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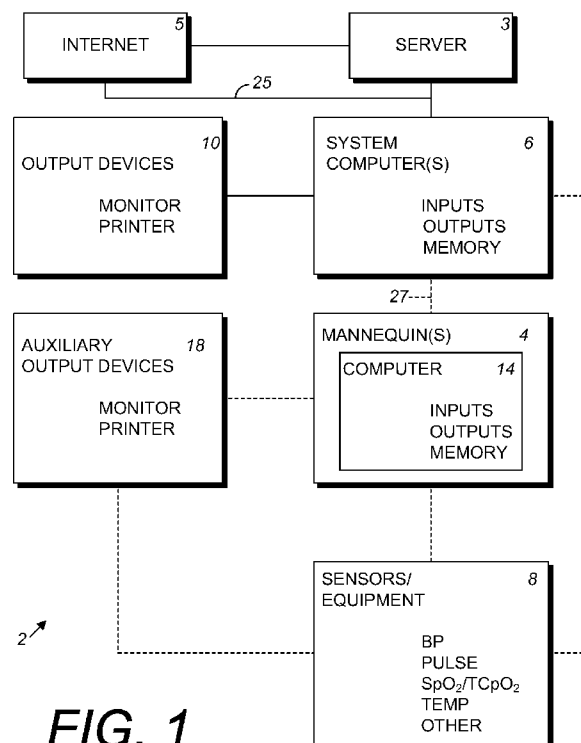
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(54) Title: MEDICAL DEVICE AND PROCEDURE SIMULATION AND TRAINING

**FIG. 1**

(57) Abstract: A healthcare simulation system including a mannequin with active physiological characteristics, a display monitor adapted for displaying physiological parameters, and a computer for controlling the mannequin and the monitor. A healthcare simulation method including the steps of programming the computer with healthcare scenarios, operating active characteristics of the mannequin, and dynamically displaying physiological parameters corresponding to patient vital signs. Alternative aspects of the invention include tools, such as computers and other equipment, for obtaining and displaying information and for interconnecting and interfacing participants, subjects and controllers in training systems and methods. Additional aspects of the invention include systems and methods for glucometer simulation and training.



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MEDICAL DEVICE AND PROCEDURE SIMULATION AND TRAINING**CROSS-REFERENCE TO RELATED APPLICATIONS**

[0001] This application claims priority in U.S. Patent Application Serial No. 14/607,013, filed January 27, 2015, which is a continuation-in-part of and claims priority in U.S. Patent Application Serial No. 14/594,126, filed January 10, 2015, which is a continuation-in-part of U.S. Patent Application Serial No. 14/165,485, filed January 27, 2014, which is a continuation-in-part of U.S. Patent Application Serial No. 13/597,187, filed August 28, 2012, which is a continuation-in-part of U.S. Patent Application Serial No. 11/751,407, filed May 21, 2007, now Patent No. 8,251,703, issued August 28, 2012. The contents of all of the aforementioned applications are incorporated by reference herein in their entireties.

BACKGROUND OF THE INVENTION**1. Field of the Invention**

[0002] The present invention relates to healthcare simulation, and in particular to a portable, dedicated display device, such as a touch-screen monitor, for displaying simulated, noninvasively-obtained vital signs from a healthcare instructional scenario programmed into a computer for conducting the scenario and controlling the monitor display and the simulated physiological functions of a mannequin or other patient model corresponding to the displayed vital signs. The present invention also relates to medical devices and procedures, and more particularly to medical device and procedure simulation and training systems and methods.

2. Description of the Related Art

[0003] The field of patient monitoring with electronic display devices, such as bedside monitors, is well-developed and standard for critical (intensive) care units (ICUs) at many institutions and for many surgical procedures. Patient rooms in critical care units and operating rooms (ORs) at many institutions are equipped with monitors, which receive inputs from electrodes and other input instruments connected invasively and noninvasively to patients. The monitors commonly provide displays corresponding to patient data, such as blood pressure, pulse rate, temperature, electrocardiographic heart rhythm strips, central venous pressure, pulmonary artery pressure, cardiac output, intracranial pressure, pulmonary pressure and other signals from catheters and transducers. Ventilator pressure can be utilized in connection with ventilator monitoring. Gas content analyzers can directly display gas partial pressures for anesthesiology and measured and calculated ventilator pressures for pulmonary functions.

[0004] Patient physiological instrumentation and monitoring equipment can provide output in a wide variety of formats corresponding to instantaneous (real-time) and historical patient data and vital signs. Analog (e.g., continuous wave-form) and digital readout displays and graphical

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user interfaces (GUIs) are utilized in existing equipment. Physiological variables can be sampled at predetermined intervals for tracking and displaying trends whereby healthcare practitioners can identify and appropriately respond to improving and deteriorating patient conditions.

5 **[0005]** Computer systems are currently used in the field of patient simulation for healthcare training and education. Mannequins are currently used for training exercises in which they are programmed to automatically model various lifelike symptoms and physiological responses to trainees' treatments, such as normal and abnormal cardiac and respiratory physiology and functions. They can be programmed with various scenarios for instructional simulation of
10 corresponding physiological conditions and specific healthcare problems. For example, Medical Education Technology, Inc. (METI) of Sarasota, Florida; Gaumard Scientific Company of Miami, Florida; and Laerdal Medical Corporation (U.S.) of Wappingers Falls, New York all provide patient simulator mannequins, which are adapted for simulating cardio-pulmonary performance with simulated electrocardiogram (EKG) outputs. Such simulation systems enable
15 students to train and learn in settings that closely resemble actual clinical settings and enable practicing on inanimate mannequins. Training under conditions which closely approximate actual clinical patient scenarios will improve patient care and outcomes. Students will have increased levels of skill and competency prior to providing care to actual patients by training under conditions which closely approximate actual clinical patient scenarios. Such automated
20 simulation systems have been successfully utilized in training for specialized procedures and settings, such as cardio-pulmonary, intensive care, anesthesiology, pilot training in flight simulation, etc.

[0006] More basic mannequins have been employed for instructing students on a wide range of procedures and treatment scenarios, and provide an alternative to instruction on "live" patients
25 or "standard" patients (e.g., actors, other students and instructors). Thus, the patient models adaptable for use with the present invention range from such "live" patients acting roles to abstract, virtual patients, including avatars and holograms.

[0007] The use of glucometers measuring blood sugar (glucose) levels from blood samples has increased dramatically as the incidence and prevalence of diabetes has increased. Because of
30 this trend, the need for a simulation model for a glucometer for teaching at all levels of care for diabetic patients has increased correspondingly. Simulation of testing blood sugar levels with a glucometer can be extremely valuable for training medical practitioners as well as for training diabetic patients to use a glucometer at home.

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[0008] As the sophistication of simulation scenarios for healthcare teaching has increased in realism and fidelity, the perceived need to train in conditions closely simulating actual medical situations has become more generally recognized. The importance of and the need for these types of portable simulation adjuncts and auxiliaries has become more critical. For example, glucometers represent an example of a medical diagnostic instrument used routinely worldwide for the benefit of large numbers of patients. Diabetic patients tend to use glucometers frequently and regularly. They are also used for monitoring, diagnosing and facilitating the treatment of other blood-glucose level related conditions. Many glucometer users lack formal medical education and would benefit from practical, hands-on training. Anatomically and physiologically accurate simulation of pricking a finger, obtaining a blood droplet, and testing with a glucometer would be extremely valuable medical training.

[0009] Effective medical training in the use of glucometers and other devices could improve the overall quality of healthcare universally. The training systems and methods of the present invention are adapted for effective training in scenarios closely mimicking actual patient conditions and physiological responses. Such training scenarios can be reliably replicated for universally consistent training and for standardizing the medical training experiences of students and practitioners. For example, new procedures and treatment techniques can be quickly and easily distributed to all users of the present invention. Such distribution and appropriate software upgrades could occur wirelessly over the Internet “in the cloud.” Training and testing results could also be efficiently distributed using the Internet. Student evaluations and training certifications can be handled remotely and efficiently via high-speed Internet connections and cloud-based computing, including data storage and transfer.

[00010] Medical device simulation can also benefit from current modeling technology, including 3-D printing. Equipment, medical device components and patient interfaces can be accurately and efficiently created and replicated using such technology. Customizable devices and patient-specific interfaces can be produced in 3-D model form for simulation and training. For example, patient-specific templates can be used by appropriate computer technology for producing customized medical devices. Patient fittings and adjustments can thus be handled efficiently and accurately. Equipment components can also be modeled for familiarizing students with their general configurations and operational characteristics.

SUMMARY OF THE INVENTION

[00011] In the practice of an aspect of the present invention, a portable healthcare simulation system and method are provided that utilize a mannequin, from a passive doll to a high-fidelity simulator for displaying certain physiological characteristics obtained noninvasively. A display

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device comprising a monitor displays vital signs in continuous (real-time) or digital time line modes of operation. The system is controlled by a computer, which can be programmed with various scenarios including outputs responding to various treatment procedures and mannequin control signals. Alternative aspects of the invention include a finger cot or finger splint for providing simulated blood serum and a wide variety of tools for interconnecting participants, components and information, all for use in connection with the present invention.

[00012] In the practice of other aspects of the present invention, a medical device simulation and training system includes a computer programmed with medical scenarios, including the inputs and outputs corresponding to a variety of patient conditions. Time-varying parameters can correspond to patient condition improvement and deterioration. Moreover, changes in patient conditions can be time-compressed, time-expanded and paused for training purposes. For example, students can observe immediate patient responses to various treatments, which might develop over hours or days in real-time. Instructors can pause exercises and training procedures as needed to emphasize certain patient physiological condition trends and revise treatments as necessary to affect and determine outcomes.

[00013] In the practice of alternative aspects of the present invention, a computer simulation can be implemented via a mannequin or a live subject, such as a volunteer. "Standard Patient" ("SP") physiological parameters and conditions can be preprogrammed. Student interface can be accomplished via devices for conveying the simulated patient conditions. Actual diagnostic and monitoring devices can be employed for realism. For example, a stethoscope can be modified with speakers for simulating the audible indicators of physiological parameters, including cardio, pulmonary, gastro-intestinal ("GI"), etc.

[00014] Controllers, e.g., instructors, can remotely manipulate the training exercises via touch-screen inputs and other control devices. Patient models can be projected on screen for activating touch-screen selection of particular patient conditions. Intensity, timing and other variables can likewise be instructor-controlled.

[00015] In other aspects of the present invention, simulated substances, such as blood serum, can be extracted for analysis with actual devices, such as glucometers. The aspects and embodiments discussed below can accommodate punctures by lancets with corresponding extraction of simulated blood serum. In an embodiment of the invention, a finger splint is utilized with a blood serum-filled bleb on each of the right and left sides of the finger splint for simulation of testing blood-glucose levels without actually puncturing a mannequin or subject's finger. Student participants can thus experience the procedures in nearly real-time conditions. The timing of such condition changes can simulate patient conditions and provider inputs.

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[00016] However, heretofore there has not been available an automated, portable simulation system and method utilizing a passive or semi-active mannequin with a dedicated monitor and a computer for conducting scenarios with concurrent (real-time) or time-delay display of basic vital sign physiological information, which can be obtained noninvasively, with the advantages and features of the present invention, nor has there been available a glucometer simulation and training system and method with the advantages and features of the present invention.

BRIEF DESCRIPTION OF THE DRAWINGS

[00017] Fig. 1 is a block diagram of a healthcare training system embodying a first aspect of the present invention.

10 [00018] Fig. 2 is a view of a display of a monitor thereof, particularly showing digital display outputs corresponding to patient vital signs.

[00019] Fig. 3 is a view of a display of an alternative monitor thereof, particularly showing patient vital sign parameters at programmable intervals.

[00020] Fig. 4 is a flowchart showing a simulation scenario embodying an aspect of the method of the present invention, which can be adapted to various condition-specific and patient-specific scenarios.

[00021] Fig. 5 is a flowchart showing another simulation scenario involving an initial student trainee assessment of the conditions associated with the mannequin.

20 [00022] Fig. 6 is a block diagram of a healthcare training system embodying a second aspect of the present invention.

[00023] Fig. 7 is a flowchart showing a training session variable initialization procedure therefor.

[00024] Fig. 8 shows the instructor controls and display therefor.

[00025] Fig. 9 shows the student display therefor.

25 [00026] Fig. 10 shows a typical prior art glucometer, which can be used in connection with an alternative aspect of the present invention.

[00027] Fig. 11 shows a finger cot, which can optionally be used for simulated patient blood serum modeling in connection with an alternative aspect of the present invention.

30 [00028] Fig. 12 shows the finger cot being punctured by a lancet instrument for obtaining a simulated blood serum sample on a reagent strip.

[00029] Fig. 13 shows a simulated blood serum sample being drawn for application to the reagent strip.

[00030] Fig. 14 shows the simulated blood serum sample on the reagent strip.

[00031] Fig. 15 shows a prior art monitor/defibrillator adapted for use in connection with an alternative aspect of the present invention.

[00032] Fig. 16 is a block diagram of multiple applications, equipment, participants and configurations of various aspects of the present invention.

5 [00033] Fig. 17 is a schematic diagram of a device and procedure simulation and training system embodying another aspect of the present invention, with instructor and student touch-screen monitors.

[00034] Fig. 18 is an enlarged diagram of an instructor touch-screen monitor comprising an input/output (I/O) device for use with the system, taking generally within area 18 in Fig. 17.

10 [00035] Figs. 19-27 show additional alternative embodiments of the present invention with finger cots, puncture-resistant shields and serum-filled blebs for glucometer training simulations embodying additional alternative aspects of the present invention.

[00036] Fig. 28 shows a top, perspective view of an embodiment of a blood serum interface including a simulated finger with two fluid-holding blebs and a common fillable reservoir for
15 training with a fluid analyzer.

[00037] Fig. 29 is a side, elevational view of the blood serum interface including a simulated finger with two fluid-holding blebs and a common fillable reservoir.

[00038] Fig. 30 is a front, elevational view of the blood serum interface including a simulated finger with two fluid-holding blebs and a common fillable reservoir.

20 [00039] Fig. 31 is a back, elevational view of the blood serum interface including a simulated finger with two fluid-holding blebs and a common fillable reservoir.

[00040] Fig. 32 is a top, plan view of the blood serum interface including a simulated finger with two fluid-holding blebs and a common fillable reservoir.

[00041] Fig. 33 is a bottom, plan view of the blood serum interface including a simulated
25 finger with two fluid-holding blebs and a common fillable reservoir.

[00042] Fig. 34 is an XY-plane cross-sectional, top, perspective view of the back portion of the blood serum interface including a simulated finger with two fluid-holding blebs and a common fillable reservoir.

[00043] Fig. 35 is a XZ-plane cross-sectional, top, perspective view of the bottom portion of
30 the blood serum interface including a simulated finger with two fluid-holding blebs and a common fillable reservoir.

[00044] Fig. 36 is a YZ-plane cross-sectional, top, perspective view of one side of the blood serum interface including a simulated finger with two fluid-holding blebs and a common fillable reservoir.

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[00045] Fig. 36a shows a perspective view of a protective shield for clipping over a finger under the interface.

[00046] Figs. 37-43 show another modified embodiment of a blood serum interface including a finger splint mounting two fluid-holding blebs and a common fillable reservoir for training
5 with a fluid analyzer.

[00047] Figs. 44-49 show another modified embodiment of a blood serum interface.

[00048] Figs. 50-52 show another modified embodiment of a blood serum interface.

[00049] Fig. 53 shows another modified embodiment of a blood serum interface.

[00050] Fig. 54 shows a side, elevational view of an embodiment of a blood serum interface
10 including a simulated finger and a protective shield and sealing wedge combination.

[00051] Fig. 55 shows a top, back, exploded, perspective view of the blood serum interface including a simulated finger and a protective shield and sealing wedge combination.

[00052] Fig. 56 is a cross-sectional view of the blood serum interface including a simulated
15 finger and a protective shield and sealing wedge combination showing reticulated, open-cell foam within the simulated finger.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

[00053] As required, detailed embodiments of the present invention are disclosed herein; however, it is to be understood that the disclosed embodiments are merely exemplary of the invention, which may be embodied in various forms. Therefore, specific structural and
20 functional details disclosed herein are not to be interpreted as limiting, but merely as a basis for the claims and as a representative basis for teaching one skilled in the art to variously employ the present invention in virtually any appropriately detailed structure.

[00054] Certain terminology will be used in the following description for convenience in reference only and will not be limiting. For example, up, down, front, back, right and left refer
25 to the invention as oriented in the view being referred to. The words "inwardly" and "outwardly" refer to directions toward and away from, respectively, the geometric center of the embodiment being described and designated parts thereof. Said terminology will include the words specifically mentioned, derivatives thereof and words of similar meaning.

[00055] Referring to the drawings in more detail, the reference numeral 2 generally designates
30 a portable healthcare simulator system embodying aspects of the present invention. Without limitation on the generality of useful applications of the system 2, it is particularly adapted for training healthcare practitioners in assessing and treating various patient conditions under replicated clinical conditions using programmed "scenarios" with a human-like patient simulator or mannequin 4 exhibiting vital signs and life-like physiological responses in an educational

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environment. The scenarios can be programmed into a system computer 6, which controls the mannequin 4 and provides output to system output devices 10.

[00056] The system 2 can be configured with various components and can operate standalone or be connected to other systems, e.g., via a server 3 connected to the Internet (worldwide web) 5 whereby multiple mannequins 4 can be linked and controlled in multiple institutions, which can be widely geographically distributed. The term "computer" is broadly used to encompass logic automated control devices, including microprocessors, personal computers, mainframes, etc. The computers disclosed herein typically include such components as memory, inputs and outputs for connection to various peripheral devices, such as the output devices 10, which can include monitors, printers, telecommunications, data storage, etc. The system computer 6 accepts inputs from various sources, including the mannequin 4 and various input devices, such as keyboards. Moreover, the scenarios and their corresponding patient condition sets can be programmed into the system computer 6 or downloaded to its memory via suitable media, such as CDs or DVDs, or via an Internet (worldwide web) connection.

[00057] One or more of the components of the system 2 can be portable for accommodating training needs in various locations, e.g. different rooms in particular facilities and in multiple facilities. Interconnections can be hardwired or wireless using various interconnectivity technologies, as appropriate.

[00058] The mannequin 4 can be provided with its own computer 14, which can be programmed to provide various, life-like physiological functions and corresponding outputs in response to corresponding inputs. For example, pulmonary and cardiac functions such as breathing and pulse can be programmed to vary as appropriate for various patient physiological "conditions." Other physiological functions, such as eye movement, can also be provided. Still further, the mannequin 4 can be interactive and can include an audio output source for speaking monologue patient comments and complaints concerning various symptoms. Such mannequins are capable of providing simulated EKG (electrocardiogram) output through lead attachment points to a suitable, external cardiac monitor. In addition to the EKG output, other "patient" physiological information comprising part of the outputs of the mannequin 4 can preferably be obtained noninvasively using sensors and equipment 8 for such physiological condition parameters as blood pressure, pulse, SpO₂, TCpO₂, temperature and others. Alternatively, such simulated patient physiological information can be generated and output to the output devices 10, 18 by the system computer 6, and in a training scenario would be virtually indistinguishable from comparable equivalent outputs from the mannequin 4 and its computer 14.

[00059] The mannequin 4 can also include a calibrated fluid pressure control pump mechanism capable of delivering fluid pressure corresponding to the patient blood pressures for the programmed scenarios. Various other physiological functions can be simulated with the mannequin 4 and incorporated in the scenarios. The mannequin computer 14 can control its various functionalities, e.g. in a standalone mode of operation or in conjunction with the system computer 6. Multiple mannequins 4 can be provided and their computers 14 networked to the system computer 6, which can function as a server in this system architecture. As noted above, the system computer 6 can be networked with other computers, including a server 3, and ultimately networked to the Internet 5. Components of the system 2 can be linked in an appropriate network, i.e. LAN or WAN, whereby scenarios can be shared among students, including remotely for virtual classroom types of applications.

[00060] The system output devices 10 can include a monitor connected to the computer 6. The term "monitor" is used in the broad sense to include various types of displays and GUIs appropriate for the particular applications of the system 2. Auxiliary output devices 18 can be hardwired (hardwired connections indicated at 25) or wirelessly connected (wireless connections indicated at 27) to the mannequin 4 or to the computer 6 directly as a supplement to or in place of the system computer output devices 10. For example, the auxiliary output devices 18 can display, print, record, transmit, etc. the simulated outputs of the sensors and equipment 8 corresponding to simulated physiological variables associated with the mannequin 4, which can include its own computer 14, or be completely passive. The sensors and equipment 8 can be hardwired or wirelessly connected to the auxiliary output devices 18, the mannequin computer 14 and/or the system computer 6. The sensors 8 are adapted to interface with the mannequin 4 and can comprise a wide variety of conventional medical instrumentation, such as: cuffs for blood pressure (BP); pulse oximetry sensors for clipping on a finger of the mannequin 4 and sensing pulse, SpO₂ and TCpO₂; thermometers; and other devices. The sensors 8 are preferably of the noninvasive type and either comprise actual medical instrumentation or are adapted for realistically interfacing with the mannequin 4.

[00061] An example of an auxiliary monitor 20 is shown in Fig. 2 and can comprise, for example, a handheld unit with a display screen 22 for receiving the output of the mannequin computer 14 and/or the sensors 8. By way of example and without limitation on the generality of useful information that can be displayed on the auxiliary monitor 20, a basic set of vital signs comprising blood pressure (BP), pulse, oxygen saturation in percent (SpO₂) and temperature is displayed on the monitor display 22, as shown in Fig. 2. A fifth parameter comprising

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transcutaneous oxygen tension (TCpO₂) can be utilized in place of SpO₂, particularly for pediatric scenarios. The use of these parameters will be described below.

[00062] Blood pressure is conventionally represented by systolic over diastolic. Digital readouts are shown for the vital sign parameters, but one or more could be replaced or supplemented with analog displays. The most recent blood pressure reading can be held on the display screen or GUI 22 of the monitor 20 until the next reading is "taken" (or computer-generated via computer simulation). A blood pressure sensing mechanism can be used for reading the actual pressure on the mannequin's arm or, alternatively, the system computer 6 or the mannequin computer 14 can inflate and deflate a blood pressure cuff, and generate an audible tone (i.e., "beep") with a simulated pulse in the usual manner, except that the blood pressure signals can be completely controlled and generated by the computers 6 and/or 14. In this configuration the mannequin 4 is passive, with the computer(s) generating all of the active commands, signals, inputs, outputs, etc.

[00063] The computer 6 can be programmed to obtain blood pressure values and display same at programmable intervals, e.g. 1-60 minutes. A simplified output would provide the most recent blood pressure readings only. As shown in Fig. 2, the BP acquisition time is displayed, along with the current time. The monitor 20 displays patient parameters obtained noninvasively and is preferably coupled to the mannequin 4 and the system computer 6 (e.g., hardwired, wireless or network) for interfacing (graphically and otherwise) with the users for simulation healthcare training.

[00064] The system 2 provides a "duality" whereby vital sign inputs and outputs can be obtained from the mannequin 4, the computer 6, or both. In a classroom setting, an instructor or instructors can oversee training exercises on the monitor output device 10 connected to the system computer 6, while the students/trainees directly observe mannequins 4 and/or vital sign readings on displays 22. Student/trainee performances can thus be monitored on site, or even remotely. Record and playback features of the system 2 permit post-scenario evaluations and critiques. Still further, a live subject could be utilized for one or more of the vital sign inputs, with others being computer-generated in order to simulate virtual medical conditions and output simulated virtual patient "responses" to various treatments.

[00065] Fig. 3 shows a modified or alternative display 24 displaying a digital time line or history 26 indicating patient parameters taken at programmed intervals. For example, blood pressure readings can be "taken" (or generated by the computers 6, 14 according to the program or scenario being run) at suitable time intervals, which can be either predetermined or selected by the students as part of a training exercise. Along with the blood pressure readings,

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instantaneous values corresponding to the other patient parameters can be taken or computer-generated. In the example display 24 shown, the last five readings are displayed digitally at 26 to provide a recent patient history and identify trends, which could be symptomatic and provide indications of various assessment and intervention options. This feature enables detecting and tracking vital sign "trends," which can provide important information concerning the patient's improvement or declining condition based on his or her records over periods of time. All of the parameters/vital signs can be tracked with respect to time in this manner and the computer 6 can be programmed for suitable time intervals (t). More or fewer time line entries can be retained and/or displayed. The display 24 can comprise an auxiliary output device 18 (Fig. 1), or it can be incorporated in the system output devices 10, for example, as an optional screen display or window in a main monitor display accessible through a pull-down menu. The computer 6 can also be programmed to provide digital time lines specific to one or more patient parameters.

[00066] In addition to normal real-time operation of the display devices 10 and 18, the computer 6 can be programmed to compress or expand time in order to conduct efficient training exercises. For example, blood pressure readings that might normally change at hourly intervals can be programmed to change at 10-minute intervals in order to accelerate the simulated changes in patient condition and provide students and trainees with appropriate training on assessing and treating unstable patients in response to changes in their vital signs, including compressed reaction times to such trainee treatments. Other vital signs can be programmed to change at corresponding compressed or expanded intervals. Still further, intervals can be extended to provide a "slow-motion" or "freeze-frame" changing-condition experience as appropriate for particular training scenarios.

[00067] Still further, the computer 6 can perform a record-keeping function whereby such changes are recorded and stored to a patient's file. Saved data can be recalled and displayed in order to determine the patient's history and trends and for purposes of comparison with present readings. Users can trigger or initiate repeat vital sign reading procedures for determinations on-demand and in real-time at predetermined or desired time intervals. Predetermined numbers of prior readings can be recalled for comparison with current readings.

[00068] Although only a limited number of lines of data are displayed at a time, the system computer 6 memory can be designed to store large amounts of data for multiple virtual patients, which can be identified by patient number. Such data can be retrieved and displayed in various formats, including an interactive "scrolling" display whereby an operator can scroll forward and backward while displaying a limited amount of data at a time. The default display can be the current and the most recent values.

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[00069] The computer 6 can store data applicable to different "patients" and scenarios. Thus, for training and education purposes patient profiles can be created and subjected to different scenarios in order to provide instructional variety and realism. Of course, some of the vital signs would change more or less quickly than others, whereby different time references for the different vital signs can be utilized as appropriate. Temperature and SpO₂, for example, would tend to change relatively gradually, as compared to, for example, pulse and blood pressure.

[00070] A pulse-oximeter sensor function (mannequin 4, computer 6 or both) can emulate the performance of a helium-neon ("he-ne") laser light type of sensor, which is clipped on a fingertip. An intermittent mode of operation can be provided whereby the oximetry result can be displayed and the result recorded. The sensor 8 and the display monitor 10 can then be removed. Temperature, pulse, and SpO₂ could be displayed continuously in real-time, or compared over time with blood pressure (BP) trends. The default timing for pulse, temperature, and SpO₂ recording can be keyed on whenever a blood pressure value is also recorded, but different times for just these other readings can also be used.

[00071] The monitor display 22 content may be determined, at least in part, by the particular mannequin 4, which may include software for controlling its operation, i.e., active responses in the form of outputs to various procedures in the form of inputs. The healthcare simulation mannequin 4 preferably provides certain noninvasive patient monitoring functionalities and simulated physiological functions, such as breathing, heartbeat, blood pressure (BP), temperature, audible output, eye/eyelid movement, etc. Input and output signals for the various components of the system 2 can be transferred via connecting cables or wirelessly. Preferred hardwired connections are shown by continuous lines 25 and preferred wireless connections are shown by broken lines 27 in Fig. 1, although many other combinations of connections are possible.

[00072] The temperature function is preferably capable of both intermittent and continuous real-time display for this modality. Patient temperature generally corresponds physiologically to the other parameters of the program according to the particular scenario being utilized. In other words, temperature is an important indicator of physiological condition, and trends (both increasing and decreasing) can inform practitioners of changing conditions and treatment efficacies. Like blood pressure, it can be useful to display temperature in relationship to a time line (e.g., Fig. 3), including an indication of when it was last obtained. Also like blood pressure, the temperature can be controlled by existing scenario software loaded on the computer 6, which is not always the same as real-time and may be capable of manipulation. The mannequin 4 can be temperature-passive, i.e. providing no output signal corresponding to patient temperature.

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However, passive instruments, such as dummy tympanic membrane temperature probes can be provided for simulating the temperature-taking procedures in the scenarios. Sensors are available for quickly obtaining measurements (e.g., from the ear canal), which can be simulated by the scenario software and the computer 6.

- 5 [00073] The system 2 is preferably capable of incorporating continuous temperature displays associated with continuous monitoring, which can be achieved with existing equipment. It will be appreciated that the range of thermometers and temperature sensors is relatively large, whereby the system 2 can be programmed to simulate the operation and outputs associated with such a wide range of temperature input devices. The system 2 can be programmed for simulated
- 10 temperature readings from different sources, such as axillary, oral, etc., and the scenarios can reflect temperature readings obtained by students from such different sources. Both Centigrade and Fahrenheit readings are available. Pediatric, neonatal, post-anesthesia, sensory depressed, comatose and medicated patients may require and will tolerate continuous temperature sensing from instruments which can be continuously left in place, such as a rectal temperature probe.
- 15 Continuous temperature sensing in awake or awakening patients can be accomplished with suitable noninvasive surface equipment, such as forehead strips, axillary and skin-surface probes. Just as it is currently possible to use an actual working portable automated blood pressure monitor on existing mannequin models with controlled hydraulic conduits that simulate bronchial arteries, and just as it is possible to use current actual clinical intensive care monitors
- 20 to pick up cardiac rhythms from predetermined electrical outlets on the mannequin, so it is possible to design a mannequin with vital sign outputs that would enable staff training with their own actual portable automated vinyl signed display devices (VSDD). All output points are controlled by the mannequin and system computer working in concert with the programmed scenario. The blood pressure would be projected by the hydraulic palms in the system as
- 25 described above. The temperature signal would be transmitted by carefully controlled thermal plates located at strategic points. These can include a plate as the tympanic membrane producing a temperature control chamber in the ear for a scope-type thermal probe, and a plate against the lingual jaw inside and out for an oral probe and a spot on the forehead for a skin surface probe, etc. A specific mannequin model can be equipped with a single play or any combination. The
- 30 same duality applies to the choices for all the signal output sides for all signals. The SpO₂ output signal could be computer-controlled, synchronized infrared and red light output that would simulate the actual transmitted red signal for a specific level of saturation and pulse. This could be transmitted from the mannequin and a designated spot, e.g., the nailbed level of the ring finger. The sensing clip can be oriented so that the receptor signed his against the output sign of

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the finger. Alternatively, the output signal could be obtained from both the dorsal and the lingual sides of the mannequin finger so that, as in actual practice, it would not matter with the orientation and it is a "transmitted" through signal.

[00074] On-demand display of clock time (e.g., 24-hours or other suitable time period) can be coordinated to the time frame chosen for the scenario, or real-time. Preferably the scenario can be started at any chosen time, which "sets the clock" or starts the clock running to set in motion a series of programmed physiological occurrences affected by inputs corresponding to the treatment procedures and scenario plan. The computer 6 also preferably enables "pause" functionalities whereby immediate instruction and feedback can be provided in order to facilitate the instructional aspect of the exercise. Thus, instruction can be timely provided with the simulated patient's condition suspended in pause mode without further deterioration of the patient's physiology. Of course, such deteriorating (or improving) patient conditions can be programmed into the scenarios in real-time for greater realism, or even accelerated to demonstrate the consequences to the patient of various conditions and/or treatments. Also, by selecting key moments and running them in sequence, a cycle which would normally occur over several days can be time-compressed into hours.

[00075] As an alternative or supplement to SpO₂, transcutaneous oxygen tension (TCpO₂) can be modeled by the software. The TCpO₂ value is obtained by determining the actual partial pressure of oxygen in the blood at the skin surface, as opposed to the "saturation" percentage of hemoglobin in the SpO₂. TCpO₂ is determined by heating the skin surface in a small sealed chamber and reading the change in the oxygen level as the gas escapes the skin. TCpO₂ sensors are therefore noninvasive surface probes. The computer program of the system 2 provides SpO₂ output, for which TCpO₂ can be substituted. The scenarios can include the steps of attaching passive SpO₂ and TCpO₂ detection and monitoring equipment to the mannequin 4, with the computer 6 providing the actual output signals corresponding to these vital signs.

[00076] Fig. 4 is a flowchart showing a healthcare educational method of the present invention. Beginning with a start 29, variables are preset at 30 and correspond to computer inputs and outputs. A time reference is selected at 32 and can be based on continuous (real-time) display 34, trend display 36, and most recent 38. Output is provided to a mannequin at 40, which in turn provides output to a monitor at 42. Treatment is initiated at 44, the mannequin is treated at 46 and the physiological effects of the treatment are computed at 48. The treatment results are output at 50, and can include mannequin reactions such as audible output and changes in physical condition at 52. The treatment results are displayed and mannequin condition is reassessed at 54. An affirmative decision at "More Treatment?" decision box 56 leads to a repeat

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of the treat mannequin step and sequence beginning at 46. A negative decision at 56 leads to recording the scenario at 58, outputting the scenario at 60 and a decision box for "Another Scenario?" at 62, with an affirmative decision leading to a repeat of the sequence beginning at 30 and a negative decision leading to a debrief of the simulation results 64 and ending the exercise 66.

[00077] Fig. 5 is a flowchart of another procedure or scenario embodying the method of the present invention. Beginning with a start 68, variables are preset at 70 and the mannequin is programmed at 72. A trainee or student assesses the mannequin condition at 74 and initiates treatment at 76 by treating the mannequin at 78. The treatment physiological effects are computed at 80 and output at 82. The mannequin reacts at 84 and the treatment results are displayed and mannequin condition is reassessed at 86. An affirmative decision at "More Treatment" decision box 88 repeats the cycle beginning at the "Treat Mannequin" step 78. A negative decision leads to the record scenario step 90, the output scenario step 92 and the "Another Scenario" decision box 94, from which an affirmative decision repeats the cycle beginning at "Preset Variables" 70 and a negative decision leading to a debrief of the simulation results 96 and ends the exercise 98.

[00078] An exemplary training exercise practicing the method of the present invention using the system 2 could include wheeling the "patient" (i.e., mannequin 4) into a training room, which can consist of or be modeled after a hospital room. The student or trainee can attach noninvasive sensors, such as a blood pressure cuff, thermometer, finger-clip pulse/SpO2 sensor, etc. If the initial reading is considered ineffective or erroneous, the student/trainee has the option of canceling or deleting it and retaking the initial reading. The computers 6, 14 and/or the sensors/equipment 8 can be configured to detect incorrect applications of the sensors/equipment 8 to the mannequin 4, e.g., improper blood pressure cuff wrappings or SpO2 sensor placements. The system 2 can provide appropriate outputs alerting the students to the incorrect applications. The computer 6 can initiate a training scenario with programmed outputs and responses to various inputs corresponding to "treatment." The initial readings obtained by the system 2 can be output on the display 18 (Fig. 2) and can also comprise the first time line entries on the display 18 (Fig. 3). Thereafter the scenario can present predetermined changes in the physiological variables in order to simulate a deteriorating patient condition, prompting the trainee to react with appropriate treatment protocols. As shown in Fig. 3, additional memory line values are obtained and displayed at intervals, which can be predetermined or set by the students as part of the training exercises. For example, blood pressure readings taken once an hour can correspond to the updates in the other physiological values whereby trends can be identified

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from the display 18. Thus, even if the initial readings are relatively normal, subsequent changes can indicate a deteriorating condition necessitating treatment.

[00079] Fig. 6 shows a block diagram of a system 102 comprising a second aspect of the invention and including a student computer 104 with a vital signs display device (VSDD) 106, inputs 108 and memory 110. A passive mannequin 112 can be placed in proximity to the student computer 104 for simulated "treatment" in response to the VSDD 106 output. These components can operate in a standalone mode. Alternatively, an optional instructor computer 114 can be provided and linked to the student computer 104 by connection 116. The instructor computer can include a VSDD 118, inputs 120 and memory 122. The functionalities of the student and instructor computers 104, 114 can be combined and separate VSDDs 106, 118 can be provided on opposite sides of an enclosure housing the computer whereby the student's VSDD 106 is in the student's field of vision, but the instructor's VSDD 118 is concealed from the student either by its orientation or by a removable cover.

[00080] Fig. 7 shows a flowchart for a procedure for setting variables for the system 102. Beginning with a start 124, the system then initializes at 126 and proceeds to a select mode step at 128. The vital signs can be associated with default variables, which are displayed at step 130. The variables can be accepted at 132, increased at 134, or decreased at 136. Thereafter the method proceeds to selecting the time reference at 138, which is generally an instantaneous (real-time) or sequential (time history) value. A positive answer at decision box 140 leads to the select mode step at 128. A negative answer at 140 leads to an end 142.

[00081] Fig. 8 shows an instructor controls and display 144 for the optional instructor computer 114 with a controls section 146 and the VSDD 118. Suitable controls for power 148, mode (e.g., blood pressure systolic/diastolic, pulse, temperature, SpO2 and/or TCpO2) select 150, display 152, start 154, pause 156, stop 157, scroll up 149 and scroll down 151 can be provided as shown.

[00082] The VSDD 118 includes a temperature module 158 with a start/reset switch 160, a Fahrenheit/Centigrade switch 162 and a normal/monitor switch 164. A blood pressure module 166 includes an auto/manual switch 168, a start switch 170, and a cancel switch 172. An alarms module 174 includes a select switch 176, a silence (mute) switch 178, a high limit switch 180, and a low limit switch 182. The limit switches 180, 182 permit entry of values corresponding to high and low blood pressure (or other variable) values which, when exceeded, cause an alarm to be output. A blood pressure (BP) cycle module 186 includes an interval select switch 188 for inputting time units (e.g., minutes) between readings. A start switch is provided at 190 and a prior data switch 192 causes prerecorded data to be displayed.

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[00083] Fig. 9 shows the student VSDD 106, which can be essentially identical to the instructor VSDD 118. In operation, the instructor can program the system 102 and interactively control its operation while monitoring the instructor VSDD 118. The student can assess and treat the passive mannequin 112 while observing the student VSDD 106.

5 [00084] Figs. 10-14 show an alternative aspect of the present invention being used in connection with a glucometer 202, comprising a standard instrument used for measuring blood glucose levels. Blood sugar concentration or blood glucose level is the amount of glucose (sugar) present in the blood, which is normally tightly regulated as part of metabolic homeostasis. Hyperglycemia is a common indicator of a diabetic medical condition. Long-term hyperglycemia
10 can cause health problems associated with diabetes, including heart disease, eye, kidney, and nerve damage.

[00085] Conversely, hypoglycemia is a potentially fatal medical condition, which can be associated with lethargy, impaired mental function, muscular weakness and brain damage. Patients with such medical conditions are commonly carefully monitored at frequent intervals in
15 order to avoid serious medical complications. Simulating blood glucose levels can thus be useful in training healthcare providers in the assessment and treatment of various medical conditions indicated by abnormal blood glucose levels.

[00086] Figs. 11-14 show a finger cot 204 adapted for placement over a finger 206 of a simulated patient, which can be an individual assuming the role of a patient, or a mannequin. The
20 cot 204 includes a protective, puncture-resistant thimble 208 and a latex-like or rubber-like, penetrable cover 210 placed over the thimble 208 and forming an intermediate space 212 adapted for receiving simulated blood serum 214, which can be retained by a perimeter seal 216 located at a proximate end of the thimble 208. The cover 210 can be rolled at its proximate end 218 and unrolled to an appropriate length to cover part of the finger 206 and thus retain the
25 finger cot 204 securely thereon. The finger cot 204 can also be secured with adhesive or tape.

[00087] In operation the cover 210 is penetrated by an instrument, such as a lancet 220, and a small quantity, such as a single drop, is applied to a reagent strip 222. The reagent strip 222 can be placed in the glucometer 202, which provides a glucose level reading.

[00088] Fig. 15 shows a monitor/defibrillator 230 adapted for use in connection with an
30 alternative aspect of the present invention. Without limitation on the generality of useful equipment, the monitor/defibrillator 230 can comprise a LifePak model, which is available from Physio-Control, Inc. of Redmond, Washington. The monitor/defibrillator 230 can optionally be connected to the system computer 6 and/or a patient model, such as the mannequin 4. Alternatively, the monitor/defibrillator 230 can be configured as a "smart" unit with an internal

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processor programmed for simulating procedures corresponding to patient conditions and responses. Individuals can interact with the monitor/defibrillator 230 by administering simulated treatments in response to simulated patient outputs, such as physiological conditions and vital signs, as described above.

5 [00089] Such monitor/defibrillators 230 are commonly used in emergency procedures, and are typical equipment on emergency vehicles, such as ambulances, "Med-Act" vehicles, and "Life Flight" helicopters and other aircraft. For training purposes, students can practice interactive procedures with mannequins or live actors using the monitor/defibrillators 230. Alternatively, "smart" monitor/defibrillators can be used in a "standalone" mode for interacting with students
10 and displaying appropriate outputs in response to different conditions and treatments. Various other types of equipment can be used in connection with the system and method of the present invention. For example, chest drainage systems can be monitored and/or simulated in operation. Pleur-Evac chest drainage systems are available from Teleflex Medical OEM of Kenosha, Wisconsin.

15 [00090] Fig.16 is a block diagram showing various alternative configurations and functions of the aspects of the present invention. For example, the patient model can be a live actor with a script, a mannequin (interactive or passive), an avatar, a hologram or a virtual patient existing only in computer memory and represented visually as a still photo, a video clip or an animated or graphic image. Still further, student interfaces with both the patient model and the tools can
20 range from direct contact to remote, on-line interaction. Likewise, the instructor interface can assume a wide variety of contact and communication media and methods. Automated interfaces can be substituted for or supplement direct, human interaction.

[00091] Fig. 17 shows a diagram of a simulation system 302 including instructor and student touchscreen monitors 304, 305 for use as input/output (I/O) components. The monitors 304, 305
25 are connected to a system computer(s) 6 (Fig. 1), which can be preprogrammed with various simulation training and educational scenarios. For example, the monitors 304, 305 can display anterior and posterior patient images 306, 307 with predetermined touch-screen areas 308 for initiating interaction. Additional inputs can be entered via touch-screen buttons 319 (Figs. 17 and 18). The monitors 304, 305 can also be used in conjunction with a student interface
30 configured like a stethoscope 310, which can comprise a "smart" device providing audible output signals via headphone-type speakers 312. Input signals can be provided by placing an input 314 of the stethoscope 310 on the touchscreen areas 308, whereby the computer 6 provides corresponding responses. Alternatively, the stethoscope input 314 can be placed on a mannequin or an individual portraying a patient. The output of the stethoscope 310 can be preprogrammed

on the system computer 6, or controlled in real-time by an instructor. A suitable input/output (I/O) interface component 320 is connected to the system computer 6 for interfacing with the various input and output (I/O) devices. For example, the I/O interface component 320 can include analog-to-digital (A/D) converters, filters, amplifiers, data compression, data storage, etc. The stethoscope 310 output can be "On Demand," i.e., placement determining the output sounds via the touchscreen whereby variants of chosen heart rates and breathing sounds can be preprogrammed and altered, e.g., by a rheostat-type sliding scale control 318.

[00092] By way of example and without limitation, a preprogrammed scenario can involve placing the stethoscope input 314 on lung areas 308 whereby audible output corresponding to patient breathing sounds are delivered via the headphone speakers 312. The scenarios and the corresponding output signals, including the stethoscope 310 outputs, can be controlled via an instructor monitor 304 displaying a patient image 306, which is similar to that shown on the student monitor 305. For example, the instructor monitor 304 can include the rheostat-type sliding scale control 318 for adjusting a parameter of an output signal, such as volume, intensity and frequency. Breathing patterns, i.e., shallow-to-deep, slow-to-rapid, etc. can be controlled by an instructor for simulating various patient medical conditions. Such audio outputs can be made self-sensing by placing a band around the chest of the mannequin or SP which senses the respiration rate and depth and signals this to the controlling computer 6. These audio signals and pulses can be coupled to an EKG strip displayed on a vital sign monitor control by the controlling computer 6, which senses all of these effects. The system computer 6 can also interface with and output to a monitor/defibrillator 230 (fig. 15) and a 2-D/ 3-D printer modeler 316.

[00093] Other instructor-to-student audio applications include cardiac and gastro-intestinal (G.I.). Instructors can present patient distress indications via the interface monitor 304, with appropriate condition changes based on treatments administered by the students. The timing of such signal interactions can be varied and paused as appropriate for accomplishing the training objectives. For example, patient condition changes naturally occurring over several days can be compressed into training exercises corresponding to a class period.

[00094] Of course, many patient condition indicators and physiological parameters are interrelated. Such interrelated relationships and their visible/audible indicators can be programmed and presented to students for training purposes. For example, worsening conditions are often indicated by labored breathing, rapid pulse, fever, etc. Conversely, improving conditions can be indicated by restoring normal breathing patterns, normal heart rate, moderate blood pressure, normal temperature, etc. Visual indicators can include pale versus flushed skin

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appearance, pupil dilation, perspiration, etc. All of these parameters can be preprogrammed or manually manipulated by the instructors as appropriate for training exercise objectives.

[00095] It will be appreciated that such training exercises can occur remotely, with the instructors and students connected via the Internet or otherwise by telecommunications. By linking the participants with the Internet and other telecommunications technology, significant training efficiencies can be achieved. For example, instructors and students can be dispersed globally at remote locations with Internet access providing the interaction. Moreover, scenarios and student responses can be digitally stored for later replay and evaluation, e.g., via the I/O interface 320, in the cloud 322, etc.

[00096] Glucometer applications are shown in Figs. 19-53. Glucometers, such as the portable example shown at 202, are frequently used by both trained medical personnel and untrained individuals, including patients. The present invention includes systems and methods for glucometer training. A glucometer training system 402 includes a computer 6, an I/O interface 320, software and participants (i.e., instructor, student and/or patient) as described above. The patient/subject role can be filled by an individual, a mannequin, or a device, such as a simulated fingertip 442 (Figs. 24-27) described below.

[00097] Figs. 19 and 20 show a glucometer training system 402 with a blood serum simulation interface 404 including a finger cot 406 placed over a bleb 408, which can be filled with simulated blood serum 410. The interface 404 can include a thimble or fingertip shield 412, which protects an underlying part of the fingertip 426 from penetration by a lancet 414. The shield 412 can comprise any suitable material conformable to the fingertip. For example, metals and hard plastics can be used for forming the shield 412. Still further, padded shields can be provided. The bleb 408 is preferably filled with a semi-viscous fluid 410 forming a droplet 416 when discharged. The fluid 410 can include appropriate physiological composition characteristics, such as blood-sugar levels for glucose testing. Alternatively, the fluid 410 can be inert, with the characteristics preprogrammed and simulated by the computer 6.

[00098] Figs. 21-23 show another alternative aspect of the present invention comprising a glucometer training system 420 with a soft, protective gel or latex pad 422 placed on a volar portion 424 of the fingertip 426 with a bleb 428 placed on the pad 422. A suitable finger cot 430 can be placed over the pad 422 and the bleb 428, which is adapted for refilling with a syringe 432.

[00099] Figs. 24-27 show another alternative aspect of the present invention comprising a glucometer training system 440 with a simulated fingertip 442 placed over an individual's fingertip, or used standalone. The simulated fingertip 442 is fitted with a pad 444, which is

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similar to the pad 422 described above. A bleb 446 is placed on the pad 444 and can be internally refilled with a syringe 432, as shown in Fig. 25. Fig. 26 shows the system 440 being placed on an actual fingertip. Optionally, a finger cot 430 can be placed over the system 440.

[000100] Figs. 28-36a show an alternative embodiment of a glucometer simulation and training system 502 including a patient, a blood serum interface 504, and an analyzer. The patient may be an individual or a mannequin, and at least one of the patient's fingers is required for the glucometer simulation and training system 502. The analyzer may be a glucometer such as the portable example shown at 202, a computer programmed to simulate fluid analysis, or another type of fluid analyzer.

10 [000101] In this embodiment, the blood serum interface 504 includes a simulated finger 506 configured to hold semi-viscous fluid simulating blood and to slide over a simulated patient or mannequin's finger 526. The simulated finger 506 is preferably made of flexible, flesh-like material that is capable of sealing itself after puncture. In this embodiment, a protective shield 534 may optionally be placed on the patient/subject's finger 526 prior to sliding the simulated
15 finger 506 over the patient/subject's finger 526 to provide protection from cuts. The protective shield 534 may be made of metals, hard plastics, and/or other materials capable of protecting a finger from being cut, and preferably, the protective shield 534 snaps around the patient/subject's finger 526. Alternatively, the protective shield may be built into the inside of the simulated finger 506 to protect the finger 526.

20 [000102] In this application, finger joint is synonymous with knuckle. Additionally, anatomical terms are given their usual meanings. For example, when referring to the hand, dorsal means the top, or back, of the hand, and ventral means the bottom, or palm side, of the hand. Proximal means closer to the trunk of the body, and distal means further from the trunk of the body. So, in reference to a finger, distal is closer to the fingertip, and proximal is closer to
25 the palm and back of the hand. There are two bones that make up the human forearm: the radius and the ulna. With palms facing towards the back of the body, the radius is closer to the torso, and the ulna is further from the torso. The terms radial and ulnar are references to the proximity to the radius and ulna bones, respectively. Thus, with palms facing back, the radial side of a hand or finger is the inside, and the ulnar side is the outside. The bones that make up the fingers
30 are called phalanges, and a single finger bone is called a phalanx. The distal phalanges are the bones from fingertips to the most distal knuckles, the intermediate phalanges are bones between the most distal knuckles and the middle knuckles, and the proximal phalanges are the bones between the middle knuckles and the most proximal knuckles. The most distal knuckle of each finger, between the distal phalanx and the intermediate phalanx, is called the distal

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interphalangeal (“DIP”) joint. The middle knuckle, between the intermediate phalanx and the proximal phalanx, is called the proximal interphalangeal (“PIP”) joint. The most proximal knuckle is called the metacarpophalangeal (“MCP”) joint. It is preferable for the simulated finger 506 to extend at least as long as halfway between the DIP and PIP joints of the finger, or
5 halfway across the intermediate phalanx. Extension of the simulated finger 506 beyond the DIP joint helps ensure that the simulated finger 506 will stay on the patient/subject’s finger 526 when the finger 526 is handled by a student or trainee.

[000103] Preferably, the simulated finger 506 has a nail-like indentation 518 on its dorsal side or an open nail portion showing the patient/subject’s nail underneath. This nail-like indentation 518
10 or open nail portion gives the simulated finger 506 a more anatomically correct look, and more importantly, it helps with placing the simulated finger 506 on the patient/subject’s finger 526 and using the simulated finger 506 in the proper orientation. Figs. 28-36 show an embodiment of the simulated finger 506 having a nail-like indentation 518. The simulated finger 506 can be placed on any finger 526 of a mannequin or simulated patient, with the middle (3rd) finger or ring (4th)
15 finger being the preferred placement. Different sizes of simulated fingers 506 may be utilized to better fit different finger sizes.

[000104] The simulated finger 506 includes a bleb 508, or stick site, below the nail on each of the radial and ulnar sides of the simulated finger 506. A bleb 508 is a cavity or receptacle configured to hold semi-viscous fluid simulating blood. These blebs 508 cover a large portion of
20 each of the radial and ulnar sides of the distal phalanx. In this embodiment, the blebs 508 are formed within the simulated finger 506. Fig. 34 shows a cross-sectional view of the blebs 508. The two blebs 508 share a common reservoir 520 configured to be filled with blood serum 510. After the common reservoir 520 is filled with simulated blood serum, blood serum can be pushed into the blebs 508 by applying pressure to the reservoir 520. The common reservoir 520 may be
25 configured for injection with a syringe, or the reservoir 520 may be capable of filling via IV connectors, Leur-Lok hub connectors, or other tubing or bladder connectors. The common reservoir 520 may or may not have a specific fill site 522, and the common reservoir 520 could either be placed on the dorsal side or the ventral side of the simulated finger 506. Figs. 28-36 show an embodiment including a common reservoir 520 on the ventral side of a simulated finger
30 506. This embodiment also has a fill site 522 for filling the reservoir 520 with blood serum. Figs. 35 and 36 are cross-sectional views of the simulated finger 506 showing the inside of the common reservoir 520.

[000105] Alternatively, the simulated finger could have just one bleb with a separate filling reservoir on the dorsal or ventral side of the simulated finger. Another alternative would be for

the simulated finger to have two reservoirs, each leading to a separate bleb. With dual reservoirs, one bleb could be filled with a simulated blood serum having one set of characteristics, and the other bleb could be filled with a simulated blood serum having a different set of characteristics.

5 [000106] In reality, when using a glucometer to test blood-glucose levels, a patient or subject's finger is pricked with a lancet on the side of the finger in order to avoid nerve damage to the finger and to minimize pain. Thus, a glucometer training system 502 with stick sites 508 on the sides of the finger provides an anatomically correct simulation for training medical professionals and patients, such as those having diabetes.

10 [000107] The simulated blood fluid can include appropriate physiological composition characteristics, such as blood-sugar levels for glucose testing with a glucometer. Alternatively, the fluid, or simulated blood serum, can be inert with characteristics preprogrammed and simulated by a computer 6. To simulate testing blood glucose levels, an instructor can fill the common reservoir 520 with blood serum and apply pressure to the reservoir 520, filling the two
15 blebs 508 with blood serum. The protective shield 534, optionally, and the simulated finger 506 can be placed on a patient or mannequin's finger 526 either before or after applying pressure to the reservoir 520 to fill the blebs 508. A student or trainee can then prick one of the blebs 508, or stick sites, with a lancet, extract a droplet of blood serum, and test the glucose level of the blood serum using a glucometer 202 or simulated glucometer. The simulated blood serum may
20 include a sealant configured to seal off holes poked into the blebs 508, or the blood serum may include properties causing the blood serum to coagulate, or clot, around holes poked through the blebs 508.

[000108] For a simulated finger including two blebs with each having a separate fillable reservoir, the blebs could be filled with different simulated blood serums. The simulated finger
25 can be placed on a patient/subject's finger, and a student or trainee can prick the radial side bleb with a lancet to test one of the fluids. The simulated finger can then be removed and placed on the corresponding finger of the patient/subject's other hand. The student or trainee can then prick the radial side bleb with a lancet to test the other fluid. Alternatively, the student or trainee can prick the ulnar side bleb for both tests, switching hands in between, to test the two different
30 fluids, or the simulated finger could remain on the same finger with the student or trainee pricking the radial side bleb for one test and the ulnar side bleb for the other.

[000109] Fig. 36a shows an optional protective shield 534 with an outwardly-convex configuration adapted for placement over a finger. The shield 534 can comprise sheet metal, rigid plastic, puncture-resistant fabric or some other suitable puncture-resistant material. The

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shield 534 functions to avoid lacerating a test patient or mannequin if a lancet penetrates the interface 504. Alternatively, a suitable shield can be integrally formed with the interface 504.

[000110] Figs. 37-43 show an alternative aspect of the present invention comprising a glucometer simulation and training system 602 with a patient, a blood serum interface 604, and an analyzer. The patient may be an individual or a mannequin, and at least one of the patient's fingers is required for the glucometer simulation and training system 602. The analyzer may be a glucometer such as the portable example shown at 202, a computer programmed to simulate fluid analysis, or another type of fluid analyzer.

[000111] The blood serum interface 604 in this embodiment includes a finger splint 606 with a layer of protective material 612 to protect a patient/subject's finger 626 and a membrane capable of forming blebs 608. The blebs 608 form adjacent to the protective layer 612 and are configured for holding semi-viscous fluid 610 simulating blood. The fluid 610 can include appropriate physiological composition characteristics, such as blood-sugar levels for glucose testing with a glucometer. Alternatively, the fluid, or simulated blood serum 610, can be inert with characteristics preprogrammed and simulated by a computer 6.

[000112] The protective layer 612 may consist of metals, hard plastics, and/or other materials capable of protecting a finger from being cut. Existing splints (e.g., DIP splints for ruptured extensor tendons, such as Stax-type splints) are readily available for use as a platform for adding simulated blood blebs. This embodiment of the blood serum interface 604 can be placed on any finger 626 of a mannequin or simulated patient, with the middle (3rd) finger or ring (4th) finger being the preferred placement. Different sizes of finger splints 606 may be utilized to better fit different finger sizes. It is important for the finger splint 606 to extend beyond the DIP joint of the patient/subject's finger 626 to help ensure that the interface 604 will stay on the finger 626 when the finger 626 is handled by a student or trainee. It is also preferable to have an open nail portion 618 or a nail-like indentation on the finger splint 606 to make the simulation more anatomically correct and to aid in placing the finger splint 606 in the correct orientation on the patient/subject's finger 626. Figs. 37-43 show an embodiment of the blood serum interface 604 having an open nail portion 618.

[000113] Preferably, the membrane is made of flexible, self-sealing material, capable of sealing itself after being punctured. In this embodiment, two blebs 608 form adjacent to the protective layer 612, one on the radial side and one on the ulnar side of the finger. The blebs 608 cover a large portion of the radial and ulnar sides of the distal phalanx, below the nail. In real practice, when using a glucometer to test blood-glucose levels, a patient or subject's finger is pricked with a lancet on the side of the finger in order to avoid nerve damage to the finger and to minimize

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pain. Thus, a glucometer training system 602 with blebs 608 on the side of the finger configured for being pricked with a lancet 614 provides an anatomically correct simulation.

[000114] In this embodiment, the two blebs 608 share a common reservoir 620 capable of being filled with simulated blood serum 610. The blebs 608 and common reservoir 620 may be adhered to the finger splint 606, or they may form a separate piece that clips over or attaches to the finger splint 606. Pressure can be applied to the common reservoir 620 to simultaneously fill both blebs 608 with fluid 610 from the reservoir 620. Placement of the common reservoir 620 can either be on the dorsal side or the ventral side of the finger splint 606. The common reservoir 620 can either be injectable with a syringe 632 or configured for filling with blood serum 610 via IV connectors, Leur-Lok hub connectors, or other tubing or bladder connectors. The common reservoir 620 may or may not have a specific fill site 622. Figs. 37-43 show an interface 604 having a common reservoir 620 on the ventral side of a finger splint 606 with a fill site 622 for filling with simulated blood serum 610.

[000115] To simulate testing blood glucose levels, an instructor can fill the common reservoir 620 with simulated blood serum 610 and apply pressure to the reservoir 620 to fill the blebs 608 with blood serum 610. The finger splint 606 can be placed on a patient or mannequin's finger 626 either before or after applying pressure to the reservoir 620 to fill the blebs 606 with blood serum 610. A student can then prick a bleb 608 with a lancet 614, extract a droplet 616 of blood serum 610, and test the glucose level of the blood serum 610 using a glucometer 202 or simulated glucometer. The simulated blood serum 610 may include a sealant configured to seal off holes poked into the blebs 608, or the blood serum 610 may include properties causing the blood serum 610 to coagulate, or clot, around holes poked through the blebs 608.

[000116] Alternatively, a variation of the glucometer simulation and training system 652 could include a blood serum interface 654 with just one bleb 658 and a separate filling reservoir 670.

In an embodiment having one bleb 658 with a separate filling reservoir 670, the layer of protective material 662 may only cover the side of the patient/subject's finger 626 which mounts the bleb 658, leaving the other side of the distal phalanx open, as shown in Figs. 44-49. This embodiment would also include hard material on the opposite side of the finger 626 from the bleb 658 to provide a cantilever effect for the interface 654. This embodiment could be achieved by attaching a bleb 658 with a fillable reservoir 670 to the bottom of a Stax-type splint 656, and placing the splint 656 on a patient/subject's finger 626 turned 90 degrees. By turning the splint 656 sideways, the bleb 658 is located on the side of the patient/subject's finger 626 while still having at least part of the patient/subject's fingernail visible, making the simulation more anatomically correct.

[000117] Another embodiment of a glucometer simulation and training system 702, shown in Figs. 50-52, includes a patient, a blood serum interface 704, and an analyzer. The patient may be an individual or a mannequin, and at least one of the patient's fingers is required for the glucometer simulation and training system 702. The analyzer may be a glucometer such as the portable example shown at 202, a computer programmed to simulate fluid analysis, or another type of fluid analyzer.

[000118] This embodiment of a blood serum interface 704 includes a finger splint 706 with a layer of protective material 712. The interface 704 also includes a membrane adhered to the inside and to the ventral side of the finger splint 706 with an unadhered portion of the membrane on each of the radial and ulnar sides of the finger splint 706. The unadhered portions of the membrane are configured to form blebs 708 capable of holding semi-viscous fluid 710 simulating blood. The blebs 708 cover a large portion of the radial and ulnar sides of the distal phalanx of the finger. When really using a glucometer to test blood-glucose levels, a patient or subject's finger is pricked with a lancet on the side of the finger in order to avoid nerve damage to the finger and to minimize pain. Thus, a glucometer training system 702 with blebs 708 on the side of the finger configured for being pricked with a lancet 714 provides an anatomically correct simulation.

[000119] The protective layer 712 of the finger splint 706 may consist of metals, hard plastics, and/or other materials capable of protecting a finger from being cut. Existing splints (e.g., DIP splints for ruptured extensor tendons, such as Stax-type splints) are readily available for use as a platform for adding simulated blood blebs. The layer of protective material 712, in this embodiment, has at least one perforation 713 on each of the radial and ulnar sides of the finger splint 706, leading to the unadhered portions of the membrane, or blebs 708. The perforations 713 are large enough to allow a syringe needle to fit through but small enough to not allow a lancet 714 to fit through, protecting the patient/subject's finger.

[000120] Prior to training, the blebs 708 of the blood serum interface 704 can be filled with simulated blood serum 710 from the inside of the finger splint 706, using a syringe 732. The fluid 710 can include appropriate physiological composition characteristics, such as blood-sugar levels for glucose testing with a glucometer 202. Alternatively, the fluid, or simulated blood serum 710, can be inert with characteristics preprogrammed and simulated by a computer 6. The simulated blood serum 710 may include a sealant configured to seal off holes poked into the blebs 708, or the blood serum 710 may include properties causing the blood serum 710 to coagulate, or clot, around holes poked through the blebs 708.

[000121] The blebs 708 can be filled by placing a syringe needle through the membrane, through a perforation 713, and into an unadhered portion of the membrane; filling the bleb 708 with blood serum 710 from the syringe 732; and removing the syringe 732. Either one or both of the blebs 708 can be filled with blood serum 710 in this manner in preparation for training. After
5 at least one bleb 708 has been filled with blood serum 710, the finger splint 706 can be placed on a patient/subject's finger. A student or trainee can then prick the outside of the bleb 708 with a lancet 714, obtain a droplet 716 of blood serum 710, and test the glucose level of the blood serum 710 using a glucometer 202 or simulated glucometer, thus simulating the actual process for checking someone's blood-glucose level.

10 [000122] The finger splint 706 can be placed on any finger of a mannequin or simulated patient, with the middle (3rd) finger or ring (4th) finger being the preferred placement. There may be different sizes of finger splints 706 to better fit different finger sizes. It is important for the finger splint 706 to extend beyond the DIP joint of the patient/subject's finger to help ensure that the splint 706 will stay on the finger when the finger is handled by a student or trainee.
15 Additionally, it is preferable to have an open nail portion 718 or a nail-like indentation on the finger splint 706 to make the simulation more anatomically correct and to aid in placing the finger splint 706 in the correct orientation on the patient/subject's finger. Figs. 50-52 show the finger splint 706 having an open nail portion 718.

[000123] Another alternative embodiment of a glucometer simulation and training system 802,
20 shown in Fig. 53, includes a patient, a blood serum interface 804, and an analyzer. The patient may be an individual or a mannequin, and at least one of the patient's fingers is required for the glucometer simulation and training system 802. The analyzer may be a glucometer such as the portable example shown at 202, a computer programmed to simulate fluid analysis, or another type of fluid analyzer.

25 [000124] The blood serum interface 804 includes a finger splint 806 with a layer of protective material 812 and a bleb 808 configured for holding a semi-viscous fluid 810 simulating blood. The protective layer 812 may consist of metals, hard plastics, and/or other materials capable of protecting a finger from being cut. Existing splints (e.g., DIP splints for ruptured extensor tendons, such as Stax-type splints) are readily available for use as a platform for adding a
30 simulated blood bleb. The bleb 808, in this embodiment, spans both the inside and outside of the protective layer 812 of the finger splint 806. The protective layer 812 includes perforations 813 large enough for a syringe needle 834 to go through but small enough to prevent a lancet 814 from going through, protecting a patient/subject's finger 826 from being cut.

[000125] The bleb 808 can be filled with simulated blood serum 810 from the inside of the finger splint 806 with a syringe 832 by pointing the syringe needle 834 through one of the perforations 813 in the protective layer 812. The fluid 810 can include appropriate physiological composition characteristics, such as blood-sugar levels for glucose testing with a glucometer.

5 Alternatively, the fluid, or simulated blood serum 810, can be inert with characteristics preprogrammed and simulated by a computer 6. The simulated blood serum 810 may include a sealant configured to seal off holes poked into the bleb 808, or the blood serum 810 may include properties causing the blood serum 810 to coagulate, or clot, around holes poked through the blebs 808.

10 [000126] After being filled with blood serum 810, the blood bleb 808 sits underneath the patient/subject's finger 826. A filled bleb 808 can be pricked with a lancet 814, and a droplet 816 of the blood serum 810 can be tested for glucose levels using a glucometer 202 or simulated glucometer. The finger splint 806 can be placed on any finger 826 of a mannequin or simulated patient, with the middle (3rd) finger or ring (4th) finger being the preferred placement. There
15 may be different sizes of finger splints 806 to better fit different finger sizes. It is important for the finger splint 806 to extend beyond the DIP joint of the patient/subject's finger 826 to help ensure that the interface 804 will stay on the finger 826 when the finger 826 is handled by a student or trainee. It is also preferable to have an open nail portion 818 or a nail-like indentation on the finger splint 806 to make the simulation more anatomically correct and to aid in placing
20 the finger splint 806 in the correct orientation on the patient/subject's finger 826. Fig. 53 shows the finger splint 806 having an open nail portion 818.

[000127] Alternatively, the finger splint 806 could be placed on the patient/subject's finger 826 rotated 90 degrees. Turning the splint 806 sideways places the bleb 808 on the side of the patient/subject's finger 826, which is where an actual finger would be pricked when testing for
25 blood glucose levels. With an open-nail 818 finger splint 806 configuration, at least part of the patient/subject's fingernail would be visible with the splint 806 turned sideways. A visible fingernail helps with training where to stick a finger when obtaining a droplet of blood serum for blood glucose testing.

[000128] In an embodiment of the glucometer simulation and training system 902, the blood
30 serum interface 904 includes a simulated finger 906. The simulated finger 906, made up of a soft, flesh-like material, includes two proximal end openings, a finger opening for placement over a patient/subject's finger and a reservoir opening 942. The flesh-like material could be made up of polyurethane or other soft plastics or rubbers, such as silicone, latex, butyl rubber, etc. The proximal end reservoir opening 942 of the simulated finger 906 must be sealed in order

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for its fillable reservoir to hold simulated blood serum without leaking. Another layer of soft flesh-like material and/or sealant can be sealed to the back of the reservoir opening 942 of the simulated finger 906. Alternatively, a sealing wedge 936, shaped to match up with the reservoir opening 942 of the simulated finger 906 and preferably made of the same flesh-like material as the simulated finger 906, can be wedged into the reservoir opening 942 of the simulated finger 906. The wedge 936 seals off the fillable reservoir, allowing the reservoir to adequately hold simulated blood serum. Sealant may optionally be applied to the wedge 936 for optimum sealing.

[000129] Since the simulated finger 906 is made of soft material, the blood serum interface 904

in this embodiment includes a layer of protective material 934 or a thimble-like structure to protect the patient/subject's actual finger from being cut. The protective layer, or protective shield 934, may be made of rigid plastic, metal, fabric capable of resisting puncture, or some other puncture-resistant material. The protective layer 934 may cover only the areas of the patient/subject's finger directly underneath the blebs and reservoir of the simulated finger 906 to protect the patient/subject's actual finger from being cut with a lancet or syringe needle.

Alternatively, the protective layer 934 may cover the entire surface area of the inside of the simulated finger 906, providing maximum protection to the patient/subject's actual finger. The layer of protective material 934 can either be integrated into the design of the simulated finger 906 or be a separate piece configured for sliding underneath the simulated finger 906.

[000130] If the protective layer 934 is not integrated into the structure of the simulated finger 906, the protective layer 934 can be connected to a wedge 936 for sealing the proximal end reservoir opening 942 of the simulated finger 906. A protective layer and sealing wedge combination 938 provides protection to the patient/subject's actual finger from being cut, and it also seals the reservoir opening 942 of the simulated finger 906. A protective shield and sealing wedge combination 938 is designed to slide underneath a simulated finger like embodiment 506 with the external surface of the protective shield 934 matching up with the internal surface of the finger opening of the simulated finger. The sealing wedge portion 936 of the protective shield and wedge combination 938 fits into and seals the proximal end reservoir opening 942 of the simulated finger 906. Additional sealant may optionally be applied to the wedge 936.

[000131] Figs. 54-56 show the blood serum interface 904 including a protective shield and wedge combination 938 that is configured for being inserted into the simulated finger 906. In this embodiment, the wedge portion 936 of the shield/wedge combination 938 attaches to the protective shield portion 934 via a channel 940. When the shield/wedge combination 938 is inserted into the simulated finger 906, the channel 940 rests against the proximal end of the

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simulated finger 906, the wedge 936 is inserted into the open reservoir and seals off the reservoir opening 942 of the simulated finger 906, and the protective shield 934 lays directly against the interior surface of the finger opening of the simulated finger 906 arched in the shape of an actual finger.

5 [000132] This embodiment of the simulated finger 906 includes reticulated, open-cell foam 924 inserted within the empty spaces in the blebs and fillable reservoir. The foam 924 must be reticulated and open-cell, such as reticulated polyurethane foam, to allow the simulated blood fluid to flow freely through the foam. The simulated finger 906 can be injected with foam-forming material, or pre-manufactured foam can be placed inside the blebs and fillable reservoir
10 of the simulated finger. A foam core 924 within the blebs and fillable reservoir helps to evenly disperse the blood serum, minimizing air pockets and helping to ensure that a droplet 916 of blood serum will form at whichever part of the bleb a student or trainee pricks.

[000133] Additionally, the foam 924 aids in making the simulated finger 906 look and feel like an actual finger, and it allows the outer layer of soft, flesh-like material forming the blebs to be
15 thinner. A thin outer layer of skin-like material on the blood serum interface 904 is important for glucometer simulation because of the popularity of spring-loaded lancets in real practice. Spring-loaded lancets each have a button that, when pressed, shoots out a small needle or blade for puncturing skin for obtaining small blood samples. Typical spring-loaded lancets only expose about three millimeters of their needles, and as little as one millimeter of a lancet needle
20 may actually pierce the skin. Thus, it is important for the simulated finger 906 to have a thin outer layer of flesh-like material forming the blebs so that the blood serum interface 904 can be used for simulating glucometer testing with real spring-loaded lancets. Fig. 56 shows a cross-sectional view of the simulated finger 906 having reticulated foam within the fluid-holding portions of the simulated finger 906. Reticulated, open-cell foam 924 can be inserted into the
25 fluid-holding portions of any of the above-mentioned blood serum interfaces.

[000134] Simulated fingers 906, 506 are intended for multiple uses. To allow for multiple uses, the puncture holes in the blebs must be properly sealed after use. The flesh-like material preferably has self-sealing properties so that the puncture hole closes after a blood serum droplet is obtained. However, sealant must also be applied to the puncture site so that the puncture hole
30 does not leak when pressure is applied to the bleb. Liquid sealant, such as sealant used for patching holes in flat tires, could be internally integrated into the inside of the simulated finger blebs and reservoir or integrated into the simulated blood serum. Alternatively, a sealant could be externally applied to the puncture hole after use of the simulated finger 906, 506 and given

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time to dry prior to subsequent use. Different embodiments of simulated fingers 906, 506 may be configured for single use.

[000135] The glucometer training systems 402, 420, 440, 502, 602, 652, 702, 802, and 902 are adapted for use with a wide variety of training protocols and procedures. Moreover, the components can be customized, e.g. with 3-D printing, for specific individuals and different digits. Still further, other training exercises and protocols within the scope of the present invention can simulate obtaining samples, e.g., fluid and tissue, for extracting medical information from real and virtual patients. Such sampling exercises can be used in conjunction with other training protocols, as described above. Moreover, fluid can be added via various connections, such as IV tubing connected to the bleb. Additionally, fluids simulating other relevant bodily fluids could be used instead of simulated blood serum for different types of medical training. Also, instead of using testing strips and a glucometer, droplets of blood serum could be taken in a capillary tube from the blood serum interface and brought into a lab for microchemistry and/or histology testing.

[000136] Still further, the fluid and other simulation characteristics can be located at various parts of a mannequin. For example, mannequin arms, elbows, wrists, etc. can be placed within the mannequins for supplying simulated fluid. Still further, the connections can be accomplished via commonly available medical devices, including standard Leur-Lok hub connectors, IV connections, etc.

[000137] Life-Pak simulation units, such as that shown in Fig. 15, can be utilized for simulation and training. Dedicated units can be labeled "Simulation Only." Other functions, such as defibrillator simulations can be provided with such units. Vital sign machines can be simulated with hydraulic models providing pulsing and respiratory simulations, all of which are variable and controllable. Beeps can be utilized to indicate pulse and other functions, including emergency "no pulse" conditions indicating emergency measures. Temperature probes and pulse-oximetry functions can be included. Simulated electronic medical records (EMRs) can be output. The systems described herein can be installed on new "OEM" mannequins, or retrofit onto existing mannequins.

[000138] It is to be understood that the invention can be embodied in various forms, and is not to be limited to the examples discussed above. Other components and configurations can be utilized in the practice of the present invention. For example, various combinations of mannequins, simulated patients, computers, outputs, signals, sensors, memories, software, inputs, and diagnostic instruments can be utilized in configuring various aspects of the system 2 comprising the present invention.

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CLAIMS

Having thus described the invention, what is claimed as new and desired to be secured by Letters Patent is:

1. A fluid analysis simulation and training system comprising:
 - 5 an interface configured for placement over a simulated patient or mannequin's finger; wherein said interface includes a simulated finger having at least one bleb configured for containing a quantity of liquid simulating a patient fluid;
 - an extracting instrument configured for puncturing and extracting said simulated patient fluid from said at least one bleb; and
 - 10 an analyzer configured for analyzing said extracted fluid.
2. The fluid analysis simulation and training system according to claim 1, wherein:
 - said simulated patient fluid is configured for simulating blood; and
 - said analyzer is configured for analyzing blood-glucose levels of said simulated blood.
- 15 3. The fluid analysis simulation and training system according to claim 1, wherein said interface further comprises:
 - a layer of protective material configured for protecting said simulated patient or mannequin's finger from being cut.
4. The fluid analysis simulation and training system according to claim 1,
 - 20 wherein said simulated finger further comprises:
 - a fillable reservoir connected to said at least one bleb configured for being filled with said simulated patient fluid; and
 - wherein said at least one bleb is configured for being refilled by applying pressure to said fillable reservoir.
- 25 5. The fluid analysis simulation and training system according to claim 4, wherein:
 - said simulated finger includes a proximal end reservoir opening; and
 - said interface further comprises a wedge configured for attachment to and sealing of said proximal end reservoir opening.
- 30 6. The fluid analysis simulation and training system according to claim 5, wherein:
 - said wedge is attached to a layer of protective material configured for protecting said simulated patient or mannequin's finger from being cut.

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7. The fluid analysis simulation and training system according to claim 1, wherein said simulated finger further comprises reticulated, open-cell foam within fluid-holding sections of said simulated finger.

8. The fluid analysis simulation and training system according to claim 1,
5 further comprising sealant configured for sealing puncture holes in said at least one bleb.

9. The fluid analysis simulation and training system according to claim 1, further comprising:

a computer configured for programming to simulate medical devices and procedures;

a first input subsystem connected to said computer and configured for providing input

10 corresponding to a simulated patient physiological condition;

an output subsystem including a monitor configured for displaying said simulated patient condition;

a second input subsystem connected to said computer and configured for receiving a simulated response to said patient condition;

15 said computer being configured for simulating an outcome based on said response and

displaying a corresponding patient outcome on said output monitor; and

an instructor interface adapted for controlling glucose simulations.

10. A fluid analysis simulation and training method including a simulated finger having at least one bleb, which method comprises the steps of:

20 filling said at least one bleb with simulated patient fluid;

placing said simulated finger on a simulated patient or mannequin's finger;

pricking one of said blebs with an extracting instrument;

extracting a droplet of said simulated patient fluid from said pricked bleb; and

an analyzer analyzing said extracted fluid.

25 11. The method according to claim 10, wherein said simulated finger further comprises a fillable reservoir connected to said at least one bleb.

12. The method according to claim 11, further comprising the steps of:

filling said fillable reservoir with simulated patient fluid; and

said filling said at least one bleb with simulated patient fluid comprises applying pressure
30 to said fillable reservoir, pushing said simulated patient fluid into said at least one bleb.

13. The method according to claim 11, wherein said simulated finger includes a proximal end reservoir opening, the method further comprising the step of:

sealing said simulated finger proximal end reservoir opening.

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14. The method according to claim 10, further comprising the steps of:
applying sealant to the outside of the puncture hole in said pricked bleb; and
allowing said sealant to dry prior to subsequent use of said simulated finger.

15. A fluid-holding simulated finger, which comprises:
5 at least one bleb configured for containing a quantity of liquid simulating a patient fluid;
and
wherein said at least one bleb is configured for being punctured with an extracting
instrument to extract said simulated patient fluid.

16. The fluid-holding simulated finger according to claim 15, further
10 comprising a layer of protective material configured for resisting puncture.

17. The fluid-holding simulated finger according to claim 15, further
comprising:
a fillable reservoir connected to said at least one bleb configured for being filled with said
simulated patient fluid; and
15 wherein said at least one bleb is configured for being refilled by applying pressure to said
fillable reservoir.

18. The fluid-holding simulated finger according to claim 17, further
comprising:
a proximal end reservoir opening configured for being sealed with a sealing wedge.

19. The fluid-holding simulated finger according to claim 15, further
20 comprising reticulated, open-cell foam within fluid-holding sections.

20. The fluid-holding simulated finger according to claim 15, further
comprising sealant within said at least one bleb configured for sealing puncture holes in said at
least one bleb.

25

AMENDED CLAIMS

received by the International Bureau on 08 July 2015 (08.07.2015)

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The following will replace all prior versions, and listings, of claims in the application:

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1. A fluid analysis simulation and training system comprising:
an interface having a contoured surface configured for placement over a simulated patient
or mannequin's finger having a contoured finger surface;
wherein said interface contoured surface is configured for mating with said contoured
finger surface;
wherein said interface includes a simulated finger having at least one bleb configured for
containing a quantity of liquid simulating a patient fluid;
an extracting instrument configured for puncturing and extracting said simulated patient
fluid from said at least one bleb; and
an analyzer configured for analyzing said extracted fluid.

2. The fluid analysis simulation and training system according to claim 1,
wherein:

said simulated patient fluid is configured for simulating blood; and
said analyzer is configured for analyzing blood-glucose levels of said simulated blood.

3. The fluid analysis simulation and training system according to claim 1,
wherein said interface further comprises:

a layer of protective material configured for protecting said simulated patient or
mannequin's finger from being cut.

4. The fluid analysis simulation and training system according to claim 1,
wherein said simulated finger further comprises:

a fillable reservoir connected to said at least one bleb configured for being filled with said
simulated patient fluid; and

wherein said at least one bleb is configured for being refilled by applying pressure to said
fillable reservoir.

5. The fluid analysis simulation and training system according to claim 4,
wherein:

said simulated finger includes a proximal end reservoir opening; and
said interface further comprises a wedge configured for attachment to and sealing of said
proximal end reservoir opening.

6. The fluid analysis simulation and training system according to claim 5,
wherein:

said wedge is attached to a layer of protective material configured for protecting said
simulated patient or mannequin's finger from being cut.

7. The fluid analysis simulation and training system according to claim 1,
wherein said simulated finger further comprises reticulated, open-cell foam within fluid-holding
sections of said simulated finger.

8. The fluid analysis simulation and training system according to claim 1, further comprising sealant configured for sealing puncture holes in said at least one bleb.

9. The fluid analysis simulation and training system according to claim 1, further comprising:

a computer configured for programming to simulate medical devices and procedures;
a first input subsystem connected to said computer and configured for providing input corresponding to a simulated patient physiological condition;
an output subsystem including a monitor configured for displaying said simulated patient condition;
a second input subsystem connected to said computer and configured for receiving a simulated response to said patient condition;
said computer being configured for simulating an outcome based on said response and displaying a corresponding patient outcome on said output monitor; and
an instructor interface adapted for controlling glucose simulations.

10. A fluid analysis simulation and training method including a simulated finger having a contoured surface configured for mating with a contoured finger surface of a simulated patient or mannequin's finger, said simulated finger having at least one bleb, which method comprises the steps of:

filling said at least one bleb with simulated patient fluid;
placing said simulated finger on a simulated patient or mannequin's finger;
pricking one of said blebs with an extracting instrument;
extracting a droplet of said simulated patient fluid from said pricked bleb; and
an analyzer analyzing said extracted fluid.

11. The method according to claim 10, wherein said simulated finger further comprises a fillable reservoir connected to said at least one bleb.

12. The method according to claim 11, further comprising the steps of:
filling said fillable reservoir with simulated patient fluid; and

said filling said at least one bleb with simulated patient fluid comprises applying pressure to said fillable reservoir, pushing said simulated patient fluid into said at least one bleb.

5 13. The method according to claim 11, wherein said simulated finger includes a proximal end reservoir opening, the method further comprising the step of:
sealing said simulated finger proximal end reservoir opening.

10 14. The method according to claim 10, further comprising the steps of:
applying sealant to the outside of the puncture hole in said pricked bleb; and
allowing said sealant to dry prior to subsequent use of said simulated finger.

15 15. A fluid-holding simulated finger, which comprises:
at least one bleb configured for containing a quantity of liquid simulating a patient fluid;
wherein said simulated finger has a contoured surface configured for mating with a
contoured finger surface of a simulated patient or mannequin's finger; and
wherein said at least one bleb is configured for being punctured with an extracting
instrument to extract said simulated patient fluid.

20 16. The fluid-holding simulated finger according to claim 15, further
comprising a layer of protective material configured for resisting puncture.

25 17. The fluid-holding simulated finger according to claim 15, further
comprising:
a fillable reservoir connected to said at least one bleb configured for being filled with said
simulated patient fluid; and
wherein said at least one bleb is configured for being refilled by applying pressure to said
fillable reservoir.

30 18. The fluid-holding simulated finger according to claim 17, further
comprising:
a proximal end reservoir opening configured for being sealed with a sealing wedge.

19. The fluid-holding simulated finger according to claim 15, further comprising reticulated, open-cell foam within fluid-holding sections.

20. The fluid-holding simulated finger according to claim 15, further
5 comprising sealant within said at least one bleb configured for sealing puncture holes in said at least one bleb.

STATEMENT UNDER ARTICLE 19(1)

25 Accompanying the amendment filed concurrently or with, Applicant submits the following statement under Article 19 (1).

 Independent claims 1, 10, and 15 have been amended to more distinctly claim the present invention.

 The Greater Glasgow NHS Board reference cited by the Examiner discloses a medical teaching aid having a reservoir for an artificial blood substance with a pierceable latex coating to permit puncture
30 by a needle or incision device. The Greater Glasgow NHS Board reference also discloses that the teaching aid may be configured to simulate a finger. However, Greater Glasgow NHS Board does not disclose a simulated finger with a contoured surface configured for sliding over the contoured finger surface of an actual human finger or a mannequin's finger. Language has been added to the independent
35 claims to more clearly claim this placement of the simulated finger over a simulated patient or mannequin's finger.

 Thus, claims 1, 10 and 15 have been amended to more particularly distinguish them over the prior art of record (as identified in the written opinion of the International Searching Authority).

Respectfully submitted,



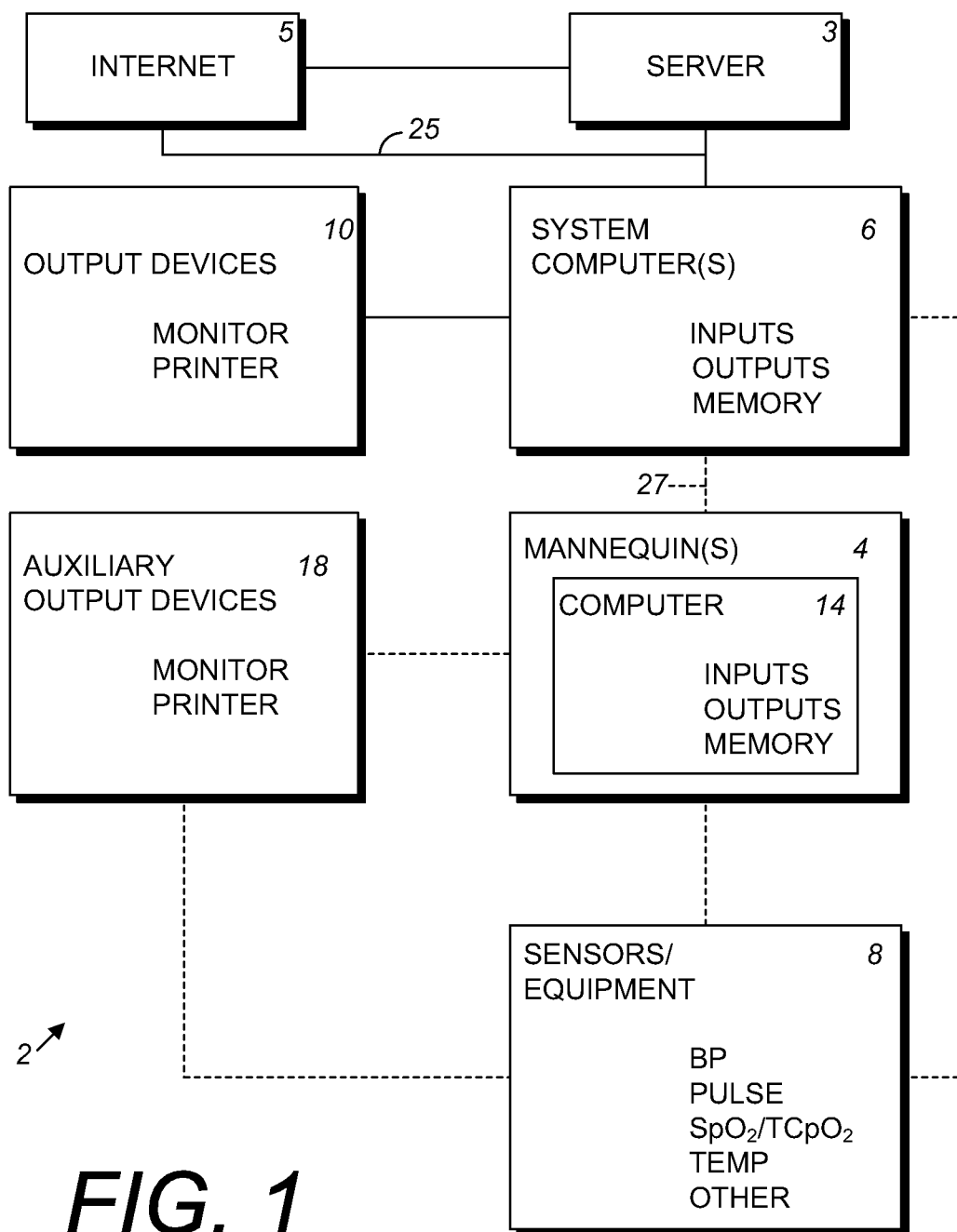
Mark Brown

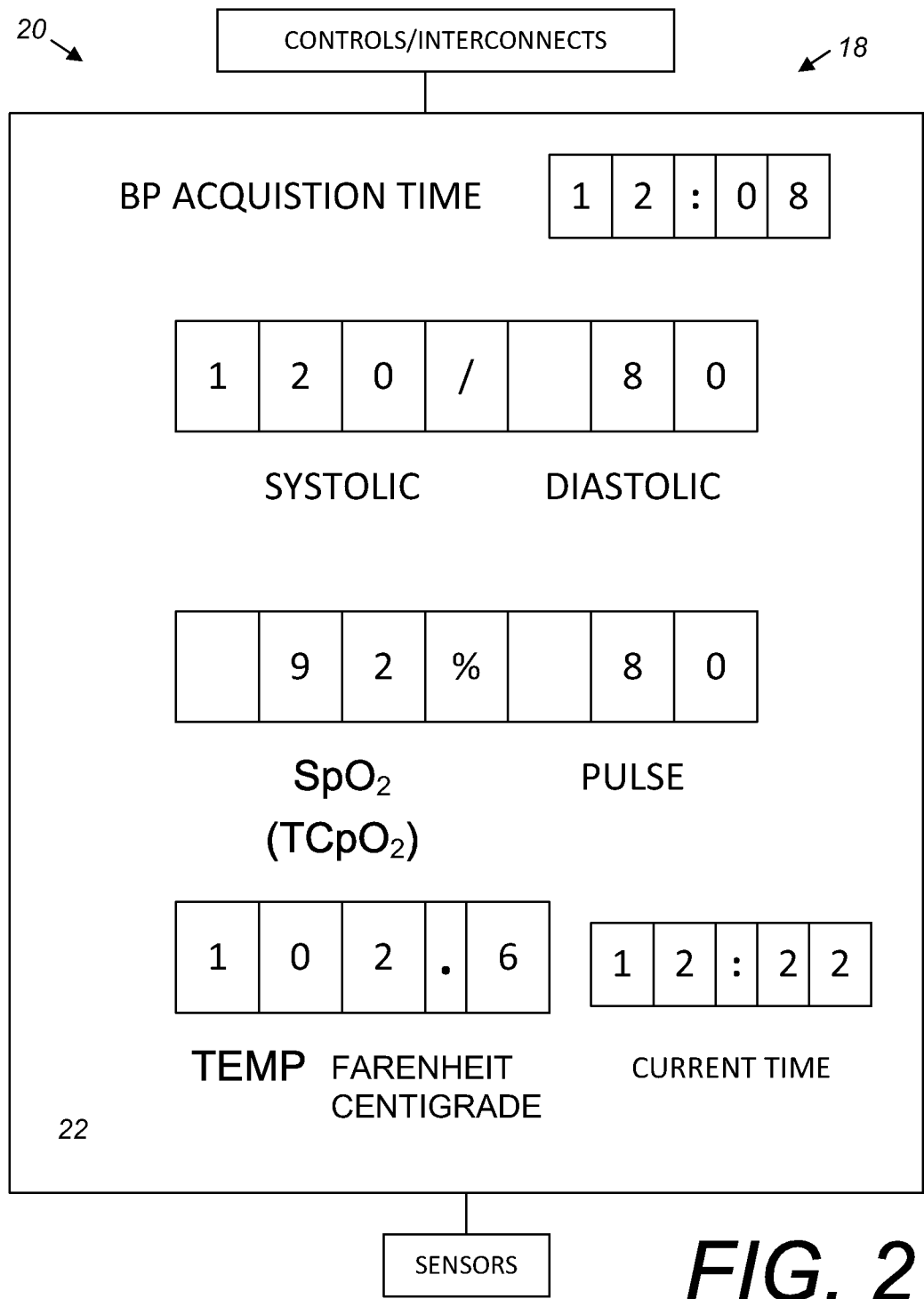
July 7, 2015

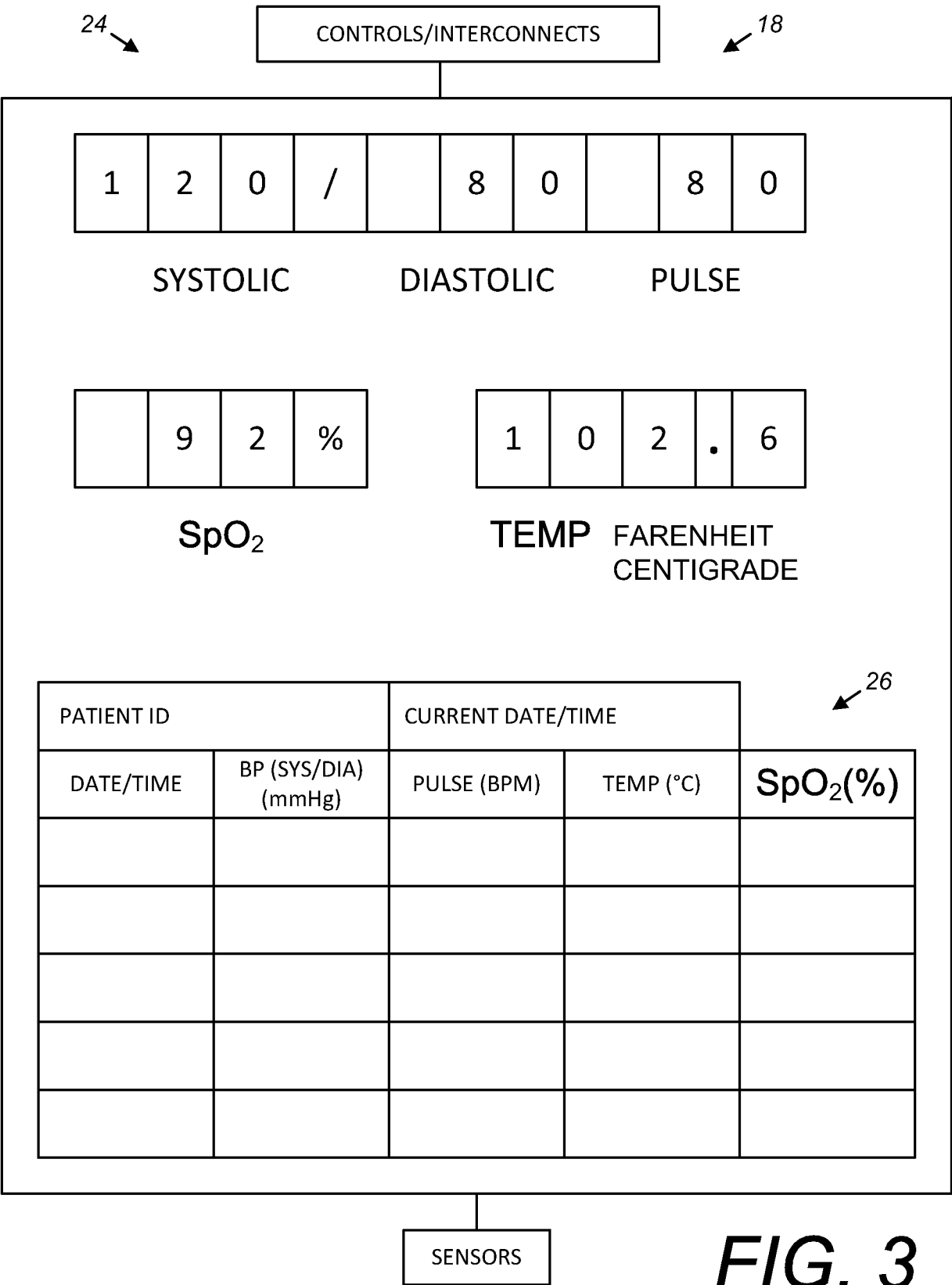
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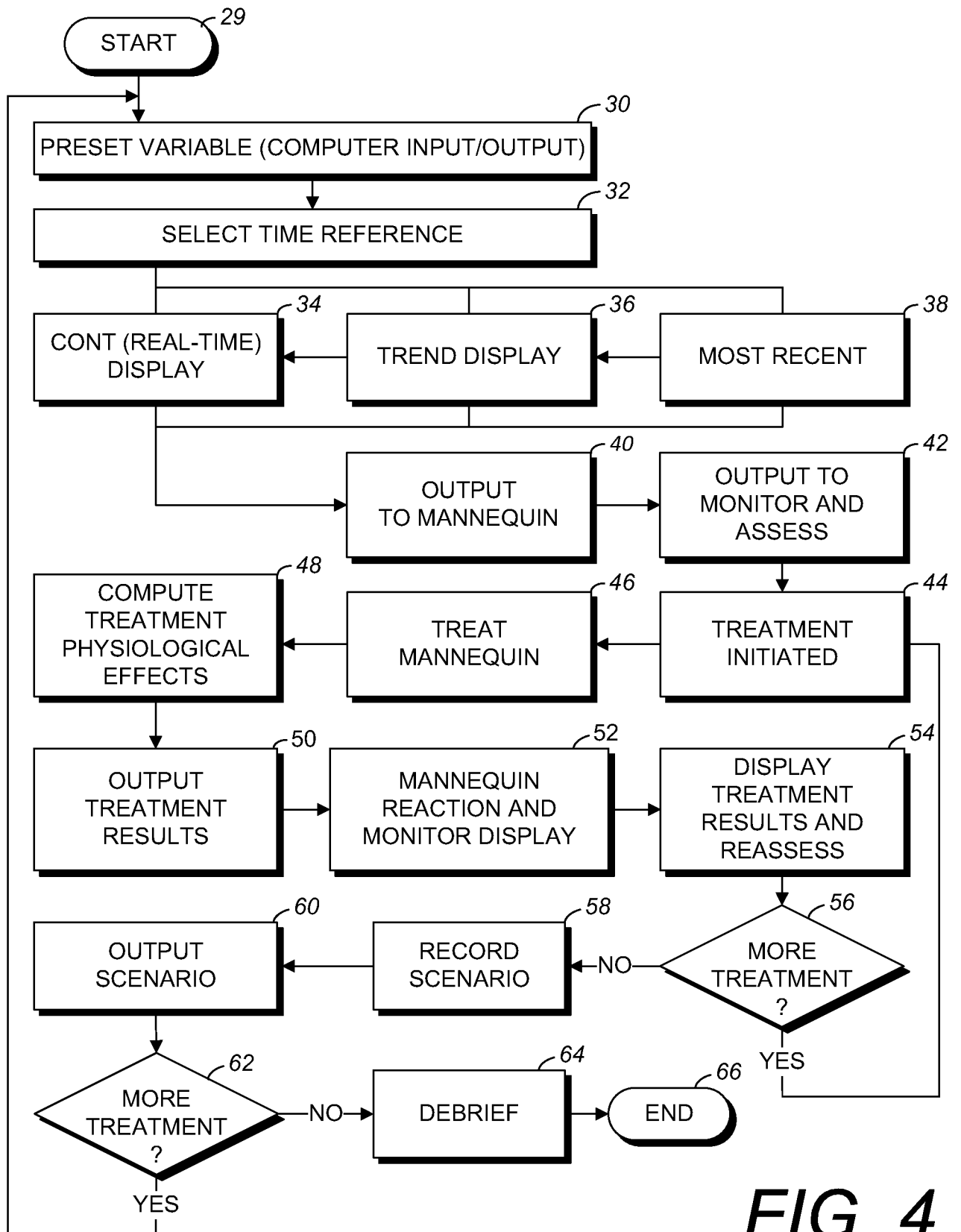
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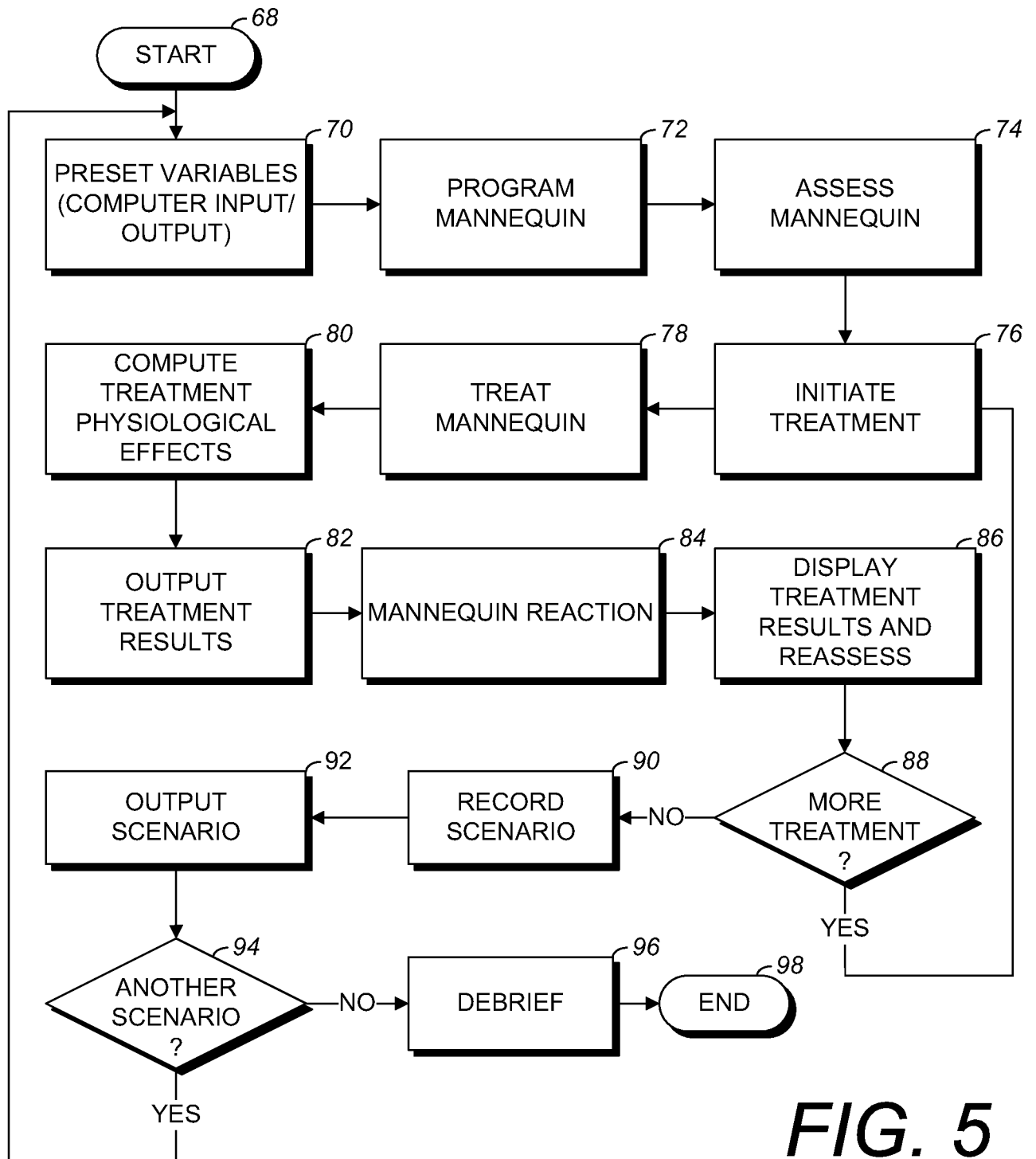
Attorneys for Applicant

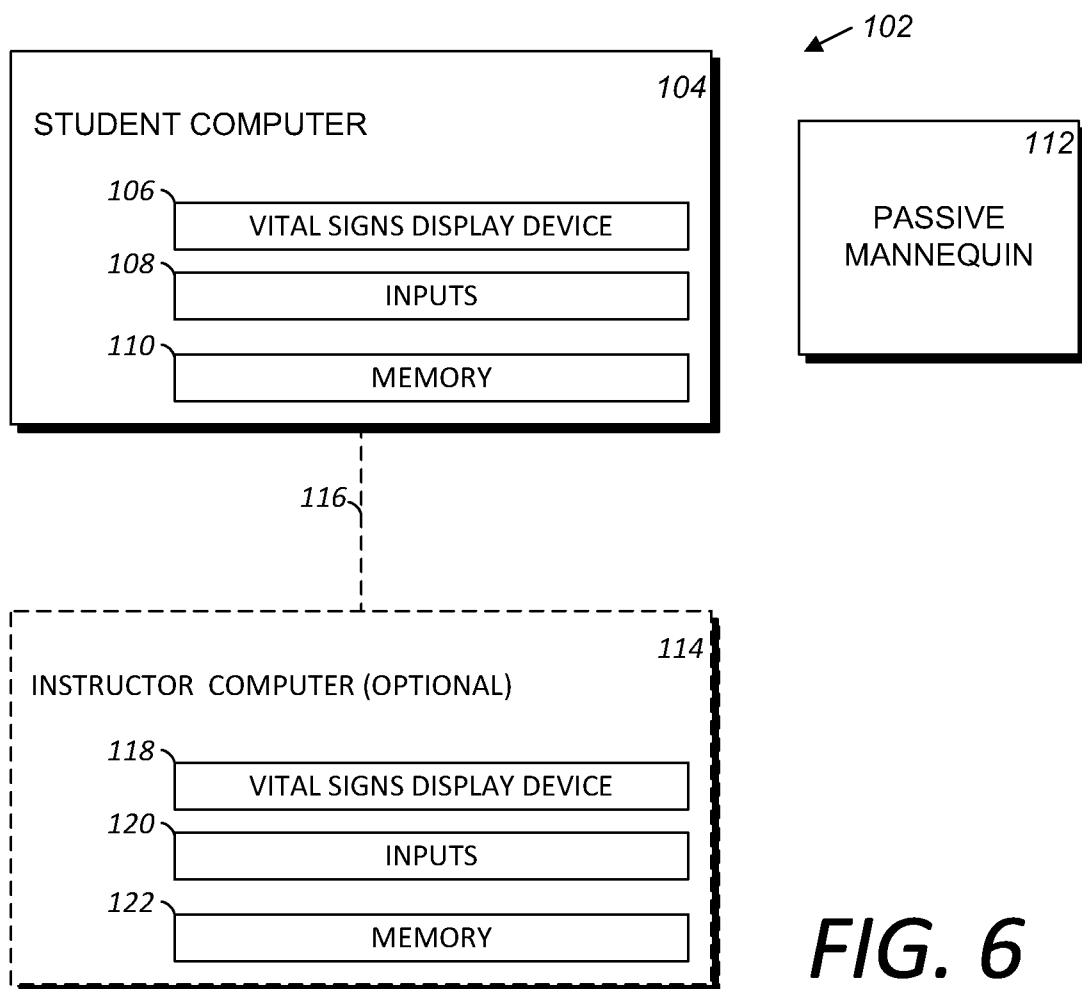




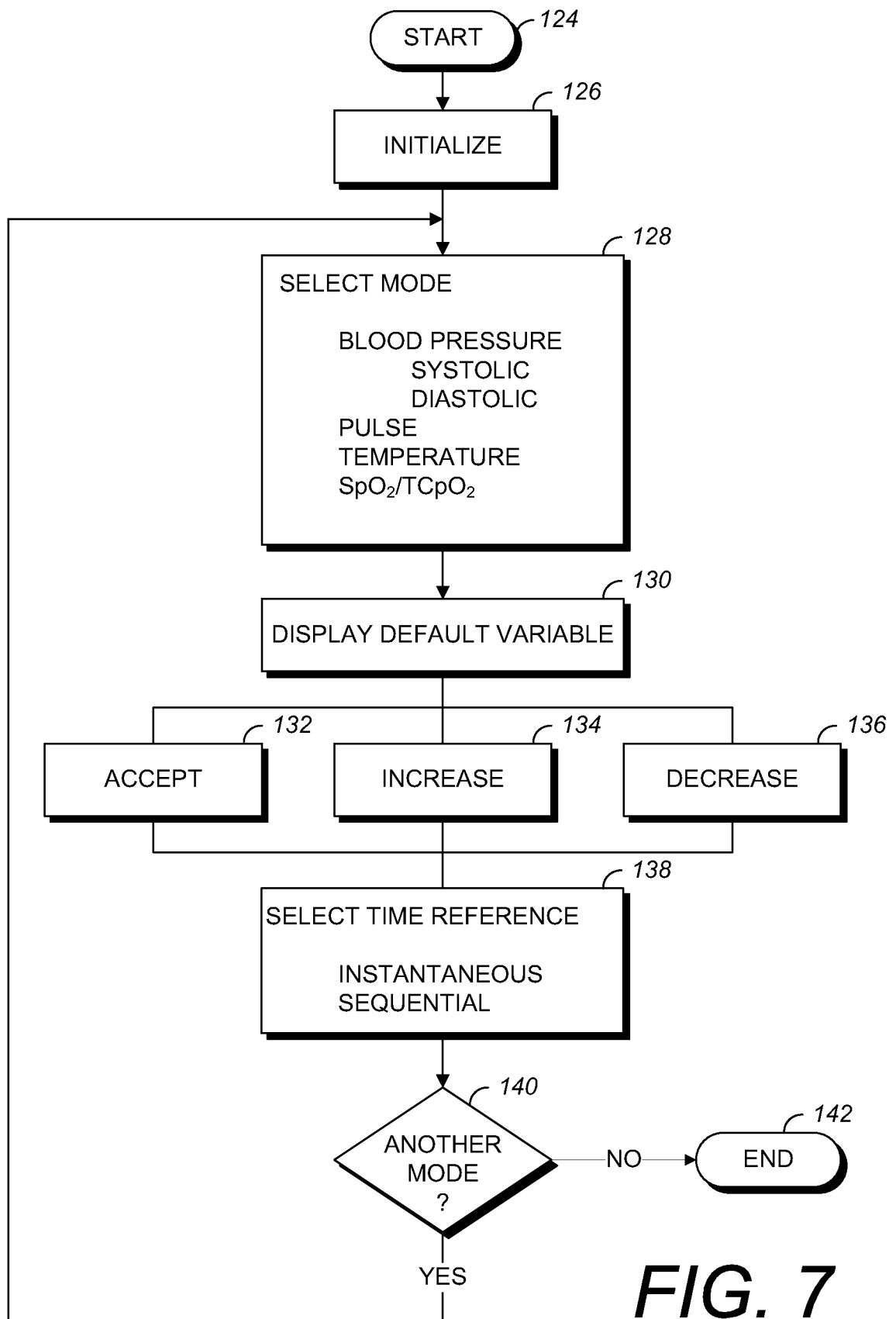


**FIG. 4**

**FIG. 5**

**FIG. 6**

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**FIG. 7**

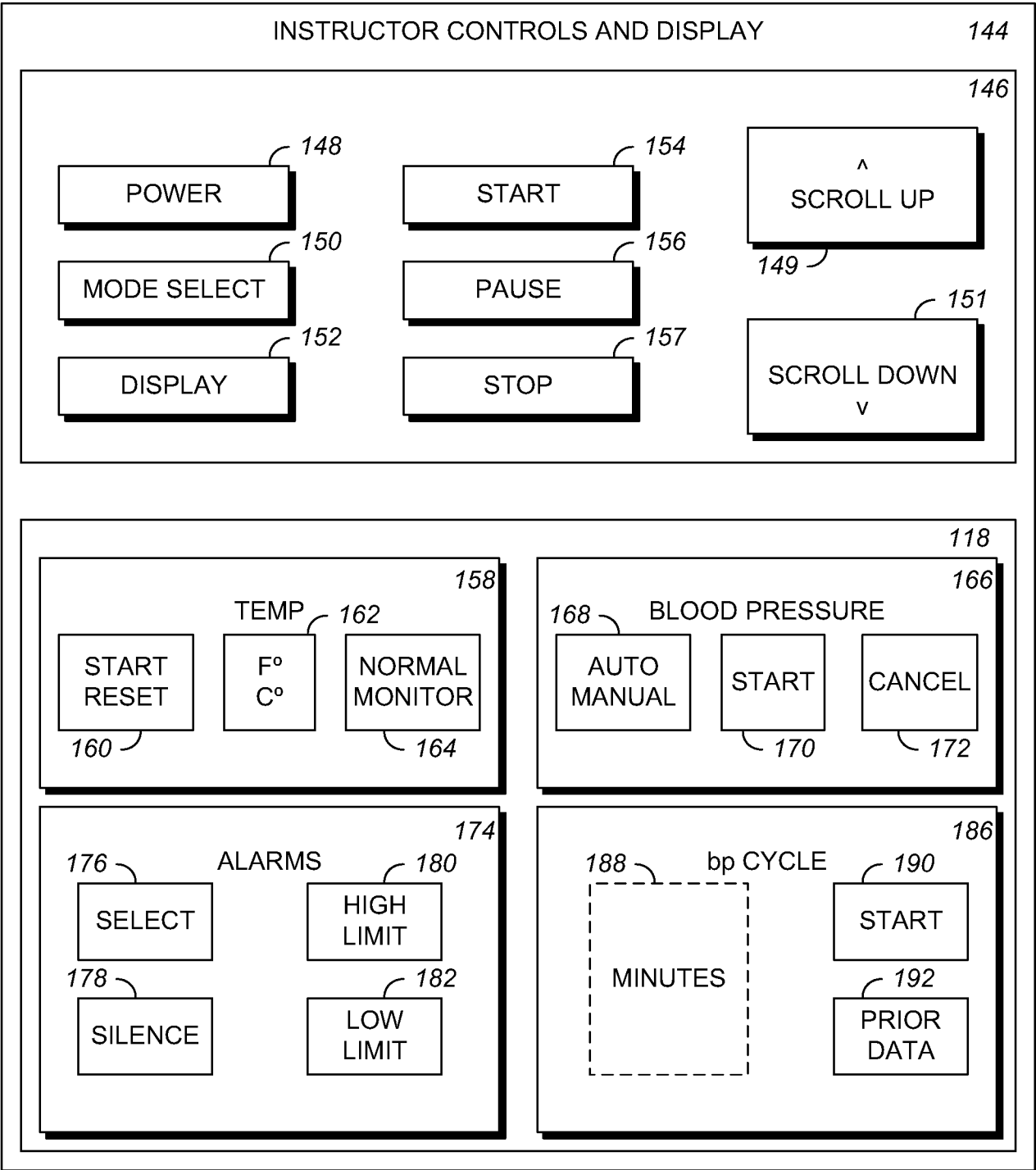
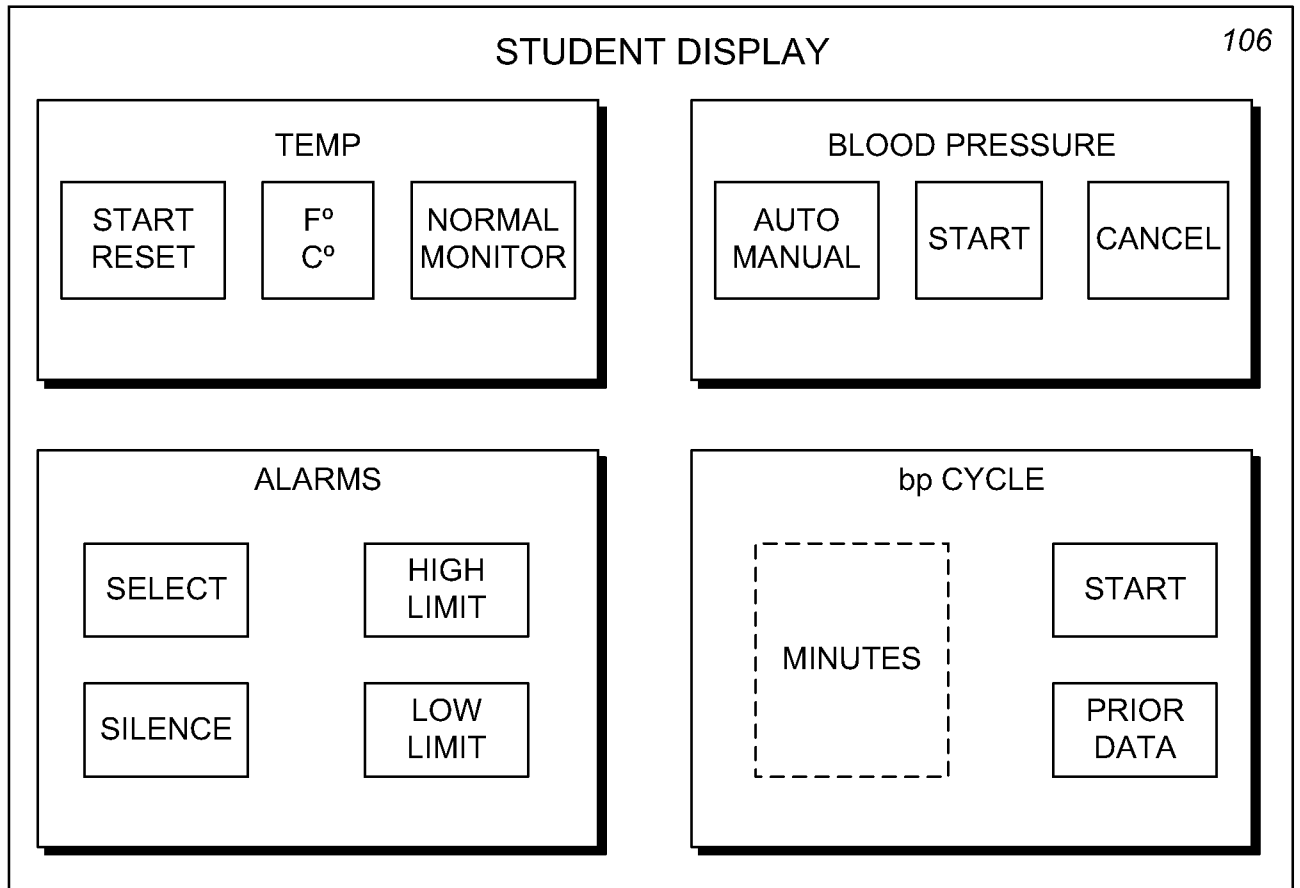


FIG. 8

**FIG. 9**

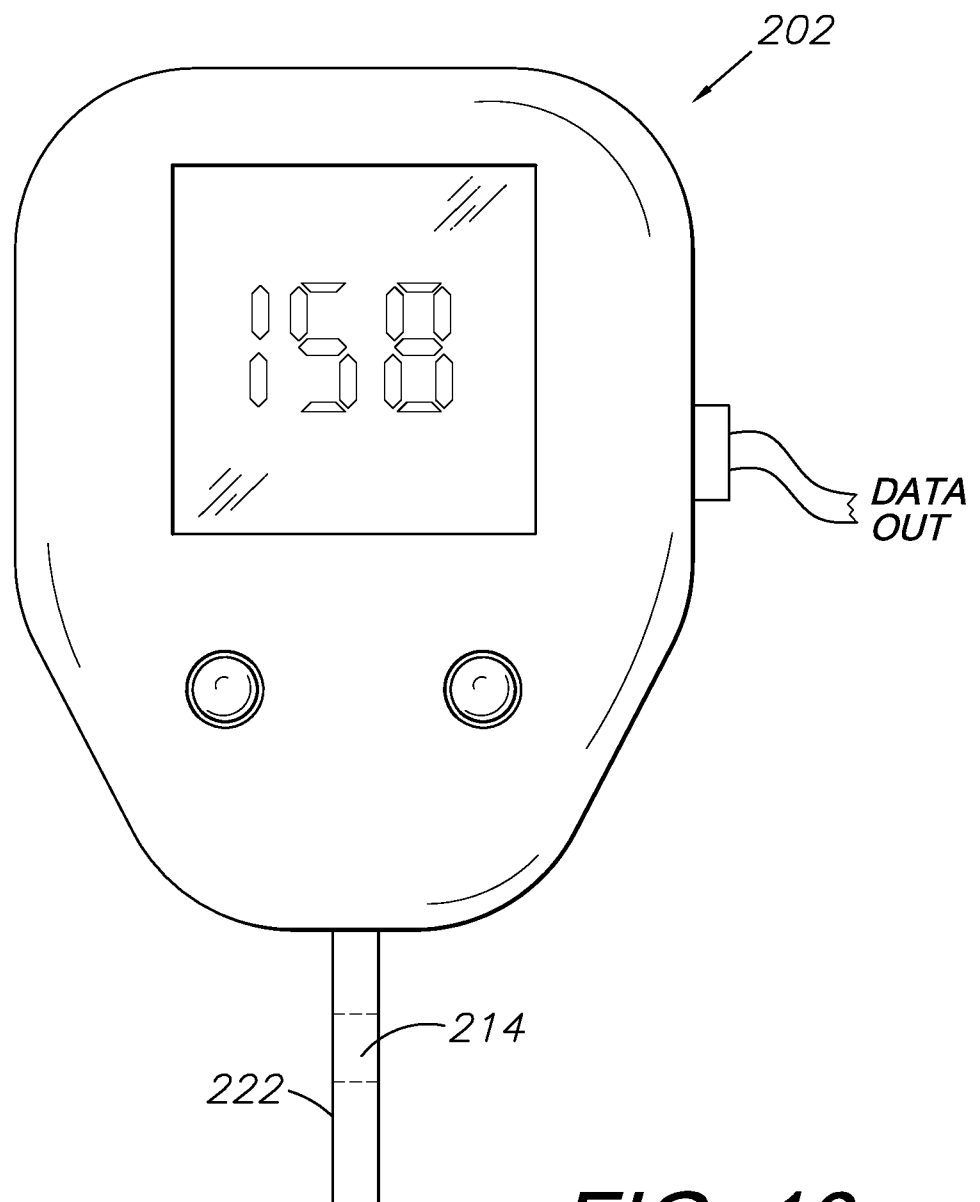
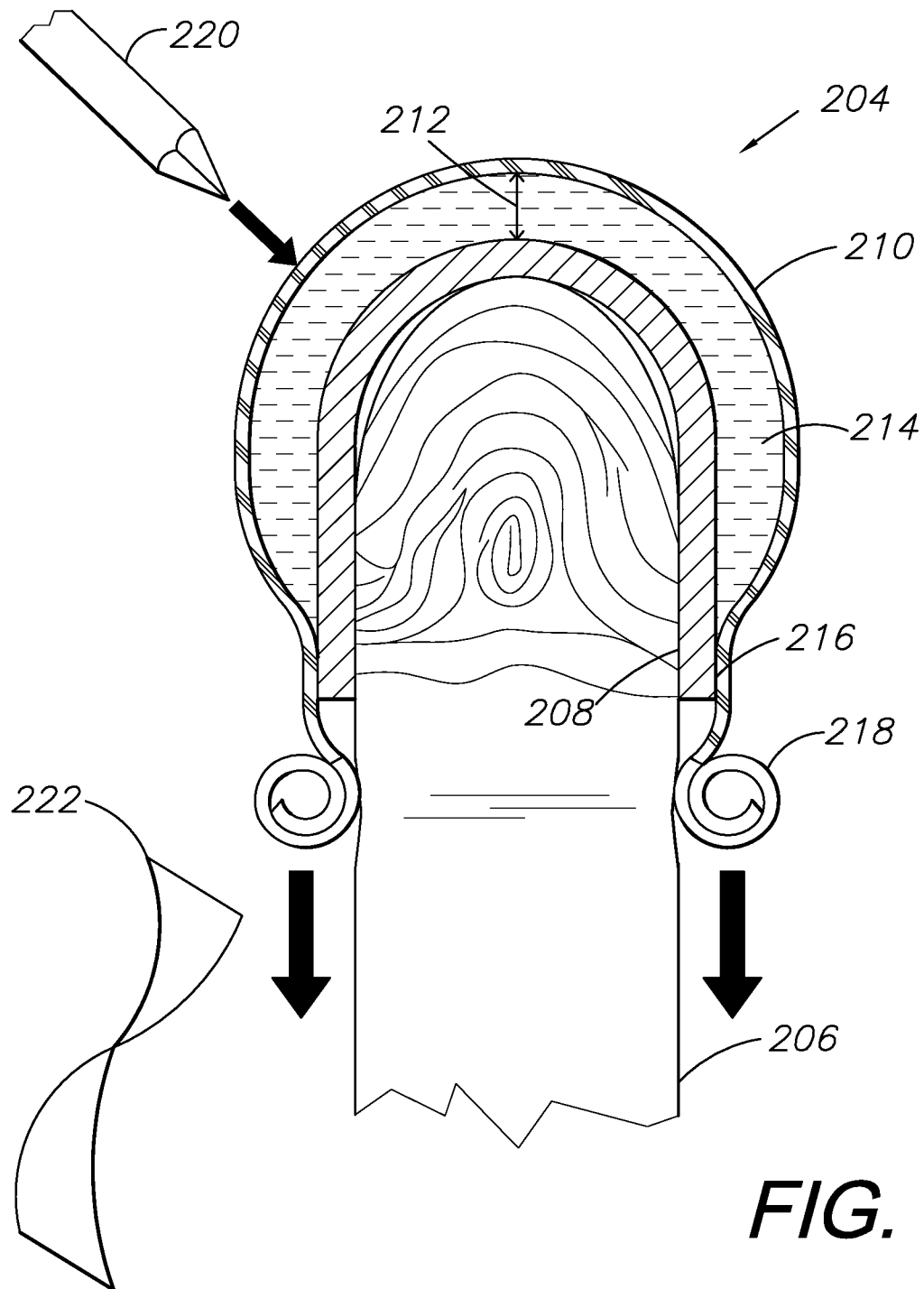


FIG. 10
PRIOR ART

**FIG. 11**

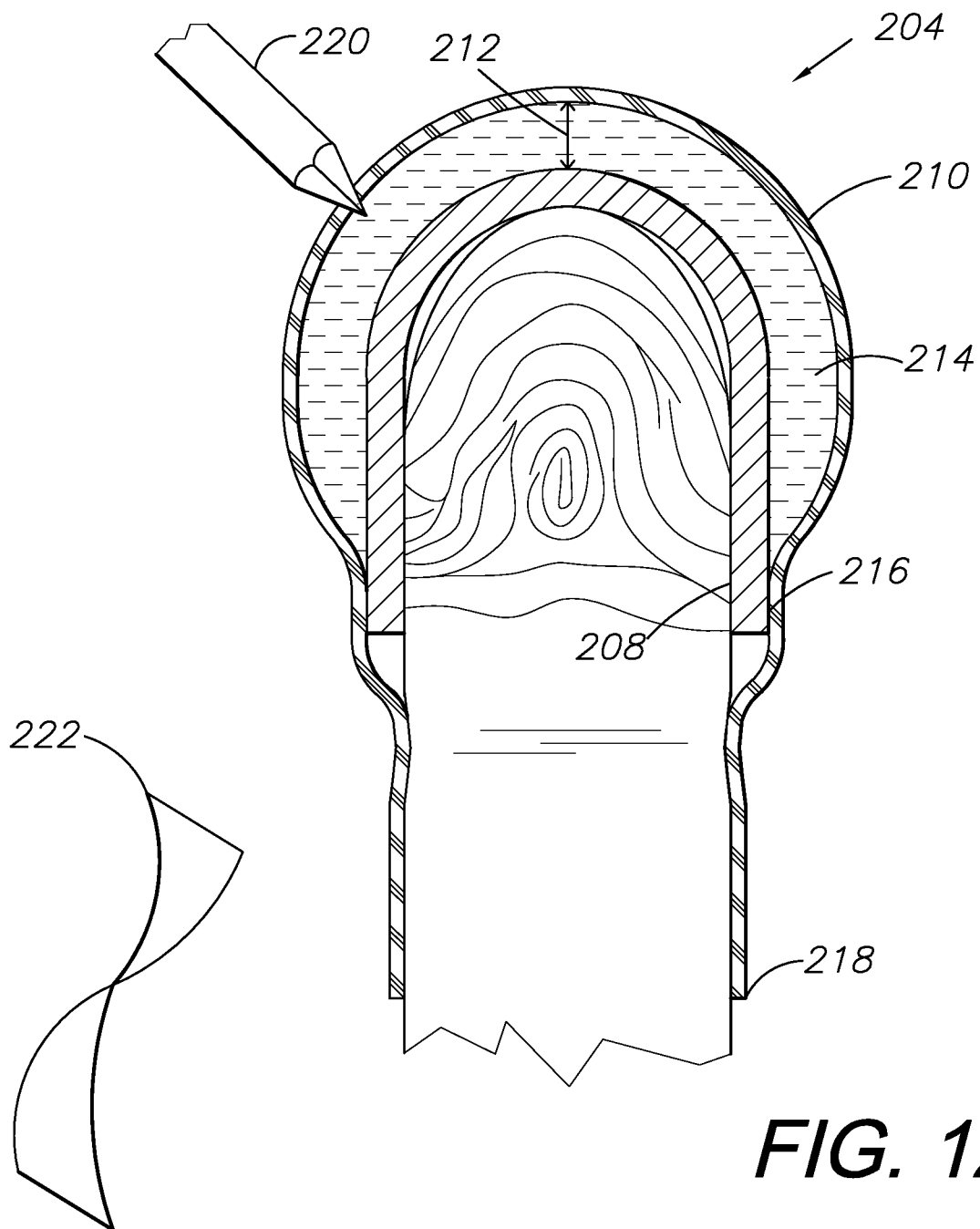
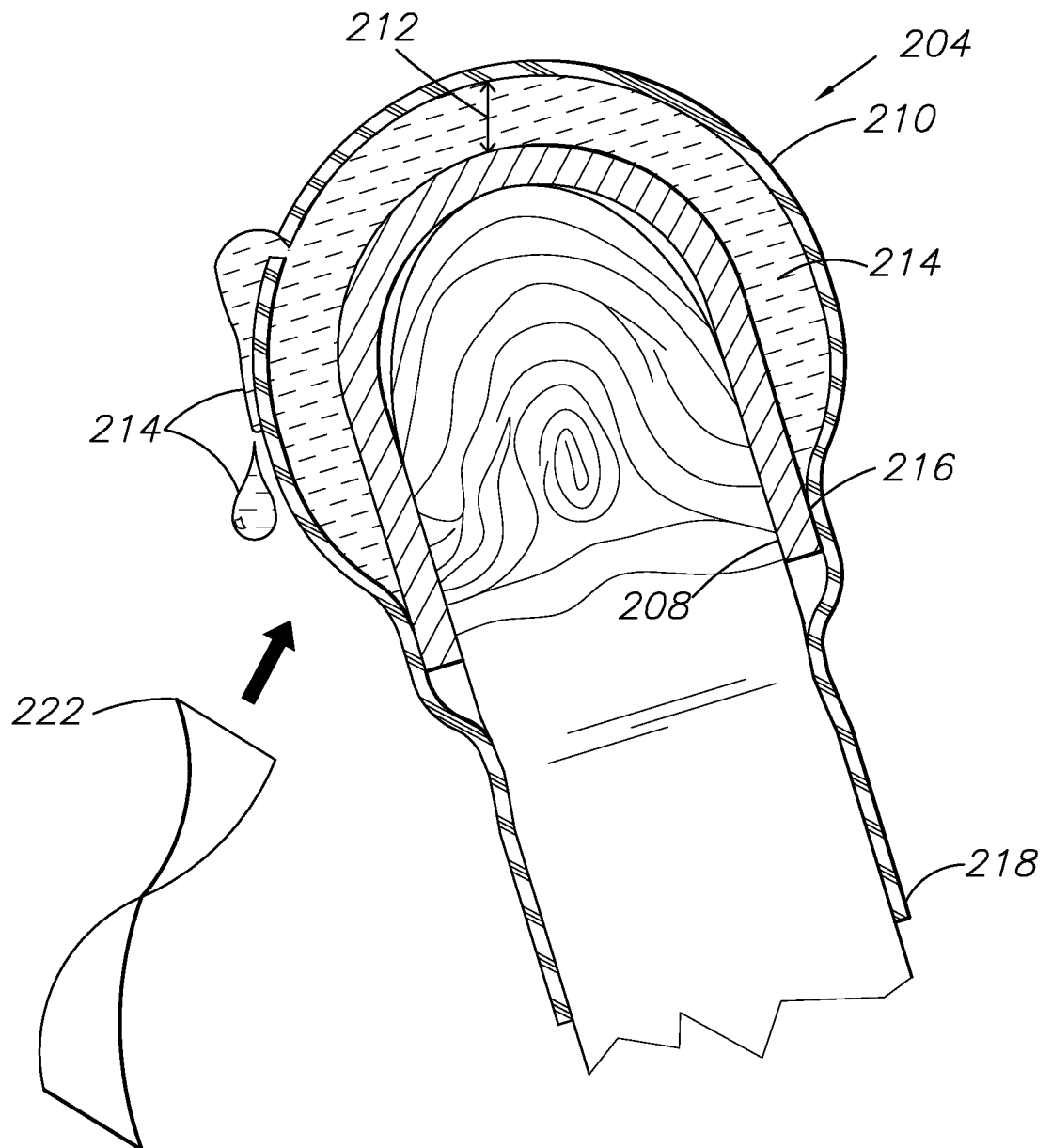
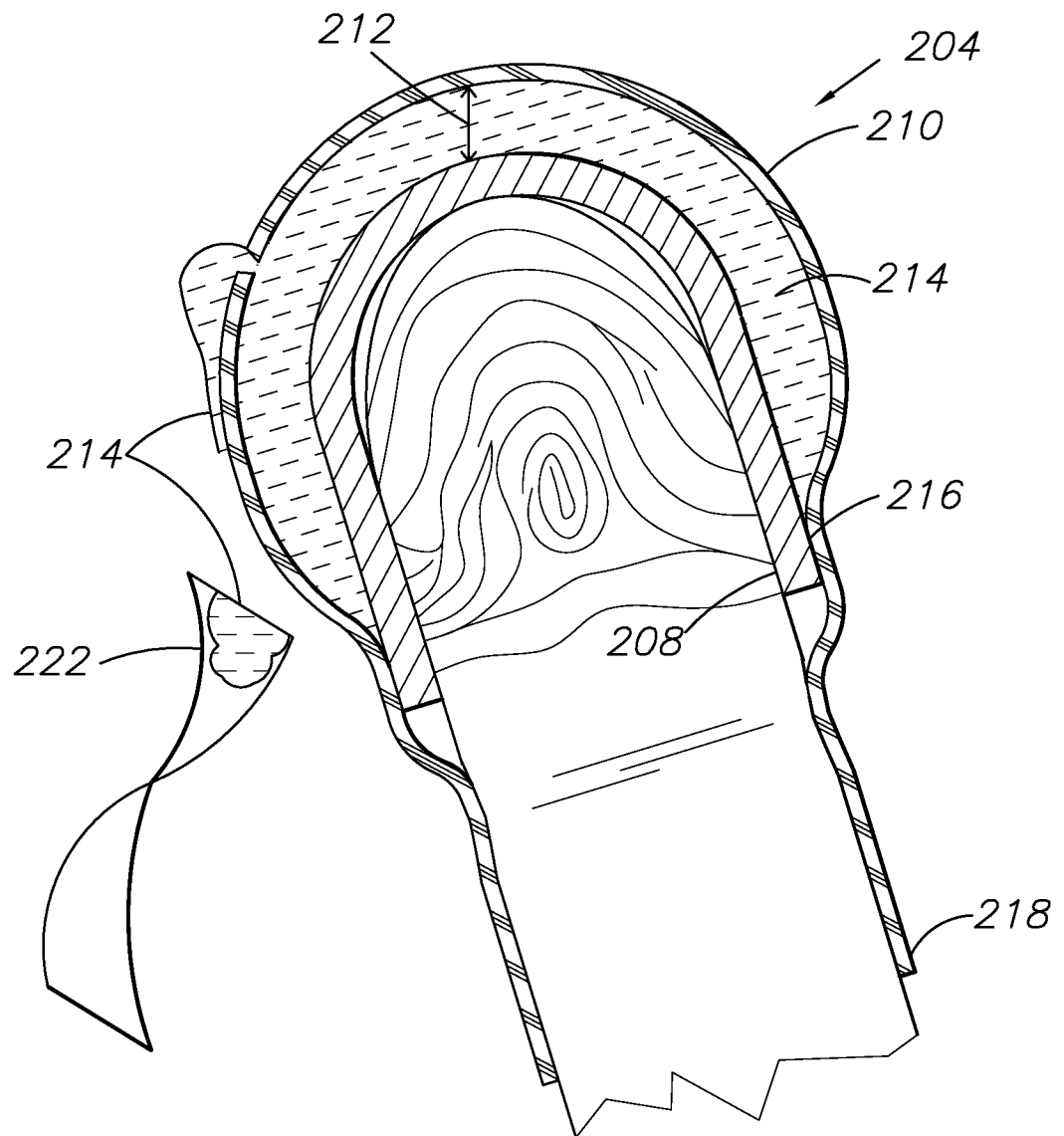


FIG. 12

**FIG. 13**

**FIG. 14**

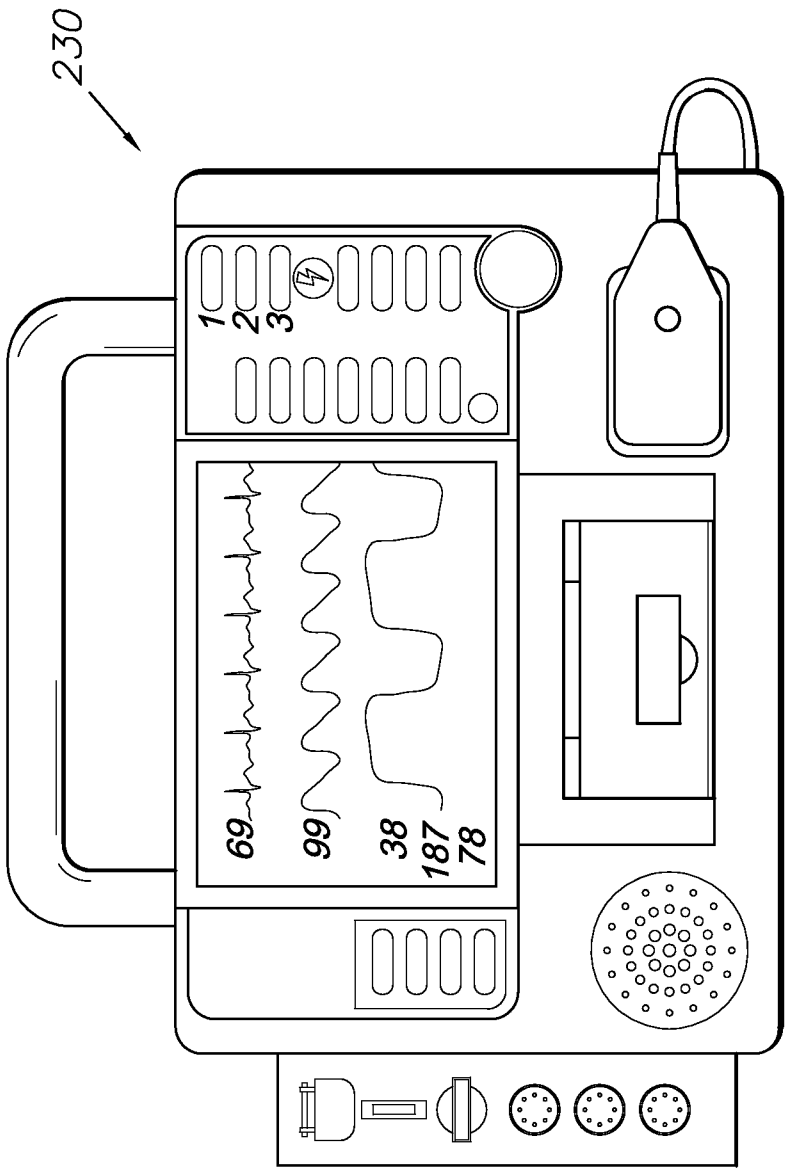


FIG. 15
PRIOR ART

PARTICIPANT (e.g., STUDENT)

- Direct Contact
- Monitor
- Indicator
- Analyzer
- Physical Inputs
- Physical Outputs
- Equipment
- Remote
- Virtual I/O
- Progress Records
- Testing/Certification

SUBJECT (e.g., PATIENT)

- Direct Contact
- Monitor
- Indicator
- Live Actor, Script
- High-Fidelity Mannequin
- Low-Fidelity Mannequin
- Avatar
- Hologram
- Virtual Patient

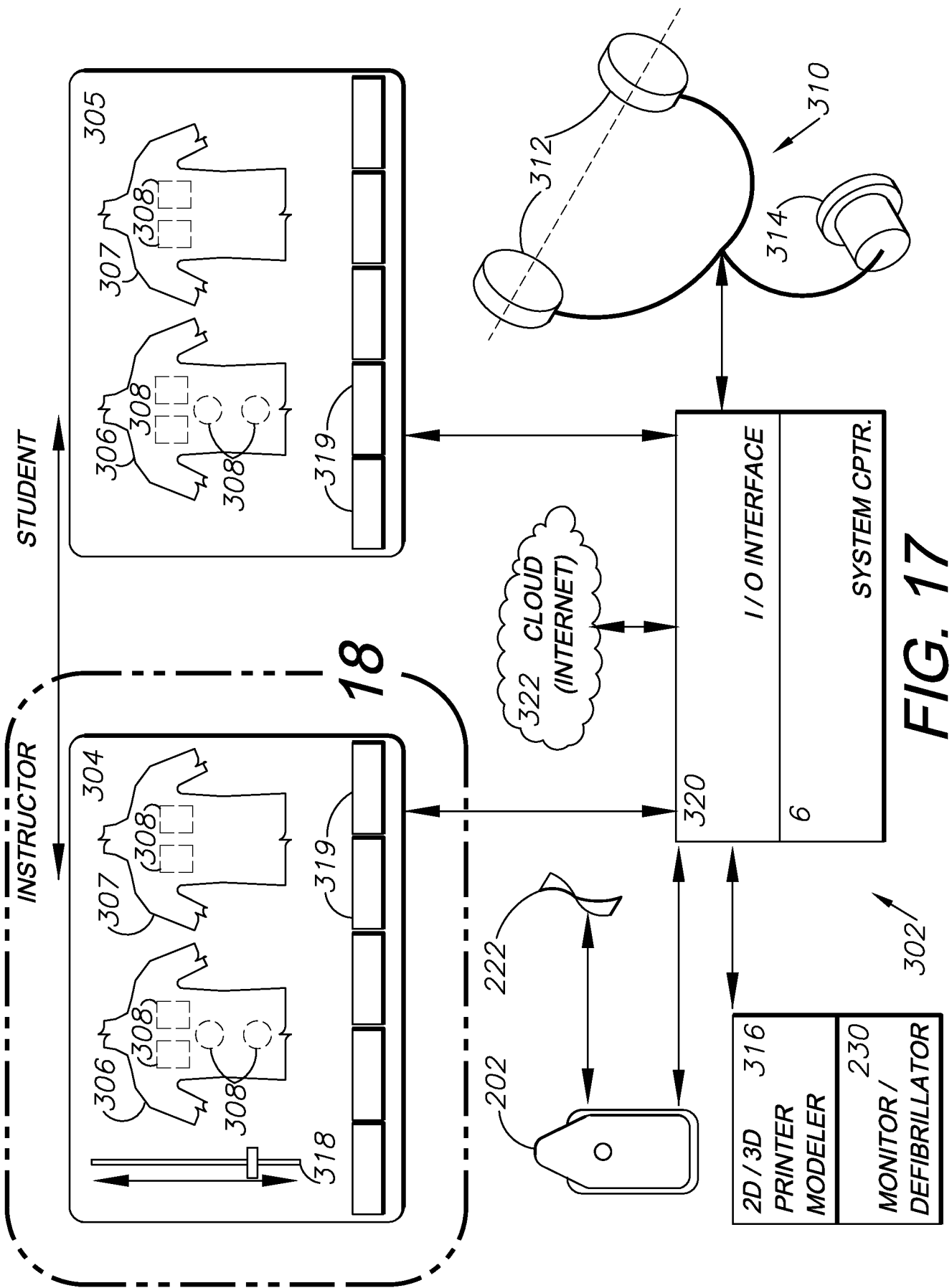
CONTROLLER (e.g., INSTRUCTOR)

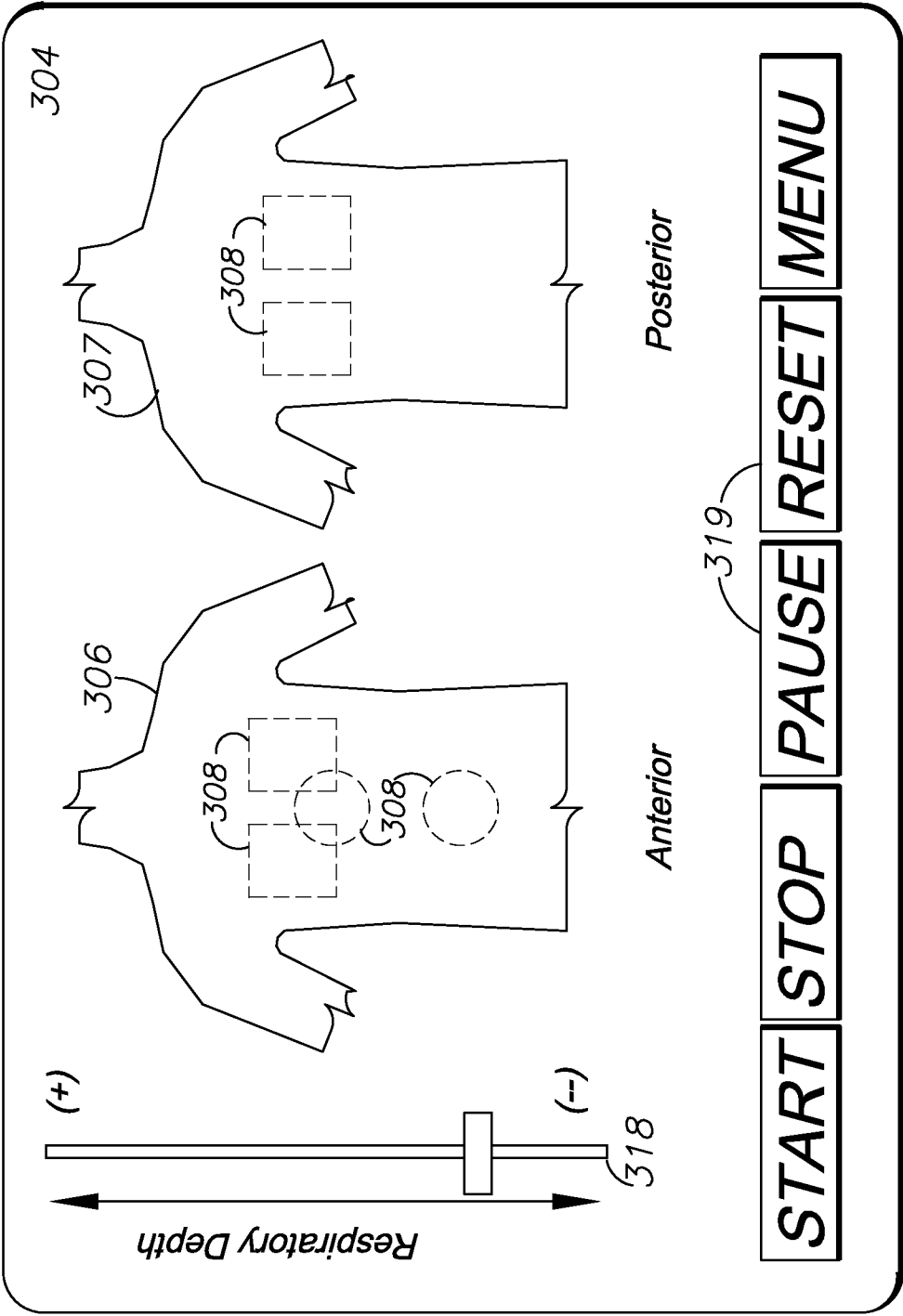
- Direct Contact
- Indicator
- Monitor
- Physical Inputs
- Physical Outputs
- "Smart" Equipment
- Remote
- Virtual I/O
- Progress Records
- Testing/Certification

TOOLS / COMPUTER

- Direct Contact
- Network (LAN)
- Internet (Cloud-Based)
- Automated Response
- Inputs
- Outputs
- Preprogrammed Scenarios
- Memory
- Monitor
- Indicator
- Equipment
- Devices
- Instruments
- Analyzers
- Physical Inputs
- Physical Outputs
- Remote
- Virtual I/O
- Progress Records
- Testing/Certification
- Curriculum

FIG. 16





INSTRUCTOR TOUCH-SCREEN MONITOR **FIG. 18**

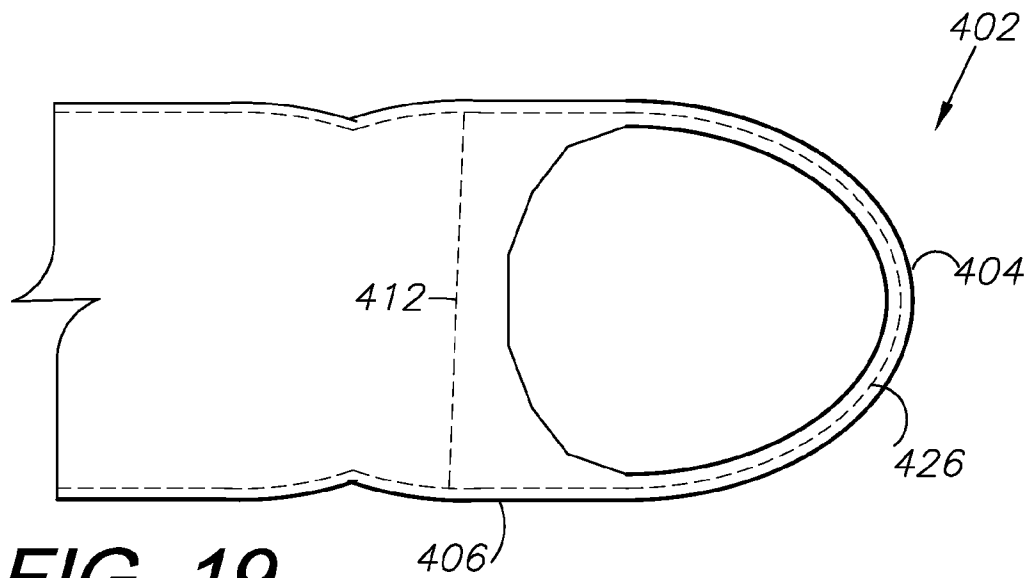


FIG. 19

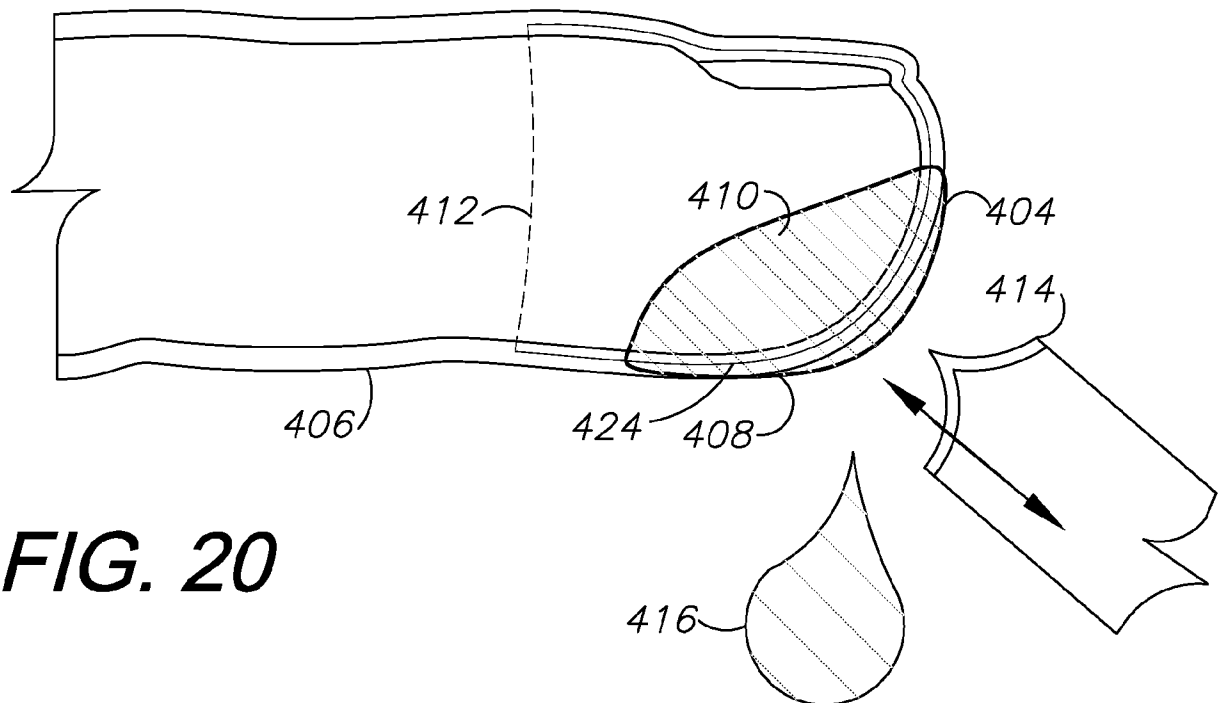


FIG. 20

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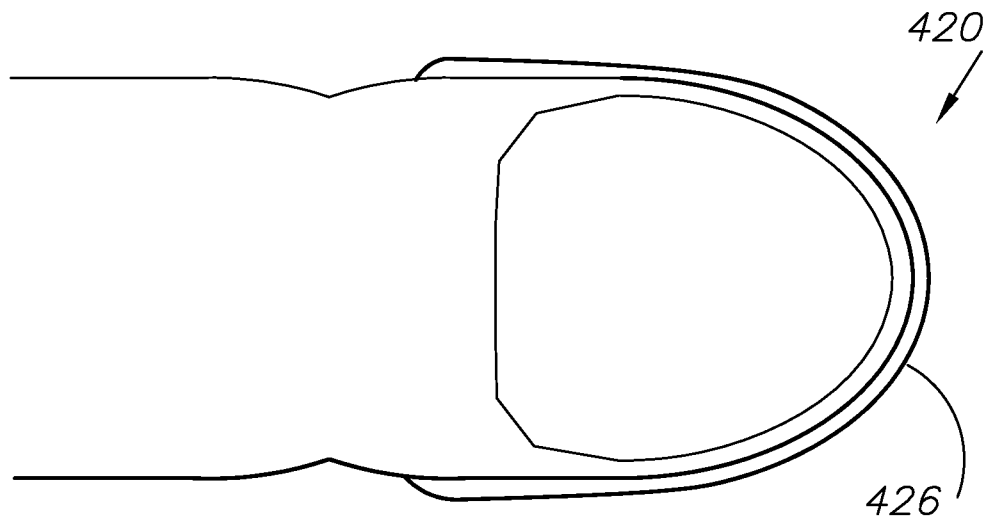


FIG. 21

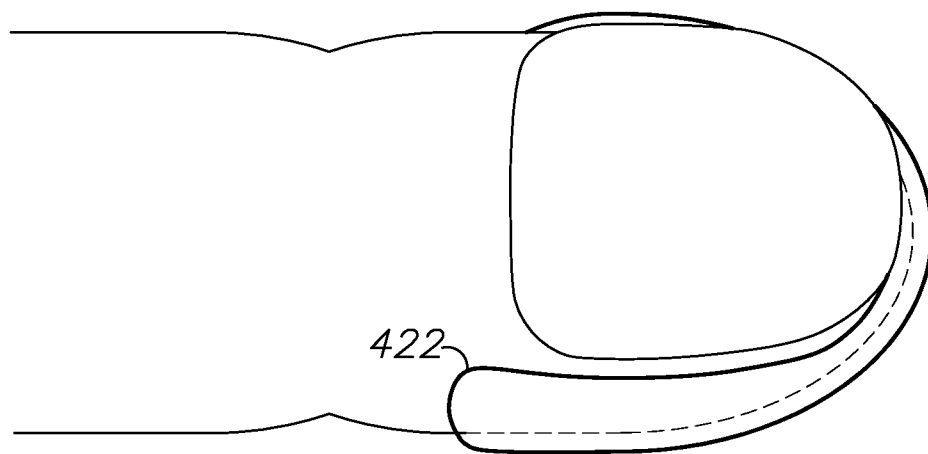


FIG. 22

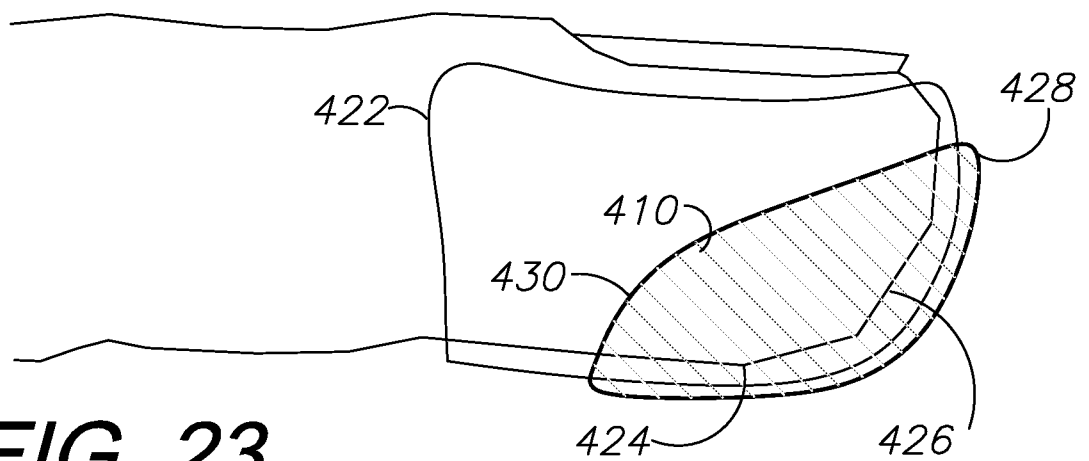


FIG. 23

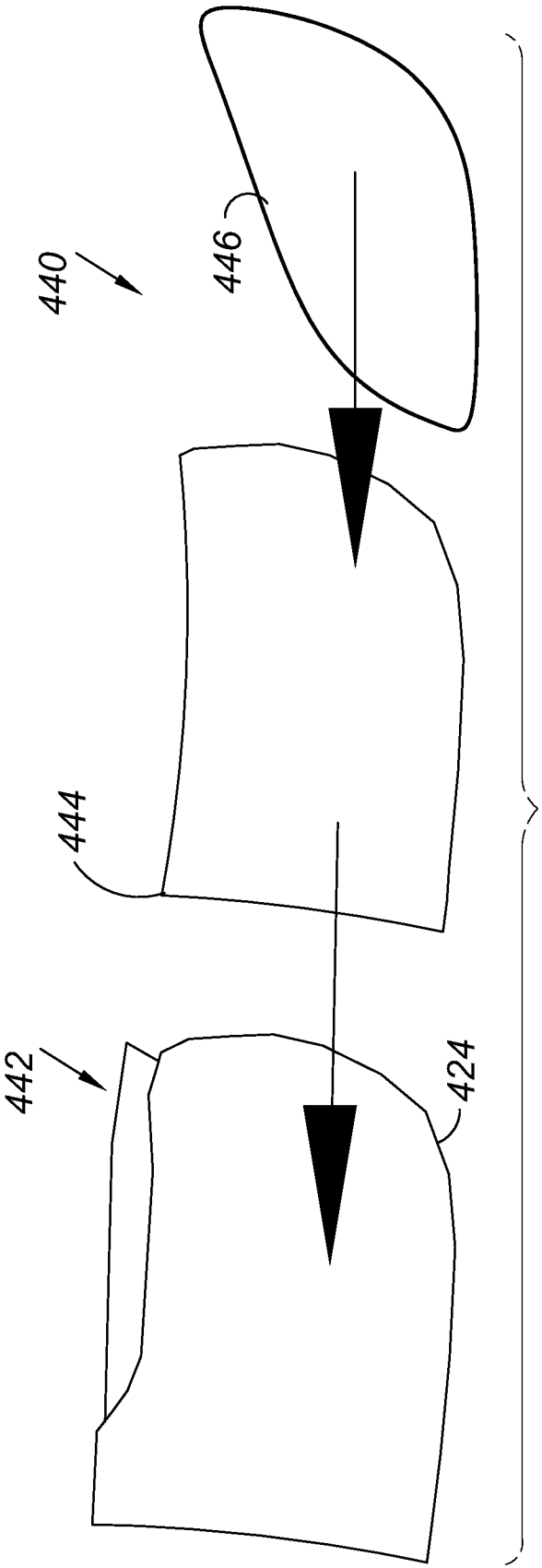


FIG. 24

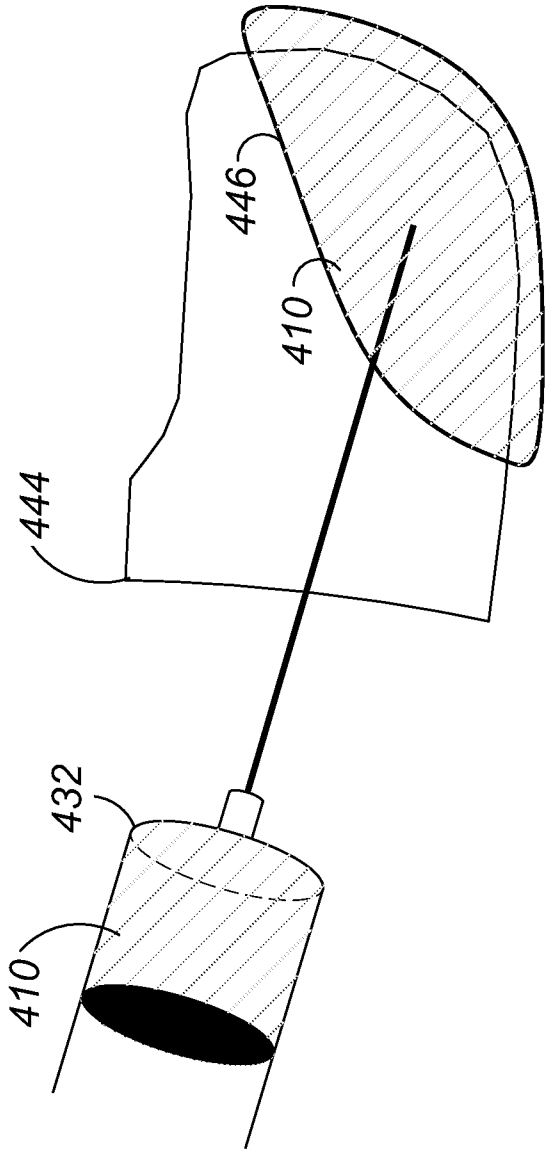


FIG. 25

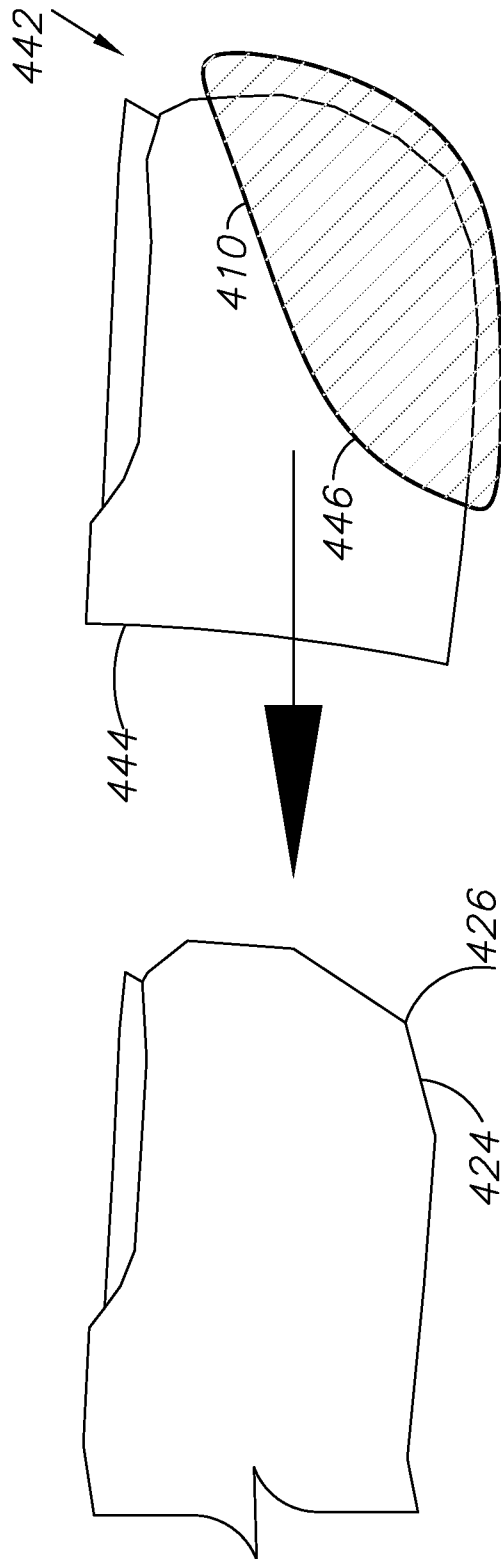


FIG. 26

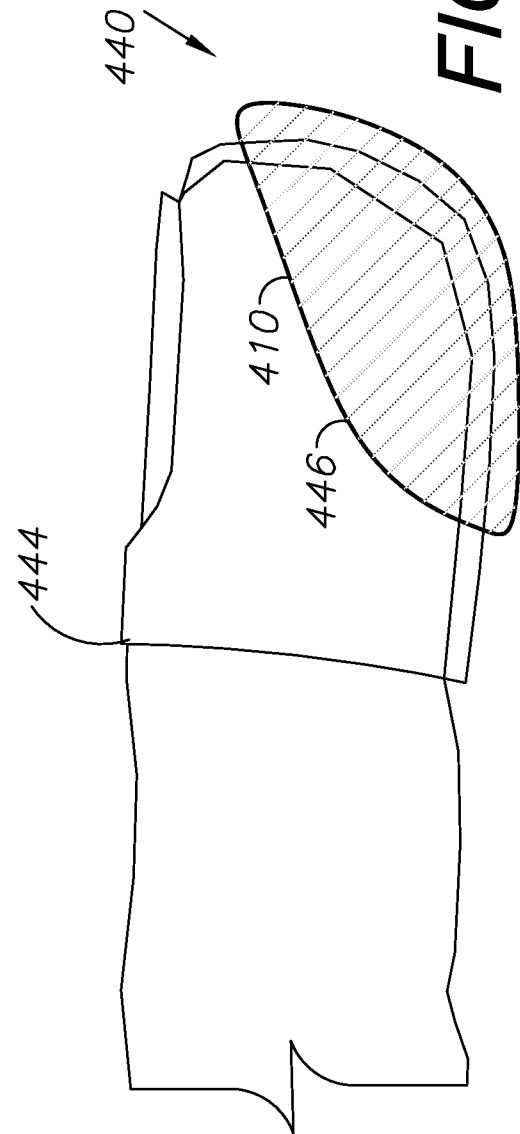


FIG. 27

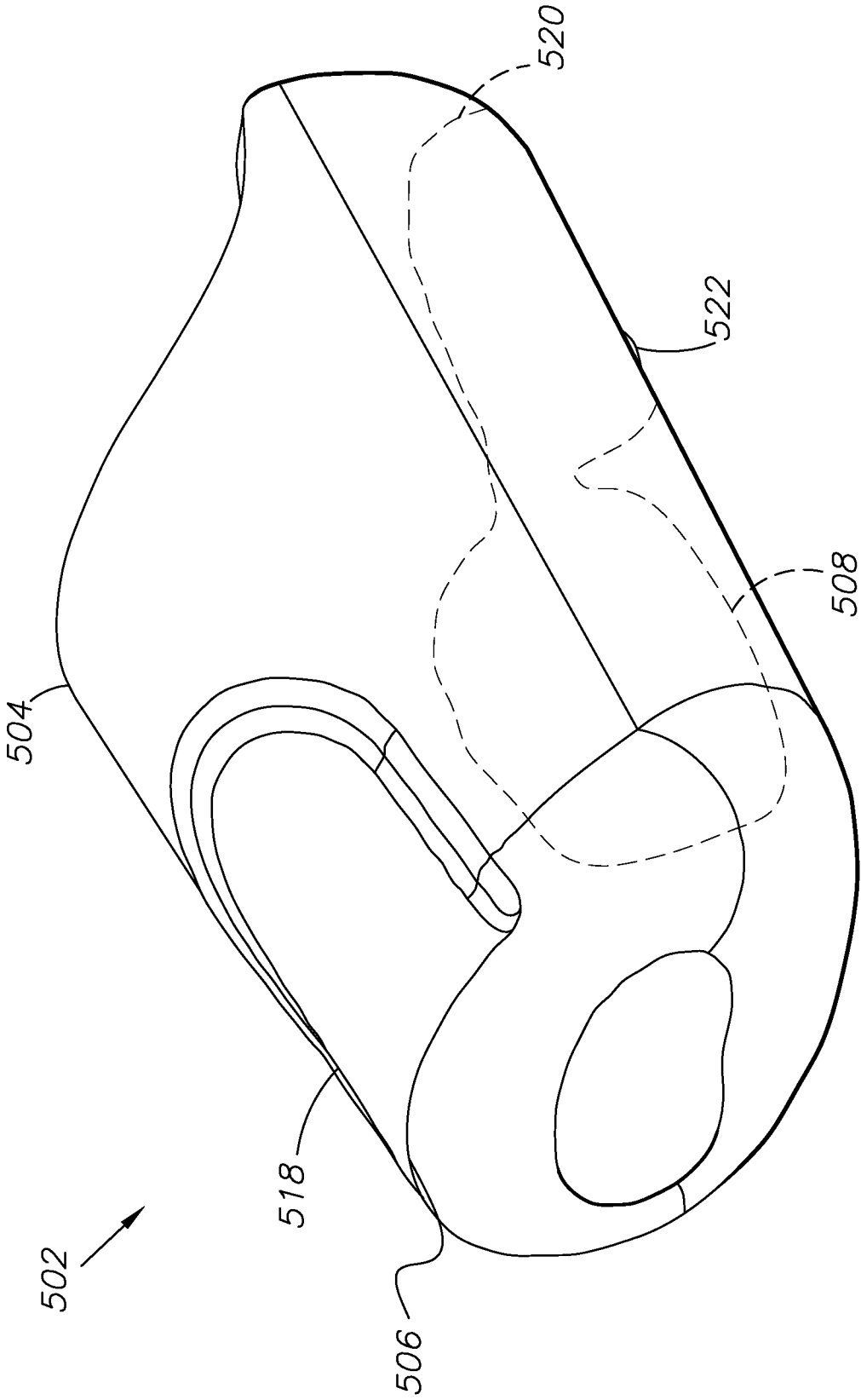


FIG. 28

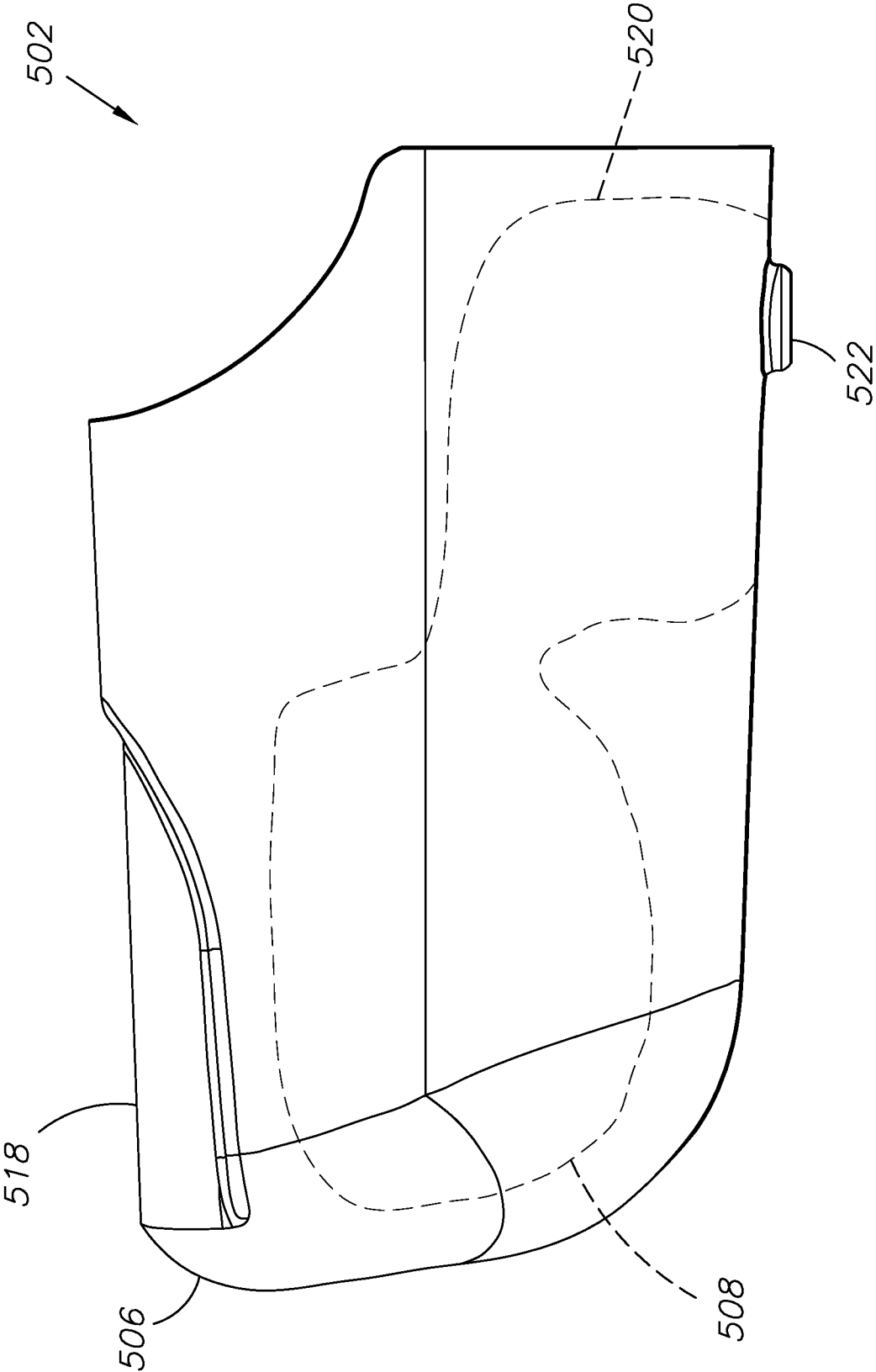


FIG. 29

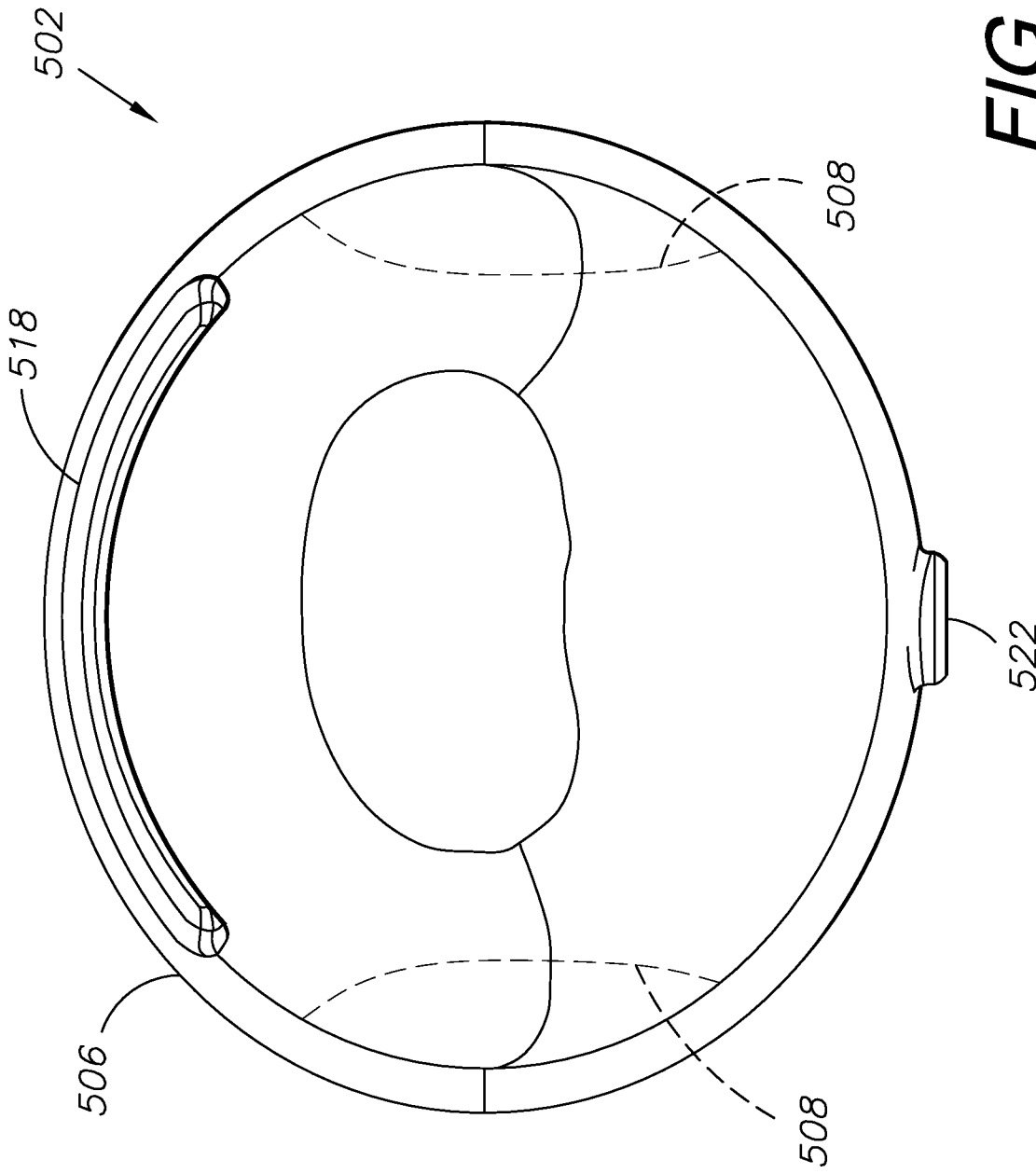


FIG. 30

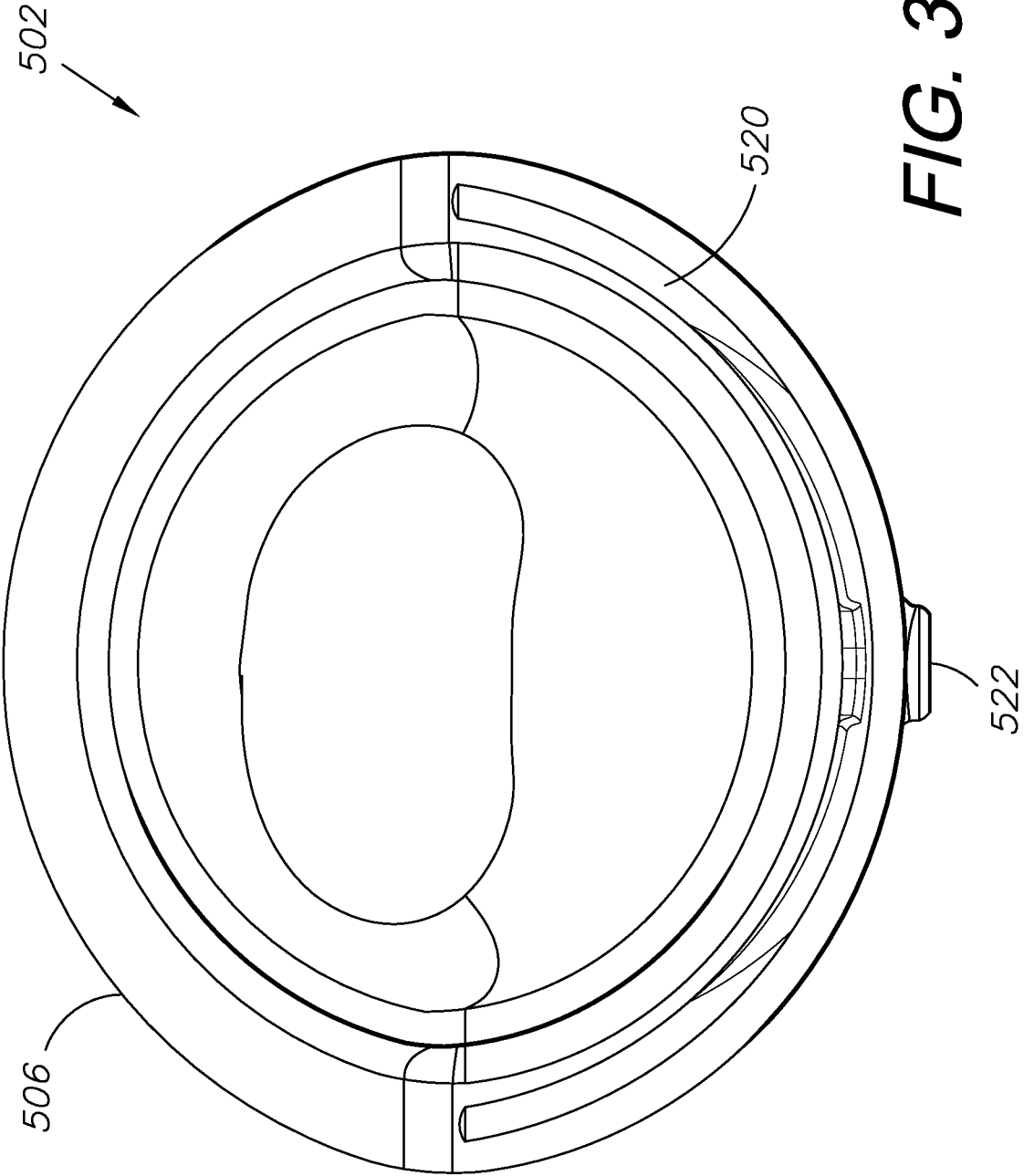


FIG. 31

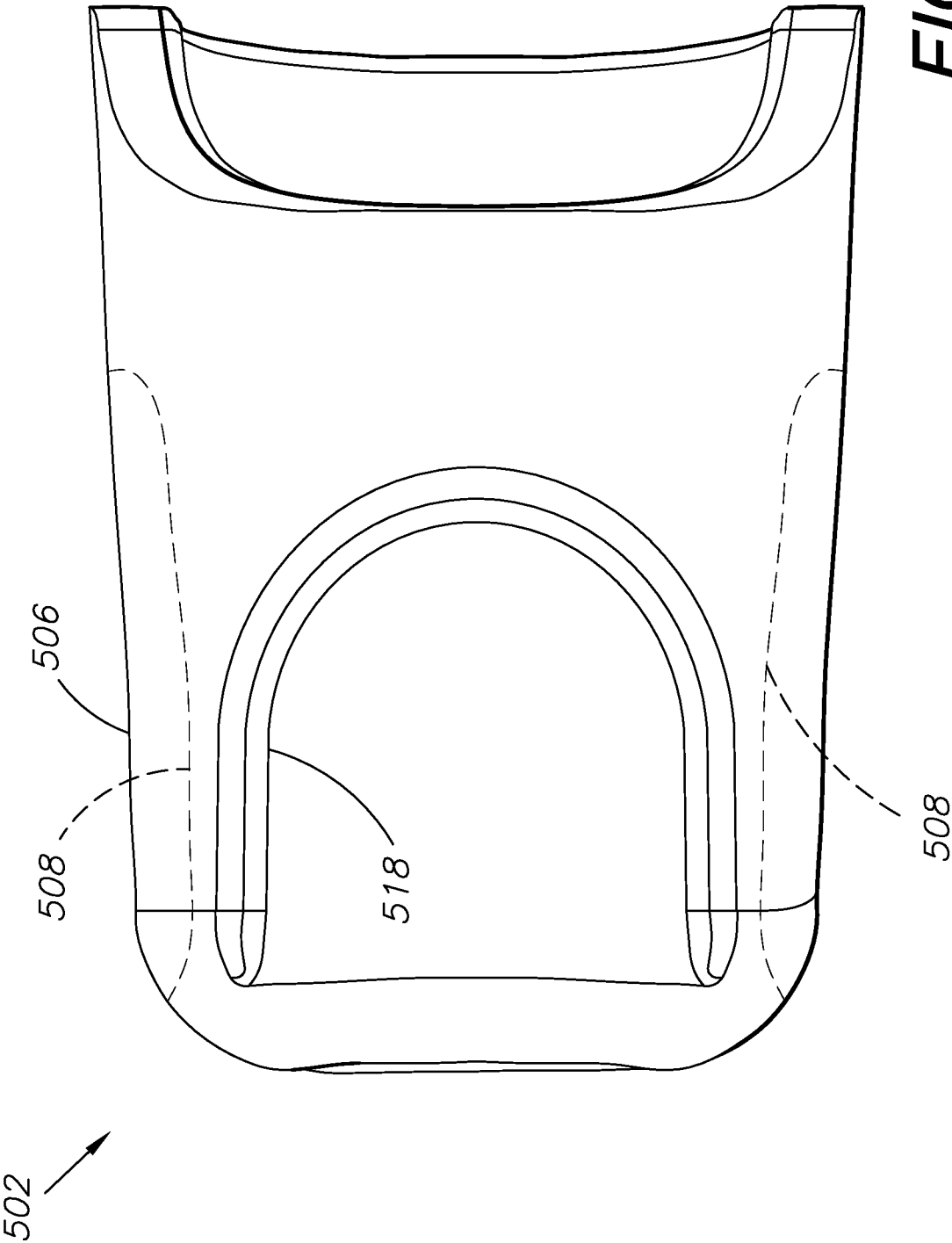


FIG. 32

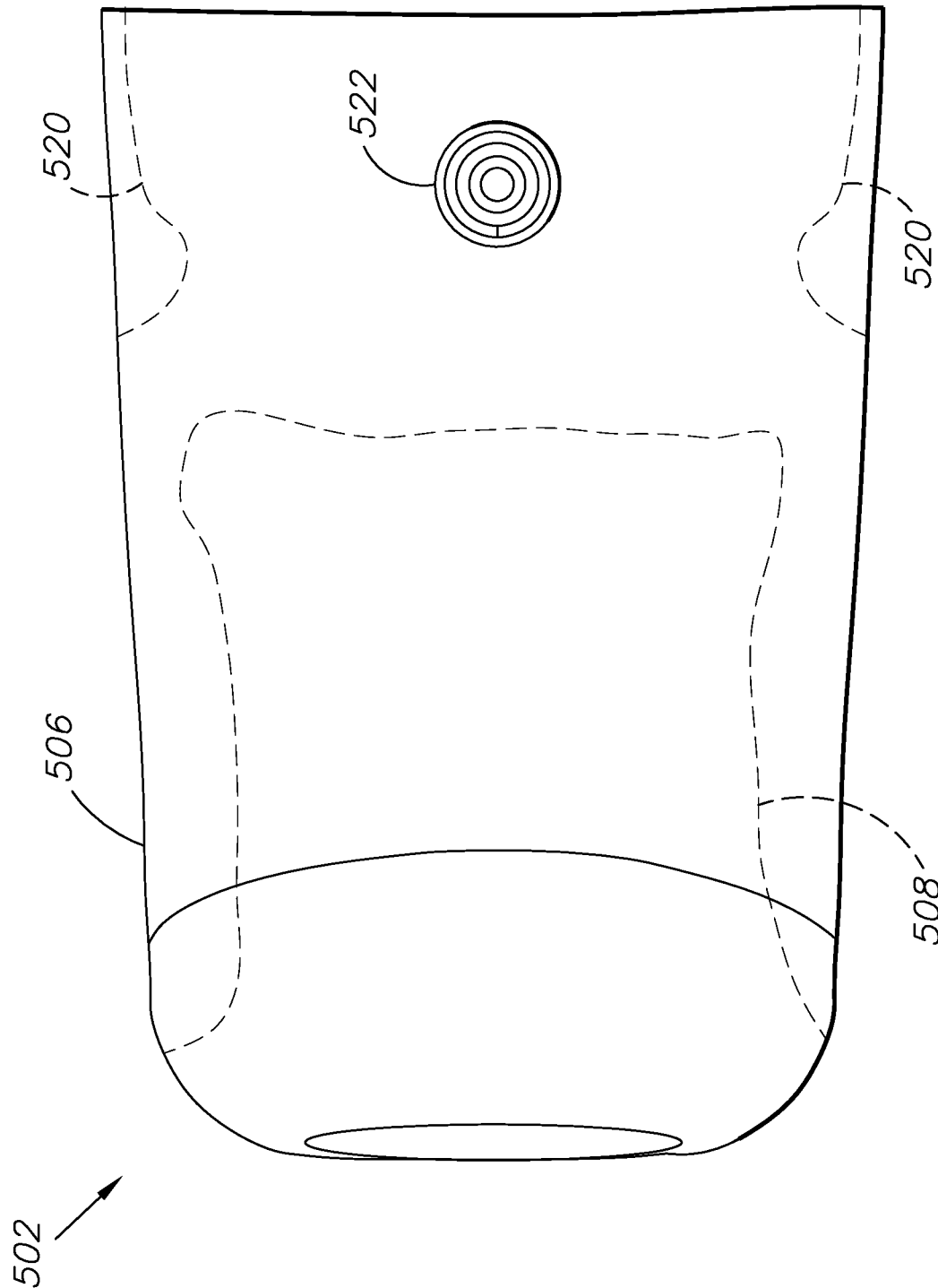


FIG. 33

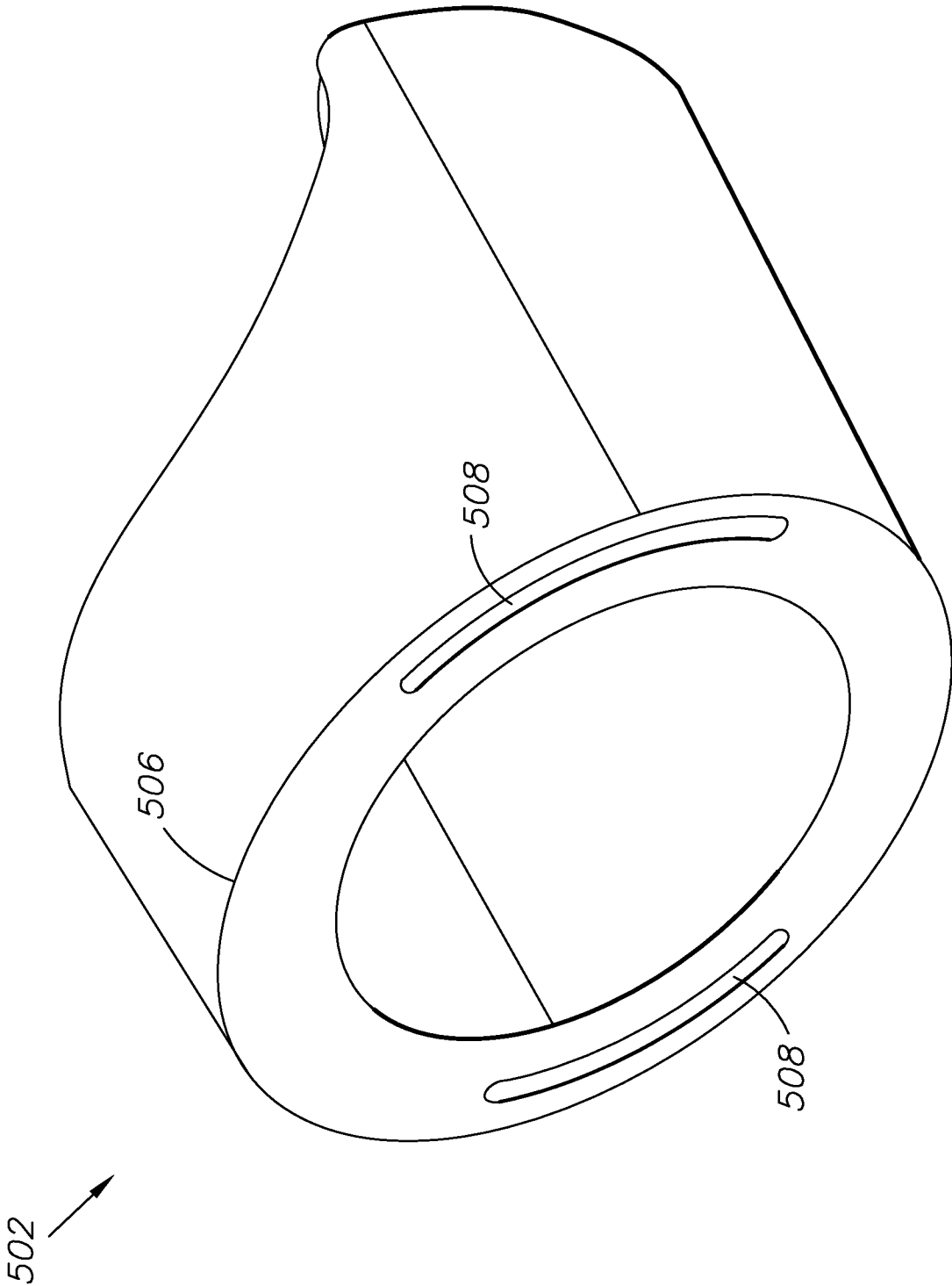


FIG. 34

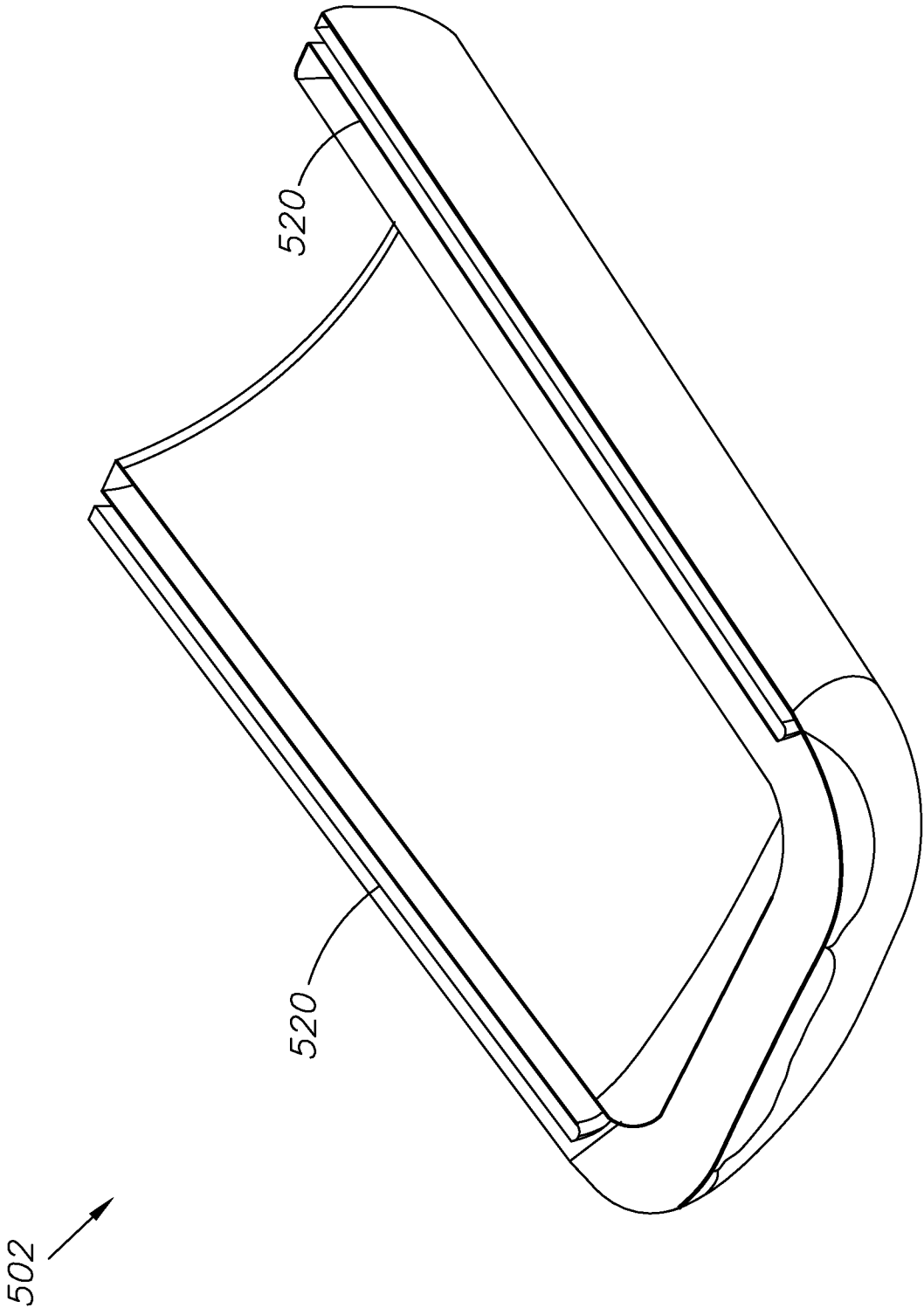


FIG. 35

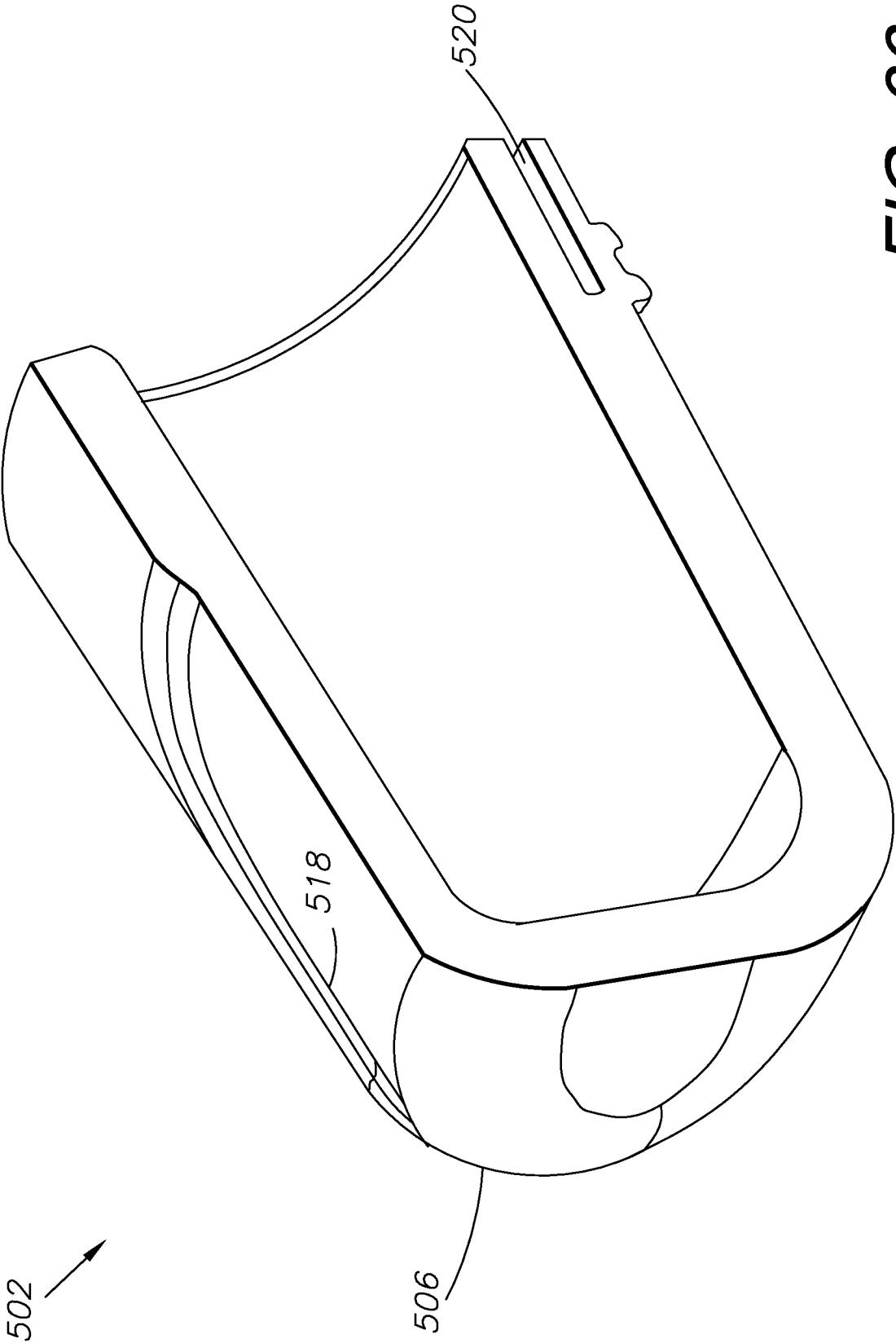
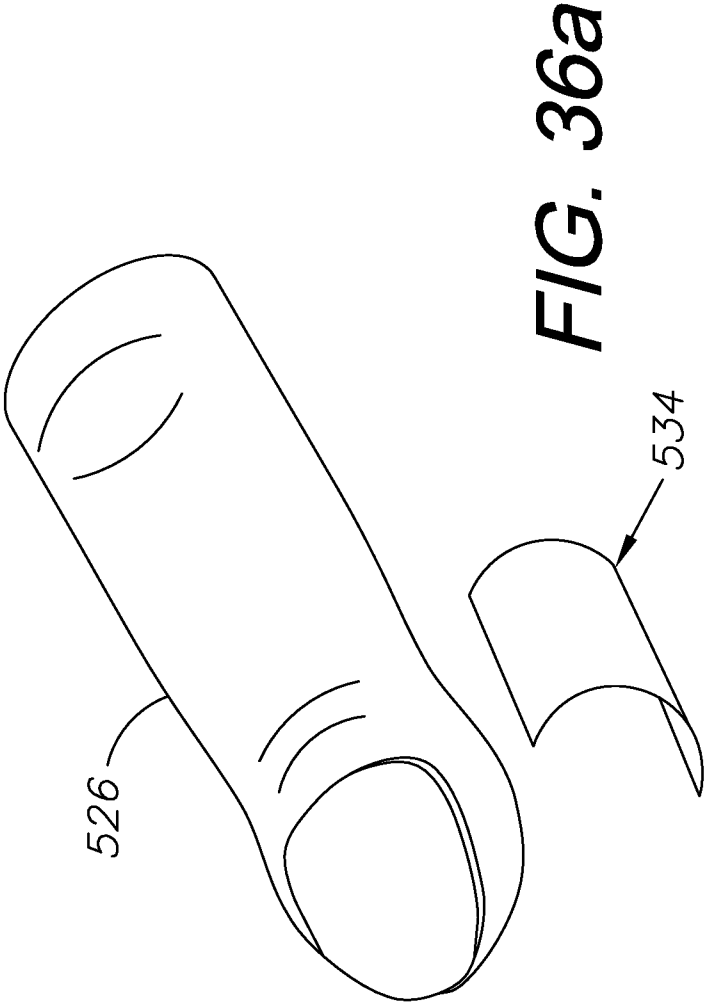
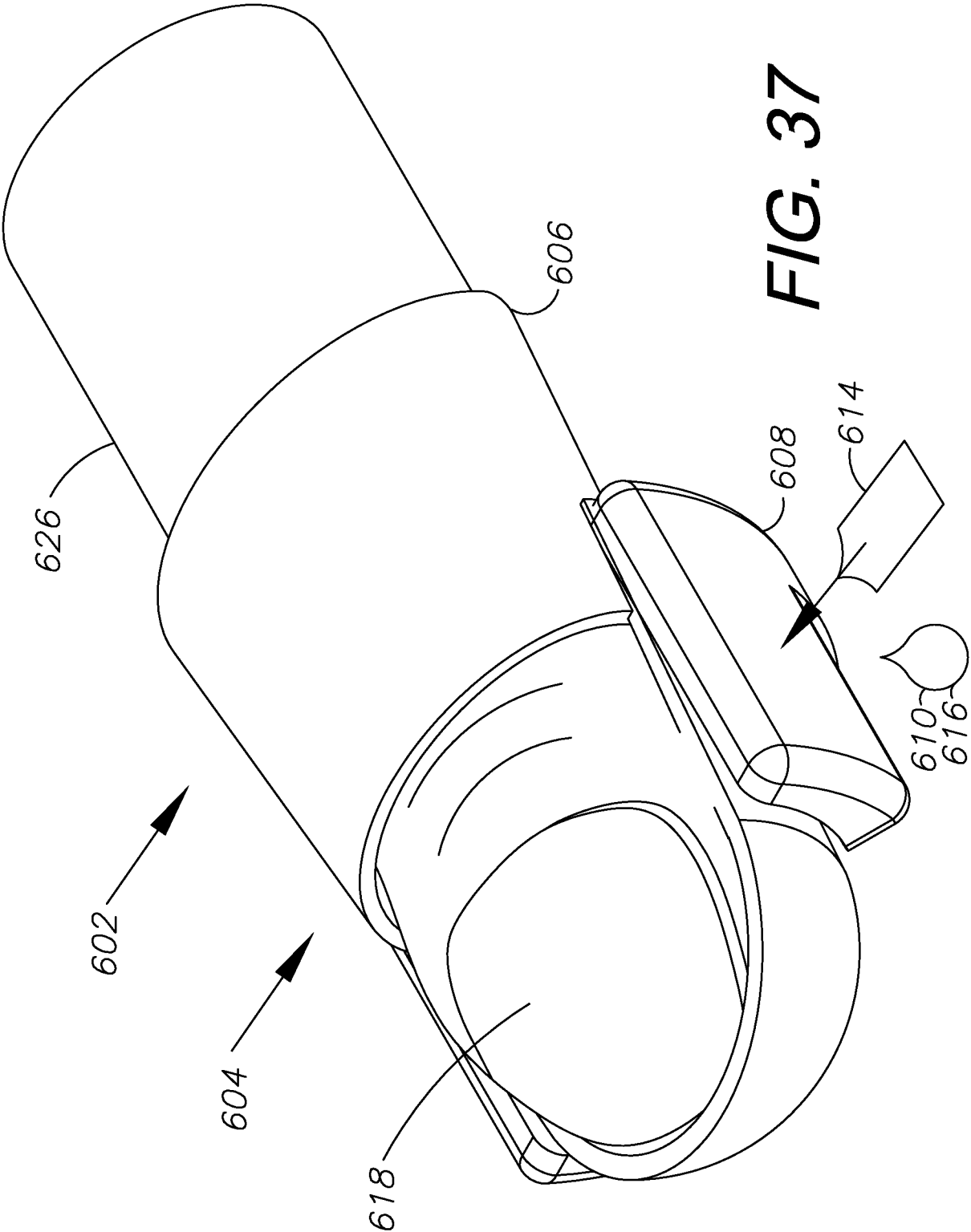
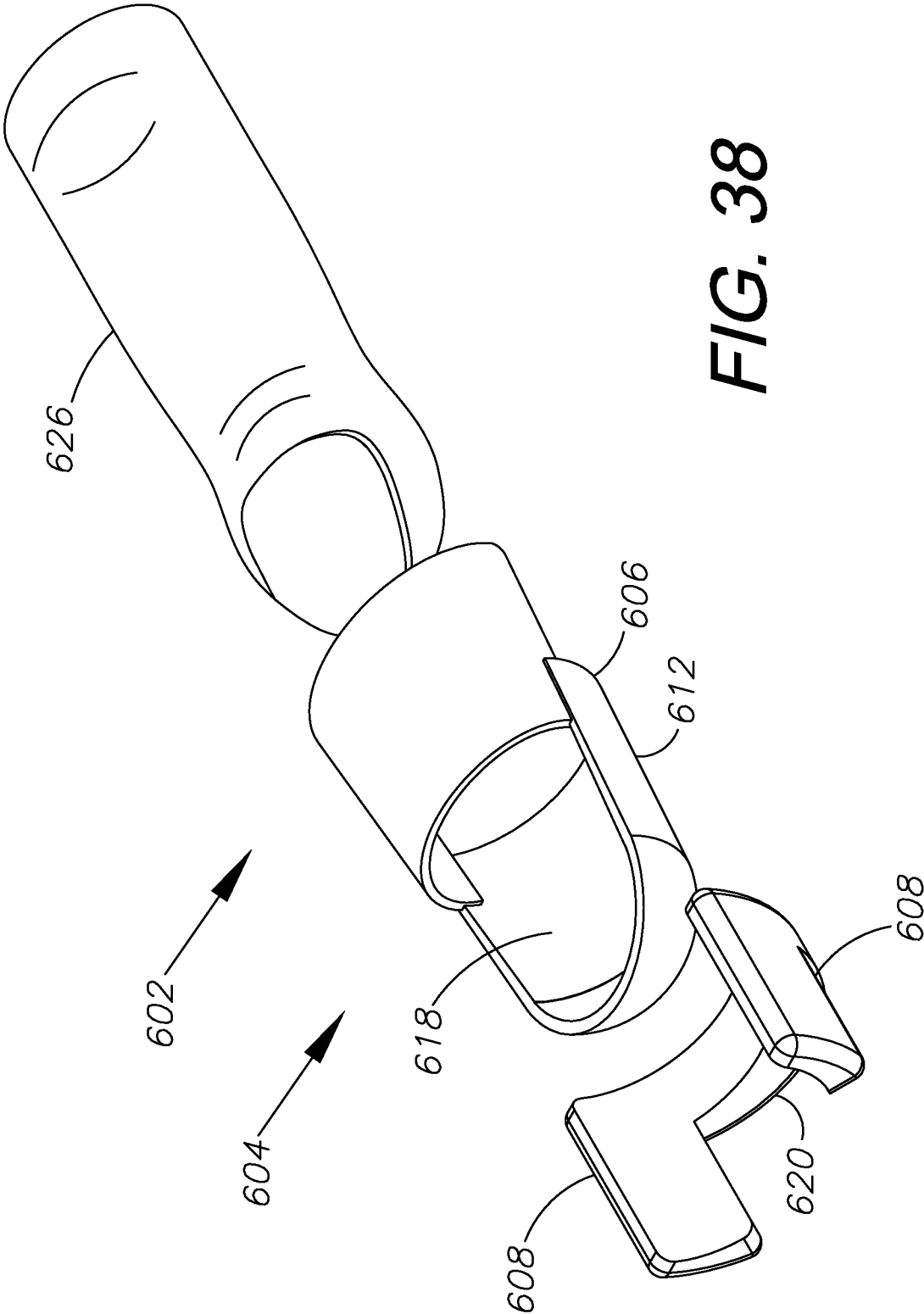


FIG. 36







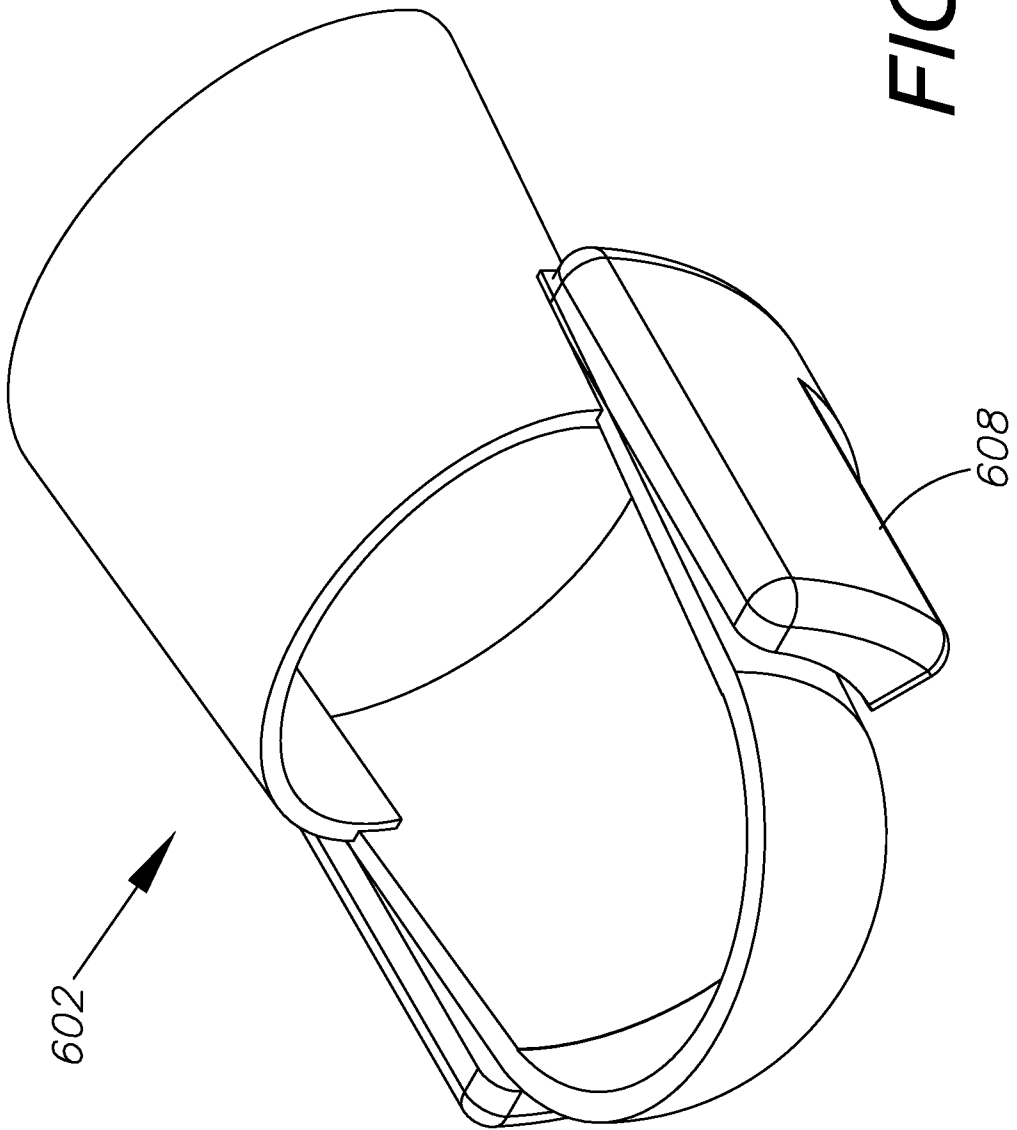
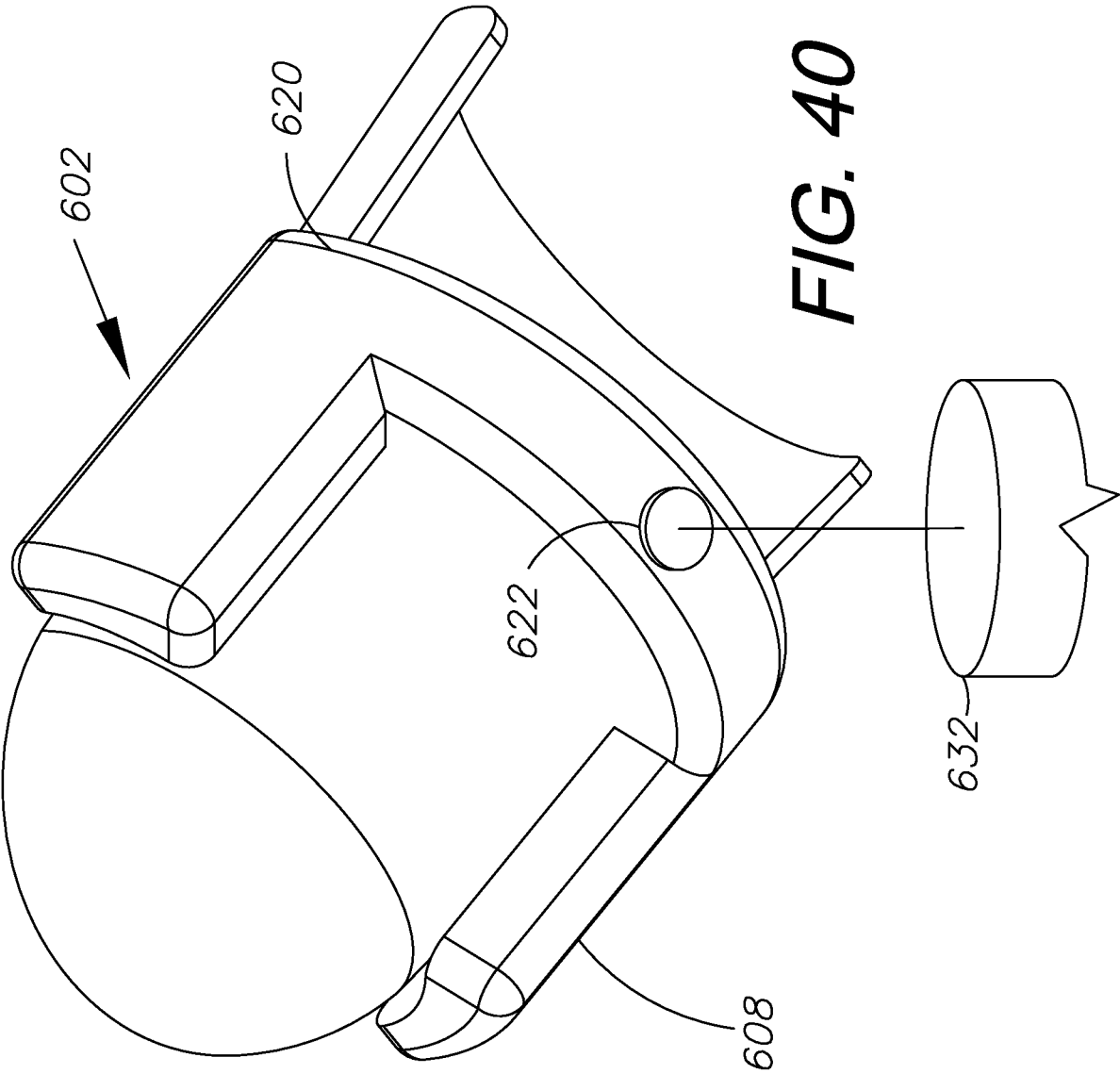
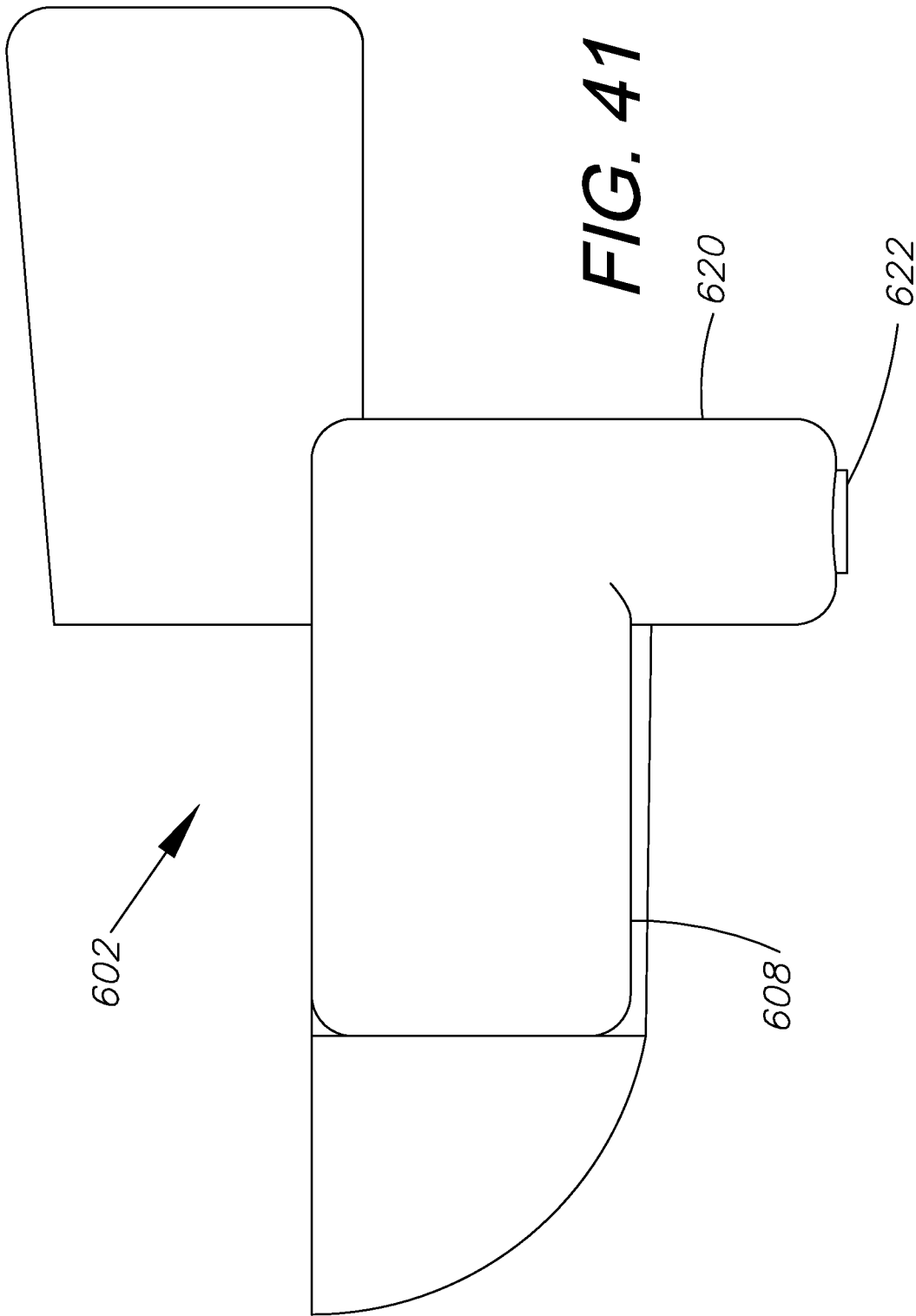


FIG. 39





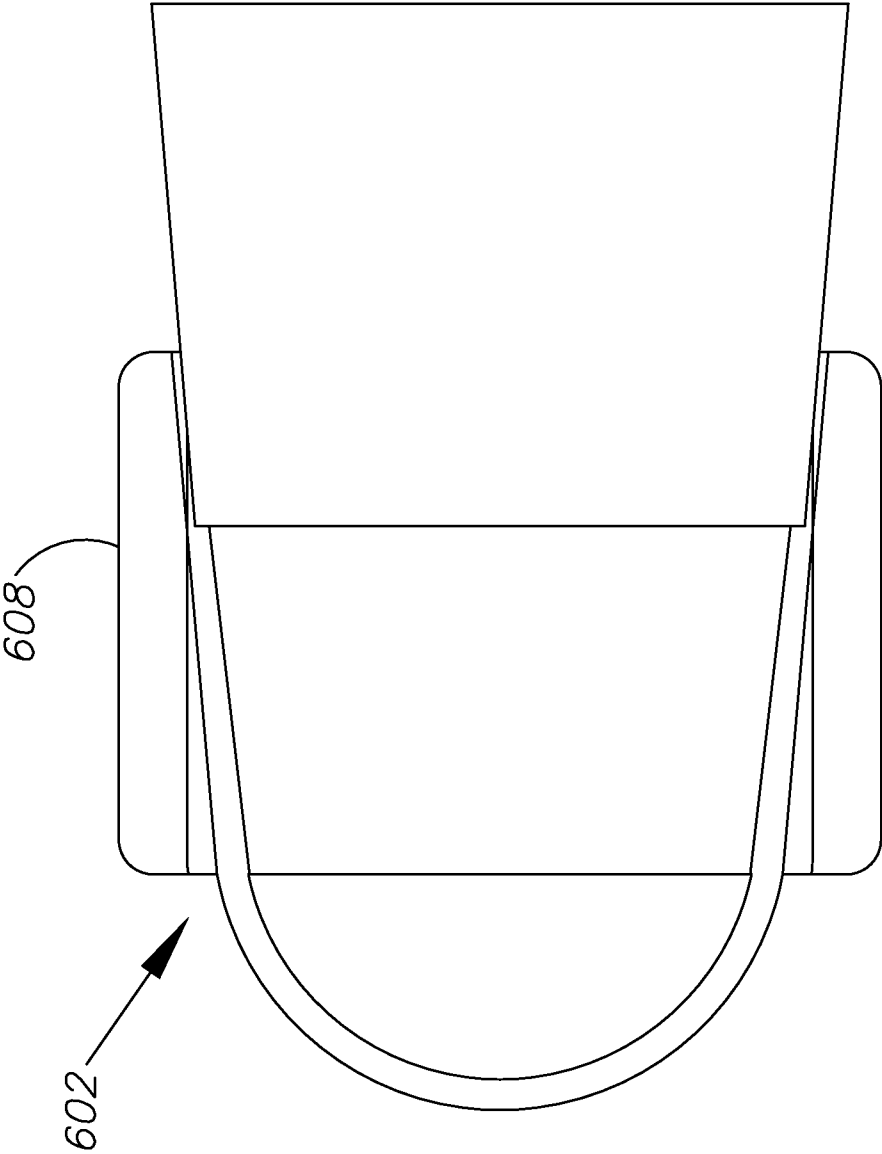
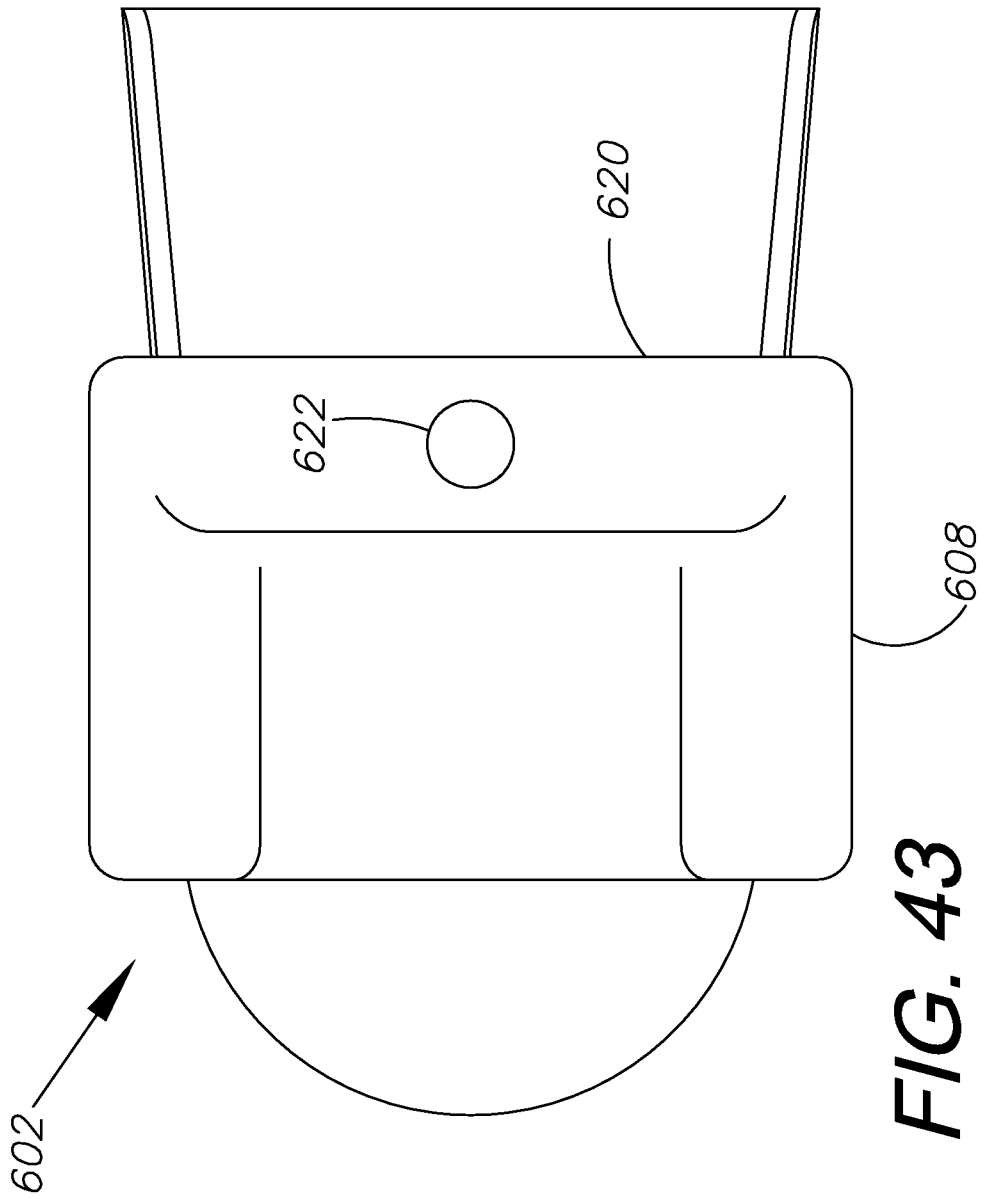


FIG. 42



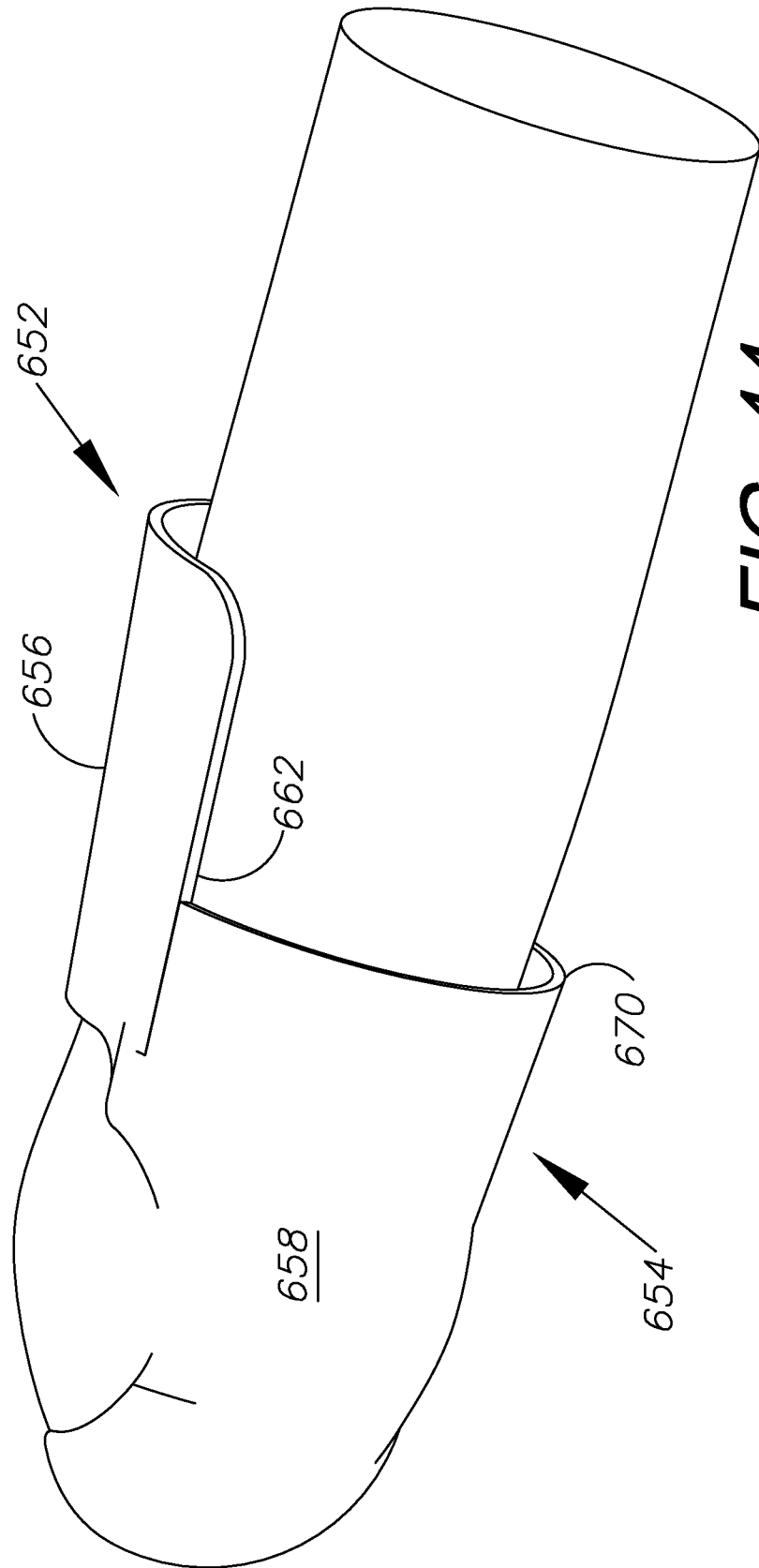


FIG. 44

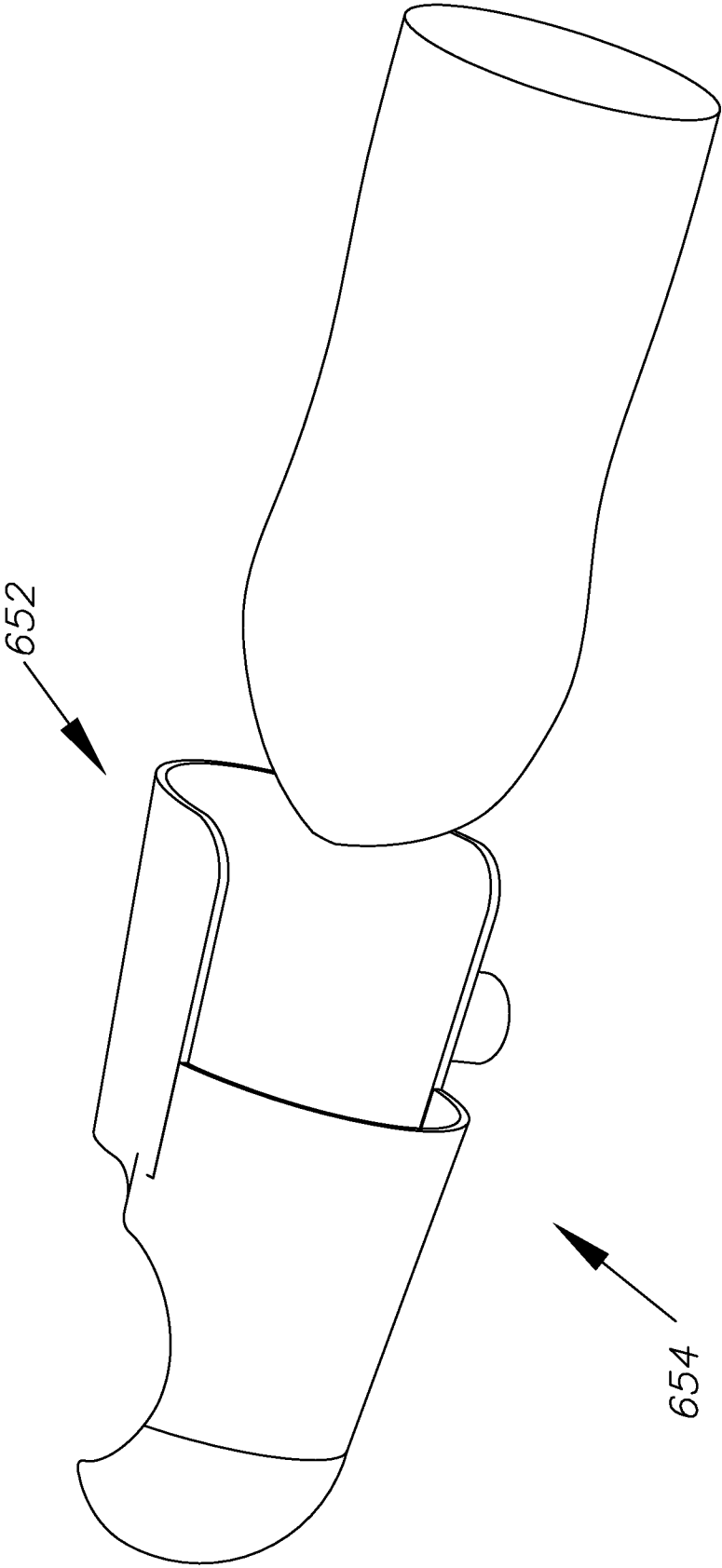


FIG. 45

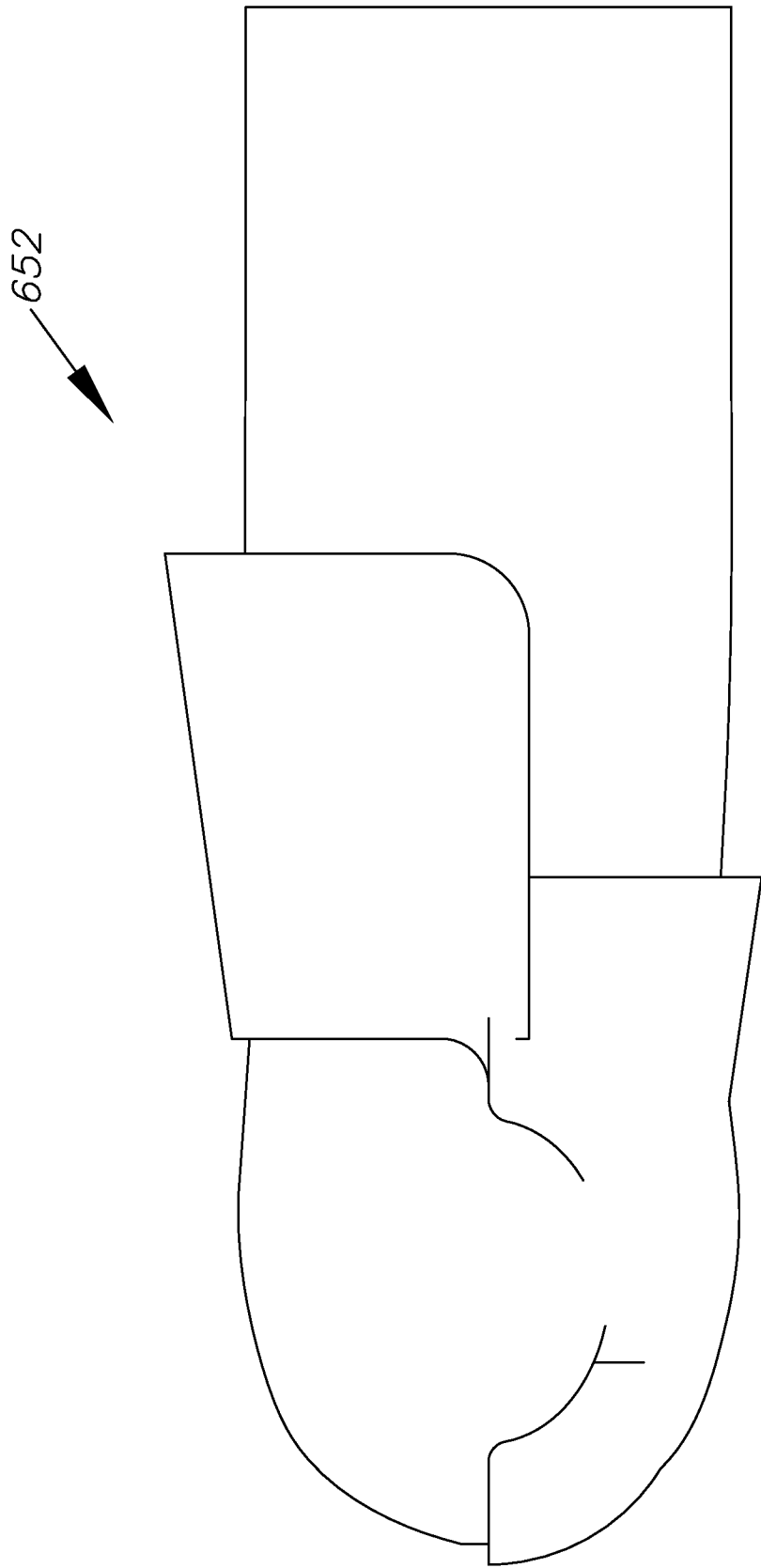
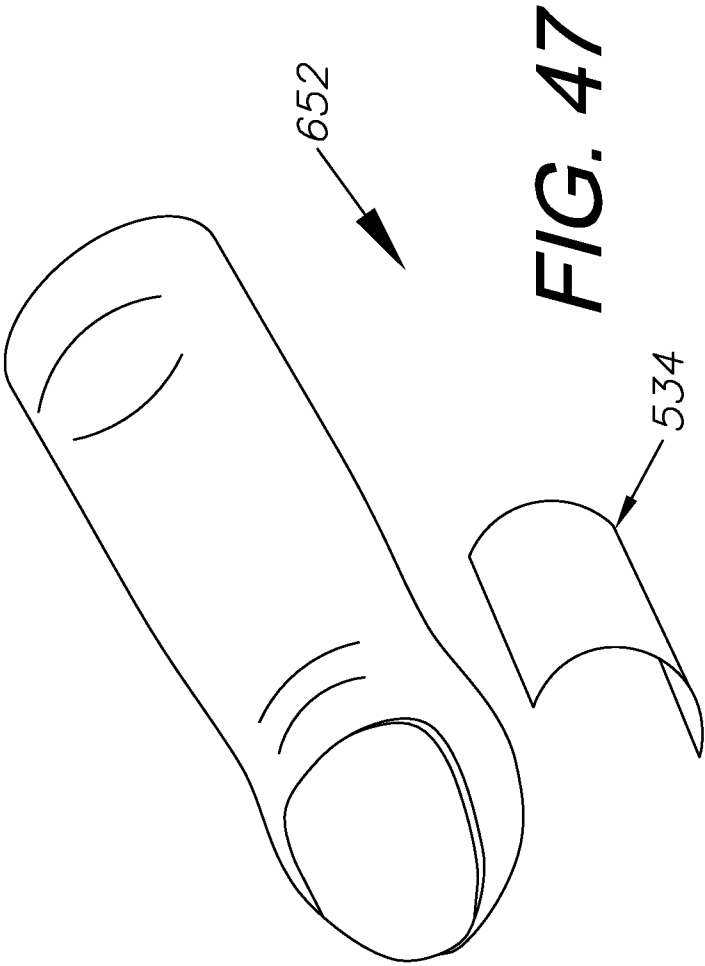


FIG. 46



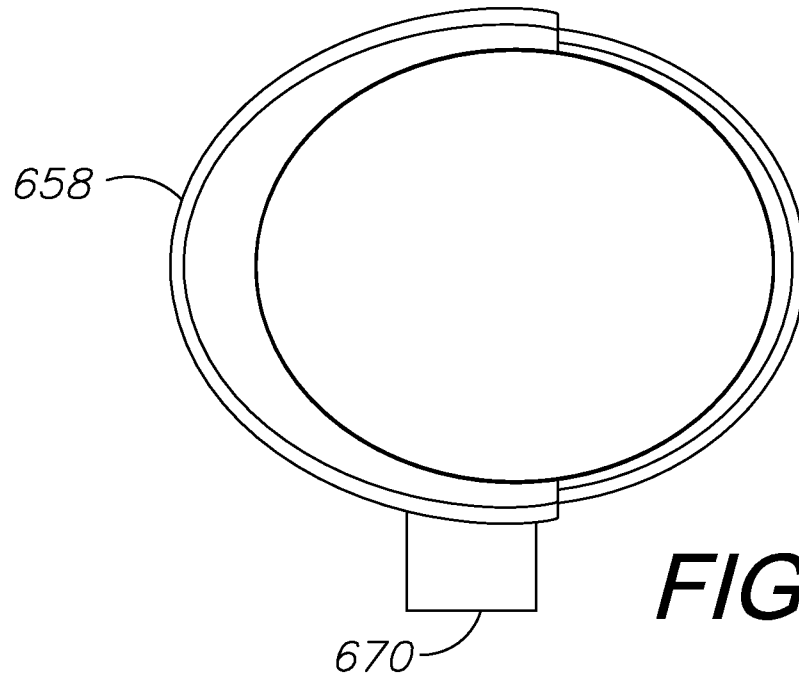


FIG. 48

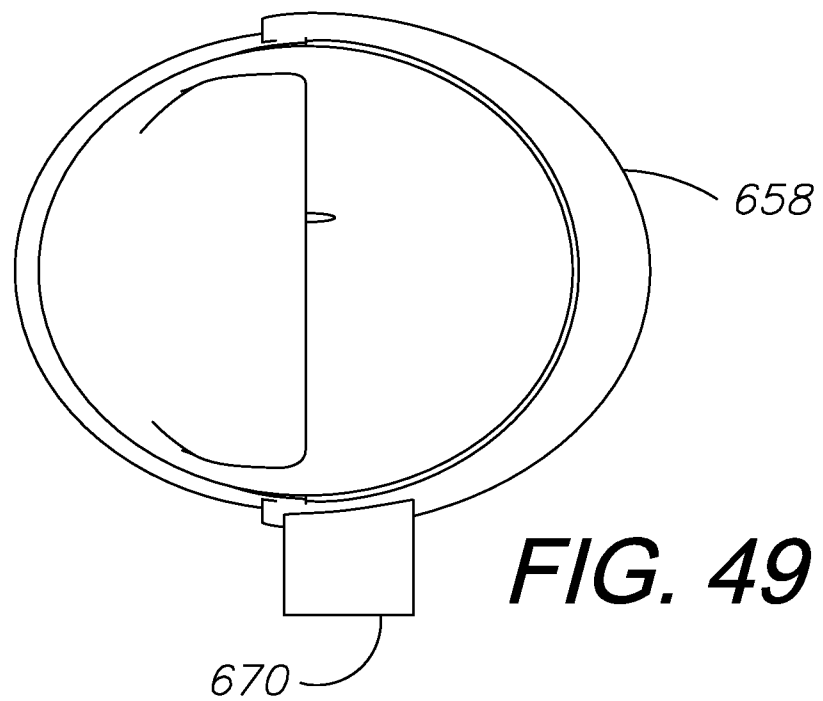
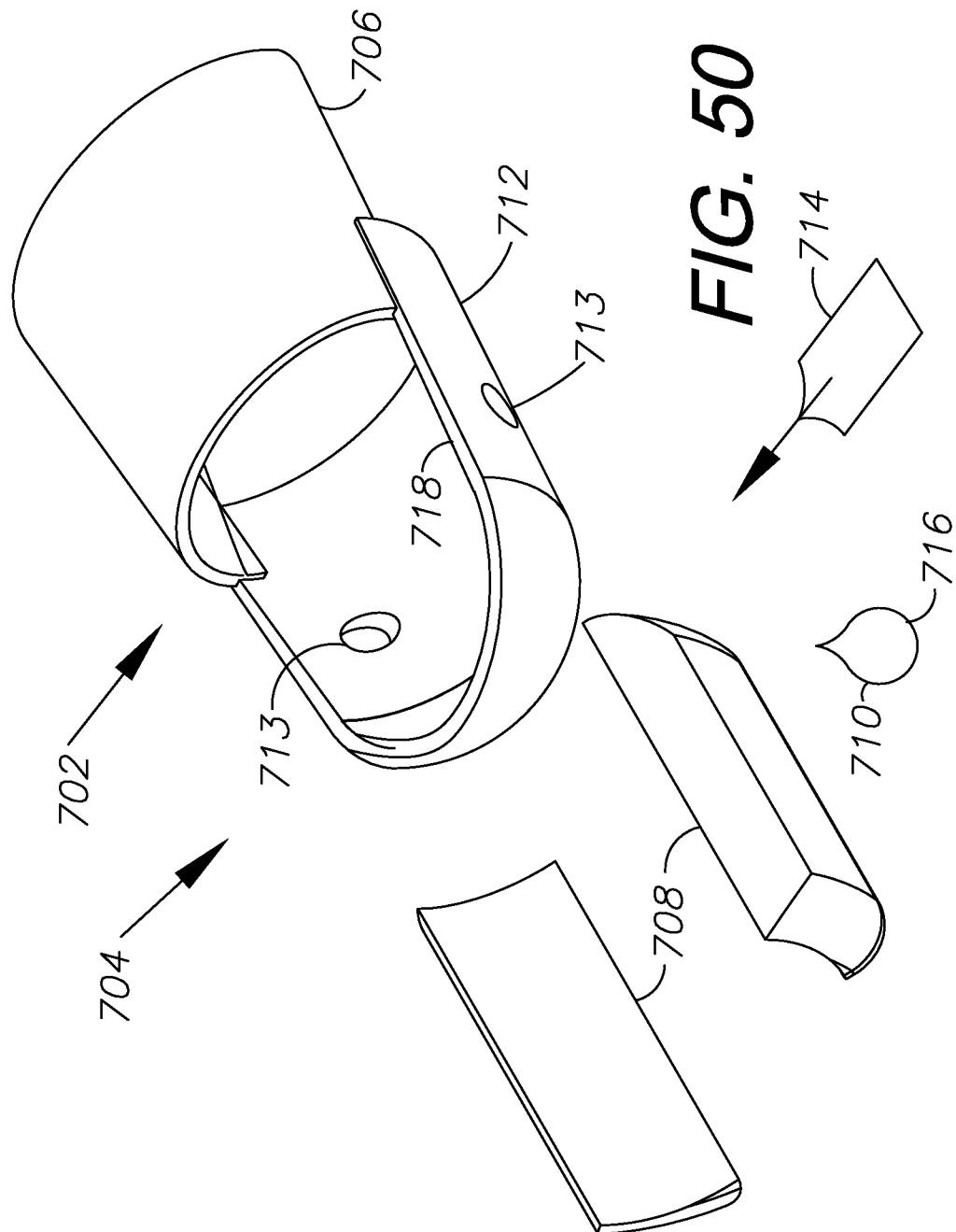


FIG. 49



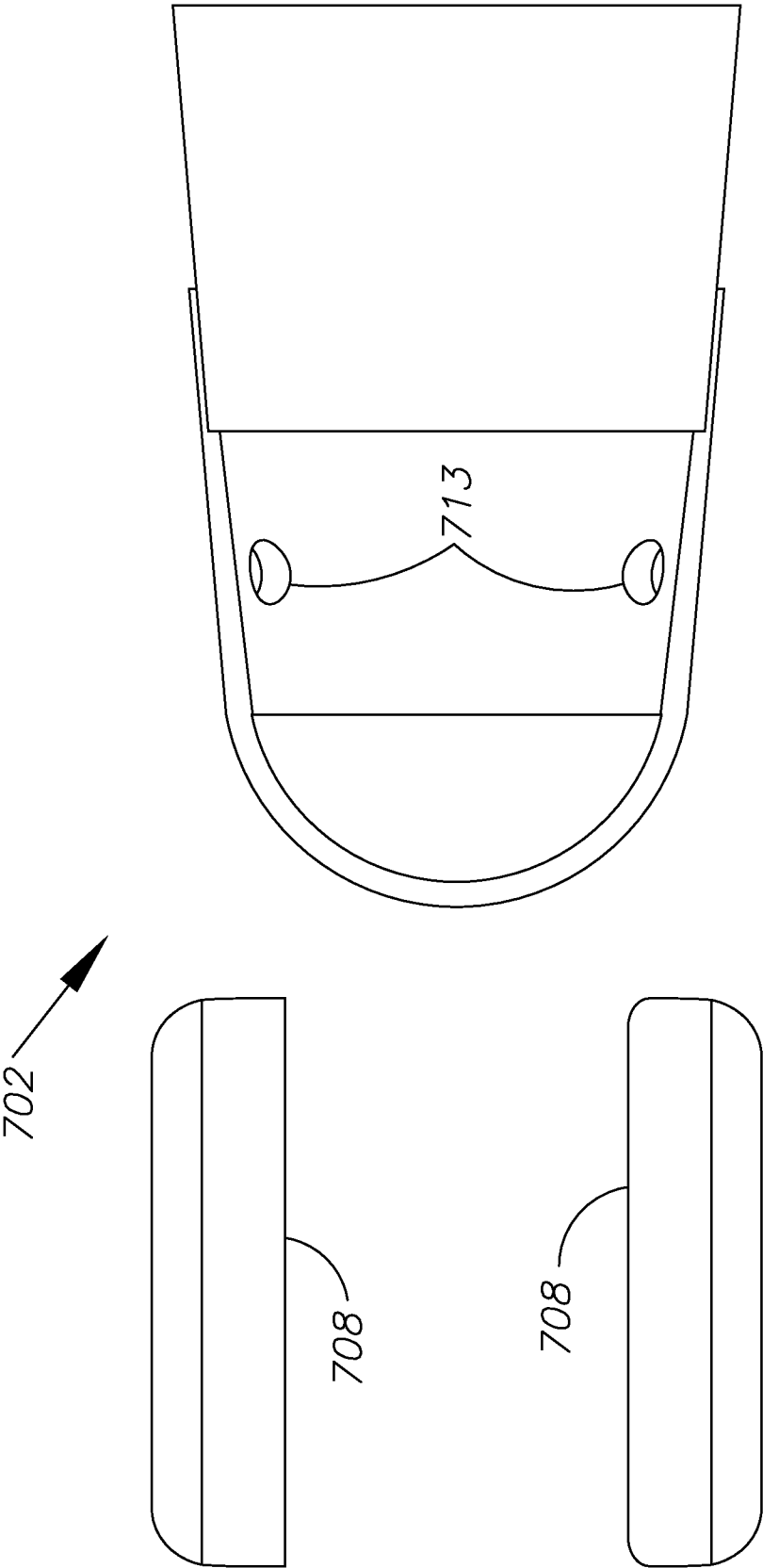
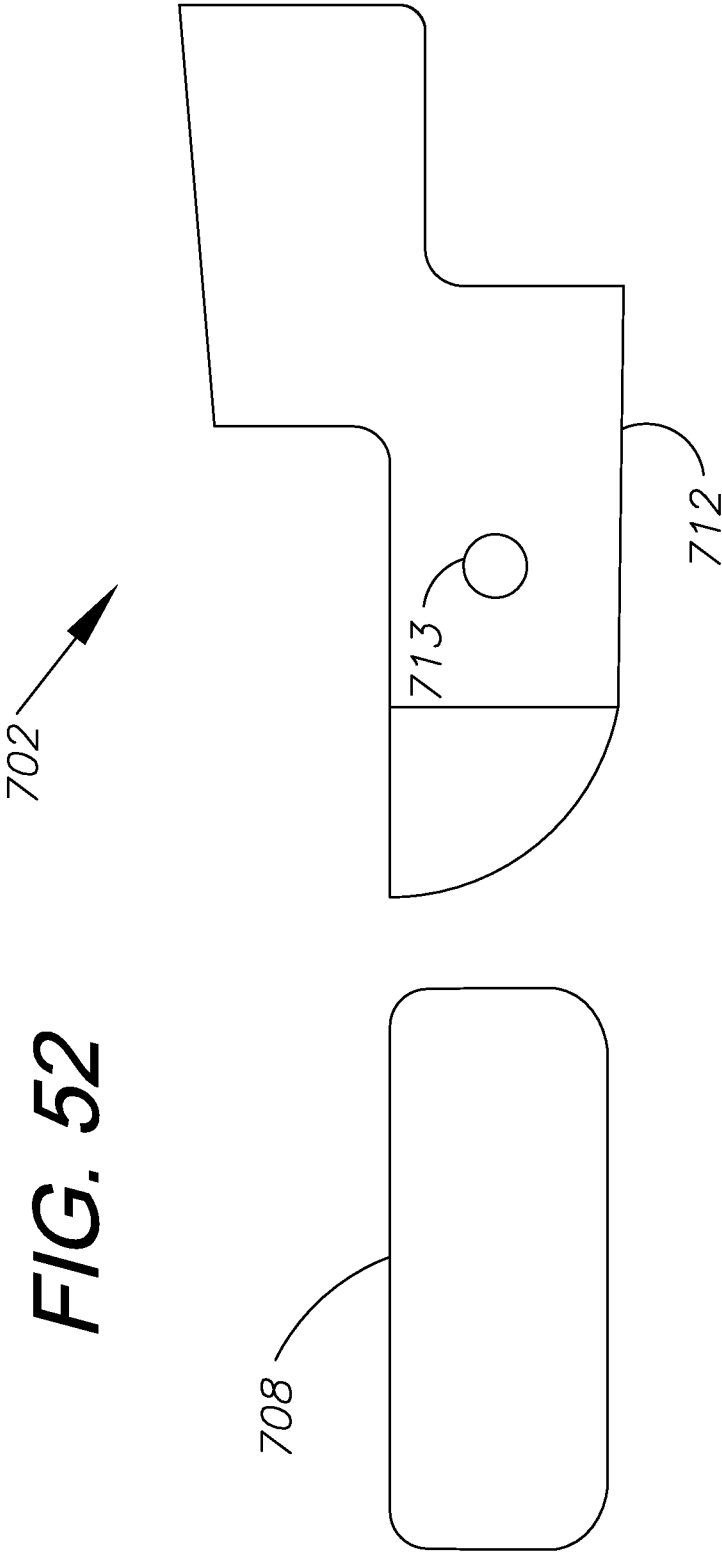
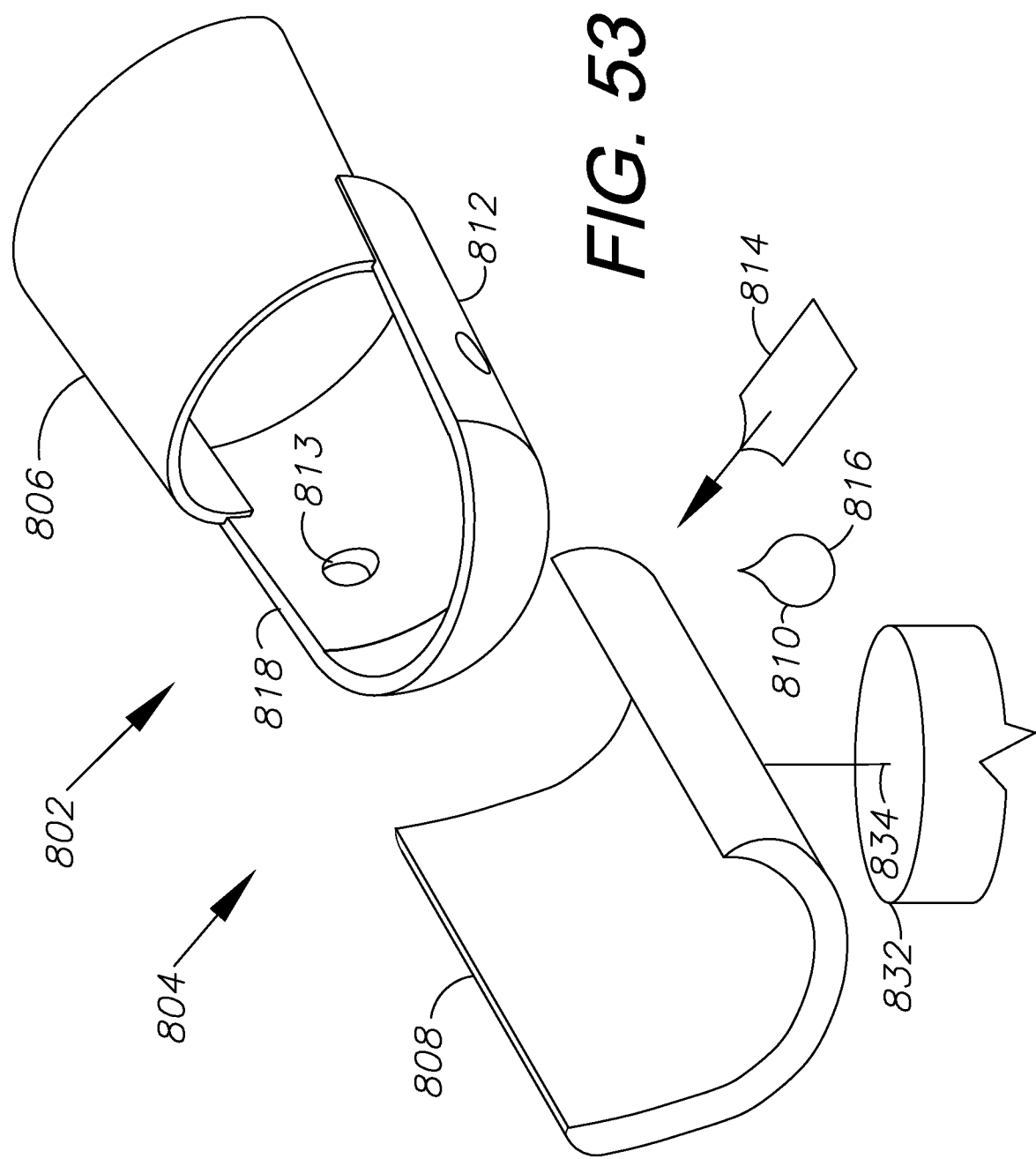


FIG. 51





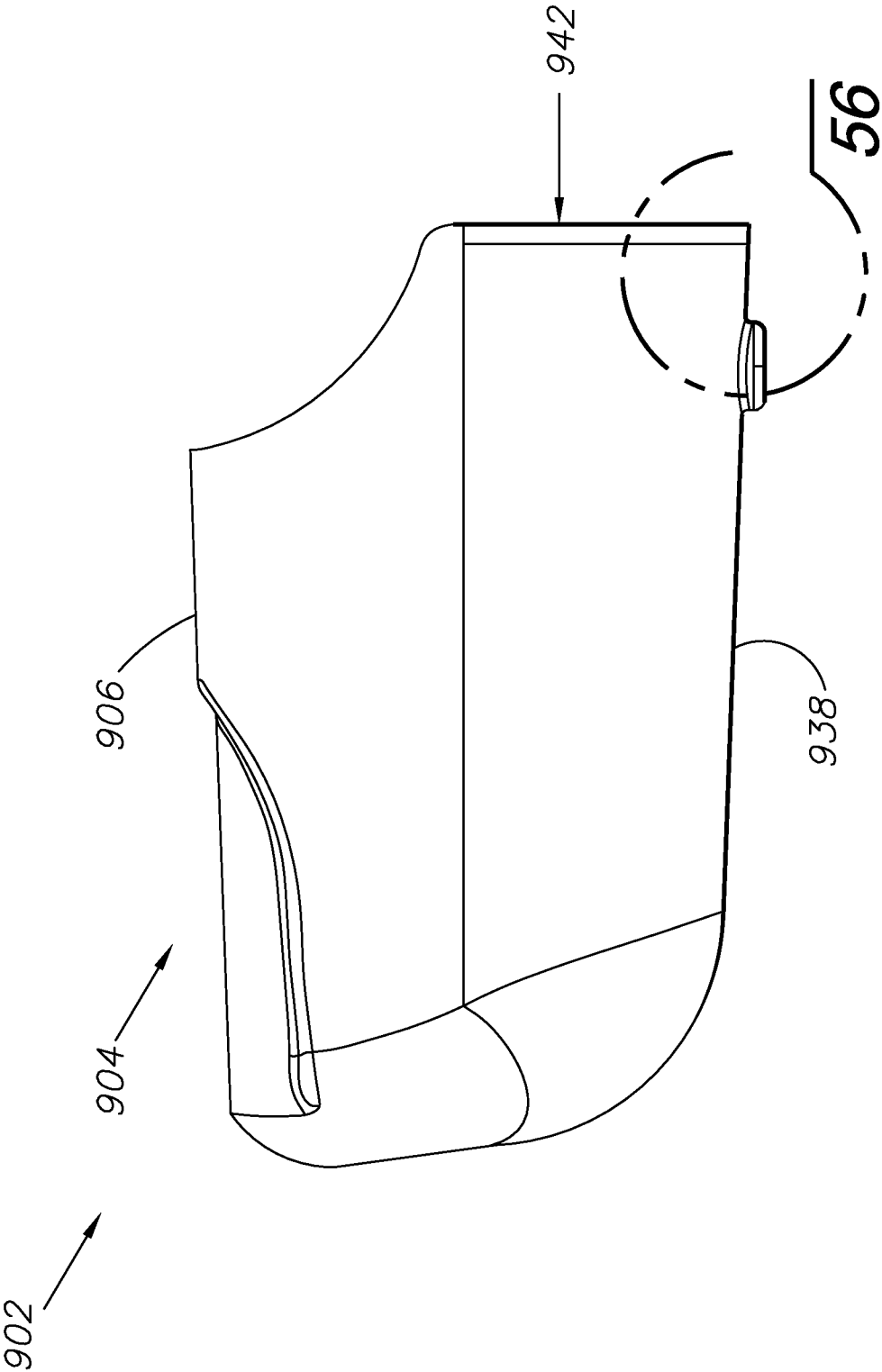
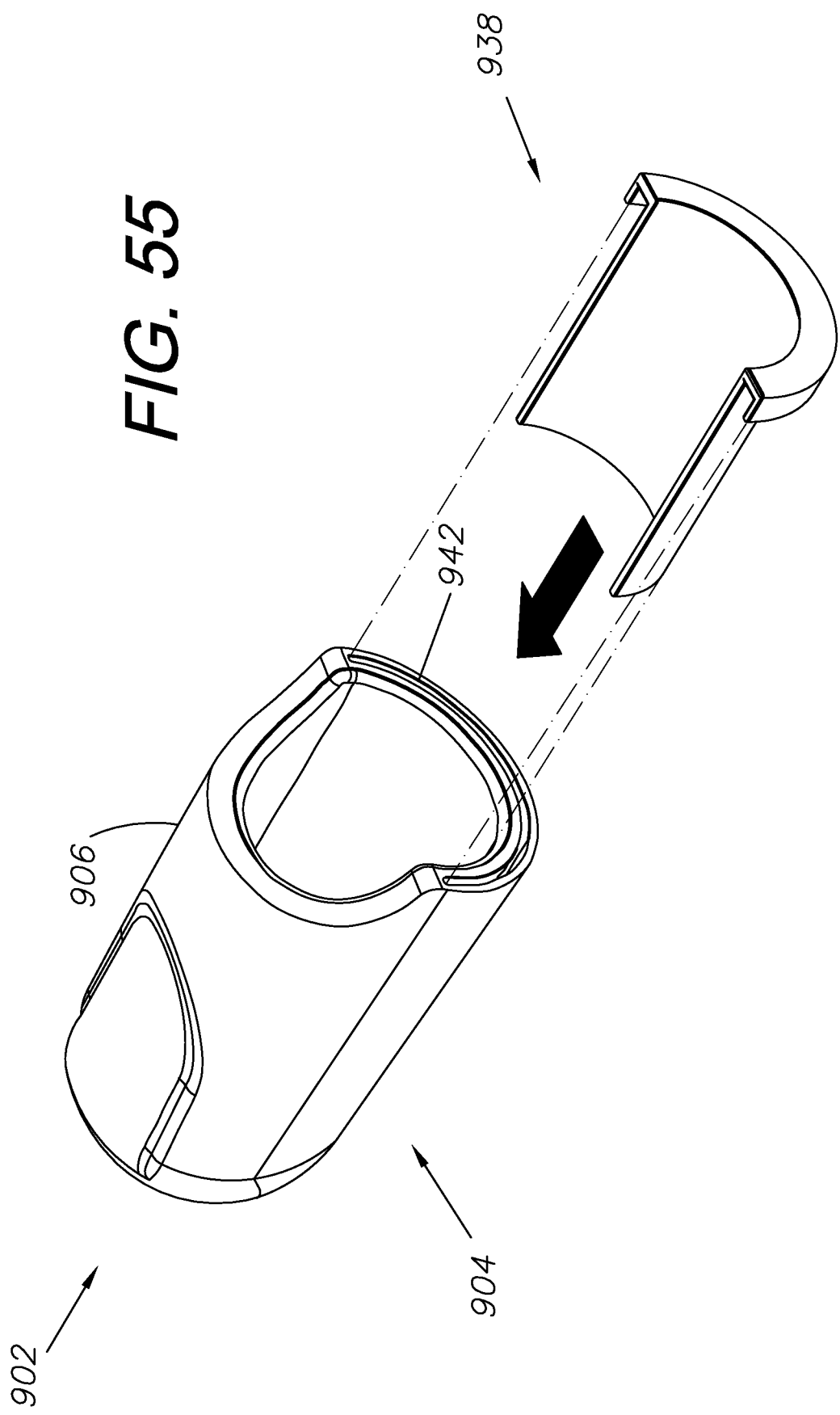


FIG. 54

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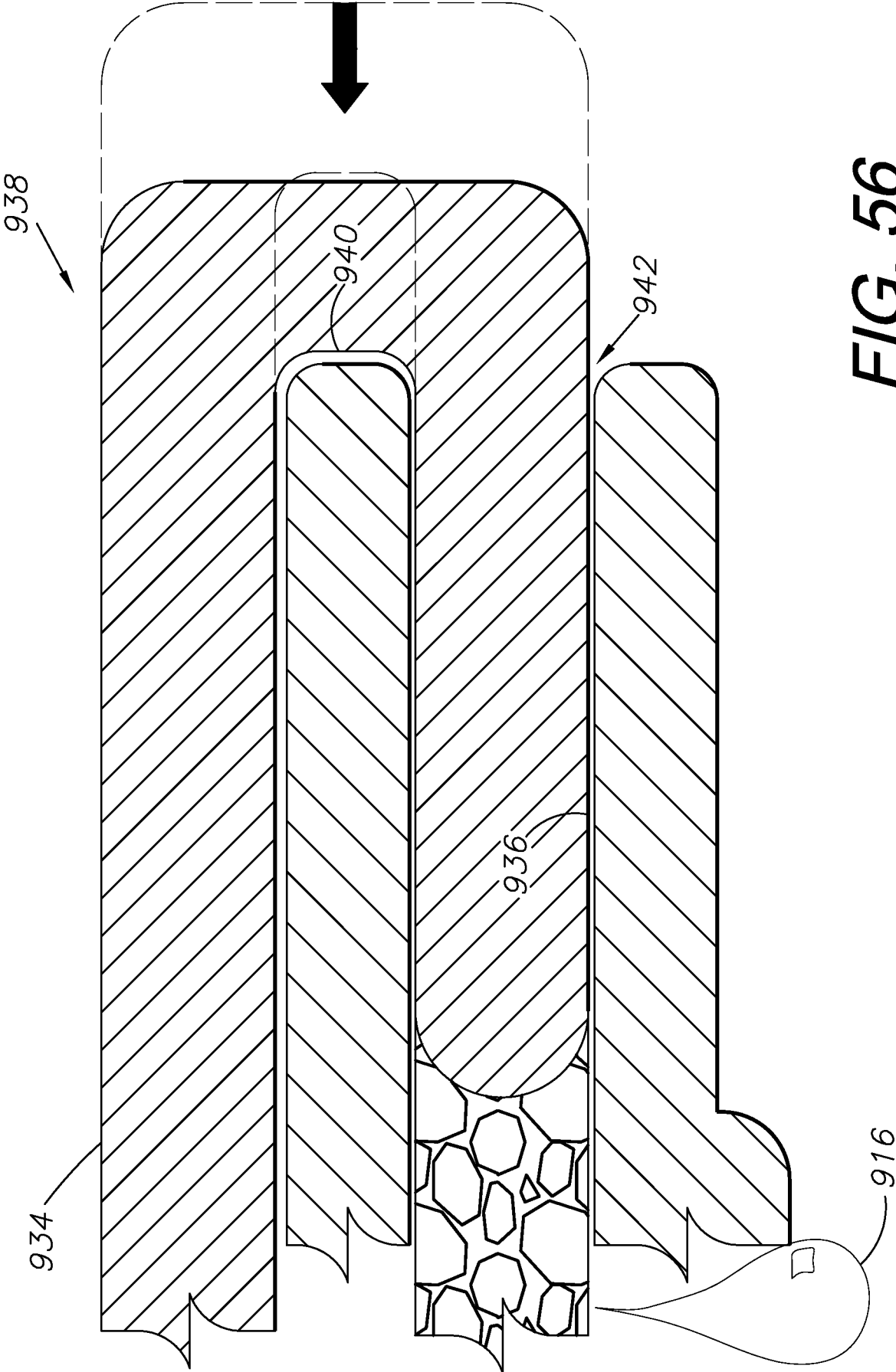


FIG. 56

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2015/013147

A. CLASSIFICATION OF SUBJECT MATTER

IPC(8) - G09B 23/30 (2015.01)

CPC - G09B 23/303 (2015.01)

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)

IPC(8) - G09B 23/00, 23/28, 23/30, 23/32, 23/34 (2015.01)

CPC - G09B 23/00, 23/28, 23/30, 23/303, 23/306, 23/32, 23/34 (2015.01) (keyword delimited)

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

USPC - 434/262, 267, 268, 272

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

Orbit, Google Patents, Google Scholar.

Search terms used: fluid analysis, simulation, mannequin, finger, glucose, tester, training

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X ----- Y	WO 2005/122105 A2 (GREATER GLASGOW NHS BOARD) 22 December 2005 (22.12.2005) entire document	1, 3-7, 10, 11, 13, 15-19 ----- 2, 8, 9, 14, 20
Y	US 2009/0187351 A1 (ORR et al) 23 July 2009 (23.07.2009) entire document	2
Y	US 2,689,415 A (HAVER) 21 September 1954 (21.09.1954) entire document	8, 14, 20
Y	US 2007/0111174 A1 (KOZMENKO et al) 17 May 2007 (17.05.2007) entire document	9
A	US 2013/0052626 A1 (HOSKINS) 28 February 2013 (28.02.2013) entire document	1-20
A	US 2006/0269906 A1 (WHITE) 30 November 2006 (30.11.2006) entire document	1-20
A, P	US 2014/0065589 A1 (ZAMIEROWSKI et al) 06 March 2014 (06.03.2014) entire document	1-20

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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

31 March 2015

Date of mailing of the international search report

07 MAY 2015

Name and mailing address of the ISA/US

Mail Stop PCT, Attn: ISA/US, Commissioner for Patents
P.O. Box 1450, Alexandria, Virginia 22313-1450

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