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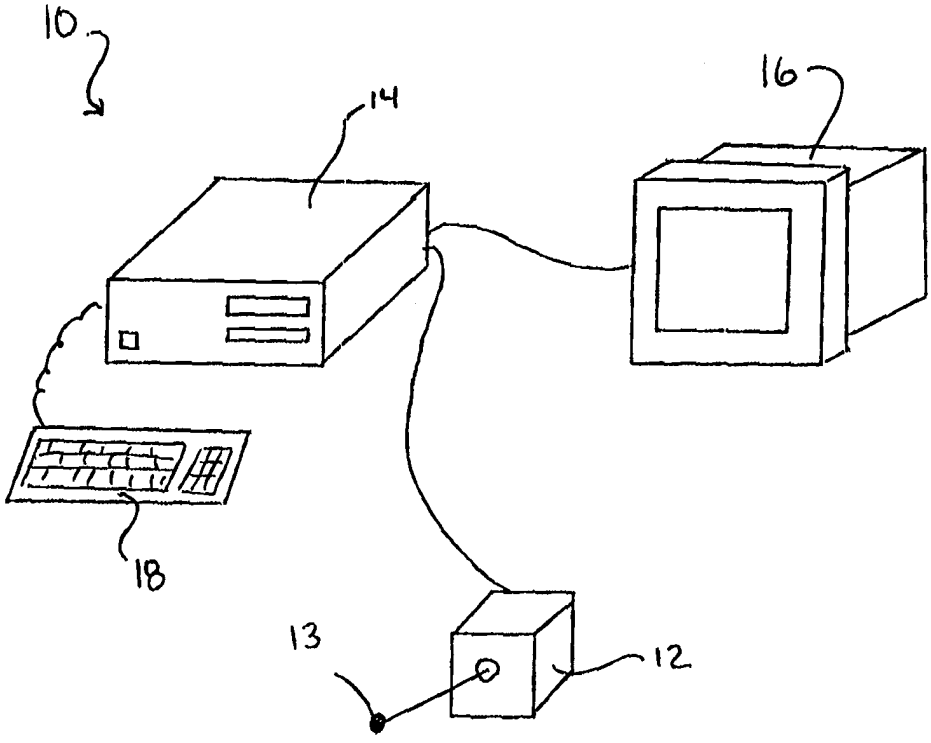
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(54) Title: CORONARY ANGIOPLASTY SIMULATOR APPARATUS

(57) Abstract

A system is disclosed in which a physician interacts with a computer (14) driven simulator to learn, perfect and maintain skills in the diagnosis and treatment of coronary artery disease with angioplasty procedures. The physician is presented with a simulated angioplasty device (12) and video monitor (16) which displays realistic fluoroscopic images of a diseased coronary artery. In response to displayed images and user selected or computer selected parameters the user diagnoses coronary arterial disease, selects the appropriate angioplasty procedure and instrumentation to treat the diagnosed condition and simulates performing the actual angioplasty procedure viewing the procedure on the video monitor. Upon completion of the simulated angioplasty procedure the physician receives a critique of his or her diagnostic, medical judgment and surgical skill performance.



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TITLE OF THE INVENTION

CORONARY ANGIOPLASTY SIMULATOR APPARATUS

BACKGROUND OF THE INVENTION

1 Field of the Invention

This invention relates to computer based simulators used in the training of personnel in the medical field. More particularly, the invention pertains to a system in which a physician interacts with a computer driven simulator to learn, perfect and maintain skills in the diagnosis of coronary artery disease and the treatment of same with angioplasty procedures. The physician is presented with a simulated angioplasty device and video monitor displaying realistic fluoroscopic images of a diseased coronary artery. In response to images appearing on the display and user selected or computer selected parameters, the user diagnoses coronary arterial disease, selects the appropriate angioplasty procedure and instrumentation to treat the diagnosed condition and simulates performing the actual angioplasty procedure viewing the procedure on the video monitor. Upon completion of the simulated angioplasty procedure the physician receives a critique of his or her diagnostic, medical judgment and surgical skill performance.

Further, the user may select from a practice mode and a simulation mode. The practice mode permits individual development of skills associated with each of diagnosis, medical judgment and surgical skill. The simulation mode permits the user to perform a complete simulated angioplasty procedure wherein perfection of all three skills of diagnosis, medical judgment and surgical skill is required.

Though disclosed herein as being applicable to coronary disease and angioplasty procedures, the present invention and the principals thereof have further application in permitting individuals to learn, perfect and maintain their skills

in the diagnosis of other diseases and treatment of those and others using other vascular and interventional procedures.

2. The Prior Art

In recent years, an effort has been made to minimize, where possible, the use of open invasive surgical procedures. Due to the nature of open procedures, the possible complications, the patient recovery period and the associated hospital and physician costs, alternative methods of treatment, and even cure, have been developed to minimize the undesirable aspects of open surgery. One particular procedure having gained widespread favor in the field of cardiology is coronary angioplasty whereby certain types of coronary artery disease may be treated with a substantially noninvasive medical procedure. In such a procedure the physician introduces a guidewire catheter into the patient's arterial system which is then manipulated by the physician along the arterial system to the location of the arterial blockage. A balloon catheter, or other blockage clearing device, is then passed over the guidewire catheter and moved into a position adjacent the arterial blockage. In the case of a balloon catheter, the balloon is then inflated to a predetermined pressure and size and allowed to remain in place for a period of time all controlled by the physician. The compressive forces exerted by the balloon catheter serve to clear the blockage and substantially restore blood flow through the artery obviating the need for a "coronary by-pass" operation.

Given the substantially non-invasive nature of the procedure the physician of course does not have a direct view of the arterial system or blockage site. Instead, the physician must view the relevant portions of the patients anatomy on a video display generated by an fluoroscopic imaging device and rely upon tactile feedback felt by the physician through the angioplasty control device in order to determine the position of the guidewire and balloon catheter.

This procedure, among others, requires much training to learn the basic techniques and perfect and maintain the necessary skills. Indeed, the training of such procedures demands perfection in three fundamental aspects of surgery namely, diagnosis, medical judgment and surgical skill. In performing an angioplasty procedure the practitioner must diagnose the complication, accurately use his/her medical judgment to select the appropriate procedure and devices to correct the complication, and execute the surgical techniques operating the devices required to perform the chosen procedure. Due to the nature of an angioplasty procedure, it is often difficult to provide a developing practitioner with opportunities to assist in or directly perform an actual angioplasty procedure given the finite number of live patients upon whom such procedures are performed in any given medical institution as well as in view of the potential liabilities associated with any medical procedure.

Due to the inability to "practice" most medical procedures extensively on live patients, most prior art techniques designed to teach medical procedures to physicians in training are directed to simulating live conditions in nonliving substitutes. An example of such a prior art device is U.S. Patent No. 4,360,345 granted November 23, 1982 to David C. Hon which discloses a instruction system incorporating a three dimensional mannequin as a non-living substitute for a live patient. The mannequin is attached to a computer intended to teach an individual how to administer cardiopulmonary resuscitation (CPR), a non-invasive technique to manually force blood flow through an individual in cardiac arrest. The system is designed to receive, analyze and compare the CPR technique which is administered to the non-living substitute and compare this CPR technique to the proper CPR technique which is stored in the memory of the computer. This prior art reference does not disclose or contemplate simulation of an invasive or semi-invasive medical procedure on a patient and instead relies physical inputs applied to the exterior of the mannequin and does not contemplate the simulation of complex manipulations

of medical devices, much less medical devices which are used within a body, such as in an angioplasty procedure.

A further prior art teaching device is disclosed in U.S. Patent No. 4,907,973, granted to David C. Hon on March 13, 1990, which discloses a medical investigative system in which a person interacts with a three dimensional model of a portion of the human anatomy designed to accept the introduction of a three dimensional probe, or the like, to simulate performing an invasive or semi-invasive procedure. The system disclosed relies upon a three dimensional physical model, such an actual model of a stomach, and a model of a medical device, such as an endoscope. In operation the user moves the model of the medical device about the interior of the model of the physical organ and in the process trips certain sensors positioned within the anatomical model. The output of these sensors are analyzed by an attached computer and a video image is retrieved from an attached video disk storage device which images are in turn displayed on a monitor to display an internal view of the organ as would be seen by the user when viewing an actual organ through an actual endoscope. Based on the particular sensor that is activated, the computer selects from a discrete number of stored images on the video disk to display.

One potential limitation of such a prior art device is that the procedures which may be simulated are limited to those types of procedures that are compatible with the modeling system, and the available physical organ models. The models of the physical organs and the medical devices must include the hardware necessary for attachment and communication with the computer. Accordingly, it may be difficult and cost prohibitive to simulate various procedures with various different medical devices on various physical organs of the body. Further, while in a limited sense, this reference facilitates the simulation for improving the physical skill of the physician, this reference does not provide the user with any interactive education toward improving the diagnosis and the medical judgment skills of the user, skills which are invaluable in the training of a physician.

It is thus an object of the present invention to provide a computerized simulator having the ability to simulate semi-invasive medical procedures, such as angioplasty, for the training of medical practitioners without the use of a live patient.

It is also an object of the present invention to provide a computerized simulator to develop diagnosis, medical judgment and physical dexterity skills of practitioners.

It is a further objective of the present invention to provide a computerized simulator capable of simulating invasive surgery of various body organs using variety of medical devices.

It is still a further objective of the present invention to provide a computerized simulator capable of introducing complications during the simulation of invasive surgery.

It is yet another object of the present invention to provide a computerized simulator capable of permitting the user to select a particular medical condition which the user may attempt to treat using the simulated angioplasty device.

These and other objects of the present invention will become apparent in light of the present specification, claims, and drawings.

SUMMARY OF THE INVENTION

An invasive medical procedure simulator system is disclosed for use by a practitioner to learn, perfect and maintain skills in the diagnosis of coronary artery disease and the treatment of same with coronary interventional procedures. A video display is provided for presenting the user with a photo-realistic fluoroscopic image of a diseased coronary artery. Processor means are operably connected to the video display for controlling the presentation of video images on the video display. Selection means permits the user to enter a diagnosis of coronary arterial disease, to select an appropriate angioplasty procedure and designate the invasive instrumentation and operating parameters most appropriate to treat the diagnosed condition in response to images appearing on the video display. Input means are operably connected to the processor means for manipulation by the user to simulate the operation of the selected instrumentation and advancement through the displayed coronary artery toward further simulating performing an actual angioplasty procedure wherein manipulation of the input means causes a corresponding image of the instrumentation to appear on the video display.

In one embodiment of the invention means are further provided for providing the user upon completion of a simulated procedure with a critique evaluating the user's ability to accurately diagnose coronary artery disease, to properly exercise medical judgment toward selecting the proper corrective procedure, devices and operating parameters and to properly execute the physical aspects of the angioplasty procedure.

In one embodiment, the input device comprises a joystick while in another the input device comprises a controller configured to imitate an actual medical device used to perform an invasive medical procedure such as a guidewire and means for sensing the movement of the guidewire.

In the preferred embodiment of the invention the processor means comprises a personal computer. and the image displayed on the display device is a

fluoroscopic x-ray image of a coronary artery. In an alternative embodiment of the present invention the invasive medical procedure simulator for use by a practitioner to learn, perfect and maintain skills in the diagnosis of disease and the treatment of same with procedures includes means for selecting at least one predetermined medical procedure for simulation, an input device simulating a medical device capable for use in performing the at least one predetermined medical procedure, processor means for detecting and analyzing movement of the input device by the practitioner relative to the selected at least one predetermined medical procedure, and a display device interconnected with the processor means displaying a realistic representation of the movement of the input device relative to the predetermined medical procedure, the display device further prompting the user as to further movement of the input device.

The present invention further includes a method for simulating an invasive medical procedure, the method comprising the steps of selecting at least one predetermined medical procedure for simulation; displaying a realistic representation of portion of the human anatomy on a video display; providing for the manipulation an input device simulating the movement of an invasive medical instrument within the human body; displaying the movement of the medical instrument on the video display; and repeating the steps until the simulated medical procedure is completed.

In the preferred method of the present invention the invention further includes the step of comparing the movement of the input device within the boundary of the portion of the human anatomy displayed toward providing the user with a critique of his or her surgical skill performance.

Another embodiment of the present invention comprises a method for simulating an invasive medical procedure and includes the steps of: providing a series of diagnostic parameters for selection by a user; displaying a visual display comprising a realistic representation of portion of the human anatomy on a video display based upon parameters is selected by the user; accepting as an input the

user's diagnosis of the medical condition; manipulating an input device to simulate performing a medical procedure selected to correct the diagnosed medical condition; analyzing the movement of the input device relative to the displayed portion of the human anatomy; displaying a realistic representation of the movement of the input device relative to the displayed portion of the human anatomy; and repeating these steps until the medical procedure is completed.

BRIEF DESCRIPTION OF THE DRAWINGS

Fig. 1 of the drawings is a graphical representation of the present coronary angioplasty simulator apparatus,

Fig. 2 of the drawings is a graphical representation of an input device used in the present coronary angioplasty simulator apparatus,

Fig. 3 of the drawings is a graphical representation of an alternative embodiment of an input device used in the present coronary angioplasty simulator apparatus;

Fig. 4 of the drawings is a flowchart illustrating the various steps in the operation of the present invention; and

Fig. 5 of the drawings is a pictorial representation of a sample video display generated by the present coronary angioplasty simulator apparatus.

DETAILED DESCRIPTION OF THE DRAWINGS

While this invention is susceptible of embodiment in many different forms, there is shown in the drawings and will herein be described in detail, several specific embodiments with the understanding that the present disclosure is to be considered as an exemplification of the principles of the invention and is not intended to limit the invention to the embodiments illustrated.

Figure 1 is a graphical representation of the present coronary angioplasty simulator apparatus 10 which includes input device 12, computer 14, keyboard 18 and visual display 16. Although coronary angioplasty simulator apparatus 10 is shown in Figure I as including three distinct components, it will be known to those skilled in the art that any of these components may be modified so as to incorporate the system into fewer components without altering the fundamental nature of the invention.

Coronary angioplasty simulator apparatus 10 allows a medical practitioner to perform a simulated angioplasty procedure in a substantially realistic environment in order to learn, perfect and/or maintain the skills necessary to perform coronary angioplasty. Coronary angioplasty simulator apparatus 10 upon completion of a simulated procedure further provides the user with a critique evaluating the user's ability to accurately diagnose coronary artery disease, to properly exercise medical judgment toward selecting the proper corrective procedure, devices and operating parameters and to properly execute the physical aspects of the angioplasty procedure.

The present coronary angioplasty simulator apparatus 10 is capable of operating in both a learning mode and in a simulator mode. In a learning mode the user has the ability to select a particular type of coronary lesion and the particular coronary section upon which he or she would like to practice. After selecting the lesion and coronary section the user then selects the appropriate angioplasty device, such as a balloon catheter, specifying the specific size and type, given the

nature of the lesion and its location. The coronary angioplasty simulator apparatus 10 will then display to the user on the video monitor 16 the chosen lesion to be angioplastized located in the chose coronary artery section. The image displayed on monitor 16 will be a digitized image of a fluoroscopically generated view of the coronary artery section and the lesion located therein which provides a realistic simulation of the fluoroscopic images typically viewed by the physician during an angioplasty procedure in an actual operating theater situation dealing with a live patient.

Using input device 12 the operator will guide a catheter to take a picture of the coronary artery and then through the guide cathetor the operator will manipulate a guidewire viewed on display 16 into the coronary artery system to the site of the coronary lesion. It is contemplated that the user using the keyboard 18 can command that the procedure start at a point where the guidewire is already positioned well into the arterial system whereby the user may practice manipulating the guidewire from that point forward on to its final destination at the lesion site. Alternatively, it is contemplated that the user may command simulator 10 to begin the procedure at the very beginning such that the video image tracks the procedure from the start, e.g. where the guidewire is first inserted into the patient.

During the process of routing the guidewire to the site of the lesion the user, as in an actual procedure, must rely solely upon the fluoroscopic image appearing on the video monitor. The present invention superimposes onto the simulated fluoroscopic display an image corresponding to the guidewire. As in real life, given the radio opaque nature of the guidewire the fluoroscopic image will include a display of the wire and its tip- As the user manipulates the input device 12 the video image 16 will track and display in real time the image of the guidewire as it moves through the arterial system.

As in an actual procedure the user must manipulate the angioplasty device control to properly advance the guidewire through the coronary artery system. As the user sees the tip of the guidewire approach curves or branches in the coronary

artery pictured in the simulated fluoroscopic display 16 the user must manipulate the input device 12 accordingly to be able to direct the guidewire down the desired path. In practice, as in real life, the tip of the guidewire contains a compound bend of two 45 degree angles. By advancing the guidewire forward and rotating the guidewire about a 360 degree axis via the input control 12 the user may route the guidewire through the arterial system.

The coronary angioplasty simulator apparatus 10 detects the movement of the tip of the guidewire as commanded by the users manipulation of input device 12 and continually compares the position tip of the guidewire to the boundaries defining the interior surface of the arterial wall such that it may be determined whether the user has failed to properly manipulate the guidewire such by applying too much force or failing to turn the tip to follow the path of the artery, each of which might result in a perforation of the arterial wall from the inside. In such event the coronary angioplasty simulator apparatus 10 may modify the video display to present to the user a video image of such event.

Once the user has successfully positioned the wire at the site of the lesion the user again manipulating input device routes 12 the selected angioplasty device, such as a balloon catheter to the site of the lesion. As with the positioning of the guidewire the advancement and position of the balloon catheter will be viewable on video monitor 16. Once the balloon catheter is in place the user again using keyboard 18 chooses the appropriate inflation pressure to inflate the balloon and time of inflation to dilate the lesion. After the user successfully completes the dilation the practice mode will end and the user will be presented with a summary and/or evaluation or critique. In the practice mode the critique may contain information indicating to the user that an inappropriate device was selected given the selected lesion and location, that improper inflation pressure or time was applied or that the user failed to recognize and react to a perforation or other user induced event. It is further contemplated that the critique may inform the user of a failure to recognize and react to a computer generated complication (if such feature is

enabled) such as a device failure, distal embolization, sudden occlusion, dissection or patient medical problem.

In the simulation mode the user first encounters an image displayed upon the video monitor of a fluoroscopically generated picture of a coronary artery. The user may further access patient medical charts, test data and other information relevant to the patient's condition. The user must then diagnose the situation and determine the nature of the lesion and its location. From this point on the simulation mode follows the same general operation as the practice mode.

In a preferred embodiment of the present invention computer 14 is comprises a conventional personal computer well known to those skilled in the art which has the ability to accept user inputs and process and analyze data and generate outputs. Personal computer 14 also includes means for storing digitized fluoroscopic images which are utilized in the computer simulation of the angioplasty procedure where such images replicate various user or computer selected portions of the arterial system.

Personal computer 14 further includes means for storing arrays of medical conditions, medical emergencies, patient data and other contingencies and complications which may arise during an actual angioplasty procedure as well as with hypothetical patient medical diagnoses and case histories of patients who may be candidates for undergoing the simulated procedure so as to provide a more realistic setting for the simulation. Furthermore, personal computer 14 may include means for storing or logging the user supplied inputs which occur throughout the simulated procedure toward providing the user with a comprehensive performance critique at the end of the simulation.

It is further contemplated that personal computer 14 may also comprise an output device such as a printer which would allow the user to receive hardcopy documentation of the results or critique of the simulation and specifically feedback concerned the diagnosis, medical judgment and manual dexterity of the user.

Figure 2 is a graphical representation of input device 12. Input device 12 is shown in Figure 2 comprising a conventional joystick styled mechanical input device similar to those which are commonly known within the personal computer art. In the present invention, input device 12 is used to simulate the advancement of an invasive medical device, such as a catheter guidewire commonly used in coronary angioplasty. Said input device 12 comprises joystick 20, joystick housing 22, and knob 24.

In a first embodiment of input device 12 shown in Fig. 2, device 12 is a joystick device of the type wherein joystick 20 is able to be moved in both the "x" axis and "y" axis wherein movement "up" and "down" along the "y" axis represents movement of the guidewire "in" and "out" respectively, and wherein movement "left" and "right" along the "x"" axis represents the rotational movement of the guidewire "counter clockwise" and "clockwise", respectively.

Joystick 20 is preferably spring mounted within joystick housing 22 so that after the external force applied to joystick 20 is removed in any of the directions and manners permitted, the joystick returns to a neutral or centered point. The ability of joystick 20 to return to this neutral point ensures the guidewire does not advance or retreat beyond the distance commanded by the user.

In a second embodiment of input device 12, device 12 is a joystick device of the type wherein joystick 20 is able to be moved in the "x" axis representing movement of the guidewire "in" and "out", and is able to be rotated about a "z" axis where such movement represents the rotational movement of the guidewire "clockwise" and „counterclockwise". In such an alternative embodiment it is contemplated that joystick 20 will return to a neutral or centered point ensures the guidewire does not advance or retreat beyond the distance commanded by the user. The ability to freely rotate 360 degrees provides the user with a more accurate simulation of the physical movements applied to an actual controller toward moving a coronary catheter guidewire through the arterial system of a live patient. Such movements simulate the difficulty inherent in placing a guidewire into position during

a typical angioplasty procedure and reinforces the learning, developing and maintaining of the hand to eye coordination necessary to properly perform an angioplasty procedure.

It is also contemplated that joystick 20 may include means to apply resistive force to restrict or impede the movement of joystick 20. Such means may comprise motors, magnets and/or mechanical brakes or rollers, controlled by computer 14, which when activated will create resistance against the practitioners movement of the joystick 20 thereby corresponding to the resistance which a practitioner would feel in advancing and moving the guidewire in a living patient such as when encountering a bend in the artery or unknown obstruction. Such controlled resistance will likewise simulate the feeling experienced by the practitioner in real life when placing a guidewire into position during a typical angioplasty procedure.

Figure 2 also shows the input device 12 having knob 24. It is further contemplated that knob 24 could also comprise a simulated coronary angioplasty handle 24, not shown, or any other type of hand-held inner body medical maneuvering device.

Figure 3 is a graphical representation of a further contemplated embodiment of input device 12. Input device 12, as is shown in Figure 3, comprises device housing 30, simulated coronary guidewire 32, and means 34 for detecting movement of coronary guidewire 32 within device 20. Means 34 for detecting movement of simulated coronary guidewire 32 may comprise mechanical rollers or magnetic or optical sensors positioned strategically within device housing 30 in order detect the movement of guidewire 32 as it is passed through the device housing 30. In operation the practitioner advances guidewire 32 through device 20 by passing it through entry port 31. Exit port 33 serves to permit the length of guidewire to exit housing 30. Such a construction adds further realism to the simulation by more closely resembling the actual movement of the guidewire and balloon catheter when performing an angioplasty procedure. It is further contemplated that this alternative embodiment of device 20 may include resistive

motors and/or magnets, controlled by computer 14, which when activated will create resistance against the practitioners advancement and rotation of guidewire 32 thereby corresponding to the resistance which a practitioner would feel in advancing and rotating the guidewire in a living patient such as when the guidewire abuts an inner wall of an artery or encounters an unknown obstacle.

The advantages of using input device 12, as shown in Figure 3, are that it provides a realistic feel and appreciation for the actual amount of guidewire used in an actual angioplasty procedure; and that it enhances the coordination of visual and manual responses -- indeed, the user's ability to see the guidewire move, results in an increased appreciation of the manual dexterity necessary for such a procedure.

Figure 4 of the drawings illustrates a flow diagram describing the operation of the present coronary angioplasty simulator apparatus. It is contemplated that the present invention be used to simulate an angioplasty procedure in which the user identifies particular parameters to be applied to the hypothetical patient. It is contemplated that the users ability to select said parameters will result in a simulator which allows for the use of incorrect and traditionally forbidden parameters being selected in performing the angioplasty procedure. Incorrectly selected parameters allows the user to learn from mistakes without jeopardizing the well-being of a live patient. In operation, step one is the selection of the practice parameters, namely the type of lesion and the lesion bearing coronary section on which the procedure is to be performed. For example the user may select any one of lesion types A, B or C having various morphology, calcium or thrombus, and size 1, 11 or III, <2.5mm, 2.6 - 3.0mm or 3.0mm respectively. The user may then select the coronary section bearing the lesion, such as right coronary artery, left circumflex and left anterior descending as well as proximal, mid and distal portions thereof. Thereafter the user selects the particular angioplasty device the user desires to use to treat the defined lesion. Among the possible choices are PTCA (balloon catheters), be they balloon over-the-wire, balloon on-the-wire, autoperfusion or monorail balloon catheters, as

well as rotating cutting catheters with and without suction (TEC and Rotoblator) or DVI or laser or stenting.

By permitting the user to select the particular lesion type, composition, size and location the user may experience the aspects of treatment associated therewith, namely the appropriate device type, size, inflation pressures, rotation speeds and suction pressures and duration as well as the dexterity required to position the angioplasty device at the required location.

Moreover, it is preferable for the simulator to allow the user to select parameters which are typically inconsistent with performing a successful procedure to provide the user with an opportunity to experiment with unorthodox techniques and procedures and learn from one's mistakes.

Once the user has chosen the particular parameters, visual display 16 provides the user with a picture of the coronary artery section selected, the type of lesion selected, and the initial placement of the coronary angioplasty guidewire. The visual display 16 is preferably a fluoroscopic or x-ray view of the appropriate area of the coronary artery and is substantially identical to the images which a physician might see when performing an actual procedure. At this point the user advances the guidewire catheter along through the arterial pathway to the point past where the lesion is located. It is the movement of the guidewire which requires a great deal of manual dexterity. The angles imparted upon the tip of the guidewire allows for the user to have directional control of the guidewire by advancing and rotating the wire from the proximate end toward placement of the guidewire in the arterial pathway- a pathway which often branches away from the main corridor at an angle of as much as 90 degrees. The simulated display allows a user to visualize, in real time, the movement of the guidewire, and provides the user with the opportunity to practice, develop and maintain the hand to eye coordination necessary to perform the procedure.

After the user has advanced the guidewire into the desired position, the user will then send a command, either through the input device 12 or through another

input device, such as a keyboard, connected to computer 14, in order to simulate the positioning of the balloon catheter over the guidewire. The user then uses input device 12 to advance the balloon catheter along the guidewire to the site of the lesion to be treated. As the balloon approaches the lesion, the user must manipulate it into correct placement at the midpoint of the lesion. Once the balloon has been properly positioned, or even improperly positioned as the case may be, the user will then select the pressure necessary to inflate the balloon and dilate the lesion. Again by sending instructions to the computer 14 via keyboard 14 the user may command the inflation pressure and time. It is important to note that choosing either the correct or incorrect dilation pressure may result in rupturing the artery or causing an occlusion to be injected into the arterial system and it is contemplated that the present invention may in fact cause such complications to occur if it is detected that the user has in fact selected to great a pressure or otherwise leaves the balloon inflated for too long. After dilation has been successfully accomplished, the program ends and the user is provided with a didactic summary which includes, but is not limited to, comparing the user's decisions with standardized responses, Said analyses may be supplied to the user in tabular form or in a narrative summary which provides a rating and comparison scale. Furthermore, the didactic summary material may also provide a critique of the user's ability to appropriately place the cathode balloon in the area of the lesion, and the likelihood that an artery was perforated or otherwise damaged during guidewire placement. Finally, the didactic summary material may include the time that it took to perform the procedure and a comparison of the user's time to a typical procedure.

A simulation mode of the present invention operates in substantially the same manner except that the simulator selects the lesion type, size and composition and location. It is left to the user to properly diagnose such aspects of the lesion using the visual image provided and/or other data available to the user such as test results associated with the particular patient image. The user, as with the practice mode, must then select the appropriate device and operating parameters and

perform the procedure by routing the guidewire and then the angioplasty device to the site of the lesion. In the simulation mode, the computer or an instructor may introduce further complications which the user must recognize and react properly to. For example, the simulator may present the user with a device failure, distal embolization, sudden occlusion, dissection or patient medical problem.

Figure 5 is a graphical representation of visual display 40 generated by the present invention. Visual display 40 contains two distinct informational sections; general diagnostic data information section 42 and fluoroscopic display section 44. General diagnostic data section 42 may be further divided into quadrants which may include, but are not limited to, displays representing diagnostic information of a hypothetical patient; such as the heart rate, oxygen saturation level, respiration rate, blood pressure, procedure's elapsed time, and other medical information that is relevant and/or necessary in order for a medical practitioner to perform an angioplasty procedure successfully. Fluoroscopic display section 44 includes a simulated view of a predetermined coronary section associated with an interventional procedure. As can be seen from Figure 5, said fluoroscopic view 44 is a two dimensional view of a cross-section of the arterial system 46. This view allows the user to visually monitor the movement and position of the simulated coronary guidewire and catheter as they are thread through the arterial pathway and positioned in proper proximity to the lesion.

Although the invention hereof has been described by way of examples of a preferred embodiment, namely a coronary angioplasty procedure, it will be evident that other adaptations and modifications may be employed without departing from the spirit and scope thereof. For example, various combinations of operative procedures could be employed, provided that the principles herein described were maintained so as to provide a high degree of care in avoiding stimuli which may distract a user so as to preclude the practice of diagnostic determinations involving patient conditions and the use of hand to eye coordination and manual dexterity within a medical procedure.

The foregoing description and drawings are merely to explain and illustrate the invention and the invention is not limited thereto except insofar as the appended claims are so limited, as those skilled in the art who have the disclosure before them will be able to make modifications and variations therein without departing from the scope of the invention.

WHAT IS CLAIMED IS:

-1-

An invasive medical procedure simulator system for use by a practitioner to learn, perfect and maintain skills in the diagnosis of coronary artery disease and the treatment of same with angioplasty procedures, the system comprising:

- video display for presenting the user with a photo-realistic fluoroscopic image of a diseased coronary artery;

- processor means operably connected to the video display for controlling the presentation of video images on the video display;

- selection means for permitting the user to enter a diagnosis of coronary arterial disease and to select an appropriate angioplasty procedure and designate the invasive instrumentation and operating parameters most appropriate to treat the diagnosed condition in response to images appearing on the video display;

- input means operably connected to the processor means for manipulation by the user to simulate the operation of the selected instrumentation and advancement through the displayed coronary artery toward further simulating performing an actual angioplasty procedure wherein manipulation of the input means causes a corresponding image of the instrumentation to appear on the video display.

-2-

The invention according to Claim 1 further including means for providing the user upon completion of a simulated procedure with a critique evaluating the user's ability to accurately diagnose coronary artery disease, to properly exercise medical judgment toward selecting the proper corrective procedure, devices and operating parameters and to properly execute the physical aspects of the angioplasty procedure.

-3-

The invention according to claim 1 wherein the input device comprises a joystick.

-4-

The invention according to claim 1 wherein the input device comprises a guidewire and means for sensing the movement of the guidewire.

-5-

The invention according to claim 1 wherein the processor means comprises a personal computer.

-6-

The invention according to Claim 1 wherein the imaged displayed on the display device is a fluoroscopic x-ray image of a coronary artery.

-7-

An invasive medical procedure simulator, for use by a practitioner to learn, perfect and maintain skills in the diagnosis of disease and the treatment of same with procedures, the system comprising:

- means for selecting at least one predetermined medical procedure for simulation;

- an input device simulating a medical device capable for use in performing the at least one predetermined medical procedure;

- processor means for detecting and analyzing movement of the input device by the practitioner relative to the selected at least one predetermined medical procedure; and

- a display device interconnected with the processor means displaying a realistic representation of the movement of the input device relative to the predetermined medical procedure, the display device further prompting the user as to further movement of the input device.

-8-

A method for simulating an invasive medical procedure, the method comprising the steps of

(a) selecting at least one predetermined medical procedure for simulation;

(b) displaying a realistic representation of portion of the human anatomy on a video display;

(c) providing for the manipulation an input device simulating the movement of an invasive medical instrument within the human body;

(d) displaying the movement of the medical instrument on the video display; and

(e) repeating steps (b) through (d) until the simulated medical procedure is completed.

-9-

The method according to Claim 8 wherein the invention further includes the step of comparing the movement of the input device within the boundary of the portion of the human anatomy displayed toward providing the user with a critique of his or her surgical skill performance.

A method for simulating an invasive medical procedure, the method comprising the steps of:

(a) providing a series of diagnostic parameters for selection by a user;

(b) displaying a visual display comprising a realistic representation of portion of the human anatomy on a video display based upon parameters is selected by the user;

(c) accepting as an input the user's diagnosis of the medical condition;

(d) manipulating an input device to simulate performing a medical procedure selected to correct the diagnosed medical condition;

(e) analyzing the movement of the input device relative to the displayed portion of the human anatomy;

(f) displaying a realistic representation of the movement of the input device relative to the displayed portion of the human anatomy; and

(g) repeating steps (c) through (f) until the medical procedure is completed.

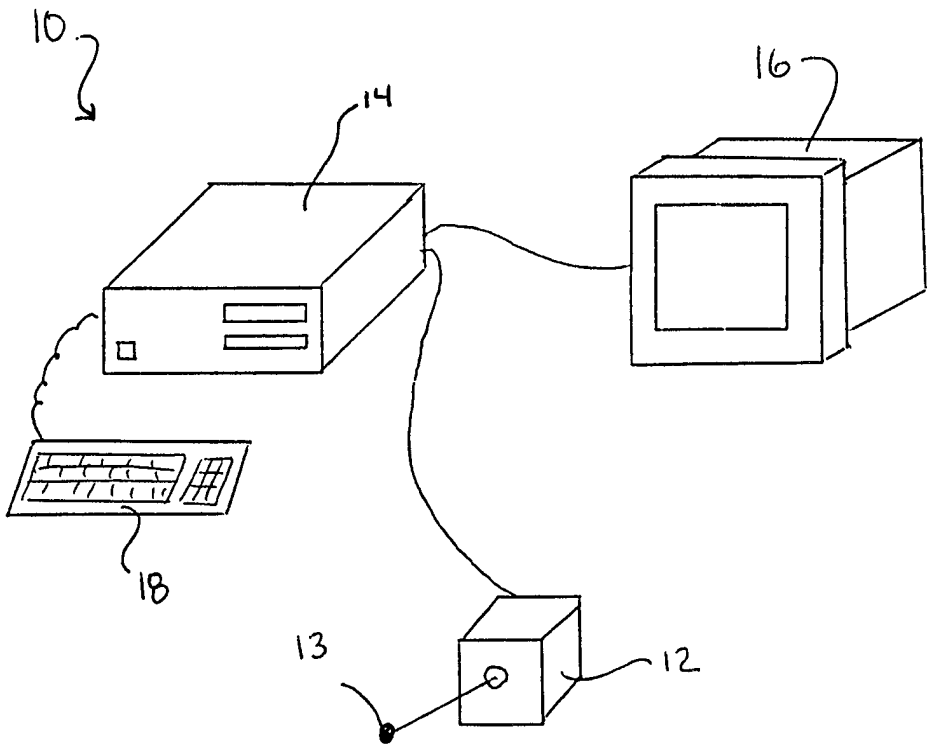


FIG. 1

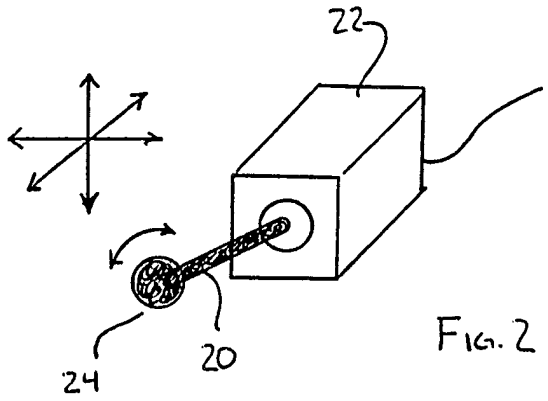


FIG. 2

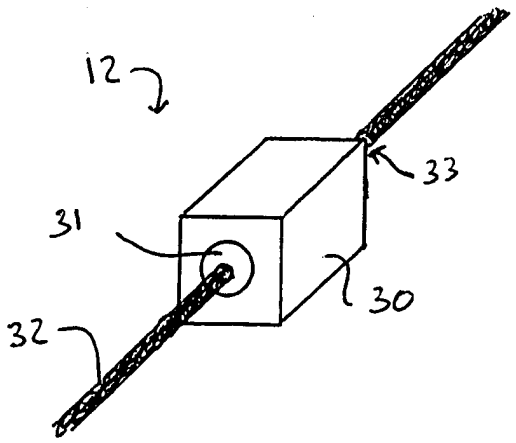


FIG. 3

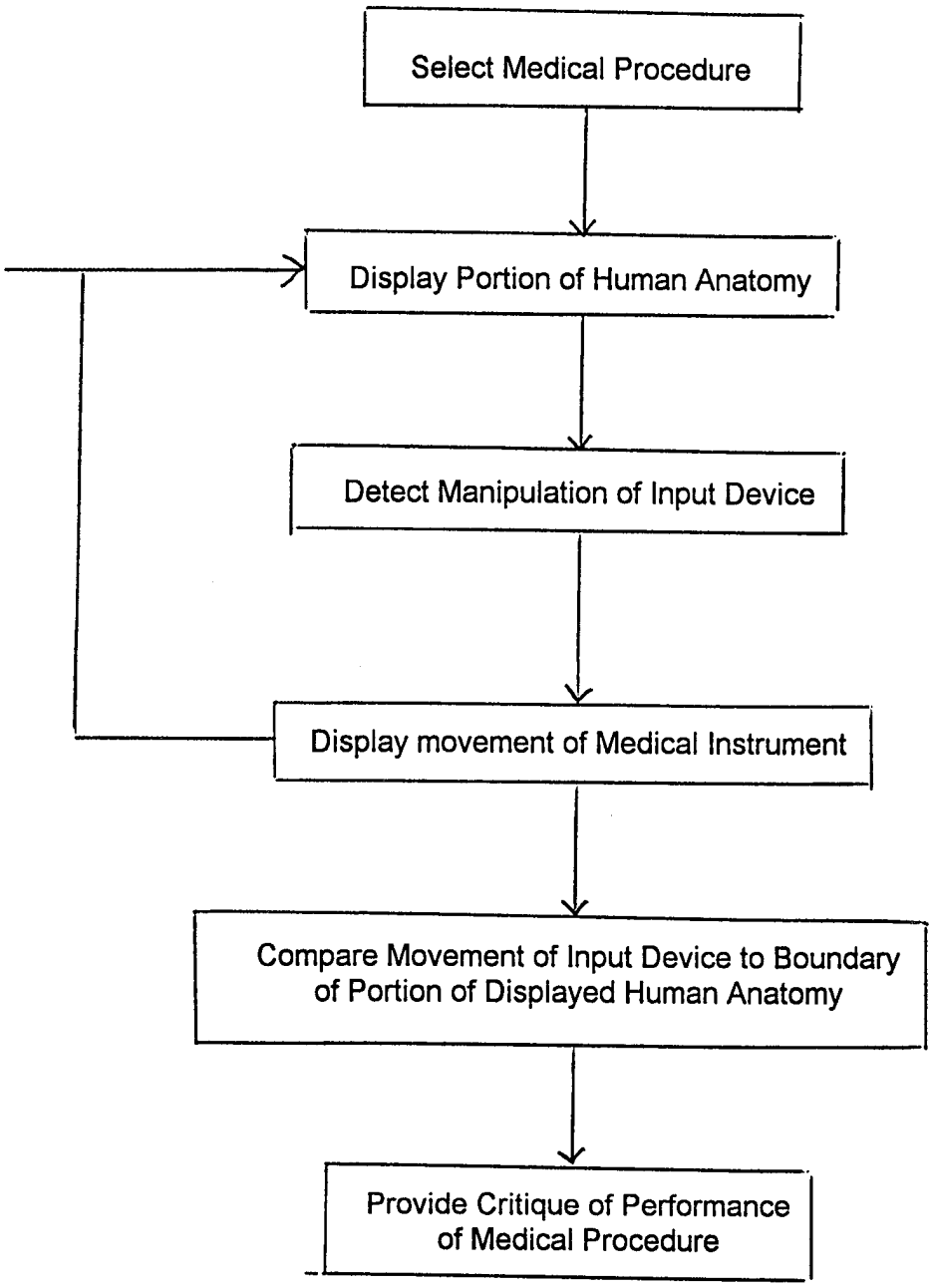

Select Medical Procedure
Display Portion of Human Anatomy
Detect Manipulation of Input Device
Display movement of Medical Instrument
Compare Movement of Input Device to Boundary of Portion of Displayed Human Anatomy
Provide Critique of Performance of Medical Procedure

FIG. 4

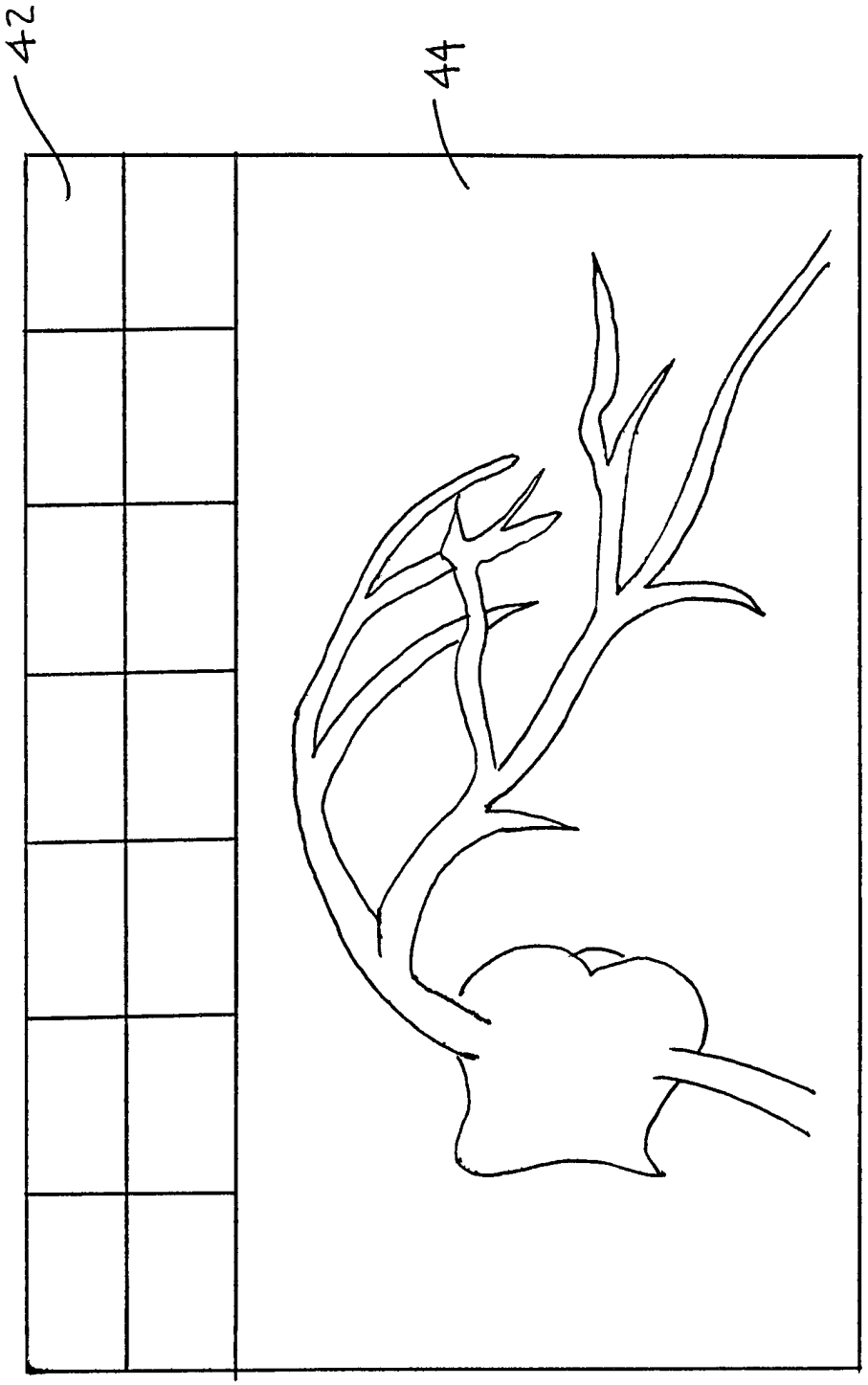


Fig. 5

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US97/22330

A. CLASSIFICATION OF SUBJECT MATTER
IPC(6) :G09B 23/28,
US CL :434/262, 267, 272
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)

U.S. : 434/262, 267, 272

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

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

APS search terms: simulation, medical, catheter, angioplasty

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 96/28800 A (MERRIL ET AL) 19 SEPTEMBER 1996, SEE ENTIRE DOCUMENT	1-10
X	US 4,642,055 A (SALITERMAN) 10 FEBRUARY 1987, SEE ENTIRE DOCUMENT	1-10
Y	US 5,454,722 A (HOLLAND ET AL) 03 OCTOBER 1995, SEE ENTIRE DOCUMENT	1, 2, 5
X	US 4,907,973 A (HON) 13 MARCH 1990, SEE ENTIRE DOCUMENT	1-10
X, E	US 5,704,791 A (GILLIO) 06 JANUARY 1998, SEE ENTIRE DOCUMENT	1-10
X --- Y	WO 95/02233 A (JACOBUS ET AL) 19 JANUARY 1995, SEE ENTIRE DOCUMENT	7, 8, 9 --- 1-6, 10

[X] Further documents are listed in the continuation of Box C. [ ] See patent family annex.

*	Special categories of cited documents:	"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
"A"	document defining the general state of the art which is not considered to be of particular relevance	"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
"E"	earlier document published on or after the international filing date	"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
"L"	document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	"&"	document member of the same patent family
"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		

Date of the actual completion of the international search 20 MARCH 1998	Date of mailing of the international search report 13 APR 1998
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INTERNATIONAL SEARCH REPORT

International application No.
PCT/US97/22330

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	VIRTUAL REALITY SURGERY: IMPLEMENTATION OF A CORONARY ANGIOPLASTY TRAINING SIMULATOR SURGICAL TECHNOLOGY INTERNATIONAL IV 1995	1-10
X	SURGICAL SIMULATION USING VIRTUAL REALITY TECHNOLOGY: DESIGN, IMPLEMENTATION, AND IMPLICATIONS SURGICAL TECHNOLOGY INTERNATIONAL III, date preceding 1995, that of Surgical Technology International IV.	1-10
Y	MERRIL ET AL. VIRTUAL HEART SURGERY: TRADE SHOW AND MEDICAL EDUCATION. July 1994.	1-10