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Elliott

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[54] **NEEDLE AND STERILIZING APPARATUS THEREFOR**

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[22] Filed: **Feb. 23, 1972**

[21] Appl. No.: **228,620**

Related U.S. Application Data

[63] Continuation-in-part of Ser. No. 148,869, June 1, 1971, abandoned.

[52] **U.S. Cl.** ..... **128/2.1 E,** 21/82 H, 128/2 E, 204/195 B

[51] **Int. Cl.** **A61b 5/00**

[58] **Field of Search** ..... 128/2.1 E, 2.1 R, 2 R, 128/2 S; 204/195 B, 195 R, 195 P; 21/56, 82 H, 82 R, 88, 90, 91, DIG. 4; 28/16.5, 16.6, 46 ST, 63.2 A, 63.2 R, 63.4, 63.5

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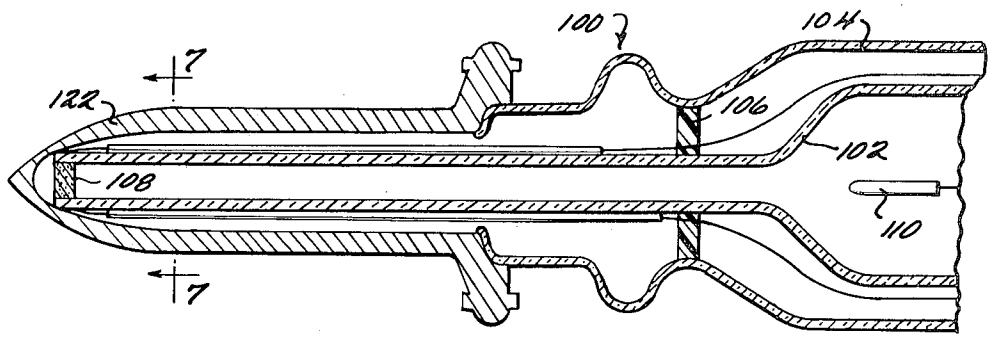
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Attorney, Agent, or Firm—Cushman, Darby & Cushman

[57] **ABSTRACT**

An apparatus and method for sterilizing medical tools, particularly needles of syringes and a novel apparatus for performing in vivo measurements. The in vivo measuring apparatus includes a hollow tube which is filled with an electrolyte solution and is sealed at an open end by a fiber seal. A plurality of electrodes are disposed about the tube, extend to a location adjacent the open end of the tube and are coated with electrical insulation except at that location. For an in vivo measurement, the tube and electrode can be placed within the hollow interior of a disposable syringe needle so that the open end of the tube is adjacent the opening in the needle and thus, after the needle is inserted, the in vivo solution electrically couples the electrodes to the electrolyte in the hollow tube. After each measurement, the tube and electrodes can be sterilized by placing them in a housing which has a chamber and some means for introducing sterilizing gas into the chamber. In one embodiment, the housing has an inner chamber for receiving a needle or other medical tool so that it is sealed within and an outer chamber containing a quantity of sterilizing gas under a pressure above atmospheric. A valve communicates the two chambers and is actuable to permit gas to pass from the outer to the inner chamber to sterilize the tool. In a further embodiment, a glass vial is disposed within the chamber and can be broken by pinching the housing to liberate the sterilizing gas. In a third embodiment, the sterilizing gas can be injected into the sealed chamber from an exterior source. In yet another embodiment, a glass vial having a narrow neck is disposed within a partially flexible tube preferably with the neck away from the inserted needle. The neck can be manually broken by pinching the tube to release a sterilizing gas with the broken tip held away from the needle.

11 Claims, 9 Drawing Figures



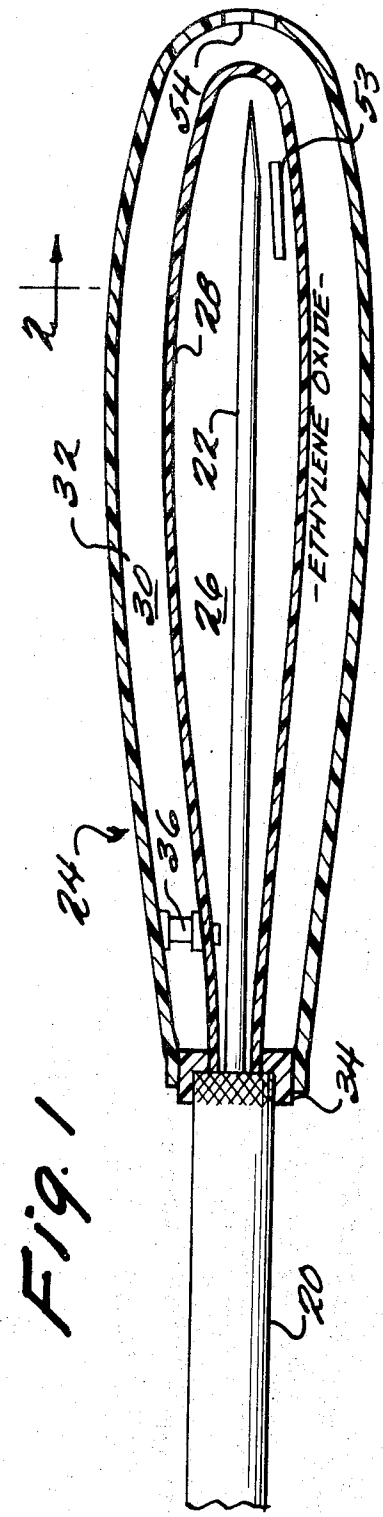


Fig. 1

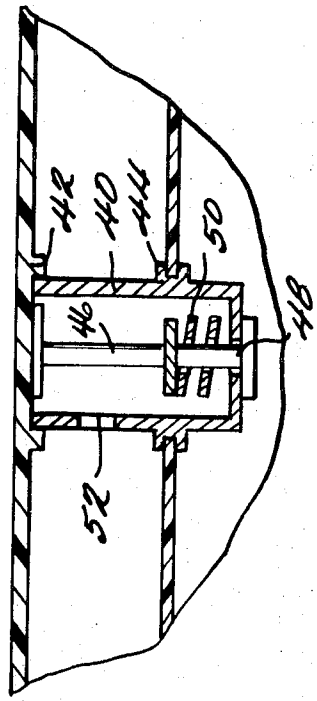


Fig. 3

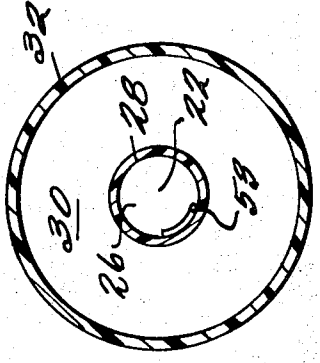


Fig. 2

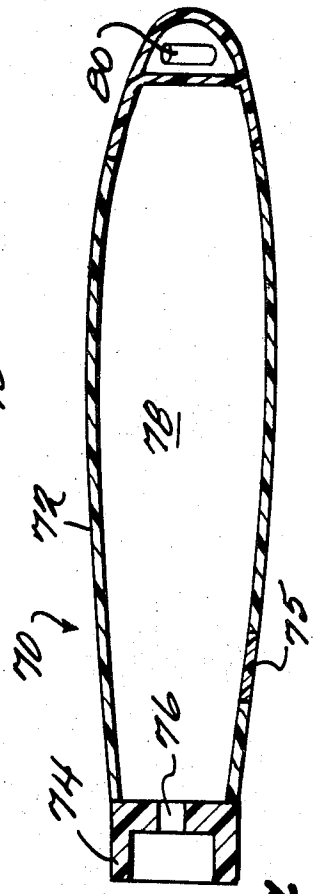


Fig. 4

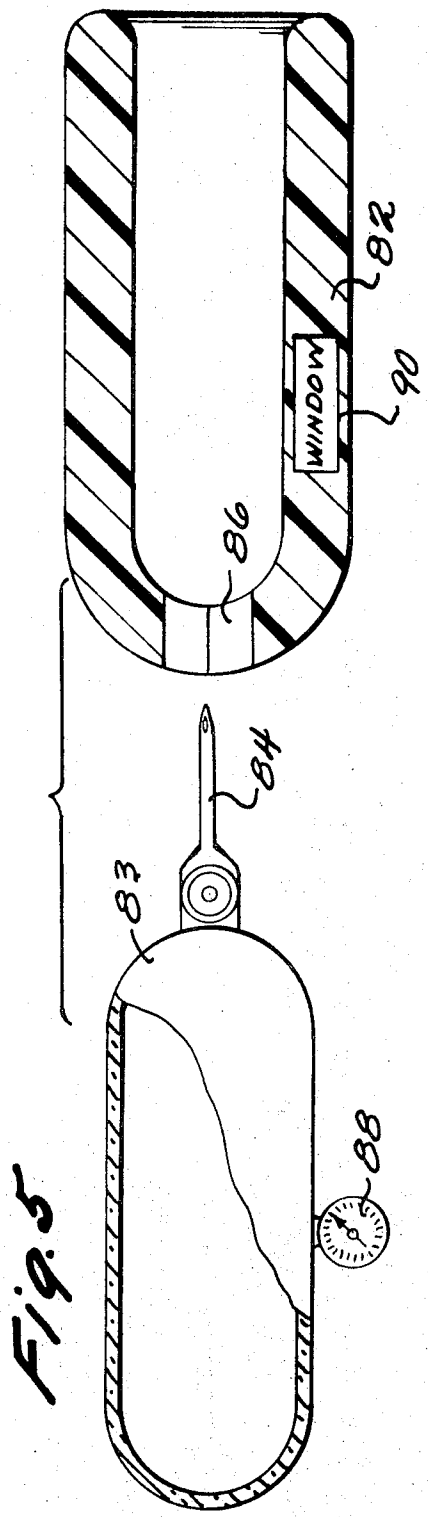


Fig. 5

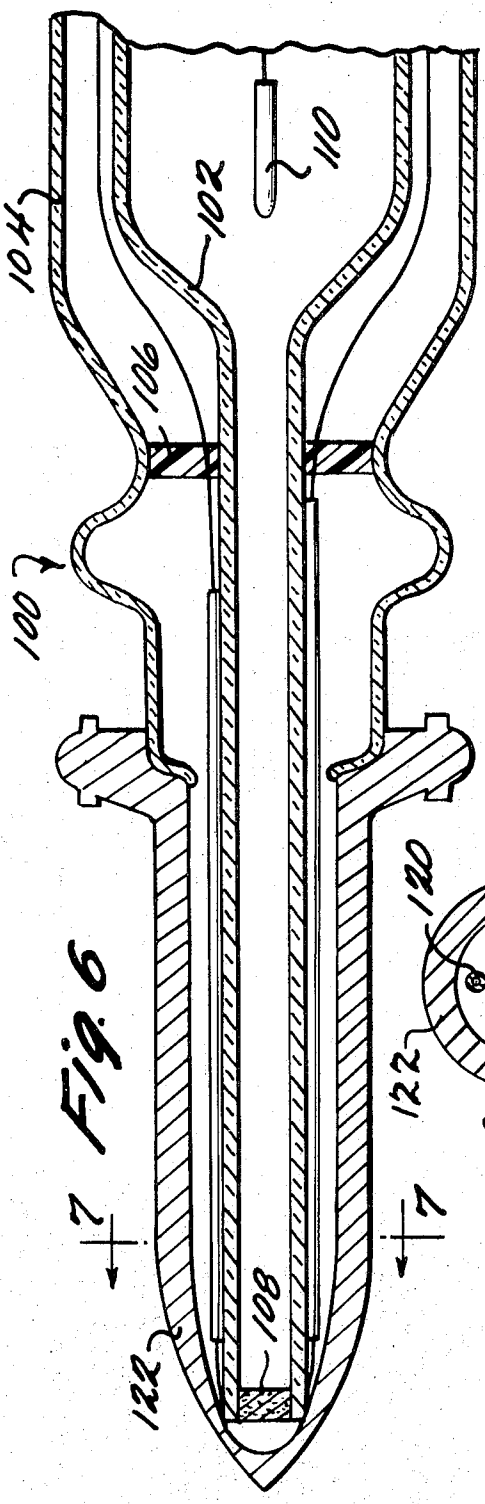


Fig. 6

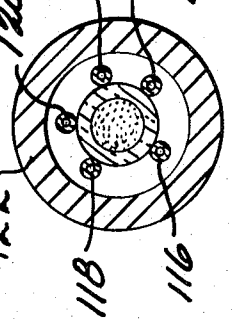


Fig. 7

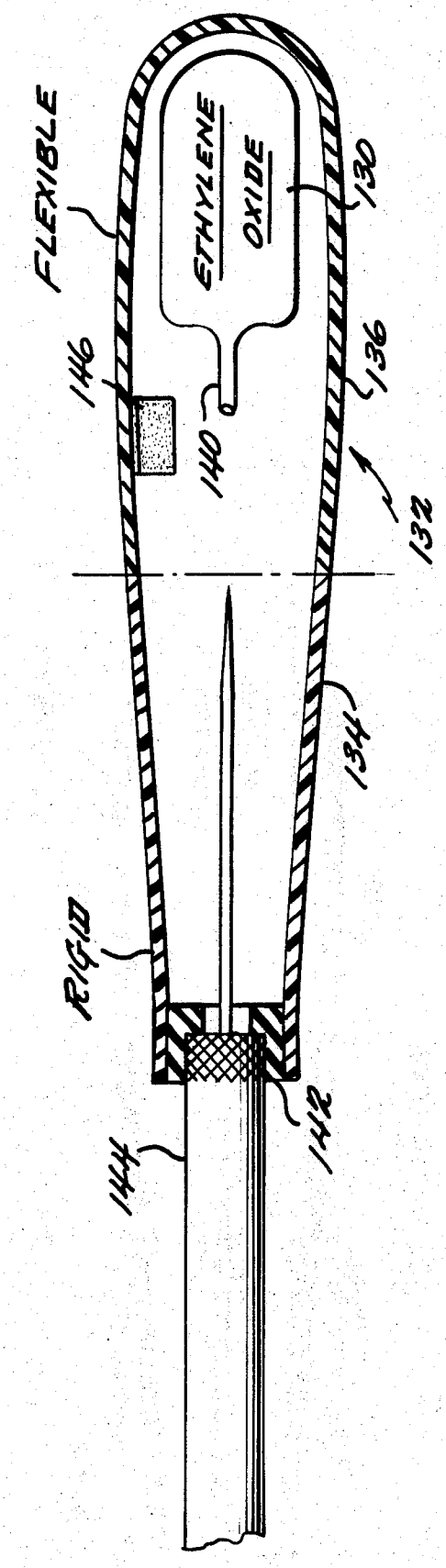

FLEXIBLE
ETHYLENE OXIDE
130
146
136
140
132
134
RIGID
142
144

Fig. 8

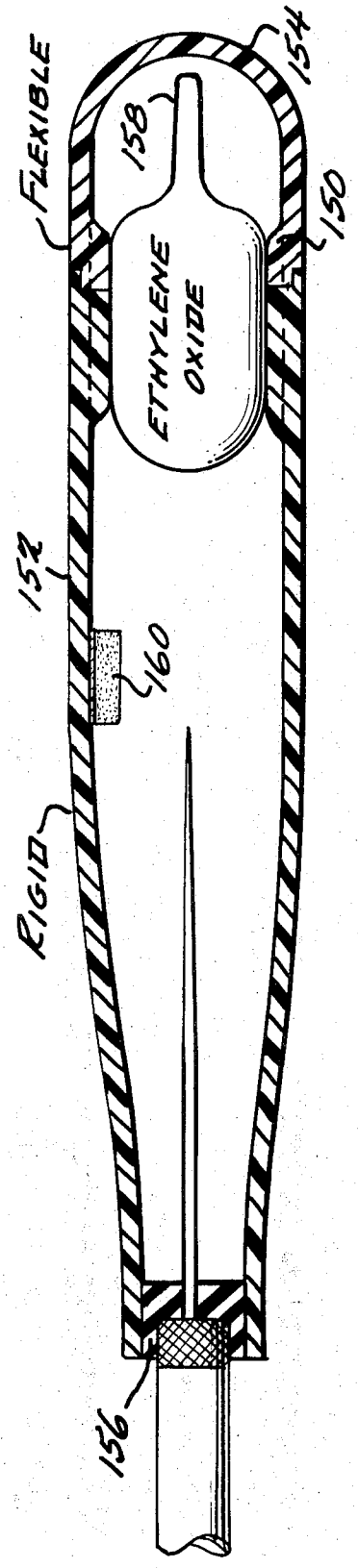


Fig. 9

NEEDLE AND STERILIZING APPARATUS THEREFOR

This application is a continuation-in-part of Ser. No. 148,869, filed June 1, 1971, now abandoned.

The invention relates to a method and apparatus for sterilizing medical tools, such as syringe needles, and to an apparatus and method for performing in vivo measurements.

Needles which are used with syringes for administering medicines to humans and animals, as well as for performing tests and experiments, must normally be sterilized before each use. Single use disposable syringes with attached needles which are sterilized after assembly and sealed in a flexible bag are suitable for many applications. However, in many instances the syringe required is too expensive to be practically used only once. Other similar medical tools require sterilization before each use.

Ethylene oxide is one of the most effective of a number of sterilizing gases which can be employed to sterilize objects by surrounding them with the gas in a suitable chamber. The U.S. Pat. No. to Leeds, 3,473,886, discloses such an apparatus with a chamber for receiving contact lenses which is adapted to be filled with ethylene oxide. However, sterilization in such devices is slow and inefficient and the devices themselves are costly to construct and maintain.

The present invention relates in part to a method and apparatus for simply, quickly and easily sterilizing syringe needles and other similar medical tools. The apparatus includes a sheath or housing which can be fitted onto a conventional syringe with the needles extending into an internal chamber which is sealed at one end by the syringe. In one embodiment, the sheath or housing walls further bound an outer chamber which is about the needle-containing chamber. This outer chamber is filled with ethylene oxide or another suitable gas under pressure and communicates with the needle-containing chamber via a suitable manually actuable valve. After the needle is sealed in its chamber, the valve between the two chambers is opened so that the ethylene oxide under pressure flows into the needle-containing chamber to surround and sterilize the needle. After a short interval, sterilization is complete and the needle can be withdrawn and the process repeated with a different syringe. More gas can be added to the outer chamber through a suitable valve as needed from time to time.

In a further embodiment, at least part of the cap or housing is flexible and has a single internal chamber into which the needle extends and which is also sealed by the syringe. A small glass vial or the like is attached to the sheath in the interior of the chamber and contains a suitable amount of ethylene oxide or other suitable gas under pressure. After the needle is disposed in the internal chamber with the syringe sealing that chamber, the vial is broken, for example, by pinching the portion of the flexible housing adjacent the vial, to liberate the gas which quickly sterilizes the needle. Normally, the housing would then be discarded after a single use. According to another embodiment, the glass vial has a neck portion with the part of the tube surrounding it made flexible to permit the neck to be broken to liberate the sterilizing gas. Preferably, the neck faces away from the needle with the vial held in the

tube so that the broken neck cannot damage the needle.

In a third embodiment, sterilizing gas can be injected into the housing chamber after the needle or other tool is within.

The invention also relates to an apparatus for performing in vivo measurements which can be sterilized with particular effectiveness according to the method and apparatus discussed above. Measuring the quantities of certain substances within the body is a medical tool which is valuable in both diagnosis and following treatment. Unfortunately, techniques now employed for such measurements are difficult, complex and expensive. One particularly difficult problem is in sterilizing the device between uses.

In the embodiment below, the apparatus includes a hollow capillary tube which contains an electrolyte solution and which is sealed at one end by a fiber seal. A plurality of electrodes for each measuring a different in vivo concentration are disposed about the tube and extend to the open end. The tube and electrodes can be placed in a conventional, hollow, disposable syringe needle which is then inserted into the in vivo solution, for example the bloodstream. An electrical connection is thus made between the electrodes and the electrolyte and measurements from the electrodes and the electrolyte can be quickly and simply made. After each use, the needle can be discarded and the tube and electrodes placed in a sterilizing apparatus of the type described above for a short time.

Many other objects and purposes of the invention will be clear from the following detailed description of the drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. **1** shows a cut-away view of one embodiment of this invention for sterilizing medical tools;

FIG. **2** shows a cut-away view of the apparatus of FIG. **1** along the lines **2–2'**;

FIG. **3** shows a cut-away view of the valve communicating the outer chamber to the needle-containing chamber in the embodiment of FIG. **1**;

FIG. **4** shows a further embodiment of this invention for sterilizing medical tools;

FIG. **5** shows a further embodiment of this invention for sterilizing medical tools;

FIG. **6** shows a cut-away view of an apparatus for performing in vivo measurements; and

FIG. **7** shows a cut-away view of the apparatus of FIG. **6** along the lines **6–6'**;

FIG. **8** shows a further embodiment of this invention for sterilizing medical tools;

FIG. **9** shows another embodiment similar to the embodiment of FIG. **8.**

DETAILED DESCRIPTION OF THE DRAWINGS

Reference is now made to FIGS. **1** and **2** which show a cut-away view of a conventional syringe **20** having a needle **22** inserted in one embodiment of the novel sterilizing apparatus **24** of this invention. Needle **22** fits within a first chamber **26** which is bounded by a first wall **28** which is preferably rigid to protect needle **24.** Chamber **26** is open at one end for receiving needle **22** and this end is then sealed by syringe **20.** Threads on the syringe and gasket **34** can be provided if desired for better sealing. A flexible outer chamber **30** is disposed about chamber **26** and is bounded by wall **28,** outer

wall 32, and sealing ring gasket 34. A conventional valve 36 communicates chamber 26 to chamber 30 as shown in detail in FIG. 3.

As discussed above, chamber 30 is filled with a suitable sterilizing gas, preferably ethylene oxide, under a pressure which is above atmospheric. To sterilize needle 22, or any other medical tool, the needle is first placed in chamber 26 as shown in FIG. 1. Next, valve 36 is manually opened so that the sterilizing gas in chamber 30 flows into chamber 26 until the pressure in the two chambers is roughly equal.

Referring to FIG. 3, conventional valve 36 includes a first housing member 40 which extends between the two chambers and is fixedly attached between walls 28 and 32 by rings 42 and 44. Ring 42 also seals the aperture in wall 28 through which member 40 extends. A valve member 46 is disposed within member 40 and normally seals aperture 48 as shown, with spring 50 continually urging member 48 upward, closing aperture 48. To open valve 36, manual pressure is exerted on the exterior of flexible wall 32 to cause member 46 to move down and open aperture 48 so that the sterilizing gas in chamber 30 flows through aperture 52, through the interior of valve 36, out aperture 48 and into chamber 26.

After chamber 26 has received a sufficient quantity of the sterilizing gas, sterilization takes place rapidly and the syringe can then be withdrawn and used. Material 53 of the type which changes color when sterilization is complete can be disposed within chamber 26 and at least portions of walls 28 and 32 made transparent so that a positive indication that sterilization is complete is given. A different syringe or other can then be inserted and sterilized. Additional gas can be added to chamber 30 as necessary via conventional valve 54.

FIG. 4 shows a further embodiment of this invention which is intended to be used once and discarded. Apparatus 70 includes a sheath or housing 72 which is attached to a ring 74 which has an aperture 76 extending through it for receiving a syringe needle as shown in FIG. 1. The syringe itself seals the needle in chamber 78. A glass or other vial 80 is attached to sheath 72 within chamber 78 and contains an appropriate quantity of ethylene oxide or other sterilizing gas. At least the portion of sheath or housing 72 adjacent vial 80 is flexible so that after the needle is in chamber 78, vial 80 can be broken, for example, by pinching flexible sheath 72, to liberate the gas which quickly sterilizes the needle. Preferably, the portion of housing 72 about the needle is rigid to protect. A window 75 is provided for viewing material of the type which changes color when sterilization is complete. After a single use, apparatus 70 can be discarded.

FIG. 8 illustrates another embodiment similar to that shown in FIG. 4 whereby a glass or other vial 130 is disposed within a tube 132 having a rigid portion 134 and a flexible portion 136. Tube 132 can be constructed of plastic materials or any other suitable materials. Vial 130 has an extending narrow neck 140 which can be easily broken by pinching flexible portion 136 of tube 132 to liberate a sterilizing gas such as ethylene oxide. A flexible stopper 142 is disposed at the open end of tube 132 for sealing tightly the tube when a medical tool such as syringe 144 is inserted as shown. A suitable indicator 146 is disposed within tube 132 for visually indicating when sterilization has been completed.

Similarly in the embodiment of FIG. 9 a vial 150 containing ethylene oxide or another sterilizing gas is disposed within a chamber bounded by rigid tube portion 152 and flexible tube portion 154. Vial 150 is held away from a needle or other structure which is inserted into the chamber via flexible stopper 156. Vial 150, like vial 130 in FIG. 8, has a neck portion 158 which can be broken to liberate the gas in vial 150 by pinching flexible tube portion 154. The liberated gas passes along the ribs which hold vial 150 in place to sterilize the needle or other implement. The broken neck, however, cannot reach the region occupied by the needle and accordingly cannot damage it. An indicator 160 is disposed within the sterilizing chamber as described above.

Reference is now made to FIG. 5 which shows a further embodiment whereby a medical tool to be sterilized is placed within housing 82 so that the object seals the open end thereof. Next a needle 84, which is connected to a source 83 of ethylene oxide, or other sterilizing gas, which is at a pressure above atmospheric, is introduced into the interior of housing 82 via the opening through valve 86. Valve 86 is of the type which is comprised of flexible material, such as rubber. An opening extends through the valve but is kept normally sealed by the flexible material which is in slight compression. However, a needle can be pushed through the opening to introduce gas into housing 82. A pressure meter 88 is preferably provided on source 83 for indicating when the pressure is insufficient to introduce enough sterilizing gas into housing 82. A window 90 is preferably provided in housing 82, which may be intended for single or multiple use for observing material within housing 82 which changes color when sterilization is complete.

Reference is now made to FIGS. 6 and 7 which show an apparatus 100 for performing in vivo measurements. As mentioned above, apparatus 100 includes a capillary tube 102, for example glass, which can be mounted within a conventional syringe 104, a portion of which is shown in FIG. 6. In this embodiment, an epoxy ring 106 holds tube 102 in place within syringe 104. Tube 102 is sealed at its lower open end by a fiber seal 108. Such seals are wellknown and permit electrical connection between an electrolyte solution such as .1 NHCL and an in vivo solution exterior to the open end of tube, while at the same time preventing any significant quantities of the electrolyte from seeping into and contaminating the in vivo solution or vice-versa. A conventional electrode 110, for example Calomel, is also mounted within tube 102 and in electrical connection with the electrolyte as shown.

A plurality of electrodes are circumferentially disposed about tube 102 and extend along its length as shown and suitable wires connect to these electrodes to connect them to devices exterior to apparatus 100. In this embodiment five electrodes 112, 114, 116, 118 and 120 are employed but it will, of course, be understood that any number of electrodes can be employed as desired. Each electrode is used to perform a different test so that information on a number of in vivo concentrations can be derived simultaneously. Normally, different electrodes will be of different materials and the electrodes performed for measuring concentrations of different substances are well-known. Each of the electrodes about tube 102 are preferably coated with

a suitable electrical insulation, except at the portions adjacent the open end of tube **102.**

For making an in vivo measurement, a hollow needle **122,** which is preferably disposable, is placed conventionally on syringe **104** with the hollow tube **102** and electrodes exterior to it extending through the needle and the open end of tube **102** adjacent the opening in needle **122.** Needle **122** can then be inserted into an in vivo solution, for example, the bloodstream of a human or animal or perhaps even the solution within a single cell, so that the in vivo solution electrically couples the electrolyte in tube **102** to the electrodes disposed about **102.** Signals can then be derived from the electrodes and employed conventionally to determine the concentrations of various substances in the vivo solution.

After each use, needle **122** can be discarded and tube **102** and the electrodes exterior to it sterilized by the use of one of the sterilizing apparatus described above. Such apparatus provide a simple, quick and effective way to sterilize the instrument after each use. Alternatively, a permanent, rather than disposable needle can be employed and also sterilized after each use.

Many changes and modifications in the above embodiments of the invention can, of course, be made without departing from the spirit of the invention. Accordingly, the scope of the invention is intended to be limited only by the scope of the appended claims.

What is claimed is:

1. Apparatus for performing in vivo measurement comprising:

an electrolyte solution,

hollow tube means for containing said electrolyte solution and having an open end,

a reference electrode extending within said hollow tube means,

means for sealing said open end so that said reference electrode in said tube means when in use will be in electrical connection, via said electrolyte solution, with an in vivo solution which is exterior to said tube means about said open end,

a plurality of different electrodes disposed circumferentially about and connected to said tube means exterior to said tube means and each extending to a location adjacent said open end of said tube means so that each said electrode will be in electrical connection with said electrolyte solution via said sealing means and said in vivo solution, and

a plurality of output wires each connected to one of said electrodes.

2. Apparatus as in claim **1** further including electrical insulating material about each said electrode except for a portion of each electrode in the vicinity of said sealing means.

3. Apparatus as in claim **1** wherein said sealing means is a fiber seal.

4. Apparatus as in claim **1** wherein said hollow tube means includes a glass capillary tube.

5. Apparatus as in claim **1** further including a hollow needle having an opening at one end for receiving said tube means and said electrodes and an opening at the other end for communicating said in vivo solution with said tube means and said electrodes.

6. Apparatus as in claim **1** wherein said reference electrode is a Calomel reference electrode disposed in said tube means in electrical connection with said electrolyte solution.

7. Apparatus for performing in vivo measurement comprising: an electrolyte solution

hollow tube means for containing said electrolyte solution and having an open end,

a reference electrode extending within said hollow tube means,

means for sealing said open end so that said reference electrode in said tube means when in use will be in electrical connection, via said electrolyte solution, with an in vivo solution which is exterior to said tube means about said open end,

a plurality of electrodes disposed circumferentially about and connected to said tube means exterior to said tube means and extending to a location adjacent said open end of said tube means so that each said electrode will be in electrical connection with said electrolyte solution via said sealing means and said in vivo solution,

a plurality of output wires each connected to one of said electrodes,

a housing having a chamber receiving said hollow tube means and electrodes exterior to it and means forming a seal with said tube means so that said chamber is sealed with said tube means and electrode in it,

means containing a quantity of sterilizing gas at a pressure above atmospheric, and

means for communicating and containing means and said chamber so that said gas passes into said chamber to sterilize said tube means and electrode exterior to it.

8. Apparatus as in claim **7** wherein said containing means is an outer chamber about said chamber in said housing and said communicating means includes actuable valve means communicating said outer chamber with said chamber in said housing so that gas from said outer chamber passes into said chamber in said housing to sterilize said tube means and electrode exterior to it.

9. Apparatus as in claim **8** wherein said containing means is a glass vial.

10. Apparatus as in claim **7** wherein said containing means includes a manually breakable container disposed in said chamber.

11. Apparatus as in claim **7** wherein said communicating means includes valve means comprised of flexible material and having an aperture extending through it which is normally sealed but through which a needle can be extended to communicate a source of sterilizing gas to said chamber so that said gas passes into said chamber to sterilize said tube means and electrode exterior to it.

* * * * *