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Pelissier et al.

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(54) **HIGHLY CONFIGURABLE MEDICAL ULTRASOUND MACHINE AND RELATED METHODS**

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G06F 19/00 (2011.01)

(52) **U.S. Cl.**
CPC . ***A61B 8/00*** (2013.01); ***A61B 8/463*** (2013.01); ***A61B 8/465*** (2013.01); ***A61B 8/467*** (2013.01); ***A61B 8/585*** (2013.01); ***G06F 19/321*** (2013.01)

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USPC 600/437, 443, 459
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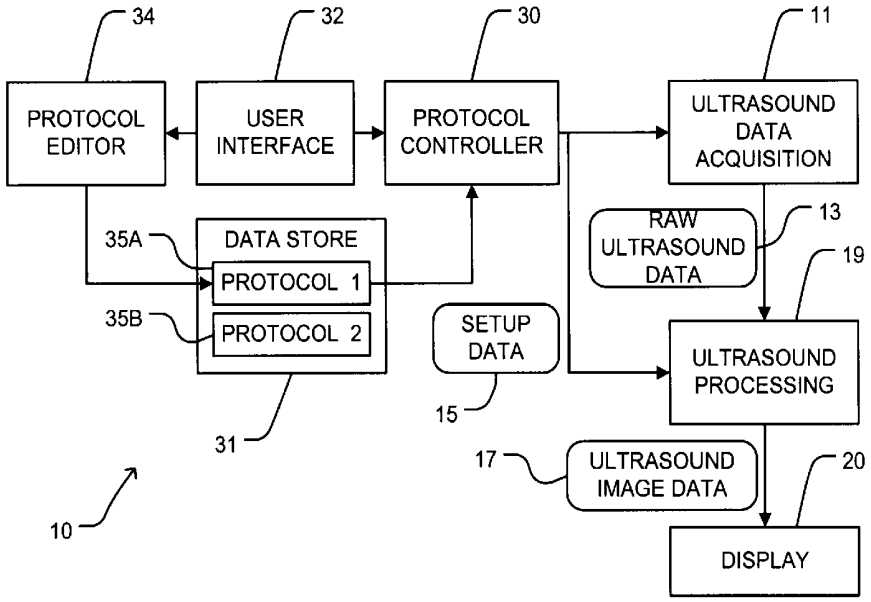
(57) **ABSTRACT**

An ultrasound machine is operated by executing a protocol. Executing the protocol configures the ultrasound machine, controls for operating the ultrasound machine and a display for the ultrasound machine. Protocols may be defined to provide a streamlined configuration of controls for operating the ultrasound machine, and to provide instructions that guide a user's operation of the ultrasound machine.

26 Claims, 10 Drawing Sheets



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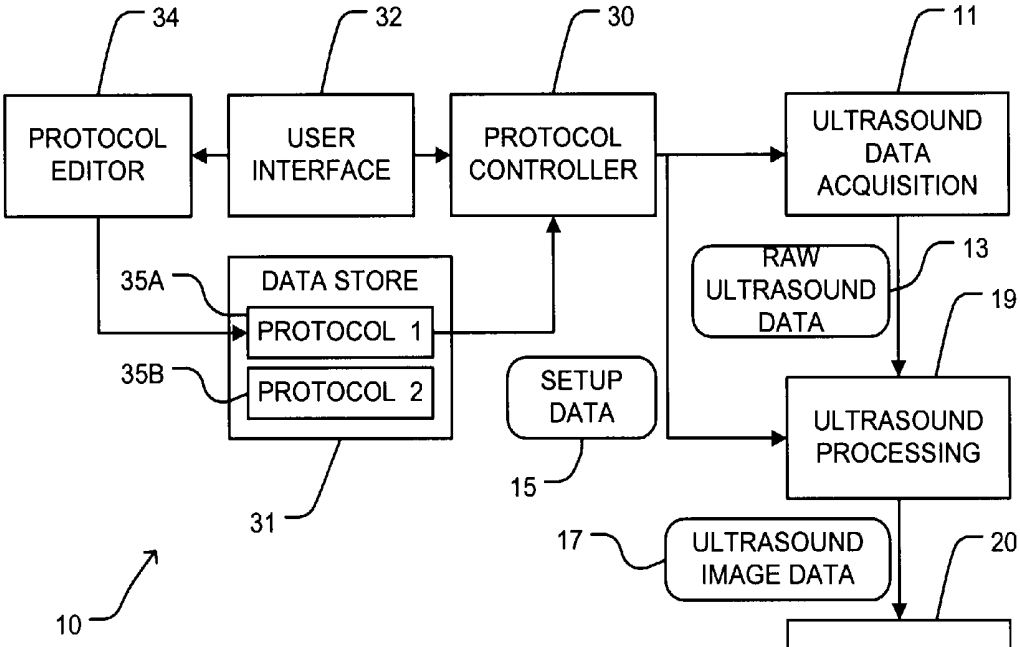
34
32
30
11
PROTOCOL EDITOR
USER INTERFACE
PROTOCOL CONTROLLER
ULTRASOUND DATA ACQUISITION
35A
DATA STORE
PROTOCOL 1
35B
PROTOCOL 2
31
RAW ULTRASOUND DATA
13
19
SETUP DATA
15
ULTRASOUND PROCESSING
17
ULTRASOUND IMAGE DATA
20
DISPLAY
10

FIGURE 1

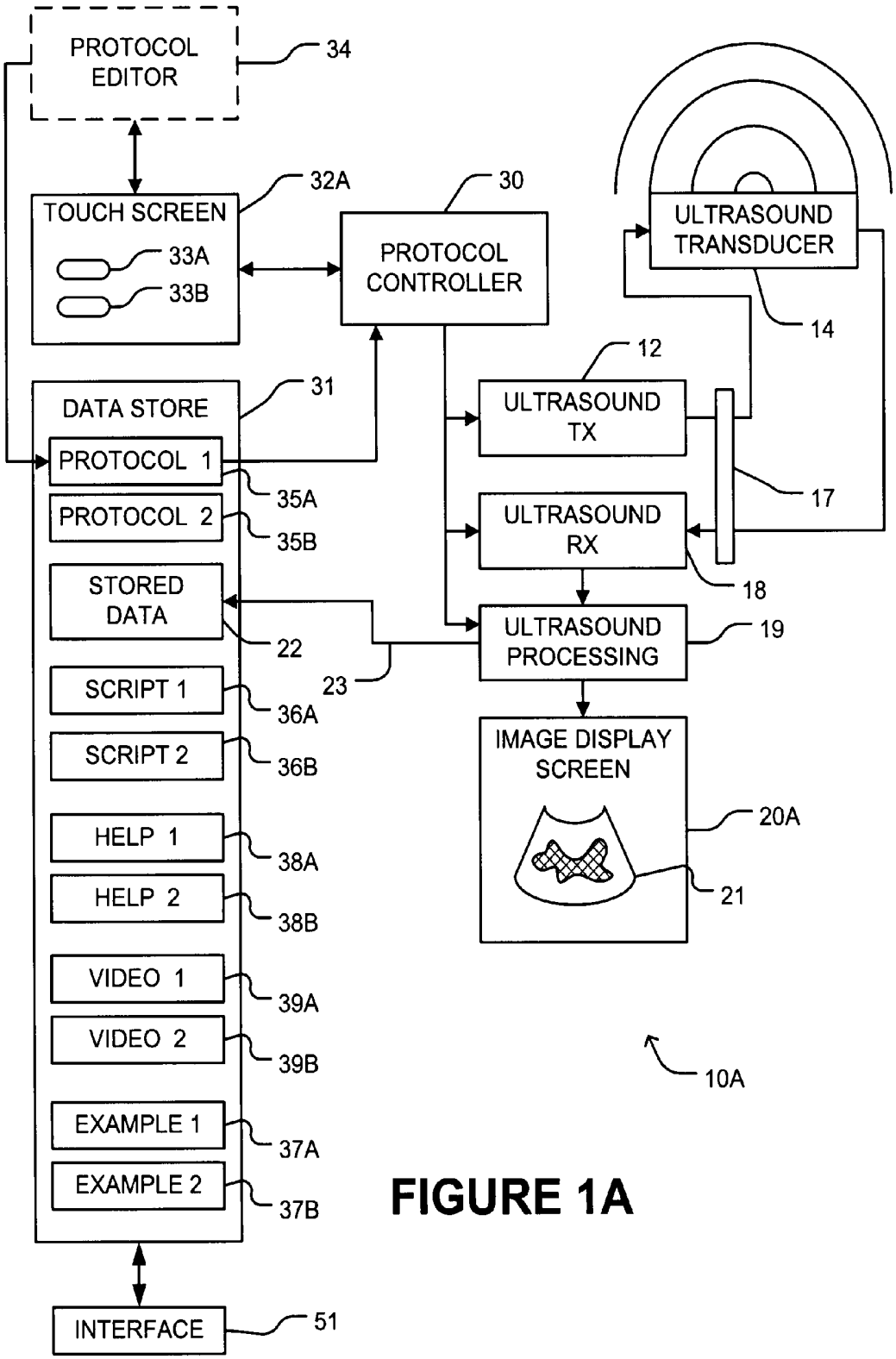
PROTOCOL EDITOR
34
TOUCH SCREEN
32A
33A
33B
PROTOCOL CONTROLLER
30
ULTRASOUND TRANSDUCER
14
12
DATA STORE
31
PROTOCOL 1
35A
PROTOCOL 2
35B
STORED DATA
22
SCRIPT 1
36A
SCRIPT 2
36B
HELP 1
38A
HELP 2
38B
VIDEO 1
39A
VIDEO 2
39B
EXAMPLE 1
37A
EXAMPLE 2
37B
INTERFACE
51
ULTRASOUND TX
ULTRASOUND RX
17
18
ULTRASOUND PROCESSING
19
23
IMAGE DISPLAY SCREEN
20A
21
10A

FIGURE 1A

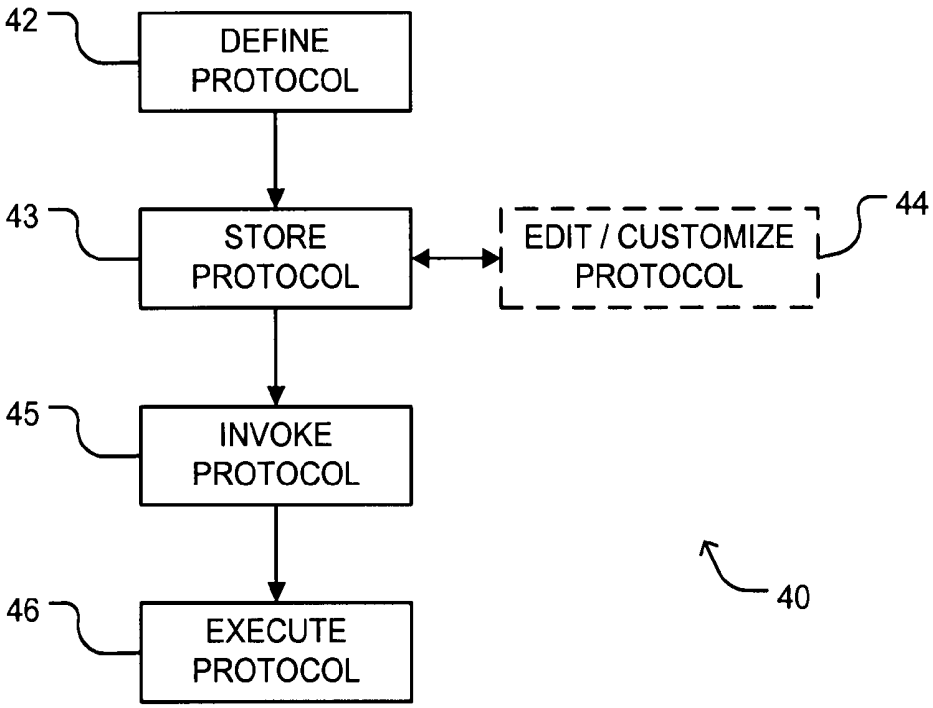
42
DEFINE PROTOCOL
43
STORE PROTOCOL
EDIT / CUSTOMIZE PROTOCOL
44
45
INVOKE PROTOCOL
40
46
EXECUTE PROTOCOL

FIGURE 2

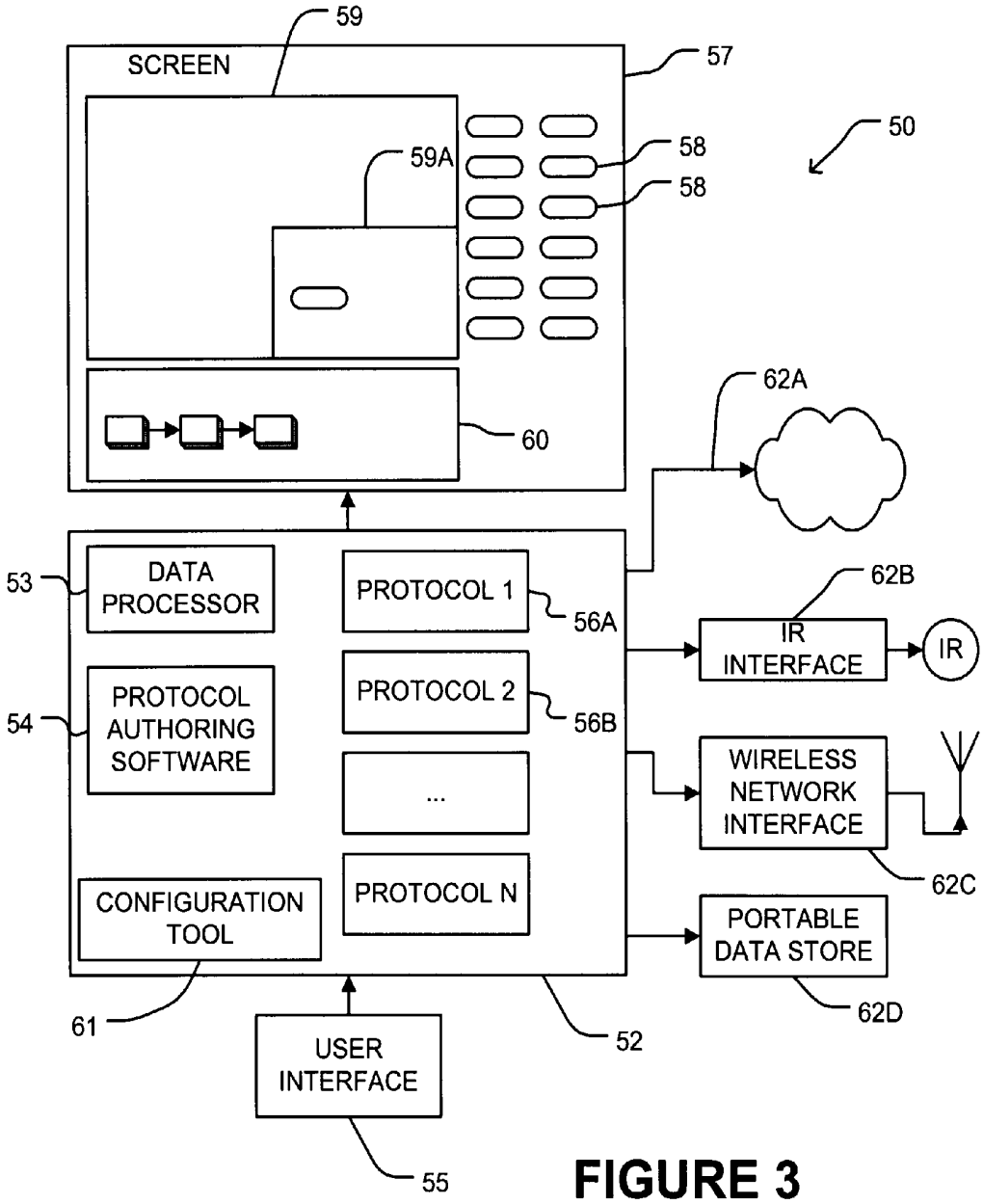
59
SCREEN
57
50
59A
58
58
62A
60
53
DATA PROCESSOR
PROTOCOL 1
56A
62B
IR INTERFACE
IR
54
PROTOCOL AUTHORING SOFTWARE
PROTOCOL 2
56B
WIRELESS NETWORK INTERFACE
...
62C
CONFIGURATION TOOL
PROTOCOL N
PORTABLE DATA STORE
62D
61
52
USER INTERFACE
55

FIGURE 3

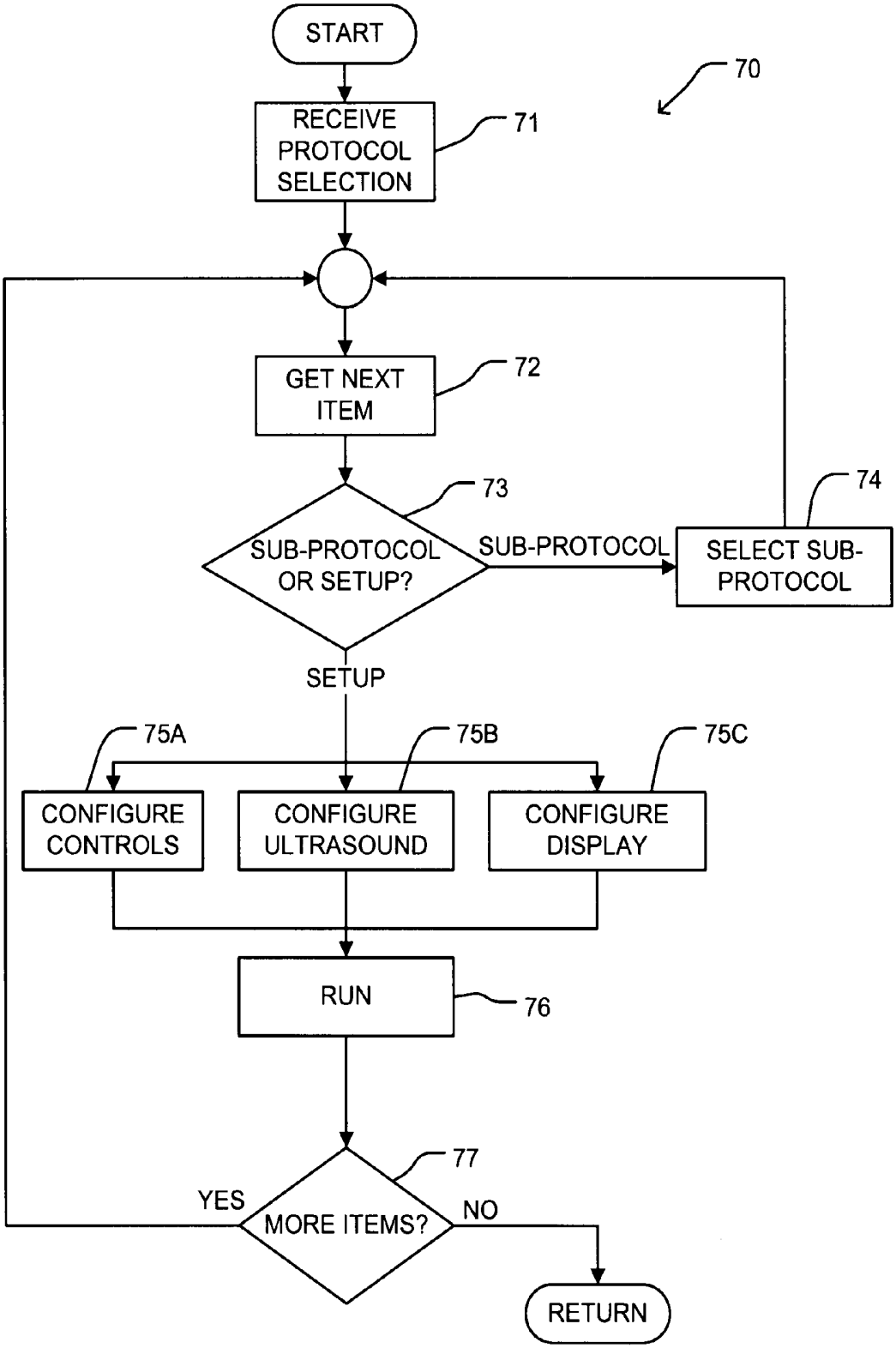
START
70
RECEIVE PROTOCOL SELECTION
71
GET NEXT ITEM
72
73
74
SUB-PROTOCOL OR SETUP?
SUB-PROTOCOL
SELECT SUB-PROTOCOL
SETUP
75A
75B
75C
CONFIGURE CONTROLS
CONFIGURE ULTRASOUND
CONFIGURE DISPLAY
RUN
76
77
YES
MORE ITEMS?
NO
RETURN

FIGURE 4

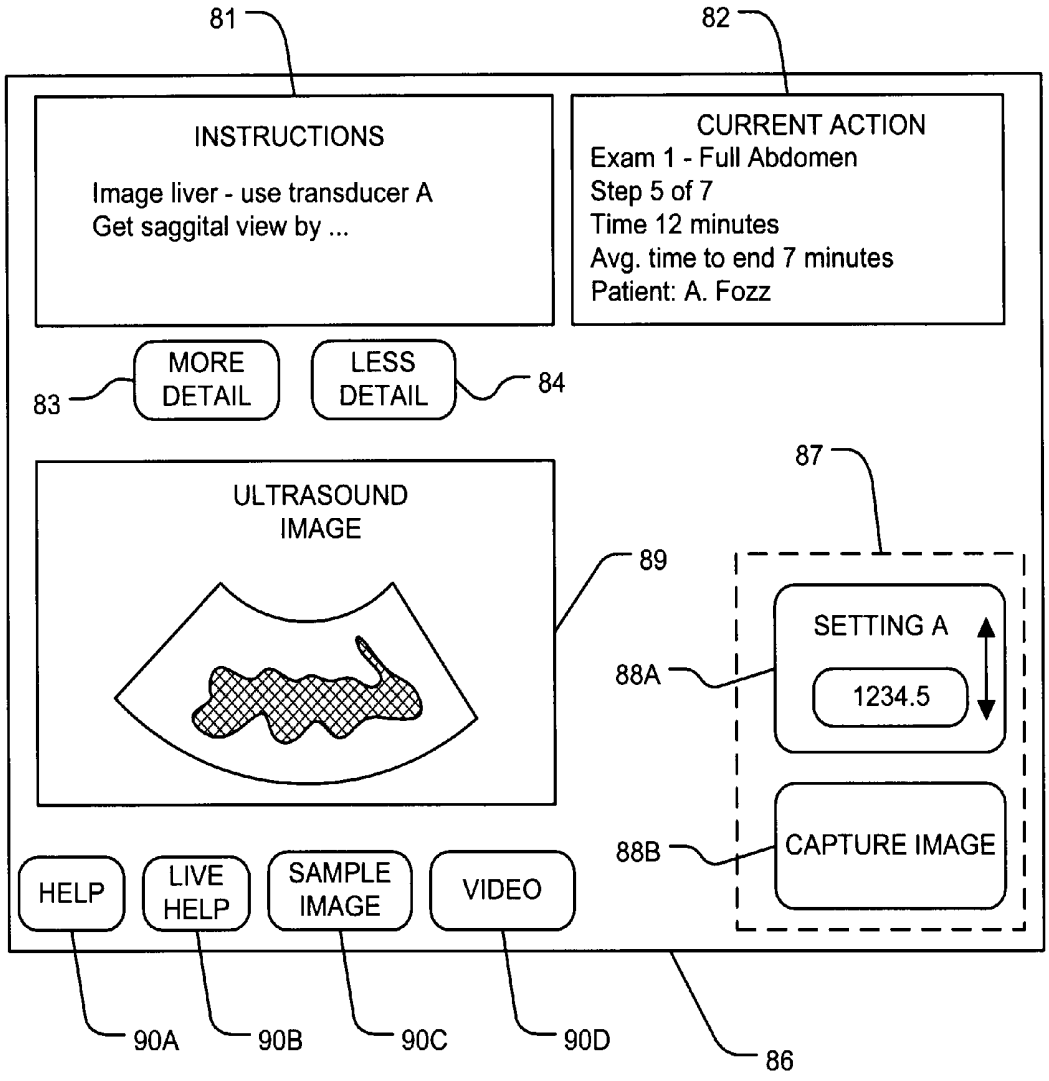
81
82
INSTRUCTIONS
Image liver - use transducer A
Get saggital view by ...
CURRENT ACTION
Exam 1 - Full Abdomen
Step 5 of 7
Time 12 minutes
Avg. time to end 7 minutes
Patient: A. Fozz
MORE DETAIL
LESS DETAIL
83
84
87
ULTRASOUND IMAGE
89
SETTING A
1234.5
88A
88B
CAPTURE IMAGE
HELP
LIVE HELP
SAMPLE IMAGE
VIDEO
90A
90B
90C
90D
86

FIGURE 5A

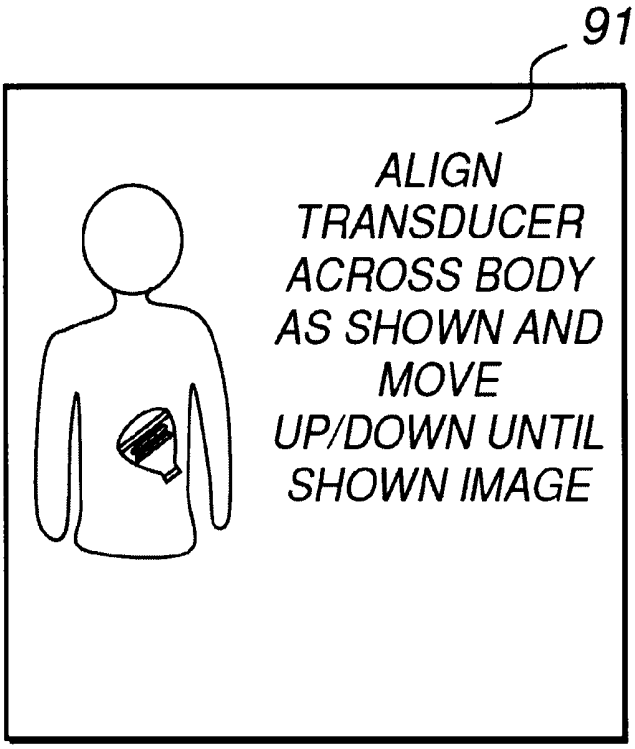

FIGURE 5B

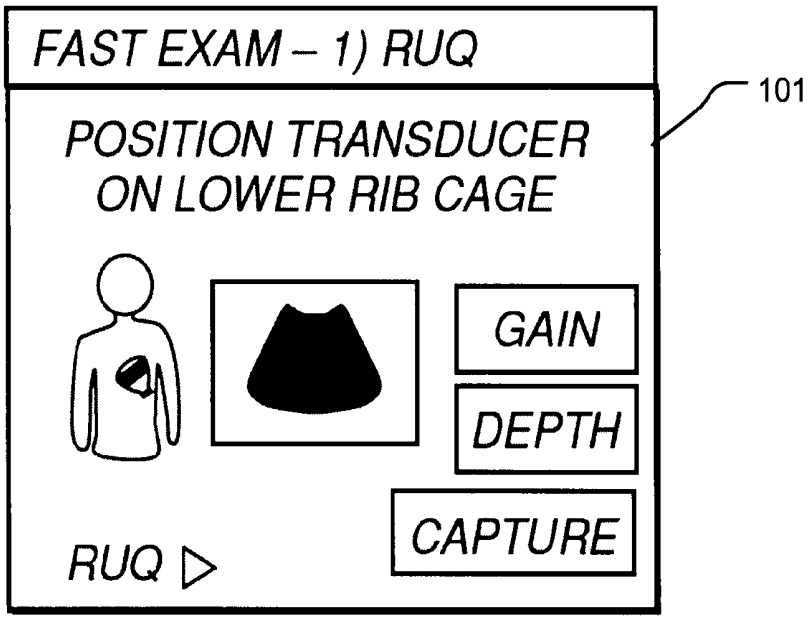

FIGURE 6A

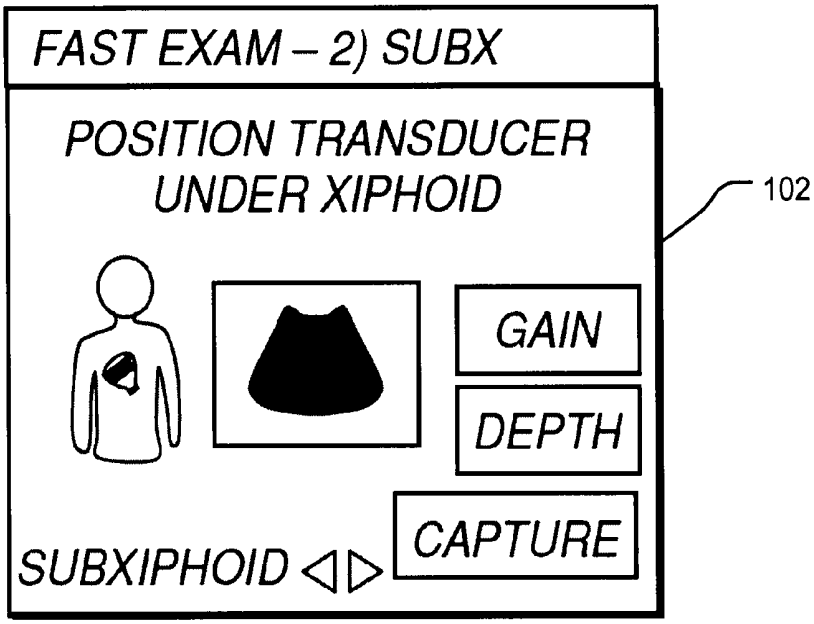

FIGURE 6B

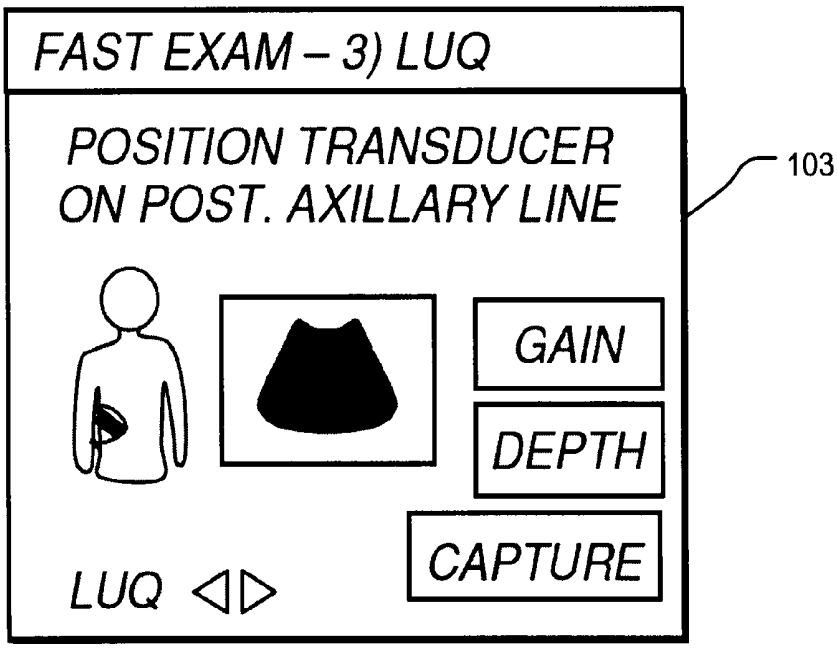

FIGURE 6C

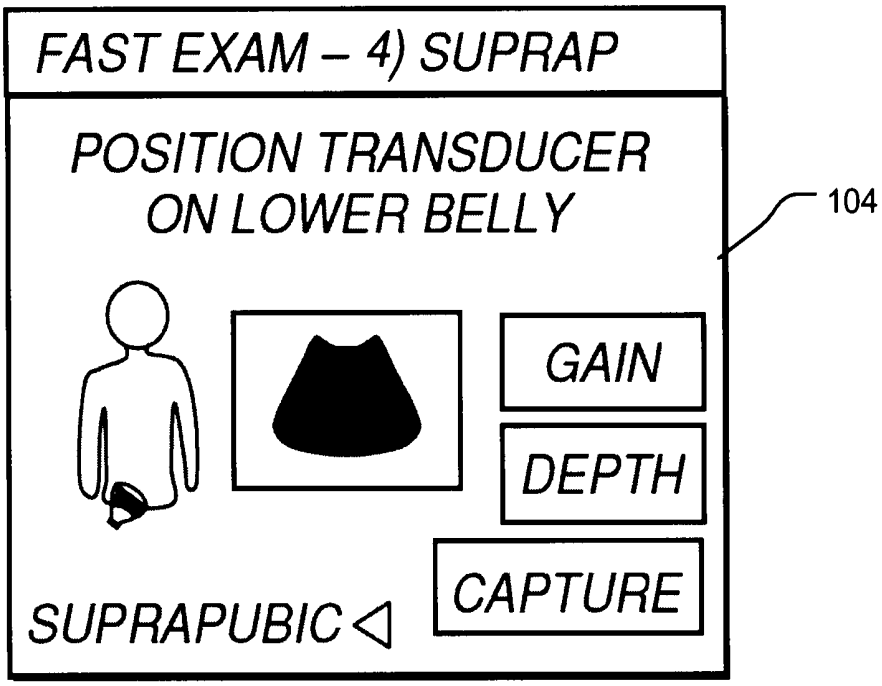

FIGURE 6D

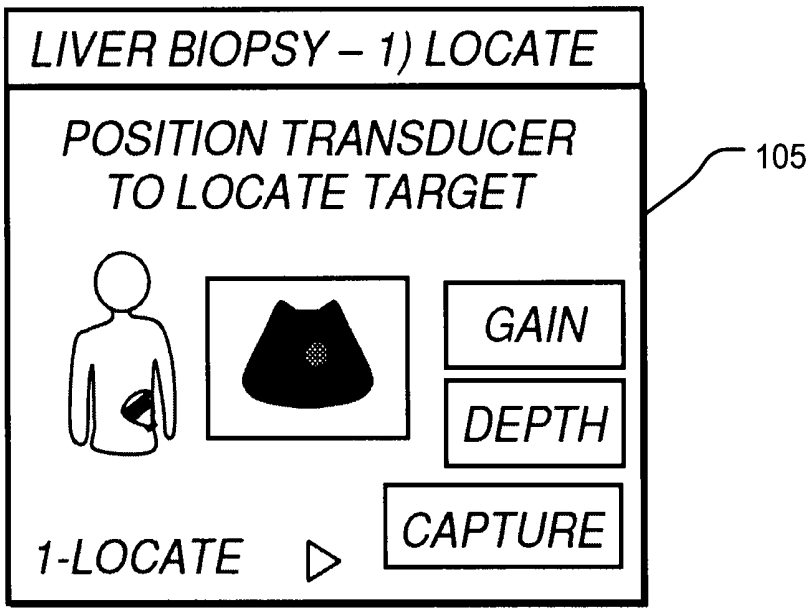

FIGURE 7A

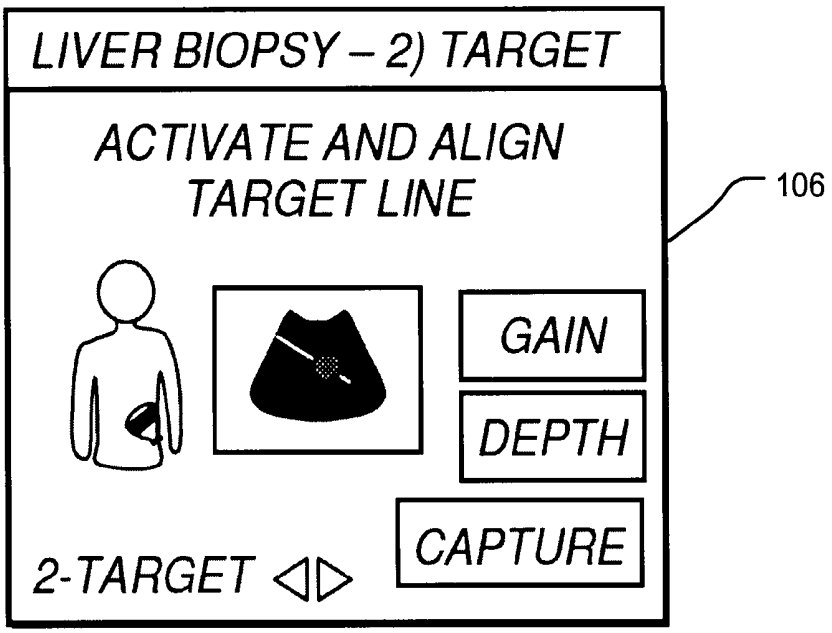

FIGURE 7B

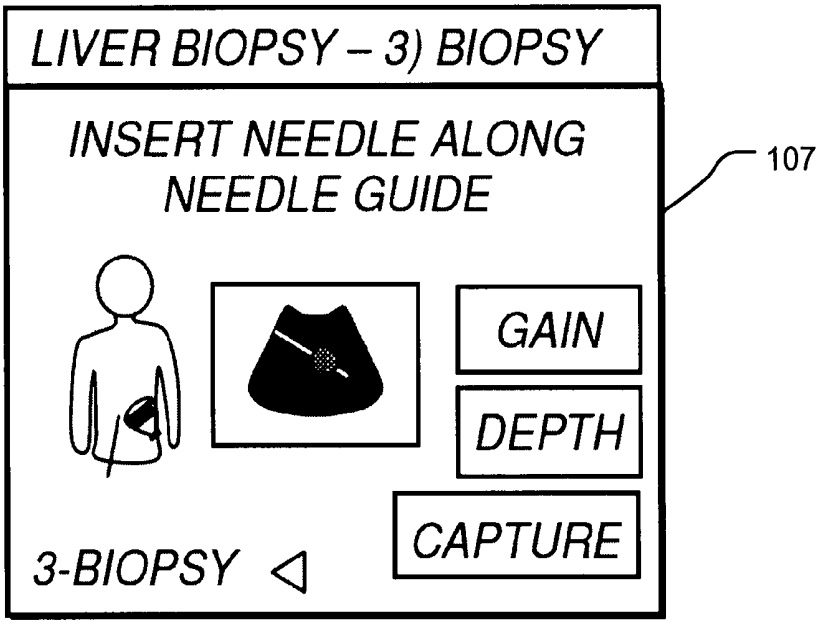

FIGURE 7C

HIGHLY CONFIGURABLE MEDICAL ULTRASOUND MACHINE AND RELATED METHODS

REFERENCE TO RELATED APPLICATION

This application claims the benefit under 35 U.S.C. §119 of U.S. patent application No. 61/091,285 filed 22 Aug. 2008 and entitled "HIGHLY CONFIGURABLE MEDICAL ULTRASOUND MACHINE AND RELATED METHODS", which is hereby incorporated by reference herein.

TECHNICAL FIELD

This invention relates to medical ultrasound machines which can be configured to perform specific ultrasound data acquisition and/or measurement tasks. Embodiments of the invention provide ultrasound machines configured to acquire one or more ultrasound images and/or measurements according to a previously-defined ultrasound protocol.

BACKGROUND

Modern ultrasound machines can operate in a range of imaging modes. In any imaging mode, the operation of an ultrasound machine can be adjusted by setting various parameters. The parameters can affect things such as the nature of acoustic signals emitted by the ultrasound machine, the way received echo signals are processed, and the way that ultrasound images are created and displayed. An ultrasound machine typically has a large number of controls that can be used to set the operating mode of the ultrasound machine and the parameters that will affect the operation of the ultrasound machine in that mode. This can be confusing, especially for inexperienced operators.

There is a need for ultrasound machines that are simple to operate. There is a particular need for ultrasound machines that are capable of sophisticated ultrasound imaging operations and are simple to operate.

SUMMARY OF THE INVENTION

The invention has a variety of aspects. Aspects of the invention provide apparatus for operating ultrasound machines, apparatus for defining protocols for operating ultrasound machines and methods for operating ultrasound machines displays, controller for displays and methods for controlling displays.

In one method aspect, a method is provided for operating an ultrasound machine comprising the steps of: defining a protocol; making the protocol available to the ultrasound machine; invoking the protocol; and executing the protocol; wherein the protocol comprises a setup and the setup comprises a configuration of the ultrasound machine, a configuration of controls for operating the ultrasound machine, and a configuration of a display for the ultrasound machine.

In a related method aspect, the step of defining the protocol comprises the steps of performing an ultrasound exam using an ultrasound machine, the exam comprising one or more procedures; recording the controls used for operating the ultrasound machine during the one or more procedures; generating a draft protocol comprising one or more draft setups, each draft setup comprising a configuration of controls for operating the ultrasound machine that comprises the controls used during a corresponding procedure; and determining for each draft setup whether each of the controls used during the corresponding procedure should be fixed or should be user-controllable.

In an apparatus aspect, apparatus is provided for operating an ultrasound machine comprising a protocol controller configured to execute a protocol to configure the ultrasound machine, configure controls for operating the ultrasound machine, and configure a display for the ultrasound machine.

In another apparatus aspect, apparatus is provided for defining protocols for operating an ultrasound machine comprising a display, wherein the display comprises graphical representations for a range of available controls for operating the ultrasound machine and an authoring area into which a user can introduce and arrange controls for operating the ultrasound machine.

Further aspects of the invention and feature of embodiments of the invention are described below and illustrated in the accompanying drawings.

BRIEF DESCRIPTION OF DRAWINGS

Non-limiting example embodiments are illustrated in the appended drawings.

FIG. **1** is a block diagram illustrating a medical ultrasound machine according to an example embodiment of the invention.

FIG. **1**A is a block diagram illustrating a medical ultrasound machine according to another example embodiment of the invention.

FIG. **2** is a flowchart illustrating a method for causing a medical ultrasound machine to perform a specific protocol.

FIG. **3** is a schematic view of a system for developing new imaging protocols for a configurable ultrasound machine.

FIG. **4** is a flowchart illustrating a method for operating an ultrasound machine to perform an ultrasound protocol.

FIG. **5**A is an example of a possible touchscreen display for an image acquisition phase of a protocol.

FIG. **5**B is an example context-sensitive help screen for the protocol step illustrated in FIG. **5**A.

FIGS. **6**A through **6**D are example touchscreen displays for a number of successive stages in an example protocol for a focus assessment by sonography in trauma exam.

FIGS. **7**A through **7**C are example touchscreen displays for a number of successive stages in an example protocol for a freehand biopsy procedure.

DETAILED DESCRIPTION

FIG. **1** is a block diagram of an ultrasound machine **10** according to an example embodiment. FIG. **1**A is a more specific block diagram of an ultrasound machine **10**A according to a specific example embodiment.

Referring to FIG. **1**, machine **10** includes an ultrasound data acquisition stage **11** which acquires raw ultrasound data **13**. Ultrasound data acquisition stage **11** may include, for example, a number of probes, each comprising an array of transducer elements. Raw ultrasound data **13** may comprise digitized ultrasound signals. Ultrasound data acquisition stage **11** provides raw ultrasound data **13** to an ultrasound processing stage **19**. Ultrasound processing stage **19** processes raw ultrasound data **13** to produce ultrasound image data **17**, which is provided to a display **20**.

Ultrasound machine **10** includes a protocol controller **30**. Protocol controller **30** can set the configurations of other parts of ultrasound machine **10**. In the embodiment of FIG. **1**, protocol controller **30** provides setup data **15** to ultrasound data acquisition stage **11** and ultrasound processing stage **19**.

For example, protocol controller **30** can control how ultrasound data acquisition stage **11** transmits ultrasound signals in order to:

- provide different types of beamforming,
- generate signals for different subsets of transducer elements of a given probe;
- generate signals suitable for driving the transducer elements of different probes;
- generate set of signals for driving different numbers of transducer elements and/or different geometries;
- adjust the intensity of acoustic pulses to be delivered;
- adjust the waveforms of signals used to generate the pulses;
- adjust the phasing of signals to be used for driving different sets of transducer elements;
- etc.

Similarly, protocol controller **30** can control ultrasound data acquisition stage **11** to process received ultrasound signals to generate raw ultrasound data **13** in various ways. For example, protocol controller **30** may have access to:

- set the gain of amplification stages;
- set cut-off frequencies, knee points, and other parameters for filters;
- etc.

within the range of adjustment provided for in ultrasound data acquisition stage **11**. Protocol controller **30** may also have access to alter the ultrasound processing performed in ultrasound processing stage **19** to create a desired type of image based upon the received ultrasound signals. For example, protocol controller **30** may have access to select from among various ultrasound processing algorithms and to set parameters for a selected algorithm.

Protocol controller **30** may comprise software executing on a programmable data processor. The software may cause the data processor to place ultrasound machine **10** in a desired operational state by writing parameters or other values to control registers that determine the state of the ultrasound machine **10**, loading or pointing to specific software components for execution by processors of ultrasound machine **10** and/or configuring images and other information to be displayed on displays associated with ultrasound machine **10**.

Protocol controller **30** is connected to a data store **31** which may contain a number of setup files **35** (individually numbered **35**A, **35**B, etc.). Each setup file **35** specifies a particular configuration for ultrasound machine **10**. Protocol controller **30** can place ultrasound machine **10** in a desired configuration by retrieving a setup file **35** that specifies the desired configuration from data store **31** and then configuring the ultrasound machine **10** according to information in the retrieved setup file.

Ultrasound machine **10** also includes a protocol editor **34** and a user interface **32** for interacting with protocol controller **30** and protocol editor **34**. A user may edit setup files **35** and other files stored in data store **31** using protocol editor **34**, and may cause ultrasound machine **10** to execute protocols using protocol controller **34**.

Referring to FIG. **1**A, ultrasound machine **10**A includes an ultrasound transmitter stage **12** which comprises or may be configured to provide a beamformer. Ultrasound transmitter stage **12** delivers driving signals to an ultrasound transducer **14** comprising an array of elements. Transducer **14** may also sometimes be referred to as a "probe". The elements of transducer **14** may comprise piezoelectric elements for example. Transducer **14** may be coupled to the rest of machine **10**A by a suitable connector **17**. In alternative embodiments for specialized applications transducer **14** could be hard wired to ultrasound machine **10**A.

Ultrasound transmitter stage **12** causes the elements of transducer **14** to emit acoustic signals. The intensity, phasing, waveforms, and other characteristics of the acoustic signals are determined by the configuration of ultrasound transmitter stage **12**.

Ultrasound machine **10**A includes transducer elements that detect the acoustic signals after the acoustic signals have interacted with structures inside a subject's body. In the illustrated embodiment, the elements act both as transducers that generate acoustic signals and as transducers that receive acoustic signals and convert the received acoustic signals into electrical signals. Separate sets of transducers could be used for transmitting and receiving ultrasound.

Acoustic signals detected at transducer **14** are provided to an ultrasound receiver stage **18**. Ultrasound receiver stage **18** performs some processing on received signals and passes the result to ultrasound processing stage **19**. In some embodiments, ultrasound receiver stage **18** includes signal conditioning electronics, such as amplifiers, filters, and the like. Received signals are digitized in ultrasound receiver stage **18** and the digitized signals are passed to ultrasound processing stage **19**. Processing of received ultrasound signals may be divided between stages **18** and **19** in any suitable ways. In some embodiments, ultrasound receiver stage **14** provides processing primarily in the analog domain while ultrasound processing stage **19** provides processing primarily in the digital domain. In some embodiments ultrasound processing stage **19** includes a data processor that is programmed to process signals received from ultrasound receiver stage **18**.

An image **21** generated by ultrasound processing stage **19** may be displayed on an image display screen **20**A of ultrasound machine **10**A.

Ultrasound machine **10**A also includes a protocol controller **30** and a protocol editor **34**, as discussed above in reference to ultrasound machine **10** of FIG. **1**. In some embodiments, protocol editor **34** may be provided in a device which is separate from ultrasound machine **10**A, as indicated by the dashed box used to represent protocol editor **34** in FIG. **1**A.

In example ultrasound machine **10**A of FIG. **1**A, the user interface comprises a touch screen **32**A. Touchscreen **32**A can display different controls **33** (individually numbered **33**A, **33**B, etc.). Controls **33** can be actuated by a user in order to control operation of ultrasound machine **10**A in a way corresponding to the control. In some embodiments, protocol controller **30** determines which controls **33** are displayed on touchscreen **32**A at any given time. In some embodiments, the locations and/or appearances of the controls **33** being displayed are set by protocol controller **30**.

As discussed above with respect to ultrasound machine **10**, protocol controller **30** and protocol editor **34** of ultrasound machine **10**A are connected to a data store **31** which may contain a number of setup files **35** (individually numbered **35**A, **35**B, etc.). Each setup file **35** specifies a particular configuration for ultrasound machine **10**A. Protocol controller **30** can place ultrasound machine **10**A in a desired configuration by retrieving a setup file **35** that specifies the desired configuration from data store **31** and then configuring the ultrasound machine **10**A according to information in the retrieved setup file **35**. Protocol editor **34** can be used, through touchscreen **32**A, to edit setup files **35** or other files stored in data store **31**. In the illustrated embodiment, setup files **35** include information that defines the controls **33** to be displayed on a touchscreen **32**A for a configuration specified by the setup file **35** and the locations in which those controls are to be displayed on touchscreen **32**A.

Protocol controller **30** may execute a script which causes ultrasound machine **10**A to be placed in a succession of

different configurations and to acquire and store and/or display ultrasound data for each of the configurations. Ultrasound data **23** generated by ultrasound processing stage **19** may be stored in a memory area **22** that is in or accessible to ultrasound machine **10**. As discussed in more detail below, in executing the script, protocol controller **30** may cause prompts and other information to be displayed for the assistance of a user.

In the illustrated embodiment, a number of script files **36** (individually numbered **36**A, **36**B etc.) containing different scripts are available to protocol controller **30** in data store **31**. Script files **36** contain instructions which cause protocol controller **30** to perform a sequence of actions including configuring ultrasound machine **10** according to at least one setup file **35**.

It can be appreciated that an ultrasound machine **10** or **10**A, as described herein, may be configured in a way that is very useful for a novice ultrasound machine user. For example, consider the case where a protocol requires a user to acquire a sequence of ultrasound images of various internal organs of a subject. The protocol may also require the user to make certain measurements of anatomical features imaged in the images. An ultrasound machine **10** or **10**A may be equipped with a script which is executed by protocol controller **30**. The script may cause protocol controller **30** to place ultrasound machine **10** or **10**A in a configuration suitable for acquiring a first image required by the protocol. At the same time a prompt is displayed on display **20** of machine **10** or touchscreen **32**A and/or image display screen **20**A of machine **10**A. The prompt may instruct the operator to acquire the image in question and may contain additional information. For example, the prompt may include an image showing how to apply a transducer to acquire the ultrasound image in question. The prompt may include other information such as a particular transducer to use, how to make a particular measurement, or the like.

Additional help may be provided in the form of context-sensitive help screens **38** (individually numbered **38**A, **38**B etc.) or context-sensitive video presentations **39** (individually numbered **39**A, **39**B etc.), as shown in FIG. **1**A. A help screen **38** and/or a video presentation **39** may be associated with each setup of ultrasound machine **10**A. Touch screen **32**A may be configured to display controls which permit a user to view the associated help screen **38** and/or the associated video **39**. For example, where a setup configures ultrasound machine **10**A to acquire a transverse image of a subject's liver, a corresponding help screen **38** may include a description of how to apply the probe to acquire the necessary image and may have some photographs or drawings which illustrate this. A corresponding video **39** may show a short video clip of a good way to acquire suitable transverse images of the liver.

One or more example images **37** (individually numbered **37**A, **37**B etc.) may be associated with each setup. The example image **37** may, for example, show an image having an acceptable contrast and the like. A user can compare the example image with the image being shown on image display screen **20**A to determine whether the acquired image **21** is of the correct anatomical structure and is generally satisfactory. Optionally example images **37** may be provided that show unacceptable views as well. In some embodiments the example image is shown together with image **21** on one or both of touch screen **32**A and image display screen **20**A so that the example image and acquired image can be readily compared.

Therefore, for each setup specified by the script, the user may be informed regarding what the user is required to do. Additionally, since protocol controller **30** controls the controls **33** to be displayed on touch screen **32**A, only the controls required for the current setup need to be displayed on touch screen **32**A. Controls that are not required can be omitted. Furthermore, the main control that may be required to make an adjustment, take a measurement, or the like may be displayed consistently in a convenient main control area on touch screen **32**A. For each setup, the user can readily locate the particular control that is most important for the current step in the protocol by looking at the main control area. Thus, by following instructions, a user can step through a protocol of any length or complexity.

A protocol may define activities that need to occur between different setups. For example, different setups may require different probes. A protocol may require that a probe be changed between different setups. In some embodiments, the protocol may display a request that the probe be changed. The protocol can indicate the required probe (and show a picture or other identifying information for the required probe) and include instructions on how to change the probe. The ultrasound device may detect automatically when the required probe has been attached (in cases where the ultrasound machine can auto-detect the type of connected probe). In other embodiments, the protocol may request user input confirming that the required probe has been located and connected to the machine.

This functionality permits a protocol to conduct an examination which may involve using a first probe operating in a first mode to obtain one or more results and then switching to using a second probe operating in a second mode to obtain one or more further results etc.

A protocol may comprise a sequence of steps. The steps may include:

- machine configuration steps (which configure an ultrasound machine appropriately for subsequent steps);
- data acquisition steps;
- measurement and display steps;
- data storing steps;
- steps which prompt a user to take specific actions; and
- steps which provide context-dependent help information. The help information may include things such as example images, video demonstrations, help text, and troubleshooting hints. The example images may be taken on the identical type of machine operating in the identical mode.

In some embodiments, a help desk control is provided. When a user invokes the help desk control the current image as well as information regarding the current setup and information regarding the subject is electronically forwarded by way of a suitable wired or wireless data communication network to a terminal manned by a person who can provide advice to the user or confirm whether or not an acquired image of video sequence is acceptable.

FIG. **2** illustrates a method **40** for operating an ultrasound machine **10**. In block **42** a protocol is defined. The protocol may be defined, for example, by an expert in ultrasound imaging who can define the setup to be used at each step of the protocol. The protocol definition may include any of:

- configuration choices that are not user-selectable at the time the protocol is executed;
- features that a user can control during execution of the protocol;
- limits on the extent which a user can control various features;
- etc.

The author of the protocol may specify which controls will be available to a user at each setup and what sequence of setups will be performed to complete the protocol. The output of

block **42** may be a script that can be executed by a protocol controller of an ultrasound machine.

In some embodiments, block **42** is performed on an ultrasound machine, like ultrasound machine **10**A. In other embodiments, block **42** is performed on separate apparatus, such as a programmed computer which executes protocol definition software. Where block **42** is performed on an ultrasound machine **10**A, ultrasound machine **10**A may have a training mode in which controls of a wide or full range of controls are available for selection.

In block **43**, the protocol is saved and made available to an ultrasound machine. In block **44**, a user may optionally edit or customize a protocol which has been saved.

In block **45**, a user invokes the protocol. In some embodiments, the protocol is invoked automatically upon a user starting, logging into, or otherwise initializing an ultrasound machine. In other embodiments, a user is presented with a selection of two or more protocols and invoking the protocol may comprise selecting the protocol from among protocols available for selection. In some embodiments, a particular button on an ultrasound machine causes display of the protocols available for selection or a screen from which such protocols can be accessed.

In block **46** the protocol is executed. Block **46** results in the acquisition and display and/or storage of a number of (zero or more) ultrasound images as well as the acquisition and storage of a number of (zero or more) measurements.

In an example embodiment, a protocol is defined on an ultrasound machine like ultrasound machine **10**A being operated in a training mode. In the training mode, an expert performs an exam using an ultrasound machine. All available controls are displayed. During the examination, the ultrasound machine records which controls are used at each stage. After the examination has been completed, the ultrasound machine creates a draft protocol in which only those controls used for each setup are displayed. In some embodiments, the expert user can indicate whether or not a setting should be fixed in the protocol or whether a control should be provided to enable a user of the protocol to change a value associated with the control. This permits an experienced user operating in the training mode to fully specify each setup while simplifying the selection of controls to be displayed to a user who uses the ultimate protocol. If desired, the draft protocol may be refined by loading the draft protocol into a protocol editor (which may be provided by the ultrasound machine or provided on a platform external to the ultrasound machine) and editing the draft protocol.

FIG. **3** shows an example apparatus **50** for defining protocols. Apparatus **50** may comprise a programmed computer **52** comprising a data processor **53**, and a user interface **55** for interacting with computer **52**. Computer **52** may execute protocol-authoring software **54** and store information defining one or more protocols **56** (individually numbered **56**A, **56**B, etc.) for delivery to an ultrasound machine (such as, for example, an ultrasound machine **10**A).

A protocol **56** may be delivered to an ultrasound machine **10**A in any of a wide range of ways. Illustrated schematically in FIG. **3** are:

- a direct wired connection, such as an ethernet or other network connection **62**A;
- an infrared wireless connection **62**B;
- a wireless networking connection **62**C;
- a portable data store **62**D or other computer-readable medium that can retrieve a copy of a protocol **56** from apparatus **50** and be physically carried to deliver the copy of the protocol to a configurable ultrasound machine.

In the ultrasound machine **10**A illustrated in FIG. **1**A, there is provided an interface **51** which can receive an incoming protocol **56** in the form of a script file and make that protocol available for execution by ultrasound machine **10**A. Setups **35** required by a protocol may also be imported by way of interface **51**.

In the illustrated embodiment, apparatus **50** includes a display **57** which includes graphical representations for a complete range of available controls **58** and an authoring area **59** into which a user who is defining a protocol can introduce and arrange different controls **58**. Main controls for each setup (typically one or two controls) may be placed in a main control area **59**A. Main control area **59**A may comprise an area which is smaller than the total area of display **57**, and may be located in authoring area **59** (as in the illustrated embodiment) or some other convenient location on display **57**. Main control area **59**A may be delineated by a boundary which separates main control area **59**A from the rest of display **57** in some embodiments. When the protocol is executed on an ultrasound machine **10**A the controls that have been selected as main controls will be displayed in main control area **59**A of a display on the ultrasound machine **10**A where they will stand out and be easy for a user to access. The main controls displayed in main control area **59**A may be different in different steps of the protocol. For example, the main controls may adjust operating parameters of ultrasound machine **10**A in some steps, may acquire images in other steps, and may take measurements or store data in other steps.

A user can generate a protocol by creating one or more setups. Each setup may include a configuration for an ultrasound machine and an arrangement of one or more controls **58** that will be made available to a user when the protocol is executed. A user of apparatus **50** may define a configuration for an ultrasound machine to be specified in a protocol by invoking a configuration tool **61** which provides (graphically, in text, or in some other representation) settings for parameters that control the operation of the ultrasound machine and allows the user to set those parameters to have desired values. Advantageously, configuration tool **61** permits users to access a range of pre-defined presets for creating setups. Each preset contains a set of parameters useful for configuring an ultrasound machine **10** to perform particular types of measurement. For example, presets may be provided for applications such as:

- imaging soft tissues;
- imaging musculo-skeletal features;
- special imaging modes such as Doppler imaging modes;
- etc.

In some cases a category may include a number of more specific presets. For example, several different presets may be provided for different musculo-skeletal imaging applications. By way of example only, there may be separate presets for imaging:

- angle
- knee
- shoulder
- wrist
- etc.

A user may adopt all of the parameter values specified by a preset, load a preset and then alter one or more parameter values to adjust the preset or set parameter values manually.

A user of apparatus **50** may define the selection and arrangement of controls that will be made available to a user of an ultrasound machine executing the protocol by, for example, placing prototype controls **58** onto area **59**. The user can then define a complete protocol by specifying a sequence of one or more setups in area **60**.

In some embodiments, a protocol can include sub-protocols. Such embodiments facilitate the reuse of all or portions of existing protocols to make new protocols. Such embodiments also facilitate the maintenance of protocols. In such embodiments a user of apparatus **50** may insert a call to invoke another protocol as a sub-protocol in a protocol being defined. When a protocol that includes a sub-protocol is executed, the sub-protocol is executed at an appropriate point. After the sub-protocol has completed executing, the protocol proceeds to the next setup (or sub-protocol) following the point at which the sub-protocol was invoked. In general, sub-protocols may operate in a manner analogous to sub-routines in computer programming.

FIG. **4** illustrates a method **70** which may be invoked on an ultrasound machine to perform a previously-defined protocol. In block **71** a protocol selection is received. Where only one protocol is defined or available then block **71** is not necessary. In block **72** the next item (which will initially be the first item) of the selected protocol is obtained. Block **73** determines if the item is a sub-protocol or a setup. If the item is a sub-protocol, method **70** proceeds to block **74** where the sub-protocol is selected, then returns to block **72** to process the next (first) item of the selected sub-protocol. If the item is a setup, method **70** proceeds to one or more of blocks **75**A-C, depending on the type of setup.

Blocks **75**A, **75**B, and **75**C respectively configure the user controls, ultrasound transmission and reception, and display characteristics according to the current setup, which is initially the first setup. Blocks **75**A, **75**B and **75**C may be performed in parallel, as shown in FIG. **4**, or may be performed sequentially in any suitable order. In block **76** the current setup is run. Block **76** may, for example, configure operating the ultrasound machine to generate ultrasound as specified in block **75**B, process the received ultrasound as specified in block **75**B, configure display parameters as specified in block **75**C and accept user input from controls provided according to configuration **75**A. When block **76** has completed then method **70** continues to block **77** which determines whether the protocol (or sub-protocol) includes additional items. If yes, then method **70** returns to block **72** to process the next item. In the case of a sub-protocol, if block **77** determines that the sub-protocol has no more items then the main protocol, which called the sub-protocol, is checked at block **77** for additional items. If there are no more items then method **70** ends.

Block **76** may be determined to have completed based on one or more of a variety of different indications. These may include indications such as:

- a user activates a control which requests that the protocol move to the next setup;
- an image or other data required by the setup has been successfully received or saved;
- an operation specified by the setup (e.g. taking a specified measurement) has been completed; or
- the like.

FIG. **5**A shows a screen **86** that may be displayed during a procedure. Screen **86** includes a primary area **87** in which the main controls with which a user can interact to control aspects of operation of an ultrasound machine in the current setup can be displayed. In the illustrated embodiment, controls **88**A and **88**B are displayed in primary area **87**. More or fewer controls could be displayed in any particular setup. In the illustrated embodiment a current parameter value corresponding to control **88**A is displayed on the control **88**A.

In the illustrated embodiment, screen **86** includes an image area **89**. Where an ultrasound machine includes both a touch screen and an image display screen (for example in apparatus **10**A of FIG. **1**A which includes an image display screen **20**A and a touch screen **32**A) image area **89** may depict a version of the same image being shown on the image display screen. Screen **86** may also comprise an instruction area **81** wherein relevant instructions may be displayed, and a current action area **82** where information about the current action of the procedure being performed may be displayed. A more detail button **83** and a less detail button **84** may be provided for respectively increasing and decreasing the level of detail of instructions shown in instruction area **81**.

Also provided in screen **86** are controls **90**A, **90**B, **90**C and **90**D which respectively link to help, live help, sample images, and video, each related to the current setup. For example, FIG. **5**B shows a screen **91** that may be displayed in response to a user invoking help button **90**A. Screen **91** includes text that explains to the user how to operate the ultrasound machine to acquire the information needed in the current setup and also includes a diagram that illustrates where and how to position an ultrasound transducer to acquire the necessary image. In environments where live help is available, the user could invoke control **90**B to be connected by way of a suitable wired or wireless data communication network to a terminal manned by a person who can provide advice to the user. The user could invoke control **90**C to see sample images which are suitable and/or unsuitable. The user can invoke control **90**D to cause a short video to be shown. The video may illustrate how to properly manipulate a transducer and otherwise operate the ultrasound machine to acquire whatever image or other data is required for the current step. As one skilled in the art will appreciate, when a different procedure is being performed, different additional controls may optionally be provided outside of primary area **87**, different text instructions may be provided and help sample image and video buttons linked to help sample images and video related to different setups than the setup to which example screen **86** corresponds.

It can be appreciated that methods as described herein may be used to define protocols of arbitrary length and complexity and to lead users through the protocols. FIGS. **6**A through **6**D depict a set of screens which illustrate a sequence of steps that may be provided for a specific protocol for the purpose of a focus assessment by sonography in trauma (FAST) exam. FIG. **6**A shows a screen **101** which may be displayed for scanning the right upper quadrant. FIG. **6**B shows a screen **102** which may be displayed for scanning the subxiphoid area. FIG. **6**C shows a screen **103** which may be displayed for scanning the left upper quadrant. FIG. **6**D shows a screen **104** which may be displayed for scanning the suprapubic area. FIGS. **7**A through **7**C depict a set of screens which illustrate a sequence of setups that may be provided for a specific protocol for the purpose of a freehand liver biopsy procedure. FIG. **7**A shows a screen **105** which may be displayed for positioning the probe to target a lesion. FIG. **7**B shows a screen **106** which may be displayed for activating a needle guide. FIG. **7**C shows a screen **107** which may be displayed for inserting a needle using the guide. Each of screens **101**-**107** shows the desired position of the probe and an example image, along with various controls and other information relevant to the current step of the procedure being performed.

In some embodiments, the selection and arrangement of controls for a particular setup may be defined in a markup language such as hypertext markup language (HTML) or extended markup language (XML). An ultrasound machine (for example, ultrasound machine **10**A) may include browser software which reads the markup language and displays the specified controls on touch screen **32**A according to the markup language.

The high degree of flexibility provided by the architecture described herein may permit protocols to be defined which vary based upon the level of experience of a user. The selection of an appropriate protocol may be manual. For example, a user may manually select between "basic" and "advanced" versions of the same protocol. In the alternative, the protocols may be made available to users based upon stored information regarding the level of experience possessed by the user. More rigid protocols may be provided for less experienced users. Protocols intended for more experienced users may be afforded more options for advanced control of the protocols. The availability of different protocols and/or the default selection of protocols may be defined at the user level. For example, each user could have a unique user profile, and an ultrasound machine may have a group of protocols to display for each user profile.

In some embodiments, the type of sample images provided may be selected based upon the type of patient. For example, different sample images may be displayed depending upon whether the subject is male or female. Different sample images may be displayed depending upon whether the subject is a child or an adult. Different sample images may be displayed depending upon whether the subject is obese or not. The sample images may be selected based upon information about a patient that has been input into or made available to an ultrasound machine in advance.

The available help may also be based upon characteristics of the patient. For example:

- if the patient is identified as being obese then the help selection may include specific help directed to obtaining satisfactory images from obese subjects;
- if the patient is identified as being a child then the help selection may include specific help directed to obtaining satisfactory images of pediatric subjects;
- etc.

Some ultrasound protocols require that various measurements be made of certain characteristics in ultrasound images. In some embodiments, a measurement control is provided. A person specifying a protocol can select the measurement control and then specify which measurements are to be made. The measurement control may, for example, include components capable of providing any of a wide range of different sorts of measurements. Some examples of measurements that a measurement control could be configured to provide are:

- the distance between two anatomical features depicted in an image;
- Doppler measurements at a point in an image;
- the volume of an organ or other anatomical structure;
- the perimeter of an organ or other anatomical structure;
- etc.

In some cases, the operation of a measurement control may be specified by a measurement template. The measurement template may permit the definition of custom measurements. An example of a custom measurement is a measurement for determining the volume of an organ such as the liver or heart based on three distance measurements. The measurement template may permit a name to be given to a custom measurement so that the custom measurement may be retrieved by name in future. The measurement template may also specify annotations (which could, for example, explain how to obtain the required measurement), pictograms and/or animations (which may illustrate how to obtain the required measurement).

Since a protocol can be defined as a sequence of different setups, it is not mandatory that the setups and the protocol be generated at the same time. Some embodiments permit a protocol to be created by selecting previously-defined setups and/or by selecting previously-defined protocols to be executed as sub-protocols. Previously-defined setups and/or other protocols can be organized in a desired sequence to be performed by the protocol. In some embodiments, a protocol may include conditional branches. Such conditional branches may be based upon outputs from previous setups. For example, if a certain measurement is in a defined range then the protocol may specify that other measurements should also be made, or other images should also be obtained. These additional measurements or images may not be required in other cases.

In some embodiments, a protocol can be defined prior to the definition of some or all of the setups. Such embodiments permit the overall structure of a protocol to be defined first and the individual setups to be defined later.

In some embodiments, an ultrasound machine is configured to record notes, comments, or other observations simultaneously with acquiring images. A record of the observations may be stored with the results of the protocol. Various interfaces may be provided to receive such observations. In some embodiments, for example ultrasound machine **10**A of FIG. **1**A, a user can bring up a worksheet on touch screen **32**A while continuing to image on a main image display screen **20**A. The user may enter information into the worksheet directly. For example, text may be entered using a keyboard connected to ultrasound machine **10**A or a keyboard control displayed on touchscreen **32**A.

In other cases, information may automatically be inserted into the worksheet. For example, where a particular measurement is specified by a protocol, the result of the measurement may automatically be entered into the worksheet. The worksheet may also include images and/or other information acquired by the protocol. This feature allows a detailed report in an electronic format to be generated automatically during the execution of the protocol. The overall format of the content of the report may be specified in advance and may be part of the protocol definition. The report may be printed out and/or stored electronically.

The visual manifestation of some controls may include image depictions. For example, a control for moving a focal zone or selecting a different biopsy target point may include a depiction of an ultrasound image. The focal zone or biopsy target point may be selected by touching an appropriate location on the image. Other manipulations, such as zooming, making an image lighter or darker, making image crisper, etc. may also be provided by touch screen manipulations.

In some embodiments, a persistent control bar is provided in a consistent location on the screen displayed by a protocol. The control bar permits a user to navigate through the execution of protocol steps.

In some embodiments, the controls available include a time gain control (TGC) panel. A TGC panel may permit a user to define a new TGC curve by tracing a finger across touch screen **32** at the location of the control.

In some embodiments, a presets panel is provided. A preset contains all the necessary imaging parameters to configure an ultrasound machine for a specific scan. The presets panel is a control that provides a set of presets for a specified application. For example, for a musculoskeletal application, the presets panel may provide ankle, knee, shoulder and wrist presets, among others. The presets panel allows the user to select any of the presets for the specified application.

In some embodiments, each setup corresponds to a particular state of an ultrasound system. The functionality available

is different in each state. For example, the following table lists three groups of states:

Imaging Mode States	Operation Mode States	Other Operation States
B mode	freeze	system menu
M Mode	measurements mode	protocol selection
dual mode	annotations mode	3-D application
color Doppler mode	pictograms mode	reporting
power Doppler mode	arrow mode	patient ID
pulsed wave mode		patient review
continuous wave mode		
3-D/4-D mode		

A system may permit one state from each column to be active at the same time. The selection of a mode can drive the selection of a layout of controls displayed on a touch screen.

In the foregoing description specific details are set forth in order to provide a more thorough understanding to persons skilled in the art. However, well known elements may not have been shown or described in detail to avoid unnecessarily obscuring the disclosure. Accordingly, the description and drawings are to be regarded in an illustrative, rather than a restrictive, sense.

Certain implementations of the invention comprise computer processors which execute software instructions which cause the processors to perform a method of the invention. For example, one or more processors in an ultrasound machine may implement methods for executing protocols or defining protocols as described herein by executing software instructions in a program memory accessible to the processor(s). One or more processors in apparatus for defining protocols may perform protocol definition methods as described herein by executing software instructions in a program memory accessible to the processor(s).

Certain aspects of the invention may also be embodied in the form of a program product. The program product may comprise any tangible medium which carries a set of computer-readable signals comprising instructions which, when executed by a data processor, cause the data processor to execute a method of the invention. Program products according to the invention may be in any of a wide variety of forms. The program product may comprise, for example, physical media such as magnetic data storage media including floppy diskettes, hard disk drives, optical data storage media including CD ROMs, DVDs, electronic data storage media including ROMs, flash RAM, or the like. The computer-readable signals on the program product may optionally be compressed or encrypted.

Where a component (e.g. a software component, processor, assembly, device, circuit, etc.) is referred to above, unless otherwise indicated, reference to that component (including a reference to a "means") should be interpreted as including as equivalents of that component any component which performs the function of the described component (i.e. that is functionally equivalent), including components which are not structurally equivalent to the disclosed structure which performs the function in the illustrated exemplary embodiments of the invention.

As will be apparent to those skilled in the art in the light of the foregoing disclosure, many alterations and modifications are possible in the practice of this invention without departing from the spirit or scope thereof. For example, additional embodiments may be generated by making modifications, permutations, additions and sub-combinations of the features of the example embodiments described above.

What is claimed is:

1. A method for operating an ultrasound machine, the method comprising:

performing a training mode ultrasound examination with the ultrasound machine in a training mode in which all available controls are displayed;

recording, during the training mode ultrasound examination and by the ultrasound machine, which controls are used at each stage of the training mode ultrasound examination:

creating, after completion of the training mode ultrasound examination, a custom protocol in which only those controls used for each stage of the training mode ultrasound examination are displayed;

providing a plurality of protocols for the ultrasound machine, the plurality of protocols including the custom protocol, and each protocol of the plurality of protocols specifying a series of one or more ultrasound images to be acquired and step-by-step instructions for acquiring the one or more ultrasound images, wherein each protocol includes patient imaging configuration choices that are not user-selectable at the time the protocol is executed to image a patient, features that a user controls during execution of the protocol, and limits on an extent which the user controls various features;

receiving subject information specifying one or more characteristics of a current subject of an ultrasound examination;

determining a subset of the plurality of protocols based on the subject information, the subset including two or more of the plurality of protocols and including only protocols applicable to subjects having the one or more characteristics of the current subject of the ultrasound examination, wherein the two or more of the plurality of protocols include is the custom protocol;

displaying the subset of the plurality of protocols to a user of the ultrasound machine;

receiving a user-selected one of the displayed protocols, wherein the user-selected one of the protocols is the custom protocol; and

executing the user-selected protocol, which activates the ultrasound machine to acquire an image and which visually displays a prompt via a display screen that provides the step-by-step instructions associated with the selected protocol to guide the user to acquire the one or more ultrasound images specified by the selected protocol, wherein the prompt includes information regarding a particular transducer to apply and how to make a particular measurement, and a graphical representation graphically showing how to apply the particular transducer to acquire an image.

2. A method according to claim **1** wherein the user selected protocol specifies a plurality of images to be acquired and comprises:

a setup for each image to be acquired, each setup comprising configurations for the ultrasound machine; and

one or more activities to be performed between acquiring images in the series of ultrasound images wherein, executing the user-selected protocol comprises operating the ultrasound machine to prompt the user to perform the one or more activities between acquiring the images.

3. A method according to claim **2** wherein the ultrasound machine has a touch screen display and the user-selected protocol comprises, for each image to be acquired and each activity to be performed between acquiring images, a layout of controls to be displayed on the touch screen display and the

method comprises, for each of the images to be acquired and for each activity to be performed between images, displaying controls on the display according to the corresponding layout.

4. A method according to claim **3** wherein the user selected protocol defines, for each image to be acquired and each activity to be performed between acquiring images, one or more main controls for acquiring the image or performing the activity, and wherein the method comprises displaying main controls associated with each image to be acquired in a main control area of the touch screen display during acquisition of the image and the method comprises displaying in the main control area the main controls associated with the activity during performance of the activity.

5. A method according to claim **2** wherein the activity comprises making a measurement of an anatomical structure.

6. A method according to claim **5** wherein the measurement comprises a plurality of distance measurements between anatomical features depicted in ultrasound images.

7. A method according to claim **1** comprising defining the plurality of protocols wherein defining one of the plurality of protocols comprises providing a protocol editor and a plurality of setup files, wherein the protocol editor enables protocols to be defined by specifying a series of steps and selecting a setup file for each of the series of steps.

8. A method according to claim **7** wherein defining a protocol comprises invoking another protocol as a sub protocol.

9. A method according to claim **7** wherein defining a protocol comprises specifying one or more conditional steps, wherein the one or more conditional steps are configured only to be executed when a predetermined result occurs in one or more previous steps.

10. A method according to claim **1** wherein the one or more characteristics comprises a gender of the current subject.

11. A method according to claim **1** wherein the one or more characteristics comprises an age of the current subject.

12. A method according to claim **1** wherein the one or more characteristics comprises a height and weight of the current subject.

13. A method according to claim **1** wherein executing the user-selected protocol comprises displaying a visual record of an acquisition of at least one of the series of one or more ultrasound images specified by the user selected-protocol for a reference subject having the one or more characteristics of the current subject.

14. A method according to claim **1** comprising receiving user information specifying an experience level of a user of the ultrasound machine, wherein the determining the subset is based on the user information.

15. A method according to claim **14** wherein the plurality of protocols comprise an advanced version and a basic version of each protocol, and wherein displaying the subset comprises for each protocol, displaying only the basic version unless the user has an experience level exceeding a predetermined threshold experience level.

16. A method according to claim **1** wherein the user-selected protocol requires the user to acquire a sequence of two or more ultrasound images of more than one internal organ of the subject and the step-by-step instructions specified by the protocol guide the user to acquire each of the two or more ultrasound images, wherein the step-by-step instructions comprise instructing a user to use one type of probe for acquiring one of the images and another type of probe for acquiring another one of the images.

17. A method according to claim **1** wherein the user-selected protocol comprises a plurality of example images and executing the user-selected protocol comprises displaying an acquired image and a corresponding example image at the same time to permit a user to compare the acquired image to the corresponding example image.

18. A method according to claim **17** wherein the user-selected protocol comprises a plurality of sets of example images each associated with a corresponding set of one or more subject characteristics and the method comprises automatically selecting one of the sets of example images based on the characteristics of the current subject and displaying the example images from the automatically selected set of example images.

19. A method according to claim **18** wherein the plurality of sets of example images includes at least one set of child example images, one set of adult example images, one set of male example images, and one set of female example images.

20. A method according to claim **1**, wherein the configuration choices that are not user-selectable at the time the protocol is executed are not user-selectable to all users of the ultrasound machine.

21. A method according to claim **1**, wherein executing the user-selected protocol executes a script which causes the ultrasound machine to be placed in a succession of different configurations and to acquire and at least one of store or display ultrasound data for each of the configurations.

22. A method according to claim **1**, wherein the prompt includes a series of images that are sequentially displayed, one after the other, each graphically showing a next different position of the transducer relative to the subject for a different image of the protocol.

23. A method according to claim **1**, wherein the prompt includes a series of screens sequentially displayed, which instruct a user to activate a needle guide and insert a needle along the guide.

24. A method according to claim **23**, wherein the protocol requires the user to make measurements of anatomical features imaged in the images.

25. A method according to claim **24**, wherein the prompts include an image showing how to make the measurement.

26. Apparatus for operating an ultrasound machine, the apparatus comprising

a data store;

a processor and a display;

the data store comprising a plurality of protocols for the ultrasound machine, each protocol specifying a series of one or more ultrasound images to be acquired and step-by-step instructions to acquire the one or more ultrasound images, wherein each protocol includes at least one of configuration choices that are not user-selectable at the time the protocol is executed, features that a user controls during execution of the protocol, or limits on an extent which the user controls various features; and

the processor configured to:

record, during a training mode ultrasound examination in which all available controls are displayed, which controls are used at each stage of the training mode ultrasound examination;

create, after completion of the training mode ultrasound examination, a custom protocol in which only those controls used for each stage of the training mode ultrasound examination are displayed;

receive subject information specifying one or more characteristics of a subject of an ultrasound examination;

determine a subset of the plurality of protocols, the plurality of protocols including the custom protocol, based on the subject information, the subset including only protocols applicable to subjects having the one or more characteristics of the subject of the ultrasound

examination; cause the display to display the subset to a user of the ultrasound machine;

receive a user-selected one of the subset of protocols; and

execute the user-selected protocol, which activates the ultrasound machine to acquire an image and which visually displays a prompt via a display screen that provides the step-by-step instructions to guide the user to acquire the one or more ultrasound images, wherein the prompt includes information regarding a particular transducer to apply and how to make a particular measurement, and a graphical representation graphically showing how to apply the particular transducer to acquire the one or more images.

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专利名称(译)	高度可配置的医疗超声机器和相关方法		
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申请(专利权)人(译)	ULTRASONIX医疗法人		
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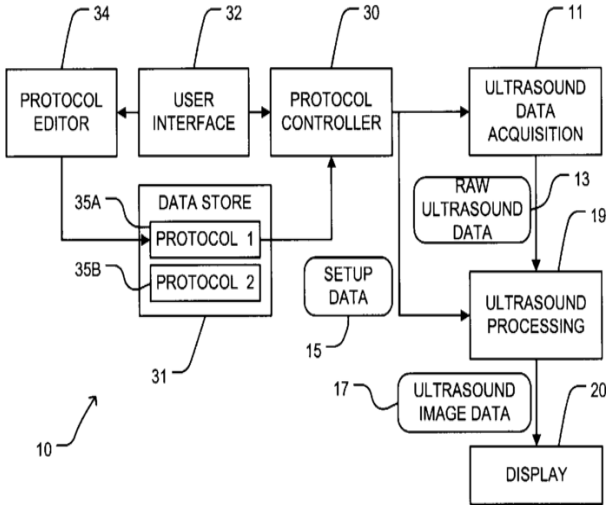
摘要(译)

通过执行协议来操作超声机器。执行该协议配置超声机器，用于操作超声机器的控制器和用于超声机器的显示器。可以定义协议以提供用于操作超声机器的控制的流线型配置，并提供指导用户操作超声机器的指令。