



US005833367A

United States Patent [19]
Cheslock et al.

[11] **Patent Number:** **5,833,367**
[45] **Date of Patent:** **Nov. 10, 1998**

[54] **TYMPANIC THERMOMETER PROBE COVER**

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[73] Assignee: **TruTek, Inc.**

[21] Appl. No.: **747,423**

[22] Filed: **Nov. 12, 1996**

[51] **Int. Cl.⁶** **G01K 1/08**; A61B 6/00; A61B 5/00; A61B 1/227

[52] **U.S. Cl.** **374/158**; 374/121; 600/184; 128/664; 128/736

[58] **Field of Search** 374/158, 209, 374/121; 128/664, 736; 600/200, 203, 186, 184; 206/306

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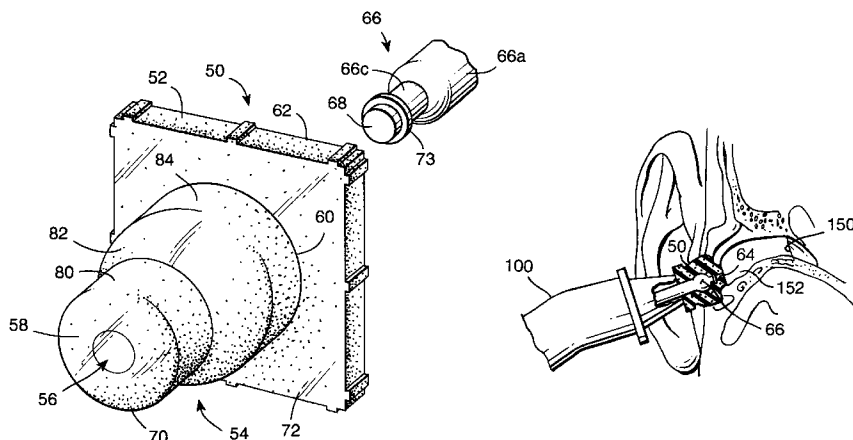
Attorney, Agent, or Firm—Nixon & Vanderhye P.C.

[57]

ABSTRACT

A disposable probe cover for an electronic tympanic ("ear") thermometer is made of closed-cell foam that is laminated with a sheet of high density polyethylene plastic film substantially transparent to infrared radiant energy. The probe cover is hollow, defining a central passageway that accepts an oversized probe and can potentially accommodate a variety of different probe configurations. The foam construction allows the probe cover to stretch over the oversized probe—retaining the probe cover on the probe during use. The foam construction also allows the probe cover to deform when inserted into a patient's ear—sealing the patient's ear canal to prevent external heat and light from affecting the measurement, and providing a high degree of cushioning and comfort not available in any prior disposable probe cover design. The film laminate and foam provide a barrier that is impervious to germs, fluids and other secretions—further reducing the already low risk of cross-contamination. The probe cover design facilitates accurate, repeatable measurements using a temperature measuring instrument based on receiving and analyzing the radiant infrared heat energy emitted by the tympanic membrane (eardrum).

22 Claims, 11 Drawing Sheets



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Fig. 1A
(PRIOR ART)

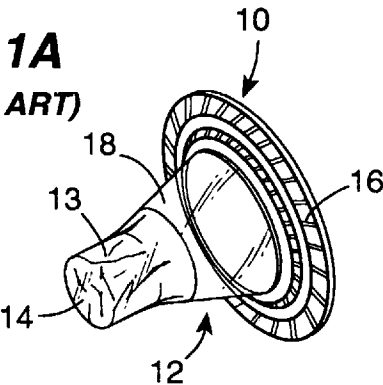


Fig. 1B
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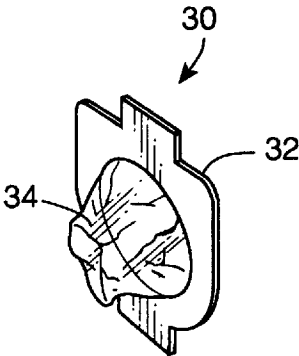
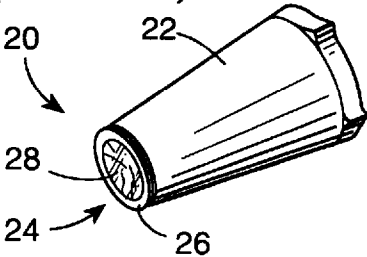


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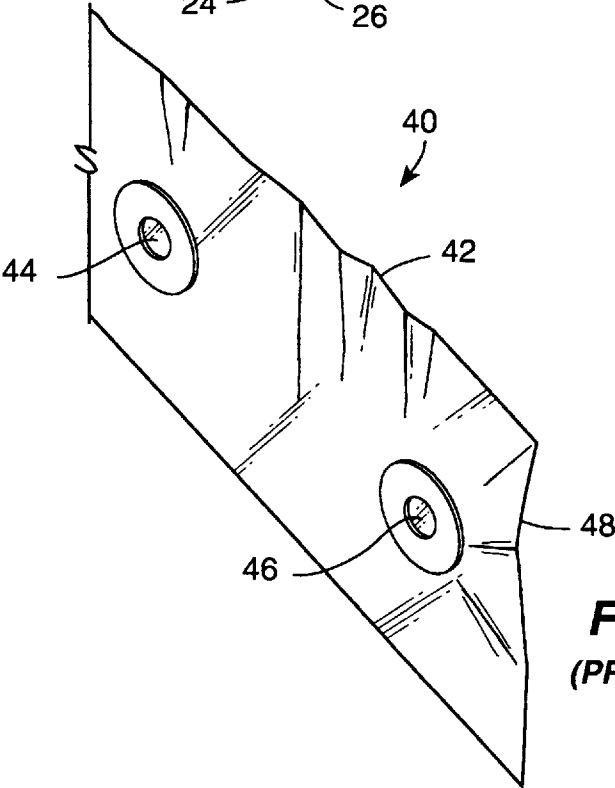
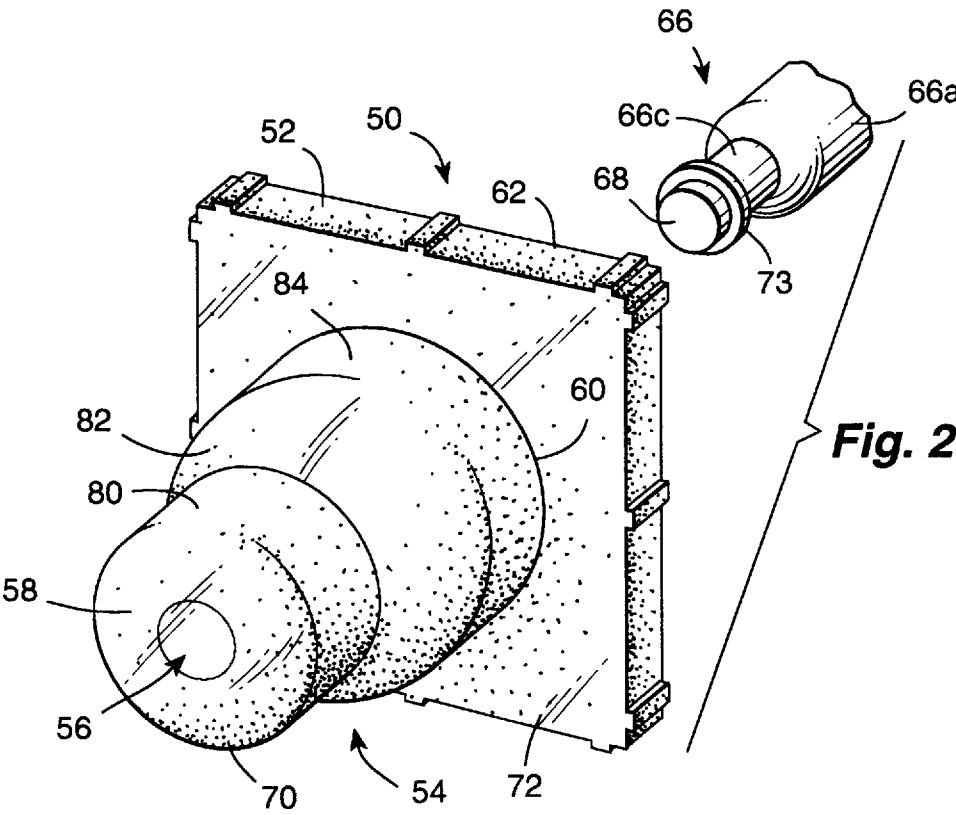


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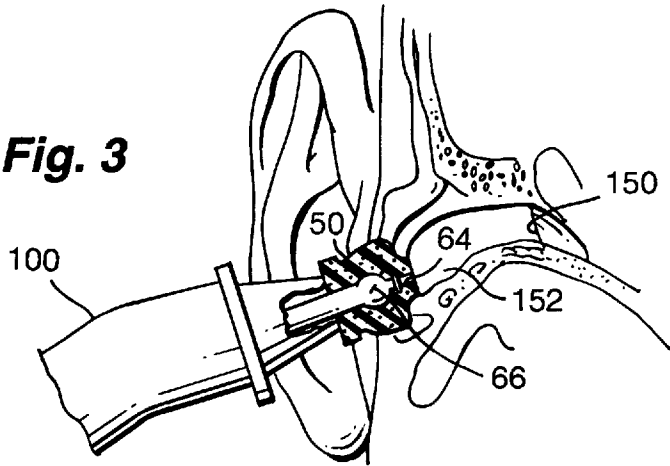
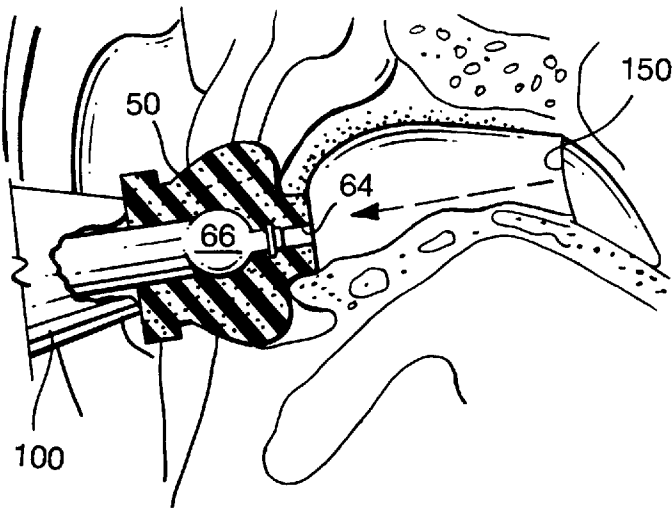


Fig. 3A



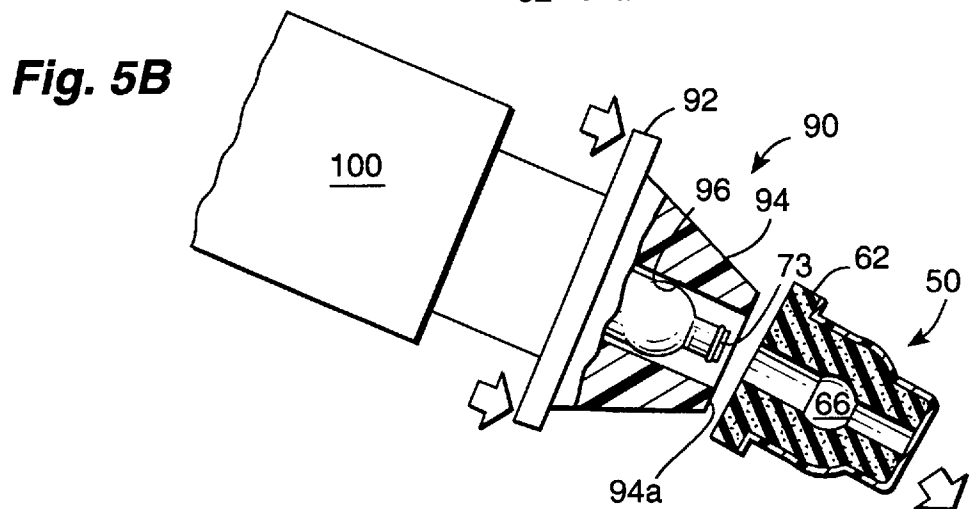
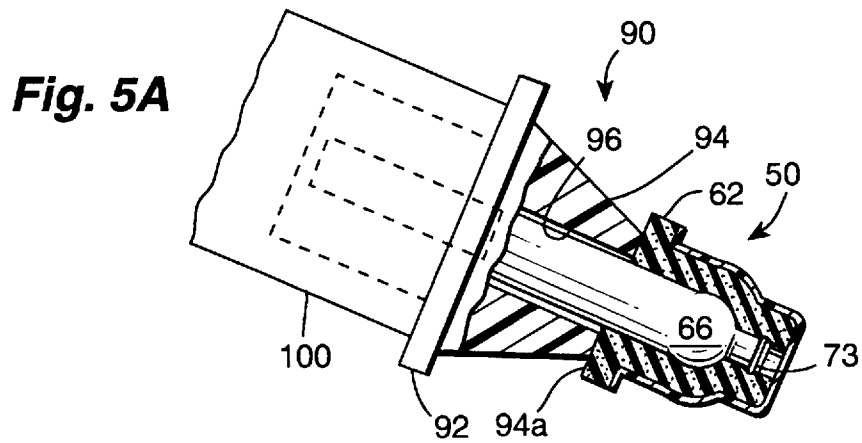
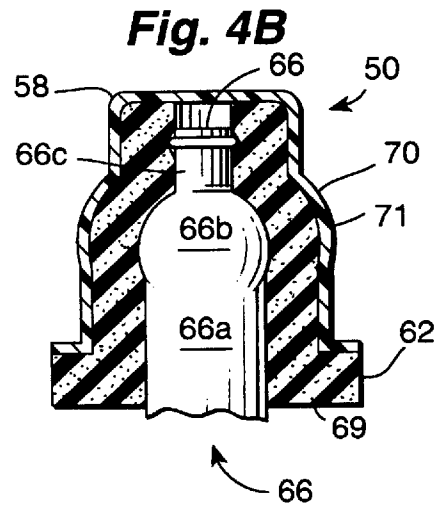
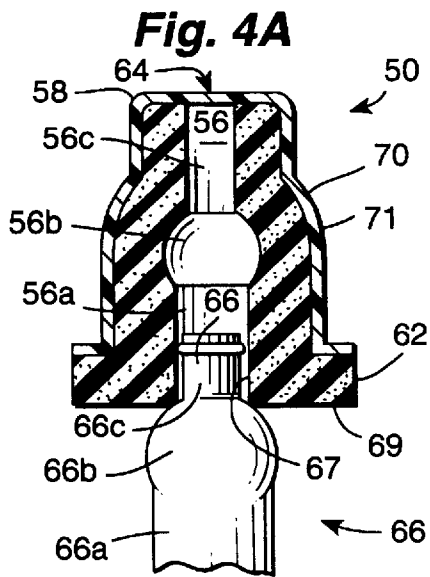


Fig. 6A

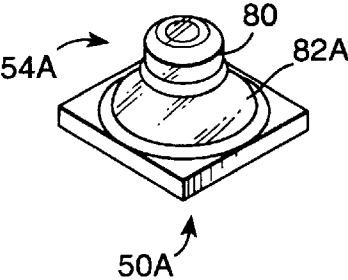


Fig. 6B

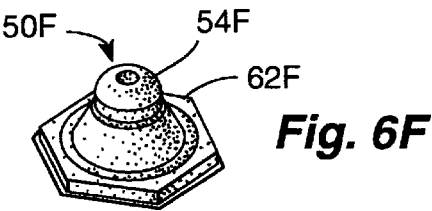
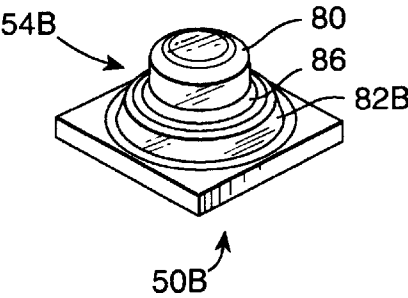


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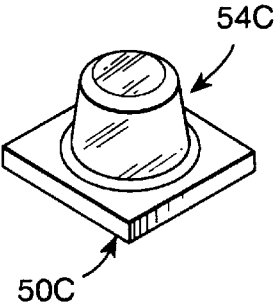


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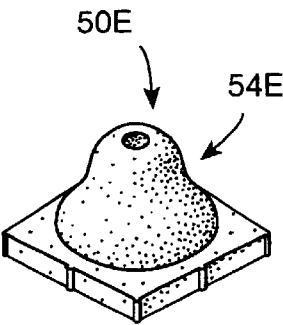


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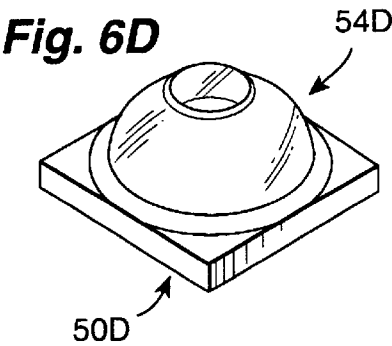
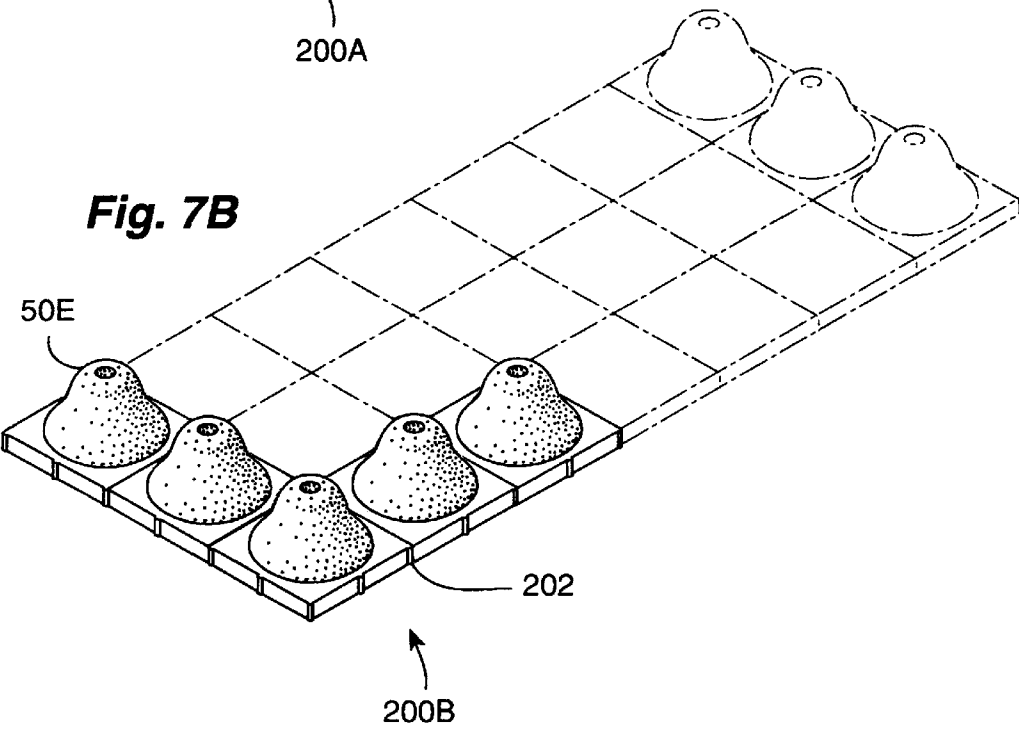
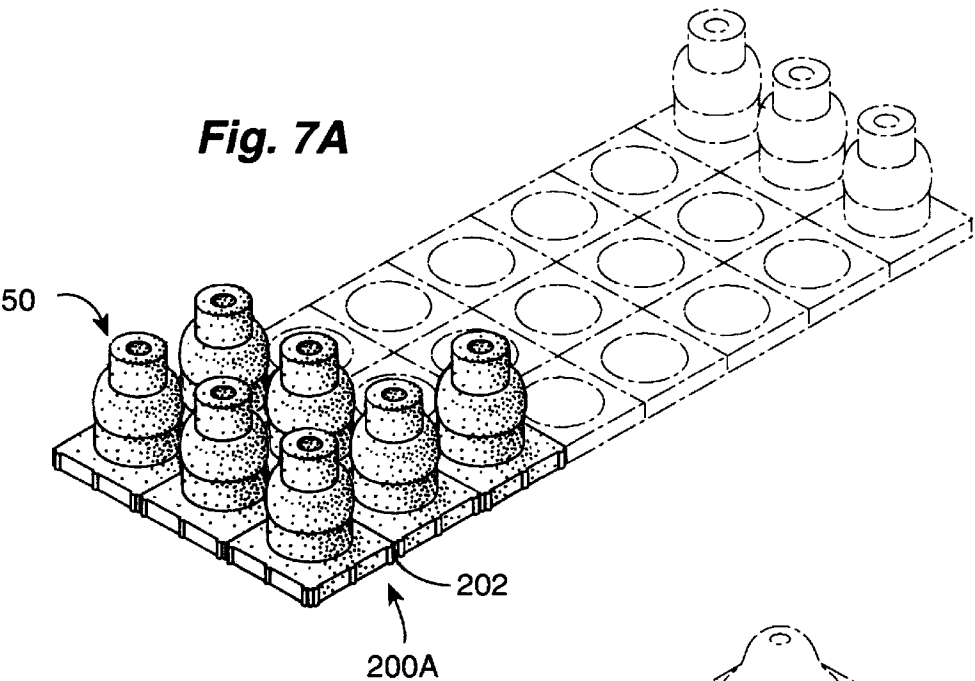


Fig. 6D



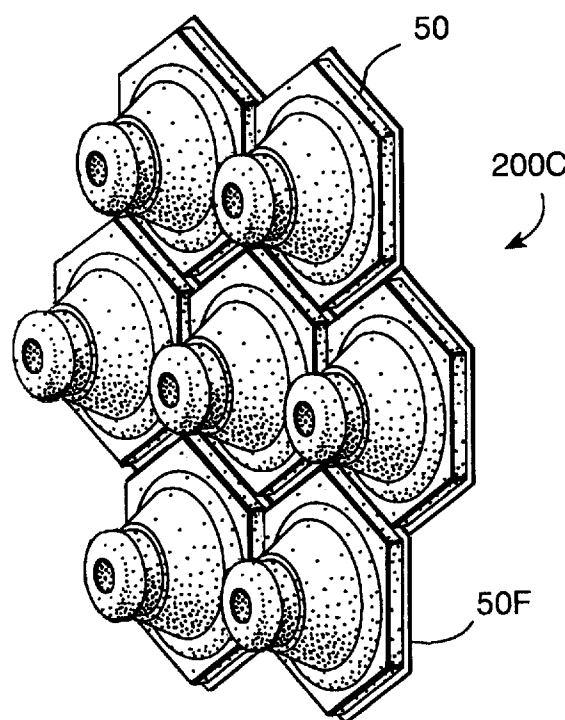


Fig. 7C

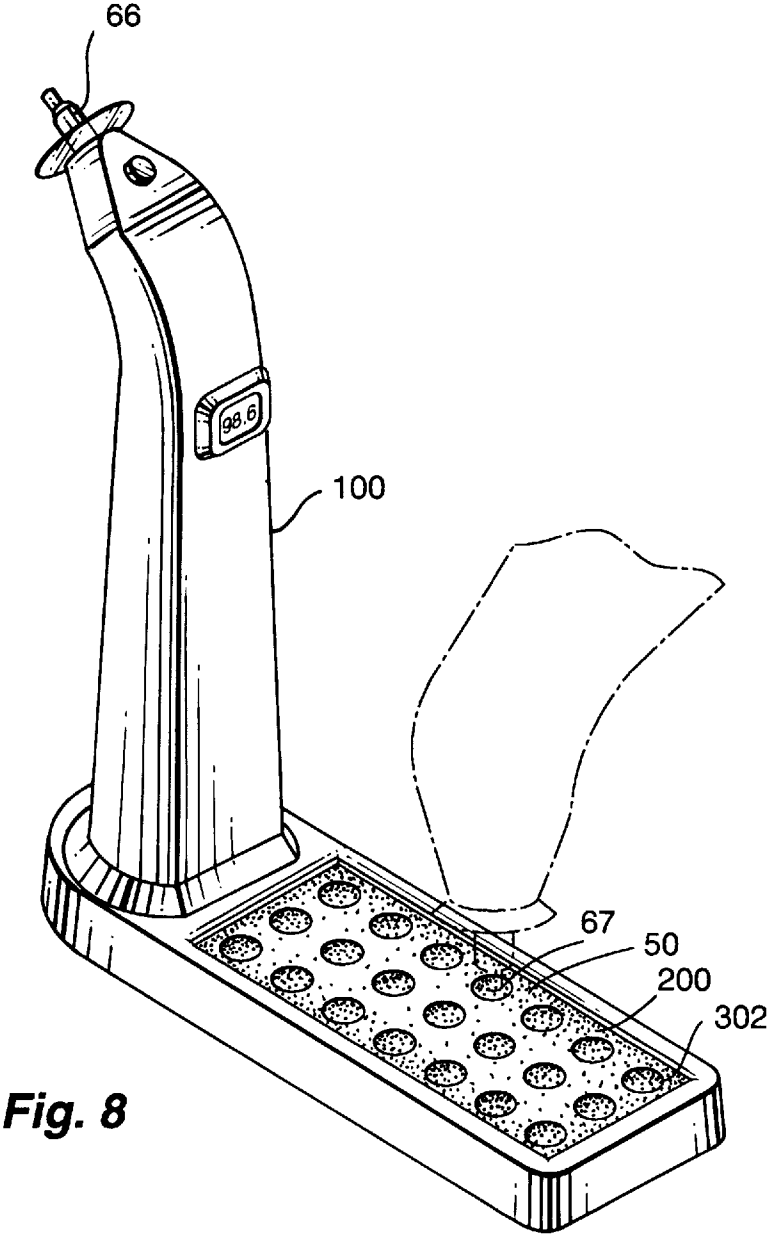


Fig. 9A

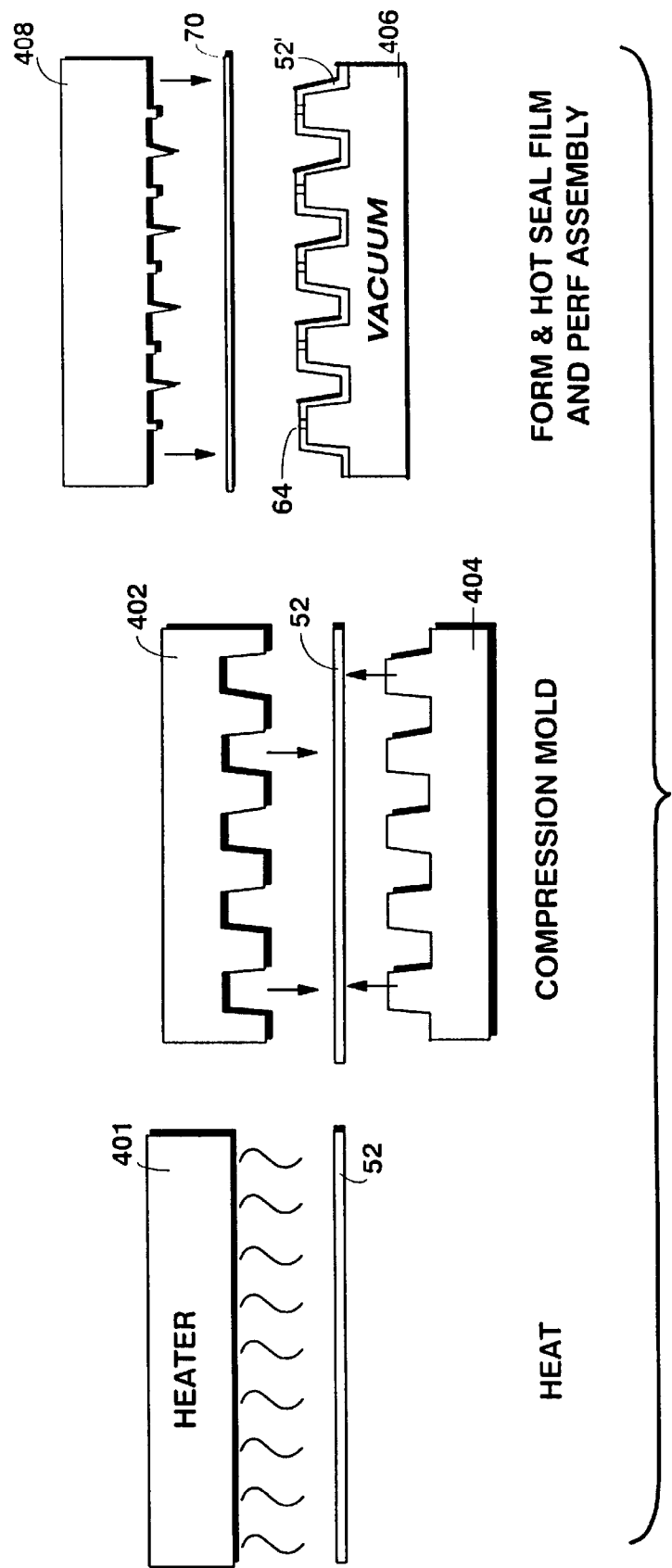


Fig. 9B

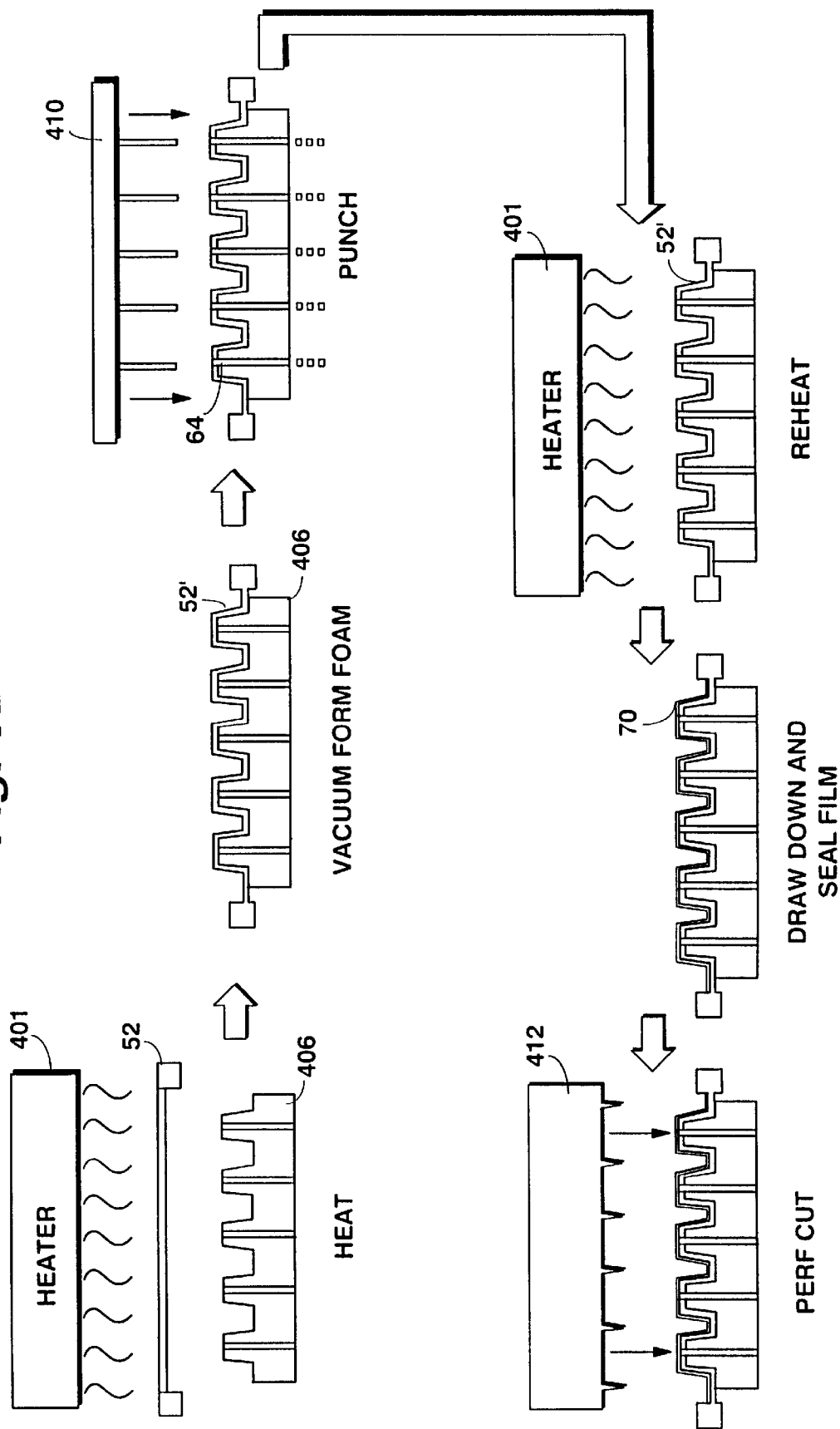
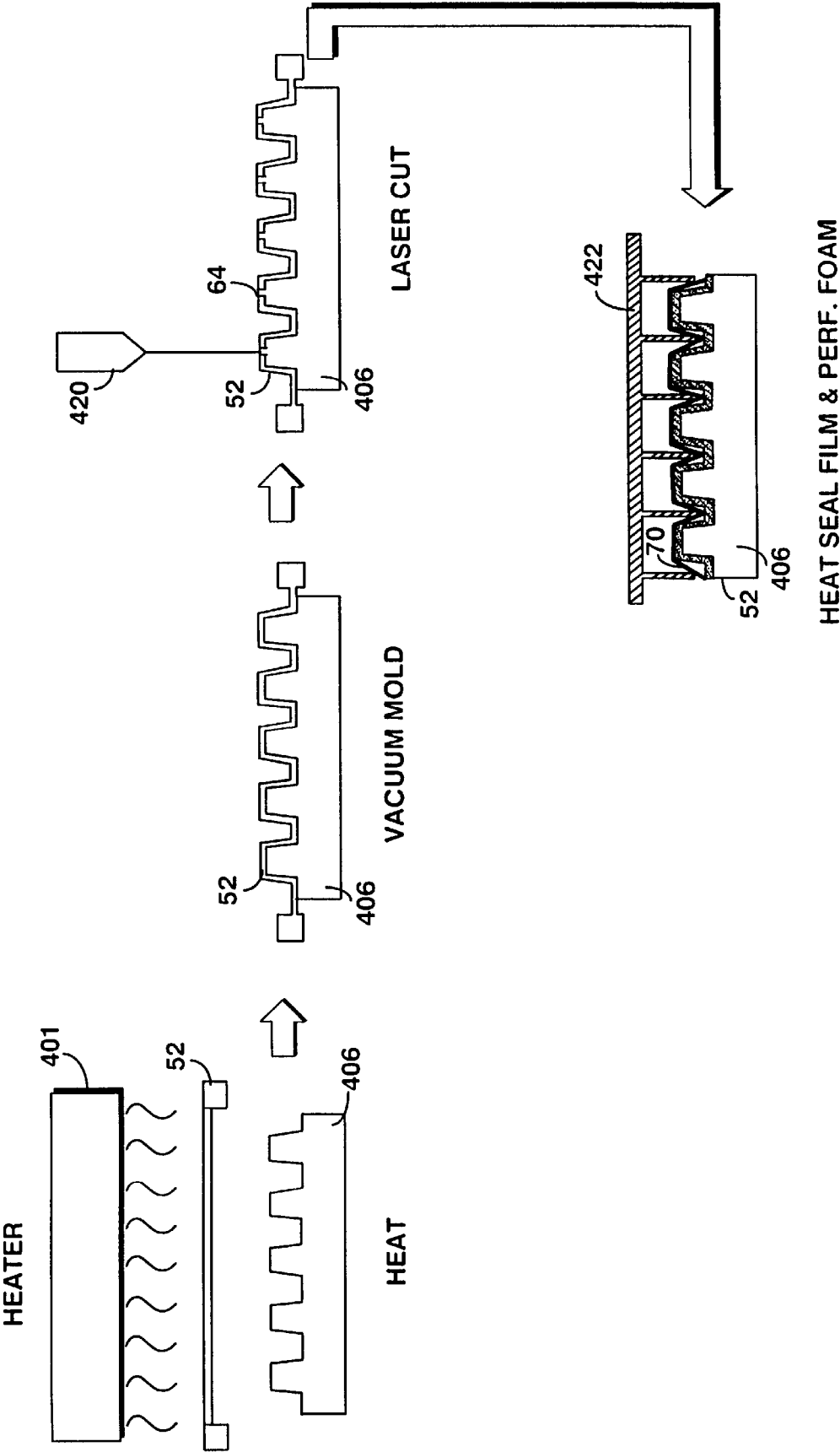


Fig. 9C



TYMPANIC THERMOMETER PROBE COVER

This invention relates to a probe cover for a thermometer that measures temperature by sensing the radiant energy given off by the eardrum ("tympanic membrane"). More particularly, the invention relates to a disposable foam probe cover that increases the comfort, accuracy and repeatability of an ear thermometer temperature measuring system.

BACKGROUND AND SUMMARY OF THE INVENTION

Doctors, nurses, parents, and other care providers all need to be able to rapidly and accurately measure a person's body temperature. To find out whether a person is sick, the first thing a care provider usually does is take the person's temperature. Someone running a fever is likely to have an infection. A doctor or nurse can tell a lot about how a patient is doing by monitoring the patient's temperature over time and noting how it has changed.

There are three kinds of thermometers in wide use today: glass thermometers,

"electronic" thermometers, and

ear ("tympanic") thermometers.

Glass thermometers are very inexpensive, very small and easy to store, and don't require batteries or other special supplies. For this reason, glass thermometers are probably the most widely used temperature measuring device in the home. However, glass thermometers have the disadvantage that they are very slow in making measurements—they typically require several minutes to reach body temperature. This is uncomfortable for the patient, and may be very troublesome when it is necessary to take the temperature of a small child or an invalid. In addition, glass thermometers are typically accurate only to within a degree, may be susceptible to errors in placement, and can be broken easily.

Because of these disadvantages, most hospitals and doctors' offices now use instruments commonly known as "electronic" thermometers. Most of us have had our temperature taken by an electronic thermometer at one time or another. The electronic thermometer includes a portable, hand-held battery powered unit with a display, and a separate probe. A wire usually connects the probe to the hand-held unit. The probe is long and thin, and has the same general shape as a glass thermometer. To use this kind of electronic thermometer, a nurse first covers the probe with a long thin disposable plastic probe cover that completely covers the probe. The disposable probe cover helps prevent the spread of disease by avoiding direct contact between the reusable probe and the germs in the patient's mouth. The nurse then puts the end of the probe under the patient's tongue. An electronic temperature sensor within the probe electrically senses the patient's temperature, and sends a signal to a microcomputer in the hand-held unit. The hand-held unit usually beeps when the temperature measurement is finished, and displays the patient's temperature on the display. The nurse can then remove the probe from the patient's mouth, strip the probe cover off the probe, and throw away the used disposable probe cover.

This type of electronic thermometer has achieved wide acceptance in hospitals because it is reasonably accurate, can be used with familiar placement techniques, and is (because of its disposable, replaceable probe covers) easily reusable for a number of different patients. Although the electronic hand-held unit is itself more expensive than most households are willing to pay, the overall cost of using this kind

of electronic thermometer is relatively low because the disposable probe covers are inexpensive (two to three cents per cover, for example) and a single hand-held electronic unit may last for years and can be used to take the temperatures of many thousands of patients.

Electronic thermometers offer speed, ease of reading, and accuracy improvements over glass thermometers, and also eliminate the possibility of mercury poisoning. Although such electronic thermometers have achieved a fair degree of success, they have certain significant disadvantages. For example, they need to be constantly calibrated, are relatively easily broken, and often require a relatively long time (thirty seconds or more in many cases) to make an accurate measurement. There are also problems with taking a temperature from the patient's mouth due to breathing, keeping the thermometer under the patient's tongue, etc. Cross-contamination of infectious diseases is also a concern because the mouth is a "wet orifice."

More recently, a new kind of electronic thermometer has appeared on the market. This new kind of thermometer works by measuring the temperature of your eardrum. Since the eardrum is also known as the "tympanic membrane," these thermometers are sometimes called "tympanic thermometers."

Why the eardrum? The carotid artery that supplies blood to the hypothalamus—the body's temperature control center—passes through the eardrum. For this reason, the temperature of your eardrum corresponds very closely to the core temperature of your body. Although doctors and scientists have known this fact for many years, only since the mid-1980's have commercial devices been available to measure eardrum temperature in a clinical setting.

Ear or "tympanic" thermometers work by receiving and analyzing the radiant heat ("infrared") energy coming from the eardrum. Just as you can feel the heat when you hold your hands up in front of a warm fire, a tympanic thermometer can detect eardrum temperature without having to actually touch the eardrum by receiving the radiant heat energy coming from the eardrum.

Commercially available tympanic thermometers consist of a portable, hand-held battery powered main unit providing electronics, a display and a probe containing a "thermopile" or pyroelectric heat sensor. This special heat sensor called a "thermopile" is especially sensitive to the eardrum's radiant heat energy. Microelectronics can determine eardrum temperature from the electrical signals provided by the "thermopile" sensor. The thermopile's sensing probe or "nacelle" is typically an integral part of the tympanic thermometer's main unit—reducing the potential for breakage of the sensor assembly and (at least potentially) increasing reliability and accuracy.

The sensing probe typically has a tapered or cone shape for easy insertion into the outer ear canal. All of the commercially available tympanic thermometers accept disposable probe covers. These disposable probe covers further minimize the risk of spreading disease, and also promote cleanliness by preventing ear wax and other secretions from contacting the probe. Different manufacturers have different probe cover configurations (see FIGS. 1A–1B), but all of these probe covers have the common characteristic that they are relatively transparent to (and thus do not block or reduce) the radiant heat energy given off by the eardrum.

To use the ear thermometer, a nurse or other care provider inserts a disposable probe cover onto the instrument's sensing probe. Once the disposable probe cover is in place, the nurse or other caregiver inserts the covered probe into the patient's outer ear and then presses a button to command the

instrument to make a measurement. The measurement time is usually very rapid—on the order of two seconds or less. The patient's temperature instantly shows on the instrument's display. The instrument may then be removed from the patient's ear, and the disposable cover can be stripped off the instrument and discarded.

Ear thermometry has advantages over other temperature measuring techniques:

The measuring time is very rapid—usually less than two seconds.

Because the ear is a dry orifice, cross-contamination is not much of an issue—and individual, disposable probe covers further reduce the already low cross-contamination risks.

The theoretical accuracy of the measurement is very high (for example, on the order of one tenth of one degree).

Because of the short measurement time and the use of the ear as the measuring point, it is possible to rapidly measure the temperature of children, invalids and sleeping patients—and in other situations where it is difficult to get a patient to sit still for thirty seconds with a probe under their tongue.

Despite these many clear advantages, ear thermometry has not yet achieved wide success in the medical marketplace. Even though many hospitals are believers in the concept of ear thermometry, the hospital market overall has converted less than twenty-five per cent of its temperature measurements to ear thermometry—and the hospitals that have converted are often displeased with their choice.

The main reason for past failures is that existing ear thermometer/probe cover combinations do not provide the high, repeatable accuracy required in a demanding hospital environment. Nurses are often unable to duplicate ear thermometer readings. If you try to measure the same person's temperature twice with existing commercial ear thermometer/probe cover combinations, you may get two very different readings. Since accurate, repeatable temperature measurements are important or even critical to medical diagnosis and treatment (for example, to detect a 101.5° F. hospital fever threshold or to establish a temperature pattern over time), it is important for temperature measurements to be as accurate and repeatable as possible.

For an ear thermometer to make an accurate, repeatable measurement, the ear thermometer probe must be aimed directly at the eardrum. Readings will be different unless the orientation of the probe within the ear is duplicated nearly exactly from one reading to the next. Because different structures within the ear give off, absorb and reflect different amounts and types of radiant energy, even slight differences in alignment between the probe sensor and the patient's eardrum can cause significant differences in the temperature reading.

Poor technique is the leading cause of ear thermometer inaccuracy and non-repeatability—and disposable probe cover design is an important factor in the nurse's ability to repeatably, correctly align the probe within the patient's ear. There have been several general approaches to tympanic thermometer probe cover design in the past. In one design approach, the disposable probe cover has a generally rigid structure designed to guide and place the probe (see FIGS. 1A & 1B for examples). In another design approach, the probe cover has very little structure, acting solely as a barrier against contamination and playing no role at all in probe placement (see FIGS. 1C & 1D for examples).

FIGS. 1A–1D show some examples of prior art tympanic thermometer probe covers. Prior art FIGS. 1A and 1B show examples of prior art probe covers that are designed to assist

in guiding and placing the probe. The FIG. 1A prior art probe cover **10** is made by Thermoscan, Inc. of San Diego Calif. and marked with "U.S. Pat. No. 5,088,834". This probe cover **10** is made out of a single unitary piece of thin, lightweight, semi-rigid, stiff hollow translucent plastic material shaped into a cone **12**. The cone **12** includes a thicker "shank" portion **18**, and terminates in a thinner end portion **13** comprising an integral piece of thin plastic film **14** that is impervious to moisture but transparent to (and does not absorb) radiant heat energy at the infrared wavelengths emitted by the eardrum. The FIG. 1A one-piece probe cover **10** is designed to be inserted over a correspondingly cone-shaped probe. A surrounding retaining ring base **16** retains cover **10** on the probe during use. When cover **10** is inserted over the probe, plastic film **14** is stretched tightly over the end of the probe to provide a thin, wrinkle-free film "window" that is substantially transparent to infrared radiant energy. The conically shaped stiff "shank" portion **18** of cover **10** tapers to glide into the passageway of a person's ear leading to the eardrum thus—helping to position the probe relative to the eardrum. This stiff construction also allows probe covers **10** to be stacked one inside another for compact shipment.

FIG. 1B shows a different prior art probe cover **20** sold by Sherwood Medical Co. of St. Louis, Mo. (this design is also explained in Sherwood's U.S. Pat. Nos. 5,516,010, 5,293, 862, 5,179,936, 4,790,324, 4,662,360 and/or 4,602,642 and possibly also in a still-pending continuing application of these). The FIG. 1B probe cover **20** comprises a thick rigid plastic cone **22** for insertion into a person's ear. Probe cover **20** is made out of injection molded, rigid polyethylene or polypropylene white plastic. Small tabs or "ears" within the hollow inner space formed within plastic cone **22** retain cover **20** on a specially designed corresponding probe. Plastic cone **22** terminates in a circular opening **24**. A retaining ring **26** formed around opening **24** retains a thin transparent polypropylene or polyethylene plastic film membrane **28**. Film membrane **28** is in an unstretched and wrinkled condition when the cover is not in position over a probe. When rigid probe cover **20** is inserted over a probe, the film membrane **28** stretches over the probe end to remove the wrinkles and provide a thin, substantially transparent film layer of uniform thickness. This stretched film layer **28** allows infrared radiant energy to pass through and reach the infrared probe inside rigid probe cover **20** without letting fluid, earwax, germs or anything else from the ear cavity come into contact with the probe.

The rigidity of disposable probe covers **10**, **20** shown in FIGS. 1A and 1B can help a nurse insert the probe into and position the probe within the patient's ear. The rigidity of these probe covers **10**, **20** also facilitates easy ejection of the probe covers from the probe after measurement. Unfortunately, this same rigidity makes these probe covers exceedingly uncomfortable for the patient. Because every person's ear has a different opening size, the "one size fits all" approach of the FIG. 1B probe cover **20** leads to discomfort and other problems. For example, probe cover **20** shown in FIG. 1B is known to become stuck in a person's ear, and can also scratch the inside of the ear. Frequently also, the probe tip will puncture the membrane film of the FIG. 1B probe cover when the clinician is inserting the thermometer into the probe cover.

The FIG. 1A probe cover **10** design is somewhat less uncomfortable than the FIG. 1B design, but the rather large diameter of conical shank **18** can be uncomfortable for some people. Moreover, its unitary, one-piece construction requires sophisticated techniques for drawing thin film por-

tion 14 from the relatively thicker shank portion 18 during manufacture without puncturing the film. Also due to their rigidity, the FIG. 1A and FIG. 1B designs do not allow for total sealing of the ear canal to prevent external light and heat from entering during a measurement—degrading the accuracy and repeatability of temperature measurement.

FIGS. 1C and 1D show example prior art probe covers that follow a different approach of being mechanically transparent so as not to affect probe placement in any way. The FIG. 1C probe cover 30 is manufactured by Diatek, Inc. of San Diego, Calif. See U.S. Pat. No. Re. 34,599. This probe cover 30 includes a flat paper backing 32 that supports a piece of transparent film 34. Film 34 is stretchable, and completely envelopes the probe when cover 30 is placed over the probe—stretching tightly over the probe so as to provide a radiation-transparent film layer between the probe and the patient's ear. The FIG. 1C design has several advantages, including inexpensive construction, flat storage, and stackability. A big disadvantage of the FIG. 1C probe cover 30 is that the probe cover is of no assistance in reliably, repeatably positioning the probe within the person's ear. This probe cover 30 is designed to be used with a temperature sensing “gun” also manufactured by Diatek (see U.S. Pat. No. 4,863,281)—an unpopular design because of the bad connotations associated with putting a gun to someone's head.

FIG. 1D represents another prior art probe cover 40 manufactured by Exergen Corp. of Newton, Massachusetts and marked “U.S. Pat. No. 4,993,419.” This disposable probe cover 40 comprises a film sheet 42 that is dispensed in a pre-perforated roll. In use, the nurse inserts a pin portion of the ear thermometer positioned opposite the probe into a first hole 44, and then wraps film 42 around the front of the probe and continues wrapping until a second hold 46 is aligned with the same pin portion. The nurse can then tear sheet 42 from the rest of the roll along the line of perforations 48. Holes 44, 46 retain sheet 42 on the probe during measurement. Although probe cover 40 is inexpensive to manufacture, it is difficult for a nurse to position properly onto the probe. In addition, the FIG. 1D probe cover 40 may not always reliably wrap around the front portion of the probe—creating wrinkles that can effect measuring accuracy. The FIG. 1D probe cover 40 can also slip off the probe without the nurse realizing.

The FIG. 1D cover also has repeatability problems. In actual use, clinicians regard repeatability as implying accuracy. If the same reading can be obtained from the same ear, within several tenths of a degree, then the thermometer is regarded as accurate, regardless of the actual core temperature of the patient. All of the manufacturers currently recommend that if a second temperature measurement is required, that it should be made in the other ear. The reason for this is not obvious, but it does have a tremendous bearing on a major problem concerning accurate measurements.

Simply stated, because the nacelles of tympanic thermometers are generally at or near room temperature, which can be up to forty degrees below patient core temperature, the nacelle can rapidly draw off heat from the ear canal, impacting successive measurements dramatically. An excellent demonstration of this effect is to place the Exergen unit in a patient's ear and leave it in place for about a minute, while taking temperatures every ten seconds during this time frame. The average decrease in readings is always several degrees over a minute. The Exergen models produce the most dramatic thermal reductions because the heat transfer is taking place between the ear canal, a FIG. 1D thin layer of film, and a large stainless steel mass. To a lesser extent,

the FIG. 1A–1C probe cover designs exhibit the same, effect, albeit to a lesser extent.

As evidenced by the example prior art tympanic thermometer probe covers shown in FIGS. 1A–1D, there is a long felt but unsolved need for an ear thermometer disposable probe cover that:

- is helpful to the nurse or other care provider in correctly, repeatably positioning the probe relative to the patient's eardrum,
 - is inexpensive to make,
 - is easy to place over the probe before use and easy to strip from the probe after use,
 - is comfortable for the patient, and
 - promotes measuring accuracy.
- No prior solution meets all of these needs.

The present invention provides a new disposable probe cover for an ear thermometer that meets all of these needs and provides other advantages as well. The disposable probe cover provided by this invention is made from a compressible, deformable material such as plastic foam. The disposable probe cover provided by this invention has the following advantages:

- Very easy to use.
- Easy to strip off probe after use.
- Much more comfortable to the patient.
- Unlikely to lodge in the ear canal.
- Foam provides a spring action to push itself out of the ear—helping to prevent it from becoming lodged in the ear.
- Will not cause scratches or other abrasive injury.
- Completely conformable, allowing a comfortable sealing of the ear canal.
- The patient can detect proper sealing by the effect it has on the change of hearing—allowing the patient to confirm to the nurse that the probe is properly in position.
- Prevents external light and heat sources from adding inaccuracies to the temperature measurement.
- Provides excellent thermal isolation between the ear canal and the thermometer probe body—improving measurement accuracy by reducing thermal drift associated with the cold junction of a thermopile-type measurement instrument.
- Is an excellent thermal insulator and barrier. By limiting the amount of heat drawn off the ear canal, the ability to achieve repeatable measurements is greatly enhanced.
- Provides extremely low emissivity in the infrared wavelength band of interest—further reducing error factors introduced through reflection within the ear canal.
- Is inexpensive to manufacture.
- Stretches over the probe to retain the probe cover without any special retention tabs or other mechanisms.
- Can stretch to fit a variety of different configuration probes
- Provides conforming resiliency that accommodate a wide range of different ear sizes without being uncomfortable.
- Can, in one embodiment, provide an externally-bonded thin-walled pre-stretched barrier (which can be less than 0.0075 inches) of high-density polyethylene that is substantially transparent to infrared radiation of interest while providing an industry accepted form of infection resistance and control.

Can be inexpensively vacuum-formed from a sheet of closed-cell foam that is dye cut and further laminated with a sheet of high density polyethylene.

Allows use of a variety of different oversized probe configurations.

In one embodiment, preferred black or darker color foam provides greater repeatability by blocking extraneous light, absorbing stray ambient light, and having very low emissivity with negligible thermal mass.

BRIEF DESCRIPTION OF THE DRAWINGS

These and other features and advantages provided by the present invention will be better and more completely understood by referring to the following detailed description of preferred embodiments in conjunction with the drawings of which:

FIGS. 1A–1D show some examples of prior art disposable ear thermometer probe cover designs;

FIG. 2 shows an example disposable probe cover provided in accordance with this invention;

FIG. 3 shows an example of how the FIG. 2 probe cover can be used with a tympanic thermometer to make an accurate, repeatable temperature measurement;

FIG. 3A shows a more detailed view of how the preferred embodiment probe cover provided by this invention seals the ear passage while providing sufficient resilient conformal support to assist a nurse in repeatably positioning the infrared probe relative to the person's eardrum;

FIGS. 4A and 4B show how the preferred embodiment probe cover can accept and stretch over an oversized probe;

FIGS. 5A and 5B show how the preferred embodiment probe cover can be easily ejected from the probe;

FIGS. 6A–6F show examples of alternate preferred embodiment probe cover configurations;

FIGS. 7A–7C show examples of how multiple probe covers can be packaged and distributed in a common, pre-perforated block;

FIG. 8 shows an example ear thermometer and associated probe cover dispenser tray designed to accept the probe cover block shown in FIGS. 7A–7C; and

FIGS. 9A–9C show example processes for manufacturing the preferred embodiment probe cover.

DETAILED DESCRIPTION OF PRESENTLY PREFERRED EXAMPLE EMBODIMENTS

FIG. 2 shows an example disposable probe cover 50 provided by this invention. Probe cover 50 provides a cover or sheath for covering an ear thermometer radiant energy sensing probe 66. Probe cover 50 prevents germs and secretions within a person's ear canal 152 (see FIG. 3) from contacting probe 66 while being substantially invisible to infrared radiant heat energy emitted by the person's eardrum that is directed along the path toward probe sensing end 68.

FIG. 2 shows probe 66 before it has been inserted into and covered by probe cover 50. FIGS. 3, 3A, 4A, 4B and 5A show probe cover 50 in cross-section after the probe 66 has been inserted into and covered by the probe cover.

Probe cover 50 in the preferred embodiment is made of closed-cell black plastic foam (e.g., a closed cell polyolefin foam such as polyethylene or polypropylene, thermoset closed-cell polyurethane foam, or expanded polystyrene foam). The foam may have a density of anywhere from 2 pounds to 6 pounds per cubic foot for example. In this embodiment, the foam wall thickness of the finished probe

cover 50 will vary, but in the preferred embodiment may have a thickness of between $\frac{1}{16}$ and $\frac{3}{16}$ of an inch to provide a desired cushioning and sealing effect. The foam construction of probe cover 50 allows the probe cover to deform when inserted into a patient's ear (see FIGS. 3 and 3A)—sealing the patient's ear canal and providing a high degree of cushioning and comfort not available in any prior disposable probe cover design. The closed-cell foam construction probe cover 50 also provides a barrier that is impervious to germs, fluids and other secretions—further reducing the already low risk of cross-contamination.

Probe cover 50 in this embodiment is hollow, defining a central passageway 56 that accepts oversized sensor probes 66 of potentially different configurations. The foam construction of probe cover 50 allows the probe cover to stretch over the oversized probe 66—retaining the probe cover on the probe during use. The foam construction of probe cover 50 also provides a heat insulating effect—insulating the probe 66 from heat sources other than the eardrum the temperature of which is to be measured.

In more detail, probe cover 50 a base portion 62 and a hollow tubular projection 54—which may both be molded from the same foam sheet 52. Base portion 62 may be square in shape (and, in one embodiment, may have dimensions of 0.80 inches by 0.80 inches). Hollow tubular projection 54 projects outwardly from square base portion 62 (so that, in one embodiment, the total length of probe cover 50 may be 0.88 inches). Hollow tubular projection 54 has two ends 58, 60. The first end 58 (closest to the viewer in FIG. 2) is for insertion into a person's outer ear canal 152—see FIG. 3. The other end 60 joins and is integral with base 62.

Tubular projection 54 includes a central hollow passageway 56 disposed axially within and extending its length. This passageway 56 extends the entire length of probe cover 50, and in one example is defined along the central axis of projection 54. The passageway 56 terminates at an opening 64 at the projection first end 58, and at an opening 67 defined in an outer surface 69 of square base portion 62 (see FIG. 4A).

In use, a radiant energy temperature sensing probe 66 is inserted into passageway 56 through the base portion opening 67.

The projection first end 58 is then inserted into the person's ear canal 152 (see FIG. 3). Infrared radiant heat energy emitted by the person's eardrum 150 (see FIG. 3A) passes through opening 64 and impinges upon the probe's sensing end 68 (which is now encased within the probe cover 50).

In this example, passageway 56 is dimensioned and shaped to accept an oversized heat sensing probe 66. Central passageway 56 terminates at end 58 in a substantially circular opening or window 64. The sensor end 68 of probe 66 (which may also be circular—and, in one example, forms the end of a circular infrared waveguide) is aligned with and aimed at probe cover circular opening 64 when probe 66 is inserted into probe cover 50. Radiant heat (infrared) energy can pass through opening 64 to impinge on probe sensing end 68.

In this example, the probe cover outer surface 71 has a cushioning obstruction 82 that prevents the probe cover 50 (and thus the probe 66) from being inserted too far into ear canal 152 and also providing a relatively fixed spacing between the probe end 68 and eardrum 150 each time the probe is inserted into the ear canal 152. In more detail, the preferred embodiment probe cover tubular projection 54 may comprise three sections: an end, insertion section 80; a

middle, obstructing section **82**; and a base joining section **84**. In this particular example, sections **80**, **82**, **84** may have different diameters and shapes.

For example, insertion section **80** may be substantially circularly cylindrical with a uniform diameter along its length extending 0.13 inches radially outwardly from the edge of circular window **64**. Insertion section **80** is preferably shaped and dimensioned to conveniently and easily slide into ear canal **152** without discomfort.

Middle obstructing **82** in this example preferably has a diameter that is substantially larger than that of end section **80** so it won't slide into the ear canal **152**. Middle, obstructing section **82** acts as a "stop" to limit how much of probe cover **50** that can be inserted into the ear canal **152**. In this example, middle section **82** may have a spherical shape providing an abrupt increasing diameter such that it acts as a stop—abutting against the ear lobe and/or other part of the auricle (see FIG. 3A) to limit penetration of probe cover **50** into ear canal **152**—and also providing a sealing effect (discussed below). The rapidly increasing diameter of the probe cover middle, obstructing section **82** helps ensure repeatable temperature measurements by positioning probe end **68** the same distance from eardrum **150** each time the covered probe **66** is inserted into a given patient's ear. This constant distance between probe end **68** and ear drum **150** is helpful in reliably establishing a temperature pattern over time.

Base joining section **84** in this example may have a diameter that is slightly reduced relative to the maximum diameter of middle section **82**. The purpose of base joining section **84** is simply to join the rest of projection **54** to base **62**.

Although the particular shape and outer contours of probe cover **50** shown in FIG. 2 provides various advantages, modifications to this shape may be desirable in certain situations. FIGS. 6A–6E show some possible alternate configurations for probe cover **50**. These alternate configurations are preferably each made from a foam sheet but may provide different outer surface shapes. For example:

FIG. 6A shows a modified probe cover **50a** that eliminates tubular base portion **84**, and provides a cylindrical end portion **80** and a middle portion **82A** shaped as a hemisphere.

FIG. 6B shows another example foam probe cover **50b** that provides a flat ledge **86** in the transition region between end section **80** and tapered portion **82A**. This flat ledge **86** may abut against the ear lobe or other part of the auricle to provide a positive stop preventing further insertion of probe cover **50** into ear canal **152**.

The FIG. 6C probe cover **50c** design provides an extending projection **54c** that is uniformly linearly tapered.

The probe cover **50d** design shown in FIG. 6D provides a projection **54d** that is tapered as an ellipsoid to provide a hemispherical shape.

FIG. 6E shows a still additional probe cover design **50e** in which the projection **54e** has a complex tapered shape.

FIG. 6F shows a probe cover design **50f** in which projection **54f** has a conical shape terminating in a bulbous end portion, and has a hexagon shaped base portion **62f**.

In one embodiment, probe cover internal central passageway **56** may be formed to match the outer surface contour of probe **66**. This feature is shown most clearly in FIGS. 4A & 4B. In the particular example shown for illustrative purposes, probe **66** comprises a cylindrical portion **66a**, a bulbous center portion **66b**, and a terminal cylindrical por-

tion **66c** that terminates in probe sensing end **68**. In this particular example, the diameter of terminal cylindrical portion **66c** is less than the diameter of cylindrical portion **66a**—and the bulbous center portion **66b** has a generally hemispherical shape having the same diameter as that of cylindrical portion **66a**. The shape of passageway **56** generally matches the shape of probe **66** except that the outer dimensions of the probe are greater than the inside dimensions of the passageway. Thus, in this example the probe cover internal passageway **56** may similarly define a lower cylindrical hollow **56a**, a bulbous center hollow **56b**, and an upper cylindrical hollow **56c** communicating with one another to form a continuous passageway. In this embodiment, the probe **66** is "oversized" with respect to passageway **56** in this example in that:

(a) the inner diameter of probe cover internal passageway lower cylindrical hollow **56a** is less than the diameter of probe cylindrical portion **66a**;

(b) the inner diameter of probe cover passageway bulbous hollow **66b** is less than the outer diameter of probe bulbous portion **66b**; and

(c) the inner diameter of probe cover internal passageway upper cylindrical hollow **56c** is less than the outer diameter of probe cylindrical terminal portion **66c**.

When probe **66** is fully inserted into the probe cover internal passageway **56**, the probe cover **50** stretches and conforms around probe **66** (due to its foam construction) to form a tight friction fit. Compare FIG. 4A with FIG. 4B. In this particular embodiment, the probe bulbous portion **66b** mates with the probe cover bulbous hollow **56b** to hold the probe cover **50** on the probe **66**. More specifically, in this particular embodiment, the foam material defining the probe cover bulbous hollow **56b** expands and stretches around the probe bulbous portion **66b** to prevent axial movement of the probe **66** relative to the probe cover **50** (and thus ear canal **152** and eardrum **150**) during measurement. The tight friction fit provided by the stretching of the foam material over probe **66** is aided by a high surface tension between the foam and the probe **66** to provide good retention. The coefficient of friction between the foam surface and the probe **66** is high due to the molecular interaction between the two surfaces. The stretchable characteristic of foam also cover **50** allows the cover to adapt to a variety of differently dimensioned (and/or shaped) probes **66**.

In one particular example, the probe cover end **58** may be covered by a sanitary barrier **70**. Barrier **70** may, in one embodiment, cover the entire outer surface **72** of probe cover **50**—or it can be placed across opening **64**. Barrier **70** prevents germs, fluids, ear wax and other contaminants from passing through opening **64** into contact with probe **66**. Barrier **70** in one embodiment may comprise a thin clear high-density pre-stretched polyethylene plastic film sheet. For example, barrier **70** may be a plastic film membrane in the range of 0.0005" and 0.010" thick. Barrier **70** is substantially transparent to infrared radiant energy in the wavelength range of 8 to 14 microns emitted by the human eardrum—allowing such radiant energy to pass substantially unimpeded from the eardrum through circular opening **64** and passageway **56** to strike probe sensing end **68**.

In use, barrier **70** across circular opening **64** should be of uniform thin thickness without any bumps, wrinkles, distortions or other obstructions. In this particular example, barrier **70** comprises a plastic film that is pre-stretched across opening **64** in an entirely unwrinkled state at time of manufacture. Barrier **70** therefore has no wrinkles in it at any time. Since probe cylindrical portion **66c** may in one example be oversized (and/or include an oversized portion

73) with respect to probe cover internal passageway cylindrical hollow 56c as discussed above, inserting the probe 66 into cover 50 may cause the barrier 70 to further stretch across opening 64—from an already pre-stretched condition to a further stretched condition. The expansion of probe cover 50 around oversized probe 66 (e.g., structure 73) may cause the normally-stretched barrier 70 to stretch even further across window 64 to provide a uniformly thin (e.g., less than 0.0075") high-density barrier that is impervious to germs and other contaminants but substantially transparent to at least a part of infrared radiant energy within the wavelength range emitted by eardrum 150. Deformation of foam based probe cover 50 upon contact with the ear may cause barrier 70 to stretch still further. More specifically, when the probe cover 50 is inserted into ear canal 152, the cover deforms axially outwardly to further stretch the barrier 70. This additional stretching of barrier 70 does not have any adverse effects so long as the barrier doesn't stretch so much that it punctures. Since the thickness of barrier 70 during measurement is a factor in the temperature reading, it is desirable to have different individual probe covers 50 provide about the same amount of stretching for insertion of a given probe 66.

Probe sensing end 68 may be positioned any desired distance from barrier 70 when the probe 66 is fully inserted into probe cover 50. However, since the barrier 70 can never be a 100% transparent to radiant energy (and will generally exhibit some reflectivity characteristics), it is desirable to control the distance between the probe sensing end 68 and the barrier 70 so as to provide a higher degree of measurement repeatability. Therefore, in this particular example, the mating of probe bulbous portion 66b with the corresponding stretch-fit probe cover passageway bulbous hollow 56b causes probe sensing end 68 to be disposed some fixed axial, repeatable distance from (without contacting) the barrier 70 pre-stretched across and covering the opening 64.

FIGS. 3 and 3A show how probe cover 50 can be used with a tympanic thermometry instrument 100 to make a temperature measurement. Probe 66 is first fully inserted into the probe cover central passageway 56 by inserting probe sensing end 68 into base opening 67 and then exerting pressure. Because of its deformable, stretchable foam construction, probe cover 50 stretches over probe 66 to provide a friction fit that securely retains the probe cover on the probe's outer surface—and also compensates for differences in shape and dimensions for differently configured probe heads.

Conforming the central passageway 56's inner surface to the probe 66's outer surface also exactly aligns the probe sensing end 68 with the probe cover window 64.

The nurse or other care provider then inserts probe cover 50 insertion end 58 into the external acoustic meatus (ear canal) 152 of the patient. Probe cover insertion end 58 easily slides into ear canal 152. Because of its compressible foam construction, probe cover 50 conforms to the shape and dimensions of the ear canal 152—provide a high degree of patient comfort and also sealing the ear canal to prevent external light, air currents and radiant heat from entering the ear canal during temperature measurement. Such external heat, air currents and/or light can affect the temperature measurement. Additionally, since the foam has an extremely low emissivity and high absorption in the wavelength bands of interest, it further reduces error factors introduced through reflection within ear canal 152. For example, black foam provides very low emissivity and thermal mass, and also absorbs and has low reflectivity to ambient light due to high visible light absorption factor. White colored foam can also

be used. The foam color can be chosen to provide optimal radiant and optical characteristics (i.e., passivity, emissivity, absorption and reflectivity). In this example, the foam body has low reflectivity of ambient light and of the wavelength bands of interest; has a high attenuation to ambient light; has a low passivity to ambient light; and is substantially opaque to ambient light.

As mentioned above, the foam construction also provides a useful cushioning effect that keeps the hard surfaces of probe 66 away from the ear canal 152, provides a generally comfortable feel, and easily accommodates ear canals 152 having different sizes and shapes. See FIG. 3A. It keeps patient discomfort to a minimum, and is unlikely to lodge in the ear canal 152 or cause abrasive injury. Anyone who has ever had their temperature taken with a prior art rigid probe cover 50 as shown in FIGS. 1A and 1B will remember how uncomfortable the experience was. The soft, supple foam construction of preferred embodiment probe cover 50 provides an altogether different, much more pleasing experience. With probe cover 50 inserted the patient may feel pressure and will also have his or her hearing muffled due to the probe cover's sealing effect (e.g., as if you put your ear up to a sea shell). Thus, the patient can tell when the probe cover 50 has been fully inserted—an additional benefit if the patient is taking his or her own temperature (or to help train nurses in using proper temperature measuring technique). The inserted probe cover 50 does not feel like a too-big, hard object—the sensation most people experience with the prior art probe cover designs of FIGS. 1A and 1B.

The preferred embodiment probe cover 50 provided by the present invention also provides a useful positioning function—guiding and centering probe 66 within ear canal 152 to aim probe 66 more or less directly at eardrum 150. This centering and aiming function provided by probe cover 50 improves the measuring accuracy and repeatability of tympanic thermometer 100 by ensuring that probe 66 is aimed at eardrum 150 and assumes more or less the same position relative to the eardrum and the ear canal 152 each time the probe is inserted into the same patient's ear canal. While some of the aiming and guiding responsibility still falls upon the nurse's technique (for example, how he or she grasps the instrument 100 relative to the patient's ear canal 152), probe cover 50 is helpful in this guiding and placement function.

Probe cover 50 also performs an important insulating function. Because foam is a natural insulator, it provides excellent thermal isolation of the ear canal 152 and the probe 66 (in particular, the so-called "cold junction mass" within the thermopile sensor of the thermometer 100 nacelle). The largest degree of error in any thermopile-type measurement instrument is usually the thermal drift associated with the cold junction. The foam construction of probe cover 50 dramatically reduces the $\Delta\text{Temp}/\Delta\text{Time}$ relative to contact with the ear canal 152—reducing such thermal drift and improving measurement accuracy and repeatability. The ability to achieve repeatable measurements from the same or different ear is greatly enhanced by the insulative effect of probe cover 50 limiting the amount of heat drawn off the ear canal.

Once the measurement is completed, disposable cover 50 can be stripped from probe 66 and discarded. One way to strip cover 50 from probe 66 is simply to grasp the cover with the hands and pull it off the probe. However, it is desirable to make the stripping operation as simple, fast and easy as possible while minimizing contact between the nurse's hands and any portion of cover 50 that has been in contact with the patient. FIGS. 5A and 5B show how probe

cover **50** can be easily stripped from instrument **100** after use through use of an ejecting ring structure **90**.

In this example, instrument **100** may be equipped with a retractable ejection ring structure **90**. Ejection ring structure **90** may be moved between two positions: a retracted position (as shown in FIG. **5A**) and an extended, ejecting position (as shown in FIG. **5B**). Ejection ring structure **90** may include an annular grasping portion **92** and a conical stripping ring **94**. Probe cover base **62** may abut an upper surface **94a** of stripping ring **94** and the probe **66** may pass through a central cylindrical passage **96** within the ejection ring structure **90** when the probe cover **50** is fully inserted onto probe **66** and the ejecting ring structure is in the retracted position. To strip probe cover **50** from probe **66**, the user simply moves ejection ring structure **90** from its retracted position to its ejecting position. In the ejecting position, ejection ring structure **90** may extend fully over probe **66** (see FIG. **5B**)—overcoming the friction between the probe cover and the probe and stripping off the probe cover.

It also is desirable to help the nurse insert probe **66** into a probe cover **50** as easily and rapidly as possible without requiring the nurse to touch, with his or her hands, any part of the cover that will be placed into direct contact with the patient. FIG. **7A–7C** show how multiple foam probe covers **50** can be distributed together in the form of a block **200** for use with a dispensing tray **300** shown in FIG. **8**. By way of example, the block **200a** shown in FIG. **7A** comprises twenty-one individual probe covers **50** of the type shown in FIG. **2**. FIG. **7B** shows a block **200b** of twenty-one probe covers **50c** of the type shown in FIG. **6E**. FIG. **7C** shows a block **200c** of probe covers **50f** of the type shown in FIG. **6F**, the hexagonal base portions **54f** providing a very compact packing density so many probe covers can be provided in a small flat surface area. In each case, the individual probe covers **50** are attached together by small foam fingers extending across a cut or perforated line **202**. Probe covers **50** can be easily separated from one another by application of a small amount of mechanical pulling force—but stay attached to one another during shipment and handling of block **200** as a whole.

FIG. **8** shows an example probe cover dispenser tray **300** designed to accept and dispense a probe cover block **200**. In this example, the probe cover block **200** is inserted into a rectangular tray opening **302** defined by tray **300**, with the probe cover projecting portions **54** facing downward into the tray. This leaves opening **67** into which probe **66** is to be inserted completely exposed. To attach an individual probe cover **50** to probe **66**, a user may grasp the tympanic thermometer instrument **100** and insert probe **66** into probe cover opening **67** (see phantom lines in FIG. **8**). The nurse then pushes probe **66** downwardly into probe cover passage **56**—deforming and stretching the probe cover as shown in FIG. **4B** to provide a tight frictional, high surface tension fit between the probe cover and the probe.

The probe **66** may stretch the foam composition of probe cover **50**—causing the already stretched barrier **70** to become further stretched. The probe head expanded portion **73** helps to further stretch barrier **70** without requiring any contact between the probe end **68** and the barrier **70**. Gently pulling the thermometer **100** away from tray **300** will provide enough force to separate the individual probe cover **50** from block **200**—leaving probe **66** fully inserted into probe cover passage **54**. The advantage of using the dispensing tray **300** shown in FIG. **8** is that it allows a nurse to very rapidly cover probe **66** with a probe cover **50** without having to ever touch or otherwise contact the outer probe

cover surface **71** that is to come into contact with the patient. As discussed above, the barrier **70** may become still further stretched from its already-stretched position upon insertion of probe cover **50** into the ear canal **152** due to the outward deformation of the probe cover upon contact with the structures of the ear.

FIGS. **9A–9C** show different example processes for manufacturing probe covers **50**. In the FIG. **9A** example, a foam sheet **52** of desired thickness (for example, between $\frac{1}{64}$ " of an inch and $\frac{1}{4}$ " of an inch—and preferably between $\frac{1}{16}$ " and $\frac{3}{16}$ " of an inch thick) is heated by a heater **401**, and is then placed between two mating compression halves **402**, **404**. The compression mold halves **402**, **404** are shaped to provide the desired probe cover shape and inner passageway **54** shape (see FIGS. **6A–6E**). In this example, the compression mold process may be used to pinch form the passageway **54**. The compression mold halves **402**, **404** may be opened and the resulting formed sheet **52'** may then be held in place on a workpiece **406** (or on lower mold half **404**) by a vacuum. A film sheet **70** of desired thickness is then laminated on top of the formed foam sheet **52'** using a hot die **408** that also punches opening **64** and provides perforations **202** between individual probe covers **50**—or a numerically controlled ("NC") laser cutting device can be used to cut the perforations between the individual probe covers. Film sheet **70** may be laminated over the entire molded foam sheet **52'**, or it may also be cut so as to cover a smaller surface area—but at least all of openings **64**.

In the FIG. **9B** example manufacturing process, a foam sheet **52** is heated by a heater **401** and is then placed onto a heated vacuum workpiece **406** that vacuum forms the foam sheet into the desired shape. A punch **410** cuts openings **64** into the sheet **52** to form individual probe covers **50**. The same or different heater **401** is used to reheat the formed, punched foam sheet **52'**. A film sheet **70** is then drawn down and sealed to provide a laminated film seal covering openings **64**. A perforator **412** is then used to cut the perforations between the individual finished probe covers **50** to allow for separation of the individual pieces.

In the FIG. **9C** example, heater **401** is used to heat the foam sheet **52** and a vacuum Workpiece **406** forms the foam sheet into the desired shape as shown in FIG. **9B**. A laser **420** is then used to cut the holes **64** (and can also be used to cut the perforation between probe covers). Film **70** is then placed over the foam **52** and a heated die **422** is lowered into position. Pressure exerted by heated die **422** pre-stretches film **70** over holes **64**, and the heat from the die bonds film **70** to foam **52** to maintain the film in a pre-stretched, wrinkle-free state. The film **70** is not pre-heated except locally along the edges of the perforations. Because the film **70** is heated only locally, it does not sag or become loose or wrinkled in the neighborhood of hole **64** but instead remains tightly stretched across the hole.

When you are sick, you want to make sure your doctor has the most accurate information concerning your condition—and you also dread having to put up with uncomfortable procedures. They take your temperature many times a day in the hospital. The last thing you want is to feel uncomfortable every time they take your temperature. The prior art ear thermometer probe covers (see for example FIGS. **1A** and **1B**) are extremely uncomfortable because of their rigidity and other shortcomings. They can even get stuck in your ear, and they can scratch your ear. The present invention provides a new foam probe cover design that is much more comfortable and effective as compared to prior approaches.

While the invention has been described in connection with what is presently considered to be the most practical

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and preferred embodiment, it is to be understood that the invention is not to be limited to the disclosed embodiment, but on the contrary, is intended to cover various modifications and equivalent arrangements included within the spirit and scope of the appended claims.

We claim:

1. A disposable probe cover for a tympanic thermometer of the type having a radiant energy sensing structure for sensing at least one wavelength of radiant energy emitted by the eardrum, the probe cover having an insertion end for being inserted into an ear canal communicating with the eardrum and another end which remains outside of the ear canal so as to seal the ear canal, at least the probe cover insertion end comprising a deformable foam body defining a passage terminating in an opening, the passage accepting at least a part of the radiant energy sensing structure and communicating the radiant energy sensing structure with the opening, the probe cover further comprising a barrier that substantially occludes the passage, the barrier preventing ear canal contaminants from entering the opening while substantially allowing the radiant energy to pass therethrough and impinge upon the radiant energy sensing structure.
2. A probe cover as in claim 1 wherein the foam body includes a deformable obstructing portion that, in uses, limits insertion of the body into the ear canal and substantially seals the ear canal to prevent at least one of external light, heat and air currents from entering the ear canal during a temperature measurement.
3. A probe cover as in claim 1 wherein the foam body comprises black plastic foam having a high visible light absorption factor.
4. A probe cover as in claim 1 wherein the foam body comprises a closed-cell foam sheet.
5. A probe cover as in claim 1 wherein the barrier comprises a sheet of pre-stretched high density plastic film.
6. A probe cover as in claim 1 wherein the barrier is pre-stretched over the opening when the sensing structure is not inserted into the passage.
7. A probe cover as in claim 6 wherein the barrier is further stretched over the opening upon inserting the sensing structure into the passage.
8. A probe cover as in claim 1 wherein the foam body comprises a vacuum-formed, die-cut foam sheet.

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9. A probe cover as in claim 1 wherein the foam body comprises a compression molded foam sheet.

10. A probe cover as in claim 1 wherein the foam body comprises a laser cut foam sheet.

11. A probe cover as in claim 1 wherein the foam body allows a comfortable sealing of the ear canal.

12. A probe cover as in claim 1 wherein the eardrum is included within an ear which also has an auricle, and at least a part of the foam body, in use, compressibly deforms against at least a part of the auricle to at least in part seal the ear canal from at least one of external heat and light sources.

13. A probe cover as in claim 1 wherein the foam body, in use, thermally insulates the sensing structure.

14. A probe cover as in claim 1 wherein the foam body, in use, at least in part thermally isolates the sensing structure from the ear canal.

15. A probe cover as in claim 1 wherein the foam body has a low emissivity in the wavelength bands of interest.

16. A probe cover as in claim 1 wherein the foam body has a high absorption in the wavelength bands of interest.

17. A probe cover as in claim 1 wherein the foam body has low reflectivity of ambient light and of the wavelength bands of interest.

18. A probe cover as in claim 1 wherein the foam body has a high attenuation to ambient light.

19. A probe cover as in claim 1 wherein the foam body has a low passivity to ambient light.

20. A probe cover as in claim 1 wherein the foam body is substantially opaque to ambient light.

21. A probe cover as in claim 1 wherein the foam body has a hexagonally shaped base member.

22. In combination:

a tympanic thermometer probe; and

a hollow compressible foam body stretched over the probe to provide a friction fit that securely retains the foam body on the probe's outer surface, the foam body providing heat isolation for the probe and increasing comfort when, in use, the probe and foam body are together inserted into a human ear canal.

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Adverse Decision In Interference

No. 5,833,367, Edward P. Cheslock, Eric L. Canfield, Richard K. Harris, TYMPANIC THERMOMETER PROBE COVER, Interference No. 104,708, final judgment adverse to the patentees rendered November 26, 2002 as to claims 1-4 and 8-22.

(Official Gazette January 14, 2003)