

TOSHIBA

Toshiba famio XG SSA-530A Operation Manual

Diagnostic ultrasound system

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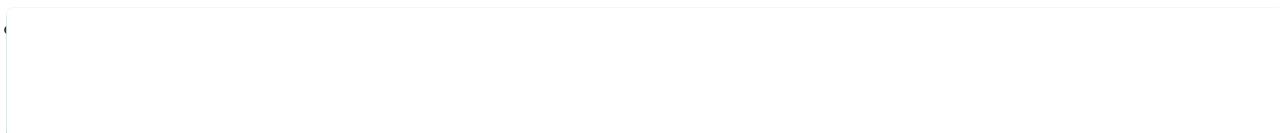
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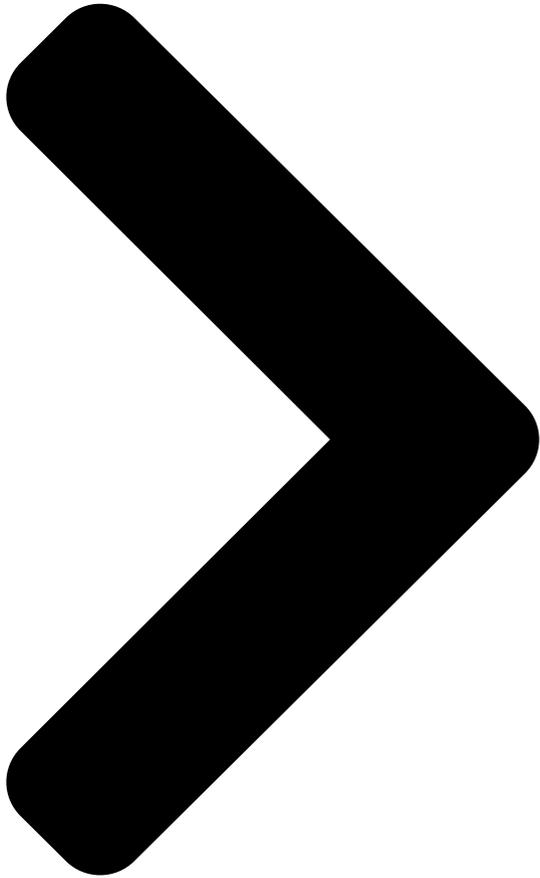
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No. 2B730-973EN*1

TOSHIBA
OPERATION MANUAL

FOR
DIAGNOSTIC ULTRASOUND SYSTEM
MODEL SSA-530A
[FUNDAMENTALS]
(2B730-973EN*D)

IMPORTANT!

Read and understand this manual before operating
the equipment. After reading, keep this manual in an

famio XG

easily accessible
TOSHIBA

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Diagnostic ultrasound system (272 pages)

[Medical Equipment Toshiba Aplio 500 TUS-A500 Operation Manual](#)

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[Medical Equipment Toshiba Alexion TSX-033A Service Manual](#)

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Summary of Contents for Toshiba famio XG SSA-530A

[Page 1](#) No. 2B730-973EN*D OPERATION MANUAL DIAGNOSTIC ULTRASOUND SYSTEM MODEL SSA-530A [FUNDAMENTALS] (2B730-973EN*D) IMPORTANT! Read and understand this manual before operating the equipment. After reading, keep this manual in an easily accessible place. © TOSHIBA MEDICAL SYSTEMS CORPORATION 2008-2010 ALL RIGHTS RESERVED...

[Page 2: Introduction](#)

SSA-530A. To ensure safe and correct operation of the system, carefully read and understand the manual before operating the system. Trademarks Famio XG is a trademark of Toshiba Medical Systems Corporation. This manual may include trademarks or registered trademarks of other companies. IMPORTANT! 1.

[Page 3](#) REVISION RECORD REASON PAGE REV. DATE SER. DOC. (MM/YY) PRODUCT. /AUTHOR CHANGED INI. 10/'08 Mr. Wakabayashi ----- TM-WI2 10/'08 Support of IEC60601-2-37 Amd. 2 S-8, 20-1 to Mr. Wakabayashi 20-6, 24-1 02/'09 Support of IEC60601-1-2 Amd. 1 24-1, 26-1 Mr. Wakabayashi 02/'10 Update of precautions Mr.

[Page 4: Intellectual Property](#)

Intellectual Property Availability of This Software and Related Documents is Restricted. The software used for this system is licensed to Toshiba Medical Systems Corporation by a Licensor. (1) The software and related documents must be used only for this system.

[Page 5: Organization Of The Operation Manuals](#)

Operation Manuals A TOSHIBA service person or instructor will explain the basic operating procedures for this system at the time of delivery. However, read this operation manual carefully before using the system in order to understand the detailed operating procedures, functions, performance, and maintenance procedures.

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[Page 12: Safety Precautions](#)

Safety Precautions Meaning of Signal Words DANGER WARNING CAUTION In this operation manual, the signal words , and used regarding safety and other important instructions. The signal words and their meanings are defined as follows. Please understand their meanings clearly before reading this manual. Signal word Meaning Indicates an imminently hazardous situation which, if not avoided,...

[Page 13](#) (To use another medical device in combination with this system, an equipotential wire for connecting to an equipotential bus must be supplied. For more information, contact your TOSHIBA representative. * Be sure to connect the potential-equalization lead wire before inserting the equipment power plug into the receptacle.

[Page 14](#) 8. Do not connect to the system transducers other than those specified by TOSHIBA, to prevent accidents such as burns, electrical shock, or fire. 9. Do not subject the transducers to knocks. Use of defective transducers may cause an electric shock.

[Page 15](#) 15. The use of transducers and cables other than those specified, with the exception of transducers and cables sold by Toshiba Medical Systems Corporation as replacement parts, may result in increased emissions or reduced system performance.

[Page 16](#) Peripheral units should be connected to the service outlet of the system. For the connection procedures, contact your TOSHIBA representative. In addition, be sure to use the cable supplied with the system to connect a Deskjet series printer. If a different cable is used, there is a risk of electric shock.

[Page 17](#) The droplets may cause small stains when they dry or may enter the LCD surface, possibly resulting in failure. 11. If there is any possibility of secondary infection, cover the entire system with a sterile cover. To obtain a sterile cover, contact your TOSHIBA representative. No. 2B730-973EN*D...

[Page 18](#) CAUTION: 12. Precautions regarding patient information entry (1) Before examining a new patient, press to delete the patient information and data recorded in the image memory for the previous patient. Otherwise, the new data may be confused with the data of the previous patient. PATIENT (2) If the patient information is modified by pressing , the...

[Page 19](#) CAUTION: (3) Do not use lens cleaner to clean the disk. Lens cleaner will damage the drive. 16. Acoustic power (1) The FDA allows ultrasound equipment to output acoustic power level TRACK3, which is higher than TRACK1, provided that MI/TI values are displayed on the system. This means that users have a higher degree of responsibility for safety than manufacturers.

[Page 20](#) CAUTION: 20. Main panel switch configuration (1) The switch configuration on the main panel of this system can be changed. The switch settings may therefore differ depending on the system. Confirm the switch configuration of your system before use. For details, refer to subsection 3.2 "Main Panel". (2) The descriptions in this operation manual are based on the

standard switch configuration.

[Page 21](#) 17. The air filter at the left of the system must be cleaned once every 6 months. If the air filter is clogged, the internal temperature will rise, shortening the service life of the system. For inspection and cleaning by service personnel, contact your TOSHIBA representative. No. 2B730-973EN*D S-10...

[Page 22](#) 20. If the main switch is tripped, be sure to consult your TOSHIBA representative. If the main switch is turned ON again without checking the problem, the system or the device may be damaged more seriously.

[Page 23](#) Warning Labels Various warning labels are attached to this system in order to call the user's attention to potential hazards. * The symbol on the warning labels attached to the system indicates safety precautions. The warning labels use the same signal words as used in the descriptions in the operation manuals.

[Page 24](#) <<System to which pictogram labels are attached>> • CRT system <4> <2> <1> <3> Label Meaning <1> Caution that the MI/TI must be controlled as low as reasonably achievable. <2> (a) Cautions against sitting on the system. (b) Precautions regarding the registration of panel switches <3>...

[Page 25](#) • LCD system <4> <2> <1> <3> Label Meaning <1> Caution that the MI/TI must be controlled as low as reasonably achievable. <2> (a) Cautions against sitting on the system. (b) Precautions regarding the registration of panel switches <3> (a) Urges caution related to handling of the transducers.

[Page 26](#) <<System to which labels containing pictogram and characters are attached>> • CRT system <4> <2> <1> <3> Label Meaning <1> Caution that the MI/TI must be controlled as low as reasonably achievable. <2> (a) Cautions against sitting on the system. (b) Precautions regarding the registration of panel switches <3>...

[Page 27](#) • LCD system <4> <2> <1> <3> Label Meaning <1> Caution that the MI/TI must be controlled as low as reasonably achievable. <2> (a) Cautions against sitting on the system. (b) Precautions regarding the registration of panel switches <3> (a) Cautions that the system must not be used around flammable gasses.

[Page 28: Important Information](#)

Important data must be backed up on external recording media such as clinical records, notebooks, or CD-R. TOSHIBA shall not be liable for loss of data stored in the memory of this system caused by operator error or accidents. This manual contains warnings regarding foreseeable potential dangers. Be alert at all times to dangers other than those indicated.

[Page 29](#) When disposing of this system, contact your TOSHIBA representative. Do not dispose of this system without consulting TOSHIBA representative first. TOSHIBA does not assume any responsibility for damage resulting from disposal of this system without consulting TOSHIBA. NOTE: Concerning the WEEE label...

[Page 30: Intended Use, Operating Principles, And Specifications](#)

1. Intended Use, Operating Principles, and Specifications Intended Use (1) This system visualizes structures, characteristics, and dynamic processes within the human body and displays image information for diagnosis. It provides ultrasound images in B mode and M mode. (2) This system is a general-purpose diagnostic ultrasound imaging system. This system conforms to Real Time Display of Thermal and Mechanical Output Indices on Diagnostic Ultrasound Equipment.

[Page 31: Specifications](#)

Specifications (1) Power (a) Line voltage 100 VAC ±10% 120 VAC ±10% 100 VAC to 127 VAC ±10% 220 VAC to 240 VAC ±10% (b) Line frequency 47 Hz to 63 Hz (c) Power consumption Maximum 600 VA (including external devices) (100 V, 120 V, and 100 V to 127 V system) Maximum 580 VA (including external devices) (220 V to 240 V system)

[Page 32: Patient Environment](#)

Patient Environment This system is designed to be used in the environment specified in the figure below. 1.5 m 1.5 m 1.5 m No. 2B730-973EN*D...

[Page 33: System Configuration](#)

The following list is accurate and complete at the time of printing. Due to constant developments, certain products may change or be no longer available at a later stage. For an up-to-date overview of available options, please consult your TOSHIBA representative.

[Page 34: List Of Peripheral Devices](#)

TP-8010 (MITSUBISHI) Printer Deskjet 5650/5652 (HP) * It may not be possible to use some of the peripheral devices listed above depending on the power conditions of the country. For details, contact your Toshiba representative. List of Available Transducers Transducer name...

[Page 35: System Overview](#)

3. System Overview Name of Each Part • CRT system Monitor Transducer cable hanger Transducer holder Main panel CD-R drive Transducer connector Side panel Caster Handle Subswitch Rear panel Power panel * Before disconnecting the power cable of the system from the commercial power supply, turn OFF the sub switch, wait until the screen display disappears, and then turn OFF the main switch on the power panel.

[Page 36](#) • LCD system Monitor Transducer cable hanger Transducer holder Main panel CD-R drive Transducer connector Side panel Caster Handle Subswitch Rear panel Power panel * Before disconnecting the power cable of the system from the commercial power supply, turn OFF the sub switch, wait until the screen display disappears, and then turn OFF the main switch on the power panel.

[Page 37: Main Panel](#)

Main Panel <1> <2> <3> <4> <5> <6> PRESET TRANSDUCER STANDBY <7> PATIENT A / B ACOUSTIC POWER <8> Shift Ctrl <13> <14> <12> <17> <18> <19> <11> <10> F-POSI <15> <16> <9> <26> <22> <23> <24> <20> <27> <25> <21>...

[Page 38](#) Name Function <11> Multifunctional dial Used for editing measurements. Also used to adjust the angle of the needle mark, input auto annotation, and rotate the transducer mark on the body mark. <12> IP Adjusts the image quality according to the registered image conditions.

[Page 39](#) * To check the functions registered to the user function switches, select [Panel View] from the [Other] menu. 2. CINE, SET, and NEXT switches can be reassigned as SET, NEXT, and CINE respectively. For details, contact your TOSHIBA representative. No. 2B730-973EN*D...

[Page 40: Side Panel](#)

Side Panel NOTE: The ECG input is optional. GAIN ECG gain ECG position POSI. PATIENT Input terminal for ECG lead FOOT SW For connection of the footswitches No. 2B730-973EN*D...

[Page 41: Rear Panel](#)

Rear Panel CAUTION: 1. Only equipment that conforms to the safety standards must be connected to the ETHERNET terminal on the rear panel. Otherwise, smoke or an electric shock may result. 2. Turn OFF the system power before connecting or disconnecting the cable from the ETHERNET terminal.

[Page 42: Power Panel](#)

Power Panel NOTE: The voltage and current indications of the AC line differ depending on the area. <1> <2> <3> <4> FUSE 250V T4.0A 100V TOTAL MAX. 264VA 100V 50/60Hz (ISOLATED/SWITCHED) 600VA <5> <6> Name Functions <1> FUSE Fuse <2> Main switch This is a circuit breaker.

[Page 43: Symbols](#)

Symbols This system uses the following symbols. For safety symbols, refer to page S-1. Symbol Description Functional grounding Equipotentiality Main switch OFF (The AC power is turned OFF.) Main switch ON (The AC power is turned ON.) Subswitch OFF (The power to electronic

circuits is turned OFF: Standby status) Subswitch ON (The power to electronic circuits is turned ON.) Transducer connector A...

[Page 44: Preparation For Examination](#)

4. Preparation for Examination Moving the System CAUTION: 1. Be sure to install the system on a level floor and lock the casters. If this is not done, the system may move, injuring the patient. 2. Do not push the system from the side. If the system is pushed from the side, it may fall down and cause injury.

[Page 45: Connecting The Transducer](#)

Connecting the Transducer CAUTION: Turn OFF the system subswitch or stop transmission by FREEZE switch before connecting or disconnecting a transducer. If a transducer is connected or disconnected with an image displayed, the system and/or the transducer may malfunction. (1) Connect the transducer and turn the lock handle clockwise to lock the connector.

[Page 46: Connecting The Power Cable And Protective Earth](#)

To use another medical device in combination with this system, an equipotential wire for connecting to an equipotential bus must be supplied. For more information, contact your TOSHIBA representative. * Be sure to connect the potential-equalization lead wire before inserting the equipment power plug into the receptacle.

[Page 47: Power On/Off](#)

6. Power ON/OFF Power ON CAUTION: Make sure that no recording media is present in the corresponding drives before the system power is turned ON. Otherwise, the media may be damaged or a malfunction may result. (1) Check the items below before turning the power ON.
• ...

[Page 48: Preparation For Use During An Operation Or For Emergency Cases](#)

Preparation for Use During an Operation or for Emergency Cases WARNING: Prepare a backup system when an urgent examination is to be performed, for example during an operation or for an emergency case. If a severe problem should occur with the system, the normal operation of the system may not be recovered by resetting the system and the examination may not be able to continue.

[Page 49: Checks Before And After Use](#)

7. Checks Before and After Use In the interests of safety, it is the user's responsibility to carry out the following checks before and after using the system. Checks Before Turning ON the Power Before turning ON the power, perform the following checks. Check item Check column The temperature, humidity, and atmospheric pressure should meet the...

[Page 50: Check After Turning On The Power](#)

Checks After Turning ON the Power After turning ON the power, perform the following checks. Check item Check column There should be no abnormal sound, unusual smells, or overheating. No error message is displayed. There should be no obviously abnormal noise, discontinuous display, or dark areas for B-mode images.

[Page 51: Basic Screen And Menu](#)

"Display and Operation in Each Mode" for the display specific to each mode. Patient ID Scanning direction Heart rate Preset name Date Time 123456789012 Abdominal 2004/03/16 TOSHIBA Hospital name ABCDEF 9.9C9.9 100% PM 07:05:43 Transducer frequency Acoustic power Focus mark...

[Page 52: Display And Operation Of The Menu](#)

Display and Operation of the Menu The functions not available on the panel are displayed in the menu. The menu should be displayed when required. (1) Press . The menu appropriate for the current display mode is displayed. MENU Functions that cannot be selected or switched in the menu are displayed in gray. (a) Movement of the menu display position The menu can be moved to the left or right by operating the trackball to the left or right.

[Page 53](#) (3) Press on the main panel. • For an item with only ON and OFF options The item

toggles between ON and OFF each time is pressed. • For an item with several options When is pressed or the trackball is slightly moved laterally, a pull-down menu appears next to the menu.

[Page 54: Entering The Patient Id](#)

9. Entering the Patient ID CAUTION: Observe the following precautions to avoid erroneous diagnosis. 1. Before examining a new patient, press to delete the patient information and data recorded in the image memory for the previous patient. Otherwise, the new data may be confused with the data of the previous patient.

[Page 55: Entering And Saving Data On The Patient Id Registration Screen](#)

Entering and Saving Data on the Patient ID Registration Screen (1) Press to initialize the system. PATIENT (2) Press . The patient ID registration screen appears. Patient Data Input 2004/03/16 ID Number AM06:54:47 Name Date of Birth (YYYY/MM/DD) Male Female Unknown Height Weight...

[Page 56](#) NOTE: (1) Units of height and weight The units of height and weight differ depending on the setting of "Entry System" in the preset menu. (a) Metric "cm" and "kg" (b) English .."feet", "inch", "lb", or "cm", "kg" (2) Formula for body surface area The formula differs depending on the setting of "Calculation"...

[Page 57: Sorting And Calling A Patient Id](#)

Sorting and Calling a Patient ID (1) Press [ID List] on the patient ID registration screen. The list of patient IDs saved in the system is displayed in ascending order of ID number. ID List Name Select Delete Delete All Used: Sort key Free:...

[Page 58: Selecting Presets](#)

10. Selecting Presets 10.1 Introduction In this system, 12 types of initial settings can be saved for examinations. These initial settings are called presets. The examination presets can be selected by pressing the PRESET switch on the main panel. 10.2 Procedure for Selecting Presets When is pressed, the corresponding preset is selected.

[Page 59: Display And Operation In Each Mode](#)

11. Display and Operation in Each Mode 11.1 B Mode (1) Entering B single mode Press (2) Entering B dual display mode Press No. 2B730-973EN*D 11-1...

[Page 60](#) (3) Adjustment on the panel PRESET TRANSDUCER STANDBY PATIENT A / B ACOUSTIC POWER <3> Shift Ctrl <4> <2>, <6> <5> F-POSI <7> <1> <8> GAIN Adjustment items Procedures <1> Sensitivity of the entire image Use the GAIN dial of the palm controller. Gain GAIN <2>...

[Page 61](#) Adjustment items Procedures <6> Magnification, reduction, and Use the DEPTH/ZOOM dial and the trackball. movement of the image (1) When the DEPTH LED is lit, hold down the dial (PAN/ZOOM) to light the ZOOM LED. (2) When the dial is turned, the image is magnified/reduced.

[Page 62](#) (4) Adjustment using the menu When is pressed, the B menu is displayed. MENU Automatically sets the focus of the ultrasound beam. Increases image sharpness. Adjust the dynamic range. Adjusts the image smoothness. Focal Ptn Adjusts the image smoothness in the axial direction. Density Adjusts the image smoothness in the lateral direction.

[Page 63: M Mode](#)

11.2 M Mode (1) Entering M mode Press (2) Entering M + B mode Press (3) Setting the M mark (a) Enter M + B mode. The M mark is displayed on the B-mode image. (b) Move the M mark display position using the trackball. (4) Adjustment on the panel Refer to page 11-2.

[Page 64](#) (5) Adjustment using the menu When is pressed, the M menu is displayed. MENU Adjusts the sweep speed of the M-mode image. Adjusts the dynamic range. Adjusts the sensitivity of the M-mode image. M Speed M DR Enhances the edge of the image. M Gain Cmp M E.Enhance Adjusts the image smoothness in the axial direction.

[Page 65: Cine Function](#)

12. Cine Function 12.1 Introduction CAUTION: When performing examination of a new patient, press delete the recorded data in the image memory. Otherwise, the new data may be confused with the data of the previous patient. When an image is frozen, the images immediately before the frozen image can be played back and edited.

[Page 66: Display Of Reference Signals](#)

13. Display of Reference Signals Electrocardiographic (ECG) reference signals can be displayed during B-mode display, B Dual mode display, M-mode display, and M+B mode display. This function is optional. WARNING: 1. To prevent electric shock, check the following items before operation. •...

[Page 67: Display Procedures](#)

13.1 Display Procedures (1) Turn OFF the power of the system and connect the pick-up cable etc. to the side panel. (2) Turn ON the power of the system. (3) Attach the ECG electrodes to the patient. (4) Set the mode to M mode in which reference signals can be displayed. * If the signals need to be displayed in B-mode and B dual mode, it is necessary to preset the display setting to ON.

[Page 68: Body Mark Entry And Deletion](#)

14. Body Mark Entry and Deletion A body mark, which indicates the anatomical region for the current examination, can be displayed on the screen. 14.1 Display of a Body Mark (1) Press the body mark switch on the main panel. The preset body mark for the current examination region is displayed.

[Page 69: Movement Of The Transducer Mark](#)

14.3 Movement of the Transducer Mark (1) Operate the trackball to move the transducer mark. Transducer mark (2) The transducer mark rotates as the multifunctional dial is turned. 14.4 Movement of the Body Mark (1) Select [Mark Move] in the menu. (2) Press (3) The body mark moves as the trackball is operated.

[Page 70: Entry And Deletion Of Comments](#)

* The comment entry switch function must have been registered on the main panel. Contact your TOSHIBA representative for the registration procedure. 15.1 Entry from the Keyboard (1) Press the comment entry switch on the main panel. A cursor is displayed on the screen.

[Page 71: Entry Of The Arrow Mark](#)

15.3 Entry of the Arrow Mark (1) In comment entry mode, operate the trackball to move the cursor to the position where characters are to be displayed. (2) Enter the arrow mark. There are two input methods. • When the menu is used (a) Press .

[Page 72: Moving The Selected Comment](#)

15.5 Moving the Selected Comment In comment entry mode, place the cursor at the entered comment and press . The comment is enclosed by a box. Move the comment to the desired position using the trackball. Press to determine the new position. 15.6 Correcting the Comments Operate the trackball to move the cursor to the string to be corrected.

[Page 73: Deletion Of All Comments](#)

15.8 Deletion of All Comments Delete all comments. There are two deletion methods. Comment deletion is possible in comment entry mode. (1) When the menu is used (a) Press . The menu for comment entry appears. MENU (b) Select [Comment All Clear] in the menu. (c) Press .

[Page 74: Needle Mark Display](#)

16. Needle Mark Display This system can display the needle mark for the specified biopsy adapter on the screen. Biopsy procedures must be performed with extreme care to prevent the induction of tissue necrosis, neurological disorders, infectious diseases, and other such problems. The clinical technique should be determined after consultation with the specialists concerned.

[Page 75](#) WARNING: 4. During a biopsy procedure, the needle may deviate from the desired course due to the tissue characteristics or the type of needle. In particular, needles with small

diameters may deviate to a greater degree. Always monitor the target region and the needle end while performing a biopsy procedure.

[Page 76: Display Method](#)

16.1 Display Method The needle mark can be displayed on B mode images only. (1) Press . The B mode menu is displayed. MENU (2) Select [Needle] from the menu and press A confirmation dialog is displayed. (3) Select [OK] to display the Needle menu. Needle Guide G Angle G Display...

[Page 77: Adjustment Of The Needle Mark Angle](#)

16.2 Adjustment of the Needle Mark Angle The angle of the needle mark can be adjusted within the specified range depending on the transducer and biopsy adaptor used. * The needle mark cannot be changed (angle fixed) for some biopsy adapters. (1) Select [G Angle] in the menu and press ([G Angle] is automatically set to ON when [G Display] is set to ON.

[Page 78: Measurement](#)

2. The measured data is lost when the system is turned OFF or is pressed. * The measurement switch function must have been registered on the main panel. Contact your TOSHIBA representative for the registration procedure. (1) After freezing the image, press the measurement switch. The registered measurement function starts.

[Page 79: B-Mode Measurements](#)

17.2 B-mode Measurements The measurements listed below can be performed in B mode. Measurement item Description Distance The distance between two points is measured. Trace length The length of the traced portion of the curve is measured. Angle The angle between two lines is measured in addition to the distance between two points.

[Page 80: M-Mode Measurements](#)

17.3 M-mode Measurements The measurements listed below can be performed in M mode. Measurement item Description Distance The distance (amplitude) between two points in the M mode is measured. Time The elapsed time between two points is measured. Slope The slope between two points is measured. Heart rate The number of heartbeats for one minute is calculated based on the heart rate displayed on the screen.

[Page 81: Output/Saving Of Image Data](#)

18. Output/Saving of Image Data 18.1 Data Archive to a CD-R (1) Place a blank CD-R in the CD-R drive. (2) Press . The menu appropriate for the current display mode is displayed. MENU (3) Move the cursor to the top of the menu and then move the trackball slightly to the left or right, depending on the position in which the menu is displayed.

[Page 82: Data Archive To The Dicom Server](#)

DICOM server. * It is possible to set the system to transfer the data automatically to the DICOM server at the same time the data is saved on the HDD. Consult your Toshiba service representative.

[Page 83: Loading The Archived Data](#)

18.3 Loading the Archived Data * It is not possible to load the data that was archived to the DICOM server. NOTE: When data in CIN or FRM format is loaded, the currently displayed patient information is cleared. (1) Select [Open File] from the [Other] menu. The screen below is displayed. Load File Drive: File Type...

[Page 84: Deleting Archived Data \(Image Data In The Hdd\)](#)

18.4 Deleting Archived Data (image data in the HDD) (1) Select the [Other] menu. (2) Press [File Utility]. The Disk Manager dialog is displayed. File/Disk Manager Drive : Folders File List Name Modify Time 123.DTA 2004-08-24 18:16 456.DTA 2004-09-10 13:27 Mk Dir Del Dir Copy Dir...

[Page 85: Other Function](#)

19. Other Function 19.1 Beep Tone Adjustment The tone of the beep (generated when a switch of the main panel is pressed) can be adjusted. (1) Select [Buzzer] from the [Other] menu. (2) Select the desired volume from the pull-down menu. 19.2 Adjustment of the Panel Backlight The

brightness of the backlight of the main panel can be adjusted.

[Page 86: Using Mi/Ti](#)

20. Using MI/TI 20.1 Basic Knowledge of MI/TI (1) Concerns with bioeffects Diagnostic ultrasound is recognized as being safe. In fact, there have been no reports of injuries to patients caused by diagnostic ultrasound. It cannot be stated categorically that ultrasound is 100% safe. Studies have revealed that ultrasound with extremely high intensity is harmful to body tissues.

[Page 87](#) The idea of MI/TI has been introduced recently to increase the diagnostic capability, promoting relaxation of these acoustic power limits (TRACK3). Maximum limit for MI/TI display (TRACK3) Application I spta. 3 I sppa. 3 (mW/cm (W/cm All regions <190 <1.9 (except eyes) With this trend, control of the level of acoustic power has been transferred from manufacturers to users.

[Page 88: Mi/Ti Display Description](#)

20.2 MI/TI Display Description (1) Definition of MI Mechanical Index (MI) is the peak-rarefactional acoustic pressure P (calculated r, α considering the tissue attenuation; $\alpha = 0.3$ dB/cm-MHz) divided by the square root of the acoustic working frequency f (unit: MHz) and can be expressed as follows: r, α ...

[Page 89: Operating Procedures For Mi/Ti](#)

20.4 Operating Procedures for MI/TI The control of ultrasound output and the most useful switches for this purpose are described below. (1) ACOUSTIC POWER knob The output intensity is one of the available ultrasound output control parameters. It can be adjusted with the ACOUSTIC High POWER knob at the left end of the main panel.

[Page 90: Output Display](#)

, I spta and either 1.9 MI or 190 W/cm sppa For additional information on bioeffects beyond that contained in this labeling, contact your Toshiba representative. As further information becomes available on the potential for bioeffects, these displays may change. No. 2B730-973EN*D 20-5...

[Page 91: Parameters Affecting Mi/Ti Display](#)

20.6 Parameters Affecting MI/TI Display Transmission conditions • Transmission aperture • Focus condition • Drive frequency • Pulse duration • Voltage applied to the transducer (acoustic power control) Scan conditions • Scan width • Number of scanning lines • Method for and selection of beam steering Parameters used for the calculation of MI/TI in the equipment •...

[Page 92: Reminder](#)

For inquiries and information, contact your Toshiba representative. Additionally, as further information becomes available, we will do our utmost to keep you informed. 20.8 Ultrasonic Output Power and Acoustic Output...

[Page 93: References For Mi/Ti](#)

(3) Differences between displayed and "actual" Thermal and Mechanical effects In operation, the system will display to the operator the Acoustic Output Parameters Thermal Index, TI, or Mechanical Index, MI (or sometimes both parameters simultaneously). These parameters were developed as general indicators of risk from either thermal or mechanical action of the ultrasound wave.

[Page 94: Maintenance Check](#)

The customer is responsible for maintaining and operating the products after purchase. TOSHIBA representatives provide after-sales service for products out of warranty on a pay-for-service basis. 21.1 Maintenance Checks to Be Carried Out by Customers 21.1.1 Cleaning the system...

[Page 95](#) (a) Wipe off any stains using a soft cloth moistened with mild detergent and then tightly wrung out. When the mild detergent is required for cleaning, please contact your TOSHIBA representative. (b) Wipe the ECG cable with dry cloth and dry it well.

[Page 96](#) (6) Cleaning the LCD monitor Use a clean, soft cloth to clean the LCD surface. (a) Monitor cover • Clean the monitor cover using a soft cloth moistened with mild detergent. (b)

LCD surface • Use a soft cotton cloth or lens cleaning paper to clean the LCD surface. •...

[Page 97](#) (8) Cleaning the air filters (a) Press down the tabs of the air filter to remove the air filter cover. Air filter cover Tabs (b) Press the tabs to separate the dust-proof net from the air filter cover. Tabs Dust-proof net (c) Vacuum dust from the air filter cover and dust-proof net at least once a month.

[Page 98: Maintenance Checks To Be Carried Out By Service Personnel](#)

21.2 Maintenance Checks to Be Carried Out by Service Personnel The following checks are required to ensure the performance and safety of the system. Contact your TOSHIBA representative when carrying out these checks, because they require special techniques. Check category...

[Page 99: Checks Before The System Is Judged Defective](#)

If the system cannot be turned ON, or problems are not resolved, or the system seems abnormal after checking the above items, contact your TOSHIBA representative. CAUTION: If the main switch is tripped, be sure to consult your TOSHIBA representative. If the main switch is turned ON again without checking the problem, the system or the device may be damaged more seriously.

[Page 100: Accuracy Of Measurement](#)

23. Accuracy of Measurement Accuracy of Each Clinical Measurement Parameter Parameter Ranges Accuracy - Image Depth Scale 20 to 240 mm < +/- 5% of full scale - ECG/Image Time Scales 1, 2, 4, 8 s 1 s: 3 ms (max.) 2 s: 6 ms (max.) 4 s: 12 ms (max.) 8 s: 24 ms (max.)

[Page 101: Conformance Standards](#)

24. Conformance Standards (1) General IEC60601-1 (1988), Amd. 1 (1991), Amd. 2 (1995) (IEC60601-1-1 (2000), IEC60601-1-2 (2001)/UL2601-1, 1ST Edition/CAN/CSA C22.2 No. 601.1-M90) (2) Particular IEC60601-2-37 (2001), Amd. 1 (2004), Amd. 2 (2005) (3) Acoustic power Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers (1997) (FDA guidance) (4) Electromagnetic...

[Page 102: Safety Classification](#)

25. Safety Classification This system is classified with respect to safety characteristics. (1) According to the type of protection against electric shock: • CLASS I EQUIPMENT (2) According to the degree of protection against electric shock: • EQUIPMENT WITH TYPE-BF APPLIED PARTS (3) According to the degree of protection against harmful ingress of water: •...

[Page 103: Guidance And Manufacturer's](#)

26. Guidance and Manufacturer's Declaration This product complies with the EMC standard IEC60601-1-2 (2001), Amd. 1 (2004) Guidance and manufacturer's declaration - electromagnetic emissions The SSA-530A is intended for use in the electromagnetic environment specified below. The customer or the user of the SSA-530A should assure that it is used in such an environment. Emissions test Compliance Electromagnetic environment - guidance RF emissions...

[Page 104](#) Guidance and manufacturer's declaration - electromagnetic immunity The SSA-530A is intended for use in the electromagnetic environment specified below. The customer or the user of the SSA-530A should assure that it is used in such an environment. Electromagnetic Immunity test IEC 60601 test level Compliance level environment - guidance...

[Page 105](#) Guidance and manufacturer's declaration - electromagnetic immunity The SSA-530A is intended for use in the electromagnetic environment specified below. The customer or the user of the SSA-530A should assure that it is used in such an environment. Electromagnetic Immunity test IEC 60601 test level Compliance level environment - guidance...

[Page 106](#) Recommended separation distances between portable and mobile RF communications equipment and the SSA-530A The SSA-530A is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the SSA-530A can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the SSA-530A as recommended below, according to the maximum output power of the

communications equipment.

[Page 107: Indication Of Year Of Manufacture](#)

27. Indication of Year of Manufacture The year of manufacture is shown on the label attached on the rear of the system. No. 2B730-973EN*D 27-1...

[Page 108](#) No. 2B730-973EN*D...

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