Abstract: Disclosed is a tissue probe system comprising a probe (600), a sheath (110) and a boot (400). The probe has an elongate shaft (602) extending from a shaped handle (604). The sheath is formed of (i) an elongate tube (200) shaped to envelope the shaft and having a coupling end (204) including an interior (224) configured for coupling to the probe, and a tip end (202), and (ii) a contact unit (300) closing the tip end of the tube, the contact unit including electrical contacts (316) configured to engage tissue and spring electrical connections (308,320) arranged to secure the unit within the tube and to electrically couple to contacts arranged on the shaft of the probe when inserted into the tube. The boot is configured to couple to an exterior of the coupling end of the tube, the boot being shaped to complement and envelop at least part of the handle.
SHEATH SYSTEM FOR TISSUE PROBE

Technical Field

The present invention relates to the probes used for medical testing and, in particular, relates to a disposable sheath system for a tissue probe that can operate with optical and electrical signals.

Background

United States Patent No. 5,800,350 discloses diagnostic apparatus for assessing tissue types to detect the presence of precancerous or cancerous tissues. A particular embodiment described in that document relates to a probe configured for insertion into the vagina for contacting the cervix of a patient and operable using a combination of electrical and optical signals to assess tissue types on the surface of the cervix. Electrical and optical responses from the tissue are assessed to provide an indication as to presence of cancerous or non-cancerous tissues.

Since the probe is inserted into a bodily orifice, it may be required that the probe be either disposable or sterilised between use on different patients. As a consequence of the cost of manufacture and technology incorporated into the probe, disposability is not presently commercially viable. Sterilisation of a used probe is problematic as autoclaving can seriously damage the probe and/or alter the parameters of performance. The latter can be essentially equivalent to destroying the probe as any substantial alteration in performance may cause the probe to provide an unacceptable occurrence of false negative or false positive indications. Often however the probe can be cleaned by either bathing in a disinfectant solution, wiping with an alcohol swab, or similar. These modes of cleaning and sterilisation are generally effective however the chance of some contamination may exist, if only in the mind of the next patient. Patients generally have a clear desire for sealed products to be used.
European Patent No. EP 0865761 (corresponding to US Patent No. 5,830,146) discloses a disposable sheath arrangement for use with a probe of the type described above. The described arrangement includes a rigid tubular sheath configured to envelope the probe and having an optical window through which optical signals may pass and electrical connections by which electrical contacts formed on the sheath may electrically connect to spring connections on the probe.

Not described also is a rubberised boot which attaches to the end of the sheath and is configured to envelope a body portion of the probe which is held by the user. Both the sheath and the boot are disposable and when properly used, prevent the probe being contaminated with bodily fluids.

Problems exist with the existing sheath arrangement in that the spring connections on the probe were vulnerable to damage. Further, the sheath was not configured to engage with the probe in a manner that ensured firm location of the sheath nor did it provide for the spacing between the end of the probe and the window of the sheath to be reproducible.

Summary

It is an object of the present invention to substantially overcome, or at least ameliorate, at least one difficulty associated with prior art arrangements.

Disclosed is a sheath for a medical probe. The sheath comprises an elongate tube having a coupling end for at least longitudinally releasably affixing the sheath to the probe. A contact unit is positioned at a probing end of the tube, the contact unit having a plurality of resiliently flexible electrical connectors arranged to longitudinally position the contact unit in the probe end.

Desirably the coupling end comprises a longitudinal key configured to mate with a complementary longitudinal slot formed on a boot, and at least one interior protrusion
configured to engage and seat within an annular groove of the probe when the key is mated with the slot. In a specific implementation, the coupling end comprises a plurality of the interior protrusions, arranged at different longitudinal distances from end of the tube. The probe end may include an interior annular groove into which portions of the electrical connectors engage to longitudinally position the contact unit in the probe end. The contact unit is desirably formed of resiliently flexible insulating material upon which the electrical connections are formed by affixing conductive material to portions of the contact unit. Preferably the electrical connections are formed by sputtering of a metal. The metal may be gold or a suitable alternative.

The contact unit comprises a ring having one closed end and a plurality of legs each extending generally longitudinally from the other open end of the ring, the legs each being outwardly biased from a circumference of the ring and having an end configured to be engaged in the interior annular groove of the probing end, the electrical connections each extending from an interior of each leg adjacent the open end of the ring, around to an exterior of the corresponding leg, across the ring and onto an adjacent electrical contact segment on the closed end.

Also disclosed is a sheath system comprising a sheath as discussed above and a boot configured for resilient coupling to the coupling end of the tube. The sheath and the boot are desirably coupled by engagement of an interior annular protuberance of the boot within an exterior annular groove of the coupling end, the engagement being aligned by the key and slot mentioned above.

Also disclosed is a tube for use with a tissue probe, the tube being elongate and shaped to at least substantially envelope a shaft of the probe, the tube having a tip end and coupling end, the tip end being shaped to complementarily receive internally a lens and contact unit to thereby close the tip end, the coupling end having structures for
longitudinally coupling the tube to the shaft and for aligning and longitudinally coupling the tube to a boot.

Also disclosed is a lens and contact unit for a tissue probe sheath, the contact unit comprising a ring having one closed end forming a lens and a plurality of legs each extending generally longitudinally from the other open end of the ring, the legs each being outwardly biased from a circumference of the ring and having a leg end configured to be engaged in an interior annular groove of the probe sheath, the unit further comprising a plurality of electrical contacts formed on the closed end, each said contact having a corresponding electrical connection that extends from the contact across the ring and along at least part of an exterior of one of the legs and an interior of the one leg adjacent the open end of the ring. Desirably the unit is formed of resiliently flexible plastics material with the electrical contacts and connections being affixed to the material, the legs thus forming spring contacts that aid in securing the unit within the probe sheath.

Also disclosed is a tissue probe system comprising a probe having an elongate shaft extending from a shaped handle, a sheath formed of (i) an elongate tube shaped to envelope the probe and having a coupling end including an interior configured for coupling to the probe and a tip end, and (ii) a contact unit closing the tip end of the tube, the contact unit including electrical contacts configured to engage tissue and spring electrical connections arrange to secure the unit within the tube and to couple to contacts arranged on the shaft of the probe when inserted into the tube; and a boot configured to couple to an exterior of the coupling end of the tube, the boot being shaped to complement and envelop at least part of the handle.

Other features and aspects are also disclosed. The arrangements described provide for apparatus that is relatively inexpensive to manufacture, and hence may be
disposable, whilst affording reliable operation of the probe for its intended purpose. The arrangements are also simple to use.

**Brief Description of the Drawings**

At least one embodiment of the present invention will now be described with reference to the drawings in which:

- Fig. IA is a perspective view of a sheath system for a tissue probe configured for use;
- Fig. IB is a longitudinal cross sectional view of the arrangement of Fig. IA;
- Figs. 1C and 1D are respectively plan and side elevation views of the arrangement of Fig. IA;
- Fig. 2A is a perspective view of a tube of the sheath of Figs. IA-1D;
- Figs. 2B to 2G are various other views of the tube of Fig. 2A;
- Fig. 3A is a perspective view of a lens and contact unit configurable with the tube of Figs. 2A to 2F;
- Figs. 3B to 3F are further views of the lens and contact unit of Fig. 3A;
- Fig. 4A is a perspective view of a boot forming part of the sheath system of Figs. 1A-1D;
- Figs. 4B to 4F are further views of the boot of Fig. 4A;
- Fig. 5A is a plan cross-sectional view of the lens and contact unit when inserted into the tube;
- Fig. 5B is a cross-sectional partial view of an interconnection between the tube, the probe, and the boot;
- Fig. 6A is a perspective view of the probe;
- Fig. 6B is a side elevation view of the probe of Fig. 6A; and
Fig. 7 is partial cross-section illustrating the connection between the sheath tube and the probe.

**Detailed Description including Best Mode**

Fig. 1A shows a sheath system 100 for a tissue probe. The sheath system 100 is formed by an elongate sheath 110 coupled to a boot 400 in a coupling region 114 distanced from a probe end 112 of the sheath 110.

The sheath system 100 is configured, in use, to envelope the operative parts of a tissue diagnostic probe such as the probe 600 shown in Figs. 6A and 6B. The probe 600 includes an elongate shaft 602 which couples to a handle 604, only part of which is shown in the drawings. The shaft 602 has a generally circular cross-section and a distal end forming a tip 606 defining an optical window 608 by which light signals may be transmitted from, and received by, the probe 600. The light signals may for example emanate from an optical fibre bundle (not illustrated) terminating in the tip 606 at the window 608. Such an optical fibre bundle forms an optical receiver/transmitter. A number of electrical contacts 610 are formed on the exterior longitudinal surface of the shaft 602 immediately adjacent to the tip 606 and the window 608. Typically, three (3) contacts 610 are used spaced evenly about the tip 606 and, as such, only two (2) of the contacts 610 are seen in each of Figs. 6A and 6B. The shaft 602 is preferably substantially cylindrical however the radius of the tip 606 is desirably less than the radius of the shaft 602 at its proximal end 612, adjacent the handle 604, thus affording the shaft 602 a slightly frusto-conical shape.

The probe 600 includes annular groove 616 formed in the proximal end 612 immediately adjacent an annular ridge 614, the groove 616 being positioned between the ridge 614 and the handle 604. The purpose and operation of the various structures
described above with respect to the probe 600 will become apparent in the subsequent
description of the sheath system 100.

The structural inter-relationship between the sheath system 100 and the
probe 600 when in use is seen in the cross-sectional view of Fig. IB. The sheath
system 100, incorporating the sheath 110 and the boot 400, is configured to slide over the
tip 606 and along the shaft 602 of the probe 600 so that the tip 606 is neatly but securely
fitted within the probe end 112. This provides for appropriate electrical and optical
coupling between the probe 600 and the sheath 110, and also for physical connection
between the sheath system 100 and the proximal end 612 of the probe 600 in the coupling
region 114. The coupling region 114 also includes a coupling between the boot 400 and
the sheath 110.

The sheath 110 is formed as a unitary structure, typically in a factory
environment, by a combination of a tube 200, seen in Figs. 2A-2F, and a lens and contact
unit 300, seen in Figs. 3A-3F. The unit 300 is inserted and positioned within the tube 200
in a manner to be described. As seen in Fig. 2A, the side elevation of Fig. 2B, and in the
cross-section of Fig. 2C, the tube 200 includes a probing end 202 and a coupling end 204,
is generally cylindrical or slightly frusto-conical between the ends 202 and 204, and is
configured to slide over the shaft 602 of the probe 600. The probing end 202 is shaped to
be increasingly frusto-conical such that a tip 206, being the extremity of the tube 200, is
of smaller diameter than a shoulder 208 representing a transition in frusto-conicality
between the coupling end 204 and the probing end 202. Specifically, the tube tip 206 and
the probing end 202 are sized and shaped to receive therein the lens and contact unit 300.
As best seen in the expanded cross-section of Fig. 2D, which shows detail of the probing
end 202, adjacent the tube tip 206 is an interior cylindrical surface 210 which extends
inwardly to an interior frusto-conical surface 212, and then to a further cylindrical
surface 214. Arranged within the cylindrical surface 214 is an interior annular
groove 216 representing a depression or channel within the cylindrical surface 214. Immediately adjacent the tube tip 206 and connecting with the interior cylindrical surface 210 is an interior annular bevelled surface 220. The tube 200 is desirably manufactured of plastics material, such as polycarbonate.

Turning now to Figs. 3A-3F, the lens and contact unit 300 is structurally formed through a single moulding of resiliently flexible plastics material. Polycarbonate may again be used and such material is electrically insulating. The unit 300 is formed by a ring 302 having a peripheral bevelled edge 304 which in turn extends into a lens portion 306 closing one end of the ring 302. The lens portion 306 is preferably clear and optically fault-free and has a thickness of between about 200 to 230 micrometres. The thickness of the lens 306 must typically be less than the spacing between the fibres in the probe 600 to avoid internal reflections of the light signal by the face of the lens 306. A thicker lens may be used where the spacing between the fibres is greater. As better seen in the partial cross-sections of Figs. 3E-3F, the ring 302 has a thickness substantially greater than that of the lens 306 to provide for support to the unit 300. As best seen in the side elevation view of Fig. 3B, extending from an open end of the ring 302 are three legs 308. As better seen from Figs. 3E and 3F, each leg 308 is outwardly inclined or biased from the circumference and longitudinal extent of the ring 302 and includes a peripheral outwardly extending elbow 310 which terminates in a square section end 312 generally transverse the longitudinal extent of the unit 300.

For assembly of the sheath 110, and with reference to Figs. 2C and 2D, the lens and contact unit 300 is configured to be inserted into the tube 200 from the coupling end 204 (in view of its larger diameter). Upon reaching the probing end 202, the lens and contact unit 300, and particularly the ring 302 and bevelled edge 304, engage the frusto-
conical interior surface 212 to locate the ring 302 within the (outer) cylindrical surface 210, with the bevelled edge 304 riding and locating against the complementarily shaped bevelled surface 220 located immediately adjacent the tube tip 206. As a consequence of the configuration of the tube tip 206 and a complementary shaping of the ring 302 and bevelled edge 304, the lens and contact unit 300 can be accurately located within the tube tip 206 such that the lens portion 306 is fitted neatly with an interference fit in line with the tube tip 206. In this configuration, the legs 308 ride against the interior wall 218 of the probing end 202 until each end 312 of the legs 308 engages with and is held or retained in a resilient snap-fit connection within the groove 216, thereby securing the unit 300 within the probing end 202. This configuration, by which the sheath 110 is formed from the tube 200 and the unit 300, is illustrated in Fig. 5A.

In an alternate configuration (not illustrated), the annular groove 216 may be omitted. In this configuration, the interference fit between the tube tip 206 and the contact unit 300 may be ensured by forcing the contact unit 300 to its final position using a mandrel during assembly and securing the two components using an adhesive. In such an implementation, the bevelled surface 220 may be omitted and replaced by a cylindrical surface. Such a procedure may contribute to variability in the overall length of the tube 200 before assembly upon the probe 600.

As best seen in Fig. 3C, being a plan view of the lens and contact unit 300, each of the legs 308 has an outer surface 314 (see also Fig. 3F) which extends across the outer surface of the ring 302 and the bevelled edge 304 to form a corresponding electrical contact segment 316 in the lens portion 306. With this configuration the unit 300 may be processed with a conductive material such as metal, for example through gold sputtering, to form an electrical contact upon each of the segments 316. The gold may be further processed by a sputtering of titanium thereon, to reduce susceptibility to deterioration in
the performance of the contacts caused by the presence of proteins and the like found in bodily fluids and tissues. Further, by way of the processing, the electrical connections can then extend downward from each of the segments 316, along the outer surface of the corresponding leg 308 and then upwards along an interior surface 318 of each leg 308 to a corresponding contact region 320 formed upon the interior of each of the legs 308. With this configuration, each of the segments 316 becomes a contact surface for an electrically contacting the tissue that is to be probed. Further the connection formed along the outer surface of each leg 308 and along the interior surface 318 of the leg 308 to the contact surface 320 permits the contacts 610 on the probe 600 to engage a corresponding one of the contact regions 320 of the unit 300, thereby electrically connecting each of the contacts 610 to a corresponding segment 316.

Fig. 3D is an inverse plan view of the unit 300 showing the contact regions 320 as inclined surfaces configured to engage with the contacts 610 of the probe 600. By virtue of the legs 308 being formed of resiliently flexible plastics material, and the gold sputtering on their surfaces, the legs 308 operate as spring connectors to couple each of the contacts 610 with a respective one of the contact segments 316.

As a consequence of the positioning of the lens and contact unit 300 accurately within the probing end 202 of the tube 200, the sheath 110 is formed into which the probe 600 may be inserted such that the electrical contacts 610 of the probe tip 606 can electrically engage the corresponding contact regions 320 of the unit 300 thereby providing electrical connection to each of the segments 316. Further, the accurate positioning of the unit 300 within the probe tip 606 ensures that the optical window 608 is positioned immediately adjacent the lens portion 306 to provide for optimal optical coupling between the probe 600 and the tissue engaged by the contact segments 316 and
the lens portion 306. Consequential to assembly, the lens 306 may extend beyond the tip 206 of the tube 200, for example by up to about 0.6 mm.

Returning now to Figs. 2A and 2C, the side elevation view of Fig. 2B and the detailed partial cross-section of Fig. 2E, the structure of the tube 200 at the coupling end 204 may now be described. As best seen in Fig. 2A, the coupling end 204 includes an elongate key 222 which is configured for insertion into a complementary longitudinally arranged slot 404 of the boot 400 (see Figs. 4A and 4E) to ensure appropriate alignment between the tube 200 and the boot 400.

Further as seen in Figs. 2A, 2F and 2G, the coupling end 204 includes a notch 228. The notch 228 is used during manufacture to align the tube 200 during emplacement of the lens and contact unit 300 within the tube tip 202. Such alignment, together with the key 222 and slot 404 combination, provide for appropriate alignment in use between the contacts 610 of the probe 600 and the contact sections 320 of the unit 300.

Accurate longitudinal coupling of the tube 200 to the probe 600 is important for accurate tissue measurements. Experiments by the present inventors indicate that a separation of less than 100 microns between the tip 606/window 608 and the lens portion 306 is desirable to avoid false tissue readings. However, the length of the tube 200 can vary by more than 100 microns as a result of normal manufacturing tolerances and the selection of manufacturing and assembly techniques, as discussed above.

As best seen in Fig. 2E, the coupling end 204 includes an interior annular protuberance 224 about the interior surface of the tube 200. The protuberance 224 has a curved exterior surface and is configured to engage and seat within the groove 616 of the probe 600. By virtue of the tube 200 being manufactured of resilient plastics material such as polycarbonate, the protuberance 224 is able to resiliently ride up the inclined
surface 618 of the shaft 602 to then snap over the ridge 614, as best seen in Fig. 7. Whilst Fig. 2E shows a single annular protuberance 224, smaller sectionalized protuberances or protrusions arranged in a ring or annulus may alternatively be used. Each of these alternate protuberances, rings or annuli may be positioned at a slightly different longitudinal distance from the end 204 of the tube 200. This provides for the sheath 110 to find, under manual adjustment, a longitudinal resting point on the shaft 602 that takes account of slight differences in the length of the tube 200. Another advantage afforded by the use of multiple longitudinally offset protrusions 224 is that such afford a measure of tactile feedback to a user assembling the sheath system 100 so as to avoid excessive force by which the probe tip 606 could otherwise puncture the lens 306, which as noted above is typically only about 200 microns thick. The protrusions 224 are typically placed at two longitudinal positions to help the operator to determine when the appropriate position has been reached. The protrusions 224 typically comprise raised areas within the inside of the tube 200 that are carefully contoured to provide the tactile feedback needed.

As seen in Fig. 2B, a narrow slot or cut 230 is formed in the extreme periphery of the end 204 extending at least to the interior shoulder or wall of an exterior annular groove 226 (ie. just past the line of the protuberances 224). In some implementations, the cut 230 may continue to the end of the ramp seen adjacent the groove 226 seen in Fig. 2E. In Fig. 2B the cut 230 is shown as a single line, indicating that such has no appreciable width. The purpose of the cut 230 is to assist and facilitate the resilient snap fit afforded by the above described structures between the sheath 110 and the probe 600 by providing additional radial flexibility to the end 204. Such also aids the positioning and removal of the mandrel used for forming the sheath 110 from the tube 200 and unit 300 as described above.
It is further observed that, in the described arrangements, the electrical coupling between the probe tip 606 and the surfaces 320 in the contact assembly 300 is formed, within manufacturing tolerances, independent of the required accurate coupling of the tube 200 and the probe 600 by virtue of the spring pressure exerted by the legs 308 upon which the contact surfaces 320 are formed. With such arrangements, a predetermined accurate coupling of the probe 600 to the sheath system 100 to within 100 microns can be obtained.

Returning to Figs. 4A-4F, the boot 400, which is manufactured of resiliently flexible material such as polypropylene thereby resembling a rubberised boot, has an exterior shape configured to generally complement that of the probe handle 604. By the above described alignment structures between the tube 200 and the boot 400, the boot 400 is slid over the probing end 204 of the sheath 110 and along the tube 200 with the key 222 and slot 404 in alignment until an interior annular protrusion 402 (best seen in Fig. 4F) of the boot 400 is engaged within the exterior groove 226 of the tube 200. This coupling forms the sheath system 100 of Fig. IA.

With the sheath system 100 thus formed, the system 100 and particularly the boot 400 is slid over the probe tip 606 and along the shaft and over the handle 604. By virtue of the shaping of the handle 604 and the complementary shaping of the boot 400, the sheath system 100 thus aligns itself correctly with respect to the probe 600 and particularly the contacts 610. The boot 400 continues to slide over the handle 604, thereby inserting the shaft 602 into the sheath 110 until the protuberance 224 is snap fit engaged within the groove 616 to thus longitudinally positioning the sheath system 100 upon the probe 600. Fig. 5B shows these components in their coupled position in the coupling region 114 including the shaft 602, the tube 200 and the boot 400.
The coupling described creates a releasable affixing of the sheath system 100 to the probe 600 that prevents rotation of either relative to the other, thus maintaining alignment of the contact regions 320 with the respective contacts 610. This configuration is simple to manufacture and use, whilst permitting optimal levels of accuracy through accurate formation of the protuberance 224 and the ridge 614 thereby permitting the accurate emplacement of the probe tip 606 and its optical window 608 against the lens portion 306.

In manufacture, the sheath 110 incorporating the tube 200 and lens and contact unit 300 is provided preferably coupled to the boot 400 as the formed sheath system 100 in a sealed package. Sterilization is not essential. As such once the system 100 is removed from the package it may be directly coupled to the probe 600 and thus be ready for use.

The system 100 has a number of advantages. The system 100 includes structures that are inherently less susceptible to wear, particularly of the probe 600, with the system 100 being disposable after a single use. Further, by virtue of the simple construction, reliable accurate coupling between the structures can be obtained thereby permitting greater accuracy in positioning of the probe tip 606 within the tip of the sheath 110 to ensure appropriate optical and electrical coupling between the two. Further, whereas in the prior art the probe tip incorporated spring contacts, in the arrangement presently described resilient flexibility resides in the lens and contact unit 300, and notably the legs 308 thereof. This permits simpler and more robust construction of the probe tip 606 which rides into and between the legs 308 such that the electrical contacts 610 engage the respective contact regions 320. The use of sputtering of the electrical connections upon the lens and contact unit 300 obviates the need to structurally embed electrical contacts into the lens. Rather, the lens and contact unit 300 may be
structurally formed from a unitary moulding of plastics material which is then processed to provide the electrical contacts and connections.

The foregoing only describes one embodiment of the present invention and modifications can be made thereto without departing from the scope of the present invention.

For example, in the described example, the unit 300 has one leg 308 corresponding to each electrical contact segment 316. Where more than 3 segments 316 are required, additional legs 308 may be used. Further in some implementations, the number of legs may exceed the number of contacts in which case the excess legs assist the unit 300 mechanically but not electrically. A minimum of two contact segments 316 is generally required.

The sheath 110 described is configured for both electrical and optical operation. It will be appreciate that probe systems may be configured that operate with only one of these forms of operation. For example, in an electrical only probe system, the described lens portion 306 need not be transparent and the requirement for precise longitudinal positioning of the tube 200 relative to the shaft 602 may be relaxed somewhat. For an optical only probe system, the electrical contacts and connections in the sheath 110 may be omitted. In either of these implementations however, the described structures may nevertheless continue to be used to afford a useful sheath system for a medical probe.

In view of the non-physical coupling afforded by the optical signals, the described sheath system may find ready application to other signals that do not require physical contact. Such signals may include magnetic signals and temperature (thermal) signals.

**Industrial Applicability**
The arrangements described are applicable to the medical testing and diagnosis industries and particularly where disposable sheaths are required for expensive testing equipment.
CLAIMS:

1. A sheath for use with a medical probe, said sheath comprising:

   an elongate tube having a coupling end for at least longitudinally releasably affixing the sheath to the probe; and

   a contact unit longitudinally positioned within a probing end of the tube, the contact unit having a plurality of resiliently flexible electrical connectors for contacting the probe.

2. A sheath according to claim 1, further comprising at least one interior protrusion configured to engage and seat within an annular groove of the probe to thereby contribute to a predetermined longitudinal coupling of the tube and the probe.

3. A sheath according to claim 2 wherein the coupling end comprises a plurality of said interior protrusions, arranged at different longitudinal distances from the coupling end of the tube to afford adjustment of the predetermined longitudinal coupling.

4. A sheath according to claim 2 or 3 wherein said contact unit further comprises a lens having a plurality of electrical contact segment portions formed thereon, each segment portion being electrically connected to a corresponding resiliently flexible electrical connector, the lens being positioned at an extremity of the probing end such that the predetermined longitudinal coupling provides for contacting each of a plurality of electrical contacts of the probe with a corresponding one of the resiliently flexible electrical connectors, and for positioning an optical transmitter/receiver of the probe immediately adjacent the lens.
5. A sheath according to claim 4, wherein the contact unit is longitudinally positioned in relation to the probing end of the tube using at least one of an interference fit, a snap fit, and an adhesive, thereby contributing to the predetermined longitudinal coupling.

6. A sheath according to claim 5 wherein the probe end further comprises an interior annular groove into which portions of the electrical connectors engage to longitudinally position and retain the contact unit in the probing end according to the predetermined longitudinal coupling.

7. A sheath according to claim 5 or 6 wherein the contact unit is formed of resiliently flexible insulating material upon which said electrical contact segment portions and said electrical connectors are formed by affixing conductive material to portions of the contact unit.

8. A sheath according to claim 7 wherein the electrical connectors are formed by sputtering of a metal.

9. A sheath according to claim 8 wherein the metal comprises at least one of gold and titanium.

10. A sheath according to any one of claims 4 to 9 wherein the contact unit comprises a ring having one closed end forming the lens, and a plurality of legs each extending generally longitudinally from the other open end of the ring, the legs each
being outwardly biased from a circumference of the ring and having an end configured to
be engaged in the interior annular groove of the probing end, and the electrical connectors
each extending from an interior of each leg adjacent the open end of the ring, around to an
exterior of the corresponding leg, across the ring and onto an adjacent one of the segment
portions of the closed end.

11. A sheath according to any one of the preceding claims, wherein the coupling end
of the tube further comprises a longitudinal key configured to mate with a complementary
longitudinal slot formed on a boot to thereby align the boot with the sheath, the boot
being shaped to complement and generally envelop a handle of the probe to thereby align
the probe with the sheath upon insertion of the probe into the sheath.

12. A sheath system comprising:
   a sheath according to any one of the preceding claims; and
   a boot configured for resilient coupling to the coupling end of the tube.

13. A sheath system according to claim 12 when dependent on claim 11, wherein the
sheath and the boot are coupled by engagement of an interior annular protuberance of the
boot within an exterior annular groove of the coupling end, the engagement being aligned
by the key and slot.

14. A tube for use with a tissue probe, the tube being elongate and shaped to at least
substantially envelope a shaft of the probe, the tube having a tip end and coupling end, the
tip end being shaped to complementarily receive internally a lens and contact unit to
thereby close the tip end, the coupling end having structures for longitudinally coupling the tube to the shaft and for aligning and longitudinally coupling the tube to a boot.

15. A lens and contact unit for a tissue probe sheath, the contact unit comprising a ring having one closed end forming a lens and a plurality of legs each extending generally longitudinally from the other open end of the ring, the legs each being outwardly biased from a circumference of the ring and each having a leg end configured to engage in at least an interference fit an interior of the probe sheath, the unit further comprising a plurality of electrical contacts formed on the closed end, each said contact having a corresponding electrical connection that extends from the contact across the ring and along at least part of an exterior of one of the legs and an interior of the one leg adjacent the open end of the ring.

16. A unit according to claim 14 wherein the unit is formed of resiliently flexible plastics material with the electrical contacts and connections being affixed to the material, the legs thus forming spring electrical contacts that aid in securing the unit within the probe sheath.

17. A unit according to claim 15 or 16 wherein the leg ends are configured to engage an interior annular groove of the probe sheath in a snap fit.

18. A tissue probe system comprising:
   a probe having an elongate shaft extending from a shaped handle,
   a sheath formed of (i) an elongate tube shaped to envelope the shaft and having a coupling end including an interior configured for coupling to the probe, and a tip end, and
(ii) a contact unit closing the tip end of the tube, the contact unit including electrical
contacts configured to engage tissue and spring electrical connections arranged to secure
the unit within the tube and to electrically couple to contacts arranged on the shaft of the
probe when inserted into the tube; and

a boot configured to couple to an exterior of the coupling end of the tube, the
boot being shaped to complement and envelop at least part of the handle.

19. A tube for use as part of a tissue probe sheath, said tube being substantially as
described herein with reference to Figs. 2A to 2F of the drawings.

20. A lens and contact unit substantially as described herein with reference to
Figs. 3A to 3F of the drawings.

21. A sheath system substantially as described herein with reference to Figs. 1A -
5B of the drawings.

22. A tissue probe system substantially as described herein with reference to the
drawings.
AMENDED CLAIMS
received by the International Bureau on 16 July 2008 (16.07.2008)

1. A sheath for use with a tissue probe, said sheath comprising;
   an elongate tube, the tube having a probing end and a coupling end, the coupling
   end being for at least longitudinally releasably affixing the sheath to the probe, and at
   least one interior protrusion configured to engage and seat within an annular groove of the
   probe to thereby contribute to a predetermined longitudinal coupling of the tube and the
   probe; and
   a contact unit longitudinally positioned within the probing end of the tube, the
   contact unit having a plurality of resiliently flexible electrical connectors for contacting
   the probe, the contact unit having a lens positioned at an extremity of the probing end
   such that the predetermined longitudinal coupling provides for positioning of a tip of the
   probe immediately adjacent the lens.

2. A sheath according to claim 1 wherein the coupling end comprises a plurality of
   said interior protrusions, arranged at different longitudinal distances from the coupling
   end of the tube to afford adjustment of the predetermined longitudinal coupling.

3. A sheath according to claim 1 wherein the tube is shaped to at least substantially
   envelope the probe, with the probing end being shaped to complementarily receive
   internally the contact unit to thereby close the probing end.

4. A sheath according to claim 2 or 3 wherein said contact unit further comprises a
   plurality of electrical contact segment portions formed on the lens, each segment portion
   being electrically connected to a corresponding resiliently flexible electrical connector,
wherein the predetermined longitudinal coupling provides for contacting each of a
plurality of electrical contacts of the probe with a corresponding one of the resiliency
flexible electrical connectors, and for positioning an optical transmitter/receiver in the tip
of the probe immediately adjacent the lens.

5. A sheath according to claim 4, wherein the contact unit is longitudinally
positioned in relation to the probing end of the tube using at least one of an interference
fit, a snap fit, and an adhesive, thereby contributing to the predetermined longitudinal
coupling.

6. A sheath according to claim 5 wherein the probing end further comprises an
interior annular groove into which portions of the electrical connectors engage via a snap
fit to longitudinally position and retain the contact unit in the probing end according to the
predetermined longitudinal coupling.

7. A sheath according to claim 5 or 6 wherein the contact unit is formed of
resiliently flexible insulating material upon which said electrical contact segment portions
and said electrical connectors are formed by affixing conductive material to portions of
the contact unit,

8. A sheath according to claim 7 wherein the electrical connectors are formed by
sputtering of a metal.

9. A sheath according to claim 8 wherein the metal comprises at least one of gold
and titanium.
10. A sheath according to any one of claims 4 to 9 wherein the contact unit comprises a ring having one closed end forming the lens, and a plurality of legs each extending generally longitudinally from the other open end of the ring, the legs each being outwardly biased from a circumference of the ring and having an end configured to be engaged in the interior annular groove of the probing end, and the electrical connectors each extending from an interior of each leg adjacent the open end of the ring, around to an exterior of the corresponding leg, across the ring and onto an adjacent one of the segment portions of the closed end.

11. A sheath according to claim 10, wherein the legs each form a spring electrical contact that aids in securing the contact unit within the probing end of the tube.

12. A sheath according to claim 1 wherein the coupling end comprises structures for longitudinally coupling the tube to the probe and for aligning and longitudinally coupling the tube to a boot.

13. A sheath according to any one of the preceding claims, wherein the coupling end of the tube further comprises a longitudinal key configured to mate with a complementary longitudinal slot formed on a boot to thereby align the boot with the sheath, the boot being shaped to complement and generally envelop a handle of the probe to thereby align the probe with the sheath upon insertion of the probe into the sheath.

14. A sheath system comprising:

a sheath according to any one of the preceding claims; and
a boot configured for resilient coupling to the coupling end of the tube,

15. A sheath system according to claim 14 when dependent on claim 13, wherein the sheath and the boot are coupled by engagement of an interior annular protuberance of the boot within an exterior annular groove of the coupling end, the engagement being aligned by the key and slot.

16. A tissue probe system comprising:
   a probe having an elongate shaft extending from a shaped handle
   a sheath formed of (i) an elongate tube shaped to envelope the shaft and having a coupling end including an interior configured for coupling to the probe, and a tip end, and (ii) a contact unit closing the tip end of the tube, the contact unit including electrical contacts configured to engage tissue and spring electrical connections arranged to secure the unit within the tube and to electrically couple to contacts arranged on the shaft of the probe when inserted into the tube; and
   a boot configured to couple to an exterior of the coupling end of the tube, the boot being shaped to complement and envelop at least part of the handle.

17. A tube for use as part of a tissue probe sheath, said tube being substantially as described herein with reference to Figs. 2A to 2F of the drawings,

18. A sheath system substantially as described herein with reference to Figs. 1A - 5B of the drawings.

19. A tissue probe system substantially as described herein with reference to the drawings,
The claims set, as amended, is now directed towards a single invention; with old claims 14-17 having been deleted.

Revised claim 1 now recites a sheath for a tissue probe, with the tube comprising "at least one interior protrusion configured to engage and seat within an annular groove of the probe" to ensure an accurate (predetermined) longitudinal positioning between the sheath and the probe. This feature has been introduced from original claim 2. This ensures that the optical measurements performed by the tissue probe remain accurate,

In the present sheath system, the window (lens) must be close to the tip of the probe. However, the window can easily be ruptured by inappropriate fitting of the sheath in an effort to ensure close proximity of the tip b the window. The interior protrusion and the annular groove provide for effective coupling and thus the making of precise optical measurements.

In contrast, D1 does not disclose the need to longitudinally position the sheath. D1 assumes that the sheath will be pulled on and that its longitudinal position will be arrived at by means that are not stated. The need for accurate longitudinal positioning is not described in D1. Also, D1 does not mention the vulnerability of a thin optical window (lens).

D2 is directed to a sheath that does not require longitudinal accuracy in its positioning.

Also, D3 makes only electrical measurements, and thus does not have a window. There is therefore no need to provide accurate longitudinal positioning,
INTERNATIONAL SEARCH REPORT

International application No.
PCT/7AU2008/000449

A. CLASSIFICATION OF SUBJECT MATTER

Int. Cl.
A (5/5) 7/00 (2006.01) A61B 7/055 (2006.01) /167/3 5/00 (2006.01)

According to International Patent Classification (IPC) or to both national classification and IPC

B. MINIMUM CLASSIFICATION OF SUBJECT MATTER

Classification symbols

C. DOCUMENTS CONSIDERED TO BE RELEVANT

<table>
<thead>
<tr>
<th>Category</th>
<th>Citation of document, with indication, where appropriate, of the relevant passages</th>
<th>Relevant to claim No.</th>
</tr>
</thead>
</table>

Further documents are listed in the continuation of Box C

X See patent family annex

Date of the actual completion of the international search

15 May 2008

Name and mailing address of the ISA/ AU

AUSTRALIAN PATENT OFFICE
PO BOX 200, WODEN ACT 2606, AUSTRALIA
E-mail address pct@ipaustralia.gov.au
Facsimile No +61 2 6283 7999

Authorized officer
EMMA FRANCIS
AUSTRALIAN PATENT OFFICE
(ISO 9001 Quality Certified Service)
Telephone No (02) 6283 2667

Form PCT/ISA/2 10 (second sheet) (April 2007)
<table>
<thead>
<tr>
<th>Category*</th>
<th>Citation of document, with indication, where appropriate, of the relevant passages</th>
<th>Relevant to claim No.</th>
</tr>
</thead>
<tbody>
<tr>
<td>X</td>
<td>EP 0101595 B1 (VITAL SIGNS, INC.) 11 March 1987 See column 5, Figures 1-2, 6</td>
<td>1-2, 19</td>
</tr>
<tr>
<td>A</td>
<td>US 4362166 A (FURLER et al.) 7 December 1982 See Abstract, Figures 1, 4</td>
<td></td>
</tr>
<tr>
<td>A</td>
<td>US 5902246 A (McHENRY et al.) 11 May 1999 See Figures</td>
<td></td>
</tr>
<tr>
<td>A</td>
<td>US 2006/0276692 A1 (KUCKLICK) 7 December 2006 See Abstract, Figures</td>
<td></td>
</tr>
<tr>
<td>A</td>
<td>US 4867169 A (MACHIDA et al.) 19 September 1989 See Abstract Figures 4, 7, 8</td>
<td></td>
</tr>
</tbody>
</table>
**INTERNATIONAL SEARCH REPORT**

**Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)**

<table>
<thead>
<tr>
<th>Reason</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Claims Nos 1 because they relate to subject matter not required to be searched by this Authority, namely</td>
</tr>
<tr>
<td>2</td>
<td>Claims Nos 2 because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically</td>
</tr>
<tr>
<td>3</td>
<td>Claims Nos 3 because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6 4(a)</td>
</tr>
</tbody>
</table>

**Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)**

This International Searching Authority found multiple inventions in this international application, as follows [See supplemental sheet]

<table>
<thead>
<tr>
<th>Option</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>X</td>
<td>As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims</td>
</tr>
<tr>
<td>2</td>
<td>As all searchable claims could be searched without effort justifying additional fees, this Authority did not invite payment of additional fees</td>
</tr>
<tr>
<td>3</td>
<td>As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos</td>
</tr>
<tr>
<td>4</td>
<td>No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims, it is covered by claims Nos</td>
</tr>
</tbody>
</table>

**Remark on Protest**

- The additional search fees were accompanied by the applicant’s protest and where applicable, the payment of a protest fee
- The additional search fees were accompanied by the applicant’s protest but the applicable protest fee was not paid within the time limit specified in the invitation
- No protest accompanied the payment of additional search fees
Supplemental Box
(To be used when the space in any of Boxes I to IV is not sufficient)

Continuation of Box No: III

This International Searching Authority has found that there are different inventions as follows:

- Claims 1-13, 18, 19, 21-22 define a sheath for use with a medical probe comprising an elongate tube and a contact unit. It is considered that the contact unit comprising a plurality of electrical connectors for connecting to the probe comprises a first distinguishing feature.

- Claims 14-17, 20 define a lens and contact unit for use with a tissue probe. It is considered that the coupling end having structures for engaging a tissue sheath comprises a second distinguishing feature.

PCT Rule 13.2, first sentence, states that unity of invention is only fulfilled when there is a technical relationship among the claims inventions involving one or more of the same or corresponding special technical features. PCT Rule 13.2, second sentence, defines a special technical feature as a feature which makes a contribution over the prior art.

The only feature common to all of the claims is that both involve a tissue sheath for a probe. However this feature is generic in the art. This means that the common feature can not constitute a special technical feature within the meaning of PCT Rule 13.2, second sentence, since it makes no contribution over the prior art. Because this common feature does not satisfy the requirement for being a special technical feature it follows that it cannot provide the necessary technical relationship between the identified inventions. Therefore the claims do no satisfy the requirement of unity of invention *aposteriori*. 

Form PCT/ISA/2 IO (extra sheet)(Ap πl 2007)
This Annex lists the known "A" publication level patent family members relating to the patent documents cited in the above-mentioned international search report. The Australian Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>WO 9841281 AU 65608/98 CA 2284615 EP 1009477</td>
<td></td>
</tr>
<tr>
<td>WO 9841176 AU 68651/98 US 5941834</td>
<td></td>
</tr>
<tr>
<td>EP 0101595 CA 1224850 JP 59046939</td>
<td></td>
</tr>
<tr>
<td>US 4362166</td>
<td></td>
</tr>
<tr>
<td>US 5050436 EP 0383233 JP 2213329</td>
<td></td>
</tr>
<tr>
<td>US 5902246 CA 2250095 EP 0921752 WO 9735513</td>
<td></td>
</tr>
<tr>
<td>US 2006276692 EP 1890587 WO 2006130730</td>
<td></td>
</tr>
<tr>
<td>US 4867169 DE 3722943 JP 63036171 JP 63036173</td>
<td></td>
</tr>
</tbody>
</table>

Due to data integration issues this family listing may not include 10 digit Australian applications filed since May 2001.