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(54) **Title**: PORTABLE MEDICAL DEVICE PROTECTORS

(57) **Abstract**: This disclosure describes example portable medical device protectors that may be used in combination with various antimicrobial and/or antiseptic agents to reduce contaminants on a portable medical device. According to some embodiments, the disclosure describes that the protectors may comprise an impermeable container to store a permeable applicator impregnated with an antimicrobial or antiseptic agent.

PORTABLE MEDICAL DEVICE PROTECTORS

CROSS REFERENCE TO RELATED APPLICATION

[0001] This application claims priority to U.S. Patent Applicant No. 13/757,381 filed on February 1, 2013 entitled "Portable Medical Device Protectors" which claims priority to U.S. Provisional Patent Application No. 61/595,635 filed on February 6, 2012 entitled "Antiseptic Applicators and Protective Devices," both of which are hereby incorporated by reference in their entirety.

BACKGROUND

[0002] Healthcare acquired infection (HAI) has been recognized as a significant cause of preventable mortality and morbidity. In the United States, HAI annually costs nearly 99,000 lives and billions of dollars in additional treatment and hospitalization. Klevens, et al., *Estimating Health Care-Associated Infection and Deaths in U.S. Hospitals, 2002*, Public Health Reports, Vol. 122, p. 160, 2007. Contamination of intravascular catheters, surgical sites and invasive procedure sites, frequently leads to device removal and replacement, prolonged parenteral antimicrobial therapy, and extended hospitalizations and rehabilitation.

[0003] The spread of multi-antimicrobial resistant organisms frequently are spread by healthcare providers' hands or medical equipment, from one colonized or infected patient to other susceptible patients. Surgical site infections may result from inadequate antiseptic preparations of the skin. Widespread use of chlorhexidine

gluconate (CHG) for routine washing and wiping of pre-operative sites, has led to the increased incidence of resistant Staphyloccus aureus, both to methicillin (MRSA) and CHG, in some hospital environments.

BRIEF DESCRIPTION OF THE DRAWINGS

[0004] The detailed description is set forth with reference to the accompanying figures. In the figures, the left-most digit(s) of a reference number identifies the figure in which the reference number first appears. The use of the same reference numbers in different figures indicates similar or identical items or features.

[0005] FIG. 1 illustrates an example portable medical device protector having a permeable applicator located within an impermeable container.

[0006] FIG. 2 illustrates another example portable medical device protector having a removable tray for storing one or more permeable applicators within an impermeable container.

[0007] FIG. 3 illustrates another example portable medical device protector having a removable tray storing a permeable applicator for scrubbing a device (illustrated as a stethoscope) and an impermeable container for securing and preventing recontamination.

[0008] FIG. 4 is a flow diagram showing an example process for operating an example portable medical device protector.

DETAILED DESCRIPTION

Overview

[0009] This disclosure describes medical applicators and protectors designed to reduce and/or prevent infections. In one embodiment, the disclosure describes a portable medical device protector comprising a sealable impermeable container or receptacle to hold a portable medical device (e.g., stethoscope) and a permeable, absorbent and/or adsorbent applicator carrying an antimicrobial or antiseptic composition. In some embodiments the antimicrobial composition may comprise water, a low molecular weight alcohol, a peroxide or peroxide-generating agent, and a chelating agent. In some embodiments, the permeable applicator may be used to wipe the portable medical device to prevent and/or reduce transmission of infection as the portable medical device is used or transported between multiple patients.

[0010] The detailed discussion below begins with a section entitled "Example Antimicrobial Composition", which describes in detail an example antimicrobial composition that may be included in the medical applicators and protectors described herein. The next section entitled "Example Device Protectors" describes example cleaning and protective devices for use of a portable medical device. Next, an "Example Process" for operating an example device protector is described. Finally, the disclosure concludes with a brief "Conclusion."

[0011] This overview, including section titles, is provided to introduce a selection of concepts in a simplified form that are further described below. The overview is

provided for the reader's convenience and is not intended to limit the scope of the claims, nor the proceeding sections.

Example Antimicrobial Composition

[0012] In one example implementation, antimicrobial compositions that may be used in connection with the approaches described herein may include those described in, for example, International Patent Application No. PCT/US2011/022150, filed January 21, 2011, to Tennican et al., and, U.S. Non-Provisional Patent Application No. 13/688,078, filed November 28, 2012, to Tennican, which are incorporated herein by reference. For example, the antimicrobial compositions may include water (H_2O), a strong and non-toxic chelating agent such as ethylenediaminetetraacetic acid (EDTA)(e.g., disodium EDTA, calcium disodium EDTA, magnesium EDTA, potassium EDTA, gallium EDTA) or sodium citrate (or acids, salts, derivatives, or other forms of EDTA or sodium citrate), a short-chain monohydric alcohol (e.g., ethanol with a molecular formula of C_2H_5OH and an empirical formula of C_2H_6O), and a strong, small molecule oxidizing agent such as hydrogen peroxide (H_2O_2). In one specific example, the compositions may consist essentially of water, EDTA, ethanol, and hydrogen peroxide. Additional ingredients can include thickeners, gellants, surfactants, foamers and/or foam stabilizers. However, in other examples, other antimicrobial compositions may be used in combination with the applicators and devices described in this disclosure.

[0013] The antimicrobial compositions may be in a liquid form or a gel form, and may be combined with one or more carriers or diluents, depending on the needs of a

specific application. For example, if the antimicrobial composition is used as a cleaning agent the antimicrobial composition may be in a liquid form. In that case, the concentration of the various constituents may depend on, for example, a desired level of sanitation and/or disinfection, whether the composition is being applied directly to living tissue or to a medical device, and/or to avoid irritation of tissue to which the composition will be applied directly or indirectly (e.g., via a medical device to which the composition is or was applied).

[0014] In addition to providing disinfection at the time of the application, the antimicrobial compositions may also provide a lasting barrier against contamination. For example, even after volatile constituents of the composition (e.g., water, alcohol, hydrogen peroxide, etc.) have evaporated, the chelating agent may remain on the treated surfaces (e.g., multiple use vial or port cleaning/protecting device, stethoscope, fingers, surrounding tissue, etc.) as a barrier that will provide antibacterial, antifungal or sporicidal (e.g.,. preventing germination of the spores), anti-parasitic, spermicidal or spermiostatic (e.g., decrease the motility of spermatozoon) and antiviral qualities. By robbing the environment of components (e.g., iron, magnesium, and manganese) that are needed for the bacteria (e.g., staphylococcus aureus (MRSA), Pseudimonas aeruginosa and other resistant bacteria), spores, parasites, fungus, and viruses to reproduce, the chelating agent provides a lasting defense to contamination even after other constituents of the antimicrobial composition have evaporated. Furthermore, the hydrogen peroxide in the antimicrobial compositions may induce a charge on a surface of materials (e.g.,

silicone materials) to which the antimicrobial compositions are applied, which make the materials more resistant to bacteria or other microorganisms.

[0015] The antimicrobial composition described above may also provide a visual indication of contamination when applied to a surface or material, such indication may allow users to identify and clean surfaces to prevent infection.

[0016] The term "about" or "approximate" as used in context of describing the example antimicrobial composition is to be construed to include a reasonable margin of error that would be acceptable and/or known in the art.

Example Device Protectors

[0017] Various example protective devices are described herein. Described generally with reference to FIGS. 1-3 are example device protectors configured to prevent and/or reduce transmission of pathogenic organisms from one colonized patient, surface or user to another patient, surface or user.

[0018] FIG. 1 illustrates an example device protector 100 for use on a portable medical device. An example portable medical device include, but are not limited to, a stethoscope, a thermometer, a blood pressure monitor, a pulse oximeter, a nebulizer and associated equipment, a scope, a blood glucose monitor, a doppler, a capnograph, a suction pump, various equipment mouthpieces, diagnostic or therapeutic ultrasonic transducers and/or other diagnostic equipment. In one embodiment, an example device protector 100 may be configured to house any section of or an entire portable medical device and act as a protective cover. As illustrated in FIG. 1, the device protector 100

may contain an impermeable container 102 to house any section of or an entire portable medical device. The impermeable container 102 may be configured in any number of sizes designed to enclose any section or an entire portable medical device. For example, the impermeable container 102 may be configured to house the "bell" of a stethoscope or configured to house the entire stethoscope. Example materials for the composition of the impermeable container include, but are not limited to, polyethylene, aluminum oxide, aluminum foil, silicon oxide coated polymeric films, polypropylene, polysilicone, polytetrafluoroethylene, polyvinyl chloride, mylar, or combinations thereof.

[0019] In some embodiments, impermeable container 102 may include a closure mechanism 104 at the opening end 106 of the container 102 configured to securely enclose an inserted portion of the portable medical device. Example enclosure mechanisms may include, but are not limited to, a draw string, zip lock, foam opening, twist tie, plastic clip and/or a spring material.

[0020] In some embodiments, the closure mechanism is a draw string and/or twist tie. In these embodiments, the opening of the impermeable container may comprise a string, wire or other like material which has two ends extending from the impermeable container. The contents of the impermeable container (e.g., bell of the stethoscope) are enclosed when the ends of the string are pulled and/or twisted. Thus, closing the opening of the impermeable container.

[0021] In another embodiment, the closure mechanism on the impermeable container may be a foam opening. The foam opening may be configured to allow the portable medical device, or any part of thereof, to be inserted through the opening. Upon

receipt of the portable medical device, the foam opening may revert back to its unopened position thereby protecting the portable medical device from contaminants located outside the impermeable container.

[0022] In another embodiment, the closure mechanism comprises a spring material. The spring material may hold the opening of the impermeable container in the closed position. The user may squeeze the opposing ends of the closure mechanism to activate the spring causing the opening of the impermeable container to open and become accessible to insertion of any portion of the portable medical device.

[0023] In some embodiments, a permeable applicator 108 may be stored within the impermeable container 102. The permeable applicator 108 may be impregnated or coated with an antimicrobial or antiseptic composition, such as the antimicrobial composition described in the preceding section. In some embodiments, the permeable applicator 108 may be removable from the impermeable container 102 and may be used to clean and/or disinfect any portion of the portable medical device (e.g., diaphragm, chestpiece, tubing, eartips, or any other part of a stethoscope).

[0024] Permeable applicator 108 may be configured in various shapes and size. For example, as illustrated in FIG. 1, applicator may be smaller than the impermeable container. In other embodiments, the applicator may be substantially the same size or larger than the impermeable container. In some embodiments, the applicator may be folded, doubled, tripled, etc. upon itself in any suitable manner to allow the applicator to fit within the impermeable container.

[0025] In another embodiment, the permeable applicator 108 may be attached as the interior lining of the impermeable container 102. For example, the permeable applicator may be removably or irremovably attached to the interior walls of the impermeable container. In this embodiment, a user may place the portable medical device, or any portion thereof, within the impermeable container. Once the device is inside the container, the user may manipulate the container by, for example, using a massaging action. Such action may allow the permeable applicator attached to the interior walls of the container to scrub/disinfect the medical device with the antimicrobial composition.

[0026] Example materials for the composition of the permeable applicator 108 include, but are not limited to, starch polymer, cellulosic gel, polyethylene foam, silicone open-cell foam, or mixtures thereof. In some embodiments, the permeable applicator 108 may include different surface treatments (e.g., siping, slitting, etc.), surface finishes (e.g., macro-, micro-, or nano-structures, etc.), and/or contours (e.g., rounded, ribbed, protrusions, fingers, etc.) to allow a user to grip the applicator and aid in scrubbing or cleaning the medical device.

[0027] FIG. 2 illustrates an alternative embodiment of a device protector 200, where one or more permeable applicator(s) 202 may be stored on a removable tray 204 that is located within the impermeable container 102. The tray 204 may be sealed within the impermeable container 102 prior to use by the user. In some embodiments, the tray 204 may be removed once the impermeable container 102 is opened allowing the user to

access/use the one or more applicators 202. Tray 204 may be discarded prior to the placement of any part of the medical device within the impermeable container 102.

[0028] The one or more applicators 202 may have any of the features described above with regard to the permeable applicators of FIG. 1. In some embodiments, each of the one or more applicators on the tray may contain the same or different cleansing, antiseptic, or antimicrobial agent, or various concentrations thereof.

[0029] FIG. 2 illustrates an example draw string closure mechanism 206 as described above with reference to FIG. 1. However, in other embodiments, any of the other closure mechanism described above with reference to FIG. 1 may be used with the device protector 200.

[0030] Example materials for the composition of the tray 204 include, but are not limited to, polypropylene, high-density polyethylene, polytetrafluoroethylene, polyvinyl chloride, or any other suitable thermoplastic polymer. In some embodiments, tray 204 may be configured having one or more dividers to separate each portion storing the one or more permeable applicator(s) 202.

[0031] FIG. 3 illiterates yet another embodiment of a device protector. In this embodiment, an impermeable container 300 and a permeable applicator 302 may be located within a sterile, discardable package 304. As shown in FIG. 3, the impermeable container 300 (shown on both tray 204 and on the bell 306 of stethoscope 308) and the permeable applicator 302 may be located on tray 204 within the sterile packaging 304. Upon opening of the sterile package 304, the user may remove tray 204 and use the permeable applicator 302 that is impregnated with an antimicrobial or antiseptic

composition to disinfect any part of the portable medical device, such as the stethoscope 308 illustrated in FIG. 3. After disinfecting the portable medical device with the applicator, the user may then place the portable medical device, or any portion thereof, within the impermeable container 300 to protect it from contamination. For example, as illustrated in FIG. 3, the impermeable container 300 would protect the bell 306 of the stethoscope 308 from coming into contact with one or contaminates when the user places the bell in a pocket, bag, or the like.

[0032] In some embodiments, the applicator located within the impermeable container or on a tray in the sterile package may be an applicator having an impermeable layer attached to a permeable, absorbent and/or adsorbent bottom layer thus, preventing an existing infectious agent on the user hand from transferring to the permeable bottom layer and the portable medical device.

Example Process

[0033] FIG. 4 illustrates an example process 400 for execution of the techniques described above of operating an example protective device. The process 400 is illustrated as a logical flow graph. The order in which the operations are described is not intended to be construed as a limitation, and any number of the described operations can be combined in any order and/or in parallel to implement the process.

[0034] At operation 402, a device protector may be identified for use with a portable medical device. In the context of FIG. 3, if a user is traveling room to room in a

hospital using a stethoscope, the user may identify a device protector to use with the stethoscope or bell of the stethoscope.

[0035] At operation 404, a sealable or resealable impermeable receptacle of the device protector may be opened. In the context of FIG. 1, a user may open the impermeable container by separating the closure mechanism 104 shown as a zip-lock mechanism.

[0036] At operation 406, a permeable applicator carrying an antimicrobial or antiseptic agent may be removed from the impermeable receptacle. Again in the context of FIG. 1, the permeable applicator 108 may be removable from the impermeable container 102.

[0037] At operation 408, the permeable applicator may be applied to at least a portion of the portable medical device. For example, the permeable applicator may be used to wipe or rub an entire stethoscope or any portion of the stethoscope (e.g., the bell).

[0038] At operation 410, at least a portion of the portable medical device may be placed within the impermeable receptacle of the device protector. In the context of FIG. 3, the bell 306 of the stethoscope 308 may be placed within impermeable container 300.

[0039] Finally at operation 412, the impermeable receptacle may be removably sealed around the inserted portion of the portable medical device. For example, the impermeable receptacle may be sealed by any of the mechanisms describe above with reference to FIGS. 1 and 2.

Conclusion

[0040] Although the disclosure describes embodiments having specific structural features and/or methodological acts, it is to be understood that the claims are not necessarily limited to the specific features or acts described. Rather, the specific features and acts are merely illustrative some embodiments that fall within the scope of the claims of the disclosure.

WHAT IS CLAIMED IS:

1. A portable medical device protector comprising:

an impermeable container, the impermeable container having an inner surface configured to hold a portion of a portable medical device;

a permeable applicator within the impermeable container; and

an antimicrobial or antiseptic agent disposed on or within the permeable applicator.

2. The medical device protector of claim 1, wherein the impermeable container comprises polyethylene, aluminum oxide, silicon oxide coated polymeric films, polypropylene, polysilicone, polytetrafluoroethylene, polyvinyl chloride, mylar, or a mixture thereof.

3. The medical device protector of claim 1, wherein the impermeable container comprises a draw string, a zip-lock, a foam opening, a twist tie, a plastic clip, or a spring material to secure the impermeable container around the portable medical device.

4. The medical device protector of claim 1, wherein the permeable applicator comprises starch polymer, cellulosic gel, polyethylene foam, silicone open-cell foam, or mixtures thereof.

5. The medical device protector of claim 1, wherein the permeable applicator has a rough, a coarse, a smooth, a micro or a nano texture configured to scrub the portable medical device.

6. The medical device protector of claim 1, wherein the antimicrobial or antiseptic agent disposed within the permeable applicator comprises:

about 5 to about 50 mg/ml of ethylenediaminetetraacetic acid (EDTA);

at most about 70% ethanol, by volume;

at most about 7.5% hydrogen peroxide, by volume; and

water.

7. A method of preventing the spread of infectious agents comprising:

identifying a device protector to use with a portable medical device, the device protector comprising:

a sealable impermeable receptacle configured to hold a portion of the portable medical device;

a permeable applicator arranged within the impermeable receptacle; and

an antimicrobial or antiseptic agent carried by the permeable applicator;

using the identified device protector with the portable medical device, the using comprises:

opening the sealable impermeable receptacle;

removing the permeable applicator from the receptacle;

applying the permeable applicator containing the antimicrobial or antiseptic agent to at least a portion of the portable medical device;

placing at least a portion of the portable medical device within the impermeable receptacle; and

sealing the impermeable receptacle around the portion of the portable medical device to prevent recontamination.

8. The method as recited in claim 7, wherein the portable medical comprises at least one of a stethoscope, a thermometer, a blood pressure monitor, an ultrasonic transducers or other diagnostic equipment.

9. The method as recited in claim 7, wherein the antimicrobial or antiseptic agent may eliminate or inhibit one or more contaminants comprises one of more of bacteria, spores, parasites, viruses, bodily fluids, or mixtures thereof.

10. The method as recited in claim 9, wherein the one or more bacteria includes methicillin-resistant Staphylococcus aureus (MRSA), Pseudimonas aeruginosa and other resistant bacteria.

11. The method as recited in claim 7, wherein the sealable impermeable container comprises a draw string, a zip-lock, a foam opening, a twist tie, a plastic clip, or

a spring material to secure the impermeable container around the portable medical device.

12. The method as recited in claim 7, wherein the impermeable container comprises polyethylene, silicon oxide coated polymeric films, polypropylene, polysilicone, polytetrafluoroethylene, polyvinyl chloride, mylar, or a mixture thereof.

13. The method as recited in claim 7, wherein the permeable applicator comprises:

starch polymer, cellulosic gel, polyethylene foam, silicone open-cell foam, or mixtures thereof; and

a rough, a coarse, a smooth, a micro or a nano texture configured to scrub the portable medical device.

14. The method as recited in claim 7, wherein the antimicrobial or antiseptic agent disposed within the permeable applicator comprises:

about 5 to about 50 mg/ml of ethylenediaminetetraacetic acid (EDTA);

at most about 70% ethanol, by volume;

at most about 7.5% hydrogen peroxide, by volume; and

water.

15. A portable medical device protector system comprising:

a sterile package housing a removable tray, the removable tray comprising one or more of:

a sealable impermeable receptacle configured to enclose a portion of a portable medical device;

a permeable applicator configured to scrub the portion of the portable medical device; and

a cleansing, antimicrobial or antiseptic agent disposed on within the permeable applicator, wherein the antimicrobial agent comprises, water, a low molecular weight alcohol, a peroxide or peroxide-generating agent and a chelating agent.

16. The portable medical device protector system as recited in claim 15, wherein the removable tray comprises polypropylene, high-density polyethylene, polytetrafluoroethylene, polyvinyl chloride, or any other suitable thermoplastic polymer.

17. The portable medical device protector system as recited in claim 15, wherein the removable tray further comprises a plurality of permeable applicators, each of the plurality of permeable applicators containing various concentration of the antimicrobial agent.

18. The portable medical device protector system as recited in claim 15, wherein the sealable impermeable receptacle comprises a draw string, a zip-lock, a foam opening, a twist tie, a plastic clip, or a spring material to secure the impermeable container around the portable medical device.

19. The portable medical device protector system as recited in claim 15, wherein the sealable impermeable receptacle is further configured to enclose the entire portable medical device.

20. The portable medical device protector system as recited in claim 15, wherein the antimicrobial agent further comprises:

about 5 to about 50 mg/ml of ethylenediaminetetraacetic acid (EDTA);

at most about 70% ethanol, by volume;

at most about 7.5% hydrogen peroxide, by volume; and

water.

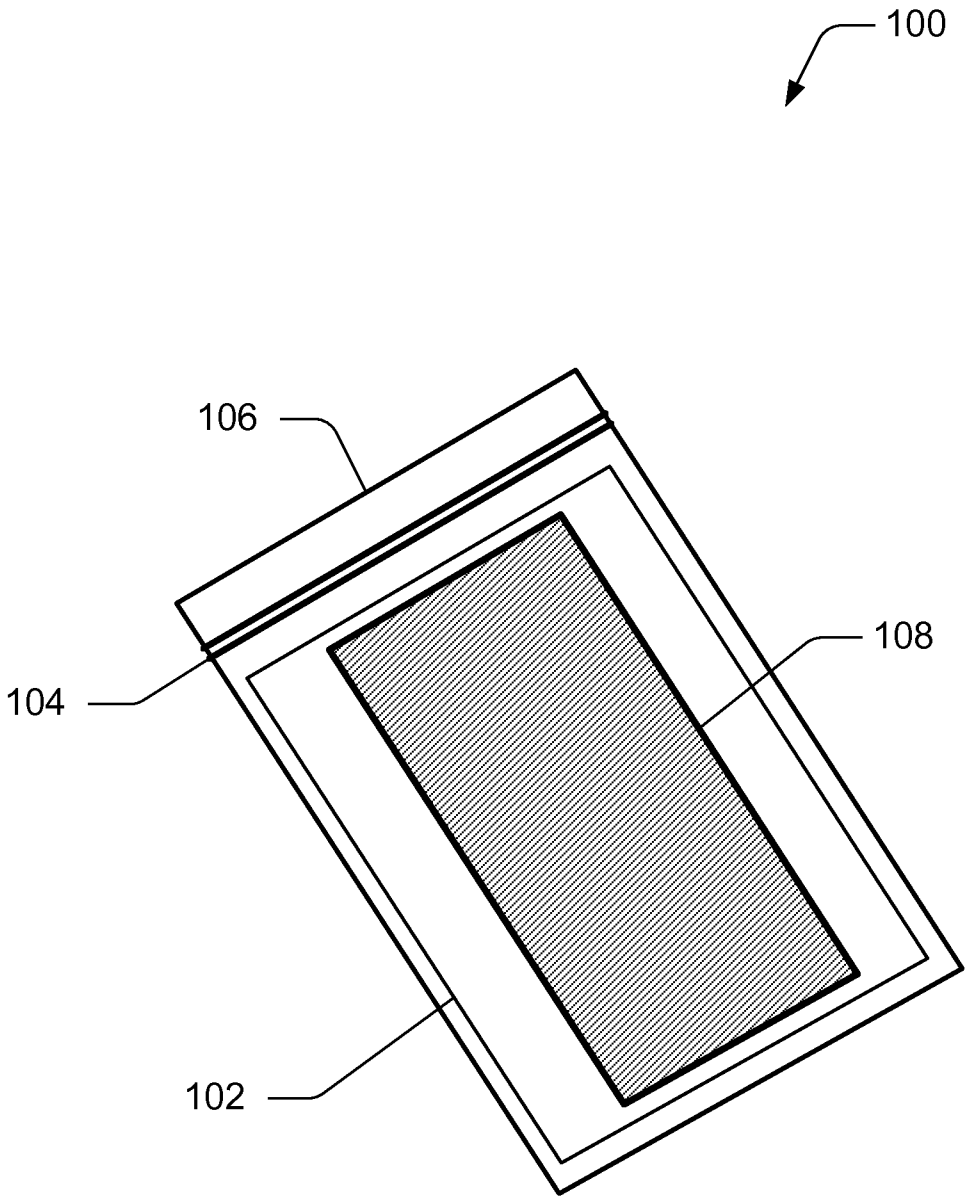

FIG. 1

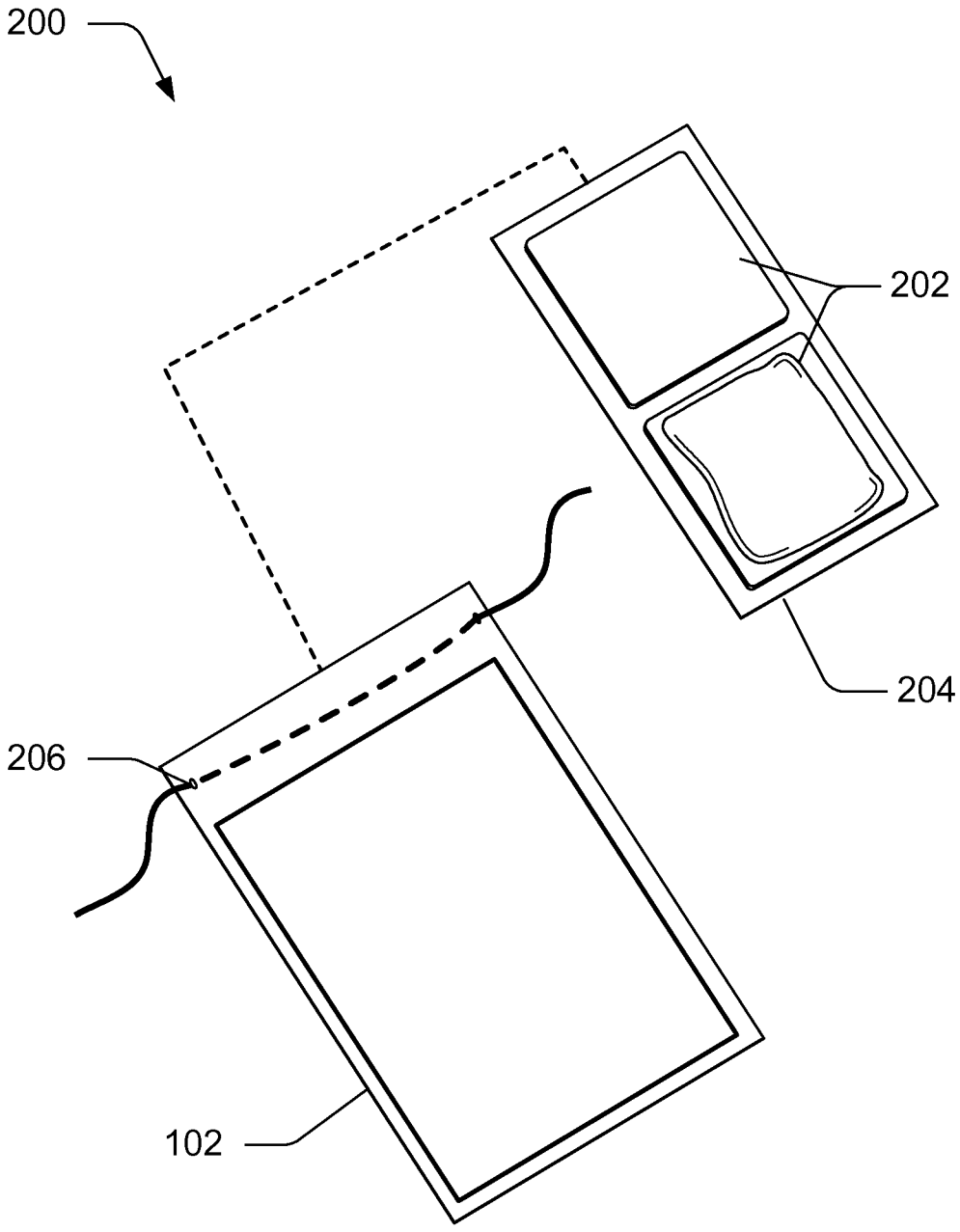

FIG. 2

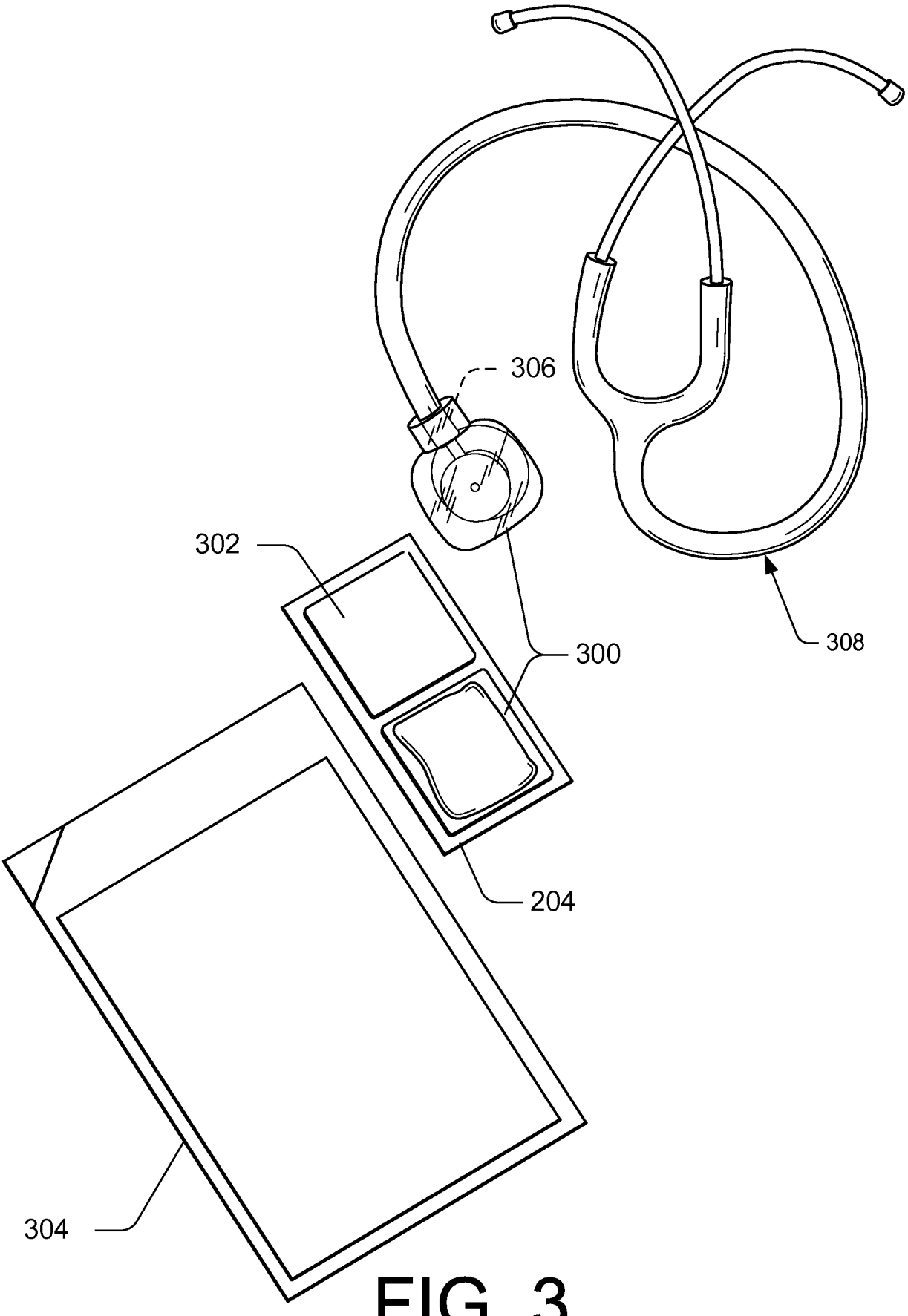

FIG. 3

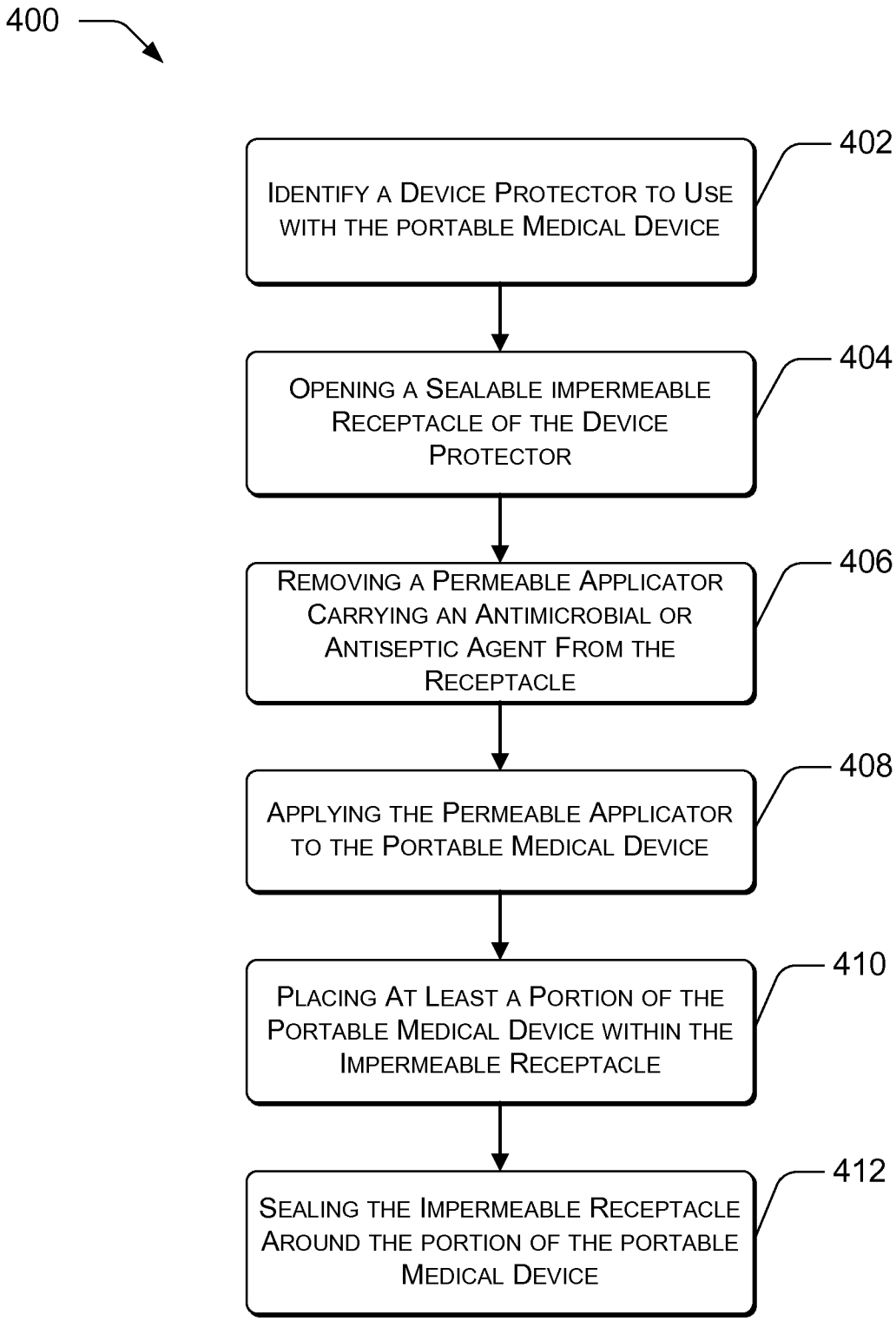
400
IDENTIFY A DEVICE PROTECTOR TO USE WITH THE PORTABLE MEDICAL DEVICE
402
OPENING A SEALABLE IMPERMEABLE RECEPTACLE OF THE DEVICE PROTECTOR
404
REMOVING A PERMEABLE APPLICATOR CARRYING AN ANTIMICROBIAL OR ANTISEPTIC AGENT FROM THE RECEPTACLE
406
APPLYING THE PERMEABLE APPLICATOR TO THE PORTABLE MEDICAL DEVICE
408
PLACING AT LEAST A PORTION OF THE PORTABLE MEDICAL DEVICE WITHIN THE IMPERMEABLE RECEPTACLE
410
SEALING THE IMPERMEABLE RECEPTACLE AROUND THE PORTION OF THE PORTABLE MEDICAL DEVICE
412

FIG. 4

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2013/024644

A. CLASSIFICATION OF SUBJECT MATTER

A61L 2/16(2006.01)i, A61L 31/14(2006.01)i, A61L 31/04(2006.01)i

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

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

A61L 2/16; B65D 30/04; A61M 31/00; A61F 13/00; NotA vai/lable; A61B 19/00; B65D 33/01

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Korean utility models and applications for utility models

Japanese utility models and applications for utility models

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

eKOMPASS(KIPO internal) & Keywords: securement, container, transport, location, identifier, medication

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5732716 A (UTECHT) 31 March 1998 See column 7, lines 22-30, 55-58; column 8, lines 47-53;	1,2,4
Y	column 9, lines 50-56; figure 1.	3,5-14
A		15-20
Y	US 2008-0119801 A1 (MOORE) 22 May 2008 See paragraphs [0048], [0053] and figure 2.	3,5,7-14
Y	US 2009-0012496 A1 (TENNICAN) 8 January 2009 See paragraphs [0053] and [0054].	6,14
A	WO 2005-089341 A2 (BULL) 29 September 2005 See pages 10-13.	1-20
A	US 5730530 A (STODDARD et al.) 24 March 1998 See claims 1-17.	1-20

☐ Further documents are listed in the continuation of Box C.

☒ See patent family annex.

* Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be of particular relevance

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"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents,such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
13 May 2013 (13.05.2013)	**13 May 2013 (13.05.2013)**
Name and mailing address of the ISA/KR Korean Intellectual Property Office 189 Cheongsa-ro, Seo-gu, Daejeon Metropolitan City, 302-701, Republic of Korea Facsimile No. 82-42-472-7140	Authorized officer KIM, Seung Beom Telephone No. 82-42-481-3371

Form PCT/ISA/210 (second sheet) (July 2009)

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No.
PCT/US2013/024644

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
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