(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
13 April 2006 (13.04.2006)

PCT

(10) International Publication Number
WO 2006/038181 A1

(51) International Patent Classification:
A61B 8/00 (2006.01)

(21) International Application Number:
PCT/IB2005/053250

(22) International Filing Date: 3 October 2005 (03.10.2005)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
60/617,491 8 October 2004 (08.10.2004) US

(71) Applicant *(for all designated States except US)*: **KONINKLIJKE PHILIPS ELECTRONICS N.V.** [NL/NL]; Groenewoudseweg 1, NL-5621 BA Eindhoven (NL).

(72) Inventors; and

(75) Inventors/Applicants *(for US only)*: **SAAD, Ashraf** [EG/US]; P.O. Box 3003, Bothell, Washington 98041-3003 (US). **SKYBA, Dan** [US/US]; P.O. Box 3003, Bothell, Washington 98041-3003 (US).

(74) Common Representative: **KONINKLIJKE PHILIPS ELECTRONICS N.V.**; c/o W. Brinton Yorks, Jr. P.O. Box 3003, 22100 Bothell Everett Highway, Bothell, Washington 98041-3003 (US).

(81) Designated States *(unless otherwise indicated, for every kind of national protection available)*: AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KM, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, LY, MA, MD, MG, MK, MN, MW, MX, MZ, NA, NG, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, SM, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, YU, ZA, ZM, ZW.

(84) Designated States *(unless otherwise indicated, for every kind of regional protection available)*: ARIPO (BW, GH, GM, KE, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IS, IT, LT, LU, LV, MC, NL, PL, PT, RO, SE, SI, SK, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Declaration under Rule 4.17:

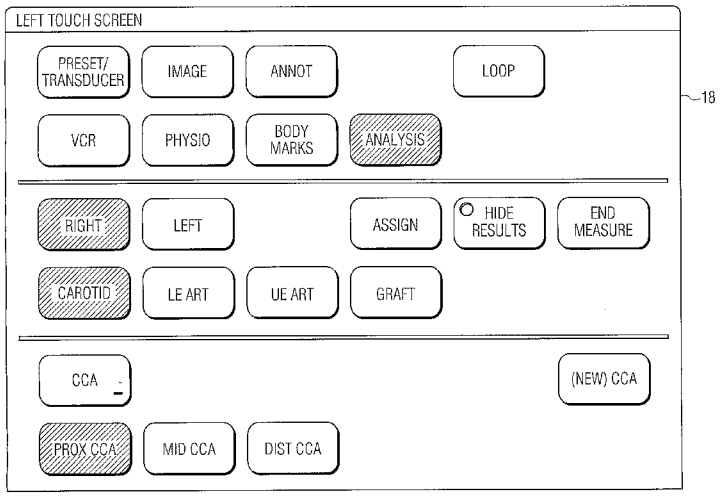
— *as to applicant's entitlement to apply for and be granted a patent (Rule 4.17(ii))*

Published:

— *with international search report*

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

(54) **Title:** ULTRASONIC DIAGNOSTIC SYSTEM WITH FLEXIBLE EXAMINATION PROTOCOLS AND REPORT GENERATION



(57) **Abstract:** An analysis feature of an ultrasonic diagnostic system contains one or more exam protocols which guide a sonographer in carrying out one or more standardized ultrasound exams. During the conduct of an exam protocol template protocol steps are available. The sonographer can augment the standard protocol by selecting one of these template protocol steps and giving it a unique name for the current protocol. The execution of this added step will automatically invoke the diagnostic tools, such as measurements and calculations, which are inherent in the cloned conventional protocol step. In addition, the sonographer can add other diagnostic tools to the added step. The results of the standard and customized protocol steps are automatically recorded in the proper sequence and context of an automatically produced diagnostic report.

WO 2006/038181 A1

ULTRASONIC DIAGNOSTIC SYSTEM WITH FLEXIBLE EXAMINATION PROTOCOLS AND REPORT GENERATION

This invention relates to ultrasonic diagnostic imaging systems and, in particular, to ultrasonic imaging systems which conduct examinations in accordance with specified clinical protocols.

In the past, ultrasound machines have been used to image any anatomy that could be clearly seen with the probe set available for the particular machine. But as ultrasonic diagnosis has become for sophisticated and the technology more refined, ultrasound machines became configured for certain types of examinations such as obstetrics, cardiology, vascular and radiology. In the recent past the practice of ultrasound diagnosis has become more standardized, with specifically designed image acquisition protocols for patients with specific symptoms. For example, a general abdominal exam protocol may call for the acquisition of specified views of the liver, kidneys, gall bladder and pancreas. A general vascular exam may call for the acquisition of specified views of the carotid artery and vasculature of the limbs of the body. Ultrasound machine manufacturers have followed this trend by providing their machines with pre-programmed exam protocols which guide the sonographer through these specified imaging sequences and produce report automatically tailored to the specified information. Such pre-programmed protocols have improved the efficiency of ultrasound exams.

While improving the efficiency of an examination, pre-programmed protocols, particularly those for a general survey exam, are generally designed to step the sonographer through a series of

views, measurements, and calculations in regions of the body to determine whether the imaged anatomy is normal or exhibits suspect characteristics. At the end of the protocol the sonographer is expected to review the findings of the exam and, if a suspicious condition is indicated, go back to the suspect anatomy and conduct more detailed imaging and analysis. However, the sonographer may desire to examine suspect anatomy in more detail at the time a possible problem is indicated, particularly if a marginal condition is indicated. This will generally require that the exam protocol be aborted, and the guided examination of other anatomy by the protocol terminated. It would be desirable to be able to modify the protocol during its execution to enable the sonographer to branch into selective, more detailed exam steps and then to continue with the exam protocol to its conclusion. It would further be desirable for the results of the spontaneous detailed exam steps to be recorded in any automated report generated as a result of the protocol execution.

In accordance with the principles of the present invention an ultrasonic diagnostic imaging system is provided with an examination protocol which is variable during the execution of the protocol. The pre-programmed protocol can be augmented by additional examination protocol steps which are user-definable. The added protocol steps are context-based so as to automatically guide the sonographer through additional detailed analysis of the anatomy for which they are employed. The results of the added protocol steps flow directly into a system-generated report in the proper sequence of the protocol exam results.

In the drawings:

FIGURE 1 shows an ultrasonic diagnostic imaging system constructed in accordance with the principles of the present invention.

FIGURE 2 illustrates in block diagram form the functional elements of the ultrasound system of FIGURE 1 and ancillary peripheral devices useful in an implementation of the present invention.

FIGURE 3 is a schematic illustration of the carotid artery.

FIGURE 4 illustrates a touchscreen containing vascular exam protocol buttons in accordance with one embodiment of the present invention.

FIGURE 5 illustrates the taking of two velocity measurements of the common carotid artery during a vascular exam.

FIGURE 6 illustrates a touchscreen containing vascular exam protocol buttons with new buttons for additional protocol steps added by the sonographer.

FIGURE 7 illustrates a pop-up display for a sonographer to label a user-created measurement protocol step.

FIGURE 8 is a schematic illustration of a stenotic carotid artery.

FIGURE 9 illustrates a vascular exam report including the results of a measurement protocol step added by the sonographer during the course of the execution of the protocol.

FIGURE 10 is a schematic illustration of a stenotic vessel which is to be analyzed.

FIGURE 11 illustrates a touchscreen containing user-created protocol steps for a % diameter reduction measurement of a stenotic vessel.

FIGURE 12 illustrates an ultrasound image display containing the distance caliper tool invoked by the user-created % diameter reduction protocol

step.

FIGURE 13 illustrates a touchscreen containing user-created protocol steps for a % area reduction measurement of a stenotic vessel.

FIGURE 14 illustrates an ultrasound image display containing the ellipse and trace tools invoked by the user-created % area reduction protocol step.

FIGURE 15 illustrates a vascular exam report containing the results of the user-created % diameter and % area reduction steps.

An ultrasound imaging system 10 constructed in accordance with one embodiment of the invention is illustrated FIGURE 1. The system 10 includes a chassis 12 containing most of the electronic circuitry for the system 10. The chassis 12 is mounted on a cart 14, and a display 16 is mounted on the chassis 12. Different imaging probes may be plugged into three connectors 26 on the chassis. The chassis 12 includes a keyboard and controls, generally indicated by reference numeral 28, for allowing a sonographer to operate the ultrasound system 10 and enter information about the patient or the type of examination that is being conducted. At the back of the control panel 28 is a touchscreen display 18 on which programmable softkeys are displayed for protocol execution in accordance with the present invention. The sonographer selects a softkey on the touchscreen display 18 simply by touching the image of the softkey on the display.

In operation, a probe is placed against the skin of a patient (not shown) and either held stationery or moved to acquire an image of blood or tissues beneath the skin. The image is presented on the display 16, and it may be recorded by a recorder (not

shown) placed on one of the accessory shelves 82. The system 10 may also record or print a report containing text and images. Data corresponding to the image may also be downloaded through a suitable data link, such as the Internet or a local area network. The type of image shown on the display 16, the type of report recorded or printed, and the type of data downloaded will depend on the type of ultrasound examination that is being conducted.

The above-described components of the imaging system 10 are conventional and are commonly used to obtain ultrasound images. The imaging system 10 according to one embodiment of the invention uses examination protocols, which may be standardized throughout the healthcare field, to automatically guide the sonographer through standard ultrasound exams. The protocols are used in a manner that will be explained in detail in connection with FIGURES 3-15.

The elements of the ultrasound imaging system 10 are illustrated in greater detail in FIGURE 2. An ultrasound imaging probe 20 is coupled by a cable 24 to one of the connectors 26 which connect to an ultrasound signal path 40 of conventional design. Although one ultrasound imaging probe is shown in FIGURE 2, it will be understood that other types of imaging probes can and generally will be used depending upon the type of ultrasound examination being conducted. In the embodiment shown in FIGURE 2, the imaging probe 20 and all other imaging probes that will be used with the system 10 preferably provide probe identifying signals to a processing unit 50 to allow the processing unit 50 to determine the type of probe 20 currently being used.

As is well-known in the art, the ultrasound

signal path 40 includes a transmitter (not shown) coupling electrical signals to the probe 20, an acquisition unit (not shown) that receives electrical signals from the probe 20 corresponding to ultrasound echoes, a signal processing unit (not shown) that processes the signals from the acquisition unit to perform a variety of functions such as isolating returns from specific depths or isolating returns from blood flowing through vessels, and a scan converter (not shown) that converts the signals from the signal processing unit so that they are suitable for use by the display 16. The processing unit in this embodiments is capable of processing both B mode (structural) and Doppler signals for the production of various B mode and Doppler displays including spectral Doppler. The ultrasound signal path 40 also includes a control module 44 that interfaces with the processing unit 50 to control the operation of the above-described units. The ultrasound signal path 40 may, of course, contain components in addition to those described above, and, it suitable instances, some of the components described above may be omitted.

The processing unit 50 contains a number of components, including a central processor unit ("CPU") 54, random access memory ("RAM") 56, and read only memory ("ROM") 58, to name a few. As is well-known in the art, the ROM 58 stores a program of instructions that are executed by the CPU 54, as well as initialization data for use by the CPU 54. The RAM 56 provides temporary storage of data and instructions for use by the CPU 54. The processing unit 50 interfaces with a mass storage device such as a disk drive 60 for permanent storage of data, such as data corresponding to ultrasound images obtained

by the system 10. However, such image data is initially stored in an image storage device 64 that is coupled to a signal path 66 extending between the ultrasound signal path 40 and the processing unit 50. The storage drive 60 also preferably stores protocols which may be called up and initiated to guide the sonographer through various ultrasound exams. However, in another embodiment the protocols are stored in a clinical information system 70 that may be accessed through suitable means such as a local area network 74, a modem 76 or a wireless communication link (not shown). The central storage method enables a facility like a hospital to store all the standardized protocols for all of the diagnostic systems in the facility, to control their modification uniformly, and to rapidly disburse the protocols to the ultrasound systems and users in the facility. Once a protocol has been retrieved by the system, it can be executed under control of the processing unit 50 to carry out the diagnostic exam of the protocol.

The processing unit 50 also interfaces with the keyboard and controls 28, which may be used to execute the protocols. The keyboard and controls 28 may also be manipulated by the sonographer to cause the ultrasound system to produce automatically generated reports at the conclusion of an examination. The processing unit 50 preferably interfaces with a report printer 80 that prints reports containing text and one or more images. The type of reports provided by the printer 80 depends on the type of ultrasound examination that was conducted by the execution of a specific protocol.

One example of the execution of a modifiable protocol in accordance with the principles of the

present invention is illustrated with reference to FIGURES 3-9. FIGURE 3 is an illustration of the carotid artery. A standard peripheral vascular examination protocol might call for measurements to be taken in the three branches of the carotid artery shown in this illustration: The internal carotid artery, the external carotid artery, and the common carotid artery. In the common carotid artery (CCA) three measurements are commonly taken: one at the distal CCA, one at the mid CCA, and one at the proximal CCA.

FIGURE 4 shows the touchscreen display 18 for a peripheral vascular examination protocol in a constructed embodiment of the present invention. The constructed embodiment has two such touchscreen displays and the protocol is shown on the left touchscreen on the ultrasound system. The touchscreen display 18 is divided into three areas, each having two rows of softkeys. The upper area has high level key for selecting controls for different functions such as imaging (the "Image" button) and VCR control (the "VCR" button). Protocols are selected by touching the "Analysis" button, which is shown in a dark color when selected as it is in this illustration. In this example there are four types of exam protocols which may be initiated through the Analysis button, a carotid artery exam, a lower extremity arterial exam ("LE Art" button), an upper extremity arterial exam ("UE Art" button), and a grafts exam, which are shown in the central area of the display. Other choices which may be presented to the sonographer could be examinations of the venous structures of the body. In this example the Carotid button has been selected to initiate a carotid exam protocol and the protocol begins with the right

carotid artery as shown by the darkened "Right" button. After the right carotid artery has been examined and measurements taken, the "Left" button will be touched to continue the protocol on the left carotid artery.

The first area of the carotid artery to be examined in this protocol example is the common carotid artery as indicated by the "CCA_" button in the lower area of the touchscreen display. As indicated in FIGURE 3, measurements will be taken at three points in the CCA which are selected by the three buttons at the bottom of the display. In this example the proximal CCA measurements will be taken first as indicated by the darkened "Prox CCA" button. To the right of the standard CCA_ measurement button is a "(New) CCA" template button by which the standard measurements can be augmented as described below.

It may be seen that the touchscreen buttons on the touchscreen display 18 are arranged hierarchically. The Analysis button for the selection of protocols is at the top, the button for the Carotid exam and the button for the Right carotid are in the center of the display, and the button for the CCA measurements of the right carotid and the three points where CCA measurements are to be taken are at the bottom. It is apparent that a tree and branches display structure could alternatively be used for this hierarchical display similar to those used for the directory and file structure display on a computer. The embodiment of FIGURE 4 combines attributes of a hierarchically structure in a functional touchscreen display.

When the sonographer wants to take measurements of the CCA, an ultrasound image of the CCA is

acquired as illustrated in FIGURE 5. In FIGURE 5 a Doppler box 104 is shown over the ultrasound image 102 of the carotid artery 110. (For clarity of illustration a schematic of an ultrasound image is shown in the drawings.) Also shown is a sample volume cursor 106 which the sonographer can align with the point in the CCA where the proximal measurement is to be taken. Below the ultrasound image 102 is a spectral display 120 acquired at the point indicated by the sample volume cursor 106. After the sonographer aligns the cursor 106 at the desired sample point for the measurement and an acceptable spectral display is acquired, the sonographer freezes the display and takes the proximal CCA measurements by touching the Prox CCA button on the touchscreen display. The sonographer does this by marking the peak systolic velocity (PSV) and the end diastolic velocity (EDV) on the spectral display as shown at 112 and 114. As FIGURE 5 shows, the quantified measurement values of the PSV and the EDV appear next to the ultrasound image 102 for review by the sonographer. If the sonographer is satisfied with these measurements the sonographer touches the "End Measure" button on the touchscreen display, the proximal CCA measurements are saved by the system, and a small checkmark (not shown) appears in the lower right-hand corner of the Prox CCA button, indicating that this measurement has been completed. The sonographer may then touch the Mid CCA or Dist CCA button to take another CCA measurement.

The protocol continues in this manner until all the protocol measurements for the right carotid artery have been taken. The sonographer then touches the Left button to take the measurements of the left

carotid artery. As the measurements are taken they are stored by the system in a report database on the ultrasound system. When the sonographer has completed the exam the sonographer can go to the Report Menu on the system and view, save, and print an automatically generated report of the examination. A typical automatically generated report of a vascular exam is shown in FIGURE 9, which shows measurements taken at the proximal, mid, and distal CCA points of the right carotid artery.

However, suppose that the measurements taken of the CCA indicate a stenosis in the mid region of the artery. In such case the sonographer will want to examine that region of the artery in greater detail. FIGURE 8, for instance, illustrates a stenosis at the CCA and indicates six points in the mid CCA where additional measurements should be taken to better define the flow profile at the stenosis. In prior art system the sonographer would have to either complete the carotid protocol and then begin a more detailed analysis in the mid CCA. Alternatively, the sonographer could abort the protocol, take the more detailed measurements, and then begin the protocol again. In accordance with the present invention, the sonographer can modify the pre-programmed carotid protocol by touching the "(New) CCA" template button, which creates a new measurement step in the protocol. The new measurement step is context-driven, and hence the system is displaying a (New) CCA button when CCA measurements are being taken. When the sonographer touches the (New) CCA template button a box appears on a system display as shown in FIGURE 7, asking the sonographer to define the new measurement step with a label. The placeholder label "Vessel" is shown in the box where the sonographer is to type a desired

name for the new measurement. In this example the sonographer types in "Stenotic CCA 1", at which moment a newly defined button appears on the touchscreen 18 as illustrated by the "Stenotic CCA 1" button above the Mid CCA button in FIGURE 9. The sonographer then acquires a Doppler image of the CCA, positions the sample volume cursor, and freezes the image as discussed above. When the sonographer touches the newly defined button, the system launches the measurement tools necessary for a CCA measurement, which in this example include velocity measurements and a caliper tool. Touching the new CCA button automatically invokes these operations without the involvement of the sonographer, reducing the time needed to conduct the exam. In this example the sonographer takes the measurements for Stenotic CCA 1, the new button is checked to indicate that the measurements have been taken, and the sonographer proceeds to the next measurement. FIGURE 8 shows that six such measurement points are to be analyzed, and the ultrasound system enables this to be done by allowing the sonographer to create six new protocol step buttons from the (New) CCA template button as shown by Stenotic CCA buttons 1-6 in FIGURE 6.

FIGURE 9 shows that, when the ultrasound system has an automatic report generation function linked to the customized protocol feature, the newly created protocol step is automatically included in the CCA measurements section of the report as seen by the Stenotic CCA 1 measurements at the top of the report screen. In accordance with a further aspect of the present invention, the sonographer can also augment the standard measurement tools of a protocol step. In this example the sonographer has touched the "Assign" button while taking the Stenotic CCA 1

measurements, and has added a distance measurement to this protocol step. This addition will launch a distance measurement tool by which the sonographer can measure the distance across the CCA at the point of the measurement. As FIGURE 9 shows, the distance measurement taken at the point of the Stenotic CCA 1 measurement is 0.444 cm. Thus, the sonographer can add new steps to the standard exam protocol and can also incorporate selected measurements into newly added protocol steps so as to better diagnose the patient's condition.

As another example suppose that a sonographer has detected reduced blood flow in the internal carotid artery (ICA; see FIGURE 3) wants to assess the percent reduction of the right carotid artery ICA caused by plaque build-up in the ICA. In this case the sonographer touches the Right button to display optional button templates for carotid artery calculations, one of which is the "% Reduction" button shown in FIGURE 11. The % Reduction button has two template buttons, one for diameter reduction and one for area reduction. The % diameter reduction template guides the sonographer in measuring the true diameter and the residual diameter of the vessel, then computes the percent reduction in effective vessel diameter as a function of the two measurements. This is shown in the illustration of an ICA in cross-section. The true diameter is the actual diameter of the vessel in the absence of any plaque. The residual diameter is the diameter of the vessel lumen remaining after the plaque is present. When the sonographer touches the (New) % diameter reduction template button a box appears (see FIGURE 7) to request that the sonographer type in a name for the new diameter reduction template step. In this

example the sonographer types "ICA % Diam Reduction," which creates a new protocol step button as shown in FIGURE 11. When the sonographer touches the new ICA % Diam Reduction button, two associated measurement buttons appear, the Diam Resid button and the Diam True button. When the sonographer touches the Diam Resid button a distance caliper tool is launched with the ultrasound image 102 as shown in FIGURE 12. This tool enables a distance measurement to be made of the residual vessel diameter on the image of the carotid artery 110, which is marked with an "X" sign as shown in the center of FIGURE 12. The caliper tool enables the sonographer to place these X markers on the appropriate points of the anatomy in the image, and the quantified numerical results of the residual diameter measurement appears to the left of the ultrasound image 102. When the sonographer touches the Diam True button another distance caliper tool is launched for the true diameter measurement, this one marked with a "+" sign. The sonographer aligns the + signs with the proper points on the ultrasound image and touches the ICA % Diam Reduction button. The ultrasound system then uses the two diameter measurements just taken and computes the % diameter reduction of the vessel, which appears just below the two measurements as shown in FIGURE 12. When the sonographer touches the End Measure button the two measurements and the % diameter reduction calculation are saved by the system and a check mark appears on the ICA % Diam Reduction button to indicate that this protocol step has been completed. The measurement and calculation results will now appear in the linked automatically generated report as shown in FIGURE 15.

As an illustration of a further embodiment of the present invention, suppose that the sonographer

wants to assess the % area reduction of the vessel. The sonographer will touch the (New) % Area Reduction template button, which will display a box in which the sonographer can name the new area reduction step (see FIGURE 7). In this example the sonographer types in "ICA % Area Reduction" and the named new protocol step button appear as shown in FIGURE 13. When the sonographer touches the new ICA % Area Reduction button, two associated measurement buttons appear, the Area Resid button and the Area True button. Touching the Area True button launches an ellipse tool, since the ultrasound system knows that the true area of a vessel is measured with an ellipse graphic. The ellipse graphic is produced over the carotid artery 110 in the ultrasound image 102 as shown in FIGURE 14 by the dashed lines with the + signs. The sonographer grabs the ellipse with a cursor and fits it to the actual inner circumference of the blood vessel. The quantified area measurement obtained by the fitted ellipse appears numerically to the left of the ultrasound image 102. The sonographer touches the Diam Resid button which launches a tracing tool over the ultrasound image. The sonographer then traces the actual inner diameter of the stenosis with the tool, as indicated by the dotted line with the X on it in FIGURE 14. The Area Resid measurement appears numerically with the Area True measurement, and the calculated % Area Reduction calculation appears below the two measurements. If the sonographer is satisfied with the results the sonographer touches the End Measure button (see FIGURE 4) to save the results of the protocol step for the automatically generated report and a check mark appears on the ICA % Area Reduction button, marking the step as complete. A sample page of an

automatically generated report with the results of these two protocol steps shown on the page is illustrated in FIGURE 15.

At the conclusion of the ultrasound exam the modified exam protocol can be deleted from the ultrasound system so that the selection of the exam protocol for another exam will initiate the same standardized exam protocol which was initiated at the start of the modified exam. Alternatively, the sonographer may decide to save the modified exam protocol, which may be used in the future, for example, to examine the same patient at a later point in time in accordance with the same modified exam protocol.

WHAT IS CLAIMED IS:

1. An ultrasonic diagnostic imaging system which executes a pre-programmed protocol to guide a user through the steps of an ultrasound examination comprising:

a display of the steps of an exam protocol;

an optional user selection by which a user can add a new step to the exam protocol,

wherein the optional new step is functionally related to the context of the ultrasound exam at the point in the protocol where it is added; and

wherein the optional new step includes a diagnostic tool appropriate to the function of the new protocol step.

2. The ultrasonic diagnostic imaging system of Claim 1, wherein the optional user selection further includes means for enabling the user to identify the new protocol step.

3. The ultrasonic diagnostic imaging system of Claim 1, wherein the diagnostic tool comprises at least one of a measurement tool and a calculation tool.

4. The ultrasonic diagnostic imaging system of Claim 3, wherein the measurement tool is one of a distance measurement, an area measurement, a volume flow measurement, or a velocity measurement.

5. The ultrasonic diagnostic imaging system of Claim 1, wherein a step of an exam protocol guides a user in the examination of a particular anatomical feature,

wherein the option new step is functionally related to the examination of the particular anatomical feature.

6. The ultrasonic diagnostic imaging system of Claim 5, wherein a plurality of the steps of an exam protocol guide a user in the examination of a plurality of anatomical features,

wherein the option new step is functionally related to the examination of the particular anatomical feature at the point in the protocol where the new step is added.

7. The ultrasonic diagnostic imaging system of Claim 1, further comprising means for executing an added step of a protocol.

8. The ultrasonic diagnostic imaging system of Claim 7, wherein the means for executing an added step of a protocol includes mean for launching a diagnostic tool of the new protocol step in conjunction with an ultrasound image.

9. The ultrasonic diagnostic imaging system of Claim 1, further comprising means for indicating the completion of an added step of an exam protocol.

10. The ultrasonic diagnostic imaging system of Claim 1, further comprising an automatic examination report subsystem linked to the exam protocol,

wherein the results of pre-programmed protocol step and newly added protocol steps are recorded by the report subsystem.

11. The ultrasonic diagnostic imaging system of

Claim 10, wherein the results of a newly added protocol step is recorded in association with a pre-programmed protocol step at the point in the protocol where the new protocol step is added.

12. A method for conducting an ultrasound examination with an ultrasound system having a pre-programmed exam protocol comprising:

executing the steps of a pre-programmed exam protocol in an examination sequence;

adding, in conjunction with a step of the pre-programmed exam protocol, a new protocol step which is functionally related to the context of the ultrasound exam at the point in the protocol where the new protocol step is added,

wherein the new protocol step includes a diagnostic tool operable by a user which is appropriate to the function of the new protocol step.

13. The method of Claim 12, wherein adding further comprises naming the new protocol step.

14. The method of Claim 12, wherein executing the step of a pre-programmed exam protocol comprises acquiring ultrasonic information as directed by the step of the exam protocol,

wherein adding a new protocol step at the step of the pre-programmed exam protocol further comprises adding a new protocol step which acquires ultrasonic information which is related to the ultrasonic information of the step of the pre-programmed exam protocol.

15. The method of Claim 12, further comprising executing a new protocol step,

wherein executing a new protocol step comprises making a measurement or calculation from an ultrasound image under the direction of a diagnostic tool of the new protocol step.

16. The method of Claim 12, further comprising adding a new function to an added new protocol step.

17. The method of Claim 16, wherein adding a new function to an added new protocol step further comprises adding a new diagnostic tool to the new protocol step.

18. The method of Claim 12, further comprising executing a new protocol step,

wherein executing a new protocol step comprises launching at least one diagnostic tool appropriate to the function of the new protocol step.

19. The method of Claim 12, further comprising reporting the results of executing the steps of a pre-programmed exam protocol and the results of executing an added new protocol step in an automatically generated report.

20. The method of Claim 19, wherein reporting the results further comprises reporting the results of executing an added new protocol step in conjunction with the reporting of the results of the step of the pre-programmed exam protocol in conjunction with which the new protocol step was added.

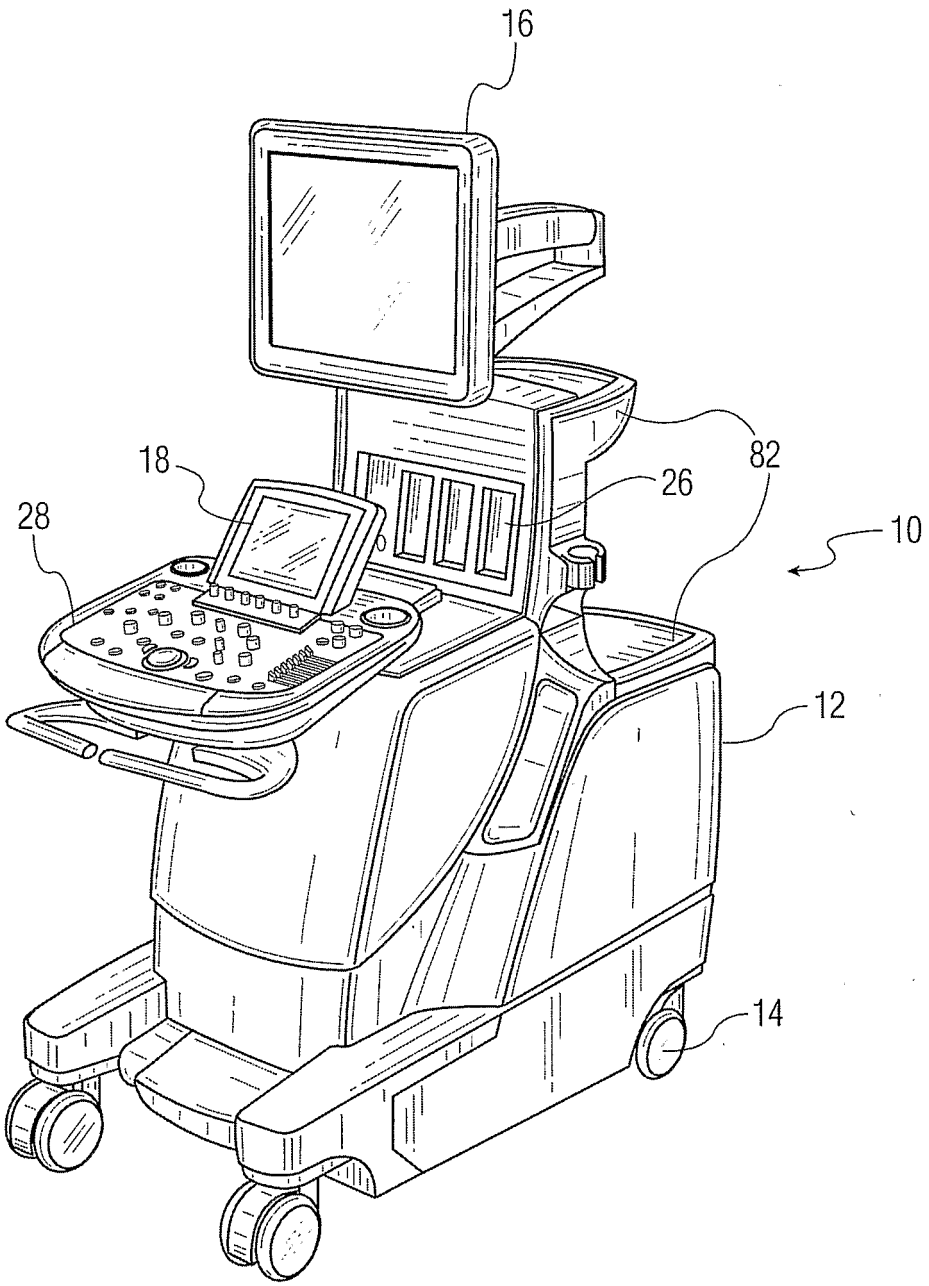


FIG. 1

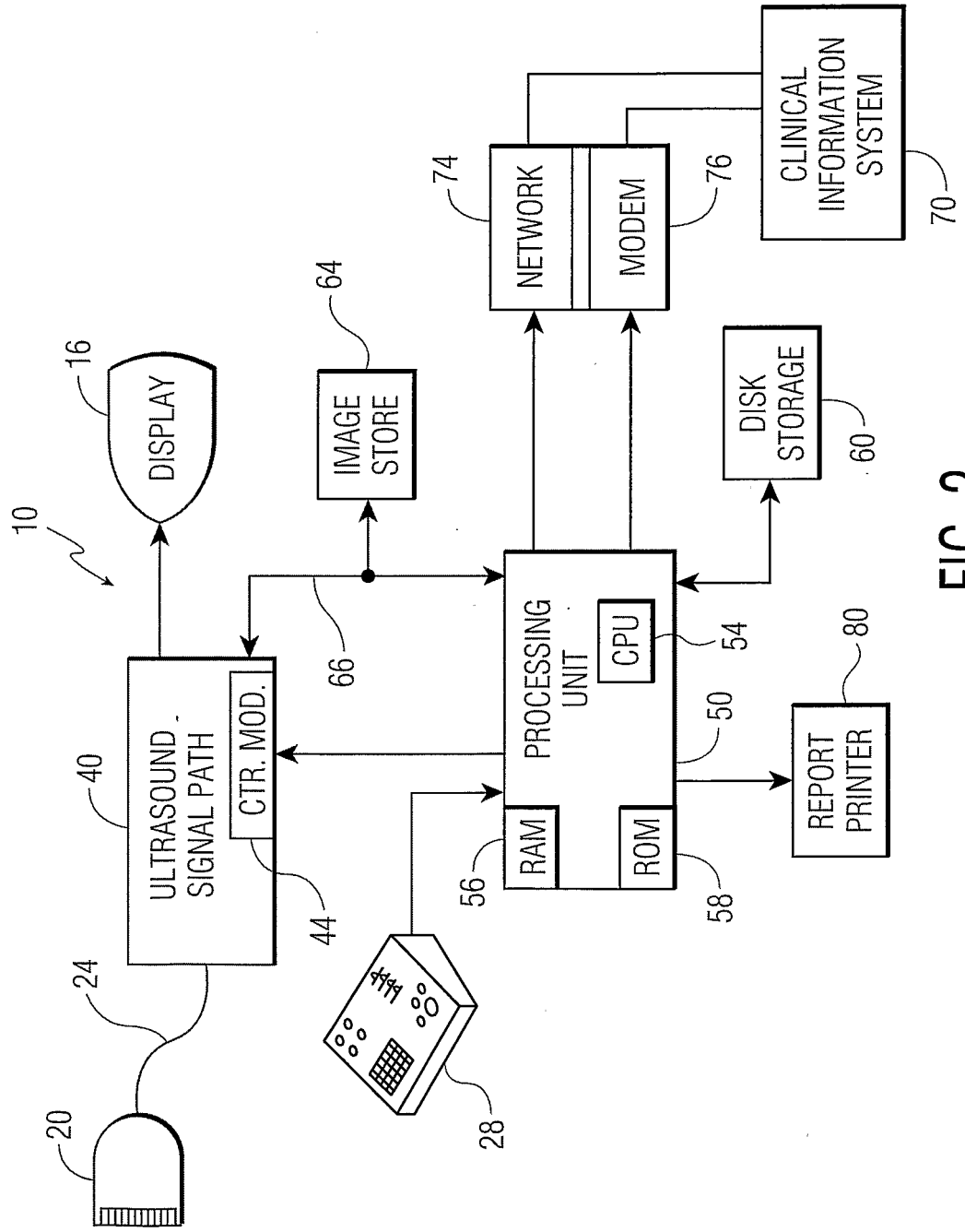

10
16
DISPLAY
64
IMAGE STORE
74
NETWORK
MODEM
76
CLINICAL INFORMATION SYSTEM
70
DISK STORAGE
60
66
PROCESSING UNIT
CPU
54
80
REPORT PRINTER
40
ULTRASOUND SIGNAL PATH
CTR. MOD.
50
RAM
ROM
56
58
44
24
28
20

FIG. 2

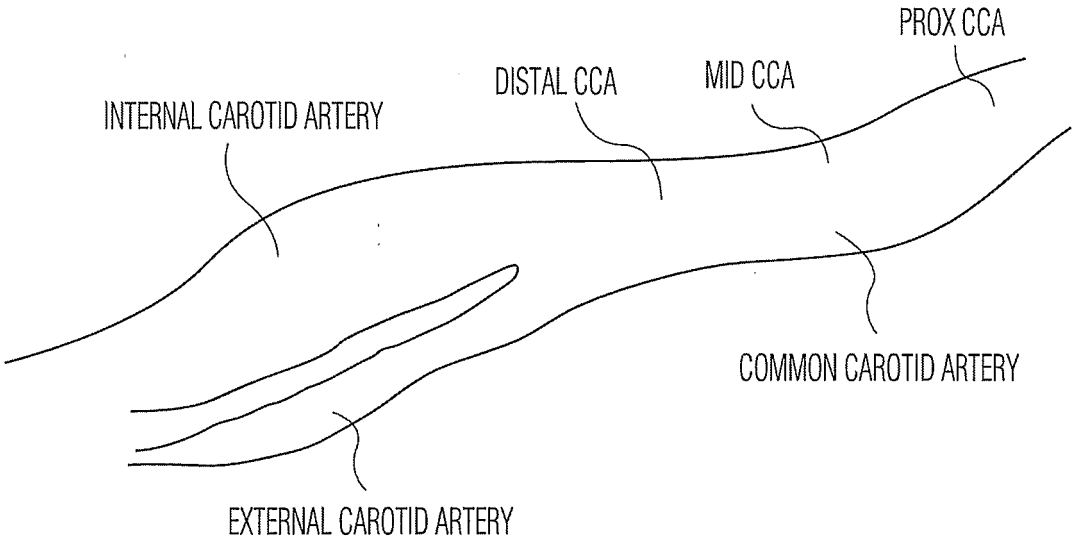

PROX CCA
DISTAL CCA
MID CCA
INTERNAL CAROTID ARTERY
COMMON CAROTID ARTERY
EXTERNAL CAROTID ARTERY

FIG. 3

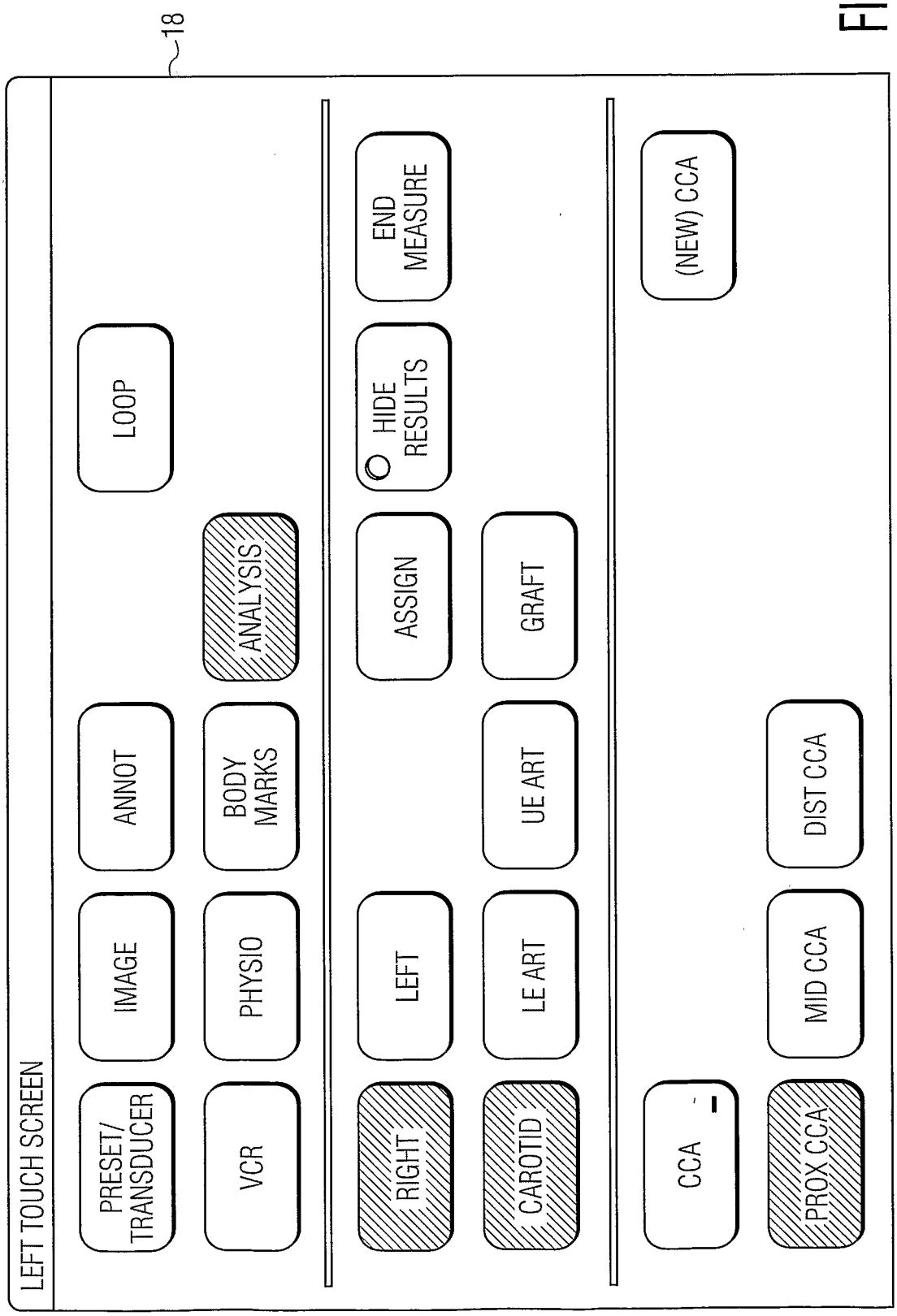

18
LEFT TOUCH SCREEN
PRESET/ TRANSDUCER
IMAGE
ANNOT
LOOP
VCR
PHYSIO
BODY MARKS
ANALYSIS
RIGHT
LEFT
ASSIGN
HIDE RESULTS
END MEASURE
CAROTID
LE ART
UE ART
GRAFT
CCA
PROX CCA
MID CCA
DIST CCA
(NEW) CCA

FIG. 4

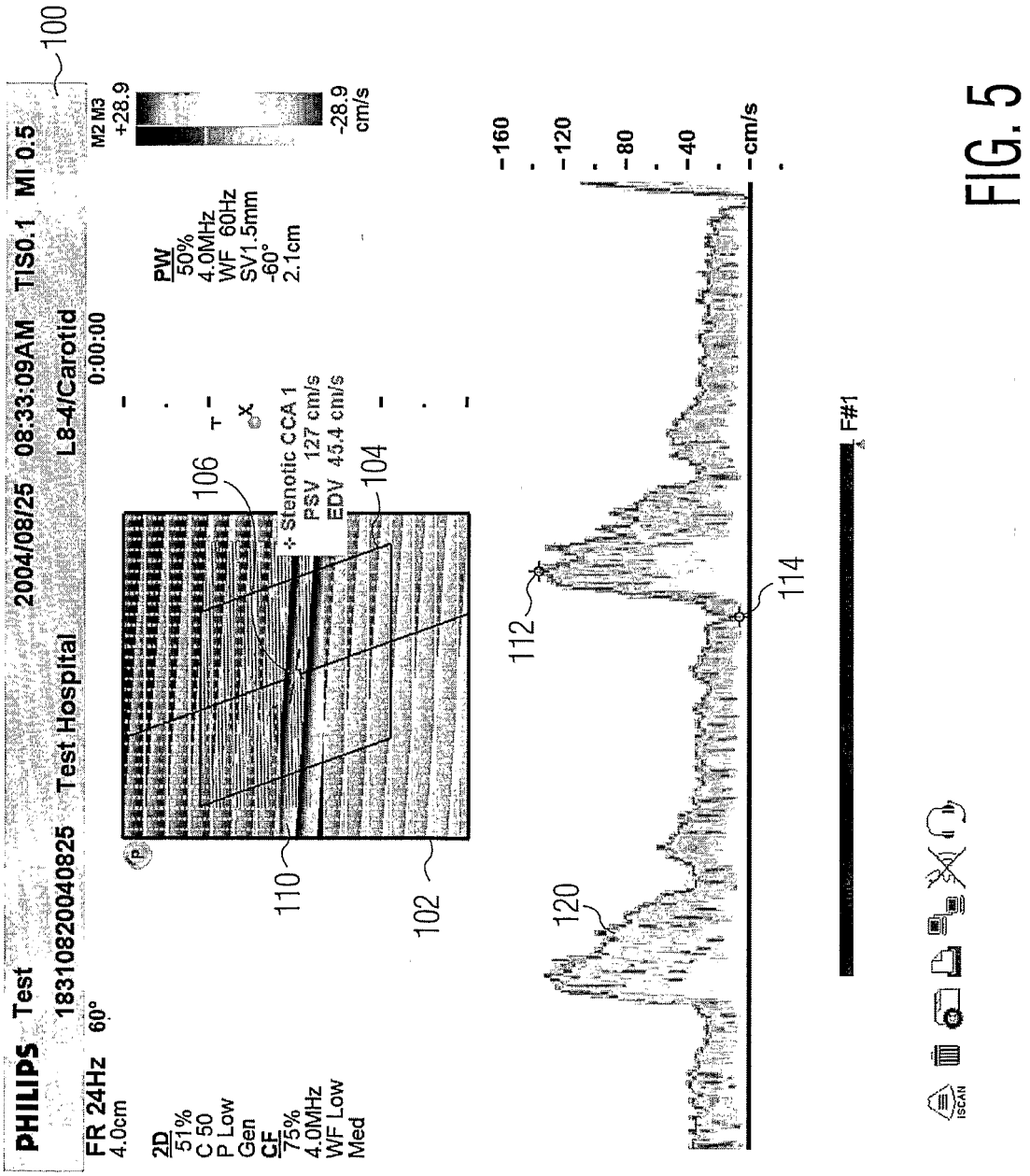

PHILIPS Test
1831082004082S 2004/08/25 08:33:09AM TIS0.1 MI 0.5
Test Hospital L8-4/Carotid
FR 24Hz 60°
4.0cm
0:00:00
2D
51%
C 50
P Low
Gen
CF
75%
4.0MHz
WF Low
Med
PW
50%
4.0MHz
WF 60Hz
SV1.5mm
-60°
2.1cm
M2 M3
+28.9
-28.9
cm/s
Stenotic CCA 1
PSV 127 cm/s
EDV 45.4 cm/s
-160
-120
-80
-40
cm/s
F#1
100
102
104
106
110
112
114
120

FIG. 5

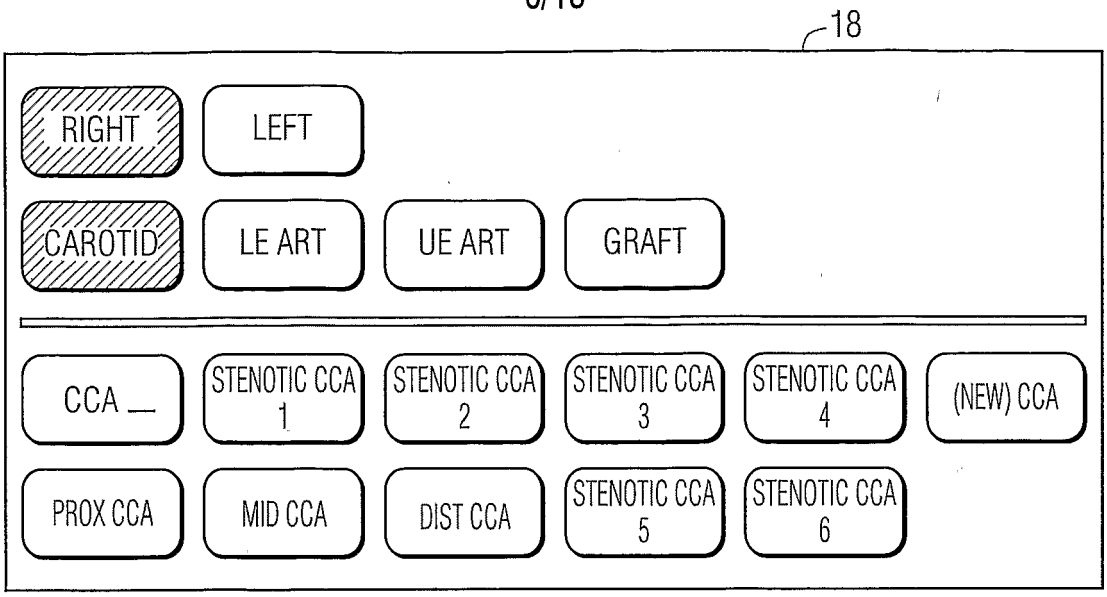

18
RIGHT
LEFT
CAROTID
LE ART
UE ART
GRAFT
CCA __
STENOTIC CCA 1
STENOTIC CCA 2
STENOTIC CCA 3
STENOTIC CCA 4
(NEW) CCA
PROX CCA
MID CCA
DIST CCA
STENOTIC CCA 5
STENOTIC CCA 6

FIG. 6

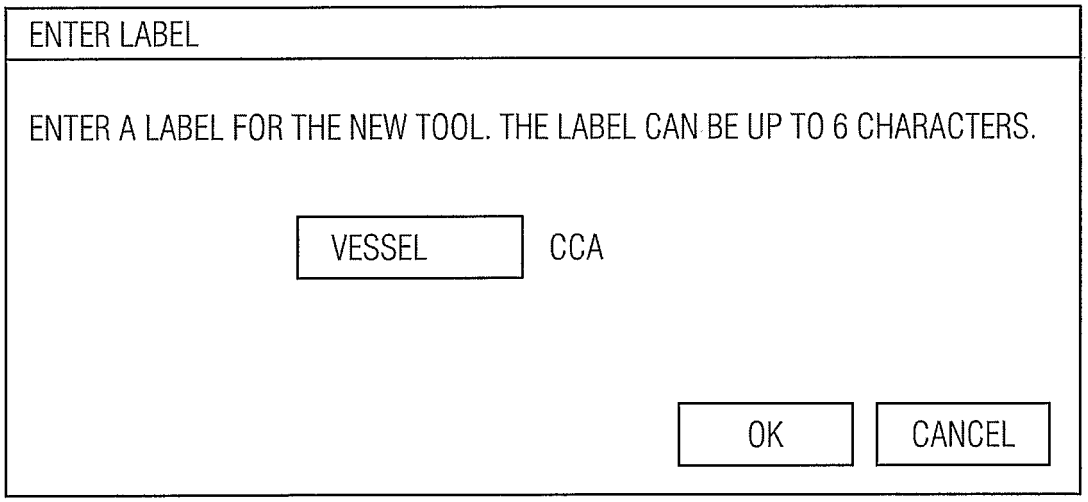

ENTER LABEL
ENTER A LABEL FOR THE NEW TOOL. THE LABEL CAN BE UP TO 6 CHARACTERS.
VESSEL
CCA
OK
CANCEL

FIG. 7

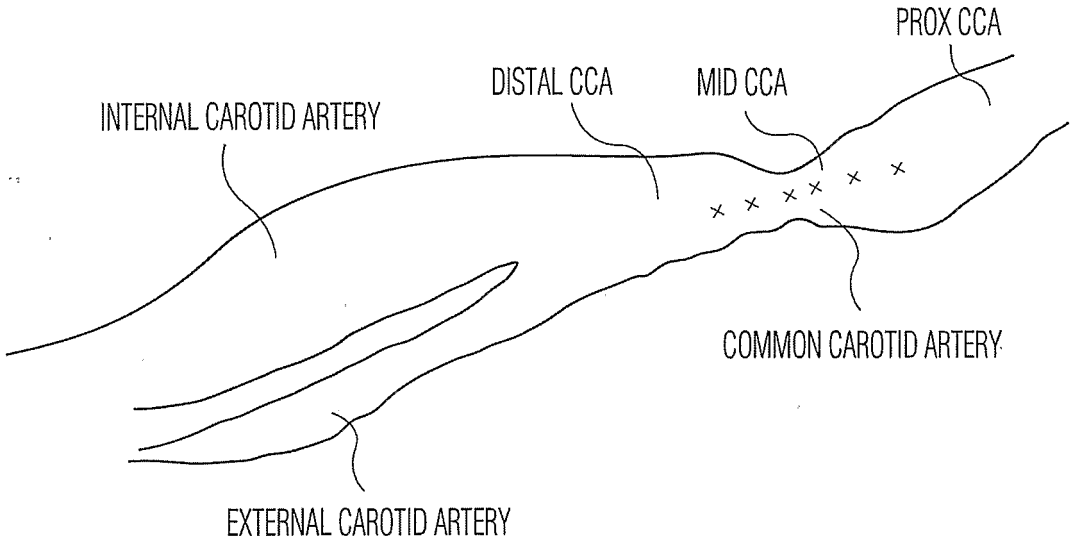

PROX CCA
DISTAL CCA
MID CCA
INTERNAL CAROTID ARTERY
COMMON CAROTID ARTERY
EXTERNAL CAROTID ARTERY

FIG. 8

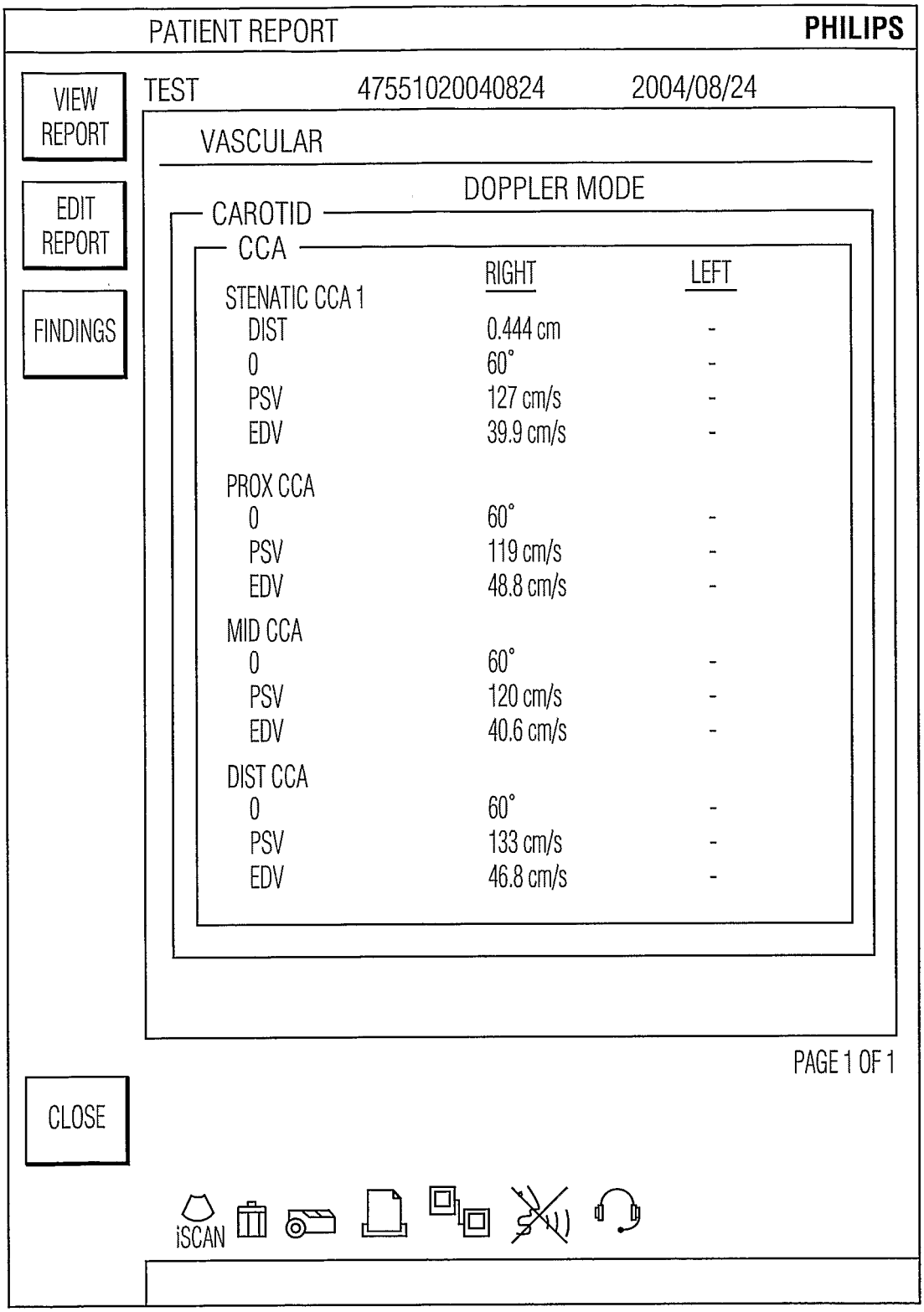

PATIENT REPORT
PHILIPS
VIEW REPORT
EDIT REPORT
FINDINGS
CLOSE
TEST 47551020040824 2004/08/24
VASCULAR
DOPPLER MODE
CAROTID
CCA
RIGHT LEFT
STENATIC CCA 1
DIST 0.444 cm -
0 60° -
PSV 127 cm/s -
EDV 39.9 cm/s -
PROX CCA
0 60° -
PSV 119 cm/s -
EDV 48.8 cm/s -
MID CCA
0 60° -
PSV 120 cm/s -
EDV 40.6 cm/s -
DIST CCA
0 60° -
PSV 133 cm/s -
EDV 46.8 cm/s -
PAGE 1 OF 1
iSCAN

FIG. 9

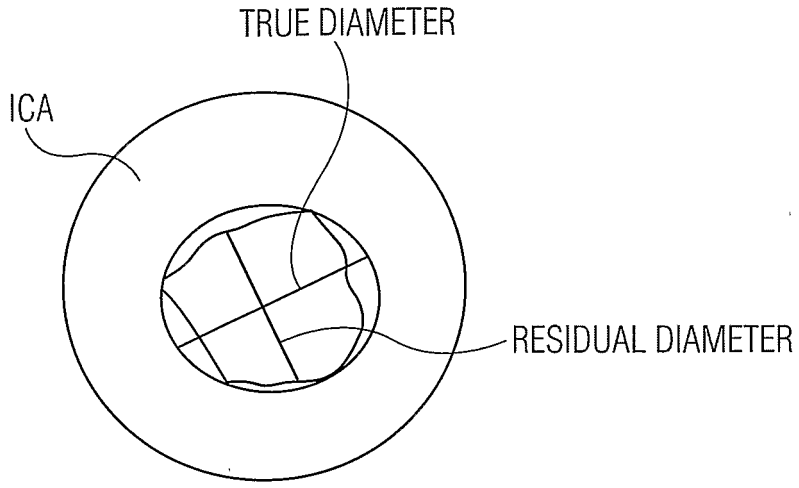

TRUE DIAMETER
ICA
RESIDUAL DIAMETER

FIG. 10

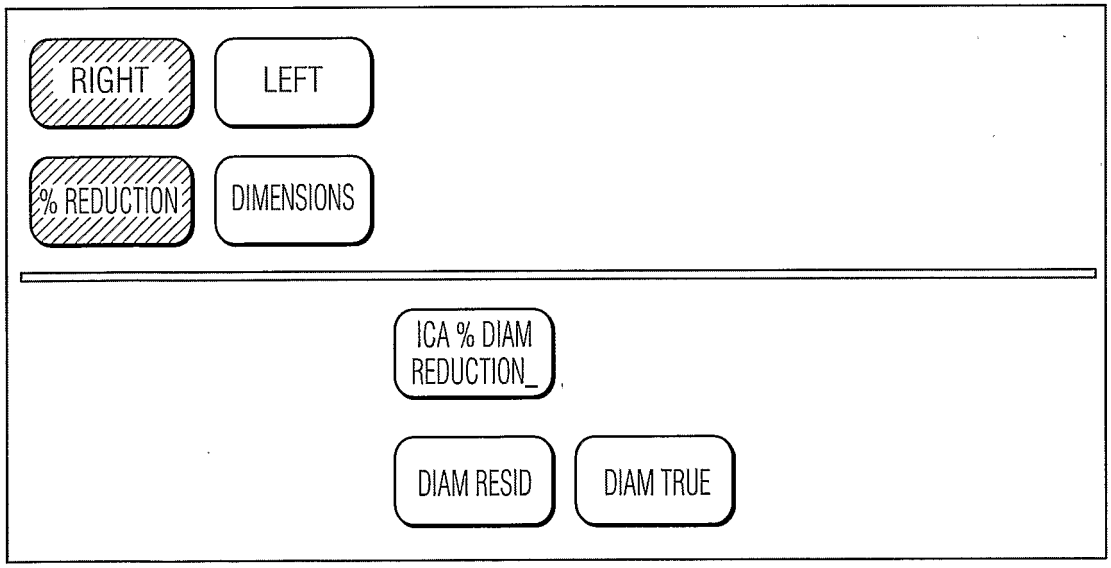

RIGHT
LEFT
% REDUCTION
DIMENSIONS
ICA % DIAM REDUCTION_
DIAM RESID
DIAM TRUE

FIG. 11

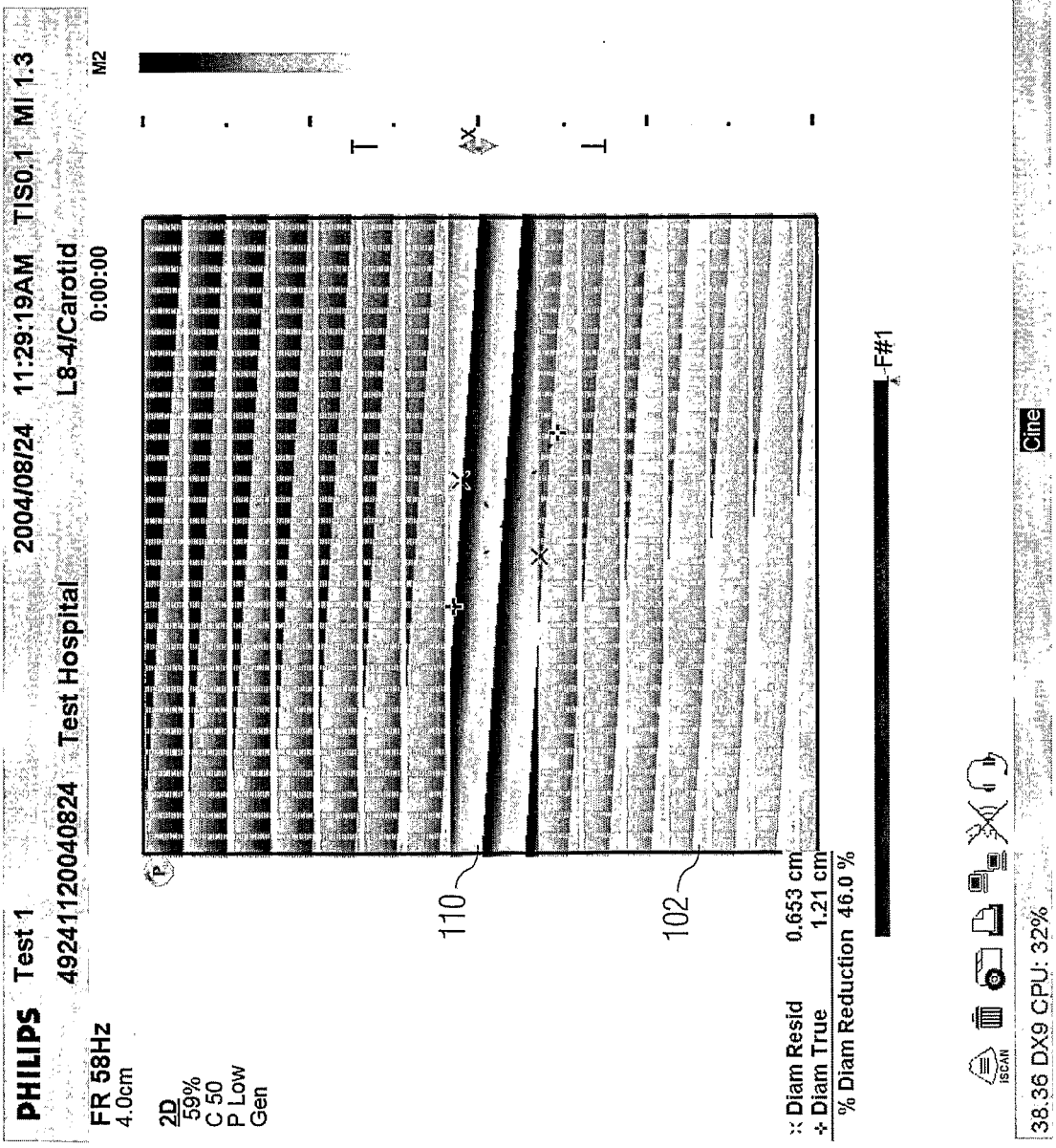

PHILIPS Test 1
2004/08/24 11:29:19AM TIS0.1 MI 1.3
49241120040824 Test Hospital L8-4/Carotid
0:00:00
FR 58Hz
4.0cm
2D
59%
C 50
P Low
Gen
M2
F#1
110
102
Diam Resid 0.653 cm
Diam True 1.21 cm
% Diam Reduction 46.0 %
38.36 DX9 CPU: 32%
Cine

FIG. 12

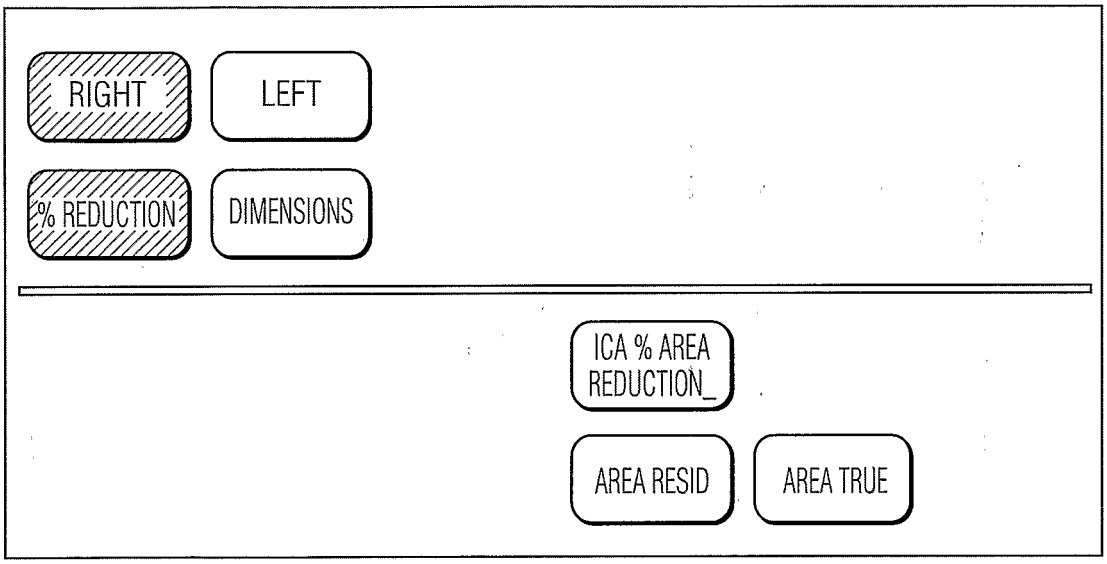

RIGHT
LEFT
% REDUCTION
DIMENSIONS
ICA % AREA REDUCTION_
AREA RESID
AREA TRUE

FIG. 13

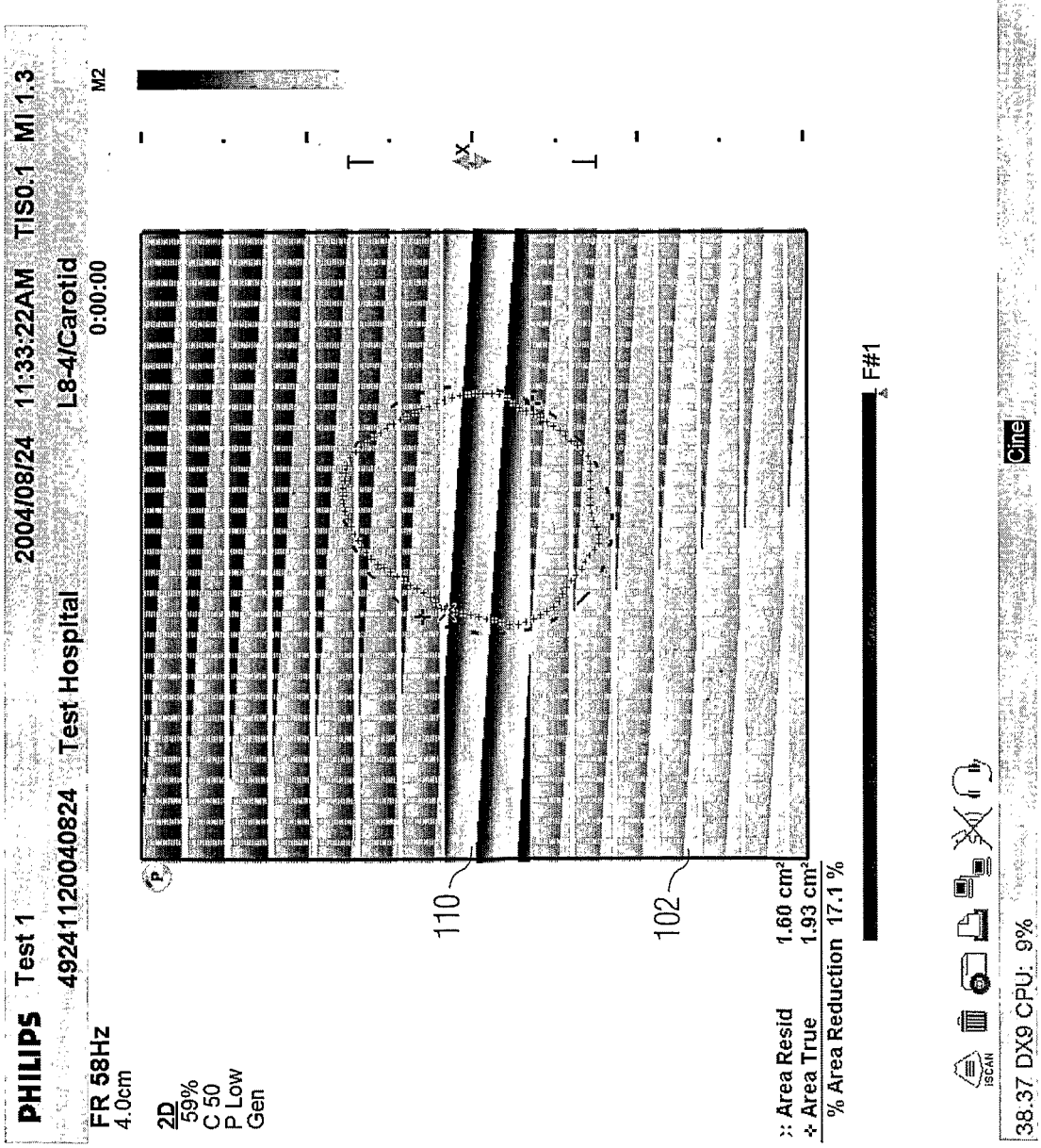

PHILIPS Test 1
2004/08/24 11:33:22AM TIS0.1 MI 1.3
492411200408 24 Test Hospital
L8-4/Carotid
0:00:00
FR 58Hz
4.0cm
2D
59%
C 50
P Low
Gen
M2
110
102
:: Area Resid 1.60 cm²
Area True 1.93 cm²
% Area Reduction 17.1 %
F#1
Cine
38.37 DX9 CPU: 9%

FIG. 14

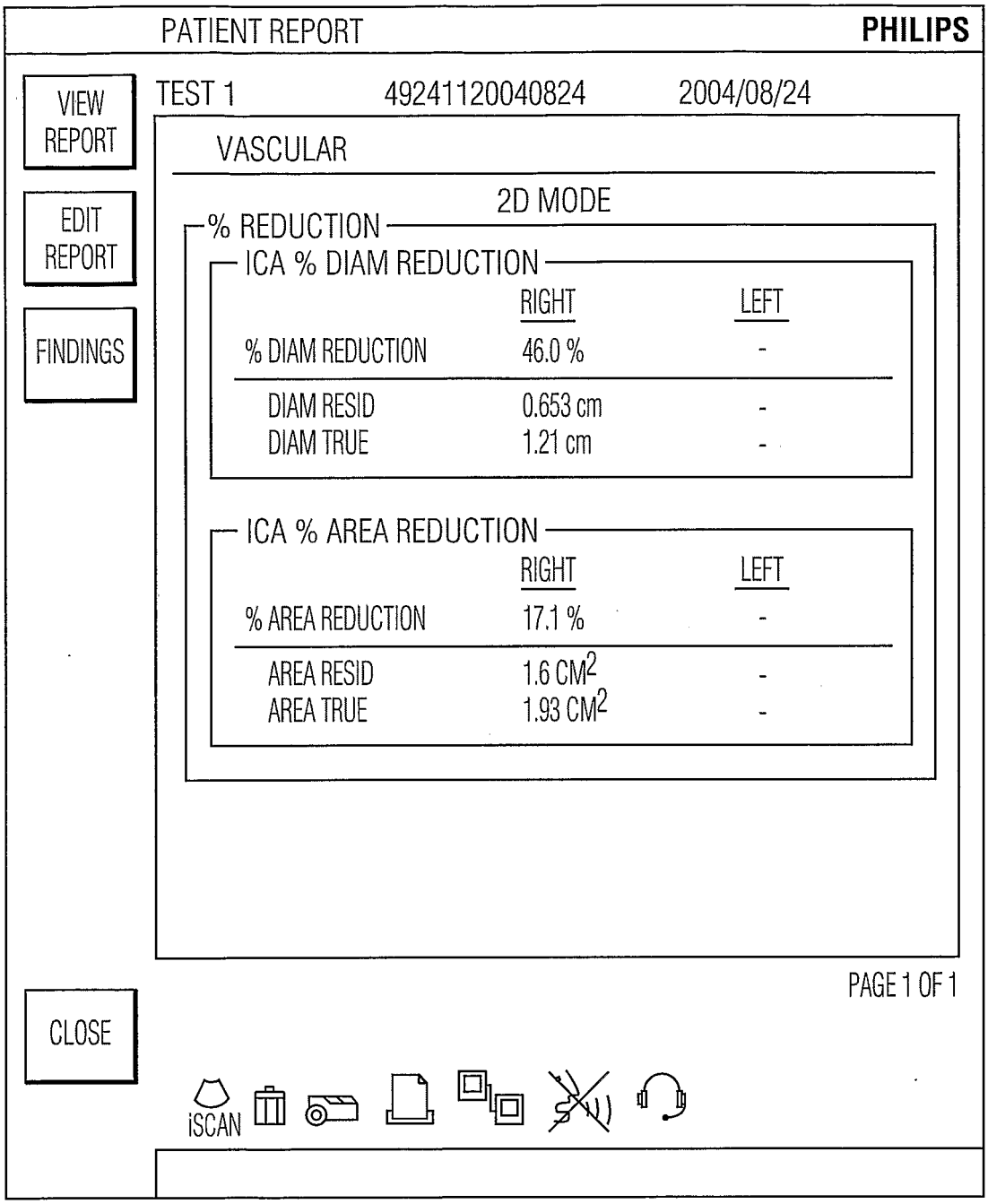

PATIENT REPORT
PHILIPS
VIEW REPORT
EDIT REPORT
FINDINGS
TEST 1
49241120040824
2004/08/24
VASCULAR
2D MODE
% REDUCTION
ICA % DIAM REDUCTION
RIGHT
LEFT
% DIAM REDUCTION
46.0 %
-
DIAM RESID
0.653 cm
-
DIAM TRUE
1.21 cm
-
ICA % AREA REDUCTION
RIGHT
LEFT
% AREA REDUCTION
17.1 %
-
AREA RESID
1.6 CM2
-
AREA TRUE
1.93 CM2
-
PAGE 1 OF 1
CLOSE
iSCAN

FIG. 15

INTERNATIONAL SEARCH REPORT

International Application No
PCT/IB2005/053250

A. CLASSIFICATION OF SUBJECT MATTER
A61B8/00

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)
A61B

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 practical, search terms used)
EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 6 458 081 B1 (MATSUI SUSUMU ET AL) 1 October 2002 (2002-10-01) figures 4,5,9,37,38,42 column 12, lines 21-31 column 13, line 62 - column 14, line 2 column 15, lines 23-31 column 18, line 39 - column 19, line 27 column 19, lines 59-62 column 22, line 3 - column 23, line 47 column 28, lines 43-49	1-20
X	US 6 149 594 A (ROCK ET AL) 21 November 2000 (2000-11-21) figures 1-4 column 4, lines 16-54 column 9, lines 6-28; figure 9b	1-6,12, 14

-/--

[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

° Special categories of cited documents :

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

"E" earlier document but published on or after the international filing date

"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)

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

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

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

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

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

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
22 December 2005	04/01/2006

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Kronberger, R

3

Form PCT/ISA/210 (second sheet) (January 2004)

INTERNATIONAL SEARCH REPORT

International Application No
PCT/IB2005/053250

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 6 306 089 B1 (COLEMAN MICHAAL ET AL) 23 October 2001 (2001-10-23) column 1, line 22 - column 2, line 18; figures 1,2,5,6,10,14 column 3, line 45 - column 4, line 20 column 4, line 42 - column 5, line 5 column 5, lines 19-66 column 7, line 56 - column 8, line 9 column 8, lines 37-57	1-11
X	US 2003/026464 A1 (KAMIYAMA NAOHISA ET AL) 6 February 2003 (2003-02-06) paragraphs '0073! - '0075!, '0118! - '0134!; figures 9,10	1-3,5-8, 10-12, 14-20

3

INTERNATIONAL SEARCH REPORT

International Application No
PCT/IB2005/053250

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 6458081 B1	01-10-2002	NONE	
US 6149594 A	21-11-2000	NONE	
US 6306089 B1	23-10-2001	WO 0123905 A1 EP 1141745 A1 JP 2003510145 T	05-04-2001 10-10-2001 18-03-2003
US 2003026464 A1	06-02-2003	NONE	

专利名称(译)	具有灵活检查协议和报告生成的超声诊断系统		
公开(公告)号	EP1799111A1	公开(公告)日	2007-06-27
申请号	EP2005787200	申请日	2005-10-03
[标]申请(专利权)人(译)	皇家飞利浦电子股份有限公司		
申请(专利权)人(译)	皇家飞利浦电子N.V.		
当前申请(专利权)人(译)	皇家飞利浦N.V.		
[标]发明人	SAAD ASHRAF SKYBA DAN		
发明人	SAAD, ASHRAF SKYBA, DAN		
IPC分类号	A61B8/00 G01S7/52 G06F19/00		
CPC分类号	A61B8/467 A61B8/00 A61B8/461 A61B8/465 G01S7/52098 G06F19/321 G06F19/324 G16H40/63		
优先权	60/617491 2004-10-08 US		
其他公开文献	EP1799111B1		
外部链接	Espacenet		

摘要(译)

超声诊断系统的分析特征包含一个或多个检查协议，其引导超声医师进行一个或多个标准化的超声检查。在执行检查协议模板期间，可以使用协议步骤。超声检查者可以通过选择这些模板协议步骤之一并为其赋予当前协议的唯一名称来增强标准协议。执行此添加的步骤将自动调用诊断工具，例如测量和计算，这些是克隆的传统协议步骤中固有的。此外，超声医师可以为添加的步骤添加其他诊断工具。标准和定制协议步骤的结果将自动记录在自动生成的诊断报告的正确顺序和上下文中。