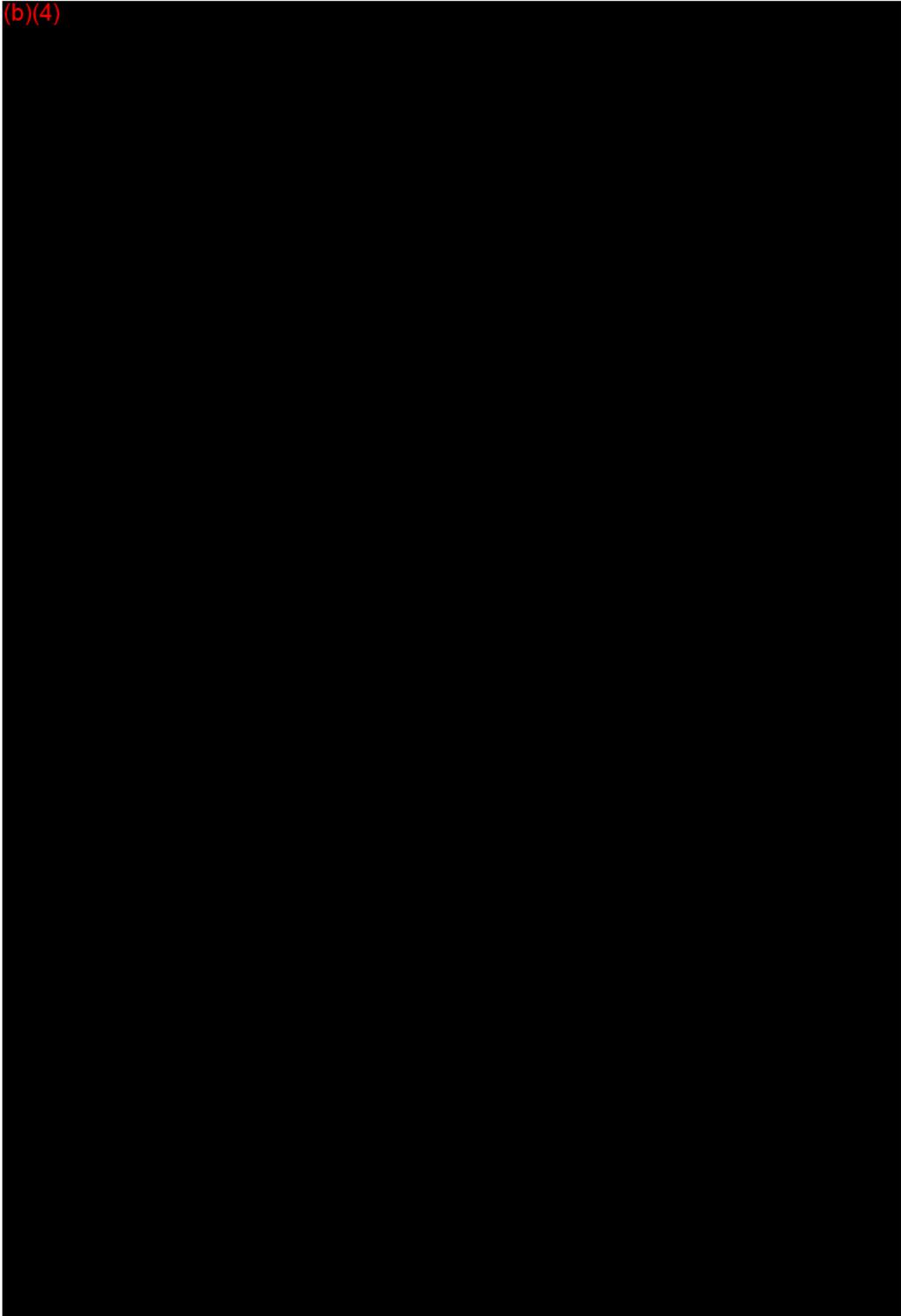
Second, Exergen has tested and validated the TemporalScanner to demonstrate that the device functions correctly and properly with a (b)(4) -based thermopile infrared sensor. Third, (b)(4) substrates are used in cleared FDA medical devices, such as the Braun Predicate, for measuring infrared radiation to calculate body temperature. Fourth, it is important to note that minor variations from thermopile to thermopile are taken into account in that every TemporalScanner device is individually calibrated in the manufacturing process and rechecked in the QC process. As such, the Applicant concludes that no new issues of safety or effectiveness are raised with respect to the (b)(4) substrate.

Measuring the temperature by measuring infrared radiation above the temporal artery does not raise new issues of safety and effectiveness. Both the TemporalScanner and the Predicate devices measure two variables in order to determine human body temperature - ambient temperature and infrared emissions from a body surface. The amount of infrared energy emitted from any body part depends on several factors, such as the temperature of the blood transporting heat to that body part, that body part's emissivity, and the ambient temperature of that body parts. Thus, the TemporalScanner and the Predicate devices each have the same issues of safety and effectiveness with respect to the location of temperature measurement. The temporal artery has certain advantages for temperature measurement. First, it is not an anastomosing vessel and therefore does not have wide fluctuations in blood flow. Second, the temperature of the blood reaching the temporal artery varies little from the temperature of the blood leaving the heart. Thus, measuring the infrared radiation from a position on the skin over the temporal artery does not raise new issues of safety or effectiveness.

Exhibit 8-A

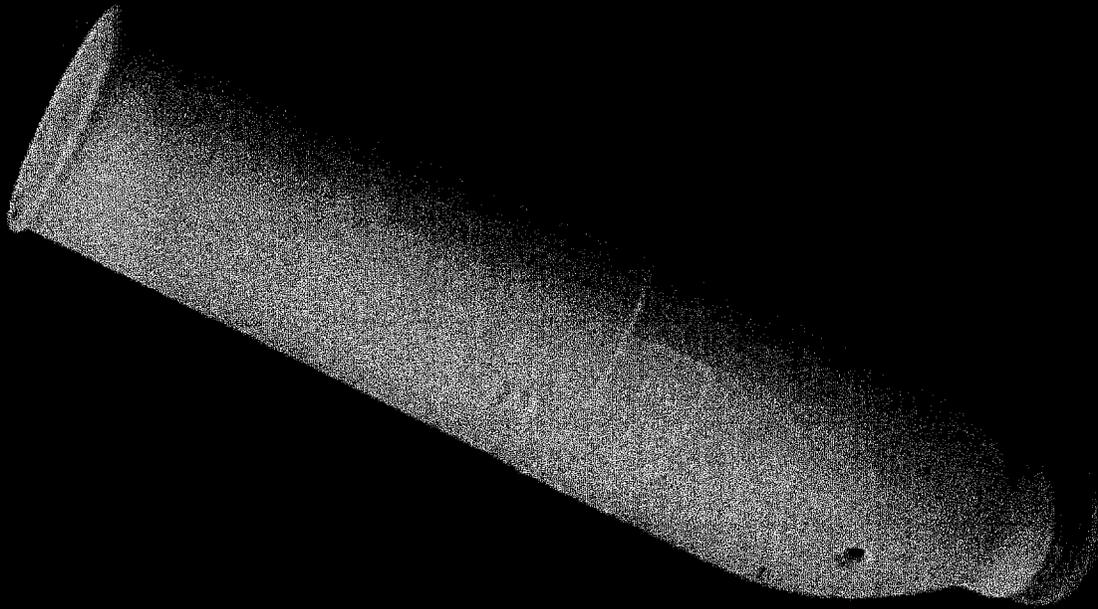
Operational Block Diagram of Typical IR Thermometer:

(b)(4)

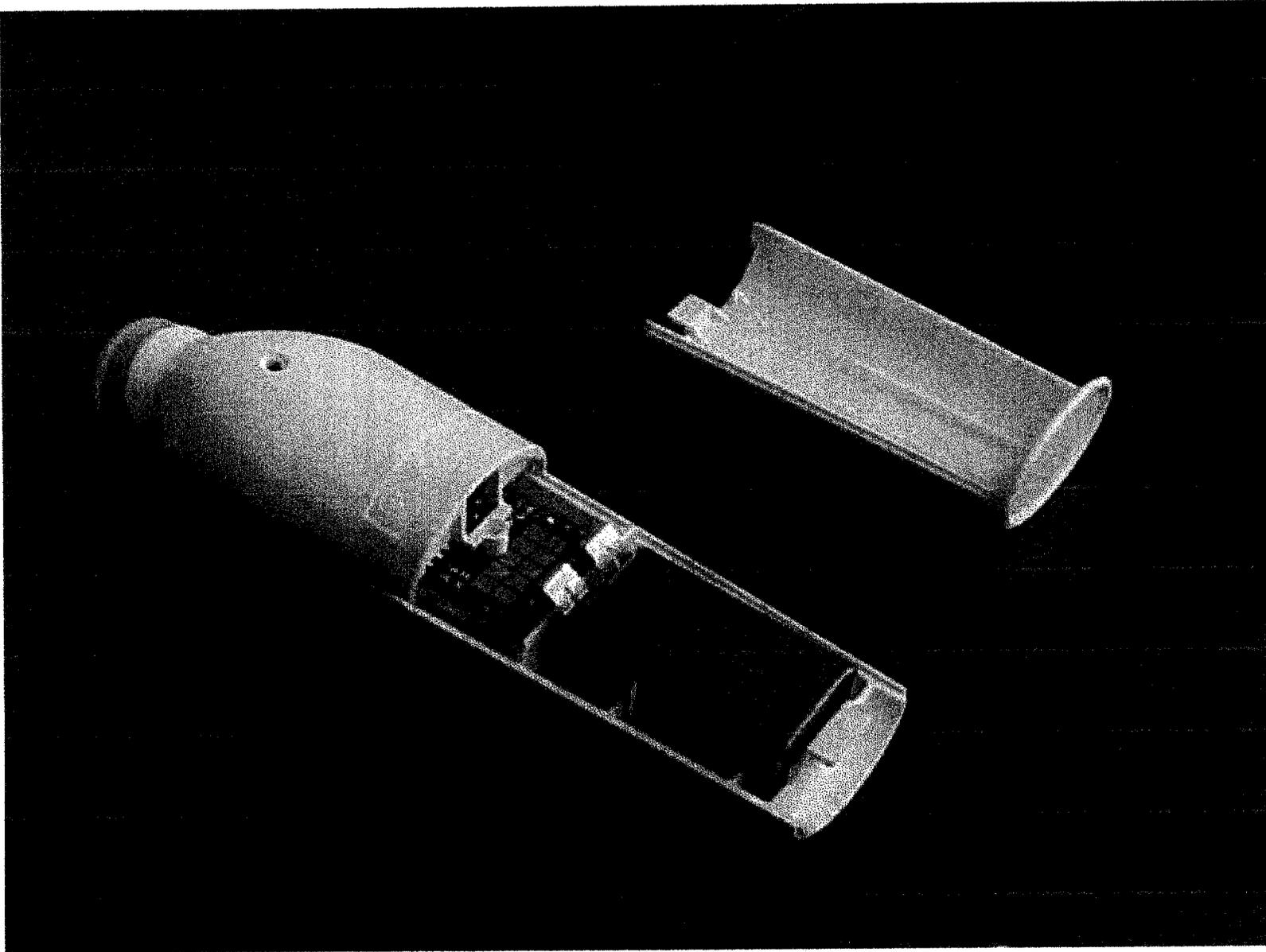


112

TemporalScanner 8B-1

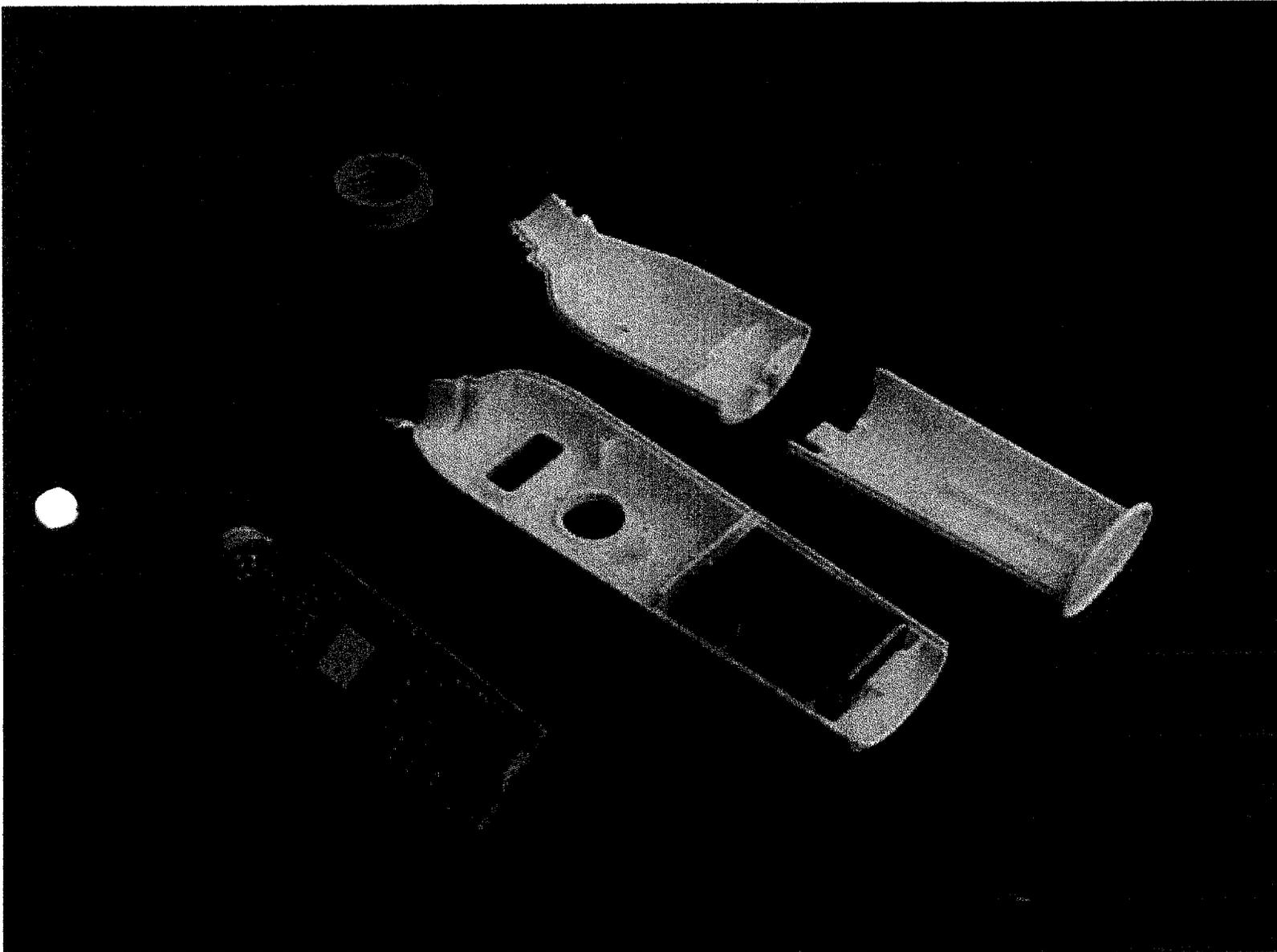


TemporalScanner 8B-2



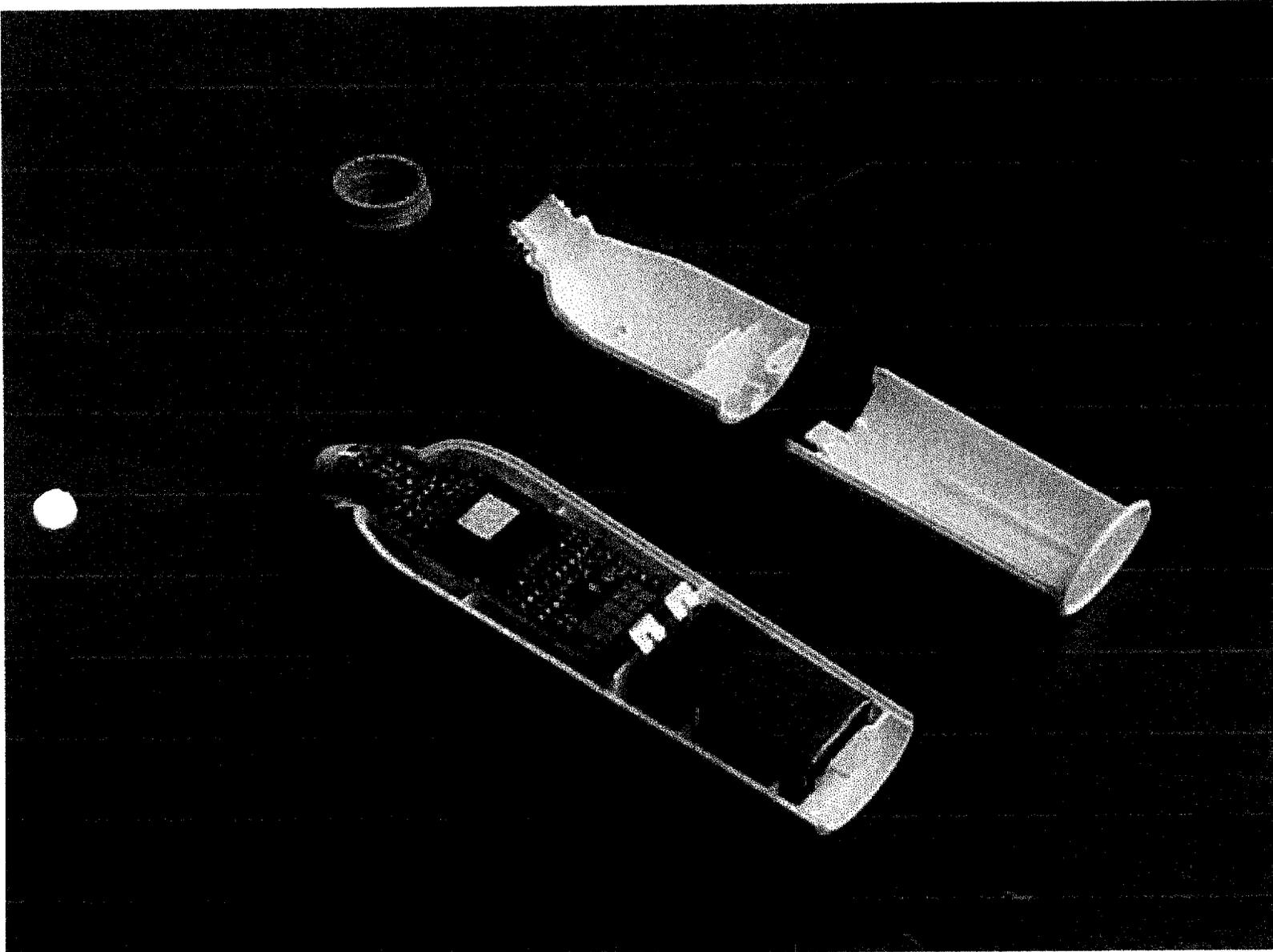
114

TemporalScanner 8B-3



115

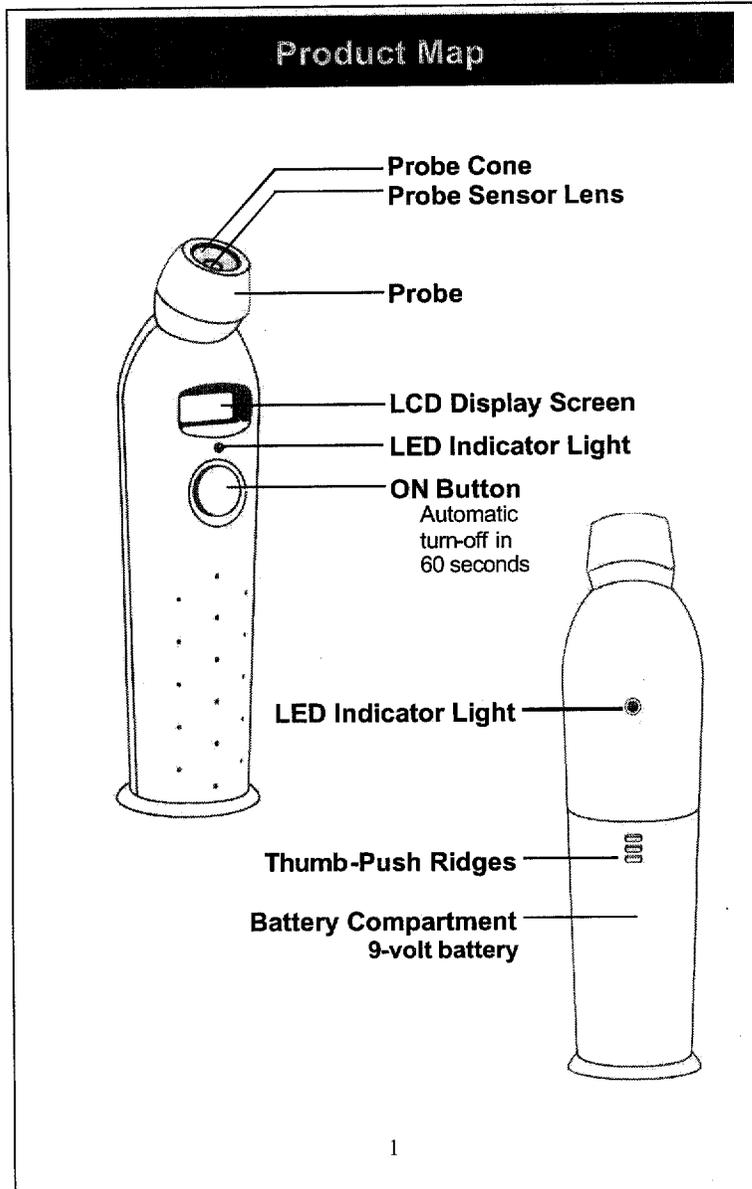
TemporalScanner 8B-4



116

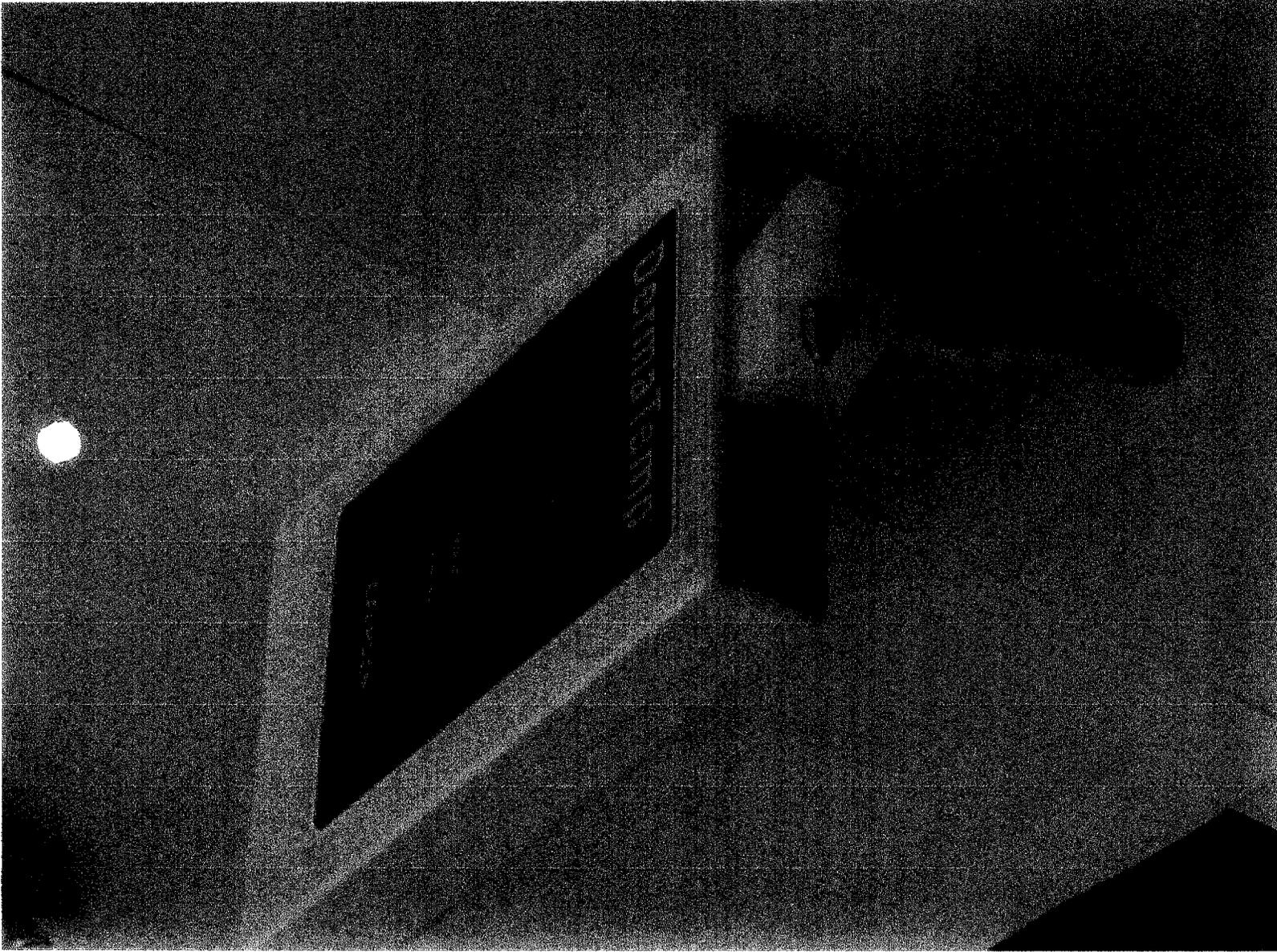
Labeled Diagram:

TemporalScanner 8B-5

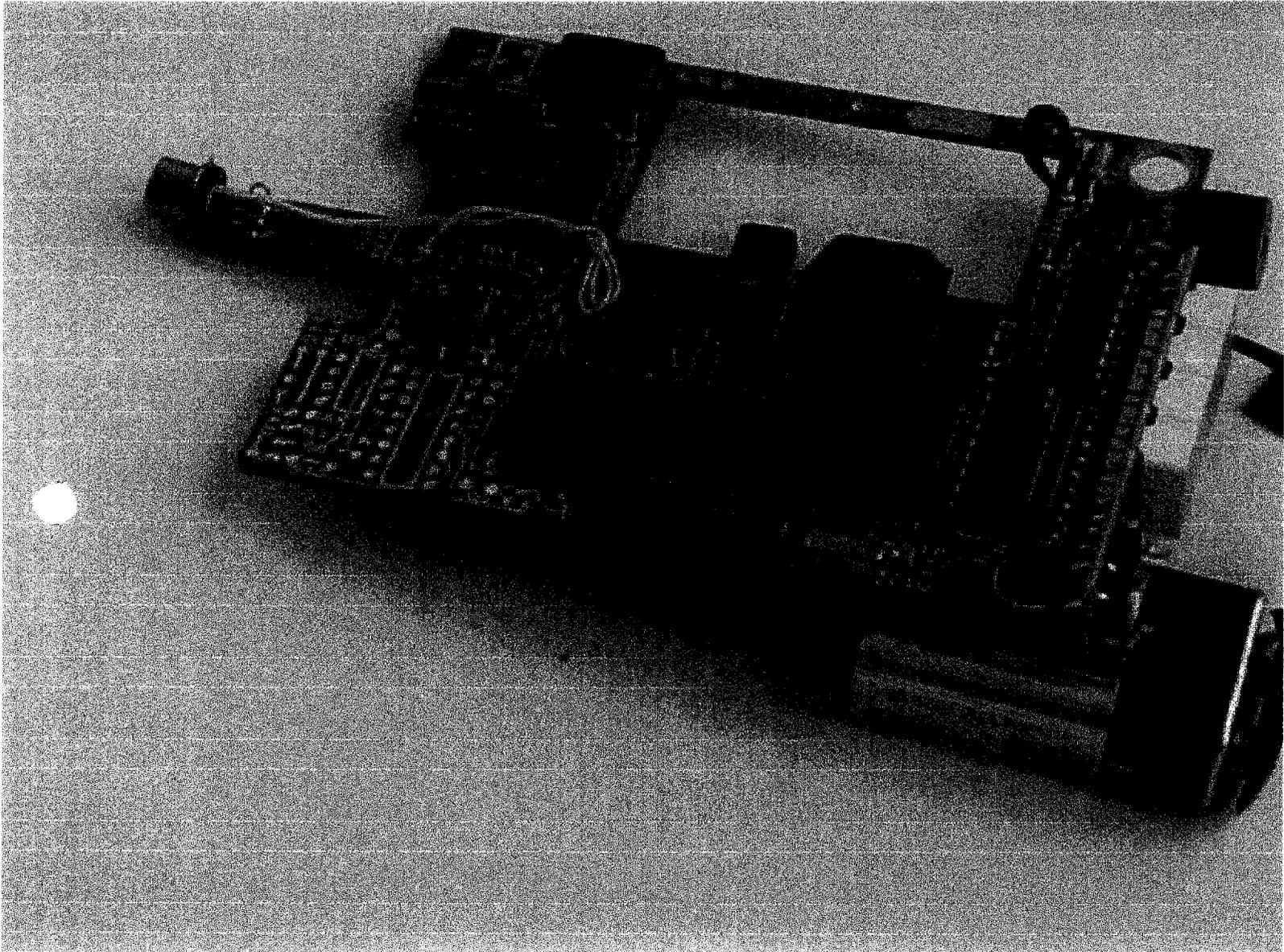


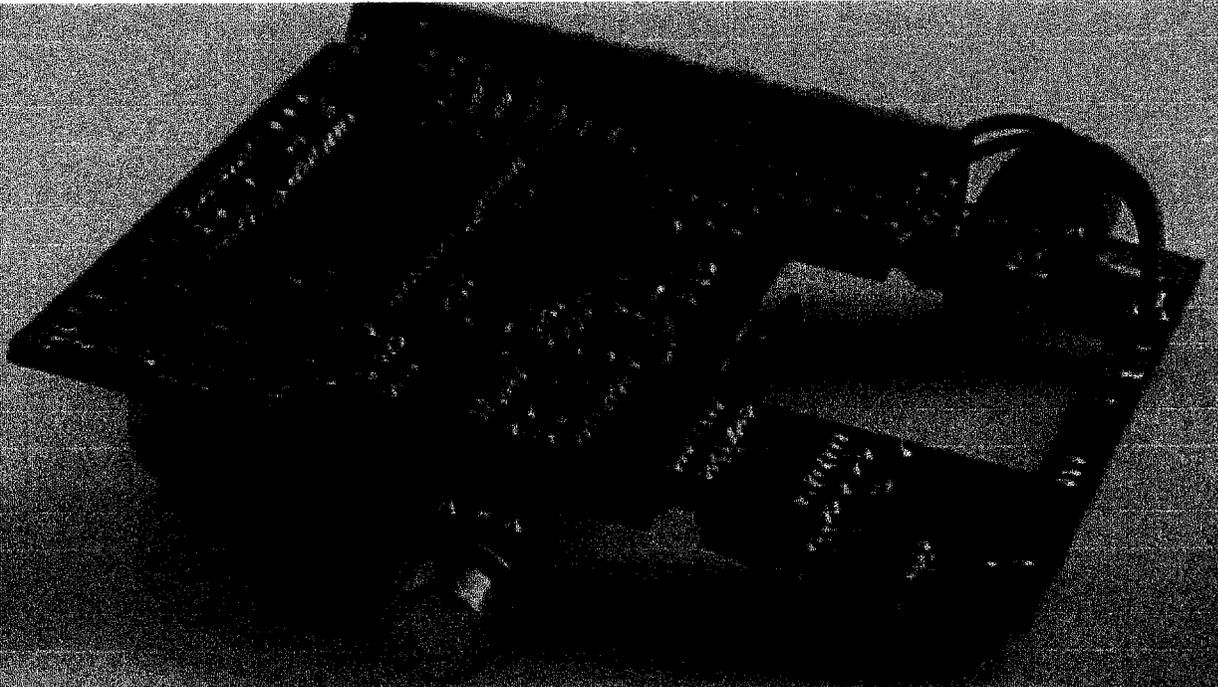
SensorTouch Components

(17)

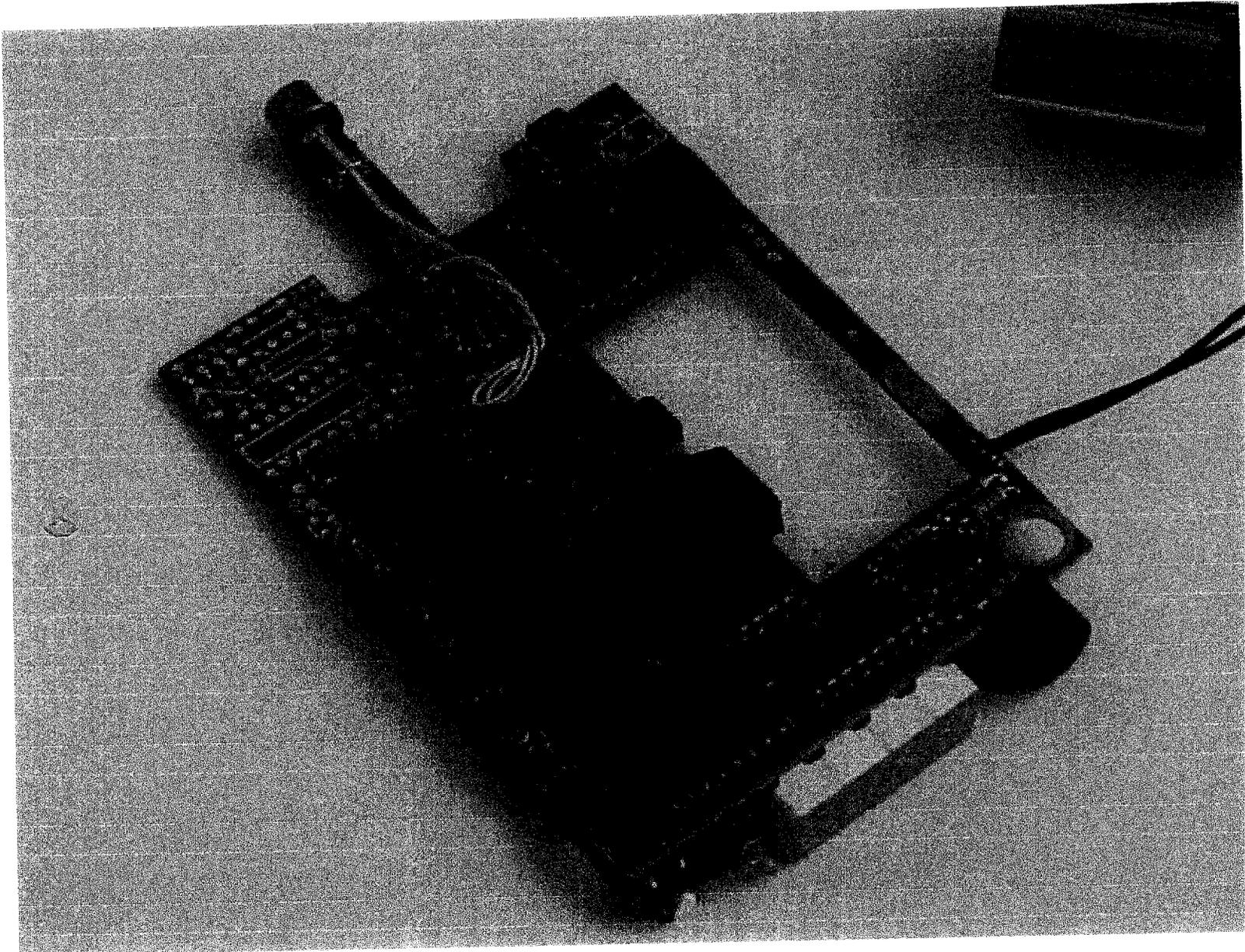


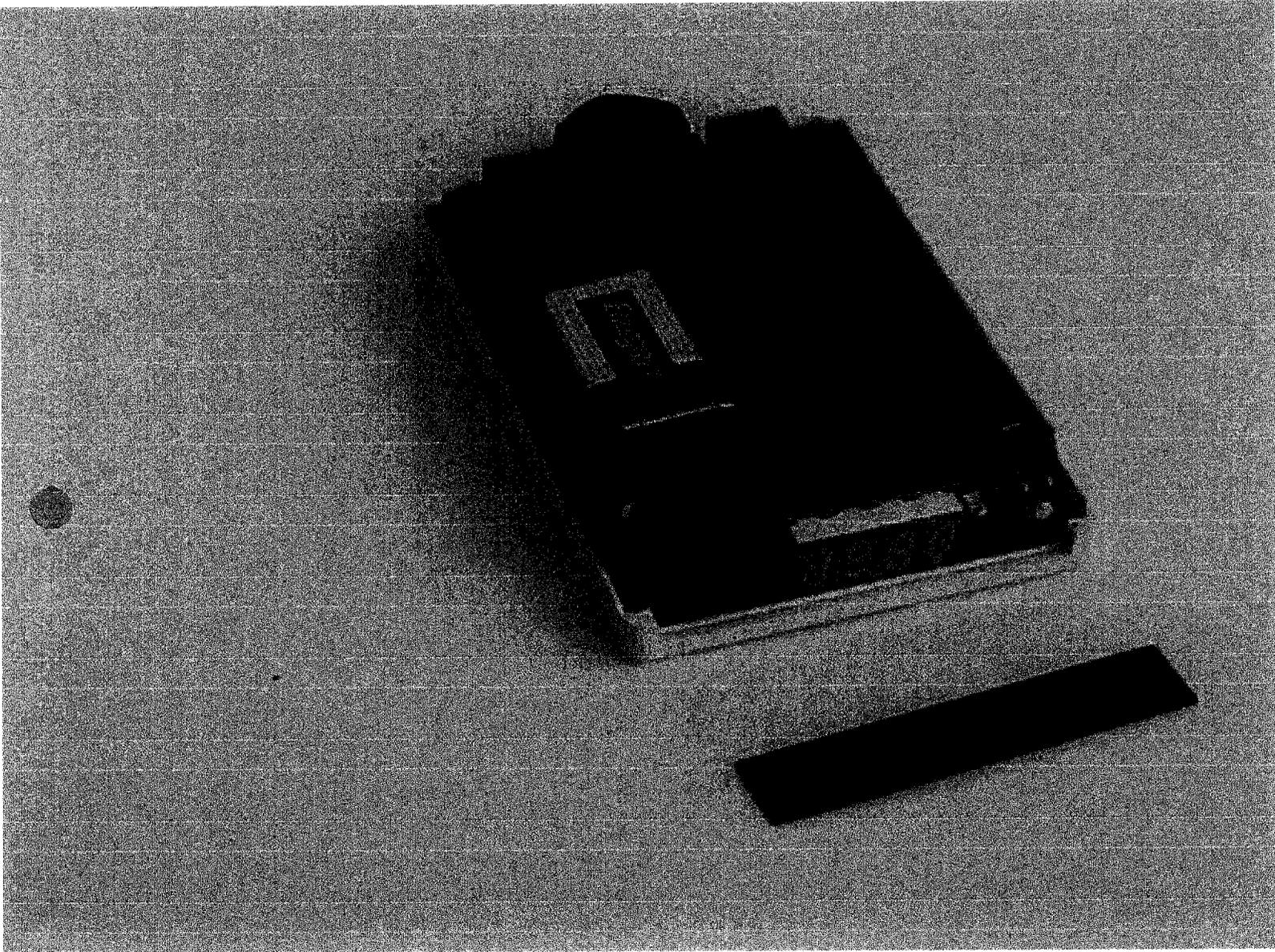
118



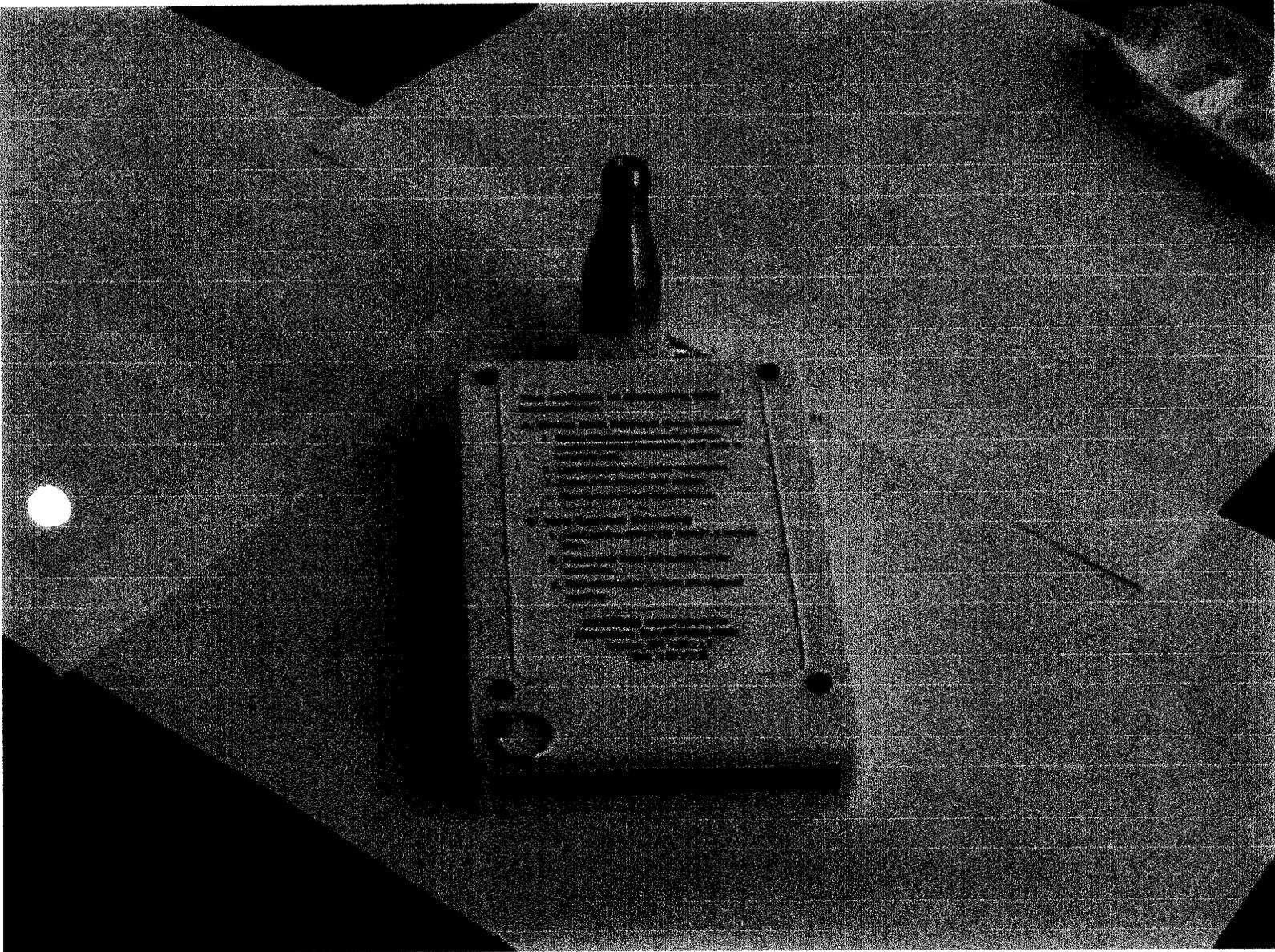


120

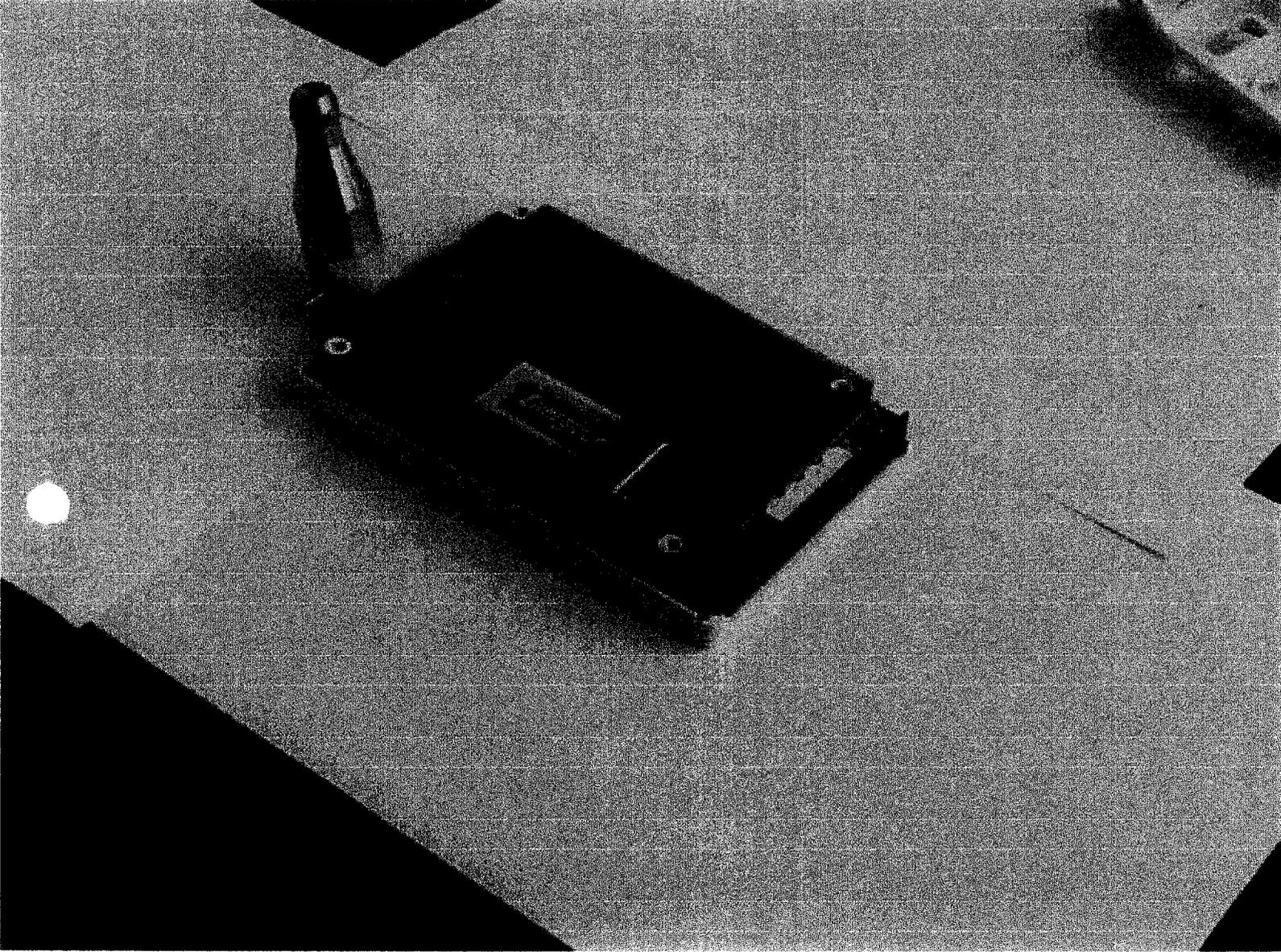




123

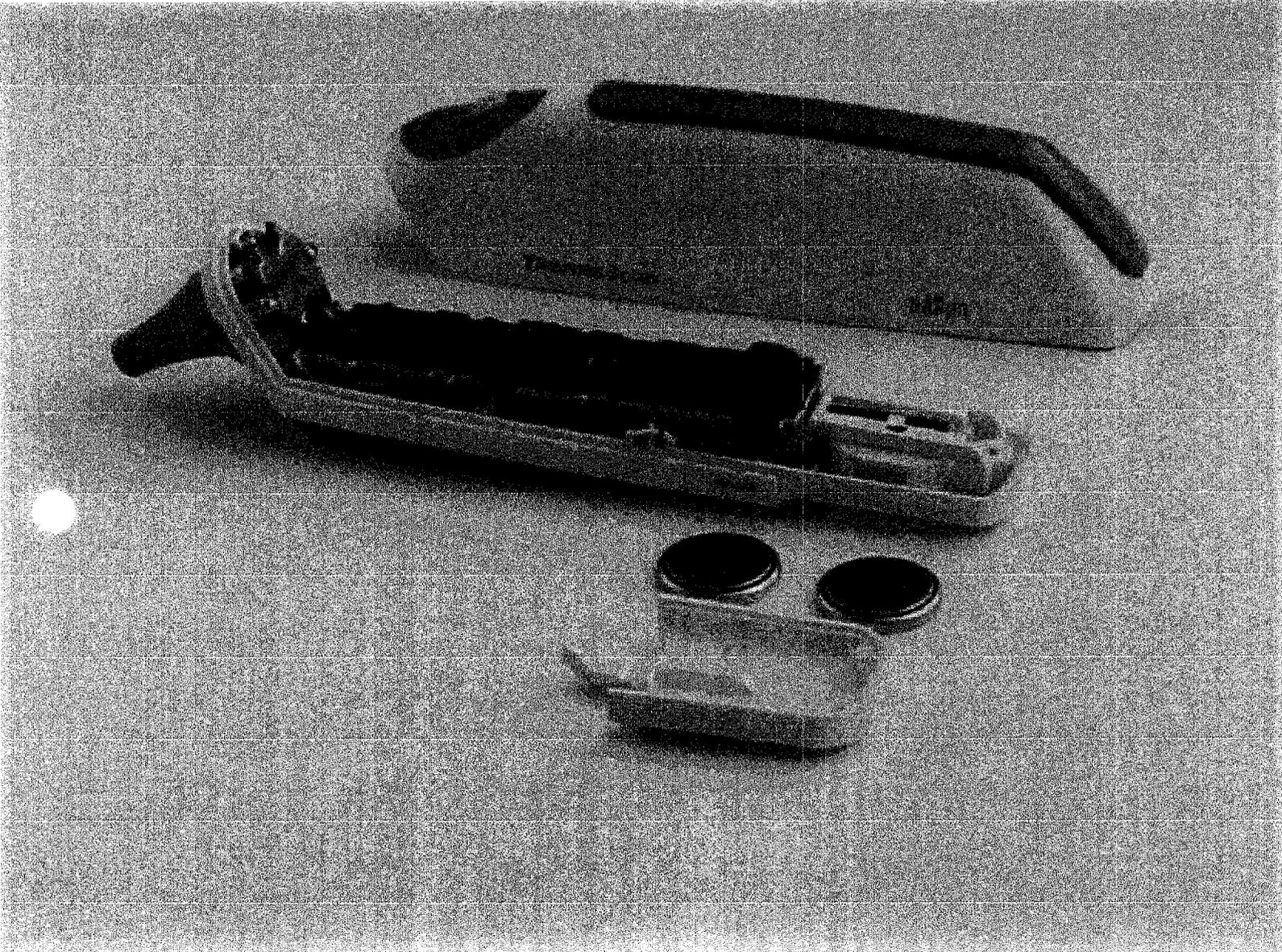


129



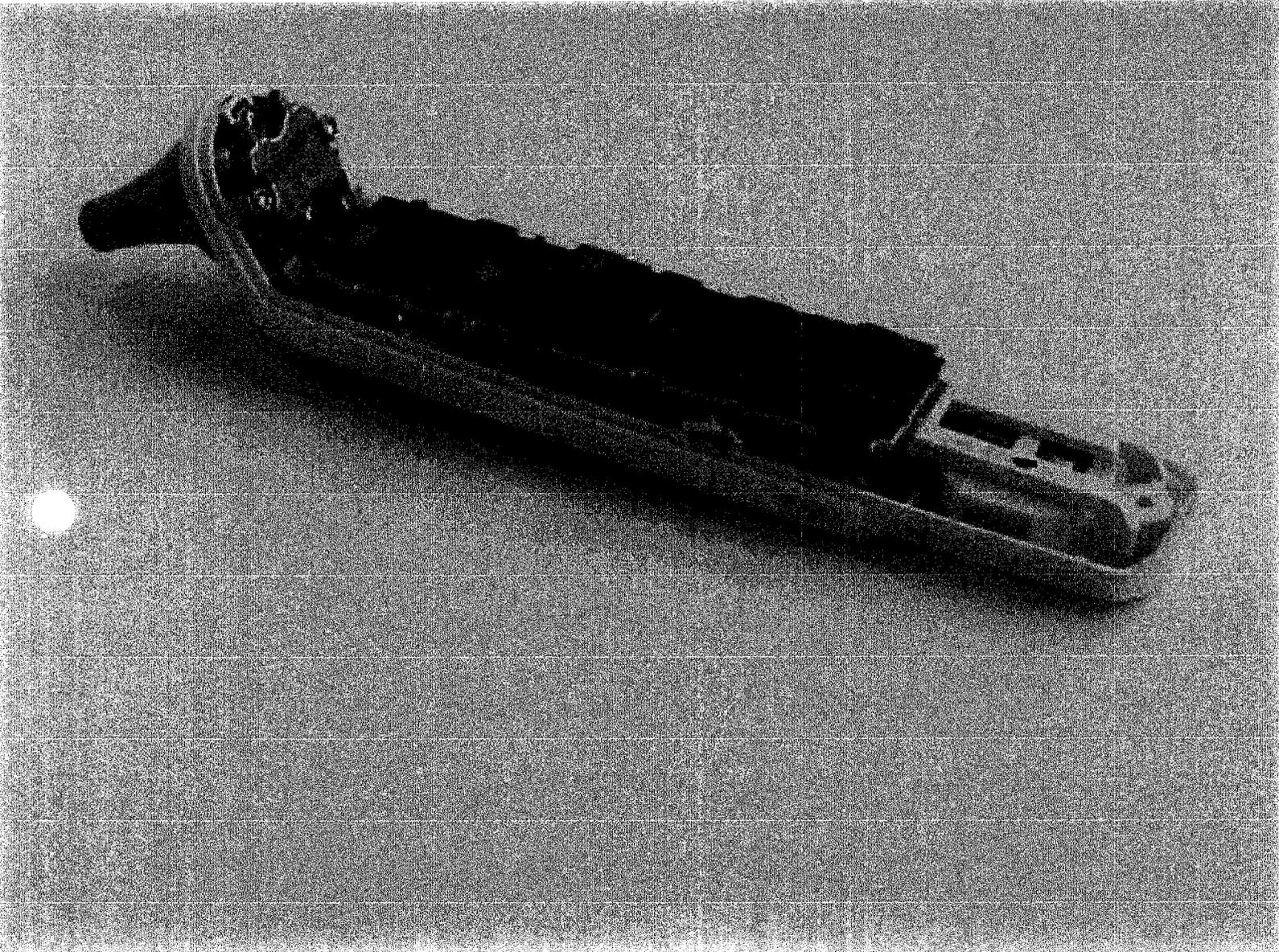
125

Braun Thermoscan 8D-1



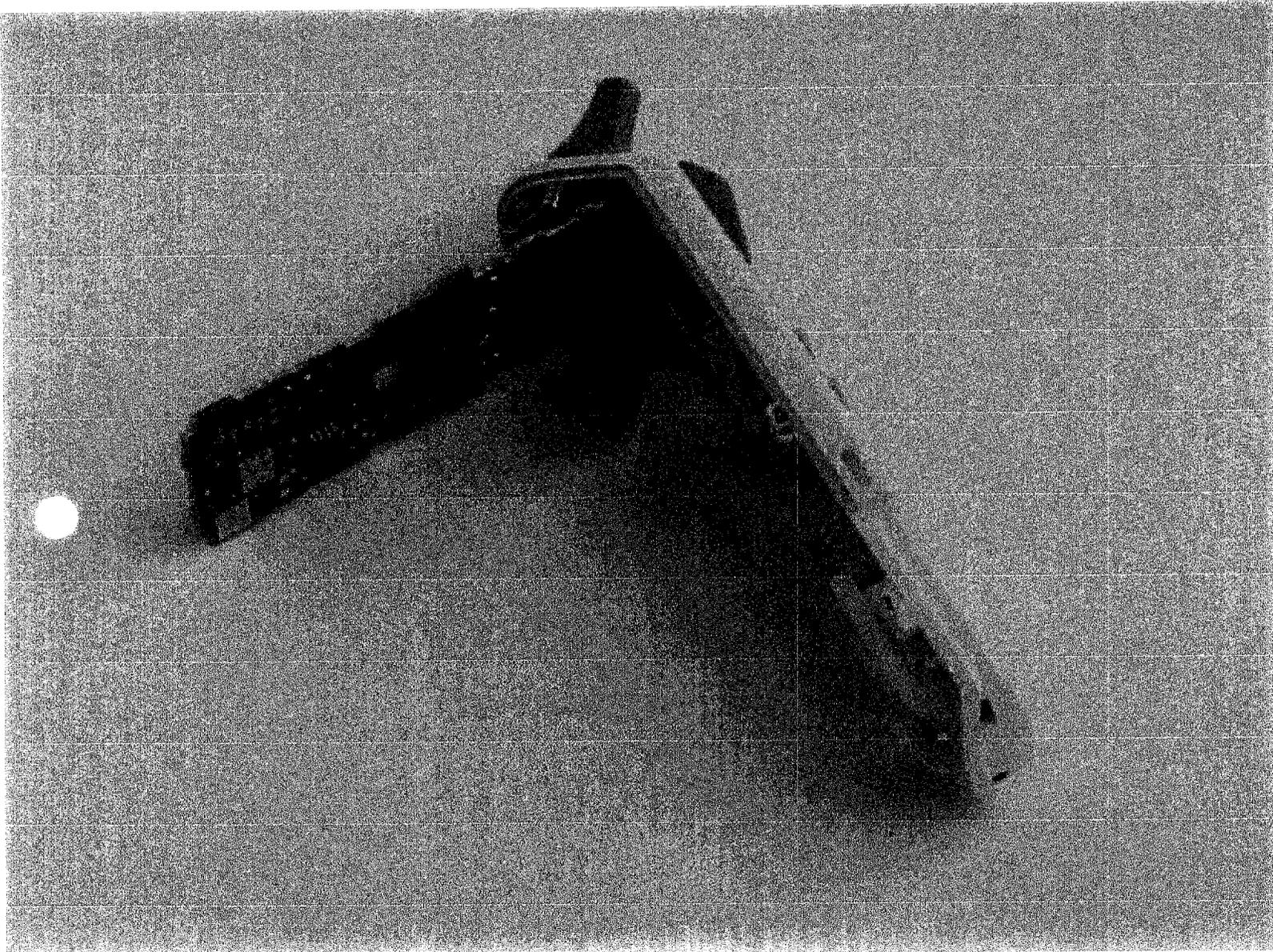
126

Braun Thermoscan 8D

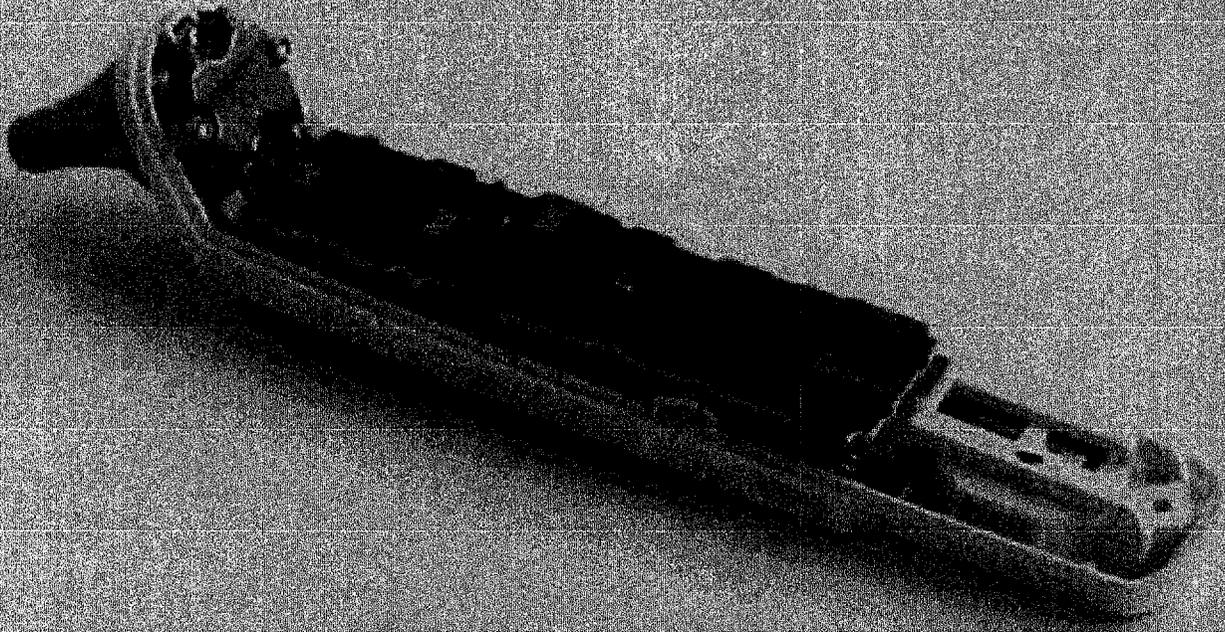


129

Braun Thermoscan 8D-3



Braun Termoscan 8D-4



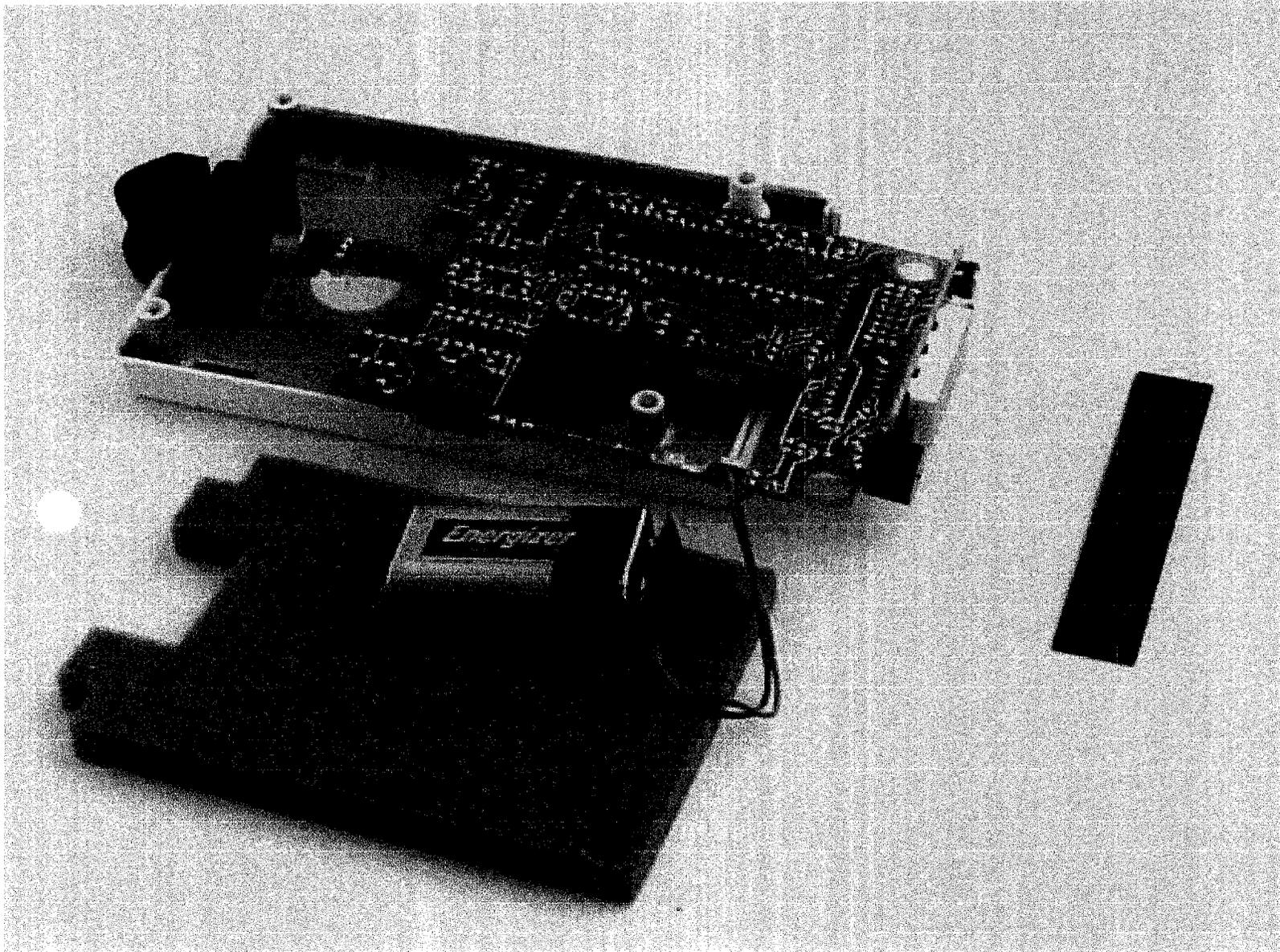
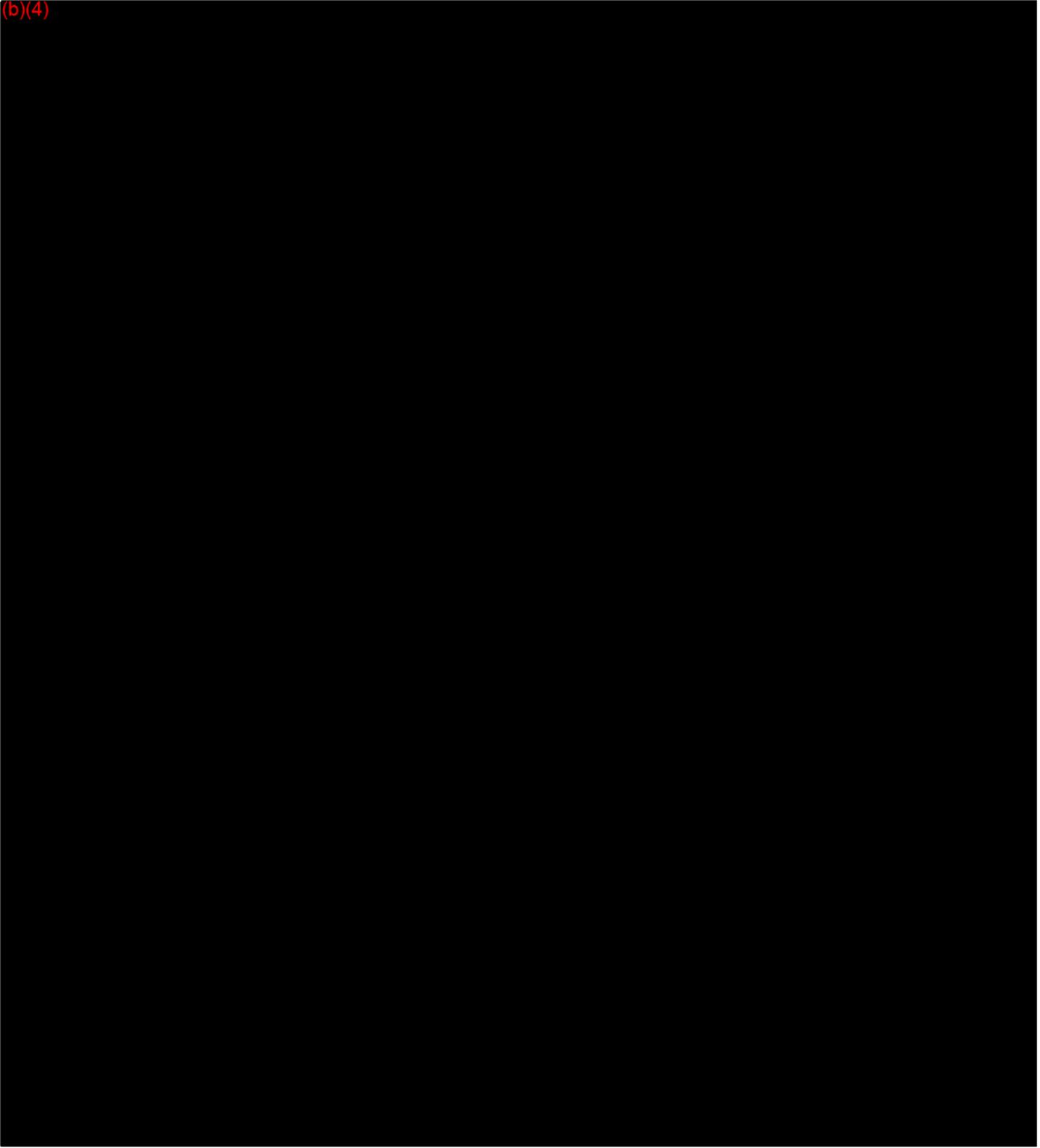


Exhibit 8-E

FLOW CHART FOR ALGORITHM
(Same for cleared device and updated device)

(b)(4)



Section 9 Performance

The SensorTouch, model HF 370, (predecessor name for Temporal Scanner Thermometer) was originally manufactured by Exergen Corporation for Philips Domestic Appliance and Personal Care B. V. of Groningen. Acceptance by Philips of the product was to be based on compliance with the European standard for infrared thermometers being developed at the time, working document (WD 1247-5), which was the predecessor of the EN12470-5 standard which now applies to infrared thermometers. EN12470-5 is, the European counterpart to ASTM E1965-98. Some of the performance data presented here is the result of testing performed in (b)(4). The data is presented as follows:

1. Performance testing by Philips for product acceptance (Tab 9A)
2. Philips Declaration of Conformity to comply with CE-Marking Directive (93/42/EEC) (Tab 9B)
3. EMC testing conducted by Philips for CE mark (Tab 9C)
4. Recent safety testing conducted for Exergen for CE technical file (Tab 9D)
5. (b)(4) testing (9E)
6. Independent, unsolicited evaluation of the device and one of the predicate devices by Consumer Reports (9F).
7. Results of human studies in (b)(4) (9G)
8. Results of clinical trials in (b)(4) (Tab 9H)

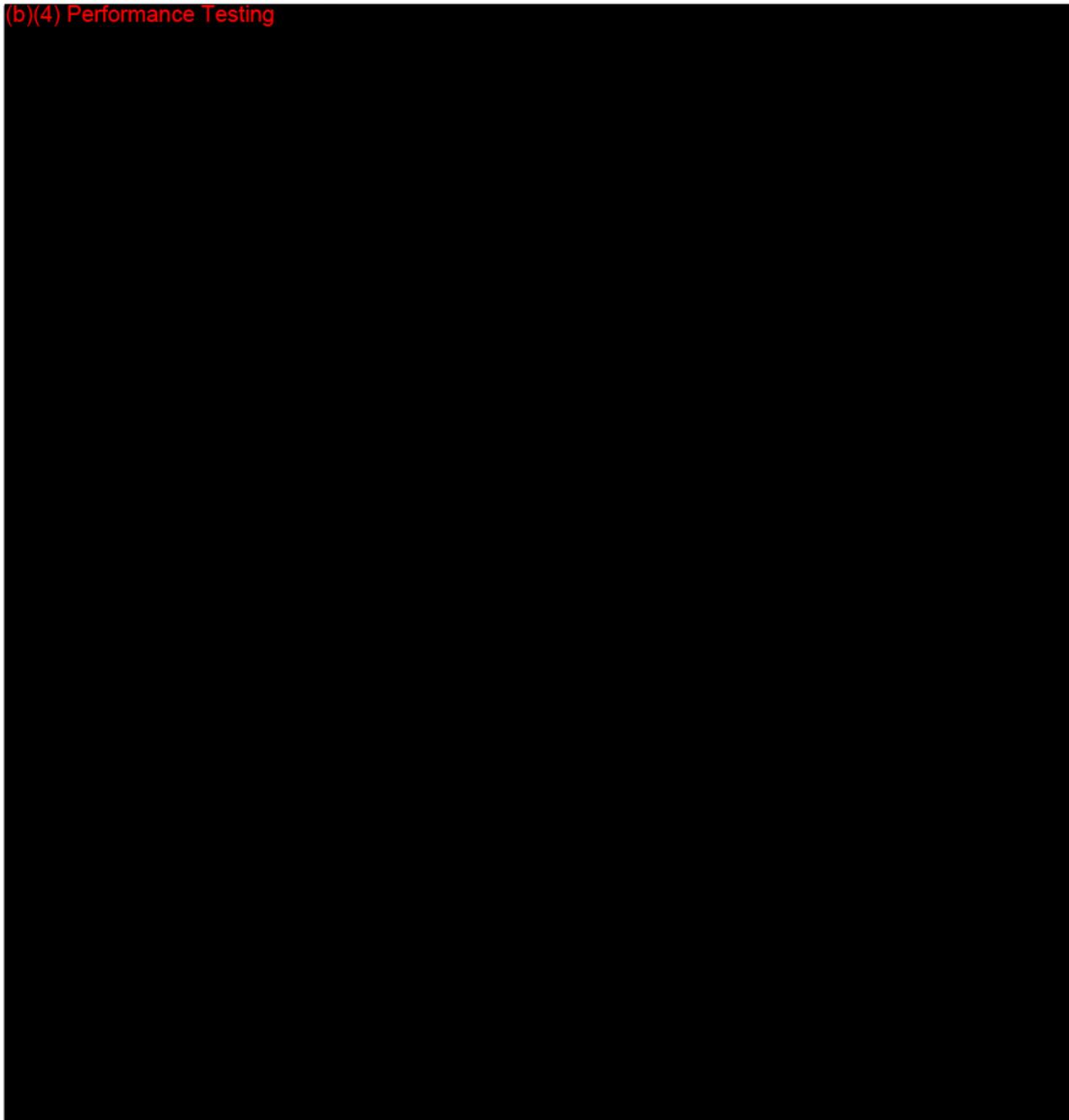
9A
Performance Testing for
Product Acceptance

139



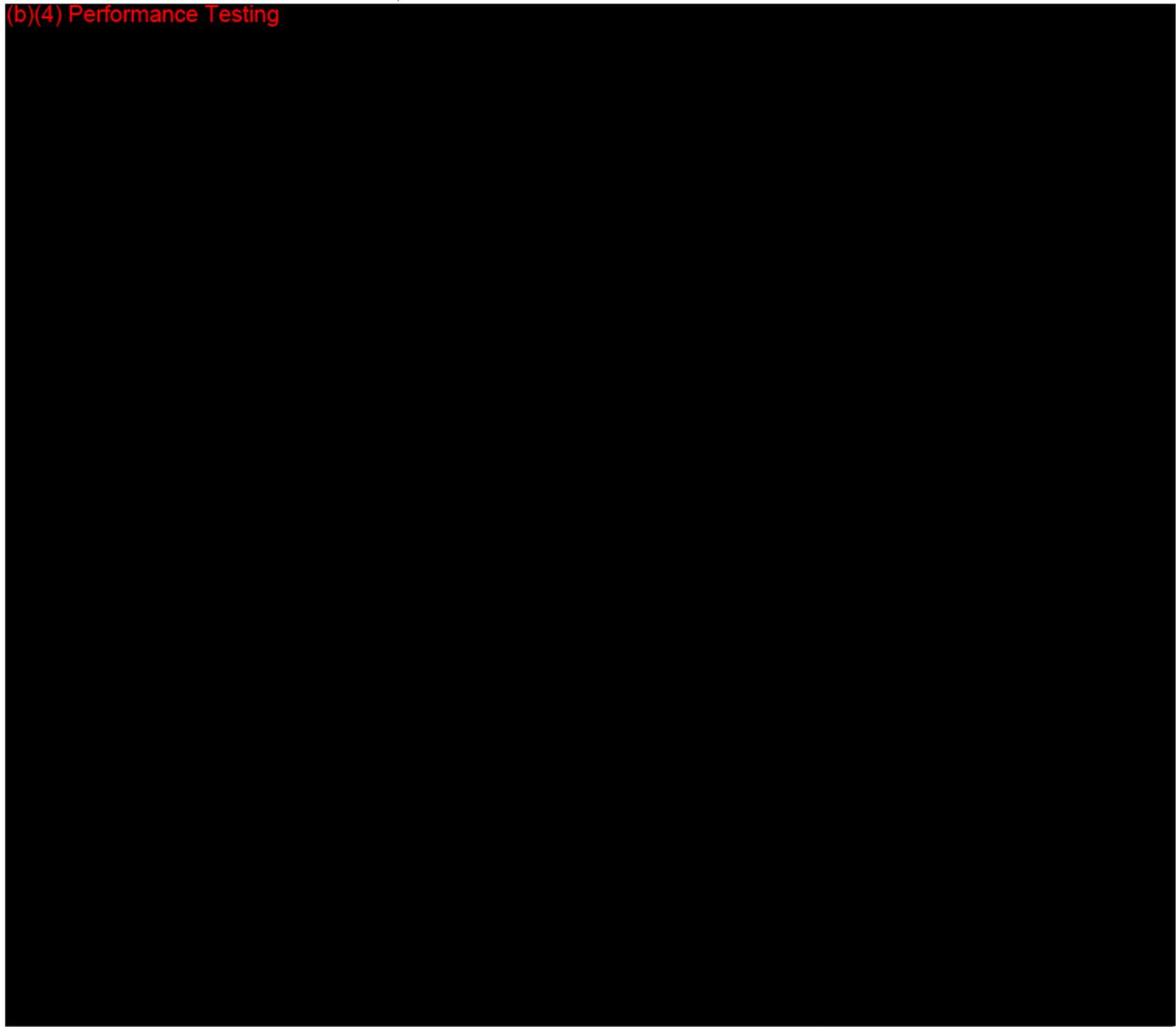
PHILIPS

(b)(4) Performance Testing

A large black rectangular redaction box covers the majority of the page content, starting below the Philips logo and ending above the footer. The text "(b)(4) Performance Testing" is written in red at the top left corner of this redacted area.

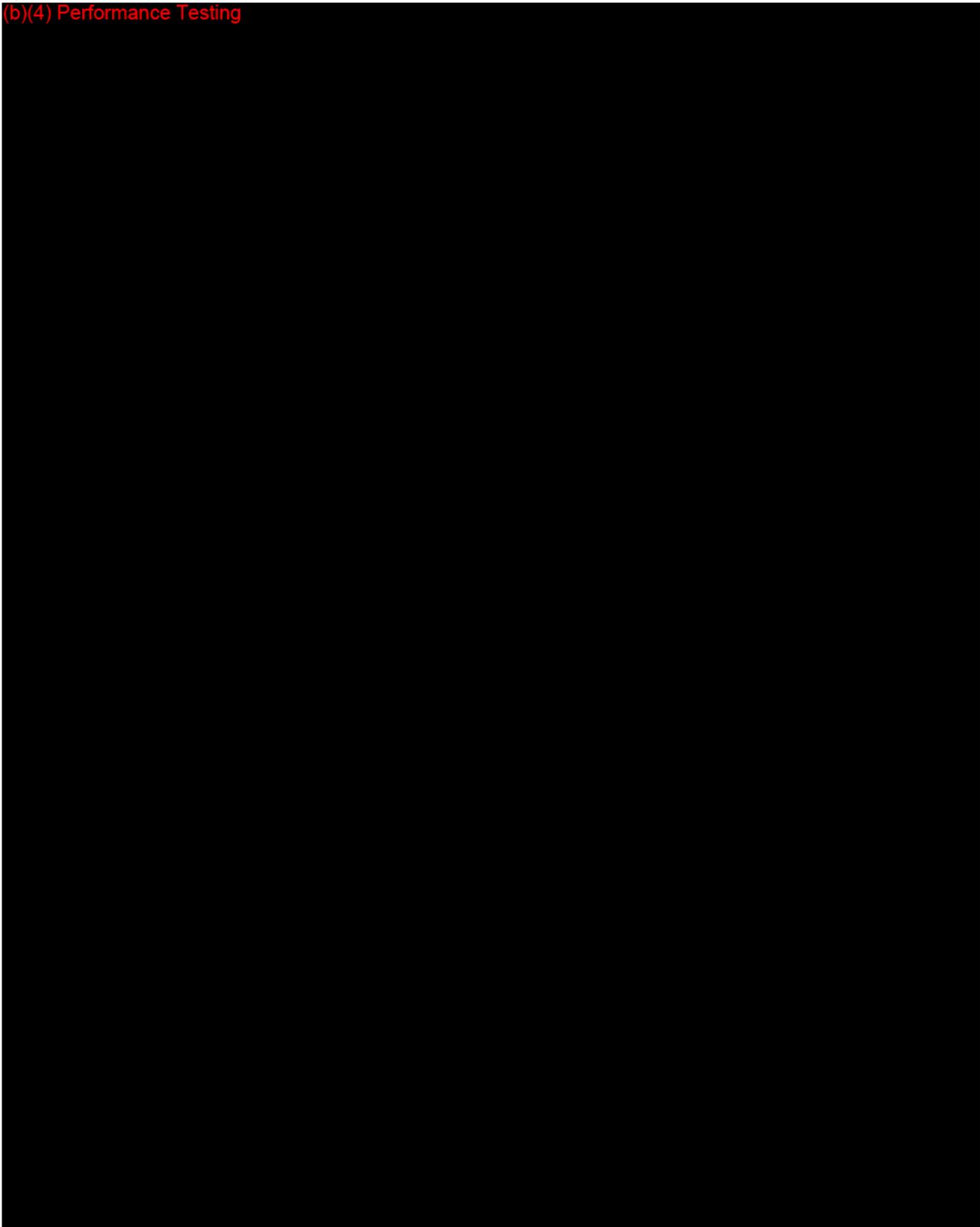
135

(b)(4) Performance Testing



136

(b)(4) Performance Testing



1/87

9B
Philips Declaration of Conformity to
Directive 93/42/EEC



PHILIPS

AMB 532-30591
1 April 1999

Declaration of Conformity

Manufacturer's Name and Address:

PHILIPS DAP B.V.

(b)(4)

Product Categories:

Non invasive infrared thermometer

Model Number:

HF 370 / 375

Medical Product Class:

IIa

The above-mentioned devices prove compliance with the standards of
Directive 93/42/EEC.

Signed on this day of 1 April 1999.

(b)(6)

(b)(6)
Central Quality Department



PHILIPS

Philips Domestic Appliances and Personal Care

(b)(6)
(Report No.)

EC DECLARATION OF CONFORMITY

We, PHILIPS DOMESTIC APPLIANCES & PERSONAL CARE B.V.
(Manufacturer's name)

(b)(6)
(Manufacturer's address)

declare under our responsibility that the electrical products:

PHILIPS HF 370 and HF 375
(Type or Model)

Temple Thermometer
(Product description)

to which this declaration relates is in conformity with the following standards:

SAFETY	EMC	
EN 60601-1	EN 55011 (3-1991)	EN 60601-1-2 (1993)
	EN 55014 (4-1993)	EN 61000-3-3 (1995)
	EN 55015 (1995)	EN 55014-2 (1995)

(Title and/or number and date of issue of the standards)

following the provisions of the Medical Device Directive 93/42/EEC

and are produced under a quality scheme at least in conformity with ISO 9002 or CENELEC Permanent Documents **(b)(4)**.

Groningen, 1999-05-03
(Place, date)

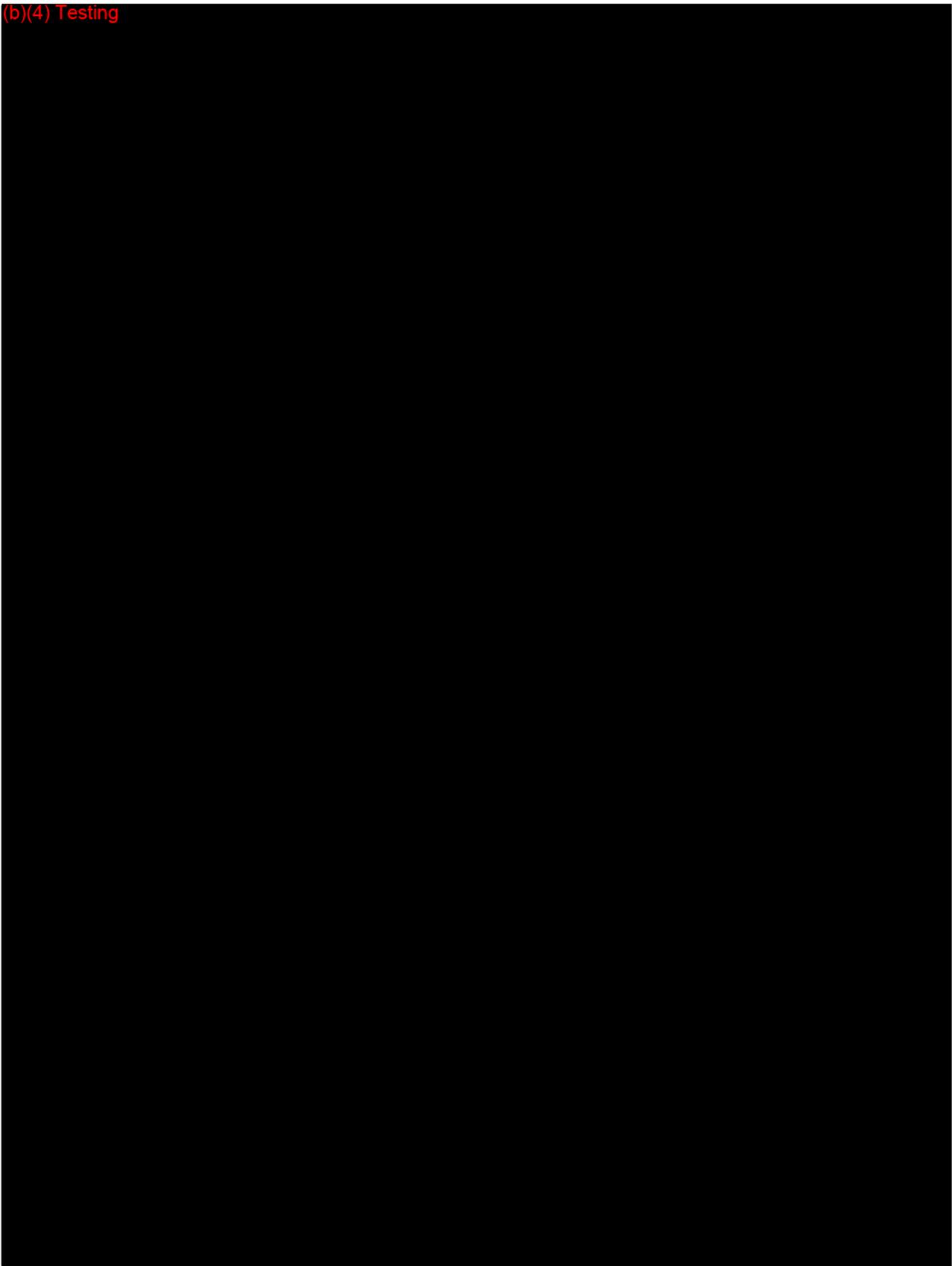
(b)(6) **(b)** Q-manager
(b)(6)

HO

9C
EMC Testing Conducted By Philips

141

(b)(4) Testing



142

9D
Safety Testing Conducted on Behalf of
Exergen

143

9E

(b)(4) Testing

**Testing Conducted
By Exergen**

147

Using (b)(4)
Testing

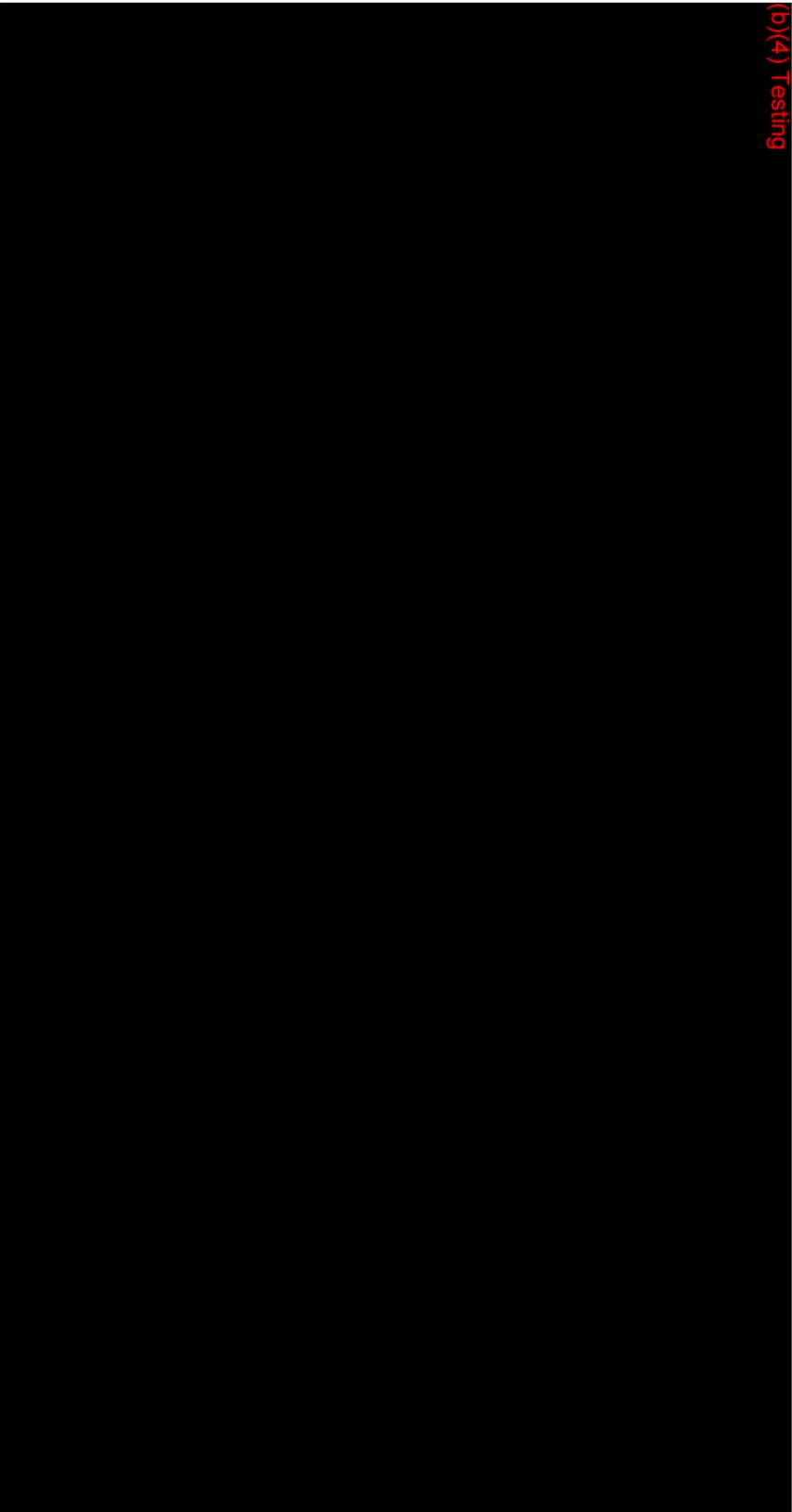
Test 1 Conditions:

(b)(4) Testing



Test 2 Conditions:

(b)(4) Testing

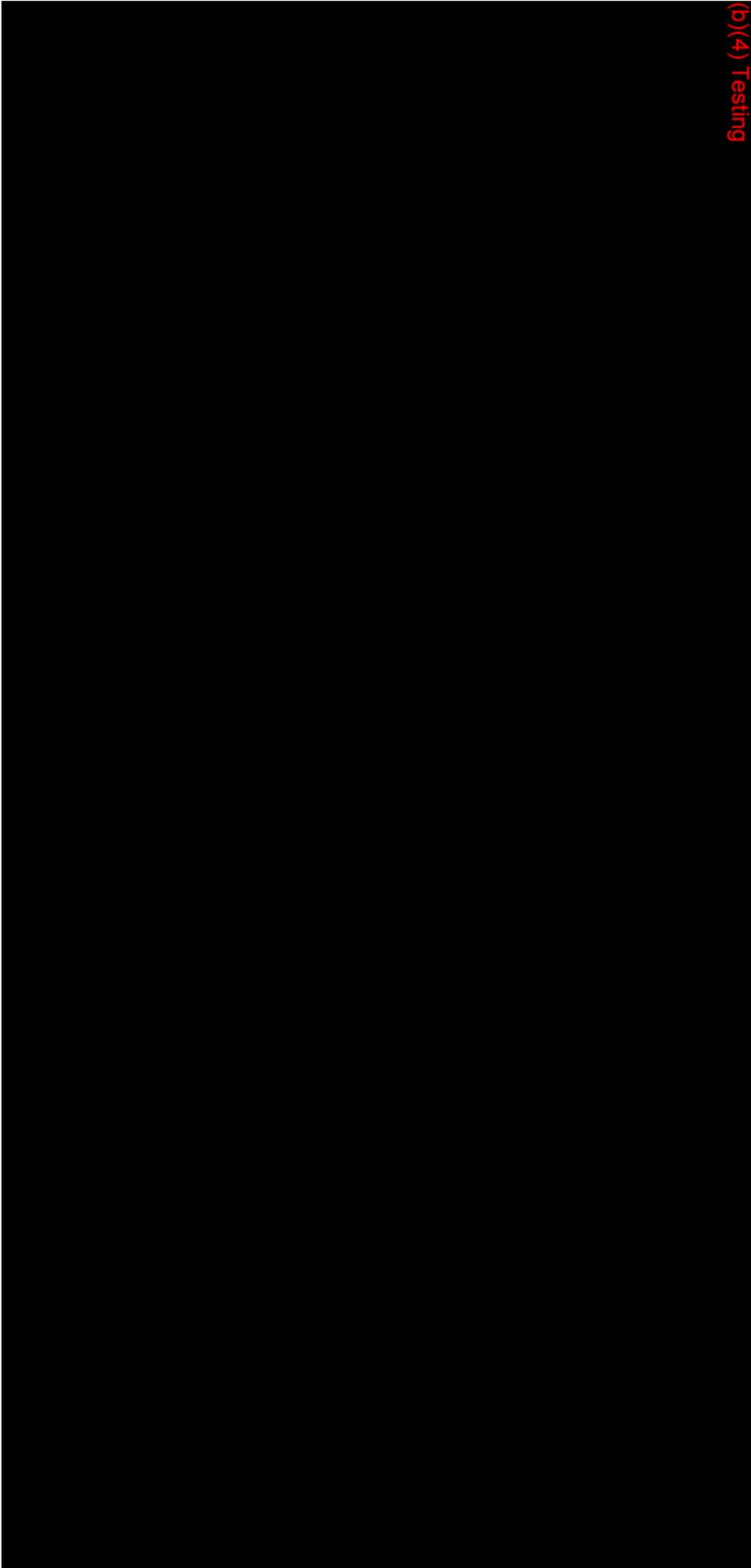


148

(b)(4)
Using Testing
Test 1 Conditions
(b)(4) Testing

Test 2 Conditions:

(b)(4) Testing



149

9F
Consumer Reports Testing

150

Consumer Reports

www.ConsumerReports.org

Product test

Feeling flush?

Taking the temperature of a feverish child can be tricky. Kids are often too fidgety for an accurate reading orally, rectally, or axially (under the armpit). That may be why ear thermometers are popular. Now a new product, the *Philips SensorTouch Temple Thermometer*, promises quick and accurate readings when you slide it across the forehead. It's pricey at \$95, but it works.



We compared the *SensorTouch HF370*, the *Braun ThermoScan IRT 3520* ear thermometer, \$54, and the *PolyMedica 760* digital oral thermometer, \$12, in our labs and in the homes of a small group of panelists with young children. Our engineers found the *SensorTouch* as reliable as the others for home use. (Our previous tests found digital oral thermometers more accurate than mercury thermometers.)

The *SensorTouch* and the *ThermoScan* take only a few seconds, and panelists judged them equally easy to use, once they got the hang of them. The oral thermometer took more than a minute for a reading. No one preferred it to the other thermometers.

The *SensorTouch* could be handy, especially if a temperature needs checking often. With an ear or forehead thermometer, establish a baseline temperature when the child is not sick, and compare it with the reading from an oral, rectal, or axial thermometer. You'll get a sense of whether the readings run a little high or low. If you consult a doctor, tell him or her the kind of thermometer you used.

9G
Results of Clinical Trials in the
(b)(4) Testing

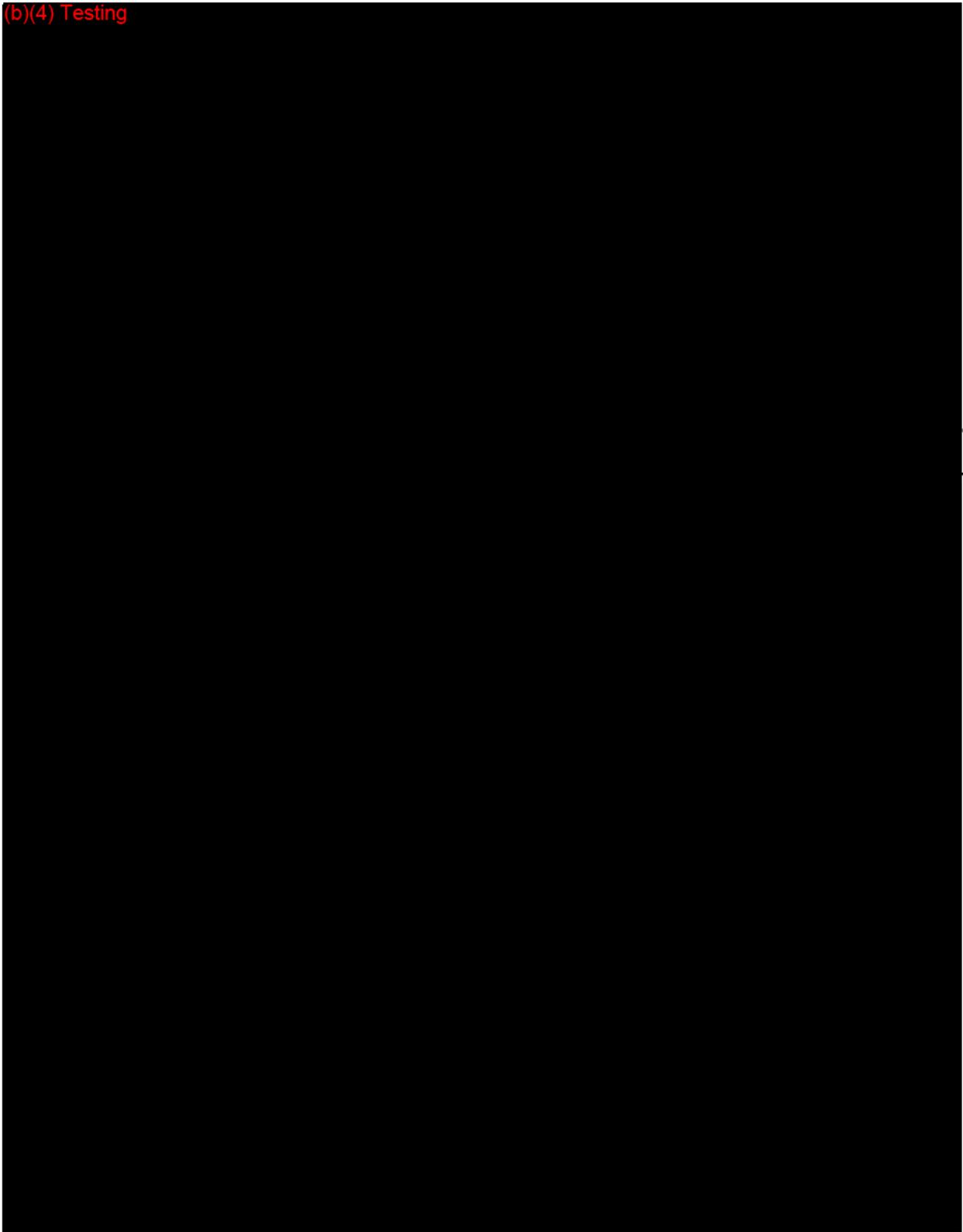
152

 PHILIPS

(b)(4) Testing

153

(b)(4) Testing



159

(b)(4) Testing



185

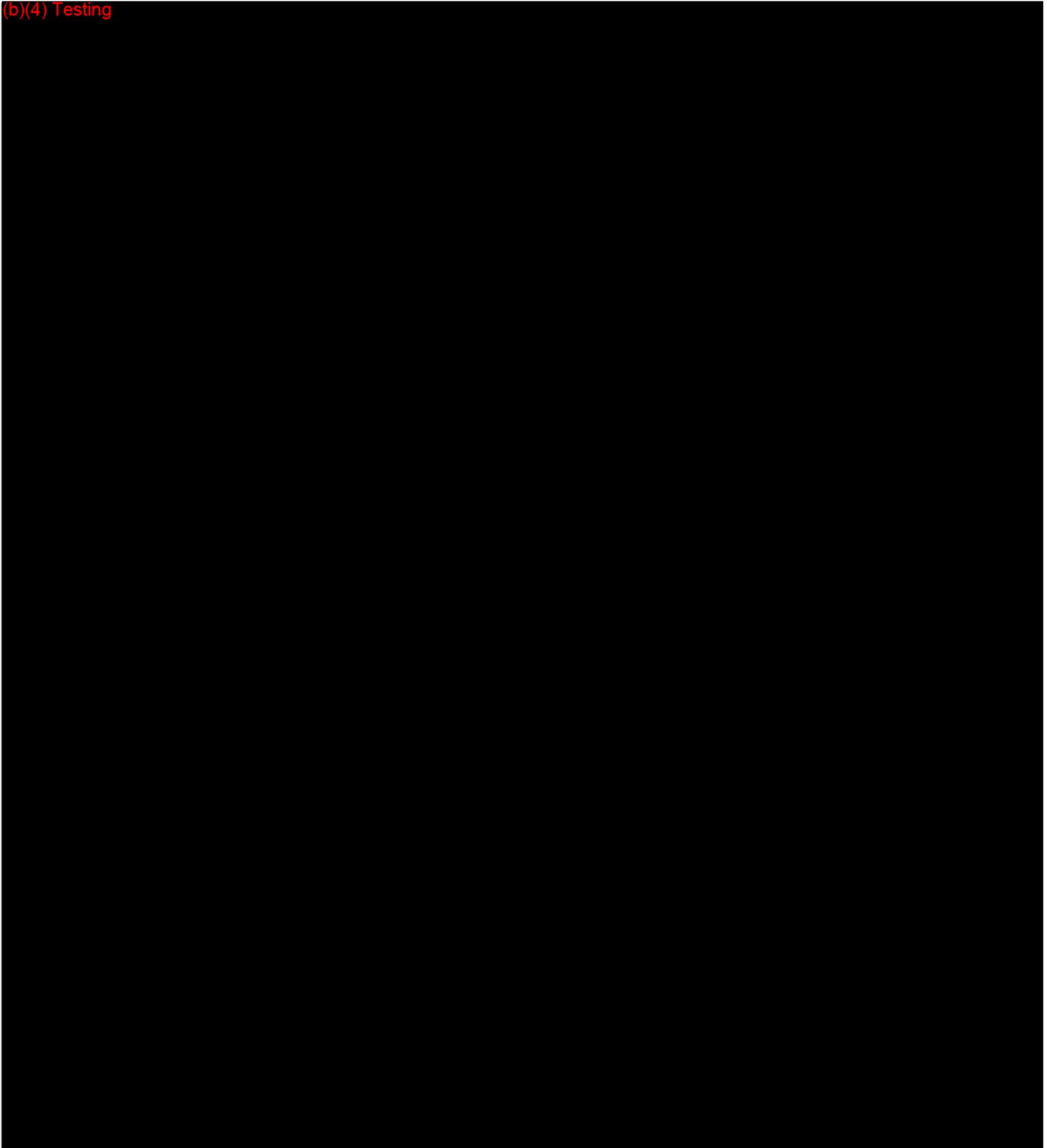
9H
Results of Clinical Trials
In (b)(4) Testing 

182

EXERGEN
CORPORATION

CONFIDENTIAL

(b)(4) Testing

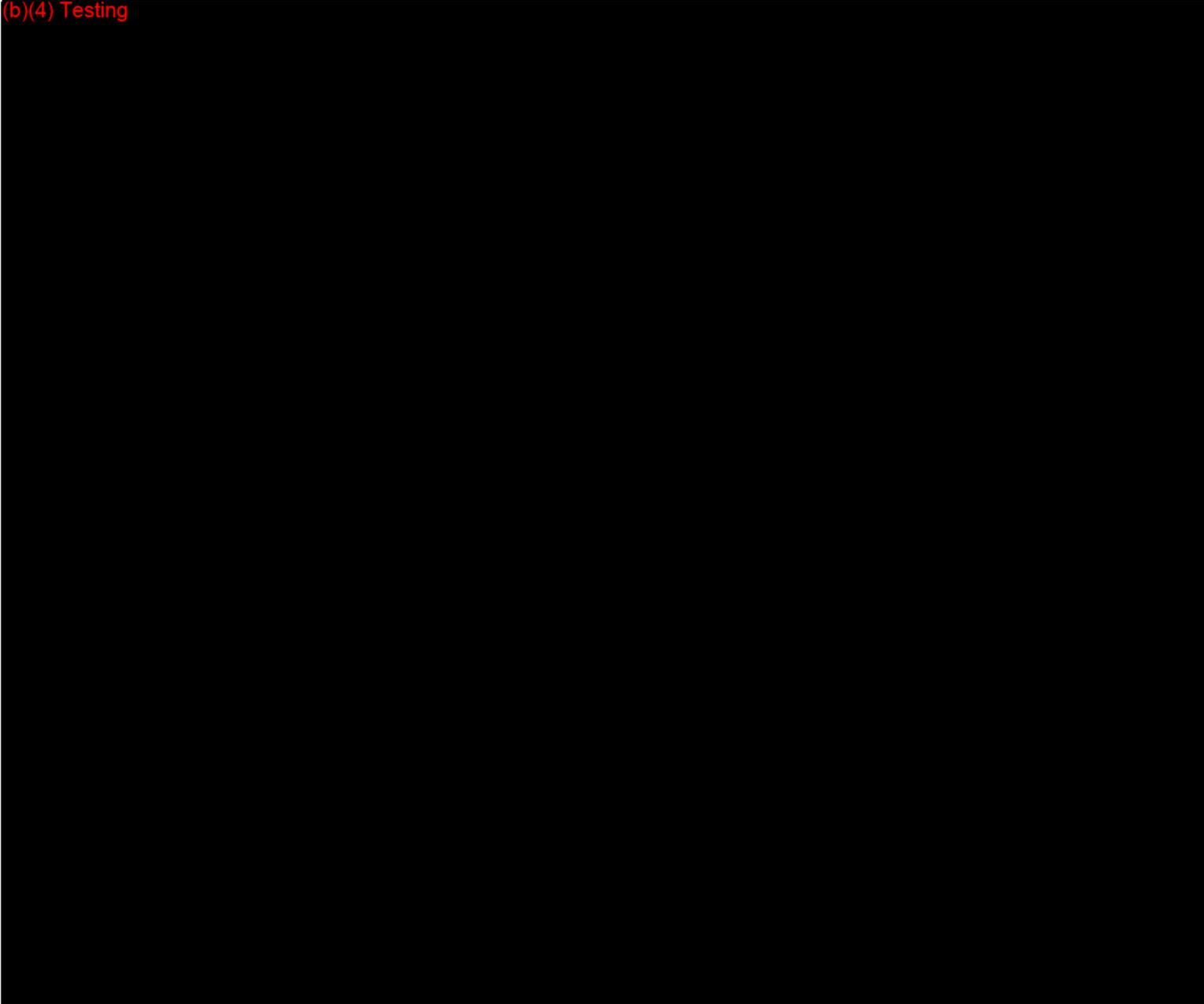


157

EXERGEN
CORPORATION

CONFIDENTIAL

(b)(4) Testing

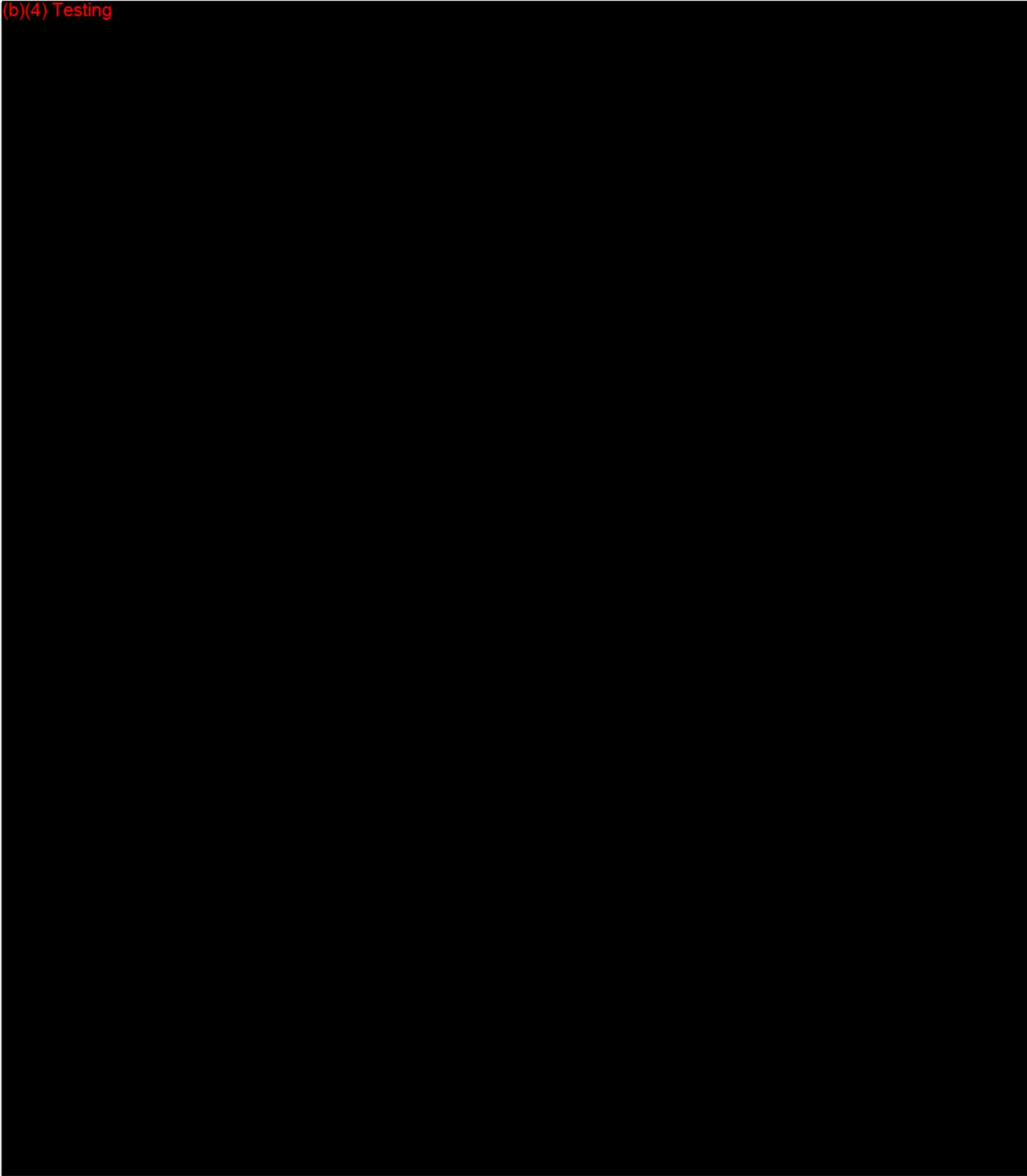


158

EXERGEN
CORPORATION

CONFIDENTIAL

(b)(4) Testing

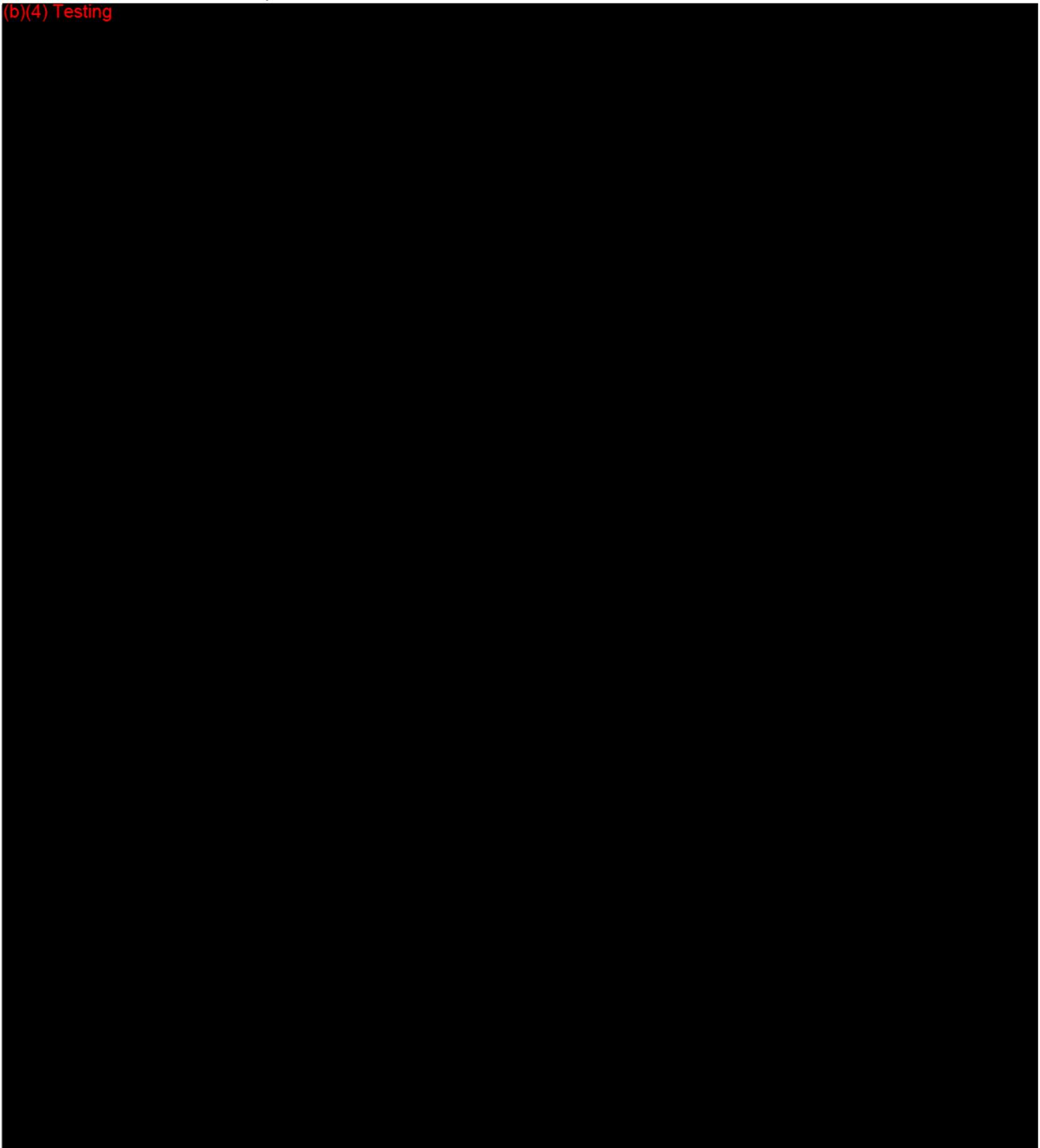


159

EXERGEN
CORPORATION

CONFIDENTIAL

(b)(4) Testing

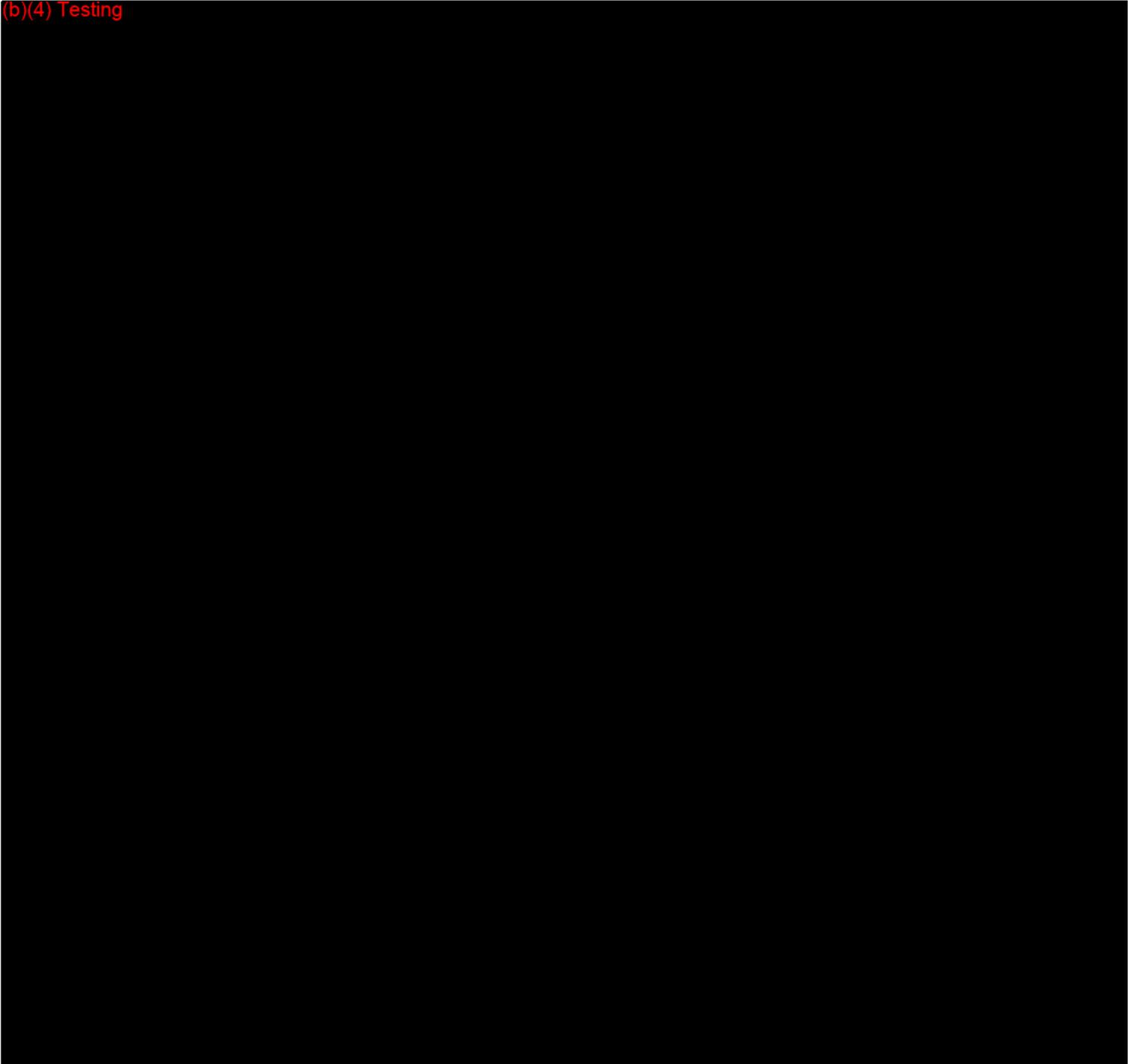


160

EXERGEN
CORPORATION

CONFIDENTIAL

(b)(4) Testing



161

Clinical Study No. (b)(4) 

162

Accuracy of a Noninvasive Temporal Artery Thermometer for Use in Infants

David S. Greenes, MD; Gary R. Fleisher, MD

Objectives: To assess the accuracy of a new noninvasive temporal artery (TA) thermometer in infants; to compare the accuracy of the TA thermometer with that of a tympanic thermometer, using rectal thermometry as the criterion standard; and to compare the tolerability of the TA thermometer with that of the tympanic and rectal thermometers.

Design: Prospective evaluation of the accuracy of TA and tympanic thermometry, using rectal thermometry as the criterion standard.

Setting: Emergency department of an urban pediatric hospital.

Subjects: Convenience sample of 304 infants younger than 1 year presenting for care.

Main Outcome Measures: Temperatures were measured using TA, tympanic, and rectal thermometers for all infants. Agreement between TA or tympanic and rectal temperatures was assessed. The sensitivity and specificity of TA or tympanic thermometers for detecting rec-

tal fever were determined. Discomfort scores, using a standardized scale, were assessed by trained observers after each temperature measurement was made.

Results: Linear regression analysis of the relation between TA and rectal temperatures yielded a model with a slope of 0.79 (vs a slope of 0.68 for tympanic vs rectal temperature; $P = .02$) and an r of 0.83 (vs $r = 0.75$ for tympanic vs rectal temperature; $P < .001$). Among 109 patients with a rectal temperature of 38°C or higher, the TA thermometer had a sensitivity of 0.66 compared with the tympanic thermometer's sensitivity of 0.49 ($P < .001$). Discomfort scores with TA thermometry were significantly lower than with rectal thermometry ($P = .007$).

Conclusions: The TA thermometer has limited sensitivity for detecting cases of rectal fever in infants. However, the TA thermometer is more accurate than the tympanic thermometer in infants, and it is better tolerated by infants than rectal thermometry.

Arch Pediatr Adolesc Med. 2001;155:376-381

Highlights Added

From the Division of
Emergency Medicine,
Children's Hospital, Harvard
Medical School, Boston, Mass.

RECTAL THERMOMETRY has generally been considered the standard for measurement of temperature in infants. Published guidelines for the management of febrile infants have based their recommendations on measurement of rectal temperature,¹ and other thermometry methods have generally been evaluated with rectal temperature as the criterion standard.²⁻¹⁹

Although rectal thermometry has evolved as the standard, it has several disadvantages, including discomfort for the patient, emotional upset for the patient and parent,²⁰⁻²² risk for traumatic injury to the rectum,²³⁻³⁰ and transmission of stool-borne pathogens.³¹⁻³³ Several alternative methods of thermometry, which eliminate the problems inherent in rectal thermometry, have been shown to have limited value

in other regards. Axillary^{2,11,12,18,34,35} and supralingual^{3,4,13} thermometers have generally proven too inaccurate for routine clinical use. Tympanic thermometers, although popular with patients and parents and fairly reliable in adults,²² have not proven adequate for infants and young children.^{6,10,12,14,19,36-38} Thus, a continued need exists for a form of thermometry that is as well tolerated as the tympanic technique but gives results that closely agree with rectal temperature.

The purpose of this study was to evaluate the performance of a new noninvasive temporal artery (TA) thermometer for clinical use in infants. Our objectives were (1) to evaluate the accuracy of the TA thermometer, using rectal temperature as the criterion standard; (2) to compare the accuracy of the TA thermometer with that of a tympanic thermom-

PATIENTS AND METHODS

PATIENT SELECTION

We performed a prospective study of a convenience sample of infants presenting to the triage area of an emergency department in a tertiary care pediatric hospital. Children were eligible for inclusion in the study if they were younger than 1 year. Children were excluded if they had any medical condition that contraindicated the use of a rectal, tympanic, or TA thermometer. Children were also excluded if they were too ill to remain at triage for an initial assessment before proceeding to a treatment room.

Patients were enrolled during shifts when trained research assistants were available. During these shifts, the research assistants attempted to enroll all eligible patients.

Our study was approved by the Committee on Clinical Investigation of Children's Hospital, Boston, Mass. The committee required that verbal consent be obtained from the parents of study subjects.

THERMOMETRY MEASUREMENTS

On arrival to the triage area of the emergency department, patients and their families were invited to participate in the study. After oral consent was obtained, 4 successive temperature measurements were made, including a rectal temperature, a tympanic temperature, and left- and right-sided TA temperatures. Rectal temperatures were measured using the Diatek electronic thermometer (Welch Allyn Inc, Skaneateles Falls, NY). Tympanic temperatures were measured using the First Temp Genius tympanic thermometer (Sherwood Medical, St Louis, Mo). Both thermometers are used for routine clinical care in our hospital and were maintained by the hospital's medical engineering

department. Left- and right-sided TA temperatures were measured using the Exergen TempScan Temporal Artery Thermometer (model LXTA) (Exergen Corp, Watertown, Mass).

The TA thermometer is a handheld device that is operated by placing its probe on the patient's forehead and then sweeping it laterally until the hairline of the temporal scalp is reached. The device continually measures surface temperature as it moves along its path and assumes the highest temperature recorded to be the TA temperature. Using a simultaneous measure of ambient temperature from a separate thermistor, the device calculates the patient's core temperature and instantaneously reports this calculated temperature.

All temperatures were measured by trained research assistants. These assistants were trained by the nursing staff of our emergency department to use the rectal and tympanic thermometers, and they were certified by the nursing department so that their measurements could be used in the clinical care of patients. Representatives from Exergen trained the assistants in the use of the TA thermometer. During a pilot phase, the assistants had several days of practice sessions, in which their thermometry technique and results were reviewed by the authors and representatives from Exergen, before data collection began.

Research assistants were instructed to make each measurement only once. Only when there were obvious mechanical failures (eg, the patients pulled their heads away during the process) were the research assistants allowed to repeat measurements with any of the thermometers. Research assistants were told not to consider the measured temperature reading in determining whether a measurement needed to be repeated. Conditions that appeared to the research assistants to make a measurement unreliable

Continued on next page

eter; and (3) to compare patients' discomfort with the use of the TA thermometer with their discomfort with tympanic and rectal thermometry.

RESULTS

During the 3-month study period, 304 patients were enrolled, of whom 109 (36%) had rectal fever and 49 (16%) had high rectal fever. Rectal temperature was $37.9^{\circ}\text{C} \pm 1.0^{\circ}\text{C}$ (mean \pm SD), with a range of 35.7°C to 40.7°C . Temporal artery temperature was $37.6^{\circ}\text{C} \pm 0.9^{\circ}\text{C}$, with a range of 35.9°C to 40.7°C . Tympanic temperature was $37.1^{\circ}\text{C} \pm 0.9^{\circ}\text{C}$, with a range of 35.0°C to 39.9°C .

AGREEMENT BETWEEN LEFT- AND RIGHT-SIDED TA TEMPERATURES

For the purpose of this subanalysis, 44 patients were excluded because the research assistants noted that either the left- or right-sided TA temperature measurements were potentially unreliable. Among the remaining 260 patients, the mean \pm SD left-right difference was $0^{\circ}\text{C} \pm 0.39^{\circ}\text{C}$, with a range of -1.3°C to 1.0°C . The r between left- and right-sided TA temperatures was 0.91. A paired sample

t test found no significant difference between left- and right-sided TA temperatures ($P = .59$).

AGREEMENT BETWEEN TA OR TYMPANIC AND RECTAL TEMPERATURES

For all remaining analyses, all 304 patients were included. Linear regression analysis of the relation between TA temperature and rectal temperature (**Figure 1**) yielded a model with a slope of 0.79 and an r of 0.83. Linear regression analysis of the relation between tympanic temperature and rectal temperature (**Figure 2**) yielded a model with a slope of 0.68 and an r of 0.75. Both slopes were significantly different from 1 ($P < .001$), indicating that neither tympanic nor TA temperature was equivalent to rectal temperature.

The slopes generated for the 2 curves differed significantly from one another ($P = .02$), indicating that TA temperature was significantly closer to equivalence with rectal temperature than was tympanic temperature. Comparison of the correlation coefficients from the 2 models using the Fischer z transform showed significantly closer correlation between TA and rectal temperature than between tympanic and rectal temperature ($P = .006$).

164

(eg, patient's forehead buried in parent's chest, making TA temperature potentially unreliable) were recorded.

DISCOMFORT ASSESSMENTS

To assess the experience of children with thermometry, a semi-quantitative discomfort scale was used. The scale, adapted from the work by Shane et al.³⁹ is shown in **Table 1**. Research assistants were asked to assess behavior of the patients and to assign a discomfort score immediately after measuring the rectal, tympanic, and left-sided TA temperatures.

To ensure that the behavioral responses recorded after the use of a given thermometer would not be influenced substantially by the preceding measurements, the order of routes was varied from patient to patient. The right-sided TA temperature was always the fourth measurement made. The order of the other 3 measurements was dictated by a pre-printed data collection form. The data collection form for each patient was taken blindly from the top of a shuffled stack of data forms after the patient consented to enrollment.

DATA ANALYSIS

Reproducibility of TA temperature was assessed by performing a paired sample *t* test and calculating a correlation coefficient for the relation between left- and right-sided TA temperatures. For the purpose of this analysis, cases in which 1 of the 2 TA measurements was noted to be unreliable were excluded.

To evaluate the accuracy of TA and tympanic thermometry, rectal temperature was considered the criterion standard. Both TA temperature and tympanic temperature were assessed for their ability to predict rectal temperature. In doing this analysis, left-sided TA temperature was used as the representative TA temperature. In cases in

which the left-sided TA temperature was noted to be unreliable, right-sided temperatures were used.

Linear regression analysis was performed and correlation coefficients were calculated for the relation between TA and rectal temperature and for the relation between tympanic and rectal temperature. In addition, *t* tests were performed to compare the slopes of each of the 2 lines generated by the linear regression models to a value of 1 to determine whether TA or tympanic temperature readings were equivalent to rectal temperatures. The slopes of the 2 lines generated were compared with one another using a *t* test as well. Correlation coefficients were compared using the Fischer *z* transform technique.

Patients with a rectal temperature of 38°C or higher were considered to have rectal fever, and those with a rectal temperature of 39°C or higher were considered to have high rectal fever. The sensitivity and specificity of tympanic and TA thermometers for detecting temperatures of 38°C or higher in cases of rectal fever were calculated. The sensitivities of tympanic and TA thermometers for detecting temperatures of 38°C or higher in cases of high rectal fever were calculated separately. Sensitivities and specificities of the 2 thermometry methods were compared with one another using the McNemar test. When comparisons showed no significant differences between the 2 thermometry methods, post hoc power calculations were performed.

Discomfort scores for each of the 3 methods were compared with one another using the Wilcoxon signed rank test. Because multiple (3) comparisons were done in assessing discomfort scores, a Bonferroni correction was used, with $P \leq .017$ considered significant for this analysis.

Statistical analysis was performed using the Statistical Program for the Social Sciences, version 6.0 for Windows (SPSS Inc, Chicago, Ill), and the Stata statistical package for Windows (Stata Inc, College Station, Tex).

SENSITIVITY AND SPECIFICITY

The sensitivities of the TA and tympanic thermometers for detecting fever in patients with rectal fever (temperature $\geq 38^\circ\text{C}$) or high rectal fever (temperature $\geq 39^\circ\text{C}$) are shown in **Table 2**. Using the McNemar test, we found the TA thermometer to be significantly more sensitive than the tympanic thermometer for detecting rectal fever ($P < .001$) and high rectal fever ($P = .004$).

The specificities of the TA and tympanic thermometers in patients with no rectal fever are shown in Table 2. Using the McNemar test, we found no significant difference between the specificity of the tympanic and TA thermometers ($P = .07$). A post hoc power calculation indicated that our study had a power of 0.35 for detecting a statistically significant difference between 2 thermometry methods with the measured specificities.

DISCOMFORT SCORES

The median discomfort score for the rectal thermometer was 3, with a range of 1 to 5. For both the tympanic and TA thermometers, the median discomfort score was 2, with a range of 1 to 5. The tympanic thermometer was

associated with significantly lower discomfort scores than the rectal thermometer ($P < .001$). The TA thermometer was also associated with significantly lower discomfort scores than the rectal thermometer ($P = .007$).

COMMENT

We have found the TA thermometer to be significantly more accurate than the tympanic thermometer for predicting rectal temperature in infants. The TA thermometer is significantly more sensitive than the tympanic thermometer for the detection of rectal fever in infants. In addition, the TA thermometer is better tolerated by patients than the rectal thermometer.

Previous investigations have also suggested that tympanic thermometry is a poor predictor of rectal temperature in infants. Brennan et al⁶ found that tympanic thermometry had a sensitivity of only 0.76 for detecting rectal fever in children 6 months to 6 years of age. Hooker¹⁰ reported that tympanic thermometers had a sensitivity of 0.67 for detecting rectal fever in patients younger than 6 years. Muma et al¹² reported that tympanic thermometers had a sensitivity of 0.55 for detecting fever in 87 children younger than 3 years.

Table 1. Infant Discomfort Scale*

Score	Description of Behavior
1, Drowsy/asleep	Eyes closed, may respond to stimulation, accepts intervention passively
2, Relaxed	Sitting or lying with eyes open, accepts intervention readily
3, Anxious	Verbally or nonverbally seeks support but accepts intervention reluctantly
4, Upset	Tearful, may be clinging to parent, considerable effort required to achieve compliance with intervention
5, Agitated	General loud or high-pitched crying, requires significant physical restraint, strongly refuses intervention

* Adapted from Shane et al.²⁹

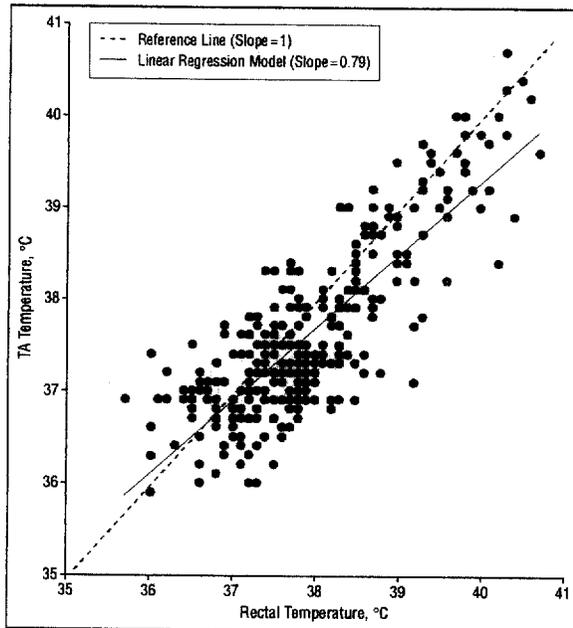


Figure 1. Scatterplot of rectal vs temporal artery (TA) temperatures.

Our data suggest that TA thermometry is a better choice than tympanic thermometry for use in infants. However, TA thermometry does not reliably predict rectal temperature in all clinical situations. Thirty-five percent of all cases of rectal fever and 6% of cases of high-grade rectal fever were missed by the TA thermometer.

One limitation of our study is that we do not have a true measure of core body temperature to use as a criterion standard. In the literature, esophageal or pulmonary artery (PA) temperatures are generally considered to be true measures of core body temperature.⁴⁰⁻⁵⁴ Several published investigations have evaluated the accuracy of rectal thermometry as an indicator of core body temperature compared with these invasive methods. Some early studies^{55,56} of the physiology of human body temperature suggested a lag between instantaneous changes in core body temperature and more delayed changes in rectal temperature. It is possible, therefore, that in cases with large discrepancies between TA and rectal measure-

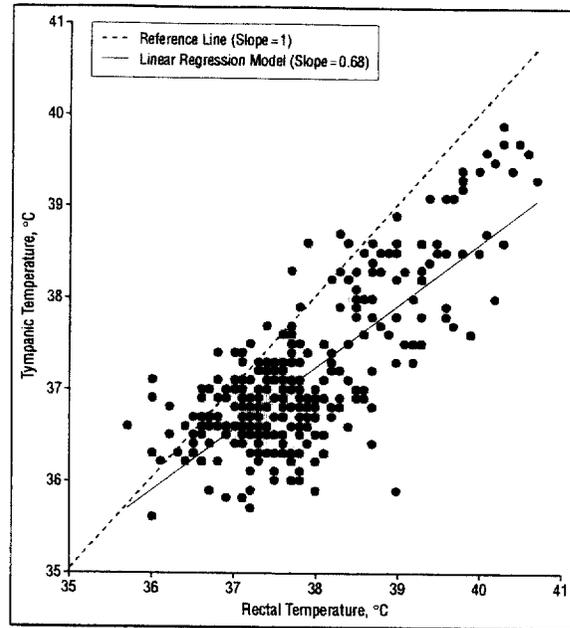


Figure 2. Scatterplot of rectal vs tympanic temperatures.

ments, the TA thermometer may be correctly reflecting a rapid change in core body temperature, whereas the rectal temperature is lagging behind. For instance, if antipyretics had been given several minutes before the temperatures were measured, the TA temperature might accurately reflect a lowered core body temperature, while the rectal temperature still reflects the preceding fever. Future studies evaluating the changes in TA and rectal temperatures in response to changes in core body temperature would be of interest.

Although we must acknowledge this theoretical limitation, the bulk of the published literature suggests that rectal thermometry is the best available noninvasive indicator of core body temperature. In a study of 16 adults admitted to an intensive care unit (ICU), Stavem et al⁴³ reported better agreement between rectal and PA temperatures than between tympanic and PA temperatures. Similarly, Schmitz et al⁴⁷ reported that rectal temperatures were a better predictor of PA temperatures than were oral, tympanic, or axillary temperatures in 13 adult patients in an ICU. In a study of 20 patients in a pediatric ICU, Romano et al⁵² found that rectal thermometry had less bias and variability than tympanic or axillary thermometers in predicting PA temperature. In a study of 9 adult patients in an ICU, Milewski et al⁵⁴ found a better correlation between rectal and PA temperature than between tympanic and PA temperature. Only Rotello et al,⁴⁶ in a study of 20 adult patients in an ICU, found a closer agreement between tympanic temperature and PA temperature than between rectal and PA temperatures. Even in this study, however, there was less variability in the difference between rectal and PA temperatures than in the difference between tympanic and PA temperatures.⁴⁶ Given these reports, we believe that rectal thermometry is an appropriate criterion standard for noninvasive clinical thermometry.

166

Table 2. Sensitivity and Specificity of Temporal Artery and Tympanic Thermometers*

Device	Sensitivity (95% CI)		Specificity (95% CI) (n = 195)
	In Cases of Rectal Fever (n = 109)	In Cases of High Rectal Fever (n = 49)	
	Temporal artery	0.66 (0.56-0.75)	
Tympanic	0.49 (0.39-0.58)	0.76 (0.60-0.86)	0.99 (0.96-0.999)

*CI indicates confidence interval.

Another limitation of our study is that we included only infants in our sample. Given that the tympanic thermometer has been shown to be especially unreliable in young infants, we caution the reader against extrapolating our findings to older children or adults. Future studies comparing the TA thermometer to the tympanic thermometer in older children or adults would be of interest.

We conclude that the TA thermometer has limited sensitivity for detecting cases of rectal fever in infants. However, the TA thermometer is more accurate than the tympanic thermometer in infants, and it is better tolerated by infants than rectal thermometry. Rectal thermometry should still be considered the preferred method for temperature measurement in infants. For clinicians who choose not to use rectal thermometry for infants, the TA thermometer appears to be a better alternative than the tympanic thermometer.

Accepted for publication October 23, 2000.

This study was funded by a grant from the Exergen Corporation.

Presented as an abstract at the annual meeting of the Pediatric Academic Societies, Boston, Mass, May 14, 2000.

We thank James DiCanzio for his statistical consultation. We thank Kelly Johnston, BA, John Branda, MD, Jeanne Smith, MS, and Joyce Lee, MD, for their help with patient enrollment and data collection.

Corresponding author and reprints: David S. Greenes, MD, Division of Emergency Medicine, Children's Hospital, 300 Longwood Ave, Boston, MA 02115 (e-mail: david.greenes@tch.harvard.edu).

REFERENCES

- Baraff LJ, Bass JW, Fleisher GR, et al. Practice guideline for the management of infants and children 0 to 36 months of age with fever without source: Agency for Health Care Policy and Research [published erratum appears in *Ann Emerg Med*. 1993;22:1490]. *Ann Emerg Med*. 1993;22:1198-1210.
- Anagnostakis D, Matsaniotis N, Grafakos S, Sarafidou E. Rectal-axillary temperature difference in febrile and afebrile infants and children. *Clin Pediatr*. 1993;32:268-272.
- Banco L, Jayashakaramurthy S, Graffam J. The inability of a temperature-sensitive pacifier to identify fevers in ill infants. *AJDC*. 1988;142:171-172.
- Beckstrand RL, Wilshaw R, Moran S, Schaalje GB. Supralingual temperatures compared to tympanic and rectal temperatures. *Pediatr Nurs*. 1996;22:436-438.
- Bernardo LM, Clemence B, Henker R, Hogue B, Schenkel K, Walters P. A comparison of aural and rectal temperature measurements in children with moderate and severe injuries. *J Emerg Nurs*. 1996;22:403-408.
- Brennan DF, Falk JL, Rothrock SG, Kerr RB. Reliability of infrared tympanic thermometer in the detection of rectal fever in children. *Ann Emerg Med*. 1995;25:21-30.
- Chamberlain JM, Grandner J, Rubinoff JL, Klein BL, Waisman Y, Huey M. Comparison of a tympanic thermometer to rectal and oral thermometers in a pediatric emergency department. *Clin Pediatr*. 1991;30:24-29. Discussion 34-35.
- Childs C, Harrison R, Hodkinson C. Tympanic membrane temperature as a measure of core temperature. *Arch Dis Child*. 1999;80:262-266.
- Erickson RS, Woo TM. Accuracy of infrared ear thermometry and traditional temperature methods in young children. *Heart Lung*. 1994;23:181-195.
- Hooker EA. Use of tympanic thermometers to screen for fever in patients in a pediatric emergency department. *South Med J*. 1993;86:855-858.
- Morley CJ, Hewson PH, Thornton AJ, Cole TJ. Axillary and rectal temperature measurements in infants. *Arch Dis Child*. 1992;67:122-125.
- Muma BK, Treloar DJ, Wurlinger K, Peterson E, Vitae A. Comparison of rectal, axillary, and tympanic membrane temperatures in infants and young children. *Ann Emerg Med*. 1991;20:41-44.
- Press S, Quinn BJ. The pacifier thermometer: comparison of supralingual with rectal temperatures in infants and young children. *Arch Pediatr Adolesc Med*. 1997;151:551-554.
- Romanovsky AA, Quint PA, Benikova Y, Kiesow LA. A difference of 5°C between ear and rectal temperatures in a febrile patient. *Am J Emerg Med*. 1997;15:383-385.
- Shann F, Mackenzie A. Comparison of rectal, axillary, and forehead temperatures. *Arch Pediatr Adolesc Med*. 1996;150:74-78.
- Terndrup TE, Milewski A. The performance of two tympanic thermometers in a pediatric emergency department. *Clin Pediatr*. 1991;30:18-23. Discussion 34-35.
- Weisse ME, Reagen MS, Boule L, France N. Axillary vs. rectal temperatures in ambulatory and hospitalized children. *Pediatr Infect Dis J*. 1991;10:541-542.
- Wilshaw R, Beckstrand R, Waid D, Schaalje GB. A comparison of the use of tympanic, axillary, and rectal thermometers in infants. *J Pediatr Nurs*. 1999;14:88-93.
- Yetman RJ, Coody DK, West MS, Montgomery D, Brown M. Comparison of temperature measurements by an aural infrared thermometer with measurements by traditional rectal and axillary techniques. *J Pediatr*. 1993;122:769-773.
- McDonald R. Objection to taking rectal temperatures. *Clin Pediatr*. 1968;7:707.
- McCaffery M. Children's responses to rectal temperatures: an exploratory study. *Nurs Res*. 1971;20:32-45.
- Barber N, Kilmon CA. Reactions to tympanic temperature measurement in an ambulatory setting. *Pediatr Nurs*. 1989;15:477-481.
- Frank JD, Brown S. Thermometers and rectal perforations in the neonate. *Arch Dis Child*. 1978;53:824-825.
- Lau JT, Ong GB. Broken and retained rectal thermometers in infants and young children. *Aust Paediatr J*. 1981;17:93-94.
- Ficarra BJ. Rectal thermometer misplaced. *Am J Proctol*. 1970;21:212-214.
- Merenstein GB. Rectal perforation by thermometer. *Lancet*. 1970;1:1007.
- Shaw EB. Rectal perforation by thermometer. *Lancet*. 1970;1:416.
- Smiddy FG, Benson EA. Rectal perforation by thermometer. *Lancet*. 1969;2:805-806.
- Wolfson JJ. Rectal perforation in infant by thermometer: case report with review of literature on rectal perforation. *AJDC*. 1966;111:197-200.
- Young DG. Thermometers and rectal perforations in the neonate [letter]. *Arch Dis Child*. 1979;54:242.
- Brooks S, Khan A, Stoica D, et al. Reduction in vancomycin-resistant *Enterococcus* and *Clostridium difficile* infections following change to tympanic thermometers. *Infect Control Hosp Epidemiol*. 1998;19:333-336.
- Im SW, Chow K, Chau PY. Rectal thermometer mediated cross-infection with *Salmonella wandsworthi* in a paediatric ward. *J Hosp Infect*. 1981;2:171-174.
- Porwancher R, Sheth A, Remphey S, Taylor E, Hinkle C, Zervos M. Epidemiological study of hospital-acquired infection with vancomycin-resistant *Enterococcus faecium*: possible transmission by an electronic ear-probe thermometer. *Infect Control Hosp Epidemiol*. 1997;18:771-773.
- Androkites AL, Werger AM, Young ML. Comparison of axillary and infrared tympanic membrane thermometry in a pediatric oncology outpatient setting. *J Pediatr Oncol Nurs*. 1998;15:216-222.
- Zengaya ST, Blumenthal I. Modern electronic and chemical thermometers used in the axilla are inaccurate. *Eur J Pediatr*. 1996;155:1005-1008.
- Petersen-Smith A, Barber N, Coody DK, West MS, Yetman RJ. Comparison of aural infrared with traditional rectal temperatures in children from birth to age three years. *J Pediatr*. 1994;125:83-85.
- Freed GL, Fraley JK. Lack of agreement of tympanic membrane temperature assessments with conventional methods in a private practice setting. *Pediatrics*. 1992;89:384-386.

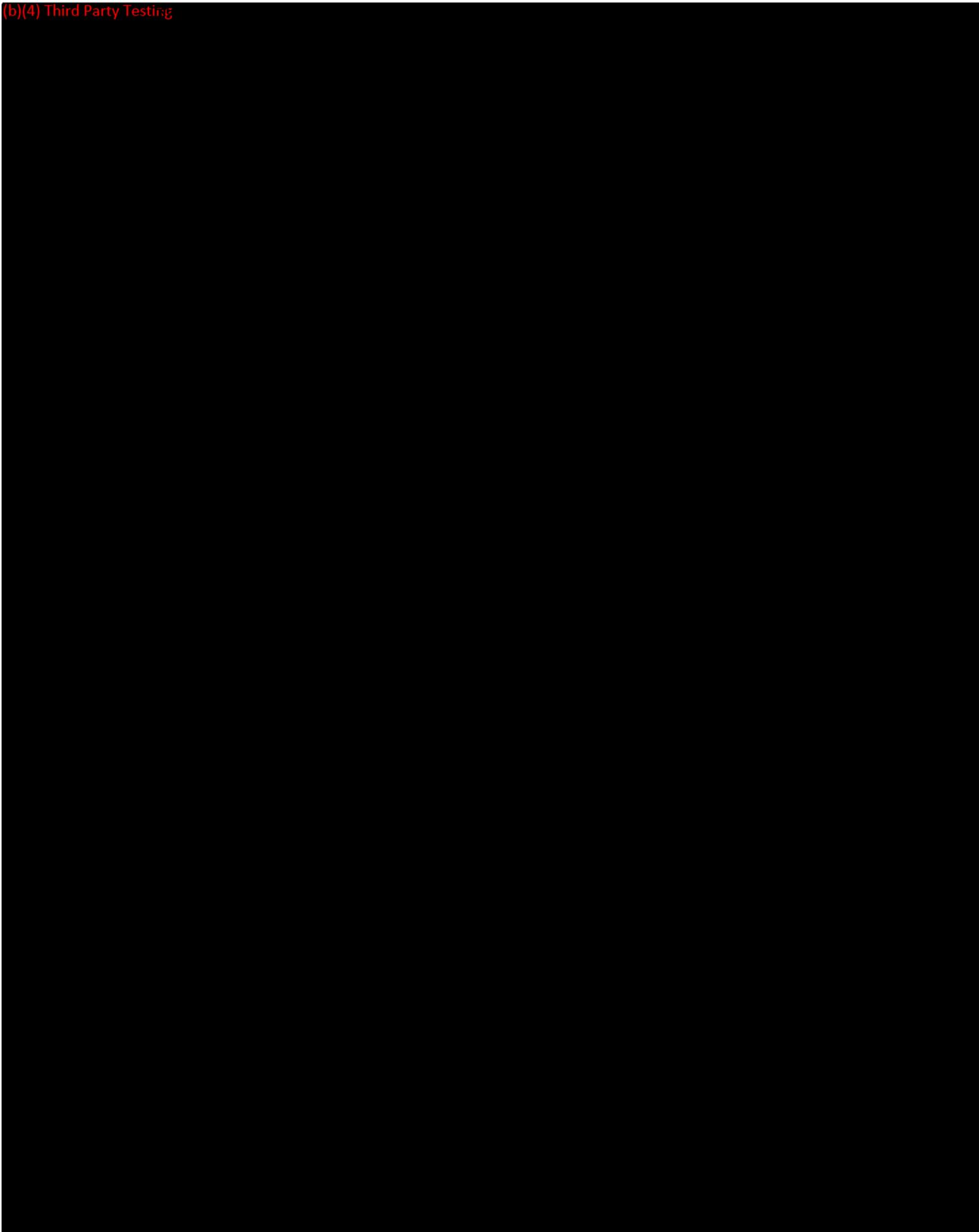
167

38. Lanham DM, Walker B, Klocke E, Jennings M. Accuracy of tympanic temperature readings in children under 6 years of age. *Pediatr Nurs*. 1999;25:39-42.
39. Shane SA, Fuchs SM, Khine H. Efficacy of rectal midazolam for the sedation of preschool children undergoing laceration repair. *Ann Emerg Med*. 1994;24:1065-1073.
40. Giuliano KK, Scott SS, Elliot S, Giuliano AJ. Temperature measurement in critically ill orally intubated adults: a comparison of pulmonary artery core, tympanic, and oral methods. *Crit Care Med*. 1999;27:2188-2193.
41. Hoffman C, Boyd M, Briere B, Loos F, Norton PJ. Evaluation of three brands of tympanic thermometer. *Can J Nurs Res*. 1999;31:117-130.
42. Harasawa K, Kemmotsu O, Mayumi T, Kawano Y. Comparison of tympanic, esophageal and blood temperatures during mild hypothermic cardiopulmonary bypass: a study using an infrared emission detection tympanic thermometer. *J Clin Monit Comput*. 1997;13:19-24.
43. Stavem K, Saxholm H, Smith-Erichsen N. Accuracy of infrared ear thermometry in adult patients. *Intensive Care Med*. 1997;23:100-105.
44. Thomas KA, Savage MV, Brengelmann GL. Effect of facial cooling on tympanic temperature. *Am J Crit Care*. 1997;6:46-51.
45. Patel N, Smith CE, Pinchak AC, Hagen JF. Comparison of esophageal, tympanic, and forehead skin temperatures in adult patients. *J Clin Anesth*. 1996;8:462-468.
46. Rotello LC, Crawford L, Terndrup TE. Comparison of infrared ear thermometer derived and equilibrated rectal temperatures in estimating pulmonary artery temperatures. *Crit Care Med*. 1996;24:1501-1506.
47. Schmitz T, Bair N, Falk M, Levine C. A comparison of five methods of temperature measurement in febrile intensive care patients. *Am J Crit Care*. 1995;4:286-292.
48. White N, Baird S, Anderson DL. A comparison of tympanic thermometer readings to pulmonary artery catheter core temperature recordings. *Appl Nurs Res*. 1994;7:165-169.
49. Erickson RS, Meyer LT. Accuracy of infrared ear thermometry and other temperature methods in adults. *Am J Crit Care*. 1994;3:40-54.
50. Klein DG, Mitchell C, Petrinec A, et al. A comparison of pulmonary artery, rectal, and tympanic membrane temperature measurement in the ICU. *Heart Lung*. 1993;22:435-441.
51. Erickson RS, Kirkin SK. Comparison of ear-based, bladder, oral, and axillary methods for core temperature measurement. *Crit Care Med*. 1993;21:1528-1534.
52. Romano MJ, Fortenberry JD, Autrey E, et al. Infrared tympanic thermometry in the pediatric intensive care unit. *Crit Care Med*. 1993;21:1181-1185.
53. Nierman DM. Core temperature measurement in the intensive care unit. *Crit Care Med*. 1991;19:818-823.
54. Milewski A, Ferguson KL, Terndrup TE. Comparison of pulmonary artery, rectal, and tympanic membrane temperatures in adult intensive care unit patients. *Clin Pediatr*. 1991;30:13-16; discussion 34-35.
55. Gerbrandy J, Snell E, Cranston W. Oral, rectal, and oesophageal temperatures in relation to central temperature control in man. *Clin Sci (Colch)*. 1954;13:615-624.
56. Molnar G, Read R. Studies during open-heart surgery on the special characteristics of rectal temperature. *J Appl Physiol*. 1974;36:333-336.

168

Clinical Study No. (b)(4) 

169



Clinical Study No. (b)(4)

234

Section 10 Biocompatibility

280

Biocompatibility

Exergen drawings and specifications call for all case parts to be made from (b))
(b)(4) They also call for use of an FDA approved material. Checks with
suppliers indicate the material used for the casing of the TemporalScanner is commonly
used as a casing for medical devices.

287

Section 11 Software

852

Attached is the firmware validation for the TemporalScanner.

(b)(4)

(b)(4)

283

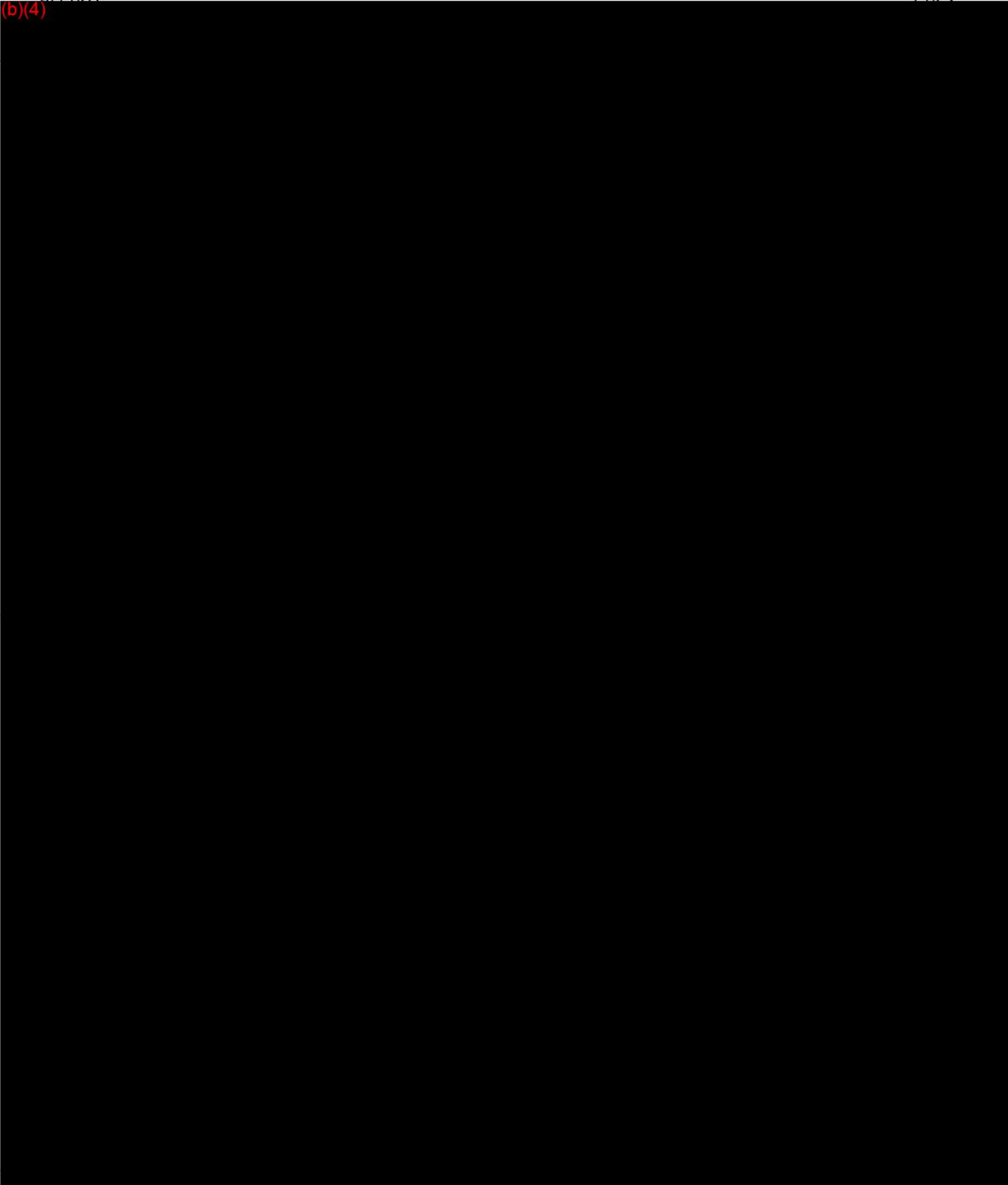
Exergen Corporation
Firmware Mitigation Plan

(b)(4)

4/11/01

1 of 7

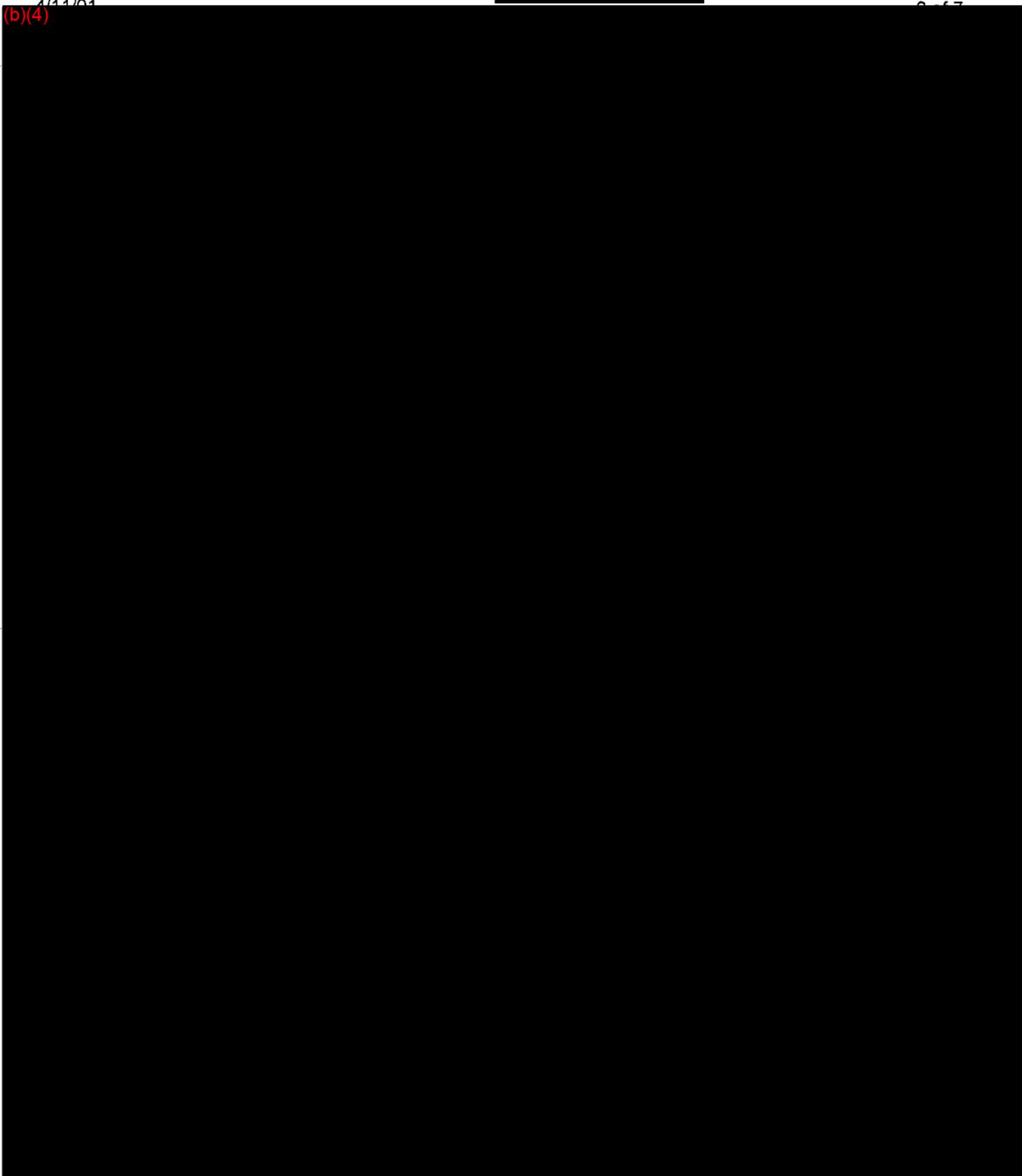
(b)(4)



284

Exergen Corporation
Firmware Validation Plan (b)(4)

4/11/01
(b)(4)



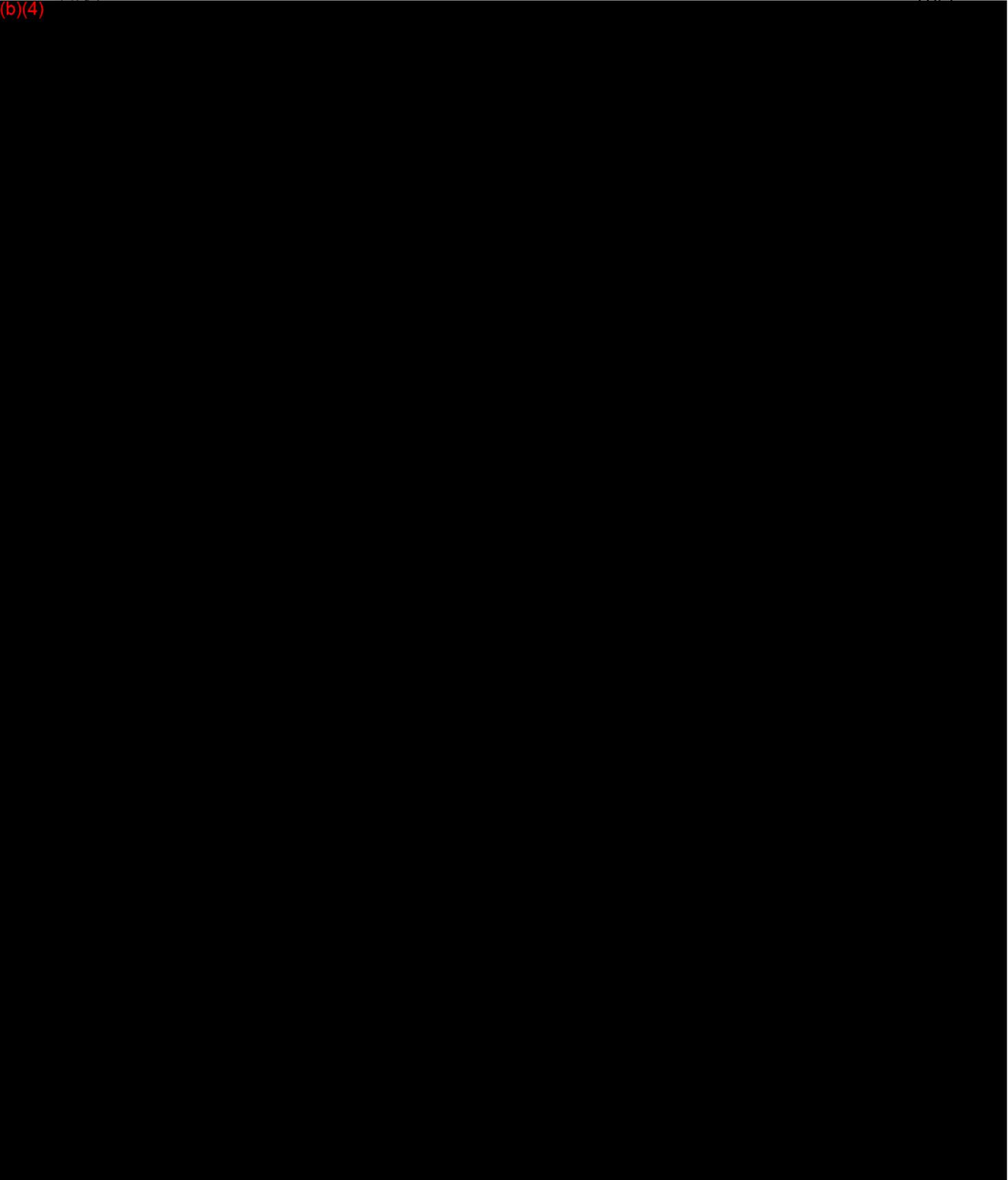
285

Exergen Corporation
Firmware Validation Plan, (b)(4)

4/11/01

3 of 7

(b)(4)



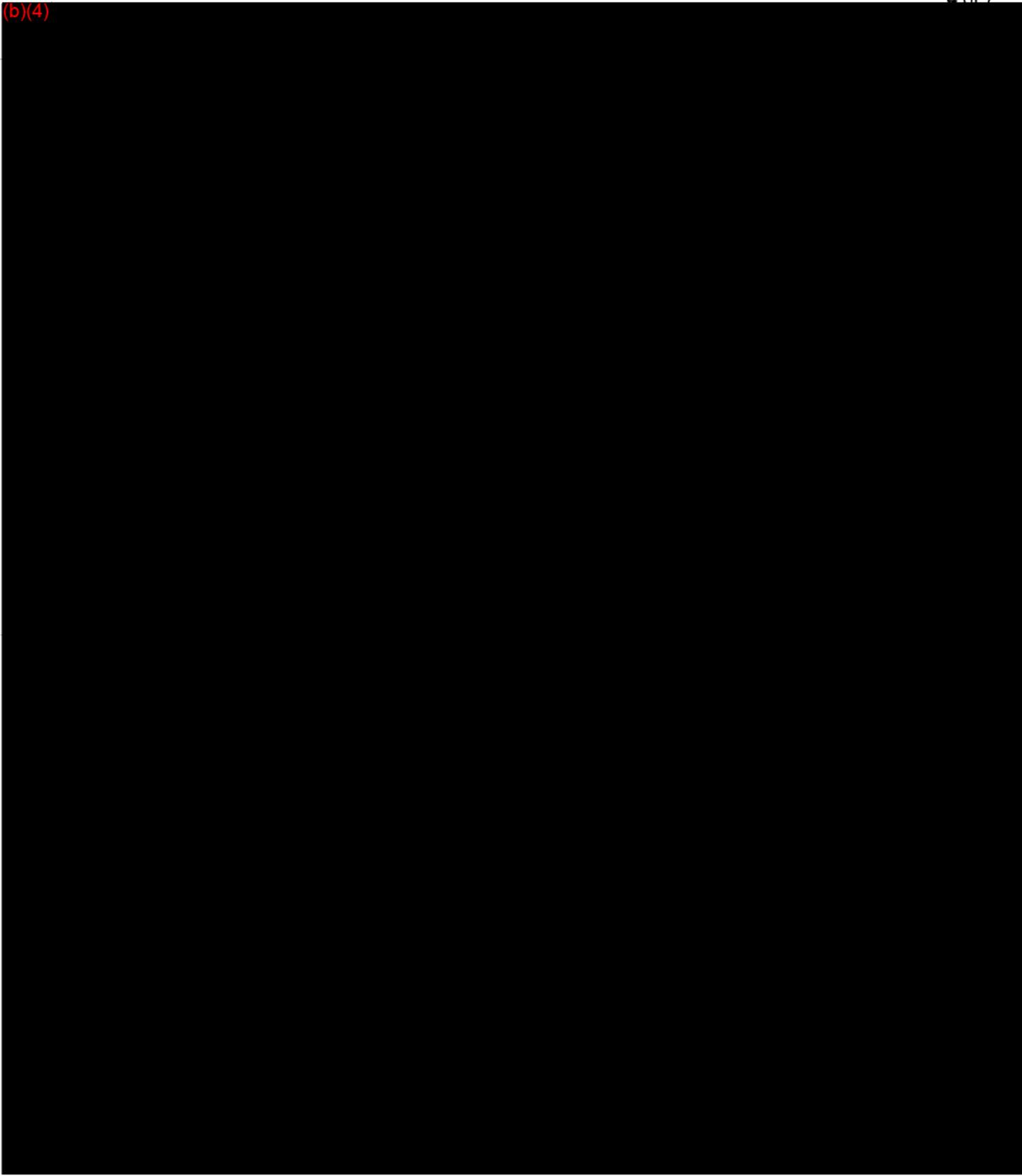
286

Exergen Corporation
Firmware Validation Plan, (b)(4)

4/11/01

4 of 7

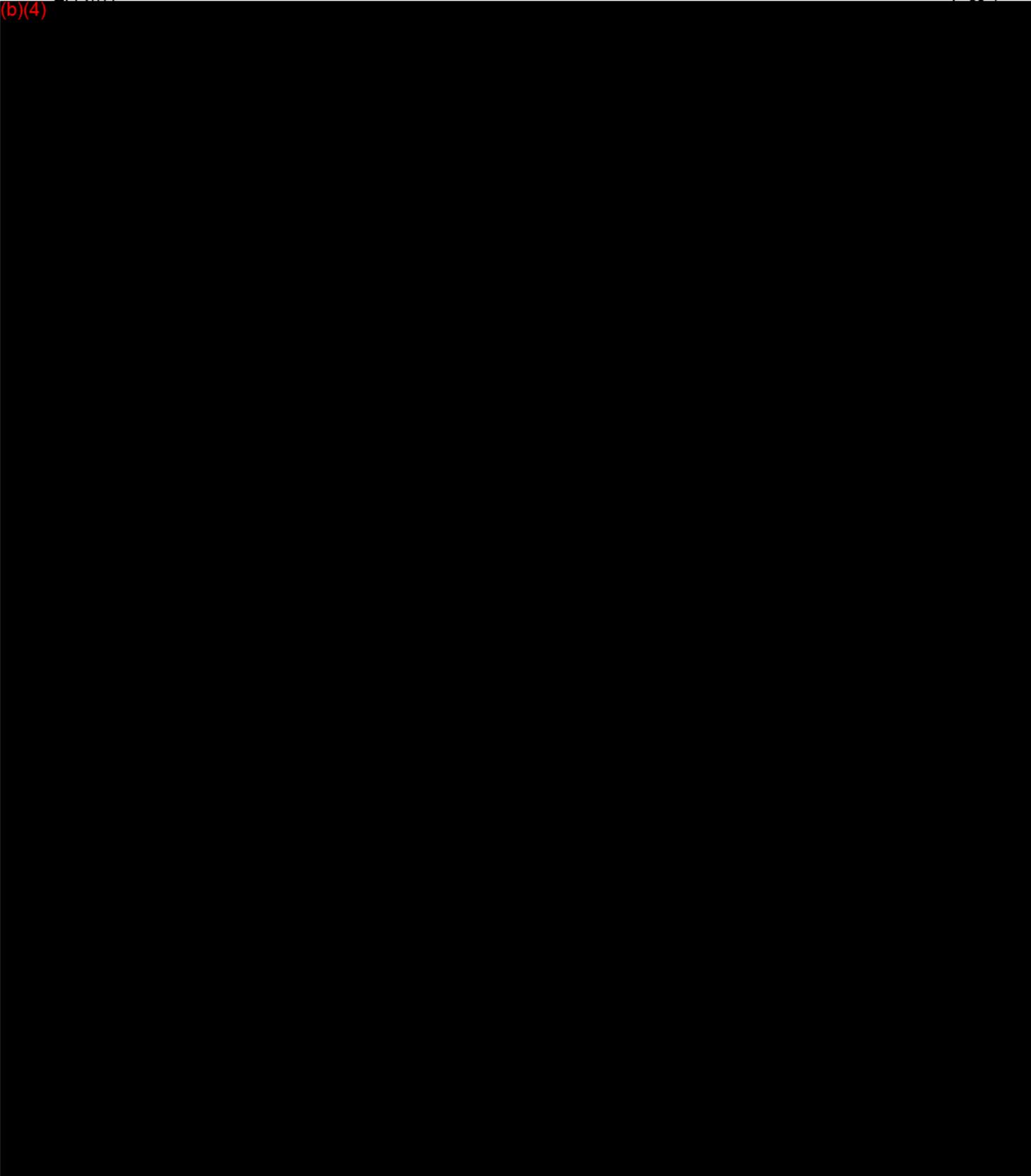
(b)(4)



287

Exergen Corporation
Firmware Validation Plan (b)(4)

4/11/01



(b)(4)

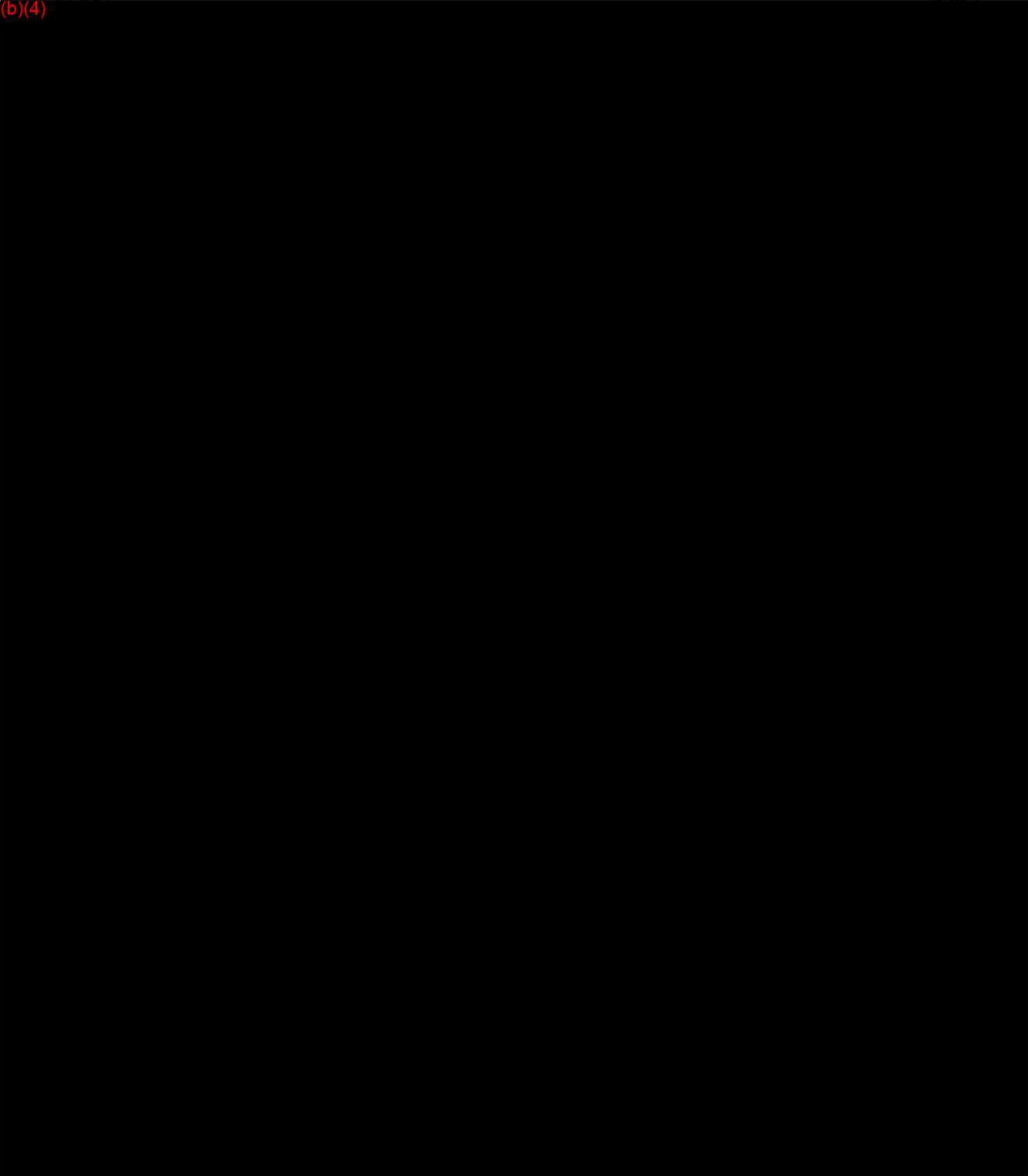
288

Exergen Corporation
Firmware Validation Plan, (b)(4)

4/11/01

(b)(4)

6 of 7



289

Exergen Corporation
Firmware Mitigation Plan

4/11/01

7 of 7

(b)(4)



JL

Section 12

Financial Certification Submitted Pursuant to 21 CFR Part 54

Certification Pursuant to 21 CFR Part 54

By its duly authorized representative, Exergen Corporation (Exergen) hereby certifies that, in none of the clinical studies supporting this section 510(k) premarket notification for the TemporalScanner (Submitted Studies), did any of the clinical investigators have any financial interests in the Submitted Studies which were required to be disclosed to the Food and Drug Administration pursuant to 21 CFR (b)(6)

Signed this ^R26 day of April

(b)(6)

VICE PRESIDENT
Title

(b)(4) doc

JBT

FDA/CDRH IMAGING SYSTEM
Page Count Discrepancy Information

The page after page 121 was numbered 123.

Verifiers Initials

(b)(6)

A large black rectangular redaction box covers the area where the Verifiers Initials would be located.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 12 2001

Exergen Corporation
C/O Mr. William Hare
Associate
Fish and Richardson, PC
601 13th Street, NW
Washington, DC 20005

Re: K011291
Trade/Device Name: TemporalScanner Thermometer,
SensorTouch
Regulation Number: 880.2910
Regulatory Class: II
Product Code: FLL
Dated: April 27, 2001
Received: April 27, 2001

Dear Mr. Hare:

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 legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). 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 Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory

Page 2 - Mr. Hare

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.

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) 594-4692. 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" (21CFR 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 "<http://www.fda.gov/cdrh/dsma/dsmamain.html>".

Sincerely yours,



to Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K011291
Device Name: TemporalScanner Thermometer

Indications For Use: The TemporalScanner Thermometer is an infrared thermometer intended for the intermittent measurement of human body temperature of people of all ages.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____
Per 21 CFR 801.109)

OR

Over-The-Counter Use

(Optional Format 1-2-96)

90428.W11

Susan Remy

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices

510(k) Number K011291

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

3

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

Memorandum

From: Reviewer(s) - Name(s) William M. Burdick

Subject: 510(k) Number K 011291

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

- Refused to accept.
- Requires additional information (other than refuse to accept).
- Is substantially equivalent to marketed devices.
- NOT substantially equivalent to marketed devices.

De Novo Classification Candidate? YES NO

Other (e.g., exempt by regulation, not a device, duplicate, etc.)

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

This 510(k) contains:

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

A 510(k) summary OR A 510(k) statement

The required certification and summary for class III devices *N/A*

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

Material of Biological Origin YES NO

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

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

Predicate Product Code with class:

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

80 FLL, Class II

800-29102 Electronic Thermometer (Infrared)

Review: Patricia Cuervo
(Branch Chief)

CD/DB
(Branch Code)

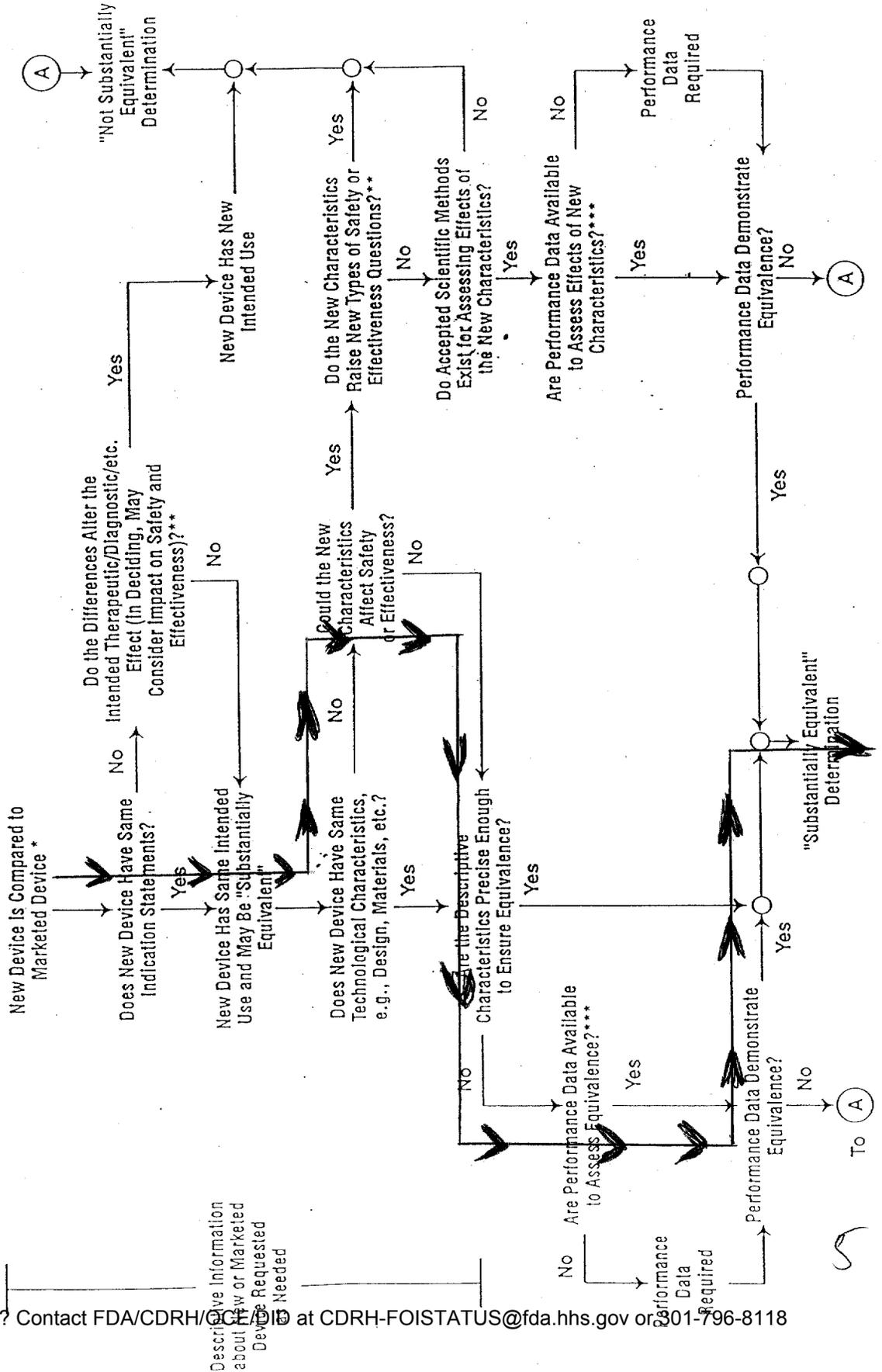
7/12/01
(Date)

Final Review: Susan Punon
(Division Director)

7/12/01
(Date)

Revised: 8/17/99

510(k) "Substantial Equivalence" Decision-Making Process (Detailed)



Questions? Contact FDA/CDRH/OCE/DTP at CDRH-FOISTATUS@fda.hhs.gov or 201-796-8118

* 510(k) Submissions Compare New Devices to Marketed Devices. FDA Requests Additional Information if the Relationship Between Marketed and "Predicate" (Pre-Amendment or Reclassified Post-Amendments) Devices is Unclear.
 ** This Decision is Normally Based on Descriptive Information Alone, But Information is Sometimes Required.
 *** Data May be Limited To the 510(k), Other 510(k)s, The Center's Classification Files, or the Literature.

"SUBSTANTIAL EQUIVALENCE" (SE) DECISION MAKING DOCUMENTATION

K011291

Reviewer: William M. Burdick

Division/Branch: DDIGD/GHDB

Device Name: Exergen TemporalScanner Infrared Thermometer

Product To Which Compared (510(K) Number If Known): Please refer to 3L of attached "510(k) REVIEW".

		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?		X	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?	X		If NO = Request Data
11.	Data Demonstrate Equivalence?	X		Final Decision: SE

(Continued on Next Page.)

1. Intended Use: Please refer to #2 of attached "510(k) REVIEW".
2. Device Description: Provide a statement of how the device is either similar to and/or different from other marketed devices, plus data (if necessary) to support the statement. Is the device life-supporting or life sustaining? Is the device implanted (short-term or long-term)? Does the device design use software? Is the device sterile? Is the device for single use? Is the device for home use or prescription use? Does the device contain drug or biological product as a component? Is this device a kit? Provide a summary about the devices design, materials, physical properties and toxicology profile if important.

Please refer to #1 of attached "510(k) REVIEW".

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

1. Explain why not a device: N/A
2. Explain why not subject to 510(k): N/A
3. How does the new indication differ from the predicate device's indication: N/A
4. Explain why there is or is not a new effect or safety or effectiveness issue: N/A
5. Describe the new technological characteristics: Please refer to 3N of attached "510(k) REVIEW".
6. Explain how new characteristics could or could not affect safety or effectiveness: The new characteristics are design, component, and software changes which are characteristics of legally marketed predicate devices.
7. Explain how descriptive characteristics are not precise enough: Clinical testing was necessary to assure that the thermometer would provide accurate measurements over the range of possible body temperatures for all patient ages from neonatal to geriatric.
8. Explain new types of safety or effectiveness questions raised or why the questions are not new: N/A
9. Explain why existing scientific methods can not be used: N/A
10. Explain what performance data is needed: N/A
11. Explain how the performance data demonstrates that the device is or is not substantially equivalent: The clinical results supported the clinical accuracy of the thermometer.

ATTACH ADDITIONAL SUPPORTING INFORMATION

Please refer to the attached "510(k) REVIEW".

Page 1 of 510(k) review

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

K011291

DATE: July 6, 2001

FROM: William M. Burdick

DIVISION: DDIGD/GHDB

COMPANY NAME: Exergen Corporation

DEVICE NAME: Exergen TemporalScanner Infrared Thermometer

"SUBSTANTIAL EQUIVALENCE" (SE) DECISION-MAKING DOCUMENTATION

NARRATIVE DEVICE DESCRIPTION

1. SUMMARY DESCRIPTION OF THE DEVICE UNDER REVIEW:

This submission is for a hand-held, battery-operated, infrared forehead thermometer designed to measure the temperature of the surface of the skin over the temporal artery. This device, as with all infrared thermometers, measures the infrared radiation emitted by the patient and converts the measurement to a temperature according to the Stefan-Boltzman Law. IR sensing is based on thermopile instead of pyroelectric technology for this device. The structure of the sensor is based on conventional semiconductor technology and includes a housing in which a layer of (b)(4) material is covered with a thermocouple film. When the thermocouple film is struck by infrared radiation, the temperature of the thermocouple film changes. Voltages are generated that are indicative of the amount of infrared radiation received and the ambient temperature as measured by a thermistor. These outputs are amplified and conditioned, and the resulting signals are sent to a microprocessor within the unit. In the microprocessor, algorithms are used to convert the amplified and conditioned signals to a body temperature measurement. For additional technical information, please refer to ATTACHMENT A.

Clinical testing was performed in order to assure the accuracy of the subject thermometer. The clinical test results appeared to be satisfactory (please refer to consult memorandum from Dr. Joy Samuels-Reid). Dr. Samuels-Reid stated that, "The sponsor will need to provide explicit instructions for placement of the device during temperature taking." It appears that the sponsor has provided adequate instructions in the Directions for Use (DFU).

Bench test data was not provided in this submission, but the sponsor did claim conformance to the FDA consensus standard for infrared thermometers. ASTM E 1965-98.

2. INTENDED USE:

This device is an infrared thermometer intended for the intermittent measurement of human body temperature of people of all ages.

DEVICE DESCRIPTION:

- A. Life-supporting or life-sustaining: No
- B. Implant (short-term or long-term): No

Page 2 of 510(k) review

- C. Is the device sterile? No
If yes, is sterility information provided? No
- D. Is the device for single use? No
- E. Is the device for prescription use? No
- F. Is the device for home use or portable? Yes
Whether the answer is yes or no, is adequate environmental testing, including EMC, performed for the intended environment, and are results provided, including test protocols, data, and a summary? Yes
- G. Does the device contain drug or biological product as a component?
No
- H. Is this device a kit? No
- I. Software-driven: Yes
Estimated level of concern: (Major, Moderate, Minor)? Moderate
Has the firm provided a hazard analysis, software requirements and design information, adequate test plans/protocols with appropriate data and test reports, documentation of the software development process including quality assurance activities, configuration management plan, and verification activities and summaries, commensurate with the level of concern, as discussed in the Reviewer Guidance for Computer Controlled Medical Devices? Yes
Software version: N/A
- J. Electrically Operated: Yes (battery-operated)
If yes, are AAMI or IEC leakage currents met and is the test protocol, data, and results provided? Yes, EN 60601-1
- K. Applicable standards to which conformance has been demonstrated (e.g., IEC, ANSI, ASTM, etc.):
- ASTM E 1965-98: Standard Specification for Infrared Thermometers for Intermittent Determination of Patient Temperature.
 - EN 60601-1:1990 - Medical Electrical Equipment Part 1: General Requirements for Safety.
 - EN 606011-1-2:1993 - Medical Electrical Equipment Part 1: General Requirements for Safety; 2. Collateral standard: Electromagnetic Compatibility - Requirements and Tests.
 - EN 55011 - EMC.
- L. Device(s) to which equivalence is claimed, manufacturer, and 510(k) number or preamendment status:
- Thermoscan Clinical Electronic Thermometer, Model IRT 3020/3520 (K983295), mfred. by Braun.
- M. Submission provides comparative specifications? Yes
comparative in in vitro data? No
performance data? No
animal testing? No
clinical testing? Yes
biocompatibility testing? No

Page 3 of 510(k) review

- N. Provide a statement of how the device is either similar to and/or different from other marketed devices, plus data (if necessary) to support the statement. Provide a summary about the devices design, materials, physical properties and toxicology profile if important.

Please refer to ATTACHMENT B for a comparison of the relative similarities and differences between the two devices.

No new issues of safety or effectiveness exist for this device.

- O. Does the submission include a summary of safety and effectiveness information upon which an equivalence determination is based? Yes

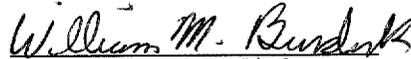
P. RECOMMENDATION:

I believe that this device is equivalent to: 80 FLL

Classification should be based on:

880.2910 - Clinical Electronic Thermometer (Infrared Thermometer)

Class: II


William M. Burdick
Biomedical Engineer

- Attachments: ATTACHMENT A - Technical Specifications
ATTACHMENT B - SE Comparison

cc.: K011291
Burdick/CHRON

ATTACHMENT 13

Substantial Equivalence Table

Item	Exergen TemporalScanner Thermometer (TemporalScanner) [†]	Exergen Surface Temperature Scanner (Exergen Predicate)	Braun Thermoscan IRT 3020/3520 Thermometer K983295 (Braun Predicate)
Intended Use	The TemporalScanner Thermometer is an infrared thermometer intended for the intermittent measurement of human body temperature of people of all ages.	The Surface Temperature Scanner is intended for the intermittent determination of surface temperature anywhere on the skin surface of a patient	The Braun predicate is intended for the intermittent measurement and monitoring of human body temperature in the home for use on people of all ages.
Where used	Skin surface of the forehead	Anywhere on the skin surface	Skin surface of the auditory canal
Technology Used	Arterial Heat Balance	Arterial Heat Balance	Arterial Heat Balance
Performance Specifications:			
Measurement range (max accuracy)	60 °F to 107.6 °F (15.5 °C to 42 °C)	96 °F to 102 °F (35 °C to 39 °C)	68 °F to 108 °F (20 °C to 42.2 °C)
Total range (min accuracy)	60 °F to 107.6 °F (15.5 °C to 42 °C)	60 °F to 110 °F (15 °C to 43 °C)	68 °F to 108 °F (20 °C to 42.2 °C)
Accuracy (max)	+/- 0.4 °F (0.2 °C)	+/- 0.2 °F (0.1 °C)	+/- 0.4 °F (0.2 °C)
Operating Ambient Range:			
Temperature	60 to 104 °F (15.5 to 40 °C)	65 °F to 95 °F (18 °C to 35 °C)	50 °F to 104 °F
Humidity	Per ASTM 1965-98, up to 95% noncondensing	Per ASTM 1965-98, up to 95% noncondensing	Per ASTM 1965-98, up to 95% noncondensing
Display resolution	0.1 °F or °C	0.1 °F or °C	0.1 °F or °C
Temperature scales	degrees F or C (factory selectable)	degrees F or C (user selectable)	degrees F or C (user selectable)
Storage:			
Temperature	-4° to 122 °F (-20 to 50 °C)	-4° to 122 °F (-20 to 50 °C)	-4° to 122 °F (-20° to 50 °C)

[†] Formerly the SensorTouch

humidity (max)	up to 95% noncondensing	up to 95% noncondensing	95% noncondensing
Electromagnetic compatible	Yes per EN 60601-1-2	Yes per EN 60601-1-2	Yes per EN 60601-1-2
Item	SensorTouch and Exergen TemporalScanner Thermometer (TemporalScanner)*	Exergen Surface Temperature Scanner K873010 (Exergen Predicate)	Braun Thermoscan IRT 3020/3520 Thermometer K983295 (Braun Predicate)
Display modes	Displayed temperature is the actual temperature of the temple artery plus a mathematical adjustment to approximate the familiar rectal range	Displayed temperature is the actual temperature of the surface of the skin at the point of measurement.	Displayed temperature is the actual ear temperature plus a mathematical adjustment to approximate the familiar oral range
Power source	9 volt Alkaline	9 volt Alkaline	2 lithium batteries CR/2032/DL 2032
display	LCD	LED	LCD
IR transducer	Thermopile	Thermopile	Thermopile
Indicators			
Battery low warning	yes, audible and visual	yes, audible	yes
User error	Yes	no	yes
Instrument Malfunction	Yes	no	yes
Disposable covers	not required	not required	yes
Case material	(b)(4)	(b)(4)	unknown
memory function	No	no	yes
Auto off	Yes	yes	yes
Standards met	ASTM E1965-98	ASTM E1965-98	ASTM E1965-98
UL listed	Yes	no	yes
CE mark	Yes	Yes	yes

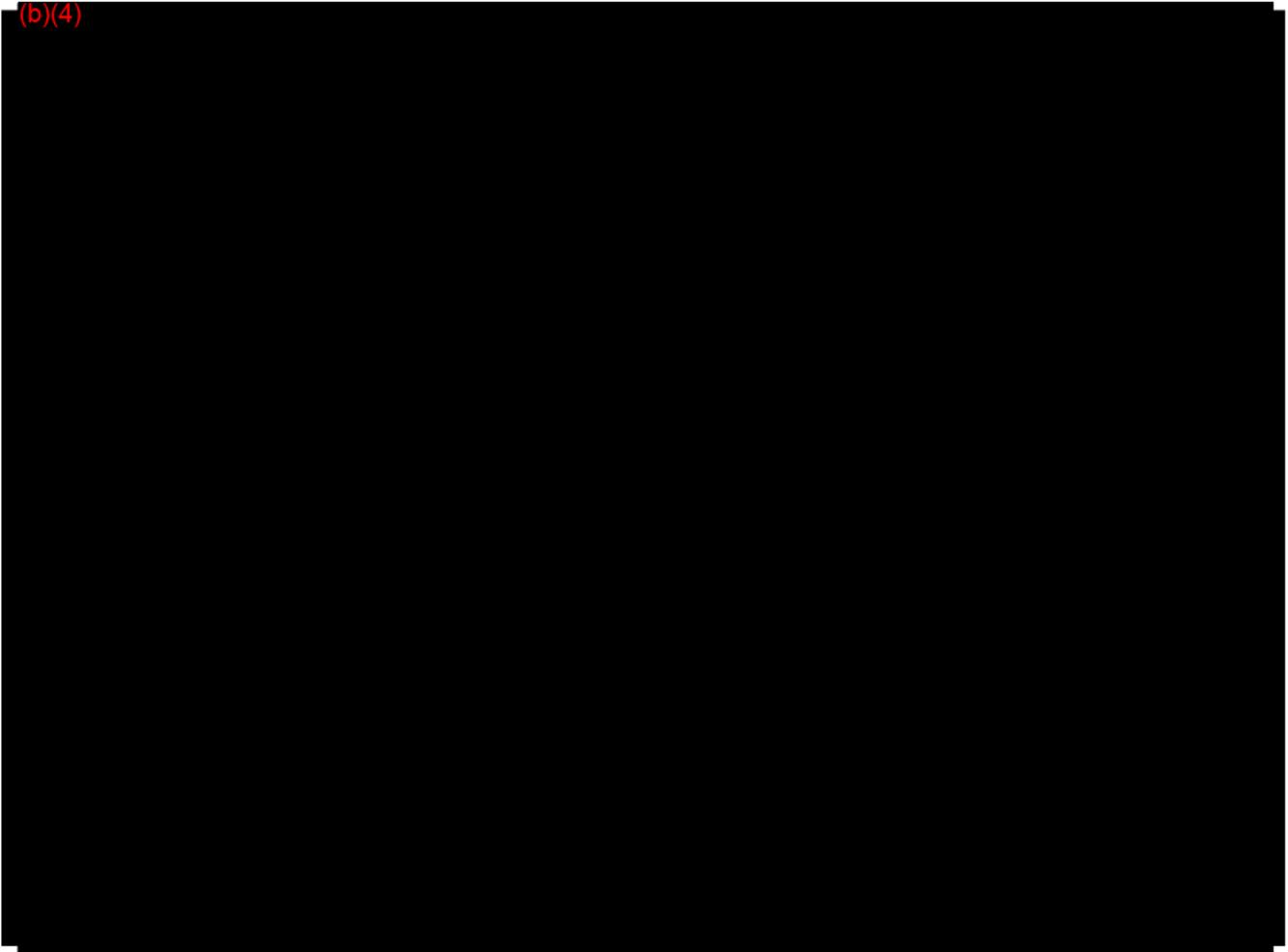
Discussion of Table

Similarities:

1. Same intended use demonstrates equivalence.
2. All units meet the same standard; therefore, the three devices should perform the same.
3. All units are battery operated.
4. All units use solid-state displays, minimizing battery drain.
5. All units have warning displays, such as battery low.
6. All units are CE marked, showing an independent third party assessment of the safety of the devices.
7. The SensorTouch, (renamed TheTemporalScanner), and the Thermoscan are UL listed, another independent third party assessment of the safety of the devices.
8. Consumer Report evaluation on the SensorTouch and the Thermoscan shows an independent third party assessment of the performance of the two devices.

Differences:

(b)(4)



ATTACHMENT A

Product Specifications

Clinical Accuracy	Meets ASTM E1965-98 and MDD 93142/EEC standards for electronic and radiation thermometers to the extent applicable to thermometers which measure the surface of the skin over the temporal artery.
Regulatory Approvals	CE Mark to -0197, TUV, Declaration of Conformity-ISO 9003/08.94, NIST certifiable traceable calibrations.
EMI/ RFI Protection	Error message displayed
Calibration Protection	Error message displayed
Temperature Range	15.5 to 42°C (60 to 107.5°F)
Operating Environment	15.5 to 40°C (60 to 104°F)
Resolution	0.1°C or °F
Response Time	Approximately 0.004 seconds
Time Displayed on Screen	30 seconds before automatic shutdown
Battery Life	Approximately 7,500 readings
Size	7.0 in x 1.75 in x 1.25 in(17.8 cm x 4.45 cm x 3.18 cm)
Weight	4.16 oz (120 grams) incl batt
Display Type	High contrast LCD
Construction Method	Impact resistant casing, Hermetically sealed sensing system
Warranty	1 Year
Laboratory Error:	+/- 4°F (+/- 0.2°C)
Storage Range:	-4°F - 122°F (-20°C-50°C)

14

Date: June 12, 2001

From: Joy H. Samuels-Reid, M.D., Medical Officer, CDRH/DDIGD

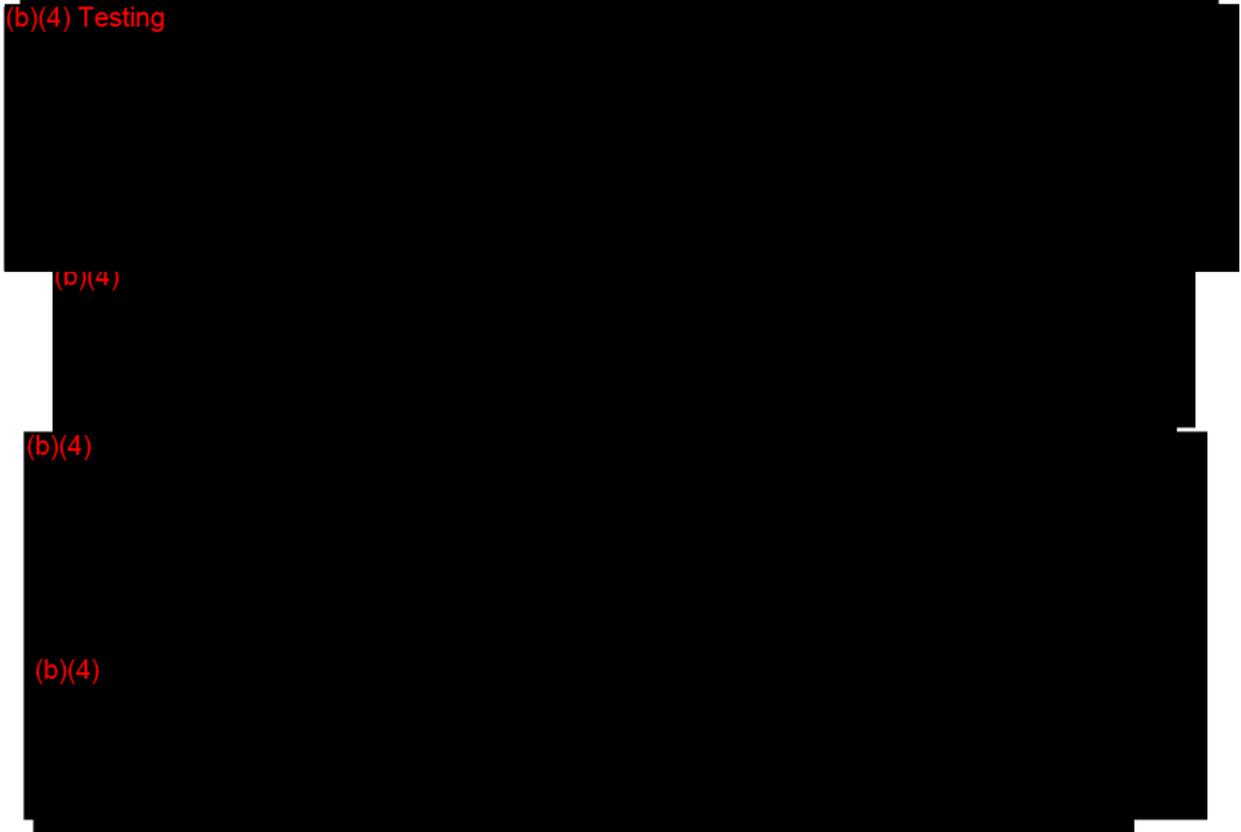
To: William M. Burdick, Biomedical Engineer, CDRH/ ODE/DDIGD/GHDB

Device: Exergen Temporal Scanner Infrared Thermometer -K011291

Sponsor: Exergen Corporation

Re: Clinical Trials

(b)(4) Testing



(b)(4)

(b)(4)

(b)(4)

The supporting data, taken together, provide adequate documentation for the temporal artery thermometer as an adjunct in assessing temperature. The sponsor will need to provide explicit instructions for placement of the device during temperature taking. It will be necessary to specify site or technique differences due to age.



Joy H. Samuels-Reid, M.D.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

MEMORANDUM

Food and Drug Administration
Office of Device Evaluation
9200 Corporate Avenue
Rockville, MD 20850

REQUEST FOR CONSULTING REVIEW

Date: June 4, 2001

From: William M. Burdick, Biomedical Engineer, CDRH/ODE/DDIGD/GHDB (HFZ-480)

To: Joy Samuels-Reid, M.D., Medical Officer, CDRH/ODE/DDIGD (HFZ-480)

PMA/IDE/510(k)#: K011291

Device Name: Exergen TemporalScanner Infrared Thermometer

Sponsor Name: Exergen Corporation

REASON FOR REQUEST

- New Submission Response to Deficiency Letter
- Protocol Change Design Change
- New Material(s) Labeling
- Indication(s)
- Other: _____

TYPE OF REVIEW REQUESTED

- Engineering Materials
- Sterility Toxicology
- Clinical Statistical
- Labeling Regulatory Status Determination
- Jurisdiction Determination
- Other: _____

COMMENTS: Joy,

I need an assessment from you that their clinical trials are okay for this thermometer. Sorry I didn't get it to you, sooner. Please be aware that this is a **forehead IR thermometer**. Their site of placement of the thermometer IR sensor must be stated in a very specific manner. Any questions, I will be in on Wednesday.

Bill

Please Respond By: July 11, 2001

Signature of Requester: William M. Burdick

16

Screening Checklist

For all Premarket Notification 510(k) Submissions

3-30-01

Device Name: <i>Temperalscanner Thermometer</i>						K 011291						
Submitter (Company): <i>Exergen Corp.</i>												
Items which should be included (circle missing & needed information)						S P E C I A L	A B B R E V I A T E D		T R A D I T I O N A L		✓ IF ITEM IS NEEDED AND IS MISSING	
						YES	NO	YES	NO	YES	NO	
1. Cover Letter clearly identifies Submission as:												
a) "Special 510(k): Device Modification"										✓		
b) "Abbreviated 510(k)"												
c) Traditional 510(k)						GO TO # 2,3		GO TO # 2,4,5		GO TO #2, 5		
2. GENERAL INFORMATION: REQUIRED IN ALL 510(K) SUBMISSIONS												✓ IF ITEM IS NEEDED
Financial Certification or Disclosure Statement for 510(k)s with a Clinical Study 807.87(i) including forms 3454 and/or 3455						NA		YES		NO		AND IS MISSING
						SPECIALS		ABBREVIATED		TRADITIONAL		
						YES	NO	YES	NO	YES	NO	
a) trade name, classification name, establishment registration number, device class										✓		
b) OR a statement that the device is not yet classified						FDA-may be a classification request; see coordinator						
c) identification of legally marketed equivalent device						NA				✓		
d) compliance with Section 514 - performance standards						NA				✓		
e) address of manufacturer										✓		
f) Truthful and Accurate Statement										✓		
g) Indications for Use enclosure										✓		
h) SMDA Summary or Statement (FOR ALL DEVICE CLASSES)										✓		
i) Class III Certification & Summary (FOR ALL CLASS III DEVICES)										✓		
j) Description of device (or modification) including diagrams, engineering drawings, photographs, service manuals										✓		
k) Proposed Labeling:										✓		
i) package labeling (user info)										✓		
ii) statement of intended use										✓		
iii) advertisements or promotional materials										✓		
i) MRI compatibility (if claimed)										✓		
l) Comparison Information (similarities and differences) to named legally marketed equivalent device (table preferred) should include:										✓		
i) Labeling										✓		
ii) intended use										✓		
iii) physical characteristics										✓		
iv) anatomical sites of use										✓		
v) performance (bench, animal, clinical) testing						NA						
vi) safety characteristics						NA						
m) If kit, kit certification										✓		
3. "SPECIALS" - ONLY FOR MODIFICATIONS TO MANUFACTURER'S OWN CLASS II, III OR RESERVED CLASS I DEVICE												
a) Name & 510(k) number of legally marketed (unmodified) predicate device												
b) STATEMENT - INTENDED USE AND INDICATIONS FOR USE OF MODIFIED DEVICE AS DESCRIBED IN ITS												
						* if no - STOP not a special						

LABELING HAVE NOT CHANGED*				
c)	STATEMENT - FUNDAMENTAL SCIENTIFIC TECHNOLOGY OF THE MODIFIED DEVICE HAS NOT CHANGED*			* If no - STOP not a special
d)	Design Control Activities Summary			
i)	Identification of Risk Analysis method(s) used to assess the impact of the modification on the device and its components, and the results of the analysis			
ii)	Based on the Risk Analysis, an identification of the verification and/or validation activities required, including methods or tests used and acceptance criteria to be applied			
iii)	A declaration of conformity with design controls. The declaration of conformity should include:			
	1) A statement signed by the individual responsible, that, as required by the risk analysis, all verification and validation activities were performed by the designated individual(s) and the results demonstrated that the predetermined acceptance criteria were met			
	2) A statement signed by the individual responsible, that manufacturing facility is in conformance with design control procedure Requirements as specified in 21 CFR 820.30 and the records are available for review.			

	SPECIALS		ABBREVIATED		TRADITIONAL		✓ IF ITEM IS NEEDED AND IS MISSING
	YES	NO	YES	NO	YES	NO	
4. ABBREVIATED 510(K): SPECIAL CONTROLS/CONFORMANCE TO RECOGNIZED STANDARDS - PLEASE FILL OUT THE STANDARDS ABBREVIATED FORM ON THE H DRIVE							
a)	For a submission, which relies on a guidance document and/or special control(s), a summary report that describes how the guidance and/or special control(s) was used to address the risks associated with the particular device type						
b)	If a manufacturer elects to use an alternate approach to address a particular risk, sufficient detail should be provided to justify that approach.						
c)	For a submission, which relies on a recognized standard, a declaration of conformity to the standard. The declaration should include the following:						
	i) An identification of the applicable recognized consensus standards that were met						
	ii) A specification, for each consensus standard, that all requirements were met, except for inapplicable requirements or deviations noted below						
	iii) An identification, for each consensus standard, of						

18

any way(s) in which the standard may have been adapted for application to the device under review, e.g., an identification of an alternative series of tests that were performed			
iv) An identification, for each consensus standard, of any requirements that were not applicable to the device			
v) A specification of any deviations from each applicable standard that were applied			
vi) A specification of the differences that may exist, if any, between the tested device and the device to be marketed and a justification of the test results in these areas of difference			
vii) Name/address of test laboratory/certification body involved in determining the conformance of the device with applicable consensus standards and a reference to any accreditations for those organizations			
d) Data/information to address issues not covered by guidance documents, special controls, and/or recognized standards			

5. Additional Considerations: (may be covered by Design Controls)							
a) Biocompatibility data for all patient-contacting materials, OR certification of identical material/formulation:							
i) component & material							
ii) identify patient-contacting materials							
iii) biocompatibility of final sterilized product							
b) Sterilization and expiration dating information:							
i) sterilization method							
ii) SAL							
iii) packaging							
iv) specify pyrogen free							
v) ETO residues							
vi) radiation dose							
c) Software validation & verification:							
i) hazard analysis							
ii) level of concern							
iii) development documentation							
iv) certification							

Items shaded under "NO" are necessary for that type of submission. Circled items and items with checks in the "Needed & Missing" column must be submitted before acceptance of the document.

Passed Screening Yes No

Reviewer: William M. Burdick
 Concurrence by Review Branch: 6/4/01

Date: MAY - 2 2001

Internal Administrative Form

	YES	NO
1. Did the firm request expedited review?		✓
2. Did we grant expedited review?		✓
3. Have you verified that the Document is labeled Class III for GMP purposes?		✓
4. If, not, has POS been notified?		✓
5. Is the product a device?	✓	
6. Is the device exempt from 510(k) by regulation or policy?	✓	✓
7. Is the device subject to review by CDRH?		
8. Are you aware that this device has been the subject of a previous NSE decision?		✓
9. If yes, does this new 510(k) address the NSE issue(s), (e.g., performance data)?		✓
10. Are you aware of the submitter being the subject of an integrity investigation?		✓
11. If, yes, consult the ODE Integrity Officer.		
12. Has the ODE Integrity Officer given permission to proceed with the review? (Blue Book Memo #191-2 and Federal Register 90N0332, September 10, 1991.		✓

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

April 30, 2001

EXERGEN CORP.
C/O FISH AND RICHARDSON, PC
601 13TH STREET, NW
WASHINGTON, DC 20005
ATTN: WILLIAM HARE

510(k) Number: K011291
Received: 27-APR-2001
Product: TEMPORALSCANNER
THERMOMETER,
SENSORTOUCH

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 (DSMA) at the telephone or web site below for more information.

Please remember that all correspondence concerning your submission MUST be sent to the Document Mail Center (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).

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

Sincerely yours,

Marjorie Shulman
Consumer Safety Officer
Premarket Notification Staff
Office of Device Evaluation

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

21

**Table of Contents to Section 510(k) Premarket
Notification of the TemporalScanner Thermometer
by Exergen Corporation**

Section	Title	Page
1	FDA Cover Sheet	1-1
2	Truthful and Accurate Statement	2-1
3	Performance Standards	3-1
4	Labeling	4-1
	Proposed TemporalScanner DFU	4-2
	Draft Device Labels for TemporalScanner Thermometer	4-13
	Exergen Predicate Device Labeling	4-16
	Braun Predicate Device Labeling	
5	Statement of Indications for Use	5-1
6	Substantial Equivalence Table	6-1
	Table	6-2
	Discussion of SE Table	6-3
7	Summary	7-1
8	Description	8-1
	Operational Block Diagram of Typical IR Thermometer	8-6
	Temporal Scanner Pictures	8-7
	Exergen Predicate Pictures	8-12
	Braun Predicate Pictures	8-20
	Flowchart for Algorithm	8-24
9	Performance Data	9-1
	Performance Data for Product Acceptance	9-2
	Declaration of Conformity to Directive 93/42/EEC	9-6
	EMC Testing Conducted By Phillips	9-9
	Safety Testing Conducted on Behalf of Exergen	9-11
	(b)(4) Testing Testing Conducted By Exergen	9-15
	Consumer Reports Testing	9-18
	Results of Clinical Testing	9-20

	Reports of Clinical Trials in (b)(4)	9-24
	Summary	9-25
	Clinical Study No. 1	9-30
	Clinical Study No. 2	9-37
	Clinical Study No. 3	9-87
	Clinical Study No. 4	9-99
	Clinical Study No. 5	9-101
10	Biocompatibility Data	10-1
11	Software	11-1
12	Clinical Trial Financial Certification	12-1

**Table of Contents to Section 510(k) Premarket
Notification of the TemporalScanner Thermometer
by Exergen Corporation**

Section	Title	Page
1	FDA Cover Sheet	1-1
2	Truthful and Accurate Statement	2-1
3	Performance Standards	3-1
4	Labeling	4-1
	Proposed TemporalScanner DFU	4-2
	Draft Device Labels for TemporalScanner Thermometer	4-15
	Exergen Predicate Device Labeling	4-18
	Braun Predicate Device Labeling	4-38
5	Statement of Indications for Use	5-1
6	Substantial Equivalence Table	6-1
	Table	6-2
	Discussion of SE Table	6-3
7	Summary	7-1
8	Description	8-1
	Operational Block Diagram of Typical IR Thermometer	8-6
	Temporal Scanner Pictures	8-7
	Exergen Predicate Pictures	8-12
	Braun Predicate Pictures	8-20
	Flowchart for Algorithm	8-24
9	Performance Data	9-1
	Performance Data for Product Acceptance	9-2
	[Redacted] Declaration of Conformity to Directive 93/42/EEC	9-6
	EMC Testing Conducted By Phillips	9-9
	Safety Testing Conducted on Behalf of Exergen	9-11
	(b)(4) Testing Conducted By Exergen	9-15
	Consumer Reports Testing	9-18
	Results of Clinical Trials in (b)(4)	9-20

200

	Reports of Clinical Trials in (b)(4)	9-24
	Summary	9-25
	Clinical Study No. 1	9-30
	Clinical Study No. 2	9-37
	Clinical Study No. 3	9-87
	Clinical Study No. 4	9-99
	Clinical Study No. 5	9-101
10	Biocompatibility Data	10-1
11	Software	11-1
12	Clinical Trial Financial Certification	12-1

11

Section 1

FDA Cover Sheet

42

CDRH SUBMISSION COVER SHEET

Date of Submission:

FDA Document Number:

Section A Type of Submission

PMA	PMA Supplement	PDP	510(k)	Meeting
<input type="checkbox"/> Original submission <input type="checkbox"/> Modular submission <input type="checkbox"/> Amendment <input type="checkbox"/> Report <input type="checkbox"/> Report Amendment	<input type="checkbox"/> Regular <input type="checkbox"/> Special <input type="checkbox"/> Panel Track <input type="checkbox"/> 30-day Supplement <input type="checkbox"/> 30-day Notice <input type="checkbox"/> 135-day Supplement <input type="checkbox"/> Real-time Review <input type="checkbox"/> Amendment to PMA Supplement	<input type="checkbox"/> Presubmission summary <input type="checkbox"/> Original PDP <input type="checkbox"/> Notice of intent to start clinical trials <input type="checkbox"/> Intention to submit Notice of Completion <input type="checkbox"/> Notice of Completion <input type="checkbox"/> Amendment to PDP <input type="checkbox"/> Report	<input type="checkbox"/> Original submission: <input type="checkbox"/> Traditional <input type="checkbox"/> Special <input type="checkbox"/> Abbreviated <input checked="" type="checkbox"/> Additional information: <input type="checkbox"/> Traditional <input type="checkbox"/> Special <input type="checkbox"/> Abbreviated	<input type="checkbox"/> Pre-IDE meeting <input type="checkbox"/> Pre-PMA meeting <input type="checkbox"/> Pre-PDP meeting <input type="checkbox"/> 180-day meeting <input type="checkbox"/> Other (specify):
IDE	Humanitarian Device Exemption	Class II Exemption	Evaluation of Automatic Class III Designation	Other Submission
<input type="checkbox"/> Original submission <input type="checkbox"/> Amendment <input type="checkbox"/> Supplement	<input type="checkbox"/> Original submission <input type="checkbox"/> Amendment <input type="checkbox"/> Supplement <input type="checkbox"/> Report	<input type="checkbox"/> Original submission <input type="checkbox"/> Additional information	<input type="checkbox"/> Original submission <input type="checkbox"/> Additional information	Describe submission:

Section B Applicant or Sponsor

Company / Institution name: Exergen Corporation	Establishment registration number: 1221195	
Division name (if applicable):	Phone number (include area code): (617) 923-9900	
Street address: 51 Water Street	FAX number (include area code): (617) 923-9911	
City: Watertown	State / Province: MA 02172	Country: USA
Contact name: Gerald A. Clay		
Contact title: Director, Regulatory Affairs	Contact e-mail address: gclay@exergen.com	

Section C Submission correspondent (if different from above)

Company / Institution name: Fish & Richardson, PC	Establishment registration number: NA	
Division name (if applicable):	Phone number (include area code): (202) 783-5070	
Street address: 601 13th Street, NW	FAX number (include area code): (202) 783-2331	
City: Washington	State / Province: DC	Country: USA 20005
Contact name: William Hare (Associate) or Jill B. Deal (Partner)		
Contact title:	Contact e-mail address: hare@fr.com deal@fr.com	

Section D1	Reason for Submission — PMA, PDP, or HDE	
<input type="checkbox"/> New device <input type="checkbox"/> Withdrawal <input type="checkbox"/> Additional or expanded indications <input type="checkbox"/> Licensing agreement <input type="checkbox"/> Process change <input type="checkbox"/> Manufacturing <input type="checkbox"/> Sterilization <input type="checkbox"/> Packaging <input type="checkbox"/> Other (specify below) <input type="checkbox"/> Response to FDA correspondence: <input type="checkbox"/> Request for applicant hold <input type="checkbox"/> Request for removal of applicant hold <input type="checkbox"/> Request for extension <input type="checkbox"/> Request to remove or add manufacturing site <input type="checkbox"/> Other reason (specify):	<input type="checkbox"/> Change in design, component, or specification: <input type="checkbox"/> Software <input type="checkbox"/> Color Additive <input type="checkbox"/> Material <input type="checkbox"/> Specifications <input type="checkbox"/> Other (specify below) <input type="checkbox"/> Labeling change: <input type="checkbox"/> Indications <input type="checkbox"/> Instructions <input type="checkbox"/> Performance Characteristics <input type="checkbox"/> Shelf life <input type="checkbox"/> Trade name <input type="checkbox"/> Other (specify below)	<input type="checkbox"/> Location change: <input type="checkbox"/> Manufacturer <input type="checkbox"/> Sterilizer <input type="checkbox"/> Packager <input type="checkbox"/> Distributor <input type="checkbox"/> Report submission: <input type="checkbox"/> Annual or periodic <input type="checkbox"/> Post-approval study <input type="checkbox"/> Adverse reaction <input type="checkbox"/> Device defect <input type="checkbox"/> Amendment <input type="checkbox"/> Change in ownership <input type="checkbox"/> Change in correspondent
Section D2	Reason for Submission — IDE	
<input type="checkbox"/> New device <input type="checkbox"/> Addition of institution <input type="checkbox"/> Expansion / extension of study <input type="checkbox"/> IRB certification <input type="checkbox"/> Request hearing <input type="checkbox"/> Request waiver <input type="checkbox"/> Termination of study <input type="checkbox"/> Withdrawal of application <input type="checkbox"/> Unanticipated adverse effect <input type="checkbox"/> Notification of emergency use <input type="checkbox"/> Compassionate use request <input type="checkbox"/> Treatment IDE <input type="checkbox"/> Continuing availability request <input type="checkbox"/> Other reason (specify):	<input type="checkbox"/> Change in: <input type="checkbox"/> Correspondent <input type="checkbox"/> Design <input type="checkbox"/> Informed consent <input type="checkbox"/> Manufacturer <input type="checkbox"/> Manufacturing process <input type="checkbox"/> Protocol - feasibility <input type="checkbox"/> Protocol - other <input type="checkbox"/> Sponsor <input type="checkbox"/> Report submission: <input type="checkbox"/> Current investigator <input type="checkbox"/> Annual progress <input type="checkbox"/> Site waiver limit reached <input type="checkbox"/> Final	<input type="checkbox"/> Response to FDA letter concerning: <input type="checkbox"/> Conditional approval <input type="checkbox"/> Deemed approved <input type="checkbox"/> Deficient final report <input type="checkbox"/> Deficient progress report <input type="checkbox"/> Deficient investigator report <input type="checkbox"/> Disapproval <input type="checkbox"/> Request extension of time to respond to FDA <input type="checkbox"/> Request meeting
Section D3	Reason for Submission — 510(k)	
<input type="checkbox"/> New device <input type="checkbox"/> Additional or expanded indications <input checked="" type="checkbox"/> Other reason (specify):	<input type="checkbox"/> Change in technology <input type="checkbox"/> Change in design	<input type="checkbox"/> Change in materials <input type="checkbox"/> Change in manufacturing process

YH

Section E Additional Information on 510(k) Submissions					
Product codes of devices to which substantial equivalence is claimed:				Summary of, or statement concerning, safety and effectiveness data: <input type="checkbox"/> 510(k) summary attached <input type="checkbox"/> 510(k) statement	
1880FLL	2	3	4		
5	6	7	8		
Information on devices to which substantial equivalence is claimed:					
510(k) Number	Trade or proprietary or model name			Manufacturer	
1 K873010	1 Surface Temperature Scanner			1 Exergen Corporation	
2 K983295	2 Thermoscan JRT 30201/3520			2 Braun Thermoscan	
3	3			3	
4	4			4	
5	5			5	
6	6			6	
Section F Product Information — Applicable to All Applications					
Common or usual name or classification name:					
Trade or proprietary or model name				Model number	
1 TemporalScanner Thermometer, SensorTouch				1 not known at this time	
2				2	
3				3	
4				4	
5				5	
FDA document numbers of all prior related submissions (regardless of outcome):					
1	2	3	4	5	6
7	8	9	10	11	12
Data included in submission: <input type="checkbox"/> Laboratory testing <input type="checkbox"/> Animal trials <input type="checkbox"/> Human trials					
Section G Product Classification — Applicable to All Applications					
Product code: 80FL	C.F.R. Section: 880.2910			Device class: <input type="checkbox"/> Class I <input checked="" type="checkbox"/> Class II <input type="checkbox"/> Class III <input type="checkbox"/> Unclassified	
Classification panel: General Hospital & Personal Use Device					
Indications (from labeling): The TemporalScanner Thermometer is an infrared thermometer intended for the intermittent measurement of human body temperature of subjects of all ages					

Note: Submission of this information does not affect the need to submit a 2891 or 2891a Device Establishment Registration form.		FDA Document Number:	
Section H Manufacturing / Packaging / Sterilization Sites Relating to a Submission			
<input checked="" type="checkbox"/> Original <input type="checkbox"/> Add <input type="checkbox"/> Delete		FDA establishment registration number:	
<input checked="" type="checkbox"/> Manufacturer <input type="checkbox"/> Contract manufacturer		<input type="checkbox"/> Contract sterilizer <input type="checkbox"/> Repackager / relabeler	
Company / Institution name: Exergen Corporation		Establishment registration number: 1221195	
Division name (if applicable):		Phone number (include area code): (617) 923-9900	
Street address: 51 Water St.		FAX number (include area code): (617) 923-9911	
City: Watertown	State / Province: MA 02172	Country: USA	
Contact name: Gerald A. Clay			
Contact title: Director, Regulatory Affairs		Contact e-mail address: gclay@exergen.com	
<input type="checkbox"/> Original <input type="checkbox"/> Add <input type="checkbox"/> Delete		FDA establishment registration number:	
<input type="checkbox"/> Manufacturer <input type="checkbox"/> Contract manufacturer		<input type="checkbox"/> Contract sterilizer <input type="checkbox"/> Repackager / relabeler	
Company / Institution name:		Establishment registration number:	
Division name (if applicable):		Phone number (include area code): ()	
Street address:		FAX number (include area code): ()	
City:	State / Province:	Country:	
Contact name:			
Contact title:		Contact e-mail address:	
<input type="checkbox"/> Original <input type="checkbox"/> Add <input type="checkbox"/> Delete		FDA establishment registration number:	
<input type="checkbox"/> Manufacturer <input type="checkbox"/> Contract manufacturer		<input type="checkbox"/> Contract sterilizer <input type="checkbox"/> Repackager / relabeler	
Company / Institution name:		Establishment registration number:	
Division name (if applicable):		Phone number (include area code): ()	
Street address:		FAX number (include area code): ()	
City:	State / Province:	Country:	
Contact name:			
Contact title:		Contact e-mail address:	

Section 2

Truthful and Accurate Statement

**PREMARKET NOTIFICATION
TRUTHFUL AND ACCURATE STATEMENT**

[As required by 21 CFR 807.87(k)]

I certify that, in my capacity as Director of Regulatory Affairs of *Exergen, Corporation*, I believe to the best of my knowledge, that all data and information submitted in the premarket notification are truthful and accurate and that no material fact has been omitted.

Gerald A. Clay

(Signature)

Gerald A. Clay

(Typed Name)

April 27, 2001

(Dated)

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

78

Section 3

Performance Standards

Performance Standards

The TemporalScanner Thermometer (formerly called the SensorTouch) has been tested to and found to comply with the following National or International voluntary standards:

1. ASTM E1965-98, and a working document (WD 124370-5) for EN 12470-5, the European Standard which is the European counterpart of ASTM E1965-98, to the extent these standards apply to an infrared thermometer which measures the temperature of the surface of the skin over the temporal artery.
2. EN 60601-1-2 - EMC
3. EN 55011 - EMC
4. EN60601-1 - Safety

Section 4 Labeling

Contents of Section 4 Labeling

Topic	Exhibit
Draft Instructions for Use for TemporalScanner Thermometer	4 -A
Draft Device Labels for TemporalScanner Thermometer	4 -B
Exergen Predicate Surface Temperature Scanner (Dermatemp) Labeling	4 - C
Braun Predicate (ThermoScan) Labeling	4 -D

Proposed Directions for Use for TemporalScanner

JS

Introduction

Congratulations and thank you for purchasing the Exergen TemporalScanner Thermometer for consumer use.

Your new TemporalScanner Thermometer is a totally non-invasive system with advanced infrared technology providing maximum ease of use with quick, consistently accurate measurements. Advanced, patented technology measures temperatures with a gentle stroke across the forehead.

The TemporalScanner Thermometer has been clinically tested for accuracy compared to rectal thermometers and accepted for use in major hospitals, making it the ideal thermometer for use with newborns, infants, children or adults.*

The TemporalScanner Thermometer has patented software, providing arterial heat balance. This unique process determines temperature by accurately measuring the balance between the tissues warming from arterial blood and tissues cooling caused by heat loss (gain) to the environment.

Why take temperature measurements at the skin surface over the temporal artery?

The best place to measure temperature is the center of the heart, but this can be done only under a doctor's supervision. Doctors know that measurement of the blood temperature in a major artery accurately reflects true body temperature. The TemporalScanner Thermometer is designed to measure the temperature of the skin surface over the temporal artery, a major artery.

The temporal artery is connected to the heart via the carotid artery, directly leading from the aorta, the main trunk of the arterial system. It offers constant blood flow. It is the only such artery positioned close enough to the skin surface to provide access needed to take an accurate measurement. It is easy to use because it is ideally located at the front portion of the forehead. The TemporalScanner is easier to use than other types of measurements devices such as oral, rectal, underarm and in-ear because it is non-invasive.

How does the TemporalScanner Thermometer work?

As you gently stroke the thermometer across the forehead crossing over the temporal artery, the sensor in its head performs two processes:

First, it scans like a video camera, capturing naturally emitted infrared heat from the arterial blood supply locking in the highest temperature it senses and;

* Comparison of Temperature Assessment of Infants and Toddlers via the Temporal Artery of Infants and Toddlers via the Temporal Artery and Rectum [where published or presented]; Comparison of New Temporal Artery Thermometer for Home Use with Rectal Thermometer in Two Pediatric Emergency Departments [where published or presented]. Available on Exergen's website: www.Exergen.com

Second, at the same time, a patented system measures the temperature of the site where the temperature is being taken. The patented “arterial heat balance” (AHB) software then synthesizes the two separate readings to accurately determine and display peak temperature.

As with any thermometer, taking temperatures properly is critical to obtaining accurate temperatures, so please read all instructions carefully and thoroughly before using this product.

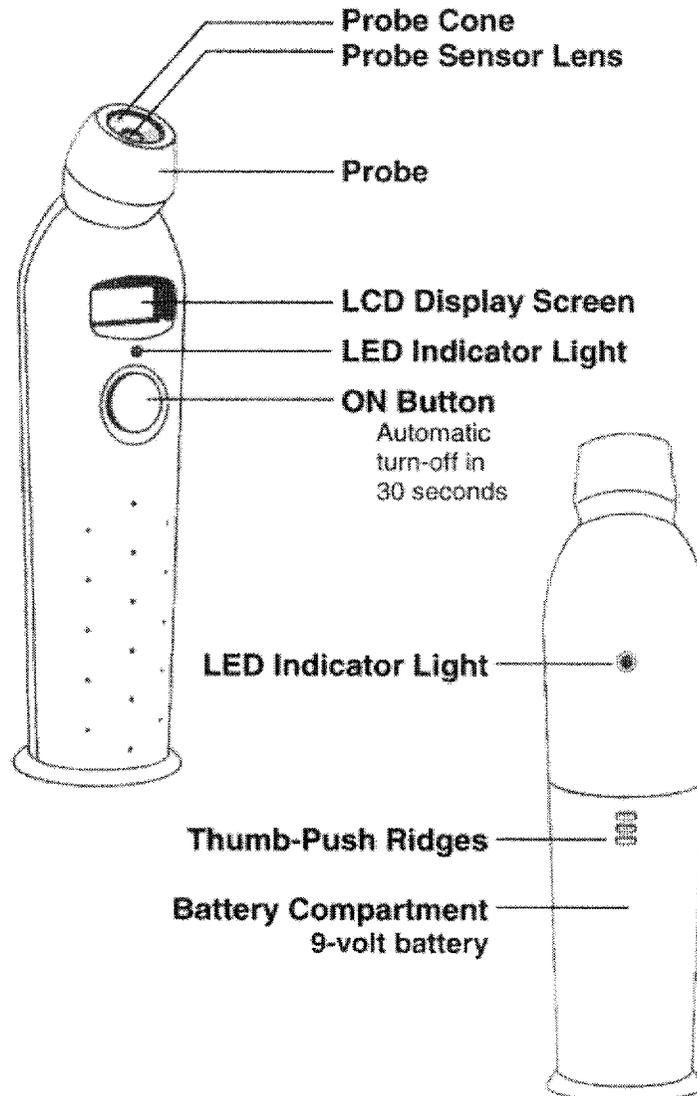
IMPORTANT

- Keep out of reach of children.
- Do not let children put the thermometer or its cap in their mouths.
- Do not take temperatures with this thermometer in places where the temperature is less than 60 °F or greater than 104 °F (105.5°C to 40°C).
- Do not expose this thermometer to a place where the temperature is below -4°F or exceeds 122°F (-20°/50°C) or to a place where it is excessively humid (95% RH non-condensing).
- Do not take temperatures with this thermometer near places that are very hot, such as fireplaces and stoves.
- Do not use this thermometer outdoors.
- Do not take temperatures over scar tissue, open sores or abrasions.
- Do not take temperatures on skin surfaces that are broken out or inflamed, e.g. pimples, dermatitis.
- Always store this thermometer in a clean, dry place in its travel case, protective cover or plastic case in a place where it will not become excessively cold (-4°F) or excessively hot (over 122°F).
- Always take basic safety precautions, especially when using the thermometer on or near children or disabled persons.
- Do not use this thermometer as a substitute for contacting your doctor; it is not meant for this purpose.
- This thermometer is not waterproof, so do not use it while bathing or place or store it where it might fall into water.
- The thermometer is not shock proof. Do not drop it or expose it to electrical shocks.
- This thermometer is not intended to be sterile. Do not try to sterilize it. Follow the cleaning instructions after each use.
- Use this product only for the uses as described in this manual. Do not use attachments which have not been recommended by Exergen Corporation
- Don't operate this thermometer if it is not working properly, if it has been dropped, exposed to temperature extremes, damaged, been subject to electrical shocks or immersed in water.
- There are no parts that you can service yourself except for the battery, which you should replace when low following the instructions in this manual. For service, examination, repair or adjustments, return your thermometer to Exergen.

- Do not operate where aerosol (spray) products are being used or where oxygen is being administered.
- Never drop or insert any object into any opening.
- Use this thermometer only to measure the temperature of the surface of the skin over the temporal artery.
- If your thermometer will not be used regularly, remove the battery to prevent possible damage due to chemical leakage. If battery leaks, remove carefully. Do not allow bare skin to touch leaking fluid.
- Dispose of used batteries properly. Do not wrap them in metal or aluminum foil. Wrap them in newspaper before disposing of them. Do not burn them. Battery may explode if overheated.

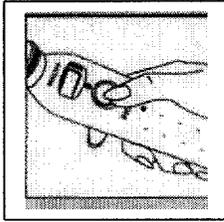
SAVE THESE INSTRUCTIONS !

Features



86

How to Take a Temperature

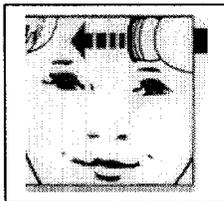


1

Remove protective cap before use. Be sure lens is clean. If not, clean with a cotton swab dipped in alcohol and let dry. Place the thermometer in your hand as shown with your thumb on the button.



Do not press the button yet

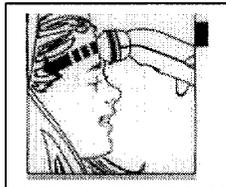


2

Gently position the sensor flush (flat) on the center of the forehead, midway between the eyebrow and the hairline. Press and hold the ON/OFF button.



Wait until the sensor is flush (flat) against the forehead before pressing the button.



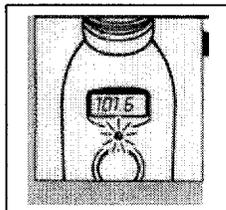
3

Slowly slide the thermometer across the forehead, keeping the sensor flat and in contact with the skin until you have reached the area at the top of the ear.



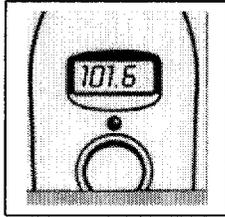
You will hear a beeping and the red light will blink to indicate a measurement is taking place.

Be careful not to keep the sensor on one spot too long. Otherwise, the thermometer will indicate the measurement is complete before you have reached the surface of the skin over the temporal artery.



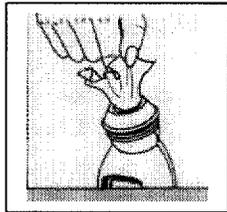
4

After the long beep when the red light remains on, the measurement is complete. Release the ON/OFF button and remove the thermometer from the head.



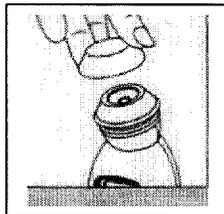
5 Read the temperature on the display. Press and release the button to turn the thermometer off.

→ The thermometer will automatically turn off in 30 seconds if you forget.



6 To clean the thermometer, point the sensor downwards and gently wipe with a cotton swab or soft cloth dampened with rubbing alcohol or water.

→ Do not use a paper towel or abrasive cleaners



7 Place the protective cap on the thermometer to protect the sensor when not in use

58

Factors that may affect measurement accuracy



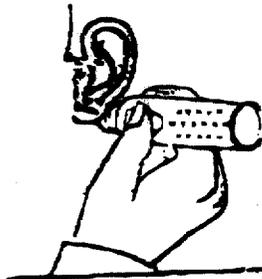
The patented AHB technology in your TemporalScanner actually makes two separate measurements: (1) the temperature of the skin over the temporal artery and (2) the temperature of the room. To determine the most accurate reading, it measures both temperatures some 2,000 times a second as you sweep the TemporalScanner across the forehead. The AHB system then calculates how much the blood has cooled down during its journey from the heart to the skin over the temporal artery and makes allowance for this in the temperature it displays. The result is a highly accurate reading - delivered extremely fast and with no discomfort.

To ensure that the reading always reflects the body temperature accurately, you need to take account of the following factors which may affect an accurate reading:

Sweating

When you develop a fever, your body tries to quickly bring its temperature down by sweating. TemporalScanner detects this reduction in temperature immediately - long before a rectal thermometer can do so. However, sweating also causes extra cooling of the skin. As a result, the reading given by the TemporalScanner may be low. You should therefore either wait until the sweating has stopped or use the following method, which has been clinically proven to provide an accurate result:

- Take the temperature on the forehead, as normal.
- Then also take the temperature behind the ear lobe, as shown in the figure.
- Gently nestle TemporalScanner, on head, directly behind ear lobe.
- Press the on/off button, maintaining skin contact until you hear the long beep.
- The higher of the two readings is the accurate one.



Note: Normally, the artery behind the ear lobe does not provide a sufficiently accurate reading. However, this area is less affected by sweating than the forehead. In addition, during sweating the increased blood flow and higher skin temperature result here in a good reflection of the body temperature. That is why on such occasions taking the temperature behind the ear may give a better result.

Environmental effects

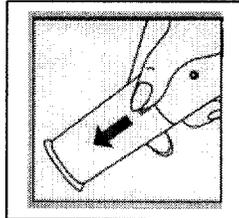
As part of its AHB system, TemporalScanner measures the temperature of the surrounding environment. For this measurement to be accurate, it needs to have become acclimatised to the temperature of the room in which it is to be used. If it is taken from a cold room into a hot room, or vice versa, allow it to acclimatise for at least 30 minutes before using it. Avoid holding the TemporalScanner by the head, as it will mistake the temperature of your hand for that of the room.

59

Tips on Using Your TemporalScanner Thermometer

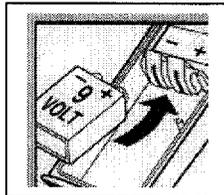
- Measure only the side of the head exposed. Anything covering the area, such as hair, hats, bandages and the like, will insulate the area and may give you readings that are falsely high.
- Slide the thermometer straight ACROSS the forehead NOT down the side of the face.
- When taking a temperature behind the ear lobe, first push away any hair, exposing the area.
- Infants frequently have blankets and clothing covering the neck. Unless your infant is visibly sweating, one measurement is usually enough to get an accurate temperature. However, if you feel the reading is too low, push aside any blankets or clothing covering the neck for 30 seconds and repeat the measurement.

Battery Installation / Replacement



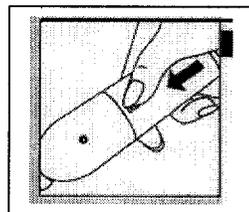
1

Slide the battery cover down as shown to open.



2

Insert the new 9 Volt battery as indicated. Make sure that the (+) and (-) leads are positioned correctly.



3

Close the battery cover.

Product Specifications

Clinical Accuracy	Meets ASTM E1965-98 and MDD 93142/EEC standards for electronic and radiation thermometers to the extent applicable to thermometers which measure the surface of the skin over the temporal artery.
Regulatory Approvals	CE Mark to -0197, TUV, Declaration of Conformity-ISO 9003/08.94, NIST certifiable traceable calibrations.
EMI/ RFI Protection	Error message displayed
Calibration Protection	Error message displayed
Temperature Range	15.5 to 42°C (60 to 107.5°F)
Operating Environment	15.5 to 40°C (60 to 104°F)
Resolution	0.1°C or °F
Response Time	Approximately 0.004 seconds
Time Displayed on Screen	30 seconds before automatic shutdown
Battery Life	Approximately 7,500 readings
Size	7.0 in x 1.75 in x 1.25 in(17.8 cm x 4.45 cm x 3.18 cm)
Weight	4.16 oz (120 grams) incl batt
Display Type	High contrast LCD
Construction Method	Impact resistant casing, Hermetically sealed sensing system
Warranty	1 Year
Laboratory Error:	+/- 4°F (+/- 0.2°C)
Storage Range:	-4°F - 122°F (-20°C-50°C)

Clinical accuracy characteristics and procedures are available from Exergen

Patents

Protected by one or more of the following US patents: 6056435, 6047205, 6045257, 5893833, 5874736, 5653238, 5628323, 5445158, 5381796, 5325863, 5199436, 5017019, 5012813, 4993419, 4874253, 4636091, RE035554, D03708. Other US and foreign patents pending.

Normal body temperature is not a single temperature, but a range of temperatures influenced by age, time of day and measurement site. You can establish your family's normal ranges by taking a number of temperatures from each member during a day and keeping records of them. Many people may not have an elevated temperature even if they are ill. These include, but are not limited to, infants under 90 days old, people on steroids, antibiotics or antipyretics (acetamenaphin, ibuprofen, aspirin), people with compromised immune systems (including the elderly and those having HIV/AIDS). Consult your doctor if you feel someone is ill even if their temperature is not elevated.

An elevated temperature or fever is often viewed as a danger sign. In fact, fever can be beneficial. It should be evaluated in the light of other physical symptoms. A doctor should be consulted in the following situations where fever is present: vomiting, diarrhea, changes in appetite, activity or breathing, or with children who are irritable, lethargic or unusually sleepy.

Normal Human Body Temperature Ranges At Various Measurement Sites

Oronasal (nose)

96. 6 - 99. 0° F

(35.9 - 37.2° C)

Axillary (under the arm)

95. 5 - 98. 8° F

(35.3 - 37.1° C)

Rectal

97.7 - 100.3° F

(36.5 - 37.9° C)

Arterial

97.4 -100. 1° F

(36.3 - 37.8° C)

Oral (mouth)

96. 6 - 99. 5° F

63

(35.9 - 37.5° C)

ASTM laboratory accuracy requirements in the display range of 37° to 39°C (98-102°F) for IR thermometers is $\pm 0.2^{\circ}\text{C}$ ($\pm 0.4^{\circ}\text{F}$) whereas for mercury-in-glass and electronic thermometers, the requirement per ASTM standards E667-86 and E1112 is $\pm 0.1^{\circ}\text{C}$ ($\pm 0.2^{\circ}\text{F}$)

Insert A Draft Instructions for Use – Section 4

This infrared thermometer meets requirements established in ASTM standard E1965-98 to the extent they are applicable to thermometers that measure the temperature of the surface of the skin over the temporal artery. Full responsibility for this product meeting applicable portions of this standard is assumed by Exergen Corporation, Watertown MA 02172.

68

Proposed TemporalScanner Labels

B.F. CONNECTIONS LLC D-15044 3RD PROOF

Device P/N TAT2000

Labeling

ACTUAL SIZE

EXERAEN \

Temp scanner / infrared thermometer

The following two pages describe the proposed device labeling. The labels are like the labels

Probe lens and cone should be shiny clean, if not, wipe with an alcohol prep.

for other models so they are shown here with the model number taken out.

Your artwork is being proofed to you as it was provided to us via your E-Mail or disk. Please check all aspects before approving, as subtle changes may have occurred being transferred electronically or in translating your file into a format that we use for the screen printing process,

1. With probe flush on center of forehead, depress button, *keep depressed*.
2. Slowly slide probe across forehead into hairline.
3. Lift probe from forehead, touch on neck just behind ear lobe.

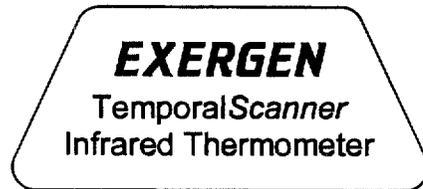
CUT LINE WILL NOT PRINT

ENLARGED FOR PROOFREADING

INSET BORDER

4. Release button, read, record temperature.

Model TAT-2000
EXERGEN Corporation
Watertown, MA 617-923-9900
www.exergen.com



T
MINIMUM AMOUNT OF SPACE BETWEEN BORDER & CUT LINE FOR DIE-CUTTING TOLERANCE

Probe lens and cone should be shiny clean, if not, wipe with an alcohol prep.

REV 1 SHEET

SIZE: 1 @ 1.08" X .48" OVERALL, .06" RADIUS CORNERS CUSTOM SHAPE
1 @ 1.41" X .36", .06" RADIUS CORNERS
1 @ 1.41" X 2" OVERALL, .06" RADIUS CORNERS CUSTOM SHAPE
(NO CORNER RADIUS WAS SPECIFIED FOR THIS LABEL. HAS BEEN MADE AT .06" AS OTHERS)

COLOR: BLACK TEXT, COLOR MATCH 954 BLUE INSET BORDERS COLOR MATCH 953 OFF-WHITE BKGD.

MATERIAL: .006" TEXTURED PVC, 3M 467(2-MIL) YNDHE

1-18
N
Handwritten signature/initials

1. With probe flush on center of forehead, depress button, *keep depressed*.
 2. Slowly slide probe across forehead into hairline.
 3. Lift probe from forehead, touch on neck just behind ear lobe.
 4. Release button, read, record temperature.
- Model
EXERGEN Corporation
Watertown, MA 617-923-9900
www.exergen.com

4-16

67

200%

MAC#769906

TAT models are protected by one or more of the following US patents: 6056435, 6047205, 6045257, 5893833, 5874736, 5653238, 5628323, 5445158, 5381796, 5325863, 5199436, 5017019, 5012813, 4993419, 4874253, 4636001, RE035554, D03708

68

Exergen Predicate Device Labeling

69

I·N·S·T·R·U·C·T·I·O·N·S

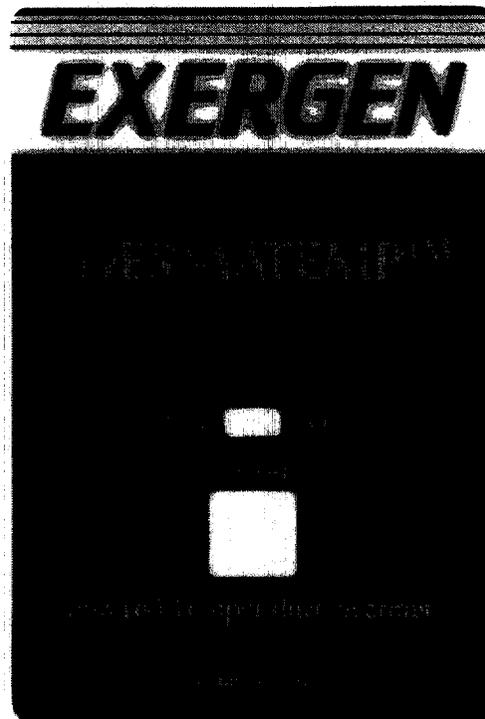
- 1** **Make sure lens is clean.**
If not, clean with a cotton swab dipped in alcohol and let dry.

- 2** **Select SCAN, MAX, or MIN mode.**
 - SCAN mode: Reads continuously.
 - MAX mode: Reads highest reading.
 - MIN mode: Reads lowest reading.

- 3** **Press red ON button and hold it down while scanning the surface. Release button to lock reading.**
For best accuracy bring the probe to within 1 mm of the surface being measured.

Patent Nos.: 4,636,091 and 4,993,419

Model DT-1001 Serial No. 3385
EXERGEN Corporation • Watertown, MA



BACK

FRONT

20

Five Year Warranty

Exergen Corporation warrants each new Exergen DemaTemp (except battery) against defects in materials or workmanship for a period of five years from the date of purchase, and agrees to repair or replace any defective product without charge.

IMPORTANT: This warranty does not cover damage resulting from accident, misuse or abuse, lack of reasonable care, the affixing of any attachment not provided with the product or loss of parts or subjecting the product to any but the specified battery.* Use of unauthorized replacement parts will void this warranty.

Exergen Corporation will not pay for warranty service performed by a non-authorized repair service and will not reimburse the customer for damage resulting from warranty service performed by a non-authorized repair service. No responsibility is assumed for any special, incidental or consequential damages.

In order to obtain warranty service, simply call Exergen Corporation Customer Service, 617-923-9900, for an Return Material Authorization number (RMA). Then send the product, postage or shipping prepaid, to Exergen in accordance with the instructions given with the RMA number. It is suggested that for your protection, you ship the product, insurance prepaid. Damage occurring during shipment is not covered by this warranty.

NOTE: No other warranty, written or verbal, is authorized by Exergen Corporation. This warranty gives you specific legal rights and you may also have other rights which vary from state to state. Some states do not allow the exclusion or limitation of incidental or consequential damages, so the above exclusion and limitations may not apply to you.



EXERGEN CORPORATION . 51 WATER STREET . WATERTOWN, MA, 02472
PHONE: 617.923.9900 . FAX: 617.923.9911
WWW.EXERGEN.COM

P/N: 818511 Rev 1

EXERGEN

USER'S MANUAL AND REFERENCE BOOK

DermaTemp 1001 Infrared Thermographic Scanner



Unparalleled Accuracy
... at the Speed of Light

V. Product Specifications

<i>Clinical Accuracy</i>	± 0.2°F or 0.1°C
<i>Temperature Range</i>	65 to 110°F (18 to 43°C)
<i>Operating Environment</i>	60 to 110°F (16 to 43°C)
<i>Resolution</i>	0.1°F or °C
<i>Response Time</i>	Approximately 0.1 second
<i>Emissivity Compensation</i>	Automatic
<i>Time Displayed on Screen</i>	10 Seconds
<i>Battery Life</i>	Approximately 5,000 readings
<i>Case Dimensions</i>	3.5" x 7" x 0.75" (9 cm x 18 cm x 2 cm)
<i>Weight</i>	9 oz (255 gm)
<i>Case Shielding</i>	Complete copper coating for EMI and RFI protection
<i>Display Type and Size</i>	Large, bright red LED's, easily readable in any lighting
<i>Construction</i>	Industrial duty, impact resistant casing, hermetically sealed sensing system
<i>NIST</i>	Certifiable traceable calibrations
<i>ASTM</i>	Meets or exceeds standards for electronic and radiation thermometers.
<i>Patents</i>	Protected by one or more of the following US patents: 6056435, 6047205, 6045257, 5893833, 5874736, 5653238, 5628323, 5445158, 5381796, 5325863, 5199436, 5017019, 5012813, 4993419, 4874253, 4636091, RE035554, D03708. Other US and foreign patents pending.

ell

²¹ Most RS, Simcock P. The epidemiology of lower extremity amputations in diabetic individuals. *Diabetes Care*. 6:87-91, 1983.

²² Bertholdt HT. Thermography on insensitive limbs. *Medical Thermography, Theory and Clinical Applications* 69-79, ed Uematsu S, Brentwood Publishing Co., Los Angeles, 1976.

²³ Dorgan MB, Birke JA, Moretto JA, Patour CA, Rehm BD. Performing foot screening for diabetic patients. *AJN* 32:37, Nov 1995.

²⁴ Uematsu S. Thermographic imaging of cutaneous sensory segment in patients with peripheral nerve injury. *J Neurosurg* 62:716-720, 1985.

²⁵ Rasmussen TB, Freedman H. Treatment of causalgia: analysis of 100 cases. *J Neurosurg* 3:165-173, 1946.

²⁶ Uematsu S, Shendler N, Hungerford D, et al: Thermography and electromyography in the differential diagnosis of chronic pain syndromes and reflex sympathetic dystrophy.

²⁷ Wexler CE, Small RB: Thermographic demonstration of a sensory nerve deficit. *J Neuro Orthoped Surg* 3:73-75, 1981.

²⁸ Ackerman RH, Noninvasive diagnosis of carotid disease in the era of digital subtraction angiography. *Neurool Clin*:1:70-85, 1983.

²⁹ Abernathy M, Nichols R, Robinson C, Brandt M. Noninvasive testing for carotid stenosis: Thermography's place in the diagnostic profile. *Thermology*:1:61-66, 1985.

³⁰ Abernathy M, Chang L, et al. Cerebrovascular thermography: technique and quality control. *Am Acad of Thermology Ann Mtg*. Georgetown University Medical Center, 1985.

³¹ Perlestein P. Future directions for device design and infant management. *Medical Instrumentation* 21:1:36-41, Feb, 1987.

³² Robicsek F, et al. The value of thermography in the early diagnosis of postoperative sternal wound infections. *Thorac. Cardiovasc. Surg.* 32, 260-65, 1984.

³³ Warshaw TG, Lopez F. Thermoregulatory function in skin: an aspect of psoriasis. *Acta Thermographica* 5:22, 1980.

³⁴ Stuttgart G. Thermographic evaluation of the benign diseases and reactive changes of the skin. *Biomedical Thermology*, ed Gautherie M, Albert E. 397-411, Alan R. Liss, Inc., NY, 1982.

³⁵ Boycke E, Well MH. Toe temperature as an indication of blood flow in the critically ill. *Biology and Medicine*, Ch 190, 2073-2078.

³⁶ Kholoussy AM, Sulhan S, Pavlides C, Matsumoto T. Central peripheral temperature: its value and limitations in the management of critically ill surgical patients. *Am J of Surgery*, Vol 140:609-612, Nov, 1980.

³⁷ Tsuji T. Patient monitoring during and after open heart surgery by an improved deep body thermometer. *Medical Progress Through Technology* 12, 25-38, Martinus Nijhoff Publishers, Boston, 1987.

³⁸ Benzinger TH. Heat regulation: Homeostasis of central temperature in man. *Physiol Rev* 49:671-759, 1969.

³⁹ Bassel LW, Gold RH, Clements PJ, Furst D. Hand thermography in normal subjects and scleroderma. *Acta Thermographica*:5:19-22, 1980.

⁴⁰ Haberman JD, Ethlich GE, Levenson C. Thermography in rheumatic diseases. *Arch. Phys. Med and Rehab* 48:187-191, 1968.

Table of Contents

I. The Instruments..... 1

The Instruments' Features..... 2

Optional Disposable Covers..... 2

Instructions for Applying Disposable Covers..... 3

Contact vs. Non-Contact Measurements..... 3

Operation and Controls..... 4

ON/OFF..... 4

To Lock Reading..... 4

To Restart..... 4

Operating Modes..... 5

Non-Contact Scanning..... 5

Changing the Battery..... 5

Fahrenheit or Celsius Conversion..... 6

Care and Maintenance..... 6

Self-Diagnostics..... 7

Customer Service..... 8

II. Body Surface Temperature..... 9

History and Introduction..... 9

Body Surface Temperature..... 10

Infrared Thermometry..... 11

The Dermal Temp Infrared Thermographic Scanner..... 13

Method Impedimenta..... 13

Ambient Effect on Body Surface Temperature..... 14

Solving the Problems..... 14

Emissivity..... 15

Alice's Quest for Emissivity..... 17

Correcting for Emissivity Automatically..... 18

Detection by Exception..... 18

III. Clinical Applications..... 20

Regional Blocks..... 20

Epidural Catheter Positioning..... 21

Joint Inflammation..... 21

Digital Perfusion Assessment..... 22

Reconstructive Surgery..... 22

Lower Back Pain..... 23

Diabetic Foot Screening..... 23

Peripheral Nerve Injury..... 24

Cerebrovascular Disorders..... 24

Neonatal Skin Temperature..... 25

Wound Management..... 25

Thermal Assessment of Skin Diseases and Allergy..... 26

Skin Temperature in Prognosis of the Critically Ill..... 26

Temperature Gradients in Detection of Shock..... 27

Raynaud's Syndrome..... 27

Other Areas or Applications of Interest..... 28

IV. References..... 29

V. Product Specifications..... 31

73

IV. References

- ¹ Chambliss J. Case of traumatic femoral aneurism (sic) treated by digital compression-ligation afterwards of the external iliac artery. *Confederate States Med Surg J*, 1:97-99, 1864.
- ² Coar T. The Aphorisms of Hippocrates with a Translation into Latin and English 88 (AJ Valpy, London 1822).
- ³ Robertson T. Clinical Temperature Measurement - Survey. CEC/Bell & Howell.
- ⁴ Uematsu S. Thermographic imaging of cutaneous sensory segment in patients with peripheral nerve injury. *J Neurosurg*, Vol 62, 717-720, May 1985.
- ⁵ Chamberlain DP, Chamberlain BDL. Changes in the skin temperature of the trunk and their relationship to sympathetic blockade during spinal anesthesia. *Anesthesiology* 65:139-143, 1986.
- ⁶ Shin Y, Pearson L, Burnett M. *Anesthesiology* V77, No 3A, Sep 1992.
- ⁷ Guadagni DN, Dreith F, Smyth CJ, Bartholomew BA. Skin temperature as an indicator of joint inflammation. *ISA BM* 74321 (105-110), 1974.
- ⁸ Levinsohn G, Gordon L, Sessler DI: Comparison of four objective methods of monitoring digital venous congestion; *J Hand Surgery*, Vol 16, No 6, 1056-1062, Nov 1991.
- ⁹ Bloomenstein RB. Viability prediction in pedicle flaps by infrared thermography. *Plast Reconstr. Surg.* 421:452-461, 1968.
- ¹⁰ Sirrat CR, Seaber AV, Urbaniak JR, Bright DS. Temperature monitoring in digital replantation. *J of Hand Surg*, Am Soc Surg of the Hand, 1978.
- ¹¹ Weinstein SA, Weinstein G. Thermography, EMG, CT Scan, Myelography and Surgery in 800 Patients: Georgetown University Medical Center, 14th Ann Meeting, Am Acad of Thermology.
- ¹² Barkan I. Thermography: A useful adjunct to differential diagnosis: lumbar radiculopathy versus plexopathy in 10 cases. Georgetown University Medical Center, 14th Ann Meeting, Am Acad of Thermology
- ¹³ Albert SM, Glickman M, Kailish M: Thermography in orthopedics, Ann NY Academy of Science 121, 157-170, 1964.
- ¹⁴ Heinz ER, Goldberg HI, Taveras JM: Experiences with thermography in neurologic patients. Annual NY academy of Science 121:177-189, 1964.
- ¹⁵ Raskin M, Martinez-Lopez M, Sheldon JJ: Lumbar thermography in discogenic disease. *Radiology*:119:149-152, 1976.
- ¹⁶ Tischauer IR: The objective corroboration of back pain through thermography. *J Occup Med*:19:727-731, 1977.
- ¹⁷ Ching C, Wexler CE: Peripheral thermographic manifestations of lumbar disc disease. *Appl Rad*:100:53-58, 1978.
- ¹⁸ Levin ME: Pathophysiology of diabetic foot lesions. In Davidson JK (ed): *Clinical Diabetes Mellitus: A Problem-Oriented Approach*, p504. Thieme Medical, NY, 1991.
- ¹⁹ Gibbons G, Eilopoulos GM. Infection of the diabetic foot. In: Kozak GP, Hoar CS, Rowbotham JL, (eds). *Management of Diabetic Foot problems*. 97-102, WB Saunders, 1984.
- ²⁰ Pliskin MA, Todd WF, Edelson GW. Presentations of Diabetic Feet. *Arch Fam Med*, 3:273-279, 1994.

phenomenon, particularly those with sclerodérama and progressive systemic sclerosis where it is the first symptom in 90% of cases, and may precede other manifestations by many years.^{3,4}

Other Areas or Applications of Interest

- Bone Fractures
- Diabetic Neuropathy
- Oncology
- Stress Fractures
- Breast Cancer Screening
- Diseases of Scrotum and/or Testicles
- Orthopedic Surgery
- Trigger Points
- Burn Injury
- Hansen's Disease
- Pagets Disease
- Tumor Screening
- Carpal Tunnel Syndrome
- Headache Clinic
- Pain Management
- Varicocoele Detection
- Cerebral Vascular Disease
- Joint Trauma
- Peripheral Nerve Injury
- Vascular Obstruction
- Nerve Root Compression
- Soft Tissue Injuries
- Dentistry
- Neuromuscular Injury
- Sports Medicine

I. The Instruments

The DermaTemp is a high precision hand-held infrared thermographic scanner designed to detect the subtle skin temperature variations caused by underlying perfusion variations.

These instruments feature a patented automatic emissivity compensation system for absolute accuracy regardless of skin type or color, and provide an instant temperature measurement on any surface location on the human body without the need for tissue contact.

In those applications where tissue contact is desirable or cross-contamination is an issue, the use of disposable wraps or sheaths allows even moist or wet tissue to be measured with precision accuracy.

The models include:

DT-1001

the standard model



DT-1001 LT

has a conveniently angled stainless steel probe, and can be used with or without disposable probe wraps



DT-1001 LN

has a longer probe than the DT-1001, and can be used with or without a disposable sheath. The sheath encases the entire instrument.



DT-1001 RS

has a remote stainless steel sensor attached to the instrument by cable, convenient for those especially hard to reach areas.



All instruments can be cleaned with any hospital approved disinfectant, including bleach, and can be gas or plasma sterilized.

The DermaTemp is recommended for use in such areas as plastic and vascular surgery, anesthesiology, pain management, rheumatology, neurology, oncology, and wound management.

The Instruments Feature:

- Full range resolution to 0.1°F/C
- SCAN, MAX and/or MIN modes of operation, model specific
- Fahrenheit/Celsius conversion
- A 10-second display lock
- An audible beeper to signal functional or conditional changes
- Hermetically sealed sensing system to withstand gas and plasma sterilization, and cleaning with any hospital approved disinfectant including bleach and alcohol.
- Pencil-like stainless steel sensor on the RS version.
- Optional disposable cover usage:
 - Complete encasement with disposable sheaths for the LN version.
 - Full probe covering with disposable wraps for the LT version.

Optional Disposable Covers

The use of disposable covers with the DT-1001 LT is optional, depending on the requirements of the application. Recommended guidelines are as follows:

Use With Disposable Cover

For absolute accuracy, minimizing the effects of emissivity and evaporative cooling, contact with the measurement site is recommended. Accordingly, when direct contact is employed, use of a disposable probe cover is recommended.

When touching moist tissue, use of a disposable cover is required specifically to avoid a lower temperature from the effects of evaporative cooling, and to protect against the risk of cross contamination.

Use Without Disposable Cover

If the measurement site is dry, direct contact can confidently be made without the use of a disposable cover. When the site is dry and the precise temperature is not a prerequisite, the measurement can be made without even contacting the skin. The probe can be cleaned with any hospital approved disinfectant, even bleach solution.

Temperature Gradients In Detection of Shock

Temperature monitoring of the gradient between forehead and sole temperatures has been demonstrated to provide early detection of masked symptoms during and after surgery. The effect of treatment and the prognosis for the patient are predictable according to the trends of the two temperatures as divergent or convergent. The dissociation when the two temperature are more than 7°C apart from each other suggests that the hemodynamical condition is worse than in the convergence when they remain within 2°C.¹

The blood flow in finger skin is known to be very susceptible to sympathetic nervous activity. Palm tissue temperature varies more with the emotional stress than does sole tissue temperature. Assuming forehead and abdominal readings correspond to core temperature,² and sole and palm readings to shell temperature, the hemodynamical condition in convergence is usually better than in dissociation. If dissociation is observed in a post-op patient, the hemodynamical parameters have to be checked. When the arterial systolic pressure is less than 90 mmHg and the urine output less than 1ml/min/mg, a state of shock can be diagnosed based on the dissociation (difference >7°C).

A chilling sensation or shivering is common in dissociation, however, the symptoms can be overlooked in the patient just after surgery because an intubated patient cannot complain of a chilling sensation, and shivering does not occur in patients whose muscles are flaccid owing to residual pharmacological effects of anesthesia. Monitoring of the patient's body surface temperature allows for early detection of shock in postoperative patients with minimum discomfort and maximum safety to the patient.

Raynaud's Syndrome

Temperature monitoring of patients with Raynaud's Syndrome provides a useful, non-invasive method of quantifying temperature and heat patterns in determining the underlying pathogenesis of Raynaud's attacks, and in the evaluation of any subsequent therapy. Temperature monitoring may also be useful diagnostic tool in differentiating primary from secondary Raynaud's. Preliminary research data suggest Raynaud's may be a common denominator in certain sleep disorders. Many patients with connective tissue diseases present with Raynaud's



Evidence of Raynaud's Syndrome

26

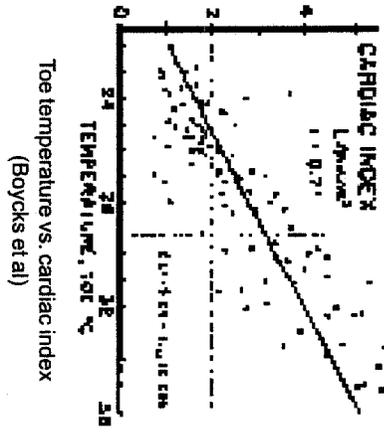
Thermal Assessment of Skin Diseases and Allergy

Temperature monitoring provides an objective assessment of skin diseases² as well as allergy and vasomotor tests³ since most of the skin diseases, or the percutaneous injection of pharmacodynamic substances used for testing, generate significant changes in the thermal pattern of the skin.

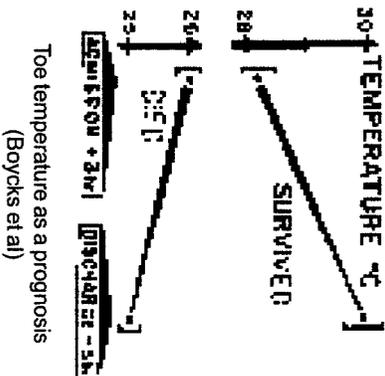
Skin Temperature in Prognosis of the Critically Ill

Skin temperature has been the subject of several studies monitoring blood flow in the critically ill.

Data from these studies indicate increases in the temperature of skin, especially the big toe, were accompanied by improvement in the clinical status of the patient, and significantly greater survival. Boycks and Weill⁴ concluded toe temperature provided the best correlation with cardiac index and prognosis of survival compared to arm, finger, thigh, or rectal temperatures.



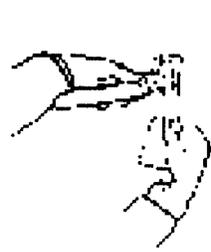
Kholoussy et al (1980)⁵ demonstrated attainment of normal rectal-toe temperature gradient consistently coincided with hemodynamic stabilization of the patient as indicated by other simultaneously measured parameters and by the clinical condition. In all the patients that died, rectal-toe temperature gradient gradually and progressively increased as the patient's condition became terminal.



Monitoring central peripheral temperature gradient was determined can accurately reflect the state of peripheral circulation, though may be limited by peripheral vascular disease, central hyperthermia, and the use of vasoactive drugs.

Instructions for Applying Disposable Covers

Model 1001 LT Only

- 1  Start with film perforation at edge of box tongue. Pinch bottom of white ring, push ring over peg.
- 2  Release pinch, gently pull box away from probe to release film from box. Pinch just below next ring, before perforation.
- 3  Rotate instrument into film until probe faces opposite direction, push ring on peg.
- 4  Release pinch. Pull box slightly away until next white ring is visible. Pinch ring, break film apart at perforation.

Contact vs. Non-Contact Measurements

In using any infrared temperature device, closer is always better, as the field of view increases proportionately to the distance from the surface. Accordingly, for maximum accuracy the probe must contact the surface at the point of interest. It does not need to be tightly pressed to the surface; a gentle touch is all that is required.

When contact with the surface is not an option, position the probe within 1/2 inch from the surface of interest. If using a non-contact protocol, the relative temperature indication of the instrument will be accurate.

Operation and Controls

The DermaTemp infrared thermographic scanner models 1001, 1001 LN, LT and RS are all identical in performance and specifications. All are maximized for ease of use. The remote sensor on the RS version can either be left attached to the instrument for one-handed operation, or separated for use in hard-to-reach areas of interest. The LN and LT models can be used with or without disposable covers

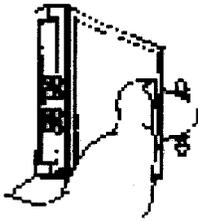
Using the DermaTemp

The DermaTemp is equipped with an ON/OFF power button and a mode selector switch, model specific. The mode selector switch allows you to choose one of the three modes of operation, SCAN, MAX, or MIN. The LT model is designed in a peak select mode, and automatically selects and locks the highest reading when the ON/OFF button is released.

ON/OFF:

To turn the instrument on, depress the red ON/OFF power push button. The single beep will audibly indicate that the instrument is on.

The display will momentarily read 8888, an indication that the microprocessor is performing a self-diagnostic check. After the test, the unit will measure and display temperature in the selected operating mode for as long as the power button is depressed.



To Lock Reading:

Release the red ON/OFF button to lock reading on display. The single beep will audibly indicate that the display is locked. The DermaTemp will hold the last reading on the display for 10 seconds before it automatically turns off.

If you are using a DermaTemp 1001 LT, the highest temperature measured will be retained before automatic turn off.

To Restart:

Depress the button anytime to restart. It is not necessary to wait until the display is clear. The DermaTemp automatically recalibrates each time the button is depressed.

Neonatal Skin Temperature

The goal of neonatal thermal management is to establish an environment of thermoneutrality in which the metabolic heat production requirement is minimal. Perstein¹⁴ indicates that both the core and surface temperature of the neonate are required to quantify the rate of heat loss. The greater the difference between core and surface temperatures, the greater the heat loss from the infant. (This holds only if vasomotor activity is absent, as is the case for a neonate.) A typical surface temperature for minimum heat loss is indicated as 36.0-36.5°C (96.8-97.7°F).

Conventional thermal sensor systems are sensitive to the thermal contact resistance between the surface of the patient and the surface mounted device. A large thermal resistance will result in inaccurate surface temperature readings, tending to be on the low side of the actual surface temperature. This technique requires time for the sensor to equilibrate and great care in the surface mounting methodology for accurate measurements. As a consequence, conventional surface detectors are usually used to monitor one location on the neonate and multiple site readings are rarely taken.

Infrared thermometry provides a method for accurate surface temperature measurements on multiple skin surface locations. The infrared technology has a short one-second time interval between readings, is essentially independent of user technique, and has no variable thermal contact resistance problem. The capability of rapid and accurate multi-surface temperature measurements provides the clinician a new and expanded method for the assessment of heat loss from the body surface of the neonate.



Wound Management

Increased skin temperature has long been associated with infection, thus measuring the changes in skin temperature in the area of incision or trauma when compared to the surrounding tissue provide the necessary quantifiable information for early recognition of such infections, well before the process has caused any visible skin changes.

Temperature measurement is especially useful for early diagnosis of postoperative wound infections¹, those at the IV site, and decubitus ulcers, for example, and provides for routine quantification of the infection and subsequent monitoring of the healing process in an objective manner by the clinical staff.

Temperature is an early indicator of foot problems in diabetic patients⁵. Long before any clinical manifestations, heat can be detected, and the more sensitive the detection instrument, the earlier the warning. As a key indicator of complications from the disease, temperature has been incorporated into routine diabetic foot screening protocols.⁶

Two foot problems of major concern are foot ulcers and neuropathic fractures. Because of peripheral neuropathy, diabetic patients may not feel pain, and can continue walking on the foot. If the problem is not identified and treated in a timely fashion, they are at high risk for ulceration, infection, and deformities, with amputation of a lower limb always a real and devastating complication.

Using the DermaTemp for temperature monitoring in diabetic foot screening can immediately determine the thermal geography of the area of concern, identify hot spots, and locate cool areas. As a diagnostic tool, it is objective and quantifiable. Because it is relatively insensitive to user technique, many physicians have recommended their patients monitor their own foot and leg temperatures with the DermaTemp as part of their patient's self-care program.

Peripheral Nerve Injury

Temperature monitoring can be used in the quantification of peripheral nerve injury, differentiating among organic nerve damage, psychogenic factors, or even malingering.⁷ Skin temperature is altered in the field of an impaired peripheral nerve due to sympathetic vasomotor disturbance. Skin temperature in a normal individual differs between sides of the body only $0.24 \pm 0.073^{\circ}\text{C}$. In patients with peripheral nerve injury, the temperature of the skin innervated by the damaged nerve deviates an average of 1.55°C .^{8, 9, 10}

Temperature monitoring has been found to be highly successful in identifying the difficult pain problems e.g., diabetic or ischemic radiculopathy, facial pain syndrome, carpal tunnel, whiplash injuries of neck and upper back, and the phantom limb pain seen in amputees.

Cerebrovascular Disorders

Temperature monitoring is a useful method for screening for cerebrovascular disease before subjecting the patient to the risk of invasive procedures. In the evaluation of extracranial carotid complex, temperature monitoring demonstrates a high degree of sensitivity in detection of hemodynamically significant stenosis of the internal carotid artery.^{11, 12} Early detection allows the physician to institute appropriate therapy before a stroke occurs.¹³

Operating Modes (*Model Specific*)

- **SCAN:** In the SCAN mode, the target's instantaneous temperature is continuously displayed and updated 10 times per second for as long as you keep the button depressed. After the power button is released, the display will lock on the last temperature measured and hold that reading for 10 seconds.
- **MAX:** In the MAX (peak hold) mode, the display will lock on the highest temperature measured for as long as you hold the power button down. Each time a new peak temperature is measured or repeated, an audible beep will sound. After you release the power button, the display will lock on the maximum recorded temperature and hold that reading for 10 seconds.

- **MIN:** In the MIN (valley hold) mode, the display will lock on the lowest temperature measured as long as the power button is depressed. Each time a new low temperature is measured, a beep will sound. After the power button is released, the display will lock on the minimum recorded temperature and hold that reading for 10 seconds.

Non-Contact Scanning

For situations where even light contact is contraindicated, bring the instrument nose as close to the measuring site as safely possible, keeping the following in mind:

The instrument's field-of-view, also referred to as the distance-to-spot ratio, is 1:1. A 1:1 field-of-view means that the sensor sees a circular area with a diameter equal to the distance between the sensor and the target area.

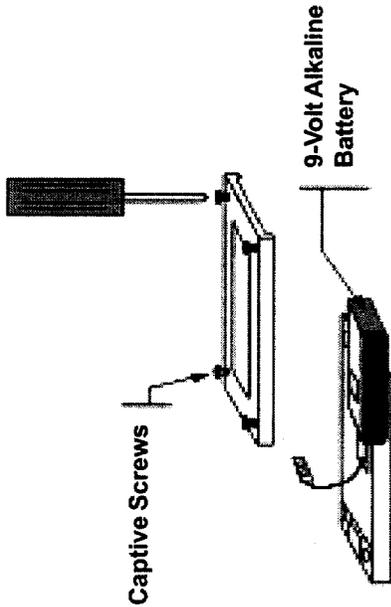
For example, at a distance of 2 inches (5 cm), the sensor sees a 2 inch (5 cm) diameter spot. The minimum spot size is approximately 1/4 inch (6 mm) when touching.

The DermaTemp averages the temperature of everything in its field-of-view.

A small hot spot may get lost in a large viewing area. The closer you hold the instrument to a surface, the sharper its target resolution.

Changing the Battery

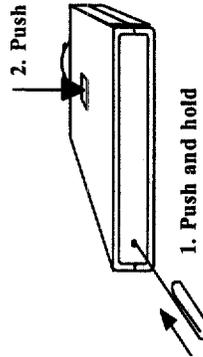
A standard 9-Volt alkaline battery will require replacement only once or twice per year under normal use. To replace, loosen the four captive screws and remove the cover. Disconnect the old battery and replace with a new one in the same location. Replace the cover and tighten the four screws. Use only high quality alkaline batteries or their equivalent.



Fahrenheit or Celsius Conversion

The DermaTemp can be used in either °F or °C. The only tool necessary to convert from one scale to the other is a paper clip.

- Find the small hole on the left side of the red display filter.
- Straighten the paper clip.
- Insert the end of the paper clip into the hole and push to activate the small switch underneath.
- While holding the paper clip pressed into the switch, turn the instrument on by pressing the red button.
- Remove the paper clip.
- To return to the original setting, repeat the process.



tized or ecchymotic digits, calling the physician for significant changes. The technique is atraumatic, and avoids patient anxiety which produces unwanted peripheral vasoconstriction. Temperature monitoring is also inexpensive and readily available.

Lower Back Pain

Lower back pain is one of the most common complaints of patients seeing a physician. Many complaints originate from work related accidents and contribute to a tremendously large number of hours lost from work. A study of 800 patients presenting with lumbar complaints and radicular asymptomatology by Weinstein et al³ compared the relative value of five diagnostic modalities and confirmed the accuracy of temperature as a method of confirming the presence or absence of root syndrome in low back pathology to be well above the 90th percentile.



Barkan demonstrated that lumbar radiculopathy can be detected by temperature measurement with accuracy equal to CT Scan or myelogram.⁴ These studies support the findings of many other similar studies,^{5, 6, 7, 8, 9} and clearly support the use of temperature measurement as a non-invasive technique without radiation, capable of reducing the number of invasive and uncomfortable myelograms and expensive CT scans of the lumbar spine.

Diabetic Foot Screening

Pedal infection is the most common cause of hospital admissions for diabetic patients in the United States and Great Britain^{1, 2, 3}, with more than 50% of the 125,000 amputations performed in the United States each year directly attributable to their disease.⁴ The American Diabetes Association estimates the costs of treating lower extremity amputations approaches \$10 billion annually, but interestingly, data from the Centers for Disease Control demonstrate up to 85% of diabetic foot and leg amputations can be prevented.

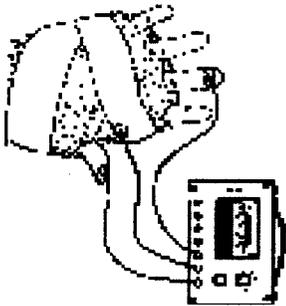


Digital Perfusion Assessment

Levinsohn et al (1991)¹ demonstrated that the infrared method of assessing perfusion was as reliable as Doppler methods, but far less expensive, much faster, and easier to use.

- A: Venous congestion was induced by placing a 28 mm wide cuff on the proximal phalanx of the long finger and then inflating the cuff to 5 mm Hg above resting diastolic pressure. With the aid of a nitrogen pressure regulator, cuff pressure was maintained for 60 minutes and assessment of digital perfusion was performed at 10 minute intervals using:
 - B: Laser Doppler Flowmetry
 - C: Pulse Oximetry
 - D: Skin Surface Fluorescence
 - E: Skin Surface Temperature Measurement via a DermaTemp (Levinsohn et al 1991).

Evaluation of methods of detecting perfusion impairment



Stirrat et al (1978) study on the effect of temperature on digital replantation

A study by Stirrat et al (1978)² on the effect of temperature monitoring in digital replantation demonstrated a decline in perfusion may be recognized earlier via temperature monitoring and improvement gained by clinical measures before the need for reoperation occurs. The objective temperature measurements allow a nurse or nurses aide to follow condition, especially where skin color cannot be followed easily, e.g. dark-skinned patients or with severely trauma-

Care and Maintenance

Handling

Your DermaTemp is designed and built to industrial durability standards in order to provide long and trouble-free service. However, it is also a high precision optical instrument, and should be accorded the same degree of care in handling as you would provide other precision optical instruments, such as cameras or otoscopes.

Calibration

Factory calibration data is installed via a computer through an optical link with the microprocessor. The instrument automatically self-calibrates each time it is turned on using this data, and will never require recalibration. If readings are not correct, the instrument should be returned for repair.

Cleaning

The DermaTemp can be gas or plasma sterilized, or wiped down with any hospital approved disinfectant, even bleach. With normal use, the only maintenance required is to keep the lens on the end of the probe clean. It is made of special mirror-like, infrared-transmitting material called Germanium.

Dirt, greasy films or moisture on the lens will interfere with the passage of infrared heat and affect the accuracy of the instrument. If necessary, clean the lens with an alcohol prep or a cotton swab dipped in alcohol. Periodic cleaning is a good practice.

Self Diagnostics

Continuous Single Beeping

The high performance DermaTemp continuously monitors its ability to produce accurate temperature readings. If either the target's temperature or the unit's ambient temperature exceeds the operational limits, the beeper will sound once per second and the LED display will default to a display message.

When the target temperature is outside of the instrument's operating range, the unit will display either HI or LO and will beep continuously at one beep per second. When the instrument's own temperature is outside operating limits for ambient temperature, the display will show either HI A or LO A, and will beep continuously at one beep per second.

Handwritten mark resembling a stylized 'S' or '2'.

Continuous Double Beeping

The battery voltage is also monitored. A low battery is indicated by a continuous double beep per second. Temperatures will continue to be displayed as long as accuracy can be assured. If the battery drops below 5.7 volts, it is considered "dead" and the display defaults to (---).

Customer Service

If repair is required:

- Contact Exergen for a Return Materials Authorization Number (RMA).
- Mark the RMA number on the outside of your package and packing slips.
- Include a description of the fault if possible.
- Send the instrument freight/postage prepaid to

Exergen Corporation
 51 Water Street
 Watertown, MA 02172
 Attention: RMA _____

- The instrument will be returned freight/postage prepaid.

Questions:

Should you have any clinical or technical questions, please contact a customer service representative in the medical division at Exergen Corporation. They may be contacted either by phone (617-923-9900), fax (617-923-9911) or email to medical@exergen.com.

sia, concluding skin temperature increase to be a useful indicator of sympathetic blockade, demonstrating that temperature elevation always preceded the upper limits of sensory blockade, and had a similar pattern of onset.

Epidural Catheter Positioning in Labor and Delivery

Foot temperature has successfully been demonstrated as an indicator in the functional positioning of an epidural catheter. In a recent study conducted at Georgetown University Medical Center involving 70 patients, Shin et al¹ confirmed the associated temperature changes provided better and objective evidence compared to the sensory pinprick test or subjective pain scales. The rapid and differential rise of foot temperature allowed early positioning of the patient with the unblocked cooler side down.

Joint Inflammation

Thermographic techniques have generally been used to demonstrate that surface temperature variations are an effective means to assess joint inflammation due to trauma and disease. Although the technique is effective it is not readily available in most clinical situations. In almost any clinical environment, infrared thermometry can provide the same basic data rapidly and at low cost.

In a paper on skin temperature as an indicator of joint inflammation, Guadagni et al (1974)² describe the surface temperature elevation over arthritic joints and the correlation of this measurement with the more conventional inflammatory index. They concluded averaged joint skin temperature not only offers quantitative but as reliable and reproducible information about the degree of joint inflammation as conventionally used parameters such as inflammatory index, grip strength, and joint size. Recorded temperature data provides an objective means for the evaluation of the joint and its treatment modality over time. Both the magnitude of the temperature elevation and its profile across the joint may be used in the evaluation.



Evidence of connective tissue disease

88

A striking example of perfusion effects can be demonstrated by compromise of circulation to the arm. A complete or partial occlusion of the artery in the upper arm will result in an immediate drop in hand temperature, and detectable in less than 30 seconds from the time of occlusion. The rapid response and the simplicity of infrared measurements make the technique effective in the hospital environment.

III. Clinical Applications

The following is a brief synopsis of a number of clinical applications for surface temperature measurements. These subjects are not covered in sufficient detail to be used for clinical protocols and are intended to be general indications for the use of infrared temperature measurements for clinical purposes. Because of the sensitivity of surface temperatures to the environment, it is important that certain precautions be followed in making surface temperature measurements. They are:

1. Provide for adequate equilibration time in the room environment at which the measurements will take place.
2. Protect the patient from drafts and exposure to cold surfaces (windows in winter).
3. Consider the use of a skin surface marker to ensure the measurement sites are repeatable.

Regional Blocks

The effectiveness of regional blocks can be monitored using the change in surface temperature due to sympathetic vasodilation of the tissue in the blocked area, eliminating the subjective pin prick assessment method. Depending on the type and location of the block, one can expect to see a temperature increase in the order of 1 to 1.5°C on the skin surface of the blocked area in 10 to 30 minutes after the injection of the blockade drug.



Using the DermaTemp to verify the geography of the block

In a recent study on sympathetic blockade, Chamberlain et al (1986)¹ measured the dynamic pattern of skin changes during spinal anes-

II. Body Surface Temperature

History and Introduction

As early as 2800 BC, the Egyptians, using the scanning sensitivity of the fingers over the surface of the body, recognized that the body produces heat, and that heat increases with disease. Further recognizing the distinction between local inflammation and fever, the Egyptians set the foundation for monitoring body surface temperature as a separate and distinct diagnostic methodology from the monitoring of core body temperature.

But the ancient diagnostic technique of feeling for heat is highly subjective, and only as sensitive as the hand of the feeler. The test of temperature is relative to the detector. A cold hand will indicate a warm body surface that a warm hand will indicate as cold. Certainly, the hand of an experienced physician laid upon the skin could provide much useful information about the temperature of the patient and the course of an illness, but eventually a more objective assessment was possible with the introduction of the clinical thermometer developed during the last century.



Typical 19th Century Thermometer

One of the earliest references to actually quantifying body surface temperature as a clinical diagnostic was in 1864 during the Civil War. Dr. Jackson Chambliss, a surgeon in the Confederate Army, used a thermometer to diagnose a traumatic femoral aneurysm by showing that surface temperature was decreased distally in the affected leg.¹

In more recent times, the measurement of the surface temperature of the human body has not been routinely undertaken in many clinical environments - not because the measurement lacks clinical significance, but because it has been difficult to acquire. Conventional mercury or electronic thermometers have generally been ineffective for surface temperature measurements for three reasons: 1) they are difficult to properly attach to the body surface, 2) they require a significant amount of time for the sensor portion of the device to equilibrate to the body



Electronic Thermometer

temperature measurements for three reasons: 1) they are difficult to properly attach to the body surface, 2) they require a significant amount of time for the sensor portion of the device to equilibrate to the body

surface temperature and 3) they are prone to low readings because it is not always evident that the surface thermal connection is adequate.

Body Surface Temperature

Heat signatures vary considerably over the surface of the human body, and physicians have long appreciated the relationship between heat and disease. In fact as early as 400 BC, Hippocrates wrote "*In whatever part of the body excess of heat or cold is felt, the disease is there to be discovered.*" Undoubtedly the earliest use of clinical thermography, Hippocrates found when he covered his patient's body with wet clay, the mud dried quicker on the diseased area, thus presenting a crude but dramatic demonstration of the heat signatures.



Thermographic scan of the patient with clay on his body. (Dorex, Inc. CA)

It is impossible to define the surface temperature by any single normal value, since it is the result of a thermal balance between energy supplied from the core via perfusion and energy lost to the environment via radiation, conduction, convection, and evaporation. All objects, whether animate or inanimate, homeothermic or poikilothermic, radiate electromagnetic energy (radiation) to the surroundings at a rate dependent on its temperature. In accordance with a basic law of physics, this invisible radiation is constantly emitted, absorbed, and re-emitted by everything in our surroundings so that thermal equilibrium can be maintained. A simple example: left in normal room temperature, a cup of hot coffee quickly cools and a glass of iced tea quickly warms to the temperature of the room.

If the human eye had the optical power to see the emitted radiation, which has all the same properties as a beam of light, but differing in wavelength, all mankind would have an incandescent glow. Because the temperature over the surface of the human body changes at a rapid rate in response either to its external environment or to its internal control mechanism, the incandescence would be quite bright over some areas and quite dark over others. This variability of the temperature pattern gives question as to its significance, and yet it is a remarkable indication of the underlying body physiology.

All biological tissue generates energy in proportion to the metabolic activity occurring within the cells. About 80% of the energy developed by

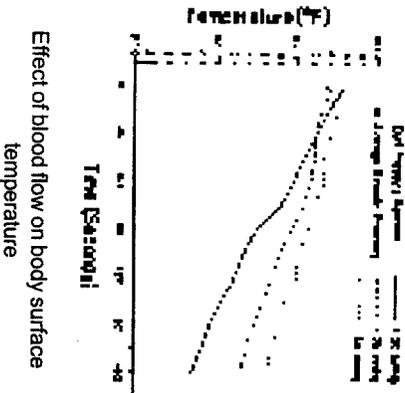
bilateral symmetry. Skin temperature differences from one side of the body compared to the other are not only extremely small, but also very stable, and unaffected by the age of the patient. Data show differences between sides at the forehead to be 0.12°C at the forehead, and 0.25°C at the lumbar region of the back. This symmetry forms the foundation for clinical interpretation of the varying surface temperature data.

In general, it is the relative readings between the body surface temperatures that are of interest. Hence, the general principle is *all detection is by exception*. Accordingly, the temperature data from the normal or reference area can then be used to adjust for the circadian variations and for variations in the ambient temperature.

The change in body surface temperature with compromised blood flow is profound. A recent study was undertaken to mimic both partial and complete occlusion of blood flow to an extremity. The results indicate changes in skin surface temperature of an extremity reflect blood flow interruption or alteration in blood flow to that extremity.

A baseline for systolic blood pressure was determined for each subject and the manometer cuff inflated to three levels, 30 mmHg above systolic, 25 mmHg below systolic and 50 mmHg below systolic, with temperature readings taken on the inside wrist at 15 second intervals. Even at the lowest cuff pressure, there is a clear indication at the end of three minutes of the surface temperature change due to the lowered tissue perfusion caused by the reduction in arterial blood flow. The data also indicate the time between occlusion or partial occlusion and a measurable temperature drop is very short, well under one minute.

The surface temperature readings of the human body tend to be quite close between the bilaterally symmetric surfaces of region because of perfusion symmetry, but vary by several degrees on different body locations because of perfusion differences. Both the hands and the feet can be substantially colder than the rest of the body surface due to vasoconstriction of arteriovenous shunts as a thermoregulatory response.

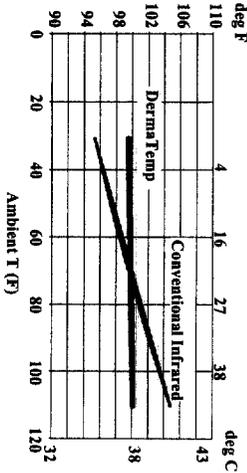
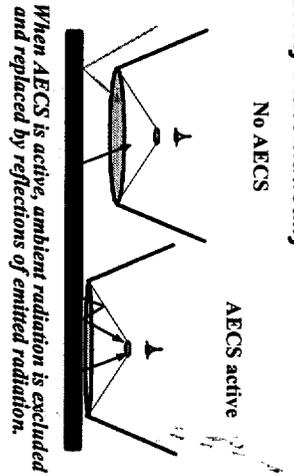


Effect of blood flow on body surface temperature

20

Correcting for Emissivity Automatically

Biological tissue has high emissivity, i.e. ~0.95. Accordingly, the reflected component will be about 5% of the energy measured by the DermaTemp, which translates to an absolute error of ~1°F (0.5°C). In addition, skin emissivity varies due to color, texture, etc. over the approximate range of 0.92 to 0.98. An uncertainty of approximately ±1°F (0.5°C) results from this emissivity variation, which can appreciably influence the assessment of a subtle perfusion issue.



A more significant error is due to the reflected energy, which can vary considerably if the ambient radiation includes sunlight, radiant warmers, etc. To solve this problem the DermaTemp is equipped with a unique patented feature called Automatic Emissivity Compensation System (AECS). The reflective cup on the end of the probe automatically compensates for emissivity when it is touching, or brought to within approximately 1mm of the surface. By excluding ambient radiation, and replacing it with reflections of emitted radiation, the emissivity is corrected, and the accurate temperature indicated.

Detection by Exception

The distribution of the temperature on the body surface varies appreciably. For example, on a normal individual, the highest average skin temperature is the forehead at 34.5°C (±0.73°C) and the lowest average temperature is the toes at 27.1°C (±2.72°C).¹ Considering the temperature of the skin is highly influenced by ambient temperature, one could wonder what diagnostic role, if any, temperature would play. The answer is that it plays a significant role, and the reason is the

the human body is converted into heat, with the balance converted into external work or into tissue growth. The circulatory system, in addition to circulating blood for its metabolic characteristics also distributes heat, thus replacing the heat energy lost to the environment, as well as nourishing the tissue. The resultant increase in heat energy delivered by the blood causes the temperature to rise until the heat energy lost to the environment again balances with the heat delivered.

It has long been recognized that where there is injury or infection, there is inflammation, but injury or infection of itself does not create heat energy. When there is trauma, whether an injury or abnormal stimulation caused by a physical, chemical, or biologic agent, a pathologic process of reactions occurs in the blood vessels and adjacent tissues in response to the perturbation. The natural defense mechanism triggered immediately increases the flow of blood to the area of concern, causing the temperature to rise in proportion to the increase in blood flow. However, the maximum temperature can be no higher than that of the core arterial supply to the trauma tissue.

Consider as a simple analogy, the action of washing your hands in a sink. If the water from the hot faucet were to be trickling in a small stream, it is likely it would feel only lukewarm. However, if you were to open that tap full force, the rushing water would feel quite hot. But, no matter how intense the rush, the water could never be hotter than the water from its source of heat, the furnace.

The ancient diagnostic technique of feeling for heat over the body is a longtime indicator of inflammation. While localized temperature elevations may be felt merely by the touch of the hand, the technique is highly subjective, and not sufficiently sensitive to detect the subtle temperature rises indicative of increased cellular or metabolic activity. With the introduction of infrared techniques, accurate surface temperature patterns are immediately quantifiable and any changes easily detected. It is this knowledge that enables us to study any disease process resulting in a change in heat generation or thermal properties of the tissue.

Infrared Thermometry

Temperature is a fundamental property of all matter related to its energy content, and can be described by a numeric value expressed on a scale of temperature. A human's touch produces an instinctive sense of hot or cold to judge the relative temperature of two objects. However, as a practical matter, clinicians must have a temperature scale that is independent of the observer, by which unknown temperatures

85

can be evaluated. With a proper temperature scale, measurements taken at different times or places can be compared. Without a thermometer, it would be impossible to measure the temperature of a human with respect to a fixed scale of reference. Remember, the human test of temperature is relative to the detector. A cold hand will indicate a warm body surface that a warm hand will indicate as cold.

Numerous techniques and devices are employed in the measurement of temperature. Many of these techniques, such as the use of glass mercury thermometers or electronic display devices using thermocouples or thermistors, are generally understood and as a result well accepted in clinical medical practice. All three of the devices have one very important characteristic: they measure their own temperature, not the temperature of the object being measured, except in an indirect way. In order to make an accurate temperature determination using one of these measurement techniques, it is necessary for the device to have intimate contact with the subject for sufficient time to raise the temperature of the thermometer to the same, or close to the same, temperature as that of the subject. Thermal contact thermometers require too much time to equilibrate, are sensitive to variations in contact pressure resulting in changes in the thermal resistance between the skin and the temperature detector, and tend to have too great a variation from reading to reading. If these devices are not properly located, properly attached, or left in place for enough time to equilibrate, they all will give incorrect readings.

The infrared method is fundamentally different from the other methods in that there is no temperature device to heat. Like an eye, the infrared instrument simply looks at the heat radiation naturally emitted from the body surface. Since there is nothing to heat, the measurement can be made very fast, orders of magnitude faster than the probe devices.

Historically, most of the published clinical data on body surface temperature measurements are based on the use of infrared thermography. Infrared thermography has long been recognized as a reliable, highly technical diagnostic tool, and refers to the process of recording and interpreting variations in temperature of the surface of the skin in color or shades of gray. The clinical information is contained in the relative temperature profiles. The technique is effective, but the equipment is complex and expensive.

Decades ago, the common image of a computer was that of an enormous, very expensive piece of equipment, something requiring an environmentally controlled room and complex installation. Today's computers have been reduced to hand held units. Infrared thermography



Alice's Quest for Emissivity

Is it possible to see a mirror?

When the mirror is looked at, all other objects in the room are seen.

Is it invisible?

No, if it were, the wall would show behind it.

So how can it be seen?

If crayon spots are painted on the mirror, then the mirror can be seen.

Of course, it can only be seen where there are spots.

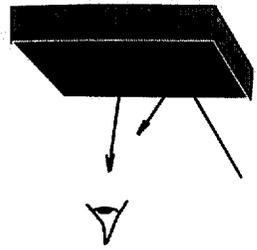
Everywhere else still reflects.

Thus, light is emitted from the spots and reflected from the non-spots.

(Full reprint available from Exergen)

86

ample, we saw 90% of the mirror as a perfect reflector and 10% as imperfections, 90% of the mirror would reflect; the remaining 10% would emit. Therefore, the emissivity equals 0.1.



Good Emitter
Emissivity = 0.9
Reflectivity = 0.1

1.0

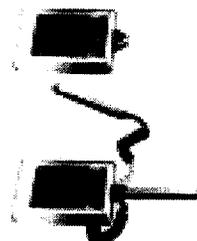
Consider for a moment the exact opposite of a perfect mirror, which is a perfect emitter. The eye looks at a perfect emitter and sees no reflection at all, only the emitting surface. Since 100% of the surface emits, and 0% reflects, the emissivity equals 1.0. This type of object is called a blackbody.

And finally, consider a good emitter. The eye sees a small amount of reflection interspersed with the large amount emitting. If, for example, 10% of the surface did not emit, and instead reflected, then we would have 10% reflecting and the remaining 90% emitting. Therefore, the emissivity equals 0.9. Accordingly, we can state the following rule of emissivity: **The emissivity of the surface is simply the percentage of the surface that emits. The remaining percentage of the surface reflects.**

was not a lot different: large and expensive, requiring environmentally controlled rooms, trained technicians, and exotic gases. Today's advanced technology makes it possible to put the power of infrared thermography in the palm of your hand, at a fraction of the cost of all previous techniques. While there are a variety of infrared thermometers available, only one is designed specifically to meet the stringent clinical requirements, the DermaTemp Infrared Thermographic Scanner.

The DermaTemp Infrared Thermographic Scanner

The DermaTemp is a high precision handheld infrared thermographic scanner designed to detect the subtle skin temperature variations caused by underlying perfusion variations. These instruments instantly measure temperature on any surface location on the human body without the need for tissue contact.



DermaTemp DT 1001 and DT 1001-RS

The DermaTemp is highly recommended for use in plastic and vascular surgery, anesthesiology, pain management, rheumatology, neurology, oncology, and wound management. Other applications follow this section.

Infrared thermometry is fast, stable, repeatable, and is relatively insensitive to user technique. Skin temperature measurements with infrared thermometry are attractive because they are objective, low cost, and cause absolutely no trauma or discomfort to the patient. The versatility of the products allows for absolute temperature measurement, surface scanning, and comparative methods of temperature differential.

Method Impedimenta

Despite the tremendous benefits of using infrared technology for clinical applications, there are several impediments which should cause pause, such as variable skin characteristics, wet skin, and environmental influences. Since the process of measuring temperature by viewing the infrared radiation of the surface is significantly faster than the other techniques mentioned earlier, the user needs to be aware of several important considerations. The surface temperature of the human body is sensitive to the external environment and can vary by several degrees in a short period of time. Drafts will lower the surface temperature. A cold room environment will lower the surface temperature. Any surface moisture will lower the surface temperature. Exercise will raise the surface temperature due to increased perfusion as a ther-

more regulatory response. Exposure to the sun or any other warm surface will raise the surface temperature. The user needs to be aware of these concepts and not be surprised in the event the temperature readings are not as expected.

Ambient Effect on Body Surface Temperature

The cardinal rule of interpretation of skin temperature is that the same environment will produce the same temperature if perfusion is the same. If the environment is the same and the temperature is different, then perfusion must be different. But body surface temperature can be significantly influenced by the temperature of the surrounding environment as evidenced in the table.

Effect of Ambient Temperature on Skin¹

Ambient	Hand	Forehead
4°C	8.9°C	13.7°C
23°C	26.9°C	29.2°C
27°C	33.2°C	33.2°C

Therefore, absolute temperature readings must be interpreted in relation to the environment, and the practitioner should be careful to protect the patient from drafts or exposure to large cold surfaces, to position the extremities to minimize pooling, and to allow time for the surface temperature to equilibrate to its environment.

The distribution of the temperature on the body surface is generally bilaterally symmetric. This symmetry can form the basis for clinical interpretation of the surface temperature data. The temperature data from the normal or reference area can also be used to adjust for the circadian variations and for variations in the temperature environment. In general, it is the relative readings between the body surface temperatures that is of interest.

Solving the Problems

The DermaTemp is the result of many years of active scientific research in both the technology and clinical requirements. The patented reflective cup on the probe of the DermaTemp provides accuracy heretofore unavailable for clinical use. The instrument is completely unaffected by conditions prohibiting the use of other infrared devices. Because of its unique design, the classical problems in producing accurate temperatures have been solved.

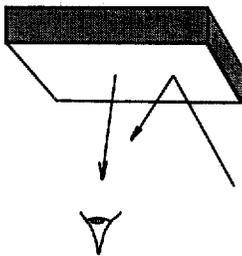


Reflective cup on probe tip

Emissivity

An important concept needed to understand how temperature is measured using infrared radiation is the one of emissivity. Emissivity is a surface property which determines just how well an object's temperature can be measured by an infrared device. Emissivity (along with background thermal radiation) is the primary source of errors in infrared temperature measurement. Emissivity can be more easily understood if it is realized that infrared has similar properties to visible light.

Simply stated, emissivity is the opposite of reflectivity. A perfect mirror has a reflectivity of unity and an emissivity of zero. A perfect black body has an emissivity of unity and a reflectivity of zero. In actuality, all real bodies (including human ones) have an emissivity between these two limits.



Poor Emitter
Emissivity = 0.1
Reflectivity = 0.9

1.0

It is not possible to accurately measure the surface temperature of any body with an emissivity of less than 1.0 without making a correction for this source of error. Human skin is near but not equal to 1.0 and, if not accounted for, can introduce errors in the order of one to two degrees. The cup-like mirror used in the nosepiece of the DermaTemp scanner removes this source of error by trapping all of the radiation from the skin surface and in effect causing the skin surface to act like a black body with an emissivity of 1.0.



Blackbody
Emissivity = 1.0
Reflectivity = 0.0

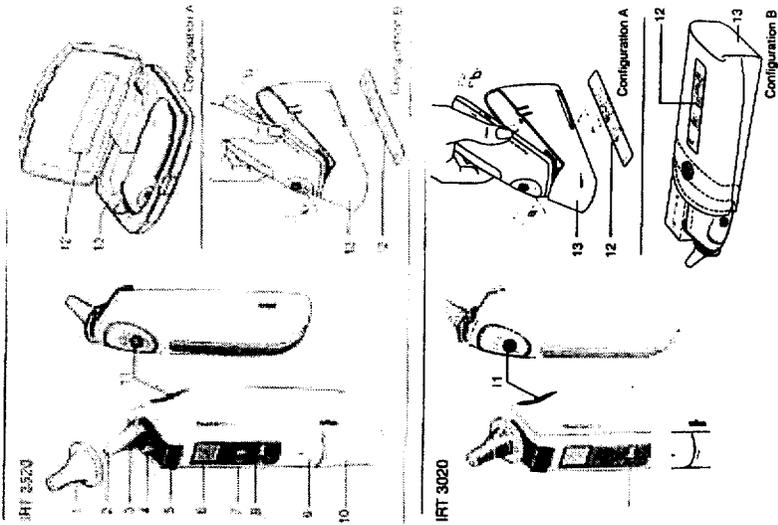
1.0

Mirrors figure prominently in the discussion of heat radiation and emissivity. Since heat and light radiation behave the same way, we can use what we see with our eyes as examples of what the DermaTemp sees. When you look in the mirror, you see only reflections, nothing of the mirror itself. If the mirror is perfect, it has 100% reflectivity. Because it reflects everything, it emits nothing. For this condition, the emissivity is zero.

If we consider an imperfect mirror, the eye then sees mostly reflection, but also some of the imperfections on the mirror surface. If, for ex-

Braun Predicate Device Labeling

89



English

The Braun ThermoScan thermometer has been carefully developed for accurate, safe and fast human body temperature measurements in the ear. The shape of the thermometer prevents it from being inserted too far into the ear canal to damage the eardrum.

However, as with any thermometer, proper technique is critical to obtaining accurate temperatures. Therefore, please read all instructions carefully and thoroughly before using this product.

Important

- The operating ambient temperature range for this thermometer is 50 °F to 104 °F (10 °C to 40 °C).
- Do not expose the thermometer to temperature extremes below - 4 °F or over 122 °F (- 20 / 50 °C) or excessive humidity (> 95 % RH non-condensing).
- This thermometer must only be used with genuine Braun ThermoScan Lens Filters (LF 40). Never use this thermometer without a new, clean lens filter attached.
- If the thermometer is ever accidentally used without a lens filter attached, clean the lens (see Care and Cleaning).
- Always store thermometer in travel case, protective cover or plastic case.
- Basic safety precautions should always be observed, especially when using the thermometer on or near children and disabled persons.
- Keep lens filters out of reach of children.
- This thermometer is intended for home use only.
- Use of this thermometer is not intended as a substitute for consultation with your physician.
- Do not leave thermometer or lens filters with infants or children at any time.

How does Braun ThermoScan work ?

The Braun ThermoScan thermometer measures the infrared heat generated by the eardrum and surrounding tissue. To help ensure accuracy, the thermometer - scans - by taking 8 measurements in just one second and displaying the highest temperature. The displayed ThermoScan temperature is the actual measured ear canal temperature plus a mathematical adjustment to approximate the familiar oral range. However, this is not necessarily the same as an oral temperature measured at the same time.

Why measure in the ear ?

The goal of thermometry is to measure core body temperature, which is the temperature of the vital organs. Clinical studies have shown that the ear is an excellent site to measure body temperature, since ear temperatures reflect core body temperature. The eardrum shares blood supply with the temperature control center in the brain, the hypothalamus, allowing changes in body temperature to be reflected sooner in the ear than at other sites.

- Axillary temperatures reflect skin temperature which may not indicate core body temperature.
- Oral temperatures are influenced by drinking, eating and breathing through the mouth.
- Rectal temperatures often lag behind changes in core body temperature and there is a risk of cross-contamination.

Body temperature

Normal body temperature is a range. The following table shows that ranges of normal also vary by site. Therefore, readings from different sites, even if taken at the same time, should not be directly compared.

Axillary:	94.5 °F - 98.1 °F	34.7 °C - 37.3 °C
Oral:	95.9 °F - 98.5 °F	35.5 °C - 37.5 °C
Rectal:	97.9 °F - 100.4 °F	36.6 °C - 38.0 °C
ThermoScan [®] :	96.4 °F - 100.4 °F	35.8 °C - 38.0 °C

Also, a person's normal temperature range tends to decrease with age. The following table shows normal ThermoScan ranges by age.

Normal ThermoScan temperature ranges¹

0 - 2 years	97.5 °F - 100.4 °F	36.4 °C - 38.0 °C
3 - 10 years	97.0 °F - 100.0 °F	36.1 °C - 37.8 °C
11 - 65 years	96.6 °F - 98.7 °F	35.9 °C - 37.6 °C
> 65 years	96.4 °F - 98.5 °F	35.8 °C - 37.5 °C

However, the range of normal also varies from person to person and fluctuates throughout the day. It is therefore important to determine your and your family members' normal temperature ranges. This is easily done using Braun ThermoScan. Practice taking temperatures on yourself and healthy family members to determine their normal temperature ranges.

Note: When consulting your physician, communicate that the ThermoScan temperature is a temperature measured in the ear and if possible, note the individual's normal ThermoScan temperature range as additional reference.

1. Chamberlain, J.M., Tenopus, T.E., New Light on Ear Thermometer Readings, Contemporary Pediatrics, March 1994, 114, 41. 2. Chamberlain, J.M., et al., Determination of Normal Ear Temperature with an Infrared Emission Detection Thermometer, Annals of Emergency Medicine, January 1992.

90

Memory mode

The last temperature taken before the thermometer powers down is stored in memory. To enter the memory mode, press the  /mem button.

Even in memory mode, a new temperature can be taken provided that the ready symbol  is shown.

IRT 3020

The last stored temperature is displayed along with the MEM symbol. To quit the memory mode, press the  /mem button again.

IRT 3520

This model allows you to store up to 8 temperatures.

When pressing the  /mem button, the display shows the memory cell number (e.g. MEM 1). When releasing the  /mem button, the stored temperature is displayed.

Each time the  /mem button is pressed, a new memory cell is displayed (up to MEM 8).

An empty memory cell shows " - - °F". Only the first empty memory cell will be displayed.

To quit the memory mode, press the  /mem button again after reaching MEM 8 or " - - °F".

Memory clear

Press the  /mem button for 5 seconds to clear the temperatures stored in memory. Release the  /mem button to return to the ready symbol .

LCD light (model IRT 3520 only) for easy nighttime reading

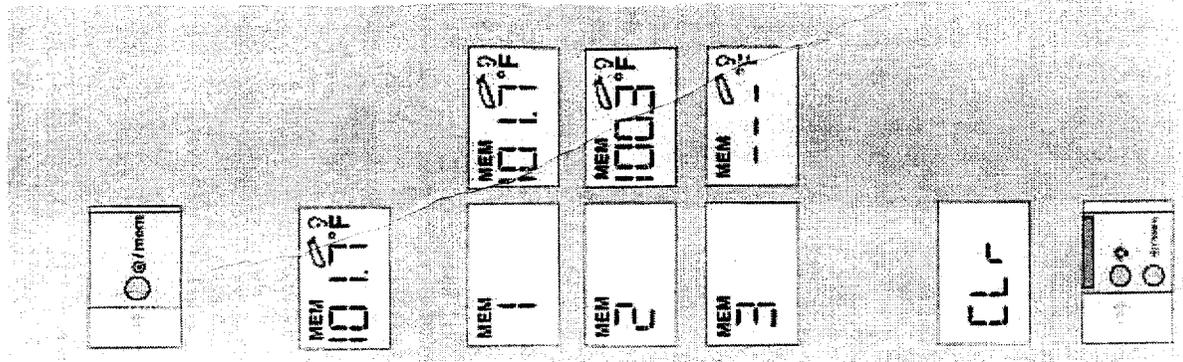
Note: In the following situations, it is recommended that you take three temperatures in the same ear. If they differ, use the highest reading.

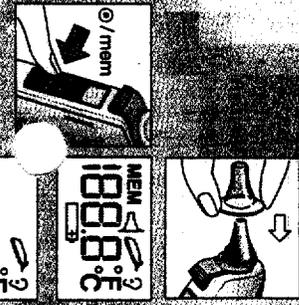
- Infants in the first 90 days of life.
- Children under three years of age who have a condition such as a compromised immune system and for whom the presence or absence of fever is critical.
- When you are first learning to use the ear thermometer until you are comfortable with the technique and are obtaining consistent readings.

Important: As with any type of thermometer, slight temperature variations ($\pm 0.3 - 0.5^\circ\text{F}$ / $\pm 0.2 - 0.3^\circ\text{C}$) can occur, if consecutive measurements are taken.

Temperature taking hints

- The right ear reading may differ from the reading taken at the left ear. Therefore, always take the temperature in the same ear.
- The ear must be free from obstructions or excess earwax build-up to take an accurate reading.
- External factors may influence ear temperatures, including when an individual has:
 - been lying on one ear or the other
 - had their ears covered
 - been exposed to very hot or very cold temperatures, or
 - been recently swimming or bathing.
 In these cases, remove the individual from the situation and wait 20 minutes prior to taking a temperature.





Product description

1. Lens filter
2. Probe tip
3. Probe
4. Lens filter detector
5. Lens filter ejector
6. Display (LCD)
7. LCD light button * (IRT 3520 only)
8. ⊙ /mem button (On / memory function)
9. Battery door lock
10. Battery door
11. Activation button
12. Label
13. Travel case/protective cover/storage pouch (depending on configuration)

Package components

- Braun ThermoScan thermometer
- Use and Care manual
- Quick Reference Guide
- Lens filters (20, plus one on the thermometer)
- Owner registration / warranty card
- Additional items may be included as noted on outer packaging
- Label

The first time you use the thermometer, please make sure to apply the special label included in the package, in the language of your choice (item 12 on page 3).

How to use Braun ThermoScan

1. Always make sure a new, clean lens filter is in place to help ensure an accurate reading. The thermometer will not function without a lens filter attached (see Changing the lens filter).
2. Press the ⊙ /mem button. The LCD (liquid crystal display) is activated, showing all segments.

When the ready symbol  is displayed the thermometer is ready for use.

To help ensure an accurate temperature reading, use the following technique: If you are right handed, hold the thermometer in the right hand and take the temperature in the right ear. If you are left handed, hold it in the left hand and use the left ear.

3. Perform an ear tug to straighten the ear canal. This gives the thermometer a clear view of the eardrum.

Children under 1 year:
Pull the ear straight back.

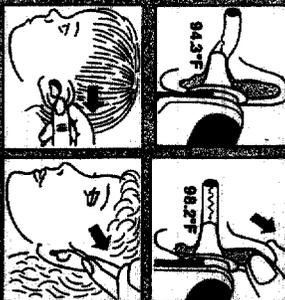
Children aged 1 year to adult:
Pull the ear up and back.

An ear tug is best performed by using your free hand to grasp the outer edge of the top half of the ear. To take your own temperature, wrap your free hand around the back of your head and grab your ear from behind.

4. While tugging the ear, fit the probe snugly into the ear canal as far as possible and press the activation button. Release it when you hear a beep. This is the Temp Beep that confirms the end of measurement.

5. Remove the thermometer from the ear canal. The LCD displays the temperature measured.

6. Replace the lens filter after each measurement: press the ejector button and put on a new, clean lens filter.



92

Changing the temperature scale

This thermometer is shipped with the Fahrenheit temperature scale activated. If you wish to switch to Celsius (°C), proceed as follows:

- Turn on the thermometer.
- (If it is already turned on, make sure it is not in memory mode.) Press the \odot /mem button and keep it pressed. Then press and release the activation button to switch over to the «change temperature scale» mode.
- By pressing the activation button again, the Celsius scale is activated, «C» is displayed on the LCD. Each further pressing of the activation button toggles the scale between °C and °F.
- Release the \odot /mem button to return to the ready symbol \odot .

All temperatures stored in memory will automatically be converted to the selected scale when displayed on the LCD.

Changing the lens filter

The thermometer is supplied with a lens filter in place. To assure accuracy and sanitary practice, Braun recommends replacing the lens filter after each use. To install a new lens filter, first remove the one in place by pressing the lens filter ejector. Check the lens for any damage. Then take a new lens filter from the box, and holding it by its edges, slide it onto the probe until it snaps in place.

Caution: Do not touch the tip of the probe or lens filters when installing. Fingerprints, ear wax, dust and other soiling compounds reduce the transparency, resulting in lower temperature readings (see also Care and cleaning).

Should you run out of lens filters and need to take a temperature, you may use the following lens filter cleaning procedure:

- Clean the lens filter without removing it from the thermometer with a soft cloth or cotton swab moistened with alcohol.
- Do not use hot or boiling water.
- Dry completely with a soft cloth before reusing.
- Replace lens filter as soon as possible with a new one (LF 40).
- Additional lens filters (LF 40) are available at most stores

carrying Braun ThermoScan thermometers or at Braun Service Centers.

- If you have accidentally placed the thermometer in your ear without a lens filter in place, be sure and clean the probe (see Care and cleaning) and then apply a clean lens filter.

Care and cleaning

The probe tip is the most delicate part of the thermometer. It has to be clean and intact to ensure accurate readings.

If the thermometer is ever accidentally used without a lens filter, clean the lens as follows:

- Hold the appliance with the probe tip facing down to prevent liquid from entering the probe tip area. Very gently wipe the surface with a cotton swab or soft cloth moistened with alcohol.
- After cleaning, allow at least 45 minutes drying time before reattaching a new, clean lens filter and taking a temperature. If the probe tip is damaged, contact Braun.

Use a soft, dry cloth to clean the thermometer display and exterior. Do not use abrasive cleaners. Never submerge the thermometer in water or any other liquid.

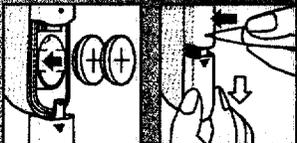
Store thermometer and lens filters in a dry location free from dust and contamination and away from direct sunlight. The ambient temperature at the storage location should remain fairly constant and within the range of 50 °F to 104°F (10 °C - 40 °C).

Always keep cleaning solutions and rubbing alcohol away from children.

Replacing the batteries

The thermometer is supplied with two 3 V lithium batteries (CR 2032/DL 2032). Insert new batteries when the battery symbol \square appears on the display.

Using the tip of a ball-point pen, press the battery door lock to open the battery compartment. Remove the batteries and replace with new batteries, making sure the poles are in the right direction. Slide battery door back in until it snaps in place.



Troubleshooting

Situation	Solution
No lens filter is attached.	Attach new, clean lens filter
No lens filter is attached and activation button was pressed while probe was in the ear.	Make sure probe tip is clean; refer to section "Care and cleaning" if necessary. Attach new, clean lens filter to stop error beeps.
Ambient temperature is not within the allowed operating range 50 °F to 104 °F (10 °C - 40 °C) or changing too rapidly.	Allow the thermometer to remain in a room for 30 minutes where the temperature is between 50 °F to 104 °F (10 °C - 40°C)
Temperature taken is not within typical human temperature range (93.2 °F - 108 °F / 34 °C - 42.2°C).	Make sure new, clean lens filter is attached and thermometer is properly inserted. Then, take a new temperature.
HI = too high LO = too low	
Battery is low, but thermometer will still operate correctly. (No light function on IRT 3020 models.)	Insert new batteries
Battery is too low to take correct temperature readings.	Insert new batteries
System error	Wait 2 minutes until thermometer powers down, then turn on again. ... reset the thermometer by removing the batteries and putting them back in. ... call Braun ThermoScan Customer Services at 1-800-327-7226.
• If error persists	
• If error still persists	

Special situations

The Braun ThermoScan thermometer has been shown in clinical studies to obtain accurate temperatures on persons of all ages. However, there are certain situations when the ear thermometer should not be used. These include but may not be limited to the following situations:

- If there is blood or drainage in the external ear canal.
- For persons who have deformities of the face and ear canal where the probe of the thermometer cannot be inserted fully into the ear canal.
- For persons wearing hearing aids or ear plugs, remove the device and wait 20 minutes prior to taking a temperature.
- Use the untreated ear if prescription ear drops or other ear medications have been placed in the ear canal.
- Never attempt to clean inside ears. You could damage the ear drum or surrounding tissues. You should remove excess ear wax only when you can reach it with a wash cloth. If you suspect that you or your child has excess ear wax, consult your physician.

Fever facts

Many persons may not have an elevated temperature even when they are ill. These include, but are not limited to infants under 90 days of age, persons taking steroids, antibiotics or antipyretics (acetaminophen, ibuprofen, aspirin), persons with compromised immune systems, including the elderly or persons with some chronic illnesses. Consult your physician if you feel an illness is present even if there may not be an elevated temperature.

Fever is described as an elevation of body temperature over an individual's "normal" temperature.

An elevated temperature or fever is often viewed as a danger sign. In fact, a fever can be very beneficial, and helps our immune system work more effectively. A fever should be evaluated in the light of other physical symptoms. With the exception of newborn infants, the presence of fever, without any other symptoms of illness, or in a child who is behaving normally may not be cause for concern. On the other hand, a physician should be consulted in the following situations:

- vomiting
- diarrhea
- changes in appetite, activity or breathing, or
- with children who are irritable, lethargic or unusually sleepy.

Some people, like the elderly, infants under 90 days of age, those with compromised immune systems, or persons who take steroids, for example are often unable to build a response to illness or environmental conditions. These individuals may not be lower than expected for the severity of their illness. Other medications such as anti-inflammatory and some analgesics may also mask fever.

The presence or absence of fever should rarely be used as the only measurement of the significance of illness. Your physician should be contacted whenever there is a question about your family's health.

Antipyretics, like acetaminophen or ibuprofen, are usually recommended to relieve the aches and associated symptoms of fever, not the fever itself. Febrile seizures, or convulsions, which usually occur in children six months to six years of age, are thought to occur not because a fever is present, but because of the rate of rise of the child's temperature. Call your physician if your child has a febrile seizure or you desire further information.

Use of the Braun ThermoScan thermometer is not intended as a substitute for consultation with your physician.

Product specifications

Displayed temperature range 93.2 °F -108 °F (34°C - 42.2 °C)
 Operating ambient temperature range 50 °F -104 °F (10°C - 40 °C)
 Display resolution 0.1 °F or °C

Accuracy for patient temperature range

96.8 °F -102.2 °F (36 °C - 39 °C): ± 0.4 °F ± 0.2 °C
 outside this range: ± 0.5 °F ± 0.3 °C

Long term storage ranges

Temperature: -4 °F to 122 °F (- 20 °C to 50 °C)
 Humidity: 95 % non-condensing

Battery life:

2 years / 1000 measurements.

This infrared thermometer meets requirements established in ASTM Standard E 1965-98. Full responsibility for the conformance of the product to the standard is assumed by Braun GmbH, 61476 Kronberg, Germany.

ASTM laboratory accuracy requirements in the display range of 98.8°F to 102.2°F (36°C to 39°C) for infrared thermometers is ± 0.4°F (± 0.2°C), whereas for mercury-in-glass and electronic thermometers, the requirement per ASTM Standards E 667-86 and E 1112-86 is ± 0.2 °F (± 0.1°C).

The Braun ThermoScan thermometer has been proven to be safe. To ensure the best results, please take the time to read this manual completely and keep it handy for future reference.

In the unlikely event you experience any difficulty using the Braun ThermoScan thermometer, simply call us toll free at : 1 (800) 327-7226.



TYPE BF
 EQUIPMENT

Attention, consult
 ACCOMPANYING
 DOCUMENTS

MEDICAL ELECTRICAL EQUIPMENT
 CLASSIFIED BY UNDERWRITERS LABORATORIES, INC.®
 WITH RESPECT TO ELECTRIC SHOCK, FIRE AND
 MECHANICAL HAZARDS ONLY
 IN ACCORDANCE WITH UL 2801-1 / CAN CSA C22.2
 No.601.1 104K

Internally Powered Equipment
 Continuous Operation
 Not Protected against Ingress of Water
 U.S. Patent No. 5,088,834 Other Patents Pending

25

Section 5 Indications for Use

510(k) Number (if known): K011291
Device Name: TemporalScanner Thermometer

Indications For Use: The TemporalScanner Thermometer is an infrared thermometer intended for the intermittent measurement of human body temperature of people of all ages.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____
Per 21 CFR 801.109)

OR

Over-The-Counter Use

(Optional Format 1-2-96)

90428.W11

91

Section 6 Substantial Equivalence Comparison Table

Substantial Equivalence Table

Item	Exergen TemporalScanner Thermometer (TemporalScanner)†	Exergen Surface Temperature Scanner K873010 (Dermatemp) (Exergen Predicate)	Braun ThermoScan IRT 3020/3520 Thermometer K983295 (Braun Predicate)
Intended Use	The TemporalScanner Thermometer is an infrared thermometer intended for the intermittent measurement of human body temperature of people of all ages.	The Surface Temperature Scanner is intended for the intermittent determination of surface temperature anywhere on the skin surface of a patient	The Braun predicate is intended for the intermittent measurement and monitoring of human body temperature in the home for use on people of all ages.
Where used	Skin surface of the forehead	Anywhere on the skin surface	Skin surface of the auditory canal
Technology Used	Arterial Heat Balance	Arterial Heat Balance	Arterial Heat Balance
Performance Specifications:			
Measurement range (max accuracy)	60 °F to 107.6 °F (15.5 °C to 42 °C)	96 °F to 102 °F (35 °C to 39 °C)	68 °F to 108 °F (20 °C to 42.2 °C)
Total range (min accuracy)	60 °F to 107.6 °F (15.5 °C to 42 °C)	60 °F to 110 °F (15 °C to 43 °C)	68 °F to 108 °F (20 °C to 42.2 °C)
Accuracy (max)	+/- 0.4 °F (0.2 °C)	+/- 0.2 °F (0.1 °C)	+/- 0.4 °F (0.2 °C)
Operating Ambient Range:			
Temperature	60 to 104 °F (15.5 to 40 °C)	65 °F to 95 °F (18 °C to 35 °C)	50 °F to 104 °F
Humidity	Per ASTM 1965-98, up to 95% noncondensing	Per ASTM 1965-98, up to 95% noncondensing	Per ASTM 1965-98, up to 95% noncondensing
Display resolution	0.1 °F or °C	0.1 °F or °C	0.1 °F or °C
Temperature scales	degrees F or C (factory selectable)	degrees F or C (user selectable)	degrees F or C (user selectable)
Storage:			
Temperature	-4° to 122 °F (-20 to 50 °C)	-4° to 122 °F (-20 to 50 °C)	-4° to 122 °F (-20° to 50 °C)

† Formerly the SensorTouch and licensed to Braun ThermoScan

humidity (max)	up to 95% noncondensing	up to 95% noncondensing	95% noncondensing
Electromagnetic compatible	Yes per EN 60601-1-2	Yes per EN 60601-1-2	Yes per EN 60601-1-2
Item	SensorTouch and Exergen TemporalScanner Thermometer	Exergen Surface Temperature Scanner K873010	Braun Thermoscan IRT 3020/3520 Thermometer K983295
	(TemporalScanner)*	(Exergen Predicate)	(Braun Predicate)
Display modes	Displayed temperature is the actual temperature of the temple artery plus a mathematical adjustment to approximate the familiar rectal range	Displayed temperature is the actual temperature of the surface of the skin at the point of measurement.	Displayed temperature is the actual ear temperature plus a mathematical adjustment to approximate the familiar oral range
Power source	9 volt Alkaline	9 volt Alkaline	2 lithium batteries CR/2032/DL 2032
display	LCD	LED	LCD
IR transducer	Thermopile	Thermopile	Thermopile
Indicators			
Battery low warning	yes, audible and visual	yes, audible	yes
User error	Yes	no	yes
Instrument Malfunction	Yes	no	yes
Disposable covers	not required	not required	yes
Case material	(b)(4)	(b)(4)	unknown
memory function	No	no	yes
Auto off	Yes	yes	yes
Standards met	ASTM E1965-98	ASTM E1965-98	ASTM E1965-98
UL listed	Yes	no	yes
CE mark	Yes	Yes	yes

100

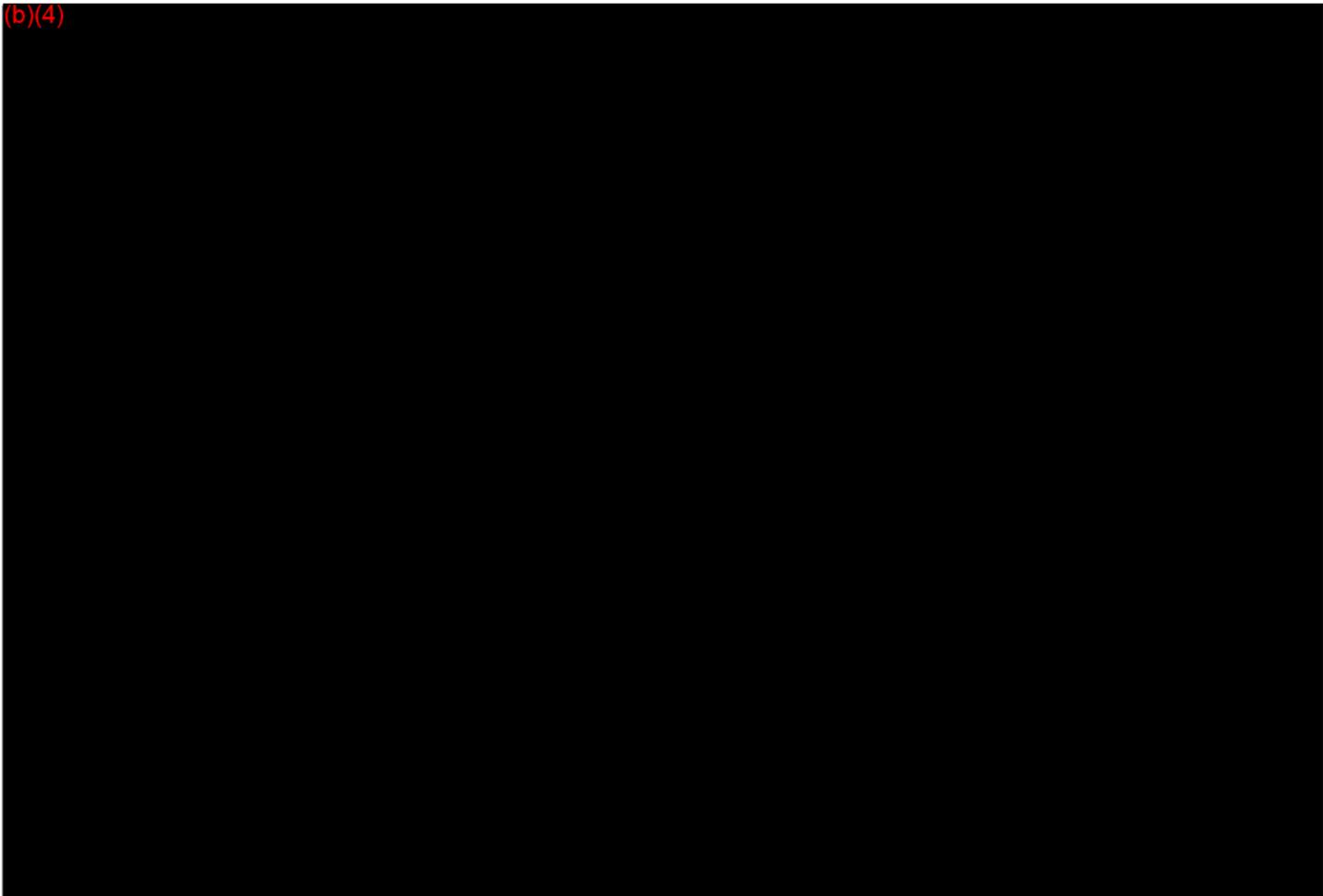
Discussion of Table

Similarities:

1. Same intended use demonstrates equivalence.
2. All units meet the same standard; therefore, the three devices should perform the same.
3. All units are battery operated.
4. All units use solid-state displays, minimizing battery drain.
5. All units have warning displays, such as battery low.
6. All units are CE marked, showing an independent third party assessment of the safety of the devices.
7. The SensorTouch, (renamed TheTemporalScanner), and the Thermoscan are UL listed, another independent third party assessment of the safety of the devices.
8. Consumer Report evaluation on the SensorTouch and the Thermoscan shows an independent third party assessment of the performance of the two devices.

Differences:

(b)(4)



101

Section 7 Summary

510(k) Summary

Submitter's Name: Exergen Corporation

Address: 51 Water Street
Watertown, MA 02172

Phone: (617) 923-9900
(800) 422-3006

Fax: (617) 923-9911

Contact: Gerald A. Clay

Date of Summary: April 27,2001

Trade Name: TemporalScanner Thermometer, formerly known as SensorTouch

Classification: Thermometer, Clinical, Electronic
Product Code: FLL
Regulation No. 880.2910
Class: II
Panel: 80 (General Hospital)

Predicate Device(s): Exergen Surface Temperature Scanner (K 873010) (Exergen Predicate)

Braun Thermoscan IRT 3020/3520 (K983295)(Braun Predicate)

Device Description: The TemporalScanner is a hand held, battery operated device that measures the skin temperature of the skin over the temporal artery. Operation is based on measuring the natural thermal infrared radiation emitted from the surface of the skin over the temporal artery.

Intended Use: The TemporalScanner Thermometer is an infrared thermometer intended for the intermittent measurement of human body temperature of people of all ages.

Technological

Characteristics: The TemporalScanner Thermometer and the predicate devices are all used to measure the temperature of a human by means of a thermopile

infrared sensor transducer coupled with electronic signal amplification, conditioning, and display unit.

The Exergen Predicate employed solid-state electronic signal amplification which is technology similar to the electronic surface mount technology used by the TemporalScanner Thermometer and the Braun Predicate. The Braun Predicate's signal conditioning consists of making mathematical adjustments to display the familiar oral range. Similarly, the TemporalScanner Thermometer's signal conditioning consists of making mathematical adjustments to the temperature measured at the skin surface over the temporal artery to display the familiar rectal range. All display units are solid-state displays, with the Exergen Predicate using an LED display while the TemporalScanner Thermometer and the Braun Predicate employ an LCD display.

All of the devices meet ASTM E1965-98 *Standard for Infrared Thermometers for Intermittent Determination of Patient Temperature, to the extent that this standard applies to them.*

The primary difference between the TemporalScanner Thermometer and the Braun Predicate is that the Braun Predicate measures the temperature of the auditory canal and mathematically converts and displays a familiar oral temperature, while the TemporalScanner measures surface skin temperature over the temporal artery and mathematically converts and displays a familiar rectal temperature.

Summary of non-clinical Performance Testing:

Performance test	Results
Accuracy tests	Pass
(b)(4) tests	Pass
(b)(4) tests	Pass
(b)(4) tests	Pass
(b)(4) tests	Pass
(b)(4) test	Pass
EMC tests	Pass
(b)(4) test	Pass
	Pass

104

Conclusion:

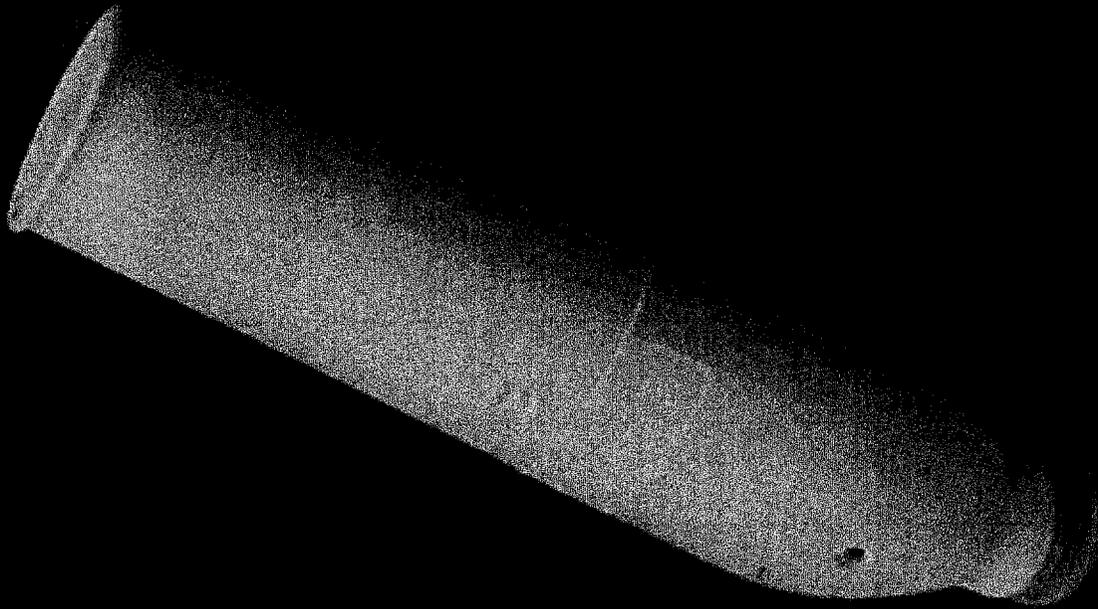
Since performance testing confirms conformance to the same standard as both predicate devices, we conclude the device is substantially equivalent to those devices.

W5

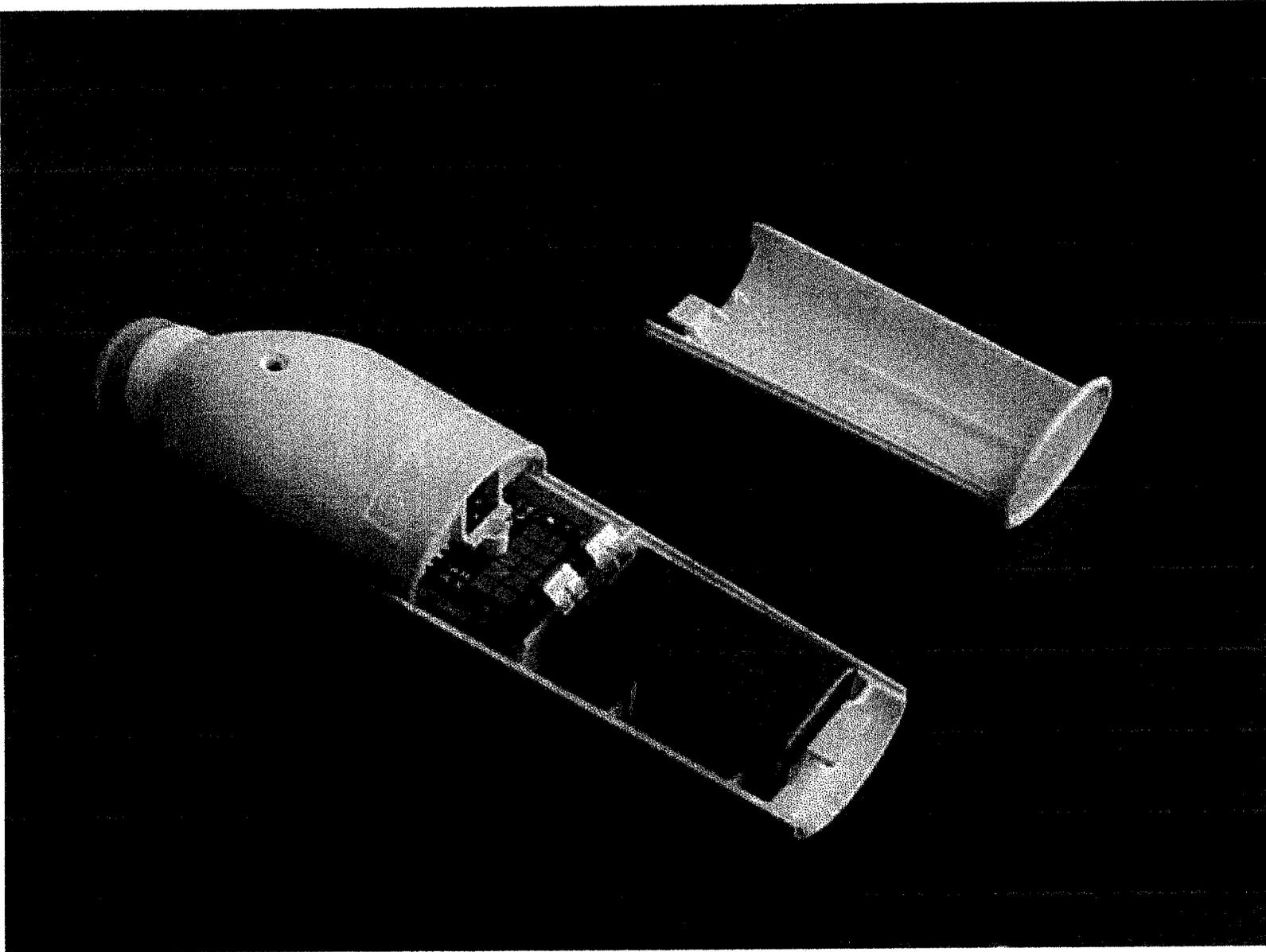
Section 8 Description

106

TemporalScanner 8B-1

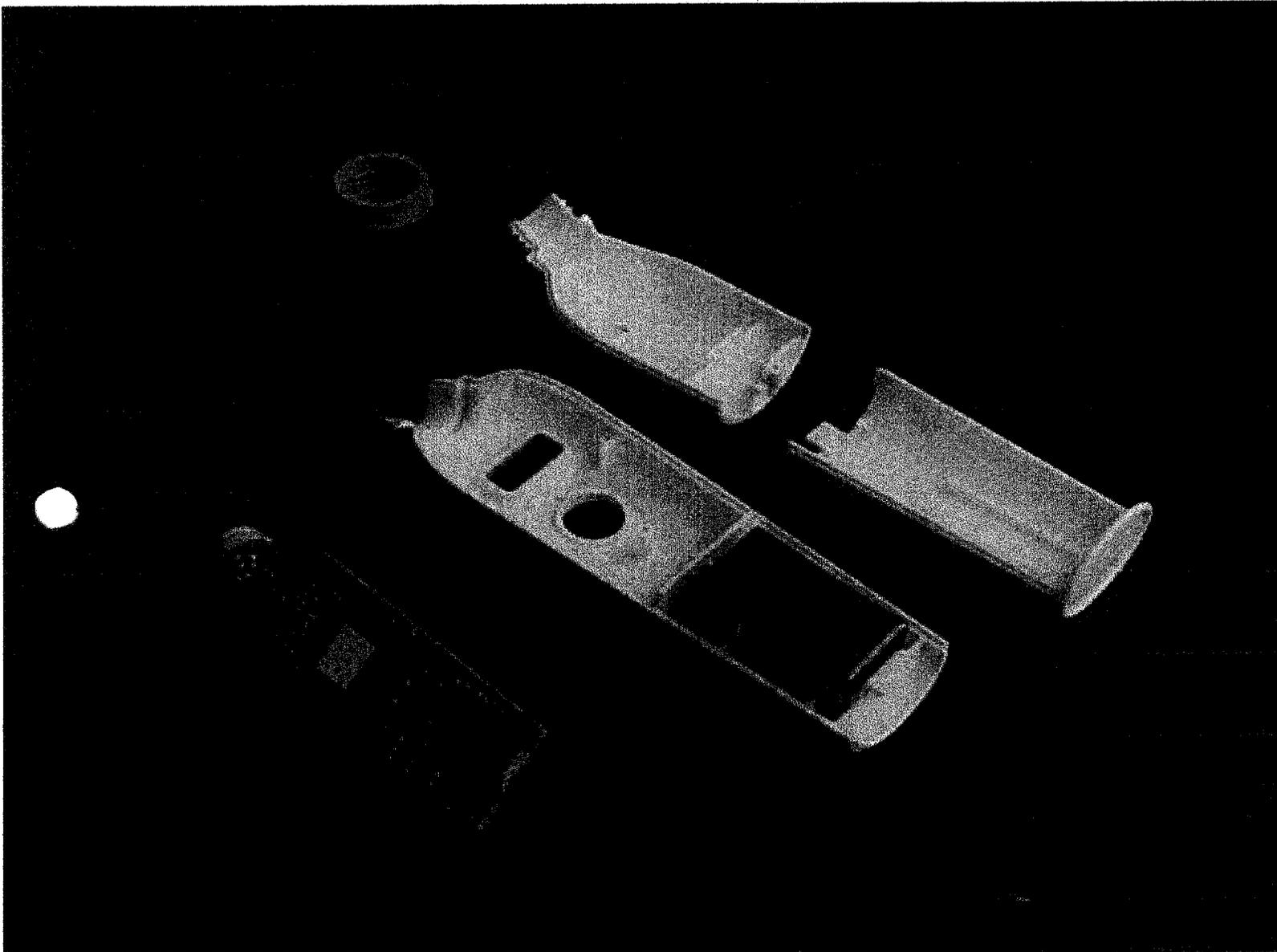


TemporalScanner 8B-2



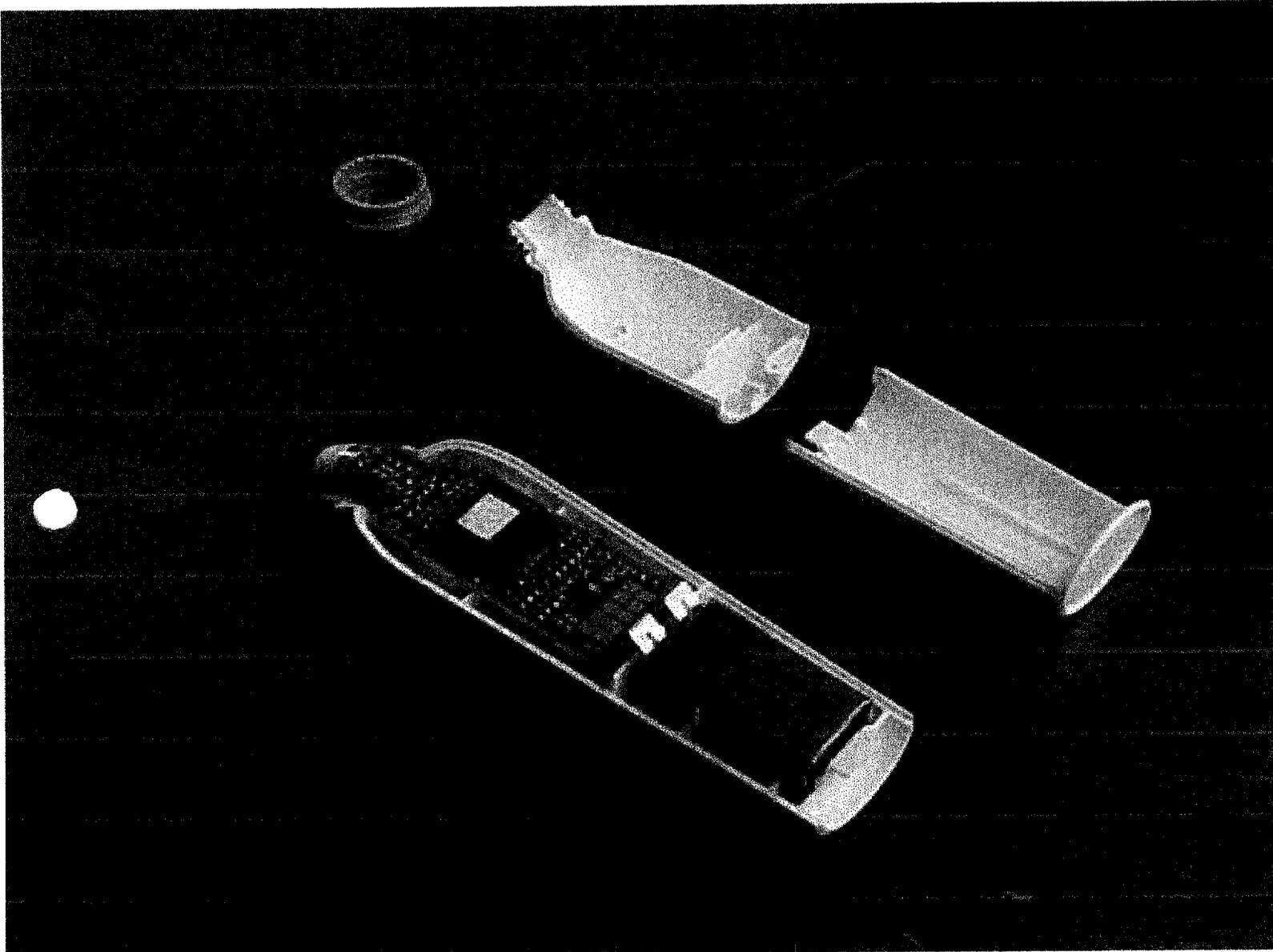
114

TemporalScanner 8B-3



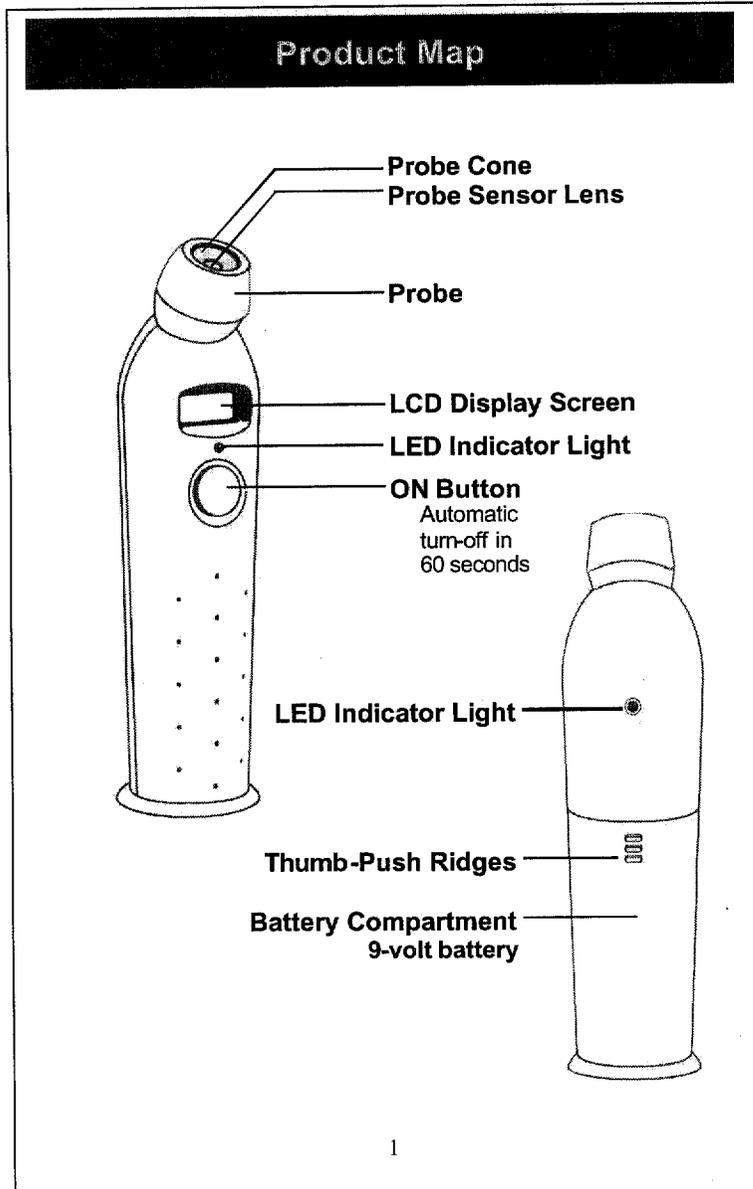
115

TemporalScanner 8B-4



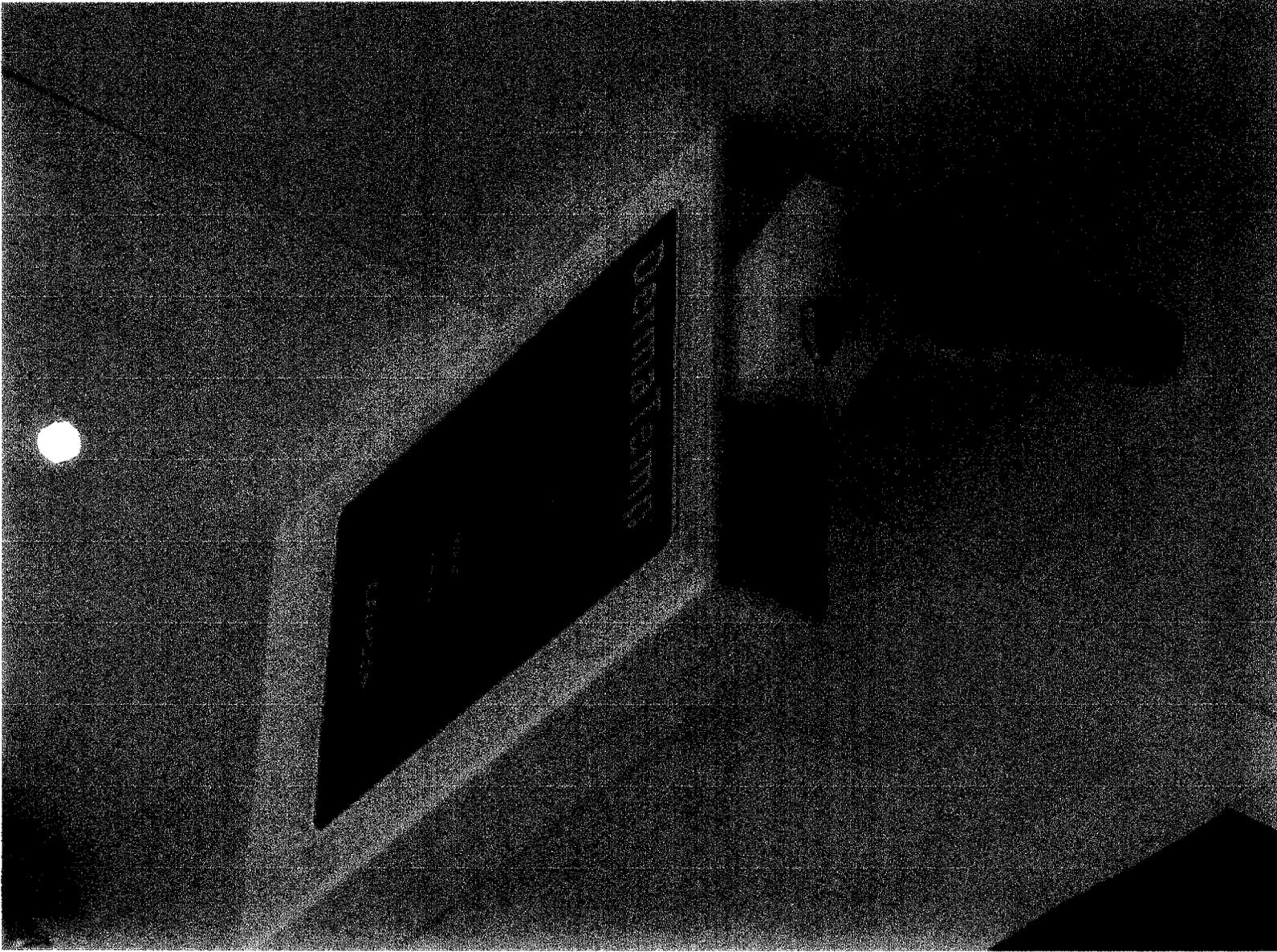
Labeled Diagram:

TemporalScanner 8B-5

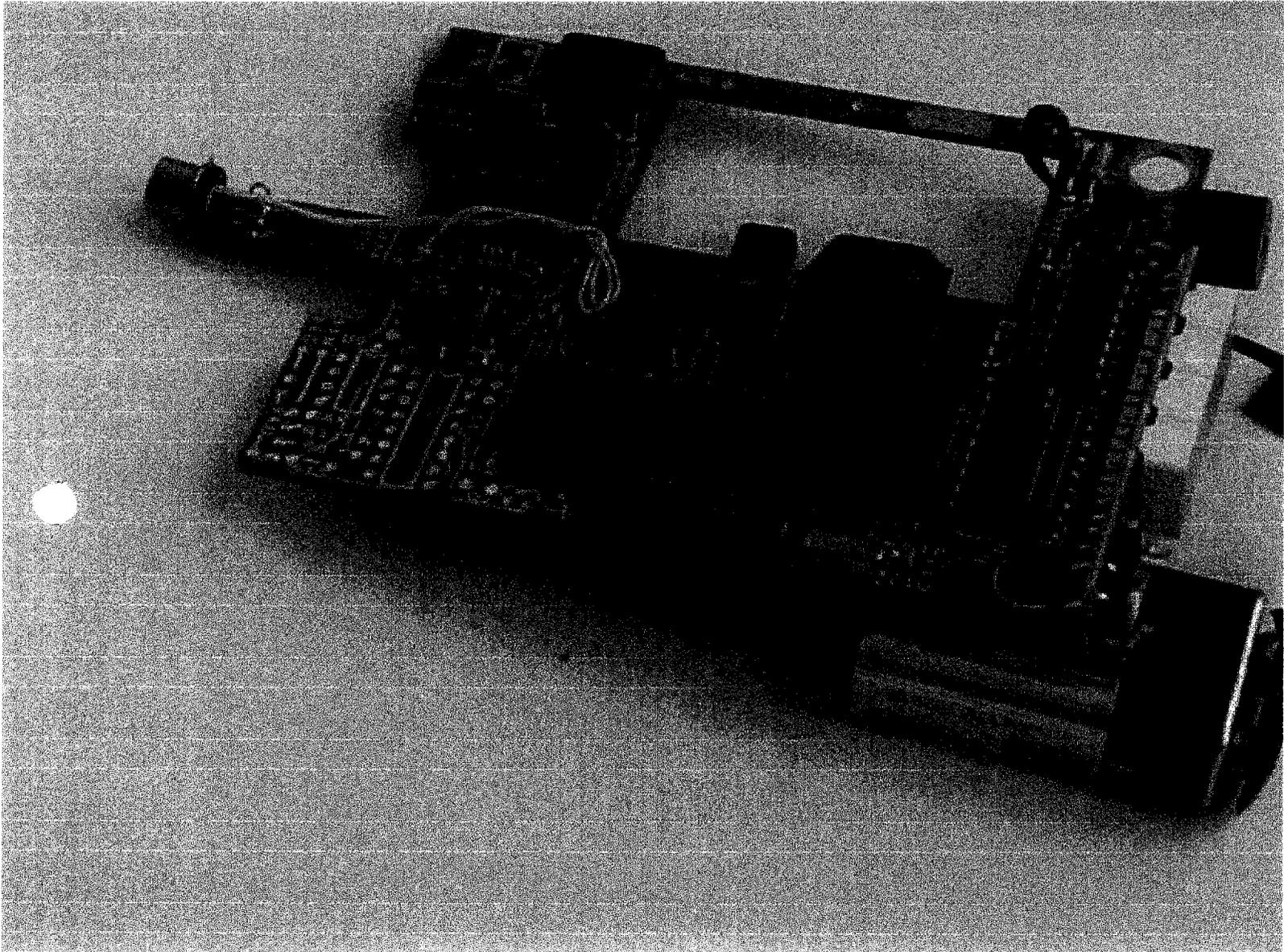


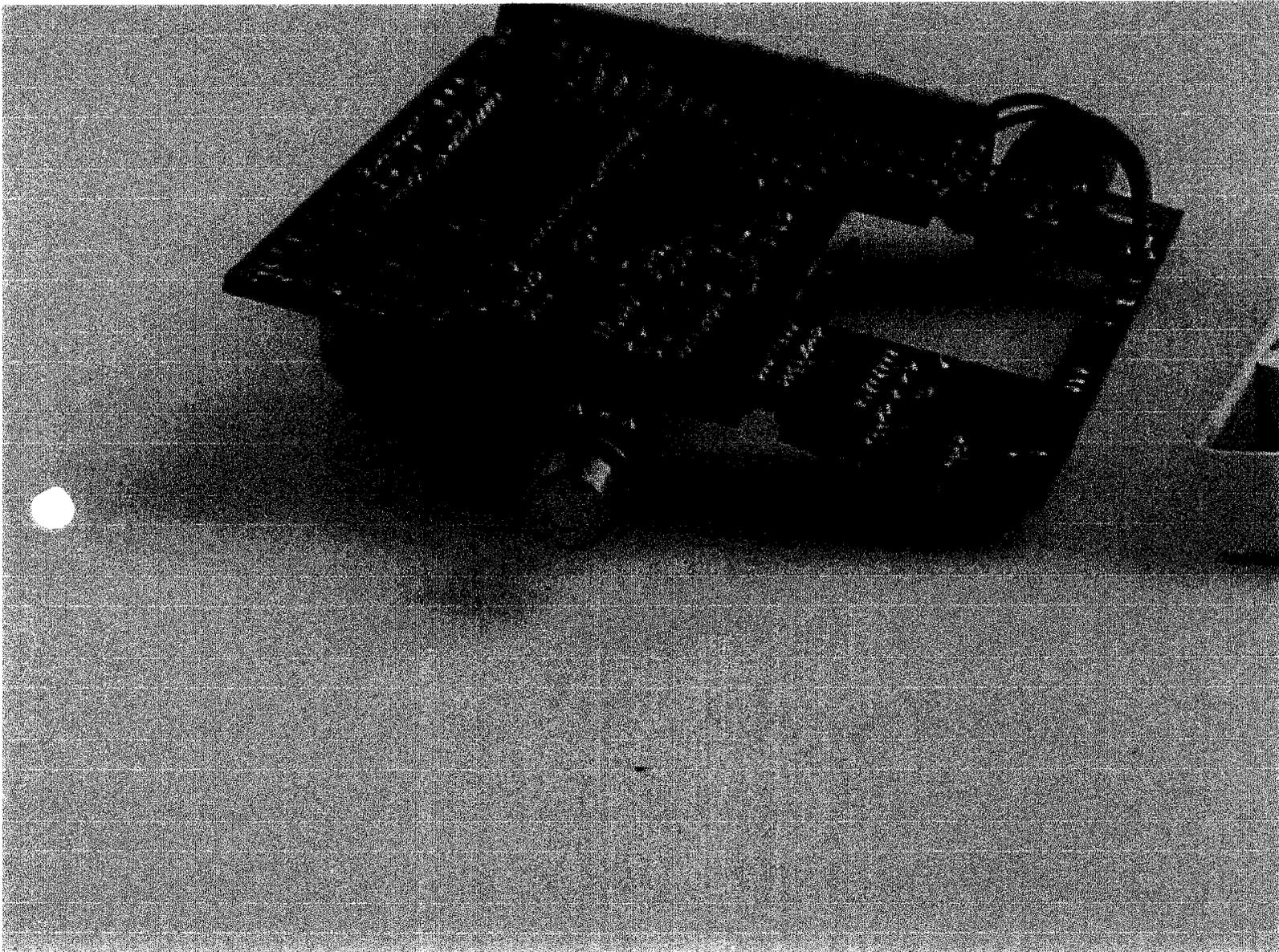
SensorTouch Components

(17)

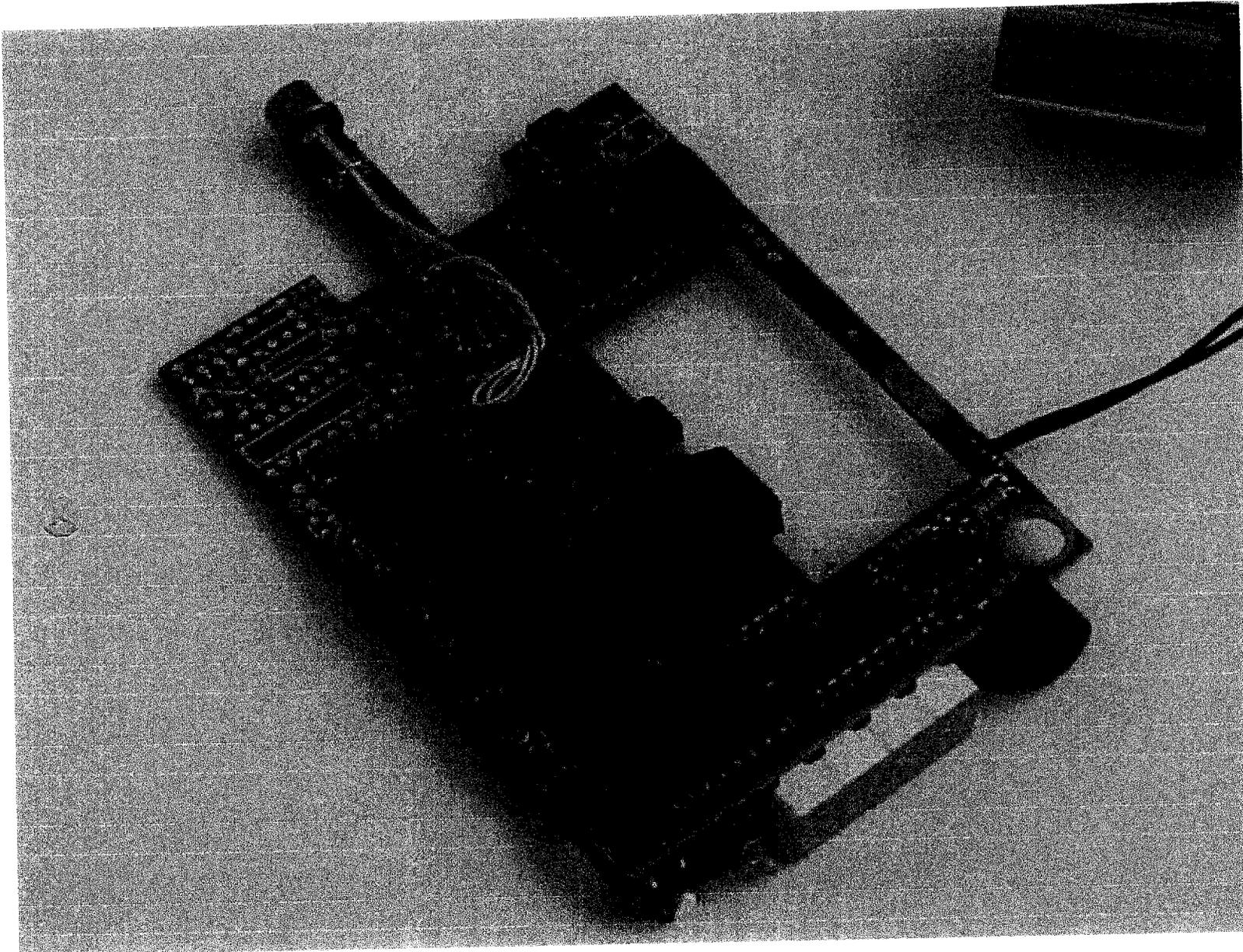


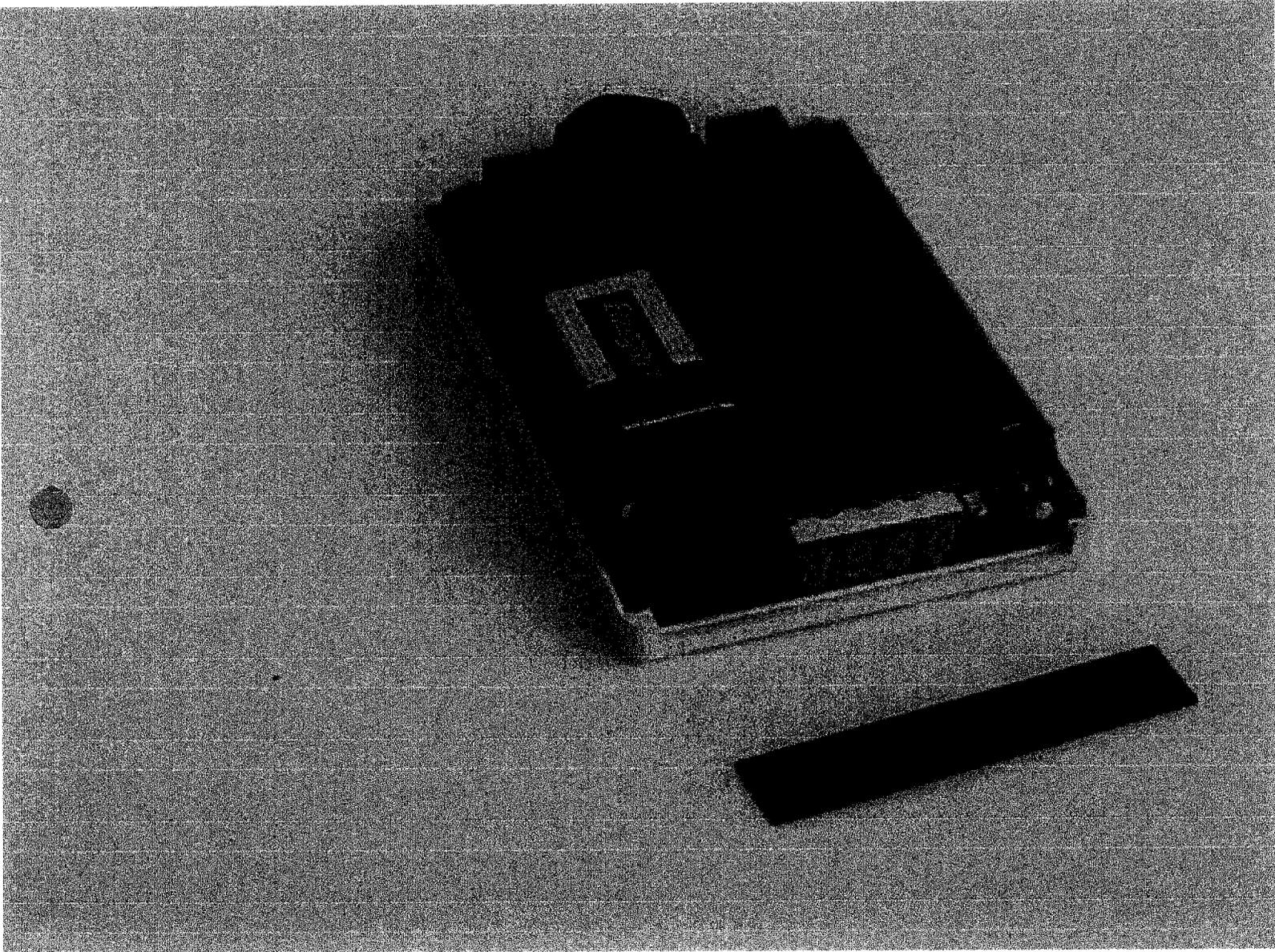
118



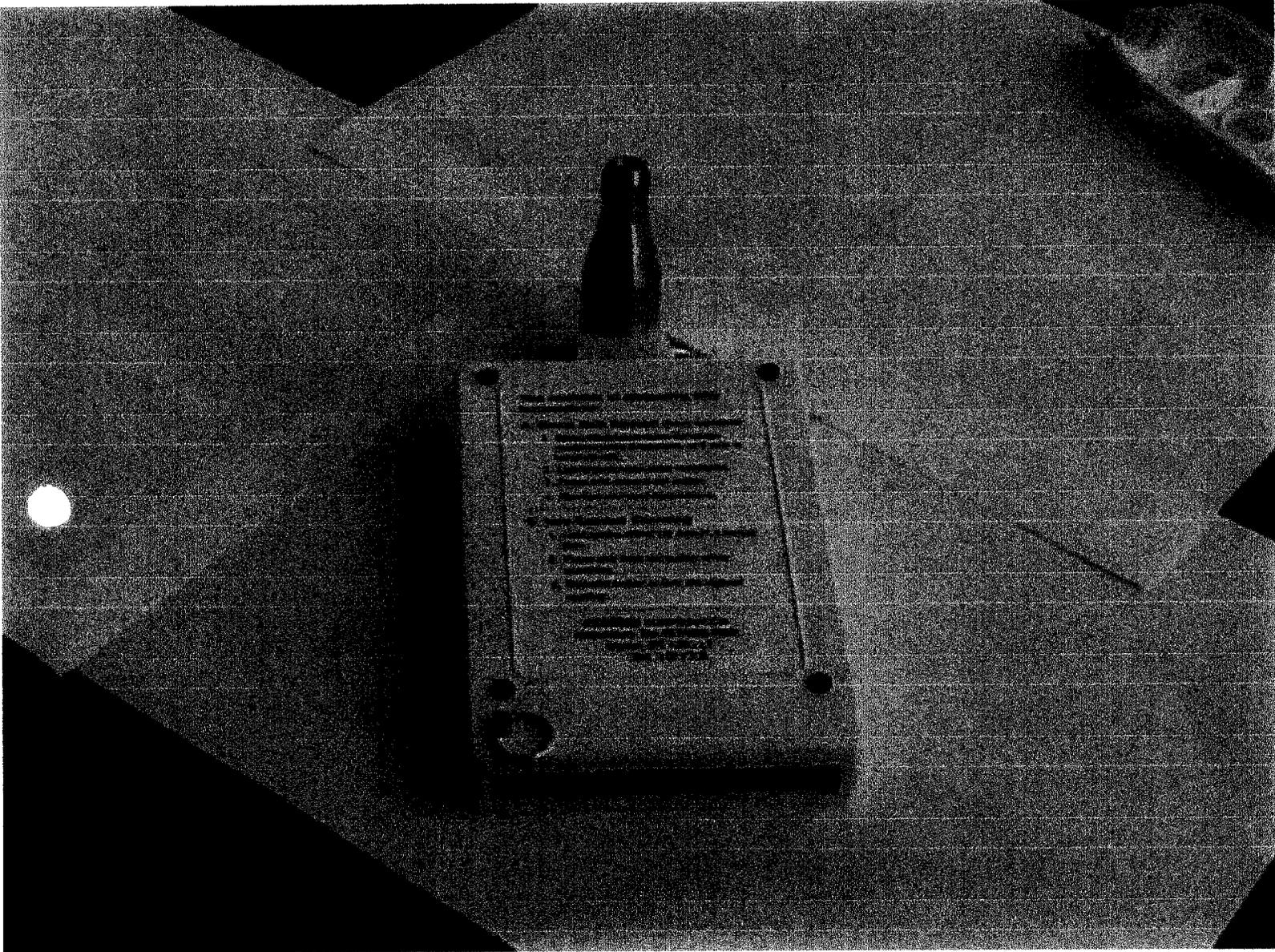


120

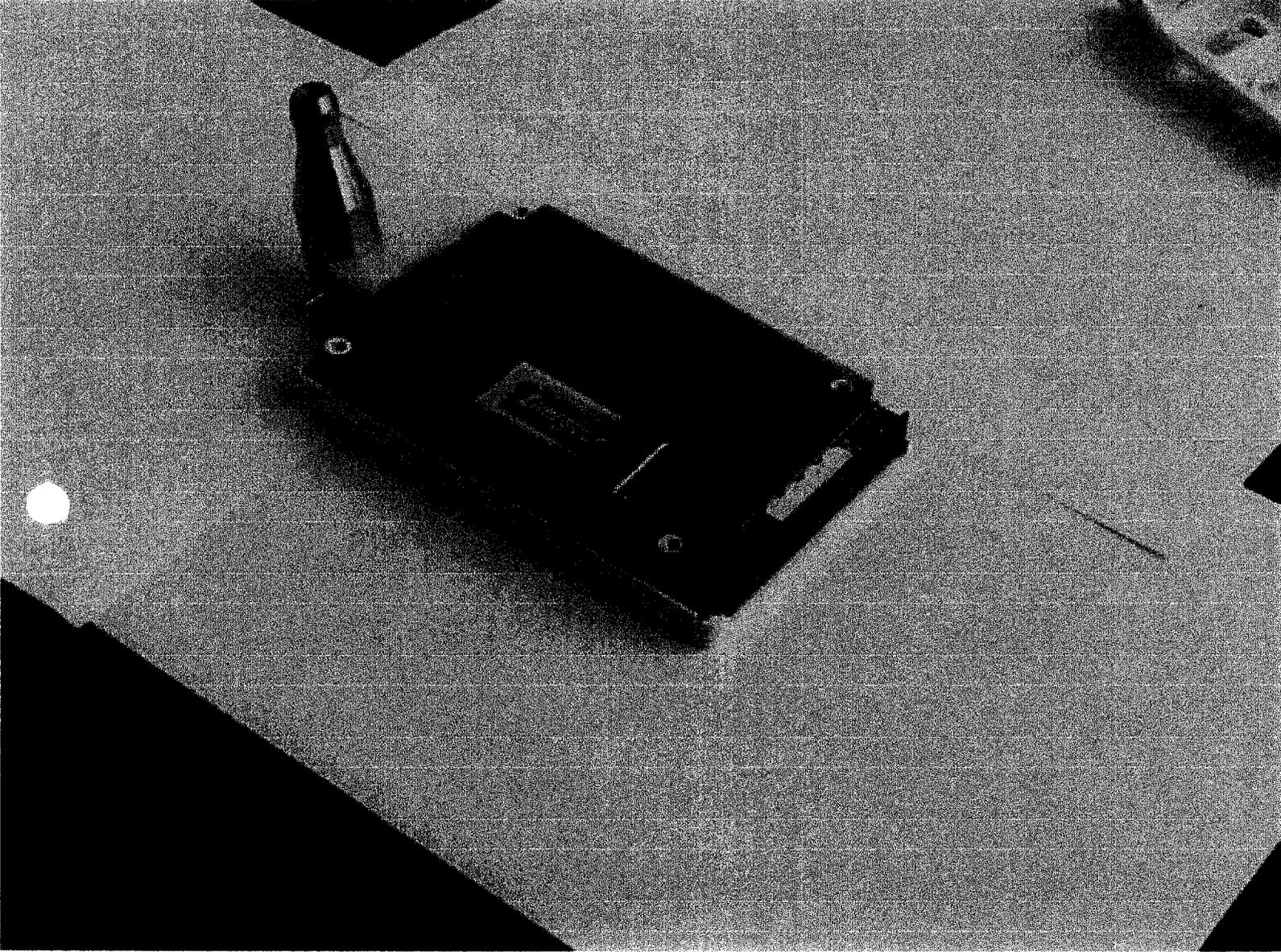




123

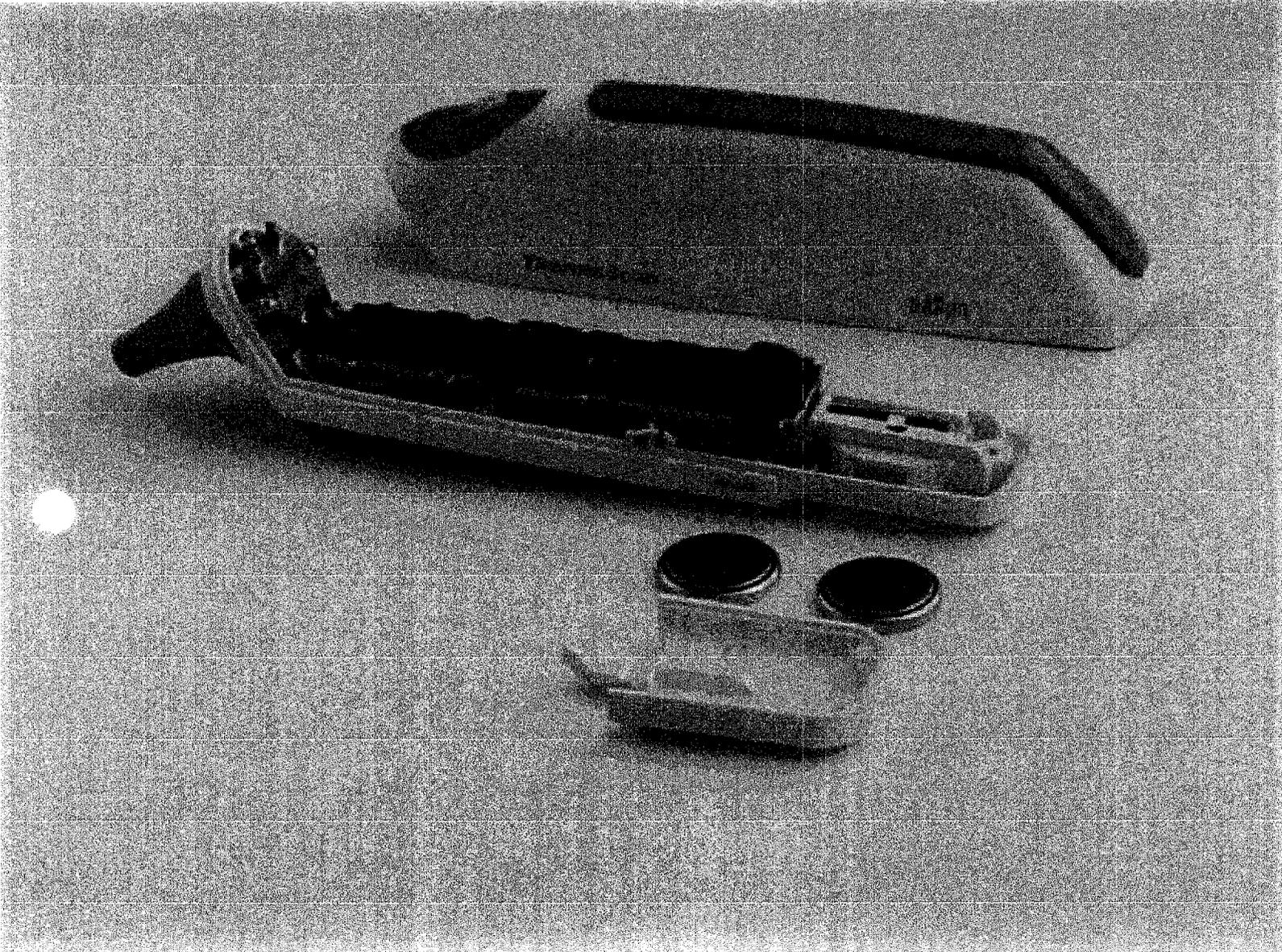


129



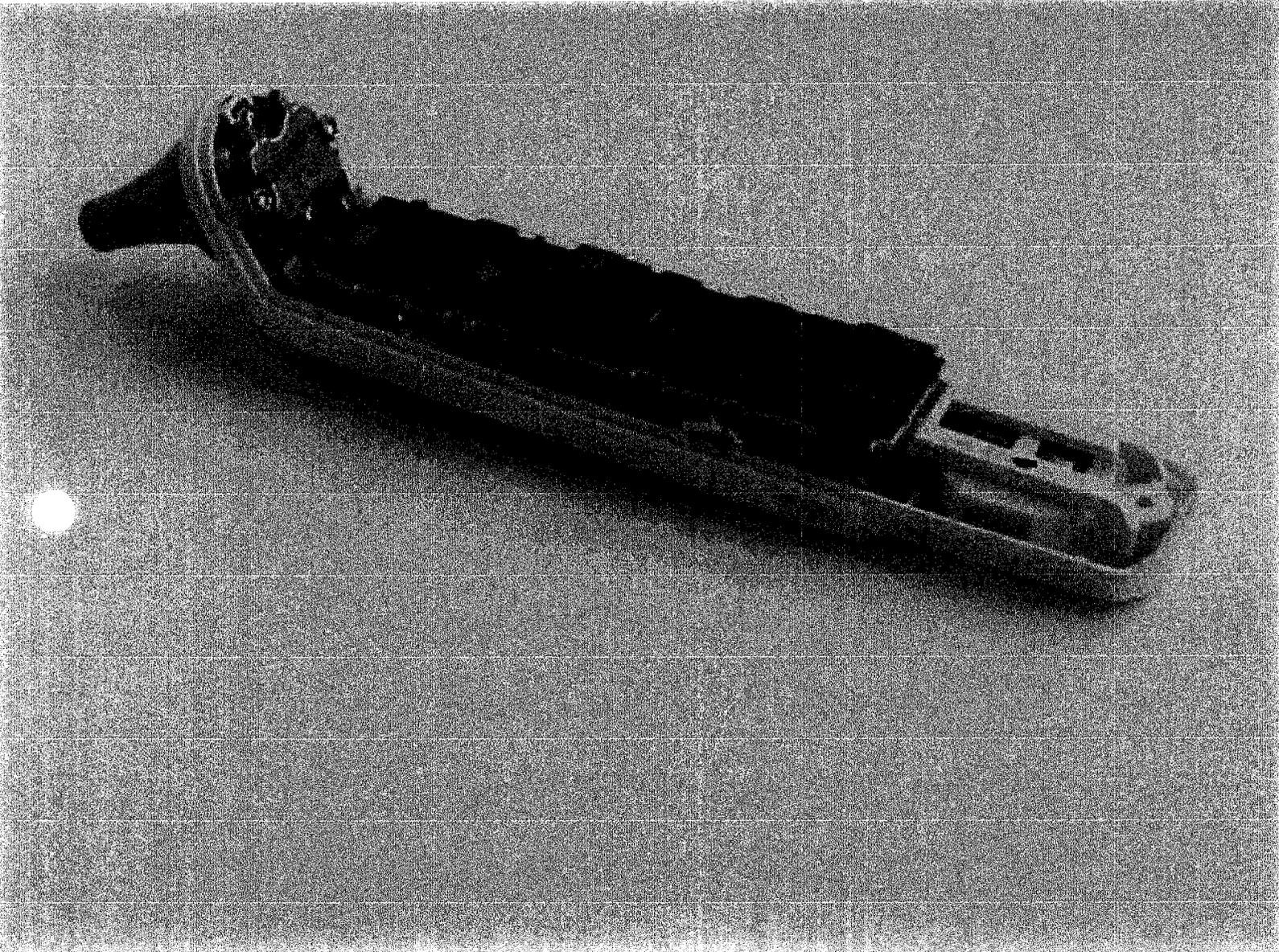
125

Braun Thermoscan 8D-1



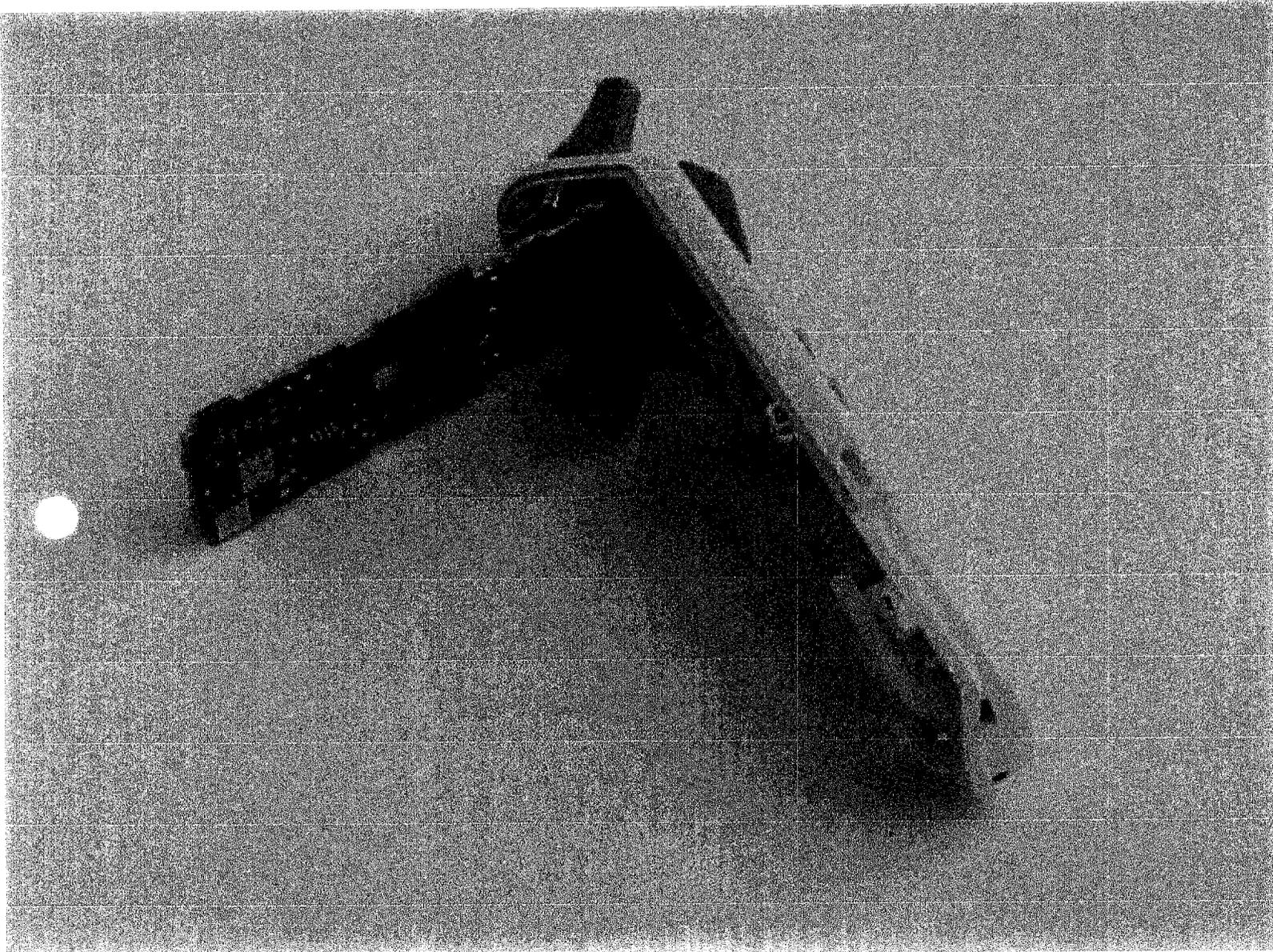
126

Braun Thermoscan 8D

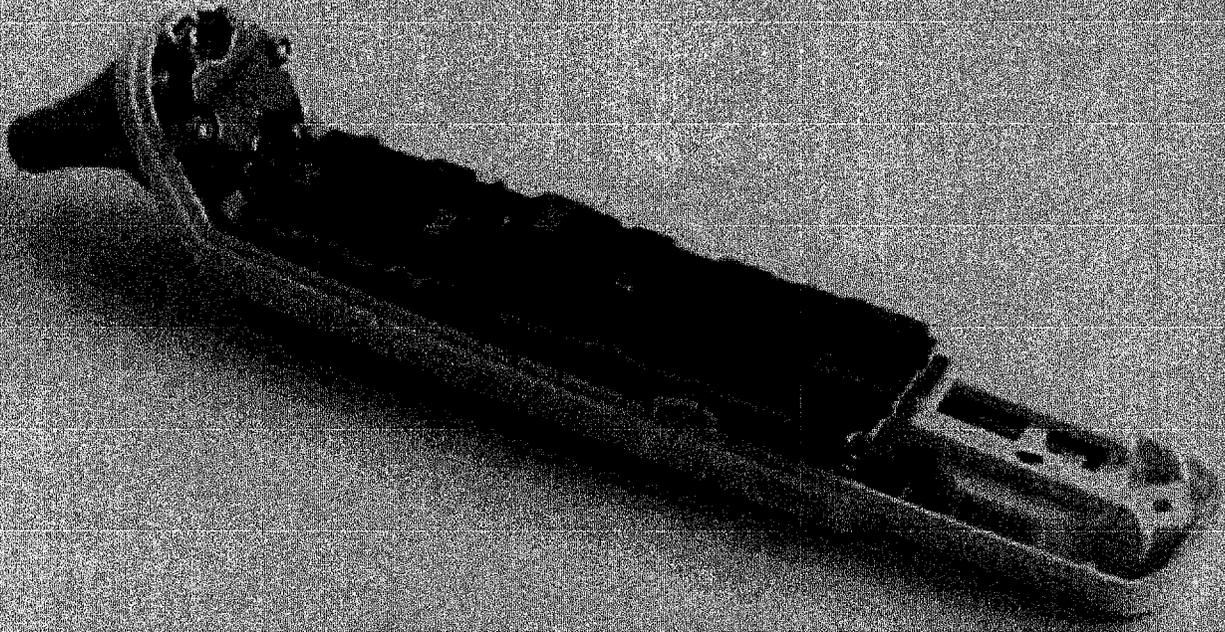


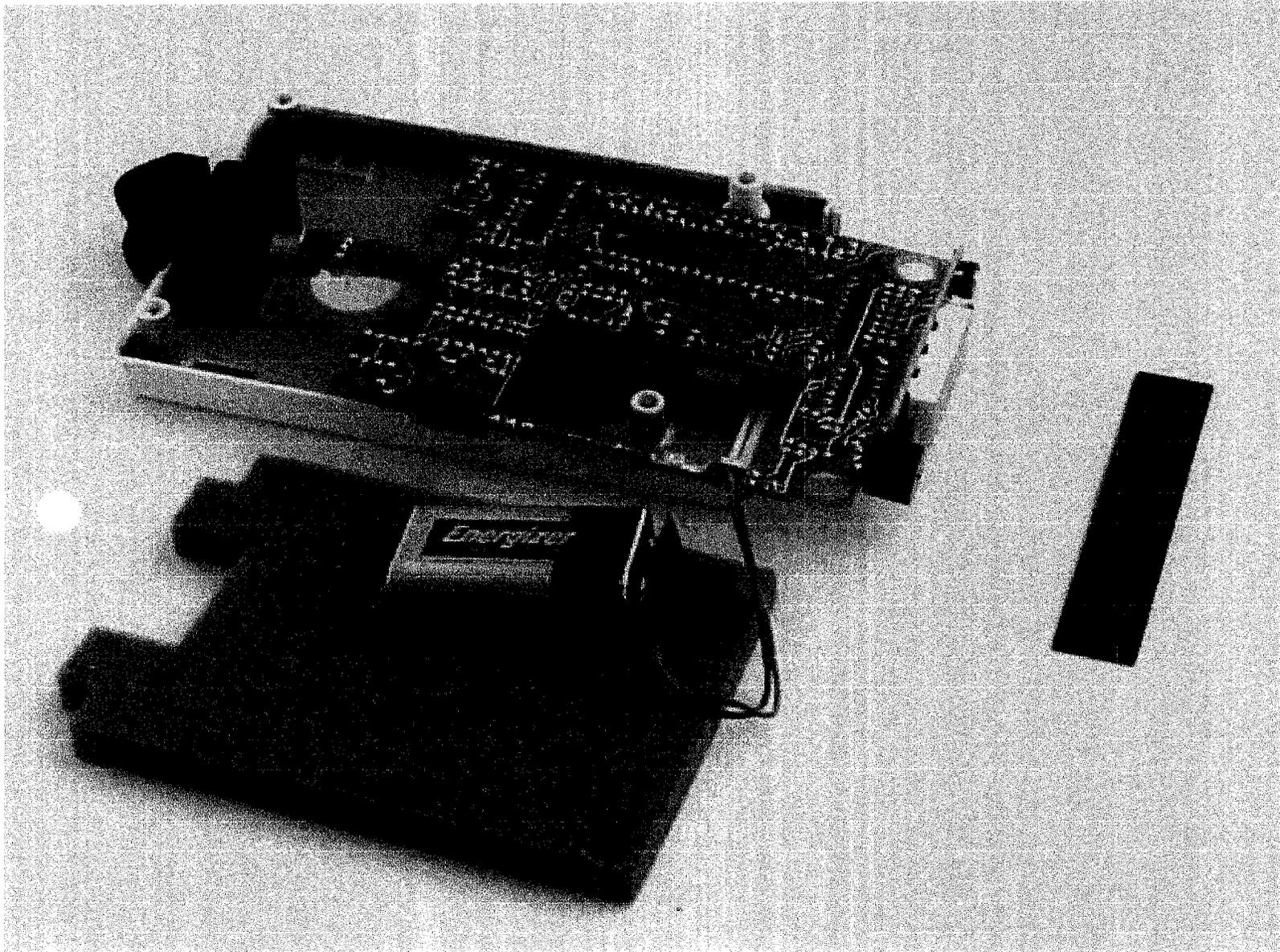
129

Braun Thermoscan 8D-3



Braun Termoscan 8D-4





Section 9 Performance

The SensorTouch, model HF 370, (predecessor name for Temporal Scanner Thermometer) was originally manufactured by Exergen Corporation (b)(4)

(b)(4)

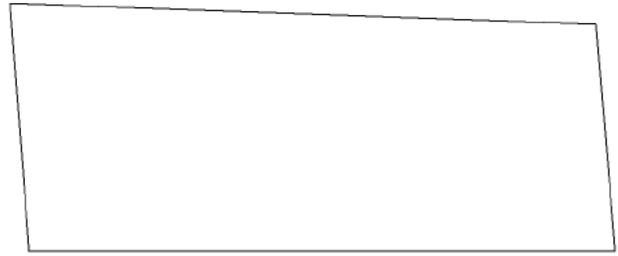
was to be based on compliance with the European standard for infrared thermometers being developed at the time, working document (WD 1247-5), which was the predecessor of the EN12470-5 standard which now applies to infrared thermometers. EN12470-5 is, the European counterpart to ASTM E1965-98. Some of the performance data presented here is the result of testing performed (b)(4) e data is presented as follows:

1. Performance testing by (b)(4) product acceptance (Tab 9A)
2. (b)(4) Declaration of Conformity to comply with CE-Marking Directive (93/42/EEC) (Tab 9B)
3. EMC testing conducted by (b)(4) for CE mark (Tab 9C)
4. Recent safety testing conducted for Exergen for CE technical file (Tab 9D)
5. (b)(4) testing (9E)
6. Independent, unsolicited evaluation of the device and one of the predicate devices by Consumer Reports (9F).
7. Results of human studies in (b)(4)
8. Results of clinical trials in (b)(4) (Tab 9H)

133

9A
Performance Testing for
Product Acceptance

139



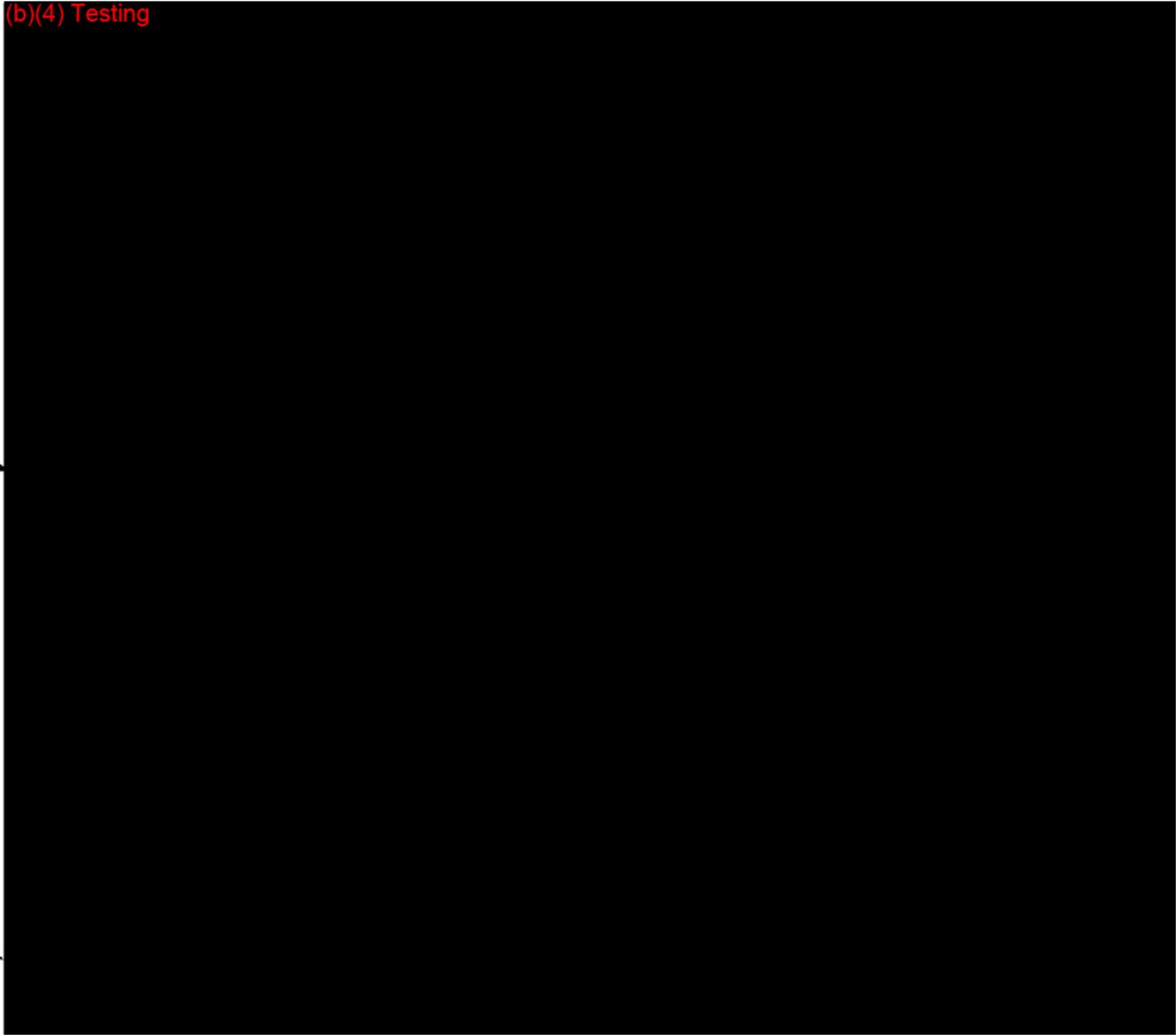
Release report of items from (b)(4) Testing

(b)(4) Testing



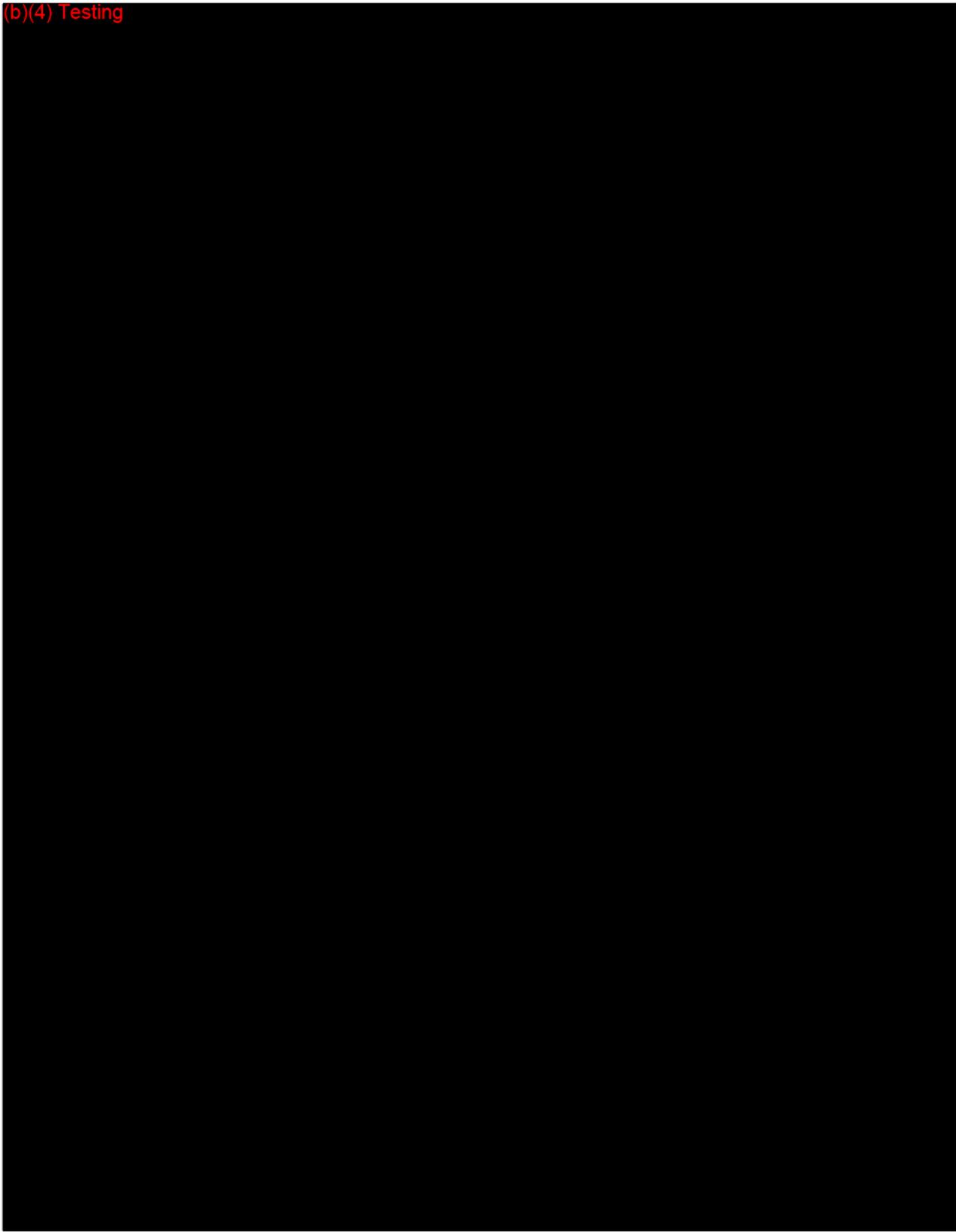
135

(b)(4) Testing



136

(b)(4) Testing



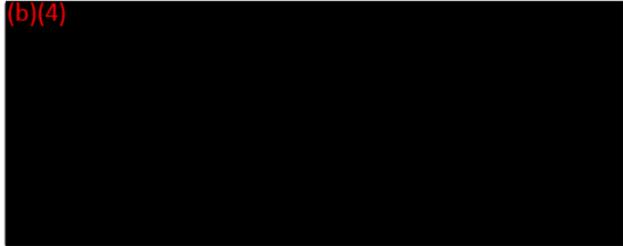
1/87

9B

(b)(4)

**Declaration of Conformity to
Directive 93/42/EEC**

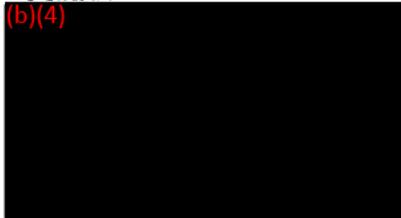
(b)(4)



Declaration of Conformity

Manufacturer's Name and Address:

(b)(4)

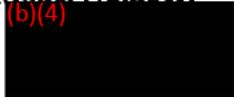


Product Categories:

Non invasive infrared thermometer

Model Number:

(b)(4)



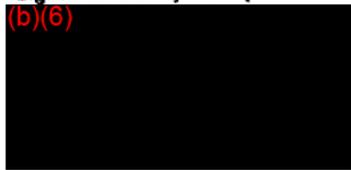
Medical Product Class:

IIa

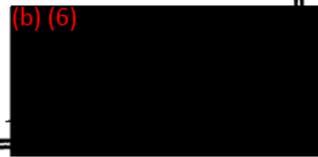
The above-mentioned devices prove compliance with the standards of Directive 93/42/EEC.

Signed on this day of 1 April 1999,

(b)(6)



(b)(6)





EC DECLARATION OF CONFORMITY



Temple Thermometer

(Product description)

to which this declaration relates is in conformity with the following standards:

SAFETY

EMC

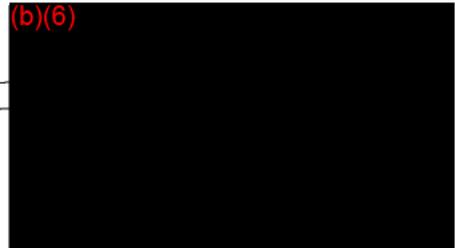
EN 60601-1	EN 55011 (3-1991)	EN 60601-1-2 (1993)
	EN 55014 (4-1993)	EN 61000-3-3 (1995)
	EN 55015 (1995)	EN 55014-2 (1995)

(Title and/or number and date of issue of the standards)

following the provisions of the Medical Device Directive 93/42/EEC

and are produced under a quality scheme at least in conformity with ISO 9002 or CENELEC Permanent Document (b)(4)

Groningen, 1999-05-03
(Place, date)



HO

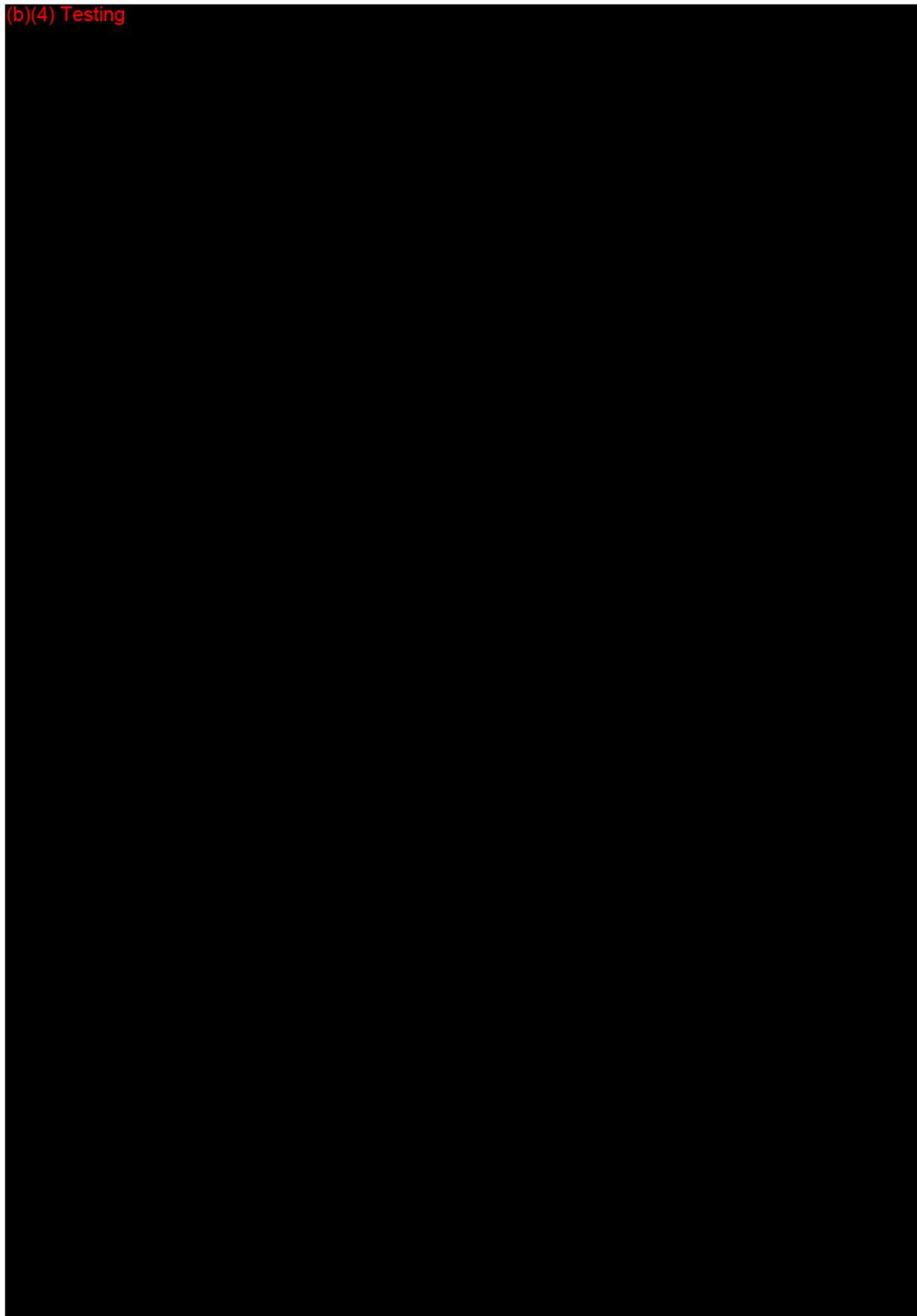
9C
EMC Testing Conducted By

(b)(4)

A large black rectangular redaction box covers the text following "Conducted By".

141

(b)(4) Testing



142

9D
Safety Testing Conducted on Behalf of
Exergen

143

9E

(b)(4) Testing

**Testing Conducted
By Exergen**

147

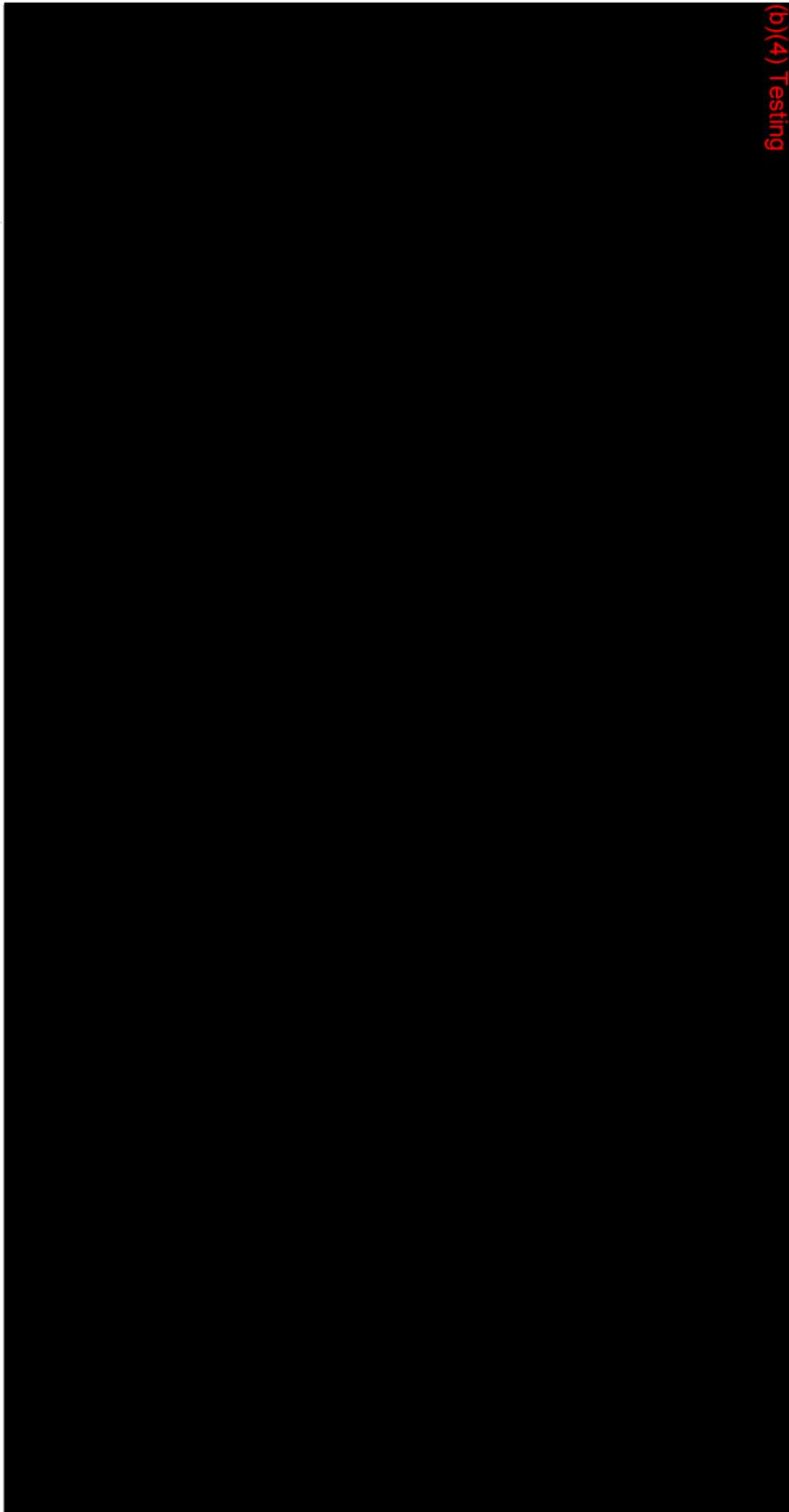
(b)(4)

Test 1 Conditions:

(b)(4) Testing

Test 2 Conditions:

(b)(4) Testing



148

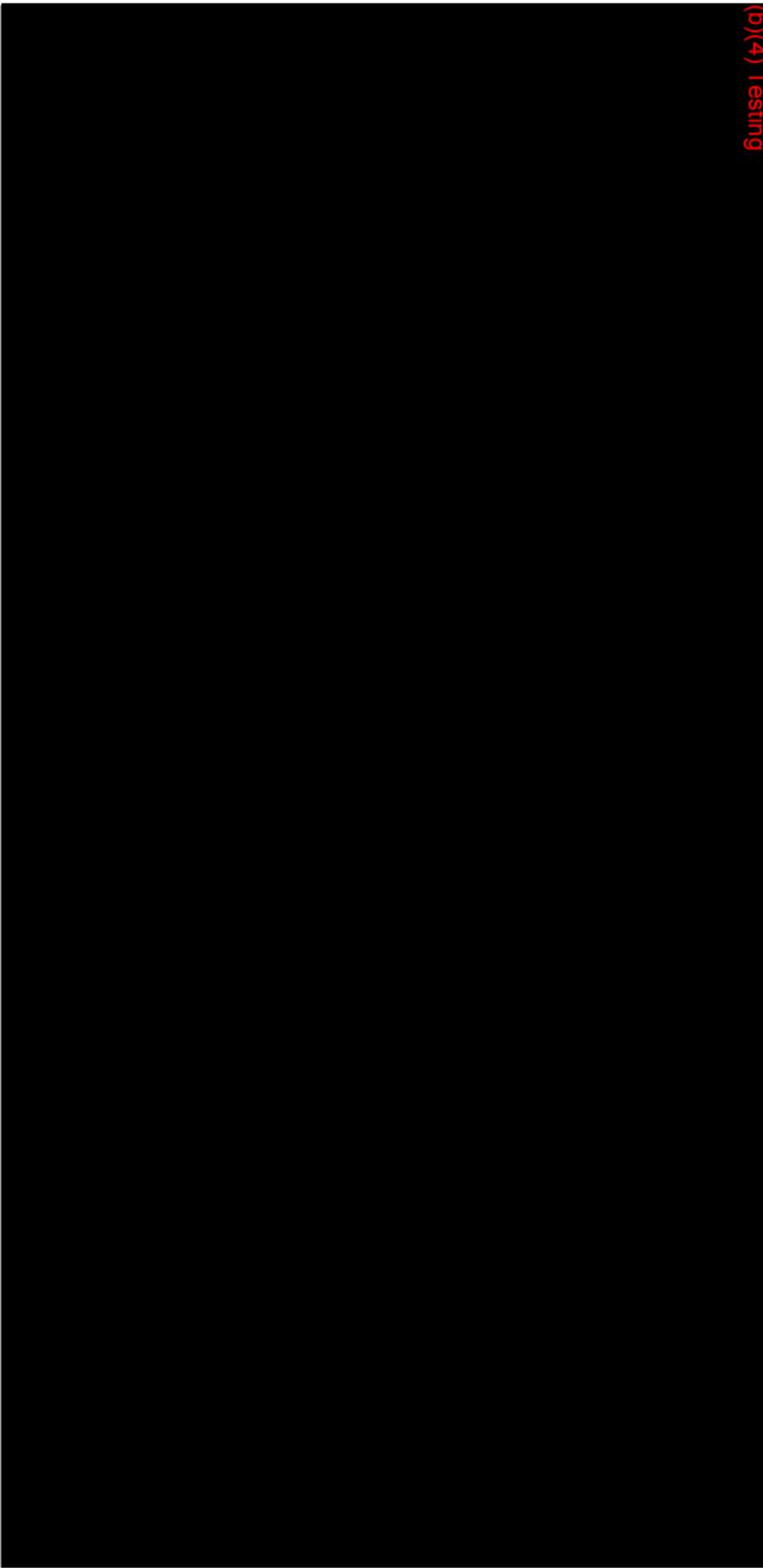
(b)(4)

Test 1 Conditions

(b)(4) Testing

Test 2 Conditions:

(b)(4) Testing



149

9F
Consumer Reports Testing

150

Consumer Reports

www.ConsumerReports.org

Product test

Feeling flush?

Taking the temperature of a feverish child can be tricky. Kids are often too fidgety for an accurate reading orally, rectally, or axially (under the armpit). That may be why ear thermometers are popular. Now a new product, the *Philips SensorTouch Temple Thermometer*, promises quick and accurate readings when you slide it across the forehead. It's pricey at \$95, but it works.



We compared the *SensorTouch HF370*, the *Braun ThermoScan IRT 3520* ear thermometer, \$54, and the *PolyMedica 760* digital oral thermometer, \$12, in our labs and in the homes of a small group of panelists with young children. Our engineers found the *SensorTouch* as reliable as the others for home use. (Our previous tests found digital oral thermometers more accurate than mercury thermometers.)

The *SensorTouch* and the *ThermoScan* take only a few seconds, and panelists judged them equally easy to use, once they got the hang of them. The oral thermometer took more than a minute for a reading. No one preferred it to the other thermometers.

The *SensorTouch* could be handy, especially if a temperature needs checking often. With an ear or forehead thermometer, establish a baseline temperature when the child is not sick, and compare it with the reading from an oral, rectal, or axial thermometer. You'll get a sense of whether the readings run a little high or low. If you consult a doctor, tell him or her the kind of thermometer you used.

9G
Results of Clinical Trials

(b)(4)

(b)(4) Testing

152

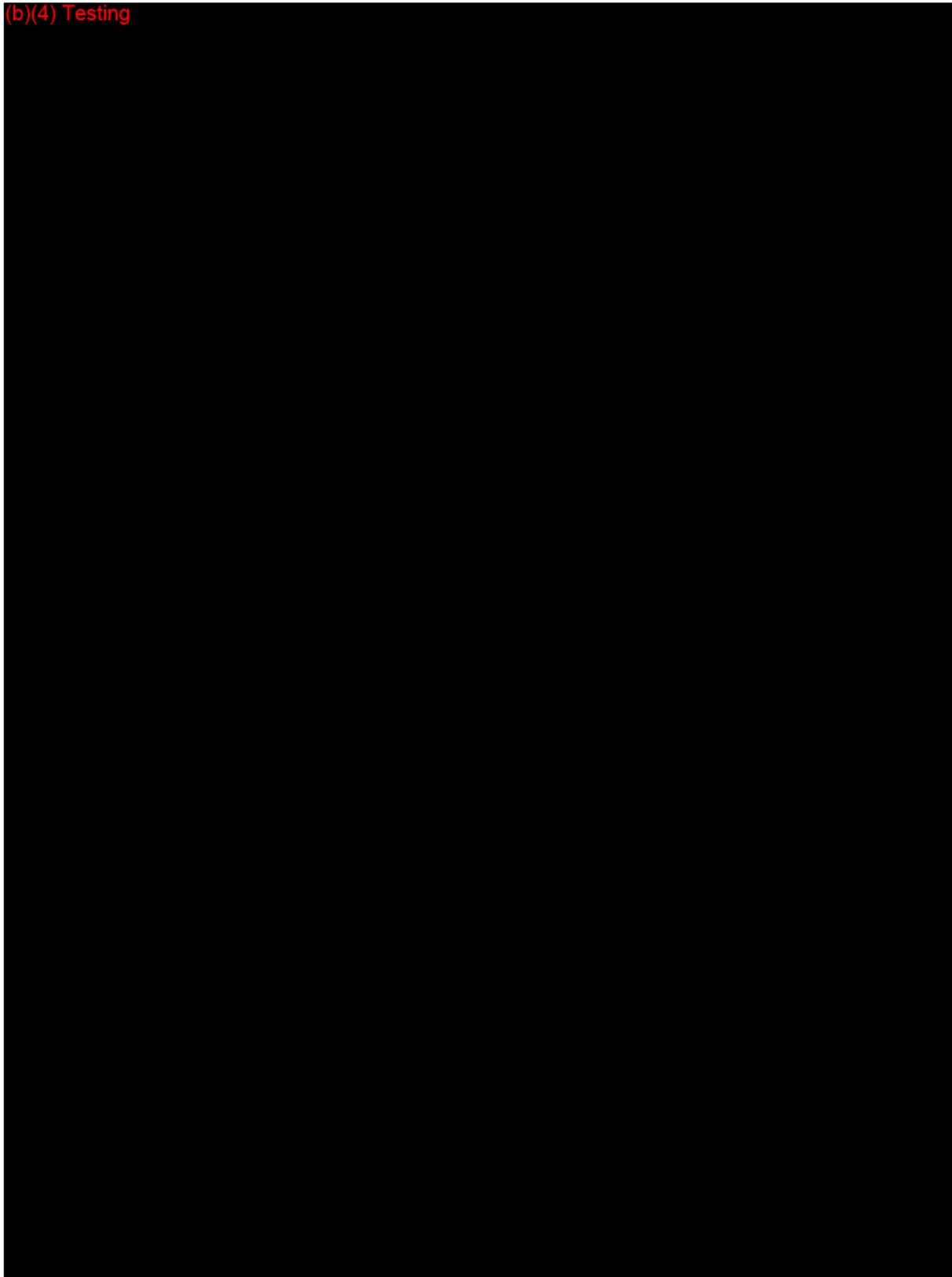
(b)(4) Testing



(b)(4)

153

(b)(4) Testing



159

(b)(4) Testing



185

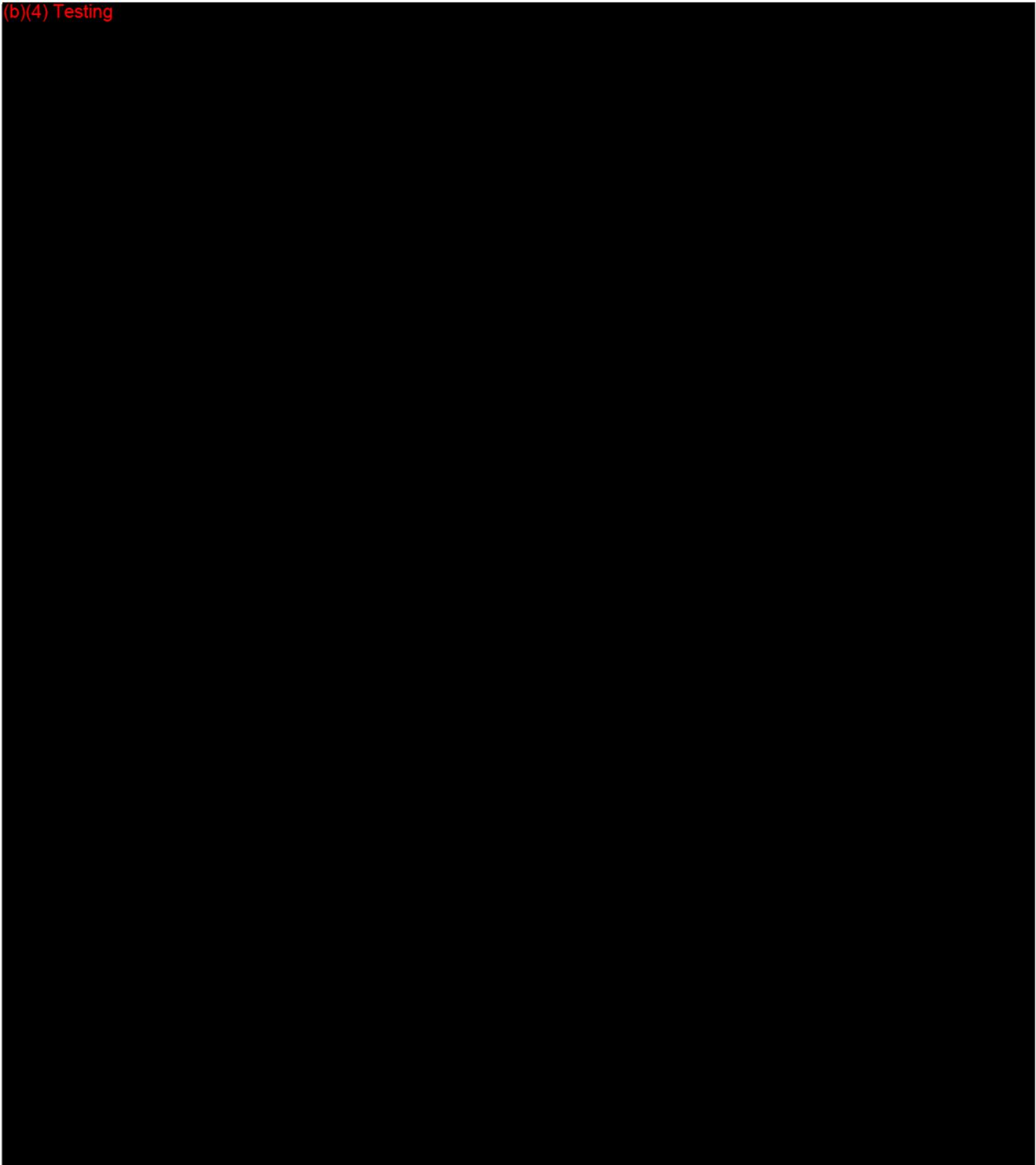
9H
Results of Clinical Trials
In (b)(4) Testing 

182

EXERGEN
CORPORATION

CONFIDENTIAL

(b)(4) Testing

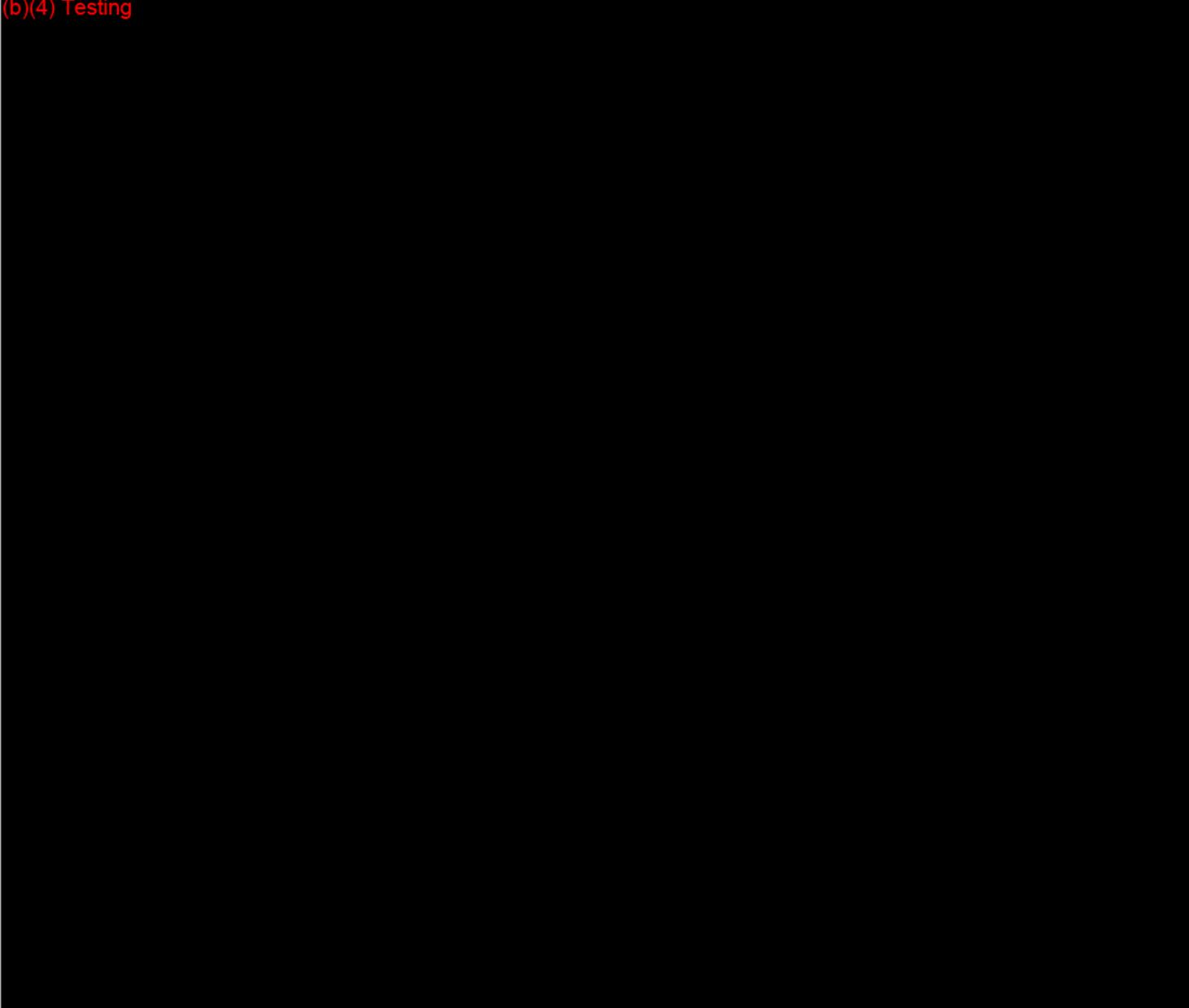


157

EXERGEN
CORPORATION

CONFIDENTIAL

(b)(4) Testing

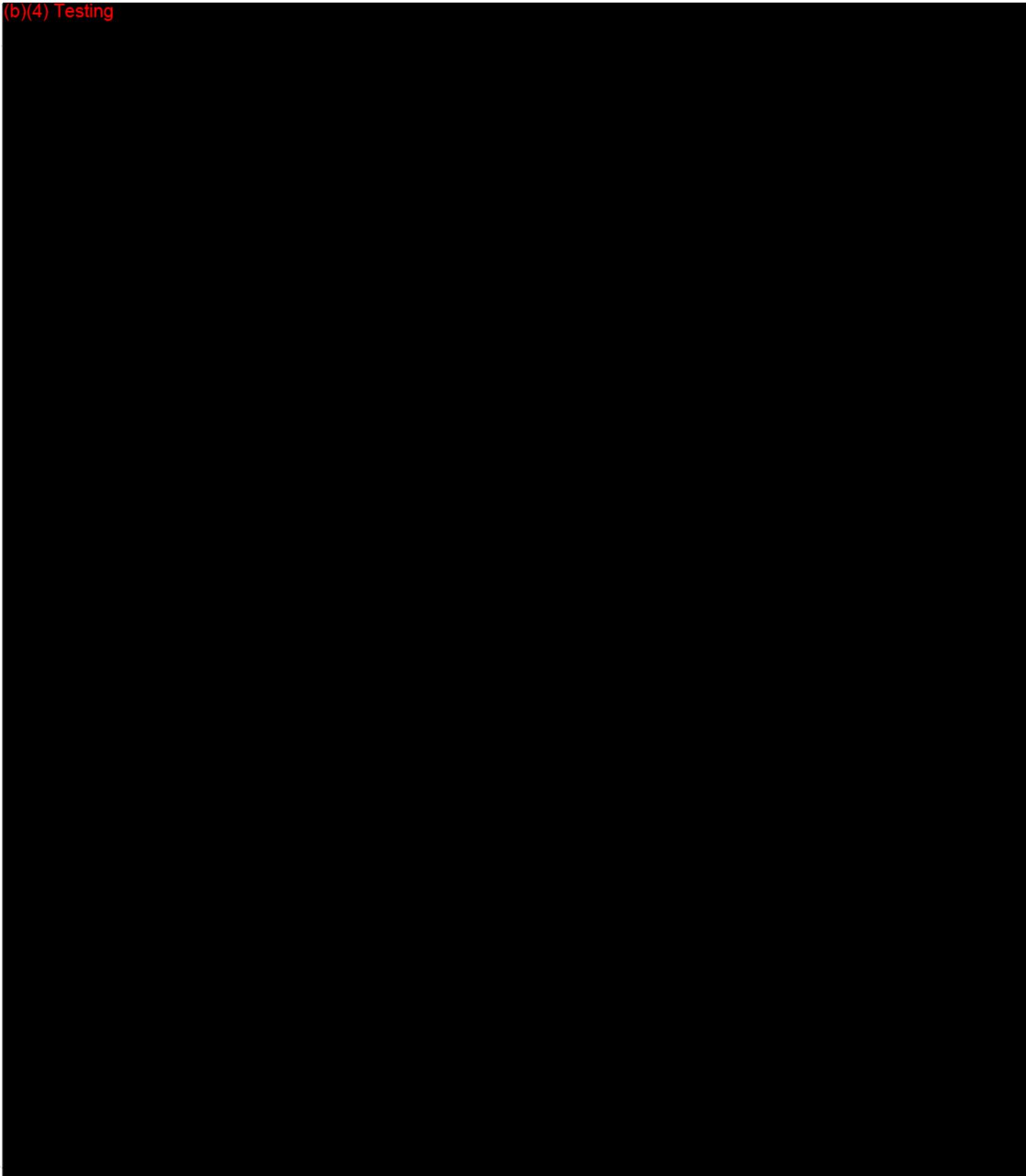


158

EXERGEN
CORPORATION

CONFIDENTIAL

(b)(4) Testing

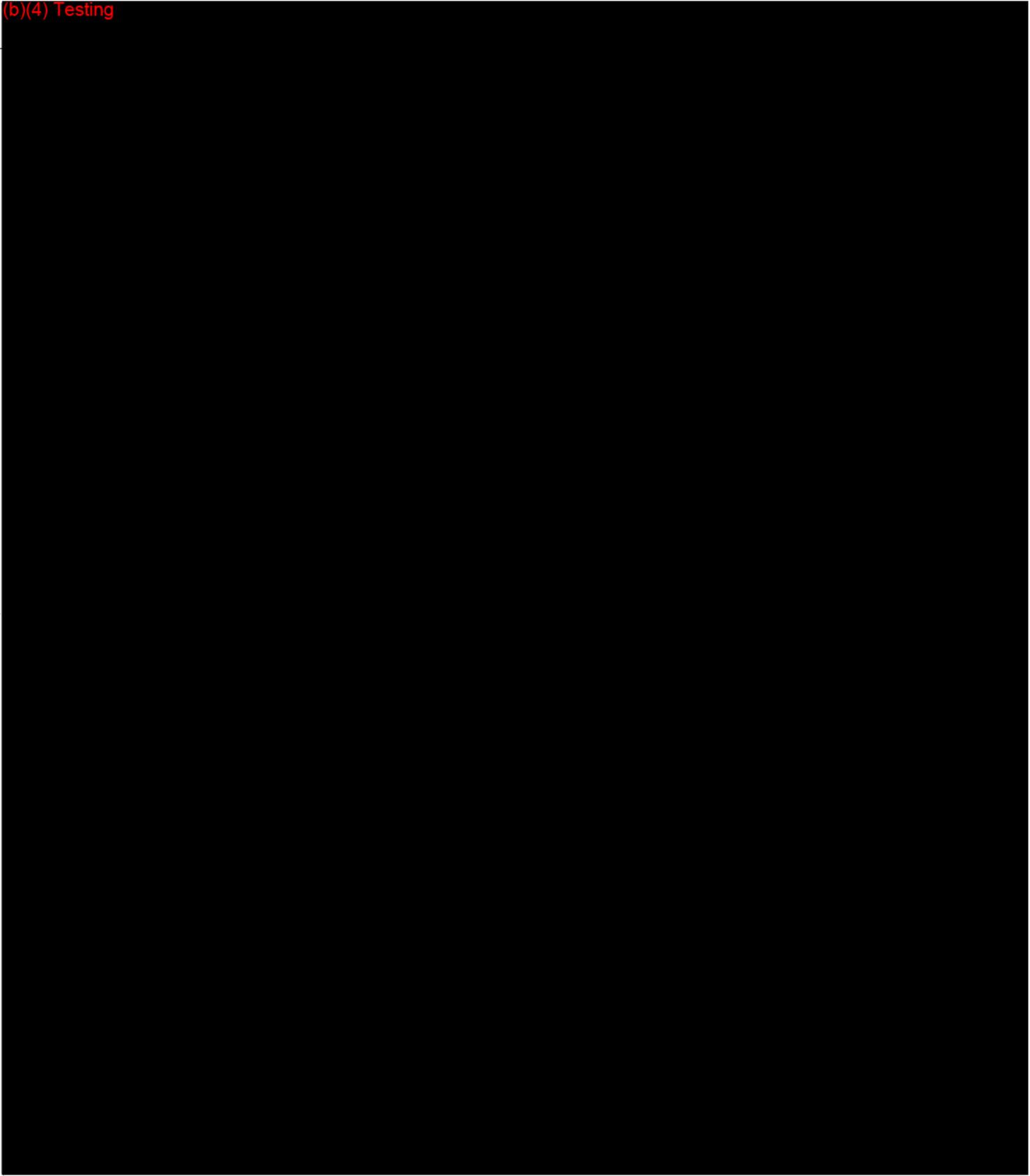


159

EXERGEN
CORPORATION

CONFIDENTIAL

(b)(4) Testing

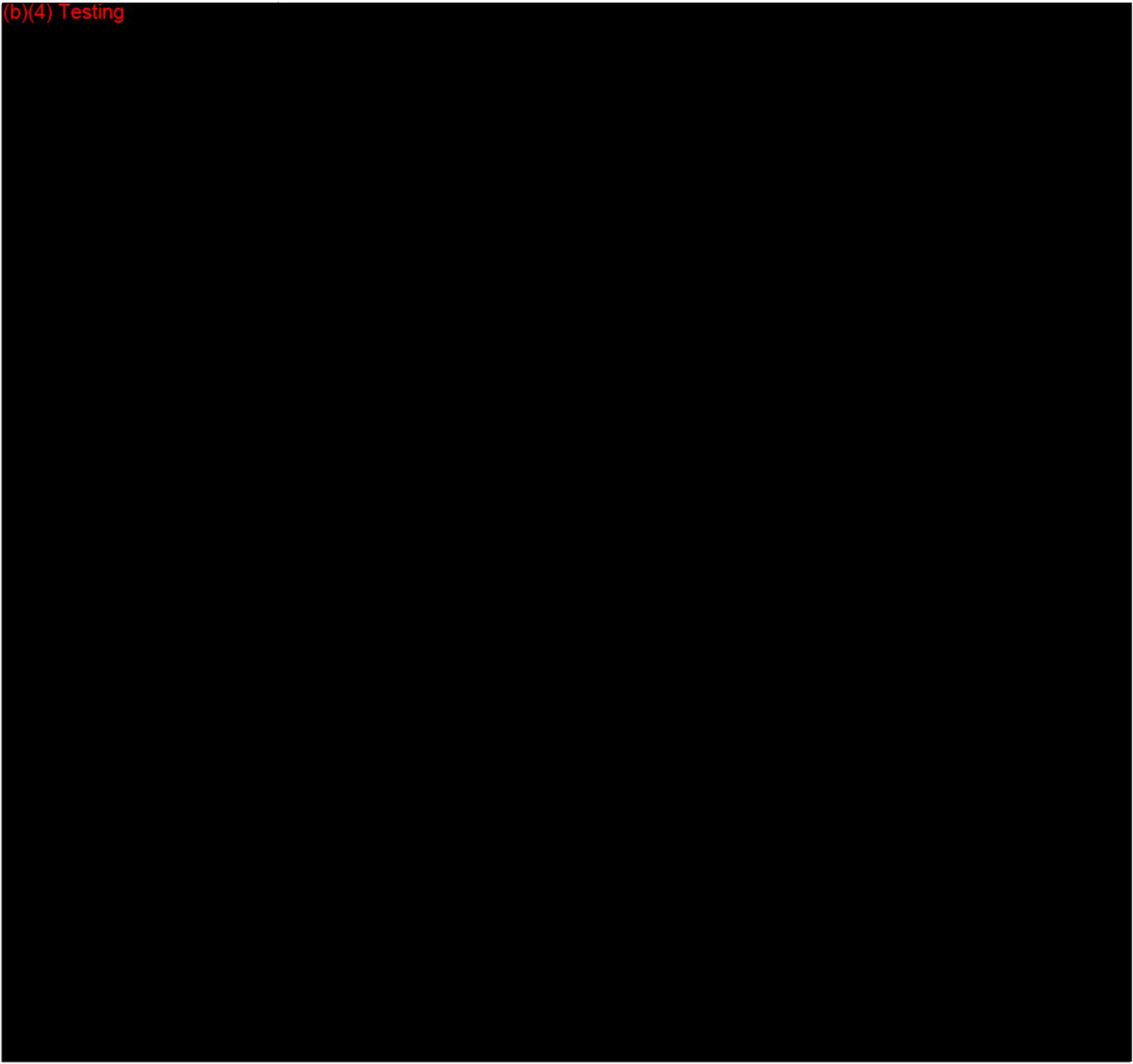


160

EXERGEN
CORPORATION

CONFIDENTIAL

(b)(4) Testing



161

Clinical Study No. (b)(4)

162

Accuracy of a Noninvasive Temporal Artery Thermometer for Use in Infants

David S. Greenes, MD; Gary R. Fleisher, MD

Objectives: To assess the accuracy of a new noninvasive temporal artery (TA) thermometer in infants; to compare the accuracy of the TA thermometer with that of a tympanic thermometer, using rectal thermometry as the criterion standard; and to compare the tolerability of the TA thermometer with that of the tympanic and rectal thermometers.

Design: Prospective evaluation of the accuracy of TA and tympanic thermometry, using rectal thermometry as the criterion standard.

Setting: Emergency department of an urban pediatric hospital.

Subjects: Convenience sample of 304 infants younger than 1 year presenting for care.

Main Outcome Measures: Temperatures were measured using TA, tympanic, and rectal thermometers for all infants. Agreement between TA or tympanic and rectal temperatures was assessed. The sensitivity and specificity of TA or tympanic thermometers for detecting rec-

tal fever were determined. Discomfort scores, using a standardized scale, were assessed by trained observers after each temperature measurement was made.

Results: Linear regression analysis of the relation between TA and rectal temperatures yielded a model with a slope of 0.79 (vs a slope of 0.68 for tympanic vs rectal temperature; $P = .02$) and an r of 0.83 (vs $r = 0.75$ for tympanic vs rectal temperature; $P < .001$). Among 109 patients with a rectal temperature of 38°C or higher, the TA thermometer had a sensitivity of 0.66 compared with the tympanic thermometer's sensitivity of 0.49 ($P < .001$). Discomfort scores with TA thermometry were significantly lower than with rectal thermometry ($P = .007$).

Conclusions: The TA thermometer has limited sensitivity for detecting cases of rectal fever in infants. However, the TA thermometer is more accurate than the tympanic thermometer in infants, and it is better tolerated by infants than rectal thermometry.

Arch Pediatr Adolesc Med. 2001;155:376-381

Highlights Added

From the Division of
Emergency Medicine,
Children's Hospital, Harvard
Medical School, Boston, Mass.

RECTAL THERMOMETRY has generally been considered the standard for measurement of temperature in infants. Published guidelines for the management of febrile infants have based their recommendations on measurement of rectal temperature,¹ and other thermometry methods have generally been evaluated with rectal temperature as the criterion standard.²⁻¹⁹

Although rectal thermometry has evolved as the standard, it has several disadvantages, including discomfort for the patient, emotional upset for the patient and parent,²⁰⁻²² risk for traumatic injury to the rectum,²³⁻³⁰ and transmission of stool-borne pathogens.³¹⁻³³ Several alternative methods of thermometry, which eliminate the problems inherent in rectal thermometry, have been shown to have limited value

in other regards. Axillary^{2,11,12,18,34,35} and supralingual^{3,4,13} thermometers have generally proven too inaccurate for routine clinical use. Tympanic thermometers, although popular with patients and parents and fairly reliable in adults,²² have not proven adequate for infants and young children.^{6,10,12,14,19,36-38} Thus, a continued need exists for a form of thermometry that is as well tolerated as the tympanic technique but gives results that closely agree with rectal temperature.

The purpose of this study was to evaluate the performance of a new noninvasive temporal artery (TA) thermometer for clinical use in infants. Our objectives were (1) to evaluate the accuracy of the TA thermometer, using rectal temperature as the criterion standard; (2) to compare the accuracy of the TA thermometer with that of a tympanic thermom-

PATIENTS AND METHODS

PATIENT SELECTION

We performed a prospective study of a convenience sample of infants presenting to the triage area of an emergency department in a tertiary care pediatric hospital. Children were eligible for inclusion in the study if they were younger than 1 year. Children were excluded if they had any medical condition that contraindicated the use of a rectal, tympanic, or TA thermometer. Children were also excluded if they were too ill to remain at triage for an initial assessment before proceeding to a treatment room.

Patients were enrolled during shifts when trained research assistants were available. During these shifts, the research assistants attempted to enroll all eligible patients.

Our study was approved by the Committee on Clinical Investigation of Children's Hospital, Boston, Mass. The committee required that verbal consent be obtained from the parents of study subjects.

THERMOMETRY MEASUREMENTS

On arrival to the triage area of the emergency department, patients and their families were invited to participate in the study. After oral consent was obtained, 4 successive temperature measurements were made, including a rectal temperature, a tympanic temperature, and left- and right-sided TA temperatures. Rectal temperatures were measured using the Diatek electronic thermometer (Welch Allyn Inc, Skaneateles Falls, NY). Tympanic temperatures were measured using the First Temp Genius tympanic thermometer (Sherwood Medical, St Louis, Mo). Both thermometers are used for routine clinical care in our hospital and were maintained by the hospital's medical engineering

department. Left- and right-sided TA temperatures were measured using the Exergen TempScan Temporal Artery Thermometer (model LXTA) (Exergen Corp, Watertown, Mass).

The TA thermometer is a handheld device that is operated by placing its probe on the patient's forehead and then sweeping it laterally until the hairline of the temporal scalp is reached. The device continually measures surface temperature as it moves along its path and assumes the highest temperature recorded to be the TA temperature. Using a simultaneous measure of ambient temperature from a separate thermistor, the device calculates the patient's core temperature and instantaneously reports this calculated temperature.

All temperatures were measured by trained research assistants. These assistants were trained by the nursing staff of our emergency department to use the rectal and tympanic thermometers, and they were certified by the nursing department so that their measurements could be used in the clinical care of patients. Representatives from Exergen trained the assistants in the use of the TA thermometer. During a pilot phase, the assistants had several days of practice sessions, in which their thermometry technique and results were reviewed by the authors and representatives from Exergen, before data collection began.

Research assistants were instructed to make each measurement only once. Only when there were obvious mechanical failures (eg, the patients pulled their heads away during the process) were the research assistants allowed to repeat measurements with any of the thermometers. Research assistants were told not to consider the measured temperature reading in determining whether a measurement needed to be repeated. Conditions that appeared to the research assistants to make a measurement unreliable

Continued on next page

eter; and (3) to compare patients' discomfort with the use of the TA thermometer with their discomfort with tympanic and rectal thermometry.

RESULTS

During the 3-month study period, 304 patients were enrolled, of whom 109 (36%) had rectal fever and 49 (16%) had high rectal fever. Rectal temperature was $37.9^{\circ}\text{C} \pm 1.0^{\circ}\text{C}$ (mean \pm SD), with a range of 35.7°C to 40.7°C . Temporal artery temperature was $37.6^{\circ}\text{C} \pm 0.9^{\circ}\text{C}$, with a range of 35.9°C to 40.7°C . Tympanic temperature was $37.1^{\circ}\text{C} \pm 0.9^{\circ}\text{C}$, with a range of 35.0°C to 39.9°C .

AGREEMENT BETWEEN LEFT- AND RIGHT-SIDED TA TEMPERATURES

For the purpose of this subanalysis, 44 patients were excluded because the research assistants noted that either the left- or right-sided TA temperature measurements were potentially unreliable. Among the remaining 260 patients, the mean \pm SD left-right difference was $0^{\circ}\text{C} \pm 0.39^{\circ}\text{C}$, with a range of -1.3°C to 1.0°C . The r between left- and right-sided TA temperatures was 0.91. A paired sample

t test found no significant difference between left- and right-sided TA temperatures ($P = .59$).

AGREEMENT BETWEEN TA OR TYMPANIC AND RECTAL TEMPERATURES

For all remaining analyses, all 304 patients were included. Linear regression analysis of the relation between TA temperature and rectal temperature (**Figure 1**) yielded a model with a slope of 0.79 and an r of 0.83. Linear regression analysis of the relation between tympanic temperature and rectal temperature (**Figure 2**) yielded a model with a slope of 0.68 and an r of 0.75. Both slopes were significantly different from 1 ($P < .001$), indicating that neither tympanic nor TA temperature was equivalent to rectal temperature.

The slopes generated for the 2 curves differed significantly from one another ($P = .02$), indicating that TA temperature was significantly closer to equivalence with rectal temperature than was tympanic temperature. Comparison of the correlation coefficients from the 2 models using the Fischer z transform showed significantly closer correlation between TA and rectal temperature than between tympanic and rectal temperature ($P = .006$).

(eg, patient's forehead buried in parent's chest, making TA temperature potentially unreliable) were recorded.

DISCOMFORT ASSESSMENTS

To assess the experience of children with thermometry, a semi-quantitative discomfort scale was used. The scale, adapted from the work by Shane et al.³⁹ is shown in **Table 1**. Research assistants were asked to assess behavior of the patients and to assign a discomfort score immediately after measuring the rectal, tympanic, and left-sided TA temperatures.

To ensure that the behavioral responses recorded after the use of a given thermometer would not be influenced substantially by the preceding measurements, the order of routes was varied from patient to patient. The right-sided TA temperature was always the fourth measurement made. The order of the other 3 measurements was dictated by a pre-printed data collection form. The data collection form for each patient was taken blindly from the top of a shuffled stack of data forms after the patient consented to enrollment.

DATA ANALYSIS

Reproducibility of TA temperature was assessed by performing a paired sample *t* test and calculating a correlation coefficient for the relation between left- and right-sided TA temperatures. For the purpose of this analysis, cases in which 1 of the 2 TA measurements was noted to be unreliable were excluded.

To evaluate the accuracy of TA and tympanic thermometry, rectal temperature was considered the criterion standard. Both TA temperature and tympanic temperature were assessed for their ability to predict rectal temperature. In doing this analysis, left-sided TA temperature was used as the representative TA temperature. In cases in

which the left-sided TA temperature was noted to be unreliable, right-sided temperatures were used.

Linear regression analysis was performed and correlation coefficients were calculated for the relation between TA and rectal temperature and for the relation between tympanic and rectal temperature. In addition, *t* tests were performed to compare the slopes of each of the 2 lines generated by the linear regression models to a value of 1 to determine whether TA or tympanic temperature readings were equivalent to rectal temperatures. The slopes of the 2 lines generated were compared with one another using a *t* test as well. Correlation coefficients were compared using the Fischer *z* transform technique.

Patients with a rectal temperature of 38°C or higher were considered to have rectal fever, and those with a rectal temperature of 39°C or higher were considered to have high rectal fever. The sensitivity and specificity of tympanic and TA thermometers for detecting temperatures of 38°C or higher in cases of rectal fever were calculated. The sensitivities of tympanic and TA thermometers for detecting temperatures of 38°C or higher in cases of high rectal fever were calculated separately. Sensitivities and specificities of the 2 thermometry methods were compared with one another using the McNemar test. When comparisons showed no significant differences between the 2 thermometry methods, post hoc power calculations were performed.

Discomfort scores for each of the 3 methods were compared with one another using the Wilcoxon signed rank test. Because multiple (3) comparisons were done in assessing discomfort scores, a Bonferroni correction was used, with $P \leq .017$ considered significant for this analysis.

Statistical analysis was performed using the Statistical Program for the Social Sciences, version 6.0 for Windows (SPSS Inc, Chicago, Ill), and the Stata statistical package for Windows (Stata Inc, College Station, Tex).

SENSITIVITY AND SPECIFICITY

The sensitivities of the TA and tympanic thermometers for detecting fever in patients with rectal fever (temperature $\geq 38^\circ\text{C}$) or high rectal fever (temperature $\geq 39^\circ\text{C}$) are shown in **Table 2**. Using the McNemar test, we found the TA thermometer to be significantly more sensitive than the tympanic thermometer for detecting rectal fever ($P < .001$) and high rectal fever ($P = .004$).

The specificities of the TA and tympanic thermometers in patients with no rectal fever are shown in Table 2. Using the McNemar test, we found no significant difference between the specificity of the tympanic and TA thermometers ($P = .07$). A post hoc power calculation indicated that our study had a power of 0.35 for detecting a statistically significant difference between 2 thermometry methods with the measured specificities.

DISCOMFORT SCORES

The median discomfort score for the rectal thermometer was 3, with a range of 1 to 5. For both the tympanic and TA thermometers, the median discomfort score was 2, with a range of 1 to 5. The tympanic thermometer was

associated with significantly lower discomfort scores than the rectal thermometer ($P < .001$). The TA thermometer was also associated with significantly lower discomfort scores than the rectal thermometer ($P = .007$).

COMMENT

We have found the TA thermometer to be significantly more accurate than the tympanic thermometer for predicting rectal temperature in infants. The TA thermometer is significantly more sensitive than the tympanic thermometer for the detection of rectal fever in infants. In addition, the TA thermometer is better tolerated by patients than the rectal thermometer.

Previous investigations have also suggested that tympanic thermometry is a poor predictor of rectal temperature in infants. Brennan et al⁶ found that tympanic thermometry had a sensitivity of only 0.76 for detecting rectal fever in children 6 months to 6 years of age. Hooker¹⁰ reported that tympanic thermometers had a sensitivity of 0.67 for detecting rectal fever in patients younger than 6 years. Muma et al¹² reported that tympanic thermometers had a sensitivity of 0.55 for detecting fever in 87 children younger than 3 years.

Table 1. Infant Discomfort Scale*

Score	Description of Behavior
1, Drowsy/asleep	Eyes closed, may respond to stimulation, accepts intervention passively
2, Relaxed	Sitting or lying with eyes open, accepts intervention readily
3, Anxious	Verbally or nonverbally seeks support but accepts intervention reluctantly
4, Upset	Tearful, may be clinging to parent, considerable effort required to achieve compliance with intervention
5, Agitated	General loud or high-pitched crying, requires significant physical restraint, strongly refuses intervention

* Adapted from Shane et al.²⁹

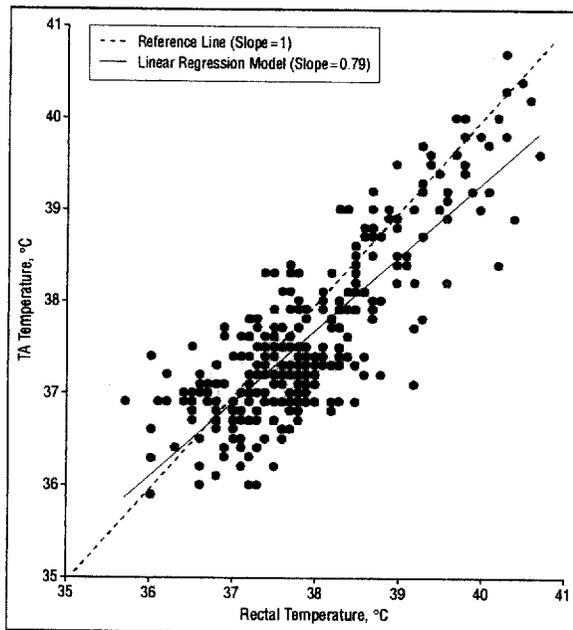


Figure 1. Scatterplot of rectal vs temporal artery (TA) temperatures.

Our data suggest that TA thermometry is a better choice than tympanic thermometry for use in infants. However, TA thermometry does not reliably predict rectal temperature in all clinical situations. Thirty-five percent of all cases of rectal fever and 6% of cases of high-grade rectal fever were missed by the TA thermometer.

One limitation of our study is that we do not have a true measure of core body temperature to use as a criterion standard. In the literature, esophageal or pulmonary artery (PA) temperatures are generally considered to be true measures of core body temperature.⁴⁰⁻⁵⁴ Several published investigations have evaluated the accuracy of rectal thermometry as an indicator of core body temperature compared with these invasive methods. Some early studies^{55,56} of the physiology of human body temperature suggested a lag between instantaneous changes in core body temperature and more delayed changes in rectal temperature. It is possible, therefore, that in cases with large discrepancies between TA and rectal measure-

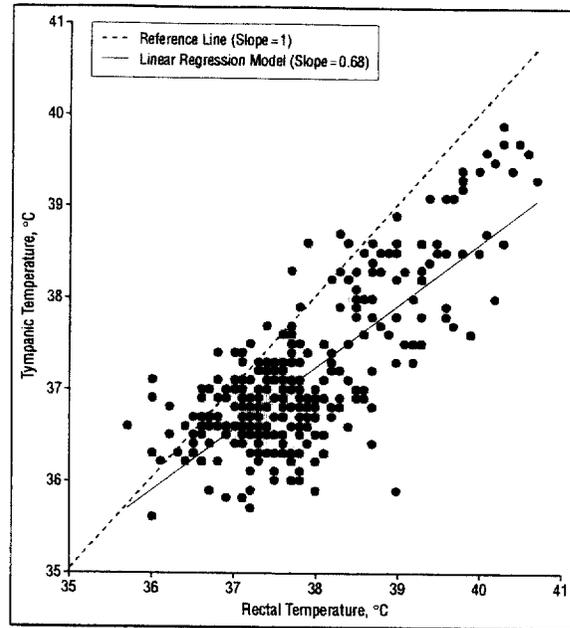


Figure 2. Scatterplot of rectal vs tympanic temperatures.

ments, the TA thermometer may be correctly reflecting a rapid change in core body temperature, whereas the rectal temperature is lagging behind. For instance, if antipyretics had been given several minutes before the temperatures were measured, the TA temperature might accurately reflect a lowered core body temperature, while the rectal temperature still reflects the preceding fever. Future studies evaluating the changes in TA and rectal temperatures in response to changes in core body temperature would be of interest.

Although we must acknowledge this theoretical limitation, the bulk of the published literature suggests that rectal thermometry is the best available noninvasive indicator of core body temperature. In a study of 16 adults admitted to an intensive care unit (ICU), Stavem et al⁴³ reported better agreement between rectal and PA temperatures than between tympanic and PA temperatures. Similarly, Schmitz et al⁴⁷ reported that rectal temperatures were a better predictor of PA temperatures than were oral, tympanic, or axillary temperatures in 13 adult patients in an ICU. In a study of 20 patients in a pediatric ICU, Romano et al⁵² found that rectal thermometry had less bias and variability than tympanic or axillary thermometers in predicting PA temperature. In a study of 9 adult patients in an ICU, Milewski et al⁵⁴ found a better correlation between rectal and PA temperature than between tympanic and PA temperature. Only Rotello et al,⁴⁶ in a study of 20 adult patients in an ICU, found a closer agreement between tympanic temperature and PA temperature than between rectal and PA temperatures. Even in this study, however, there was less variability in the difference between rectal and PA temperatures than in the difference between tympanic and PA temperatures.⁴⁶ Given these reports, we believe that rectal thermometry is an appropriate criterion standard for noninvasive clinical thermometry.

166

Table 2. Sensitivity and Specificity of Temporal Artery and Tympanic Thermometers*

Device	Sensitivity (95% CI)		Specificity (95% CI) (n = 195)
	In Cases of Rectal Fever (n = 109)	In Cases of High Rectal Fever (n = 49)	
	Temporal artery	0.66 (0.56-0.75)	
Tympanic	0.49 (0.39-0.58)	0.76 (0.60-0.86)	0.99 (0.96-0.999)

*CI indicates confidence interval.

Another limitation of our study is that we included only infants in our sample. Given that the tympanic thermometer has been shown to be especially unreliable in young infants, we caution the reader against extrapolating our findings to older children or adults. Future studies comparing the TA thermometer to the tympanic thermometer in older children or adults would be of interest.

We conclude that the TA thermometer has limited sensitivity for detecting cases of rectal fever in infants. However, the TA thermometer is more accurate than the tympanic thermometer in infants, and it is better tolerated by infants than rectal thermometry. Rectal thermometry should still be considered the preferred method for temperature measurement in infants. For clinicians who choose not to use rectal thermometry for infants, the TA thermometer appears to be a better alternative than the tympanic thermometer.

Accepted for publication October 23, 2000.

This study was funded by a grant from the Exergen Corporation.

Presented as an abstract at the annual meeting of the Pediatric Academic Societies, Boston, Mass, May 14, 2000.

We thank James DiCanzio for his statistical consultation. We thank Kelly Johnston, BA, John Branda, MD, Jeanne Smith, MS, and Joyce Lee, MD, for their help with patient enrollment and data collection.

Corresponding author and reprints: David S. Greenes, MD, Division of Emergency Medicine, Children's Hospital, 300 Longwood Ave, Boston, MA 02115 (e-mail: david.greenes@tch.harvard.edu).

REFERENCES

- Baraff LJ, Bass JW, Fleisher GR, et al. Practice guideline for the management of infants and children 0 to 36 months of age with fever without source: Agency for Health Care Policy and Research [published erratum appears in *Ann Emerg Med*. 1993;22:1490]. *Ann Emerg Med*. 1993;22:1198-1210.
- Anagnostakis D, Matsaniotis N, Grafakos S, Sarafidou E. Rectal-axillary temperature difference in febrile and afebrile infants and children. *Clin Pediatr*. 1993; 32:268-272.
- Banco L, Jayashakaramurthy S, Graffam J. The inability of a temperature-sensitive pacifier to identify fevers in ill infants. *AJDC*. 1988;142:171-172.
- Beckstrand RL, Wilshaw R, Moran S, Schaalje GB. Supralingual temperatures compared to tympanic and rectal temperatures. *Pediatr Nurs*. 1996;22:436-438.
- Bernardo LM, Clemence B, Henker R, Hogue B, Schenkel K, Walters P. A comparison of aural and rectal temperature measurements in children with moderate and severe injuries. *J Emerg Nurs*. 1996;22:403-408.
- Brennan DF, Falk JL, Rothrock SG, Kerr RB. Reliability of infrared tympanic thermometer in the detection of rectal fever in children. *Ann Emerg Med*. 1995;25: 21-30.
- Chamberlain JM, Grandner J, Rubinoff JL, Klein BL, Waisman Y, Huey M. Comparison of a tympanic thermometer to rectal and oral thermometers in a pediatric emergency department. *Clin Pediatr*. 1991;30:24-29. Discussion 34-35.
- Childs C, Harrison R, Hodkinson C. Tympanic membrane temperature as a measure of core temperature. *Arch Dis Child*. 1999;80:262-266.
- Erickson RS, Woo TM. Accuracy of infrared ear thermometry and traditional temperature methods in young children. *Heart Lung*. 1994;23:181-195.
- Hooker EA. Use of tympanic thermometers to screen for fever in patients in a pediatric emergency department. *South Med J*. 1993;86:855-858.
- Morley CJ, Hewson PH, Thornton AJ, Cole TJ. Axillary and rectal temperature measurements in infants. *Arch Dis Child*. 1992;67:122-125.
- Muma BK, Treloar DJ, Wurlinger K, Peterson E, Vitae A. Comparison of rectal, axillary, and tympanic membrane temperatures in infants and young children. *Ann Emerg Med*. 1991;20:41-44.
- Press S, Quinn BJ. The pacifier thermometer: comparison of supralingual with rectal temperatures in infants and young children. *Arch Pediatr Adolesc Med*. 1997;151:551-554.
- Romanovsky AA, Quint PA, Benikova Y, Kiesow LA. A difference of 5°C between ear and rectal temperatures in a febrile patient. *Am J Emerg Med*. 1997;15:383-385.
- Shann F, Mackenzie A. Comparison of rectal, axillary, and forehead temperatures. *Arch Pediatr Adolesc Med*. 1996;150:74-78.
- Terndrup TE, Milewski A. The performance of two tympanic thermometers in a pediatric emergency department. *Clin Pediatr*. 1991;30:18-23. Discussion 34-35.
- Weisse ME, Reagen MS, Boule L, France N. Axillary vs. rectal temperatures in ambulatory and hospitalized children. *Pediatr Infect Dis J*. 1991;10:541-542.
- Wilshaw R, Beckstrand R, Waid D, Schaalje GB. A comparison of the use of tympanic, axillary, and rectal thermometers in infants. *J Pediatr Nurs*. 1999;14:88-93.
- Yetman RJ, Coody DK, West MS, Montgomery D, Brown M. Comparison of temperature measurements by an aural infrared thermometer with measurements by traditional rectal and axillary techniques. *J Pediatr*. 1993;122:769-773.
- McDonald R. Objection to taking rectal temperatures. *Clin Pediatr*. 1968;7:707.
- McCaffery M. Children's responses to rectal temperatures: an exploratory study. *Nurs Res*. 1971;20:32-45.
- Barber N, Kilmon CA. Reactions to tympanic temperature measurement in an ambulatory setting. *Pediatr Nurs*. 1989;15:477-481.
- Frank JD, Brown S. Thermometers and rectal perforations in the neonate. *Arch Dis Child*. 1978;53:824-825.
- Lau JT, Ong GB. Broken and retained rectal thermometers in infants and young children. *Aust Paediatr J*. 1981;17:93-94.
- Ficarra BJ. Rectal thermometer misplaced. *Am J Proctol*. 1970;21:212-214.
- Merenstein GB. Rectal perforation by thermometer. *Lancet*. 1970;1:1007.
- Shaw EB. Rectal perforation by thermometer. *Lancet*. 1970;1:416.
- Smiddy FG, Benson EA. Rectal perforation by thermometer. *Lancet*. 1969;2:805-806.
- Wolfson JJ. Rectal perforation in infant by thermometer: case report with review of literature on rectal perforation. *AJDC*. 1966;111:197-200.
- Young DG. Thermometers and rectal perforations in the neonate [letter]. *Arch Dis Child*. 1979;54:242.
- Brooks S, Khan A, Stoica D, et al. Reduction in vancomycin-resistant *Enterococcus* and *Clostridium difficile* infections following change to tympanic thermometers. *Infect Control Hosp Epidemiol*. 1998;19:333-336.
- Im SW, Chow K, Chau PY. Rectal thermometer mediated cross-infection with *Salmonella wandsworthi* in a paediatric ward. *J Hosp Infect*. 1981;2:171-174.
- Porwancher R, Sheth A, Remphey S, Taylor E, Hinkle C, Zervos M. Epidemiological study of hospital-acquired infection with vancomycin-resistant *Enterococcus faecium*: possible transmission by an electronic ear-probe thermometer. *Infect Control Hosp Epidemiol*. 1997;18:771-773.
- Androkites AL, Werger AM, Young ML. Comparison of axillary and infrared tympanic membrane thermometry in a pediatric oncology outpatient setting. *J Pediatr Oncol Nurs*. 1998;15:216-222.
- Zengaya ST, Blumenthal I. Modern electronic and chemical thermometers used in the axilla are inaccurate. *Eur J Pediatr*. 1996;155:1005-1008.
- Petersen-Smith A, Barber N, Coody DK, West MS, Yetman RJ. Comparison of aural infrared with traditional rectal temperatures in children from birth to age three years. *J Pediatr*. 1994;125:83-85.
- Freed GL, Fraley JK. Lack of agreement of tympanic membrane temperature assessments with conventional methods in a private practice setting. *Pediatrics*. 1992;89:384-386.

167

38. Lanham DM, Walker B, Klocke E, Jennings M. Accuracy of tympanic temperature readings in children under 6 years of age. *Pediatr Nurs*. 1999;25:39-42.
39. Shane SA, Fuchs SM, Khine H. Efficacy of rectal midazolam for the sedation of preschool children undergoing laceration repair. *Ann Emerg Med*. 1994;24:1065-1073.
40. Giuliano KK, Scott SS, Elliot S, Giuliano AJ. Temperature measurement in critically ill orally intubated adults: a comparison of pulmonary artery core, tympanic, and oral methods. *Crit Care Med*. 1999;27:2188-2193.
41. Hoffman C, Boyd M, Briere B, Loos F, Norton PJ. Evaluation of three brands of tympanic thermometer. *Can J Nurs Res*. 1999;31:117-130.
42. Harasawa K, Kemmotsu O, Mayumi T, Kawano Y. Comparison of tympanic, esophageal and blood temperatures during mild hypothermic cardiopulmonary bypass: a study using an infrared emission detection tympanic thermometer. *J Clin Monit Comput*. 1997;13:19-24.
43. Stavem K, Saxholm H, Smith-Erichsen N. Accuracy of infrared ear thermometry in adult patients. *Intensive Care Med*. 1997;23:100-105.
44. Thomas KA, Savage MV, Brengelmann GL. Effect of facial cooling on tympanic temperature. *Am J Crit Care*. 1997;6:46-51.
45. Patel N, Smith CE, Pinchak AC, Hagen JF. Comparison of esophageal, tympanic, and forehead skin temperatures in adult patients. *J Clin Anesth*. 1996;8:462-468.
46. Rotello LC, Crawford L, Terndrup TE. Comparison of infrared ear thermometer derived and equilibrated rectal temperatures in estimating pulmonary artery temperatures. *Crit Care Med*. 1996;24:1501-1506.
47. Schmitz T, Bair N, Falk M, Levine C. A comparison of five methods of temperature measurement in febrile intensive care patients. *Am J Crit Care*. 1995;4:286-292.
48. White N, Baird S, Anderson DL. A comparison of tympanic thermometer readings to pulmonary artery catheter core temperature recordings. *Appl Nurs Res*. 1994;7:165-169.
49. Erickson RS, Meyer LT. Accuracy of infrared ear thermometry and other temperature methods in adults. *Am J Crit Care*. 1994;3:40-54.
50. Klein DG, Mitchell C, Petrinec A, et al. A comparison of pulmonary artery, rectal, and tympanic membrane temperature measurement in the ICU. *Heart Lung*. 1993;22:435-441.
51. Erickson RS, Kirkin SK. Comparison of ear-based, bladder, oral, and axillary methods for core temperature measurement. *Crit Care Med*. 1993;21:1528-1534.
52. Romano MJ, Fortenberry JD, Autrey E, et al. Infrared tympanic thermometry in the pediatric intensive care unit. *Crit Care Med*. 1993;21:1181-1185.
53. Nierman DM. Core temperature measurement in the intensive care unit. *Crit Care Med*. 1991;19:818-823.
54. Milewski A, Ferguson KL, Terndrup TE. Comparison of pulmonary artery, rectal, and tympanic membrane temperatures in adult intensive care unit patients. *Clin Pediatr*. 1991;30:13-16; discussion 34-35.
55. Gerbrandy J, Snell E, Cranston W. Oral, rectal, and oesophageal temperatures in relation to central temperature control in man. *Clin Sci (Colch)*. 1954;13:615-624.
56. Molnar G, Read R. Studies during open-heart surgery on the special characteristics of rectal temperature. *J Appl Physiol*. 1974;36:333-336.

168

Clinical Study No. (b)(4)

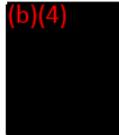
169

Clinical Study No. (b)(4)

200

Clinical Study No. (b)(4)

232

Clinical Study No. (b)(4) 

Section 10 Biocompatibility

280

Biocompatibility

Exergen drawings and specifications call for all case parts to be made from (b)(4) (b)(4) They also call for use of an FDA approved material. Checks with suppliers indicate the material used for the casing of the TemporalScanner is commonly used as a casing for medical devices.

287

Section 12

Financial Certification Submitted Pursuant to 21 CFR Part 54

Certification Pursuant to 21 CFR Part 54

By its duly authorized representative, Exergen Corporation (Exergen) hereby certifies that, in none of the clinical studies supporting this section 510(k) premarket notification for the TemporalScanner (Submitted Studies), did any of the clinical investigators have any financial interests in the Submitted Studies which were required to be disclosed to the Food and Drug Administration pursuant to 21 CFR Part (b)(6)

Signed this ²26 day of April 2001

(b)
(A)
VICE PRESIDENT
Title

(b)(4) doc

JBT

FDA/CDRH IMAGING SYSTEM
Page Count Discrepancy Information

The page after page 121 was numbered 123.

Verifiers Initials

(b)(6)

A large black rectangular redaction box covers the area where the Verifiers Initials would be located.