

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

EXERGEN CORPORATION,

Plaintiff,

v.

WAL-MART STORES INC.,
S.A.A.T. SYSTEMS APPLICATION OF
ADVANCED TECHNOLOGY LTD.,
DAIWA PRODUCTS, INC. and
HANA MICROELECTRONICS CO., LTD.,

Defendants.

DOCKETED

Civil Action No.: 01-CV-11306-RCL

OCT 2 2 55 PM '01

FIRST AMENDED COMPLAINT AND DEMAND FOR JURY TRIAL

For its Complaint, Plaintiff alleges as follows:

The Parties

1. Plaintiff Exergen Corporation ("Exergen") is a corporation organized and existing under the laws of the Commonwealth of Massachusetts and having its principal place of business at 51 Water Street, Watertown, Massachusetts, within this judicial District.

2. Exergen is a leading innovator in the field of medical thermometry. Exergen's founder and president, Francesco Pompei, is the inventor of over forty United States patents. Exergen Corporation has developed a forehead thermometer, the Exergen TemporalScanner, which provides accurate and convenient temperature measurements via the temporal artery. The Exergen TemporalScanner has been proven to be more accurate in infants than ear thermometry and better tolerated by infants than rectal thermometry. See Greenes, David S. et al., *Accuracy of a Noninvasive Temporal Artery Thermometer for Use in Infants*, Vol. 155 Arch. Pediatr. Adolesc. Med. pages 376-381, (March 2001). The Exergen TemporalScanner is covered by numerous issued and pending U.S. patents.

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3. Defendant Wal-Mart Stores Inc. ("Wal-Mart") is, upon information and belief, a corporation organized and existing under the laws of the state of Delaware, having a place of business at 702 Southwest 8th Street, Bentonville, AR 72712.

4. Defendant S.A.A.T. Systems Application of Advanced Technology Ltd. ("S.A.A.T.") is, upon information and belief, an Israeli limited liability company, having a place of business at 17 Nahshon St, Petah Tikva 49130, Israel.

5. Defendant Daiwa Products, Inc. ("Daiwa") is, upon information and belief, a Delaware corporation having its principal place of business at 200 E. Las Olas Boulevard, Suite 1480, Fort Lauderdale, FL 33301.

6. Defendant Hana Microelectronics Co., Ltd. ("Hana") is, upon information and belief, a limited liability company, having a place of business at 2568 Gudai Lu, Shanghai, 201100, China.

Jurisdiction and Venue

7. This is an action for patent infringement, arising under the patent laws of the United States, Title 35 of the United States Code.

8. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338(a).

9. Venue is proper in this court under 28 U.S.C. §§ 1391 and 1400(b).

COUNT I

(Infringement of U.S. Patent No. 5,012,813)

10. Exergen is the owner of United States Letters Patent No. 5,012,813, entitled RADIATION DETECTOR HAVING IMPROVED ACCURACY ("the '813 patent"). The '813 patent was duly and legally issued by the United States Patent Office on May 7, 1991, and is valid and subsisting and in full force and effect. A copy of the '813 patent is attached to the Complaint as Exhibit A.

11. Upon information and belief, each of the defendants has infringed, contributed to the infringement of, and/or actively induced infringement of the '813 patent by making, using, offering to sell, selling and/or importing devices embodying the patented invention in the United States and will continue to do so unless enjoined by this Court.

COUNT II

(Infringement of U.S. Patent No. 5,199,436)

12. Exergen is the owner of United States Letters Patent No. 5,199,436, entitled RADIATION DETECTOR HAVING IMPROVED ACCURACY ("the '436 patent"). The '436 patent was duly and legally issued by the United States Patent Office on April 6, 1993, and is valid and subsisting and in full force and effect. A copy of the '436 patent is attached to the Complaint as Exhibit B.

13. Upon information and belief, each of the defendants has infringed the '436 patent by making, using, offering to sell, selling and/or importing devices embodying the patented invention in the United States and will continue to do so unless enjoined by this Court.

COUNT III

(Infringement of U.S. Patent No. 5,653,238)

14. Exergen is the owner of United States Letters Patent No. 5,653,238, entitled RADIATION DETECTOR PROBE ("the '238 patent"). The '238 patent was duly and legally issued by the United States Patent Office on August 5, 1997, and is valid and subsisting and in full force and effect. A copy of the '238 patent is attached to the Complaint as Exhibit C.

15. Upon information and belief, each of the defendants has infringed the '238 patent by making, using, offering to sell, selling and/or importing devices embodying the patented invention in the United States and will continue to do so unless enjoined by this Court.

COUNT IV

(Infringement of U.S. Patent No. 6,047,205)

16. Exergen is the owner of United States Letters Patent No. 6,047,205, entitled RADIATION DETECTOR PROBE (“the ‘205 patent”). The ‘205 patent was duly and legally issued by the United States Patent Office on April 4, 2000, and is valid and subsisting and in full force and effect. A copy of the ‘205 patent is attached to the Complaint as Exhibit D.

17. Upon information and belief, each of the defendants has infringed the ‘205 patent by making, using, offering to sell, selling and/or importing devices embodying the patented invention in the United States and will continue to do so unless enjoined by this Court.

COUNT V

(Infringement of U.S. Patent No. 6,292,685)

18. Exergen is the owner of United States Letters Patent No. 6,292,685, entitled TEMPORAL ARTERY TEMPERATURE DETECTOR (“the ‘685 patent”). The ‘685 patent was duly and legally issued by the United States Patent Office on September 18, 2001, and is valid and subsisting and in full force and effect. A copy of the ‘685 patent is attached to the Complaint as Exhibit E.

19. Upon information and belief, each of the defendants has infringed the ‘685 patent by making, using, offering to sell, selling and/or importing devices embodying the patented invention in the United States and will continue to do so unless enjoined by this Court.

Willful Infringement

20. Upon information and belief, defendants have notice and knowledge of the '813, '436, '238, '205 and '685 patents.

21. Upon information and belief, defendants' infringement of the '813, '436, '238, '205 and '685 patents has been and continues to be willful.

WHEREFORE, Exergen prays that this Court:

A. Enter judgment that each of the defendants has infringed the '813, '436, '238, '205 and '685 patents.

B. Enter an order preliminarily and permanently enjoining each of the defendants, its agents and employees, and any others acting in concert with it, from infringing U.S. Patent Nos. 5,012,813; 5,199,436; 5,653,238; 6,047,205; and 6,292,685;

C. Award Exergen its damages resulting from defendants' patent infringement pursuant to 35 U.S.C. § 284;

D. Find that defendants' infringement has been willful and increase the damages awarded to Exergen three times the amount assessed, pursuant to 35 U.S.C. § 284;

E. Find this to be an exceptional case and award Exergen its attorney's fees, pursuant to 35 U.S.C. § 285;

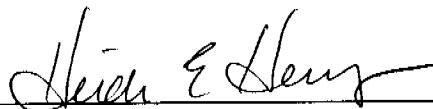
F. Award Exergen its prejudgment interest and post judgment interest on its damages and award Exergen its costs; and

G. Award Exergen such other and further relief as it deems just and appropriate.

Plaintiff demands a trial by jury.

By its attorneys

Dated: October 2, 2001



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EXERGEN CORPORATION

CERTIFICATE OF SERVICE

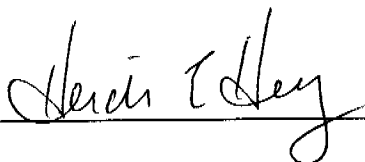
I hereby certify that a true copy of the foregoing FIRST AMENDED COMPLAINT AND DEMAND FOR JURY TRIAL was served by first class mail on counsel for the parties listed below at the following address(es):

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S.A.A.T. SYSTEMS
APPLICATION OF
ADVANCED TECHNOLOGY
LTD.,
and
DAIWA PRODUCTS, INC.

this 7th day of October, 2001.



United States Patent [19]

[11] **Patent Number:** 5,012,813

Pompei et al.

[45] **Date of Patent:** May 7, 1991

- [54] **RADIATION DETECTOR HAVING IMPROVED ACCURACY**
- [75] **Inventors:** Francesco Pompei, Wellesley Hills; Philip R. Gaudet, Jr., Concord, both of Mass.
- [73] **Assignee:** Exergen Corporation, Natick, Mass.
- [21] **Appl. No.:** 338,968
- [22] **Filed:** Apr. 14, 1989

4,636,091	1/1987	Pompei et al.	
4,790,324	12/1988	O'Hara et al.	
4,797,840	1/1989	Fraden	
4,831,258	5/1989	Paulk et al.	
4,895,164	1/1990	Wood	128/736

OTHER PUBLICATIONS

Y. Houdas and E. F. J. Ring, Human Body Temperature, (Plenum Press: New York), p. 83.

Primary Examiner—Max Hindenburg
Assistant Examiner—J. P. Lacyk

- Related U.S. Application Data**
- [63] Continuation-in-part of Ser. No. 280,546, Dec. 6, 1988.
 - [51] **Int. Cl.³** A61B 6/00
 - [52] **U.S. CL** 128/664; 128/736; 374/130
 - [58] **Field of Search** 128/736, 738, 664; 374/121, 130-131, 116

[57] **ABSTRACT**

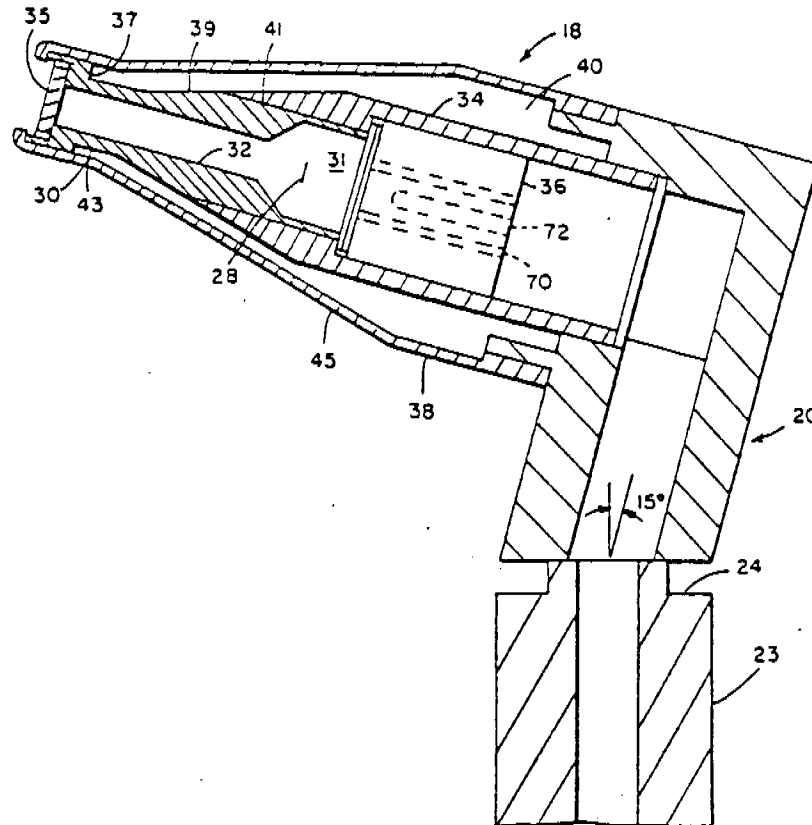
Tympanic temperature measurements are obtained from the output of a thermopile mounted in an extension from a housing. The housing has a temperature display thereon and supports the electronics for responding to sensed radiation. The thermopile is mounted in a highly conductive can which includes a radiation guide and thermal mass. The guide provides a narrow field of view due to a fairly high emissivity. Electronics determine the target temperature as a function of the temperature of the hot junction of the thermopile determined from the cold junction temperature and a thermopile coefficient. The tympanic temperature is adjusted to provide an indication of core temperature.

[56] **References Cited**

U.S. PATENT DOCUMENTS

2,710,559	6/1955	Heitmuller	374/130 X
2,984,747	5/1961	Walker	374/130 X
3,282,106	11/1966	Barnes	
3,491,596	1/1970	Dean	
3,581,570	6/1971	Wortz	
4,602,642	7/1986	O'Hara et al.	
4,626,686	12/1986	Pompei et al.	

8 Claims, 7 Drawing Sheets



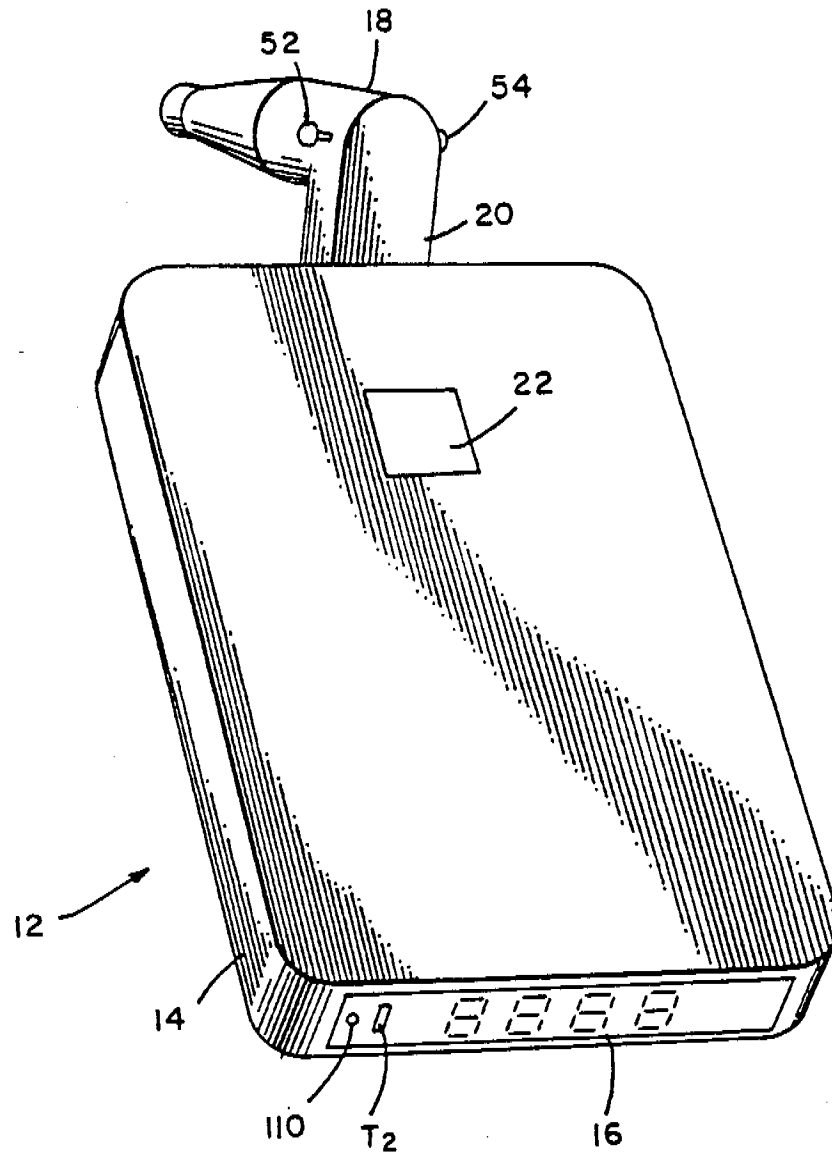


FIG. 1

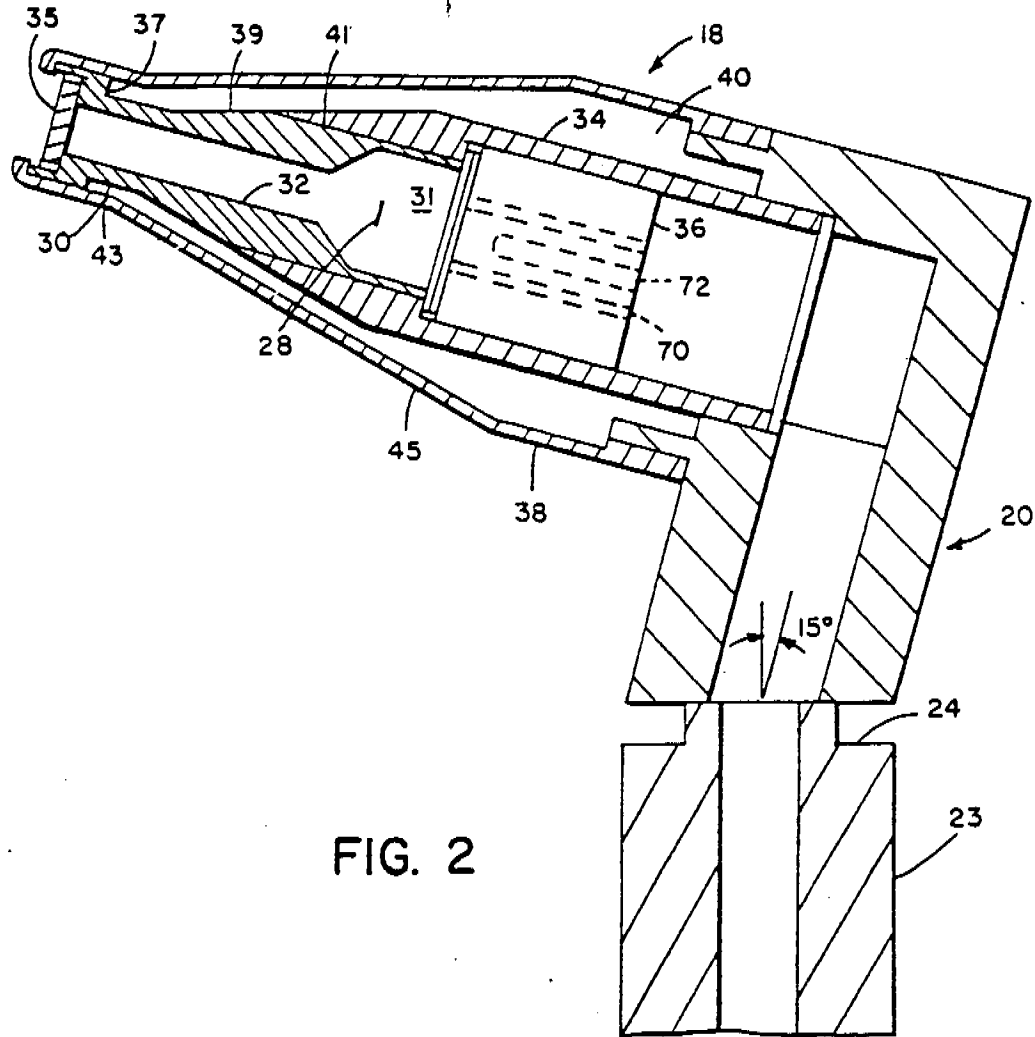


FIG. 2

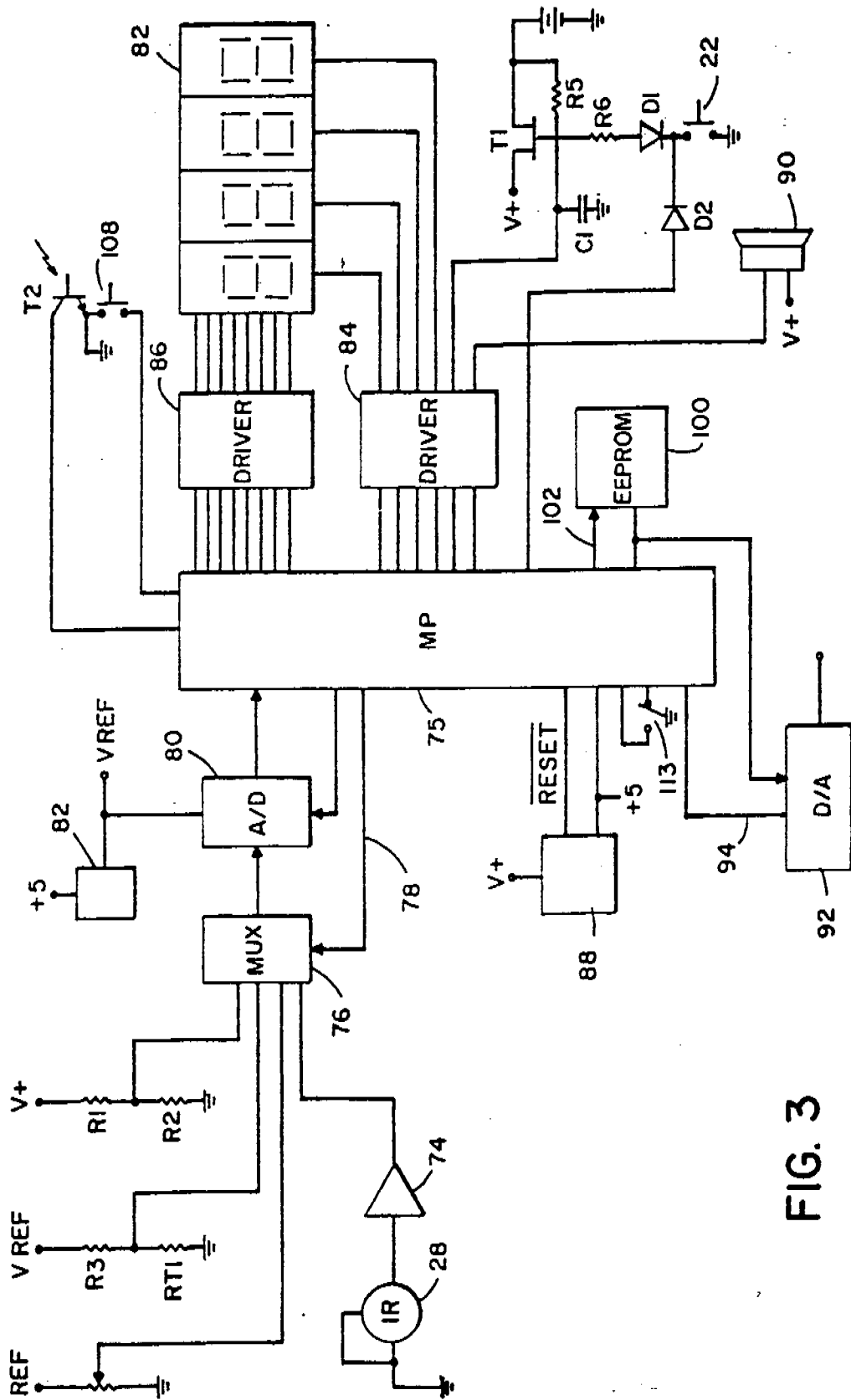


FIG. 3

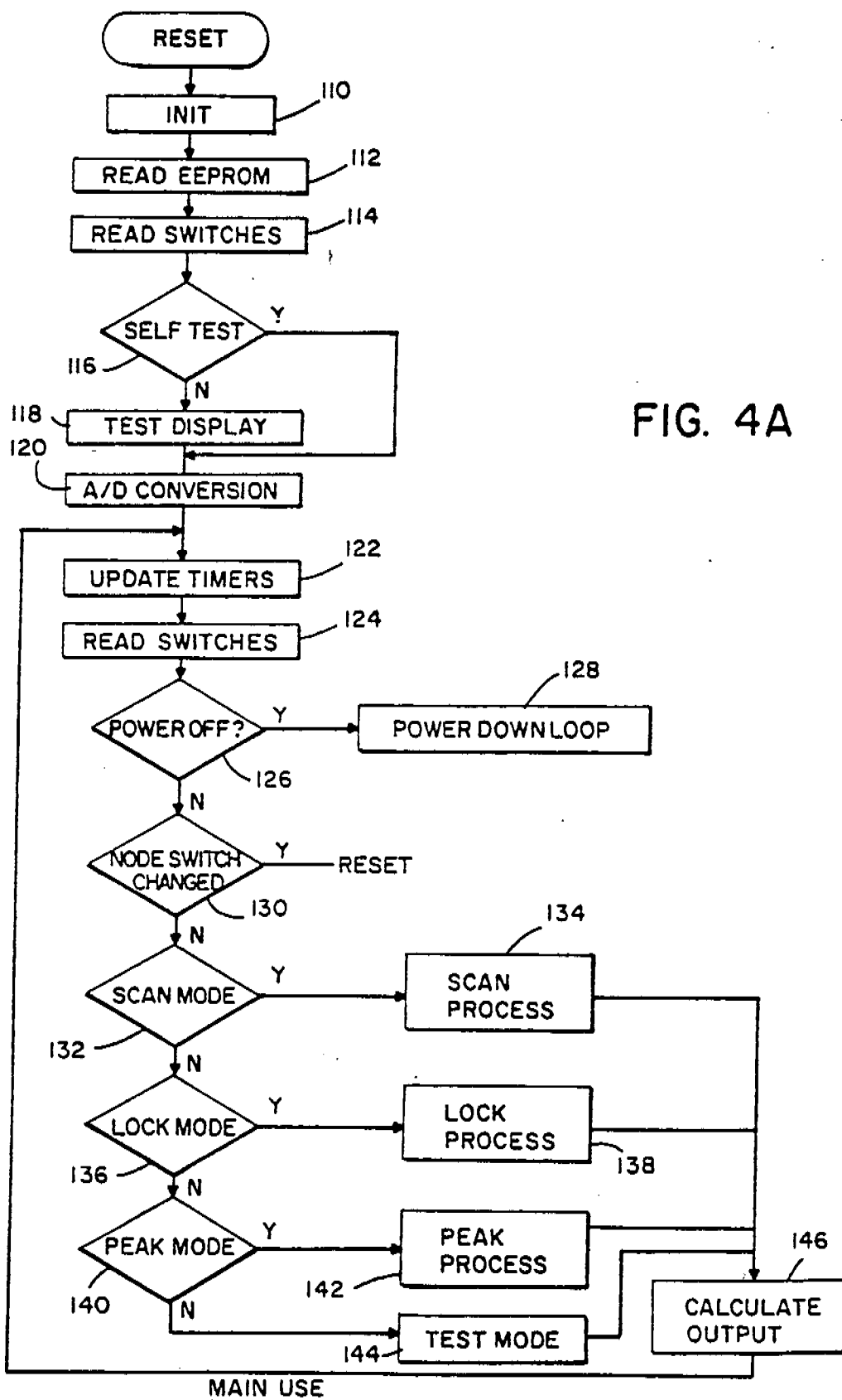


FIG. 4A

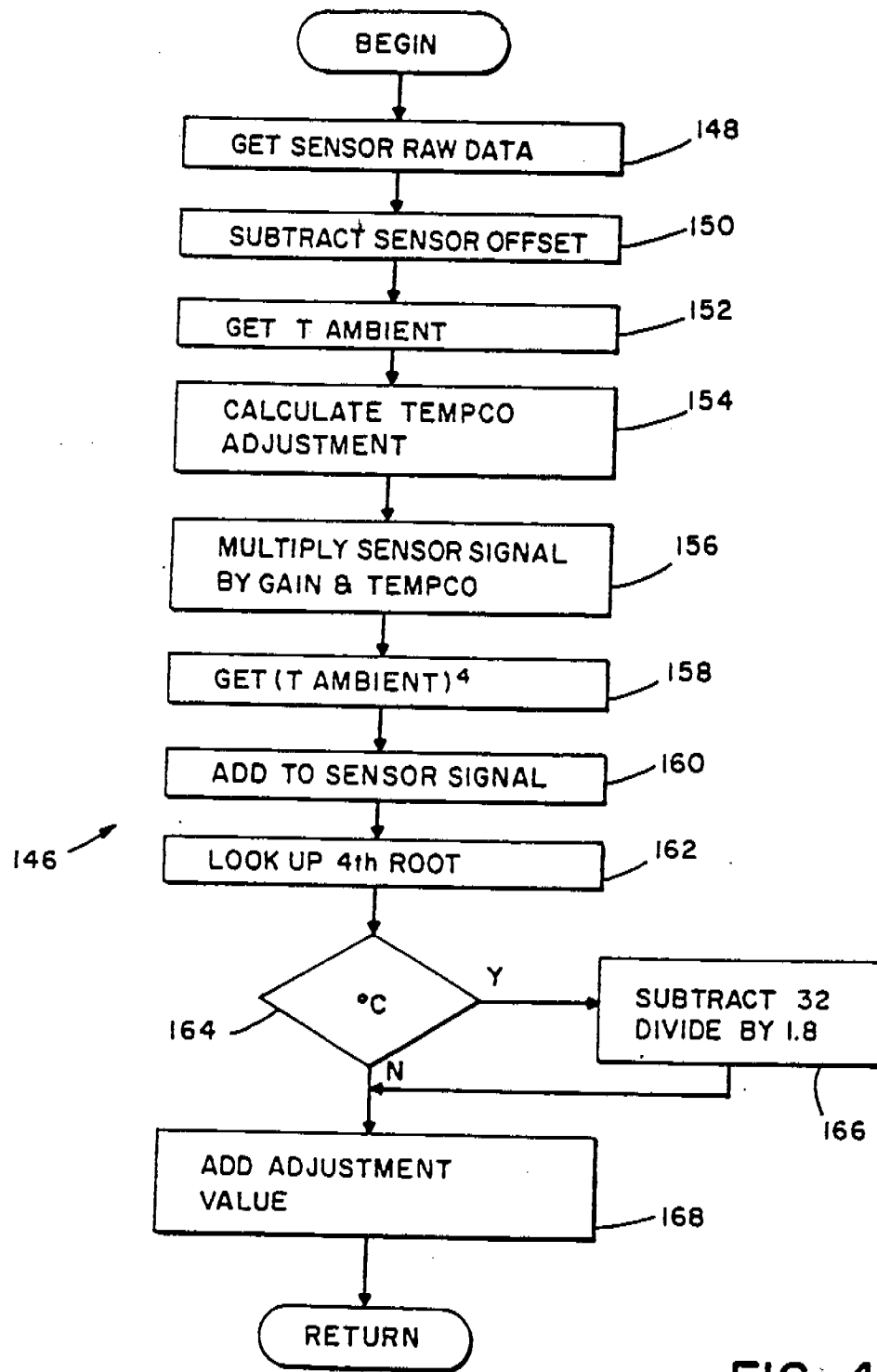
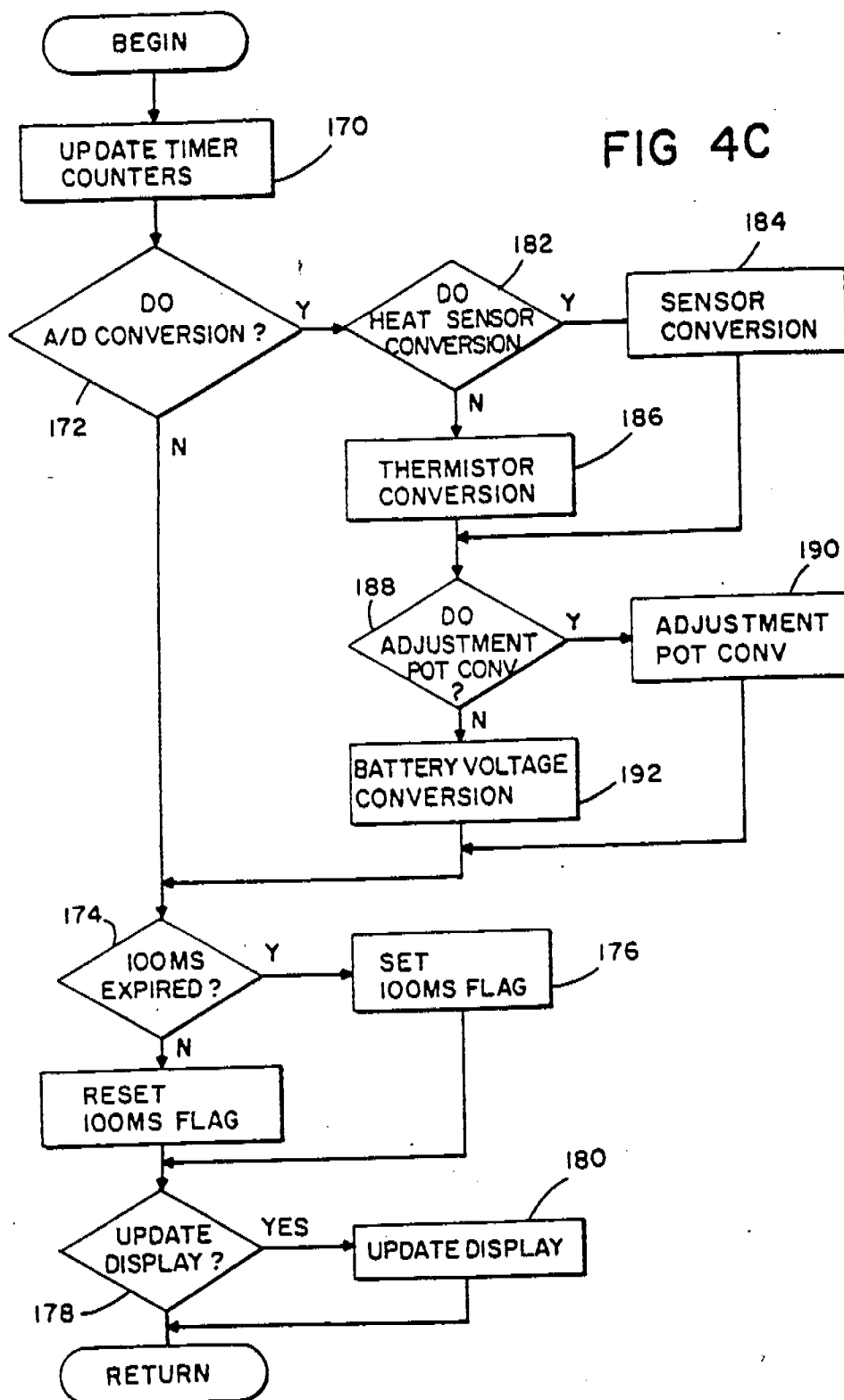


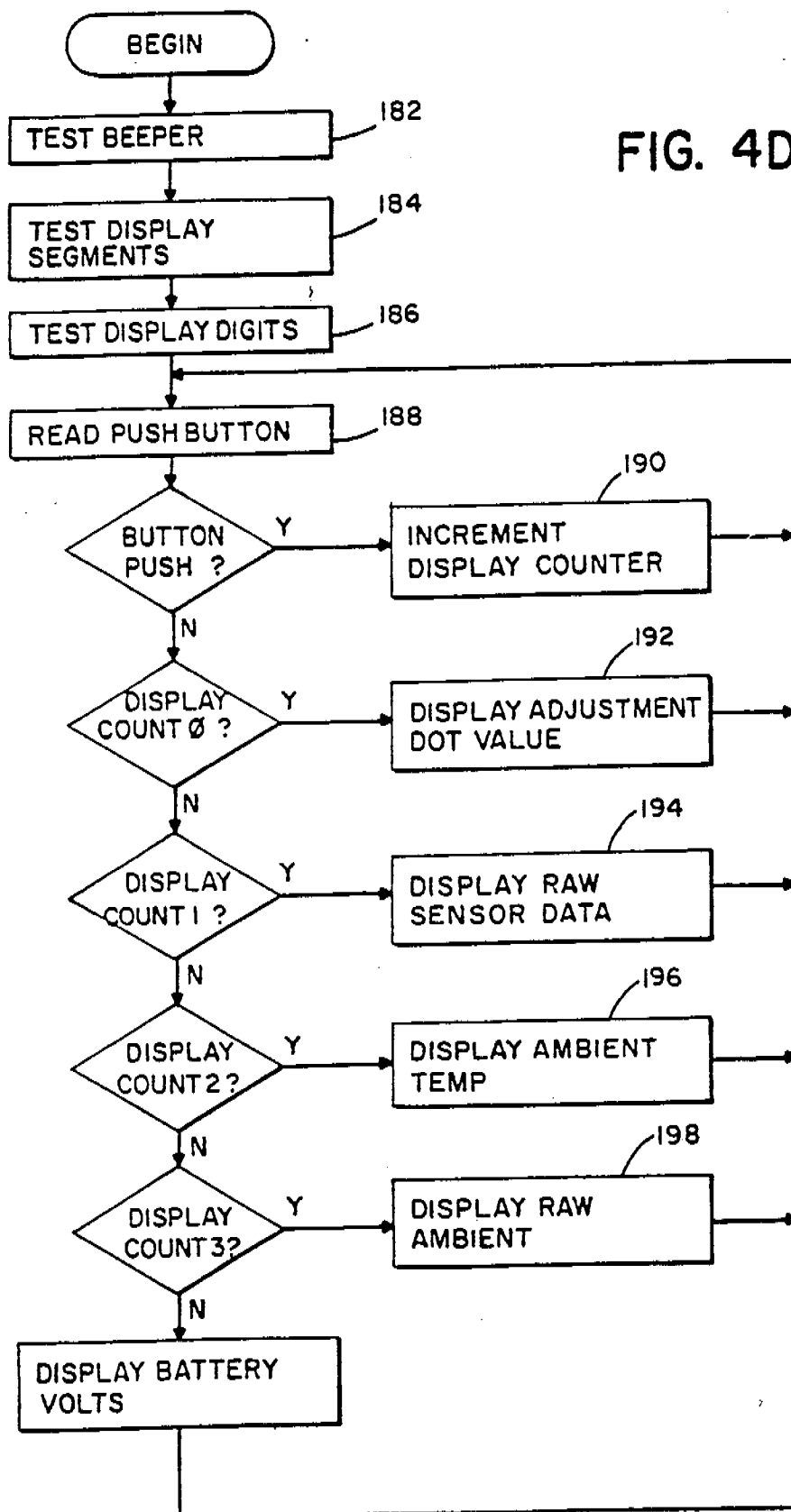
FIG. 4B

CALCULATE OUTPUT PROCEDURE



A/D CONVERSION INTERRUPT SERVICE ROUTINE

FIG. 4D



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RADIATION DETECTOR HAVING IMPROVED ACCURACY

RELATED APPLICATION

This is a continuation in part of Application No. 07/280,546 filed Dec. 6, 1988 pending for "Radiation Detector Suitable for Tympanic Temperature Measurement" which is incorporated herein by reference.

BACKGROUND

Radiation detectors which utilize thermopiles to detect the heat flux from target surfaces have been used in various applications. An indication of the temperature of a target surface may be provided as a function of the measured heat flux. One such application is the testing of electrical equipment. Another application has been in the scanning of cutaneous tissue to locate injured subcutaneous regions. An injury results in increased blood flow which in turn results in a higher surface temperature. Yet another application is that of tympanic temperature measurement. A tympanic device relies on a measurement of the temperature of the tympanic membrane area in the ear of an animal or human by detection of infrared radiation as an alternative to traditional sublingual thermometers.

SUMMARY OF THE INVENTION

An improved tympanic temperature measurement device is presented in parent Application No. 07/280,546. That device provides for accuracy within one-tenth of a degree over limited ranges of ambient temperature and accuracy to within one degree over a wide range of ambient temperatures. An object of the present invention is to provide a tympanic temperature measurement device which would provide accuracy to within one-tenth degree over a wide range of ambient temperatures. In obtaining that accuracy, an object of the invention was to continue to avoid any requirement for a reference target or for control of the temperature of the thermopile as such requirements had resulted in complexity and difficulties in prior tympanic temperature measurement devices.

A radiation detector comprises a thermopile and a can enclosing the thermopile. The can structure includes an elongated radiation guide of a first internal diameter. The radiation guide extends from a viewing window to a rear volume of larger internal diameter in which the thermopile is mounted. The guide may be gold plated.

In accordance with one feature of the present invention, the portions of the can forming the radiation guide and rear volume are formed in a unitary structure of high thermal conductivity material. The can structure has an outer surface with an outer diameter at its end adjacent to the window which is less than an outer diameter about the rear volume. The outer surface is tapered about the radiation guide such that a unitary thermal mass of increasing outer diameter is provided about the end of the radiation guide adjacent to the rear volume. The unitary can structure maximizes conductance and thermal mass within a limited diameter. To avoid changes in fixtures used in mounting the thermopile within the can, the unitary can of limited diameter may be supplemented with an additional thermal mass which surrounds the rear volume and a portion of

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the unitary thermal mass and which is in close thermal contact with the can structure.

It has been found that a narrow field of view radiation detector provides a more accurate reading of tympanic temperature. In the detector of the present invention, that field of view is obtained by controlling the reflectance of the surface of the radiation guide, the length of the guide and the position of the thermopile behind the guide. A field of view of less than about sixty degrees allows for viewing of only a portion of the ear canal within about 1.5 centimeters of the tympanic membrane.

Accuracy of the detector may be improved electronically as well. Accordingly, an electronic circuit is coupled to a thermopile, having a cold junction and a hot junction mounted to view a target, and to a temperature sensor for sensing the temperature of the cold junction. The electronic circuit is responsive to the voltage across the thermopile and a temperature sensed by the temperature sensor to determine the temperature of the target. The electronic circuit determines the temperature of the target as a function of the temperature of the hot junction of the thermopile determined from the cold junction temperature and a known thermopile coefficient. A display provides an indication of the target temperature determined by the electronic circuit.

As in prior systems, the electronic circuit determines target temperature from the relationship $T_T^2 = (KH) + T^2$, where T_T is the target temperature, K is a gain factor, H is a sensed voltage from the thermopile and T is a junction temperature of the thermopile. In accordance with the present invention in a preferred embodiment, the junction temperature is the temperature of the hot junction. The hot junction temperature T_H is determined from the sensed thermopile voltage and cold junction temperature and a thermopile coefficient. The thermopile coefficient is specified at a predetermined temperature and is temperature compensated by the electronic circuit as a function of a temperature between the hot and cold junctions, specifically the average temperature. Further, the electronic circuit determines the gain factor K as a function of the difference between a calibration temperature and a temperature between the hot and cold junction temperatures.

When used to measure a biological temperature, the radiation detector is further improved by providing an indication of an internal temperature within biological tissue. The electronic circuit determines the internal temperature by adjusting a measured temperature of surface tissue for ambient temperature. In particular, the biological surface tissue may be tympanic membrane or the ear canal adjacent to the membrane, and the display may provide an indication of core temperature.

BRIEF DESCRIPTION OF THE DRAWINGS

The foregoing and other objects, features and advantages of the invention will be apparent from the following more particular description of preferred embodiments of the invention, as illustrated in the accompanying drawings in which like reference characters refer to the same parts throughout the different views. The drawings are not necessarily to scale, emphasis instead being placed upon illustrating the principles of the invention.

FIG. 1 illustrates a radiation detector for tympanic temperature measurements in accordance with the present invention.

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FIG. 2 is a cross-sectional view of the extension of the detector of FIG. 1 in which the thermopile radiation sensor is positioned.

FIG. 3 is a block diagram of the electronic circuit of the detector of FIG. 1.

FIGS. 4A-4D are flow charts of the system firmware.

DESCRIPTION OF A PREFERRED EMBODIMENT

The radiation detector 12 of FIG. 1 includes a flat housing 14 with a digital display 16 for displaying a tympanic temperature measurement. Although the display may be located anywhere on the housing, it is preferred that it be positioned on the end so the user is not inclined to watch it during a measurement. The instrument makes an accurate measurement when rotated to scan the ear canal, and the user should concentrate on only the scanning motion. Then the display can be read. A thermopile radiation sensor is supported within a probe 18 at the opposite end of the housing 14. The extension 18 extends orthogonally from an intermediate extension 20 which extends at an angle of about 15 degrees from the housing 14. As such, the head of the detector, including the extension 18 and 20, has the appearance of a conventional otoscope. An on/off switch 22 is positioned on the housing.

A cross-sectional view of the extension of the detector is illustrated in FIG. 2. A base portion 23 is positioned within the housing 14, and the housing clamps about a groove 24. As noted, the portion 20 extends at about a 15 degree angle from the housing and thus from the base portion 23. The extension 18 is tapered toward its distal end at 26 so that it may be comfortably positioned in the ear to view the tympanic membrane and/or ear canal.

A preferred disposable element to be used over the extension 18 is presented in parent Application No. 07/280,546 and will not be discussed here.

The edge at the end of the probe is rounded so that when the probe is inserted into the ear it can be rotated somewhat without discomfort to the patient. The probe is also curved like an otoscope to avoid interference with the ear. By thus rotating the probe, the ear canal is scanned and, at some orientation of the probe during that scan, one can be assured that the maximum temperature is viewed. Since the ear canal cavity leading to the tympanic area is the area of highest temperature, the instrument is set in a peak detection mode, and the peak detected during the scan is taken as the tympanic temperature.

An improved assembly within the extension 18 is illustrated in FIG. 2. A thermopile 28 is positioned within a can 30 of high conductivity material such as copper. The conductivity should be greater than two watts per centimeter per degree Kelvin. The can is filled with a gas of low thermal conductivity such as Xenon. The thermopile 28 is positioned within a rear volume 31. It is mounted to an assembly which includes a flange 33. The volume is sealed by cold welding of the flange 33 to a flange 41 extending from the can. Cold welding is the preferred approach to making the seal and, to utilize past welding fixtures, the outer diameter of the can is limited.

The thermopile views the tympanic membrane area through a radiation guide 32. The radiation guide 32 is gold plated to minimize oxidation. It is closed at its forward end by a germanium window 35. To minimize

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expense, the window is square with each side slightly longer than the diameter of the radiation guide 32. The window is cemented with epoxy within a counterbore in a flange 37 at the end of the radiation guide. The epoxy serves as a gas seal and mechanical support for the somewhat brittle germanium window. The flange serves to protect the germanium window should the detector be dropped. The diagonal of the window is less than the diameter of the counterbore, and its thickness is less than the depth of the counterbore. Therefore, if the detector is dropped, any force which presses the plastic housing toward the window is absorbed by the flange. The germanium need only withstand the forces due to its own inertia.

Whereas the detector disclosed in the parent application had a wide field of view of about 120°, it has been determined that a significantly narrower field of view of about sixty degrees or less provides a more accurate indication of tympanic temperature. With a narrower field of view, the thermopile flake, when directly viewing the tympanic membrane, also views no more than about 1.5 centimeters along the ear canal and preferably less than one centimeter. A better view of the tympanic membrane also results from the cylindrical extension 43 beyond the conical portion of the extension 18. With the ear canal straightened by the probe, the extension 43 can extend well into the ear canal beyond any hair at the canal opening.

The tympanic membrane is about 2.5 centimeters from the opening of the ear canal. The conical portion of the extension 18 prevents the tip of the extension from extending more than about eight millimeters into the ear canal. Beyond that depth, the patient suffers noticeable discomfort. With a field of view of about sixty degrees, the ear canal which is about eight millimeters wide is viewed about eight millimeters from the tip of the extension 18. Thus, only the ear canal within about 1.5 centimeters of the tympanic membrane is viewed as the radiation guide is directed toward the membrane. The result is a more accurate reading of the tympanic temperature which is closer to core temperature.

With the present instrument, the narrow field of view is obtained by two changes to the prior radiation guide. The reflectivity within the guide is reduced. Radiation entering the tube at greater angles must be reflected a greater number of times from the radiation guide before reaching the thermopile flake. With the higher emissivity, such radiation is less likely to reach the flake to be detected. The field of view is further decreased by extending the enlarged rear volume between the flake and the radiation guide. Radiation which enters the radiation guide at greater angles, yet travels through the radiation guide, leaves the guide at greater angles and is thus unlikely to be viewed by the flake. The length of the radiation guide is another parameter which affects the field of view. By using a planoconvex lens as the window 35, the field of view can be further limited.

Both of the above approaches to decreasing the field of view increase the amount of heat which is absorbed by the can in which the thermopile is mounted. The added heat load adds to the importance that the can, including the radiation guide, have a large thermal mass and high thermal conductivity as discussed below.

As distinguished from the structure presented in the parent application, the volume 31 surrounding the thermopile and the radiation guide are formed of a single piece of high conductivity copper. This unitary con-

struction eliminates any thermal barriers between the foremost end of the radiation guide and the portion of the can surrounding the thermopile which serves as the cold junction of the thermopile. Further, at least a portion of added thermal mass which surrounds the radiation guide is unitary with the can as well. Specifically, a taper 39 results in an enlarged region 41 which serves as a thermal mass in accordance with the principals of the parent application. The taper 39 continues along a conductive thermal mass 34 which surrounds the can and a conductive plug 36. Both the mass 34 and plug 36 are of copper and are in close thermal contact with the can 30.

The outer sleeve 38 of the extension 18 and the intermediate extension 20 are of plastic material of low thermal conductivity. The sleeve 38 is separated from the can 30 and thermal mass 34 by an insulating air space 40. The taper of the can 30 and thermal mass 34 permits the insulating space to the end of the extension while minimizing the thermal resistance from the end of the tube 32 to the thermopile, a parameter discussed in detail below. The inner surface of the plastic sleeve 38 may be coated with a good thermal conductor to distribute across the entire sleeve any heat received from contact with the ear. Twenty mils of copper coating would be suitable.

In contrast with the prior design, the portion of the sleeve 38 at the foremost end of extension 18 has a region 43 of constant outer diameter before a tapered region 45. The region of constant outer diameter reduces the outer diameter at the distal end and minimizes interference when rotating the extension in the ear to view the tympanic membrane area. The tapered region is spaced six millimeters from the end of the extension to allow penetration of the extension into the ear canal by no more than about eight millimeters.

One of the design goals of the device was that it always be in proper calibration without requiring a warm-up time. This precluded the use a heated target in a chopper unit or heating of the cold junction of the thermopile as was suggested in the O'Hara et al. patent 4,602,642. To accomplish this design goal, it is necessary that the system be able to operate with the thermopile at any of a wide range of ambient temperatures and that the thermopile output have very low sensitivity to any thermal perturbations.

The output of the thermopile is a function of the difference in temperature between its warm junction, heated by radiation, and its cold junction which is in close thermal contact with the can 30. In order that the hot junction respond only to radiation viewed through the window 35, it is important that the radiation guide 32 be, throughout a measurement, at the same temperature as the cold junction. To that end, changes in temperature in the guide 32 must be held to a minimum, and any such changes should be distributed rapidly to the cold junction to avoid any thermal gradients. To minimize temperature changes, the tube 32 and the can 30 are, of course, well insulated by means of the volume of air 40. Further, a high conductance thermal path is provided to the cold junction. This conductance is enhanced by the unitary construction. Further, the can 30 is in close thermal communication with the thermal masses 34 and 36, and the high conductivity and thickness of the thermal masses increase the thermal conductance. A high thermal conductivity epoxy, solder or the like joins the can and thermal masses. The solder or epoxy provides a significant reduction in thermal resistance. Where solder is used, to avoid damage to the

thermopile which is rated to temperatures of 125° C., a low temperature solder of indium-tin alloy which flows at 100° C. is allowed to flow into the annular mass 34 to provide good thermal coupling between all elements.

The thermal resistance from the outer surface of the plastic sleeve 38 to the conductive thermal mass is high to minimize thermal perturbations to the inner thermal mass. To minimize changes in temperature of the guide 32 with any heat transfer to the can which does occur, the thermal mass of the can 30, annular mass 34 and plug 36 should be large. To minimize thermal gradients where there is some temperature change in the tube during measurement, the thermal resistance between any two points of the thermal mass should be low.

Thus, due to the large time constant of the thermal barrier, any external thermal disturbances, such as when the extension contacts skin, only reach the conductive thermal mass at extremely low levels during a measurement period of a few seconds; due to the large thermal mass of the material in contact with the cold junction, any such heat transfer only causes small changes in temperature; and due to the good thermal conductance throughout the thermal mass, any changes in temperature are distributed quickly and are reflected in the cold junction temperature quickly so that they do not affect temperature readings.

The thermal RC time constant for thermal conduction through the thermal barrier to the thermal mass and tube should be at least two orders of magnitude greater than the thermal RC time constant for the temperature response of the cold junction to heat transferred to the tube and thermal mass. The RC time constant for conduction through the thermal barrier is made large by the large thermal resistance through the thermal barrier and by the large thermal capacitance of the thermal mass. The RC time constant for response of the cold junction is made low by the low resistance path to the cold junction through the highly conductive copper can and thermal mass, and the low thermal capacitance of the stack of beryllium oxide rings and pin conductors to the thermopile.

Although the cold junction capacitance is naturally low, there are size constraints in optimizing the thermal capacitance of the thermal mass, the thermal resistance through the thermal barrier and the internal thermal resistance. Specifically, the external thermal resistance can be increased by increased radial dimensions, the capacitance of the thermal mass can be increased by increasing its size, and the thermal resistance through the longitudinal thermal path through the tube can be decreased by increasing its size. On the other hand, the size must be limited to permit the extension to be readily positioned and manipulated within the ear.

Besides the transfer of heat from the environment, another significant heat flow path to the conductive thermal mass is through leads to the system. To minimize heat transfer through that path, the leads are kept to small diameters. Further, they are embedded in the plug 36 through bores 70; thus, any heat brought into the system through those leads is quickly distributed throughout the thermal mass, and only small changes in temperature and small gradients result.

Because the temperature of the thermal mass is not controlled, and the response of the thermopile 28 is a function of its cold junction temperature, the cold junction temperature must be monitored. To that end, a thermistor is positioned at the end of a central bore 72 in the plug 36.

A schematic illustration of the electronics in the housing 14, for providing a temperature readout on display 16 in response to the signal from the thermopile, is presented in FIG. 3. The system is based on a microprocessor 73 which processes software routines included in read only memory within the processor chip. The processor may be a 6805 processor sold by Motorola.

The voltage generated across the thermopile 28 due to a temperature differential between the hot and cold junctions is amplified in an operational amplifier 74. The analog output from the amplifier 74 is applied as one input to a multiplexer 76. Another input to the multiplexer 76 is a voltage taken from a voltage divider R1, R2 which is indicative of the potential $V+$ from the power supply 78. A third input to the multiplexer 76 is the potential across a thermistor RT1 mounted in the bore 72 of block 36. The thermistor RT1 is coupled in a voltage divider circuit with R3 across a reference potential V_{Ref} . The final input to the multiplexer is a potential taken from a potentiometer R4 which may be adjusted by a user. The system may be programmed to respond to that input in any of a number of ways. In particular, the potentiometer may be used as a gain control or as a DC offset control.

At any time during the software routine of the microprocessor 73, one of the four inputs may be selected by the select lines 78. The selected analog signal is applied to a multiple slope analog system 80 used by the microprocessor in an integrating analog-to-digital conversion 80. The subsystem 80 may be a TSC500A sold by Tele-dyne. It utilizes the reference voltage V_{Ref} from a reference source 82. The microprocessor 73 responds to the output from the convertor 80 to generate a count indicative of the analog input to the convertor.

The microprocessor drives four 7-segment LED displays 82 in a multiplexed fashion. Individual displays are selected sequentially through a column driver 84, and within each selected display the seven segments are controlled through segment drivers 86.

When the switch 22 on the housing is pressed, it closes the circuit from the battery 78 through resistors R5 and R6 and diode D1 to ground. The capacitor C1 is quickly charged, and field effect transistor T1 is turned on. Through transistor T1, the $V+$ potential from the storage cell 78 is applied to a voltage regulator 86. The regulator 86 provides the regulated +5 volts to the system. It also provides a reset signal to the microprocessor. The reset signal is low until the +5 volt reference is available and thus holds the microprocessor in a reset state. When the +5 volts is available, the reset signal goes high, and the microprocessor begins its programmed routine.

When the switch 22 is released, it opens its circuit, but a charge is maintained on capacitor C1 to keep transistor T1 on. Thus, the system continues to operate. However, the capacitor C1 and transistor T1 provide a very simple watchdog circuit. Periodically, the microprocessor applies a signal through driver 84 to the capacitor C1 to recharge the capacitor and thus keep the transistor T1 on. If the microprocessor should fail to continue its programmed routine, it fails to charge the capacitor C1 within a predetermined time during which the charge on C1 leaks to a level at which transistor T1 turns off. Thus, the microprocessor must continue in its programmed routine or the system shuts down. This prevents spurious readings when the processor is not operating properly.

With transistor T1 on, the switch 22 can be used as an input through diode D2 to the microprocessor to initiate any programmed action of the processor.

In addition to the display, the system has a sound output 90 which is driven through the driver 84 by the microprocessor.

In order to provide an analog output from the detector, a digital-to-analog convertor 92 is provided. When selected by line 94, the convertor converts serial data on line 96 to an analog output made available to a user.

Both calibration and characterization data required for processing by the microprocessor may be stored in an electrically erasable programmable read only memory (EEPROM) 100. The EEPROM may, for example, be a 93c46 sold by International CMOS Technologies, Inc. The data may be stored in the EEPROM by the microprocessor when the EEPROM is selected by line 102. Once stored in the EEPROM, the data is retained even after power down. Thus, though electrically programmable, once programmed the EEPROM serves as a virtually nonvolatile memory.

Prior to shipment, the EEPROM may be programmed through the microprocessor to store calibration data for calibrating the thermistor and thermopile. Further, characterization data which defines the personality of the infrared detector may be stored. For example, the same electronics hardware, including the microprocessor 73 and its internal program, may be used for a tympanic temperature detector in which the output is accurate in the target temperature range of about 60° F. to a 110° F. or it may be used as an industrial detector in which the target temperature range would be from about 0° F. to 100° F. Further, different modes of operation may be programmed into the system. For example, several different uses of the sound source 90 are available.

Proper calibration of the detector is readily determined and the EEPROM is readily programmed by means of an optical communication link which includes a transistor T2 associated with the display. A communication boot may be placed over the end of the detector during a calibration/characterization procedure. A photodiode in the boot generates a digitally encoded optical signal which is filtered and applied to the detector T2 to provide an input to the microprocessor 73. In a reverse direction, the microprocessor, may communicate optically to a detector in the boot by flashing specific segments of the digital display 82. Through that communication link, an outside computer 106 can monitor the outputs from the thermistor and thermopile and perform a calibration of the devices. A unit to be calibrated is pointed at each of two black body radiation sources while the microprocessor 73 converts the signals and sends the values to the external computer. The computer is provided with the actual black body temperatures and ambient temperature in the controlled environment of the detector, computes calibration variables and returns those variable to be stored in the detector EEPROM. Similarly, data which characterizes a particular radiation detector may be communicated to the microprocessor for storage in the EEPROM.

A switch 108 is positioned behind a hole 110 (FIG. 1) in the radiation detector so that it may be actuated by a rigid metal wire or pin. Through that switch, the user may control some specific mode of operation such as converting the detector from degrees Fahrenheit to degrees centigrade. That mode of operation may be stored by the microprocessor 73 in the EEPROM so

that the detector continues to operate in a specific mode until a change is indicated by closing the switch 108.

A switch 106 may be provided either internally or through the housing to the user to set a mode of operation of the detector. By positioning the switch at either the lock position, the scan position or a neutral position, any of three modes may be selected. The first mode is the normal scan mode where the display is updated continuously. A second mode is a lock mode where the display locks after a selectable delay and then remains frozen until power is cycled or, optionally, the power-on button is pushed. The sound source may be caused to sound at the time of lock. The third mode is the peak mode where the display reads the maximum value found since power-on until power is cycled or, optionally, the power-on button is pushed.

The processor determines when the voltage from the divider R1, R2 drops below each of two thresholds. Below the higher threshold, the processor periodically enables the sound source to indicate that the battery is low and should be replaced but allows continued readout from the display. Below the lower threshold, the processor determines that any output would be unreliable and no longer displays temperature readings. The unit would then shut down upon release of the power button.

In the present system, the target temperature is computed from the relationship

$$T_T^4 - Kh(H - H_0) + T_H^4 \quad (1)$$

where T_T is the target temperature, Kh is a gain calibration factor, H is the radiation sensor signal which is offset by H_0 such that $(H - H_0) = 0$ when the target is at the cold junction temperature of the device to counter any electronic offsets in the system, and T_H is the hot junction temperature. This relationship differs from that previously used in that Kh is temperature compensated relative to the average temperature of the thermopile rather than the cold junction, or ambient, temperature. Further, the hot junction temperature rather than the cold junction temperature is referenced in the relationship.

The gain calibration factor Kh is temperature compensated by the relationship

$$Kh = G \left(1 - T_{co} \left(\frac{T_H - T_C}{T} - T_z \right) \right) \quad (2)$$

where G is an empirically determined gain in the system, T_{co} is the temperature coefficient of the Seebeck coefficient of the thermopile and T_z is the temperature at which the instrument was calibrated. The use of the average temperature of the thermopile rather than the cold junction temperature provides for a much more accurate response where a target temperature is significantly different from the ambient temperature.

As noted, the relationship by which the target temperature is determined includes the hot junction temperature as the second term rather than the cold junction temperature. Hot junction temperature is computed from the relationship

$$V_S = JN \alpha_{av} (T_H - T_C) \quad (3)$$

where JN is the number of junctions in the thermopile and α_{av} is the Seebeck coefficient at the average tem-

perature of the thermopile. The Seebeck coefficient can be determined from the relationship

$$\alpha_{av} = \alpha_{is} \left(1 - T_{co} \left(\frac{T_H - T_C}{T} - T_z \right) \right) \quad (4)$$

where α_{is} is the specified Seebeck coefficient at a particular specification temperature and T_S is that specification temperature. Again, it can be seen that temperature compensation is based on the average thermopile temperature rather than just the cold junction temperature. By substituting equation (4) into equation (3) and solving for T_H , the hot junction temperature is found to be

$$T_H = ((T_{co} \times T_S + 1) \pm ((T_{co} \times T_S + 1)^2 - (2 \times T_{co}) \times [(T_{co}(T_C \times T_S) - (T_C^2/2)) + T_C + (V_S/JN \alpha_{is})])^{1/2}) / T_{co} \quad (5)$$

The actual sensor output V_S can be determined from the digital value available to the processor from the equation:

$$V_S = (H - H_0) \frac{K_{AD}}{GFE} \quad (6)$$

where K_{AD} is the analog-to-digital conversion factor in volts/bit and GFE is the gain of the front end amplifier.

Reference to the hot junction temperature rather than the cold junction temperature in each term of the relationship for determining the target temperature provides for much greater accuracy over a wide range of ambient temperatures and/or target temperatures.

To provide a temperature readout, the microprocessor makes the following computations: First the signal from thermistor RT1 is converted to temperature using a linear approximation. Temperature is defined by a set of linear equations

$$y = M(x - x_0) + b$$

where x is an input and x_0 is an input end point of a straight line approximation. The values of M , x_0 and b are stored in the EEPROM after calibration. Thus, to obtain a temperature reading from the thermistor, the microprocessor determines from the values of x_0 the line segment in which the temperature falls and then performs the computation for y based on the variables M and b stored in the EEPROM.

The hot junction temperature is computed. A fourth power representation of the hot junction temperature is then obtained by a lookup table in the processor ROM.

The sensed radiation may be corrected using the gain calibration factor Kh , the sensor gain temperature coefficient T_{co} , the average of the hot and cold junction temperatures and a calibration temperature T_z stored in the EEPROM. The corrected radiation signal and the fourth power of the hot junction temperature are summed, and the fourth root is taken. The fourth root calculation is also based on a linear approximation which is selected according to the temperature range of interest for a particular unit. Again, the break points and coefficients for each linear approximation are stored in the EEPROM and are selected as required.

An additional factor based on ambient temperature may also be included as an adjustment. The temperature of the ear T_e which is sensed by the thermopile is not actually the core temperature T_{cr} . There is thermal resistance between T_{cr} and T_e . Further, there is thermal resistance between the sensed ear temperature and the

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ambient temperature. The result is a sense temperature T_e which is a function of the core temperature of interest and the ambient temperature. Based on an assumed constant K_c which is a measure of the thermal resistances between T_{cr} , T_e and T_a , core temperature can be computed as

$$T_{cr} = T_a + \frac{T_e - T_a}{K_c}$$

This computation can account for a difference of from one-half to one degree between core temperature and sensed ear temperature, depending on ambient temperature.

A similar compensation can be made in other applications. For example, in differential cutaneous temperature scanning, the significance of a given differential reading may be ambient temperature dependent.

The actual computations performed by the processor are as follows, where:

H is the digital value of radiation signal presented to the processor

H_0 is the electronic offset

H_c is corrected H (deg K^4)

T_c is ambient and cold junction temperature (deg F)

T_{af} is 4th power of T_{amb} (deg K^4)

T_t is target temperature (deg F)

T_z is ambient temp during cal (deg F)

T_d is the displayed temperature

R_t is the thermistor signal

K_h is a radiation sensor gain cal factor

Z_t is a thermistor zero cal factor

T_h is the hot junction temperature

α_{ts} is the Seebeck coefficient of the thermopile at a specified temperature

J is the number of junctions in the thermopile

T_{co} is a temperature coefficient for the Seebeck coefficient

T_s is the temperature at which α_{ts} is specified

T_{cr} is core temperature

k_c is a constant for computing core temperature

V_S is the sensor output voltage

GFE is the gain of the front end amplifier

K_{AD} is the analog-to-digital conversion factor

$V_S = (H - H_0) K_{AD} / GFE$

$T_c(\text{deg F}) = \text{Thermistor lookup table}(R_t) - Z_t$

$T_H = [(T_{co} \times T_s + 1) \pm \{(T_{co} \times T_s + 1)^2 - (2 \times T_{co}) \times [(T_{co}(T_c \times T_s) - (T_c^2/2)) + T_c + (V_S / J \times \alpha_{ts})]\}^{1/2}] / T_{co}$

$H_c(\text{deg } K^4) = K_h \times (H - H_0) \times (1 + T_{co} \times ((T_h - T_c) / 2 - T_z))$

$T_{hf}(\text{deg } K^4) = 4\text{th power lookup table}(T_c)$

$T_t(\text{deg F}) = (H_c + T_{hf})^{1/4}(\text{Final lookup table})$

$T_{cr} = T_e + (T_t - T_e) / k_c$

$T_t(\text{deg C}) = (5/9) \times (T_t(\text{deg F}) - 32)$ optional

The following is a list of the information which may be contained in the EEPROM and therefore be programmable at the time of calibration:

Radiation sensor offset

Radiation sensor gain

Radiation sensor temperature coefficient

Thermistor offset

Ambient temperature at calibration

Thermistor lookup table

Final temperature lookup table

Adjustment factor F

Sound source functions:

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Beep at button push in lock mode
none/20/40/80 milliseconds long

Beep at lock
none/20/40/80 milliseconds long

Beep at power down
none/20/40/80 milliseconds long

Beep at low battery
none/20/40/80 milliseconds long
interval 1/2/3 sec

single/double beep

Timeout functions:

Time to power-down
.5 to 128 sec in .5 sec increments

Delay until lock
.5 to 128 sec in .5 sec increments

Other functions:

Power-on button resets lock cycle

Power-on button resets peak detect

Display degrees C / degrees F

EEPROM "Calibrated" pattern to indicate that the device has been calibrated

EEPROM checksum for a self-check by the processor

FIGS. 4A-4D provide a flowchart of the firmware stored in the microprocessor 73. From reset when the instrument is turned on, the system is initialized and the contents of the EEPROM are read into memory in the microprocessor at 112. At 114, the processor reads the state of power and mode switches in the system. At 116, the system determines whether a mode switch 113 has placed the system in a self test mode. If not, all eight are displayed on the four-digit display 82 for a brief time. At 120, the system performs all A-to-D conversions to obtain digital representations of the thermopile output and the potentiometer settings through multiplexor 76. The system then enters a loop in which outputs dictated by the mode switch are maintained. First the timers are updated at 122 and the switches are again read at 124. When the power is switched off, from 126 the system enters a power down loop at 128 until the system is fully down. At 130, the mode switch is checked and if changed the system is reset. Although not in the tympanic temperature detector, some detectors have a mode switch available to the user so that the mode of operation can be changed within a loop.

At 132, 136 and 140, the system determines its mode of operation and enters the appropriate scan process 134, lock process 138 or peak process 142. In a scan process, the system updates the output to the current reading in each loop. In a lock process, the system updates the output but locks onto an output after some period of time. In the peak process, the system output is the highest indication noted during a scan. In each of these processes, the system may respond to the programming from the EEPROM to perform any number of functions as discussed above. In the peak process which is selected for the tympanic temperature measurement, the system locks onto a peak measurement after a preset period of time. During assembly, the system may be set at a test mode 144 which will be described with respect to FIG. 4D.

In any of the above-mentioned modes, an output is calculated at 146. Then the system loops back to step 122. The calculation 146 is illustrated in FIG. 4B.

At 148 in FIG. 4B, the raw sensor data is obtained from memory. The sensor offset taken from the EEPROM is subtracted at 150, and the ambient temperature previously obtained from the potentiometer RT1 is accessed at 152. The temperature coefficient adjustment is calculated at 154. At 156, the sensed signal is multiplied by the gain from EEPROM and by the temperature coefficient. At 158, the fourth power of the ambient temperature is obtained, and at 160 it is added to the sensor signal. At 162, the fourth root of the sum is obtained through a lookup table. Whether the display is in degrees centigrade or degrees Fahrenheit is determined at 164. If in degrees centigrade, a conversion is performed at 166. At 168, adjustment values, including that from the potentiometer R4, are added.

Analog-to-Digital conversion is performed periodically during an interrupt to the loop of FIG. 4A which occurs every two milliseconds. The interrupt routine is illustrated in FIG. 4C. Timer counters are updated at 170. A-to-D conversions are made from 172 only every 100 milliseconds when a flag has been set in the prior interrupt cycle. During most interrupts, an A/D conversion does not occur. Then, the 100-millisecond counter is checked at 174, and if the count has expired, a flag is set at 176 for the next interrupt. The flag is checked at 178 and, if found, the display is updated at 180. The system then returns to the main loop of FIG. 4A.

Where the 100 millisecond flag is noted at 172, an A-to-D conversion is to be performed. The system first determines at 182 whether a count indicates there should be a conversion of the thermopile output at 184 or a conversion of the thermistor output at 186. The thermopile sensor conversion is performed nine out of ten cycles through the conversion loop. At 188, the system checks to determine whether a conversion is made from the potentiometer R4 or from the battery voltage divider R1, R2 at 192. These conversions are made alternately.

FIG. 4D illustrates the self-test sequence which is called by the mode switch 113 only during assembly. During the test, the beeper sounds at 182 and all display segments are displayed at 184. Then the system steps each character of the display from zero through nine at 186. The system then enters a test loop. At 188, the system senses whether the button 108 has been pressed. If so, a display counter is incremented at 190. The display for the unit then depends on the count of the display counter. With the zero count, the adjustment potentiometer value is displayed at 192. Thereafter, if the display counter is incremented by pressing the button 108, the raw sensor data is displayed. With the next increment, ambient temperature is displayed at 196, and with the next increment, the raw output from the ambient temperature sensor RT1 is displayed. With the next increment, the battery voltage is displayed. After the test, the assembler sets the mode switch to the proper operating mode.

While this invention has been particularly shown and described with references to preferred embodiments thereof, it will be understood by those skilled in the art that various changes in form and details may be made therein without departing from the spirit and scope of the invention as defined by the appended claims.

We claim:

1. A radiation detector comprising:

a thermopile having a hot junction and a cold junction, the hot junction being mounted to view a target;
 a temperature sensor for sensing the temperature of the cold junction;
 an electronic circuit coupled to the thermopile and responsive to the voltage across the thermopile and a temperature sensed by the temperature sensor to determine the temperature of the target, the electronic circuit determining the temperature of the target as a function of the voltage across the thermopile and the temperature of the hot junction of the thermopile determined from the cold junction temperature and a thermopile coefficient; and
 a display for displaying an indication of the temperature of the target determined by the electronic circuit.

2. A radiation detector as claimed in claim 1 wherein the electronic circuit determines target temperature from the relationship $T_T^4 = (KhH) + T_H^4$ where T_T is the target temperature, Kh is a gain factor, H is a sensed voltage from the thermopile and T_H is the hot junction temperature of the thermopile.

3. A radiation detector as claimed in claim 2 wherein the electronic circuit determines the hot junction temperature T_H from the sensed voltage and cold junction temperature and a thermopile coefficient which is specified at a predetermined temperature, the thermopile coefficient being temperature compensated by the electronic circuit as a function of a temperature between the hot and cold junctions.

4. A radiation detector as claimed in claim 3 wherein the electronic circuit determines the gain factor Kh as a function of the difference between a calibration temperature and a temperature between the hot and cold junction temperatures.

5. A radiation detector as claimed in claim 2 wherein the electronic circuit determines the gain factor Kh as a function of the difference between a calibration temperature and a temperature between the hot and cold junction temperatures.

6. A radiation detector as claimed in claim 1 wherein the electronic circuit determines the target temperature from the relationship $T_T^4 = (KhH) + T$ where T_T is the target temperature, H is a sensed voltage from the thermopile, T is a temperature of the thermopile and Kh is a gain factor which is a function of the difference between a calibration temperature and a temperature between the hot and cold junction temperatures.

7. A radiation detector comprising:

a thermopile mounted to view a target of biological surface tissue;
 a temperature sensor for sensing ambient temperature;
 an electronic circuit coupled to the thermopile and temperature sensor and responsive to the voltage across the thermopile and the temperature sensed by the sensor to provide an indication of an internal temperature within the biological tissue adjusted for the ambient temperature to which the surface tissue is exposed; and
 a display for providing an indication of the internal temperature.

8. A radiation detector as claimed in claim 7 wherein the biological surface tissue is tympanic membrane and the display provides an indication of core temperature.



US005199436A

United States Patent [19]

[11] **Patent Number:** 5,199,436

Pompei et al.

[45] **Date of Patent:** * Apr. 6, 1993

- [54] **RADIATION DETECTOR HAVING IMPROVED ACCURACY**
- [75] **Inventors:** Francesco Pompei, Wellesley Hills; Philip R. Gaudet, Jr., Concord, both of Mass.
- [73] **Assignee:** Exergen Corporation, Newton, Mass.
- [*] **Notice:** The portion of the term of this patent subsequent to Feb. 19, 2008 has been disclaimed.
- [21] **Appl. No.:** 646,855
- [22] **Filed:** Jan. 28, 1991

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Related U.S. Application Data

- [60] Division of Ser. No. 338,968, Apr. 14, 1989, Pat. No. 5,012,813, which is a continuation-in-part of Ser. No. 280,546, Dec. 6, 1988, Pat. No. 4,993,419.
- [51] **Int. Cl.⁵** A61B 6/00
- [52] **U.S. Cl.** 128/664; 128/736
- [58] **Field of Search** 128/664, 736; 374/123, 374/127, 129, 132-133, 135

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Assistant Examiner—John P. Lacyk
Attorney, Agent, or Firm—Hamilton, Brook, Smith & Reynolds

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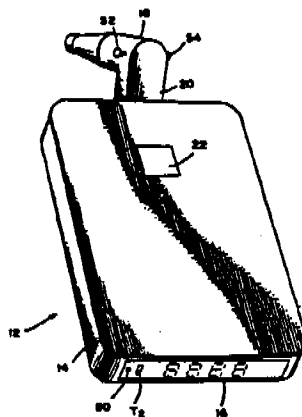
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[57] **ABSTRACT**

Tympanic temperature measurements are obtained from the output of a thermopile mounted in an extension from a housing. The housing has a temperature display thereon and supports the electronics for responding to sensed radiation. The thermopile is mounted in a highly conductive can which includes a radiation guide and thermal mass. The guide provides a narrow field of view due to a fairly high emissivity. Electronics determine the target temperature as a function of the temperature of the hot junction of the thermopile determined from the cold junction temperature and a thermopile coefficient. The tympanic temperature is adjusted to provide an indication of core temperature.

5 Claims, 7 Drawing Sheets



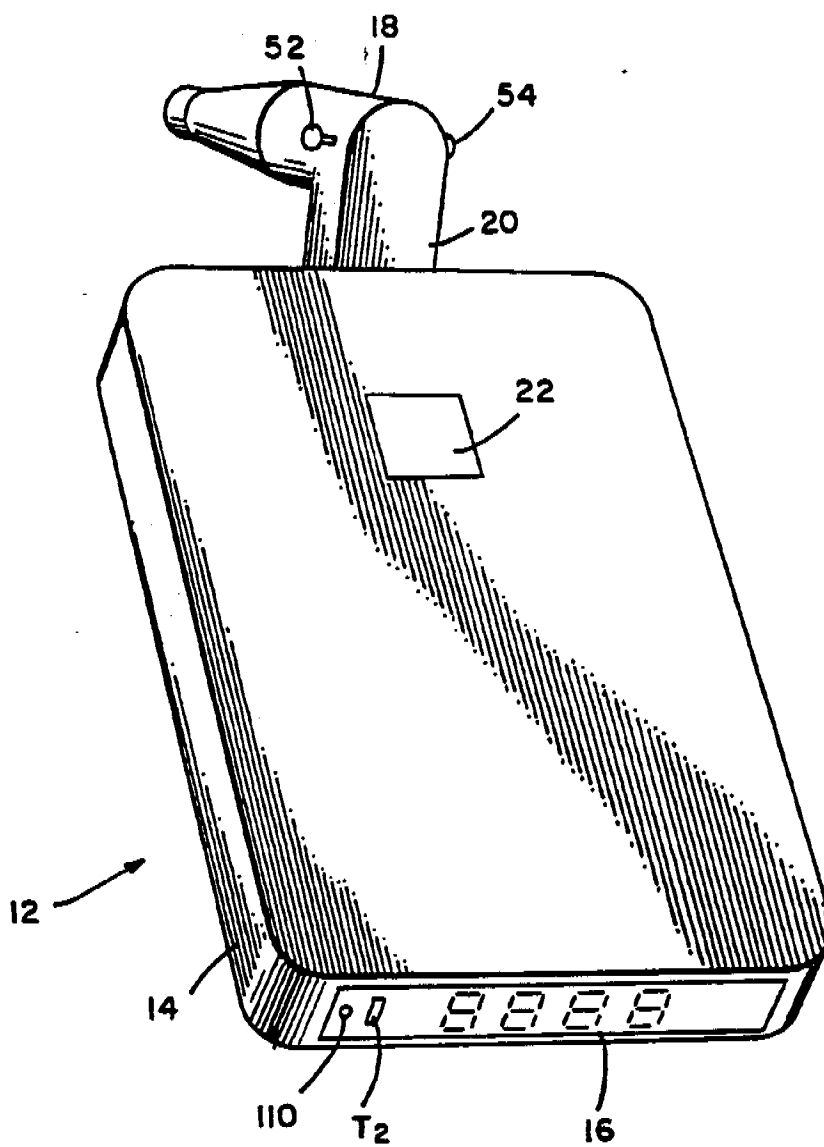
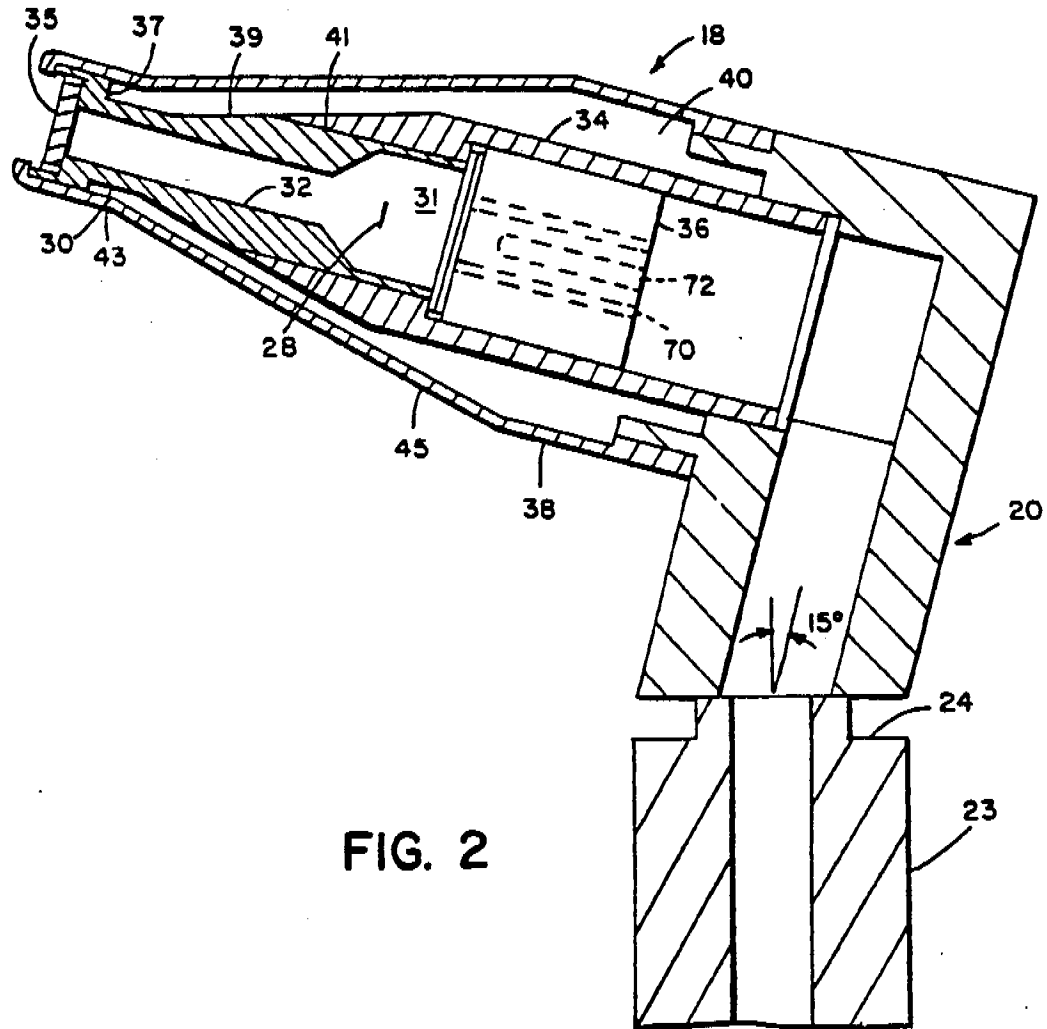


FIG. 1



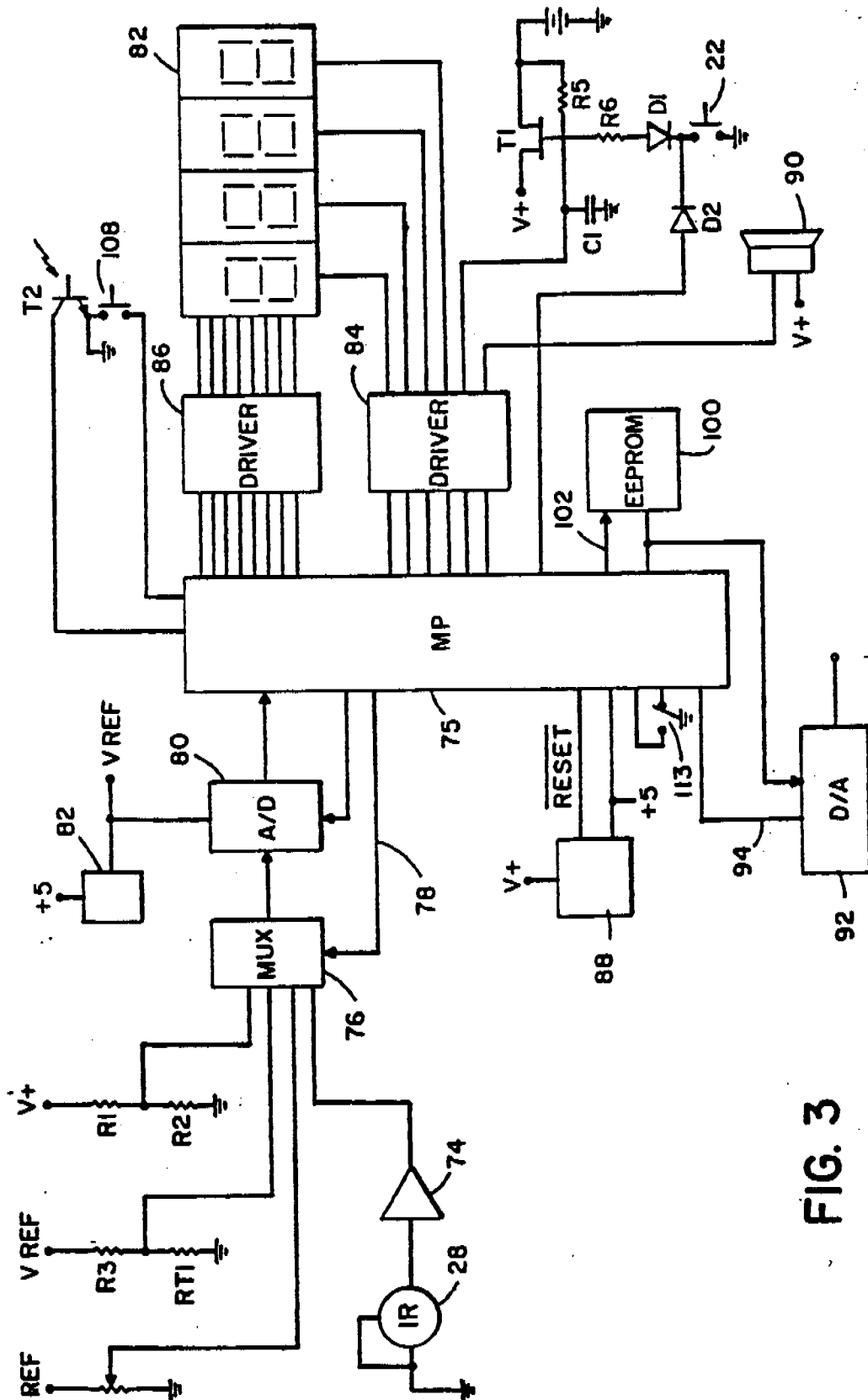


FIG. 3

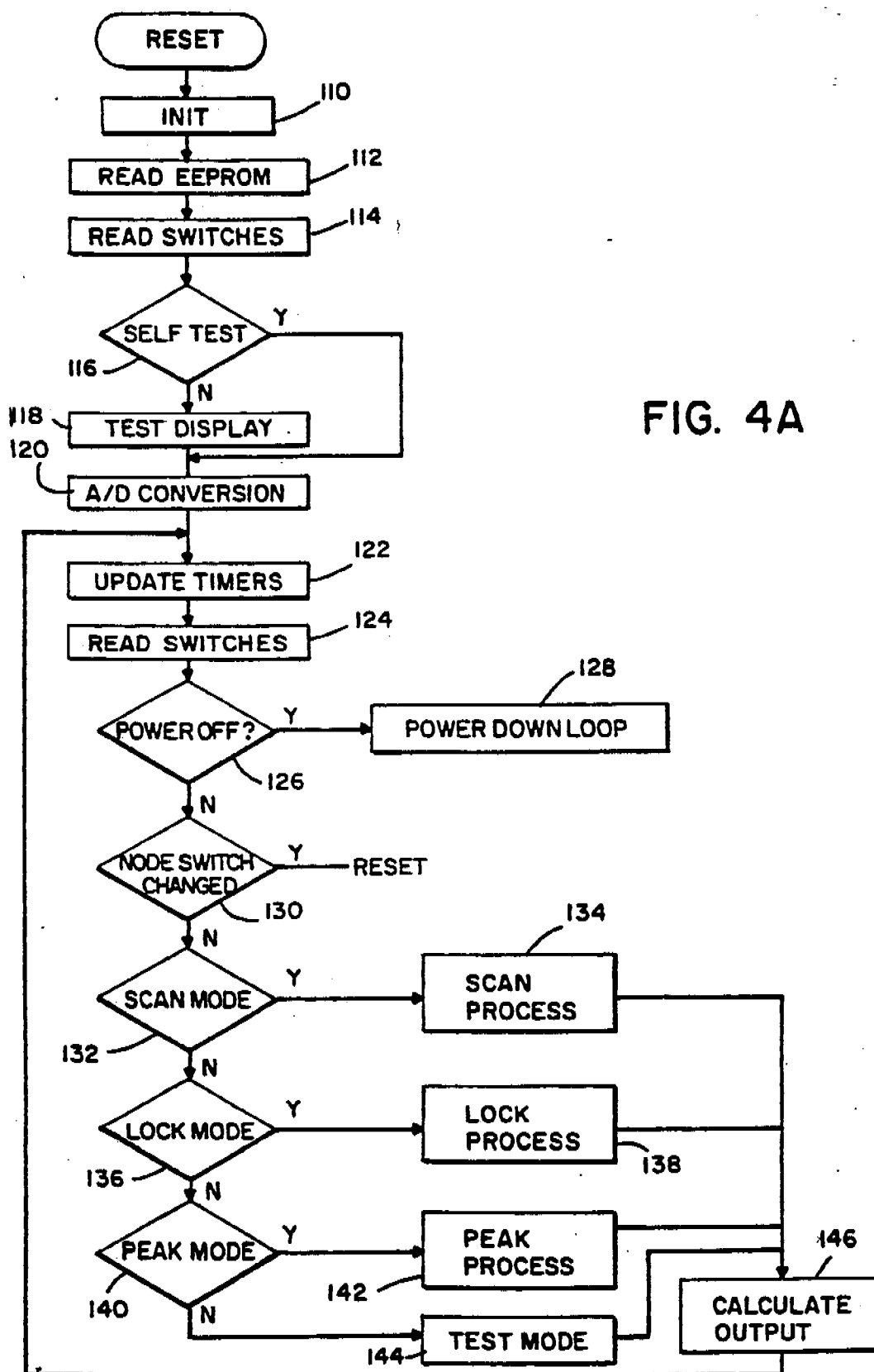


FIG. 4A

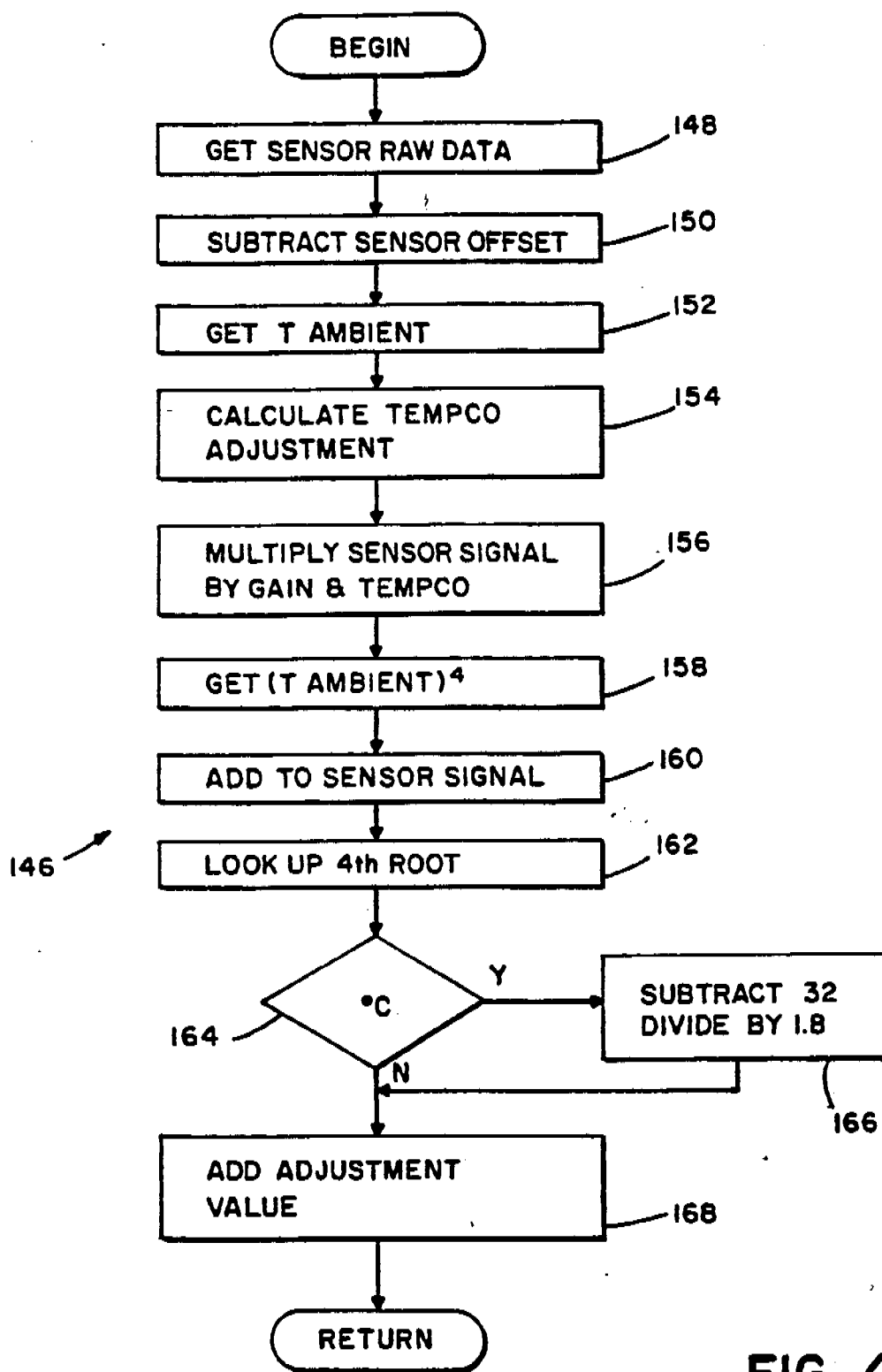


FIG. 4B

FIG 4C

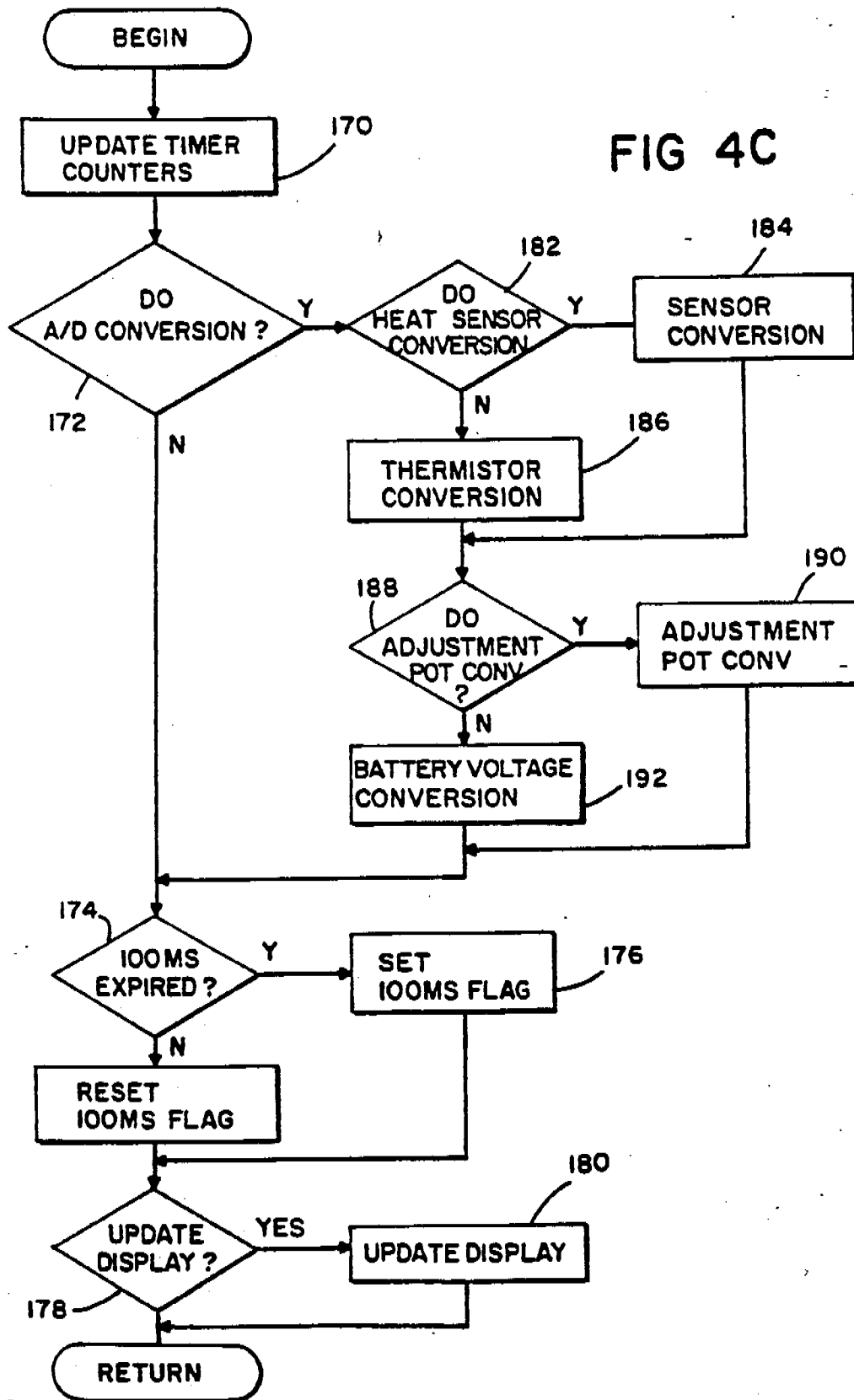
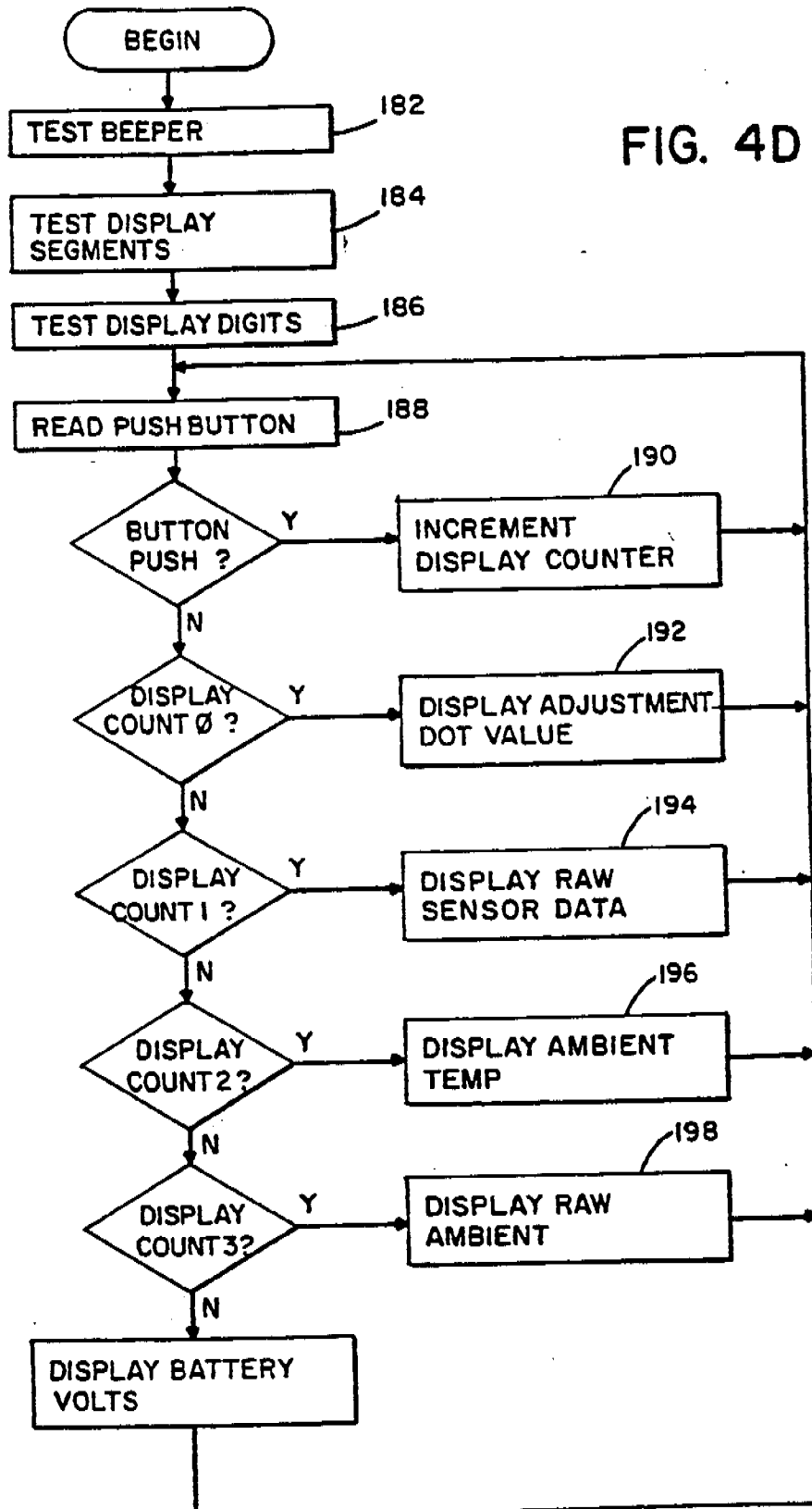


FIG. 4D



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RADIATION DETECTOR HAVING IMPROVED ACCURACY

RELATED APPLICATION

This application is a division of application Ser. No. 07/338,968, filed Apr. 14, 1989, now U.S. Pat. No. 5,012,813, which is a continuation-in-part of application Ser. No. 07/280,596, filed Dec. 6, 1988, now U.S. Pat. No. 4,993,419.

BACKGROUND

Radiation detectors which utilize thermopiles to detect the heat flux from target surfaces have been used in various applications. An indication of the temperature of a target surface may be provided as a function of the measured heat flux. One such application is the testing of electrical equipment. Another application has been in the scanning of cutaneous tissue to locate injured subcutaneous regions. An injury results in increased blood flow which in turn results in a higher surface temperature. Yet another application is that of tympanic temperature measurement. A tympanic device relies on a measurement of the temperature of the tympanic membrane area in the ear of an animal or human by detection of infrared radiation as an alternative to traditional sublingual thermometers.

SUMMARY OF THE INVENTION

An improved tympanic temperature measurement device is presented in parent U.S. patent application No. 07/280,546 That device provides for accuracy within one-tenth of a degree over limited ranges of ambient temperature and accuracy to within one degree over a wide range of ambient temperatures. An object of the present invention is to provide a tympanic temperature measurement device which would provide accuracy to within one-tenth degree over a wide range of ambient temperatures. In obtaining that accuracy, an object of the invention was to continue to avoid any requirement for a reference target or for control of the temperature of the thermopile as such requirements had resulted in complexity and difficulties in prior tympanic temperature measurement devices.

A radiation detector comprises a thermopile and a can enclosing the thermopile. The can structure includes an elongated radiation guide of a first internal diameter. The radiation guide extends from a viewing window to a rear volume of larger internal diameter in which the thermopile is mounted. The guide may be gold plated.

In accordance with one feature of the present invention, the portions of the can forming the radiation guide and rear volume are formed in a unitary structure of high thermal conductivity material. The can structure has an outer surface with an outer diameter at its end adjacent to the window which is less than an outer diameter about the rear volume. The outer surface is tapered about the radiation guide such that a unitary thermal mass of increasing outer diameter is provided about the end of the radiation guide adjacent to the rear volume. The unitary can structure maximizes conductance and thermal mass within a limited diameter. To avoid changes in fixtures used in mounting the thermopile within the can, the unitary can of limited diameter may be supplemented with an additional thermal mass which surrounds the rear volume and a portion of

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the unitary thermal mass and which is in close thermal contact with the can structure.

It has been found that a narrow field of view radiation detector provides a more accurate reading of tympanic temperature. In the detector of the present invention, that field of view is obtained by controlling the reflectance of the surface of the radiation guide, the length of the guide and the position of the thermopile behind the guide. A field of view of less than about sixty degrees allows for viewing of only a portion of the ear canal within about 1.5 centimeters of the tympanic membrane.

Accuracy of the detector may be improved electronically as well. Accordingly, an electronic circuit is coupled to a thermopile, having a cold junction and a hot junction mounted to view a target, and to a temperature sensor for sensing the temperature of the cold junction. The electronic circuit is responsive to the voltage across the thermopile and a temperature sensed by the temperature sensor to determine the temperature of the target. The electronic circuit determines the temperature of the target as a function of the temperature of the hot junction of the thermopile determined from the cold junction temperature and a known thermopile coefficient. A display provides an indication of the target temperature determined by the electronic circuit.

As in prior systems, the electronic circuit determines target temperature from the relationship $T_T^4 = (KH) + T^4$, where T_T is the target temperature, K is a gain factor, H is a sensed voltage from the thermopile and T is a junction temperature of the thermopile. In accordance with the present invention in a preferred embodiment, the junction temperature is the temperature of the hot junction. The hot junction temperature T_H is determined from the sensed thermopile voltage and cold junction temperature and a thermopile coefficient. The thermopile coefficient is specified at a predetermined temperature and is temperature compensated by the electronic circuit as a function of a temperature between the hot and cold junctions, specifically the average temperature. Further, the electronic circuit determines the gain factor K as a function of the difference between a calibration temperature and a temperature between the hot and cold junction temperatures.

When used to measure a biological temperature, the radiation detector is further improved by providing an indication of an internal temperature within biological tissue. The electronic circuit determines the internal temperature by adjusting a measured temperature of surface tissue for ambient temperature. In particular, the biological surface tissue may be tympanic membrane or the ear canal adjacent to the membrane, and the display may provide an indication of core temperature.

BRIEF DESCRIPTION OF THE DRAWINGS

The foregoing and other objects, features and advantages of the invention will be apparent from the following more particular description of preferred embodiments of the invention, as illustrated in the accompanying drawings in which like reference characters refer to the same parts throughout the different views. The drawings are not necessarily to scale, emphasis instead being placed upon illustrating the principles of the invention.

FIG. 1 illustrates a radiation detector for tympanic temperature measurements in accordance with the present invention.

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FIG. 2 is a cross-sectional view of the extension of the detector of FIG. 1 in which the thermopile radiation sensor is positioned.

FIG. 3 is a block diagram of the electronic circuit of the detector of FIG. 1.

FIGS. 4A-4D are flow charts of the system firmware.

DESCRIPTION OF A PREFERRED EMBODIMENT

The radiation detector 12 of FIG. 1 includes a flat housing 14 with a digital display 16 for displaying a tympanic temperature measurement. Although the display may be located anywhere on the housing, it is preferred that it be positioned on the end so the user is not inclined to watch it during a measurement. The instrument makes an accurate measurement when rotated to scan the ear canal, and the user should concentrate on only the scanning motion. Then the display can be read. A thermopile radiation sensor is supported within a probe 18 at the opposite end of the housing 14. The extension 18 extends orthogonally from an intermediate extension 20 which extends at an angle of about 15 degrees from the housing 14. As such, the head of the detector including the extension 18 and 20, has the appearance of a conventional otoscope. An on/off switch 22 is positioned on the housing.

A cross-sectional view of the extension of the detector is illustrated in FIG. 2. A base portion 22 is positioned within the housing 14, and the housing clamps about a groove 24. As noted, the portion 20 extends at about a 15 degree angle from the housing and thus from the base portion 22. The extension 18 is tapered toward its distal end at 26 so that it may be comfortably positioned in the ear to view the tympanic membrane and/or ear canal.

A preferred disposable element to be used over the extension 18 is presented in parent U.S. patent application No. 07/280,546 and will not be discussed here.

The edge at the end of the probe is rounded so that when the probe is inserted into the ear it can be rotated somewhat without discomfort to the patient. The probe is also curved like an otoscope to avoid interference with the ear. By thus rotating the probe, the ear canal is scanned and, at some orientation of the probe during that scan, one can be assured that the maximum temperature is viewed. Since the ear canal cavity leading to the tympanic area is the area of highest temperature, the instrument is set in a peak detection mode, and the peak detected during the scan is taken as the tympanic temperature.

An improved assembly within the extension 18 is illustrated in FIG. 2. A thermopile 28 is positioned within a can 30 of high conductivity material such as copper. The conductivity should be greater than two watts per centimeter per degree Kelvin. The can is filled with a gas of low thermal conductivity such as Xenon. The thermopile 28 is positioned within a rear volume. 31 It is mounted to an assembly which includes a flange 33. The volume is sealed by cold welding of the flange 33 to a flange 41 extending from the can. Cold welding is the preferred approach to making the seal and, to utilize past welding fixtures, the outer diameter of the can is limited.

The thermopile views the tympanic membrane area through a radiation guide 32. The radiation guide 32 is gold plated to minimize oxidation. It is closed at its forward end by a germanium window 35. To minimize

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expense, the window is square with each side slightly longer than the diameter of the radiation guide 32. The window is cemented with epoxy within a counterbore in a flange 37 at the end of the radiation guide. The epoxy serves as a gas seal and mechanical support for the somewhat brittle germanium window. The flange serves to protect the germanium window should the detector be dropped. The diagonal of the window is less than the diameter of the counterbore, and its thickness is less than the depth of the counterbore. Therefore, if the detector is dropped, any force which presses the plastic housing toward the window is absorbed by the flange. The germanium need only withstand the forces due to its own inertia.

Whereas the detector disclosed in the parent application had a wide field of view of about 120°, it has been determined that a significantly narrower field of view of about sixty degrees or less provides a more accurate indication of tympanic temperature. With a narrower field of view, the thermopile flake, when directly viewing the tympanic membrane, also views no more than about 1.5 centimeters along the ear canal and preferably less than one centimeter. A better view of the tympanic membrane also results from the cylindrical extension 43 beyond the conical portion of the extension 18. With the ear canal straightened by the probe, the extension 43 can extend well into the ear canal beyond any hair at the canal opening.

The tympanic membrane is about 2.5 centimeters from the opening of the ear canal. The conical portion of the extension 18 prevents the tip of the extension from extending more than about eight millimeters into the ear canal. Beyond that depth, the patient suffers noticeable discomfort. With a field of view of about sixty degrees, the ear canal which is about eight millimeters wide is viewed about eight millimeters from the tip of the extension 18. Thus, only the ear canal within about 1.5 centimeters of the tympanic membrane is viewed as the radiation guide is directed toward the membrane. The result is a more accurate reading of the tympanic temperature which is closer to core temperature.

With the present instrument, the narrow field of view is obtained by two changes to the prior radiation guide. The reflectivity within the guide is reduced. Radiation entering the tube at greater angles must be reflected a greater number of times from the radiation guide before reaching the thermopile flake. With the higher emissivity, such radiation is less likely to reach the flake to be detected. The field of view is further decreased by extending the enlarged rear volume between the flake and the radiation guide. Radiation which enters the radiation guide at greater angles, yet travels through the radiation guide, leaves the guide at greater angles and is thus unlikely to be viewed by the flake. The length of the radiation guide is another parameter which affects the field of view. By using a planoconvex lens as the window 35, the field of view can be further limited.

Both of the above approaches to decreasing the field of view increase the amount of heat which is absorbed by the can in which the thermopile is mounted. The added heat load adds to the importance that the can, including the radiation guide, have a large thermal mass and high thermal conductivity as discussed below.

As distinguished from the structure presented in the parent application, the volume 31 surrounding the thermopile and the radiation guide are formed of a single piece of high conductivity copper. This unitary con-

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struction eliminates any thermal barriers between the foremost end of the radiation guide and the portion of the can surrounding the thermopile which serves as the cold junction of the thermopile. Further, at least a portion of added thermal mass which surrounds the radiation guide is unitary with the can as well. Specifically, a taper 39 results in an enlarged region 41 which serves as a thermal mass in accordance with the principals of the parent application. The taper 39 continues along a conductive thermal mass 34 which surrounds the can and a conductive plug 36. Both the mass 34 and plug 36 are of copper and are in close thermal contact with the can 30.

The outer sleeve 38 of the extension 18 and the intermediate extension 20 are of plastic material of low thermal conductivity. The sleeve 38 is separated from the can 30 and thermal mass 34 by an insulating air space 40. The taper of the can 30 and thermal mass 34 permits the insulating space to the end of the extension while minimizing the thermal resistance from the end of the tube 32 to the thermopile, a parameter discussed in detail below. The inner surface of the plastic sleeve 38 may be coated with a good thermal conductor to distribute across the entire sleeve any heat received from contact with the ear. Twenty mils of copper coating would be suitable.

In contrast with the prior design, the portion of the sleeve 38 at the foremost end of extension 18 has a region 43 of constant outer diameter before a tapered region 45. The region of constant outer diameter reduces the outer diameter at the distal end and minimizes interference when rotating the extension in the ear to view the tympanic membrane area. The tapered region is spaced six millimeters from the end of the extension to allow penetration of the extension into the ear canal by no more than about eight millimeters.

One of the design goals of the device was that it always be in proper calibration without requiring a warm-up time. This precluded the use a heated target in a chopper unit or heating of the cold junction of the thermopile as was suggested in the O'Hara et al. U.S. Pat. No. 4,602,642. To accomplish this design goal, it is necessary that the system be able to operate with the thermopile at any of a wide range of ambient temperatures and that the thermopile output have very low sensitivity to any thermal perturbations.

The output of the thermopile is a function of the difference in temperature between its warm junction, heated by radiation, and its cold junction which is in close thermal contact with the can 30. In order that the hot junction respond only to radiation viewed through the window 35, it is important that the radiation guide 32 be, throughout a measurement, at the same temperature as the cold junction. To that end, changes in temperature in the guide 32 must be held to a minimum, and any such changes should be distributed rapidly to the cold junction to avoid any thermal gradients. To minimize temperature changes, the tube 32 and the can 30 are, of course, well insulated by means of the volume of air 40. Further, a high conductance thermal path is provided to the cold junction. This conductance is enhanced by the unitary construction. Further, the can 30 is in close thermal communication with the thermal masses 34 and 36, and the high conductivity and thickness of the thermal masses increase the thermal conductance. A high thermal conductivity epoxy, solder or the like joins the can and thermal masses. The solder or epoxy provides a significant reduction in thermal resistance. Where solder is used, to avoid damage to the

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thermopile which is rated to temperatures of 125° C. a low temperature solder of indium-tin alloy which flows at 100° C. is allowed to flow into the annular mass 34 to provide good thermal coupling between all elements.

The thermal resistance from the outer surface of the plastic sleeve 38 to the conductive thermal mass is high to minimize thermal perturbations to the inner thermal mass. To minimize changes in temperature of the guide 32 with any heat transfer to the can which does occur, the thermal mass of the can 30, annular mass 34 and plug 36 should be large. To minimize thermal gradients where there is some temperature change in the tube during measurement, the thermal resistance between any two points of the thermal mass should be low.

Thus, due to the large time constant of the thermal barrier, any external thermal disturbances, such as when the extension contacts skin, only reach the conductive thermal mass at extremely low levels during a measurement period of a few seconds; due to the large thermal mass of the material in contact with the cold junction, any such heat transfer only causes small changes in temperature; and due to the good thermal conductance throughout the thermal mass, any changes in temperature are distributed quickly and are reflected in the cold junction temperature quickly so that they do not affect temperature readings.

The thermal RC time constant for thermal conduction through the thermal barrier to the thermal mass and tube should be at least two orders of magnitude greater than the thermal RC time constant for the temperature response of the cold junction to heat transferred to the tube and thermal mass. The RC time constant for conduction through the thermal barrier is made large by the large thermal resistance through the thermal barrier and by the large thermal capacitance of the thermal mass. The RC time constant for response of the cold junction is made low by the low resistance path to the cold junction through the highly conductive copper can and thermal mass, and the low thermal capacitance of the stack of beryllium oxide rings and pin conductors to the thermopile.

Although the cold junction capacitance is naturally low, there are size constraints in optimizing the thermal capacitance of the thermal mass, the thermal resistance through the thermal barrier and the internal thermal resistance. Specifically, the external thermal resistance can be increased by increased radial dimensions, the capacitance of the thermal mass can be increased by increasing its size, and the thermal resistance through the longitudinal thermal path through the tube can be decreased by increasing its size. On the other hand, the size must be limited to permit the extension to be readily positioned and manipulated within the ear.

Besides the transfer of heat from the environment, another significant heat flow path to the conductive thermal mass is through leads to the system. To minimize heat transfer through that path, the leads are kept to small diameters. Further, they are embedded in the plug 36 through bores 70; thus, any heat brought into the system through those leads is quickly distributed throughout the thermal mass, and only small changes in temperature and small gradients result.

Because the temperature of the thermal mass is not controlled, and the response of the thermopile 28 is a function of its cold junction temperature, the cold junction temperature must be monitored. To that end, a thermistor is positioned at the end of a central bore 72 in the plug 36.

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A schematic illustration of the electronics in the housing 14, for providing a temperature readout on display 16 in response to the signal from the thermopile, is presented in FIG. 3. The system is based on a microprocessor 73 which processes software routines included in read only memory within the processor chip. The processor may be a 6805 processor sold by Motorola.

The voltage generated across the thermopile 28 due to a temperature differential between the hot and cold junctions is amplified in an operational amplifier 74. The analog output from the amplifier 74 is applied as one input to a multiplexer 76. Another input to the multiplexer 76 is a voltage taken from a voltage divider R1, R2 which is indicative of the potential V_+ from the power supply 78. A third input to the multiplexer 76 is the potential across a thermistor RT1 mounted in the bore 72 of block 36. The thermistor RT1 is coupled in a voltage divider circuit with R3 across a reference potential VRef. The final input to the multiplexer is a potential taken from a potentiometer R4 which may be adjusted by a user. The system may be programmed to respond to that input in any of a number of ways. In particular, the potentiometer may be used as a gain control or as a DC offset control.

At any time during the software routine of the microprocessor 73, one of the four inputs may be selected by the select lines 78. The selected analog signal is applied to a multiple slope analog system 80 used by the microprocessor in an integrating analog-to-digital conversion 80. The subsystem 80 may be a TSC500A sold by Teledyne. It utilizes the reference voltage VRef from a reference source 82. The microprocessor 73 responds to the output from the convertor 80 to generate a count indicative of the analog input to the convertor.

The microprocessor drives four 7-segment LED displays 82 in a multiplexed fashion. Individual displays are selected sequentially through a column driver 84, and within each selected display the seven segments are controlled through segment drivers 86.

When the switch 22 on the housing is pressed, it closes the circuit from the battery 78 through resistors R5 and R6 and diode D1 to ground. The capacitor C1 is quickly charged and field effect transistor T1 is turned on. Through transistor T1 the V_+ potential from the storage cell 78 is applied to a voltage regulator 86. The regulator 86 provides the regulated +5 volts to the system. It also provides a reset signal to the microprocessor. The reset signal is low until the +5 volt reference is available and thus holds the microprocessor in a reset state. When the +5 volts is available, the reset signal goes high, and the microprocessor begins its programmed routine.

When the switch 22 is released, it opens its circuit, but a charge is maintained on capacitor C1 to keep transistor T1 on. Thus, the system continues to operate. However, the capacitor C1 and transistor T1 provide a very simple watchdog circuit. Periodically, the microprocessor applies a signal through driver 84 to the capacitor C1 to recharge the capacitor and thus keep the transistor T1 on. If the microprocessor should fail to continue its programmed routine, it fails to charge the capacitor C1 within a predetermined time during which the charge on C1 leaks to a level at which transistor T1 turns off. Thus, the microprocessor must continue in its programmed routine or the system shuts down. This prevents spurious readings when the processor is not operating properly.

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With transistor T1 on, the switch 22 can be used as an input through diode D2 to the microprocessor to initiate any programmed action of the processor.

In addition to the display, the system has a sound output 90 which is driven through the driver 84 by the microprocessor.

In order to provide an analog output from the detector, a digital-to-analog convertor 92 is provided. When selected by line 94, the convertor converts serial data on line 96 to an analog output made available to a user.

Both calibration and characterization data required for processing by the microprocessor may be stored in an electrically erasable programmable read only memory (EEPROM) 100. The EEPROM may, for example, be a 93c46 sold by International CMOS Technologies, Inc. The data may be stored in the EEPROM by the microprocessor when the EEPROM is selected by line 102. Once stored in the EEPROM, the data is retained even after power down. Thus, though electrically programmable, once programmed the EEPROM serves as a virtually nonvolatile memory.

Prior to shipment, the EEPROM may be programmed through the microprocessor to store calibration data for calibrating the thermistor and thermopile. Further, characterization data which defines the personality of the infrared detector may be stored. For example, the same electronics hardware, including the microprocessor 73 and its internal program, may be used for a tympanic temperature detector in which the output is accurate in the target temperature range of about 60° F. to a 110° F. or it may be used as an industrial detector in which the target temperature range would be from about 0° F. to 100° F. Further, different modes of operation may be programmed into the system. For example, several different uses of the sound source 90 are available.

Proper calibration of the detector is readily determined and the EEPROM is readily programmed by means of an optical communication link which includes a transistor T2 associated with the display. A communication boot may be placed over the end of the detector during a calibration/characterization procedure. A photodiode in the boot generates a digitally encoded optical signal which is filtered and applied to the detector T2 to provide an input to the microprocessor 73. In a reverse direction, the microprocessor, may communicate optically to a detector in the boot by flashing specific segments of the digital display 82. Through that communication link, an outside computer 106 can monitor the outputs from the thermistor and thermopile and perform a calibration of the devices. A unit to be calibrated is pointed at each of two black body radiation sources while the microprocessor 73 converts the signals and sends the values to the external computer. The computer is provided with the actual black body temperatures and ambient temperature in the controlled environment of the detector, computes calibration variables and returns those variable to be stored in the detector EEPROM. Similarly, data which characterizes a particular radiation detector may be communicated to the microprocessor for storage in the EEPROM.

A switch 108 is positioned behind a hole 110 (FIG. 1) in the radiation detector so that it may be actuated by a rigid metal wire or pin. Through that switch, the user may control some specific mode of operation such as converting the detector from degrees Fahrenheit to degrees centigrade. That mode of operation may be stored by the microprocessor 73 in the EEPROM so

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that the detector continues to operate in a specific mode until a change is indicated by closing the switch 108.

A switch 106 may be provided either internally or through the housing to the user to set a mode of operation of the detector. By positioning the switch at either the lock position, the scan position or a neutral position, any of three modes may be selected. The first mode is the normal scan mode where the display is updated continuously. A second mode is a lock mode where the display locks after a selectable delay and then remains frozen until power is cycled or, optionally, the power-on button is pushed. The sound source may be caused to sound at the time of lock. The third mode is the peak mode where the display reads the maximum value found since power-on until power is cycled or, optionally, the power-on button is pushed.

The processor determines when the voltage from the divider R1, R2 drops below each of two thresholds. Below the higher threshold, the processor periodically enables the sound source to indicate that the battery is low and should be replaced but allows continued read-out from the display. Below the lower threshold, the processor determines that any output would be unreliable and no longer displays temperature readings. The unit would then shut down upon release of the power button.

In the present system, the target temperature is computed from the relationship

$$T_T^4 = Kh(H - H_0) + T_H^4 \quad (1)$$

where T_T is the target temperature, Kh is a gain calibration factor, H is the radiation sensor signal which is offset by H_0 such that $(H - H_0) = 0$ when the target is at the cold junction temperature of the device to counter any electronic offsets in the system, and T_H is the hot junction temperature. This relationship differs from that previously used in that Kh is temperature compensated relative to the average temperature of the thermopile rather than the cold junction, or ambient, temperature. Further, the hot junction temperature rather than the cold junction temperature is referenced in the relationship.

The gain calibration factor Kh is temperature compensated by the relationship,

$$Kh = G \left(1 - T_{co} \left(\frac{T_H - T_C}{2} - T_z \right) \right) \quad (2)$$

where G is an empirically determined gain in the system. T_{co} is the temperature coefficient of the Seebeck coefficient of the thermopile and T_z is the temperature at which the instrument was calibrated. The use of the average temperature of the thermopile rather than the cold junction temperature provides for a much more accurate response where a target temperature is significantly different from the ambient temperature.

As noted, the relationship by which the target temperature is determined includes the hot junction temperature as the second term rather than the cold junction temperature. Hot junction temperature is computed from the relationship

$$V_s = J_{N} \alpha_{av} (T_H - T_C) \quad (3)$$

where J_N is the number of junctions in the thermopile and α_{av} is the Seebeck coefficient at the average tem-

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perature of the thermopile. The Seebeck coefficient can be determined from the relationship

$$\alpha_{av} = \alpha_N \left(1 - T_{co} \left(\frac{T_H - T_C}{2} - T_z \right) \right) \quad (4)$$

where α_N is the specified Seebeck coefficient at a particular specification temperature and T_z is that specification temperature. Again, it can be seen that temperature compensation is based on the average thermopile temperature rather than just the cold junction temperature. By substituting equation (4) into equation (3) and solving for T_H , the hot junction temperature is found to be

$$T_H = \frac{(T_{co} T_z + 1) \pm [(T_{co} T_z + 1)^2 - 2 T_{co}]^{1/2}}{[T_{co} (T_C - T_z) - (T_C^2/2) + T_C + (V_s/J_N \alpha_N)]^{1/2}} / T_{co} \quad (5)$$

The actual sensor output V_s can be determined from the digital value available to the processor from the equation:

$$V_s = (H - H_0) \frac{K_{AD}}{G_{FE}} \quad (6)$$

where K_{AD} is the analog-to-digital conversion factor in volts/bit and G_{FE} is the gain of the front end amplifier.

Reference to the hot junction temperature rather than the cold junction temperature in each term of the relationship for determining the target temperature provides for much greater accuracy over a wide range of ambient temperatures and/or target temperatures.

To provide a temperature readout, the microprocessor makes the following computations: First the signal from thermistor RT1 is converted to temperature using a linear approximation. Temperature is defined by a set of linear equations

$$y = M(x - x_0) + b$$

where x is an input and x_0 is an input end point of a straight line approximation. The values of M , x_0 and b are stored in the EEPROM after calibration. Thus, to obtain a temperature reading from the thermistor, the microprocessor determines from the values of x_0 the line segment in which the temperature falls and then performs the computation for y based on the variables M and b stored in the EEPROM.

The hot junction temperature is computed. A fourth power representation of the hot junction temperature is then obtained by a lookup table in the processor ROM.

The sensed radiation may be corrected using the gain calibration factor Kh , the sensor gain temperature coefficient T_{co} , the average of the hot and cold junction temperatures and a calibration temperature T_z stored in the EEPROM. The corrected radiation signal and the fourth power of the hot junction temperature are summed, and the fourth root is taken. The fourth root calculation is also based on a linear approximation which is selected according to the temperature range of interest for a particular unit. Again, the break points and coefficients for each linear approximation are stored in the EEPROM and are selected as required.

An additional factor based on ambient temperature may also be included as an adjustment. The temperature of the ear T_e which is sensed by the thermopile is not actually the core temperature T_{cp} . There is thermal resistance between T_{cp} and T_e . Further, there is thermal

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resistance between the sensed ear temperature and the ambient temperature. The result is a sense temperature T_e which is a function of the core temperature of interest and the ambient temperature. Based on an assumed constant K_c which is a measure of the thermal resistances between T_c , T_e and T_a , core temperature can be computed as

$$T_c = T_e + \frac{T_e - T_a}{K_c} \quad 10$$

This computation can account for a difference of from one-half to one degree between core temperature and sensed ear temperature, depending on ambient temperature.

A similar compensation can be made in other applications. For example, in differential cutaneous temperature scanning, the significance of a given differential reading may be ambient temperature dependent.

The actual computations performed by the processor are as follows, where:

H is the digital value of radiation signal presented to the processor

H_0 is the electronic offset

H_c is corrected H (deg K^4)

T_c is ambient and cold junction temperature (deg F)

Taf is 4th power of T_{amb} (deg K^4)

T_t is target temperature (deg F)

T_z is ambient temp during cal (deg F)

T_d is the displayed temperature

R_t is the thermistor signal

K_h is a radiation sensor gain cal factor

Z_t is a thermistor zero cal factor

T_h is the hot junction temperature

α_B is the Seebeck coefficient of the thermopile at a specified temperature

J is the number of junctions in the thermopile

T_{co} is a temperature coefficient for the Seebeck coefficient

T_s is the temperature at which α_B is specified

T_{cr} is core temperature

k_c is a constant for computing core temperature

V_S is the sensor output voltage

G_{FG} is the gain of the front end amplifier

K_{AD} is the analog-to-digital conversion factor

$V_S = (H - H_0) \cdot K_{AD} / G_{FE}$

T_c (deg F) = Thermistor lookup table (R_t) - Z_t

$T_H = [(T_{co} \cdot T_s + 1) \pm \{(T_{co} \cdot T_s + 1)^2 - (2 \cdot T_{co}) \cdot [(T_{co} \cdot (T_c \cdot T_s) - (T_c^2 / 2)) + T_c + (V_S / J \cdot \alpha_B)]\}^{1/2}] / T_{co}$

H_c (deg K^4) = $K_h \cdot (H - H_0) \cdot (1 + T_{co} \cdot (T_h - T_c) / 2 - T_z)$

T_{hf} (deg K^4) = 4th power lookup table (T_c)

T_t (deg F) = $(H_c + T_{hf})^{1/4}$ (Final lookup table)

$T_{cr} = T_e + (T_t - T_e) / k_c$

T_t (deg C) = $(5/9) \cdot (T_t$ (deg F) - 32) optional

The following is a list of the information which may be contained in the EEPROM and therefore be programmable at the time of calibration:

Radiation sensor offset

Radiation sensor gain

Radiation sensor temperature coefficient

Thermistor offset

Ambient temperature at calibration

Thermistor lookup table

Final temperature lookup table

Adjustment factor F

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Sound source functions:

Beep at button push in lock mode

none/20/40/80 milliseconds long

Beep at lock

none/20/40/80 milliseconds long

Beep at power down

none/20/40/80 milliseconds long

Beep at lowbattery

none/20/40/80 milliseconds long

interval 1/2/3 sec

single/double beep

Timeout functions:

Time to power-down

0.5 to 128 sec in 0.5 sec increments

Delay until lock

0.5 to 128 sec in 0.5 sec increments

Other functions:

Power-on button resets lock cycle

Power-on button resets peak detect

Display degrees C / degrees F

EEPROM "Calibrated" pattern to indicate that the device has been calibrated

EEPROM checksum for a self-check by the processor

25 FIGS. 4A-4D provide a flowchart of the firmware stored in the microprocessor 73. From reset when the instrument is turned on, the system is initialized at 110 and the contents of the EEPROM are read into memory in the microprocessor at 112. At 114 the processor reads the state of power and mode switches in the system. At 116, the system determines whether a mode switch 113 has placed the system in a self-test mode. If not all eights are displayed on the four-digit display 82 for a brief time At 120 the system performs all A-to-D conversions to obtain digital representations of the thermopile output and the potentiometer settings through multiplexor 76.

30 The system then enters a loop in which outputs dictated by the mode switch are maintained. First the timers are updated at 122 and the switches are again read at 124. When the power is switched off, from 126 the system enters a power down loop at 128 until the system is fully down. At 130, the mode switch is checked and if changed the system is reset. Although not in the tympanic temperature detector, some detectors have a mode switch available to the user so that the mode of operation can be changed within a loop.

45 At 132, 136 and 140, the system determines its mode of operation and enters the appropriate scan process 134, lock process 138 or peak process 142. In a scan process, the system updates the output to the current reading in each loop. In a lock process, the system updates the output but locks onto an output after some period of time. In the peak process, the system output is the highest indication noted during a scan. In each of these processes, the system may respond to the programming from the EEPROM to perform any number of functions as discussed above. In the peak process which is selected for the tympanic temperature measurement, the system locks onto a peak measurement 50 after a preset period of time. During assembly, the system may be set at a test mode 144 which will be described with respect to FIG. 4D.

In any of the above-mentioned modes an output is calculated at 146. Then the system loops back to step 122. The calculation 146 is illustrated in FIG. 4B.

65 At 148 in FIG. 4B the raw sensor data is obtained from memory. The sensor offset taken from the EEPROM is subtracted at 150 and the ambient temperature

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previously obtained from the potentiometer RT1 is accessed at 152. The temperature coefficient adjustment is calculated at 154. At 156, the sensed signal is multiplied by the gain from EEPROM and by the temperature coefficient. At 158, the fourth power of the ambient temperature is obtained, and at 160 it is added to the sensor signal. At 162, the fourth root of the sum is obtained through a lookup table. Whether the display is in degrees centigrade or degrees Fahrenheit is determined at 164. If in degrees centigrade, a conversion is performed at 166. At 168, adjustment values, including that from the potentiometer R4, are added.

Analog-to-Digital conversion is performed periodically during an interrupt to the loop of FIG. 4A which occurs every two milliseconds. The interrupt routine is illustrated in FIG. 4C. Timer counters are updated at 170. A-to-D conversions are made from 172 only every 100 milliseconds when a flag has been set in the prior interrupt cycle. During most interrupts, an A/D conversion does not occur. Then, the 100-millisecond counter is checked at 174, and if the count has expired, a flag is set at 176 for the next interrupt. The flag is checked at 178 and, if found, the display is updated at 180. The system then returns to the main loop of FIG. 4A.

Where the 100 millisecond flag is noted at 172 an A-to-D conversion is to be performed. The system first determines at 182 whether a count indicates there should be a conversion of the thermopile output at 184 or a conversion of the the thermistor output at 186. The thermopile sensor conversion is performed nine out of ten cycles through the conversion loop. At 188, the system checks to determine whether a conversion is made from the potentiometer R4 or from the battery voltage divider R1, R2 at 192. These conversions are made alternately.

FIG. 4D illustrates the self-test sequence which is called by the mode switch 113 only during assembly. During the test, the beeper sounds at 182 and all display segments are displayed at 184. Then the system steps each character of the display from zero through nine at 186. The system then enters a test loop. At 188, the system senses whether the button 108 has been pressed. If so, a display counter is incremented at 190. The display for the unit then depends on the count of the display counter. With the zero count, the adjustment potentiometer value is displayed at 192. Thereafter, if the display counter is incremented by pressing the button 108, the raw sensor data is displayed. With the next increment, ambient temperature is displayed at 196, and with the next increment, the raw output from the ambient temperature sensor RT1 is displayed. With the next

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increment, the battery voltage is displayed. After the test, the assembler sets the mode switch to the proper operating mode.

While this invention has been particularly shown and described with references to preferred embodiments thereof, it will be understood by those skilled in the art that various changes in form and details may be made therein without departing from the spirit and scope of the invention as defined by the appended claims.

We claim:

1. A temperature detector comprising:
 - a housing adapted to be held by hand;
 - an extension from the housing adapted to be inserted into an ear;
 - a radiation sensor supported within the detector and which receives radiation passing into the extension from a target area in the ear;
 - a temperature display on the housing for displaying temperature; and
 - a battery powered electronics in the housing for converting radiation sensed by the sensor to temperature displayed by the display, the electronics including a processor for providing an inner body temperature displayed on the housing as a function of the received radiation, indicating target temperature, compensated by an indication of ambient temperature to provide an inner body temperature approximation.
2. A temperature detector as claimed in claim 1 wherein the inner body temperature is core temperature.
3. A radiation detector comprising:
 - a radiation sensor mounted to view a target of biological surface tissue;
 - a temperature sensor for sensing ambient temperature;
 - an electronic circuit coupled to the radiation sensor and temperature sensor and responsive to a signal from the radiation sensor and the temperature sensed by the temperature sensor to provide an indication of an internal temperature adjusted for the ambient temperature to which the surface tissue is exposed; and
 - an output for providing an indication of the internal temperature.
4. A radiation detector as claimed in claim 3 wherein the output is a display.
5. A radiation detector as claimed in claim 3 wherein the biological surface tissue includes a tympanic membrane and the display provides an indication of core temperature.

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US005653238A

United States Patent [19]

[11] **Patent Number:** 5,653,238

Pompei

[45] **Date of Patent:** *Aug. 5, 1997

[54] **RADIATION DETECTOR PROBE**

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[75] **Inventor:** Francesco Pompei, Boston, Mass.

[73] **Assignee:** Exergen Corporation, Watertown, Mass.

[*] **Notice:** The term of this patent shall not extend beyond the expiration date of Pat. No. 4,993,419.

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[22] **Filed:** Nov. 2, 1994

Related U.S. Application Data

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[51] **Int. Cl.⁶** A61B 6/00

[52] **U.S. Cl.** 128/664; 128/736

[58] **Field of Search** 128/664, 736, 128/738; 324/123, 127, 129, 132-3, 135

Primary Examiner—Angela D. Sykes

Assistant Examiner—John P. Lacyk

Attorney, Agent, or Firm—Hamilton, Brook, Smith & Reynolds, P.C.

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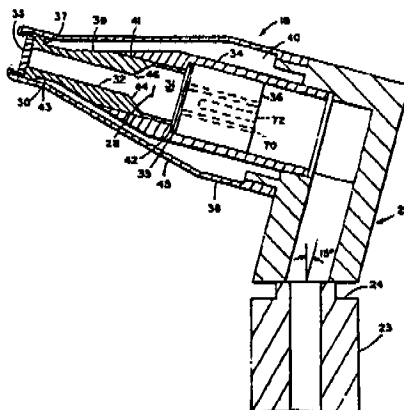
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[57] **ABSTRACT**

Tympanic temperature measurements are obtained from the output of a radiation sensor mounted in an extension from a housing. The housing has a temperature display and supports electronics for responding to sensed radiation. The sensor is mounted in an improved extension which is shaped to fit into smaller ear canals, such as a child's ear canal or a swollen adult ear canal. Within the extension, the sensor is positioned in a highly conductive environment and receives radiation from an external target through a tube. Electronics determine the target temperature based on the sensor output signal and a temperature sensor signal.

39 Claims, 11 Drawing Sheets



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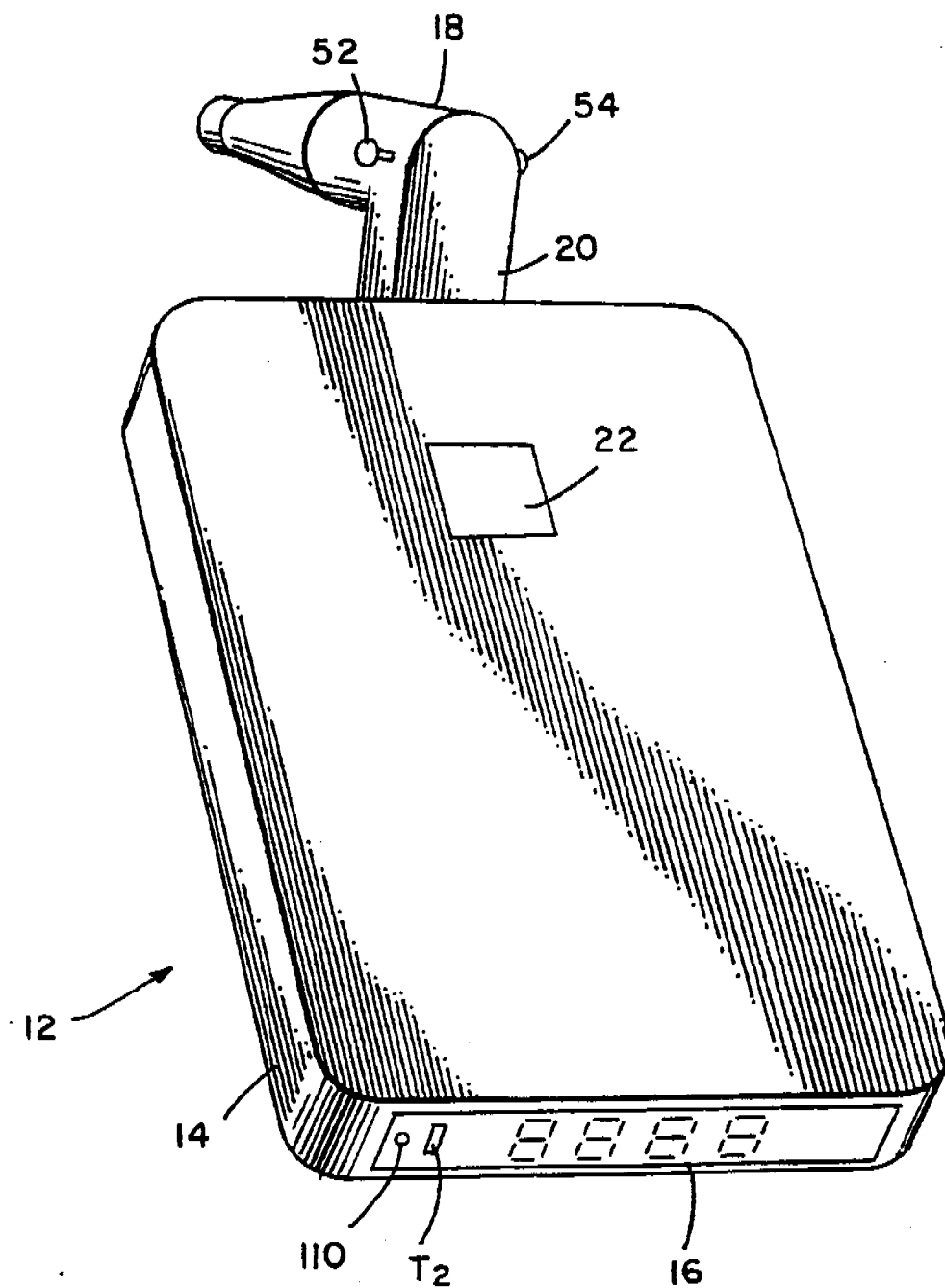


FIG. 1

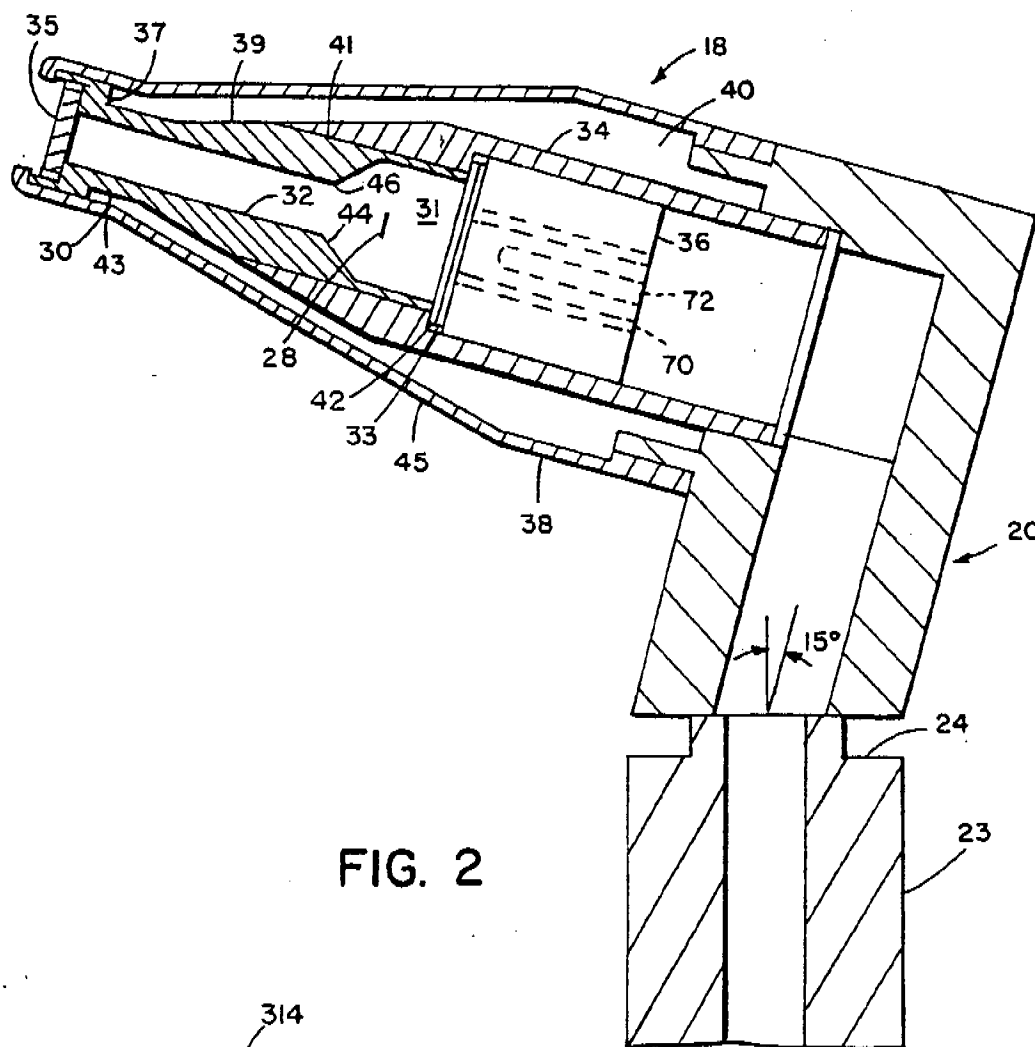


FIG. 2

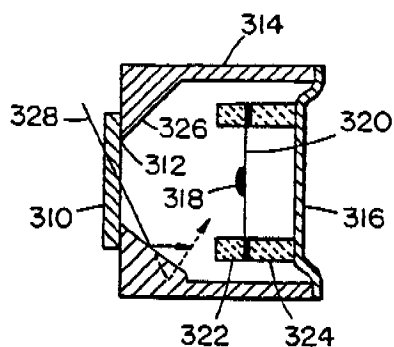


FIG. 10

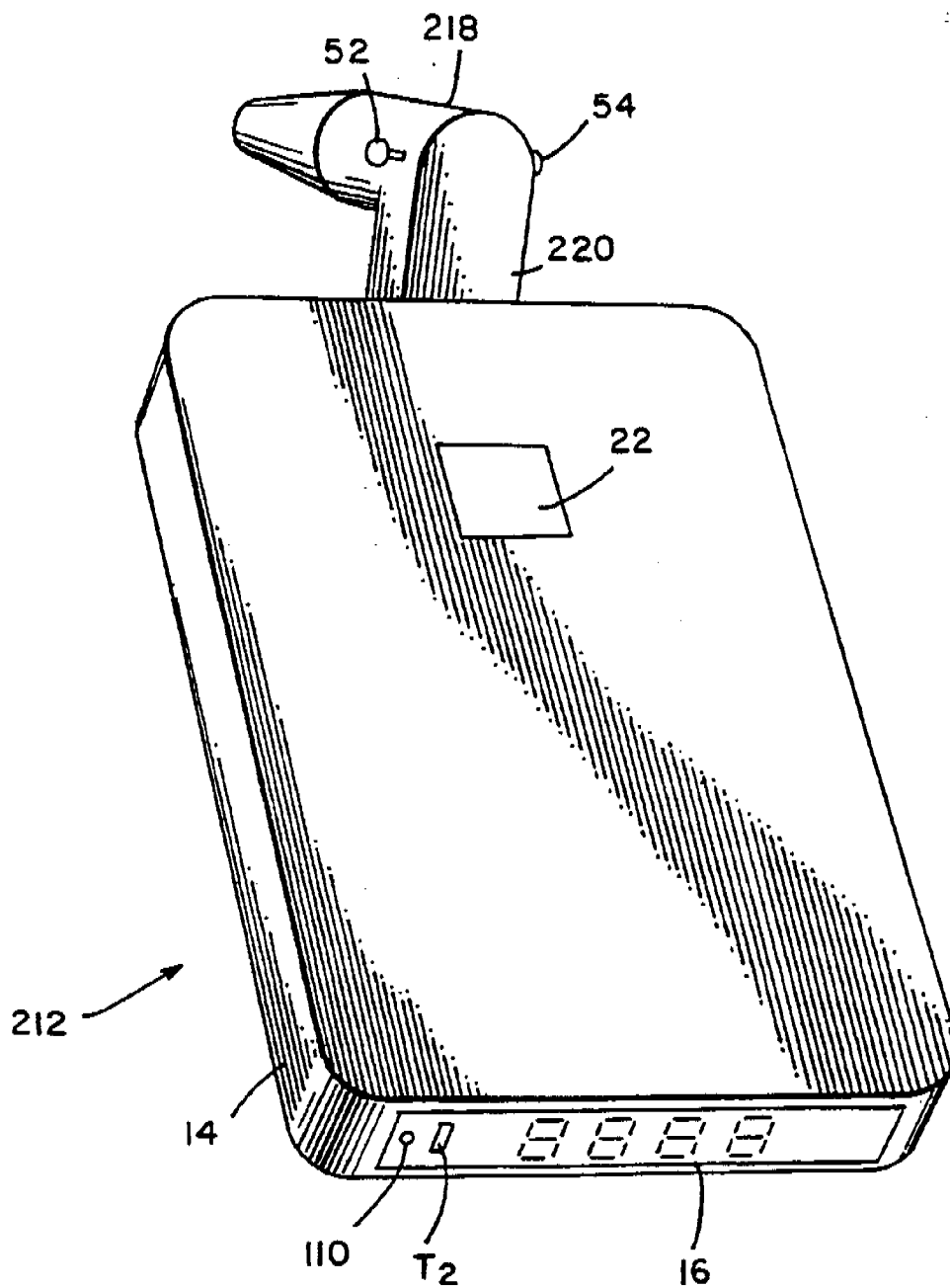
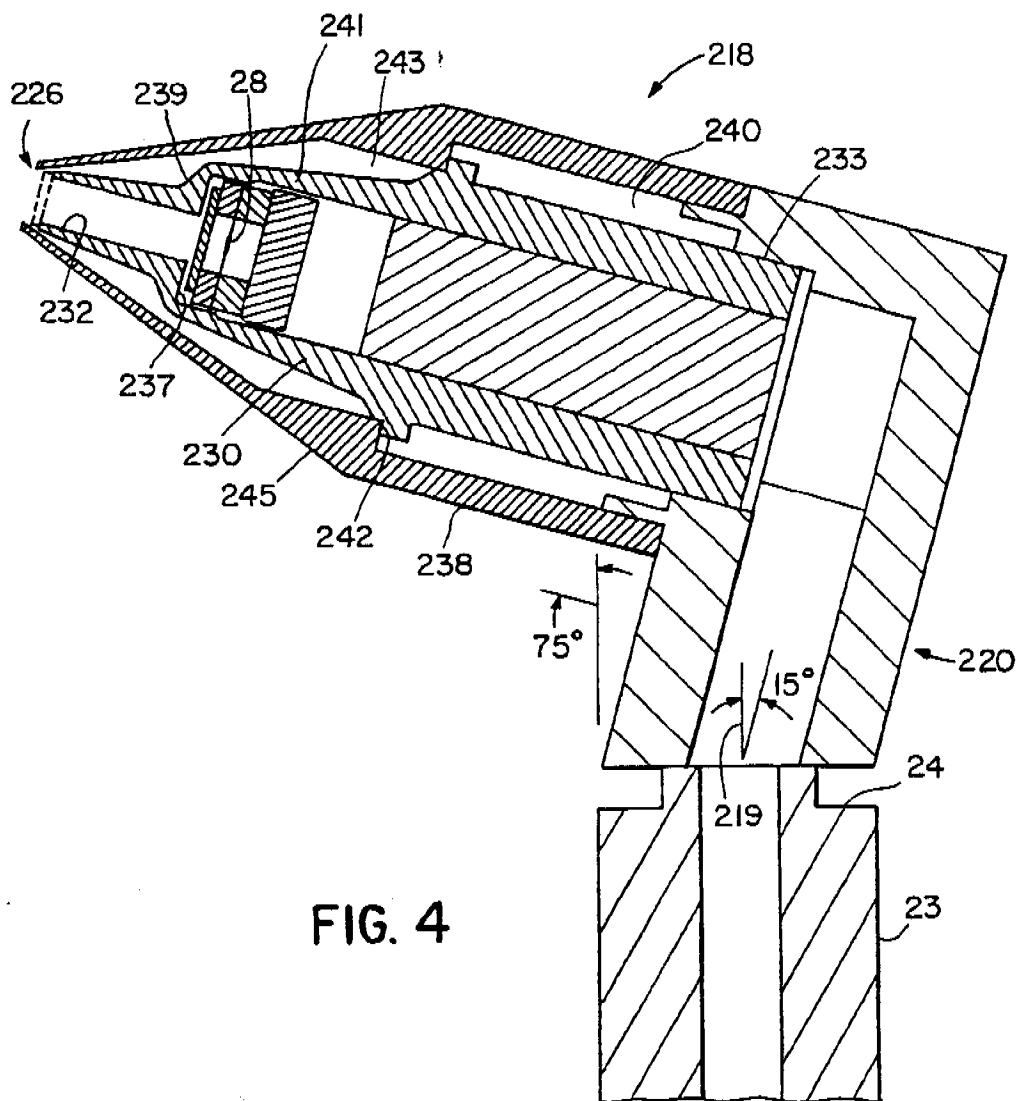


FIG. 3



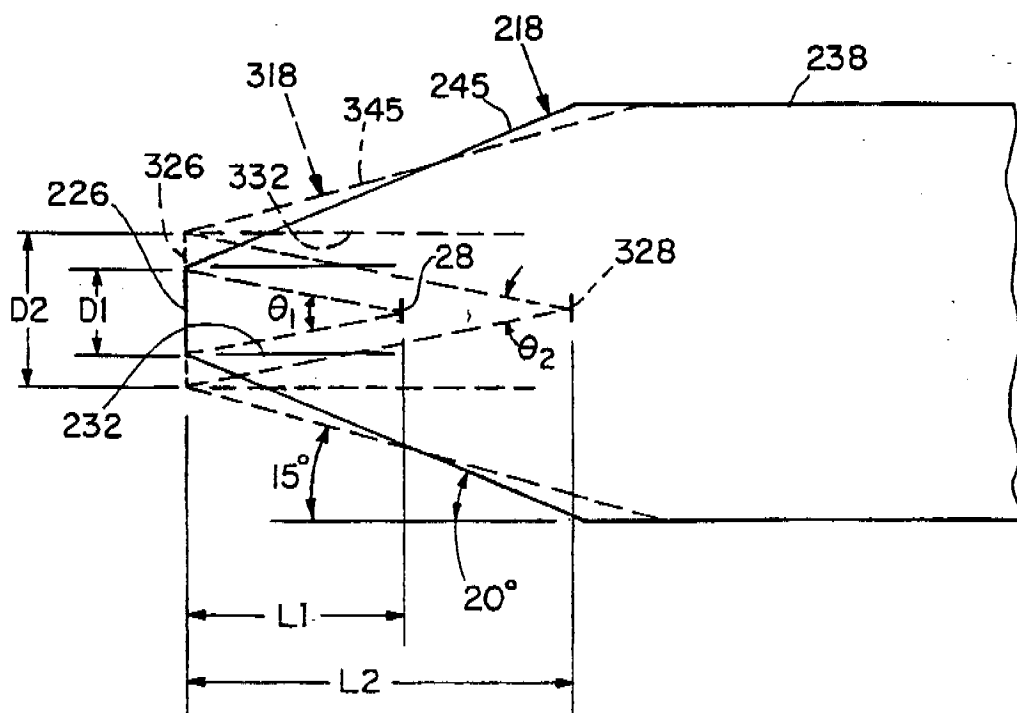


FIG. 5

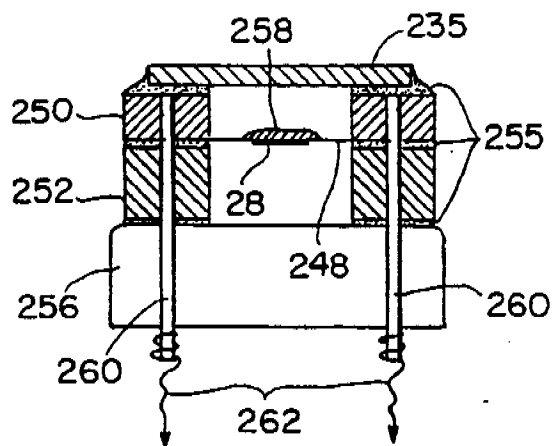
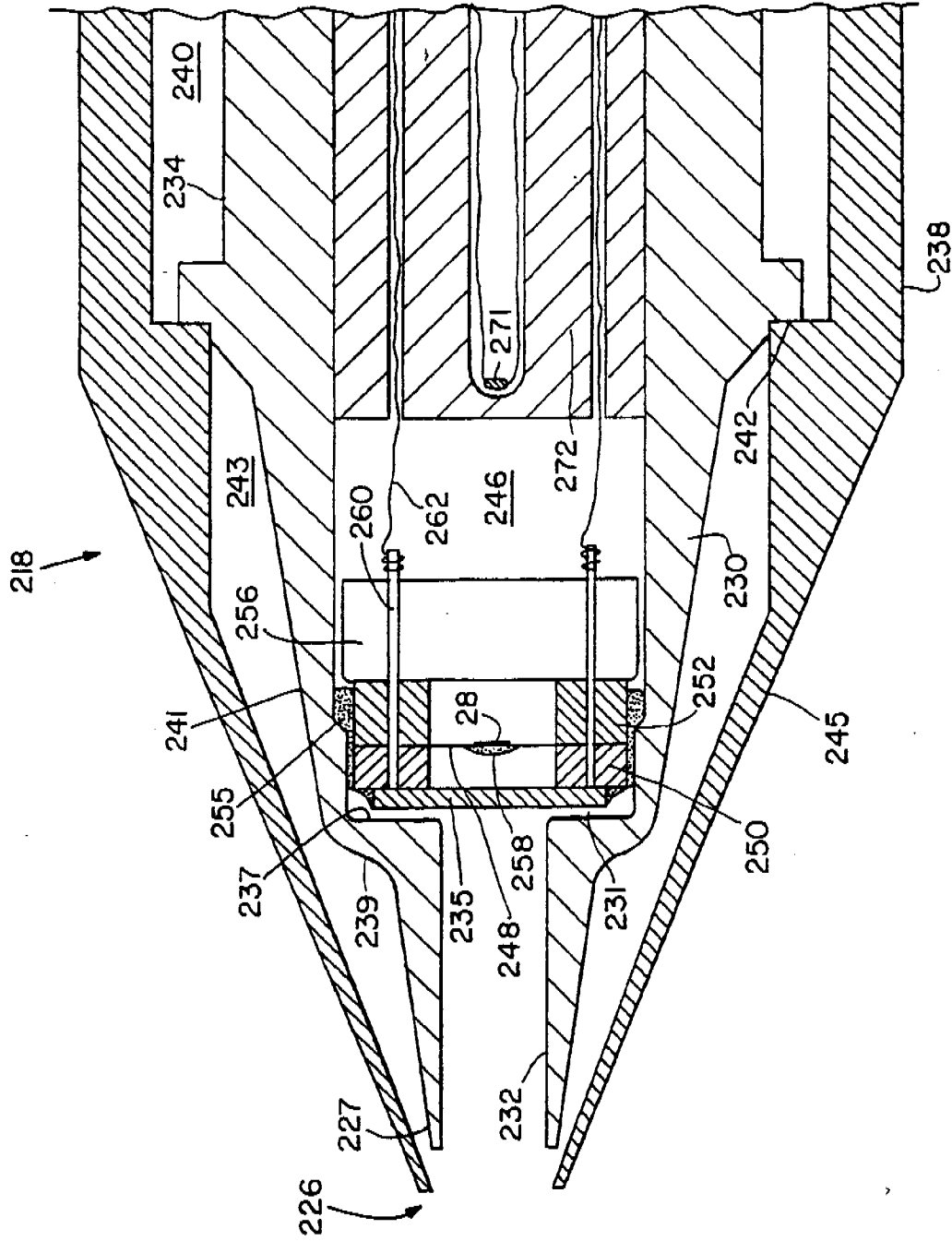


FIG. 7

FIG. 6



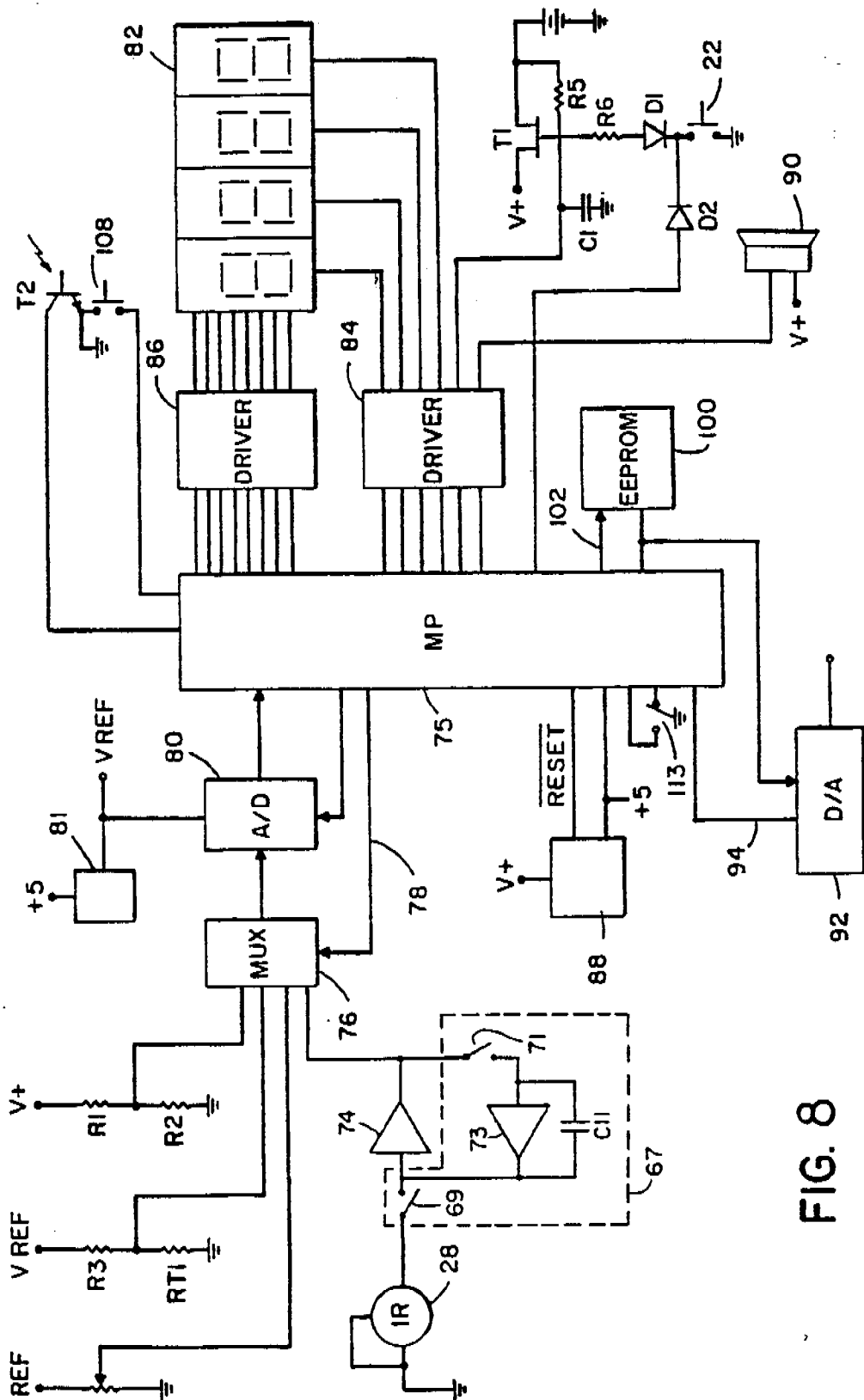


FIG. 8

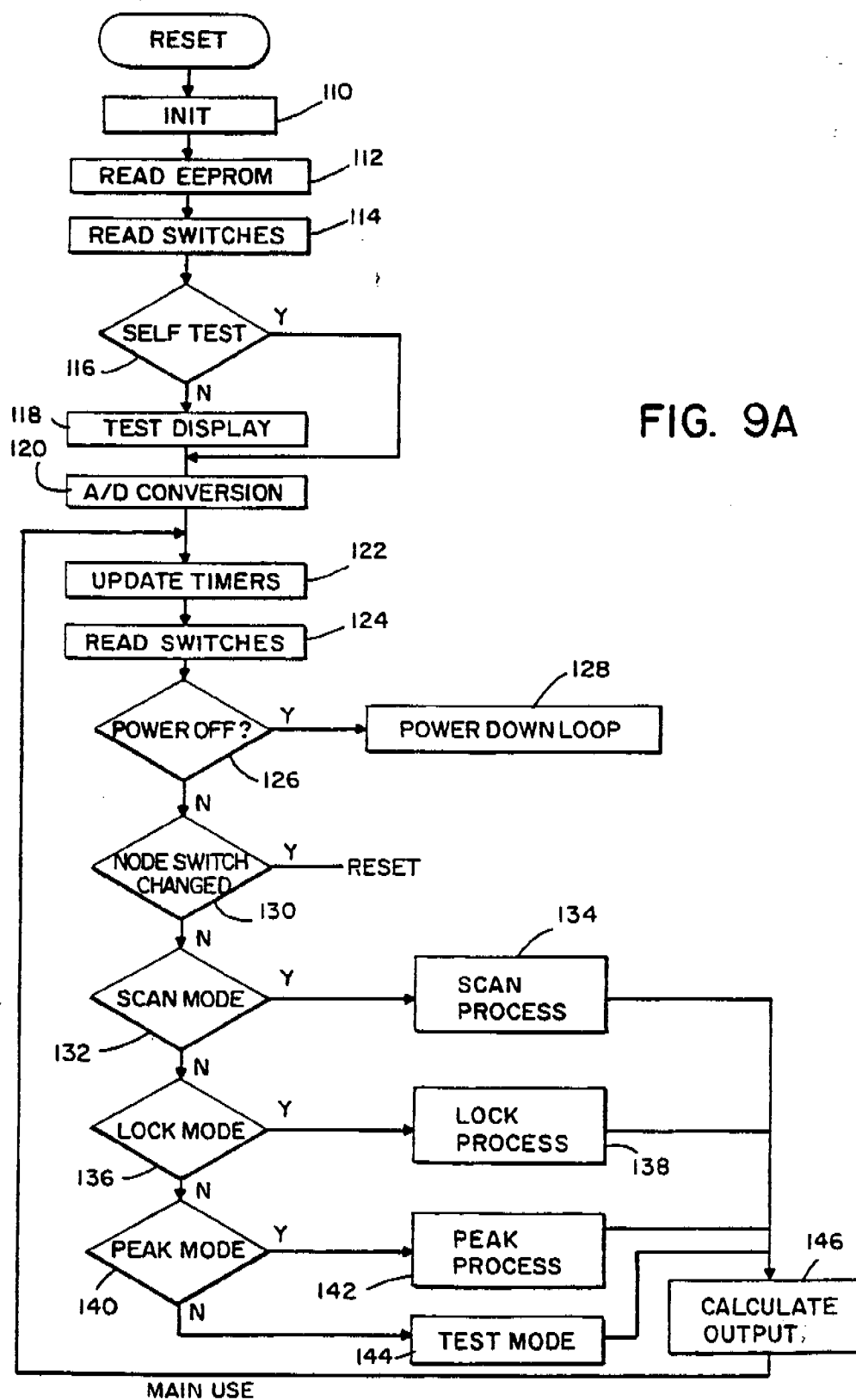


FIG. 9A

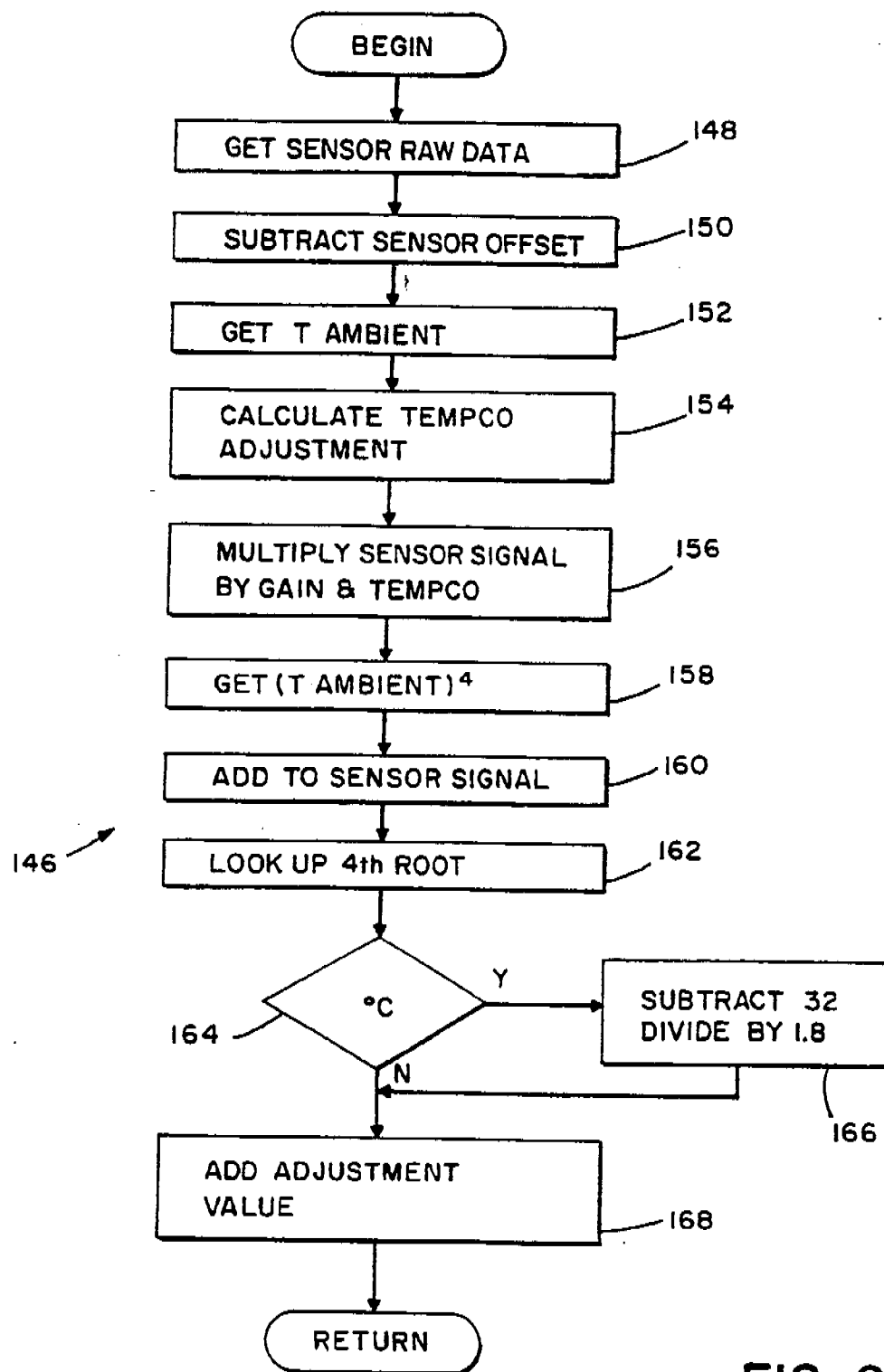
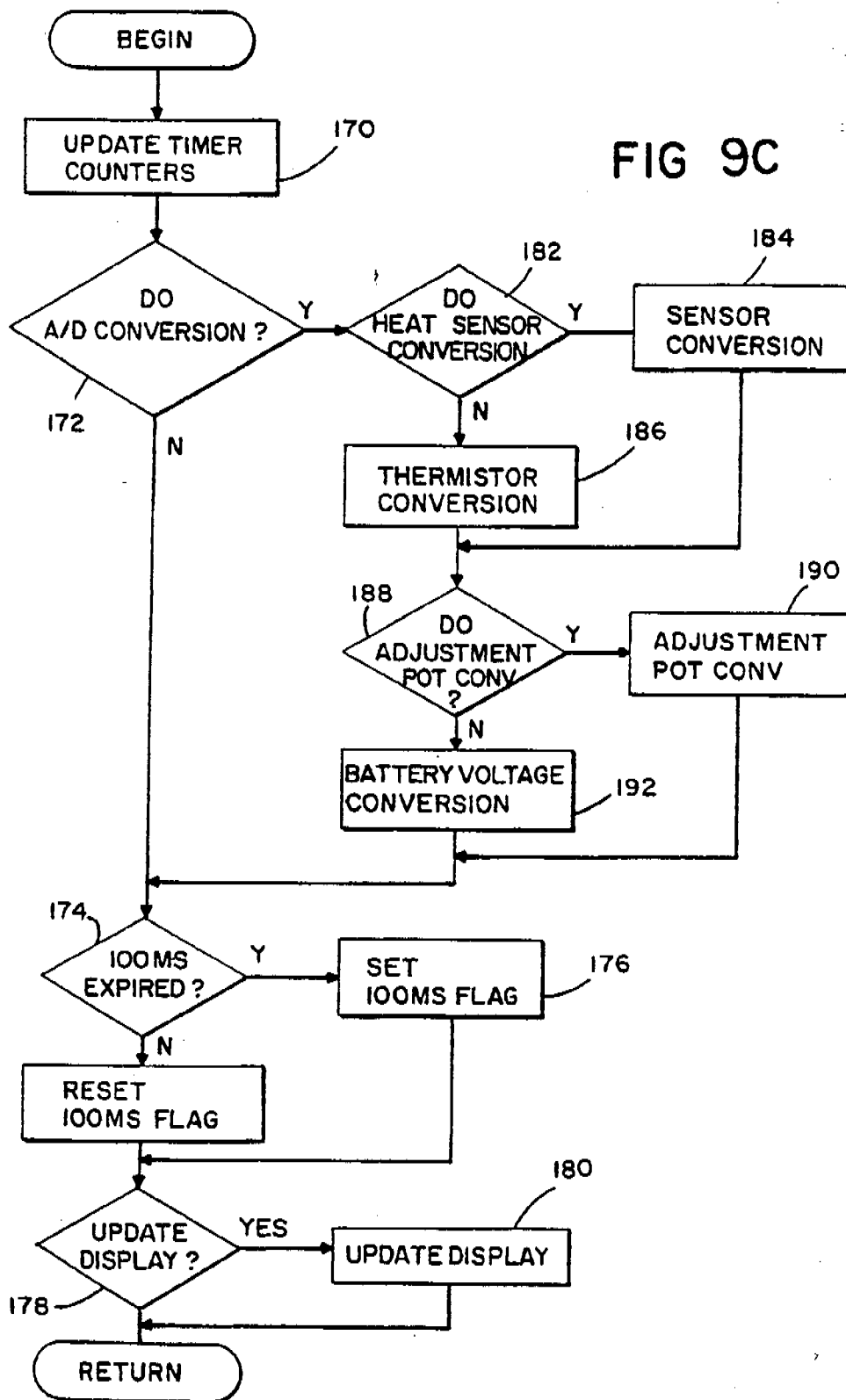


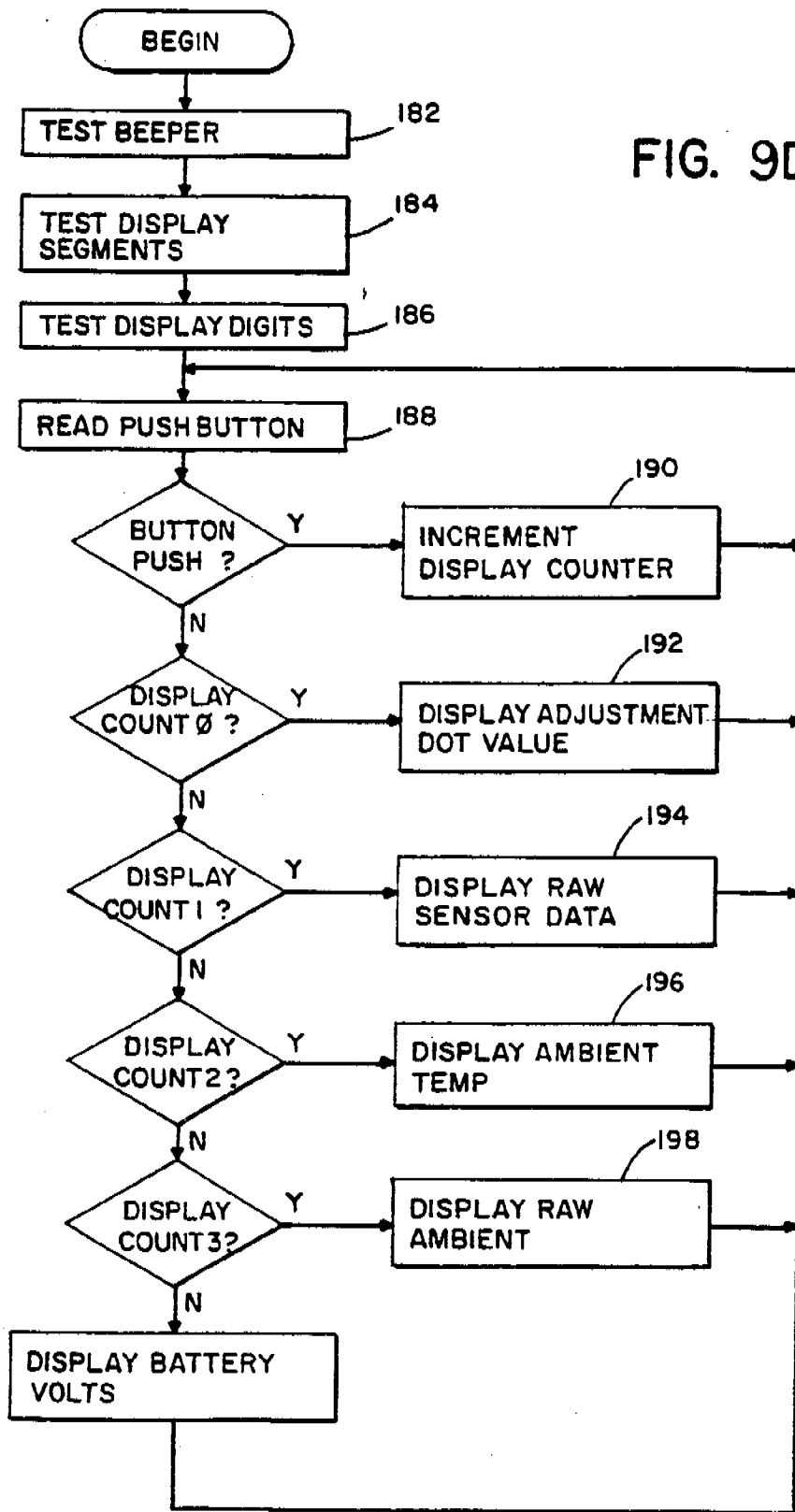
FIG. 9B

CALCULATE OUTPUT PROCEDURE



A/D CONVERSION INTERRUPT SERVICE ROUTINE

FIG. 9D



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RADIATION DETECTOR PROBE**RELATED APPLICATIONS**

This is a Continuation-in-part of application Ser. No. 07/832,109, filed Feb. 6, 1992 for "RADIATION DETECTOR WITH HIGH THERMAL STABILITY," now U.S. Pat. No. 5,325,863 and of application Ser. No. 07/889,052, filed May 22, 1992, for "EAR THERMOMETER RADIATION DETECTOR," now U.S. Pat. No. 5,381,796 and of application Ser. No. 07/760,006, filed Sep. 13, 1991, for "RADIATION DETECTOR PROBE," now U.S. Pat. No. 5,445,158, which is a Continuation-in-part of application Ser. No. 07/646,855, filed Jan. 28, 1991 for "RADIATION DETECTOR HAVING IMPROVED ACCURACY," now U.S. Pat. No. 5,199,436, which is a divisional of application Ser. No. 07/338,968 filed Apr. 14, 1989, now U.S. Pat. No. 5,012,813, which is a Continuation-in-part of application Ser. No. 07/280,546 filed Dec. 6, 1988 for "RADIATION DETECTOR SUITABLE FOR TYMPANIC TEMPERATURE MEASUREMENT," now U.S. Pat. No. 4,993,419, all of the above noted related applications are incorporated herein by reference.

BACKGROUND

Radiation detectors which utilize thermopiles to detect the heat flux from target surfaces have been used in various applications. An indication of the temperature of a target surface may be provided as a function of the measured heat flux. One such application is the testing of electrical equipment. Another application has been in the scanning of cutaneous tissue to locate injured subcutaneous regions. An injury results in increased blood flow which in turn results in a higher surface temperature. Yet another application is that of ear temperature measurement. More specifically, a tympanic device relies on a measurement of the temperature of the tympanic membrane area in the ear of an animal or human by detection of infrared radiation as an alternative to traditional sublingual thermometers. Other ear temperature measurements may be limited to the outer region of the ear canal.

SUMMARY OF THE INVENTION

In one embodiment of the present invention, a radiation detector comprises a radiation sensor such as a thermopile and a thermal mass enclosing the thermopile. The thermal mass includes an elongated thermally conductive tube of a first internal diameter. The tube extends from the distal end of the detector to a rear volume of larger internal diameter in which the sensor is mounted. In one device, the tube is gold plated and is thus highly reflective. In another device the tube is plated with a metal oxide for high absorption of radiation. A rigid window is mounted adjacent to an end of the tube, preferably the distal end where it seals the tube.

In accordance with one feature of the present invention, the portions of the thermal mass forming the tube and rear volume are formed in a unitary structure of high thermal conductivity material. The unitary thermal structure has an outer surface with an outer diameter at its distal end which is less than an outer diameter about the rear volume. The outer surface is tapered about the tube such that a unitary thermal mass of increasing outer diameter is provided about the end of the tube adjacent to the rear volume. The unitary thermal mass maximizes conductance and thermal mass within a limited diameter. To avoid changes in fixtures used in mounting the thermopile within the unitary thermal structure, in one embodiment the thermal structure is of

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limited diameter and may be supplemented with an additional thermal mass. The additional thermal mass surrounds the rear volume and a portion of the tube and is in close thermal contact with the unitary thermal structure. In another embodiment, the unitary thermal structure extends from the distal end of the detector to a housing such that no additional thermal mass is required.

It has been found that a narrow field of view radiation detector provides a more accurate and reliable reading of tympanic temperature. In the detector of the present invention, that field of view is obtained by controlling the reflectance of the inner surface of the tube, the length and diameter of the tube and the position of the thermopile behind the tube. In one embodiment, the tube has a reflective inner surface providing a field of view from the thermopile of about sixty degrees or less. A field of view of less than about sixty degrees allows for viewing of only a portion of the ear canal within less than about 1 centimeter of the tympanic membrane. In another embodiment, the tube has a nonreflective inner surface which produces a field of view from the thermopile of about thirty degrees or less. In either embodiment, the thermopile response may be fine tuned by changing the position of the thermopile behind the tube which changes the field of view and alters the thermopile response signal level.

In accordance with another aspect of the present invention, the infrared radiation sensor is mounted in the rear volume within the unitary thermal mass. The sensor has an active area influenced by radiation from an external target and a reference area of known temperature which is substantially unaffected by radiation. The sensor is preferably a thermopile having its cold junction reference area thermally coupled to the thermal mass but it may be a pyroelectric device. The thermally conductive tube is thermally coupled to the thermal mass and passes radiation to the sensor from the external target. A thermal barrier surrounds the thermal mass and tube. The temperature of the thermal mass, and thus of the sensor reference area, is allowed to float with ambient. A temperature measurement of the thermal mass is made to compensate the sensor output.

Temperature differences between the tube and sensor reference area would lead to inaccurate readings. To avoid those differences, the large unitary thermal mass minimizes temperature changes from heat which passes through the thermal barrier, and good conductivity within the mass increases conductance and minimizes temperature gradients. The outer thermal RC time constant for thermal conduction through the thermal barrier to the thermal mass and tube is at least two, and preferably at least three orders of magnitude greater than the inner thermal RC time constant for the temperature response of the reference area to heat transferred to the tube and thermal mass. For prompt readings, the inner RC time constant should be about 1/2 second or less.

Preferably, the thermally conductive tube is thermally coupled to the sensor by a thermally conductive material such as epoxy. In accordance with the present invention, the amount of thermally conductive material is tuned to the detector to minimize the response of the sensor to undesired thermal perturbations of the tube. Providing an insufficient amount of material causes a positive error response from the sensor for thermal perturbations, while too much material causes a negative error response from the sensor for thermal perturbations. By providing the proper amount of material between the sensor and the tube, the added thermal conductance from the material tunes the reference area and the active area of the sensor to respond in phase to thermal perturbations such that the sensor response is substantially unaffected by said perturbations.

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In the radiation detector of the present invention, the radiation sensor and the tube are positioned in an extension which is particularly suited for obtaining tympanic temperature measurements. To accomplish this, the extension is inserted into a subject's ear, and preferably into the ear canal. Once inserted, the extension is pivoted and the sensor scans the ear canal and senses the emitted radiation. The detector employs electronics which detects the peak radiation sensed by the sensor and converts it to a tympanic temperature indication.

The probe extension which supports the radiation sensor extends from a housing which displays the tympanic temperature. The housing extends along a first axis and the extension preferably extends at an angle of about 75 degrees from the first axis. This housing supports the battery powered electronics for converting radiation sensed by the sensor to tympanic temperature displayed by the display. The electronics included a processor for providing the displayed temperature based on radiation received from the tympanic membrane. If the sensor receives radiation from the cooler outer ear instead of the tympanic membrane, the processor determines the displayed temperature as a function of the received radiation compensated by an indication of ambient temperature to produce a core temperature approximation. The entire instrument is housed in a single hand-held package. The small additional weight of the electronics in the hand-held unit is acceptable because readings can be made quickly.

In accordance with another aspect of the present invention, the probe extension is adapted to be inserted into an ear canal. More specifically, the diameter of the distal tip as well as the shape and taper of the extension may be set to provide a detector useful in normal adult ear canals or a pediatric detector useful in small ear canals, especially children's ear canals, and swollen adult ear canals. To that end, the extension has a diameter of about 3-8 mm about its distal end and a substantially conical shape increasing in diameter along its length from its distal end and characterized by an included angle of about 25-60 degrees. As such, the extension is capable of being inserted into an ear canal up to one-third of the length of the ear canal.

In a pediatric detector embodiment the conical shape of the extension has an included angle of about forty degrees. Further, the diameter of the tip of the distal end of the extension is preferably in the range of 3-6 mm. As such, the pediatric detector is particularly useful on subjects having small ear canals but is also useful on adult subjects. In another embodiment the conical portion of the extension has an included angle of about thirty degrees. The diameter of the tip of the distal end of the extension is no more than about 7 mm. As such, the detector is particularly useful on adult subjects having normal ear canals, but it may also be used on children.

The radiation sensor assembly of a preferred embodiment includes a sensing device which is mounted within a rigid structure of high thermal conductivity such as beryllium oxide and has its reference area thermally coupled thereto. The passage through a thermally conductive tube passes thermal radiation from the external target, such as a tympanic membrane, to the thermopile. A window is mounted on the rigid structure such that it is in close thermal contact with the structure.

In one embodiment of the present invention, a detector comprises a substantially conical extension employing the above-described radiation sensor assembly. Preferably, the sensor assembly includes a thermopile sensor. In this

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embodiment, the tube provides a field of view from the thermopile of about thirty degrees or less. A thermal mass of high thermal conductivity material surrounds the tube and encloses the rigid structure in a rear volume. The thermal mass has a region within the rear volume which is defined between a rearwardly facing surface of the thermal mass and forward a face of the window. The region is preferably filled with air, providing a low thermal conductivity environment therein. The high thermal conductivity mass provides close thermal contact among the tube, the rigid structure, the thermopile cold junction and the ends of the window. As such, a continuous low thermal resistance path is formed from the tube to the cold junction of the thermopile and the window is held to the cold junction temperature.

BRIEF DESCRIPTION OF THE DRAWINGS

The foregoing and other objects, features and advantages of the invention will be apparent from the following more particular description of preferred embodiments of the invention, as illustrated in the accompanying drawings in which like reference characters refer to the same parts throughout the different views. The drawings are not necessarily to scale, emphasis instead being placed upon illustrating the principles of the invention.

FIG. 1 illustrates one embodiment of a radiation detector for tympanic temperature measurements in accordance with the present invention.

FIG. 2 is a cross-sectional view of the extension of the detector of FIG. 1 in which the thermopile radiation sensor is positioned.

FIG. 3 illustrates another embodiment of the radiation detector for tympanic temperature measurements in accordance with the present invention.

FIG. 4 is a cross-sectional view of the extension of the detector of FIG. 3 in which the thermopile radiation sensor is positioned.

FIG. 5 is a profile of pair of configurations of the extension of FIG. 4.

FIG. 6 is an enlarged cross-sectional view of the extension of FIG. 4.

FIG. 7 is a cross-sectional view of a radiation sensor assembly of the detector of FIG. 6.

FIG. 8 is a block diagram of the electronic circuit can embodying a feature of the present invention.

FIGS. 9A-9D are flow charts of the system firmware.

FIG. 10 is a cross-sectional view of a thermopile can embodying a feature of the present invention.

DETAILED DESCRIPTION OF A PREFERRED EMBODIMENT

In one embodiment of the present invention, the radiation detector 12 of FIG. 1 includes a flat housing 14 with a digital display 16 for displaying a tympanic temperature measurement. Although the display may be located anywhere on the housing, it is preferred that it be positioned on the end so the user is not inclined to watch it during a measurement. The instrument makes an accurate measurement when pivoted to scan the ear canal, and the user should concentrate on only the scanning motion. Then the display can be read. A thermopile radiation sensor is supported within a probe 18 at the opposite end of the housing 14. The housing extends along a first axis 19 (FIG. 2) and the extension 18 extends orthogonally from an intermediate extension 20 which extends at an angle of about 15 degrees from the first axis.

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As such, the extension 18 extends at an angle of about 75 degrees from the first axis 19 of the housing. Thus, the head of the detector, including the extension 18 and 20, has the appearance of a conventional otoscope. An on/off switch 22 is positioned on the housing.

A cross-sectional view of the extension of the detector of FIG. 1 is illustrated in FIG. 2. A base portion 23 is positioned within the housing 14, and the housing clamps about a groove 24. As noted, the portion 20 extends at about a 15 degree angle from the first axis 19 and thus from the base portion 23. Further, the extension 18 extends at about a 75 degree angle from the first axis. The extension 18 is tapered toward its distal end at 26 so that it may be comfortably positioned in the ear canal to view the tympanic membrane and/or ear canal.

A preferred disposable element to be used over the extension 18 is presented in the '419 patent and will not be discussed here.

The edge at the end of the probe is rounded so that when the probe is inserted into the ear it can be pivoted somewhat without discomfort to the patient. The probe is also curved like an otoscope to avoid interference with the ear. By thus pivoting the probe, the ear canal is scanned and, at some orientation of the probe during that scan, one can be assured that the maximum temperature is viewed. Since the ear canal cavity leading to the tympanic area is the area of highest temperature, the instrument is set in a peak detection mode, and the peak detected during the scan is taken as the tympanic temperature.

An improved assembly within the extension 18 is illustrated in FIG. 2. A thermopile 28 is positioned within a can 30 of high conductivity material such as copper. The conductivity should be greater than two watts per centimeter per degree Kelvin. The can is filled with a gas of low thermal conductivity such as Xenon. The thermopile 28 is positioned within a rear volume 31. It is mounted to an assembly which includes a header 33. The volume is sealed by cold welding of the header 33 to a flange 42 extending from the can. Cold welding is the preferred approach to making the seal and, to utilize past welding fixtures, the outer diameter of the can is limited. Thermal epoxy may be used as an alternative.

The thermopile views the tympanic membrane area through a radiation guide 32. The radiation guide 32 is gold plated to minimize oxidation. It is closed at its forward end by a germanium window 35. The rigid germanium window assures that the radiation guide is sealed from contamination and is itself easily cleaned. Germanium is less fragile than silicon and passes higher wavelengths. To minimize expense, the window is square with each side slightly longer than the diameter of the radiation guide 32. The window is cemented with epoxy within a counterbore in a flange 37 at the end of the radiation guide. The epoxy serves as a gas seal and mechanical support for the somewhat brittle germanium window. The flange serves to protect the germanium window should the detector be dropped. The diagonal of the window is less than the diameter of the counterbore, and its thickness is less than the depth of the counterbore. Therefore, if the detector is dropped, any force which presses the plastic housing toward the window is absorbed by the flange. The germanium need only withstand the forces due to its own inertia.

From the perspective of the thermopile flake 28, the radiation guide 32 shifts the front aperture at the window 35 back to the proximal end of the radiation guide at 46. Thus, the field of view of the device is determined by the diameter of the aperture 46 and its distance from the flake 28. There

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are, however, stray rays which, though not being directed to the flake from the aperture, may ultimately strike the flake after reflection within the volume at 31. Such reflections effectively increase the field of view and are thus undesirable. The frustoconical surface 44 surrounding the aperture 46 reflects most of those stray rays toward the rear of the volume 31 rather than toward the thermopile flake. As shown in FIG. 2, the flake views itself in the surface 44, thus minimizing stray radiation.

The angled surface surrounding the aperture can be applied to more conventional thermopile cans as illustrated in FIG. 10. Here, the window 310 is mounted directly across the aperture 312 of the can 314. As in conventional assemblies, the can is closed by rear header 316. The thermopile flake 318 is centered on a polyester sheet 320 stretched between beryllium oxide rings 322 and 324. As in the case of FIG. 2, the surface 326 surrounding the aperture 312 is frustoconical such that it is angled back from the aperture. It can be seen that stray rays 328 which should not be seen by the thermopile flake 318 will be reflected rearwardly toward the beryllium oxide rings where they should be absorbed rather than toward the flake as indicated by the broken lines as they would if the surface surrounding the aperture were cylindrical.

Whereas the detector disclosed in the '419 patent had a field of view of about 120°, it has been determined that a narrower field of view of about sixty degrees or less provides the user with an easier and more accurate indication of tympanic temperature. With a narrower field of view, the thermopile flake, when directly viewing the tympanic membrane, also views less than about one centimeter along the ear canal wherein the tissue is at substantially the same temperature as the tympanic membrane. A better view of the tympanic membrane also results from the cylindrical extension 43 beyond the conical portion of the extension 18. With the ear canal straightened by the probe, the extension 43 can extend well into the ear canal beyond any hair at the canal opening.

The tympanic membrane is about 2.5 centimeters from the opening of the ear canal. The ear canal for an adult subject is typically about 8 mm wide, so the diameter of the tip of the extension is no more than about 8 mm wide. The conical portion of the extension 18 prevents the tip of the extension from extending more than about eight millimeters into the ear canal. Beyond that depth, the patient suffers noticeable discomfort. With a field of view of less than about sixty degrees, the ear canal is viewed more than about eight millimeters from the tip of the extension 18. Thus, only the ear canal within less than 9 millimeters of the tympanic membrane is viewed as the radiation guide is directed toward the membrane. The result is a more accurate and reliable reading of the tympanic temperature which is essentially core temperature.

With the present instrument, the narrow field of view is obtained by extending the enlarged rear volume between the flake and the radiation guide. Radiation which enters the radiation guide at greater angles, yet travels through the radiation guide, leaves the guide at greater angles and is thus unlikely to be viewed by the flake. The length of the radiation guide is another parameter which affects the field of view. By using a planoconvex lens as the window 35, the field of view can be further limited.

Decreasing the field of view increases the amount of heat which is absorbed by the can in which the thermopile is mounted. The added heat load adds to the importance that the can, including the radiation guide, have a large thermal mass and high thermal conductivity as discussed below.

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As distinguished from the structure presented in the '419 patent, the volume 31 surrounding the thermopile and the radiation guide are formed of a single piece of high conductivity copper. This unitary construction eliminates any thermal barriers between the foremost end of the radiation guide and the portion of the can surrounding the thermopile which serves as the cold junction of the thermopile. Further, at least a portion of added thermal mass which surrounds the radiation guide is unitary with the can as well. Specifically, a taper 39 results in an enlarged region 41 which serves as a thermal mass in accordance with the principals of the parent application. The taper 39 continues along a conductive thermal mass 34 which surrounds the can and a conductive plug 36. Both the mass 34 and plug 36 are of copper and are in close thermal contact with the can 30.

The outer sleeve 38 of the extension 18 and the intermediate extension 20 are of plastic material of low thermal conductivity. The sleeve 38 is separated from the can 30 and thermal mass 34 by an insulating air space 40. The taper of the can 30 and thermal mass 34 permits the insulating space to the end of the extension while minimizing the thermal resistance from the end of the tube 32 to the thermopile, a parameter discussed in detail below. The inner surface of the plastic sleeve 38 may be coated with a good thermal conductor to distribute across the entire sleeve any heat received from contact with the ear. Twenty mils of copper coating would be suitable.

In contrast with the prior design, the portion of the sleeve 38 at the foremost end of extension 18 has a region 43 of constant outer diameter before a tapered region 45. The region of constant outer diameter reduces the outer diameter at the distal end and minimizes interference when pivoting the extension in the ear to view the tympanic membrane area. The tapered region is spaced six millimeters from the end of the extension to allow penetration of the extension into the ear canal by no more than about eight millimeters.

One of the design goals of the device was that it always be in proper calibration without requiring a warm-up time. This precluded the use of a heated target in a chopper unit or heating of the cold junction of the thermopile as was suggested in the O'Hara et al. U.S. Pat. No. 4,602,642. To accomplish this design goal, it is necessary that the system be able to operate with the thermopile at any of a wide range of ambient temperatures and that the thermopile output have very low sensitivity to any thermal perturbations.

The output of the thermopile is a function of the difference in temperature between its warm junction, heated by radiation, and its cold junction which is in close thermal contact with the can 30. In order that the hot junction respond only to radiation viewed through the window 35, it is important that the radiation guide 32 be, throughout a measurement, at the same temperature as the cold junction. To that end, changes in temperature in the guide 32 must be held to a minimum, and any such changes should be distributed rapidly to the cold junction to avoid any thermal gradients. To minimize temperature changes, the tube 32 and the can 30 are, of course, well insulated by means of the volume of air 40. Further, a high conductance thermal path is provided to the cold junction. This conductance is enhanced by the unitary construction. Further, the can 30 is in close thermal communication with the thermal masses 34 and 36, and the high conductivity and thickness of the thermal masses increase the thermal conductance. A high thermal conductivity epoxy, solder or the like joins the can and thermal masses. The solder or epoxy provides a significant reduction in thermal resistance. Where solder is used, to avoid damage to the thermopile which is rated to tempera-

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tures of 125° C., a low temperature solder of indium-tin alloy which flows at 100° C. is allowed to flow into the annular mass 34 to provide good thermal coupling between all elements.

The thermal resistance from the outer surface of the plastic sleeve 38 to the conductive thermal mass is high to minimize thermal perturbations to the inner thermal mass. To minimize changes in temperature of the guide 32 with any heat transfer to the can which does occur, the thermal mass of the can 30, annular mass 34 and plug 36 should be large. To minimize thermal gradients where there is some temperature change in the tube during measurement, the thermal resistance between any two points of the thermal mass should be low.

Thus, due to the large time constant of the thermal barrier, any external thermal disturbances, such as when the extension contacts skin, only reach the conductive thermal mass at extremely low levels during a measurement period of a few seconds; due to the large thermal mass of the material in contact with the cold junction, any such heat transfer only causes small changes in temperature; and due to the good thermal conductance throughout the thermal mass, any changes in temperature are distributed quickly and are reflected in the cold junction temperature quickly so that they do not affect temperature readings.

The thermal RC time constant for thermal conduction through the thermal barrier to the thermal mass and tube should be at least two orders of magnitude greater than the thermal RC time constant for the temperature response of the cold junction to heat transferred to the tube and thermal mass. The RC time constant for conduction through the thermal barrier is made large by the large thermal resistance through the thermal barrier and by the large thermal capacitance of the thermal mass. The RC time constant for response of the cold junction is made low by the low resistance path to the cold junction through the highly conductive copper can and thermal mass, and the low thermal capacitance of the stack of beryllium oxide rings and pin conductors to the thermopile.

Although the cold junction capacitance is naturally low, there are size constraints in optimizing the thermal capacitance of the thermal mass, the thermal resistance through the thermal barrier and the internal thermal resistance. Specifically, the external thermal resistance can be increased by increased radial dimensions, the capacitance of the thermal mass can be increased by increasing its size, and the thermal resistance through the longitudinal thermal path through the tube can be decreased by increasing its size. On the other hand, the size must be limited to permit the extension to be readily positioned and manipulated within the ear.

Besides the transfer of heat from the environment, another significant heat flow path to the conductive thermal mass is through leads to the system. To minimize heat transfer through that path, the leads are kept to small diameters. Further, they are embedded in the plug 36 through bores 70; thus, any heat brought into the system through those leads is quickly distributed throughout the thermal mass, and only small changes in temperature and small gradients result.

Because the temperature of the thermal mass is not controlled, and the response of the thermopile 28 is a function of its cold junction temperature, the cold junction temperature must be monitored. To that end, a thermistor is positioned at the end of a central bore 72 in the plug 36.

Another embodiment of the present invention is illustrated in FIG. 3. The radiation detector 212 employs a

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thermopile radiation sensor supported within a probe extension 218 of the opposite end of the housing 14. As shown in FIG. 4, the extension 218 extends at an angle of about 75 degrees from a first axis 219 along which the housing extends. The extension 218 is tapered along its length from its distal end, making the instrument 212 particularly useful in obtaining tympanic temperature measurements without causing the subject discomfort.

As previously discussed, the other embodiment provided an extension with a constant diameter tip which works well in ear canals of about the same diameter. However, this tip does not fit within smaller ear canals, and subjects with larger diameter ear canals will suffer discomfort as the constant diameter tip of the extension contacts the walls of their ear canals during pivoting to scan the ear canal. In accordance with the present invention, the substantially conical shaped extension 218 has an increasing diameter along a portion of its length from its distal end such that the extension may be inserted into an ear canal without causing discomfort. Once inserted, the extension 218 is pivoted to scan the ear canal adjacent to and including the tympanic membrane. The conical shape of the extension 218 ensures that the edge of the tip of the extension is unable to contact the walls of the ear canal. The thermopile 28 senses radiation within the ear canal during the pivotal rotation of the extension 218. The detector 212 employs electronics in the housing 14 for detecting the peak radiation sensed by the sensor 28 and converting it to a tympanic temperature indication. Further, the electronics may also provide an audible tone indicating that peak radiation has been detected for a particular measurement period. The variable tone or variable pulse signal allows a user to know when to stop pivoting the extension for a given subject.

The diameter of the distal tip of the probe extension as well as its taper may be selected to provide a detector useful in normal ear canals or a pediatric detector useful in small ear canals. In one configuration, as shown in FIG. 5, the extension 218 has a small diameter tip and is tapered along its length at its distal end making the extension particularly suited for insertion into small ear canals. A small ear canal is about 3-6 mm wide, so the diameter of the extension 218 along the portion of its length from its distal tip 226 is no more than about 3-6 mm. Further, the extension 218 comprises an outer sleeve 238 with a tapered portion 245 extending at a twenty degree angle from the distal tip 226. As such, the conical portion 245 of the extension has an included angle of about forty degrees. With a preferred 3.4 mm outer diameter at the tip 226 and a forty degree included angle along the conical portion 245, the extension 218 is capable of being inserted about 4 mm into a small ear canal. A young child's ear canal is about 10 mm in length, so the extension may be inserted into the child's ear canal up to about one-third of the length of the ear canal without causing discomfort.

In another configuration, indicated by dashed lines in FIG. 5, an extension 318 has a larger diameter tip and is tapered such that the extension is particularly suited for normal ear canals including adult ear canals and ear canals of older children. A normal ear canal is about 8 mm wide, and the diameter of the extension 318 about its distal tip 326 is no more than 7 mm. The tapered portion 345 of the outer sleeve extends at about a fifteen degree angle from the distal tip 326 which corresponds to a thirty degree included angle. As such, the extension 318 having a preferred tip diameter of about 5 mm is capable of being inserted about 8 mm into a normal ear canal, or about one-third of the length into the canal without causing the subject discomfort.

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Referring to FIG. 5, the extensions 218 and 318 have different profiles which were selected to minimize discomfort to the subject and to provide for accurate tympanic temperature readings. To that end, the diameter of the tip of the extensions is specified and depends on the diameter of the subject's ear canal. Further, the extensions are configured to provide a field of view of about thirty degrees which provides more accurate readings as explained below. Thus, to provide a thirty degree field of view at θ_1 , with a 3 mm inner diameter of tube 232, the length 21 from the tip 226 to the thermopile 28 is about 7.5 mm. Due to the proximity of the extension 218 to the tip (7.5 mm), the extension 218 requires the steeper taper of 20 degrees so that the thermopile assembly (not shown) fits into the extension. Also, the taper of 20 degrees provides a necessary stop in close proximity to the distal end 226 for preventing insertion of the extension 218 too far into a short ear canal so as to cause discomfort. To achieve the thirty degree field of view at θ_2 , with a tube 322 diameter of about 4.5 mm, a length of L2 of about 11 mm is required. Due to the larger diameter tip 326, the thermopile 328 is further from the tip for the same field of view so that the conical portion 345 may have a 15 degree taper. An adult canal has a flap of cartilage at the outer region of the ear (the concha). Thus, the conical portion 345 having the 15 degree taper is advantageous as it allows the extension 318 to be narrower and thus be inserted past the cartilage and extend into the ear canal.

An improved assembly within the extension 218 is shown in FIG. 4. A thermopile 28 is positioned within a thermal mass 230 formed of high thermal conductivity material such as copper. In contrast to the previous embodiment, the thermal mass 230 is a one-piece structure which mounts into a bore 233 within a portion 220 of the extension 218. Further, no contact between the thermal mass 230 and the outer sleeve 238 is made at the distal end 226 of the extension. Instead, a ridge 242 in the mass 230 contacts the sleeve 238 to achieve alignment of the mass and the distal end of the sleeve. The thermopile 28 is located in a rear volume 231 and views the tympanic membrane area through a conductive tube 232 formed in the mass 230.

Referring to FIGS. 6 and 7, the thermopile is mounted on the rear surface of a sheet of polytetrafluoroethylene 248 suspended from the rear surface of a first beryllium oxide ring 250. A mass of infrared absorbing black material 258 is positioned on the opposite surface of the sheet and serves as a radiation collector. A second beryllium oxide ring 252 supports the first ring 250 and the two rings are supported by a copper header 256. A window 235 formed of silicon or germanium is mounted on the first ring 250. The rings 250 and 252, the window 235 and the header 256 are thermally coupled by high thermal conductivity epoxy 255. A pair of leads 260 formed of 20 mils of kovar provide structural support to the assembly and provide a thermopile output signal to the electronics via a pair of 40 gauge wires 262. As such, the tube and the region defined by the surface 237 and the window 235 are filled with air. A sufficient amount of silver paint may be included within the rings to oxidize all air, and thus create a nitrogen environment in the gas tight region. Alternatively, the window may be positioned at the distal end 226 of the housing 218 as indicated by the dashed lines in FIG. 4. Having the window positioned directly on the sensor assembly minimizes temperature gradients between the window and thermopile, but positioning the window at the distal end minimizes contamination of the surface of tube 232.

It has been determined that a significantly narrower field of view provides the user with an easier and more accurate

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tympanic temperature indications. The detector disclosed in the '419 patent had a wide field of view of about 120° and the detectors disclosed in the '813 patent and described in the other embodiment have a field of view of about 60° or less. Thus, one object of this embodiment was to reduce the field of view to obtain a narrower field of view of about thirty degrees or less. To that end, the narrower field of view is obtained by plating the inner surface of the tube 232 with a layer of non-reflective material. Preferably, the non-reflective layer is a metal oxide such as nickel oxide or aluminum oxide. A metal oxide layer is employed because metal oxides are durable and will not change in properties if the inner surface of the tube is cleaned. Further, the metal oxide layer should be thin (a few tenths of thousandths of an inch) such that virtually no temperature gradient exists across the layer. The metal oxide surface absorbs substantially all radiation which strikes the tube 232 and allows radiation passing directly through the tube to reach the thermopile 28.

The dimensions of the tube 232 are chosen such that radiation entering the tube at angles of only up to fifteen degrees from the longitudinal axis of the tube passes directly to the thermopile. With the thirty degree field of view, the probe can easily be positioned such that substantially only the tympanic membrane may be viewed.

The above approach to decreasing the radiation gathering aperture size to about 3 mm and reducing the field of view to about thirty degrees significantly increases the noise level at the thermopile relative to the signal level. Further, this approach increases the amount of radiation which is absorbed by the thermal mass in which the thermopile is mounted. These two effects add to the importance that the thermal mass, including the tube, provide a large thermal mass and high thermal conductivity.

The thermal mass 230 is of unitary construction which eliminates thermal barriers between the tube 232 and the portion 241 of the thermal mass surrounding the thermopile 28. Further, a plug 272 of high thermal conductivity material positioned behind the thermopile 28 is in close thermal contact with the mass 230. The outer sleeve 238 is formed of low thermal conductivity plastic and is separated from the mass 230 by an insulating air space 240. The taper 239 of the mass 230 increases the insulating air space adjacent to the end of the extension 226 while minimizing thermal resistance from the tube 232 to the thermopile. The inner surface of the plastic sleeve 238 may be coated with a good thermal conductor to distribute across the entire sleeve any heat received from contact with the ear.

In order that the hot junction respond only to radiation viewed through the window 235, it is important that the tube 232 and the window 235 be, throughout a measurement, at the same temperature as the cold junction. The thermopile 28 acts as a thermal amplifier having a gain based on the number of junctions and the Seebeck coefficient. Thus, temperature gradients sensed by the thermopile are amplified by a factor of about 100. To minimize errors, changes in temperature in the tube 232 must be held to a minimum, and any such changes should be distributed rapidly to the cold junction to avoid any thermal gradients. To minimize temperature changes, the tube 232 and the mass 230 are well insulated by means of the volume of air 240. To avoid thermal gradients, the tube 232 is plated with a thin layer of high conductance non-reflectance metal oxide which minimizes temperature gradients across the layer. Further, the thermal mass 230 is thermally coupled to the rings 250 and 252 with high conductivity thermal epoxy 255 such that a high conductance thermal path is provided from the tube 232

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to the cold junction. This conductance is enhanced by the unitary construction of the mass 230.

In accordance with another aspect of the invention, the amount of thermal epoxy 255 between the rings 250 and 252 and the mass 230 is tuned to the assembly to minimize the response of the thermopile 28 to undesired thermal perturbations at the end of the mass. Referring to FIG. 6, thermal variations in the air region 243 lead to heating of the tip 227 of the mass 230 which causes the inner surface of the tube 232 to emit radiation. If these thermal variations are not sensed by the cold junction via the high conductance thermal path from the tube 232 in phase with the sensing of the radiation by the hot junction, the thermopile 28 produces an error response.

Accordingly, the epoxy 255 may be incrementally added to adjust the high conductivity thermal path to the cold junction to bring the hot and cold junction thermal responses in phase. An insufficient amount of epoxy 255 causes a positive error response as the hot junction responds to thermal variations faster than the cold junction. Alternatively, too much epoxy 255 causes a negative error response as the cold junction responds faster to thermal variations than the hot junction. When the proper amount of epoxy has been provided, the tuned assembly produces no more than 0.1° thermopile response for up to 20° thermal variations during a test.

It has been determined in previous devices that a significant source of thermal gradients is caused by radiation from the window. To minimize these thermal gradients, the window 235 is mounted on the ring 250 with high thermal conductivity epoxy 255 such that it is thermally coupled to the cold junction. The epoxy provides a significant reduction in thermal resistance and provides good thermal coupling between all elements. On the other hand, conductance to the viewing region of the window should not be less than that to the cold junction. Thus, the window 235 is spaced from a rear face 237 of the mass 230 and its ends are spaced from the inner volume 231 by a low thermal conductivity air region. The region ensures that temperature gradients are distributed to the cold junction via the thermal mass and not directly through the window causing thermal gradients.

The thermal resistance from the outer surface of the plastic sleeve 238 to the conductive thermal mass 230 is high to minimize thermal perturbations to the inner thermal mass. The thermal mass is large to minimize changes in temperature of the tube 232 with any heat transfer to the mass which does occur. Further, the thermal resistance between any two points of the thermal mass 230, the tube 232, the window 235 or the rings 250 and 252 is low to minimize thermal gradients where there is some temperature change in the tube during measurement.

Thus, due to the large time constant of the thermal barrier 238, any external thermal disturbances, such as when the extension contacts skin, only reach the conductive thermal mass 230 at extremely low levels during a measurement period of a few seconds. Due to the large thermal mass of the materials in contact with the cold junction, any such heat transfer only causes small changes in temperature. Also, due to the good thermal conductance throughout the thermal mass, tube, window and rings any changes in temperature are distributed quickly and are reflected in the cold junction temperature quickly so that they do not affect temperature readings.

The thermal RC time constant for thermal conduction through the thermal barrier 238 to the thermal mass 230 and tube 232 is at least two orders of magnitude greater than the

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thermal RC time constant for the temperature response of the cold junction to heat transferred to the tube and thermal mass. The RC time constant for conduction through the thermal barrier 238 is made large by the large thermal resistance through the thermal barrier and by the large thermal capacitance of the thermal mass. The RC time constant for response of the cold junction is made low by the low resistance path to the cold junction through the highly conductive thermal mass, and the low thermal capacitance of the stack of beryllium oxide rings to the thermopile.

Besides the transfer of heat from the environment, another significant heat flow path in the system is through the leads 260. To minimize heat transfer through that path, the lead diameters are kept small and the leads 260 are trimmed off in the region 246. A pair of 40 gauge wires 262 are soldered to the shortened leads 260. The wires 262 extend from the region 246 through the plug 272 and provide thermopile signals to the electronics.

Yet another potential heat flow path in the system is through the header 256 to the plug 272. Since the header is in close thermal contact with the thermopile cold junction, any thermal gradients through the header 256 would be amplified 100 to 1000 times by the thermopile producing large error signals. In the present invention, the insulating region 246 of air is provided behind the header 256 to minimize heat transfer through that path. Thus, any thermal gradients in the plug would be forced to travel through the mass 230 and would be substantially dissipated without affecting the thermopile.

Because the temperature of the thermal mass 230 is not controlled and the response of the thermopile 28 is a function of its cold junction temperature, the cold junction temperature must be monitored. To that end, a thermistor 271 is positioned adjacent to the region 246 in the plug 272. The plug 272 is in thermal contact with the mass 230 such that the thermistor 271 is thermally coupled to the cold junction of the thermopile 28. However, the thermal path between the thermopile 28 and the thermistor has some thermal resistance. This resistance produces a temperature difference between the cold junction temperature and the sensed temperature which is not amplified. Therefore such error is not as significant as gradient errors amplified by the thermopile.

A schematic illustration of the electronics in the housing 14 of both embodiments of the present invention (FIGS. 1 and 3), for providing a temperature readout on display 16 in response to the signal from the thermopile, is presented in FIG. 8. The system is based on a microprocessor 73 which processes software routines included in read only memory within the processor chip. The processor may be a 6805 processor sold by Motorola.

The voltage generated across the thermopile 28 due to a temperature differential between the hot and cold junctions is amplified in an operational amplifier 74. For the detector of FIG. 1, the chopper circuit 67 is not employed and analog output from the amplifier 74 is applied as one input to a multiplexer 76. For the detector of FIG. 3, the thermopile output voltage is smaller so the amplifier 74 is configured in the chopper stabilized amplifier circuit 67. The circuit employs a switched feedback loop that removes internal offset voltages associated with the amplifier 74. The feedback loop comprises switches 69 and 71, an amplifier 73 and a storage capacitor C11. When the radiation detector is powered on, switch 69 is opened and switch 71 is closed. With this configuration, the feedback loop stores the offset voltage for the amplifier 74 in capacitor C11. The switch

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positions are then reversed such that the input signal to amplifier 74 is combined with the offset stored in the capacitor C11. The combined output is applied an input to the multiplexer 76.

Another input to the multiplexer 76 is a voltage taken from a voltage divider R1, R2 which is indicative of the potential V+ from the power supply 78. A third input to the multiplexer 76 is the potential across a thermistor RT1 mounted in the bore 72 of block 36. The thermistor RT1 is coupled in a voltage divider circuit with R3 across a reference potential VRef. The final input to the multiplexer is a potential taken from a potentiometer R4 which may be adjusted by a user. The system may be programmed to respond to that input in any of a number of way. In particular, the potentiometer may be used as a gain control or as a DC offset control.

At any time during the software routine of the microprocessor 73, one of the four inputs may be selected by the select lines 78. The selected analog signal is applied to a multiple slope analog system 80 used by the microprocessor in an integrating analog-to-digital conversion 80. The subsystem 80 may be a TSC500A sold by Teledyne. It utilizes the reference voltage VRef from a reference source 82. The microprocessor 73 responds to the output from the converter 80 to generate a count indicative of the analog input to the converter.

The microprocessor drives four 7-segment LED displays 82 in a multiplexed fashion. Individual displays are selected sequentially through a column driver 84, and within each selected display the seven segments are controlled through segment drivers 86.

When the switch 22 on the housing is pressed, it closes the circuit from the battery 78 through resistors R5 and R6 and diode D1 to ground. The capacitor C1 is quickly charged, and field effect transistor T1 is turned on. Through transistor T1, the V+ potential from the storage cell 78 is applied to a voltage regulator 86. The regulator 86 provides the regulated +5 volts to the system. It also provides a reset signal to the microprocessor. The reset signal is low until the +5 volt reference is available and thus holds the microprocessor in a reset state. When the +5 volts is available, the reset signal goes high, and the microprocessor begins its programmed routine.

When the switch 22 is released, it opens its circuit, but a charge is maintained on capacitor C1 to keep transistor T1 on. Thus, the system continues to operate. However, the capacitor C1 and transistor T1 provide a very simple watchdog circuit. Periodically, the microprocessor applies a signal through driver 84 to the capacitor C1 to recharge the capacitor and thus keep the transistor T1 on. If the microprocessor should fail to continue its programmed routine, it fails to charge the capacitor C1 within a predetermined time during which the charge on C1 leaks to a level at which transistor T1 turns off. Thus, the microprocessor must continue in its programmed routine or the system shuts down. This prevents spurious readings when the processor is not operating properly.

With transistor T1 on, the switch 22 can be used as an input through diode D2 to the microprocessor to initiate any programmed action of the processor.

In addition to the display, the system has a sound output 90 which is driven through the driver 84 by the microprocessor.

In order to provide an analog output from the detector, a digital-to-analog converter 92 is provided. When selected by line 94, the converter converts serial data on line 96 to an analog output made available to a user.

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Both calibration and characterization data required for processing by the microprocessor may be stored in an electrically erasable programmable read only memory (EEPROM) 100. The EEPROM may, for example, be a 93c46 sold by International CMOS Technologies, Inc. The data may be stored in the EEPROM by the microprocessor when the EEPROM is selected by line 102. Once stored in the EEPROM, the data is retained even after power down. Thus, though electrically programmable, once programmed the EEPROM serves as a virtually nonvolatile memory.

Prior to shipment, the EEPROM may be programmed through the microprocessor to store calibration data for calibrating the thermistor and thermopile. Further, characterization data which defines the personality of the infrared detector may be stored. For example, the same electronics hardware, including the microprocessor 73 and its internal program, may be used for a tympanic temperature detector in which the output is accurate in the target temperature range of about 60° F. to a 110° F. or it may be used as an industrial detector in which the target temperature range would be from about -100° F. to 5000° F. Further, different modes of operation may be programmed into the system. For example, several different uses of the sound source 90 are available.

Proper calibration of the detector is readily determined and the EEPROM is readily programmed by means of an optical communication link which includes a transistor T2 associated with the display. A communication boot may be placed over the end of the detector during a calibration/characterization procedure. A photodiode in the boot generates a digitally encoded optical signal which is filtered and applied to the detector T2 to provide an input to the microprocessor 73. In a reverse direction, the microprocessor may communicate optically to a detector in the boot by flashing specific segments of the digital display 82. Through that communication link, an outside computer 106 can monitor the outputs from the thermistor and thermopile and perform a calibration of the devices. A unit to be calibrated is pointed at each of two black body radiation sources while the microprocessor 73 converts the signals and sends the values to the external computer. The computer is provided with the actual black body temperatures and ambient temperature in the controlled environment of the detector, computes calibration variables and returns those variable to be stored in the detector EEPROM. Similarly, data which characterizes a particular radiation detector may be communicated to the microprocessor for storage in the EEPROM.

A switch 108 is positioned behind a hole 110 (FIG. 1) in the radiation detector so that it may be actuated by a rigid metal wire or pin. Through that switch, the user may control some specific mode of operation such as converting the detector from degrees Fahrenheit to degrees centigrade. That mode of operation may be stored by the microprocessor 73 in the EEPROM so that the detector continues to operate in a specific mode until a change is indicated by closing the switch 108.

A switch 106 may be provided either internally or through the housing to the user to set a mode of operation of the detector. By positioning the switch at either the lock position, the scan position or a neutral position, any of three modes may be selected. The first mode is the normal scan mode where the display is updated continuously. A second mode is a lock mode where the display locks after a selectable delay and then remains frozen until power is cycled or, optionally, the power-on button is pushed. The sound source may be caused to sound at the time of lock. The third mode is the peak mode where the display reads the

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maximum value found since power-on until power is cycled or, optionally, the power-on button is pushed.

The processor determines when the voltage from the divider R1, R2 drops below each of two thresholds. Below the higher threshold, the processor periodically enables the sound source to indicate that the battery is low and should be replaced but allows continued readout from the display. Below the lower threshold, the processor determines that any output would be unreliable and no longer displays temperature readings. The unit would then shut down upon release of the power button.

In the present system, the target temperature is computed from the relationship

$$T_T = Kh(H - H_o) + T_H \quad (1)$$

where T_T is the target temperature. Kh is a gain calibration factor, H is the radiation sensor signal which is offset by H_o such that $(H - H_o) = 0$ when the target is at the cold junction temperature of the device to counter any electronic offsets in the system, and T_H is the hot junction temperature. This relationship differs from that previously used in that Kh is temperature compensated relative to the average temperature of the thermopile rather than the cold junction, or ambient, temperature. Further, the hot junction temperature rather than the cold junction temperature is referenced in the relationship.

The gain calibration factor Kh is temperature compensated by the relationship

$$Kh = G \left(1 - T_{co} \left(\frac{T_H - T_C}{2} - T_z \right) \right) \quad (2)$$

where G is an empirically determined gain in the system, T_{co} is the temperature coefficient of the Seebeck coefficient of the thermopile and T_z is the temperature at which the instrument was calibrated. The use of the average temperature of the thermopile rather than the cold junction temperature provides for a much more accurate response where a target temperature is significantly different from the ambient temperature.

As noted, the relationship by which the target temperature is determined includes the hot junction temperature as the second term rather than the cold junction temperature. Hot junction temperature is computed from the relationship

$$V_S = J_N \alpha_{av} (T_H - T_C) \quad (3)$$

where J_N is the number of junctions in the thermopile and α_{av} is the specified Seebeck coefficient at the average temperature of the thermopile. The Seebeck coefficient can be determined from the relationship

$$\alpha_{av} = \alpha_w \left(1 - T_{co} \left(\frac{T_H - T_C}{2} - T_S \right) \right) \quad (4)$$

where α_w is the specified Seebeck coefficient at a particular specification temperature and T_S is that specification temperature. Again, it can be seen that temperature compensation is based on the average thermopile temperature rather than just the cold junction temperature. By substituting equation (4) into equation (3) and solving for T_H , the hot junction temperature is found to be

$$T_H = \frac{(T_{co} * T_S + 1) \pm \sqrt{(T_{co} * T_S + 1)^2 - (2 * T_{co}) * [(T_{co} * (T_C - T_S)) - (T_C^2 / 2)] + T_C}}{(V_S / J_N \alpha_w) / T_{co}} \quad (5)$$

The actual sensor output V_S can be determined from the digital value available to the processor from the equation:

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$$V_s = (H - H_o) \frac{K_{AD}}{G_{FE}} \tag{6}$$

where K_{AD} is the analog-to-digital conversion factor in volts/bit and G_{FE} is the gain of the front end amplifier.

Reference to the hot junction temperature rather than the cold junction temperature in each term of the relationship for determining the target temperature provides for much greater accuracy over a wide range of ambient temperatures and/or target temperatures.

To provide a temperature readout, the microprocessor makes the following computations: First the signal from thermistor RT1 is converted to temperature using a linear approximation. Temperature is defined by a set of linear equations

$$y = M(x - x_o) + b$$

where x is an input and x_o is an input end point of a straight line approximation. The values of M , x_o and b are stored in the EEPROM after calibration. Thus, to obtain a temperature reading from the thermistor, the microprocessor determines from the values of x_o the line segment in which the temperature falls and then performs the computation for y based on the variables M and b stored in the EEPROM.

The hot junction temperature is computed. A fourth power representation of the hot junction temperature is then obtained by a lookup table in the processor ROM.

The sensed radiation may be corrected using the gain calibration factor K_h , the sensor gain temperature coefficient T_{co} , the average of the hot and cold junction temperatures and a calibration temperature T_z stored in the EEPROM. The corrected radiation signal and the fourth power of the hot junction temperature are summed, and the fourth root is taken. The fourth root calculation is also based on a linear approximation which is selected according to the temperature range of interest for a particular unit. Again, the break points and coefficients for each linear approximation are stored in the EEPROM and are selected as required.

An additional factor based on ambient temperature may also be included as an adjustment. The temperature of the ear T_e is sensed instead of the temperature of the tympanic membrane, the temperature sensed by the thermopile is not actually the core temperature T_{cr} . There is thermal resistance between T_{cr} and T_e . Further, there is thermal resistance between the sensed ear temperature and the ambient temperature. The result is a sense temperature T_s which is a function of the core temperature of interest and the ambient temperature. Based on an assumed constant K_c which is a measure of the ratio of thermal resistances between T_{cr} , T_e and T_a , T_{cr} and T_a core temperature can be computed as

$$T_{cr} = T_a + \frac{T_s - T_a}{K_c}$$

This computation can account for a difference of from one-half to one degree or more between core temperature and sensed ear temperature, depending on ambient temperature.

A similar compensation can be made in other applications. For example, in differential cutaneous temperature scanning, the significance of a given differential reading may be ambient temperature dependent.

The actual computations performed by the processor are as follows, where:

H is the digital value of radiation signal presented to the processor

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- H_o is the electronic offset
- H_c is corrected H (deg K^4)
- T_c is ambient and cold junction temperature (deg F)
- T_{af} is 4th power of T_{amb} (deg K^4)
- T_t is target temperature (deg F)
- T_z is ambient temp during cal (deg F)
- T_d is the displayed temperature
- R_t is the thermistor signal
- K_h is a radiation sensor gain cal factor
- Z_t is a thermistor zero cal factor
- T_h is the hot junction temperature
- α_{se} is the Seebeck coefficient of the thermopile at a specified temperature
- J is the number of junctions in the thermopile
- T_{co} is a temperature coefficient for the Seebeck coefficient
- T_s is the temperature at which α_{se} is specified
- T_{cr} is core temperature
- k_c is a constant for computing core temperature
- V_s is the sensor output voltage
- G_{FE} is the gain of the front end amplifier
- K_{AD} is the analog-to-digital conversion factor
- $V_s = (H - H_o) K_{AD} / G_{FE}$
- T_c (deg F) = Thermistor lookup table (R_t) - Z_t

$$T_H = [(T_{co} * T_s + 1) \pm (T_{co} * T_s + 1)^2 - (2 * T_{co}) * (T_{co} * (T_c * T_s) - (T_c^2 / 2)) + T_c + (V_s / J * \alpha_{se})]^{1/2} / T_{co}$$

- H_c (deg K^4) = $K_h * (H - H_o) * (1 + T_{co} * ((T_h - T_c) / 2 - T_z))$
- T_{hf} (deg K^4) = 4th power lookup table (T_c)
- T_t (deg F) = $(H_c + T_{hf})^{1/4}$ (Final lookup table)
- $T_{cr} = T_c + (T_t - T_c) / k_c$
- T_t (deg C) = $(5/9) * (T_t$ (deg F) - 32) optional

The following is a list of the information which may be contained in the EEPROM and therefore be programmable at the time of calibration:

-
- Radiation sensor offset
 - Radiation sensor gain
 - Radiation sensor temperature coefficient
 - Thermistor offset
 - Ambient temperature at calibration
 - Thermistor lookup table
 - Final temperature lookup table
 - Adjustment factor F
 - Sound source functions:
 - Beep at button push in lock mode
none/20/40/80 milliseconds long
 - Beep at lock
none/20/40/80 milliseconds long
 - Beep at power down
none/20/40/80 milliseconds long
 - Beep at low battery
none/20/40/80 milliseconds long
 - interval 1/2/3 sec
 - single/double beep
 - Timeout functions:
 - Time to power-down
.5 to 128 sec in .5 sec increments
 - Delay until lock
.5 to 128 sec in .5 sec increments
 - Other functions:
 - Power-on button resets lock cycle
 - Power-on button resets peak detect

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-continued

Display degrees C./degrees F.
EEPROM "Calibrated" pattern to indicate
that the device has been calibrated
EEPROM checksum for a self-check by the
processor

FIGS. 9A-9D provide a flowchart of the firmware stored in the microprocessor 73. From reset when the instrument is turned on, the system is initialized at 110 and the contents of the EEPROM are read into memory in the microprocessor at 112. At 114, the processor reads the state of power and mode switches in the system. At 116, the system determines whether a mode switch 113 has placed the system in a self-test mode. If not, all eights are displayed on the four-digit display 82 for a brief time. At 120, the system performs all A-to-D conversions to obtain digital representations of the thermopile output and the potentiometer settings through multiplexor 76.

The system then enters a loop in which outputs dictated by the mode switch are maintained. First the timers are updated at 122 and the switches are again read at 124. When the power is switched off, from 126 the system enters a power down loop at 128 until the system is fully down. At 130, the mode switch is checked and if changed the system is reset. Although not in the tympanic temperature detector, some detectors have a mode switch available to the user so that the mode of operation can be changed within a loop.

At 132, 136 and 140, the system determines its mode of operation and enters the appropriate scan process 134, lock process 138 or peak process 142. In a scan process, the system updates the output to the current reading in each loop. In a lock process, the system updates the output but locks onto an output after some period of time. In the peak process, the system output is the highest indication noted during a scan. In each of these processes, the system may respond to the programming from the EEPROM to perform any number of functions as discussed above. In the peak process which is selected for the tympanic temperature measurement, the system locks onto a peak measurement after a preset period of time. During assembly, the system may be set at a test mode 144 which will be described with respect to FIG. 9D.

In any of the above-mentioned modes, an output is calculated at 146. Then the system loops back to step 122. The calculation 146 is illustrated in FIG. 9B.

At 148 in FIG. 9B, the raw sensor data is obtained from memory. The sensor offset taken from the EEPROM is subtracted at 150, and the ambient temperature previously obtained from the potentiometer RT1 is accessed at 152. The temperature coefficient adjustment is calculated at 154. At 156, the sensed signal is multiplied by the gain from EEPROM and by the temperature coefficient. At 158, the fourth power of the ambient temperature is obtained, and at 160 it is added to the sensor signal. At 162, the fourth root of the sum is obtained through a lookup table. Whether the display is in degrees centigrade or degrees Fahrenheit is determined at 164. If in degrees centigrade, a conversion is performed at 166. At 168, adjustment values, including that from the potentiometer R4, are added.

Analog-to-Digital conversion is performed periodically during an interrupt to the loop of FIG. 9A which occurs every two milliseconds. The interrupt routine is illustrated in FIG. 9C. Timer counters are updated at 170. A-to-D conversions are made from 172 only every 100 milliseconds when a flag has been set in the prior interrupt cycle. During most interrupts, an A/D conversion does not occur. Then, the

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100-millisecond counter is checked at 174, and if the count has expired, a flag is set at 176 for the next interrupt. The flag is checked at 178 and, if found, the display is updated at 180. The system then returns to the main loop of FIG. 9A.

Where the 100 millisecond flag is noted at 172, an A-to-D conversion is to be performed. The system first determines at 182 whether a count indicates there should be a conversion of the thermopile output at 184 or a conversion of the thermistor output at 186. The thermopile sensor conversion is performed nine out of ten cycles through the conversion loop. At 188, the system checks to determine whether a conversion is made from the potentiometer R4 or from the battery voltage divider R1, R2 at 192. These conversions are made alternately.

FIG. 9D illustrates the self-test sequence which is called by the mode switch 113 only during assembly. During the test, the beeper sounds at 182 and all display segments are displayed at 184. Then the system steps each character of the display from zero through nine at 186. The system then enters a test loop. At 188, the system senses whether the button 108 has been pressed. If so, a display counter is incremented at 190. The display for the unit then depends on the count of the display counter. With the zero count, the adjustment potentiometer value is displayed at 192. Thereafter, if the display counter is incremented by pressing the button 108, the raw sensor data is displayed. With the next increment, ambient temperature is displayed at 196, and with the next increment, the raw output from the ambient temperature sensor RT1 is displayed. With the next increment, the battery voltage is displayed. After the test, the assembler sets the mode switch to the proper operating mode.

While this invention has been particularly shown and described with references to preferred embodiments thereof, it will be understood by those skilled in the art that various changes in form and details may be made therein without departing from the spirit and scope of the invention as defined by the appended claims. For example, most features of the invention may be applied to a device having a pyroelectric radiation sensor. Also certain features such as the low reflectance, high thermal conductivity tube may provide stable response and narrow field of view even where the tube is thermally isolated from the sensor. In that case, a second temperature sensor would be provided for the tube to compensate for temperature differences between the tube and sensor cold junction.

What is claimed is:

1. An ear temperature detector comprising:
 - a housing adapted to be held by hand;
 - an extension from the housing having a distal end adapted to be inserted into an ear, the extension supporting a tube for directing radiation from an ear to a radiation sensor, the tube having a rigid window at an end thereof away from the radiation sensor;
 - a temperature display on the housing for displaying ear temperature; and
 - battery powered electronics in the housing for converting radiation sensed by the sensor to temperature displayed by the display.
2. An ear temperature detector as claimed in claim 1 wherein the radiation sensor is a thermopile, a cold junction of which is allowed to follow ambient temperature.
3. An ear temperature detector as claimed in claim 1 wherein the rigid window comprises germanium.
4. An ear temperature detector as claimed in claim 1 wherein the extension extends at an angle from the housing.
5. An ear temperature detector as claimed in claim 4 wherein the housing extends along a first axis and the extension extends at an angle of about 75 degrees from the first axis.

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6. An ear temperature detector as claimed in claim 1 wherein the extension increases in diameter along a length from its distal end and has a diameter at the distal end such that the extension is adapted to be inserted into an ear canal.

7. An ear temperature detector as claimed in claim 1 wherein the extension has a substantially constant diameter along a first portion of its length from its distal end and an increasing diameter along a second portion of its length following the first portion such that the extension is adapted to be inserted into an ear canal.

8. An ear temperature detector as claimed in claim 1 wherein the extension has a diameter of less than about 7 mm along a portion of its length from its distal end, the extension forming a substantially conical shape along said portion of its length, the conical shape further including an included angle of about 25–60 degrees such that the extension is adapted to be inserted into a normal ear canal up to about one-third of the length of the ear canal.

9. An ear temperature detector as claimed in claim 1 wherein the extension has a diameter of about 3–6 mm along a portion of its length from its distal end, the extension forming a substantially conical shape along said portion of its length, the conical shape further including an included angle of about 25–60 degrees such that the extension is adapted to be inserted into a small ear canal up to about one-third of the length of the ear canal.

10. An ear temperature detector comprising:

an infrared radiation sensor with an active area influenced by radiation from an external target and a reference area having a known reference temperature and being substantially unaffected by said radiation, the radiation sensor being mounted within a thermal mass and having its reference area within the thermal mass and thermally coupled to the thermal mass;

a thermally conductive tube coupled to the thermal mass for passing thermal radiation from an external target to the radiation sensor;

a thermal barrier surrounding the thermal mass and tube; and

an outer thermal RC time constant for thermal conduction through the thermal barrier to the thermal mass and tube being at least two orders of magnitude greater than an inner thermal RC time constant for the temperature response of the radiation sensor reference area to heat transferred to the tube and thermal mass through the thermal barrier.

11. An ear temperature detector as claimed in claim 10 wherein the outer RC time constant is at least three orders of magnitude greater than the inner RC time constant.

12. An ear temperature detector as claimed in claim 10 wherein the tube comprises a non-reflective inner surface for preventing radiation incapable of passing directly through the tube from being provided to the radiation sensor.

13. An ear temperature detector as claimed in claim 12 wherein the non-reflective inner surface of the tube is formed of metal oxide.

14. An ear temperature detector as claimed in claim 10 wherein the tube provides a narrow field of view from the radiation sensor of about sixty degrees or less.

15. An ear temperature detector as claimed in claim 10 wherein the tube provides a field of view from the radiation sensor of about thirty degrees or less.

16. An ear temperature detector as claimed in claim 10 wherein the radiation sensor is a thermopile.

17. An ear temperature detector comprising:

a housing adapted to be held by hand;

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an extension from the housing having a distal end adapted to be inserted into an ear and supporting a tube for directing radiation to a radiation sensor from the ear, the tube having a rigid window at an end thereof away from the radiation sensor, the extension increasing in diameter along a portion of its length from its distal end;

a temperature display on the housing for displaying ear temperature; and

battery powered electronics in the housing for converting radiation sensed by the sensor to temperature displayed by the display.

18. An ear temperature detector as claimed in claim 17 wherein the extension has a substantially constant diameter along a portion of its length from its distal end preceding the portion of the extension increasing in diameter.

19. An ear temperature detector as claimed in claim 17 wherein the extension forms a substantially conical shape along said portion of its length, the conical shape further including an included angle of about 25–60 degrees.

20. A tympanic temperature detector as claimed in claim 19 wherein the extension has a diameter of about 3–6 mm along a portion of its length from its distal end such that the extension is adapted to be inserted into a small ear canal up to about one-third of the length of the ear canal.

21. An ear temperature detector as claimed in claim 17 wherein the extension has a diameter of less than about 8 mm along a portion of its length from its distal end such that the extension is adapted to be inserted into a normal ear canal up to about one-third of the length of the ear canal.

22. An ear temperature detector as claimed in claim 17 wherein the extension comprises an elongated tube formed of high thermal conductivity material extending from the distal end of the extension to a rear volume in which the radiation sensor is mounted, the tube providing a field of view from the thermopile of about sixty degrees or less.

23. An ear temperature detector comprising:

a thermopile mounted within a rigid structure and having a junction thermally coupled to the rigid structure;

a thermally conductive tube and a window for passing thermal radiation from an external target to the thermopile; and

a thermal mass of high thermal conductivity material surrounding the tube and enclosing the rigid structure in a rear volume, the thermal mass being thermally coupled to the tube, the rigid structure, a junction of the thermopile and the window.

24. An ear temperature detector as claimed in claim 23 wherein the tube provides a narrow field of view of about thirty degrees or less.

25. An ear temperature detector as claimed in claim 23 further comprising an extension surrounding the tube and having a distal end adapted to be inserted into an ear canal.

26. An ear temperature detector as claimed in claim 23 wherein the tube is positioned in an extension which has a diameter of about 3–6 mm along a portion of its length extending from a distal end, the extension having a substantially conical shape along a portion of its distal end, the conical shape further including an included angle of about 25–60 degrees such that the extension is adapted to be inserted into a small ear canal.

27. A method of obtaining ear temperature comprising: providing a radiation detector comprising an extension for passing infrared radiation from an external target to a sensor, the detector further comprising electronics for detecting the peak radiation sensed by the sensor;

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inserting the extension into an ear;
 pivoting the extension to scan the ear canal, the sensor
 sensing radiation during scanning; and
 in the electronics detecting the peak radiation to obtain an
 ear temperature. 5

28. An ear temperature detector comprising:
 a housing adapted to be held by hand;
 an extension from the housing adapted to be inserted into
 an ear, the extension passing radiation from the ear to
 a radiation sensor; 10
 a temperature display on the housing for displaying ear
 temperature; and
 electronics in the housing for converting radiation sensed
 by the sensor to temperature displayed by the display,
 the electronics including a radiation peak detector such
 that a peak temperature is displayed with scanning of
 the extension in an ear. 15

29. A radiation detector comprising: 20
 an infrared radiation sensor; and
 an extended tube having a gas-tight window at a distal end
 thereof through which radiation passes to the sensor, a
 sealed gaseous environment being maintained through
 the length of the tube. 25

30. A radiation detector comprising:
 an infrared radiation sensor; and
 an extended tube having a rigid window at a distal end
 thereof through which radiation passes to the sensor. 30

31. A radiation sensor as claimed in claim 30 wherein the
 window maintains a sealed gaseous environment through the
 length of the tube.

32. A radiation sensor as claimed in claim 31 wherein the
 sealed gaseous environment through the length of the tube
 surrounds the infrared radiation sensor. 35

33. A radiation sensor as claimed in claim 30 wherein the
 window comprises germanium.

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34. A radiation detector comprising:
 a radiation sensor; and
 a can enclosing the radiation sensor, the can having an
 aperture through which the radiation sensor views a
 target along a viewing axis, the aperture being sur-
 rounded by a surface angled toward the viewing axis
 such that the surface faces the radiation sensor.

35. A radiation detector as claimed in claim 34 further
 comprising a tube directing radiation to the aperture.

36. A temperature detector comprising:
 a radiation sensor mounted to view a target;
 a temperature sensor for sensing ambient temperature;
 an electronic circuit coupled to the radiation sensor and
 temperature sensor and responsive to a signal from the
 radiation sensor and the temperature sensed by the
 temperature sensor to provide an indication of an
 internal temperature of the target adjusted for the
 ambient temperature to which the target is exposed; and
 an output for providing an indication of the internal
 temperature.

37. A temperature detector as claimed in claim 36 adapted
 to sense radiation from an ear.

38. A method of obtaining ear temperature comprising:
 providing a radiation detector comprising an extension
 through which an infrared radiation sensor receives
 radiation from an external target, the detector further
 comprising electronics for detecting the peak radiation
 sensed by the sensor;
 inserting the extension into an ear;
 scanning the ear canal, the sensor sensing radiation during
 scanning; and
 detecting the peak radiation to obtain an ear temperature
 in the electronics.

39. A method as claimed in claim 38 wherein the external
 target is scanned by pivoting the extension to scan the ear
 canal.

* * * * *

United States Patent [19]

[11] **Patent Number:** 6,047,205

Pompei

[45] **Date of Patent:** *Apr. 4, 2000

[54] **RADIATION DETECTOR PROBE**

[75] **Inventor:** Francesco Pompei, Boston, Mass.

[73] **Assignee:** Exergen Corporation, Watertown, Mass.

[*] **Notice:** This patent is subject to a terminal disclaimer.

[21] **Appl. No.:** 08/682,260

[22] **Filed:** Jul. 17, 1996

Related U.S. Application Data

[63] Continuation of application No. 08/333,205, Nov. 2, 1994, which is a continuation-in-part of application No. 07/832,109, Feb. 6, 1992, Pat. No. 5,325,863, and a continuation-in-part of application No. 07/889,052, May 22, 1992, Pat. No. 5,381,796, and a continuation-in-part of application No. 07/760,006, Sep. 13, 1991, Pat. No. 5,445,158, which is a continuation-in-part of application No. 07/646,855, Jan. 28, 1991, Pat. No. 5,199,436, which is a division of application No. 07/338,968, Apr. 14, 1989, Pat. No. 5,012,813, which is a continuation of application No. 07/280,546, Dec. 6, 1988, Pat. No. 4,993,419.

[51] **Int. Cl.** 7 **A61B 6/00**
 [52] **U.S. Cl.** 600/474; 374/121; 600/549
 [58] **Field of Search** 128/736, 738,
 128/664; 374/121, 130-1, 116

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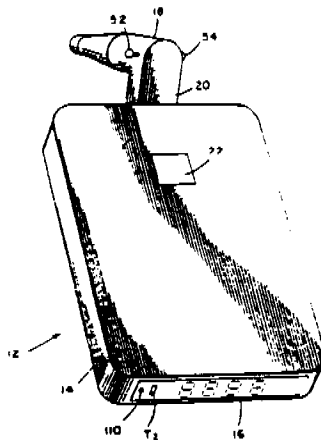
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Primary Examiner—John P. Lacy
Attorney, Agent, or Firm—Hamilton, Brook, Smith & Reynolds, P.C

[57] **ABSTRACT**

Tympanic temperature measurements are obtained from the output of a radiation sensor mounted in an extension from a housing. The housing has a temperature display and supports electronics for responding to sensed radiation. The sensor is mounted in an improved extension which is shaped to fit into smaller ear canals, such as a child's ear canal or a swollen adult ear canal. Within the extension, the sensor is positioned in a highly conductive environment and receives radiation from an external target through a tube. Electronics determine the target temperature based on the sensor output signal and a temperature sensor signal.

5 Claims, 11 Drawing Sheets



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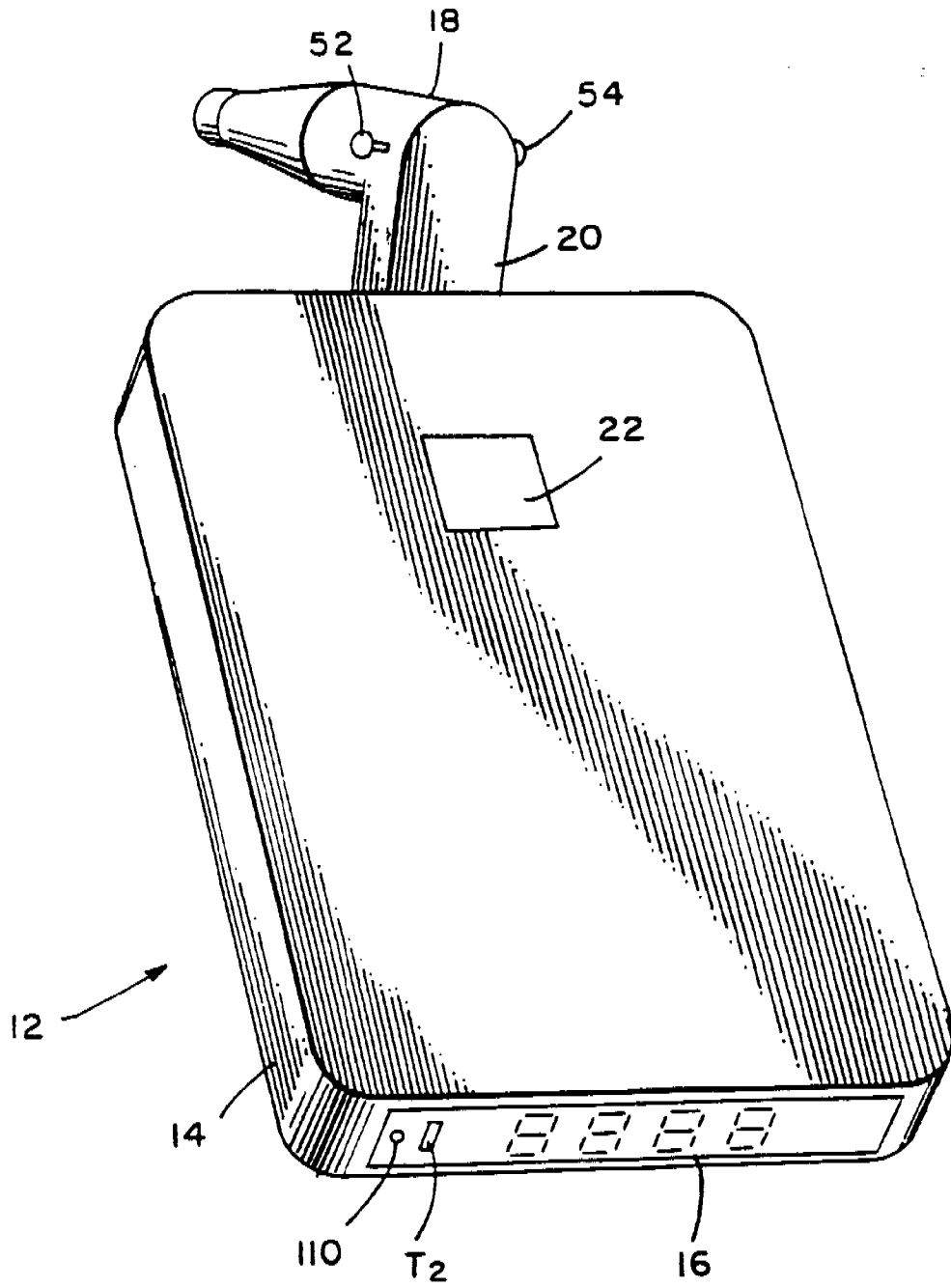


FIG. 1

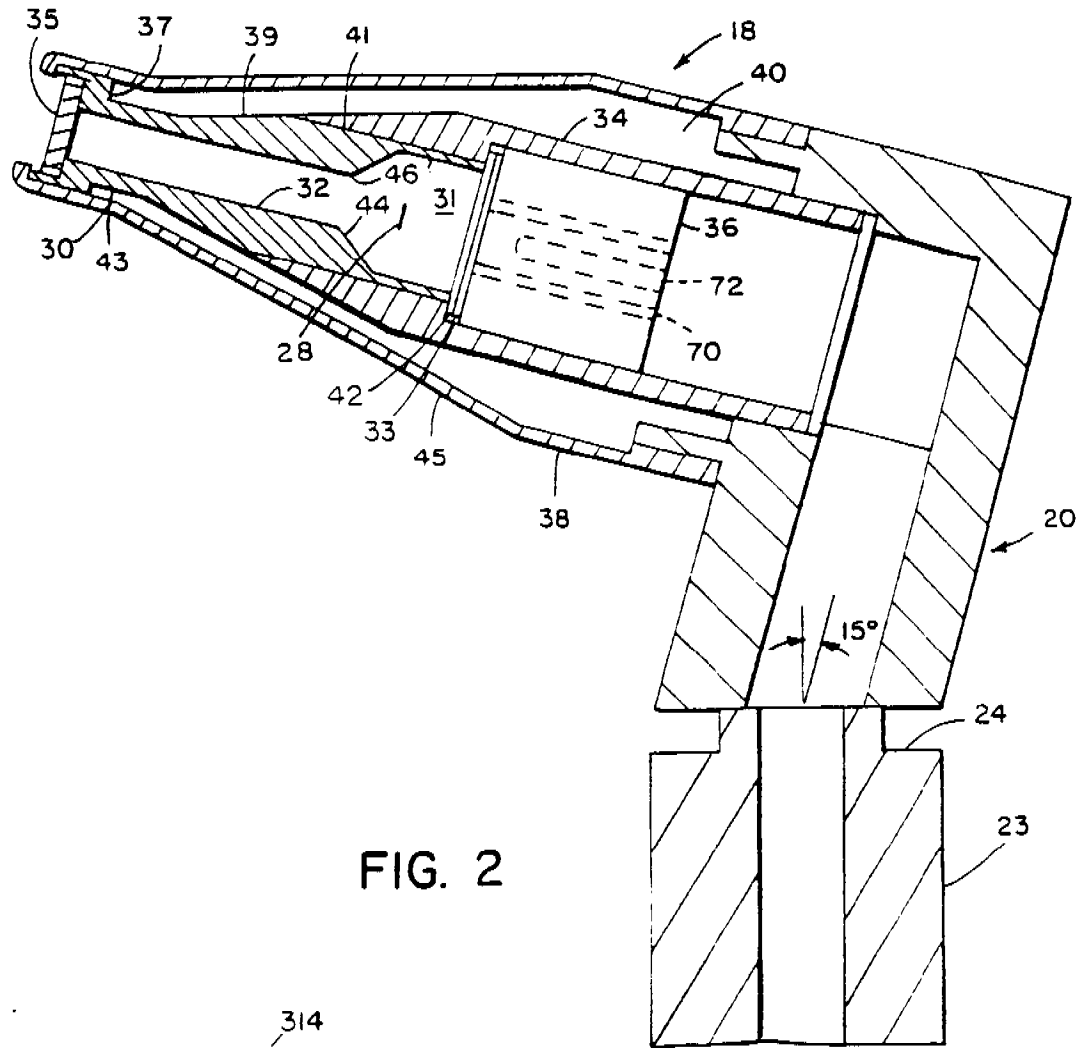


FIG. 2

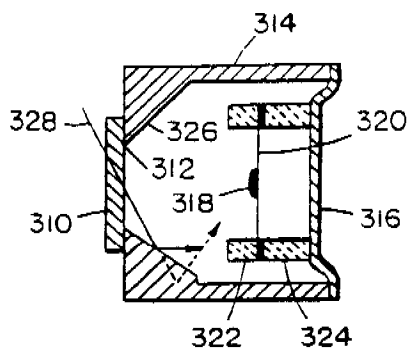


FIG. 10

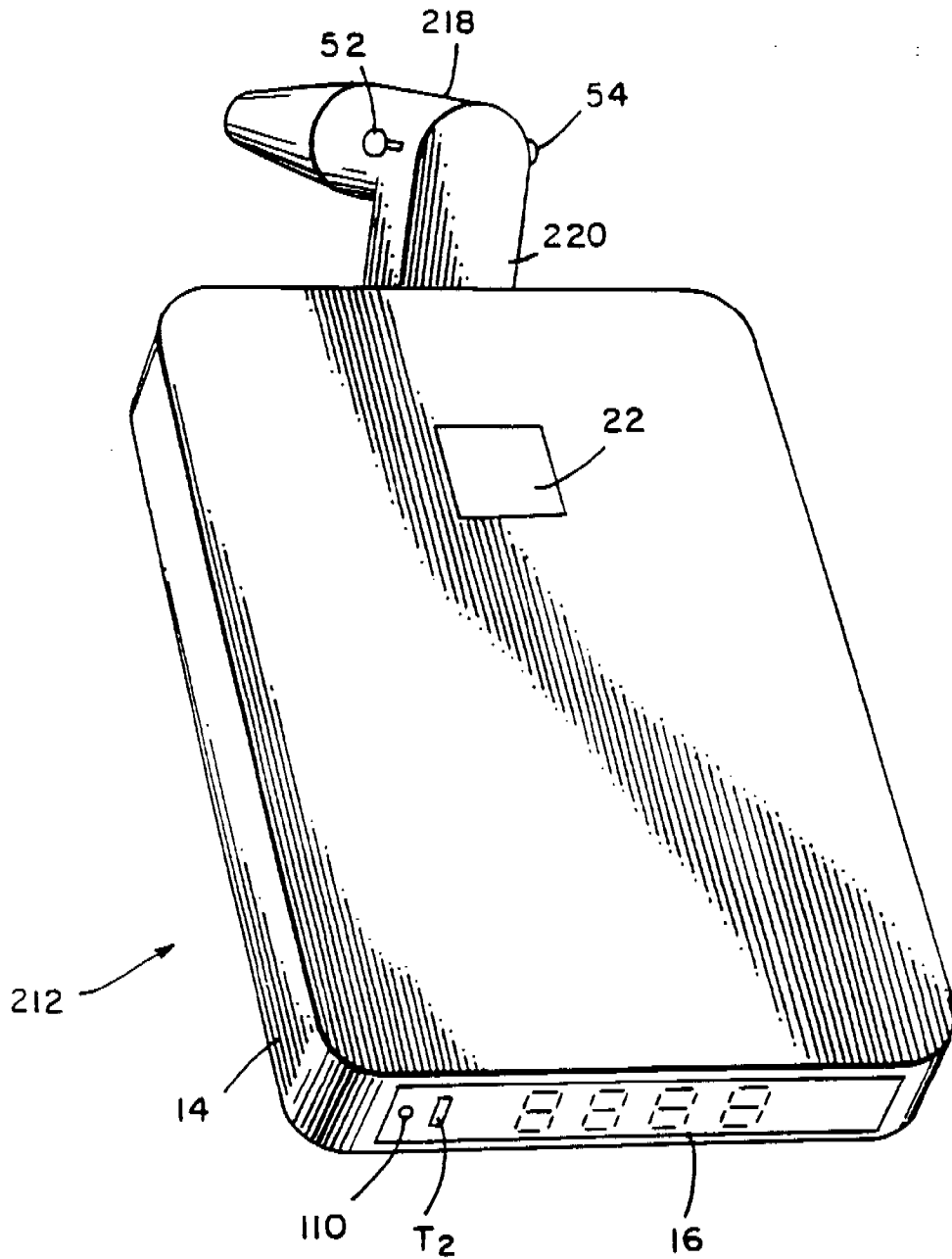
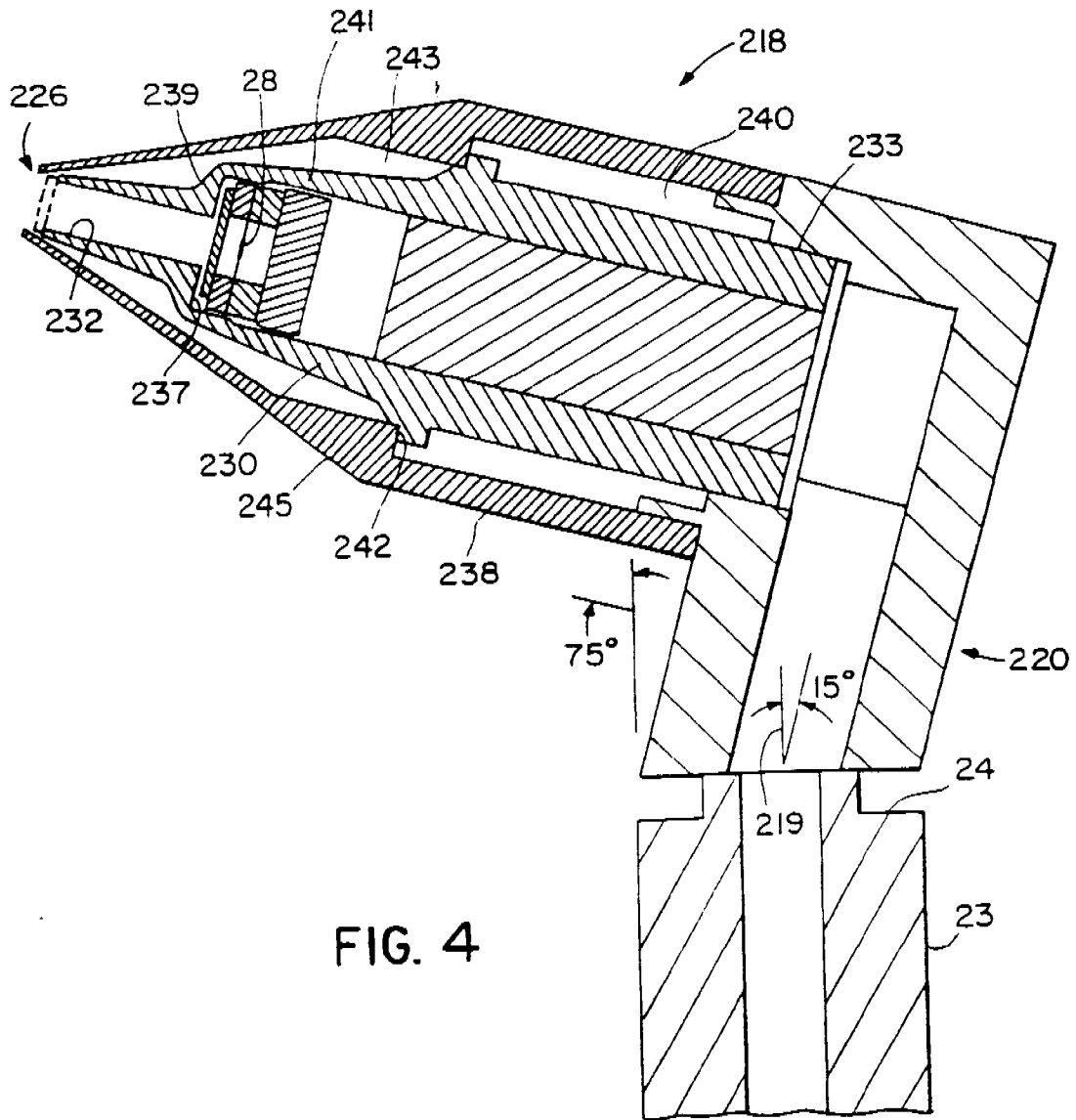


FIG. 3



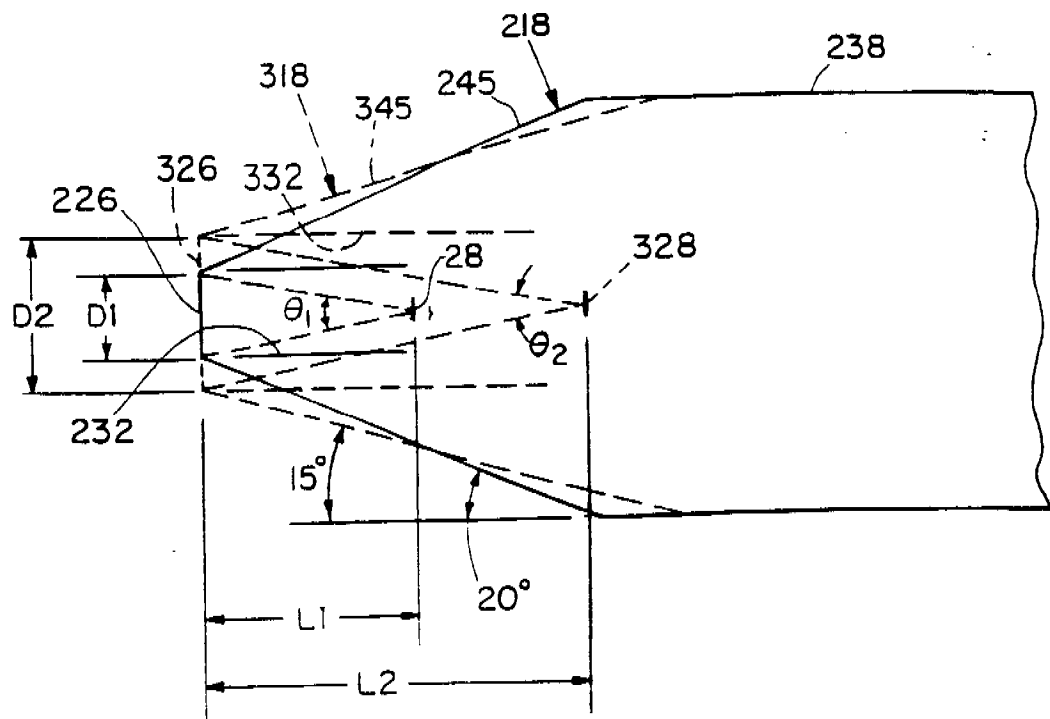


FIG. 5

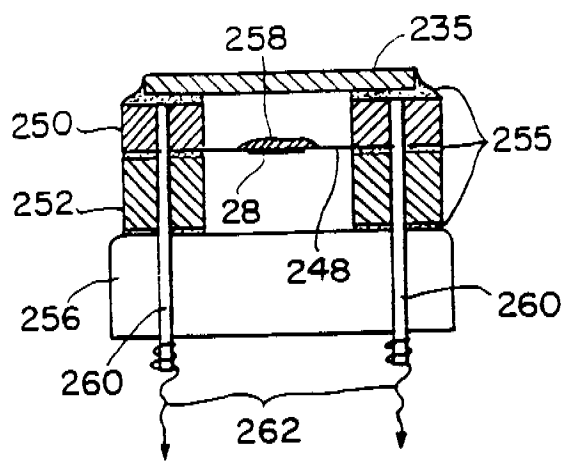
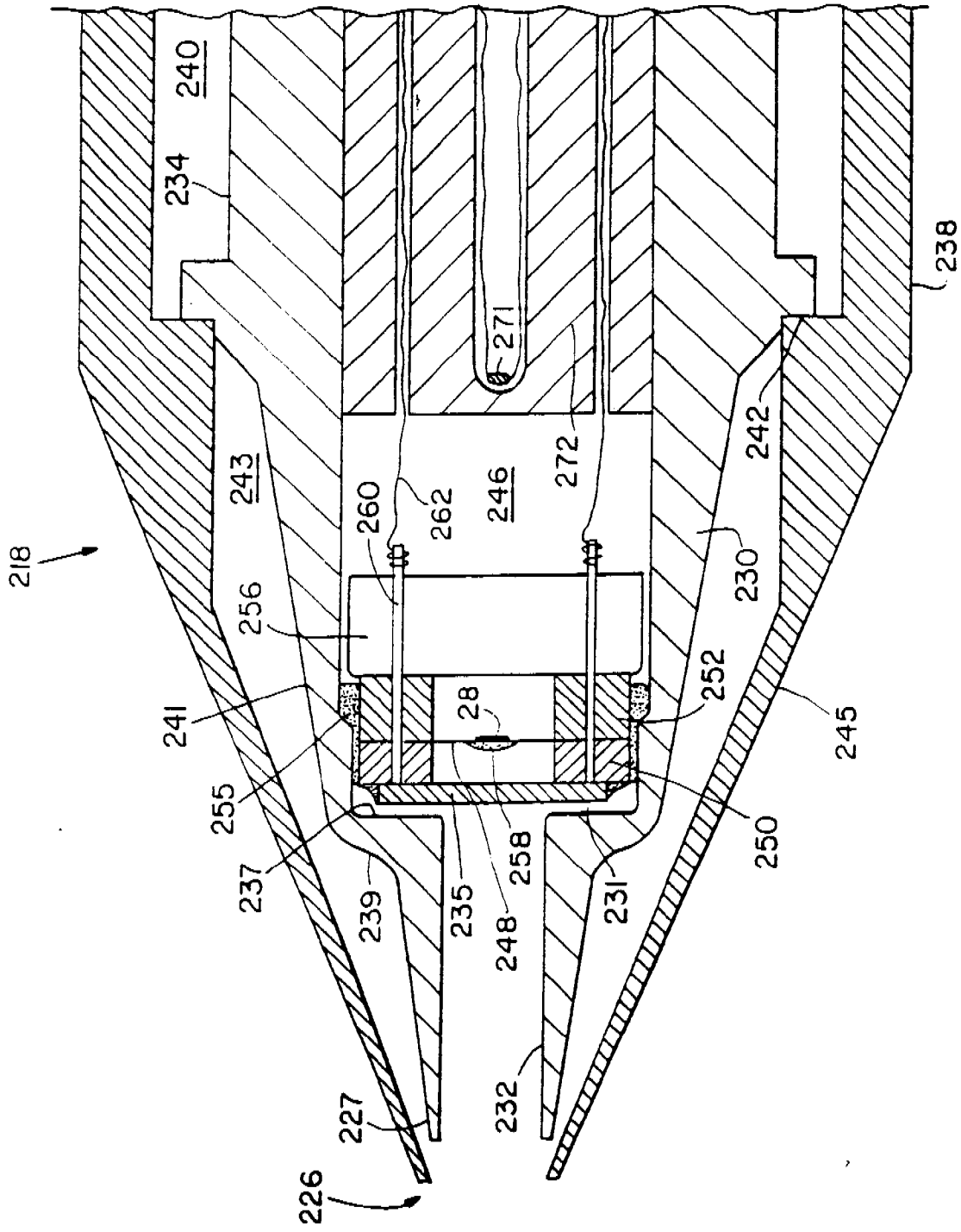


FIG. 7

FIG. 6



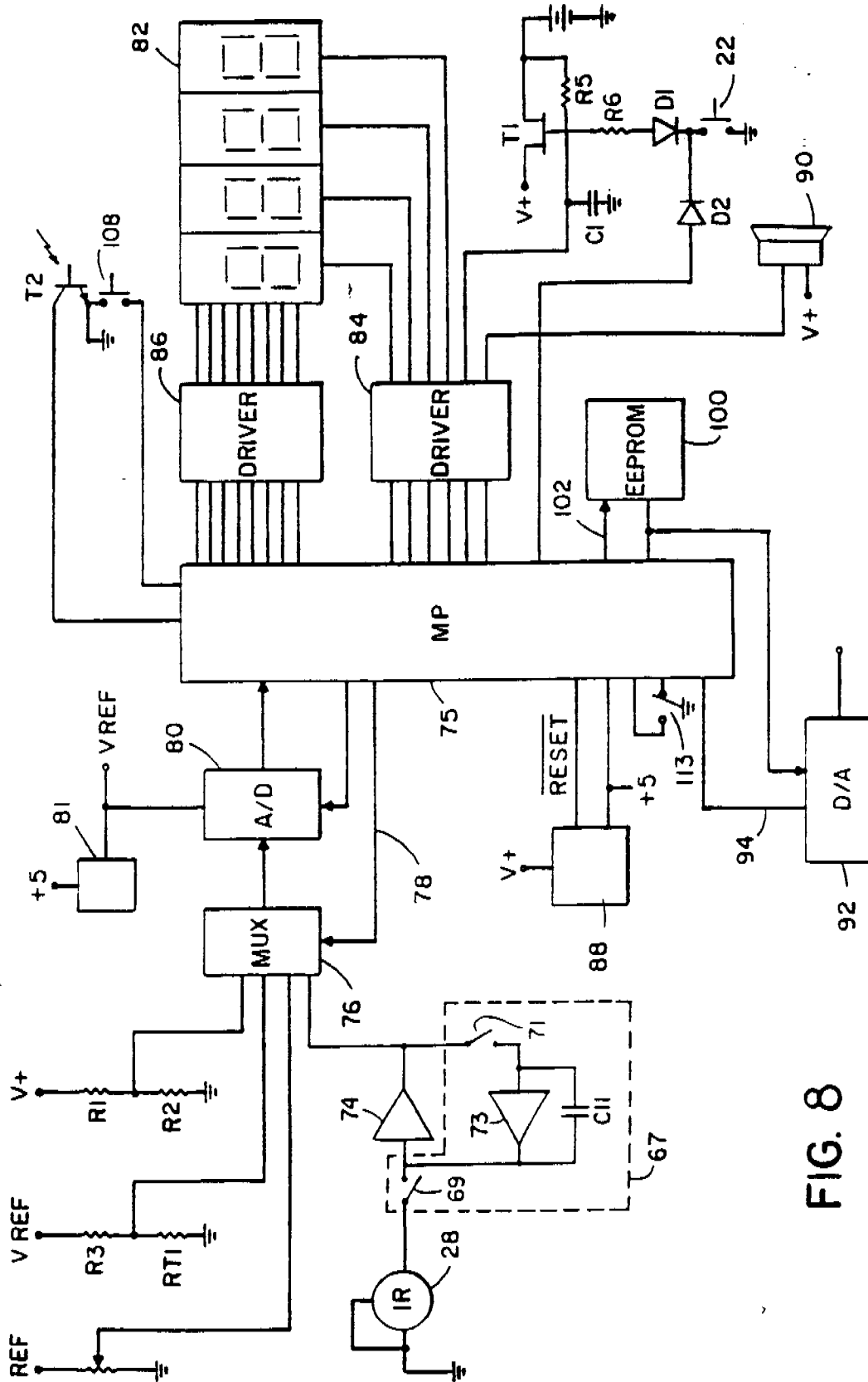


FIG. 8

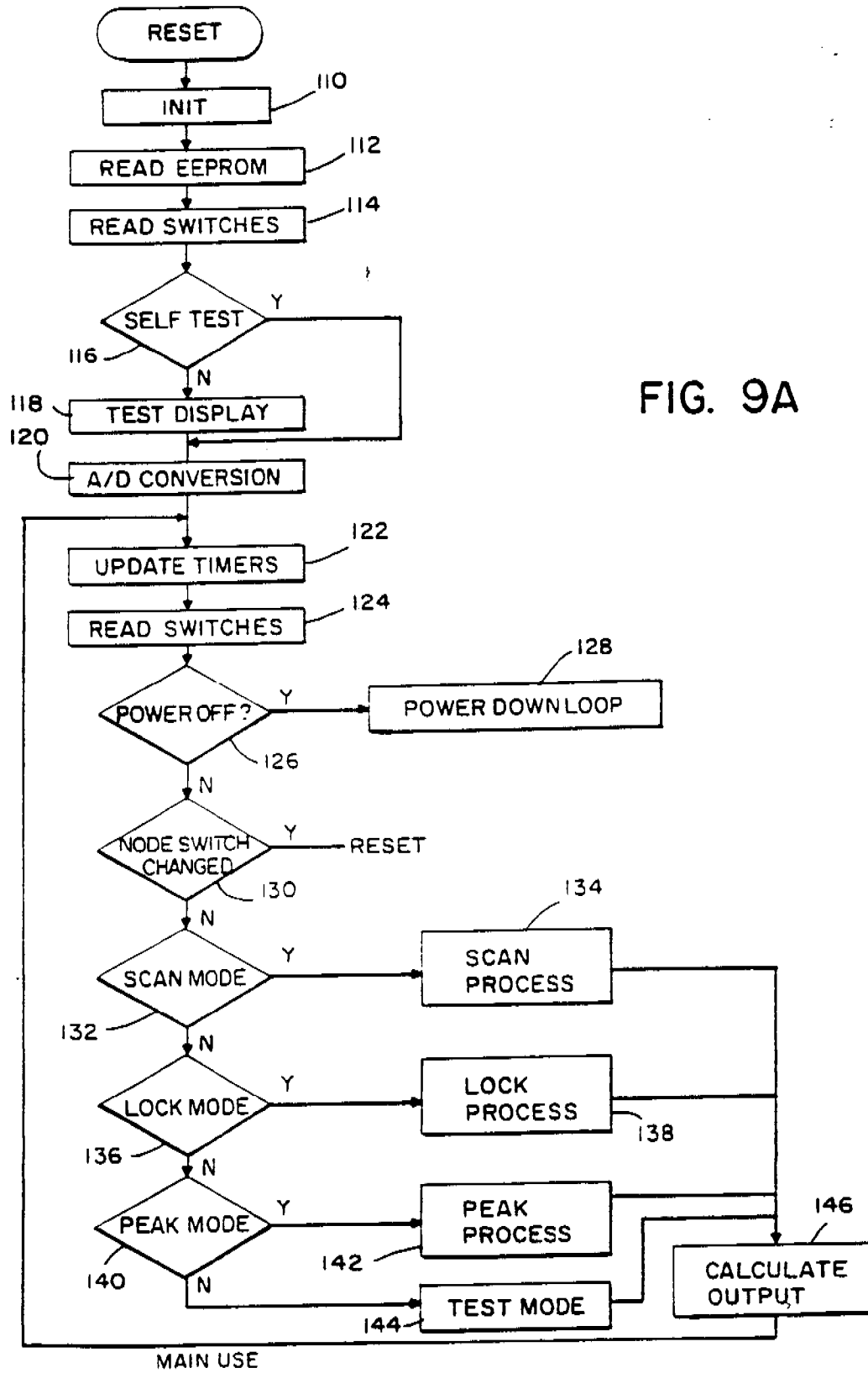


FIG. 9A

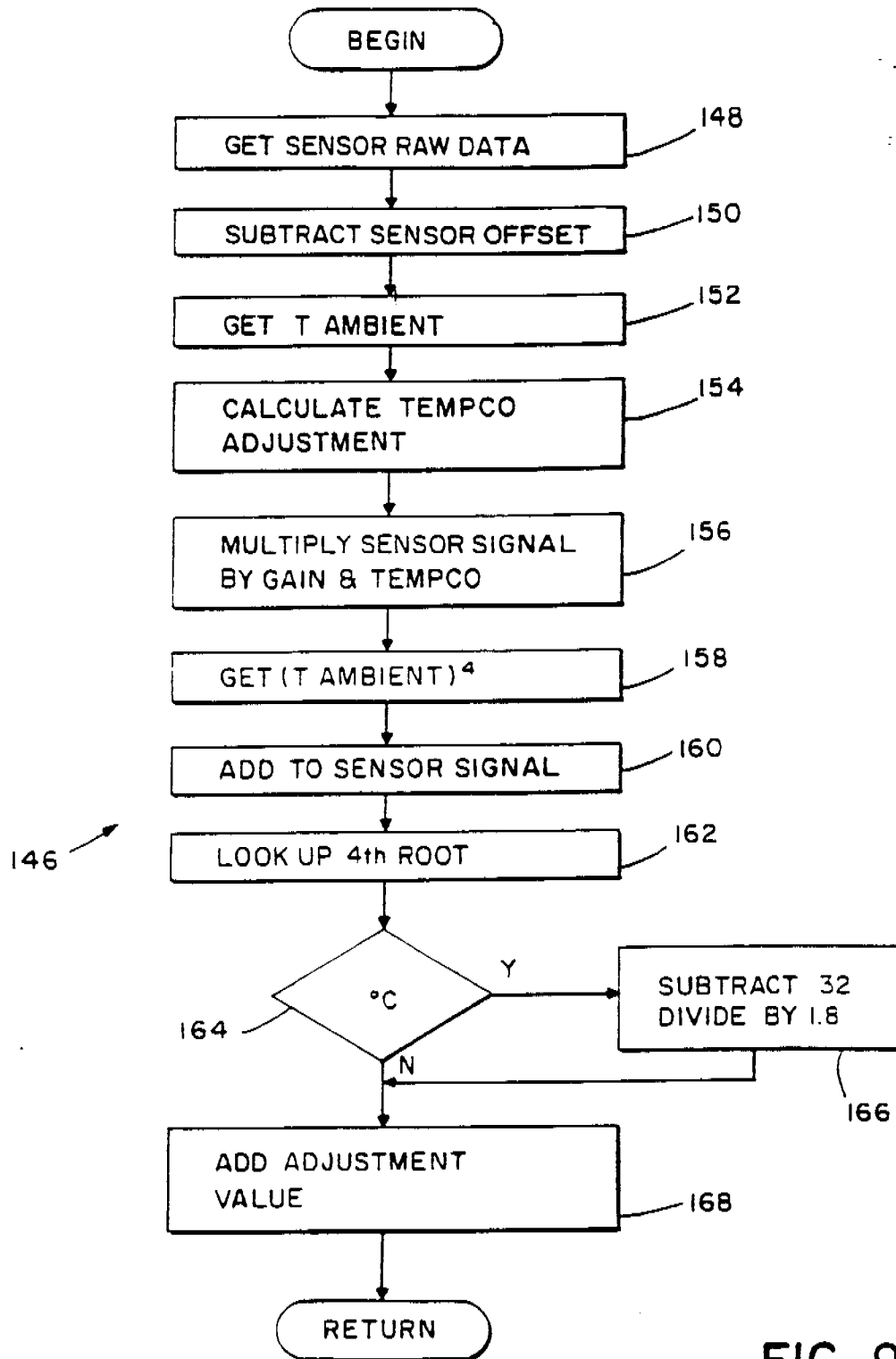
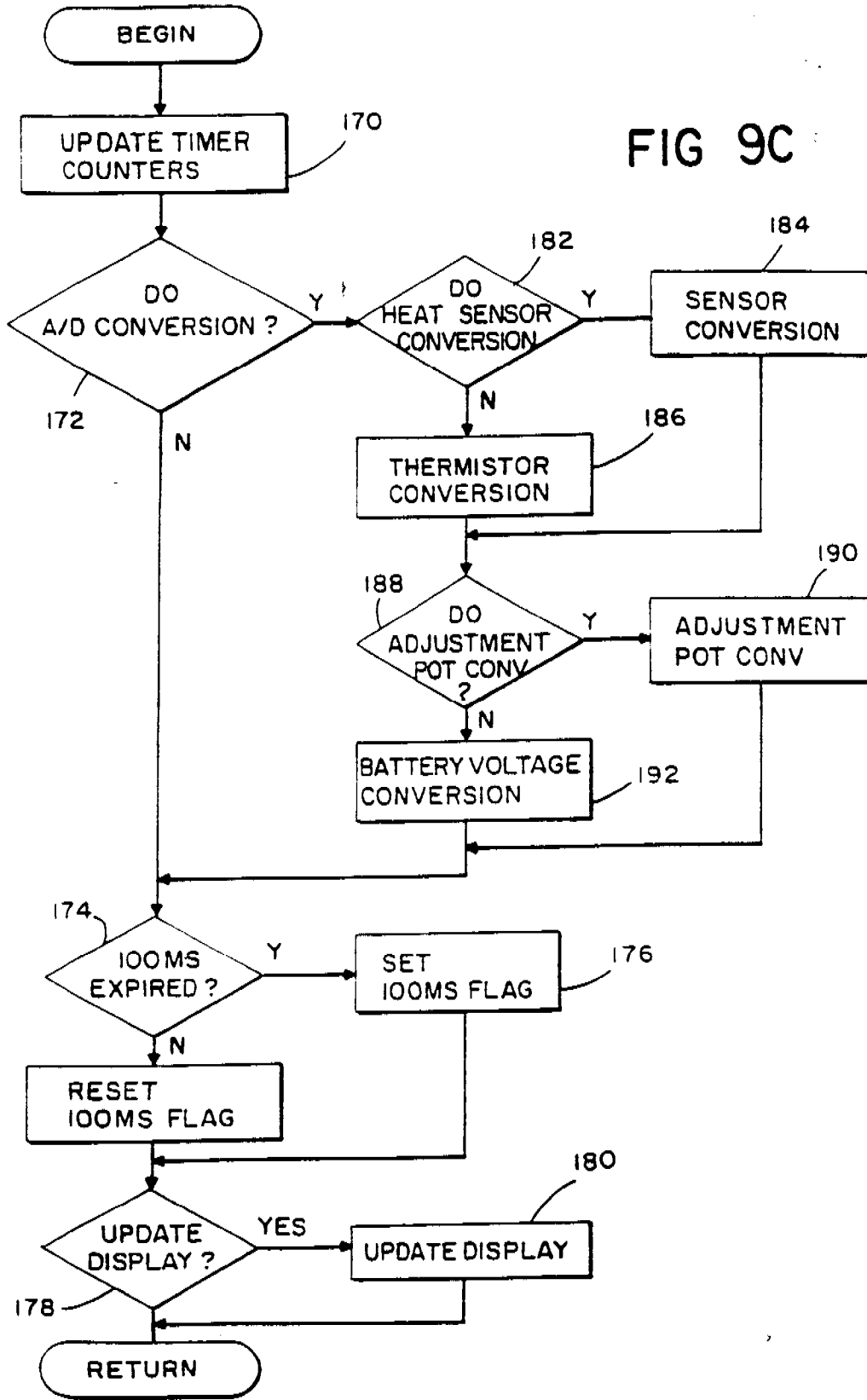


FIG. 9B

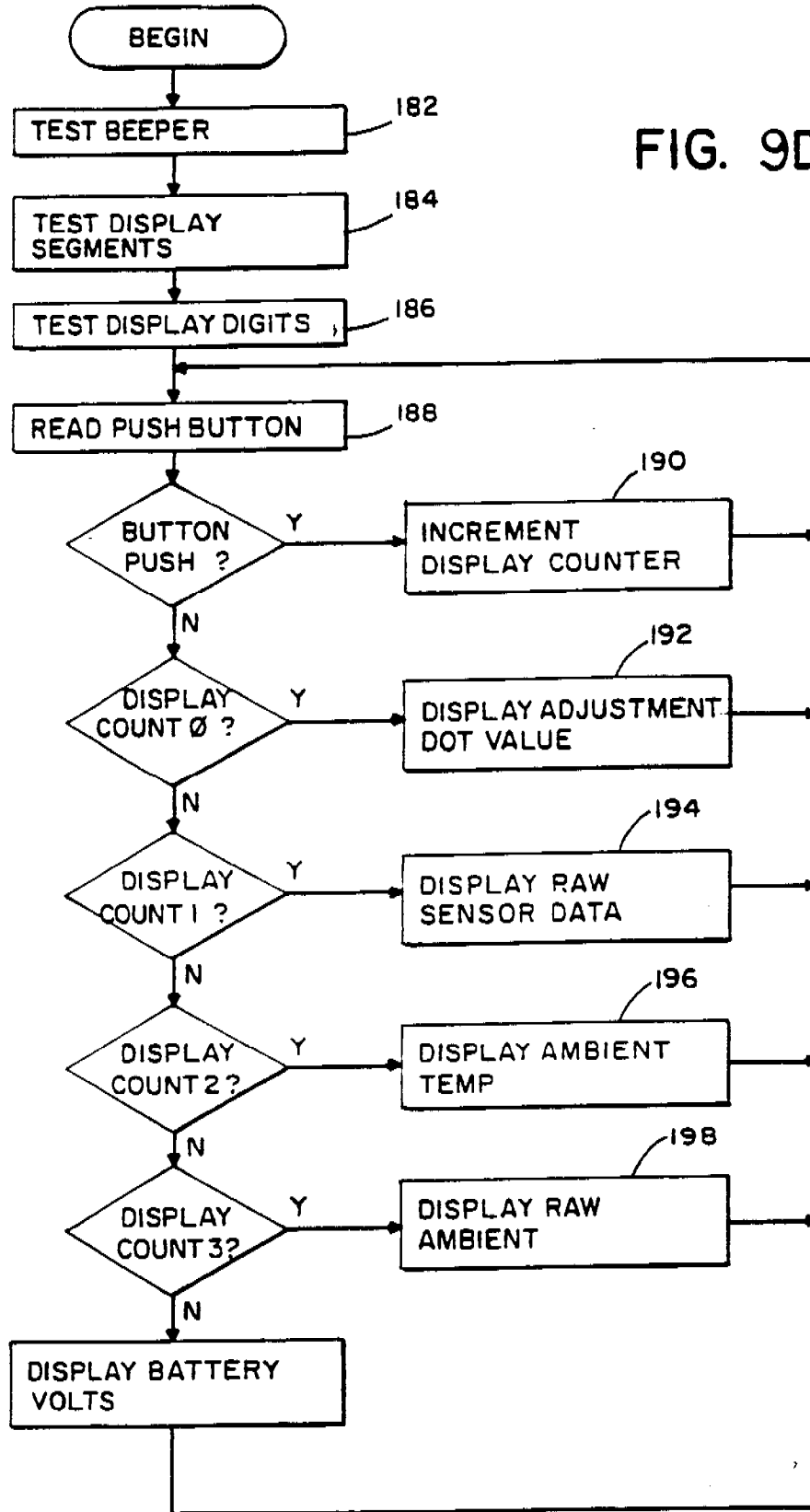
CALCULATE OUTPUT PROCEDURE

FIG 9C



A/D CONVERSION INTERRUPT SERVICE ROUTINE

FIG. 9D



RADIATION DETECTOR PROBE RELATED APPLICATIONS

This application is a continuation of co-pending applica-
tion Ser. No. 08/333,205 filed Nov. 2, 1994 which is a CIP
of Ser. No. 07/832,109 filed Feb. 6, 1992, U.S. Pat. No.
5,325,863 and of Ser. No. 07/889,052 filed May 22, 1992,
U.S. Pat. No. 5,381,796 and of Ser. No. 07/760,006 filed
Sep. 13, 1991, U.S. Pat. No. 5,445,158, which is a CIP of
Ser. No. 07/646,855 filed Jan. 28, 1991, U.S. Pat. No.
5,199,436 which is a Divisional of Ser. No. 07/338,968 filed
Apr. 14, 1989, U.S. Pat. No. 5,012,813, which is a CIP of
Ser. No. 07/280,546 filed Dec. 6, 1988, U.S. Pat. No.
4,993,419.

BACKGROUND

Radiation detectors which utilize thermopiles to detect the
heat flux from target surfaces have been used in various
applications. An indication of the temperature of a target
surface may be provided as a function of the measured heat
flux. One such application is the testing of electrical equip-
ment. Another application has been in the scanning of
cutaneous tissue to locate injured subcutaneous regions. An
injury results in increased blood flow which in turn results
in a higher surface temperature. Yet another application is
that of ear temperature measurement. More specifically, a
tympanic device relies on a measurement of the temperature
of the tympanic membrane area in the ear of an animal or
human by detection of infrared radiation as an alternative to
traditional sublingual thermometers. Other ear temperature
measurements may be limited to the outer region of the ear
canal.

SUMMARY OF THE INVENTION

In one embodiment of the present invention, a radiation
detector comprises a radiation sensor such as a thermopile
and a thermal mass enclosing the thermopile. The thermal
mass includes an elongated thermally conductive tube of a
first internal diameter. The tube extends from the distal end
of the detector to a rear volume of larger internal diameter
in which the sensor is mounted. In one device, the tube is
gold plated and is thus highly reflective. In another device
the tube is plated with a metal oxide for high absorption of
radiation. A rigid window is mounted adjacent to an end of
the tube, preferably the distal end where it seals the tube.

In accordance with one feature of the present invention,
the portions of the thermal mass forming the tube and rear
volume are formed in a unitary structure of high thermal
conductivity material. The unitary thermal structure has an
outer surface with an outer diameter at its distal end which
is less than an outer diameter about the rear volume. The
outer surface is tapered about the tube such that a unitary
thermal mass of increasing outer diameter is provided about
the end of the tube adjacent to the rear volume. The unitary
thermal mass maximizes conductance and thermal mass
within a limited diameter. To avoid changes in fixtures used
in mounting the thermopile within the unitary thermal
structure, in one embodiment the thermal structure is of
limited diameter and may be supplemented with an addi-
tional thermal mass. The additional thermal mass surrounds
the rear volume and a portion of the tube and is in close
thermal contact with the unitary thermal structure. In another
embodiment, the unitary thermal structure extends from the
distal end of the detector to a housing such that no additional
thermal mass is required.

It has been found that a narrow field of view radiation
detector provides a more accurate and reliable reading of

tympanic temperature. In the detector of the present
invention, that field of view is obtained by controlling the
reflectance of the inner surface of the tube, the length and
diameter of the tube and the position of the thermopile
behind the tube. In one embodiment, the tube has a reflective
inner surface providing a field of view from the thermopile
of about sixty degrees or less. A field of view of less than
about sixty degrees allows for viewing of only a portion of
the ear canal within less than about 1 centimeter of the
tympanic membrane. In another embodiment, the tube has a
nonreflective inner surface which produces a field of view
from the thermopile of about thirty degrees or less. In either
embodiment, the thermopile response may be fine tuned by
changing the position of the thermopile behind the tube
which changes the field of view and alters the thermopile
response signal level.

In accordance with another aspect of the present
invention, the infrared radiation sensor is mounted in the
rear volume within the unitary thermal mass. The sensor has
an active area influenced by radiation from an external target
and a reference area of known temperature which is sub-
stantially unaffected by radiation. The sensor is preferably a
thermopile having its cold junction reference area thermally
coupled to the thermal mass but it may be a pyroelectric
device. The thermally conductive tube is thermally coupled
to the thermal mass and passes radiation to the sensor from
the external target. A thermal barrier surrounds the thermal
mass and tube. The temperature of the thermal mass, and
thus of the sensor reference area, is allowed to float with
ambient. A temperature measurement of the thermal mass is
made to compensate the sensor output.

Temperature differences between the tube and sensor
reference area would lead to inaccurate readings. To avoid
those differences, the large unitary thermal mass minimizes
temperature changes from heat which passes through the
thermal barrier, and good conductivity within the mass
increases conductance and minimizes temperature gradients.
The outer thermal RC time constant for thermal conduction
through the thermal barrier to the thermal mass and tube is
at least two, and preferably at least three orders of magnitude
greater than the inner thermal RC time constant for the
temperature response of the reference area to heat trans-
ferred to the tube and thermal mass. For prompt readings, the
inner RC time constant should be about 1/2 second or less.

Preferably, the thermally conductive tube is thermally
coupled to the sensor by a thermally conductive material
such as epoxy. In accordance with the present invention, the
amount of thermally conductive material is tuned to the
detector to minimize the response of the sensor to undesired
thermal perturbations of the tube. Providing an insufficient
amount of material causes a positive error response from the
sensor for thermal perturbations, while too much material
causes a negative error response from the sensor for thermal
perturbations. By providing the proper amount of material
between the sensor and the tube, the added thermal conduc-
tance from the material tunes the reference area and the
active area of the sensor to respond in phase to thermal
perturbations such that the sensor response is substantially
unaffected by said perturbations.

In the radiation detector of the present invention, the
radiation sensor and the tube are positioned in an extension
which is particularly suited for obtaining tympanic tempera-
ture measurements. To accomplish this, the extension is
inserted into a subject's ear, and preferably into the ear
canal. Once inserted, the extension is pivoted and the sensor
scans the ear canal and senses the emitted radiation. The
detector employs electronics which detects the peak radia-

tion sensed by the sensor and converts it to a tympanic temperature indication.

The probe extension which supports the radiation sensor extends from a housing which displays the tympanic temperature. The housing extends along a first axis and the extension preferably extends at an angle of about 75 degrees from the first axis. This housing supports the battery powered electronics for converting radiation sensed by the sensor to tympanic temperature displayed by the display. The electronics included a processor for providing the displayed temperature based on radiation received from the tympanic membrane. If the sensor receives radiation from the cooler outer ear instead of the tympanic membrane, the processor determines the displayed temperature as a function of the received radiation compensated by an indication of ambient temperature to produce a core temperature approximation. The entire instrument is housed in a single hand-held package. The small additional weight of the electronics in the hand-held unit is acceptable because readings can be made quickly.

In accordance with another aspect of the present invention, the probe extension is adapted to be inserted into an ear canal. More specifically, the diameter of the distal tip as well as the shape and taper of the extension may be set to provide a detector useful in normal adult ear canals or a pediatric detector useful in small ear canals, especially children's ear canals, and swollen adult ear canals. To that end, the extension has a diameter of about 3-8 mm about its distal end and a substantially conical shape increasing in diameter along its length from its distal end and characterized by an included angle of about 25-60 degrees. As such, the extension is capable of being inserted into an ear canal up to one-third of the length of the ear canal.

In a pediatric detector embodiment the conical shape of the extension has an included angle of about forty degrees. Further, the diameter of the tip of the distal end of the extension is preferably in the range of 3-6 mm. As such, the pediatric detector is particularly useful on subjects having small ear canals but is also useful on adult subjects. In another embodiment the conical portion of the extension has an included angle of about thirty degrees. The diameter of the tip of the distal end of the extension is no more than about 7 mm. As such, the detector is particularly useful on adult subjects having normal ear canals, but it may also be used on children.

The radiation sensor assembly of a preferred embodiment includes a sensing device which is mounted within a rigid structure of high thermal conductivity such as beryllium oxide and has its reference area thermally coupled thereto. The passage through a thermally conductive tube passes thermal radiation from the external target, such as a tympanic membrane, to the thermopile. A window is mounted on the rigid structure such that it is in close thermal contact with the structure.

In one embodiment of the present invention, a detector comprises a substantially conical extension employing the above-described radiation sensor assembly. Preferably, the sensor assembly includes a thermopile sensor. In this embodiment, the tube provides a field of view from the thermopile of about thirty degrees or less. A thermal mass of high thermal conductivity material surrounds the tube and encloses the rigid structure in a rear volume. The thermal mass has a region within the rear volume which is defined between a rearwardly facing surface of the thermal mass and forward a face of the window. The region is preferably filled with air, providing a low thermal conductivity environment

therein. The high thermal conductivity mass provides close thermal contact among the tube, the rigid structure, the thermopile cold junction and the ends of the window. As such, a continuous low thermal resistance path is formed from the tube to the cold junction of the thermopile and the window is held to the cold junction temperature.

BRIEF DESCRIPTION OF THE DRAWINGS

The foregoing and other objects, features and advantages of the invention will be apparent from the following more particular description of preferred embodiments of the invention, as illustrated in the accompanying drawings in which like reference characters refer to the same parts throughout the different views. The drawings are not necessarily to scale; emphasis instead being placed upon illustrating the principles of the invention.

FIG. 1 illustrates one embodiment of a radiation detector for tympanic temperature measurements in accordance with the present invention.

FIG. 2 is a cross-sectional view of the extension of the detector of FIG. 1 in which the thermopile radiation sensor is positioned.

FIG. 3 illustrates another embodiment of the radiation detector for tympanic temperature measurements in accordance with the present invention.

FIG. 4 is a cross-sectional view of the extension of the detector of FIG. 3 in which the thermopile radiation sensor is positioned.

FIG. 5 is a profile of pair of configurations of the extension of FIG. 4.

FIG. 6 is an enlarged cross-sectional view of the extension of FIG. 4.

FIG. 7 is a cross-sectional view of a radiation sensor assembly of the detector of FIG. 6.

FIG. 8 is a block diagram of the electronic circuit of the detector of the present invention.

FIGS. 9A-9D are flow charts of the system firmware.

FIG. 10 is a cross-sectional view of a thermopile can embodying a feature of the present invention.

DETAILED DESCRIPTION OF A PREFERRED EMBODIMENT

In one embodiment of the present invention, the radiation detector 12 of FIG. 1 includes a flat housing 14 with a digital display 16 for displaying a tympanic temperature measurement. Although the display may be located anywhere on the housing, it is preferred that it be positioned on the end so the user is not inclined to watch it during a measurement. The instrument makes an accurate measurement when pivoted to scan the ear canal, and the user should concentrate on only the scanning motion. Then the display can be read. A thermopile radiation sensor is supported within a probe 18 at the opposite end of the housing 14. The housing extends along a first axis 19 (FIG. 2) and the extension 18 extends orthogonally from an intermediate extension 20 which extends at an angle of about 15 degrees from the first axis. As such, the extension 18 extends at an angle of about 75 degrees from the first axis 19 of the housing. Thus, the head of the detector, including the extension 18 and 20, has the appearance of a conventional otoscope. An on/off switch 22 is positioned on the housing.

A cross-sectional view of the extension of the detector of FIG. 1 is illustrated in FIG. 2. A base portion 23 is positioned within the housing 14, and the housing clamps about a

groove 24. As noted, the portion 20 extends at about a 15 degree angle from the first axis 19 and thus from the base portion 23. Further, the extension 18 extends at about a 75 degree angle from the first axis. The extension 18 is tapered toward its distal end at 26 so that it may be comfortably positioned in the ear canal to view the tympanic membrane and/or ear canal.

A preferred disposable element to be used over the extension 18 is presented in the '419 patent and will not be discussed here.

The edge at the end of the probe is rounded so that when the probe is inserted into the ear it can be pivoted somewhat without discomfort to the patient. The probe is also curved like an otoscope to avoid interference with the ear. By thus pivoting the probe, the ear canal is scanned and at some orientation of the probe during that scan, one can be assured that the maximum temperature is viewed. Since the ear canal cavity leading to the tympanic area is the area of highest temperature, the instrument is set in a peak detection mode, and the peak detected during the scan is taken as the tympanic temperature.

An improved assembly within the extension 18 is illustrated in FIG. 2. A thermopile 28 is positioned within a can 30 of high conductivity material such as copper. The conductivity should be greater than two watts per centimeter per degree Kelvin. The can is filled with a gas of low thermal conductivity such as Xenon. The thermopile 28 is positioned within a rear volume 31. It is mounted to an assembly which includes a header 33. The volume is sealed by cold welding of the header 33 to a flange 42 extending from the can. Cold welding is the preferred approach to making the seal and, to utilize past welding fixtures, the outer diameter of the can is limited. Thermal epoxy may be used as an alternative.

The thermopile views the tympanic membrane area through a radiation guide 32. The radiation guide 32 is gold plated to minimize oxidation. It is closed at its forward end by a germanium window 35. The rigid germanium window assures that the radiation guide is sealed from contamination and is itself easily cleaned. Germanium is less fragile than silicon and passes higher wavelengths. To minimize expense, the window is square with each side slightly longer than the diameter of the radiation guide 32. The window is cemented with epoxy within a counterbore in a flange 37 at the end of the radiation guide. The epoxy serves as a gas seal and mechanical support for the somewhat brittle germanium window. The flange serves to protect the germanium window should the detector be dropped. The diagonal of the window is less than the diameter of the counterbore, and its thickness is less than the depth of the counterbore. Therefore, if the detector is dropped, any force which presses the plastic housing toward the window is absorbed by the flange. The germanium need only withstand the forces due to its own inertia.

From the perspective of the thermopile flake 28, the radiation guide 32 shifts the front aperture at the window 35 back to the proximal end of the radiation guide at 46. Thus, the field of view of the device is determined by the diameter of the aperture 46 and its distance from the flake 28. There are, however, stray rays which, though not being directed to the flake from the aperture, may ultimately strike the flake after reflection within the volume at 31. Such reflections effectively increase the field of view and are thus undesirable. The frustoconical surface 44 surrounding the aperture 46 reflects most of those stray rays toward the rear of the volume 31 rather than toward the thermopile flake. As shown in FIG. 2, the flake views itself in the surface 44, thus minimizing stray radiation.

The angled surface surrounding the aperture can be applied to more conventional thermopile cans as illustrated in FIG. 10. Here, the window 310 is mounted directly across the aperture 312 of the can 314. As in conventional assemblies, the can is closed by rear header 316. The thermopile flake 318 is centered on a polyester sheet 320 stretched between beryllium oxide rings 322 and 324. As in the case of FIG. 2, the surface 326 surrounding the aperture 312 is frustoconical such that it is angled back from the aperture. It can be seen that stray rays 328 which should not be seen by the thermopile flake 318 will be reflected rearwardly toward the beryllium oxide rings where they should be absorbed rather than toward the flake as indicated by the broken lines as they would if the surface surrounding the aperture were cylindrical.

Whereas the detector disclosed in the '419 patent had a field of view of about 120°, it has been determined that a narrower field of view of about sixty degrees or less provides the user with an easier and more accurate indication of tympanic temperature. With a narrower field of view, the thermopile flake, when directly viewing the tympanic membrane, also views less than about one centimeter along the ear canal wherein the tissue is at substantially the same temperature as the tympanic membrane. A better view of the tympanic membrane also results from the cylindrical extension 43 beyond the conical portion of the extension 18. With the ear canal straightened by the probe, the extension 43 can extend well into the ear canal beyond any hair at the canal opening.

The tympanic membrane is about 2.5 centimeters from the opening of the ear canal. The ear canal for an adult subject is typically about 8 mm wide, so the diameter of the tip of the extension is no more than about 8 mm wide. The conical portion of the extension 18 prevents the tip of the extension from extending more than about eight millimeters into the ear canal. Beyond that depth, the patient suffers noticeable discomfort. With a field of view of less than about sixty degrees, the ear canal is viewed more than about eight millimeters from the tip of the extension 18. Thus, only the ear canal within less than 9 millimeters of the tympanic membrane is viewed as the radiation guide is directed toward the membrane. The result is a more accurate and reliable reading of the tympanic temperature which is essentially core temperature.

With the present instrument, the narrow field of view is obtained by extending the enlarged rear volume between the flake and the radiation guide. Radiation which enters the radiation guide at greater angles, yet travels through the radiation guide, leaves the guide at greater angles and is thus unlikely to be viewed by the flake. The length of the radiation guide is another parameter which affects the field of view. By using a planoconvex lens as the window 35, the field of view can be further limited.

Decreasing the field of view increases the amount of heat which is absorbed by the can in which the thermopile is mounted. The added heat load adds to the importance that the can, including the radiation guide, have a large thermal mass and high thermal conductivity as discussed below.

As distinguished from the structure presented in the '419 patent, the volume 31 surrounding the thermopile and the radiation guide are formed of a single piece of high conductivity copper. This unitary construction eliminates any thermal barriers between the foremost end of the radiation guide and the portion of the can surrounding the thermopile which serves as the cold junction of the thermopile. Further, at least a portion of added thermal mass which surrounds the

radiation guide is unitary with the can as well. Specifically, a taper 39 results in an enlarged region 41 which serves as a thermal mass in accordance with the principals of the parent application. The taper 39 continues along a conductive thermal mass 34 which surrounds the can and a conductive plug 36. Both the mass 34 and plug 36 are of copper and are in close thermal contact with the can 30.

The outer sleeve 38 of the extension 18 and the intermediate extension 20 are of plastic material of low thermal conductivity. The sleeve 38 is separated from the can 30 and thermal mass 34 by an insulating air space 40. The taper of the can 30 and thermal mass 34 permits the insulating space to the end of the extension while minimizing the thermal resistance from the end of the tube 32 to the thermopile, a parameter discussed in detail below. The inner surface of the plastic sleeve 38 may be coated with a good thermal conductor to distribute across the entire sleeve any heat received from contact with the ear. Twenty mils of copper coating would be suitable.

In contrast with the prior design, the portion of the sleeve 38 at the foremost end of extension 18 has a region 43 of constant outer diameter before a tapered region 45. The region of constant outer diameter reduces the outer diameter at the distal end and minimizes interference when pivoting the extension in the ear to view the tympanic membrane area. The tapered region is spaced six millimeters from the end of the extension to allow penetration of the extension into the ear canal by no more than about eight millimeters.

One of the design goals of the device was that it always be in proper calibration without requiring a warm-up time. This precluded the use of a heated target in a chopper unit or heating of the cold junction of the thermopile as was suggested in the O'Hara et al. U.S. Pat. No. 4,602,642. To accomplish this design goal, it is necessary that the system be able to operate with the thermopile at any of a wide range of ambient temperatures and that the thermopile output have very low sensitivity to any thermal perturbations.

The output of the thermopile is a function of the difference in temperature between its warm junction, heated by radiation, and its cold junction which is in close thermal contact with the can 30. In order that the hot junction respond only to radiation viewed through the window 35, it is important that the radiation guide 32 be, throughout a measurement, at the same temperature as the cold junction. To that end, changes in temperature in the guide 32 must be held to a minimum, and any such changes should be distributed rapidly to the cold junction to avoid any thermal gradients. To minimize temperature changes, the tube 32 and the can 30 are, of course, well insulated by means of the volume of air 40. Further, a high conductance thermal path is provided to the cold junction. This conductance is enhanced by the unitary construction. Further, the can 30 is in close thermal communication with the thermal masses 34 and 36, and the high conductivity and thickness of the thermal masses increase the thermal conductance. A high thermal conductivity epoxy, solder or the like joins the can and thermal masses. The solder or epoxy provides a significant reduction in thermal resistance. Where solder is used, to avoid damage to the thermopile which is rated to temperatures of 125° C., a low temperature solder of indium-tin alloy which flows at 100° C. is allowed to flow into the annular mass 34 to provide good thermal coupling between all elements.

The thermal resistance from the outer surface of the plastic sleeve 38 to the conductive thermal mass is high to minimize thermal perturbations to the inner thermal mass.

To minimize changes in temperature of the guide 32 with any heat transfer to the can which does occur, the thermal mass of the can 30, annular mass 34 and plug 36 should be large. To minimize thermal gradients where there is some temperature change in the tube during measurement, the thermal resistance between any two points of the thermal mass should be low.

Thus, due to the large time constant of the thermal barrier, any external thermal disturbances, such as when the extension contacts skin, only reach the conductive thermal mass at extremely low levels during a measurement period of a few seconds; due to the large thermal mass of the material in contact with the cold junction, any such heat transfer only causes small changes in temperature; and due to the good thermal conductance throughout the thermal mass, any changes in temperature are distributed quickly and are reflected in the cold junction temperature quickly so that they do not affect temperature readings.

The thermal RC time constant for thermal conduction through the thermal barrier to the thermal mass and tube should be at least two orders of magnitude greater than the thermal RC time constant for the temperature response of the cold junction to heat transferred to the tube and thermal mass. The RC time constant for conduction through the thermal barrier is made large by the large thermal resistance through the thermal barrier and by the large thermal capacitance of the thermal mass. The RC time constant for response of the cold junction is made low by the low resistance path to the cold junction through the highly conductive copper can and thermal mass, and the low thermal capacitance of the stack of beryllium oxide rings and pin conductors to the thermopile.

Although the cold junction capacitance is naturally low, there are size constraints in optimizing the thermal capacitance of the thermal mass, the thermal resistance through the thermal barrier and the internal thermal resistance. Specifically, the external thermal resistance can be increased by increased radial dimensions, the capacitance of the thermal mass can be increased by increasing its size, and the thermal resistance through the longitudinal thermal path through the tube can be decreased by increasing its size. On the other hand, the size must be limited to permit the extension to be readily positioned and manipulated within the ear.

Besides the transfer of heat from the environment, another significant heat flow path to the conductive thermal mass is through leads to the system. To minimize heat transfer through that path, the leads are kept to small diameters. Further, they are embedded in the plug 36 through bores 70; thus, any heat brought into the system through those leads is quickly distributed throughout the thermal mass, and only small changes in temperature and small gradients result.

Because the temperature of the thermal mass is not controlled, and the response of the thermopile 28 is a function of its cold junction temperature, the cold junction temperature must be monitored. To that end, a thermistor is positioned at the end of a central bore 72 in the plug 36.

Another embodiment of the present invention is illustrated in FIG. 3. The radiation detector 212 employs a thermopile radiation sensor supported within a probe extension 218 of the opposite end of the housing 14. As shown in FIG. 4, the extension 218 extends at an angle of about 75 degrees from a first axis 219 along which the housing extends. The extension 218 is tapered along its length from its distal end, making the instrument 212 particularly useful in obtaining tympanic temperature measurements without causing the subject discomfort.

As previously discussed, the other embodiment provided an extension with a constant diameter tip which works well in ear canals of about the same diameter. However, this tip does not fit within smaller ear canals, and subjects with larger diameter ear canals will suffer discomfort as the constant diameter tip of the extension contacts the walls of their ear canals during pivoting to scan the ear canal. In accordance with the present invention, the substantially conical shaped extension 218 has an increasing diameter along a portion of its length from its distal end such that the extension may be inserted into an ear canal without causing discomfort. Once inserted, the extension 218 is pivoted to scan the ear canal adjacent to and including the tympanic membrane. The conical shape of the extension 218 ensures that the edge of the tip of the extension is unable to contact the walls of the ear canal. The thermopile 28 senses radiation within the ear canal during the pivotal rotation of the extension 218. The detector 212 employs electronics in the housing 14 for detecting the peak radiation sensed by the sensor 28 and converting it to a tympanic temperature indication. Further, the electronics may also provide an audible tone indicating that peak radiation has been detected for a particular measurement period. The variable tone or variable pulse signal allows a user to know when to stop pivoting the extension for a given subject.

The diameter of the distal tip of the probe extension as well as its taper may be selected to provide a detector useful in normal ear canals or a pediatric detector useful in small ear canals. In one configuration, as shown in FIG. 5, the extension 218 has a small diameter tip and is tapered along its length at its distal end making the extension particularly suited for insertion into small ear canals. A small ear canal is about 3-6 mm wide, so the diameter of the extension 218 along the portion of its length from its distal tip 226 is no more than about 3-6 mm. Further, the extension 218 comprises an outer sleeve 238 with a tapered portion 245 extending at a twenty degree angle from the distal tip 226. As such, the conical portion 245 of the extension has an included angle of about forty degrees. With a preferred 3.4 mm outer diameter at the tip 226 and a forty degree included angle along the conical portion 245, the extension 218 is capable of being inserted about 4 mm into a small ear canal. A young child's ear canal is about 10 mm in length, so the extension may be inserted into the child's ear canal up to about one-third of the length of the ear canal without causing discomfort.

In another configuration, indicated by dashed lines in FIG. 5, an extension 318 has a larger diameter tip and is tapered such that the extension is particularly suited for normal ear canals including adult ear canals and ear canals of older children. A normal ear canal is about 8 mm wide, and the diameter of the extension 318 about its distal tip 326 is no more than 7 mm. The tapered portion 345 of the outer sleeve extends at about a fifteen degree angle from the distal tip 326 which corresponds to a thirty degree included angle. As such, the extension 318 having a preferred tip diameter of about 5 mm is capable of being inserted about 8 mm into a normal ear canal, or about one-third of the length into the canal without causing the subject discomfort.

Referring to FIG. 5, the extensions 218 and 318 have different profiles which were selected to minimize discomfort to the subject and to provide for accurate tympanic temperature readings. To that end, the diameter of the tip of the extensions is specified and depends on the diameter of the subject's ear canal. Further, the extensions are configured to provide a field of view of about thirty degrees which provides more accurate readings as explained below. Thus,

to provide a thirty degree field of view at θ_1 , with a 3 mm inner diameter of tube 232, the length 21 from the tip 226 to the thermopile 28 is about 7.5 mm. Due to the proximity of the thermopile 28 to the tip (7.5 mm), the extension 218 requires the steeper taper of 20 degrees so that the thermopile assembly (not shown) fits into the extension. Also, the taper of 20 degrees provides a necessary stop in close proximity to the distal end 226 for preventing insertion of the extension 218 too far into a short ear canal so as to cause discomfort. To achieve the thirty degree field of view at θ_2 , with a tube 322 diameter of about 4.5 mm, a length of L2 of about 11 mm is required. Due to the larger diameter tip 326, the thermopile 328 is further from the tip for the same field of view so that the conical portion 345 may have a 15 degree taper. An adult canal has a flap of cartilage at the outer region of the ear (the concha). Thus, the conical portion 345 having the 15 degree taper is advantageous as it allows the extension 318 to be narrower and thus be inserted past the cartilage and extend into the ear canal.

An improved assembly within the extension 218 is shown in FIG. 4. A thermopile 28 is positioned within a thermal mass 230 formed of high thermal conductivity material such as copper. In contrast to the previous embodiment, the thermal mass 230 is a one-piece structure which mounts into a bore 233 within a portion 220 of the extension 218. Further, no contact between the thermal mass 230 and the outer sleeve 238 is made at the distal end 226 of the extension. Instead, a ridge 242 in the mass 230 contacts the sleeve 238 to achieve alignment of the mass and the distal end of the sleeve. The thermopile 28 is located in a rear volume 231 and views the tympanic membrane area through a conductive tube 232 formed in the mass 230.

Referring to FIGS. 6 and 7, the thermopile is mounted on the rear surface of a sheet of polytetrafluoroethylene 248 suspended from the rear surface of a first beryllium oxide ring 250. A mass of infrared absorbing black material 258 is positioned on the opposite surface of the sheet and serves as a radiation collector. A second beryllium oxide ring 252 supports the first ring 250 and the two rings are supported by a copper header 256. A window 235 formed of silicon or germanium is mounted on the first ring 250. The rings 250 and 252, the window 235 and the header 256 are thermally coupled by high thermal conductivity epoxy 255. A pair of leads 260 formed of 20 mils of Kovar provide structural support to the assembly and provide a thermopile output signal to the electronics via a pair of 40 gauge wires 262. As such, the tube and the region defined by the surface 237 and the window 235 are filled with air. A sufficient amount of silver paint may be included within the rings to oxidize all air, and thus create a nitrogen environment in the gas tight region. Alternatively, the window may be positioned at the distal end 226 of the housing 218 as indicated by the dashed lines in FIG. 4. Having the window positioned directly on the sensor assembly minimizes temperature gradients between the window and thermopile, but positioning the window at the distal end minimizes contamination of the surface of tube 232.

It has been determined that a significantly narrower field of view provides the user with an easier and more accurate tympanic temperature indications. The detector disclosed in the '419 patent had a wide field of view of about 120° and the detectors disclosed in the '813 patent and described in the other embodiment have a field of view of about 60° or less. Thus, one object of this embodiment was to reduce the field of view to obtain a narrower field of view of about thirty degrees or less. To that end, the narrower field of view is obtained by plating the inner surface of the tube 232 with

a layer of non-reflective material. Preferably, the non-reflective layer is a metal oxide such as nickel oxide or aluminum oxide. A metal oxide layer is employed because metal oxides are durable and will not change in properties if the inner surface of the tube is cleaned. Further, the metal oxide layer should be thin (a few tenths of thousandths of an inch) such that virtually no temperature gradient exists across the layer. The metal oxide surface absorbs substantially all radiation which strikes the tube 232 and allows radiation passing directly through the tube to reach the thermopile 28.

The dimensions of the tube 232 are chosen such that radiation entering the tube at angles of only up to fifteen degrees from the longitudinal axis of the tube passes directly to the thermopile. With the thirty degree field of view, the probe can easily be positioned such that substantially only the tympanic membrane may be viewed.

The above approach to decreasing the radiation gathering aperture size to about 3 mm and reducing the field of view to about thirty degrees significantly increases the noise level at the thermopile relative to the signal level. Further, this approach increases the amount of radiation which is absorbed by the thermal mass in which the thermopile is mounted. These two effects add to the importance that the thermal mass, including the tube, provide a large thermal mass and high thermal conductivity.

The thermal mass 230 is of unitary construction which eliminates thermal barriers between the tube 232 and the portion 241 of the thermal mass surrounding the thermopile 28. Further, a plug 272 of high thermal conductivity material positioned behind the thermopile 28 is in close thermal contact with the mass 230. The outer sleeve 238 is formed of low thermal conductivity plastic and is separated from the mass 230 by an insulating air space 240. The taper 239 of the mass 230 increases the insulating air space adjacent to the end of the extension 226 while minimizing thermal resistance from the tube 232 to the thermopile. The inner surface of the plastic sleeve 238 may be coated with a good thermal conductor to distribute across the entire sleeve any heat received from contact with the ear.

In order that the hot junction respond only to radiation viewed through the window 235, it is important that the tube 232 and the window 235 be, throughout a measurement, at the same temperature as the cold junction. The thermopile 28 acts as a thermal amplifier having a gain based on the number of junctions and the Seebeck coefficient. Thus, temperature gradients sensed by the thermopile are amplified by a factor of about 100. To minimize errors, changes in temperature in the tube 232 must be held to a minimum, and any such changes should be distributed rapidly to the cold junction to avoid any thermal gradients. To minimize temperature changes, the tube 232 and the mass 230 are well insulated by means of the volume of air 240. To avoid thermal gradients, the tube 232 is plated with a thin layer of high conductance non-reflectance metal oxide which minimizes temperature gradients across the layer. Further, the thermal mass 230 is thermally coupled to the rings 250 and 252 with high conductivity thermal epoxy 255 such that a high conductance thermal path is provided from the tube 232 to the cold junction. This conductance is enhanced by the unitary construction of the mass 230.

In accordance with another aspect of the invention, the amount of thermal epoxy 255 between the rings 250 and 252 and the mass 230 is tuned to the assembly to minimize the response of the thermopile 28 to undesired thermal perturbations at the end of the mass. Referring to FIG. 6, thermal

variations in the air region 243 lead to heating of the tip 227 of the mass 230 which causes the inner surface of the tube 232 to emit radiation. If these thermal variations are not sensed by the cold junction via the high conductance thermal path from the tube 232 in phase with the sensing of the radiation by the hot junction, the thermopile 28 produces an error response.

Accordingly, the epoxy 255 may be incrementally added to adjust the high conductivity thermal path to the cold junction to bring the hot and cold junction thermal responses in phase. An insufficient amount of epoxy 255 causes a positive error response as the hot junction responds to thermal variations faster than the cold junction. Alternatively, too much epoxy 255 causes a negative error response as the cold junction responds faster to thermal variations than the hot junction. When the proper amount of epoxy has been provided, the tuned assembly produces no more than 0.1° thermopile response for up to 20° thermal variations during a test.

It has been determined in previous devices that a significant source of thermal gradients is caused by radiation from the window. To minimize these thermal gradients, the window 235 is mounted on the ring 250 with high thermal conductivity epoxy 255 such that it is thermally coupled to the cold junction. The epoxy provides a significant reduction in thermal resistance and provides good thermal coupling between all elements. On the other hand, conductance to the viewing region of the window should not be less than that to the cold junction. Thus, the window 235 is spaced from a rear face 237 of the mass 230 and its ends are spaced from the inner volume 231 by a low thermal conductivity air region. The region ensures that temperature gradients are distributed to the cold junction via the thermal mass and not directly through the window causing thermal gradients.

The thermal resistance from the outer surface of the plastic sleeve 238 to the conductive thermal mass 230 is high to minimize thermal perturbations to the inner thermal mass. The thermal mass is large to minimize changes in temperature of the tube 232 with any heat transfer to the mass which does occur. Further, the thermal resistance between any two points of the thermal mass 230, the tube 232, the window 235 or the rings 250 and 252 is low to minimize thermal gradients where there is some temperature change in the tube during measurement.

Thus, due to the large time constant of the thermal barrier 238, any external thermal disturbances, such as when the extension contacts skin, only reach the conductive thermal mass 230 at extremely low levels during a measurement period of a few seconds. Due to the large thermal mass of the materials in contact with the cold junction, any such heat transfer only causes small changes in temperature. Also, due to the good thermal conductance throughout the thermal mass, tube, window and rings any changes in temperature are distributed quickly and are reflected in the cold junction temperature quickly so that they do not affect temperature readings.

The thermal RC time constant for thermal conduction through the thermal barrier 238 to the thermal mass 230 and tube 232 is at least two orders of magnitude greater than the thermal RC time constant for the temperature response of the cold junction to heat transferred to the tube and thermal mass. The RC time constant for conduction through the thermal barrier 238 is made large by the large thermal resistance through the thermal barrier and by the large thermal capacitance of the thermal mass. The RC time constant for response of the cold junction is made low by the

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low resistance path to the cold junction through the highly conductive thermal mass, and the low thermal capacitance of the stack of beryllium oxide rings to the thermopile.

Besides the transfer of heat from the environment, another significant heat flow path in the system is through the leads 260. To minimize heat transfer through that path, the lead diameters are kept small and the leads 260 are trimmed off in the region 246. A pair of 40 gauge wires 262 are soldered to the shortened leads 260. The wires 262 extend from the region 246 through the plug 272 and provide thermopile signals to the electronics.

Yet another potential heat flow path in the system is through the header 256 to the plug 272. Since the header is in close thermal contact with the thermopile cold junction, any thermal gradients through the header 256 would be amplified 100 to 1000 times by the thermopile producing large error signals. In the present invention, the insulating region 246 of air is provided behind the header 256 to minimize heat transfer through that path. Thus, any thermal gradients in the plug would be forced to travel through the mass 230 and would be substantially dissipated without affecting the thermopile.

Because the temperature of the thermal mass 230 is not controlled and the response of the thermopile 28 is a function of its cold junction temperature, the cold junction temperature must be monitored. To that end, a thermistor 271 is positioned adjacent to the region 246 in the plug 272. The plug 272 is in thermal contact with the mass 230 such that the thermistor 271 is thermally coupled to the cold junction of the thermopile 28. However, the thermal path between the thermopile 28 and the thermistor has some thermal resistance. This resistance produces a temperature difference between the cold junction temperature and the sensed temperature which is not amplified. Therefore such error is not as significant as gradient errors amplified by the thermopile.

A schematic illustration of the electronics in the housing 14 of both embodiments of the present invention (FIGS. 1 and 3), for providing a temperature readout on display 16 in response to the signal from the thermopile, is presented in FIG. 8. The system is based on a microprocessor 73 which processes software routines included in read only memory within the processor chip. The processor may be a 6805 processor sold by Motorola.

The voltage generated across the thermopile 28 due to a temperature differential between the hot and cold junctions is amplified in an operational amplifier 74. For the detector of FIG. 1, the chopper circuit 67 is not employed and analog output from the amplifier 74 is applied as one input to a multiplexer 76. For the detector of FIG. 3, the thermopile output voltage is smaller so the amplifier 74 is configured in the chopper stabilized amplifier circuit 67. The circuit employs a switched feedback loop that removes internal offset voltages associated with the amplifier 74. The feedback loop comprises switches 69 and 71, an amplifier 73 and a storage capacitor C11. When the radiation detector is powered on, switch 69 is opened and switch 71 is closed. With this configuration, the feedback loop stores the offset voltage for the amplifier 74 in capacitor C11. The switch positions are then reversed such that the input signal to amplifier 74 is combined with the offset stored in the capacitor C11. The combined output is applied an input to the multiplexer 76.

Another input to the multiplexer 76 is a voltage taken from a voltage divider R1, R2 which is indicative of the potential V+ from the power supply 78. A third input to the

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multiplexer 76 is the potential across a thermistor RT1 mounted in the bore 72 of block 36. The thermistor RT1 is coupled in a voltage divider circuit with R3 across a reference potential VRef. The final input to the multiplexer is a potential taken from a potentiometer R4 which may be adjusted by a user. The system may be programmed to respond to that input in any of a number of ways. In particular, the potentiometer may be used as a gain control or as a DC offset control.

At any time during the software routine of the microprocessor 73, one of the four inputs may be selected by the select lines 78. The selected analog signal is applied to a multiple slope analog system 80 used by the microprocessor in an integrating analog-to-digital conversion 80. The sub-system 80 may be a TSC500A sold by Teledyne. It utilizes the reference voltage VRef from a reference source 82. The microprocessor 73 responds to the output from the converter 80 to generate a count indicative of the analog input to the converter.

The microprocessor drives four 7-segment LED displays 82 in a multiplexed fashion. Individual displays are selected sequentially through a column driver 84, and within each selected display the seven segments are controlled through segment drivers 86.

When the switch 22 on the housing is pressed, it closes the circuit from the battery 78 through resistors R5 and R6 and diode D1 to ground. The capacitor C1 is quickly charged, and field effect transistor T1 is turned on. Through transistor T1, the V+ potential from the storage cell 78 is applied to a voltage regulator 86. The regulator 86 provides the regulated +5 volts to the system. It also provides a reset signal to the microprocessor. The reset signal is low until the +5 volt reference is available and thus holds the microprocessor in a reset state. When the +5 volts is available, the reset signal goes high, and the microprocessor begins its programmed routine.

When the switch 22 is released, it opens its circuit, but a charge is maintained on capacitor C1 to keep transistor T1 on. Thus, the system continues to operate. However, the capacitor C1 and transistor T1 provide a very simple watchdog circuit. Periodically, the microprocessor applies a signal through driver 84 to the capacitor C1 to recharge the capacitor and thus keep the transistor T1 on. If the microprocessor should fail to continue its programmed routine, it fails to charge the capacitor C1 within a predetermined time during which the charge on C1 leaks to a level at which transistor T1 turns off. Thus, the microprocessor must continue in its programmed routine or the system shuts down. This prevents spurious readings when the processor is not operating properly.

With transistor T1 on, the switch 22 can be used as an input through diode D2 to the microprocessor to initiate any programmed action of the processor.

In addition to the display, the system has a sound output 90 which is driven through the driver 84 by the microprocessor.

In order to provide an analog output from the detector, a digital-to-analog convertor 92 is provided. When selected by line 94, the convertor converts serial data on line 96 to an analog output made available to a user.

Both calibration and characterization data required for processing by the microprocessor may be stored in an electrically erasable programmable read only memory (EEPROM) 100. The EEPROM may, for example, be a 93c46 sold by International CMOS Technologies, Inc. The data may be stored in the EEPROM by the microprocessor

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when the EEPROM is selected by line 102. Once stored in the EEPROM, the data is retained even after power down. Thus, though electrically programmable, once programmed the EEPROM serves as a virtually nonvolatile memory.

Prior to shipment, the EEPROM may be programmed through the microprocessor to store calibration data for calibrating the thermistor and thermopile. Further, characterization data which defines the personality of the infrared detector may be stored. For example, the same electronics hardware, including the microprocessor 73 and its internal program, may be used for a tympanic temperature detector in which the output is accurate in the target temperature range of about 60° F. to a 110° F. or it may be used as an industrial detector in which the target temperature range would be from about -100° F. to 5000° F. Further, different modes of operation may be programmed into the system. For example, several different uses of the sound source 90 are available.

Proper calibration of the detector is readily determined and the EEPROM is readily programmed by means of an optical communication link which includes a transistor T2 associated with the display. A communication boot may be placed over the end of the detector during a calibration/characterization procedure. A photodiode in the boot generates a digitally encoded optical signal which is filtered and applied to the detector T2 to provide an input to the microprocessor 73. In a reverse direction, the microprocessor may communicate optically to a detector in the boot by flashing specific segments of the digital display 82. Through that communication link, an outside computer 106 can monitor the outputs from the thermistor and thermopile and perform a calibration of the devices. A unit to be calibrated is pointed at each of two black body radiation sources while the microprocessor 73 converts the signals and sends the values to the external computer. The computer is provided with the actual black body temperatures and ambient temperature in the controlled environment of the detector, computes calibration variables and returns those variable to be stored in the detector EEPROM. Similarly, data which characterizes a particular radiation detector may be communicated to the microprocessor for storage in the EEPROM.

A switch 108 is positioned behind a hole 110 (FIG. 1) in the radiation detector so that it may be actuated by a rigid metal wire or pin. Through that switch, the user may control some specific mode of operation such as converting the detector from degrees Fahrenheit to degrees centigrade. That mode of operation may be stored by the microprocessor 73 in the EEPROM so that the detector continues to operate in a specific mode until a change is indicated by closing the switch 108.

A switch 106 may be provided either internally or through the housing to the user to set a mode of operation of the detector. By positioning the switch at either the lock position, the scan position or a neutral position, any of three modes may be selected. The first mode is the normal scan mode where the display is updated continuously. A second mode is a lock mode where the display locks after a selectable delay and then remains frozen until power is cycled or, optionally, the power-on button is pushed. The sound source may be caused to sound at the time of lock. The third mode is the peak mode where the display reads the maximum value found since power-on until power is cycled or, optionally, the power-on button is pushed.

The processor determines when the voltage from the divider R1, R2 drops below each of two thresholds. Below the higher threshold, the processor periodically enables the

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sound source to indicate that the battery is low and should be replaced but allows continued readout from the display. Below the lower threshold, the processor determines that any output would be unreliable and no longer displays temperature readings. The unit would then shut down upon release of the power button.

In the present system, the target temperature is computed from the relationship

$$T_z = Kh(H - H_c) + T_H \quad (1)$$

where T_z is the target temperature, Kh is a gain calibration factor, H is the radiation sensor signal which is offset by H_c , such that $(H - H_c) = 0$ when the target is at the cold junction temperature of the device to counter any electronic offsets in the system, and T_H is the hot junction temperature. This relationship differs from that previously used in that Kh is temperature compensated relative to the average temperature of the thermopile rather than the cold junction, or ambient, temperature. Further, the hot junction temperature rather than the cold junction temperature is referenced in the relationship.

The gain calibration factor Kh is temperature compensated by the relationship

$$Kh = G \left(1 - Tco \left(\frac{T_H - T_C}{2} - T_z \right) \right) \quad (2)$$

where G is an empirically determined gain in the system, Tco is the temperature coefficient of the Seebeck coefficient of the thermopile and T_z is the temperature at which the instrument was calibrated. The use of the average temperature of the thermopile rather than the cold junction temperature provides for a much more accurate response where a target temperature is significantly different from the ambient temperature.

As noted, the relationship by which the target temperature is determined includes the hot junction temperature as the second term rather than the cold junction temperature. Hot junction temperature is computed from the relationship

$$V_s = J_s \alpha_{avg} (T_H - T_C) \quad (3)$$

where J_s is the number of junctions in the thermopile and α_{avg} is the specified Seebeck coefficient at the average temperature of the thermopile. The Seebeck coefficient can be determined from the relationship

$$\alpha_{avg} = \alpha_s \left(1 - Tco \left(\frac{T_H - T_C}{2} - T_s \right) \right) \quad (4)$$

where α_s is the specified Seebeck coefficient at a particular specification temperature and T_s is that specification temperature. Again, it can be seen that temperature compensation is based on the average thermopile temperature rather than just the cold junction temperature. By substituting equation (4) into equation (3) and solving for T_H , the hot junction temperature is found to be

$$T_H = \frac{(V_s / (J_s \alpha_s)) + Tco \left(\frac{T_H - T_C}{2} - T_s \right) (T_H - T_C)}{1 - Tco \left(\frac{T_H - T_C}{2} - T_s \right)} \quad (5)$$

The actual sensor output V_s can be determined from the digital value available to the processor from the equation:

$$V_s = (H - H_o) \frac{K_{AD}}{G_{FE}} \quad (6)$$

where K_{AD} is the analog-to-digital conversion factor in volts/bit and G_{FE} is the gain of the front end amplifier.

Reference to the hot junction temperature rather than the cold junction temperature in each term of the relationship for determining the target temperature provides for much greater accuracy over a wide range of ambient temperatures and/or target temperatures.

To provide a temperature readout, the microprocessor makes the following computations: First the signal from thermistor RTI is converted to temperature using a linear approximation. Temperature is defined by a set of linear equations

$$y = M(x - x_0) + b$$

where x is an input and x_0 is an input end point of a straight line approximation. The values of M , x_0 and b are stored in the EEPROM after calibration. Thus, to obtain a temperature reading from the thermistor, the microprocessor determines from the values of x_0 the line segment in which the temperature falls and then performs the computation for y based on the variables M and b stored in the EEPROM.

The hot junction temperature is computed. A fourth power representation of the hot junction temperature is then obtained by a lookup table in the processor ROM.

The sensed radiation may be corrected using the gain calibration factor Kh , the sensor gain temperature coefficient Tco , the average of the hot and cold junction temperatures and a calibration temperature Tz stored in the EEPROM. The corrected radiation signal and the fourth power of the hot junction temperature are summed, and the fourth root is taken. The fourth root calculation is also based on a linear approximation which is selected according to the temperature range of interest for a particular unit. Again, the break points and coefficients for each linear approximation are stored in the EEPROM and are selected as required.

An additional factor based on ambient temperature may also be included as an adjustment. The temperature of the ear T_e is instead of the temperature of the tympanic membrane, the temperature sensed by the thermopile is not actually the core temperature T_c . There is thermal resistance between T_{er} and T_e . Further, there is thermal resistance between the sensed ear temperature and the ambient temperature. The result is a sense temperature T_s which is a function of the core temperature of interest and the ambient temperature. Based on an assumed constant K_c which is a measure of the ratio of thermal resistances between T_{er} , T_e and T_a , T_{er} and T_c core temperature can be computed as

$$T_{er} = T_a + \frac{T_e - T_a}{k_c}$$

This computation can account for a difference of from one-half to one degree or more between core temperature and sensed ear temperature, depending on ambient temperature.

A similar compensation can be made in other applications. For example, in differential cutaneous temperature scanning, the significance of a given differential reading may be ambient temperature dependent.

The actual computations performed by the processor are as follows, where:

H is the digital value of radiation signal presented to the processor

H_o is the electronic offset

Hc is corrected H (deg K^4)

Tc is ambient and cold junction temperature (deg F)

Taf is 4th power of $Tamb$ (deg K^4)

Tt is target temperature (deg F)

Tz is ambient temp during cal (deg F)

Td is the displayed temperature

Rt is the thermistor signal

Kh is a radiation sensor gain cal factor

Zt is a thermistor zero cal factor

Th is the hot junction temperature

α_{ex} is the Seebeck coefficient of the thermopile at a specified temperature

J is the number of junctions in the thermopile

Tco is a temperature coefficient for the Seebeck coefficient

Ts is the temperature at which α_{ex} is specified

Tcr is core temperature

kc is a constant for computing core temperature

V_s is the sensor output voltage

G_{FE} is the gain of the front end amplifier

K_{AD} is the analog-to-digital conversion factor

$$V_s = (H - H_o) K_{AD} / G_{FE}$$

Tc (deg F) = Thermistor lookup table (Rt) - Zt

$$T_{Hf} = [(Tco * Tc + 1) \pm \{ (Tco * Ts + 1)^2 - (2 * Tco) * [(Tco * (Tc * Ts) - (Tc^2 * 2)) + Tc + (V_s / J * \alpha_{ex})] \}^{1/2}] / Tco$$

$$Hc \text{ (deg } K^4) = Kh * (H - H_o) * (1 + Tco * ((Th - Tc) / 2 - Tz))$$

Thf (deg K^4) = 4th power lookup table (Tc)

$$Tt \text{ (deg } F) = (Hc + Thf)^{1/4} \text{ (Final lookup table)}$$

$$Tcr = Te + (Tt - Te) / kc$$

$$Tt \text{ (deg } C) = (5/9) * (Tt \text{ (deg } F) - 32) \text{ optional}$$

The following is a list of the information which may be contained in the EEPROM and therefore be programmable at the time of calibration:

Radiation sensor offset

Radiation sensor gain

Radiation sensor temperature coefficient

Thermistor offset

Ambient temperature at calibration

Thermistor lookup table

Final temperature lookup table

Adjustment factor F

Sound source functions.

Beep at button push in lock mode

none/20/40/80 milliseconds long

Beep at lock

none/20/40/80 milliseconds long

Beep at power down

none/20/40/80 milliseconds long

Beep at lowbattery

none/20/40/80 milliseconds long

interval 1/2/3 sec

single/double beep

Timeout functions:

Time to power-down

0.5 to 128 sec in 0.5 sec increments

Delay until lock

0.5 to 128 sec in 0.5 sec increments

Other functions:

Power-on button resets lock cycle

Power-on button resets peak detect

Display degrees C/degrees F

EEPROM "Calibrated" pattern to indicate that the device has been calibrated

EEPROM checksum for a self-check by the processor
 FIGS. 9A-9D provide a flowchart of the firmware stored in the microprocessor 73. From reset when the instrument is turned on, the system is initialized at 110 and the contents of the EEPROM are read into memory in the microprocessor at 112. At 114, the processor reads the state of power and mode switches in the system. At 116, the system determines whether a mode switch 113 has placed the system in a self-test mode. If not, all eights are displayed on the four-digit display 82 for a brief time. At 120, the system performs all A-to-D conversions to obtain digital representations of the thermopile output and the potentiometer settings through multiplexor 76.

The system then enters a loop in which outputs dictated by the mode switch are maintained. First the timers are updated at 122 and the switches are again read at 124. When the power is switched off, from 126 the system enters a power down loop at 128 until the system is fully down. At 130, the mode switch is checked and if changed the system is reset. Although not in the tympanic temperature detector, some detectors have a mode switch available to the user so that the mode of operation can be changed within a loop.

At 132, 136 and 140, the system determines its mode of operation and enters the appropriate scan process 134, lock process 138 or peak process 142. In a scan process, the system updates the output to the current reading in each loop. In a lock process, the system updates the output but locks onto an output after some period of time. In the peak process, the system output is the highest indication noted during a scan. In each of these processes, the system may respond to the programming from the EEPROM to perform any number of functions as discussed above. In the peak process which is selected for the tympanic temperature measurement, the system locks onto a peak measurement after a preset period of time. During assembly, the system may be set at a test mode 144 which will be described with respect to FIG. 9D.

In any of the above-mentioned modes, an output is calculated at 146. Then the system loops back to step 122. The calculation 146 is illustrated in FIG. 9B.

At 148 in FIG. 9B, the raw sensor data is obtained from memory. The sensor offset taken from the EEPROM is subtracted at 150, and the ambient temperature previously obtained from the potentiometer RT1 is accessed at 152. The temperature coefficient adjustment is calculated at 154. At 156, the sensed signal is multiplied by the gain from EEPROM and by the temperature coefficient. At 158, the fourth power of the ambient temperature is obtained, and at 160 it is added to the sensor signal. At 162, the fourth root of the sum is obtained through a lookup table. Whether the display is in degrees centigrade or degrees Fahrenheit is determined at 164. If in degrees centigrade, a conversion is performed at 166. At 168, adjustment values, including that from the potentiometer R4, are added.

Analog-to-Digital conversion is performed periodically during an interrupt to the loop of FIG. 9A which occurs every two milliseconds. The interrupt routine is illustrated in FIG. 9C. Timer counters are updated at 170. A-to-D conversions are made from 172 only every 100 milliseconds when a flag has been set in the prior interrupt cycle. During most interrupts, an A/D conversion does not occur. Then, the 100-millisecond counter is checked at 174, and if the count has expired, a flag is set at 176 for the next interrupt. The flag

is checked at 178 and, if found, the display is updated at 180. The system then returns to the main loop of FIG. 9A.

Where the 100 millisecond flag is noted at 172, an A-to-D conversion is to be performed. The system first determines at 182 whether a count indicates there should be a conversion of the thermopile output at 184 or a conversion of the thermistor output at 186. The thermopile sensor conversion is performed nine out of ten cycles through the conversion loop. At 188, the system checks to determine whether a conversion is made from the potentiometer R4 or from the battery voltage divider R1, R2 at 192. These conversions are made alternately.

FIG. 9D illustrates the self-test sequence which is called by the mode switch 113 only during assembly. During the test, the beeper sounds at 182 and all display segments are displayed at 184. Then the system steps each character of the display from zero through nine at 186. The system then enters a test loop. At 188, the system senses whether the button 108 has been pressed. If so, a display counter is incremented at 190. The display for the unit then depends on the count of the display counter. With the zero count, the adjustment potentiometer value is displayed at 192. Thereafter, if the display counter is incremented by pressing the button 108, the raw sensor data is displayed. With the next increment, ambient temperature is displayed at 196, and with the next increment, the raw output from the ambient temperature sensor RT1 is displayed. With the next increment, the battery voltage is displayed. After the test, the assembler sets the mode switch to the proper operating mode.

While this invention has been particularly shown and described with references to preferred embodiments hereof, it will be understood by those skilled in the art that various changes in form and details may be made therein without departing from the spirit and scope of the invention as defined by the appended claims. For example, most features of the invention may be applied to a device having a pyroelectric radiation sensor. Also certain features such as the low reflectance, high thermal conductivity tube may provide stable response and narrow field of view even where the tube is thermally isolated from the sensor. In that case, a second temperature sensor would be provided for the tube to compensate for temperature differences between the tube and sensor cold junction.

What is claimed is:

1. A method of detecting temperature of biological tissue comprising:

- providing a radiation detector for sensing infrared radiation from an external target;
- sensing radiation from multiple areas of the biological tissue with the radiation detector; and
- electronically detecting the peak radiation from the multiple areas to obtain a peak temperature signal.

2. A method as claimed in claim 1 wherein the radiation detector comprises a temperature display for displaying the peak temperature of the biological tissue during scan.

3. A method as claimed in claim 1 wherein the radiation sensor is a thermopile.

4. A method as claimed in claim 1 further comprising sounding an audible tone from the radiation detector to indicate detection of peak radiation.

5. A method as claimed in claim 1 wherein the biological tissue is scanned with movement of the radiation detector.

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US006292685B1

(12) **United States Patent**
Pompei

(10) **Patent No.:** **US 6,292,685 B1**
(45) **Date of Patent:** **Sep. 18, 2001**

(54) **TEMPORAL ARTERY TEMPERATURE DETECTOR**

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(*) **Notice:** Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

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(51) **Int. Cl.:** **A61B 6/00**

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(52) **U.S. Cl.:** **600/474; 600/475; 600/549; 374/100; 374/104; 374/112; 374/121; 374/123; 374/124; 374/126; 374/129; 374/132; 374/133**

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(58) **Field of Search:** **374/124, 121, 374/100, 104, 126, 127, 128, 129, 133; 600/310, 309, 473, 474, 475, 549**

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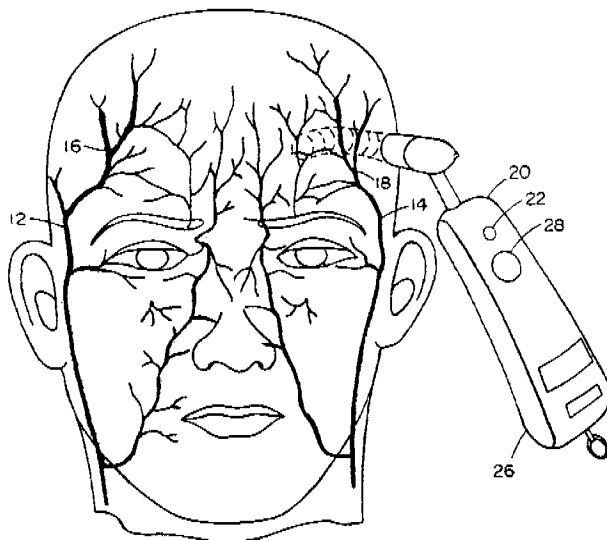
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4,636,091	*	1/1987	Pompei et al.	374/124
4,993,419	*	2/1991	Pompei et al.	128/664
5,012,813		5/1991	Pompei et al.	128/664
5,050,612	*	9/1991	Matsumura	128/670
5,150,969	*	9/1992	Goldberg et al.	374/128
5,187,943	*	2/1993	Taniguchi et al.	62/180
5,199,436		4/1993	Pompei et al.	128/664
5,271,407		12/1993	Pompei et al.	128/664
5,381,796		1/1995	Pompei	128/664
5,441,476	*	8/1995	Kitado et al.	600/26
5,445,158		8/1995	Pompei	128/664
5,653,238		8/1997	Pompei	128/664

Body temperature measurements are obtained by scanning a thermal radiation sensor across the side of the forehead over the temporal artery. A peak temperature measurement is processed to compute an internal temperature of the body as a function of ambient temperature and the sensed surface temperature. The function includes a weighted difference of surface temperature and ambient temperature, the weighting being varied with target temperature through a minimum in the range of 96° F. and 100° F. The radiation sensor views the target surface through an emissivity compensating cup which is spaced from the skin by a circular lip of low thermal conductivity.

37 Claims, 4 Drawing Sheets



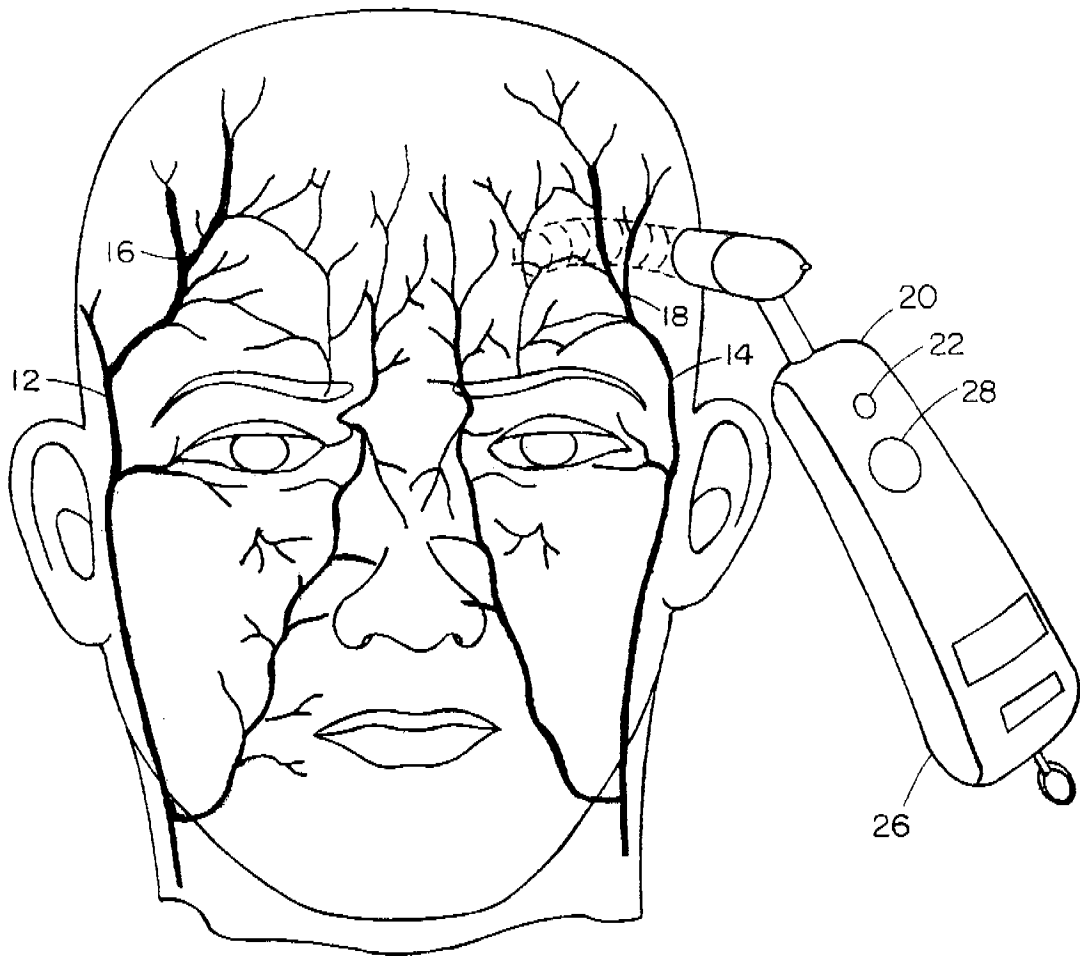


FIG. 1

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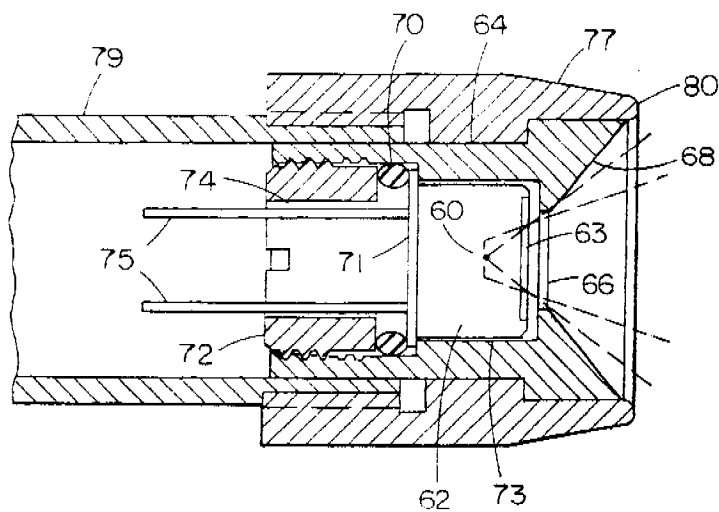


FIG. 2A

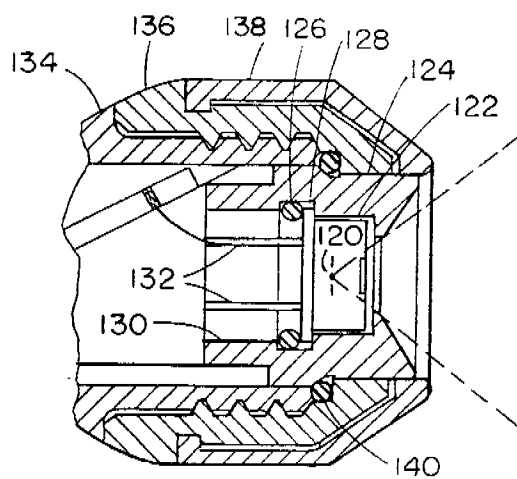


FIG. 2B

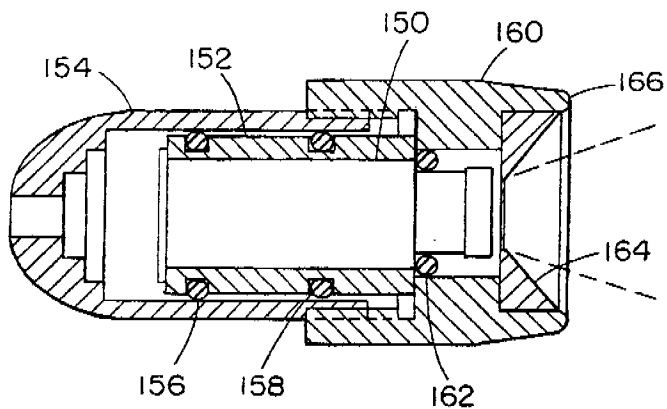


FIG. 2C

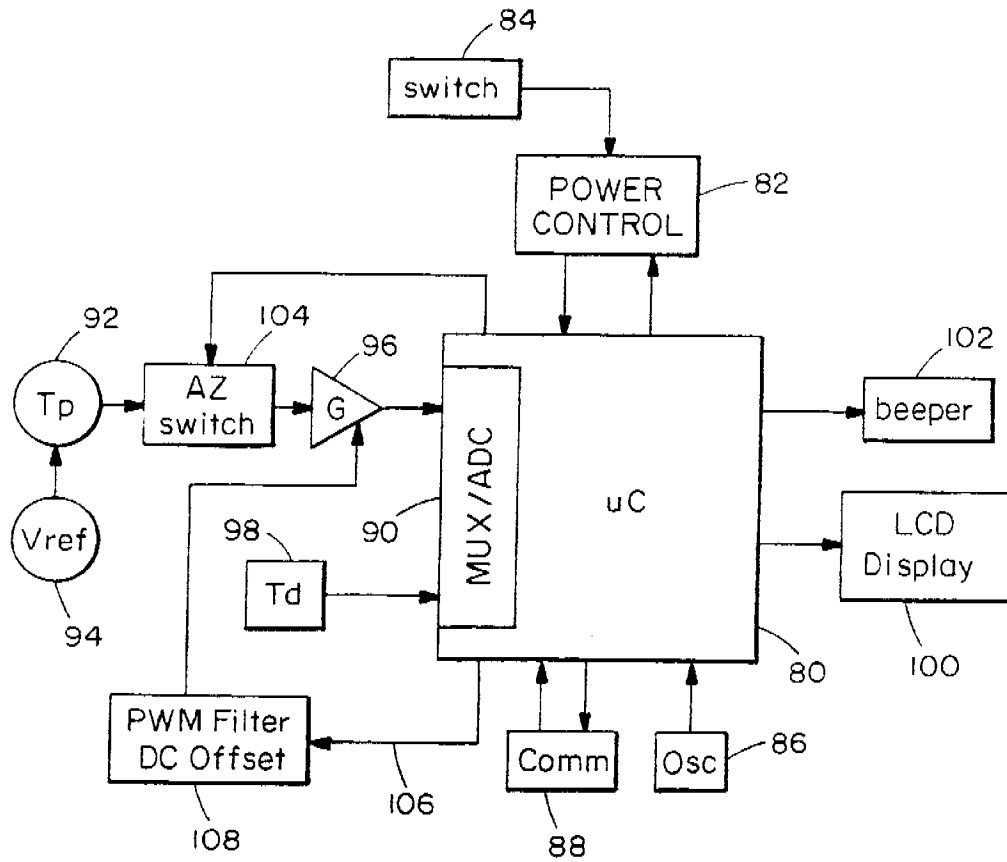


FIG. 3

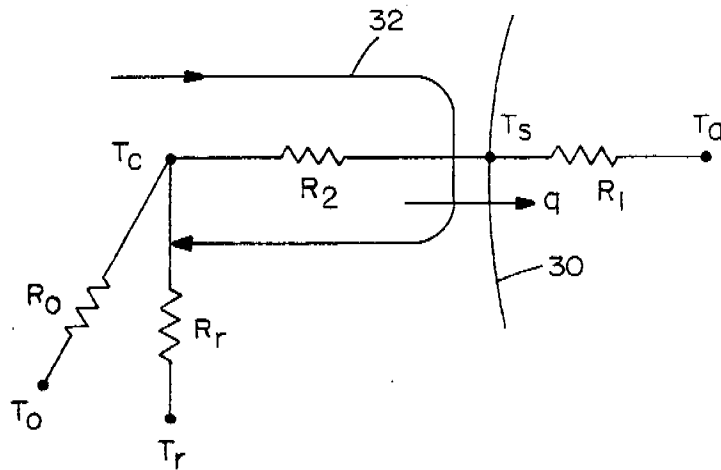


FIG. 4

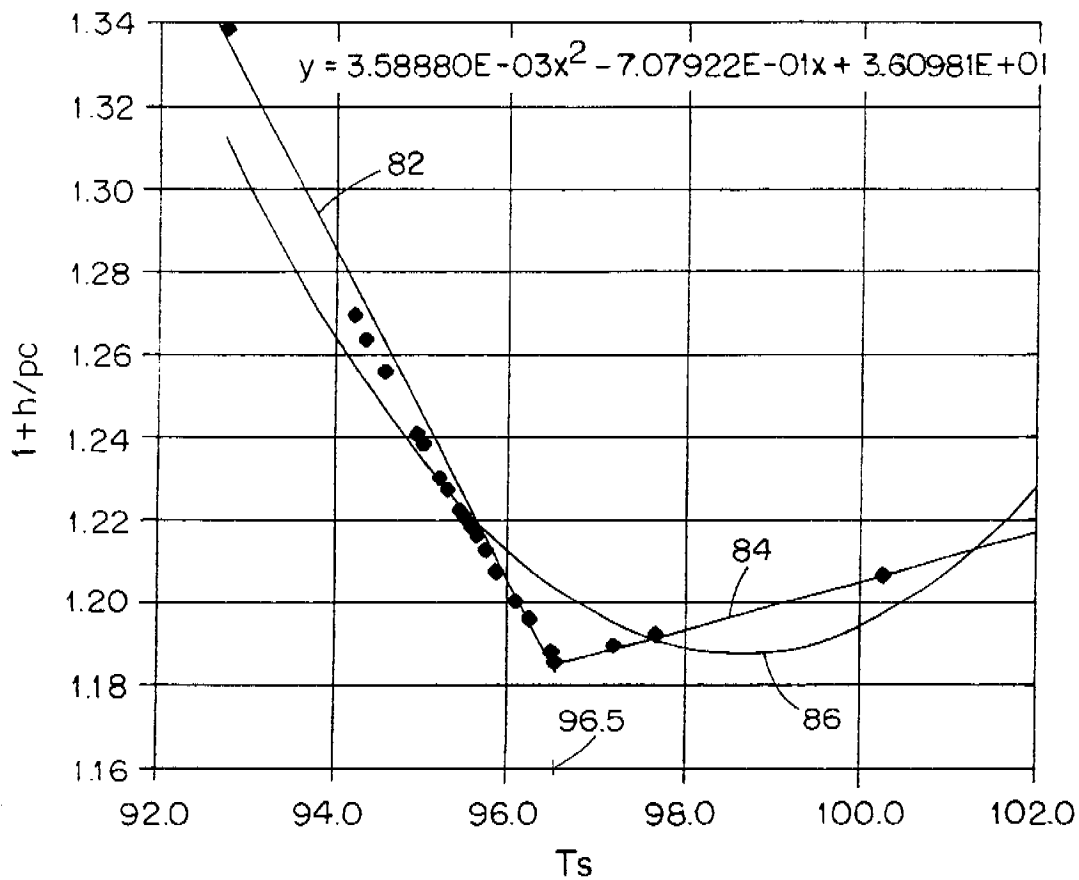


FIG. 5

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TEMPORAL ARTERY TEMPERATURE DETECTOR

BACKGROUND OF THE INVENTION

In recent years, infrared thermometers have come into wide use for detection of temperature of adults. For core temperature readings, infrared thermometers which are adapted to be inserted into the patient's ear have been very successful. Early infrared thermometers were adapted to extend into the ear canal in order to view the tympanic membrane and provide an uncorrected, direct reading of tympanic temperature which correlates with pulmonary artery temperature. More recently, however, to provide for greater comfort and ease of use, ear thermometers have been designed to provide corrected readings of the generally cooler distal ear canal. Such thermometers measure temperature of distal ear canal tissue and calculate arterial core temperature via heat balance.

Core temperature is a term used to describe deep body temperature and is approximated by oral, rectal, ear, pulmonary artery, esophageal and bladder temperatures and the like. Of those temperatures, pulmonary artery temperature is the most precise definition of core temperature since it is closest to the heart and its blood is supplied to all tissues. Calculations of arterial core temperature via heat balance provide approximations of the pulmonary artery temperature, and unless otherwise indicated, core temperature refers to the pulmonary artery temperature.

The arterial heat balance approach is based on a model of heat flow through series thermal resistances from the arterial core temperature to the ear skin temperature and from the ear skin temperature to ambient temperature. Accordingly, after sensing both the skin temperature and ambient temperature, the arterial core temperature can be calculated. The thermal resistance model also allows for computation of equivalent oral and rectal temperatures with the mere adjustment of a weighting factor in the computation. Infrared ear thermometers using the arterial heat balance are disclosed in U.S. Pat. Nos. 4,993,419; 5,012,813; 5,199,436; 5,381,796; 5,445,158; 5,653,238 and 5,271,407, the entire teachings of which are incorporated herein by reference.

To avoid clinical difficulties in using ear thermometers, particularly with neonates, axillary (underarm) infrared thermometers have been introduced. Infrared thermometers designed for axillary temperature measurements are presented in U.S. patent applications Ser. Nos. 08/469,484, 08/738,300 and 08/881,891, the entire teachings of which are incorporated herein by reference. In each of those devices, an infrared detector probe extends from a temperature display housing and may easily slide into the axilla to lightly touch the apex of the axilla and provide an accurate infrared temperature reading in as little as one-half second. The axillary thermometer also relies on the arterial heat balance approach to provide arterial, oral or rectal temperature.

The axillary infrared thermometer has found great utility not only with neonates but as a screening tool in general, and especially for small children where conventional temperature measurements such as a thermometer under the tongue or a rectal thermometer are difficult.

In ear and neonate axillary thermometry, the difference between skin temperature and ambient temperature has been weighted by a coefficient approximating h/pc , where h is an empirically determined coefficient which includes a radiation view factor between the skin tissue and ambient, p is perfusion rate and c is blood specific heat. In ear and neonate

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axillary thermometry, that coefficient was found empirically to be about 0.09 and 0.05, respectively, with only minor variations. However, with greater exposure for heat transfer and higher vasomotor functions, that coefficient has been determined empirically for the adult axillary region to be about 0.13 with much more significant variations according to the patient's temperature.

SUMMARY OF THE INVENTION

The present invention provides for particularly convenient temperature readings of neonate, child and adult temperatures by detecting the temperature of the forehead directly over the superficial temporal artery.

Because arteries receive blood directly from the heart, they are a good choice for detecting core temperature, but an artery at the extremities of the body, such as those felt as pulse points at the wrist or ankle, are highly subject to vasoconstriction. This means, for example, that when an individual is extremely sick, in shock, or even just cold or nervous, the arteries constrict to reduce the flow of blood to that area as a means of retaining heat, or as in the case of shock, in an effort to redirect the blood to more critical areas of the body. This can result in a large temperature change at the artery which is a local artifact only and not representative of core temperature.

Ruling out those arteries located in the extremities, in attempting to replicate the temperature at the source (the heart), we find, in the temporal artery, an artery as short a distance from the heart as possible, with a high and relatively constant blood flow, and that is readily accessible on all individuals. The heart, the lungs and the brain are vital to our very existence, so the supply of blood is high to these organs and continues as high as possible even through, in the face of grave illness, other areas may shut down to accommodate.

Originating in the heart is the aorta, the main trunk of the arterial system. A direct extension of the aorta is the common carotid artery, a robust artery which runs upward in the neck and divides into the internal and external carotids. But, the carotids, even the external carotid, are at best partially embedded, and at worst completely embedded in the skull, and therefore are not accessible at the skin. Extending directly from the carotid is the temporal artery, again an artery dividing internally and externally. We look to the external branch which travels in front of the ear and up into the soft temple area, terminating in a fork directly between the skin and the skull adjoining the eyebrow.

Demonstrably, the temporal artery is very easily accessible; in fact in most individuals, it is usually quite visible. Terminating in a two-prong fork, it easily doubles the assurance of measuring the correct area. Touching it does not present a risk of injury. There are no mucous membranes present, thus eliminating the risk of contaminates such as those found in the mouth and rectum. And, despite lying so close to the skin surface, the temporal artery perfusion, which is the flow of blood per unit volume of tissue, remains relatively constant and so ensures the stability of blood flow required for our measurement.

In accordance with one aspect of the invention, a temperature sensor is scanned across the forehead, preferably in the vicinity of the temporal artery, and a peak temperature reading is provided from the scan. At least three readings per second should be made during the scan, preferably about ten readings per second. The method can be extended to other arteries near the skin such as in the axilla. The preferred radiation sensor is a radiation sensor which views a target

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surface of the forehead through a reflective cup. The cup has a large open diameter close to the target surface and a window at the base of the cup through which the radiation sensor views the target, the cup being out of the field of view of the sensor. The reflective cup is spaced from the target surface by a smooth lip of low thermal conductivity material.

As in prior ear and axillary thermometers, internal core temperature can be computed from the function

$$T_s = (1 + (h/pc))(T_s - T_a) + T_a \quad (1)$$

where T_s and T_a are the skin and ambient temperatures. The function can be seen to include a weighted difference of surface temperature and ambient temperature with a weighting coefficient h/pc .

In accordance with another aspect of the invention, electronics in the detector compute an internal temperature of the body as a function of ambient temperature and sensed surface temperature. The function includes a weighted difference of surface temperature and ambient temperature, the weighting being varied with target temperature. The weighting varies with target temperature through a minimum in the range of 96° F. to 100° F., the weighting increasing above and below the minimum. In particular, the weighting is an approximation of h/pc at the forehead artery where h is a heat transfer coefficient between the target surface and ambient, p is perfusion rate and c is blood specific heat. In a preferred embodiment, the weighting is a linear approximation having a minimum between 96° F. and 97° F. The approximation of h/pc at the minimum is about 0.19. In another embodiment, the weighting includes a polynomial approximation of $1 + h/pc = k_1 T_s^2 - k_2 T_s + k_3$, where h is a heat transfer coefficient between the target surface and ambient, p is perfusion rate, c is blood specific heat, T_s is skin temperature, k_1 is approximately 0.00359, k_2 is approximately 0.708 and k_3 is approximately 36.1.

BRIEF DESCRIPTION OF THE DRAWINGS

The foregoing and other objects, features and advantages of the invention will be apparent from the following more particular description of preferred embodiments of the invention, as illustrated in the accompanying drawings in which like reference characters refer to the same parts throughout the different views. The drawings are not necessarily to scale, emphasis instead being placed upon illustrating the principles of the invention.

FIG. 1 illustrates an infrared thermometer scanning the temporal artery in the forehead in accordance with the present invention.

FIGS. 2A, B and C are cross-sectional views of three embodiments of the radiation sensor assembly of the invention.

FIG. 3 is an electrical block diagram of the electronics of the thermometer of FIG. 1.

FIG. 4 illustrates the arterial heat balance model.

FIG. 5 illustrates the change in weighting coefficient $(1+h/pc)$ with change in skin temperature.

DETAILED DESCRIPTION OF THE INVENTION

As illustrated in FIG. 1, the temporal arteries 12 and 14 extend upwardly toward the side of the human face and bifurcate at 16 and 18 in the forehead region. In that region, the temporal artery passes over the skull bone very close to the skin and is thus termed the superficial temporal artery.

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The superficial temporal artery is, therefore, particularly accessible for providing temperature readings and, as an artery, has a temperature close to the heart temperature. Further, there are no known arterial/venous anastomoses, that is, shunts between the artery and veins for regulation of skin temperature. Accordingly, the blood flow is relatively stable, varying a maximum of only 50% as opposed to as much as 500% in other areas of the skin.

To locate the temporal artery, a temperature sensor, preferably a radiation detector 20, is scanned across the side of the forehead over the temporal artery while electronics in the detector search for the peak reading which indicates the temporal artery. Preferably, that temperature reading is then further processed in accordance with an algorithm specific to the temporal artery for providing a display temperature which may, for example, correspond to core, oral or rectal temperature.

The temperature detector 20 provides an audible beep with each peak reading. A display 26 provides the temperature reading resulting from the electronic processing discussed below, updated to each new peak reading. A button 28 enables the user to activate the temperature detector. In one embodiment, an LED 22 which flashes with each peak reading can be observed when someone other than the patient performs the reading, and another LED on the other side of the housing can be observed by the patient, particularly when taking his own temperature.

FIG. 2A illustrates one sensor assembly for the radiation detector of FIG. 1. The assembly is similar to that presented in application Ser. No. 08/881,891. A thermopile 60 is mounted within a can 62 in conventional fashion. For high stability the thermopile may be a vapor deposited thermopile surrounded with xenon gas, but for reduced cost it may be a semiconductor thermopile surrounded with air. An infrared radiation transparent window 63 is provided over a viewing opening in the can. The can 62 is set within a bore within a heat sink 64. A shoulder defines an aperture 66 at the base of a conical cup 68 through which the thermopile views the target. The cup is preferably of low emissivity in order to provide emissivity compensation as disclosed in U.S. Pat. No. 4,636,091. Preferably, the heat sink 64 in which the cup is formed is of aluminum. Alternatively, the heat sink may be of brass, nickel plated in the cup region.

An elastomeric o-ring 70 is positioned behind the can 62. A plug 72 is threaded into the bore in the heat sink 64 to press the ring 70 against the rear flange 71 of the can and thus press the flange against a shoulder in the heat sink bore. With the flange pressed against the shoulder and having a close tolerance with the larger diameter of the bore, an air gap 73 is maintained about the side and front of the can. This arrangement provides for good thermal contact between the can and the heat sink 64 at the rear and also makes the thermopile highly resistant to mechanical shock since the shock is only transferred through the thin flange past the shock absorbing elastomer. If the flange were rigidly clamped between metal parts, there would be a danger of shock breaking the gas seal of the can. An opening 74 is provided through the center of the plug 72 for access of electrical leads 75 to the thermopile can. The heat sink 64 is press fit in a plastic cap 77 which is threaded on to the tubular head 79 of the detector.

The plastic cap 77 in which the sensor assembly is mounted is of low thermal conductivity, preferably less than one hundredth that of aluminum. The housing thermally isolates the heat sink 64 from the surrounding environment to minimize heat flow to the heat sink. Further, the heat sink

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64 is of significant thermal mass. Accordingly, the RC time constant for change in temperature of the radiation sensor, with change in temperature to which the housing is exposed, can be made large for a more stable temperature reading. The thermal resistance is made high by the low conductivity housing, and the thermal capacitance is made high by the large mass of the heat sink 64. That RC time constant should be at least 5 minutes and is preferably about 25 minutes.

Past designs of infrared thermometers, such as presented in U.S. Pat. No. 4,993,419, have relied on a massive thermopile can which also served as the heat sink. That design assured a high RC time constant for thermal conduction through the external thermal barrier to the heat sink relative to a thermal RC time constant for temperature response of the cold junction to heat transferred to the heat sink. The latter low RC time constant was obtained by assuring a low thermal resistance to the cold junction using expensive high conductivity material in a specially designed can/heat sink. In the present device, a design goal is to use a conventional low cost thermopile mounted in a light weight can which does not provide the low thermal resistance of the prior design. Accordingly, it is important that the can be mounted to assure that all heat conduction to the thermopile be through the rear of the can which serves as the thermal ground to the thermopile. That objective is obtained by making thermal contact to the can through the rear flange and assuring an air space about the sides and front of the can.

Forming the emissivity compensating cup 68 in the heat sink reduces the cost of the assembly and also improves the thermal characteristics. Although the emissivity of the cup is ideally zero, it is in fact about 0.1. With the cup formed as part of the heat sink, it is at the temperature to which the can is grounded. Accordingly, any thermal emissions from the surface 68 will be at substantially the same temperature as the cold junction and thus not be seen. The electronics can also be calibrated to compensate for the loss of reflectance due to non-ideal emissivity, but that calibration is affected by the temperature of the reflective surface. By assuring that the surface 68 is at the temperature to which the thermopile can is grounded, the temperature of the surface is generally known and compensation can be made temperature dependent.

When adapted to household use, concerns for patient cross-contamination associated with clinical temperature detectors is not so significant. Further, at the forehead, evaporation of moisture is not as significant as in the ear and axillary applications. Accordingly, the disposable radiation transparent covers used in prior infrared thermometers, such as in Ser. Nos. 08/469,484 and 08/738,300 is less desirable. However, in the clinical environment, the transparent cover is still preferred to prevent cross contamination.

During the scanning of the radiation detector across the forehead, contact of the housing 78 with the skin can cause cooling of the skin. To minimize that cooling, a circular lip 80 protrudes axially beyond the tip of the heat sink 64. The lip has a thin radius of 0.02 to 0.05 inch, preferably about 0.03 inch, to minimize the thermal conductance through the insulation material. The heat sink 64 is recessed 0.02 to 0.05 inch, preferably about 0.03 inch, behind the tip of the lip. For comfort during scanning, the lip has a smooth curve.

Another embodiment of the radiation sensor assembly is presented in FIG. 2B. As in the prior embodiment, the thermopile 120 is positioned within a can 122. The can is retained in a heat sink 124 by an o-ring 126 which presses against the flange 128 of the can and is set within a circumferential groove in the bore 130 of the heat sink. As

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before, wires 132 extend through that bore. The housing 134 of the detector head is a split tube formed of two parts which meet along longitudinal seams. The two tube parts are held together by a nut 136 to which a plastic cap 138 is snap fit. The heat sink is retained in the assembly by an o-ring 140 which is seated within a groove in the heat sink and a groove in the nut 136. As before, the cap 138 has a curved lip which extends beyond the tip of the heat sink 124. Cap 138 is of soft material for the comfort of the patient.

In the embodiment of FIG. 2C, the thermopile is positioned within a can 150 of high thermal mass similar to that disclosed in U.S. Pat. 5,012,813. The can is set within a sleeve 152 which is retained in the head housing 154 by o-rings 156 and 158. A plastic cap 160 is threaded onto the head 154, and the can 150 is centered within the cap by an additional o-ring 162. A low emissivity cup 164 is press fit within the cap 160 and, as before, is recessed behind a smooth lip 166.

An electrical block diagram for the radiation detector is presented in FIG. 3. A microprocessor 80 is at the heart of the circuit. A power control circuit 82 responds to activation of the button switch 84 by the user to apply power to the microprocessor and other elements of the circuit. That power is maintained until the microprocessor completes the measurement cycle and signals the power control 82 to power down. The microprocessor is clocked by an oscillator circuit 86 and may communicate with an external source for programming and calibration through communication conductors 88. The temperature determined by the microprocessor is displayed on the liquid crystal display 100, and detection of peaks during the temperature processing is indicated by a beeper 102. Peaks are detected from readings taken at least three times per second, and preferably about ten times per second, for rapid scan across the forehead to avoid cooling of the forehead through the detector. During the measurement process, the microprocessor takes readings through a multiplexer/analog-to-digital converter 90. The preferred microprocessor 80 is a PIC16C74 which includes an internal 8-bit A-D converter. To minimize expense, the circuit is designed to rely solely on that A-D converter.

Thermopile 92 provides a voltage output signal equal to the fourth power difference between target temperature and the temperature of the thermopile cold junction, offset by voltage reference 94. The voltage output from the thermopile is amplified by an amplifier 96, having a gain in the order of 1000, which also provides an offset determined by a pulse width modulated filter 108 controlled by the microprocessor. Through operation of the multiplexer, the microprocessor provides an analog-to-digital conversion of the amplified sensor output and of the detector temperature T_d provided by temperature sensor 98. The temperature sensor 98 is positioned to sense the substantially uniform temperature of the thermopile cold junction, can and heat sink. An auto zero switch 104 is included to allow for isolation of the amplifier 96 from the thermopile 92 during a calibration sequence as discussed in prior U.S. application Ser. No. 08/738,300.

It is well known that the output of the thermopile is proportional to $(T_s^4 - T_d^4)$ where T_s is the target skin temperature viewed by the radiation detector and T_d is the temperature of the detector measured by sensor 98. From that relationship, T_s can be computed. It is also known that, based on the determined skin temperature and the ambient temperature to which the skin is exposed, an internal core temperature can be computed using the arterial heat balance approach illustrated in FIG. 4. Heat flux q from the internal core temperature T_c passes through the skin 30 to the

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ambient environment at temperature T_a . The skin is thus held at some intermediate temperature T_s .

The heat loss of skin, such as at the forehead, the external ear canal or axilla, to the environment can be calculated with the following well-known equation:

$$q = hA(T_s - T_a) \quad (2)$$

where q is heat flow, A is surface area, T_s and T_a the skin and ambient temperatures, respectively, and h is an empirically determined coefficient which includes a radiation view factor between the skin tissue and ambient. The equation takes the linear form for simplicity. Although the exact form of the equation is fourth-power due to the radiation exchange, the linearized form provides excellent accuracy over the range of interest of about 90° to 105° F.

Heat flow from the core arterial source to the skin is via blood circulation, which is many times more effective than tissue conduction. Thermal transport via the circulation can be described with the following equation:

$$q = wc(T_c - T_s) \quad (3)$$

where q again is heat flow, w is blood mass flow rate, c is blood specific heat, and T_c and T_s are core and skin temperatures, respectively.

Accordingly, the skin can be viewed thermally as tissue being warmed by its blood supply as governed by equation 3, balanced by radiating heat to ambient as governed by equation 2.

Equating:

$$hA(T_s - T_a) = wc(T_c - T_s) \quad (4)$$

Simplifying by dividing by surface area A :

$$h(T_s - T_a) = pc(T_c - T_s) \quad (5)$$

where p is blood flow per unit area, also termed perfusion rate.

Equation 5 then provides a method to calculate core temperature T_c when skin temperature T_s and ambient temperature T_a are known, and the coefficients (or their ratio) have been empirically determined.

Solving for T_c :

$$T_c = (h/pc)(T_s - T_a) + T_s \quad (6)$$

where h/pc , the weighting coefficient which weights the difference of surface temperature and ambient temperature, is empirically determined on a statistical basis over a range of patients and clinical situations.

An alternative method of calculating is to employ an electrical analog technique, since equations 2 and 3 have the identical form of a simple voltage/current relationship. The method employs the convention that electrical current is analogous to heat flow and voltage differential is analogous to temperature differential.

Accordingly, equations 2 and 3 may be written as:

$$q = (1/R_1)(T_s - T_a) \quad (7)$$

$$q = (1/R_2)(T_c - T_s) \quad (8)$$

and the electrical circuit can be drawn, with T_c and T_a as constant temperature (voltage) reservoirs (FIG. 4). A third equation with a more convenient form can be written as:

$$q = (1/(R_1 + R_2))(T_c - T_a) \quad (9)$$

Using equations 7 and 9 and solving for T_c :

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$$T_c = ((R_1 + R_2)/R_1)(T_s - T_a) + T_a \quad (10)$$

and finally:

$$T_c = k(T_s - T_a) + T_a \quad (11)$$

which is the precise form of the heat balance equation programmed into arterial heat balance instruments, with $(R_1 + R_2)/R_1$ expressed as the k-factor.

The k Factor can be rewritten as follows:

$$k = \frac{R_1 + R_2}{R_1} = 1 + \frac{R_2}{R_1} = 1 + (h/pc) \quad (12)$$

Accordingly, in either form, equation 6 or 11, it can be seen that the weighting coefficient h/pc is applied to the difference of surface and ambient temperature.

In the weighting coefficient, c is a constant. In ear temperature and neonatal axillary temperature measurements, the perfusion rate is also generally constant, resulting in h/pc of about 0.09 for adult ears and 0.05 for neonates. For a normal adult, the perfusion rate of the axilla is such that the weighting coefficient h/pc is about 0.13. Further, the perfusion rate varies according to the condition of the patient. In particular, with a fever, the perfusion rate can become much higher. Similarly, in the forehead, perfusion rate varies with skin temperature.

In both the ear and axilla, the coefficient h is relatively constant. The forehead has greater exposure to the ambient environment, and the radiation heat loss increases with increased skin temperature. Thus, where the weighting coefficient h/pc decreased for all increasing skin temperatures in the ear and axilla temperature measurements, it has been found that, as illustrated in FIG. 5, the weighting coefficient reaches a minimum at near normal body temperature and then, due to the increasing value of h , increases. Empirical data suggests that the value h/pc decreases linearly to a value of about 0.19 and a temperature of about 96-97° F. The coefficient then increases linearly with skin temperature but at a lesser slope at 84. The linear approximations illustrated in FIG. 5 are used in the computations in the clinical model. However, in the consumer model, those linear approximations are replaced by a single polynomial approximation 86:

$$1 + h/pc = 0.0035888T_s^2 - 0.707922T_s + 36.0981$$

Since all body site temperatures of interest arise from the arterial temperature source, the arterial heat balance can be applied to any site. Accordingly, based on the Thevenin equivalents theorem, oral and rectal diagnostic equivalents T_o and T_r of arterial temperature can be calculated by appropriate selection of k-Factor, empirically taking into consideration resistances R_o and R_r .

Individual aspects of the radiation detector which make it particularly suited to providing temperature readings from the temporal artery and other arteries can be found in applicant's prior designs. However, none of those designs provide the unique combination of elements which enable consistent measurements of core temperature by scanning across a superficial artery. Specifically, the Exergen D501 Industrial Temperature Detector used in emissivity compensating cup and provided a peak temperature based on about ten temperature readings per second. However, that device did not perform a heat balance computation and was thus not suited to measurement of core temperature. The emissivity compensating cup was utilized in the axillary temperature detector with a heat balance computation, but that unit was

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not adapted to be scanned across the target surface. The detected peak in that device used to indicate when the reading had stabilized and could be relied upon. That peak detection was based on only one reading per second. Applicant's prior ear temperature detectors have obtained a peak temperature from ten readings per second but with pivoting of the detector rather than with lateral scan across the target surface. There was no emissivity compensating cup.

While this invention has been particularly shown and described with references to preferred embodiments thereof, it will be understood by those skilled in the art that various changes in form and details may be made therein without departing from the spirit and scope of the invention as defined by the appended claims.

What is claimed is:

1. A method of detecting human body temperature comprising:

laterally scanning a temperature detector across a forehead; and

providing a peak temperature reading from plural readings during the step of scanning.

2. A method as claimed in claim 1 wherein the temperature detector comprises a radiation sensor which views a target surface area of the forehead.

3. A method as claimed in claim 2 wherein the radiation sensor views the target surface area through a reflective cup, the cup having a large open diameter close to the target surface area and a window at the base of the cup through which the radiation sensor views the target surface area, the cup being out of the field of view of the sensor.

4. A method as claimed in claim 1 further comprising computing an internal body temperature as a function of ambient temperature and the peak temperature reading.

5. A method as claimed in claim 4 wherein the function includes a weighted difference of surface temperature and ambient temperature, the weighting including an approximation of h/pc at a forehead artery where h is a heat transfer coefficient between a target surface of the forehead and ambient, p is perfusion rate and c is blood specific heat.

6. A method as claimed in claim 5 wherein the approximation of h/pc at the minimum is about 0.19.

7. A method as claimed in claim 4 wherein the temperature detector comprises a radiation sensor which views a target surface area of the forehead.

8. A method as claimed in claim 7 wherein the radiation sensor views the target surface area through a reflective cup, the cup having a large open diameter close to the target surface area and a window at the base of the cup through which the radiation sensor views the target surface area, the cup being out of the field of view of the sensor.

9. A method as claimed in claim 8 wherein the reflective cup is spaced from the target surface area by a smooth lip of low thermal conductivity material.

10. A method as claimed in claim 4 wherein the weighting is a linear approximation having a minimum between 96° F. and 97° F.

11. A method as claimed in claim 4 wherein the weighting includes a polynomial approximation of $1+h/pc=k_1T_s^2-k_2T_s+k_3$ where h is a heat transfer coefficient between the target surface and ambient, p is perfusion rate, c is blood specific heat, k_1 is approximately 0.00359, k_2 is approximately 0.708 and k_3 is approximately 36.1.

12. A method as claimed in claim 1 wherein the temperature detector is scanned across an artery.

13. A method as claimed in claim 1 wherein the temperature detector is scanned across a temporal artery.

14. A method of detecting human body temperature comprising:

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detecting temperature at a forehead through a lateral scan across the temporal artery; and

computing an internal body temperature of the body as a function of ambient temperature and sensed surface temperature.

15. A method as claimed in claim 14 wherein the function includes a weighted difference of surface temperature and ambient temperature, the weighting being varied with target temperature through a minimum in the range of 96° F.-100° F., the weighting increasing above and below the minimum.

16. A method as claimed in claim 14 wherein the function includes a weighted difference of surface temperature and ambient temperature, the weighting including an approximation of h/pc at a forehead artery where h is a heat transfer coefficient between the target surface and ambient, p is perfusion rate and c is blood specific heat.

17. A method as claimed in claim 14 wherein the temperature detector comprises a radiation sensor which views a target surface area of the forehead.

18. A method as claimed in claim 17 wherein the radiation sensor views the target surface area through a reflective cup, the cup having a large open diameter close to the target surface area and a window at the base of the cup through which the radiation sensor views the target surface area, the cup being out of the field of view of the sensor.

19. A method as claimed in claim 18 wherein the reflective cup is spaced from the target surface area by a smooth lip of low thermal conductivity material.

20. A method as claimed in claim 14 wherein temperature is detected in the vicinity of an artery.

21. A method as claimed in claim 14 wherein temperature is detected in the vicinity of a temporal artery.

22. A method of detecting human body temperature comprising:

laterally scanning a temperature detector across an artery; and

providing a peak temperature reading from plural readings during the step of scanning.

23. A method as claimed in claim 22 wherein the temperature detector comprises a radiation sensor which views a target surface area over the artery.

24. A method as claimed in claim 23 wherein the radiation sensor views the target surface area through a reflective cup, the cup having a large open diameter close to the target surface area and a window at the base of the cup through which the radiation sensor views the target surface area, the cup being out of the field of view of the sensor.

25. A method as claimed in claim 22 further comprising computing an internal temperature of the body as a function of ambient temperature and sensed surface temperature, the function including a weighted difference of surface temperature and ambient temperature, the weighting being varied with target temperature through a minimum in the range of 96° F. to 100° F., the weighting increasing above and below the minimum.

26. A method as claimed in claim 22 wherein the temperature detector is scanned across a temporal artery.

27. A method of detecting human body temperature comprising measuring temperature of the temporal artery through skin.

28. A method as claimed in claim 27 wherein temporal artery temperature is measured with an infrared detector.

29. A method as claimed in claim 28 wherein the infrared detector is scanned across the temporal artery.

30. A method as claimed in claim 27 further comprising computing an internal temperature of the body as a function of ambient temperature and sensed surface temperature.

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31. A method as claimed in claim 30 wherein the function includes a weighted difference of surface temperature and ambient temperature, the weighting including an approximation of h/pc at a forehead artery where h is a heat transfer coefficient between the target surface and ambient, p is perfusion rate and c is blood specific heat. 5

32. A method of detecting human body temperature comprising:
 detecting temperature at a forehead; and
 computing an internal body temperature of the body as a function of ambient temperature and sensed surface temperature, the function including a weighted difference of surface temperature and ambient temperature, the weighting including an approximation of h/pc at a forehead artery where h is a heat transfer coefficient between the target surface and ambient, p is perfusion rate and c is blood specific heat. 10 15

33. A body temperature detector system comprising:
 a temperature detector; and
 electronic circuitry which measures peak temperature from at least three readings per second during scan of the temperature detector across an artery and which processes the measured peak temperature to provide a temperature display based on a model of heat balance relative to a detected arterial temperature, the electronic circuitry computing an internal temperature of the body as a function of ambient temperature and sensed surface temperature, the function including a weighted difference of surface temperature and ambient temperature, the weighting including an approximation of h/pc at a forehead artery where h is a heat transfer coefficient between the target surface and ambient, p is perfusion rate and c is blood specific heat. 20 25 30

34. A detector system as claimed in claim 33 wherein the approximation of h/pc at the minimum is about 0.19. 35

35. A body temperature detector system comprising:
 a temperature detector; and
 electronic circuitry which measures peak temperature from at least three readings per second during scan of the temperature detector across an artery and which processes the measured peak temperature to provide a temperature display based on a model of heat balance 40

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relative to a detected arterial temperature, the electronic circuitry computing an internal temperature of the body as a function of ambient temperature and sensed surface temperature, the function including a weighted difference of surface temperature and ambient temperature, the weighting being a linear approximation having a minimum between 96° F. and 97° F.

36. A body temperature detector system comprising:
 a temperature detector; and
 electronic circuitry which measures peak temperature from at least three readings per second during scan of the temperature detector across an artery and which processes the measured peak temperature to provide a temperature display based on a model of heat balance relative to a detected arterial temperature, the electronic circuitry computing an internal temperature of the body as a function of ambient temperature and sensed surface temperature, the function including a weighted difference of surface temperature and ambient temperature, the weighting including a polynomial approximation of $1+h/pc=k_1T_s^2-k_2T_s+k_3$ where h is a heat transfer coefficient between the target surface and ambient, p is perfusion rate, c is blood specific heat, k_1 is approximately 0.00359, k_2 is approximately 0.708 and k_3 is approximately 36.1.

37. A body temperature detection system comprising:
 a temperature sensor which senses temperature of a skin surface; and
 electronic circuitry which computes an internal temperature of the body as a function of ambient temperature and sensed surface temperature, the function including a weighted difference of surface temperature and ambient temperature, the weighting being varied with target temperature through a minimum in the range of 96° F.-100° F., the weighting increasing above and below the minimum, the weighting including an approximation of h/pc at a forehead artery where h is a heat transfer coefficient between the target surface and ambient, p is perfusion rate and c is blood specific heat, the approximation of h/pc at the minimum being about 0.19.

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