# Method of Preventing a Decontaminated Ultrasonic Probe from Contamination

## Field

[0001] The present disclosure relates to covers for use in protecting disinfected or decontaminated medical instrumentation from recontamination prior to use.

[0002] The disclosed technique has been developed primarily for use with cabled probes such as intracavity and surface ultrasound probes ("ultrasound probes") or Gamma probes, following disinfection, preferably high level disinfection ("HLD") and is described with reference to such a purpose, however, it will be appreciated that it is not limited solely to that use.

## Background

[0003] Ultrasound probes are used for a variety of intra cavity procedures including intra rectal, intra vaginal and oesophageal examination. Whilst the probes do not need to be completely sterile in most cases, they do need to be subjected to disinfection, usually at least HLD between each use to prevent cross-infection. HLD requires a 6 log reduction in microorganism load.

[0004] Ultrasound probes are usually temperature sensitive and cannot be heated above 55-60˚C. They can be disinfected by a variety of procedures, such the present Applicant's own aerosol methods, as described in earlier publications WO 2007/014435 and WO 2007/014436.

[0005] Typically, after an ultrasound probe has been subjected to HLD, it is stored for some time. The storage environment need not be sterile; however, ideally the probe is maintained in a clean or protected environment to prevent excessive contamination.

[0006] The disinfection of ultrasound probes presents special challenges, because the probe is typically constructed integrally with the power and data cable used to link the probe with the console. While the probe itself is always disinfected to some degree, most usually to achieve HLD, the cable projecting from the proximal end of the probe is not. As a precaution, the probe is disinfected to a point well beyond the deepest point of insertion of the probe into the patient. However, there is a point on the cable not far from the probe beyond which no disinfection is applied.

[0007] The presence of a potentially contaminated cable attached to a disinfected probe can present problems with storage of the probe between disinfection and patient use.

[0008] In some cases, ultrasound probes are stored on racks adjacent to the ultrasound apparatus ready for use. The racks maintain the disinfected, distal end of the probe upwards, with the un-disinfected cable hanging down. While this arrangement provides reasonable separation between the disinfected probe and undisinfected cable, the probe is nevertheless open to the atmosphere and has the potential to become recontaminated from either the environment or handling.

[0009] Disinfected probes are sometimes placed into cupboards or drawers. These can provide a relatively clean environment, but there is the possibility in such cases that the undisinfected cable can come into contact with the disinfected portion when being placed into a cupboard or drawer, or space that is otherwise not clean. Further, if an un-disinfected probe is accidentally placed in the cupboard or drawer, significant remedial action for the cupboard or drawer and the probes contained therein would be required.

[0010] There is a need therefore to store disinfected probes prior to use in such a way that they are protected from the wider environment generally, and the undisinfected cable projecting from their distal end in particular.

[0011] It is an object of the present disclosure to overcome or ameliorate at least one of the disadvantages of the prior art, or to provide a useful alternative.

**Summary**

[0011a] The invention is defined in the independent claim. Further embodiments of the invention are defined in the dependent claims.

[0012] According to a first aspect, the technique provides a cover for a probe, the cover comprising a flexible elongate pouch and a mouth portion for inserting the probe into the pouch, the mouth portion comprising sealing means to enable the mouth portion to be formed into sealing engagement with a proximal end of the probe.

[0013] Unless the context clearly requires otherwise, throughout the description and the claims, the words “comprise”, “comprising”, and the like are to be construed in an inclusive sense as opposed to an exclusive or exhaustive sense; that is to say, in the sense of “including, but not limited to”.

[0014] The term “seal” means that the cover is engaged with the proximal end of the probe to retain the probe in the cover. The seal may be airtight but that is not necessarily the case.

[0015] The probe to be covered may for instance be an ultrasonic probe, such as an intracavity or surface ultrasound probe or other type of diagnostic ultrasound (DU) probe, or it may be a Gamma probe.

[0016] Preferably, the pouch is formed from an impermeable plastic material. The pouch may be formed from two opposed elongate sheets of plastic, each sheet having two parallel elongate sides and two parallel short sides, the sheets being fused on each elongate side and on a first short side, the second short side defining a mouth portion.

[0017] The sealing means may be a deformably rigid portion. In that case, the mouth portion comprises a deformably rigid strip adjacent and disposed along the second short side. The deformably rigid strip may be a metallic or wire strip. Preferably, it is glued or fused to one elongate sheet.

[0018] Alternatively, the sealing means for the mouth portion may and a self adhesive strip, and integrated elastic strip or a Velcro™ strip or similar.

[0019] Any suitable means for sealing the pouch around the proximal end of the probe would be suitable.

[0020] According to a second aspect, the technique provides a method of preventing a disinfected probe from contamination comprising the step of, immediately after disinfection, inserting the probe into a cover comprising a flexible elongate pouch and a mouth portion for inserting the probe into to pouch, the mouth portion comprising a deformably rigid portion, and deforming the mouth portion into a sealing engagement with a proximal end of the probe, wherein no undisinfected portion of the probe enters the pouch.

[0021] The cover is preferably as described above.

[0022] Preferably at least a portion of the disinfected probe resides outside the bag when sealed.

[0023] In a further aspect, the technique provides a method of the second aspect further comprising the steps of applying to the pouch, when sealed, indicia identifying a unique sterilization cycle, and documenting said indicia against a record of a patent probed with said probe.

[0024] The pouch of the present disclosure is suitable for use for probes that have been disinfected to any level, i.e. low level disinfection, medium level disinfection, and high level disinfection.

**Brief Description of the Drawings**

[0025] A preferred embodiment(s) of the invention will now be described, by way of example only, with reference to the accompanying drawings(s) in which:

[0026] Figure 1 shows the pouch of the present technique.

[0027] Figure 2 shows the pouch of the present technique in relation to an ultrasound probe.

[0028] Figures 3.1 to 3.5 show the steps involved in using the pouch of the present technique.

[0029] Figure 4 shows the disinfection process involving the pouch, including optional steps of affixing indicia.

**Preferred Embodiment**

[0030] The present technique will now be described with reference to the following examples which should be considered in all respects as illustrative and non-restrictive.

[0031] As shown in Figure 1, the cover of the present technique comprises a flexible elongate pouch 1 and a mouth portion 2 for inserting the probe into to pouch.

[0032] The pouch portion is, in effect, a plastic bag, sized to hold most intracavity and surface probes, and is impermeable to microorganisms. Any suitable plastic of any gauge can be used provided that it is sufficiently robust to withstand normal use. The pouch is designed to be disposable. In order to accommodate most probes, the pouch

[0039] The sealing means may also be for instance a drawstring running in one or more loops around the mouth of the pouch.

[0040] It is important to ensure that the entire portion of the probe within the pouch has been disinfected. A disinfected portion 13 of the probe 12 should project from the mouth of the bag 2, immediately adjacent to it. If an undisinfected portion 14 of the probe is sealed within the pouch 1, the process will be self-defeating.

[0041] The probe thus stored in the pouch can be stored in any location without fear of reinfection and particularly without fear of reinfection from the cable.

[0042] When it is desired to use the probe, it can be taken to the point of use, unwrapped and immediately put to use. The cover is then discarded. The presence of the cover is an indicator that a probe is clean and it can increase patient confidence.

[0043] The use of such a bag also has additional advantages in enhancing the traceability of each HLD cycle, as shown in figure 4. Traceability means that any defective apparatus or processes can readily be detected.

[0044] Once a decontamination cycle has been completed, the article can be placed into the bag as described and the bag and a tag or sticker 20 can be applied bearing the identifying details of the decontamination cycle. In many cases, modern decontamination apparatus can provide a print out of the sterilization details, uniquely identifying the steriliser and the parameters used.

[0045] The probe, when ready for use, is then unwrapped. At that stage, the details of the sterilization cycle can be taken from the bag (in physical form, such as peel off sticker, or manually transcribed or digitally acquired) and entered into the patients record.

[0046] The cover thus provides a means to link the details of the sterilisation cycle with the individual patient. The present technique allows this to be done much more readily than known methodology.

CLAIMS

1. A method of preventing a decontaminated ultrasonic probe from contamination comprising the step of, immediately after disinfection, inserting the ultrasonic probe into a cover comprising a flexible elongate pouch and a mouth portion for inserting the probe into the pouch, the mouth portion comprising a deformably rigid portion, and deforming the mouth portion into a sealing engagement with a proximal end of the probe, wherein no undisinfected portion of the probe enters the pouch.

2. A method according to claim 1 wherein at least a portion of the decontaminated ultrasonic probe resides outside the pouch when sealed.

3. A method according to claim 1 or claim 2 wherein the pouch is formed from two opposed elongate sheets of plastic, each sheet having two parallel elongate sides and two parallel short sides, the sheets being fused on each elongate side and on a first short side, the second short side defining the mouth portion.

4. A method according to any one of claims 1 to 3 wherein the deformably rigid portion is a sealing means.

5. A method according to claim 3 wherein the mouth portion comprises a deformably rigid strip adjacent and disposed along the second short side.

6. A method according to claim 5 wherein the deformably rigid strip is a metallic or wire strip.

7. A method according to any one of claims 5 to 6 wherein the deformably rigid strip is a metallic or wire strip glued or fused to one elongate sheet of the pouch.

8. A method according to any one of claims 1 to 3 wherein the deformably rigid portion is a sealing means, and wherein the sealing means is a self adhesive strip.

9. A method according to any one of claims 1 to 3 wherein the deformably rigid portion is a sealing means, and wherein the sealing means is an integrated elastic strip.

10. A method according to any one of claims 1 to 3 wherein the deformably rigid portion is a sealing means, and wherein the sealing means is a Velcro$^{TM}$ strip.

11. A method according to any one of claims 1 to 10 further comprising the steps of applying to the pouch, when sealed, indicia identifying a unique sterilization cycle, and documenting said indicia against a record of a patient probed with said probe.