ESAOTE S.p.A.

Rev. A

May 2006

MyLab25 and MyLab30CV

INTRODUCTION

8300416000

User's kit

The box contains the licenses, the USB pen drive and the "Operator Manuals" disk.

Licenses
The licenses enable specific functions of the system, e.g. the Clip. Licenses are linked to the system's serial number and are, therefore, unique. They should be carefully stored. The system is delivered by ESAOTE, with the licenses installed.

MyLab Pen Drive
The appliance is supplied with a customised USB pen drive. The pen drive can be used as a digital support for data. For further information on how to use it, please read the Getting Started manual.

"Operator Manuals" Disk
The disk contains, in digital format, all the manuals supplied with the system. The manuals are available in the languages that can be set on the system.

Operator Manuals

These manuals refer to the **MyLab25** and **MyLab30CV** products, indicated by the name **MyLab** inside the manuals. The Operator Manuals consist of three Sections:

Getting Started
The manual describes how to install the system and provides the main instructions for using it.

This symbol is used to indicate this section of the manual. Whenever it is shown, it indicates that further information on the specific subject are available in this section.

Transducers and Consumables
The manual describes the cleaning, disinfecting and maintenance procedures for the probes and their accessories. Information is also supplied on the consumables that can be used.

This symbol is used to indicate this section of the manual. Whenever it is shown, it indicates that further information on the specific subject are available in this section.

Safety and Standards
The manual contains information about the patient's and operator's safety. The system's conformity standards are also indicated.

This symbol is used to indicate this section of the manual. Whenever it is shown, it indicates that further information on the specific subject are available in this section.

This symbol is used to indicate the "Advanced Operations" Manual, available in the "Operator Manuals" CD.

Glossary

MyLab ultrasound systems are available in two configurations: portable and mobile.

Portable configuration means that the system is equipped with a handle, whose size and weight allow it to be used to carry the system. The term "portable" is always used with this meaning in these manuals.

A **mobile configuration** is equipped with wheels allowing to carry the system from one room to another. The term "mobile" is always used with this meaning in these manuals.

For detailed information on your model and its configurations, please refer to the "Getting Started" manual, which is specific for each product.

MANUFACTURER'S RESPONSIBILITY

ESAOTE is responsible for the safety, reliability and functioning of this product only if:

- the user follows all the instructions contained in this Manual for the use and the maintenance of this system;
- this Manual is kept integral and readable in all its parts;
- calibrations, modifications and repairing are performed only by ESAOTE qualified personnel;
- the environment where the system is used complies with the current safety rules;
- the electrical plant of the environment where the system is used complies with the current applicable rules and is perfectly efficient.

DICHIARAZIONE CE DI CONFORMITA' - Direttiva 93/42/CEE - allegato II
CE DECLARATION OF CONFORMITY - *93/42/EEC Directive - annex II*
DECLARATION DE CONFORMITÉ - 93/42/CEE - annexe II
KONFORMITÄTSERKLÄRUNG - *93/42/EWG - Anhang II*
DECLARACIÓN DE CONFORMIDAD CE - Directiva ***93/42/EEC***

Noi costruttori:
We manufacturer:
Nous les Constructeurs:
Wir, die Hersteller:
Nosotros, los fabricantes

ESAOTE S.p.A. - Via di Caciolle, 15 - 50127 Firenze - Italy

dichiariamo, sotto la nostra responsabilità, che il sistema:
declare under our sole responsability that the system:
déclarons sous notre responsabilité que le système:
erklären, daß das System, unter unserer Verantwortung:
declaramos, bajo nuestra responsabilidad, que el producto:

MyLab25
MyLab30CV

è stato costruito applicando il sistema di garanzia della qualità approvato per la progettazione, fabbricazione e controllo finale del prodotto e risponde alle disposizioni presenti dell'Allegato II della direttiva 93/42/CEE sui dispositivi medici.

has been manufactured by applying the quality system approved for the design, manufacture and final inspection and meets the provisions of the 93/42/EEC-Annex II medical devices directive.

a été construit en appliquant le système de qualité approuvé pour le projet, production et contrôle final du produit et répond aux dispositions de la directive 93/42/CEE-Annexe II pour les appareils médicaux.

mit der Anwendung des geprüften Qualitätssystems für das Projekt, die Fertigung und die Schlußkontrolle des Produkts gefertigt wurde und daß es die Anordnungen der Richtlinie 93/42/EWG-Anhang II für medizinische Geräte erfüllt.

ha sido fabricado aplicando el sistema de garantía de la calidad aprobado para el diseño, fabricación y control final del producto y responde a los requisitos presentes en el Anexo II de la directiva 93/42/EEC sobre los dispositivos médicos.

Il rappresentante legale ESAOTE.
ESAOTE legal representative.
Le représentant légal de ESAOTE.
ESAOTE autorisierter Bevollmächtiger.
El representante legal de ESAOTE.

USAGE LICENSE AGREEMENT FOR THE SOFTWARE INCLUDED IN THE APPARATUS

Attention

Please read with care the terms and conditions indicated below before using the software on the unit.

Use of the software implies acceptance of the terms and conditions listed below.

PROPRIETARY RIGHTS

You have acquired a device ("DEVICE") which includes Esaote S.p.A. proprietary software and/or software licensed by Esaote S.p.A. from one or more software licensors ("Software Suppliers"). Such software products ("SOFTWARE"), as well as associated media, printed materials, and "online" or electronic documentation are protected by international intellectual property laws and treaties. The SOFTWARE is licensed, not sold. The SOFTWARE and, similarly, any copyrights and all industrial and intellectual ownership rights are and shall remain the exclusive propriety of Esaote S.p.A. or its Software Suppliers.

The user will acquire no title or right on the SOFTWARE, except for the usage license granted herein.

LICENSE RIGHTS AND LIMITATIONS

With this license, Esaote S.p.A. grants the end user the right to use the SOFTWARE on the supplied DEVICE.

The user may not, under any circumstances, make unauthorized copies and/or reproductions of the SOFTWARE or parts of it, including the enclosed documentation.

On the basis of the above, and if the SOFTWARE is not protected against copying, only one copy of the SOFTWARE may be made for security purposes (back up copy).

The user may not rent or lease the SOFTWARE, but he may transfer, on a permanent basis, the rights granted herein, on condition that he transfers all copies of the SOFTWARE and all written material, and that the transferee accepts all the conditions of this agreement. Any transfer must include the most up-to-date version and all the previous ones.

The user may not convert, decode, reverse-engineer, disassemble or change in any way the SOFTWARE.

The user may not remove, obscure or alter the copyright notice, trademarks or other proprietary rights notices affixed to or contained within the SOFTWARE.

The user may not publish data or information comparing the performances of said SOFTWARE with that of software written by others.

PRODUCT TRACEABILITY

To guarantee the product traceability according to what stated by the quality standard ISO13485 and by the European Directive on Medical Devices 93/42/EEC, ESAOTE kindly requests the original owner of the equipment to give communication to our central plants, or to one of our subsidiaries, or to one of our official distributors of any eventual conveyance of the product property. Please use a duly filled copy of the form reported below or send us a communication reporting the same data indicated in this form. All data relating to the system can be found on its identification label.

Product Traceability Form

To: ESAOTE S.p.A.
Quality Assurance Department
Via di Caciolle, 15
I-50127 Firenze

ESAOTE system/device name: .....
REF: .....
SN: .....
Name and address of the original owner: .....
.....
Name and address of the new owner: .....
.....
Date:

Signature

VIGILANCE SYSTEM

This equipment is subject to ESAOTE vigilance system (post-marketing vigilance) in case of potential or real hazards for the patient or for the operator which might occur during the normal system functioning, in order to be able to remove them with the best efficiency and timing.
Therefore if the user records any malfunction or deterioration in the characteristics and/or performances of the device, as well as any inadequacy in the labelling or the instructions for use which might lead to potential or real hazards for a patient or for an operator, we kindly request to immediately inform ESAOTE central plants, or one of our subsidiaries, or one of our official distributors immediately through the following form, or through a communication reporting the same data contained in this form. All data relating to the system can be found on its identification label. In this way we will be able to take all adequate measures with the best efficiency and timing.

Post-Marketing Vigilance Form

To: ESAOTE S.p.A.
Quality Assurance Department
Via di Caciolle, 15
I-50127 Firenze

ESAOTE system/device name: .....
REF: .....
SN: .....
Description of the potential/real hazard: .....
.....
Notes and suggestions: .....
.....
Contact Person/Department: .....
Address: .....
Phone: ..... Fax: .....
Date:

Signature

Important Information

This mark complies with the Medical Device Directive 93/42/EEC.

For US Customers: US Federal Law restricts this device to sale, distribution and use by or on the order of a physician.

ESAOTE S.p.A.

Rev. A

June 2006

MyLab25 and **MyLab30CV**

GETTING STARTED

OPERATOR MANUAL

8300415000

Introduction

This manual refers to the **MyLab25** and **MyLab30** ultrasound systems, named in the following chapters as **MyLab**. **MyLab** is available both in portable and in mobile configuration. The term "**MyLab**", used in this manual, refers to both configurations. When the information refers to only one configuration, it will be specifically indicated.

This manual explains how to install and use the **MyLab** ultrasound system. All system keys and their functions are described. Whether these keys are enabled or disabled depends on the installed software release.
This manual is organized in the following chapters:

- Chapter 1: Additional Information on Safety
  This chapter provides information about specific safety features of the **MyLab** system.
- Chapter 2: Clinical Applications
  This chapter specifies in which clinical applications the **MyLab** can be used.
- Chapter 3: System Components and Installation
  This chapter lists the available **MyLab** configurations. Moreover, it contains the installation instructions.
- Chapter 4: Control Panel
  This chapter describes the **MyLab** control panel.
- Chapter 5: Screen Lay-Out
  In this chapter one can learn how information is organized on the screen.
- Chapter 6: Exam Performance
  This chapter explains how to perform an exam with the **MyLab** system.
- Chapter 7: Measurements and Calculations
  This chapter explains how to perform measurements on ultrasound images.
- Chapter 8: Exams Archive
  This chapter describes how to use **MyLab** archive.
- Chapter 9: System Menu
  This chapter explains how to configure the **MyLab**.
- Chapter 10: System Maintenance
  This chapter lists all necessary maintenance procedures.
- Chapter 11: Technical Specifications
  This chapter lists all **MyLab** technical specifications.
- Appendix A: Acoustic Output Tables
  This chapter lists all **MyLab** acoustic output tables.

In this manual a **WARNING** pertains to possible injury to a patient and/or the operator. A **CAUTION** describes the precautions, which are necessary to protect the equipment. **Be sure that you understand and observe each of the cautions and warnings.**

In this manual control panel keys and software keys are indicated using the following graphical conventions:

Control panel keys	They are indicated by **BLUE CAPITAL LETTERS** or by the corresponding graphic symbol (e.g. ).
Software keys	They are indicated by **BLACK CAPITAL LETTERS**

The confirmation key is always indicated throughout the manual as **ENTER**, while the menu context key as **UNDO**.

Table of Contents

Chapter 1

1 - Additional Information on Safety

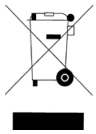
SS

This chapter provides additional information on safety specifically for **MyLab** products. Please read the "Safety and Standards" manual carefully for a complete overview of all safety aspects of **MyLab** products.

Environmental Safety

Special waste

These systems contain a lithium battery. The fluorescent lamp included in the LCD screen contains mercury. The battery and the LCD screen must be treated as special waste in conformity with applicable local regulations.



Dispose of the equipment as special waste in conformity with applicable local regulations.

Transport Safety

The system front wheels are equipped with brakes, which can be activated individually.

WARNING

Do not park the system on a slope.

Do not use the brakes to park the machine on a slope.

If your system is equipped with peripherals, make sure that they are safely attached via Velcro strips; for transportation in a vehicle, it is strongly recommended to remove the peripheral(s) and follow the device manufacturer guidelines.

MyLab in its portable configuration has a fold-away trolley. The trolley must be closed in order to transport the system.

CAUTION

Do not leave the trolley closed in the vertical position. Always leave the trolley in the open position to ensure maximum stability.

Electromagnetic Compatibility

This system was designed for use in the electromagnetic environments declared in the tables below, in compliance with standard IEC 60601-1-2:2001. The operator must make sure that s/he uses it in keeping with this standard.

Electromagnetic Emissions

Emission Test	Conformity	Electromagnetic Environment
RF emissions CISPR 11	Group 1	MyLab uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	MyLab is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions on the electric power supply mains IEC 61000-3-2	Class A	
Voltage fluctuations and flicker generation IEC 61000-3-3	Conforms	

Electromagnetic Immunity

The electromagnetic tests are aimed at simulating the typical transients of an electromagnetic environment. **MyLab** was tested for immunity to transients and at their typical levels in a domestic, hospital or commercial environment.

Immunity Test	Conformity Levels	Electromagnetic Environment and Measures to Be Taken
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV on contact ±8 kV in air	The floor should be in antistatic material (wood, ceramic,…). If covered with synthetic material, relative humidity should be maintained at least at 30%.

Immunity Test	Conformity Levels	Electromagnetic Environment and Measures to Be Taken
Transients/trains of rapid electric pulses IEC 61000-4-4	±2 kV on the power supply lines ±1 kV on the input/output lines	The quality of the electrical power supply and the mains frequency magnetic fields should be typical of domestic, commercial and hospital environments. If the MyLab user has to work without a break while power supply is interrupted, s/he is advised to have power supplied through a UPS (Uninterruptible Power Supply) unit.
Pulse IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	
Voltage gaps, brief interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5 % of rated voltage (U_T) (voltage gap >95 %) for half a cycle 40 % U_T (voltage gap 60 %) for 5 cycles 70 % U_T (voltage gap 30 %) for 25 cycles <5 % U_T (voltage gap >95 %) for 5 sec	
Magnetic fields at mains frequency (50/60 Hz) IEC 61000-4-8	3 A/m	
RF conducted fields IEC 61000-4-6	3 Vrms from 150 kHz to 80 MHz	Mobile or portable radio frequency (RF) communication appliances should be used at longer distances than those indicated on the following table. Interference may occur in the vicinity of equipment marked with the following symbol: 
RF radiated fields IEC 61000-4-3	3 V/m from 80 MHz to 2.5 GHz	

Recommended Distances between Radiofrequency (RF) Communication Systems and MyLab

SS

As stated in the Safety and Standards manual, it is recommended not to use radiofrequency (RF) transmission systems near the ultrasound system. RF systems can cause interference, which alters the echographic image and Doppler traces.

The operator can prevent interference caused by electromagnetic fields by maintaining a minimum distance between the echographic system and the RF communication systems being used (cell telephones, mobile telephones…). The

table shows the minimum distance in meters, according to the maximum power at the RF system output.

Maximum Power at Transmitter Output [W]	Distance According to Transmission Frequency [m]		
	From 150 kHz to 80 MHz $d = 1.2\sqrt{P}$	From 80 MHz to 800 MHz $d = 1.2\sqrt{P}$	From 800 MHz to 2,5 GHz $d = 2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance *d* in metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1 As a precaution, always apply the greater distance supplied by the table.

NOTE 2 Electromagnetic propagation is subjected to absorption and reflection in the presence of structures, objects and people. The values in the table are general guidelines.

The operator must remember that the intensity of the electromagnetic fields generated by fixed transmitters (radio-base stations for cellular or cordless telephony, TV and radio transmissions, amateur radio transmissions…) cannot be predicted on a theoretical basis. Consequently, a direct measure may be necessary in the use environment of a **MyLab** unit. If the intensity of the electromagnetic fields exceeds that specified in the immunity levels shown in the previous tables, and the echographic system performs incorrectly, additional measures may be necessary, i.e. positioning the system in a different way.

Probes Superficial Temperature

MyLab has been designed to keep the probes superficial temperature within the limits defined by the IEC 60601-2-37 standard. We recommend to freeze the system at the end of the exam by pressing the  key to avoid any probe overheating. The system will automatically be frozen if left inactive for a few minutes.

Chapter 2

2 - Clinical Applications

MyLab is designed for operators who are qualified in using ultrasound systems.

Models

In their complete configuration, **MyLab** systems offer several intended uses.

Carefully read Chapter 2 of the "Safety and Standards" manual.

Note

The operator must always follow the principle known as ALARA (As Low As Reasonably Achievable) and, in particular with this application, must use minimum acoustic power for the minimum time compatible with obtaining diagnostic information.

WARNING

Do not use MyLab for ophthalmic or transorbital applications.

MyLab25

The basic configuration of **MyLab25** includes an imaging system with the following license:

Application	Notes
General Imaging	Includes ABDOMEN (ABD), PEDIATRIC (PED), BREAST, THYROID, other SMALL PARTS (testicles,…) and MUSCULO-SKELETAL (MS); includes endovaginal and transrectal exams if an endocavity probe is available

MyLab30CV

The basic configuration of **MyLab30CV** includes an color system with the following license:

Application	Notes
Cardiac (adults and pediatric)	Includes transesophageal exams if a TEE022 is available

Clinical Applications

Please consult the corresponding chapter for specifications and licenses.

The tables below list **MyLab** probes and their clinical intended use.

	CAR	PED	PV	SP	THY	MS	BRE	NC	AC	UR	ABD	OB-GYN
PA Probes												
PA230	✓								✓		✓	
PA121	✓										✓	
PA122	✓	✓	✓					✓				
PA023	✓	✓	✓					✓				
LA Probes												
LA532		✓	✓	✓	✓							
LA522		✓	✓	✓	✓							
LA523		✓	✓	✓	✓	✓	✓					
LA424		✓	✓	✓	✓	✓	✓					
CA Probes												
CA621		✓	✓							✓	✓	✓
CA421		✓	✓							✓	✓	✓
CA430			✓							✓	✓	✓
CA123	✓	✓	✓	✓	✓	✓	✓	✓				
Special Probes												
TE022	✓											
EC123										✓		✓
IO323		✓	✓	✓	✓	✓	✓				✓	
LP323*											✓	
Doppler Probes												
2 CW	✓											
5 CW			✓									

CAR: Cardiac (adults and pediatric); **PED**: Pediatric **PV**: Peripheral vascular; **SP**: Small Parts and small organs; **THY**: Thyroid **MS**: musculo-skeletal; **BRE**: Breast; **NC**: Neonatal cephalic; **AC**: Adult cephalic **ABD**: Abdominal; **UR**: Urology; **OB-GYN**: Obstetric and Gynaecology

* Not for the U.S. market

WARNING

Do not use MyLab for ophthalmic or transorbital applications.

Do not use intraoperative and laparoscopic probes in direct contact with the heart, the central circulatory system and the central nervous system.

Cardiac Applications

The probe applies ultrasound energy through the thoracic cavity to obtain an image of the heart sufficient for evaluating any cardiac abnormalities. In Doppler modes, the probe applies energy through the thoracic cavity to determine the velocity and direction of blood in the heart and vessels.

In adults, the heart can also be studied through the esophagus and/or transgastrically with the TEE022 probe (**Transesophageal** exams).

Pediatric Applications

The probe applies ultrasound energy through the skin in order to obtain images and evaluate flows in pediatric and neonatal exams. In the latter case, the probe applies ultrasound energy through the fontanel in order to visualize cerebral structures (Imaging) or flows (Doppler) to detect structural or functional abnormalities.

Carefully read Chapter 2 of the "Safety and Standards" manual.

Note

The operator must always follow the principle known as ALARA (As Low As Reasonably Achievable) and, in particular with this application, must use minimum acoustic power for the minimum time compatible with obtaining diagnostic information.

WARNING

This application does not include transorbital or any other ophthalmic application.

Vascular Applications

The probe applies ultrasound energy through the neck or the limbs of a patient in order to obtain an image of the carotid artery or of other peripheral vessels. These images show the possible presence of abnormalities or obstructions of the vessels. In Doppler modes, the probe applies ultrasound energy through the neck or the hands/feet of a patient in order to evaluate blood velocity, flow or lack of flow, and the perviousness of the peripheral vessels.

Carefully read Chapter 2 of the "Safety and Standards" manual.

Note

The operator must always follow the principle known as ALARA (As Low As Reasonably Achievable) and, in particular with this application, must use minimum acoustic power for the minimum time compatible with obtaining diagnostic information.

WARNING

This does not include transcranial, transorbital or any other ophtalmic application.

Small Organs and Small Parts Application

The probe applies ultrasound energy through the skin to obtain an image or a Doppler flow visualization of small organs such as thyroid (neck), testicles (scrotal sac) and breast (breast).

Musculo-Skeletal

The probe applies ultrasound energy through the skin to obtain an image of tendons, ligaments and muscles and to determine blood flow patterns and velocities.

Adult Cephalic

The probe applies ultrasound energy through the skull in order to visualize cerbral vessels PI and flows, to detect functional abnormalities.

WARNING

This application does not include transorbital or any other ophthalmic application.

Abdominal and related Applications

The probe applies ultrasound energy through the patient abdomen to obtain an image of the abdominal organs to detect abnormalities (Imaging) and assess the blood velocity, flow and patency of abdominal vessels through the Doppler modalities. Ultrasound energy is applied through the skin to respectively image the female genito-urinary organs or the kidney and males genito-urinary structures (prostate, bladder,…). An endocavity probe can also be used to image the same organs, either **endovaginally** (gynaecologic application) or **transrectally** (urologic application).

OB Application

The probe applies ultrasound energy through a pregnant woman's abdomen to obtain an image of the fetus to detect structural abnormalities or to visualize and measure anatomic and physiologic parameters of the fetus for the purpose of assessing fetal growth. In Doppler modes, the probe applies energy through the patient abdomen to detect placental or fetal flow abnormalities. An endocavity probe can also be used for the same purposes (**endovaginal** studies).

Carefully read Chapter 2 of the "Safety and Standards" manual.

Note

The user should always follow the ALARA (As Low As Reasonably Achievable) principle, but especially in OB/fetal applications. Use the lowest amount of acoustic output power for the shortest duration of time to obtain the necessary clinical diagnostic information.

Chapter 3

3 - System Components and Installation

The **MyLab** will be installed by ESAOTE personnel. This person will be responsible for opening the packaging and ensuring that the system is correctly programmed and operational. This chapter provides an overview of the system's components and the major operations that may be necessary.

Configurations

MyLab
o Portable (with fold-away trolley)
o Mobile (hospital type trolley)

MyLab has a built-in LCD screen: in this way, the system can be used as portable configuration. **MyLab** can be supplied with a trolley, in both portable and mobile configurations.

Portable Configuration

The console contains: the electronics, the control panel with speakers, a DVD burner (on the left), the probe connectors, the input/output connectors for the ECG, the peripheral units and a mains switch (rear panel).
The console has a handle. The LCD opening and closing buttons are located at the side of the LCD.

Fold-away trolley

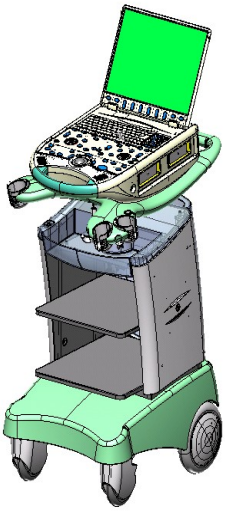
This configuration's compact size and light weight make it possible to move the **MyLab** very easily.

The fold-away trolley has a front compartment to hold accessories.

Mobile Configuration

MyLab can also be equipped with a hospital trolley, with compartments for peripheral units.

Hospital trolley



The hospital trolley can house a video recorder and a video printer. It has a compartment for additional accessories.

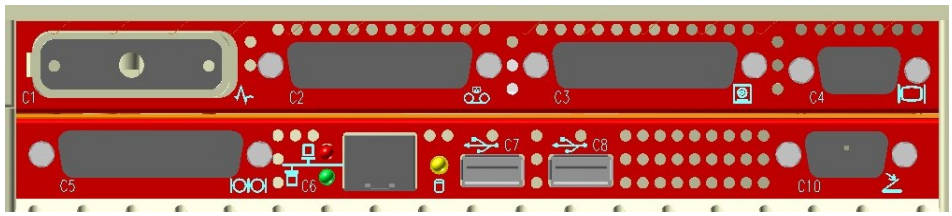
The trolley has a master switch to power up both console and peripheral units. The posterior wheels are fixed; anterior wheels are rotational and have brakes.

Installation

Identifying Connectors and Switch

With the exception of the probes, all connectors are located on the rear panel of the console. The connectors are all clearly identified according to the type of peripheral unit which they serve.

Rear panel

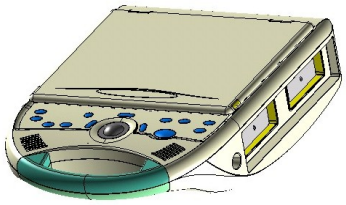


The table below lists the connectors and their intended use.

Ports indicated in italics are not currently in use

Connectors	Use
C1	ECG cable
C2	Video recorder
C3	B/W or RGB printer
C4	SVGA monitor
C5	*Not in use at present*
C6	LAN connection
C7, C8	USB connection
C10	Pedal input

The rear panel also contains the power cable socket, the fuse box and the system's power switch.



The probe connectors are located on the right. **MyLab** has two connectors for the electronic probes and one connector for the Doppler probe.

Installing the Portable Configuration

System Connection

Lay **MyLab** on the work surface. Connect the power cable to the mains socket. Connect **MyLab** to a power socket. Press the LCD's safety push-buttons to open the screen.

Probes Connection

Electronic Probes

The probes can be indiscriminately connected to EA1 or EA2 connectors. Probe connection procedure: make sure that the connector-securing device is in the "OPEN" position, align the pins of the two connectors and carefully fit the probe connector. To secure it, move the securing device to its "LOCK" position.

Doppler Probe

To connect a Doppler probe, fit its connector with its reference facing up.

MyLab is now ready to be powered up. Press the switch to turn on the system.

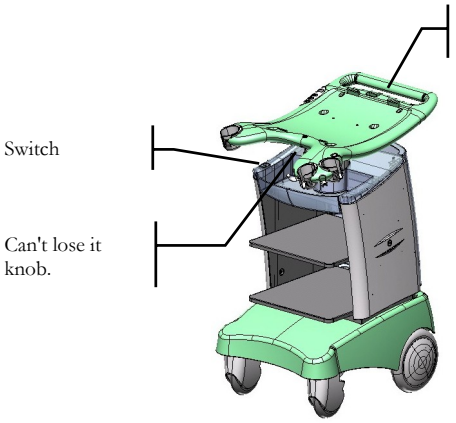
CAUTION

Do not switch off the machine before initialization has finished. MyLab can be switched off only when the window allowing to start the exam is shown - this window is used for inputting the patient data and choosing the application.

Never disconnect the probe while it is active. Press the Freeze key before disconnecting the probe.

Installation on Hospital Trolley

The hospital trolley is supplied by Esaote in a disassembled state, with the relevant assembly instructions. Esaote personnel will open the packaging and will ensure that the trolley is correctly assembled.

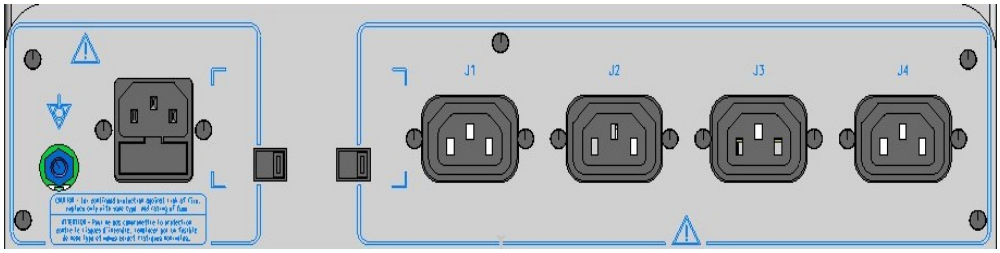


Lay the console on the top surface of the trolley, allowing it to slide to the bottom, so that the profiles of the base match the housings. Secure the console to the trolley, screwing on the 'can't lose it' knob located under the top surface.

WARNING

Make sure that the 'can't lose it' knob is completely screwed. If it is not secured correctly, MyLab could come out of the housings and fall out.

Socket panel



Use one of the additional cables supplied with the trolley to power **MyLab** from any of the trolley sockets (indicated by symbols J1, J2, J3 and J4). Plug in the power cable and connect the trolley to the power mains.

Press the LCD's safety push-buttons to open the screen. Connect the probes as described in the previous paragraph. To start the system, press the trolley's power switch located on the upper left.

The hospital trolley has brakes on the front wheels, which can be individually operated.

WARNING

Don't park the system on a slope.

Don't use the brakes to park the system on a slope.

Installation of Fold-Away Trolley

Release the wheels, by exerting light upward pressure with the tip of your toe on the lever, and open the trolley. The console's support top is fitted to the trolley frame: slight upward force is sufficient to release it and position it horizontally.

Lay the console on the horizontal surface, allowing it to slide to the bottom, so that the profiles of the base match the housings. Secure the console to the trolley, screwing on the 'can't lose it' knob located under the top surface.

WARNING

Make sure that the knob is completely screwed. If it is not secured correctly, MyLab could come out of the housings and fall.

MyLab must always be fitted on and removed from the fold-away trolley in its open position.

The trolley has neither a transformer nor additional sockets. To connect **MyLab** to the power mains and install the probes, follow the console installation instructions. Power up the system by pressing the system's master switch.

Working Position

The fold-away trolley has an extensible handle, with three different positions corresponding to three different **MyLab** heights. Push the interlocking buttons to release the handle and slide it into the desired position.

Acclimation Time

If the system has been left exposed to temperatures which are outside the range given for its correct working (15÷35°C), it must acclimate, before being switched on. The following table indicates the necessary waiting times:.

T(°C)	60	55	50	45	40	35÷15	10
Hours	8	6	4	2	1	0	1

T(°C)	5	0	-5	-10	-15	-20
Hours	2	4	6	8	10	12

Adjusting the LCD Screen

Brightness is adjusted by function keys **F6** and **F7** of the alphanumeric keyboard. The function keys are active if pressed simultaneously with the **Fn** key of the alphanumeric keyboard. Key **F6** increases brightness, while key **F7** reduces it.

However, the most important adjustment is the relative orientation of the screen vis-à-vis the operator. Current LCD technology ensures that the orientation affects the chromatic perception of light. Consult the grey tones or color scale (on left of image) to correctly position the LCD screen.

Installing the Video Peripheral Units

The "Safety and Standards" manual provides the safety requirements and standards to be observed for using peripheral units with **MyLab**.

The following cables are available for connecting the video peripheral units:

Code	Description
8830427000	Cable for S-VHS video recorder
8830428000	Cable for B/W printer
8830429000	Cable for Sony RGB printer
8830915000	Cable for Mitsubishi RGB printer
8830747000	Cable with 2 connectors for 2 printers
8830749000	USB A/B cable

Before installing the peripheral units, make sure that the system is switched off and unplug the power cable from the mains.

For video requirements see chapter "Technical Specifications"

From the **MyLab** control panel it is possible to manage both video printers and VTRs. For more information on systems which are proven to conform to the **MyLab** remote management characteristics, please contact the ESAOTE personnel.

Installation on Hospital Trolley

- Lock the trolley by engaging the brakes.
- Open the trolley's rear door.
- Fit the peripheral unit on the desired shelf and secure it with the Velcro strips.

Connection to B/W Printer

The cable has a multi-pin connector on one end and BNC and remote connectors on the other end. Connect the cable as indicated in the table below.

Cable connector	Side	Port
Multi Pin	MyLab	C3
BNC	Printer	Video
Remote	Printer	Remote control

Connection to RGB Printer

The "RGB Printer" cable has a multi-pin connector on one end and four colored BNC and a remote connector on the other end.

Cable connector	Side	Port
Multi Pin	MyLab	C3
BNC	Printer	Input connectors
Remote	Printer	Remote control

If one wishes to simultaneously connect 2 different printers to **MyLab**, one must use the 2-connector cable which duplicates port C3. The cable has a multiple-pin connector at one end and 2 multi-pin sockets on the other. The multi-pin connector should be connected to connector **C3** of the rear panel of **MyLab**. In this way, the cables of the printers can be connected to the 2 multi-pin sockets.

Connection to the Video Recorder

The cable for the video recorder (VTR) has a multi-pin connector on one end;. on the other end, there are two S-VHS connectors (IN, OUT), four audio connectors (two IN, two OUT) and one REMOTE.

Cable connector	Side	Port
Multi Pin	MyLab	C2
S-VHS IN	VTR	S-VHS In
S-VHS OUT	VTR	S-VHS Out
AUDIO IN	VTR	Audio In
AUDIO OUT	VTR	Audio Out
REMOTE	VTR	Remote control

USB Printers

MyLab can be connected to USB printers. The ports available for USB connections are **C6** and **C7**. The peripheral units must have an B-Type USB connector, to be able to use the available USB cable.

Contact ESAOTE personnel for recommended models and their configuration.

Power Feed to the Peripheral Units

- Use one of the additional cables supplied with the trolley connecting the unit to any of the trolley sockets (indicated with symbols J1, J2, J3 and J4).

CAUTION

Do not exceed the maximum absorption limits indicated for insulated sockets. There is a risk of blowing the trolley fuses.

- Switch on the switches of the peripheral unit/s.
- Close the trolley door

At this point, the system can be connected to the mains, and the entire configuration can be powered, using the trolley main switch.

WARNING

If the peripherals aren't powered through the trolley, do not place them within the patient's area (1.5 m distance - 2.5 m height).

In this latter case, peripheral units must be powered ensuring compliance with the medical security standards: please contact Esaote Service department to correctly install them.

Note

When peripherals units aren't powered thorugh the trolley, it is good practice not to touch simultaneously the patient and the peripheral unit.

Trolley-Free Installation

To correctly power the system, follow the manufacturer's instructions.

WARNING

The system must be powered to satisfy the electrical safety requirements, as specified in the "Safety and Standards" manual. ESAOTE recommends running a current leakage (patient and environment) test when installing in order to check whether the applicable limits of standard EN60601-1 are not being surpassed.

As a further precaution, the operator is recommended to position these peripheral units, whenever possible, outside the patient's area (1.5 m for distance - 2.5 m for height). In this case, peripheral units must be powered ensuring compliance with the medical security standards: please contact Esaote Service department to correctly install them.

Additional Connections

SVGA Monitor

MyLab can be connected to an external SVGA monitor. Connect the monitor's signal cable to the **C4** connector of the rear panel.

ECG Cable

The ECG cable should be connected to the connector **C1** of **MyLab**'s rear panel. The ECG cable is wired to generate a I lead. By suitably positioning the electrodes, one can however obtain a II or III lead.

The ECG cable is available as an accessory, both with an IEC lead (code 9630028000) and with an AHA lead (code 9630028010).

Footswitch

With **MyLab**, a footswitch for managing the Freeze or other real-time modes can be connected. The footswitch should be connected to connector C10 on the rear panel.

The footswitch (code 9102756000) is also available as an optional accessory.

Connection to a DICOM Server

If it has a DICOM license, **MyLab** can be connected to a DICOM server, by using the LAN **C6** port.

Moving and Transporting the System

Transport of Hospital Configuration

MyLab in his hospital configuration is provided with wheels and handle to allow the user to easily move the unit. The following precautions must be observed:

- Switch the system off and unplug the power cord.
- If the probes are connected, be sure that they are properly placed in the suitable **MyLab** probe-carriers and that the cables do not reach the floor.
- If the peripherals are also placed on an external additional platform, be sure they are disconnected from **MyLab** before moving the ultrasound unit.
- The wheels of **MyLab** are provided with brakes; be sure the brakes are disabled before moving the ultrasound apparatus.
- Avoid any unnecessary mechanical shocks to the system while moving it.

WARNING

Be sure that the probes are locked in the appropriate holders and the probe cables are properly hanged in the cable hooks during the movement of the system .

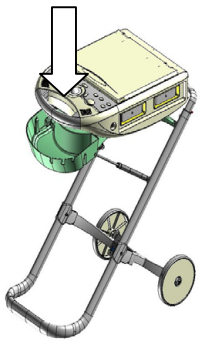
For locking the system in a stable way is necessary to lock at least two wheels.

Transport on Fold-Away Trolley

The system must be moved with the trolley in closed position. Remove any connected probes, shut the LCD screen and unplug the mains plug. If necessary, take the handle to its lowest position. When the handle is lowered, a light pressure on it is enough to release the horizontal top and close the trolley.

CAUTION

To close the trolley, push the handle only. Any pressure exerted on the hood could damage the LCD screen. Empty the accessories compartment before closing the trolley.



Close the wheels: the locking lever hooks automatically.

To facilitate transport, the fold-away trolley has an extendable handle. The handle has three different positions. Press the jointing push-buttons to release the handle, allowing it to slide to the desired position.

CAUTION

Do not leave the trolley closed in vertical position. Always leave the trolley in open position to ensure maximum stability.

Transportation

- When transporting the system on a vehicle, remind to:
  - Disconnect and remove all probes and peripherals.
  - Use the brakes to lock the system in his hospital configuration. Fasten securely the system inside the vehicle.
  - Place the system on a flat surface if in his fold-away configuration. Protect the system with some padding during transportation.

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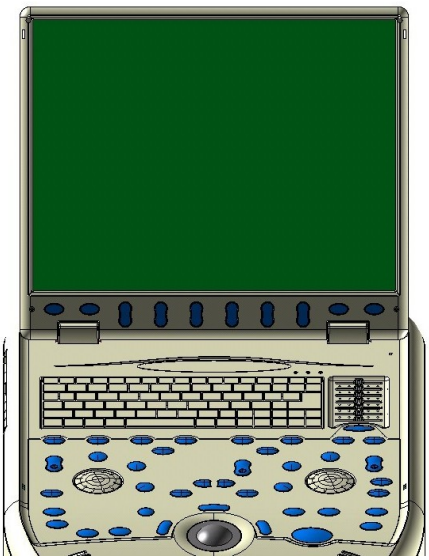
Chapter 4

4 - Control Panel

This chapter provides a brief description of the system controls.

The Control Panel



Control panel components: an alphanumeric section (keyboard, general controls), the trackball, a software keys section (at the bottom of the LCD), and a controls section.

Loudspeakers (Doppler) are in the controls section.

Alphanumeric Section

This section includes the TGC controls and an alphanumeric keyboard.

The TGC potentiometers control signal amplification in individual zones of the image. The potentiometers are used to adjust the signal zone by zone.

The alphanumeric keyboard is based on the QWERTY standard. The alphanumeric keys are used for inputting text data in the enabled windows. The **Caps Lock** key presets the keyboard to upper case characters.

The ⬆**Shift** key is used for typing in lower case or upper case characters (according to how the keyboard is set) or the characters indicated in the top left section of some keys.

Special Characters

With **MyLab**, the operator can type in the special characters through the Windows® XP standard modalities. To type in special characters, two keys have to be simultaneously pressed. The table below: shows the operating modalities.

First key	Second key	Special characters
‘ (Apostrophe)	e, y, u, i, o, a	é, ý, ú, í, ó, á
` (Grave accent)	e, u, i, o, a	è, ù, ì, ò, à
^ (Circumflex)	e, u, i, o, a	ê, û, î, ô, â
~ (Tilde)	o, a, n	õ, ã, ñ
“ (Diaeresis)	e, y, u, i, o, a,	ë, ÿ, ü, ï, ö, ä

The following characters are also available, if the operator presses the **Alt** key and the numbers sequence listed in the table below:

Alt + sequence	Special character
0231	ç
0229	å
0230	æ
0248	ø
0233	ß

Text Entry

If any of the alphanumeric keys are pressed during the exam, this automatically activates the input of text. All writing operations are managed by the alphanumeric keyboard and trackball, the latter being used to position the cursor.

The ANNOT key allows to access a glossary, which can be configured by the user. Refer to the “Advanced Operation” manual for more information on text entry.

Trackball

The trackball operates in two different modes.

Standard Mode

In its standard function, the trackball makes it possible to quickly position the cursors on the screen. The following chapters provide details of the specific functions performed by the trackball in operations requiring it to be used.

Each mode automatically activates the trackball on its cursor:

Mode	Trackball
B-Mode	Transmission focal point
M-Mode, Doppler	LINE cursor
CFM	CFM ROI cursor

When several cursors are present on the screen, the **ACTION** key switches the active cursor.

Mouse Mode

AO

Refer to "System Configuration" section for trackball configuration

The trackball can then be used to move a pointer on the screen. In Real-Time the pointer can be used to activate software keys functions and to toggle through their menus. In Freeze, Exam review and Archive review the pointer can be used to access archive menus. In this case, the keys placed on the left and right side of the trackball can be set as mouse keys (as enter and context menu keys).

Regardless of the trackball configuration, the enter and context menu keys are respectively indicated as **ENTER** and **UNDO** keys in this manual.

The **POINTER** key makes it possible to change the trackball operation from standard to mouse mode.

Software Keys

Four buttons and six menu toggles are located at the bottom of the LCD screen. The functions of these keys vary according to mode, application, and settings. The menu shown above the keys indicates the functions assigned to them.

To correctly use the software keys, keep in mind the following:

- The buttons are shown according to their status.

To be pressed	Pressed	Diasbled
		
Blue	*Sky-Blue*	*Dark Grey*

  If the button is active, the displayed function is enabled by pressing the key.

- If the displayed menu has more than six scrolling toggles, the sixth toggle (**NEXT/PREVIOUS**) is used to scroll through the menus of the first five keys. Press the push-buttons to select the required setting.

Controls Section

Exam Flow

START END is the key that opens and closes every exam. The menu is used for entering the patient data and the choice of application, probe and required presets. During the exam, one can select a different probe (key PROBE) or preset (key PRESET).

When the exam is finished, press the **START END** key again. It is then possible to archive the patient's data and produce a report on the exam. The system clears the stored data and shows the exam start window again.

Closing session

The **STARTEND** key, kept pressed for more than three seconds, activates the closing session procedure.

CAUTION

This is a PC based system; data loss or driver damage may occur if the system is turned off while working. Refer to appropriate sections of this manual for detailed information on when and how to safely power the system off.

This key is used to input or modify the patient's data during the exam.

The Mode Keys

This key re-activates a B-Mode image in real-time when it is used in any other mode. If pressed in M-Mode, Doppler or Freeze, it restores a full screen bi-dimensional image.

Color Doppler (CFM) is activated or disabled by pressing this key in B- or M-Mode.

In B-Mode, a cursor delimits the Region of Interest (ROI) where color analysis is executed and displayed. The ROI's dimensions and position can be varied with the trackball, activating the ROI cursor with key 

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The Real-Time Soft Keys menu allows the operator to vary the display modality and to switch to Power Color or TVM (Tissue Velocity Mapping). TVM[1] utilizes Doppler to display the heart walls motion, rather than flow.

The displayed menu makes it possible to vary the B-Mode and make it coincide with the ROI ("Coincident" view).

Color M-Mode is shown full screen or with a reference 2D, according to the choices on the displayed menu.

This key activates the M-Mode, and if necessary, its selection cursor (B-Line). There are five possible viewing formats: the format with full screen M-Mode; the dual format, with the screen split vertically with 2D on the left and trace on the right; the split formats, with the screen split horizontally, with the reference 2D above (out of three possible dimensions) and the M-Mode trace below. The viewing format can be preset and varied in real-time through the displayed menu.

[1] TVM and TV modes are enabled only with PA230, PA122 and TE022 probes in a cardiac application.

The **PW** key is used for activating the Pulsed Wave Doppler (PW), **CW** for activating the Continuous Wave Doppler (CW); both keys activate the positioning cursor if necessary. As in M-Mode, there are five viewing formats: the three split formats, the dual format and the full screen format. In PW, the Real-Time Soft Keys menu allows the operator to switch to the display modality TV[1] (Tissue Velocity). TV sets Doppler filters to display strong signals with low motion such as the heart walls motion, rather than flow.

During the exam, the format can be preset or varied interactively through the menu.

In 2D or CFM, the **LINE** cursor can be interactively activated or disabled to select the M-Mode or Doppler line.

Both in M-Mode and in Doppler, the 

key starts trace acquisition. If this key is pressed during acquisition, the trace is frozen and the reference 2D is temporarily re-activated.

Gain Knobs

These two keyboard knobs are used for adjusting the amplification of the echo signal. Gain is increased by turning clockwise and is reduced by turning counter-clockwise.

The knob on the right acts on the B- and M-Mode signals, adjusting amplification over the entire depth of the image. The left knob amplifies the CFM and Doppler gain, according to which mode is active. In Doppler mode, gain acts on both components of the signal (video and audio). The level of the audio signal may be independently adjusted with the **AUDIO** knob, which is disabled in the imaging modes.

If some preset parameters are varied during the exam, the 

key can be used to restore the presets set for the active application.

This key stops the current analysis or scan and puts the system in Freeze mode. To re-activate in real-time, press  a second time or directly press the key for the required mode.

According to how the system is preset or to the selections on the displayed menu, these keys activate multiple views of two (dual) or four 2D (quad) images. In Dual mode, one can display two different images or the same 2D image simultaneously.

Press any key to activate multiple presentations. The active 2D is displayed on the left (in the upper box for quad presentation). If one of the keys is then pressed, this freezes the 2D in acquisition and activates the next 2D; if the  key is pressed, or the previous if the key is pressed.

Press the 

key to restore a normal format

The Zoom function, active both in Real-Time and in Freeze, is used to selectively enlarge a zone of the image in B-Mode or in CFM.

Initial pressing of the **ZOOM** key activates a sectorial cursor that can be positioned (and possibly varied in terms of dimensions) by the trackball on the zone of interest. The second pressure activates the enlarged presentation of the selected zone. Press **ZOOM** to return to a normal format.

Use the UNDO key to cancel the enlargement factor cursor from the as yet non-enlarged image.

The **DEPTH** key increases or reduces scanning depth in all imaging modes.

When the ZOOM cursor is active, the **DEPTH** key varies the dimension of the area to be enlarged.

This key is active in real-time only and is used for varying emitted power during the exam. It operates independently for each mode: e.g. in PW mode, it controls the power of the Pulsed Wave Doppler; in 2D-CFM mode, it controls the power of the CFM.

Power control must be adjusted to the minimum possible level compatible with an acceptable image. Carefully read the "Safety and Standards" manual with reference to the guidelines on the safety of ultrasound.

In all applications where the ECG is shown, the PHYSIO key enables the operator to vary the amplitude of the ECG trace and its position selection on the screen.

Exam Storage

During the exam, the operator can save both individual images and sequences (for systems having the clip license). The keys to use are **IMAGE** for the frames and **CLIP** for the sequences (2D or CFM). The stored images and sequences are displayed as thumbnails on the right of the screen.

The EXAM REV key is used for accessing, at any time, the data stored during the current exam. To access the data archive, press the ARCHIVE REV key.

Exam Report

The following may always be executed: general measurements (key + ···· +) and access to the calculations package, specifically for the application in progress (**MEASURE** key). When the required key is pressed, the list of available measurements is shown to the right of the image.

MyLab can control two different peripheral units with keys **1** and **2**, according to the system's presets. For example, the operator can connect both a B/W printer and an RGB printer and control them separately with these keys.

This key activates and disables the VTR Menu. The software keys menu enables video recorder play-back and other VTR operations (fast forward, eject,....).

Note

To ensure correct video recorder operation, **MyLab** must be configured with the correct VTRs and with the relevant settings.

Settings

This displays the system menu for all configurations / settings (center name, preset…). The menu is explained in detail in another chapter.

Advanced Operations

Keys **MARK**, **REPORT**, **ANNOT**, **ACQUIRE** and **CONTRAST** activate advanced operations: further details on how to use them are described in the "Advanced Operations" manual l.

Chapter 5

5 - Screen Lay-Out

This chapter provides a brief description of the information on the **MyLab** screen.

Information about the Screen

The screen is subdivided into three main areas:

The video area (i.e., the screen area which can be managed by video peripherals) is a screen sub-set; it includes most of the Heading and the entire Image Area.

Heading

This area is used for displaying the icons of the following: trackball, archival systems, configured peripheral units; it also shows the following information: center and patient data, and the date.

For setting centre data, see the appropriate chapter of this manual.

Patient data are displayed only if entered at the beginning of the exam. The system displays the following patient data: last name and first name, age and patient code.

Trackball

The trackball function is indicated by the icon shown at the top left of the screen.

When there are several cursors on the screen, two icons are displayed simultaneously. The yellow icon shown on the left indicates the active cursor; the one in green on the right indicates the next cursor that can be activated. The ACTION key switches between cursors.

Archival Systems

The archival system icons are shown at top left, after the trackball icons. The icon is shown crossed out whenever there are management problems involving the specific archival system.

For more details on data archival, consult the relevant chapter and the Advanced Operations manual.

Peripheral Units

The system is able to simultaneously manage two peripheral units (b/w or RGB printer and the VTR). The icons of the peripheral units are shown at top right of the screen.

If no peripheral unit is enabled, the right side of the header bar shows two gray icons.

The icon is shown crossed out whenever there are management problems involving the specific peripheral unit.

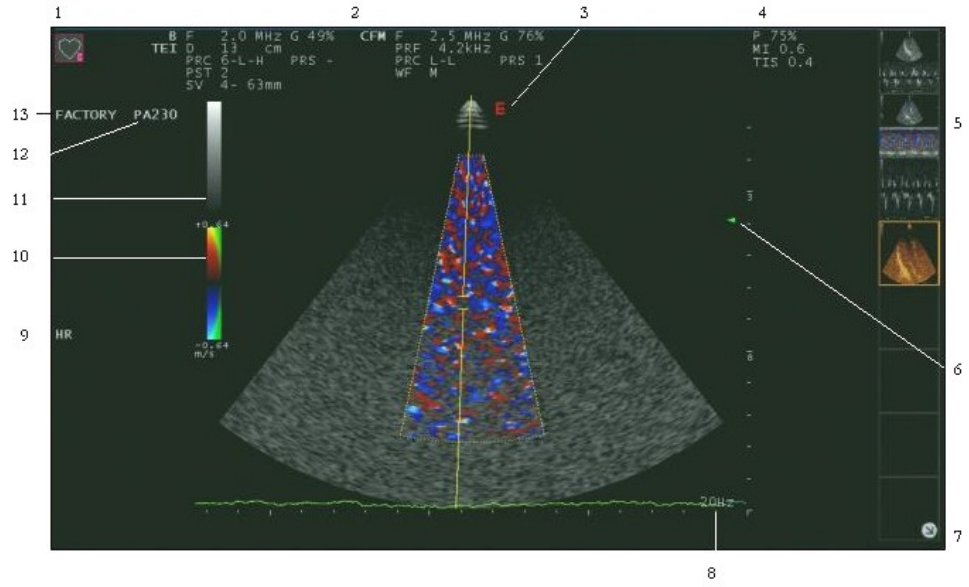
Real-Time and Freeze

A specific icon is used for the real-time and frozen image - it is shown on the right of the heading area.

Whenever an image is frozen, a memory bar is displayed (at bottom right) concerning the scrolling memories. The images acquired immediately before the system are frozen and archived in these memories. The trackball can be used to examine the 2D, M-Mode, Doppler and CFM information image by image.

Image Area

The display of the image depends on various factors such as active mode, selected application, and transducer. The following figure shows the elements in the image area that are independent of these factors.



Legenda:

Number	Icon
1	Active application
2	Machine parameters
3	Sector orientation
4	Acoustic output data
5	Thumbnails of stored images
6	Focal zone
7	If colored, it indicates images to be scrolled
8	Frame Rate
9	Heart rate
10	CFM scale
11	Imaging scale
12	Active probe
13	Selected preset

Applications

The system displays different icons according to the selected application.

Machine Parameters

Imaging

Parameter	Quantity	Description
F	*nnn* MHz	Imaging frequency or TEI mode (Resolution or Penetration), when enabled
G	*nn* %	Imaging gain (Min, %, Max)
D	*nn* cm	Depth
PRC	*n-n-l*	Dynamic range, Sharpness , Density (L: Low, H: High)
PRS	*n*	Persistence
PST	*n*	Post -processing curve
SV	*nn-nnn* mm	Sample volume Size and Depth (PW)
Θ	*nn*°	Doppler correction-angle

SV and **Θ** are displayed only if the relevant cursor is active.

CFM

Parameter	Quantity	Description
F	*nnn* MHz	CFM frequency or TVM frequency when enabled
G	*nn* %	CFM gain (Min, %, Max)
PRF	*nnn* kHz	Pulse Repetition Frequency
PRC	*n-l*	Sensitivity, Density (L: Low, H: High)
PRS	*n*	Persistence
WF	*n*	CFM filter (L: Low, M: Medium, H: High)

Doppler

Parameter	Quantity	Description
F	*nnn* MHz	Doppler frequency or TV frequency when enabled
G	*nn* %	Doppler gain (Min, %, Max)
PRF	*nnn* kHz	Pulse Repetition Frequency (kHz)
PRC	*n-n*	Pre-processing curves (Dynamic range, Rejection)
PST	*n*	Post-processing curve
WF	*nnnn* Hz	Wall filters

Chapter 6

6 - Exam Performance

This chapter describes the operations usually carried out while an exam is being performed and how to turn the system off at the end of the session.

SS

Read the Safety and Standards Manual carefully: all the safety characteristics, cautions and warnings listed apply to all exams.

Remember that it is necessary to be familiar with the mechanical and thermal indices display and the ALARA principle (As Low As Reasonably Achievable) before using any probe. The patient must be exposed to ultrasound for as short a time as possible and only for as long as it takes to achieve the diagnostic information

Exam Start and End

At power-up, at end of the initial autotest and at the start of every new exam (key Start End) the system shows the screen in the figure below. If necessary, the key Start End allows activation of real time before ending the initialization phase).

CAUTION

Do not turn the system off during the initialization phase: the hard disk coud be damaged by this operation.

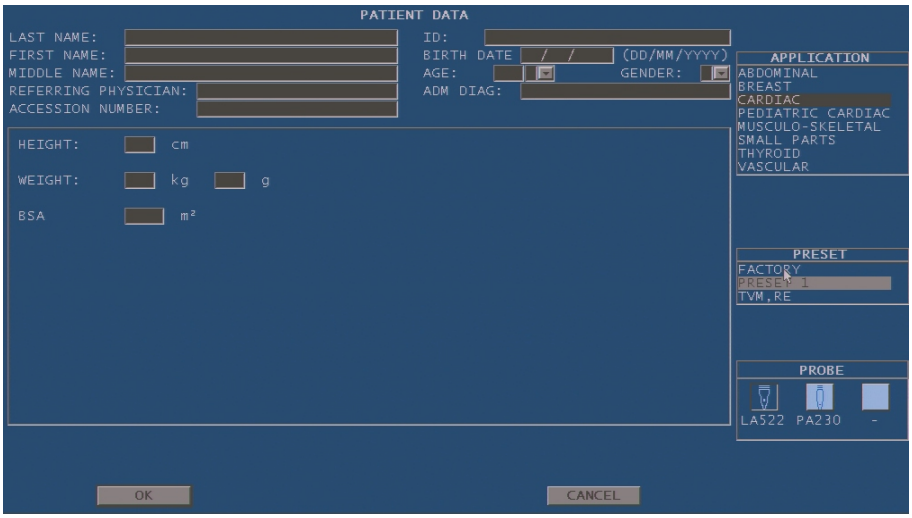
AO

Note

To guarantee data integrity and confidentiality, the system allows to configure a list of users allowed to work on the system. In this case to access the system the user needs to log in and type a password. See the "Advanced Operations" manual for further information.

The Exam Start window is used for inputting patient data, for selecting the application, as well as the required presets and probe.

Age is automatically calculated from the date of birth. In cardiac applications one can enter height, weight and BSA values.



Note

The user may program and add presets to better suit individual clinical needs or preferences, while applications depend on the installed optional licenses.

At any time during the exam, the operator can view and modify the patient's data with Patient ID and can also select a different probe and setting by using PROBE and PRESET.

WARNING

Do not use Patient ID to start a new exam as it will update existing patient's data with new entries. To activate a new procedure, always use the Start End key.

To select fields and options, use the trackball and the ENTER key: The trackball moves the cursor; the ENTER key fixes its position, opens the drop-down menu and selects the option.

How to Input Patient Data and Select an Application

- Move the cursor with the trackball.
- Input the patient's data with the alphanumeric keyboard. Key ← **Back Space** is used to clear input characters.
- To move rapidly through the different items, use the **Tab** ⇆ key.
- Select the required application, preset and probe. The selected application and presets are displayed over a black background, and the selected probe is displayed over a blue field.
- Locate the cursor over OK and press ENTER to begin the exam.

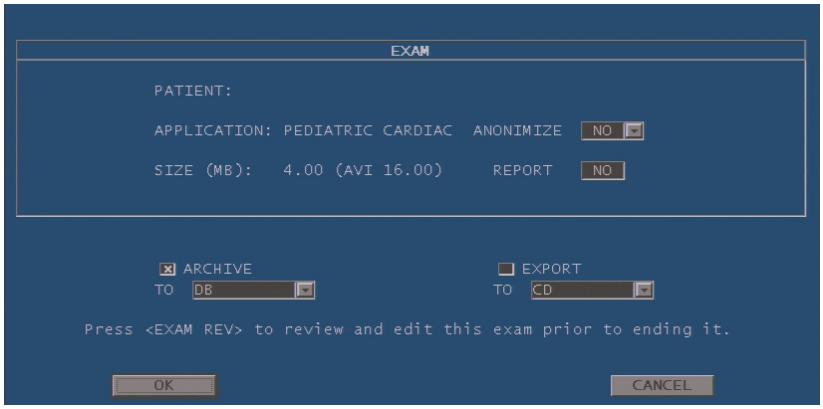
The system activates real-time in 2D. The selected application and presets automatically determine the type of format, CFM maps and power values …

WARNING

Before beginning the exam, ensure that the active probe displayed on the screen matches the one selected on the Exam Start page.

Exam End

To end the exam, press the Start End key again. The window displayed at the end of the exam is used to archive the exam. This window shows the patient's first name, the type of activated application and the dimensions of the stored images.



Further details are provided in the data archival chapter.

Before archival, the patient data can be made anonymous. The exam can be simultaneously archived and exported.

The system automatically presents the window allowing the start of the exam.

Note

At power-up, the system prompts the operator to archive the last exam performed if the system was switched off without first closing the exam in progress.

ECG

PHYSIO

When the electrodes have been applied and connected, the position of the ECG trace on the screen can be selected, and its gain can be adjusted.

- Press PHYSIO to display the software keys menu.
- Modify the signal's amplitude by pressing key **GAIN**.
- If necessary, press **POSITION** to move the ECG trace on the screen.
- The **ECG** key enables or disables the display of the trace on the screen.

Press PHYSIO to return to the real-time menu.

Performing the Exam

By pressing the different mode keys, the specific mode is activated in real -time. If the same key is pressed again, the system automatically returns to the previous presentation.


Line cursor

In the formats with a trace (M-Mode and Doppler), before activating the mode, press LINE to display the scanning line.

During scanning, UPDATE freezes the trace and re-activates the 2D reference; the **PLEX** key activates or freezes the 2D reference, maintaining the trace in real-time.

The keyboard and the commands displayed on the software keys make it possible to optimize presentation quality. Different menus correspond to each format. If the displayed menu has several levels, press key **NEXT/PREVIOUS** to scroll through all functions.

To save images and image sequences (2D or CFM), press IMAGE and CLIP in real-time. Single images are saved with full definition, whereas sequences are compressed. Sequences, or clips, are compressed in BMP format, with minimum loss of information.

For further information about clip formats, consult the next chapters.

Note

Digital data storage is typically slower than the ultrasound frame rate; the clip frame rate may therefore be lower than the original one. A Warning message is displayed if the archival frame rate drops below 20 fps, as it may occur if multiple tasks (example: burning a CD and saving new clips) are concurrently working.

The thumbnails of the saved data are shown downward in chronological order. A maximum of eight thumbnails are shown: the colored arrow in the thumbnails column indicates that further images are present for scrolling.

AO

The Advanced Operations manual provides a detailed description of all the software keys active in the different modes.

Freeze and Scrolling Memories

The ✳ key freezes the image. The system displays the scroll bar of the memories, where the images acquired just before the system was put on freeze are temporarily saved.

How to Scroll through the Memories


Trackball icon

Move the trackball horizontally to scroll through the images one by one. The scrolling bar shows the trackball position. Use the **START/END** key to automatically move to the start or end of the sequence.


Trackball icon

In the case of multiple formats, several scrolling bars are displayed; the ACTION key changes over from one bar to the other, whereas the trackball scrolls through the images of the selected bar.

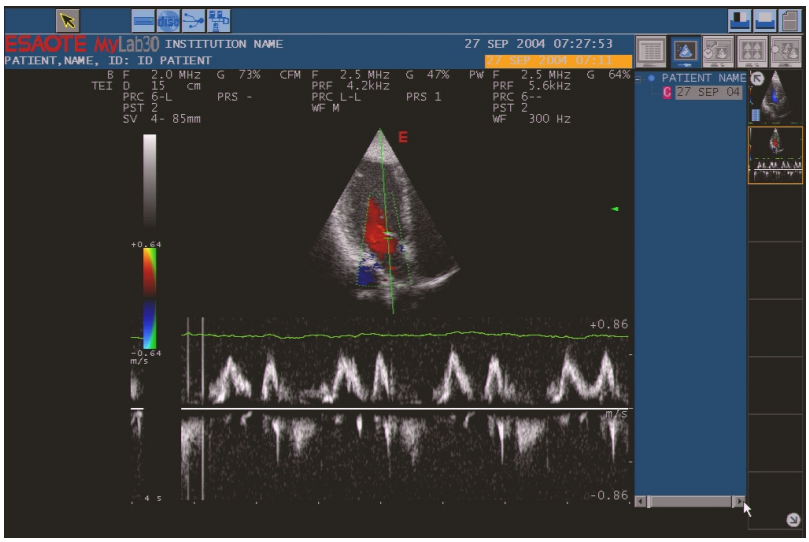
In Freeze the sequence of stored images can be seen in cine mode if the **PLAY** key is active. The sequence can be seen again at different speeds (use the **SPEED** key). The **MODE** key displays the entire contents of the memory (when enabled on **FULL**) or single cardiac cycles , when the ECG is shown, or seconds intervals when there is no ECG. Use the trackball to scroll along the bar and display another cycle/interval.

The single cardiac cycles and the intervals selected through the **CINE MODE** key can be saved by pressing the **CLIP** key.

The Advanced Operations manual provides a detailed description of all the software keys active in freeze state.

Exam Review

During the exam, the **EXAM REV** key enables the operator to review the saved images and sequences. When the key has been pressed, the trackball automatically changes over to pointer mode, allowing the operator to scroll through the thumbnails and select the data item to be reviewed. Software key **SCROLL** enables the operator to scroll through the thumbnails when more than eight images or sequences have been saved. If there are more than eight saved images and clips, the **PAGE** sofware key allows the operator to quickly scroll the thumbnails: the next eight thumbnails are displayed when the key is pressed.



The selected image or sequence is presented on the screen. Clips are presented in cine mode: the **PLAY** key disables the kinetic presentation and enables the operator to scroll through the sequence image by image with the trackball.

Note

Images are usually compressed, with some loss of information. Please see the technical specifications for more information.

Image Clearing

To clear a saved image or sequence, select it with the trackball and press the **DELETE** key.

The **EXPORT** key is used to export the image or sequence to an outside medium, which can be selected from the appropriate window.

In Exam revision single cardiac cycles and intervals selected thorugh the **CINE MODE** key can be saved as clip by pressing the corresponding key.

Annotations

If any of the alphanumeric keys are pressed during the exam, this automatically activates the input of text. All writing operations are managed by the alphanumeric keyboard and trackball, the latter being used to position the cursor.

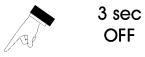
The ANNOT key provides access to a user-settable glossary. The Advanced Operations manual describes how to create and use the glossary.

System Shut Down

CAUTION

This is a PC based system; data loss or driver damage may occur if the system is turned off while working.

This shut down procedure is always recommended; it is MANDATORY that the operator interrupts any pending PC operation prior to turning the system off. Make sure that no heading archival system icon has a flashing yellow frame; if so, there is a pending PC operation, which requires the system shut down operation be performed.



When closing the session, follow this procedure:

- Keep the key Start End pressed for at least (3) seconds.
- Place the pointer on **OK** and press UNDO.

Once the operation has been completed, the system displays the shut-down message: press the ON/OFF key on the rear panel to turn the system off.

Note

If the system isn't correctly shut down, a message will be shown at next switching on.

Chapter 7

7 - Measurements and Calculations

This chapter describes how to access the generic measurements and the specific calculation packages of the applications.

General Information

Measurements can be made on frozen, stored and archived images. The available measurements are shown on the right of the image. The messages displayed on the screen guide the operator through the stages, facilitating measurement execution. The results are shown on the left of the image.

Clips are compressed for digital storage. Compressed files involve a minimal loss of information (see Technical Specifications Chapter 11). The Compression algorithm used by **MyLab** ensures the preservation of the image features for the reporting functions.

WARNING

This symbol is displayed on the screen when the image features, compared to the original one, may not be optimal for the reporting functions.

To select the views and the positioning of the cursors, we urge the operator to act according to current medical practice and the instructions of specialists in this subject.

Note

Always enlarge the format to maximize the structure/signal to be measured.

If possible, use the full screen formats for M-Mode and Doppler measurements.

The system cannot be used to measure images with ambiguous calibrations. An error message is shown on such images when the measurement is made. Measurements on QUAD formats cannot be made.

Generic Measurements

The generic measurements feature makes it possible to rapidly measure, for example: distance, area, time and speed.

This key activates the generic measurements menu. The system shows the list of available measurements, which are automatically identified according to active mode and application. Software key **MEASURE** is used for rapidly selecting the required measurement. The measurement shown in yellow is immediately operational.

Following the instructions on the monitor, position the cursors with the trackball and confirm the position by pressing ENTER. The UNDO key can be used to restart a measurement before it has been confirmed. The **Back Space** deletes point by point the traced line. The value being measured is displayed in real-time on the left of the image.

Selective Deletion of a Measurement

- Activate the trackball as a pointer by pressing POINTER.
- Position the pointer on the measurement to be deleted (the measurement is shown in yellow).
- Press the **CLEAR** key to delete the measurement.
- Press POINTER again to return to the measurements menu.

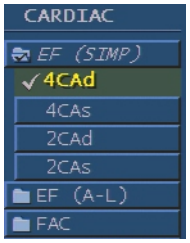
The **CLEAR ALL** key deletes all measurement cursors and the values shown in the measurements field from the screen.

The Advanced Operations manual provides a detailed description of the generic measurements available in every application.

Specific Calculation Packages

The specific calculation packages are based on the measurements to be executed on identified anatomical structures.

To access the specific calculations, press the **MEASURE**. key. The system automatically identifies the calculations package according to the selected mode and application.



The list of executable measurements is shown on the right of the screen. The measurements are arranged in groups (identified by the symbol), which correspond to specific anatomical structures. Each group includes the measurements executable in that structure. To display the measurements included in a group, position the trackball on the group and press the **EXPAND** key.

Executed measurements are marked by the symbol ✓.

How to Select a Measurement

- Freeze the image and press MEASURE.
- Using the trackball, select the required group (the selected group is displayed in yellow).
- To follow the entire measurement sequence specified by the group, press ENTER over the selected group.
- To make a specific measurement press **EXPAND**, select the required measurement with the trackball, and press ENTER.

The system displays - at the bottom of the screen - the image with the operating instructions for making the selected measurement. The trackball is used to position the measuring cursors, while ENTER is used to confirm positioning when requested by the instructions.

To delete an unconfirmed measurement or to delete a measurement selectively, the instructions provided for the generic measurements apply.

The **ACTION** key allows to interrupt the active measure and select a different group..

AO The Advanced Operations manual provides a detailed description of the specific measurements available in each application.

Chapter 8

8 - Exams Archive

This chapter describes how to archive images and to access the relevant archive.

Archive Icons

When the system accesses the archive, the relevant archive icons are shown on the right of the heading bar. The active icon is displayed on a dark background, while the icons that can be activated are shown over a blue background. Icons shown in grey are inactive.

To activate the function, locate the trackball over the required icon and press ENTER.

Data Archival

This system uses under license the MergeCOM-3 ™ Advanced DICOM[1] library of Merge Technologies Inc.

The system has an internal hard disk in which the exams can be archived (local archive). The data can be saved on external supports and on DICOM® format (for systems having a DICOM license), and exported in BMP format or AVI format (see specification for codec information). Exported data cannot be reviewed by the system.

The IMAGE and CLIP keys save single images (with full resolution) and image sequences (in compressed format). When the **CLIP** key is pressed, the system stores sequences of a preset duration, which can be set from the System Menu (see "Advanced Operations" manual). Data is compressed with a minimum loss of information, with a maximum frame rate of about 25 images.

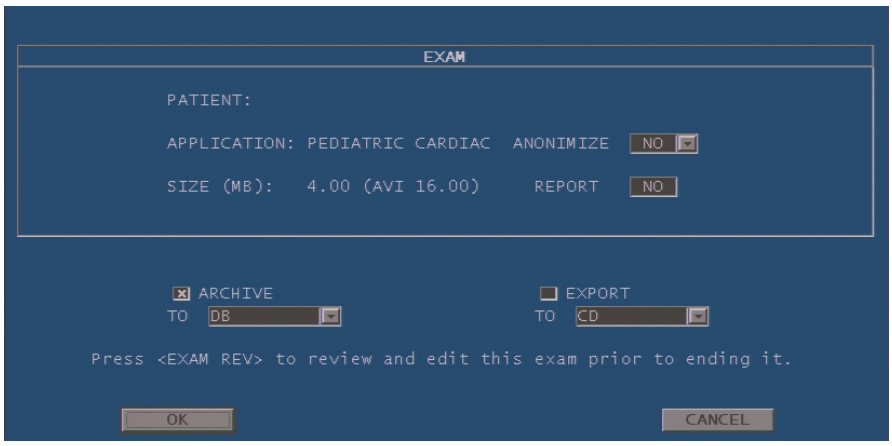
Note

Digital data storage is typically slower than the ultrasound frame rate; the clip frame rate may therefore be lower than the original one. A Warning message is displayed if the archival frame rate drops below 20 fps, as it may occur if multiple tasks (example: burning a CD and saving new clips) are concurrently working.

[1] DICOM is a registered mark of NEMA (National Electrical Manufacturers Association)

Archiving the Exam

During an exam, the images are temporarily stored on the system's hard disk. The exam ends as soon as the **START END** key is pressed. The system shows the window of the exam end, which enables the operator to select the required format (DICOM with the ARCHIVE option; BMP or AVI with the EXPORT option) and the final archival support.



When the exam is archived on CD or DVD in DICOM format, the Biopacs Lite[2] viewer is automatically enclosed in the CD or DVD. In this way the exam can be reviewed in any PC.

Before archival, the patient's data can be made anonymous.

Archival Procedure

- If necessary, use the trackball to enable archival and export of the exam
- Select the required supports.
- Locate the cursor on OK and press ENTER to confirm.

While data are being saved, the icon for the relevant destination support is outlined by a yellow flashing frame. The frame disappears when the operation ends.

CAUTION

Do not switch off the system nor remove the archiving medium while data is being saved (yellow flashing frame on the destination support). The data and the hard disk could be damaged. If necessary, you may run the Shut Down procedure to interrupt and safely power off the system.

If no option is selected, all stored data will be deleted.

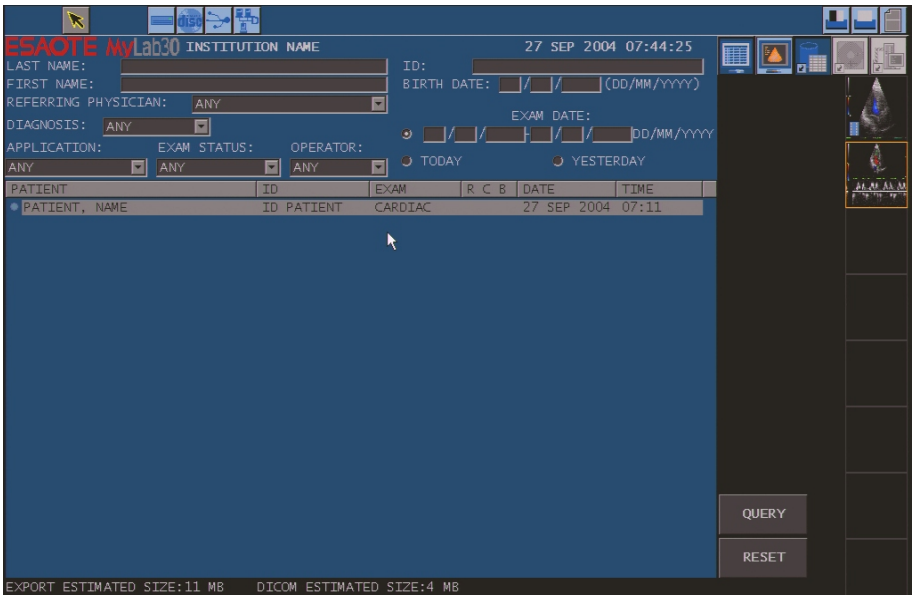
Review of Archived Exams

The operator can reload and review the patient's exams. The images can be reloaded and a specific exam can be reviewed for each patient.

[2] Biopacs Lite is an Esaote DICOM viewer .

The image shows the archive consultation window. The relevant icons are shown at top right.

This key displays the following page.



The system displays the list of archived exams and enables the operator to selectively choose the exams to be reviewed, setting query criteria such as the patient's first name, the application and the exam date.

*The **RESET** key deletes the set search criteria.*

- Use the trackball and alphanumeric keyboard to input the search criteria.
- Locate the pointer on QUERY and press ENTER to activate the search.

At the end of the search, a list of the exams within the set criteria is presented on the screen. The **SCROLL** key enables the operator to scroll inside the list and select the specific exam. To select several exams, use the trackball to position the cursor and press the **Ctrl** and ENTER keys simultaneously.

Archive display icon

After selecting, activate the archive display icon to access the data. The list of selected exams is displayed on the right of the screen next to the thumbnails. Use the trackball to locate the cursor on the required exam and press ENTER to confirm.

The system is in exam review status, and, therefore, the same instructions apply.

AO

The Advanced Operations manual provides a detailed description of the possible operations and of the active software keys.

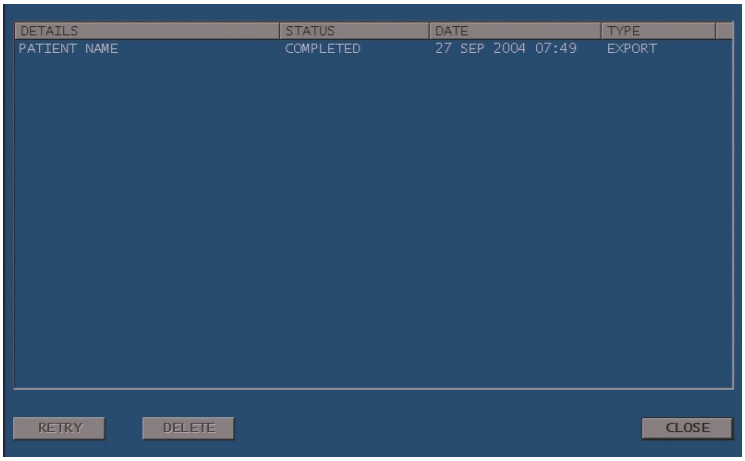
End of Archive Review

The B-MODE or * key closes the archive review session and reactivates real-time. The review session can also be closed by pressing Start End. In this case, all the open exams will be closed before starting on a new patient.

Archival Media Management

When the trackball is operating as a pointer, it is possible to determine the space available in the archive. If the pointer is positioned on the specific icon, the system displays the remaining available memory space.

The operator can also control the data transfer operations. Locate the cursor on the icon of the specific support and press ENTER.



The displayed interactive window enables the operator to follow the operation.

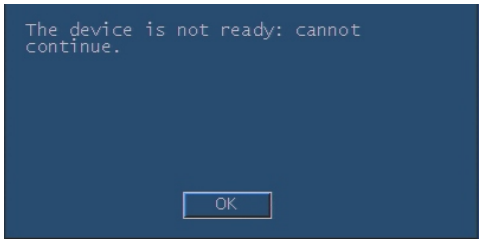
The crossed out icon indicates management problems of the specific archival support. The interactive window allows the operator to understand which operation has failed, and, if necessary, to repeat (RETRY) or cancel the failed operation.

CAUTION

Do not switch off the system nor remove the archiving medium while data are being saved (yellow flashing frame on the destination support). The data and the hard disk could be damaged. If necessary, you may run the Shut Down procedure to interrupt and safely power off the system.

Writable CDs

Empty disks must be used. If the CD contains data, the system will not allow writing and shows the following message:



Rewritable CDs

Rewritable CDs may be used for archiving data providing such CDs are empty.

CD icon

The system allows the deletion of data stored on rewritable CDs. Locate the cursor on the CD icon and press UNDO. The system displays the CD management menu: select "ERASE DEVICE" and press ENTER.

Rewritable DVDs

Empty single-layer DVDs must be used; if the DVD already contains some data, the system won't allow to burn them .

USB Pen Keys

The USB pen keys are managed in multi-sessions. Data can be added to data already on the device.

Chapter 9

9 - System Menu

This chapter describes how to set and configure the system.

Configuration Menu

The **MENU** key provides access to the system menu. The key can be pressed in any environment. The system displays the possible options.

Some menu options are arranged in groups (identified by the symbol ). To display the options included in a group, position the cursor on the group and press the **ENTER** key.

- Select the option with the trackball.
- Press  to continue.

Tools Preset

This option allows to modify the labels used in Stress Echo to identify the single views.

Application Measurements

This option allows the user to configure the available measurement packages by using the  key. **MyLab** allows to program different packages for each application. For each measurement group, one can give a description and enable the desired measures.

The "Advanced Operations" manual provides a detailed description on how to optimally configure the measurements package.

Report Customization

MyLab offers different menus allowing to configure the desired report. The following table lists the available setting options (key ):

Option	Setting
Report Header	Headers setting
Report Print Layout	Selection of data to be printed.
Edit Report Observations	Observations setting.
Report Print Layout	Selection of the template.

This option allows to choose which data have to be inserted into the report, to create a glossary to be used when writing the report, customize the print layout.

AO

Section "System Menu" of the "Advanced Operations" manual details how to configure the report.

Generic Measurements

This option allows to program the generic measurements available for each application.

General Preset

The available options are internally organized in folders. To access the different folders, position the trackball on the required folder and press ENTER.

Parameter Setting

- Position the trackball on the field to be varied and press ENTER to confirm.
- Use the alphanumeric keyboard to type in the characters.
- In the window menus, select the required option and press ENTER to confirm.
- Press OK to confirm.

The **Tab** ⇆ key is used to change over quickly from field to field; the keys **Pgup** ▲ and **Pgdn** ▼ open the window menus and scroll among the relevant options. After the modifications have been confirmed, the system displays following message:

Date/Time

This enables the operator to change the date and time, and to select the required data and time formats (12 or 24 hour).

Center
This field is used for inputting the name of the hospital/clinic, which will then be shown on the screen.

Video
This field is for selecting the required video standard (PAL or NTSC) and the video signal (S-VHS or VHS).

Measure Units
The temperature scale can be set to Celsius or Fahrenheit. This option also allows to select the measure units for height and weight.

Cine
The option allows the user to define the default size of the memory to be used for sequences and to set the default speed.

Archival
When set to auto, the unit automatically saves the exam, per user preset, at the end of the exam without displaying the end exam window.

Trackball
The menu allows the user to set the functioning mode of the trackball left key. The key can be configured as the enter key (**ENTER**) or as the context menu key (**UNDO**).

User Preset

This procedure allows to create a new preset (ADD option), and to modify (EDIT option) or cancel and existing one (CLEAR option) for both standard applications and for specific applications such as Stress Echo. The set presets can be selected in the page allowing the start of the exam or with the **PRESET** button.

Parameter Setting
The menu is organized into one general folder, four mode folders and till four probe folders.

General Folder

With this menu, the operator can assign a name to the new preset and associate a new application with it from among the available applications. From this folder the operator can set general parameters such as the display of the ECG trace, clips duration, and the final archival support for the exam. In the OB application, this folder allows to preselect the exam type (fetal growth or fetal age).

Mode Folders

Every mode (B-Mode, CFM, M-Mode and Doppler) has a specific folder, inside which different parameters can be set.

To save the settings, press SAVE: the set presets will become operable when the system is next powered up. The CLOSE key closes the menu without saving any modifications that may have been made.

The factory presets for the required application (FACTORY SETTINGS key) can be set from the same window.

Probe Folders

For the active preset the system allows to configure four probes. Each probe can be individually configured. As soon as a probe has been selected, the system shows its parameters.

Parameters are gourped in three settigns types: power values, other parameters (number of transmission focuses, 2D sector size etc) and gains.

To save the settings, press SAVE: the set presets will become operable when the system is next powered up. The CLOSE key closes the menu without saving any modifications that may have been made.

AO

The "Advanced Operations" manual provides a detailed description of which parameters can be set in the individual modes.

Peripherals

The system can remotely control (with keys **1** and **2**) recording by VTR (for specific models) and printing (in B&W and color).

The menu also enables the operator to select the required print format. The icon of the set printing format is displayed next to the printer symbol of the relevant printer, in the heading bar.

CAUTION

Do not switch the system off until the printing stage has been completed.

Glossary

When in annotation mode, the system allows the user to enter pre-existing sentences or words. Through this option, applications libraries of words can be created.

AO

The "Advanced Operations" manual provides a detailed description on how to optimally configure the application glossary.

Dicom Configuration

This option allows configuration of the Dicom servers and printers to which the **MyLab** is connected.

Network Drives Configuration

Allows to configure one network drive to be used as archive.

Gray Map

This option allows to edit and save the gray map used in the active application.

Service

This option is strictly for service use and, therefore, its details are given in the system Service Manual.

Save & Load Presets

This option allows the user to save and reload all user presets.

Security

This option allows to define the list of users allowed to work on the system: in this case the access to the system can occur only through a log in procedure, by entering a password.

Licenses

The license number can be input from this option. The license becomes functional at the next power up.

System Configuration

This option displays the system's hardware and software configuration. If a demo license is installed, it is possible to control its expiration date in the corresponding folder.

Shut Down

This option allows to shut down the system. This procedure can be used as an alternative to pressing the **STARTEND** key .

See the "Advanced Operations" manual for futher information.

Chapter 10

10 - System Maintenance

This chapter describes the system's main maintenance operations.

Cleaning of System and Peripheral Units

Periodic cleaning of the system and any connected peripheral units is important. Peripherals may contain dust sensitive parts, the reliability of which could be compromised in the event of poor maintenance.

WARNING

Turn off the system before any cleaning operation.

Make sure that the detergent has completely evaporated before turning on the equipment.

To clean the peripheral units, follow the instructions supplied by the manufacturer.

Cleaning the system

To clean the system, use a soft cloth slightly dampened with water. If necessary, apply a small amount of ammonia- and alcohol-free, not abrasive detergent onto a clean, soft cloth and then wipe the surface. Switch the system off and rub the outside with the cloth.

CAUTION

Do not use any type of ammonia-, alcohol- or benzene-based cleaners on the case.

LCD screen

To clean the LCD screen, use a soft dry cloth, lightly rubbing the display surface.

CAUTION

Do not use detergents or other liquids directly on the screen. Immediately dry any drops of water that may fall on the screen as they could stain the screen.

Cleaning the Trackball

The trackball is easy to remove. With the machine switched off, rotate counter-clockwise the crown surrounding the trackball, exerting light downward pressure. Remove the crown and then remove the trackball.

Clean the trackball with a soft cloth lightly dampened with water or alcohol. Refit the trackball in its housing and lock it by rotating the crown clockwise.

Cleaning the Probe and Gel Holders

These items (available in the mobile configuration) are easily removed from their location for cleaning and can be washed in a mild soap solution. Make sure they are completely dry prior to replacing them.

To clean the transducers, refer to the manual entitled "Transducers and Consumables".

Chapter 11

11 - Technical Specifications

This chapter describes the technical specifications[1] of the **MyLab** product.

AO

Note

Special packages (such as Stress Echo) are listed and described in the specific sections of the Advanced Operations manual.

MyLab Models

MyLab25

Basic Configuration

MyLab25 basic configuration consists in the imaging system licensed for General Imaging applications, i.e.:

- Abdominal
- Breast, Thyroid, Small parts
- Muscolo-skeletal
- Pediatric

The basic configuration may archive and export individual images only (in BMP format).

Optional Applications

The system can be equipped with the following licenses to enhance its applications range:

License	Application	Features
Cardiac	Cardiac, Pediatric cardiac	Presets, Calculations; ECG
Vascular	Peripheral Vascular, Adult cephalic	Presets, Calculations
Urology	Urology	Presets, Calculations
Obstetric	Obstetric, Fetal, Gynaecogical	Presets, Calculations

[1] The specifications can be modified without prior notice.

Optional Modes

The system can be licensed for the following additional modes:

License	Feature	Note
Doppler	Doppler	-
CFM	CFM	-
TEI	TEI	Probe dependent
TVM	TVM	Probe dependent
CMM	Compass M-Mode	Probe dependent

The CFM license requires prior installation of the Doppler license. The TVM license works only if a CFM license is already available. The CMM license requires a cardiac license first.

Optional Features

The following features are optional:

License	Feature
Clip	Clip digital storage
DICOM	DICOM classes
V-Pan	Panoramic View
Xstrain	Strain, Strain rate

MyLab30CV

Basic Configuration

MyLab30CV basic configuration consists in the color imaging system licensed for cardiac (adult and pediatric) applications.

The basic configuration may archive and export individual images only (in BMP format).

Optional Applications

The system can be equipped with the following licenses to enhance its applications range:

License	Application	Features
Vascular	Peripheral Vascular, Adult cephalic	Presets, Calculations
General Imaging	Abdominal, Muscolo-skeletal, Breast, Small parts, Thyroid, Pediatric	Presets, Calculations
Urology	Urology	Presets, Calculations
Obstetric	Obstetric, Fetal, Gynaecogical	Presets, Calculations

Optional Modes

The system can be licensed for the following additional modes:

License	Feature	Note
TEI	TEI	Probe dependent
TVM	TVM	Probe dependent
CMM	Compass M-Mode	Probe dependent

Optional Features

The following features are optional:

License	Feature
Clip	Clip digital storage
DICOM	DICOM classes[2]
V-Pan	Panoramic View
Xstrain	Strain, Strain rate

Portable Configuration

This section describes the product when fully loaded with all options; refer to the previous paragraph for basic configurations.

General

Display

- Built-in LCD, TFT technology, color XVGA

Probe connectors

- 2 electronic probes
- 1 Doppler probe

Video I/O

- XVGA (monitor)
- S-VHS I/O
- VHS I/O
- RGB (TV standard)
- Video standard
  - PAL / NTSC

Connectivity

- I/Os connectors
  - LAN RJ45
  - 2 USB
- Dedicated connectors
  - ECG input
  - Foot switch
- Other
  - Laser/Ink jet printers
- Complies with IHE integration profiles[3]

Image Files

- Formats
  - Standard output file formats (BMP, AVI)
  - Native and Dicom formats
- Clips characteristics
  - AVI Codec: Microsoft® MPEG-4 V2
  - Compression: JPEG lossy compression (about 70% of quality)
- Still frames / BMPs are stored at full resolution

[2] Refer to DICOM Conformance Statement on www.esaote.com for further details.
[3] Refer to www.esaote.com for further details

Software

- Operating system: WIN XP Embedded
- Multi-lingual

Biometry

- Basic and advanced calculation, application dependent
- Annotations, bodymarks

Keyboard

- Echografic
  - Potentiometers for TGC
  - Encoders for general gains
  - Keys for modes, peripherals management and controls

Power Cables

- Power cable with CEE socket
  - Socket: 510 IEC 320/C13 type; 10A-250V
  - Plug: VII (7) VII type; 10A-250V
  - Conductors: 3
  - Section: 1 mm^2
  - Length:2,5 m
- Power cable with CEI socket
  - Socket:: 510 IEC 320/C13 type; 10A-250V
  - Plug: I/3 CEI 23-16 type; 10A-250V
  - Conductors: 3
  - Section: 1 mm^2
  - Length: 2,5 m
- Power cable with NEMA socket
  - Socket type and amperage: 510 IEC 320/C13 type; 13A-125V
  - Plug type: NEMA 5-15; 13A-125V
  - Conductors: 3
  - Section: AWG 16
  - Length: 3 m

Dimensions

- Closed: 35.6 (L) x 15.7 (H) x 49 (D) cm
- In working position: 35.6 (L) x 41 (H) x 49 (D) cm

Weight

- about 9 kg

Power supply

- Voltage operative range
  - 100 ÷ 240 V
- Mains frequency: 50 ÷ 60 Hz
- Power consumption: ≤ 200 VA

Operating requirements

- Temperature: 15÷35°C
- Humidity: 15÷95 % (not condensing)
- Pressure: 700÷1060 hPa

Storage requirements

- Temperature: -20 ÷ +60°C
- Humidity: 5÷95 % (not condensing)
- Pressure: 700÷1060 hPa

Mobile Configuration

Trolley

- Housings:
  - Upper space about 33 (L) x 14.5 (H) x 38.5 (D) cm
  - Lower space about: 33 (L) x 17 (H) x 41 (D) cm
- Dimensions: about 50 (L) x 90 (H) x 51 (D) cm
- Weight: about 31 kg
- Auxiliary power plugs: 4 insulated

Configuration Dimensions

- About 50 (L) x 99,5 (H) x 51 (D) cm

Configuration Weight

- About 45 kg

Power Supply

- Voltage operative range:
  - 100 ÷ 115V
  - 200 ÷ 240 V
- Mains frequency: 50 ÷ 60 Hz
- Power consumption: ≤ 600 VA
- Available power for peripheral units: up to 600 VA

Safety Standards

- EN 60601-1
- EN 60601-1-1
- EN 60601-1-2
- EN 60601-1-4
- EN ISO 10993-1
- EN 60601-2-37
- EN 61157
- AIUM / NEMA UD-2 / UD-3 – FDA 510(k) Track 3

Probes Operating Frequencies and Modes

Phased Array Probes

Probe ID
PA230
PA121
PA122
PA023

Linear Probes

Probe ID
LA522
LA523
LA532
LA424

Convex Probes

Probe ID
CA430
CA421
CA621
CA123

Special Probes

Probe ID
TE022
EC123
IOE323
LP323*

*Not for the U.S. market

Doppler Probes

Probe ID
2CW
5CW

Video requirements

RGB Printer

- Input: RGB SYNC
  - RGB (analog): 0.7 Vp-p, 75 ohm
  - SYNC : 5 Vp-p
- Connectors: standard BNC
- Safety standard: IEC 950 o EN60601-1

b/w Printer

- Input: Video composite (1 Vp-p, 75 ohm)
- Connectors: standard BNC
- Safety standard: IEC 950 o EN60601-1

VTR

- I/O video: YC
  - Y: 1 Vp-p, 75 ohm
  - C: 0.3 Vp-p Color burst, 75 ohm
- Tape format: VHS, S-VHS
- Audio traces: 2
- Connectors:
  - Video: 4 pin connector
  - Audio: jack
- Safety standard: IEC 650 o EN60601-1

Appendix A

Appendix A - Acoustic Output Tables

Acoustic Output Data according to FDA

This section includes the acoustic output tables for each probe and mode of operation (tables structure and measurements precision according to the document "Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers" issued by the FDA on september 30, 1997).

Summary Table

For transducer/mode combinations marked "yes", MI or TI index is equal or greater than 1.0.

Mode	PA230E	PA121E	PA122E	PA023E	LA522E	LA523	IOE323/LP323	2CW	5CW
B/M	Yes	Yes	Yes	No	Yes	Yes	Yes	-	-
TEI (B/M)	Yes	Yes	N/A	N/A	No	Yes	N/A	-	-
CFM (B/M)	Yes	Yes	Yes	Yes	Yes	Yes	Yes	-	-
PW	Yes	Yes	Yes	Yes	Yes	Yes	Yes	-	-
CW	Yes	Yes	Yes	Yes	-	-	-	Yes	Yes

Mode	LA424	LA532E	CA421	CA621	CA430E	CA123	EC123	TE022	LV513
B/M	Yes	No	Yes	Yes	Yes	Yes	Yes	Yes	Yes
TEI (B/M)	N/A	Yes	Yes	No	Yes	Yes	No	Yes	N/A
CFM (B/M)	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
PW	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
CW	-	-	-	-	-	-	-	Yes	-

Operating conditions for maximum acoustic output

Ispta.3 data are in mW/cm².

Probe	Parameter	Max.	System Setting
TE022	Ispta.3	360	M-CFM 5.0MHz Foc=1 PRF=5.6 kHz P=Max
	MI	1.2	M 5.0MHz Foc=1 PRF=5.6 kHz P=Max
PA230E	Ispta.3	561	PW 2.0MHz SS=2mm SD=118 P=Max
	MI	1.3	PW 2.0MHz SS=2mm SD=77mm P=Max
PA122E	Ispta.3	543	PW 5.0MHz SS=2mm SD=20mm P=Max
	MI	1.5	B-CFM 5.0MHz Foc=2 PRF=5.6 kHz P=Max
PA121E	Ispta.3	524	CW 3.3MHz Foc=1 P=Max
	MI	1.5	PW 3.3MHz SS=2mm SD=19mm P=Max
PA023E	Ispta.3	546	CW 5.0MHz Foc=3 P=Max
	MI	1.1	B-CFM(Sens1) 5.0MHz Foc=5 PRF=5.6 kHz P=Max
LA532E	Ispta.3	533	M-TEI PEN Foc=7 PRF=6.7 kHz P=Max
	MI	1.5	PW-B-CFM 3.3MHz SS=2mm SD=61mm P=Max
LV513	Ispta.3	600	M-CFM 5.0MHz Foc=3 PRF=5.6 kHz P=Max
	MI	1.7	PW 6.6MHz SS=2mm SD=57mm P=Max
LA523	Ispta.3	539	B-CFM(Sens1) 6.6MHz Foc=7 PRF=5.6 kHz P=Max
	MI	1.5	B-CFM(Sens1) 5.0MHz Foc=4 PRF=0.7 kHz P=Max
LA522E	Ispta.3	544	M-CFM 5.0MHz Foc=3 PRF=5.6 kHz P=Max
	MI	1.5	B-CFM 5.0MHz Foc=3 PRF=5.6 kHz P=Max
LA424	Ispta.3	474	M-CFM 8.0MHz Foc=3 PRF=5.6 kHz P=Max
	MI	1.5	M 10.0MHz Foc=3 PRF=1.0kHz P=Max
EC123	Ispta.3	522	M 5.0MHz Foc=3 PRF=5.6 kHz P=Max
	MI	1.5	B 5.0MHz Foc=4 PRF=5.6kHz P=Max
CA621	Ispta.3	516	PW 2.5MHz SS=2mm SD=88mm P=Max
	MI	1.2	PW 2.5MHz SS=2mm SD=56mm P=Max
CA430E	Ispta.3	534	PW 2.5MHz SS=2mm SD=90mm P=Max
	MI	1.5	B-TEI PEN Foc=5 PRF=5.6 kHz P=Max
CA421	Ispta.3	529	PW 3.3MHz SS=2mm SD=86mm P=Max
	MI	1.3	PW 3.3MHz SS=2mm SD=26mm P=Max
CA123	Ispta.3	509	M-CFM 5.0MHz Foc=3 PRF=5.6 kHz P=Max
	MI	1.4	B 5.0MHz Foc=3 PRF=5.6 kHz P=Max
IOE323 LP323	Ispta.3	534	M-CFM 6.6MHz Foc=3 PRF=5.6 kHz P=Max
	MI	1.5	M 7.5MHz Foc=3 PRF=1.0kHz P=Max
2.0 CW	Ispta.3	630	CW 2.0MHz P=Max
	MI	<1.0	
5.0 CW	Ispta.3	601	CW 5.0MHz P=Max
	MI	<1.0	

Transducer Model: 2CW Operating Mode: CW

Index Label			MI	TIS			TIB	TIC
				scan	non-scan		non-scan	
					$A_{aprt} \leq 1$	$A_{aprt} > 1$		
Global Maximum Index Value			<1	a	1.1	<1	4.4	b
Assoc. Acoustic Parameter	$Pr_{.3}$	(MPa)	#					
	W_o	(mW)			116		116	
	min of $[W_{.3}(z_1), I_{TA.3}(z_1)]$	(cm)				#		
	Z_1	(cm)				#		
	Z_{bp}	(cm)				#		
	Z_{sp}	(cm)	#				2.9	
	$d_{eq}(Z_{sp})$	(cm)					0.4	
	f_c	(MHz)	#		2	#	2	
	Dim of A_{aprt}	X (cm)			0	#	0	
		Y (cm)			0	#	0	
Other Information	PD	(mSec)	#					
	PRF	(kHz)	#					
	P_r@PII_{max}	(MPa)	#					
	d_{eq}@PII_{max}	(cm)					0.4	
	Focal Length	(cm)			3.3	#		
	$I_{PA.3}$@MI_{max}	(W/cm^2)	#					
Operating Control Conditions	Mode				CW		CW	
	Frequency	(MHz)			2		2	
	Focus				1		1	
	PRF	(kHz)						
	Power				Max		Max	

Notes:
(a) This index is not required for this operating mode.
(b) This probe is not intended for transcranial or neonatal cephalic uses.
(c) This formulation for TIS is less than that for alternate formulation in this probe.
No data are reported for this operating condition since the global maximum index value is not reported for the reason listed.

Transducer Model: 5CW Operating Mode: CW

Index Label			MI	TIS			TIB	TIC
				scan	non-scan		non-scan	
					$A_{aprt} \leq 1$	$A_{aprt} > 1$		
Global Maximum Index Value			<1	a	<1	-	2.7	b
Assoc. Acoustic Parameter	$Pr_{.3}$	(MPa)	#					
	W_o	(mW)			#		33	
	min of $[W_{.3}(z_1), I_{TA.3}(z_1)]$	(cm)				-		
	Z_1	(cm)				-		
	Z_{bp}	(cm)				-		
	Z_{sp}	(cm)	#				0.3	
	$d_{eq}(Z_{sp})$	(cm)					0.2	
	f_c	(MHz)	#		#	-	5	
	Dim of A_{aprt}	X (cm)			#	-	0	
		Y (cm)			#	-	0	
Other Information	PD	(mSec)	#					
	PRF	(kHz)	#					
	$P_r@PII_{max}$	(MPa)	#					
	$d_{eq}@PII_{max}$	(cm)					0.2	
	Focal Length	(cm)			#	-		
	$I_{PA.3}@MI_{max}$	(W/cm^2)	#					
Operating Control Conditions	Mode						CW	
	Frequency	(MHz)					5	
	Focus						1	
	PRF	(kHz)						
	Power						Max	

Notes:
(a) This index is not required for this operating mode.
(b) This probe is not intended for transcranial or neonatal cephalic uses.
(c) This formulation for TIS is less than that for alternate formulation in this probe.
No data are reported for this operating condition since the global maximum index value is not reported for the reason listed.

Transducer Model: CA123 Operating Mode: B\M

Index Label			MI	TIS			TIB	TIC
				scan	non-scan		non-scan	
					$A_{aprt} \leq 1$	$A_{aprt} > 1$		
Global Maximum Index Value			1.4	<1	<1	-	1.3	b
Assoc. Acoustic Parameter	$Pr_{.3}$	(MPa)	2.9					
	W_o	(mW)		#	#		24	
	min of $[W_{.3}(z_1), I_{TA.3}(z_1)]$	(cm)				-		
	Z_1	(cm)				-		
	Z_{bp}	(cm)				-		
	Z_{sp}	(cm)	1.4				1.8	
	$d_{eq}(Z_{sp})$	(cm)					0.2	
	f_c	(MHz)	4.8	#	#	-	4.8	
	Dim of A_{aprt}	X (cm)		#	#	-	0.6	
		Y (cm)		#	#	-	0.4	
Other Information	PD	(mSec)	0.67					
	PRF	(kHz)	5.6					
	$P_r@PII_{max}$	(MPa)	3.2					
	$d_{eq}@PII_{max}$	(cm)					0.2	
	Focal Length	(cm)		#	#	-		
	$I_{PA.3}@MI_{max}$	(W/cm^2)	170					
Operating Control Conditions	Mode		B				M	
	Frequency	(MHz)	5				5	
	Focus		3				5	
	PRF	(kHz)	5.6				5.6	
	Power		Max				Max	

Notes:
(a) This index is not required for this operating mode.
(b) This probe is not intended for transcranial or neonatal cephalic uses.
(c) This formulation for TIS is less than that for alternate formulation in this probe.
No data are reported for this operating condition since the global maximum index value is not reported for the reason listed.

Transducer Model: CA123 Operating Mode: B\M-CFM

Index Label			MI	TIS			TIB	TIC
				scan	non-scan		non-scan	
					$A_{aprt} \leq 1$	$A_{aprt} > 1$		
Global Maximum Index Value			1.3	<1	<1	-	1.2	b
Assoc. Acoustic Parameter	$Pr_{.3}$	(MPa)	3					
	W_o	(mW)		#	#		10	
	min of $[W_{.3}(z_1), I_{TA.3}(z_1)]$	(cm)				-		
	Z_1	(cm)				-		
	Z_{bp}	(cm)				-		
	Z_{sp}	(cm)	1.2				1.2	
	$d_{eq}(Z_{sp})$	(cm)					0.1	
	f_c	(MHz)	4.9	#	#	-	4.8	
	Dim of A_{aprt}	X (cm)		#	#	-	0.5	
		Y (cm)		#	#	-	0.4	
Other Information	PD	(mSec)	0.79					
	PRF	(kHz)	5.6					
	$P_r@PII_{max}$	(MPa)	3.4					
	$d_{eq}@PII_{max}$	(cm)					0.1	
	Focal Length	(cm)		#	#	-		
	$I_{PA.3}@MI_{max}$	(W/cm^2)	301					
Operating Control Conditions	Mode(Sens.)		B(Sens1)				M	
	Frequency	(MHz)	5				5	
	Focus		3				3	
	PRF	(kHz)	0.7				5.6	
	Power		Max				Max	

Notes:
(a) This index is not required for this operating mode.
(b) This probe is not intended for transcranial or neonatal cephalic uses.
(c) This formulation for TIS is less than that for alternate formulation in this probe.
No data are reported for this operating condition since the global maximum index value is not reported for the reason listed.

Transducer Model: CA123 Operating Mode: B\M-TEI

Index Label			MI	TIS			TIB	TIC
				scan	non-scan		non-scan	
					$A_{aprt} \leq 1$	$A_{aprt} > 1$		
Global Maximum Index Value			1	<1	<1	-	<1	b
Assoc. Acoustic Parameter	$Pr_{.3}$	(MPa)	2.1					
	W_o	(mW)		#	#		#	
	min of $[W_{.3}(z_1), I_{TA.3}(z_1)]$	(cm)				-		
	Z_1	(cm)				-		
	Z_{bp}	(cm)				-		
	Z_{sp}	(cm)	1.1				#	
	$d_{eq}(Z_{sp})$	(cm)					#	
	f_c	(MHz)	4.4	#	#	-	#	
	Dim of A_{aprt}	X (cm)		#	#	-	#	
		Y (cm)		#	#	-	#	
Other Information	PD	(mSec)	0.62					
	PRF	(kHz)	5.6					
	$P_r@PII_{max}$	(MPa)	2.4					
	$d_{eq}@PII_{max}$	(cm)					#	
	Focal Length	(cm)		#	#	-		
	$I_{PA.3}@MI_{max}$	(W/cm^2)	115					
Operating Control Conditions	Mode		B-TEI					
	Frequency	(MHz)	PEN					
	Focus		2					
	PRF	(kHz)	5.6					
	Power		Max					

Notes:
(a) This index is not required for this operating mode.
(b) This probe is not intended for transcranial or neonatal cephalic uses.
(c) This formulation for TIS is less than that for alternate formulation in this probe.
No data are reported for this operating condition since the global maximum index value is not reported for the reason listed.

Transducer Model: CA123 Operating Mode: PW

Index Label			MI	TIS			TIB	TIC
				scan	non-scan		non-scan	
					$A_{aprt} \leq 1$	$A_{aprt} > 1$		
Global Maximum Index Value			1.3	a	<1	-	1.9	b
Assoc. Acoustic Parameter	$Pr_{.3}$	(MPa)	3.1					
	W_o	(mW)			#		33	
	min of $[W_{.3}(z_1), I_{TA.3}(z_1)]$	(cm)				-		
	Z_1	(cm)				-		
	Z_{bp}	(cm)				-		
	Z_{sp}	(cm)	1.4				1.1	
	$d_{eq}(Z_{sp})$	(cm)					0.3	
	f_c	(MHz)	5.9		#	-	4.9	
	Dim of A_{aprt} X	(cm)			#	-	0.7	
	Y	(cm)			#	-	0.4	
Other Information	PD	(mSec)	0.44					
	PRF	(kHz)	5.6					
	$P_r@PII_{max}$	(MPa)	4					
	$d_{eq}@PII_{max}$	(cm)					0.2	
	Focal Length	(cm)			#	-		
	$I_{PA.3}@MI_{max}$	(W/cm²)	333					
Operating Control Conditions	Mode		PW-B-CFM				PW	
	Frequency	(MHz)	6.6				5	
	Sample Depth	(mm)	0				45	
	Sample Size	(mm)	0				2	
	Power		Max				Max	

Notes:
(a) This index is not required for this operating mode.
(b) This probe is not intended for transcranial or neonatal cephalic uses.
(c) This formulation for TIS is less than that for alternate formulation in this probe.
No data are reported for this operating condition since the global maximum index value is not reported for the reason listed.

Transducer Model: CA421 Operating Mode: B\M

Index Label			MI	TIS			TIB	TIC
				scan	non-scan		non-scan	
					$A_{aprt} \leq 1$	$A_{aprt} > 1$		
Global Maximum Index Value			1.2	2.8	1.8	2.4	3.6	b
Assoc. Acoustic Parameter	$Pr_{.3}$	(MPa)	2.2					
	W_o	(mW)		200	114		200	
	min of $[W_{.3}(z_1), I_{TA.3}(z_1)]$	(cm)				75		
	Z_1	(cm)				2.5		
	Z_{bp}	(cm)				1.9		
	Z_{sp}	(cm)	4.8				4.5	
	$d_{eq}(Z_{sp})$	(cm)					0.4	
	f_c	(MHz)	2.9	2.9	3	3	3	
	Dim of A_{aprt}	X (cm)		1.1	0.8	1.1	1.1	
		Y (cm)		1.2	1.2	1.2	1.2	
Other Information	PD	(mSec)	0.64					
	PRF	(kHz)	5.6					
	$P_r@PII_{max}$	(MPa)	3.4					
	$d_{eq}@PII_{max}$	(cm)					0.4	
	Focal Length	(cm)		4.8	3.9	4.8		
	$I_{PA.3}@MI_{max}$	(W/cm^2)	152					
Operating Control Conditions	Mode		B	B	M	M	M	
	Frequency	(MHz)	3.5	3.5	3.5	3.5	3.5	
	Focus		6	6	4	6	6	
	PRF	(kHz)	5.6	5.6	5.6	5.6	5.6	
	Power		Max	Max	Max	Max	Max	

Notes:
(a) This index is not required for this operating mode.
(b) This probe is not intended for transcranial or neonatal cephalic uses.
(c) This formulation for TIS is less than that for alternate formulation in this probe.
No data are reported for this operating condition since the global maximum index value is not reported for the reason listed.

Transducer Model: CA421 Operating Mode: B\M-CFM

Index Label			MI	TIS			TIB	TIC
				scan	non-scan		non-scan	
					$A_{aprt} \leq 1$	$A_{aprt} > 1$		
Global Maximum Index Value			1.1	3.4	1.7	1.7	3.5	b
Assoc. Acoustic Parameter	$Pr_{.3}$	(MPa)	2.1					
	W_o	(mW)		224	118		140	
	min of $[W_{.3}(z_1), I_{TA.3}(z_1)]$	(cm)				120		
	Z_1	(cm)				1.8		
	Z_{bp}	(cm)				1.8		
	Z_{sp}	(cm)	4.3				4.2	
	$d_{eq}(Z_{sp})$	(cm)					0.4	
	f_c	(MHz)	3	3.2	3	3	3	
	Dim of A_{aprt} X	(cm)		1.3	0.8	1	1	
	Y	(cm)		1.2	1.2	1.2	1.2	
Other Information	PD	(mSec)	0.54					
	PRF	(kHz)	5.6					
	$P_r@PII_{max}$	(MPa)	3.1					
	$d_{eq}@PII_{max}$	(cm)					0.4	
	Focal Length	(cm)		5.5	4	4.3		
	$I_{PA.3}@MI_{max}$	(W/cm^2)	156					
Operating Control Conditions	Mode(Sens.)		M	B(Sens2)	M	M	M	
	Frequency	(MHz)	3.3	3.3	3.3	3.3	3.3	
	Focus		5	8	4	5	5	
	PRF	(kHz)	5.6	4.2	5.6	5.6	5.6	
	Power		Max	Max	Max	Max	Max	

Notes:
(a) This index is not required for this operating mode.
(b) This probe is not intended for transcranial or neonatal cephalic uses.
(c) This formulation for TIS is less than that for alternate formulation in this probe.
No data are reported for this operating condition since the global maximum index value is not reported for the reason listed.

Transducer Model: CA421 Operating Mode: B\M-TEI

Index Label			MI	TIS			TIB	TIC
				scan	non-scan		non-scan	
					$A_{aprt} \leq 1$	$A_{aprt} > 1$		
Global Maximum Index Value			<1	<1	<1	<1	1.5	b
Assoc. Acoustic Parameter	$Pr_{.3}$	(MPa)	#					
	W_o	(mW)		#	#		68	
	min of $[W_{.3}(z_1), I_{TA.3}(z_1)]$	(cm)				#		
	Z_1	(cm)				#		
	Z_{bp}	(cm)				#		
	Z_{sp}	(cm)	#				3.5	
	$d_{eq}(Z_{sp})$	(cm)					0.4	
	f_c	(MHz)	#	#	#	#	2.1	
	Dim of A_{aprt}	X (cm)		#	#	#	1.1	
		Y (cm)		#	#	#	1.2	
Other Information	PD	(mSec)	#					
	PRF	(kHz)	#					
	P_r@PII_{max}	(MPa)	#					
	d_{eq}@PII_{max}	(cm)					0.4	
	Focal Length	(cm)		#	#	#		
	$I_{PA.3}$@MI_{max}	(W/cm²)	#					
Operating Control Conditions	Mode						M-TEI	
	Frequency	(MHz)					RES	
	Focus						6	
	PRF	(kHz)					5.6	
	Power						Max	

Notes:
(a) This index is not required for this operating mode.
(b) This probe is not intended for transcranial or neonatal cephalic uses.
(c) This formulation for TIS is less than that for alternate formulation in this probe.
No data are reported for this operating condition since the global maximum index value is not reported for the reason listed.

Transducer Model: CA421 Operating Mode: PW

Index Label			MI	TIS			TIB	TIC
				scan	non-scan		non-scan	
					$A_{aprt} \leq 1$	$A_{aprt} > 1$		
Global Maximum Index Value			1.3	a	2.3	2.2	4.3	b
Assoc. Acoustic Parameter	$Pr_{.3}$	(MPa)	2.4					
	W_o	(mW)			138		138	
	min of $[W_{.3}(z_1), I_{TA.3}(z_1)]$	(cm)				147		
	Z_1	(cm)				2.2		
	Z_{bp}	(cm)				2.1		
	Z_{sp}	(cm)	1.4				2.2	
	$d_{eq}(Z_{sp})$	(cm)					0.5	
	f_c	(MHz)	3.2		3.2	3.2	3.2	
	Dim of A_{aprt} X	(cm)			0.7	1.3	0.7	
	Y	(cm)			1.2	1.2	1.2	
Other Information	PD	(mSec)	1.14					
	PRF	(kHz)	2.1					
	$P_r@PII_{max}$	(MPa)	2.6					
	$d_{eq}@PII_{max}$	(cm)					0.4	
	Focal Length	(cm)			4.5	5.8		
	$I_{PA.3}@MI_{max}$	(W/cm²)	167					
Operating Control Conditions	Mode		PW		PW	PW	PW	
	Frequency	(MHz)	3.3		3.3	3.3	3.3	
	Sample Depth	(mm)	26		44	135	44	
	Sample Size	(mm)	2		2	2	2	
	Power		Max		Max	Max	Max	

Notes:
(a) This index is not required for this operating mode.
(b) This probe is not intended for transcranial or neonatal cephalic uses.
(c) This formulation for TIS is less than that for alternate formulation in this probe.
No data are reported for this operating condition since the global maximum index value is not reported for the reason listed.

Transducer Model: CA431 Operating Mode: B\M

Index Label			MI	TIS			TIB	TIC
				scan	non-scan		non-scan	
					$A_{aprt} \leq 1$	$A_{aprt} > 1$		
Global Maximum Index Value			1.5	3.8	2.4	3.2	3.8	b
Assoc. Acoustic Parameter	$Pr_{.3}$	(MPa)	2.5					
	W_o	(mW)		215	136		214	
	min of $[W_{.3}(z_1), I_{TA.3}(z_1)]$	(cm)				85		
	Z_1	(cm)				2		
	Z_{bp}	(cm)				2		
	Z_{sp}	(cm)	3.9				1.1	
	$d_{eq}(Z_{sp})$	(cm)					0.9	
	f_c	(MHz)	2.5	3.7	3.5	3.5	3.5	
	Dim of A_{aprt} X	(cm)		1.2	0.7	1.2	1.2	
	Y	(cm)		1.2	1.2	1.2	1.2	
Other Information	PD	(mSec)	0.66					
	PRF	(kHz)	5.6					
	$P_r@PII_{max}$	(MPa)	3.3					
	$d_{eq}@PII_{max}$	(cm)					0.5	
	Focal Length	(cm)		5.3	2.9	5.2		
	$I_{PA.3}@MI_{max}$	(W/cm²)	214					
Operating Control Conditions	Mode		B	B	M	M	M	
	Frequency	(MHz)	2.5	6.6	5	5	5	
	Focus		6	7	3	7	7	
	PRF	(kHz)	5.6	4.8	5.6	4.8	4.8	
	Power		Max	Max	Max	Max	Max	

Notes:
(a) This index is not required for this operating mode.
(b) This probe is not intended for transcranial or neonatal cephalic uses.
(c) This formulation for TIS is less than that for alternate formulation in this probe.
No data are reported for this operating condition since the global maximum index value is not reported for the reason listed.

Transducer Model: CA431 Operating Mode: B\M-CFM

Index Label			MI	TIS			TIB	TIC
				scan	non-scan		non-scan	
					$A_{aprt} \leq 1$	$A_{aprt} > 1$		
Global Maximum Index Value			1.3	2.9	1.5	2	3.9	b
Assoc. Acoustic Parameter	$Pr_{.3}$	(MPa)	2.4					
	W_o	(mW)		216	118		192	
	min of $[W_{.3}(z_1), I_{TA.3}(z_1)]$	(cm)				154		
	Z_1	(cm)				2.1		
	Z_{bp}	(cm)				2.1		
	Z_{sp}	(cm)	4.6				4	
	$d_{eq}(Z_{sp})$	(cm)					0.5	
	f_c	(MHz)	2.7	2.8	2.8	2.7	2.5	
	Dim of A_{aprt} X	(cm)		1.3	0.8	1.3	1.2	
	Y	(cm)		1.2	1.2	1.2	1.2	
Other Information	PD	(mSec)	0.57					
	PRF	(kHz)	4.2					
	$P_r@PII_{max}$	(MPa)	3.2					
	$d_{eq}@PII_{max}$	(cm)					0.5	
	Focal Length	(cm)		5	3.1	5		
	$I_{PA.3}@MI_{max}$	(W/cm^2)	145					
Operating Control Conditions	Mode(Sens.)		M	B(Sens2)	M	M	M	
	Frequency	(MHz)	2.9	2.9	2.9	2.9	2.5	
	Focus		7	8	4	8	7	
	PRF	(kHz)	4.2	3.7	5.6	3.7	4.2	
	Power		Max	Max	Max	Max	Max	

Notes:
(a) This index is not required for this operating mode.
(b) This probe is not intended for transcranial or neonatal cephalic uses.
(c) This formulation for TIS is less than that for alternate formulation in this probe.
No data are reported for this operating condition since the global maximum index value is not reported for the reason listed.

Transducer Model: CA431 Operating Mode: B\M-TEI

Index Label			MI	TIS			TIB	TIC
				scan	non-scan		non-scan	
					$A_{aprt} \leq 1$	$A_{aprt} > 1$		
Global Maximum Index Value			1.5	3.5	2.4	3.3	3.2	b
Assoc. Acoustic Parameter	$Pr_{.3}$	(MPa)	2.3					
	W_o	(mW)		155	107		165	
	min of $[W_{.3}(z_1), I_{TA.3}(z_1)]$	(cm)				63		
	Z_1	(cm)				1.9		
	Z_{bp}	(cm)				1.9		
	Z_{sp}	(cm)	2.6				1	
	$d_{eq}(Z_{sp})$	(cm)					1	
	f_c	(MHz)	2.2	4.8	4.8	4.8	4.8	
	Dim of A_{aprt} X	(cm)		0.8	0.8	1.1	1.1	
	Y	(cm)		1.2	1.2	1.2	1.2	
Other Information	PD	(mSec)	0.82					
	PRF	(kHz)	5.6					
	$P_r@PII_{max}$	(MPa)	2.2					
	$d_{eq}@PII_{max}$	(cm)					0.5	
	Focal Length	(cm)		4.1	4.1	5		
	$I_{PA.3}@MI_{max}$	(W/cm²)	59					
Operating Control Conditions	Mode		B-TEI	B-TEI	M-TEI	M-TEI	M-TEI	
	Frequency	(MHz)	GEN	PEN	PEN	PEN	PEN	
	Focus		3	4	4	6	6	
	PRF	(kHz)	5.6	5.6	5.6	5.6	5.6	
	Power		Max	Max	Max	Max	Max	

Notes:
(a) This index is not required for this operating mode.
(b) This probe is not intended for transcranial or neonatal cephalic uses.
(c) This formulation for TIS is less than that for alternate formulation in this probe.
No data are reported for this operating condition since the global maximum index value is not reported for the reason listed.

Transducer Model: CA431 Operating Mode: PW

Index Label			MI	TIS			TIB	TIC
				scan	non-scan		non-scan	
					$A_{aprt} \leq 1$	$A_{aprt} > 1$		
Global Maximum Index Value			1.4	a	2.3	2.7	4.8	b
Assoc. Acoustic Parameter	$Pr_{.3}$	(MPa)	2.4					
	W_o	(mW)			171		230	
	min of $[W_{.3}(z_1), I_{TA.3}(z_1)]$	(cm)				75		
	Z_1	(cm)				2.1		
	Z_{bp}	(cm)				2.1		
	Z_{sp}	(cm)	1				1.1	
	$d_{eq}(Z_{sp})$	(cm)					0.9	
	f_c	(MHz)	2.8		2.8	2.8	2.8	
	Dim of A_{aprt} X	(cm)			0.8	1.3	1.2	
	Y	(cm)			1.2	1.2	1.2	
Other Information	PD	(mSec)	0.61					
	PRF	(kHz)	5.6					
	$P_r@PII_{max}$	(MPa)	2.6					
	$d_{eq}@PII_{max}$	(cm)					0.5	
	Focal Length	(cm)			3.1	5		
	$I_{PA.3}@MI_{max}$	(W/cm²)	159					
Operating Control Conditions	Mode		PW-B-CFM		PW-B-CFM	PW	PW	
	Frequency	(MHz)	2.9		2.9	2.9	2.9	
	Sample Depth	(mm)	0		0	140	107	
	Sample Size	(mm)	0		0	2	2	
	Power		Max		Max	Max	Max	

Notes:
(a) This index is not required for this operating mode.
(b) This probe is not intended for transcranial or neonatal cephalic uses.
(c) This formulation for TIS is less than that for alternate formulation in this probe.
No data are reported for this operating condition since the global maximum index value is not reported for the reason listed.

Transducer Model: CA621 Operating Mode: B\M

Index Label			MI	TIS			TIB	TIC
				scan	non-scan		non-scan	
					$A_{aprt} \leq 1$	$A_{aprt} > 1$		
Global Maximum Index Value			1.2	1.9	1.2	1.6	2.7	b
Assoc. Acoustic Parameter	$Pr_{.3}$	(MPa)	2					
	W_o	(mW)		162	100		161	
	min of $[W_{.3}(z_1), I_{TA.3}(z_1)]$	(cm)				59		
	Z_1	(cm)				3		
	Z_{bp}	(cm)				2.2		
	Z_{sp}	(cm)	4.2				5.2	
	$d_{eq}(Z_{sp})$	(cm)					0.4	
	f_c	(MHz)	2.5	2.5	2.5	2.5	2.5	
	Dim of A_{aprt}	X (cm)		1.1	0.8	1.4	1.4	
		Y (cm)		1.2	1.2	1.2	1.2	
Other Information	PD	(mSec)	1.05					
	PRF	(kHz)	5.6					
	$P_r@PII_{max}$	(MPa)	2.8					
	$d_{eq}@PII_{max}$	(cm)					0.4	
	Focal Length	(cm)		4.8	4.2	6.1		
	$I_{PA.3}@MI_{max}$	(W/cm^2)	123					
Operating Control Conditions	Mode		B	B	M	M	M	
	Frequency	(MHz)	2.5	2.5	2.5	2.5	2.5	
	Focus		5	6	4	7	7	
	PRF	(kHz)	5.6	5.6	5.6	4.8	4.8	
	Power		Max	Max	Max	Max	Max	

Notes:
(a) This index is not required for this operating mode.
(b) This probe is not intended for transcranial or neonatal cephalic uses.
(c) This formulation for TIS is less than that for alternate formulation in this probe.
No data are reported for this operating condition since the global maximum index value is not reported for the reason listed.

Transducer Model: CA621 Operating Mode: B\M-CFM

Index Label			MI	TIS			TIB	TIC
				scan	non-scan		non-scan	
					$A_{aprt} \leq 1$	$A_{aprt} > 1$		
Global Maximum Index Value			1	2.8	1.7	1.8	3.5	b
Assoc. Acoustic Parameter	$Pr_{.3}$	(MPa)	1.6					
	W_o	(mW)		181	114		232	
	min of $[W_{.3}(z_1), I_{TA.3}(z_1)]$	(cm)				171		
	Z_1	(cm)				2.8		
	Z_{bp}	(cm)				2.4		
	Z_{sp}	(cm)	4.3				3.5	
	$d_{eq}(Z_{sp})$	(cm)					0.7	
	f_c	(MHz)	2.5	3.3	3.1	2.4	2.4	
	Dim of A_{aprt}	X (cm)		1.4	0.7	1.6	1.6	
		Y (cm)		1.2	1.2	1.2	1.2	
Other Information	PD	(mSec)	1.23					
	PRF	(kHz)	5.6					
	$P_r@PII_{max}$	(MPa)	2.2					
	$d_{eq}@PII_{max}$	(cm)					0.5	
	Focal Length	(cm)		6	4.6	7.3		
	$I_{PA.3}@MI_{max}$	(W/cm²)	123					
Operating Control Conditions	Mode(Sens.)		B(Sens1)	B(Sens2)	M	M	M	
	Frequency	(MHz)	2.5	3.3	3.3	2.5	2.5	
	Focus		5	7	3	8	8	
	PRF	(kHz)	5.6	4.2	5.6	3.7	3.7	
	Power		Max	Max	Max	Max	Max	

Notes:
(a) This index is not required for this operating mode.
(b) This probe is not intended for transcranial or neonatal cephalic uses.
(c) This formulation for TIS is less than that for alternate formulation in this probe.
No data are reported for this operating condition since the global maximum index value is not reported for the reason listed.

Transducer Model: CA621 Operating Mode: PW

Index Label			MI	TIS			TIB	TIC
				scan	non-scan		non-scan	
					$A_{aprt} \leq 1$	$A_{aprt} > 1$		
Global Maximum Index Value			1.2	a	1.9	2.1	3.5	b
Assoc. Acoustic Parameter	$Pr_{.3}$	(MPa)	2					
	W_o	(mW)			132		160	
	min of $[W_{.3}(z_1), I_{TA.3}(z_1)]$	(cm)				57		
	Z_1	(cm)				3.4		
	Z_{bp}	(cm)				2.4		
	Z_{sp}	(cm)	3.9				5	
	$d_{eq}(Z_{sp})$	(cm)					0.4	
	f_c	(MHz)	2.5		3.1	3	2.5	
	Dim of A_{aprt} X	(cm)			0.8	1.6	1.4	
	Y	(cm)			1.2	1.2	1.2	
Other Information	PD	(mSec)	1.63					
	PRF	(kHz)	2.1					
	$P_r@PII_{max}$	(MPa)	2.7					
	$d_{eq}@PII_{max}$	(cm)					0.4	
	Focal Length	(cm)			4.8	7.6		
	$I_{PA.3}@MI_{max}$	(W/cm²)	142					
Operating Control Conditions	Mode		PW		PW-B-CFM	PW-B-CFM	PW	
	Frequency	(MHz)	2.5		3.3	3.3	2.5	
	Sample Depth	(mm)	56		0	0	105	
	Sample Size	(mm)	2		0	0	2	
	Power		Max		Max	Max	Max	

Notes:
(a) This index is not required for this operating mode.
(b) This probe is not intended for transcranial or neonatal cephalic uses.
(c) This formulation for TIS is less than that for alternate formulation in this probe.
No data are reported for this operating condition since the global maximum index value is not reported for the reason listed.

Transducer Model: EC123 Operating Mode: B\M

Index Label			MI	TIS			TIB	TIC
				scan	non-scan		non-scan	
					$A_{aprt} \leq 1$	$A_{aprt} > 1$		
Global Maximum Index Value			1.5	<1	<1	-	1.1	b
Assoc. Acoustic Parameter	$Pr_{.3}$	(MPa)	3.5					
	W_o	(mW)		#	#		20	
	min of $[W_{.3}(z_1), I_{TA.3}(z_1)]$	(cm)				-		
	Z_1	(cm)				-		
	Z_{bp}	(cm)				-		
	Z_{sp}	(cm)	1				1.2	
	$d_{eq}(Z_{sp})$	(cm)					0.2	
	f_c	(MHz)	5	#	#	-	5	
	Dim of A_{aprt}	X (cm)		#	#	-	0.5	
		Y (cm)		#	#	-	0.4	
Other Information	PD	(mSec)	0.44					
	PRF	(kHz)	5.6					
	$P_r@PII_{max}$	(MPa)	3.9					
	$d_{eq}@PII_{max}$	(cm)					0.2	
	Focal Length	(cm)		#	#	-		
	$I_{PA.3}@MI_{max}$	(W/cm^2)	371					
Operating Control Conditions	Mode		B				M	
	Frequency	(MHz)	5				5	
	Focus		4				7	
	PRF	(kHz)	5.6				5.6	
	Power		Max				Max	

Notes:
(a) This index is not required for this operating mode.
(b) This probe is not intended for transcranial or neonatal cephalic uses.
(c) This formulation for TIS is less than that for alternate formulation in this probe.
No data are reported for this operating condition since the global maximum index value is not reported for the reason listed.

Transducer Model: EC123 Operating Mode: B\M-CFM

Index Label			MI	TIS			TIB	TIC
				scan	non-scan		non-scan	
					$A_{aprt} \leq 1$	$A_{aprt} > 1$		
Global Maximum Index Value			1.4	<1	<1	-	1.3	b
Assoc. Acoustic Parameter	$Pr_{.3}$	(MPa)	3.1					
	W_o	(mW)		#	#		13	
	min of $[W_{.3}(z_1), I_{TA.3}(z_1)]$	(cm)				-		
	Z_1	(cm)				-		
	Z_{bp}	(cm)				-		
	Z_{sp}	(cm)	1.2				1.2	
	$d_{eq}(Z_{sp})$	(cm)					0.2	
	f_c	(MHz)	5.1	#	#	-	5	
	Dim of A_{aprt}	X (cm)		#	#	-	0.4	
		Y (cm)		#	#	-	0.4	
Other Information	PD	(mSec)	0.51					
	PRF	(kHz)	5.6					
	$P_r@PII_{max}$	(MPa)	3.6					
	$d_{eq}@PII_{max}$	(cm)					0.1	
	Focal Length	(cm)		#	#	-		
	$I_{PA.3}@MI_{max}$	(W/cm^2)	364					
Operating Control Conditions	Mode(Sens.)		B(Sens1)				M	
	Frequency	(MHz)	5				5	
	Focus		3				6	
	PRF	(kHz)	0.7				5.6	
	Power		Max				Max	

Notes:
(a) This index is not required for this operating mode.
(b) This probe is not intended for transcranial or neonatal cephalic uses.
(c) This formulation for TIS is less than that for alternate formulation in this probe.
No data are reported for this operating condition since the global maximum index value is not reported for the reason listed.

Transducer Model: EC123 Operating Mode: PW

Index Label			MI	TIS			TIB	TIC
				scan	non-scan		non-scan	
					$A_{aprt} \leq 1$	$A_{aprt} > 1$		
Global Maximum Index Value			1.4	a	<1	-	1.6	b
Assoc. Acoustic Parameter	$Pr_{.3}$	(MPa)	3					
	W_o	(mW)			#		21	
	min of $[W_{.3}(z_1), I_{TA.3}(z_1)]$	(cm)				-		
	Z_1	(cm)				-		
	Z_{bp}	(cm)				-		
	Z_{sp}	(cm)	1.2				1.4	
	$d_{eq}(Z_{sp})$	(cm)					0.2	
	f_c	(MHz)	5.1		#	-	5.1	
	Dim of A_{aprt} X	(cm)			#	-	0.5	
	Y	(cm)			#	-	0.4	
Other Information	PD	(mSec)	0.65					
	PRF	(kHz)	2.1					
	$P_r@PII_{max}$	(MPa)	3.7					
	$d_{eq}@PII_{max}$	(cm)					0.2	
	Focal Length	(cm)			#	-		
	$I_{PA.3}@MI_{max}$	(W/cm^2)	319					
Operating Control Conditions	Mode		PW				PW	
	Frequency	(MHz)	5				5	
	Sample Depth	(mm)	18				96	
	Sample Size	(mm)	2				2	
	Power		Max				Max	

Notes:
(a) This index is not required for this operating mode.
(b) This probe is not intended for transcranial or neonatal cephalic uses.
(c) This formulation for TIS is less than that for alternate formulation in this probe.
No data are reported for this operating condition since the global maximum index value is not reported for the reason listed.

Transducer Model: IOE323/LP323 Operating Mode: B\M

Index Label			MI	TIS			TIB	TIC
				scan	non-scan		non-scan	
					$A_{aprt} \leq 1$	$A_{aprt} > 1$		
Global Maximum Index Value			1.5	<1	<1	-	1.2	b
Assoc. Acoustic Parameter	$Pr_{.3}$	(MPa)	3.9					
	W_o	(mW)		#	#		26	
	min of $[W_{.3}(z_1), I_{TA.3}(z_1)]$	(cm)				-		
	Z_1	(cm)				-		
	Z_{bp}	(cm)				-		
	Z_{sp}	(cm)	1.2				1	
	$d_{eq}(Z_{sp})$	(cm)					0.2	
	f_c	(MHz)	5.8	#	#	-	5.9	
	Dim of A_{aprt}	X (cm)		#	#	-	0.7	
		Y (cm)		#	#	-	0.4	
Other Information	PD	(mSec)	0.22					
	PRF	(kHz)	1					
	$P_r@PII_{max}$	(MPa)	4.7					
	$d_{eq}@PII_{max}$	(cm)					0.2	
	Focal Length	(cm)		#	#	-		
	$I_{PA.3}@MI_{max}$	(W/cm^2)	444					
Operating Control Conditions	Mode		M				M	
	Frequency	(MHz)	7.5				7.5	
	Focus		3				8	
	PRF	(kHz)	1				6.7	
	Power		Max				Max	

Notes:
(a) This index is not required for this operating mode.
(b) This probe is not intended for transcranial or neonatal cephalic uses.
(c) This formulation for TIS is less than that for alternate formulation in this probe.
No data are reported for this operating condition since the global maximum index value is not reported for the reason listed.

Transducer Model: IOE323/LP323 Operating Mode: B\M-CFM

Index Label			MI	TIS			TIB	TIC
				scan	non-scan		non-scan	
					$A_{aprt} \leq 1$	$A_{aprt} > 1$		
Global Maximum Index Value			1.5	2.1	<1	-	1.4	b
Assoc. Acoustic Parameter	$Pr_{.3}$	(MPa)	3.8					
	W_o	(mW)		67	#		23	
	min of $[W_{.3}(z_1), I_{TA.3}(z_1)]$	(cm)				-		
	Z_1	(cm)				-		
	Z_{bp}	(cm)				-		
	Z_{sp}	(cm)	1.1				1	
	$d_{eq}(Z_{sp})$	(cm)					0.3	
	f_c	(MHz)	6.4	6.6	#	-	5.1	
	Dim of A_{aprt}	X (cm)		0.7	#	-	0.7	
		Y (cm)		0.4	#	-	0.4	
Other Information	PD	(mSec)	0.47					
	PRF	(kHz)	5.6					
	$P_r@PII_{max}$	(MPa)	4.9					
	$d_{eq}@PII_{max}$	(cm)					0.3	
	Focal Length	(cm)		1.3	#	-		
	$I_{PA.3}@MI_{max}$	(W/cm^2)	440					
Operating Control Conditions	Mode(Sens.)		B(Sens1)	B(Sens2)			M	
	Frequency	(MHz)	6.6	6.6			5	
	Focus		3	8			8	
	PRF	(kHz)	0.7	5.6			5.6	
	Power		Max	Max			Max	

Notes:
(a) This index is not required for this operating mode.
(b) This probe is not intended for transcranial or neonatal cephalic uses.
(c) This formulation for TIS is less than that for alternate formulation in this probe.
No data are reported for this operating condition since the global maximum index value is not reported for the reason listed.

Transducer Model: IOE323/LP323 Operating Mode: PW

Index Label			MI	TIS			TIB	TIC
				scan	non-scan		non-scan	
					$A_{aprt} \leq 1$	$A_{aprt} > 1$		
Global Maximum Index Value			1.5	a	1.1	-	2	b
Assoc. Acoustic Parameter	$Pr_{.3}$	(MPa)	3.8					
	W_o	(mW)			34		34	
	min of $[W_{.3}(z_1), I_{TA.3}(z_1)]$	(cm)				-		
	Z_1	(cm)				-		
	Z_{bp}	(cm)				-		
	Z_{sp}	(cm)	1.2				1.1	
	$d_{eq}(Z_{sp})$	(cm)					0.2	
	f_c	(MHz)	6.2		6.6	-	6.6	
	Dim of A_{aprt} X	(cm)			0.7	-	0.7	
	Y	(cm)			0.4	-	0.4	
Other Information	PD	(mSec)	0.33					
	PRF	(kHz)	5.6					
	$P_r@PII_{max}$	(MPa)	4.9					
	$d_{eq}@PII_{max}$	(cm)					0.2	
	Focal Length	(cm)			1.3	-		
	$I_{PA.3}@MI_{max}$	(W/cm^2)	488					
Operating Control Conditions	Mode		PW-B-CFM		PW		PW	
	Frequency	(MHz)	6.6		6.6		6.6	
	Sample Depth	(mm)	0		60		60	
	Sample Size	(mm)	0		2		2	
	Power		Max		Max		Max	

Notes:
(a) This index is not required for this operating mode.
(b) This probe is not intended for transcranial or neonatal cephalic uses.
(c) This formulation for TIS is less than that for alternate formulation in this probe.
No data are reported for this operating condition since the global maximum index value is not reported for the reason listed.

Transducer Model: LA424 Operating Mode: B\M

Index Label			MI	TIS			TIB	TIC
				scan	non-scan		non-scan	
					$A_{aprt} \leq 1$	$A_{aprt} > 1$		
Global Maximum Index Value			1.5	<1	<1	-	1	b
Assoc. Acoustic Parameter	$Pr_{.3}$	(MPa)	4.4					
	W_o	(mW)		#	#		15	
	min of $[W_{.3}(z_1), I_{TA.3}(z_1)]$	(cm)				-		
	Z_1	(cm)				-		
	Z_{bp}	(cm)				-		
	Z_{sp}	(cm)	0.7				0.6	
	$d_{eq}(Z_{sp})$	(cm)					0.2	
	f_c	(MHz)	9.1	#	#	-	9.2	
	Dim of A_{aprt}	X (cm)		#	#	-	0.5	
		Y (cm)		#	#	-	0.3	
Other Information	PD	(mSec)	0.19					
	PRF	(kHz)	1					
	$P_r@PII_{max}$	(MPa)	5					
	$d_{eq}@PII_{max}$	(cm)					0.2	
	Focal Length	(cm)		#	#	-		
	$I_{PA.3}@MI_{max}$	(W/cm^2)	585					
Operating Control Conditions	Mode		M				M	
	Frequency	(MHz)	10				10	
	Focus		3				8	
	PRF	(kHz)	1				6.7	
	Power		Max				Max	

Notes:
(a) This index is not required for this operating mode.
(b) This probe is not intended for transcranial or neonatal cephalic uses.
(c) This formulation for TIS is less than that for alternate formulation in this probe.
No data are reported for this operating condition since the global maximum index value is not reported for the reason listed.

Transducer Model: LA424 Operating Mode: B\M-CFM

Index Label			MI	TIS			TIB	TIC
				scan	non-scan		non-scan	
					$A_{aprt} \leq 1$	$A_{aprt} > 1$		
Global Maximum Index Value			1.3	1.4	<1	-	<1	b
Assoc. Acoustic Parameter	$Pr_{.3}$	(MPa)	3.6					
	W_o	(mW)		38	#		#	
	min of $[W_{.3}(z_1), I_{TA.3}(z_1)]$	(cm)				-		
	Z_1	(cm)				-		
	Z_{bp}	(cm)				-		
	Z_{sp}	(cm)	0.8				#	
	$d_{eq}(Z_{sp})$	(cm)					#	
	f_c	(MHz)	7.9	8	#	-	#	
	Dim of A_{aprt}	X (cm)		0.5	#	-	#	
		Y (cm)		0.3	#	-	#	
Other Information	PD	(mSec)	0.48					
	PRF	(kHz)	5.6					
	$P_r@PII_{max}$	(MPa)	4.4					
	$d_{eq}@PII_{max}$	(cm)					#	
	Focal Length	(cm)		0.7	#	-		
	$I_{PA.3}@MI_{max}$	(W/cm^2)	401					
Operating Control Conditions	Mode(Sens.)		B(Sens1)	B(Sens2)				
	Frequency	(MHz)	8	8				
	Focus		4	8				
	PRF	(kHz)	0.7	5.6				
	Power		Max	Max				

Notes:
(a) This index is not required for this operating mode.
(b) This probe is not intended for transcranial or neonatal cephalic uses.
(c) This formulation for TIS is less than that for alternate formulation in this probe.
No data are reported for this operating condition since the global maximum index value is not reported for the reason listed.

Transducer Model: LA424 Operating Mode: PW

Index Label			MI	TIS			TIB	TIC
				scan	non-scan		non-scan	
					$A_{aprt} \leq 1$	$A_{aprt} > 1$		
Global Maximum Index Value			1.3	a	<1	-	1.3	b
Assoc. Acoustic Parameter	$Pr_{.3}$	(MPa)	3.9					
	W_o	(mW)			#		10	
	min of $[W_{.3}(z_1), I_{TA.3}(z_1)]$	(cm)				-		
	Z_1	(cm)				-		
	Z_{bp}	(cm)				-		
	Z_{sp}	(cm)	0.8				0.7	
	$d_{eq}(Z_{sp})$	(cm)					0.2	
	f_c	(MHz)	8.1		#	-	7.9	
	Dim of A_{aprt} X	(cm)			#	-	0.5	
	Y	(cm)			#	-	0.3	
Other Information	PD	(mSec)	0.44					
	PRF	(kHz)	2.1					
	$P_r@PII_{max}$	(MPa)	4.7					
	$d_{eq}@PII_{max}$	(cm)					0.1	
	Focal Length	(cm)			#	-		
	$I_{PA.3}@MI_{max}$	(W/cm^2)	446					
Operating Control Conditions	Mode		PW				PW	
	Frequency	(MHz)	8				8	
	Sample Depth	(mm)	11				88	
	Sample Size	(mm)	2				2	
	Power		Max				Max	

Notes:
(a) This index is not required for this operating mode.
(b) This probe is not intended for transcranial or neonatal cephalic uses.
(c) This formulation for TIS is less than that for alternate formulation in this probe.
No data are reported for this operating condition since the global maximum index value is not reported for the reason listed.

Transducer Model: LA522E Operating Mode: B\M

Index Label			MI	TIS			TIB	TIC
				scan	non-scan		non-scan	
					$A_{aprt}\leq 1$	$A_{aprt}>1$		
Global Maximum Index Value			1	<1	<1	-	1.1	b
Assoc. Acoustic Parameter	$Pr_{.3}$	(MPa)	2.3					
	W_o	(mW)		#	#		34	
	min of $[W_{.3}(z_1), I_{TA.3}(z_1)]$	(cm)				-		
	Z_1	(cm)				-		
	Z_{bp}	(cm)				-		
	Z_{sp}	(cm)	1.9				1.6	
	$d_{eq}(Z_{sp})$	(cm)					0.4	
	f_c	(MHz)	4.8	#	#	-	4.9	
	Dim of A_{aprt}	X (cm)		#	#	-	1.1	
		Y (cm)		#	#	-	0.6	
Other Information	PD	(mSec)	0.25					
	PRF	(kHz)	1					
	$P_r@PII_{max}$	(MPa)	3					
	$d_{eq}@PII_{max}$	(cm)					0.3	
	Focal Length	(cm)		#	#	-		
	$I_{PA.3}@MI_{max}$	(W/cm^2)	328					
Operating Control Conditions	Mode		M				M	
	Frequency	(MHz)	7.5				7.5	
	Focus		3				8	
	PRF	(kHz)	1				6.7	
	Power		Max				Max	

Notes:
(a) This index is not required for this operating mode.
(b) This probe is not intended for transcranial or neonatal cephalic uses.
(c) This formulation for TIS is less than that for alternate formulation in this probe.
No data are reported for this operating condition since the global maximum index value is not reported for the reason listed.

Transducer Model: LA522E Operating Mode: B\M-CFM

Index Label			MI	TIS			TIB	TIC
				scan	non-scan		non-scan	
					$A_{aprt}\leq 1$	$A_{aprt}>1$		
Global Maximum Index Value			1.5	2.4	1	-	1.8	b
Assoc. Acoustic Parameter	$Pr_{.3}$	(MPa)	3.4					
	W_o	(mW)		102	47		24	
	min of $[W_{.3}(z_1), I_{TA.3}(z_1)]$	(cm)				-		
	Z_1	(cm)				-		
	Z_{bp}	(cm)				-		
	Z_{sp}	(cm)	1.7				1.7	
	$d_{eq}(Z_{sp})$	(cm)					0.2	
	f_c	(MHz)	4.8	4.9	4.6	-	3.5	
	Dim of A_{aprt}	X (cm)		1.1	1.1	-	0.6	
		Y (cm)		0.6	0.6	-	0.6	
Other Information	PD	(mSec)	0.53					
	PRF	(kHz)	5.6					
	$P_r@PII_{max}$	(MPa)	4.3					
	$d_{eq}@PII_{max}$	(cm)					0.2	
	Focal Length	(cm)		2.2	2	-		
	$I_{PA.3}@MI_{max}$	(W/cm^2)	408					
Operating Control Conditions	Mode(Sens.)		B(Sens1)	B(Sens2)	M		M	
	Frequency	(MHz)	5	5	5		3.3	
	Focus		3	8	8		3	
	PRF	(kHz)	0.7	5.6	5.6		5.6	
	Power		Max	Max	Max		Max	

Notes:
(a) This index is not required for this operating mode.
(b) This probe is not intended for transcranial or neonatal cephalic uses.
(c) This formulation for TIS is less than that for alternate formulation in this probe.
No data are reported for this operating condition since the global maximum index value is not reported for the reason listed.

Transducer Model: LA522E Operating Mode: PW

Index Label			MI	TIS			TIB	TIC
				scan	non-scan		non-scan	
					$A_{aprt} \leq 1$	$A_{aprt} > 1$		
Global Maximum Index Value			1.5	a	1.8	-	3.5	b
Assoc. Acoustic Parameter	$Pr_{.3}$	(MPa)	3.2					
	W_o	(mW)			79		79	
	min of $[W_{.3}(z_1), I_{TA.3}(z_1)]$	(cm)				-		
	Z_1	(cm)				-		
	Z_{bp}	(cm)				-		
	Z_{sp}	(cm)	0.5				1.5	
	$d_{eq}(Z_{sp})$	(cm)					0.4	
	f_c	(MHz)	4.8		4.8	-	3.3	
	Dim of A_{aprt}	X (cm)			1.1	-	1	
		Y (cm)			0.6	-	0.6	
Other Information	PD	(mSec)	0.73					
	PRF	(kHz)	2.1					
	P_r@PII_{max}	(MPa)	3.5					
	d_{eq}@PII_{max}	(cm)					0.3	
	Focal Length	(cm)			2.2	-		
	$I_{PA.3}$@MI_{max}	(W/cm^2)	313					
Operating Control Conditions	Mode		PW		PW		PW	
	Frequency	(MHz)	5		5		3.3	
	Sample Depth	(mm)	1		77		67	
	Sample Size	(mm)	2		2		2	
	Power		Max		Max		Max	

Notes:
(a) This index is not required for this operating mode.
(b) This probe is not intended for transcranial or neonatal cephalic uses.
(c) This formulation for TIS is less than that for alternate formulation in this probe.
No data are reported for this operating condition since the global maximum index value is not reported for the reason listed.

Transducer Model: LA523 Operating Mode: B\M

Index Label			MI	TIS			TIB	TIC
				scan	non-scan		non-scan	
					$A_{aprt} \leq 1$	$A_{aprt} > 1$		
Global Maximum Index Value			1.4	<1	<1	-	<1	b
Assoc. Acoustic Parameter	$Pr_{.3}$	(MPa)	3.6					
	W_o	(mW)		#	#		#	
	min of $[W_{.3}(z_1), I_{TA.3}(z_1)]$	(cm)				-		
	Z_1	(cm)				-		
	Z_{bp}	(cm)				-		
	Z_{sp}	(cm)	1.4				#	
	$d_{eq}(Z_{sp})$	(cm)					#	
	f_c	(MHz)	6.3	#	#	-	#	
	Dim of A_{aprt}	X (cm)		#	#	-	#	
		Y (cm)		#	#	-	#	
Other Information	PD	(mSec)	0.2					
	PRF	(kHz)	1					
	$P_r@PII_{max}$	(MPa)	4.7					
	$d_{eq}@PII_{max}$	(cm)					#	
	Focal Length	(cm)		#	#	-		
	$I_{PA.3}@MI_{max}$	(W/cm^2)	451					
Operating Control Conditions	Mode		M					
	Frequency	(MHz)	7.5					
	Focus		3					
	PRF	(kHz)	1					
	Power		Max					

Notes:
(a) This index is not required for this operating mode.
(b) This probe is not intended for transcranial or neonatal cephalic uses.
(c) This formulation for TIS is less than that for alternate formulation in this probe.
No data are reported for this operating condition since the global maximum index value is not reported for the reason listed.

Transducer Model: LA523 Operating Mode: B\M-CFM

Index Label			MI	TIS			TIB	TIC
				scan	non-scan		non-scan	
					$A_{aprt} \leq 1$	$A_{aprt} > 1$		
Global Maximum Index Value			1.5	1.4	<1	-	1.6	b
Assoc. Acoustic Parameter	$Pr_{.3}$	(MPa)	3.4					
	W_o	(mW)		45	#		22	
	min of $[W_{.3}(z_1), I_{TA.3}(z_1)]$	(cm)				-		
	Z_1	(cm)				-		
	Z_{bp}	(cm)				-		
	Z_{sp}	(cm)	1.3				1	
	$d_{eq}(Z_{sp})$	(cm)					0.2	
	f_c	(MHz)	5	6.5	#	-	5.2	
	Dim of A_{aprt}	X (cm)		0.7	#	-	0.7	
		Y (cm)		0.5	#	-	0.5	
Other Information	PD	(mSec)	0.54					
	PRF	(kHz)	5.6					
	$P_r@PII_{max}$	(MPa)	4.2					
	$d_{eq}@PII_{max}$	(cm)					0.2	
	Focal Length	(cm)		1.2	#	-		
	$I_{PA.3}@MI_{max}$	(W/cm^2)	475					
Operating Control Conditions	Mode(Sens.)		B(Sens1)	B(Sens1)			M	
	Frequency	(MHz)	5	6.6			5	
	Focus		4	8			7	
	PRF	(kHz)	0.7	5.6			5.6	
	Power		Max	Max			Max	

Notes:
(a) This index is not required for this operating mode.
(b) This probe is not intended for transcranial or neonatal cephalic uses.
(c) This formulation for TIS is less than that for alternate formulation in this probe.
No data are reported for this operating condition since the global maximum index value is not reported for the reason listed.

Transducer Model: LA523 Operating Mode: B\M-TEI

Index Label			MI	TIS			TIB	TIC
				scan	non-scan		non-scan	
					$A_{aprt} \leq 1$	$A_{aprt} > 1$		
Global Maximum Index Value			1.4	<1	<1	-	<1	b
Assoc. Acoustic Parameter	$Pr_{.3}$	(MPa)	3.2					
	W_o	(mW)		#	#		#	
	min of $[W_{.3}(z_1), I_{TA.3}(z_1)]$	(cm)				-		
	Z_1	(cm)				-		
	Z_{bp}	(cm)				-		
	Z_{sp}	(cm)	1.2				#	
	$d_{eq}(Z_{sp})$	(cm)					#	
	f_c	(MHz)	5.4	#	#	-	#	
	Dim of A_{aprt}	X (cm)		#	#	-	#	
		Y (cm)		#	#	-	#	
Other Information	PD	(mSec)	0.26					
	PRF	(kHz)	1					
	$P_r@PII_{max}$	(MPa)	3.7					
	$d_{eq}@PII_{max}$	(cm)					#	
	Focal Length	(cm)		#	#	-		
	$I_{PA.3}@MI_{max}$	(W/cm^2)	394					
Operating Control Conditions	Mode		B-TEI					
	Frequency	(MHz)	RES					
	Focus		3					
	PRF	(kHz)	1					
	Power		Max					

Notes:
(a) This index is not required for this operating mode.
(b) This probe is not intended for transcranial or neonatal cephalic uses.
(c) This formulation for TIS is less than that for alternate formulation in this probe.
No data are reported for this operating condition since the global maximum index value is not reported for the reason listed.

Transducer Model: LA523 Operating Mode: PW

Index Label			MI	TIS			TIB	TIC
				scan	non-scan		non-scan	
					$A_{aprt} \leq 1$	$A_{aprt} > 1$		
Global Maximum Index Value			1.4	a	<1	-	2.1	b
Assoc. Acoustic Parameter	$Pr_{.3}$	(MPa)	3.2					
	W_o	(mW)			#		28	
	min of $[W_{.3}(z_1), I_{TA.3}(z_1)]$	(cm)				-		
	Z_1	(cm)				-		
	Z_{bp}	(cm)				-		
	Z_{sp}	(cm)	1.3				1	
	$d_{eq}(Z_{sp})$	(cm)					0.2	
	f_c	(MHz)	5.1		#	-	5	
	Dim of A_{aprt}	X (cm)			#	-	0.7	
		Y (cm)			#	-	0.5	
Other Information	PD	(mSec)	0.72					
	PRF	(kHz)	2.1					
	$P_r@PII_{max}$	(MPa)	4					
	$d_{eq}@PII_{max}$	(cm)					0.2	
	Focal Length	(cm)			#	-		
	$I_{PA.3}@MI_{max}$	(W/cm^2)	326					
Operating Control Conditions	Mode		PW				PW	
	Frequency	(MHz)	5				5	
	Sample Depth	(mm)	23				51	
	Sample Size	(mm)	2				2	
	Power		Max				Max	

Notes:
(a) This index is not required for this operating mode.
(b) This probe is not intended for transcranial or neonatal cephalic uses.
(c) This formulation for TIS is less than that for alternate formulation in this probe.
No data are reported for this operating condition since the global maximum index value is not reported for the reason listed.

Transducer Model: LA532E Operating Mode: B\M-CFM

Index Label			MI	TIS			TIB	TIC
				scan	non-scan		non-scan	
					$A_{aprt}\leq 1$	$A_{aprt}>1$		
Global Maximum Index Value			1.5	1.9	1	-	3.2	b
Assoc. Acoustic Parameter	$Pr_{.3}$	(MPa)	2.6					
	W_o	(mW)		122	54		67	
	min of $[W_{.3}(z_1), I_{TA.3}(z_1)]$	(cm)				-		
	Z_1	(cm)				-		
	Z_{bp}	(cm)				-		
	Z_{sp}	(cm)	1.5				1.4	
	$d_{eq}(Z_{sp})$	(cm)					0.4	
	f_c	(MHz)	3	3.2	4	-	3	
	Dim of A_{aprt}	X (cm)		1.1	1.1	-	1	
		Y (cm)		0.6	0.6	-	0.6	
Other Information	PD	(mSec)	0.87					
	PRF	(kHz)	5.6					
	$P_r@PII_{max}$	(MPa)	2.8					
	$d_{eq}@PII_{max}$	(cm)					0.3	
	Focal Length	(cm)		3.7	4.5	-		
	$I_{PA.3}@MI_{max}$	(W/cm²)	120					
Operating Control Conditions	Mode(Sens.)		B(Sens1)	B(Sens2)	M		M	
	Frequency	(MHz)	3.3	3.3	5		3.3	
	Focus		8	8	8		7	
	PRF	(kHz)	5.6	5.6	5.6		5.6	
	Power		Max	Max	Max		Max	

Notes:
(a) This index is not required for this operating mode.
(b) This probe is not intended for transcranial or neonatal cephalic uses.
(c) This formulation for TIS is less than that for alternate formulation in this probe.
No data are reported for this operating condition since the global maximum index value is not reported for the reason listed.

Transducer Model: LA532E Operating Mode: B\M-TEI

Index Label			MI	TIS			TIB	TIC
				scan	non-scan		non-scan	
					$A_{aprt}\leq 1$	$A_{aprt}>1$		
Global Maximum Index Value			1.5	2.2	1.8	-	4.3	b
Assoc. Acoustic Parameter	$Pr_{.3}$	(MPa)	2.5					
	W_o	(mW)		182	151		144	
	min of $[W_{.3}(z_1), I_{TA.3}(z_1)]$	(cm)				-		
	Z_1	(cm)				-		
	Z_{bp}	(cm)				-		
	Z_{sp}	(cm)	1.5				1.3	
	$d_{eq}(Z_{sp})$	(cm)					0.4	
	f_c	(MHz)	2.6	2.5	2.5	-	2.5	
	Dim of A_{aprt}	X (cm)		1.1	1.1	-	1	
		Y (cm)		0.6	0.6	-	0.6	
Other Information	PD	(mSec)	0.79					
	PRF	(kHz)	1					
	$P_r@PII_{max}$	(MPa)	2.7					
	$d_{eq}@PII_{max}$	(cm)					0.4	
	Focal Length	(cm)		3.4	3.4	-		
	$I_{PA.3}@MI_{max}$	(W/cm^2)	180					
Operating Control Conditions	Mode		M-TEI	B-TEI	M-TEI		M-TEI	
	Frequency	(MHz)	RES	PEN	PEN		PEN	
	Focus		3	8	8		7	
	PRF	(kHz)	1	6.7	6.7		6.7	
	Power		Max	Max	Max		Max	

Notes:
(a) This index is not required for this operating mode.
(b) This probe is not intended for transcranial or neonatal cephalic uses.
(c) This formulation for TIS is less than that for alternate formulation in this probe.
No data are reported for this operating condition since the global maximum index value is not reported for the reason listed.

Transducer Model: LA532E Operating Mode: PW

Index Label			MI	TIS			TIB	TIC
				scan	non-scan		non-scan	
					$A_{aprt}\leq 1$	$A_{aprt}>1$		
Global Maximum Index Value			1.5	a	1	-	3.1	b
Assoc. Acoustic Parameter	$Pr_{.3}$	(MPa)	2.7					
	W_o	(mW)			65		65	
	min of $[W_{.3}(z_1), I_{TA.3}(z_1)]$	(cm)				-		
	Z_1	(cm)				-		
	Z_{bp}	(cm)				-		
	Z_{sp}	(cm)	2.4				1.5	
	$d_{eq}(Z_{sp})$	(cm)					0.3	
	f_c	(MHz)	3		3.2	-	3.2	
	Dim of A_{aprt}	X (cm)			1	-	1	
		Y (cm)			0.6	-	0.6	
Other Information	PD	(mSec)	0.69					
	PRF	(kHz)	5.6					
	$P_r@PII_{max}$	(MPa)	3.3					
	$d_{eq}@PII_{max}$	(cm)					0.3	
	Focal Length	(cm)			3.7	-		
	$I_{PA.3}@MI_{max}$	(W/cm^2)	135					
Operating Control Conditions	Mode		PW-B-CFM		PW		PW	
	Frequency	(MHz)	3.3		3.3		3.3	
	Sample Depth	(mm)	0		67		67	
	Sample Size	(mm)	0		2		2	
	Power		Max		Max		Max	

Notes:
(a) This index is not required for this operating mode.
(b) This probe is not intended for transcranial or neonatal cephalic uses.
(c) This formulation for TIS is less than that for alternate formulation in this probe.
No data are reported for this operating condition since the global maximum index value is not reported for the reason listed.

Transducer Model: LV513 Operating Mode: B\M

Index Label			MI	TIS			TIB	TIC
				scan	non-scan		non-scan	
					$A_{aprt} \leq 1$	$A_{aprt} > 1$		
Global Maximum Index Value			1.5	2	1.7	-	2.3	b
Assoc. Acoustic Parameter	$Pr_{.3}$	(MPa)	3.5					
	W_o	(mW)		83	63		68	
	min of $[W_{.3}(z_1), I_{TA.3}(z_1)]$	(cm)				-		
	Z_1	(cm)				-		
	Z_{bp}	(cm)				-		
	Z_{sp}	(cm)	1.8				0.7	
	$d_{eq}(Z_{sp})$	(cm)					0.4	
	f_c	(MHz)	4.9	4.9	5.6	-	4.9	
	Dim of A_{aprt}	X (cm)		0.9	1	-	0.9	
		Y (cm)		0.5	0.5	-	0.5	
Other Information	PD	(mSec)	0.38					
	PRF	(kHz)	6.7					
	$P_r@PII_{max}$	(MPa)	4.3					
	$d_{eq}@PII_{max}$	(cm)					0.3	
	Focal Length	(cm)		1.6	1.8	-		
	$I_{PA.3}@MI_{max}$	(W/cm^2)	487					
Operating Control Conditions	Mode		B	B	M		M	
	Frequency	(MHz)	5	5	7.5		5	
	Focus		3	7	8		7	
	PRF	(kHz)	6.7	6.7	6.7		6.7	
	Power		Max	Max	Max		Max	

Notes:
(a) This index is not required for this operating mode.
(b) This probe is not intended for transcranial or neonatal cephalic uses.
(c) This formulation for TIS is less than that for alternate formulation in this probe.
No data are reported for this operating condition since the global maximum index value is not reported for the reason listed.

Transducer Model: LV513 Operating Mode: B\M-CFM

Index Label			MI	TIS			TIB	TIC
				scan	non-scan		non-scan	
					$A_{aprt} \leq 1$	$A_{aprt} > 1$		
Global Maximum Index Value			1.5	3.4	1	-	1.7	b
Assoc. Acoustic Parameter	$Pr_{.3}$	(MPa)	3.5					
	W_o	(mW)		111	36		21	
	min of $[W_{.3}(z_1), I_{TA.3}(z_1)]$	(cm)				-		
	Z_1	(cm)				-		
	Z_{bp}	(cm)				-		
	Z_{sp}	(cm)	1.6				1.6	
	$d_{eq}(Z_{sp})$	(cm)					0.2	
	f_c	(MHz)	4.9	6.4	5.7	-	4.9	
	Dim of A_{aprt} X	(cm)		1	1	-	0.6	
	Y	(cm)		0.5	0.5	-	0.5	
Other Information	PD	(mSec)	0.59					
	PRF	(kHz)	5.6					
	$P_r@PII_{max}$	(MPa)	4.2					
	$d_{eq}@PII_{max}$	(cm)					0.2	
	Focal Length	(cm)		1.8	1.8	-		
	$I_{PA.3}@MI_{max}$	(W/cm^2)	407					
Operating Control Conditions	Mode(Sens.)		B(Sens1)	B(Sens2)	M		M	
	Frequency	(MHz)	5	6.6	6.6		5	
	Focus		3	8	8		3	
	PRF	(kHz)	5.6	5.6	5.6		5.6	
	Power		Max	Max	Max		Max	

Notes:
(a) This index is not required for this operating mode.
(b) This probe is not intended for transcranial or neonatal cephalic uses.
(c) This formulation for TIS is less than that for alternate formulation in this probe.
No data are reported for this operating condition since the global maximum index value is not reported for the reason listed.

Transducer Model: LV513 Operating Mode: PW

Index Label			MI	TIS			TIB	TIC
				scan	non-scan		non-scan	
					$A_{aprt} \leq 1$	$A_{aprt} > 1$		
Global Maximum Index Value			1.7	a	2.3	-	3.2	b
Assoc. Acoustic Parameter	$Pr_{.3}$	(MPa)	4.2					
	W_o	(mW)			69		64	
	min of $[W_{.3}(z_1), I_{TA.3}(z_1)]$	(cm)				-		
	Z_1	(cm)				-		
	Z_{bp}	(cm)				-		
	Z_{sp}	(cm)	0.8				0.6	
	$d_{eq}(Z_{sp})$	(cm)					0.4	
	f_c	(MHz)	6.3		6.3	-	5	
	Dim of A_{aprt} X	(cm)			1	-	1	
	Y	(cm)			0.5	-	0.5	
Other Information	PD	(mSec)	0.62					
	PRF	(kHz)	2.1					
	$P_r@PII_{max}$	(MPa)	5.1					
	$d_{eq}@PII_{max}$	(cm)					0.3	
	Focal Length	(cm)			1.9	-		
	$I_{PA.3}@MI_{max}$	(W/cm^2)	425					
Operating Control Conditions	Mode		PW		PW		PW	
	Frequency	(MHz)	6.6		6.6		5	
	Sample Depth	(mm)	57		88		88	
	Sample Size	(mm)	2		2		2	
	Power		Max		Max		Max	

Notes:
(a) This index is not required for this operating mode.
(b) This probe is not intended for transcranial or neonatal cephalic uses.
(c) This formulation for TIS is less than that for alternate formulation in this probe.
No data are reported for this operating condition since the global maximum index value is not reported for the reason listed.

Transducer Model: PA023E Operating Mode: B\M-CFM

Index Label			MI	TIS			TIB	TIC
				scan	non-scan		non-scan	
					$A_{aprt} \leq 1$	$A_{aprt} > 1$		
Global Maximum Index Value			1.1	1.2	<1	-	1.3	1.7
Assoc. Acoustic Parameter	$Pr_{.3}$	(MPa)	2.8					
	W_o	(mW)		48	#		21	49
	min of $[W_{.3}(z_1), I_{TA.3}(z_1)]$	(cm)				-		
	Z_1	(cm)				-		
	Z_{bp}	(cm)				-		
	Z_{sp}	(cm)	2				2.1	
	$d_{eq}(Z_{sp})$	(cm)					0.2	
	f_c	(MHz)	5.2	5.1	#	-	5.4	5.1
	Dim of A_{aprt}	X (cm)		0.7	#	-	0.6	0.7
		Y (cm)		0.6	#	-	0.6	0.6
Other Information	PD	(mSec)	0.53					
	PRF	(kHz)	5.6					
	$P_r@PII_{max}$	(MPa)	3.7					
	$d_{eq}@PII_{max}$	(cm)					0.2	
	Focal Length	(cm)		2.4	#	-		2.4
	$I_{PA.3}@MI_{max}$	(W/cm^2)	271					
Operating Control Conditions	Mode(Sens.)		B(Sens1)	B(Sens1)			M	B(Sens1)
	Frequency	(MHz)	5	5			5	5
	Focus		5	7			6	7
	PRF	(kHz)	5.6	5.6			5.6	5.6
	Power		Max	Max			Max	Max

Notes:
(a) This index is not required for this operating mode.
(b) This probe is not intended for transcranial or neonatal cephalic uses.
(c) This formulation for TIS is less than that for alternate formulation in this probe.
No data are reported for this operating condition since the global maximum index value is not reported for the reason listed.

Transducer Model: PA023E Operating Mode: CW

Index Label			MI	TIS			TIB	TIC
				scan	non-scan		non-scan	
					$A_{aprt}\leq 1$	$A_{aprt}>1$		
Global Maximum Index Value			<1	a	<1	-	1.8	1.1
Assoc. Acoustic Parameter	$Pr_{.3}$	(MPa)	#					
	W_o	(mW)			#		22	28
	min of $[W_{.3}(z_1), I_{TA.3}(z_1)]$	(cm)				-		
	Z_1	(cm)				-		
	Z_{bp}	(cm)				-		
	Z_{sp}	(cm)	#				0.7	
	$d_{eq}(Z_{sp})$	(cm)					0.2	
	f_c	(MHz)	#		#	-	5	5
	Dim of A_{aprt}	X (cm)			#	-	0.6	0.6
		Y (cm)			#	-	0.6	0.6
Other Information	PD	(mSec)	#					
	PRF	(kHz)	#					
	$P_r@PII_{max}$	(MPa)	#					
	$d_{eq}@PII_{max}$	(cm)					0.2	
	Focal Length	(cm)			#	-		2.3
	$I_{PA.3}@MI_{max}$	(W/cm^2)	#					
Operating Control Conditions	Mode						CW	CW
	Frequency	(MHz)					5	5
	Focus						2	7
	PRF	(kHz)						
	Power						Max	Max

Notes:
(a) This index is not required for this operating mode.
(b) This probe is not intended for transcranial or neonatal cephalic uses.
(c) This formulation for TIS is less than that for alternate formulation in this probe.
No data are reported for this operating condition since the global maximum index value is not reported for the reason listed.

Transducer Model: PA023E Operating Mode: PW

Index Label			MI	TIS			TIB	TIC
				scan	non-scan		non-scan	
					$A_{aprt} \leq 1$	$A_{aprt} > 1$		
Global Maximum Index Value			1.1	a	<1	-	1.4	<1
Assoc. Acoustic Parameter	$Pr_{.3}$	(MPa)	2.8					
	W_o	(mW)			#		24	#
	min of $[W_{.3}(z_1), I_{TA.3}(z_1)]$	(cm)				-		
	Z_1	(cm)				-		
	Z_{bp}	(cm)				-		
	Z_{sp}	(cm)	2.3				2.3	
	$d_{eq}(Z_{sp})$	(cm)					0.2	
	f_c	(MHz)	5.2		#	-	5.1	#
	Dim of A_{aprt}	X (cm)			#	-	0.6	#
		Y (cm)			#	-	0.6	#
Other Information	PD	(mSec)	0.73					
	PRF	(kHz)	2.1					
	P_r@PII_{max}	(MPa)	3.8					
	d_{eq}@PII_{max}	(cm)					0.2	
	Focal Length	(cm)			#	-		#
	$I_{PA.3}$@MI_{max}	(W/cm^2)	269					
Operating Control Conditions	Mode		PW				PW	
	Frequency	(MHz)	5				5	
	Sample Depth	(mm)	29				42	
	Sample Size	(mm)	2				2	
	Power		Max				Max	

Notes:
(a) This index is not required for this operating mode.
(b) This probe is not intended for transcranial or neonatal cephalic uses.
(c) This formulation for TIS is less than that for alternate formulation in this probe.
No data are reported for this operating condition since the global maximum index value is not reported for the reason listed.

Transducer Model: PA121E Operating Mode: B\M

Index Label			MI	TIS			TIB	TIC
				scan	non-scan		non-scan	
					$A_{aprt} \leq 1$	$A_{aprt} > 1$		
Global Maximum Index Value			<1	1.3	1.1	1.1	1.5	1.5
Assoc. Acoustic Parameter	$Pr_{.3}$	(MPa)	#					
	W_o	(mW)		78	65		65	80
	min of $[W_{.3}(z_1), I_{TA.3}(z_1)]$	(cm)				29		
	Z_1	(cm)				2.2		
	Z_{bp}	(cm)				2.3		
	Z_{sp}	(cm)	#				1.9	
	$d_{eq}(Z_{sp})$	(cm)					0.5	
	f_c	(MHz)	#	3.5	3.7	3.5	3.7	3.2
	Dim of A_{aprt}	X (cm)		1.4	0.7	1.4	0.7	1.1
		Y (cm)		1.3	1.3	1.3	1.3	1.3
Other Information	PD	(mSec)	#					
	PRF	(kHz)	#					
	$P_r@PII_{max}$	(MPa)	#					
	$d_{eq}@PII_{max}$	(cm)					0.5	
	Focal Length	(cm)		6.5	2	6.5		4.5
	$I_{PA.3}@MI_{max}$	(W/cm^2)	#					
Operating Control Conditions	Mode			B	M	M	M	B
	Frequency	(MHz)		5	5	5	5	3.5
	Focus			6	2	6	2	4
	PRF	(kHz)		5.6	5.6	5.6	5.6	5.6
	Power			Max	Max	Max	Max	Max

Notes:
(a) This index is not required for this operating mode.
(b) This probe is not intended for transcranial or neonatal cephalic uses.
(c) This formulation for TIS is less than that for alternate formulation in this probe.
No data are reported for this operating condition since the global maximum index value is not reported for the reason listed.

Transducer Model: PA121E Operating Mode: B\M-CFM

Index Label			MI	TIS			TIB	TIC
				scan	non-scan		non-scan	
					$A_{aprt} \leq 1$	$A_{aprt} > 1$		
Global Maximum Index Value			1.5	4	1.9	1.9	4.1	5.1
Assoc. Acoustic Parameter	$Pr_{.3}$	(MPa)	2.7					
	W_o	(mW)		256	120		120	256
	min of $[W_{.3}(z_1), I_{TA.3}(z_1)]$	(cm)				124		
	Z_1	(cm)				1.9		
	Z_{bp}	(cm)				1.9		
	Z_{sp}	(cm)	1.9				1.8	
	$d_{eq}(Z_{sp})$	(cm)					0.4	
	f_c	(MHz)	3.2	3.3	3.3	3.3	3.3	3.3
	Dim of A_{aprt}	X (cm)		0.9	0.7	0.9	0.7	0.9
		Y (cm)		1.3	1.3	1.3	1.3	1.3
Other Information	PD	(mSec)	0.45					
	PRF	(kHz)	5.6					
	$P_r@PII_{max}$	(MPa)	3.2					
	$d_{eq}@PII_{max}$	(cm)					0.4	
	Focal Length	(cm)		2.8	2.1	2.8		2.8
	$I_{PA.3}@MI_{max}$	(W/cm^2)	299					
Operating Control Conditions	Mode(Sens.)		B(Sens1)	B(Sens2)	M	M	M	B(Sens1)
	Frequency	(MHz)	3.3	3.3	3.3	3.3	3.3	3.3
	Focus		2	3	2	3	2	3
	PRF	(kHz)	5.6	5.6	5.6	5.6	5.6	5.6
	Power		Max	Max	Max	Max	Max	Max

Notes:
(a) This index is not required for this operating mode.
(b) This probe is not intended for transcranial or neonatal cephalic uses.
(c) This formulation for TIS is less than that for alternate formulation in this probe.
No data are reported for this operating condition since the global maximum index value is not reported for the reason listed.

Transducer Model: PA121E Operating Mode: B\M-TEI

Index Label			MI	TIS			TIB	TIC
				scan	non-scan		non-scan	
					$A_{aprt}\leq 1$	$A_{aprt}>1$		
Global Maximum Index Value			<1	1.2	<1	1	1.8	1.8
Assoc. Acoustic Parameter	$Pr_{.3}$	(MPa)	#					
	W_o	(mW)		109	#		109	109
	min of $[W_{.3}(z_1), I_{TA.3}(z_1)]$	(cm)				41		
	Z_1	(cm)				2.9		
	Z_{bp}	(cm)				2.3		
	Z_{sp}	(cm)	#				4.9	
	$d_{eq}(Z_{sp})$	(cm)					0.5	
	f_c	(MHz)	#	2.2	#	2.2	2.2	2.2
	Dim of A_{aprt} X	(cm)		1.4	#	1.4	1.4	1.4
	Y	(cm)		1.3	#	1.3	1.3	1.3
Other Information	PD	(mSec)	#					
	PRF	(kHz)	#					
	$P_r@PII_{max}$	(MPa)	#					
	$d_{eq}@PII_{max}$	(cm)					0.5	
	Focal Length	(cm)		6	#	6		6
	$I_{PA.3}@MI_{max}$	(W/cm^2)	#					
Operating Control Conditions	Mode			B-TEI		M-TEI	M-TEI	B-TEI
	Frequency	(MHz)		PEN		PEN	PEN	PEN
	Focus			6		6	6	6
	PRF	(kHz)		5.6		5.6	5.6	5.6
	Power			Max		Max	Max	Max

Notes:
(a) This index is not required for this operating mode.
(b) This probe is not intended for transcranial or neonatal cephalic uses.
(c) This formulation for TIS is less than that for alternate formulation in this probe.
No data are reported for this operating condition since the global maximum index value is not reported for the reason listed.

Transducer Model: PA121E Operating Mode: CW

Index Label			MI	TIS			TIB	TIC
				scan	non-scan		non-scan	
					$A_{aprt} \leq 1$	$A_{aprt} > 1$		
Global Maximum Index Value			<1	a	<1	2.5	3.9	4
Assoc. Acoustic Parameter	$Pr_{.3}$	(MPa)	#					
	W_o	(mW)			#		186	186
	min of $[W_{.3}(z_1), I_{TA.3}(z_1)]$	(cm)				155		
	Z_1	(cm)				1.8		
	Z_{bp}	(cm)				1.7		
	Z_{sp}	(cm)	#				1.1	
	$d_{eq}(Z_{sp})$	(cm)					0.8	
	f_c	(MHz)	#		#	3.3	3.3	3.3
	Dim of A_{aprt}	X (cm)			#	0.8	0.8	0.8
		Y (cm)			#	1.3	1.3	1.3
Other Information	PD	(mSec)	#					
	PRF	(kHz)	#					
	$P_r@PII_{max}$	(MPa)	#					
	$d_{eq}@PII_{max}$	(cm)					0.4	
	Focal Length	(cm)			#	6.9		6.9
	$I_{PA.3}@MI_{max}$	(W/cm^2)	#					
Operating Control Conditions	Mode					CW	CW	CW
	Frequency	(MHz)				3.3	3.3	3.3
	Focus					7	8	7
	PRF	(kHz)						
	Power					Max	Max	Max

Notes:
(a) This index is not required for this operating mode.
(b) This probe is not intended for transcranial or neonatal cephalic uses.
(c) This formulation for TIS is less than that for alternate formulation in this probe.
No data are reported for this operating condition since the global maximum index value is not reported for the reason listed.

Transducer Model: PA121E Operating Mode: PW

Index Label			MI	TIS			TIB	TIC
				scan	non-scan		non-scan	
					$A_{aprt} \leq 1$	$A_{aprt} > 1$		
Global Maximum Index Value			1.5	a	1.8	2.3	4.2	3.4
Assoc. Acoustic Parameter	$Pr_{.3}$	(MPa)	2.6					
	W_o	(mW)			104		121	172
	min of $[W_{.3}(z_1), I_{TA.3}(z_1)]$	(cm)				146		
	Z_1	(cm)				2.2		
	Z_{bp}	(cm)				2.3		
	Z_{sp}	(cm)	1.9				1.6	
	$d_{eq}(Z_{sp})$	(cm)					0.5	
	f_c	(MHz)	3.3		3.3	3.3	2.5	2.6
	Dim of A_{aprt}	X (cm)			0.7	1.4	0.7	1.1
		Y (cm)			1.3	1.3	1.3	1.3
Other Information	PD	(mSec)	0.97					
	PRF	(kHz)	2.1					
	$P_r@PII_{max}$	(MPa)	3.3					
	$d_{eq}@PII_{max}$	(cm)					0.5	
	Focal Length	(cm)			2.6	6.1		5.6
	$I_{PA.3}@MI_{max}$	(W/cm²)	217					
Operating Control Conditions	Mode		PW		PW	PW	PW	PW
	Frequency	(MHz)	3.3		3.3	3.3	2.5	2.5
	Sample Depth	(mm)	19		19	97	0	63
	Sample Size	(mm)	2		2	2	2	2
	Power		Max		Max	Max	Max	Max

Notes:
(a) This index is not required for this operating mode.
(b) This probe is not intended for transcranial or neonatal cephalic uses.
(c) This formulation for TIS is less than that for alternate formulation in this probe.
No data are reported for this operating condition since the global maximum index value is not reported for the reason listed.

Transducer Model: PA122E Operating Mode: B\M

Index Label			MI	TIS			TIB	TIC
				scan	non-scan		non-scan	
					$A_{aprt} \leq 1$	$A_{aprt} > 1$		
Global Maximum Index Value			<1	<1	<1	<1	1.1	1
Assoc. Acoustic Parameter	$Pr_{.3}$	(MPa)	#					
	W_o	(mW)		#	#		36	36
	min of $[W_{.3}(z_1), I_{TA.3}(z_1)]$	(cm)				#		
	Z_1	(cm)				#		
	Z_{bp}	(cm)				#		
	Z_{sp}	(cm)	#				1.7	
	$d_{eq}(Z_{sp})$	(cm)					0.4	
	f_c	(MHz)	#	#	#	#	4.5	4.5
	Dim of A_{aprt}	X (cm)		#	#	#	0.6	0.6
		Y (cm)		#	#	#	1	1
Other Information	PD	(mSec)	#					
	PRF	(kHz)	#					
	$P_r@PII_{max}$	(MPa)	#					
	$d_{eq}@PII_{max}$	(cm)					0.3	
	Focal Length	(cm)		#	#	#		1.9
	$I_{PA.3}@MI_{max}$	(W/cm^2)	#					
Operating Control Conditions	Mode						M	B
	Frequency	(MHz)					5	5
	Focus						3	3
	PRF	(kHz)					5.6	5.6
	Power						Max	Max

Notes:
(a) This index is not required for this operating mode.
(b) This probe is not intended for transcranial or neonatal cephalic uses.
(c) This formulation for TIS is less than that for alternate formulation in this probe.
No data are reported for this operating condition since the global maximum index value is not reported for the reason listed.

Transducer Model: PA122E Operating Mode: B\M-CFM

Index Label			MI	TIS			TIB	TIC
				scan	non-scan		non-scan	
					$A_{aprt}\leq 1$	$A_{aprt}>1$		
Global Maximum Index Value			1.5	3.4	1.7	1.2	3.1	4.2
Assoc. Acoustic Parameter	$Pr_{.3}$	(MPa)	3.4					
	W_o	(mW)		149	76		76	149
	min of $[W_{.3}(z_1), I_{TA.3}(z_1)]$	(cm)				56		
	Z_1	(cm)				1.7		
	Z_{bp}	(cm)				1.7		
	Z_{sp}	(cm)	1.1				1.7	
	$d_{eq}(Z_{sp})$	(cm)					0.3	
	f_c	(MHz)	4.6	4.8	4.6	4.3	4.6	4.8
	Dim of A_{aprt}	X (cm)		0.6	0.6	1.1	0.6	0.6
		Y (cm)		1	1	1	1	1
Other Information	PD	(mSec)	0.33					
	PRF	(kHz)	5.6					
	$P_r@PII_{max}$	(MPa)	3.8					
	$d_{eq}@PII_{max}$	(cm)					0.3	
	Focal Length	(cm)		1.9	1.9	4.4		1.9
	$I_{PA.3}@MI_{max}$	(W/cm^2)	367					
Operating Control Conditions	Mode(Sens.)		B(Sens1)	B(Sens2)	M	M	M	B(Sens1)
	Frequency	(MHz)	5	5	5	5	5	5
	Focus		2	3	3	8	3	3
	PRF	(kHz)	0.7	0.7	5.6	5.6	5.6	0.7
	Power		Max	Max	Max	Max	Max	Max

Notes:
(a) This index is not required for this operating mode.
(b) This probe is not intended for transcranial or neonatal cephalic uses.
(c) This formulation for TIS is less than that for alternate formulation in this probe.
No data are reported for this operating condition since the global maximum index value is not reported for the reason listed.

Transducer Model: PA122E Operating Mode: CW

Index Label			MI	TIS			TIB	TIC
				scan	non-scan		non-scan	
					$A_{aprt} \leq 1$	$A_{aprt} > 1$		
Global Maximum Index Value			<1	a	2.4	<1	2.9	2.8
Assoc. Acoustic Parameter	$Pr_{.3}$	(MPa)	#					
	W_o	(mW)			103		99	103
	min of $[W_{.3}(z_1), I_{TA.3}(z_1)]$	(cm)				#		
	Z_1	(cm)				#		
	Z_{bp}	(cm)				#		
	Z_{sp}	(cm)	#				2.1	
	$d_{eq}(Z_{sp})$	(cm)					0.4	
	f_c	(MHz)	#		5	#	5	5
	Dim of A_{aprt}	X (cm)			0.7	#	0.7	0.7
		Y (cm)			1	#	1	1
Other Information	PD	(mSec)	#					
	PRF	(kHz)	#					
	$P_r@PII_{max}$	(MPa)	#					
	$d_{eq}@PII_{max}$	(cm)					0.2	
	Focal Length	(cm)			4.9	#		4.9
	$I_{PA.3}@MI_{max}$	(W/cm^2)	#					
Operating Control Conditions	Mode				CW		CW	CW
	Frequency	(MHz)			5		5	5
	Focus				6		5	6
	PRF	(kHz)						
	Power				Max		Max	Max

Notes:
(a) This index is not required for this operating mode.
(b) This probe is not intended for transcranial or neonatal cephalic uses.
(c) This formulation for TIS is less than that for alternate formulation in this probe.
No data are reported for this operating condition since the global maximum index value is not reported for the reason listed.

Transducer Model: PA122E Operating Mode: PW

Index Label			MI	TIS			TIB	TIC
				scan	non-scan		non-scan	
					$A_{aprt}\leq 1$	$A_{aprt}>1$		
Global Maximum Index Value			1.5	a	2.4	1.5	3.3	2.6
Assoc. Acoustic Parameter	$Pr_{.3}$	(MPa)	3.1					
	W_o	(mW)			107		72	80
	min of $[W_{.3}(z_1), I_{TA.3}(z_1)]$	(cm)				61		
	Z_1	(cm)				1.7		
	Z_{bp}	(cm)				1.7		
	Z_{sp}	(cm)	1.3				1.5	
	$d_{eq}(Z_{sp})$	(cm)					0.4	
	f_c	(MHz)	4.8		4.8	4.7	3.4	4.5
	Dim of A_{aprt}	X (cm)			1	1.1	0.6	0.5
		Y (cm)			1	1	1	1
Other Information	PD	(mSec)	0.73					
	PRF	(kHz)	2.1					
	$P_r@PII_{max}$	(MPa)	3.9					
	$d_{eq}@PII_{max}$	(cm)					0.3	
	Focal Length	(cm)			4.1	4.5		1.3
	$I_{PA.3}@MI_{max}$	(W/cm²)	337					
Operating Control Conditions	Mode		PW		PW	PW	PW	PW-B-CFM
	Frequency	(MHz)	5		5	5	3.3	5
	Sample Depth	(mm)	11		70	99	22	0
	Sample Size	(mm)	2		2	2	2	0
	Power		Max		Max	Max	Max	Max

Notes:
(a) This index is not required for this operating mode.
(b) This probe is not intended for transcranial or neonatal cephalic uses.
(c) This formulation for TIS is less than that for alternate formulation in this probe.
No data are reported for this operating condition since the global maximum index value is not reported for the reason listed.

Transducer Model: PA230E Operating Mode: B\M

Index Label			MI	TIS			TIB	TIC
				scan	non-scan		non-scan	
					$A_{aprt}\leq 1$	$A_{aprt}>1$		
Global Maximum Index Value			<1	1	<1	<1	1.4	1.3
Assoc. Acoustic Parameter	$Pr_{.3}$	(MPa)	#					
	W_o	(mW)		95	#		87	93
	min of $[W_{.3}(z_1), I_{TA.3}(z_1)]$	(cm)				#		
	Z_1	(cm)				#		
	Z_{bp}	(cm)				#		
	Z_{sp}	(cm)	#				5.5	
	$d_{eq}(Z_{sp})$	(cm)					0.4	
	f_c	(MHz)	#	2.2	#	#	2.2	2.2
	Dim of A_{aprt}	X (cm)		2	#	#	1.6	1.8
		Y (cm)		1.4	#	#	1.4	1.4
Other Information	PD	(mSec)	#					
	PRF	(kHz)	#					
	$P_r@PII_{max}$	(MPa)	#					
	$d_{eq}@PII_{max}$	(cm)					0.4	
	Focal Length	(cm)		8.3	#	#		6.9
	$I_{PA.3}@MI_{max}$	(W/cm^2)	#					
Operating Control Conditions	Mode			B			M	B
	Frequency	(MHz)		2.5			2.5	2.5
	Focus			6			4	5
	PRF	(kHz)		4.4			5.6	5.1
	Power			Max			Max	Max

Notes:
(a) This index is not required for this operating mode.
(b) This probe is not intended for transcranial or neonatal cephalic uses.
(c) This formulation for TIS is less than that for alternate formulation in this probe.
No data are reported for this operating condition since the global maximum index value is not reported for the reason listed.

Transducer Model: PA230E Operating Mode: B\M-CFM

Index Label			MI	TIS			TIB	TIC
				scan	non-scan		non-scan	
					$A_{aprt}\leq 1$	$A_{aprt}>1$		
Global Maximum Index Value			1.2	4	<1	1.2	3.7	5.5
Assoc. Acoustic Parameter	$Pr_{.3}$	(MPa)	1.9					
	W_o	(mW)		345	#		166	370
	min of $[W_{.3}(z_1), I_{TA.3}(z_1)]$	(cm)				109		
	Z_1	(cm)				3.7		
	Z_{bp}	(cm)				2.5		
	Z_{sp}	(cm)	4.8				5.5	
	$d_{eq}(Z_{sp})$	(cm)					0.4	
	f_c	(MHz)	2	2.4	#	2.3	2.3	2
	Dim of A_{aprt}	X (cm)		1.6	#	1.6	1.6	1.6
		Y (cm)		1.4	#	1.4	1.4	1.4
Other Information	PD	(mSec)	1.35					
	PRF	(kHz)	5.6					
	$P_r@PII_{max}$	(MPa)	2.3					
	$d_{eq}@PII_{max}$	(cm)					0.4	
	Focal Length	(cm)		5.9	#	5.9		5.8
	$I_{PA.3}@MI_{max}$	(W/cm^2)	131					
Operating Control Conditions	Mode(Sens.)		B(Sens1)	B(Sens2)		M	M	B(Sens1)
	Frequency	(MHz)	2	2.5		2.5	2.5	2
	Focus		3	4		4	4	4
	PRF	(kHz)	5.6	5.6		5.6	5.6	5.6
	Power		Max	Max		Max	Max	Max

Notes:
(a) This index is not required for this operating mode.
(b) This probe is not intended for transcranial or neonatal cephalic uses.
(c) This formulation for TIS is less than that for alternate formulation in this probe.
No data are reported for this operating condition since the global maximum index value is not reported for the reason listed.

Transducer Model: PA230E Operating Mode: B\M-TEI

Index Label			MI	TIS			TIB	TIC
				scan	non-scan		non-scan	
					$A_{aprt}\leq 1$	$A_{aprt}>1$		
Global Maximum Index Value			1.2	2.5	1	2.1	4.3	3.7
Assoc. Acoustic Parameter	$Pr_{.3}$	(MPa)	1.9					
	W_o	(mW)		249	100		248	248
	min of $[W_{.3}(z_1), I_{TA.3}(z_1)]$	(cm)				89		
	Z_1	(cm)				3.4		
	Z_{bp}	(cm)				2.5		
	Z_{sp}	(cm)	4.8				5.3	
	$d_{eq}(Z_{sp})$	(cm)					0.4	
	f_c	(MHz)	2.1	2.1	2	2.1	2.1	2.1
	Dim of A_{aprt}	X (cm)		1.8	0.6	1.6	1.6	1.6
		Y (cm)		1.4	1.4	1.4	1.4	1.4
Other Information	PD	(mSec)	1.19					
	PRF	(kHz)	5.6					
	$P_r@PII_{max}$	(MPa)	2.3					
	$d_{eq}@PII_{max}$	(cm)					0.4	
	Focal Length	(cm)		6.9	1.4	5.8		5.8
	$I_{PA.3}@MI_{max}$	(W/cm²)	114					
Operating Control Conditions	Mode		B-TEI	B-TEI	M-TEI	M-TEI	M-TEI	B-TEI
	Frequency	(MHz)	RES	RES	RES	RES	RES	RES
	Focus		3	5	1	4	4	4
	PRF	(kHz)	5.6	5.1	5.6	5.6	5.6	5.6
	Power		Max	Max	Max	Max	Max	Max

Notes:
(a) This index is not required for this operating mode.
(b) This probe is not intended for transcranial or neonatal cephalic uses.
(c) This formulation for TIS is less than that for alternate formulation in this probe.
No data are reported for this operating condition since the global maximum index value is not reported for the reason listed.

Transducer Model: PA230E Operating Mode: CnTI

Index Label			MI	TIS			TIB	TIC
				scan	non-scan		non-scan	
					$A_{aprt}\leq 1$	$A_{aprt}>1$		
Global Maximum Index Value			<1	<1	<1	<1	<1	1.5
Assoc. Acoustic Parameter	$Pr_{.3}$	(MPa)	#					
	W_o	(mW)		#	#		#	103
	min of $[W_{.3}(z_1), I_{TA.3}(z_1)]$	(cm)				#		
	Z_1	(cm)				#		
	Z_{bp}	(cm)				#		
	Z_{sp}	(cm)	#				#	
	$d_{eq}(Z_{sp})$	(cm)					#	
	f_c	(MHz)	#	#	#	#	#	1.8
	Dim of A_{aprt}	X (cm)		#	#	#	#	1.6
		Y (cm)		#	#	#	#	1.4
Other Information	PD	(mSec)	#					
	PRF	(kHz)	#					
	$P_r@PII_{max}$	(MPa)	#					
	$d_{eq}@PII_{max}$	(cm)					#	
	Focal Length	(cm)		#	#	#		5.6
	$I_{PA.3}@MI_{max}$	(W/cm^2)	#					
Operating Control Conditions	Mode							CnTI(Lo)
	Frequency	(MHz)						1.6
	Focus							4
	PRF	(kHz)						5.6
	Power							Max

Notes:
(a) This index is not required for this operating mode.
(b) This probe is not intended for transcranial or neonatal cephalic uses.
(c) This formulation for TIS is less than that for alternate formulation in this probe.
No data are reported for this operating condition since the global maximum index value is not reported for the reason listed.

Transducer Model: PA230E Operating Mode: CW

Index Label			MI	TIS			TIB	TIC
				scan	non-scan		non-scan	
					$A_{aprt} \leq 1$	$A_{aprt} > 1$		
Global Maximum Index Value			<1	a	<1	1.9	5.1	3.7
Assoc. Acoustic Parameter	$Pr_{.3}$	(MPa)	#					
	W_o	(mW)			#		178	192
	min of $[W_{.3}(z_1), I_{TA.3}(z_1)]$	(cm)				162		
	Z_1	(cm)				2		
	Z_{bp}	(cm)				1.9		
	Z_{sp}	(cm)	#				2.1	
	$d_{eq}(Z_{sp})$	(cm)					0.5	
	f_c	(MHz)	#		#	2.5	2.5	2.5
	Dim of A_{aprt}	X (cm)			#	1	1	1
		Y (cm)			#	1.4	1.4	1.4
Other Information	PD	(mSec)	#					
	PRF	(kHz)	#					
	$P_r@PII_{max}$	(MPa)	#					
	$d_{eq}@PII_{max}$	(cm)					0.4	
	Focal Length	(cm)			#	5.8		5.8
	$I_{PA.3}@MI_{max}$	(W/cm^2)	#					
Operating Control Conditions	Mode					CW	CW	CW
	Frequency	(MHz)				2.5	2.5	2.5
	Focus					6	2	6
	PRF	(kHz)						
	Power					Max	Max	Max

Notes:
(a) This index is not required for this operating mode.
(b) This probe is not intended for transcranial or neonatal cephalic uses.
(c) This formulation for TIS is less than that for alternate formulation in this probe.
No data are reported for this operating condition since the global maximum index value is not reported for the reason listed.

Transducer Model: PA230E Operating Mode: PW

Index Label			MI	TIS			TIB	TIC
				scan	non-scan		non-scan	
					$A_{aprt}\leq 1$	$A_{aprt}>1$		
Global Maximum Index Value			1.3	a	<1	2	4.8	3.9
Assoc. Acoustic Parameter	$Pr_{.3}$	(MPa)	2					
	W_o	(mW)			#		295	299
	min of $[W_{.3}(z_1), I_{TA.3}(z_1)]$	(cm)				207		
	Z_1	(cm)				3.6		
	Z_{bp}	(cm)				2.9		
	Z_{sp}	(cm)	4.6				4.1	
	$d_{eq}(Z_{sp})$	(cm)					0.8	
	f_c	(MHz)	2		#	2	2	2
	Dim of A_{aprt} X	(cm)			#	2.2	2.2	2.2
	Y	(cm)			#	1.4	1.4	1.4
Other Information	PD	(mSec)	1.82					
	PRF	(kHz)	2.1					
	$P_r@PII_{max}$	(MPa)	2.6					
	$d_{eq}@PII_{max}$	(cm)					0.6	
	Focal Length	(cm)			#	9.1		9.4
	$I_{PA.3}@MI_{max}$	(W/cm²)	122					
Operating Control Conditions	Mode		PW			PW	PW	PW
	Frequency	(MHz)	2			2	2	2
	Sample Depth	(mm)	77			175	175	188
	Sample Size	(mm)	2			2	2	2
	Power		Max			Max	Max	Max

Notes:
(a) This index is not required for this operating mode.
(b) This probe is not intended for transcranial or neonatal cephalic uses.
(c) This formulation for TIS is less than that for alternate formulation in this probe.
No data are reported for this operating condition since the global maximum index value is not reported for the reason listed.

Transducer Model: TE022 Operating Mode: B\M

Index Label			MI	TIS			TIB	TIC
				scan	non-scan		non-scan	
					$A_{aprt} \leq 1$	$A_{aprt} > 1$		
Global Maximum Index Value			1.2	<1	<1	-	1	b
Assoc. Acoustic Parameter	$Pr_{.3}$	(MPa)	2.5					
	W_o	(mW)		#	#		26	
	min of $[W_{.3}(z_1), I_{TA.3}(z_1)]$	(cm)				-		
	Z_1	(cm)				-		
	Z_{bp}	(cm)				-		
	Z_{sp}	(cm)	1.6				1.6	
	$d_{eq}(Z_{sp})$	(cm)					0.3	
	f_c	(MHz)	4.2	#	#	-	4.2	
	Dim of A_{aprt}	X (cm)		#	#	-	1	
		Y (cm)		#	#	-	0.9	
Other Information	PD	(mSec)	0.21					
	PRF	(kHz)	5.6					
	$P_r@PII_{max}$	(MPa)	3.1					
	$d_{eq}@PII_{max}$	(cm)					0.3	
	Focal Length	(cm)		#	#	-		
	$I_{PA.3}@MI_{max}$	(W/cm^2)	240					
Operating Control Conditions	Mode		M				M	
	Frequency	(MHz)	5				5	
	Focus		1				1	
	PRF	(kHz)	5.6				5.6	
	Power		Max				Max	

Notes:
(a) This index is not required for this operating mode.
(b) This probe is not intended for transcranial or neonatal cephalic uses.
(c) This formulation for TIS is less than that for alternate formulation in this probe.
No data are reported for this operating condition since the global maximum index value is not reported for the reason listed.

Transducer Model: TE022 Operating Mode: B\M-CFM

Index Label			MI	TIS			TIB	TIC
				scan	non-scan		non-scan	
					$A_{aprt} \leq 1$	$A_{aprt} > 1$		
Global Maximum Index Value			1.1	<1	<1	-	1.2	b
Assoc. Acoustic Parameter	$Pr_{.3}$	(MPa)	1.4					
	W_o	(mW)		#	#		22	
	min of $[W_{.3}(z_1), I_{TA.3}(z_1)]$	(cm)				-		
	Z_1	(cm)				-		
	Z_{bp}	(cm)				-		
	Z_{sp}	(cm)	3.4				1.6	
	$d_{eq}(Z_{sp})$	(cm)					0.3	
	f_c	(MHz)	4.8	#	#	-	3.4	
	Dim of A_{aprt}	X (cm)		#	#	-	1	
		Y (cm)		#	#	-	0.9	
Other Information	PD	(mSec)	0.41					
	PRF	(kHz)	5.6					
	$P_r@PII_{max}$	(MPa)	2.5					
	$d_{eq}@PII_{max}$	(cm)					0.3	
	Focal Length	(cm)		#	#	-		
	$I_{PA.3}@MI_{max}$	(W/cm^2)	60					
Operating Control Conditions	Mode(Sens.)		B(Sens1)				M	
	Frequency	(MHz)	5				3.3	
	Focus		1				1	
	PRF	(kHz)	0.7				5.6	
	Power		Max				Max	

Notes:
(a) This index is not required for this operating mode.
(b) This probe is not intended for transcranial or neonatal cephalic uses.
(c) This formulation for TIS is less than that for alternate formulation in this probe.
No data are reported for this operating condition since the global maximum index value is not reported for the reason listed.

Transducer Model: TE022 Operating Mode: B\M-TEI

Index Label			MI	TIS			TIB	TIC
				scan	non-scan		non-scan	
					$A_{aprt} \leq 1$	$A_{aprt} > 1$		
Global Maximum Index Value			1	<1	<1	-	<1	b
Assoc. Acoustic Parameter	$Pr_{.3}$	(MPa)	1.9					
	W_o	(mW)		#	#		#	
	min of $[W_{.3}(z_1), I_{TA.3}(z_1)]$	(cm)				-		
	Z_1	(cm)				-		
	Z_{bp}	(cm)				-		
	Z_{sp}	(cm)	1.6				#	
	$d_{eq}(Z_{sp})$	(cm)					#	
	f_c	(MHz)	4	#	#	-	#	
	Dim of A_{aprt}	X (cm)		#	#	-	#	
		Y (cm)		#	#	-	#	
Other Information	PD	(mSec)	0.25					
	PRF	(kHz)	5.6					
	$P_r@PII_{max}$	(MPa)	2.3					
	$d_{eq}@PII_{max}$	(cm)					#	
	Focal Length	(cm)		#	#	-		
	$I_{PA.3}@MI_{max}$	(W/cm^2)	132					
Operating Control Conditions	Mode		B-TEI					
	Frequency	(MHz)	GEN					
	Focus		1					
	PRF	(kHz)	5.6					
	Power		Max					

Notes:
(a) This index is not required for this operating mode.
(b) This probe is not intended for transcranial or neonatal cephalic uses.
(c) This formulation for TIS is less than that for alternate formulation in this probe.
No data are reported for this operating condition since the global maximum index value is not reported for the reason listed.

Transducer Model: TE022 Operating Mode: CW

Index Label			MI	TIS			TIB	TIC
				scan	non-scan		non-scan	
					$A_{aprt} \leq 1$	$A_{aprt} > 1$		
Global Maximum Index Value			<1	a	<1	-	1	b
Assoc. Acoustic Parameter	$Pr_{.3}$	(MPa)	#					
	W_o	(mW)			#		14	
	min of $[W_{.3}(z_1), I_{TA.3}(z_1)]$	(cm)				-		
	Z_1	(cm)				-		
	Z_{bp}	(cm)				-		
	Z_{sp}	(cm)	#				0.8	
	$d_{eq}(Z_{sp})$	(cm)					0.2	
	f_c	(MHz)	#		#	-	5	
	Dim of A_{aprt}	X (cm)			#	-	0.4	
		Y (cm)			#	-	0.9	
Other Information	PD	(mSec)	#					
	PRF	(kHz)	#					
	P_r@PII_{max}	(MPa)	#					
	d_{eq}@PII_{max}	(cm)					0.2	
	Focal Length	(cm)			#	-		
	$I_{PA.3}$@MI_{max}	(W/cm^2)	#					
Operating Control Conditions	Mode						CW	
	Frequency	(MHz)					5	
	Focus						1	
	PRF	(kHz)						
	Power						Max	

Notes:
(a) This index is not required for this operating mode.
(b) This probe is not intended for transcranial or neonatal cephalic uses.
(c) This formulation for TIS is less than that for alternate formulation in this probe.
No data are reported for this operating condition since the global maximum index value is not reported for the reason listed.

Transducer Model: TE022 Operating Mode: PW

Index Label			MI	TIS			TIB	TIC
				scan	non-scan		non-scan	
					$A_{aprt} \leq 1$	$A_{aprt} > 1$		
Global Maximum Index Value			1.1	a	<1	-	1.1	b
Assoc. Acoustic Parameter	$Pr_{.3}$	(MPa)	2.3					
	W_o	(mW)			#		18	
	min of $[W_{.3}(z_1), I_{TA.3}(z_1)]$	(cm)				-		
	Z_1	(cm)				-		
	Z_{bp}	(cm)				-		
	Z_{sp}	(cm)	1.6				1.5	
	$d_{eq}(Z_{sp})$	(cm)					0.3	
	f_c	(MHz)	5		#	-	3.3	
	Dim of A_{aprt} X	(cm)			#	-	1	
	Y	(cm)			#	-	0.9	
Other Information	PD	(mSec)	0.65					
	PRF	(kHz)	2.1					
	$P_r@PII_{max}$	(MPa)	3					
	$d_{eq}@PII_{max}$	(cm)					0.3	
	Focal Length	(cm)			#	-		
	$I_{PA.3}@MI_{max}$	(W/cm²)	183					
Operating Control Conditions	Mode		PW				PW	
	Frequency	(MHz)	5				3.3	
	Sample Depth	(mm)	0				0	
	Sample Size	(mm)	2				2	
	Power		Max				Max	

Notes:
(a) This index is not required for this operating mode.
(b) This probe is not intended for transcranial or neonatal cephalic uses.
(c) This formulation for TIS is less than that for alternate formulation in this probe.
No data are reported for this operating condition since the global maximum index value is not reported for the reason listed.

Acoustic Output Data according to IEC61157

PA230E (Reference:960 0165 000)

Parameter ↓ / Mode →	Imaging B	Imaging M	Imaging B-TEI	Imaging M-TEI	CnTI	D_P	D_I	D+BCFM P	BCFM P	BCFM I	MCFM P	MCFM I	CW
p_(MPa)	2	2	2.8	2.8	1.5	3.7	2.3	2.7	3.1	2.2	2.5	2.5	0.2
I_{spta} (mW/cm^2)	77	463	257	1297	53	2295	2358	970	1019	1135	1536	1617	1726
System settings[a]	F = 3	F = 3	F = 4	F = 4	F = 3	SS = 2 SD = 104	SS = 2 SD = 104	SS = 2 SD = 90	F = 4	F = 4	F = 3	F = 4	F = 4
I_p (mm)	52	52	58	58	46	73	73	65	59	58	52	59	56
w_{pb6} (||) (mm)	3	3	3.8	3.8	3.6	4.4	4.4	3.3	3.6	3.8	3	3.6	4.2
w_{pb6} (|) (mm)	6.5	6.5	4.5	4.5	6.2	4.4	4.4	4	4.5	4.5	6.5	4.5	5.4
prr (kHz)	5.6	5.6	5.6	5.6	5.6	2.1	5.6	4.8	5.6	5.6	5.6	5.6	1
srr (Hz)	125	-	125	125	66	-	-	-	53	53	-	-	-
Output beam dimension (||) (mm)[b]	13.4	13.4	15.8	15.8	13.4	17.9	17.9	15.8	15.8	15.8	13.4	15.8	9.5
Output beam dimension (|) (mm)[b]	14	14	14	14	14	14	14	14	14	14	14	14	14
f_{awf} (MHz)	2.3	2.3	2.1	2.1	1.8	2.4	2.4	2.3	2.3	2	2.3	2.3	2.5
APF[c] (%)	-	-	-	-	-	-	-	-	-	-	-	-	-
AIF[d] (%)	100	100	137	137	75	183	114	136	154	110	123	123	12
Maximum power[e] (mW)	93.7	93.7	322.5	322.5	114	330.4	339.4	209	448.1	480.5	169.6	215.9	244.8
I_{ob} (mW/cm^2)	49.9	49.9	145.9	145.9	60.6	132.1	135.8	94.6	202.7	217.4	90.2	97.7	184.1
Power-up Mode	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Initialization mode	B	B	B	B	B	B	B	B	B	B	B	B	B
Acoustic output freeze	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
I_{tt} (mm)	-	-	-	-	-	-	-	-	-	-	-	-	-
I_{ts} (mm)	Contact	Contact	Contact	Contact	Contact	Contact	Contact	Contact	Contact	Contact	Contact	Contact	Contact
Inclusive modes		B+M		B+M			B+D B-CFM+D	B+D			B-CFM + M-CFM	B-CFM + M-CFM	B+CW B-CFM+CW

[a] SS = Sample Size SD = Sample Depth F= transmit focal point POWER = 100%

[b] ∅ defines diameter

[c] Acoustic power-up fraction

[d] Acoustic initialization fraction

[e] controllable by the user

Mode➔ / Parameter ⬇	Imaging B	Imaging M	Imaging B-TEI	Imaging M-TEI	D_P	D_I	D+BCFM P	BCFM P	BCFM I	MCFM P	MCFM I	CW
p_(MPa)	2.4	2.4	1.6	1.6	4.5	2.2	3.5	3.8	2.7	3.6	3	0.2
I_{spta} (mW/cm^2)	60	330	84	461	1730	1914	771	616	761	1367	1506	1587
System settings[a]	F = 6	F =6	F = 6	F = 6	SS = 2 SD = 97	SS = 2 SD = 97	SS = 2 SD = 97	F = 6	F = 3	F = 3	F = 5	F = 6
I_p (mm)	60	60	60	60	61	61	61	28	28	55	54	69
w_{pb6} (||) (mm)	3.9	3.9	3.9	3.9	3.3	3.5	3.3	2.2	2.2	3	3.3	4.7
w_{pb6} (|) (mm)	7.7	7.7	6.8	6.8	7.1	6.1	7.1	10.4	10.4	8	7.5	5.9
prr (kHz)	5.6	5.6	5.6	5.6	2.1	5.6	4.8	5.6	5.6	5.6	5.6	1
srr (Hz)	125	-	125	125	-	-	45	56	56	56	56	-
Output beam dimension (||) (mm)[b]	14.1	14.1	14.1	14.1	14.1	14.1	14.1	9.4	9.4	12.9	12.9	8.1
Output beam dimension (|) (mm)[b]	13	13	13	13	13	13	13	13	13	13	13	13
f_{awf} (MHz)	3.1	3.1	2.2	2.2	3.3	2.5	3.1	3.3	3.3	3.1	2.6	3.3
APF[c] (%)	-	-	-	-	-	-	-	-	-	-	-	-
AIF[d] (%)	100	100	68	68	187	90	146	156	110	149	124	9
Maximum power [e] (mW)	107.6	107.6	141.3	141.3	248.5	259.3	176.6	269.7	333.3	218	231.7	237.2
I_{ob} (mW/cm^2)	58.8	58.8	77.2	77.2	135.8	141.7	96.5	219.3	271	130.5	138.8	223.8
Power-up Mode	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Initialization mode	B	B	B	B	B	B	B	B	B	B	B	B
Acoustic output freeze	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
I_{tt} (mm)	-	-	-	-	-	-	-	-	-	-	-	-
I_{ts} (mm)	Contact	Contact	Contact	Contact	Contact	Contact	Contact	Contact	Contact	Contact	Contact	Contact
Inclusive modes		B+M		B+M		B+D B-CFM+D	B+D			B-CFM + M-CFM	B-CFM + M-CFM	B+CW B-CFM+CW

[a] SS = Sample Size SD = Sample Depth F= transmit focal point POWER = 100%

[b] ∅ defines diameter

[c] Acoustic power-up fraction

[d] Acoustic initialization fraction

[e] controllable by the user

Mode➔ / Parameter ⬇	Imaging B	Imaging M	D_P	D_I	D+BCFM P	BCFM P	BCFM I	MCFM P - I	CW
p_-(MPa)	2.7	2.7	6	6	4.2	4.4	3.1	4.2	0.3
I_{spta} (mW/cm^2)	69	366	2237	2237	991	483	1265	1404	3005
System settings[a]	F = 6	F =6	SS = 2 SD = 61	SS = 2 SD = 61	F = 7	F = 2	F = 8	F = 6	F = 5
I_p (mm)	41	41	40	40	41	11	44	39	47
w_{pb6} (||) (mm)	2.5	2.5	2.1	2.1	2.9	1	3.6	2.3	2.6
w_{pb6} (|) (mm)	4.7	4.7	4.2	4.2	4.1	8.5	3.2	4.4	2.4
prr (kHz)	5.6	5.6	2.1	2.1	5.6	5.6	5.6	5.6	1
srr (Hz)	125	-	-	-	59	42	59	63	-
Output beam dimension (||) (mm)[b]	9.2	9.2	9.2	9.2	10	4.7	10.7	9.2	6.7
Output beam dimension (|) (mm)[b]	10	10	10	10	10	10	10	10	10
f_{awf} (MHz)	4.4	4.4	4.8	4.8	4.4	4.6	3.4	4.4	5
APF[c] (%)	-	-	-	-	-	-	-	-	-
AIF[d] (%)	100	100	221	221	155	162	115	154	11
Maximum power[e] (mW)	49.2	49.2	132.1	132.1	96.7	104.3	233.5	95.3	130.3
I_{ob} (mW/cm^2)	53.2	53.2	143	143	97.1	222.9	218.6	103.2	194.4
Power-up Mode	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Initialization mode	B	B	B	B	B	B	B	B	B
Acoustic output freeze	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
I_{tt} (mm)	-	-	-	-	-	-	-	-	-
I_{ts} (mm)	Contact	Contact	Contact	Contact	Contact	Contact	Contact	Contact	Contact
Inclusive modes		B+M		B+D B-CFM+D	B+D			B-CFM + M-CFM	B+CW B-CFM+CW

[a] SS = Sample Size SD = Sample Depth F= transmit focal point POWER = 100%

[b] ∅ defines diameter

[c] Acoustic power-up fraction

[d] Acoustic initialization fraction

[e] controllable by the user

Mode➔ / Parameter ⬇	Imaging B	Imaging M	D_P	D_I	D+BCFM P	BCFM P	BCFM I	MCFM P-I	CW
p_(MPa)	3.1	3	4.4	4.3	3.6	4.3	3	3.5	0.2
I_{spta} (mW/cm^2)	84	341	1388	1629	931	1234	1283	1206	1509
System settings[a]	F = 6	F =5	SS = 2 SD = 29	SS = 2 SD = 42	SS = 2 SD = 29	F = 6	F = 7	F = 6	F = 7
I_p (mm)	23	20	24	27	24	22	24	22	23
w_{pb6} (||) (mm)	2	1.6	1.6	1.7	1.6	1.9	2.7	1.9	1.8
w_{pb6} (|) (mm)	1.5	2.3	1.7	1.6	1.7	1.6	1.5	1.6	1.7
prr (kHz)	5.6	5.6	2.1	2.1	5.6	5.6	5.6	5.6	1
srr (Hz)	125	-	-	-	67	63	63	63	-
Output beam dimension (||) (mm)[b]	6.1	5.5	5.5	6.1	5.5	6.1	6.7	6.1	5.6
Output beam dimension (|) (mm)[b]	6	6	6	6	6	6	6	6	6
f_{awf} (MHz)	6.4	6.5	5.2	5.1	5.4	5.2	5.1	5.4	5
APF[c] (%)	-	-	-	-	-	-	-	-	-
AIF[d] (%)	100	98	141	140	116	140	98	114	7
Maximum power[e] (mW)	13.9	12.2	28	31	26.9	57.8	63.8	27.1	36.7
I_{ob} (mW/cm^2)	37.9	36.9	85	84.8	81.6	157.9	158.7	74	107.9
Power-up Mode	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Initialization mode	B	B	B	B	B	B	B	B	B
Acoustic output freeze	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
I_{tt} (mm)	-	-	-	-	-	-	-	-	-
I_{ts} (mm)	Contact	Contact	Contact	Contact	Contact	Contact	Contact	Contact	Contact
Inclusive modes		B+M		B+D B-CFM+D	B+D			B-CFM + M-CFM	B+CW B-CFM+CW

[a] SS = Sample Size SD = Sample Depth F= transmit focal point POWER = 100%

[b] ∅ defines diameter

[c] Acoustic power-up fraction

[d] Acoustic initialization fraction

[e] controllable by the user

LA522E (Reference:960 0163 000)

Mode➔ / Parameter ⬇	Imaging B	Imaging M	Imaging B-TEI	Imaging M-TEI	D_P	D_I	D+BCFM P	BCFM P	BCFM I	MCFM P - I
p_(MPa)	3.4	3.4	2.6	2.8	4.9	4.9	4.1	4.9	3	3.9
I_{spta} (mW/cm^2)	43	132	31	529	1346	1832	673	517	1242	1260
System settings[a]	F = 3	F = 3	F = 3	F = 3	SS = 2 SD = 77	SS = 2 SD = 44	SS = 2 SD = 27	F = 3	F = 8	F = 3
I_p (mm)	19	19	19	19	22	29	18	18	22	18
w_{pb6} (||) (mm)	1.7	1.7	1.7	1.7	7.2	2.6	1.7	1.5	7.3	1.7
w_{pb6} (|) (mm)	1.9	1.9	2.1	2.1	1.6	1.9	1.8	1.6	1.6	1.8
prr (kHz)	1	1	6.7	6.7	2.1	2.1	5.6	5.6	5.6	5.6
srr (Hz)	34	-	34	34	-	-	-	23	23	-
Output beam dimension (||) (mm)[b]	6.4	6.4	6.4	6.4	10.8	8.3	6.4	6.4	10.8	6.4
Output beam dimension (|) (mm)[b]	6	6	6	6	6	6	6	6	6	6
f_{awf} (MHz)	4.8	4.8	4.1	4.1	4.8	4.9	4.6	4.8	4.9	4.6
APF[c] (%)	-	-	-	-	-	-	-	-	-	-
AIF[d] (%)	100	100	76	81	143	142	118	144	88	114
Maximum power[e] (mW)	4.6	4.7	25.2	25.2	103.3	55.6	28.5	64	132	26.7
I_{ob} (mW/cm^2)	12.1	12.5	66.4	66.4	158.9	111.3	75	168.3	203.1	70.2
Power-up Mode	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Initialization mode	B	B	B	B	B	B	B	B	B	B
Acoustic output freeze	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
I_{tt} (mm)	-	-	-	-	-	-	-	-	-	-
I_{ts} (mm)	Contact	Contact	Contact	Contact	Contact	Contact	Contact	Contact	Contact	Contact
Inclusive modes		B+M		B+M		B+D B-CFM+D	B+D			B-CFM + M-CFM

[a] SS = Sample Size SD = Sample Depth F= transmit focal point POWER = 100%

[b] ∅ defines diameter

[c] Acoustic power-up fraction

[d] Acoustic initialization fraction

[e] controllable by the user

Mode➔ / Parameter ⬇	Imaging B	Imaging M	Imaging B-TEI	Imaging M-TEI	D_P	D_I	D+BCFM P	BCFM P	BCFM I	MCFM P-I
p_(MPa)	5.1	5.5	4.2	4	5.3	5.2	5.2	5.6	4.8	4.3
I_{spta} (mW/cm^2)	25	120	21	400	1224	1399	1131	469	1218	1214
System settings[a]	F = 3	F =3	F = 3	F = 4	SS = 2 SD = 18	SS = 2 SD = 29	F = 2	F = 2	F = 5	F = 3
I_p (mm)	14	14	13	14	13	16	13	11	15	13
w_{pb6} (||) (mm)	1.1	1.1	1.2	1.4	1.1	2.1	1.1	1.1	2.2	1.1
w_{pb6} (|) (mm)	1	1	1	1.1	0.8	0.9	0.8	1.2	0.9	0.9
prr (kHz)	6.7	1	1	6.7	2.1	2.1	5.6	5.6	5.6	5.6
srr (Hz)	36	-	34	34	-	-	24	27	34	27
Output beam dimension (||) (mm)[b]	4.4	4.4	4.4	4.9	4.4	5.4	4.4	3.4	5.4	4.4
Output beam dimension (|) (mm)[b]	5	5	5	5	5	5	5	5	5	5
f_{awf} (MHz)	6.7	6.7	5.4	5.4	6.6	6.6	6.5	6.5	6.6	6.5
APF[c] (%)	-	-	-	-	-	-	-	-	-	-
AIF[d] (%)	100	110	84	78	105	102	104	111	95	85
Maximum power[e] (mW)	9.8	1.8	1.3	8.5	8.7	17.6	14.9	32.4	53.7	9.9
I_{ob} (mW/cm^2)	44.8	8	5.9	34.1	39.4	65	67.5	190.5	199	45.2
Power-up Mode	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Initialization mode	B	B	B	B	B	B	B	B	B	B
Acoustic output freeze	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
I_{tt} (mm)	-	-	-	-	-	-	-	-	-	-
I_{ts} (mm)	Contact	Contact	Contact	Contact	Contact	Contact	Contact	Contact	Contact	Contact
Inclusive modes		B+M		B+M		B+D B-CFM+D	B+D			B-CFM + M-CFM

[a] SS = Sample Size SD = Sample Depth F= transmit focal point POWER = 100%

[b] ∅ defines diameter

[c] Acoustic power-up fraction

[d] Acoustic initialization fraction

[e] controllable by the user

2 MHz CW (Reference: 960 0125 000)

Mode➔ / Parameter ⬇	CW
p_- (MPa)	0.2
I_{spta} (mW/cm^2)	1231
System settings[a]	F = 1
I_p (mm)	33
w_{pb6} (||) (mm)	4.8
w_{pb6} (|) (mm)	3.9
prr (kHz)	-
srr (Hz)	-
Output beam dimension Φ (mm)[b]	13
f_{awf} (MHz)	2
APF[c] (%)	-
AIF[d] (%)	99
Maximum power [e] (mW)	148.8
I_{ob} (mW/cm^2)	212.5
Power-up Mode	N/A
Initialization mode	CW
Acoustic output freeze	Yes
I_{tt} (mm)	-
I_{ts} (mm)	Contact
Inclusive modes	

[a] SS = Sample Size SD = Sample Depth F= transmit focal point POWER = 100%

[b] ∅ defines diameter

[c] Acoustic power-up fraction

[d] Acoustic initialization fraction

[e] controllable by the user

5 MHz CW (Reference: 960 0126 000)

Parameter ↓ / Mode →	CW
p_- (MPa)	0.2
I_{spta} (mW/cm^2)	937
System settings[a]	F = 1
I_p (mm)	6
w_{pb6} (||) (mm)	2.4
w_{pb6} (|) (mm)	3.5
prr (kHz)	-
srr (Hz)	-
Output beam dimension Φ (mm)[b]	6.0
f_{awf} (MHz)	5
APF[c] (%)	-
AIF[d] (%)	100
Maximum power [e] (mW)	43
I_{ob} (mW/cm^2)	306.8
Power-up Mode	N/A
Initialization mode	CW
Acoustic output freeze	Yes
I_{tt} (mm)	-
I_{ts} (mm)	Contact
Inclusive modes	

[a] SS = Sample Size SD = Sample Depth F= transmit focal point POWER = 100%

[b] ∅ defines diameter

[c] Acoustic power-up fraction

[d] Acoustic initialization fraction

[e] controllable by the user

Mode➔ / Parameter ⬇	Imaging B	Imaging M	Imaging B-TEI	Imaging M-TEI	D_P	D_I	D+BCFM P	BCFM P	BCFM I	MCFM P-I
p_(MPa)	3.9	3.9	2.8	2.7	2.9	2.1	4.6	4.4	2.2	3.5
I_{spta} (mW/cm^2)	93	893	48	469	1479	1624	1042	199	457	1226
System settings[a]	F = 3	F =3	F = 3	F = 3	SS = 2 SD = 32	SS = 2 SD = 41	F = 2	F = 2	F = 8	F = 4
I_p (mm)	14	14	13	14	21	25	14	12	14	17
w_{pb6} (||) (mm)	1.1	1.1	1.2	1.2	1.4	1.5	1	0.9	5	1.2
w_{pb6} (|) (mm)	1.6	1.6	1.7	1.6	1.5	1.7	1.7	1.9	1.4	1.4
prr (kHz)	5.6	5.6	5.6	5.6	5.6	11.1	5.6	5.6	5.6	5.6
srr (Hz)	102	-	103	93	58	58	35	35	58	35
Output beam dimension (||) (mm)[b]	4.9	4.9	4.9	4.9	6.3	6.7	4.2	4.2	7.4	5.6
Output beam dimension (|) (mm)[b]	4.2	4.2	4.2	4.2	4.2	4.2	4.2	4.2	4.2	4.2
f_{awf} (MHz)	4.8	4.8	4.4	4.8	6.4	6.4	5.9	6.2	6.4	5.8
APF[c] (%)	-	-	-	-	-	-	-	-	-	-
AIF[d] (%)	100	100	72	69	74	54	119	113	57	91
Maximum power[e] (mW)	25.4	23.5	14	12.9	23.7	31.3	23.4	26.5	40.4	16
I_{ob} (mW/cm^2)	121	111.7	66.5	61.4	91.1	111.7	129.8	147.3	130.3	66.8
Power-up Mode	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Initialization mode	B	B	B	B	B	B	B	B	B	B
Acoustic output freeze	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
I_{tt} (mm)	-	-	-	-	-	-	-	-	-	-
I_{ts} (mm)	Contact	Contact	Contact	Contact	Contact	Contact	Contact	Contact	Contact	Contact
Inclusive modes		B+M		B+M		B+D B-CFM+D	B+D			B-CFM + M-CFM

[a] SS = Sample Size SD = Sample Depth F= transmit focal point POWER = 100%

[b] ∅ defines diameter

[c] Acoustic power-up fraction

[d] Acoustic initialization fraction

[e] controllable by the user

Mode➔ / Parameter ⬇	Imaging B	Imaging M	Imaging B-TEI	Imaging M-TEI	CnTI	D_P	D_I	D+BCFM P	BCFM P	BCFM I	MCFM I
p_(MPa)	2.7	2.7	3.1	2.7	1	3.3	3.2	3.6	3.6	3.4	3.2
I_{spta} (mW/cm^2)	104	724	162	202	35	1090	1428	834	520	765	1226
System settings[a]	F =4	F = 4	F = 8	F = 6	F = 6	SS = 2 SD = 37	SS = 2 SD = 117	F = 8	F = 7	F = 6	F = 8
I_p (mm)	30	30	49	33	33	31	49	50	49	40	52
w_{pb6} (||) (mm)	3.5	3.5	5.9	5.8	5.3	3.6	6.2	6.9	5.8	5	6.9
w_{pb6} (|) (mm)	3.5	3.5	4.5	3.8	4	5	3.7	3.7	3.9	3.5	4
prr (kHz)	5.6	5.6	4.2	5.6	5.6	2.1	2.1	4.2	4.2	5.6	4.2
srr (Hz)	80	-	60	80	80	55	41	40	41	54	40
Output beam dimension (||) (mm)[b]	7.8	7.8	12.6	10.8	10.8	6.6	12	12.6	12	10.8	12.6
Output beam dimension (|) (mm)[b]	12	12	12	12	12	12	12	12	12	12	12
f_{awf} (MHz)	2.1	2.1	1.9	1.7	1.7	2.4	2.4	2.2	2.3	2.4	2.2
APF[c] (%)	-	-	-	-	-	-	-	-	-	-	-
AIF[d] (%)	100	100	112	98	38	119	118	130	132	126	116
Maximum power[e] (mW)	109.5	109.5	253.5	261	45.9	107	199.4	147.6	206.7	266.2	199.4
I_{ob} (mW/cm^2)	116.5	116.4	167.9	200.8	35.3	135.4	138.4	97.8	143.5	204.8	132
Power-up Mode	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Initialization mode	B	B	B	B	B	B	B	B	B	B	B
Acoustic output freeze	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
I_{tt} (mm)	-	-	-	-	-	-	-	-	-	-	-
I_{ts} (mm)	Contact	Contact	Contact	Contact	Contact	Contact	Contact	Contact	Contact	Contact	Contact
Inclusive modes		B+M		B+M			B+D B-CFM+D	B+D			B-CFM + M-CFM

[a] SS = Sample Size SD = Sample Depth F= transmit focal point POWER = 100%

[b] ∅ defines diameter

[c] Acoustic power-up fraction

[d] Acoustic initialization fraction

[e] controllable by the user

Mode➔ / Parameter ⬇	Imaging B	Imaging M	Imaging B-TEI	Imaging M-TEI	D_P	D_I	D+BCFM P	BCFM P	BCFM I	MCFM P-I
p_(MPa)	3.9	3.8	1.8	1.9	4.3	2.7	3.6	3.3	2.8	3.5
I_{spta} (mW/cm^2)	150	1063	57	400	2102	2216	779	422	596	1608
System settings[a]	F = 6	F = 6	F = 7	F = 6	SS = 2 SD = 116	SS = 2 SD = 108	F = 7	F = 5	F = 8	F = 5
I_p (mm)	48	48	50	46	55	55	55	43	55	43
w_{pb6} (||) (mm)	3.8	3.6	4.6	4.1	5	5	5	3.1	6.3	3.1
w_{pb6} (|) (mm)	4.5	4	4.3	4.4	3.3	3.3	3.3	5.2	3.9	5.2
prr (kHz)	5.6	5.6	5.1	5.6	2.1	5.6	4.2	5.6	4.2	5.6
srr (Hz)	78	-	71	72	32	32	32	46	42	46
Output beam dimension (||) (mm)[b]	10.8	10.8	12	10.8	12	12	12	9.6	12.6	9.6
Output beam dimension (|) (mm)[b]	12	12	12	12	12	12	12	12	12	12
f_{awf} (MHz)	2.9	2.9	2.1	2.1	3.2	3.2	2.9	3.1	3.2	3
APF[c] (%)	-	-	-	-	-	-	-	-	-	-
AIF[d] (%)	100	97	45	48	112	68	93	84	72	91
Maximum power[e] (mW)	259.4	211.2	95.5	95.6	231.8	244.4	150.8	251.9	290.7	182.4
I_{ob} (mW/cm^2)	199.5	162.5	66.3	73.6	161	169.7	104.7	219.1	192.5	158.6
Power-up Mode	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Initialization mode	B	B	B	B	B	B	B	B	B	B
Acoustic output freeze	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
I_{tt} (mm)	-	-	-	-	-	-	-	-	-	-
I_{ts} (mm)	Contact	Contact	Contact	Contact	Contact	Contact	Contact	Contact	Contact	Contact
Inclusive modes		B+M		B+M		B+D B-CFM+D	B+D			B-CFM + M-CFM

[a] SS = Sample Size SD = Sample Depth F= transmit focal point POWER = 100%

[b] ∅ defines diameter

[c] Acoustic power-up fraction

[d] Acoustic initialization fraction

[e] controllable by the user

Mode➔ / Parameter ⬇	Imaging B	Imaging M	Imaging B-TEI	Imaging M-TEI	D_{P-I}	D+BCFM P	BCFM P	BCFM I	MCFM I
p_(MPa)	3.2	3.1	1.3	1.2	3.9	3.3	3.1	2.2	3.3
I_{spta} (mW/cm^2)	379	507	41	316	2054	1395	632	716	1710
System settings[a]	F = 5	F = 5	F = 7	F = 6	SS = 2 SD = 67	F = 6	F = 6	F = 5	F = 7
I_p (mm)	42	48	55	49	52	54	49	43	60
w_{pb6} (||) (mm)	3.5	3	6.5	3.7	3.1	3.5	3.7	3.5	6.6
w_{pb6} (|) (mm)	3.1	3.2	3.3	3.1	2.7	2.7	2.8	3.1	3
prr (kHz)	5.6	5.6	5.1	5.6	2.1	4.8	4.2	5.6	4.2
srr (Hz)	57	-	52	57	57	45	45	57	43
Output beam dimension (||) (mm)[b]	9.9	9.9	13.9	11.2	9.9	11.2	11.2	9.9	13.9
Output beam dimension (|) (mm)[b]	12	12	12	12	12	12	12	12	12
f_{awf} (MHz)	2.5	3.2	2.5	2.6	3.2	3	3.1	2.5	3
APF[c] (%)	-	-	-	-	-	-	-	-	-
AIF[d] (%)	100	96	54	53	144	105	98	67	104
Maximum power[e] (mW)	119.4	71	67.6	55.5	137.7	188.2	181.3	231.7	250.5
I_{ob} (mW/cm^2)	100.3	59.7	40.7	41.1	115.7	139.4	134.3	194.7	150.9
Power-up Mode	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Initialization mode	B	B	B	B	B	B	B	B	B
Acoustic output freeze	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
I_{tt} (mm)	-	-	-	-	-	-	-	-	-
I_{ts} (mm)	Contact	Contact	Contact	Contact	Contact	Contact	Contact	Contact	Contact
Inclusive modes		B+M		B+M		B+D			B-CFM + M-CFM

[a] SS = Sample Size SD = Sample Depth F= transmit focal point POWER = 100%

[b] ∅ defines diameter

[c] Acoustic power-up fraction

[d] Acoustic initialization fraction

[e] controllable by the user

Mode➔ / Parameter ⬇	Imaging B	Imaging M	Imaging B-TEI	Imaging M-TEI	CnTI	D_P	D_I	D+BCFM P	BCFM P	BCFM I	MCFM I
p_(MPa)	1.8	2	3.3	2.6	1.2	3.6	3.5	4.7	4.7	3.5	4.9
I_{spta} (mW/cm^2)	16	55	112	1082	7	1106	1164	344	186	470	1427
System settings[a]	F = 3	F = 3	F = 5	F = 6	F = 3	SS = 2 SD = 45	SS = 2 SD = 56	F = 5	F = 5	F = 6	F = 5
I_p (mm)	18	18	22	27	16	23	26	31	28	30	28
w_{pb6} (||) (mm)	1.9	1.9	3.4	4	2.1	3.3	2.6	2.3	2.6	3.3	2.6
w_{pb6} (|) (mm)	2	2	2.8	3.3	2.2	2.4	2.6	2.2	2.2	3.2	2.2
prr (kHz)	6.7	1	6.7	6.7	8.3	2.1	2.1	5.6	5.6	5.6	5.6
srr (Hz)	34	-	34	34	22	22	21	22	22	21	22
Output beam dimension (||) (mm)[b]	6.4	6.4	8.3	9.3	6.4	8.3	9.3	8.3	8.3	9.3	8.3
Output beam dimension (|) (mm)[b]	6	6	6	6	6	6	6	6	6	6	6
f_{awf} (MHz)	3.2	3.2	2.6	2.6	2.6	3.2	3.2	4.1	4.6	3.2	4.1
APF[c] (%)	-	-	-	-	-	-	-	-	-	-	-
AIF[d] (%)	100	109	185	145	65	196	193	263	259	194	269
Maximum power [e] (mW)	12.7	2.4	117.5	153.2	12.6	52.5	55.1	18.4	29.3	139.7	53.5
I_{ob} (mW/cm^2)	33.5	6.2	234.9	273.5	33.3	104.9	98.4	36.8	58.6	249.5	107
Power-up Mode	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Initialization mode	B	B	B	B	B	B	B	B	B	B	B
Acoustic output freeze	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
I_{tt} (mm)	-	-	-	-	-	-	-	-	-	-	-
I_{ts} (mm)	Contact	Contact	Contact	Contact	Contact	Contact	Contact	Contact	Contact	Contact	Contact
Inclusive modes		B+M		B+M			B+D B-CFM+D	B+D			B-CFM + M-CFM

[a] SS = Sample Size SD = Sample Depth F= transmit focal point POWER = 100%

[b] ∅ defines diameter

[c] Acoustic power-up fraction

[d] Acoustic initialization fraction

[e] controllable by the user

Mode➔ / Parameter ⬇	Imaging B	Imaging M	D_P	D_I	D+BCFM P	BCFM P	BCFM I	MCFM P-I
p_(MPa)	5.4	6.1	6	5.8	4.7	5	3.6	4.3
I_{spta} (mW/cm^2)	36	131	1216	1228	761	359	736	947
System settings[a]	F = 5	F = 5	SS = 2 SD = 29	SS = 2 SD = 26	F = 4	F = 4	F = 8	F = 3
I_p (mm)	9	9	14	14	10	9	7	8
w_{pb6} (||) (mm)	1.2	1.2	1.5	1.5	0.9	0.9	3.2	0.8
w_{pb6} (|) (mm)	1.1	1.1	1	1	1	1.2	1.6	1.5
prr (kHz)	6.7	1	2.1	2.1	5.6	5.6	5.6	5.6
srr (Hz)	34	-	33	33	33	33	40	33
Output beam dimension (||) (mm)[b]	3.6	3.6	4.4	4.4	3.2	3.2	4.8	2.8
Output beam dimension (|) (mm)[b]	3	3	3	3	3	3	3	3
f_{awf} (MHz)	8.9	8.9	8	8	7.7	7.9	8	7.8
APF[c] (%)	-	-	-	-	-	-	-	-
AIF[d] (%)	100	113	111	108	88	93	68	79
Maximum power[e] (mW)	13.4	2.3	13.7	13.8	9	21.7	49.7	7.1
I_{ob} (mW/cm^2)	123.9	21.7	103.9	104.9	93.8	225.6	344.9	85.1
Power-up Mode	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Initialization mode	B	B	B	B	B	B	B	B
Acoustic output freeze	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
I_{tt} (mm)	-	-	-	-	-	-	-	-
I_{ts} (mm)	Contact	Contact	Contact	Contact	Contact	Contact	Contact	Contact
Inclusive modes		B+M		B+D B-CFM+D	B+D			B-CFM + M-CFM

[a] SS = Sample Size SD = Sample Depth F= transmit focal point POWER = 100%

[b] ∅ defines diameter

[c] Acoustic power-up fraction

[d] Acoustic initialization fraction

[e] controllable by the user

EC123(Reference: 960 0157 000)

Mode➔ / Parameter ⬇	Imaging B	Imaging M	Imaging B-TEI	Imaging M-TEI	D_{P-I}	D+BCFM P	BCFM P	BCFM I	MCFM P	MCFM I
p_(MPa)	4.6	4.3	2.2	2.2	5.1	4.3	4.3	3.2	3.7	3.4
I_{spta} (mW/cm^2)	150	960	22	168	1386	997	421	586	976	1036
System settings[a]	F = 3	F = 3	F = 3	F = 3	SS = 2 SD = 46	F = 5	F = 5	F = 7	F = 6	F = 3
I_p (mm)	10	10	12	12	18	13	13	14	14	13
w_{pb6} (||) (mm)	1.3	1.3	1.6	1.6	2.9	1.6	1.7	2.8	2.6	1.3
w_{pb6} (|) (mm)	1.2	1.2	1.3	1.3	1.1	1.1	1.1	1.2	1.1	1.1
prr (kHz)	5.6	5.6	5.6	5.6	2.1	5.6	5.6	5.6	5.6	5.6
srr (Hz)	137	-	122	122	58	58	58	58	58	35
Output beam dimension (||) (mm)[b]	3.2	3.2	3.2	3.2	4.7	4	4	4.7	4.3	3.2
Output beam dimension (|) (mm)[b]	4.2	4.2	4.2	4.2	4.2	4.2	4.2	4.2	4.2	4.2
f_{awf} (MHz)	5	5	4.9	4.9	6.3	5.1	5.1	5	5.8	5.9
APF[c] (%)	-	-	-	-	-	-	-	-	-	-
AIF[d] (%)	100	94	48	47	112	92	94	69	79	74
Maximum power [e] (mW)	22.4	20.2	4.3	4.3	29.3	22.6	32.5	48.2	16.7	10.4
I_{ob} (mW/cm^2)	160.3	144	30.7	31	146.5	133.2	191.3	241.1	92.9	74.1
Power-up Mode	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Initialization mode	B	B	B	B	B	B	B	B	B	B
Acoustic output freeze	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
I_{tt} (mm)	-	-	-	-	-	-	-	-	-	-
I_{ts} (mm)	Contact	Contact	Contact	Contact	Contact	Contact	Contact	Contact	Contact	Contact
Inclusive modes		B+M		B+M		B+D B-CFM+D	B+D			B-CFM + M-CFM

[a] SS = Sample Size SD = Sample Depth F= transmit focal point POWER = 100%

[b] ∅ defines diameter

[c] Acoustic power-up fraction

[d] Acoustic initialization fraction

[e] controllable by the user

TE022 (Reference:960 0170 000)

Mode➔ / Parameter ⬇	Imaging B	Imaging M	Imaging B-TEI	Imaging M-TEI	D P-I	D+BCFM P	BCFM P	BCFM I	MCFM P-I	CW
p_(MPa)	3.6	3.6	2.6	2.7	3.7	3.5	3.6	1.6	3.2	0.1
I_{spta} (mW/cm^2)	64	375	19	266	692	536	142	224	839	452
System settings[a]	F = 1	F = 1	F = 1	F = 5	SS = 2 SD = 21	SS = 2 SD = 21	F = 1	F = 2	F = 1	F = 1
I_p (mm)	18	18	17	44	16	16	18	29	18	13
w_{pb6} (||) (mm)	0.8	0.8	1.1	2.8	0.7	0.7	0.6	1.8	0.6	1.2
w_{pb6} (|) (mm)	5.9	5.9	5.6	3.3	5.5	5.5	5.9	4.9	5.9	5.4
prr (kHz)	5.6	5.6	5.6	5.6	2.1	5.6	5.6	5.6	5.6	1
srr (Hz)	125	-	66	66	-	42	42	63	42	-
Output beam dimension (||) (mm)[b]	10.2	10.2	10.2	10.2	10.2	10.2	10.2	10.2	10.2	4.5
Output beam dimension (|) (mm)[b]	9.1	9.1	9.1	9.1	9.1	9.1	9.1	9.1	9.1	9.1
f_{awf} (MHz)	4.7	4.7	4	3.5	5	4.9	4.9	3.3	5	5
APF[c] (%)	-	-	-	-	-	-	-	-	-	-
AIF[d] (%)	100	100	72	74	103	96	99	44	87	3
Maximum power[e] (mW)	30.3	30.3	15.4	27.5	18.4	24.9	26.1	35.5	20.6	18.7
I_{ob} (mW/cm^2)	32.6	32.6	16.6	29.6	19.8	26.7	28.1	38.2	22.1	39.8
Power-up Mode	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Initialization mode	B	B	B	B	B	B	B	B	B	B
Acoustic output freeze	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
I_{tt} (mm)	-	-	-	-	-	-	-	-	-	-
I_{ts} (mm)	Contact	Contact	Contact	Contact	Contact	Contact	Contact	Contact	Contact	Contact
Inclusive modes		B+M		B+M	B+D B-CFM+D	B+D			B-CFM + M-CFM	B+CW B-CFM+CW

[a] SS = Sample Size SD = Sample Depth F= transmit focal point POWER = 100%

[b] ∅ defines diameter

[c] Acoustic power-up fraction

[d] Acoustic initialization fraction

[e] controllable by the user

LV513 (Reference: 960 0181 000)

Mode➔ / Parameter ⬇	Imaging B	Imaging M	D_P	D_I	D+BCFM P	BCFM P	BCFM I	MCFM P	MCFM I
p_(MPa)	5.1	5	6.7	6.6	3.8	6	3.8	4.3	4.1
I_{spta} (mW/cm^2)	76	1353	2068	2192	713	544	1141	1552	1552
System settings[a]	F = 3	F = 3	SS = 2 SD = 40	SS = 2 SD = 34	SS = 2 SD = 28	F = 3	F = 8	F = 3	F = 3
I_p (mm)	16	18	27	25	21	18	18	18	18
w_{pb6} (||) (mm)	1.4	1.2	2.4	1.6	1.1	1.2	6.2	1.2	1.2
w_{pb6} (|) (mm)	2.1	1.8	1.7	1.6	1.6	2	1.8	2	2
prr (kHz)	6.7	6.7	2.1	2.1	5.6	5.6	5.6	5.6	5.6
srr (Hz)	52	-	57	57	57	57	57	57	57
Output beam dimension (||) (mm)[b]	5.5	5.5	7.1	6.3	5.5	5.5	9.5	5.5	5.5
Output beam dimension (|) (mm)[b]	5	5	5	5	5	5	5	5	5
f_{awf} (MHz)	4.8	5.6	6.3	6.3	5.8	6	6.4	5.7	5.7
APF[c] (%)	-	-	-	-	-	-	-	-	-
AIF[d] (%)	100	98	131	129	74	118	74	85	81
Maximum power[e] (mW)	68.4	47.5	67.5	48.9	20.2	70.7	144.2	27.9	27.9
I_{ob} (mW/cm^2)	244.3	169.7	187.5	152.8	72.3	252.3	300.4	99.8	99.8
Power-up Mode	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Initialization mode	B	B	B	B	B	B	B	B	B
Acoustic output freeze	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
I_{tt} (mm)	-	-	-	-	-	-	-	-	-
I_{ts} (mm)	Contact	Contact	Contact	Contact	Contact	Contact	Contact	Contact	Contact
Inclusive modes		B+M		B+D B-CFM+D	B+D			B-CFM + M-CFM	B-CFM + M-CFM

[a] SS = Sample Size SD = Sample Depth F= transmit focal point POWER = 100%

[b] ∅ defines diameter

[c] Acoustic power-up fraction

[d] Acoustic initialization fraction

[e] controllable by the user

LP323/IOE323 (Reference: 960 0162 000 / 960 0160 000)

Mode➔ / Parameter ⬇	Imaging B	Imaging M	D_P	D_I	D+BCFM P	BCFM P	BCFM I	MCFM P-I
p_(MPa)	5.1	5.4	3.8	3.1	5.6	5.6	3.4	4.3
I_{spta} (mW/cm^2)	28	98	663	1323	1086	243	889	1106
System settings[a]	F = 3	F = 3	SS = 2 SD = 20	SS = 2 SD = 30	F = 3	F = 3	F = 8	F = 3
I_p (mm)	12	12	12	17	12	11	13	11
w_{pb6} (||) (mm)	1.1	1.2	1.1	2	1.1	1.2	5.2	1.2
w_{pb6} (|) (mm)	1.4	1.4	1.2	1.3	1.2	1.5	1.3	1.5
prr (kHz)	6.7	1	2.1	5.6	5.6	5.6	5.6	5.6
srr (Hz)	52	-	18	25	18	18	25	18
Output beam dimension (||) (mm)[b]	4.3	4.3	4.3	5.4	4.3	4.3	7	4.3
Output beam dimension (|) (mm)[b]	4	4	4	4	4	4	4	4
f_{awf} (MHz)	5.8	5.8	6.5	6.5	6.2	6.4	6.6	6.1
APF[c] (%)	-	-	-	-	-	-	-	-
AIF[d] (%)	100	106	75	61	109	109	67	84
Maximum power [e] (mW)	11.8	2	7.7	26.4	23.4	36.2	87.2	14.3
I_{ob} (mW/cm^2)	68.2	11.4	44.3	122.3	135.2	209.5	310.3	82.9
Power-up Mode	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Initialization mode	B	B	B	B	B	B	B	B
Acoustic output freeze	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
I_{tt} (mm)	-	-	-	-	-	-	-	-
I_{ts} (mm)	Contact	Contact	Contact	Contact	Contact	Contact	Contact	Contact
Inclusive modes		B+M		B+D B-CFM+D	B+D			B-CFM + M-CFM

[a] SS = Sample Size SD = Sample Depth F= transmit focal point POWER = 100%

[b] ∅ defines diameter

[c] Acoustic power-up fraction

[d] Acoustic initialization fraction

[e] controllable by the user

ESAOTE S.p.A.

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TRANSDUCERS AND CONSUMABLES

OPERATOR MANUAL

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Introduction

This manual provides information about the probes and consumables that can be used with the Esaote **MyLab** devices. The manual is divided into the following chapters:

- Chapter 1: Care of transducers
  The chapter describes how to handle, control, store and protect ESAOTE tranducers.

- Chapter 2: Cleaning and disinfecting the transducers
  The chapter describes how to clean and disinfect non-invasive transducers and those used in semi-critical applications.
- Chapter 3: Examinations with the transesophageal probe
  The chapter lists the specific safety requirements for examinations with the trans-esophageal probe. A description is also given on how to prepare the probe for the examination.
- Chapter 4: Examinations with the endocavity probe
  The chapter lists the specific safety requirements for examinations with the endo-cavity probe. A description is also given on how to prepare the probe for the examination.
- Chapter 5: The Intraoperative probe
  The chapter lists the specific safety requirements for examinations with the intraoperative probe. A description is also given on how to prepare the probe for the examination.
- Chapter 6: The Laparoscopic probe
  The chapter lists the specific safety requirements for examinations with the laparoscopic probe. A description is also given on how to prepare the probe for the examination.
- Chapter 7: Needle guides kits
  The chapter describes the procedures for assembling the kits.
- Chapter 8 Accessories and Consumables
  The chapter describes how to check, clean and disinfect the ECG cable. The chapter also gives information about the characteristics of the consumables.
- Appendix A: **MyLab** Probes
  The appendix details available models and their main characteristics.
- Appendix B: Cables and Consumables
  The appendix details the ECG cables characteristics and recommended ECG single use electrodes.

In this manual **WARNING** identifies a risk for the patient and/or the operator. The word **CAUTION** describes the precautions necessary for protecting the equipment. **Make sure you understand and follow these instructions.**

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Chapter 1

1 - Care of Transducers

Handling Transducers

Damage caused by dropping or knocking a probe against other objects, stepping on or twisting a cable or a cable becoming entangled, are not covered by the guarantee.

Incorrect handling can seriously damage any transducer. Both the acoustic lens and the crystal elements can be damaged if the transducer is dropped or struck against another object. Cuts on the probe cable or breakage of the housing may jeopardize the electrical safety of the transducer.

There are several ways a probe can be damaged, for example:

- Dropping or knocking against another object
- Contact with sharp edged objects
- Contact with chemical agents
- Contact with hot surfaces
- Immersion in liquid substances
- Exposure to high voltage discharge
- Exposure to environmental conditions out of allowed range

WARNINGS

Do not use a probe if any of the above listed events occur until it has been established if any electrical damage to the probe has occurred by measuring the current leakage. Contact the Esaote Service Representative.

Do not tug the probe cable or bend it. If the probes are carried around on a trolley, make sure that the wheels do not roll over the cable.

Periodic Probe Control Schedule

The following tables describe the periodic control that must be made on the probes. The frequency suggested for non-invasive probes is considered to be the minimum; very frequent usage requires more frequent controls.

Operation to be performed	Frequency
Physical control of non-invasive probes	Every month or when the probe is dropped
Physical control of transesophageal, endocavity, intraoperative and laparoscopic probes	Before every examination
Physical control of the biopsy kit	Before every examination and if dropped

WARNING

Never use a probe, if it has been dropped, until you are sure that no electrical damage to the probe has occurred. This can be done by performing a leakage current test.

Transducer Controls

Non-invasive Transducers

Non-invasive transducers are intended to be used on the external parts of the body only.

A periodic control must be made on transducers to check that:

- The housing is intact. If cracks or breaks are found, have the probe repaired immediately by contacting an ESAOTE technician.
- The lens does not have any irregularities or is not broken. If any breaks are found on the scanning windows, do not use the probe again and have it repaired.
- The probe cable is not broken or damaged. If any damage is found, do not use the probe again and have it repaired.
- The connector pins are not bent. If the pins are damaged, do not use the probe and have it repaired.

WARNING

Breaks to the probe casing or to the cable could result in risks to electrical safety.

Do not use a probe if it has been dropped. A leakage current test must be performed prior to re-use to ensure that no electrical damage to the probe has occurred.

Physical damage to the probe may cause electrical or mechanical injury to the patient. Protective sheaths DO NOT provide protection against such damage nor do they guarantee that the probe is insulated electrically. DO NOT USE the probe if it is known or suspected that it has been damaged; contact ESAOTE immediately.

CAUTION

Do not try to dismantle the probe; any attempt to dismantle the probe may damage it and will void the warranty.

In order to minimize the probability of damaging the probe, the following operations are suggested:

- ***Do not touch the lens*** at the end of the probe Never exert force on the lens
- The connector is not waterproof and should always be kept dry. The control unit, although waterproof, should not be unnecessarily immersed.

After use, clean and/or disinfect the probe as specified in this manual.

Invasive Transducers

Invasive transducers penetrate the patient's body through an orifice or through the surface of the body.

Control of the Transesophageal Probe

The transesophageal probe must be carefully inspected before every examination.

- Perform a manual and visual check to ensure that there are no holes, bulges, tears or dents along the entire surface of the probe.
- Perform a manual and visual check of the endoscope while bending the tip in all possible directions; deflection must function according to characteristics and the guides must not protrude during these movements.
- Check that the deflection mechanism functions in both modes (free or with friction).
- Check the cable manually and visually; there must be no cuts or irregularities.
- Check that the connector pins are not bent. If the pins are damaged, do not use the probe and have it repaired.

WARNING

Breaks in the probe casing or in the cable could expose the patient and/or the operator to an electrical safety risk.

Do not use a probe if it has been dropped. A leakage current test must be performed prior to re-use to ensure that no electrical damage to the probe has occurred.

In case of incorrect operation of the flexion, do not use the probe and call Esaote Service Assistance.

Physical damage to the probe may cause electrical or mechanical injury to the patient. Protective sheaths DO NOT provide protection against such

damage nor do they guarantee that the probe is insulated electrically. DO NOT USE the probe if it is known or suspected that it has been damaged; contact ESAOTE immediately.

CAUTION

Do not try to dismantle the probe; any attempt to dismantle the probe may damage it and will void the warranty.

In order to minimize the probability of damaging the probe, the following operations are suggested:

- ***Do not touch the lens*** at the front of the probe. Never exert force on the lens.
- The connector is not waterproof and should always be kept dry.
- Before inserting the probe, ***do not rub or spray the tip*** of the probe with an ***anesthetic agent***..
- When not in use, store the probe as specified in the next paragraph.

After use, clean and disinfect the probe as specified in this manual.

Control of the Endocavity Probe

The endocavity probe must be checked before every examination.

- Perform both a visual and manual check to ensure that there are no holes, bulges, abrasions or dents.
- Perform a visual and manual check of the probe cable; cuts or holes in the cable may jeopardize electrical safety.
- The connector pins are not bent. If the pins are damaged, do not use the probe and have it repaired.

WARNING

Breaks in the probe casing or in the cable could expose the patient and/or operator to an electrical safety risk.

Do not use a probe if it has been dropped. A leakage current test must be performed prior to re-use to ensure that no electrical damage to the probe has occurred.

Physical damage to the probe may cause electric shock or mechanical injury to the patient. Protective sheaths DO NOT provide protection against such damage nor do they guarantee that the probe is insulated electrically. DO NOT USE the probe if it is known or suspected that it has been damaged; contact ESAOTE immediately.

CAUTION

Do not attempt to dismantle the probe; any attempt to dismantle the probe may result in damage to the probe and will void the warranty and could compromise its safety.

In order to minimize the probability of damaging the probe, the following operations are suggested:

- ***Do not touch the lens*** at the front of the probe. Never exert force on the lens.
- The connector is not waterproof and should always be kept dry.

After use, clean and disinfect the probe as specified in this manual.

Control of the Intraoperative Probe

The Intraoperative probe must be carefully inspected before every examination.

- Perform a manual and visual check to ensure that there are no holes, bulges, tears or dents along the entire surface of the probe.
- Check the cable manually and visually; there must be no cuts or irregularities.
- The connector pins are not bent. If the pins are damaged, do not use the probe and have it repaired.
- When not in use, store the probe as specified in the next paragraph.

WARNING

Breaks in the probe casing or in the cable could expose the patient and/or the operator to an electrical safety risk.

Do not use a probe if it has been dropped. A leakage current test must be performed prior to re-use to ensure that no electrical damage to the probe has occurred.

Physical damage to the probe may cause electrical or mechanical injury to the patient. Protective sheaths DO NOT provide protection against such damage nor do they guarantee that the probe is insulated electrically. DO NOT USE the probe if it is known or suspected that it has been damaged; contact ESAOTE immediately.

CAUTION

Do not try to dismantle the probe; any attempt to dismantle the probe may damage it and will void the warranty.

In order to minimize the probability of damaging the probe, the following operations are suggested:

- ***Do not touch the lens*** at the front of the probe. Never exert force on the lens.
- The connector is not waterproof and should always be kept dry.
- When not in use, store the probe in its case.

After use, clean and sterilize the probe as specified in this manual.

Control of the Laparoscopic Probe

The laparocopic probe must be carefully inspected before every examination.

- Perform a manual and visual check to ensure that there are no holes, bulges, tears or dents along the entire surface of the probe.
- Perform a manual and visual check of the endoscope while bending the tip in all possible directions; deflection must function according to characteristics and the guides must not protrude during these movements.
- Check the cable manually and visually; there must be no cuts or irregularities.
- The connector pins are not bent. If the pins are damaged, do not use the probe and have it repaired.

WARNING

Breaks in the probe casing or in the cable could expose the patient and/or the operator to an electrical safety risk.

Do not use a probe if it has been dropped. A leakage current test must be performed prior to re-use to ensure that no electrical damage to the probe has occurred.

In case of incorrect operation of the flexion, do not use the probe and call Esaote Service Assistance.

Physical damage to the probe may cause electrical or mechanical injury to the patient. Protective sheaths DO NOT provide protection against such damage nor do they guarantee that the probe is insulated electrically. DO NOT USE the probe if it is known or suspected that it has been damaged; contact ESAOTE immediately.

CAUTION

Do not try to dismantle the probe; any attempt to dismantle the probe may damage it and will annul the guarantee.

In order to minimize the probability of damaging the probe, the following operations are suggested:

- ***Do not touch the lens*** at the front of the probe. Never exert force on the lens.
- The connector is not waterproof and should always be kept dry.
- When not in use, store the probe in its case.

After use, clean and sterilize the probe as specified in this manual.

Storing and Protecting the Transducers

Daily Storage and Protection

Non-Invasive Transducers

When not in use, the transducer must be stored in the special probes slot on the machine. If all the available slots are full, place the probe in its case. All gel must always be cleaned off the probe (see the next chapter for the relative instructions).

CAUTION

Always keep the probe in its case. Otherwise it could be accidentally dropped or damaged.

Storing and Protecting the Transesophageal Probe

The probe must always be cleaned following the instructions provided in the next chapter. The probe must be kept in a clean environment and with the endoscope straight. In particular, we recommend using:

- Wall-mounted supports
- A storage drawer that is large enough to house the endoscope, bending it as little as possible

Storing and Protecting the Endocavity Probe

The probe must always be cleaned following the instructions provided in the next chapter. When not in use, the transducer must be stored in the special probes slot on the machine. If all the available slots are full, place the probe in its case.

CAUTION

Always keep the probe in its case. Otherwise it could be accidentally dropped or damaged.

Storing and Protecting the Intraoperative and Laparoscopic Probe

The probe must always be cleaned following the instructions provided in the next chapter. When not in use, place the probe in its case.

CAUTION

Always keep the probe in its case. Otherwise it could be accidentally dropped or damaged.

Transport or Long-Term Storage and Protection

All transducers are supplied with their own case that must always be used both when transporting the probe and for long-term storage. Clean the transducer carefully, following the procedures described in the following chapter before putting the probe away in its case.

For long-term storage, check that the environmental requirements indicated on the label of the case are observed.

CAUTION

Always use the original case to store the transesophageal probe. The special shape of this case prevents damage to the gastroscope due to excessive bending.

Dispatching the Transducer

Contact Esaote personnel to ensure that the transducer is correctly packed before dispatching it.

Needle Guide Kit Control

Always check that:

- The socket is not bent. Do not use the socket if it has been damaged.
- The needle guide is not bent. Do not use the guide if it has been damaged.

Storing and Protecting Needle Guide Kits

All biopsy kits are supplied with their own case. We recommend leaving any unused needle guides in the case. The kits must always be sterilized after use (see the next chapter for procedures). Please refer to the procedures used on-site for storing sterile parts.

Chapter 2

2 - Cleaning and Disinfecting Transducers and Biopsy Kits

Periodic Cleaning and Disinfecting Schedule

The following table describes the periodic maintenance to be carried out on transducers and biopsy kits depending on their application. The risk of infection establishes the type of application.

Device	Application	Operation	Frequency
Non-invasive probes	Non-critical[1]	Cleaning	Before the first use and after each exam.
		Disinfection	When necessary
Transesophageal and Endocavity probes	Semi-critical[2]	Cleaning and Disinfection	Before the first use and after each exam.
Intraoperative and Laparoscopic probes	Critical[3]	Cleaning and Sterilization	Before the first use and after each exam.
Needle Guide kits	Critical[3]	Cleaning and Sterilization	Before the first use and after each exam.

[1] The application is considered non-critical when the device is used on intact skin.
[2] The application is considered semi-critical when the device is used on the mucous membranes.
[3] The application is considered critical when the device comes into contact with blood or compromised tissue.

If non-invasive probes are used in semi-critical/critical applications and in a sterile field, apply protective sheaths during the examination. These sheaths are usually composed of latex (natural rubber).

WARNING

Make sure that patients who are allergic to latex are identified before each examination. Serious allergic reactions to latex have been reported; the Operator should be prepared to handle such reactions.

ESAOTE recommends disinfecting the probe, if the probe has not been used for an extended period.

Do not immerse the probe cable or connector in water or other liquid. Immersion may compromise the electrical safety features. The probe can be inserted in water up to the Maximum Immersion Level. (see Appendix A).

Note

Probes and needle guides supplied by ESAOTE are neither disinfected nor sterilized.

Agents

Refer to **Appendix B** for a list of recommended cleaning, disinfection and sterilization agents.

WARNING

The disinfection/sterilization agents listed are recommended because of chemical compatibility with the probe materials, and not related to biological effectiveness. For information related to the biological effectiveness of a disinfectant, refer to the guidelines and recommendations of the disinfectant manufacturer.

Use of solutions other than those referenced is not recommended. They may damage the probe housing or acoustic lens.

Follow the instructions provided by the manufacturer of the agent for proper use.

Personnel should adopt all necessary protective measures during the probe cleaning, disinfection and sterilization processes (i.e. gloves, protective glasses ….).

Never attempt to clean or disinfect the probes while they are connected to the unit.

Probes Tightness to Liquids

See Appendix A for description of probes Maximum Immersion Level.

Do not immerse the probe cable or connector in water or other liquid. The probes can be inserted in water up to the **Maximum Immersion Level** that will not compromise a probe's integrity:

WARNING

Connector immersion in water or other liquid can compromise the safety feature of the probe. Damage caused by the probe immersion is not covered under the warranty.

Cleaning Probes Used in Non-Critical Applications

The cleaning procedures described in this paragraph apply to all the probes used in non-critical applications. An application is considered non-critical when the device is used on intact skin.

Cleaning Procedure

Probes must be cleaned at regular intervals to ensure that they work properly. Esaote recommends removing the gel from the probe between one examination and the other; this keeps the probes clean between one complete cleaning procedure and the next.

- Disconnect the probe from the unit
- Remove all residues of ultrasound gel from the probe using a soft cloth.
- Clean the probe by rubbing it lightly with a soft cloth soaked in a solution of water and mild soap.
- Rub the probe with a soft damp cloth to remove any soap residue.
- Dry the probe by rubbing it with a soft dry cloth.

Disinfecting Probes Used in Non-Critical Applications

The disinfection procedures described in this paragraph apply to all probes used in non-critical applications. The application is considered non critical when the device is used on intact skin. Low-level disinfection is sufficient for these applications. The probes can be disinfected using CIDEX OPA, following the manufacturer's instructions.

Disinfection Procedure

- Disconnect the probe from the system.
- Clean the probe as described in the previous paragraph.
- Immerse the probe casing in CIDEX OPA, following the manufacturer's instructions very carefully.

WARNING

Do not immerse the entire body of the probe. The probe is not waterproof and immersion may compromise the electrical safety characteristics (see Appendix A for Maximum Immersion Level).

Do not soak the probe in the disinfection solution for periods beyond the time required to achieve a disinfection.

CAUTION

Do not try to sterilize probes using the autoclave, ultra-violet rays, gamma rays or gas, steam or heat sterilization techniques. These sterilization methods can permanently damage the probe. Any damage to the probe caused by substances or methods not approved by ESAOTE is not covered by the guarantee.

- Extract the probe, rinse it with sterile water and clean the probe handle and cable with a soft cloth dampened with isopropyl alcohol or with a mild detergent solution.
- Dry the probe carefully using a soft cloth or leave it to air dry for at least 30 minutes.

Cleaning and Disinfecting Probes Used in Semi-Critical Applications

The procedures described in this paragraph apply to all probes used in semi-critical applications. The application is considered semi-critical when the device is used on the mucous membranes. The use of sterile sheaths for this type of application is recommended, and high-level disinfection is necessary. Wearing gloves is recommended during probe cleaning and disinfecting operations. The probe must be disinfected before it is used for the first time. The probe must be cleaned and disinfected after every examination.

Esaote recommends disinfecting the probe before it is used for the first time after prolonged storage periods

- Disconnect the probe from the system.
- Remove the protective sheath; clean the probe handle, the transducer and the endoscope with the recommended agent.

Note

Handle any examination waste (protective sheath, gloves…) as if potentially infected and treat it accordingly.

- If the probe is contaminated by body fluids, disinfect it before and after cleaning.
- Immerse the probe casing in CIDEX OPA, following the manufacturer's instructions very carefully.

WARNING

Do not leave the probe immersed in the disinfectant for longer than the time indicated by the manufacturer for high-level disinfection.

Do not immerse the entire body of the probe. The probe is not waterproof and immersion may compromise the electrical safety characteristics (see Appendix A for Maximum Immersion Level).

- Extract the probe, rinse it with sterile water and clean the probe handle and cable with a soft cloth dampened with a mild detergent solution.
- Dry the probe carefully using a soft cloth or leave it to air dry for at least 30 minutes.

CAUTION

Any damage to the probe caused by substances or methods not approved by ESAOTE, such as steam (autoclave), ethylene oxide or radiation, are not covered by the guarantee. These sterilization methods can permanently damage the probe.

For information on how to store disinfected parts, refer to the locally applicable procedures.

Cleaning and Sterilization of Intraoperative, Laparoscopic probes and Needle Guide Kits

The procedures described in this paragraph apply to the intraoperative and laparoscpic probes and all the kits used in critical applications. The application is considered critical when the device comes into contact with blood or compromised tissue. Sterilization is stipulated for this type of procedure.

Wearing gloves is recommended during cleaning and sterilization operations.

WARNING

Personnel should adopt all necessary protective measures during the probe cleaning, disinfection and sterilization processes (i.e. gloves, protective glasses ….).

The probe and the kit must be sterilized before it is used for the first time. They must be cleaned and sterilized after every examination.

Esaote recommends sterilizing the probe and the kit before they are used for the first time after prolonged storage periods.

- Dismantle the kit from the probe.
- Clean the kit or the probe carefully with mild soap.
- Follow the instructions of the manufacturer of the sterilization agent.

Note

The material used for needle guide kits can undergo all the sterilization methods used for surgical instruments.

The type of tissue the transducer comes into contact with establishes the disinfection level.

For information on how to store sterilized parts, refer to the locally applicable procedures.

Chapter 3

3 - The Transesophageal Probe

The transesophageal probe (**TEE022**) is a Type BF part. The probe must be physically intact and the system correctly grounded for the electrical safety of the patient and operator.

SS

Read the Safety and Standards Manual carefully: all the safety characteristics, cautions and warnings listed also apply to the use of this probe.

In particular, remember that:

WARNING

The system must be correctly grounded: it must be supplied from a socket equipped with a protective earth connection .

Mobile configurations are fitted with insulated supply sockets for supplying documentation systems without increasing the current leakage. Incorrect connections or failure to use insulated sockets may compromise electrical safety.

In case of doubts about the protective earth connection, DO NOT use the probe and contact ESAOTE immediately.

Characteristics and Components

This probe is designed for transesophageal imaging of the heart in adult patients. The transesophageal probe incorporates an array transducer which can be rotated 180° to easily obtain all imaging planes. The probe tip can also be deflected for optimal coupling.

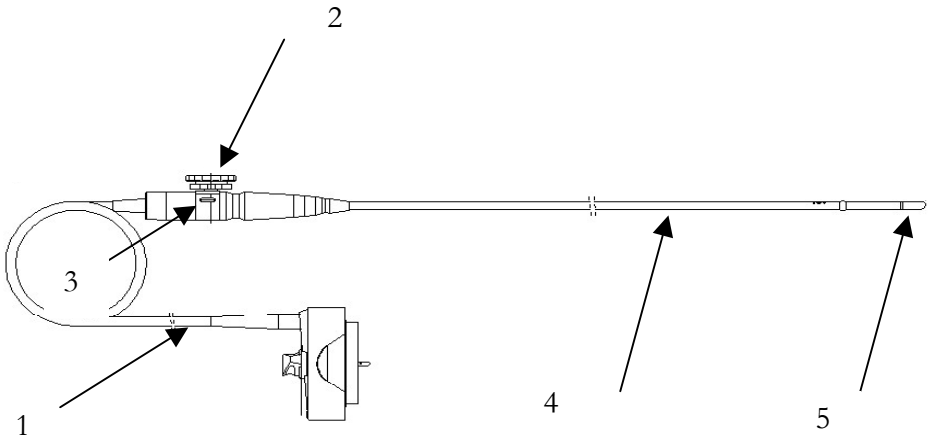
This probe is equipped with a temperature sensor; **MyLab** models are designed to use these sensor thermal data to prevent probe tip overheating.

Components

1. Probe cable and system connector
2. Probe handle with the probe tip deflection control and the transducer rotational knob
3. Locking device

4. Probe shaft; this shaft has a length of 100 cm and is labeled in 10 cm increments
5. Probe tip with the ultrasound transducer

The TEE is delivered with a carrying case.



Examination Safety

The user must know how to recognize contraindications to the examination and any possible complications, such as tip buckling.

The transesophageal examination is to be carried out by operators who have been specially trained to insert the probe and interpret the images. Carefully review current medical provisions and follow their precautions and recommendations concerning the preparation and positioning of the patient, probe insertion and manipulation techniques.

Before the Examination

Before each examination :

- Perform a manual and visual inspection of the entire probe (see Chapter 2 of this manual). DO NOT use the probe if it has been damaged or if damage is suspected.

WARNING

Physical damage to the probe may cause electrical or mechanical injury to the patient. Protective sheaths DO NOT provide protection against such damage nor do they guarantee that the probe is insulated electrically. DO NOT USE the probe if you know or suspect that it has been damaged.

- Check that the probe deflection controls function correctly in all directions and that they have not jammed.
- Make sure that the probe tip is free to move; the probe handle provides a locking device which must be set to "loose" position.
- Use protective sheaths during the examination. These sheaths are mainly composed of latex (natural rubber).

WARNING

Make sure that patients who are allergic to latex are identified before each examination. Serious allergic reactions to latex have been reported; the Operator should be prepared to handle such reactions.

- Always use a bite-proof mouthpiece to protect the probe from the patient's teeth.

WARNING

Physical damage to the probe can cause electrical or mechanical injury to the patient.

CAUTION

Damage caused to the probe due to failure to use a protective mouthpiece is not covered by the guarantee.

SS

Be familiar with the mechanical and thermal indices display and the **ALARA** principle (As Low As Reasonably Achievable) before using the probe. The patient must be exposed to ultrasound for as short a time as possible and only for as long as it takes to achieve the diagnostic information.

During the Examination

WARNING

Before probe use, check to be sure that the probe name shown on the monitor is correct.

Esaote recommends the Operator to:

- Never force the probe during manipulation and extraction; if there is any resistance in introducing the probe, interrupt the examination. Make sure that the tip is straight and released before inserting or removing the probe.

WARNING

Insertion, manipulation or forced removal can seriously damage the patient's esophagus.

- Do not leave the probe against the esophagus wall for prolonged periods.
- Cover the probe handle with a disposable cloth during examinations in which the presence of pathogenic micro-organisms is suspected.
- If it is necessary to use the defibrillator, disconnect and remove the probe from the patient.

Electric scalpels used during the TEE examination interfere with the 2D and make it impossible to use Doppler procedures.

Electric scalpels and other devices that introduce radio frequency or electro-magnetic current fields into the patient interfere with ultrasound images.

High frequency signals used by ultrasound can interfere with the functioning of pacemakers.

WARNING

Even if the possibility of interference is remote, interrupt the examination immediately if interference with a pacemaker is noticed.

While using the system in combination with high frequency devices (like electro-surgical units), be aware that a failure in the surgical device or a damage to the transducer lens can cause electro-surgical currents that can burn the patient. Thoroughly check the system and the probe before applying HF surgical currents to the patient. Disconnect the probe when not imaging.

WARNING

Physical damage to the probe may cause electrical or mechanical injury to the patient. Protective sheaths DO NOT provide protection against such damage nor do they guarantee that the probe is insulated electrically. Perform a manual and visual check before each examination to ensure that the probe is intact.

At the End of the Examination

At the end of the examination, Esaote recommends the Operator to:

- Clean and disinfect the probe, according to the instructions provided in Chapter 2 of this manual.
- Store the probe as indicated in Chapter 1 of this manual.

Temperature Control

The Advanced Operation manual indicates specific information applicable to your MyLab model.

The transesophageal probe is equipped with a temperature sensor, to provide continuous feed-back on the temperature of the probe tip; the ultrasound scanner constantly samples and displays the probe temperature.

Once the probe is connected, the temperature is displayed on the screen.

To ensure patient safety, the ultrasound scanner "allows" a maximum temperature of **42.5°**C (**108.5°**F); if the probe reaches this limit, the system automatically de-activates and displays a warning message.

As soon as the temperature goes down below the thermal limit, the message disappears and the probe starts working again. The Operator should either wait for the probe to cool down or interrupt the procedure and remove the probe from the patient.

How to Minimize Probe Heating

In normal conditions, the probe does not reach the thermal limit; the limit may be reached in patients with fever or due to breakage of the thermal sensor. A list of recommendations follows to prevent the probe from over-heating:

- Set the B-Mode angle at maximum
- The CFM mode is the greatest heat "generator"; limit the use of the CFM as much as possible in patients with a high body temperature.

- Trans-gastric projections reduce heat dissipation; repositioning the probe in the esophagus may make the probe cool down quickly.

Preparation of the Transesophageal Probe

Follow the instructions below to prepare the transesophageal probe.

> **Note**
>
> The Operator is recommended to wear gloves during the probe preparation procedure.

See Chapter on Consumables for selecting these accessory kits

The use of latex transducer covers is strongly recommended, along with a bite guard to protect the probe shaft. These items are available as accessory kits, which also contain items that facilitate placement of the probe cover on the transducer.

- Place the tip of the probe in a straight position and release it.
- Apply a sufficient quantity of ultrasound gel inside the sheath.

WARNING

The protective sheaths available on the market often contain latex. Make sure that patients who are allergic to latex are identified before each examination. Serious allergic reactions to latex have been reported; the Operator should be prepared to handle such reactions.

- Completely unroll the sheath along the transducer body, making it adhere, so as to avoid air pockets.
- Secure the sheath with the rubber band provided.

Transducer Orientation

The probe handle wheels can be used to rotate the transducer inside the tip or to change the tip position.

Transducer Rotation

The rotation of the transducer is controlled by the smallest knob and is adjustable from 0° to 180°. In the zero position, the transducer will scan the transversal plane. The zero, 90° and 180° positions are marked on the knob.

AO

The MyLab system screen displays the transducer's current orientation.

Tip Position

The probe tip can be oriented to optimize tissue contact. The articulation of the flexibile part of the probe is controlled by the largest knob; up- and back-wards adjsutments are feasable:

- 120° upwards (clockwise rotation of the knob)
- 90° backwards (counter- clockwise rotation of the knob)

The zero position is marked on the knob. This knob can be locked into position by engaging the locking device, located next to the knob. This locking device has two color coded positions: on red, the tip is locked, on grey the tip is loose.

During probe insertion, make sure that the tip is unlocked (grey locking device)

Chapter 4

4 - The Endocavity Probe

The endocavity probe (**EC123**) is a Type BF part. As per directive EN60601-1, the probe must be physically intact and the system correctly grounded for the electrical safety of the patient and operator.

SS

Read the Safety and Standards Manual carefully: all the safety characteristics, cautions and warnings listed also apply to the use of this probe.

In particular, remember that:

WARNINGS

The system must be correctly grounded: it must be supplied from a socket equipped with a protective earth connection.

Mobile configurations are fitted with insulated supply sockets for supplying documentation systems without increasing the leakage current. Incorrect connections or failure to use insulated sockets may compromise electrical safety.

In case of doubts about the protective earth connection, DO NOT use the probe and contact ESAOTE immediately.

Characteristics and Components

The **EC123** incorporates a high frequency convex transducer for sagittal (transverse) endorectal or endovaginal scanning.

The probe is delivered with the following accessories:

- Storage case
- Tubing kit (60 cc syringe with IV extension tubing and stopcock)

Examination Safety

Endocavity probes must be used by operators who have been specially trained to insert the probe and interpret the images. Carefully review current

medical provisions and follow their precautions and recommendations concerning the preparation and positioning of the patient, probe insertion and manipulation techniques.

Before the Examination

Before each examination Esaote recommends the Operator to:

- Perform a manual and visual inspection of the entire probe before using it (see Chapter 2 of this manual). DO NOT use the probe if it has been damaged or if you suspect damage.

WARNING

Physical damage to the probe may cause electrical or mechanical injury to the patient. Protective sheaths DO NOT provide protection against these damages nor do they guarantee that the probe is insulated electrically. DO NOT USE the probe if you know or suspect that it has been damaged.

- Use protective sheaths during the examination. These sheaths are mainly composed of latex (natural rubber).

Note

Esaote recommends use of sterile sheaths in intravaginal examinations.

WARNING

Make sure that patients who are allergic to latex are identified before each examination. Serious allergic reactions to latex have been reported; the Operator should be prepared to handle such reactions.

SS

The Operator should be familiar with the mechanical and thermal indices display and the **ALARA** principle (As Low As Reasonably Achievable) before using the probe. The patient must be exposed to ultrasound for as short a time as possible and only for as long as it takes to achieve the diagnostic information.

During the Examination

WARNING

Before probe use, check to be sure that the probe name shown on the monitor is correct

During the examination Esaote recommended the Operator to:

- Never force the probe during insertion or removal.

WARNING

Forced insertion or removal may wound the patient.

- Cover the probe handle with a disposable cloth during examinations in which the presence of pathogenic micro-organisms is suspected.

Electric scalpels used during the examination may interfere with the 2D and make it impossible to use Doppler procedures.

Electric scalpels, and other devices that introduce radio frequency or electro-magnetic current fields into the patient, interfere with ultrasound images.

While using the system in combination with high frequency devices (like electro-surgical units), be aware that a failure in the surgical device or a damage to the transducer lens can cause electro-surgical currents that can burn the patient. Thoroughly check the system and the probe before applying HF surgical currents to the patient. Disconnect the probe when not imaging.

WARNING

Physical damage to the probe may cause electrical or mechanical injury to the patient. Protective sheaths DO NOT provide protection against such damage nor do they guarantee that the probe is insulated electrically. Perform a manual and visual check before each examination to ensure that the probe is intact.

At the End of the Examination

At the end of the examination, Esaote recommends the Operator to:

- Clean and disinfect the probe, according to the instructions provided in Chapter 2 of this manual.
- Store the probe as indicated in Chapter 1 of this manual.

Preparation of the Endocavity Probe

Follow the instructions below for preparing the endocavity probe.

Note

The Operator is recommended to wear gloves during the probe preparation procedure

See Chapter on consumables for selecting the gel and sheathes.

- Apply a sufficient quantity of ultrasound gel inside the sheath.

WARNING

The protective sheaths available on the market often contain latex. Make sure that patients who are allergic to latex are identified before each examination. Serious allergic reactions to latex have been reported; the Operator should be prepared to handle such reactions.

- Completely unroll the sheath along the transducer body, making it adhere, so as to avoid air pockets.

- Secure the sheath with the rubber band provided.
- To make it easier to insert the endocavity probe, apply some water-based lubricating gel on the tip of the transducer.

Water Stand-Off

The endocavity probe has two communicating holes, one at the tip and one at the base, that make it possible to use water stand-off to optimize probe adherence in transrectal examinations. The probe is equipped with a 60 cc syringe with tubes that allow water to be injected.

- Cover the part of the probe that can be immersed with the stand-off cap and attach it with the rubber band provided at about 5 cm. from the tip; make sure the water intake hole is below the band.
- Fill a 60 cc syringe with sterile water.
- Apply the tap valve to the syringe.
- Connect a section of the IV tube to one end of the tap; the other end of the IV tube must be inserted into the probe-filling hole.
- Open the tap; inject about 30 cc of water into the probe.
- To eliminate air bubbles, turn the probe upwards holding it by the handle; the bubbles will rise towards the water intake hole.

Eliminate the air bubbles between the transducer and the sheath; air bubbles impede the transmission of ultrasound.

- Suck air back into the syringe; close the tap to remove the syringe and expel the air.
- Repeat this procedure until all the air bubbles have been eliminated.
- Replace water, without air, back into the syringe and close the valve; leave the tube and the syringe connected.
- Apply ultrasound examination gel to the tip of the stand-off.
- Cover the portion of the probe that is to be inserted with the protection cap.

WARNING

The protective sheaths available on the market often contain latex. Make sure that patients who are allergic to latex are identified before each examination. Serious allergic reactions to latex have been reported; the Operator should be prepared to handle such reactions.

- To make insertion easier, apply some lubricating gel to the tip of the probe.

Once the probe is in the correct position, fill the stand-off with water again. To optimize image quality, use enough water to ensure that the probe adheres as well as possible to the rectal wall.

Do not remove the probe from the rectum if the probe tip is still full of water.

Chapter 5

5 - The Intraoperative Probe

The intraoperative probe (**IOE323**) is a Type BF part. The probe must be physically intact and the system properly grounded for the electrical safety of the patient and operator.

SS

Read the Safety and Standards Manual carefully: all the safety characteristics, cautions and warnings listed also apply to the use of this probe.

In particular, remember that:

WARNING

The system must be properly grounded: it must be supplied from a socket equipped with a protective ground connection.

Mobile configurations are fitted with insulated supply sockets for supplying electricity to the systems without increasing the leakage current. Incorrect connections or failure to use insulated sockets may compromise electrical safety.

If in doubt about the protective ground connection, DO NOT use the probe and contact ESAOTE immediately.

Characteristics and Components

The **IOE323** incorporates a high frequency linear transducer for intraoperative scanning.

The probe is delivered with the following accessories:

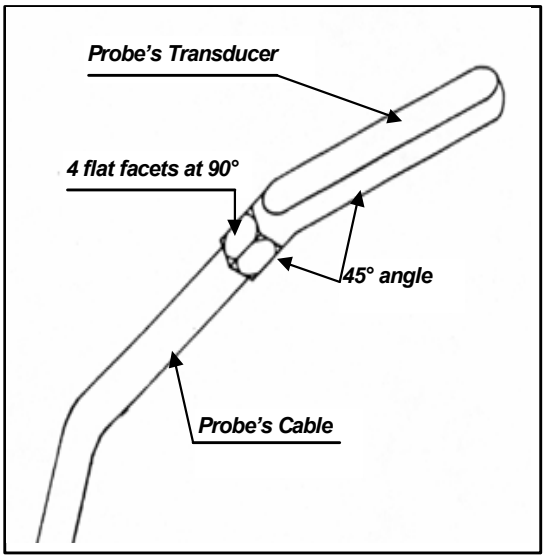
- Storage case
- Handle attachment
- Finger attachment
- Sled attachment

- Biopsy attachment.

The IOE323 probe is designed to form an angle of 45° between the head, which houses the transducer and the terminal portion where the cable is connected.

The terminal portion of the probe has a square shape to accommodate accessories available for use with the probe, offering maximum comfort during surgical ultrasonography.

The probe accessories are shaped in a manner to prevent rotation and to improve patient safety.



Examination Safety

The intraoperative examination is to be carried out by operators who have been specially trained to use the probe and interpret the images. Carefully review current medical provisions and follow their precautions and recommendations concerning the preparation and positioning of the patient, probe insertion and manipulation techniques.

WARNING

Do not use the intraoperative probe in direct contact with the heart, the central circulatory system and the central nervous system.

Before the Examination

Before each examination :

- Perform a manual and visual inspection of the entire probe prior to use (see Chapter 2 of this manual). DO NOT use the probe if it has been damaged or if damage is suspected.

WARNING

Physical damage to the probe may cause electrical or mechanical injury to the patient. Protective sheaths DO NOT provide protection against these damages nor do they guarantee that the probe is insulated electrically. DO NOT USE the probe if damage is known or suspected.

- Use protective sheaths during the examination. These sheaths are usually composed of latex (natural rubber).

WARNING

Make sure that patients who are allergic to latex are identified before each examination. Serious allergic reactions to latex have been reported; the Operator should be prepared to handle such reactions.

Note

Esaote recommends use of sterile sheaths in intraoperative examinations.

SS

The operator must be familiar with the mechanical and thermal indices display and the **ALARA** principle (As Low As Reasonably Achievable) before using the probe. The patient must be exposed to ultrasound for as short a time as possible and only for as long as necessary to achieve the diagnostic information.

During the Examination

WARNING

Before probe use, check to be sure that the probe name shown on the monitor is correct

During the examination, Esaote recommends that the Operator:

- Cover the probe handle with a disposable cloth during examinations in which the presence of pathogenic micro-organisms is suspected.

Electric scalpels used during the IOE examination interfere with the 2D and make it impossible to use Doppler procedures.

Electric scalpels and other devices that introduce radio frequency or electro-magnetic current fields into the patient interfere with ultrasound images.

While using the system in combination with high frequency devices (like electro-surgical units), be aware that a failure in the surgical device or a damage to the transducer lens can cause electro-surgical currents that can burn the patient. Thoroughly check the system and the probe before applying HF surgical currents to the patient. Disconnect the probe when not imaging.

WARNING

Physical damage to the probe may cause electrical or mechanical injury to the patient. Protective sheaths DO NOT provide protection against such damage nor do they guarantee that the probe is insulated electrically. Perform a manual and visual check before each examination to ensure that the probe is intact.

At the End of the Examination

At the end of the examination, Esaote recommends that the Operator:

- Clean and sterilize the probe, according to the instructions provided in Chapter 2 of this manual.
- Store the probe as indicated in Chapter 1 of this manual.

Preparation of the Intraoperative Probe

Follow the instructions below for preparing the intraoperative probe.

Note

The operator is recommended to wear gloves during the probe preparation procedure

See Chapter 8 on consumables for selecting the gel and sheathes.

- Apply a sufficient quantity of ultrasound gel inside the sheath.

WARNING

The protective sheaths available on the market often contain latex. Make sure that patients who are allergic to latex are identified before each examination. Serious allergic reactions to latex have been reported; the Operator should be prepared to handle such reactions.

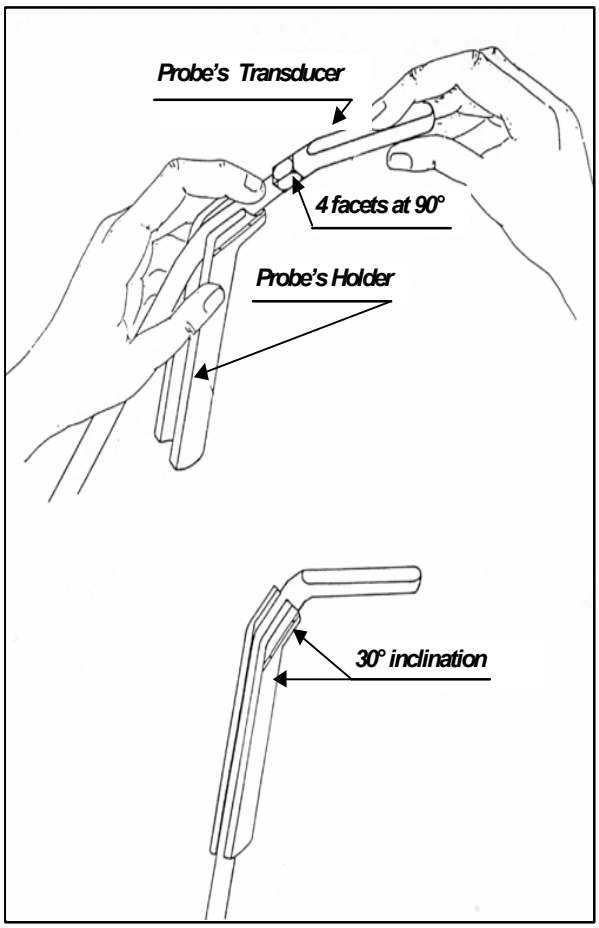
Note

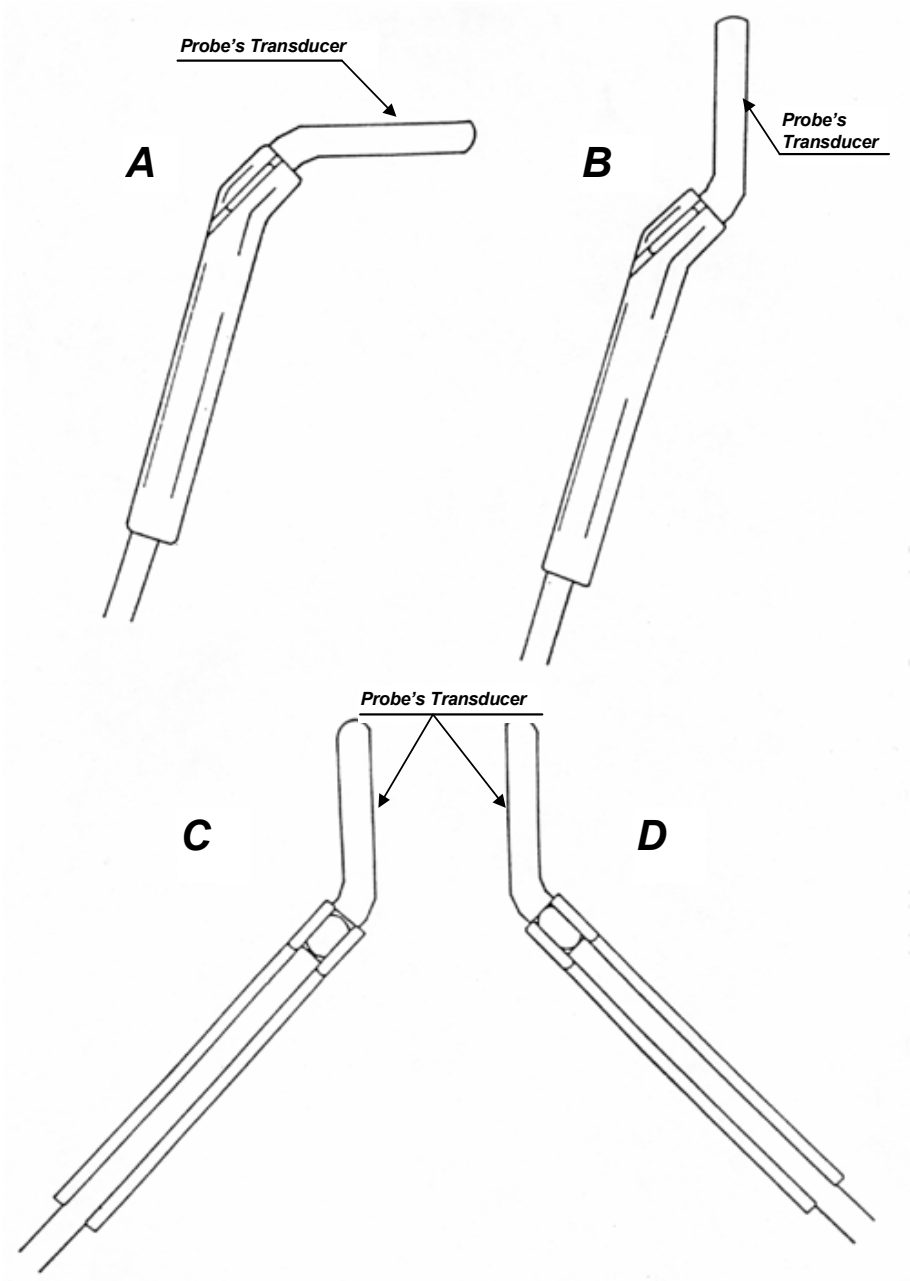
Esaote recommends use of sterile sheaths in intraoperative examinations.

- Completely unroll the sheath along the transducer body, making it adhere, so as to avoid air pockets.
- Secure the sheath with the rubber band provided.

Handle attachment

The handle attachment, is inclined 30 degrees, and can be placed on the probe in four different positions to form four different shapes (profiles) A, B, C and D as shown below and on the following pages:

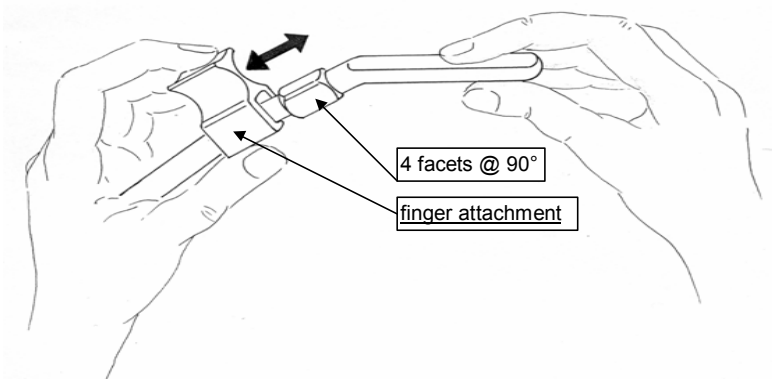


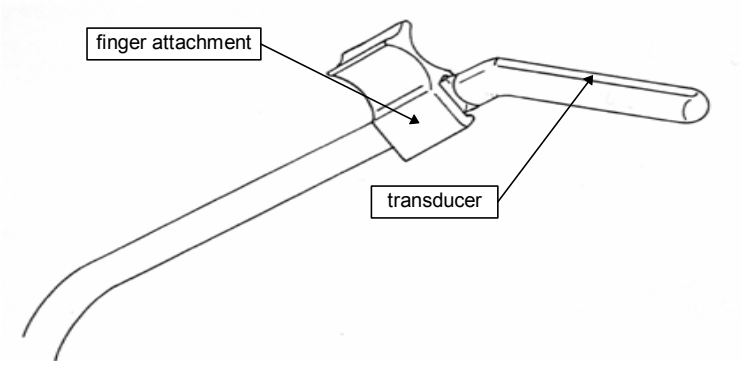

Probe's Transducer
A
B
Probe's Transducer
Probe's Transducer
C
D

Finger attachment

The Finger Attachment allows manipulation of the Intraoperative IOE323 probe for use with only two fingers.

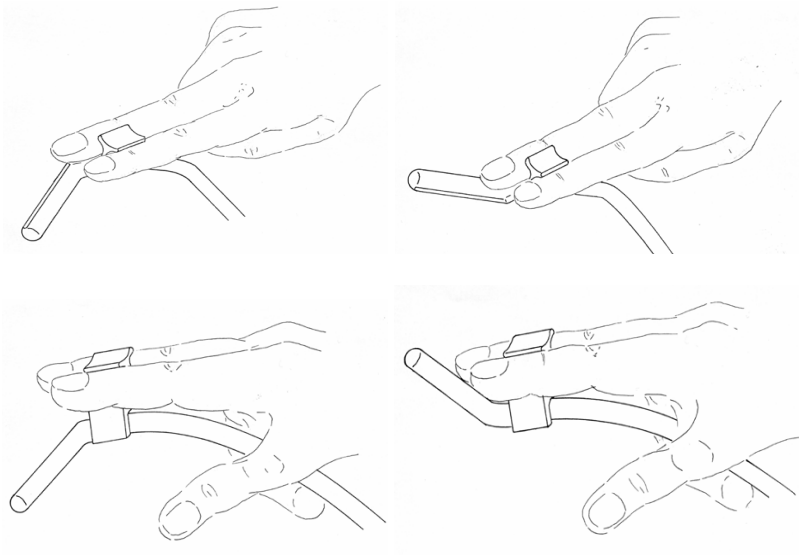
The 4 facets, at 90 degrees, allow the user to obtain four different insertion methods with the probe.





The finger attachment can be used in four different configurations in order to more closely adapt to the surface being evaluated. In intraoperative applications, it is possible to insert the probe below, adjacent to, or on top of the structure of interest.

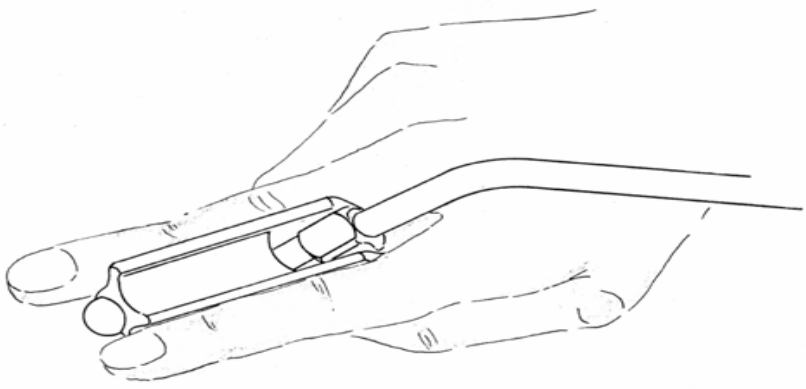
Following are the four different IOE323 probe attachment designs.



Sled attachment

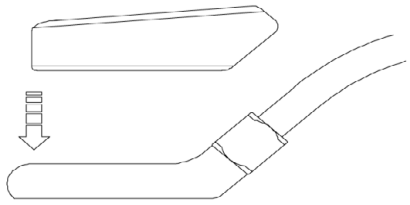
The sled attachment has been developed to provide easier manipulation of the probe during both intraoperative and superficial scanning. The attachment corresponds to the ergonomics of the probe, and is the same length as the transducer.

The correct position of the SLED attachment is shown below.

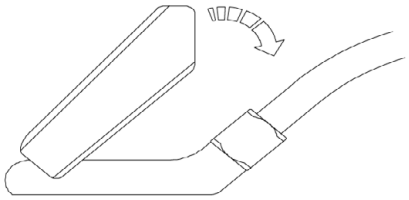


To place the attachment on the probe, follow the procedure described below. The sequence is also shown in the following design.

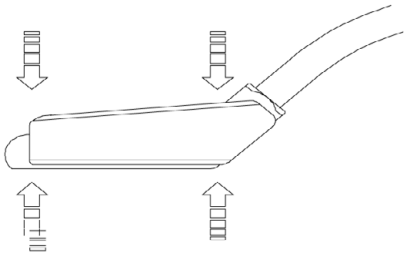
1. Place the sled attachment at the tip of the transducer.



2. Rotate the sled attachment around the probe until it is safely in place between the two lateral extensions of the attachment.



3. Press the transducer inside the holder, hearing a click, to assure secure and complete insertion.



4. To remove the sled attachment, reverse the procedure.

Chapter 6

6 - The Laparoscopic Probe

The laparoscopic probe (**LP323**) is a Type BF part. The probe must be physically intact and the system properly grounded for the electrical safety of the patient and operator.

Read the Safety and Standards Manual carefully: all the safety characteristics, cautions and warnings listed also apply to the use of this probe.

In particular, remember that:

WARNING

The system must be properly grounded: it must be supplied from a socket equipped with a protective ground connection.

Mobile configurations are fitted with insulated supply sockets for supplying electricity to the systems without increasing the leakage current. Incorrect connections or failure to use insulated sockets may compromise electrical safety.

If in doubt about the protective ground connection, DO NOT use the probe and contact ESAOTE immediately.

Characteristics and Components

The **LP323** incorporates a high frequency linear transducer for laparoscopic scanning.

The probe is delivered with the following accessories:

- Storage case
- Polyurethane laparoscopic cover
- Syringe filled with transmission gel,
- Extension tube

- Cable cover and fixing tape

LP323 Probe

The LP323 probe has an articulation that allows a double movement of its extremity in order to position the transducer directly on to the surface of the organ under evaluation. This movement is adjustable by two control levers located on the probe handle.

Examination Safety

The laproscopic examination is to be carried out by operators who have been specially trained to use the probe and interpret the images. Carefully review current medical provisions and follow their precautions and recommendations concerning the preparation and positioning of the patient, probe insertion and manipulation techniques.

WARNING

Do not use the laparoscopic probe in direct contact with the heart, the central circulatory system and the central nervous system.

Before the Examination

Before each examination :

- Perform a manual and visual inspection of the entire probe prior to use (see Chapter 2 of this manual). DO NOT use the probe if it has been damaged or if damage is suspected.

WARNING

Physical damage to the probe may cause electrical or mechanical injury to the patient. Protective sheaths DO NOT provide protection against these damages nor do they guarantee that the probe is insulated electrically. DO NOT USE the probe if damage is known or suspected.

- Use protective sheaths during the examination. These sheaths are usually composed of latex (natural rubber).

Note

Esaote recommends use of sterile sheaths in laparoscopic examinations.

WARNING

Make sure that patients who are allergic to latex are identified before each examination. Serious allergic reactions to latex have been reported; the Operator should be prepared to handle such reactions.

SS

Be familiar with the mechanical and thermal indices display and the **ALARA** principle (As Low As Reasonably Achievable) before using the probe. The patient must be exposed to ultrasound for as short a time as possible and only for as long as necessary to achieve the diagnostic information.

During the Examination

WARNING

Before probe use, check to be sure that the probe name shown on the monitor is correct

During the examination, Esaote recommends that the Operator:

- Never force the probe during insertion or removal.

WARNING

Before introducing the LP323 probe into the Trocar verify that there is no mechanical play of the tip of the probe.

While inserting the LP323 probe into the Trocar, the tip of the probe should be in a straight position.

Forced insertion or removal may harm the patient.

- Cover the probe handle with a disposable cloth during examinations in which the presence of pathogenic micro-organisms is suspected.

Electric scalpels used during the LP examination interfere with the 2D and make it impossible to use Doppler procedures.

Electric scalpels and other devices that introduce radio frequency or electro-magnetic current fields into the patient interfere with ultrasound images.

While using the system in combination with high frequency devices (like electro-surgical units), be aware that a failure in the surgical device or a damage to the transducer lens can cause electro-surgical currents that can burn the patient. Thoroughly check the system and the probe before applying HF surgical currents to the patient. Disconnect the probe when not imaging.

WARNING

Physical damage to the probe may cause electrical or mechanical injury to the patient. Protective sheaths DO NOT provide protection against such damage nor do they guarantee that the probe is insulated electrically.

Perform a manual and visual check before each examination to ensure that the probe is intact.

At the End of the Examination

At the end of the examination, Esaote recommends that the Operator:

- Clean and disinfect the probe, according to the instructions provided in Chapter 2 of this manual.
- Store the probe as indicated in Chapter 1 of this manual.

Preparation of the Laparoscopic Probe

Follow the instructions below for preparing the laparoscopic probe.

Note

The Operator is recommended to wear gloves during the probe preparation procedure

See Chapter 8 on consumables for selecting the gel and sheathes.

- Apply a sufficient quantity of ultrasound gel inside the sheath.

WARNING

The protective sheaths available on the market often contain latex. Make sure that patients who are allergic to latex are identified before each examination. Serious allergic reactions to latex have been reported; the Operator should be prepared to handle such reactions.

Note

Esaote recommends use of sterile sheaths in intraoperative examinations.

- Completely unroll the sheath along the transducer body, making it adhere, so as to avoid air pockets.
- Secure the sheath with the rubber band provided.

7 - Needle Guide Kits

AO

Consult your **MyLab** "Advanced Operations" manual for correct use of the needle guide.

ESAOTE supplies a series of optional adaptors for the biopsy needle guide, fitted with special couplings for connection to the probe. The following table lists the available kits.

Biopsy adaptor	Probe	Kit contents
ABS421	CA421	1 20° coupling, 1 30° coupling+ 5 needle guides
	CA430	
	CA431	
ABS621	CA621	1 25° coupling, 1 35° coupling + 5 needle guides
ABS523	LA523	1 coupling (45° angle) + 5 needle guides
	LA522	
	LA532	
ABS424	LA424	1 coupling (45° angle) + 5 needle guides
	LA435	
ABS123	EC123	1 coupling + 1 needle guide
ABS15	IOE323	1 coupling (45° angle) + 5 needle guides

See Appendix A in this manual for probes references. The kits for LA, CA and Intraoperative probes include 14, 18, 20, 21, and 22 gauge needles; the kit for the endocavity probe has a guide for a 16 gauge needle.

WARNING

Do not use needle guides other than those described in this manual.

ABS421, ABS424, ABS523, ABS621 and ABS15 kits are composed of stainless steel; the ABS123 needle guide kit is composed of titanium.

Examination Safety

SS

All safety information related to the use of the needle guide kits is in addition to the safety procedures described for the system and for the probes. Consult your **MyLab** "Safety & Standard" manual for additional safety information.

Before the Examination

Before each examination, Esaote recommends that the Operator:

- Handle the biopsy kit and the probe with sterile gloves.

- Perform a visual check of the adaptor and needle guides: do not use them if any damage or distortion is found.
- Use protective sheaths during the examination. These sheaths are primarily composed of latex (natural rubber).

Note

Using sterile sheaths is recommended for intraoperative and biopsy procedures.

WARNING

Make sure that patients who are allergic to latex are identified before each examination. Serious allergic reactions to latex have been reported; the Operator should be prepared to handle such a reaction.

During the Examination

Pay particular attention to the ultrasound image during the insertion of the needle into the body, checking that the needle follows the displayed line.

WARNING

The lines displayed on the monitor only provides an indication of the needle direction, according to the selected guide. Pay particular attention to the ultrasound image during the insertion of the needle into the body and be sure that the needle always stays within the displayed area.

Before performing the biopsy-test, check for the correct assembly and positioning of the biopsy kit. Also, check that the insertion angle is equal to the angle selected via the user interface software.

Needle insertion in a guide with an insertion angle other than that of the selected angle involves risks to patient safety.

At the End of the Examination

At the end of the examination Esaote recommends that the Operator:

Chapter 2 provides cleaning, disinfection and sterilization instructions.

- clean and sterilize the kit,
- clean and disinfect the probe used during the biopsy.

Mounting the Needle Guide for LA and CA Probes

Adaptors for LA and CA biopsy probes are composed of two parts: the coupling to be connected to the relative probe and the needle guide device.

- Make sure that the probe has been disinfected.
- Apply ultrasound examination gel to the probe or to the tip of the protection cap.
- Cover the probe and the needle guide device with the protective cap; secure with the rubber band provided.

WARNING

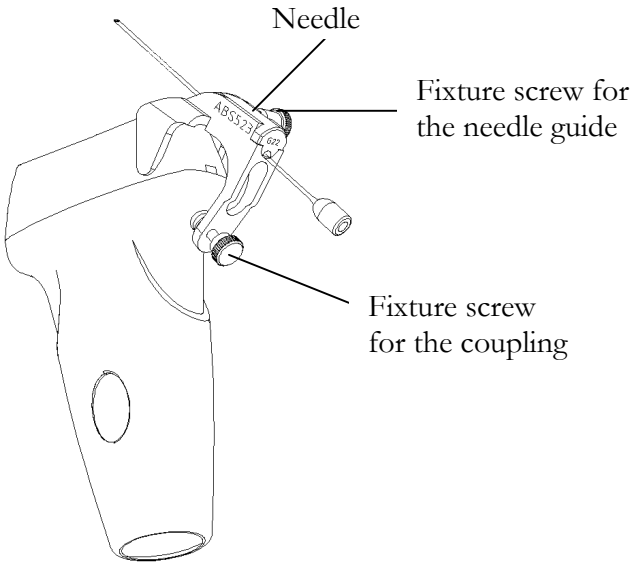
The protective sheaths available on the market often contain latex. Make sure that patients who are allergic to latex are identified before each examination. Serious allergic reactions to latex have been reported; the Operator should be prepared to handle such a reaction.

- Connect the kit to the probe, positioning the two alignment pins on the special notches on the probe:

Note

The guide device for inserting the needle must be on the same side of the probe as the LED. The coupling must click into the special notch on the probe.

The following figures show an example of how the ABS523 is assembled on the LA523.



WARNING

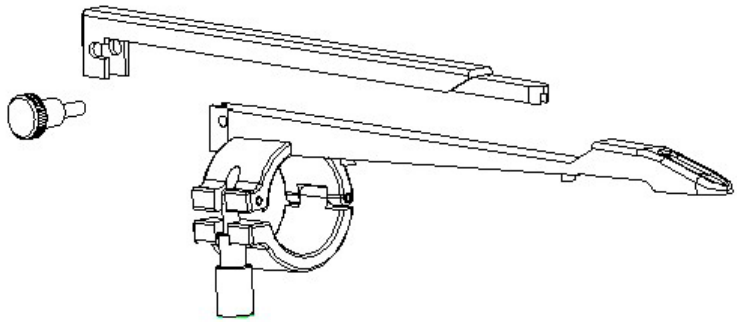
Make sure the bottom cone shaped part (at the bottom of the bracket) is screwed into the indentation at the bottom of the top curved portion of the probe. If the user does not perform this operation correctly, the insertion angle can be wrong causing a risk to patient safety.

For disassembly of the biopsy kit, reverse the previous procedure.

Mounting the Endocavity Probe Needle Guide

The endocavity biopsy probe is composed of two parts: the coupling to be connected to the probe and the needle guide device.

Biopsy kit for the EC123 probe

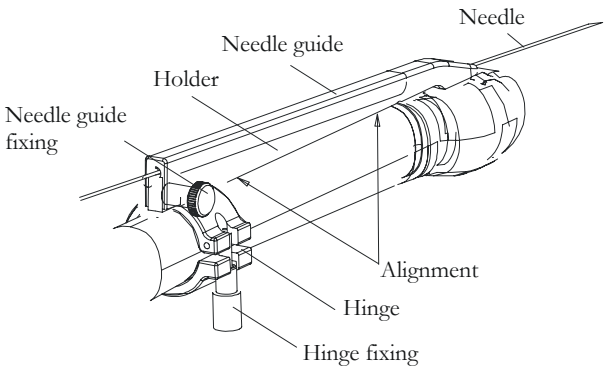


- Make sure that the probe has been disinfected.
- Apply ultrasound examination gel to the probe or to the tip of the protection cap.
- Cover the probe and the needle guide device with the protective cap; secure with the rubber band provided.

WARNING

The protective sheaths available on the market often contain latex. Make sure that patients who are allergic to latex are identified before each examination. Serious allergic reactions to latex have been reported; the Operator should be prepared to handle such a reaction.

- Connect the kit to the probe, positioning the two alignment pins on the special notches on the probe.



- Close the clamp and tighten it using the special ratchet.
- Insert the needle guide and tighten it onto the coupling.

The EC123 kit is also available with a disposable biopsy kit. The kit can be ordered from CIVCO.

Manufacturer	Manufacturer's kit code	Contents
CIVCO[1] Medical Instruments, Inc, Kalona, IA (USA)	610-693	Disposable sterile kit with needle guide, 2x20cm sheath, 3.5x20cm sheath, seal and gel.

The assembly procedure for this kit is identical to that of the metal biopsy kit; the biopsy kit must be attached to the probe using the alignment pivots.

The plastic disposable guide is sterile, but cannot be re-sterilized.

Mounting the Intraoperative Probe Needle Guide

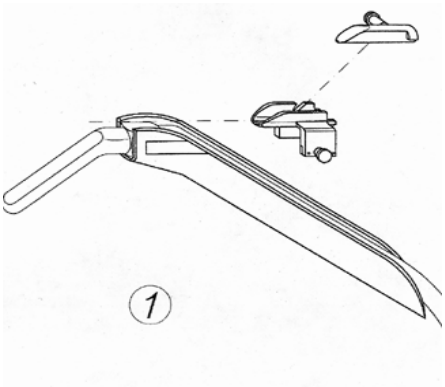
The ABS15 needle guide kit consists of two components: one bracket to hook the needle guide to the probe handle attachment and a needle guide to attach to the bracket. These two components can be disassembled to enable easier cleaning and sterilization.

Kit assembling

The ABS15 biopsy kit can only be placed on the probe handle attachment as shown below.

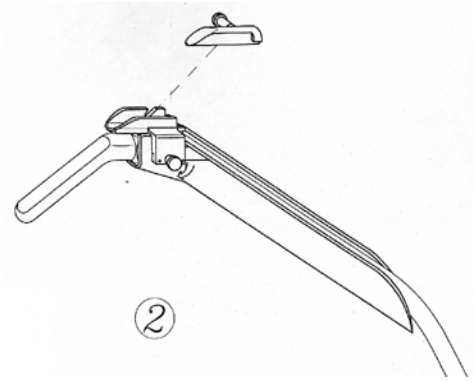
Check the integrity of the probe and needle guide and assemble the biopsy kit as follow:

- Once the biopsy kit has been positioned on the handle attachment as shown in picture 1, insert the biopsy bracket into the grooves on the handle attachment by sliding the biopsy bracket to the end of the groove. Attach the bracket with the screw provided.

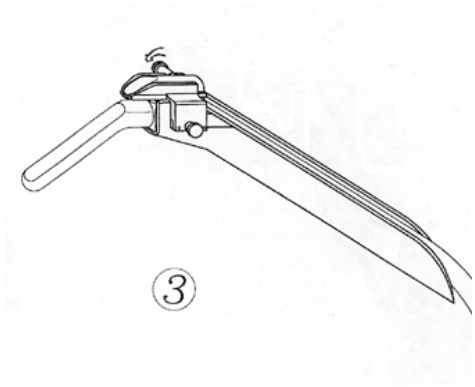


- Choose the needle guide acceptable for the diameter of the needle to be used and insert it into the bracket.

[1] Civco Medical Instruments, Kalona Iowa; www.civcomedical.com



- Attach the needle guide to the bracket with the screw provided.



- The needle can then be inserted into the hole formed between the bracket and the attached needle guide.

If necessary, the needle guide attachment can be removed from the handle attachment without removing the needle.

For disassembly of the biopsy kit reverse the previous procedure.

8 - Accessories and Consumables

ECG Cable

The leads on the ECG cable supplied by Esaote are equipped with a pliers terminal. Any button electrode can be used with the ECG cable. We recommend using disposable Ag/AgCl electrodes. Read the manufacturer's instructions carefully for correct use of the electrodes.

Checking the ECG Cable

A periodic check should be made of the ECG cable.

ECG Cable Inspection

Disconnect the cable from the system and check that there are no breaks or slits.

Note

Esaote recommends replacing the ECG cable if there are any breaks or slits.

Cleaning and Disinfecting the ECG Cable

Periodically clean the ECG cable and electrodes so that they remain in optimal working order.

WARNING

Never try to clean or disinfect the ECG cable when it is still connected to the unit.

Equipment

The equipment listed in the following table will be necessary for periodic maintenance procedures.

CIDEX OPA® is a Johnson&Johnson Ltd. Registered brand.

Agent	Destined for
Solution of mild soap and water	Cleaning the ECG cable and electrodes
CIDEX OPA	Disinfecting the ECG cable
Indicated by the manufacturer	Disinfecting the electrodes

Cleaning Procedure

- Disconnect the cable from the system.
- Dust the cable coupling with a soft cloth.
- Clean the cable by rubbing it gently with a soft cloth dampened with water and a mild detergent.

CAUTION

Do not immerse the ECG cable further than the start of the leads. The cable is not waterproof.

- Rub the cable gently with a soft cloth slightly dampened with a mild detergent solution or alcohol.
- Dry the cable by rubbing it gently with a soft, dry cloth.

Disinfection Procedure

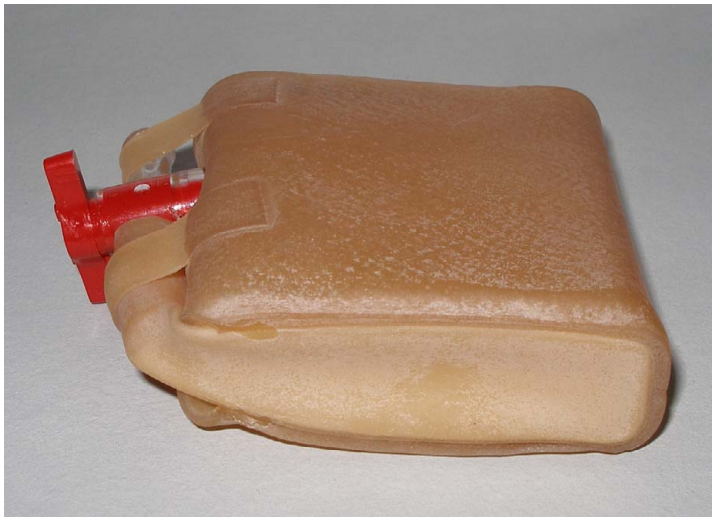
The ECG cable can be disinfected using CIDEX OPA, following the manufacturer's instructions.

- Disconnect the cable from the system.
- Clean the cable as explained in the previous paragraph.
- Immerse the ECG cable leads in CIDEX OPA. When using the disinfectant substance, carefully follow the manufacturer's instructions.

Stand Off for Linear Probes

The stand off part number 9650030000 allows to keep some distance between the probe head and the skin, thus moving the focus area of the probe. The use of a stand off is therefore valuable when studying the tissue surface in musculo-skeletal and vascular applications.

The stand off can be mounted on all MyLab linear probes with size 4 e 5 cm (LA 4XX and LA5XX probe families).



To get the desired distance the operator has to fill with water (preferably sterile) or ultrasound gel the contact pocket equipped with a cock.. The pocket can be filled and emptied using a syringe which perfectly suits into the cock opening.

CAUTION

During the exam, check that the cock is perfectly closed and correctly mounted on its case, to avoid fluid leaks or air bubbles.

Using the Stand-Off

- Immerse the stand off into water before each use.
- Apply ultrasound gel on the probe.
- Place the stand off on the probe sliding it till some gel comes out from the lower part of the pocket, on the base of the filling tube.
- Apply ultrasound gel on the stand off (between the contact pocket and the patient).

CAUTION

When the stand off is not used, it is recommended to store it far from light sources, to avoid early ageing of the rubber.

Cleaning and Disinfecting

The stand off is made of natural rubber and can be cleaned with a mild soap. Thoroughly rinse it with water , expecially after each contact with disinfectant agents.

CAUTION

The use of germicidal lamps and/or disinfectant agents containing quaternary ammonium compound is not recommended as they could damage the stand-off.

To dry the stand off, use warm air at 60° or a clean cloth.

Sterilizing

Sterilization cam be performed in autoclave at 134°C for 20 minutes, if the contact pocket doesn't contain ultrasound gel.

Gel

Transmission gel must always be applied to probes to obtain correct probe-patient contact. Esaote recommends only using water or glycerine-based ultrasound gel.

CAUTION

Do not use gels containing the substances listed below. The transducer could be damaged if such gels are used.

Substances to Be Excluded

- acetone
- methanol, ethanol, isopropyl alcohol
- denatured ethyl alcohol
- mineral oil
- iodine
- any lotion or gel containing perfume
- glycol

The following table indicates ultrasound gels that have tested compatibility with MyLab.

Product	Supplier
Aquasonic® Scan®	Parker Laboratories, Inc. New Jersey, USA

Sheaths

The use of protective sheaths is recommended in all clinical situations where there is a risk of infection. Specific sheaths are available on the market for most types of Esaote probes. The sheaths listed below are produced by CIVCO Medical Instruments Inc., Kalona, IA (USA). Refer to the manufacturer's instructions for the characteristics and use of the protective sheaths.

See later for sheaths included in accessory kits.

LA and CA Probes

Probes	Manufacturer's kit code	Measurements	Sterile	Latex
LA523, LA522, LA532, LA424	610-001	8.9 x 61 cm	Yes	No
CA421, CA621, CA430	610-002	14 x 61 cm	Yes	No

EC123 Probe

Manufacturer's code	Measurements	Sterile	Latex
610-006	It can be reduced from 11.9 to 4.6 x 61 cm	Yes	No
610-007	It can be reduced from 11.9 to 4.6 x 61 cm	No	No
610-214	3.5 x 20 cm	Yes	Yes
610-010	3.5 x 20 cm	No	Yes
610-075	2 x 20 cm	Yes	Yes
610-039	2 x 20 cm	No	Yes

IOE323 Probe

The intraoperative probe uses the Esaote sterilized sheath Ref.1000000065.

LP323 Probe

TheLaparoscopic probe uses the Esaote sterilized sheath Ref.7900000210.

Accessory Kits

The kits listed below are produced by CIVCO Medical Instruments Inc., Kalona, IA (USA). Refer to the manufacturer's instructions for the characteristics and use of the kits.

TEE022 Probe

Manufacturer's code	Content	Sterile	Latex
610-840	Bite-guard and sheath with application kit	No	No

Appendix A

Appendix A - MyLab Probes

GS

This chapter provides a list of **MyLab** probes with their main characteristics; system dependent features are described in your model documentation.

Phased Array Probes

Probe ID	Maximum immersion level
PA230	Up to 3 cm from transducer head
PA121	Up to 3 cm from transducer head
PA122	Up to 3 cm from transducer head
PA023	Up to 3 cm from transducer head

Linear Probes

Probe ID	Maximum immersion level
LA522	Up to 3 cm from transducer head
LA532	Up to 3 cm from transducer head
LA523	Up to 3 cm from transducer head
LA424	Up to 3 cm from transducer head
LA435	Up to 3 cm from transducer head

Convex Probes

Probe ID	Maximum immersion level
CA421	Up to 3 cm from transducer head
CA431	Up to 3 cm from transducer head
CA430	Up to 3 cm from transducer head
CA621	Up to 3 cm from transducer head
CA123	Up to 3 cm from transducer head

Specialty Probes

Transesophageal

Probe ID	TEE022
Type	Phased Array
Imaging plane	$0\text{-}180^0$
Maximum immersion level	Up to 1 m from transducer head

Endocavity

Probe ID	EC123
Type	Convex Array
Imaging plane	Sagittal
Maximum immersion level	Up to 25 cm from transducer head

Intraoperative

Probe ID	IOE323
Type	Linear Array
Maximum immersion level	Up to 10 cm from transducer head

Laparoscopic

Probe ID	LP323
Type	Linear Array
Maximum immersion level	Up to 10 cm from transducer head

BiScan Convex

Probe ID	BC431
Type	Convex Array
Maximum immersion level	Up to 9.5 cm from transducer head

Doppler Probes

Continuous Wave

Probe ID	Maximum immersion level
2 CW	Up to 6 cm from transducer surface
5 CW	Up to 6 cm from transducer surface

Appendix B

Appendix B - Cables and Consumables

ECG Cables

GS

This chapter provides a list of **MyLab** ECG cables with their main characteristics; refer to your system documentation for ECG capabilities..

Reference	Description
9630028000	3-Leads ECG Cable - IEC Colours
9630028010	3-Leads ECG Cable - AHA Colours

Recommended Consumables

Below is the recommended single use electrodes; the product has been tested for compatibility with the ESAOTE **MyLab** systems.

Type	Product	Manufacturer
Single Use Electrodes	Excel 3040.050	Ludlow Technical Products Massachusetts, USA

Cleaning, Disinfections and Sterilizations Agents

Use the agents listed in the following table for periodic maintenance procedures.

CIDEX OPA® is a Johnson & Johnson Ltd. Registered brand. Pera®Safe is a Antec International Limited registered brand.

Agent	Destined for
Solution of mild soap and water	Cleaning non-invasive probes, transesophageal and endocavity probes
CIDEX OPA*	Disinfecting non-invasive probes, transesophageal and endocavity probes
PeraSafe	Sterilizing intraoperative and laparoscopic probes and needle guide kits

* FDA Approved

CIDEX OPA is produced by ASP, a Johnson & Johnson company, PeraSafe is produced by Antec International Limited, Chilton Industrial Estate, Sudbury, Suffolk (UK)[1].

[1] ASP: www.sterrad.com; Antec: www.antechh.com

ESAOTE S.p.A.

Rev. B

February 2005

SAFETY AND STANDARDS

OPERATOR MANUAL

8300372000

Introduction

This manual provides information on Safety and Standards for the **MyLab** product line. This manual is organized in the following chapters:

- Chapter 1: Operator Safety
  This chapter describes the situations that could affect the operator safety when an ultrasound system is used.
- Chapter 2: Patient Safety
  This chapter describes the situations that could affect the patient safety when an ultrasound system is used.
- Chapter 3: Standards
  This chapter lists with which standards **MyLab** complies. It also lists with which standards the peripherals connected to the device have to comply.

In this manual a **WARNING** pertains to possible injury to a patient and/or the operator. A **CAUTION** describes the precautions, which are necessary to protect the equipment. **Be sure that you understand and observe each of the cautions and warnings.**

Table of Contents

Chapter 1

1 - Operator Safety

Installation Requirements

GS

The "Getting Started" manual provides detailed instructions to correctly install and connect your specific **MyLab** model. The same manual also contains all information on the recommended peripherals that may be connected to the system.

If help is needed, ESAOTE personnel will be glad to provide you with the necessary assistance to install your system.

Warnings

Incorrect installation of the system may cause operator hazard. Carefully follow the **MyLab** "Getting Started" manual instructions for installing your device

Electrical Safety

The equipment label, placed on the rear panel, specifies the device electrical requirements. Incorrect connections to the main power may compromise the electrical safety of the system.

WARNINGS

Observe the following warnings for maximum safety

Warnings

- Electrical shock hazard. Do not remove the system or the monitor cover. Refer servicing and internal adjustments to qualified ESAOTE personnel only.
- Always turn the equipment off before cleaning it.

CAUTIONS

Observe these precautions to prevent damage to your system

Cautions

- To prevent further damage to your system and the accessories, turn the unit's power off if it does not start up correctly.
- If your system incorporates an LCD, note that the screen is fragile and must be treated accordingly.

Environmental Safety

Information about Reusing/Recycling

This symbol identifies a recyclable component. Depending on the dimensions of a recyclable component, this symbol and the component's material are printed on the component by ESAOTE.

In this system, packing materials are reusable and recyclable; the unit and display devices casings (plastic) and most of the cart components (plastic) are also recyclable.

GS

Refer to the **MyLab** "Getting Started" manual for any additional information on special waste that has to be disposed of according to local regulations.

Exam Waste

Regard any exam waste as potentially infectious and dispose of it accordingly

Moving the Equipment

GS

MyLab systems are designed to be easily moved by the operator. However the equipment weight could require assistance during transportation. The **MyLab** "Getting Started" manual details the weight and dimensions of your configuration.

MyLab products can be classified as portable and mobile:

- **Portable** means that the system is equipped with a handle, whose size and weight allow it to be used to carry the system. The term "portable" is always used with this meaning in these manuals.
- A **mobile** model **or configuration** is equipped with wheels allowing to carry the system from one room to another. The term "mobile" is always used with this meaning in these manuals.

Portable

One can carry the console directly by its handle; observe the following precautions:

- make sure the console is turned off,
- if built-in, make sure the system display is secured prior to and during transportation,
- disconnect any cable or item (probes, ECG cable) attached to the system,
- should the console need to be put on the ground, lay it straight or flat,
- secure the system in a flat position if transporting it in a vehicle.

Mobile Configuration

The **MyLab** system complies with the EN60601-1: it is not unbalanced by a 10° inclination. Observe the following precautions when transporting the system:

- make sure the system is turned off,
- unlock the cart's wheels prior to moving the system,
- avoid unnecessary shocks to the unit when rolling it over door jambs or in and out of elevators,
- when transporting the system with the probes attached, make sure the cables are not dragging on the floor and that the probes are properly positioned in the cart probe holder,
- always use the handle to move the system. Never push the system from its sides.

Transportation in Vehicle

Observe the following precautions when transporting the system in a vehicle:

- disconnect any cable or item (probes, ECG cable, …) attached to the system and place the transducers in their cases,
- a portable model should be packed in the original shipment case (or other protective devices as available through ESAOTE) during transportation,
- for mobile systems, make sure the cart wheels are blocked and the cart secured during transportation.

Explosive Hazard

WARNING

The equipment is not suitable for use in the presence of a flammable anesthetic mixture with air, oxygen or nitrous oxide. Do not use the system in the presence of flammable anesthetics. Explosion is a hazard under such conditions.

Transducers

GS** and **AO

Use only ESAOTE approved transducers with the equipment. The **MyLab "**Getting Started" manual lists which probes can be connected to the system. **MyLab** "Advanced Operations" explains system related special features, when applicable.

TC

The "Transducers and Consumables" manual covers all aspects concerning transducer cleaning and disinfecting.

WARNINGS

Damage caused by dropping a probe, striking it against another object, pinching, kinking or twisting the cable are not covered under warranty.

CAUTIONS

Observe these precautions to prevent damage to your system

Warnings

- If you drop or strike a probe against another object, do not use it until an electrical leakage current measurement test has demonstrated that the electrical safety has not been compromised.
- Do not immerse the entire transducer in liquid to clean it. The transducer is not watertight and immersion may compromise the electrical safety features of the probe.

Cautions

- Never expose the probes to gas, heat or liquid sterilization procedures. These methods can permanently damage the probe.
- Do not connect or disconnect an active probe during live scanning; the system must be in freeze mode or turned off to connect or disconnect a probe.
- Carefully follow the "Probes and Consumables" manual instructions to clean or disinfect a probe.

Biocompatibility and Infection Control

TC

Probes and electrodes intended to be used on intact skin have very limited probabilities to propagate infections; basic procedures as described in the "Transducers and Consumables" manual are sufficient for infection control.

Endocavity and transesophageal transducers require specific cleaning and disinfecting procedures. See the "Transducers and Consumables" manual for complete details on these procedures.

Repetitive Strain Injury

Musculoskeletal disorders have been reported by the clinical literature[1] as a result of repetitive scanning. These musculoskeletal disorders are also described by the term Repetitive Strain Injury (RSI). To prevent the risk of RSI, it has been recommended:

- to maintain a balanced position while scanning,
- not to grip the transducer with excessive force,
- to take work breaks to allow your muscles to relax,
- to introduce routine exercises such as gentle passive stretching.

[1] Necas M. "Musculoskeletal symptomatology and Ripetitive Strani Injuries in Diagnostic Medical Sonographers", Journal of Diagnostic Medical Sonography 12, p. 266-273, 1996

Pike I, Russo A., Berkowitz J et al. " the prevalence of musculoskeletal disorders among Diagnostic Medical Sonographers", Journal of Diagnostic Medical Sonography 13, p. 219-227, 1997

Working with Video Display

Scanning can require long sessions in front of a display screen. Consequently visual problems such as eyestrain and irritation can result[2]. Visual discomfort is reduced when the following recommendations are observed :

- orientate the display so that it can be comfortably observed while scanning,
- take rest breaks after a long scanning session.

Safety Symbols

The **MyLab** device uses the EN60601-1 safety symbols for medical electronic devices to classify a connection or to warn of any potential hazards.

	On (power)
	Off (power)
	Type CF applied part (suitable for cardiac application)
	Type B applied part
	Type BF applied part
	Equipotentiality
	High Voltage
	This symbol generically means "Attention". Read carefully the appropriate sections of user manuals before using any function labeled with this symbol.
IP68	The footswitch is watertight.

[2] See for example OSHA 3092 "Working safely with video terminals display" 1997

Chapter 2

2 - Patient Safety

Electrical Safety

Warnings

WARNINGS

Observe the following warnings for maximum safety

GS

- The system must be properly grounded to prevent shock hazards. Protection is provided by grounding the chassis with a three-wire cable and plug; the system must also be powered through a properly grounded receptacle.
- Do not replace the system fuses with types different from those specified by the **MyLab** "Getting Started" manual.
- Mobile configurations provide insulated plugs and connectors to manage optional hard copy devices (VTR, printers). Follow the instructions in the "Getting Started" manual to install such a device. Incorrect connections may compromise the electrical safety of the system.
- If the Operator plans to use hard-copy devices with a portable model, and one plans to utilize hard-copy devices, read and carefully follow the instructions in the "Getting Started" manual to install such devices. Incorrect connections or use of peripherals with improper safety characteristics may compromise the electrical safety of the system.
- **MyLab** models are not watertight and provides a class IP(X)0 degree of protection to liquids; do not expose the system to rain or moisture. Avoid placing liquid containers on the system.
- Remove probes and electrocardiography leads from patient contact before applying a high voltage defibrillation pulse.
- **MyLab** systems use high frequency signals. Pacemakers could interfere with these signals. The user should be aware of this minimal potential hazard and immediately turn the unit off if interference with the pacemaker operation is noted or suspected.
- While using the system in combination with high frequency devices (like electro-surgical units), be aware that a failure in the surgical device or a damage to the transducer lens can cause electro-surgical currents that can burn the patient. Thoroughly check the system and the probe

before applying HF surgical currents to the patient. Disconnect the probe when not imaging

Electromagnetic Compatibility

Ultrasound systems require special precautions regarding EMC and must be installed and put into service according to the provided information.

Sensitivity to interference is more noticeable in Doppler modes.

Ultrasound units are designed to generate and receive radiofrequency (RF) energy and are, therefore, susceptible to other RF sources. As an example, other medical devices, information technology products or TV/radio transmitters may cause interference with the ultrasound system.

In the presence of RF interference, the physician must evaluate the image degradation and its diagnostic impact.

WARNINGS

GS

The "Getting Started" manual provides the table for equipment distance requirements.

Warnings

- Portable and mobile RF communication equipment may cause interference with the ultrasound system. Do not use these devices in the vicinity of ultrasound equipment.
- Use of accessories and cables other than those specified in the **MyLab** "Getting Started" manual may result in increased emission or decreased immunity of the system.

If an ultrasound system causes interference (This can be identified by turning the system off and on) with other devices, the user could try to solve the problem by:

- relocating the system,
- increasing the separation from other devices,
- powering the ultrasound system from an outlet different from the one of the interfering device,
- contacting ESAOTE Service personnel for help.

Electro-Surgical Units (ESUs)

Electro-surgical units or other devices that introduce radiofrequency electromagnetic fields or currents into the patient may interfere with the ultrasound image. An electro-surgical device in use during ultrasound imaging will grossly affect the 2D image and render Doppler modalities useless.

Biocompatibility and Infection Control

TC

Before each exam properly clean the probes. Refer to the "Transducers and Consumables" manual for further details on cleaning and disinfecting probes, kits and electrodes.

Items in Contact with Patient

ESAOTE probes and electrodes materials that are in contact with the patient have been proved to comply with EN ISO 10993 "Biocompatibility Tests Requirements", according to their intended use. No negative reactions to these materials have been reported.

Latex Sensitive Patient

The USA Food and Drug Administration (FDA) has issued an alert on products composed of latex, because of reports of severe allergic reactions.

Note

ESAOTE probes and electrodes do NOT contain latex.

WARNING

The transducer protective covers used during the patient exam are usually composed of latex. Carefully read the protective cover package labeling to verify the material used. Be certain to identify latex sensitive patients prior to the exam. Serious allergic reactions to latex have been reported and the user should be ready to react accordingly.

Ultrasound Safety

Introduction

MyLab "Getting Started" manual provides data about the acoustic power levels.

ESAOTE has adopted the more recent requirements and recommendations established by the USA Food and Drug Administration and by the American Institute of Medicine and Biology. **MyLab** is equipped with the **Acoustic Output Display** feature to provide the user with real-time, on-line information on the actual power of the system. The following sections describe the rationale of this methodology. ESAOTE recommends the use of the **ALARA** principle (see below), which is extensively covered in this manual.

Clinical Safety

Refer to the glossary at the end of this chapter for specific terms.

In the USA, in more than three decades of use, there has been no report of injury to patients or operators from medical ultrasound equipment.

American Institute for Ultrasound in Medicine (AIUM) Statement on Clinical Safety: October 1982, Revised March 1983, October 1983 and March 1997.

Diagnostic ultrasound has been in use for over 25 years. Given its known benefits and recognized efficacy for medical diagnosis, including use during human pregnancy, the American Institute of Ultrasound in Medicine herein addresses the clinical safety of such use:

No confirmed biological effects on patients or instrument operators caused by exposure at intensities typical of present diagnostic ultrasound instruments have been reported. Although the possibility exists that such biological effects may be identified in the future, current data indicate that the benefits to patients deriving from the prudent use of diagnostic ultrasound outweigh the risks, if any, that may be present.

The **ALARA** (As Low As Reasonably Achievable) principle is the guideline for prudent use: during an exam, the user should use for the shortest duration the least amount of acoustic output to obtain the necessary clinical information for diagnostic purposes.

Ultrasound Bioeffects

Although diagnostic ultrasound has an excellent history of safety, it has been known for a long time that ultrasound, at certain levels, can alter biological systems. The AIUM Bioeffects Committee describes two fundamental mechanisms by which ultrasound may induce biological effects: non-thermal or mechanical mechanisms[1] and thermal effects.

MECHANICAL BIOEFFECTS

"Cavitation" phenomenon

Non-thermal bioeffects, also referred to as **mechanical bioeffects**, seem to be caused by the tissue alternate expansion and contraction induced when ultrasound pressure waves pass through or near gas. The majority of these non-thermal interactions, also known as cavitation, deal with the generation, growth, vibration, and possible collapse of microbubbles within the tissue. The occurrence of cavitation depends on a number of factors, such as the ultrasonic pressure and frequency, the ultrasonic field (focused or unfocused, pulsed or continuous), the nature and state of the tissue and boundaries. Mechanical bioeffects are a threshold phenomenon, occurring only when a certain level of output is exceeded. However, the threshold level varies depending on the tissue. The potential for mechanical effects is thought to increase as peak rarefactional pressure increases, but to decrease as the ultrasound frequency increases.

Although there have been no adverse mechanical bioeffects in humans from diagnostic ultrasound exposure, it is not possible to specify thresholds at which cavitation will occur in mammals.

THERMAL BIOEFFECT

Rise in temperature of tissue exposed to acoustic energy.

Thermal bioeffect is the rise in temperature of tissue when exposed to acoustic energy. The acoustic energy is absorbed by body tissue; absorption is the conversion of this energy into heat. If the rate of energy deposition in a particular region exceeds the ability to dissipate the heat, the local temperature will rise. The rise in temperature will depend on the amount of energy, the volume of exposure, and the thermal characteristics of the tissue.

[1] American Institute of Ultrasound in Medicine Bioeffects Committee, Bioeffects Considerations for the Safety of Diagnostic Ultrasound, J. Ultrasound Med., 1988, 7 Suppl.

On-screen Real-Time Acoustic Output Display

Until recently, application-specific output limits[2] established by the USA Food and Drug Administration (FDA) and the user's knowledge of equipment controls and patient body characteristics have been the means of minimizing exposure. Now, more information is available through a new feature, named the Acoustic Output Display. The output display provides users with information that can be specifically applied to ALARA. It eliminates some of the guesswork and provides both an indication of what may actually be happening within the patient (i.e. the potential for bioeffects), and what occurs when system control settings are changed. This makes it possible for the user to get the best image possible while following the ALARA principle and thus to maximize the benefits/risks ratio.

ODS

Thermal and Mechanical Indices display to assist in making informed risk/benefit decisions

MyLab incorporates a real-time acoustic output display according to the AIUM[3]/NEMA[4] "Standard for Real-Time Display of Thermal and Mechanical Acoustic Output Indices on Diagnostic Ultrasound Equipment" publication, adopted in 1992 by both institutions. This **output display standard** is intended to provide on-screen display of these two indices, which are related to ultrasound thermal and cavitation mechanisms, to assist the user in making informed risk (i.e. patient exposure)/benefit (diagnostically useful information) decisions. Considering the type of exam, patient conditions and the case study level of difficulty, the system operator decides how much acoustic output to apply for obtaining diagnostically useful information for the patient; the thermal and mechanical indices real-time display is intended to provide information to the system operator throughout the examination so that exposure of the patient to ultrasound can be reasonably minimized while maximizing diagnostic information.

For systems with an output display, the FDA currently regulates only the maximum output. **MyLab** system has been designed to automatically default the proper range of intensity levels for a particular application. However, within the limits, the user may override the application specific limits, if clinically required. The user is responsible for being aware of the output level that is being used. The **MyLab** real-time output display provides the user with relative information about the intensity level.

The Mechanical Index

MI

Estimates mechanical bioeffects

The Mechanical Index (**MI**) is defined as the peak rarefactional pressure in MPa (derated by a tissue attenuation coefficient of 0.3 dB/cm/MHz) divided by the square root of the probe central frequency in MHz.

With the MI, the user can keep the potential for mechanical bioeffects as low as reasonably achievable while obtaining diagnostically adequate images. The higher the index, the larger the potential. However, there is not a level to indicate that

[2] Also known as the preamendments limits, those values were established on the basis of acoustic output of equipment on the market before 1976.

[3] American Institute for Ultrasound in Medicine.

[4] National Electric Manufacturers Association.

bioeffect is actually occurring: the index is not intended to give an "alarm" but to use it to implement the ALARA principle.

The Thermal Index

TI

Relates to temperature rise

The purpose of the Thermal Index (TI) is to keep the user aware of conditions that may lead to a temperature rise under certain defined assumptions. It is the ratio between the total acoustic power to the power required to raise tissue temperature by 1°C, estimated on thermal models. There are currently three thermal indices (each based on a specific thermal model) used to estimate temperature rise whether at the surface, within the tissues, or at the point where the ultrasound is focusing on bone:

1. The Soft Tissue Thermal Index (**TIS**) provides information on temperature increase within soft homogeneous tissue.
2. The Cranial Bone Thermal Index (**TIC**) indicates temperature increase of bone at or near the surface, as may occur during a cranial exam.
3. The Bone Thermal Index (**TIB**) provides information on temperature increase of bone at or near the focus after the beam has passed through soft tissue.

As with the Mechanical Index, the thermal indices are relative indicator of temperature rise: a higher value represents a higher temperature rise; they indicate that the possibility for an increase in temperature exists and they provide a relative magnitude that can be used to implement ALARA.

Acoustic Output Display

The acoustic output indices are displayed during live scanning to the right of the screen, together with the transmit power setting.

The following abbreviations are used:

Indices are displayed in 0.1 increments.

Index	Abbreviation
Soft Tissue Thermal Index	TIS
Cranial Bone Thermal Index	TIC
Bone Thermal Index	TIB
Mechanical Index	MI

The output display is organized to provide meaningful information to implement ALARA without "distracting" the user with unnecessary data. During the entry of the patient ID, the user is provided with a choice of applications (Cardio, Vascular, OB, etc.); depending on the selection, the system will default the appropriate indices.

Note

Index values below 0.4 are NOT displayed by this system.

To optimize ALARA, index values equal or higher than 0.4 are displayed even if the maximal index value does not exceed 1.0.

The Output Display

In combined modes (ex.: 2D+Doppler), the indices will show the highest value between the two modes.

The following table shows the indices used for each clinical application. Indices are displayed in 0.1 increments.

Application	MI	TIS	TIB	TIC
OB/Fetal	Yes	Yes	Yes	No
Neonatal[5]	Yes	Yes	Yes	Yes
Adult Cephalic	Yes	Yes	No	Yes
All others	Yes	Yes	Yes[6]	No

The Output Default Settings

System default settings depend upon the probe, the mode of operation and the application which is selected during the patient ID procedure. The **MyLab** defaults the transmit power to obtain output levels that are below the historic Ispta limits established by the FDA for the selected application.

Methodology and Accuracy of Display

The displayed indices values must be interpreted as relative information to help the user to achieve the ALARA principle.

Initial data are derived from laboratory measurements based on the AIUM standard. Then the indices are calculated beginning from these measurements according to the AIUM/NEMA "Standard for Real-Time Display of Thermal and Mechanical Acoustic Output Indices on Diagnostic Ultrasound Equipment" publication. Many of the assumptions used for measurements and calculation are conservative in nature. The measured water tank values are derated using the conservative attenuation coefficient established by the standard (0.3 dB/cm/MHz). Over-estimation of actual in-situ exposures is thus part of the calculation process.

INDICES ACCURACY

Accuracy: ±14% for the MI, ±30% for the TI A number of factors influence the estimation of the accuracy of the displayed indices, the most significant ones being the variability between probes and the laboratory measurements accuracy (hydrophone, operator, algorithms, etc.) itself, while variability of the system pulser and efficiency is a minor contributor.

The accuracy estimate, based on the variability range of probes and systems, and on the inherent modeling and measurements errors, is 14% for the MI and 30% for TI indices; this accuracy estimate does not consider errors in/or caused by measuring with the AIUM standard.

[5] Includes Neonatal Head studies

[6] Only when TIB≠TIS

Maximum Acoustic Output

MAXIMUM OUTPUT

- MI < 1.9
- Ispta<720 mW/cm²

This system does not use the historic FDA limits for Isppa and Imax, but rather the recently adopted MI, which is now considered a better relative indicator of non-thermal bioeffect mechanisms. The maximum MI is below 1.9 (see the "Getting Started" manual for your model actual maximum); the FDA has recognized this value as equivalent to preamendments Isppa limits. The maximum output for Ispta is limited to the preamendments FDA limit for peripheral vascular applications (720 mW/cm²).

Other application limits have been established as per this table:

Application	Preamendments Ispta Limits (mW/cm²)	MyLab Maximum (mW/cm²)
OB/Fetal	94	430
Cardiac	430	720
Pediatric	94	430
Peripheral Vascular	430	720
Other	94	720

The maximum output for a given probe can be less than the system limit, since the maximum depends on various elements (crystal efficiency, mode of operation, …).

Acoustic Output Controls

Control features may be divided into three categories:

1. controls which directly affect the intensity (**direct** controls)
2. controls which indirectly affect the intensity (**indirect** controls)
3. controls, which do not affect the intensity, such as the gains and the processing curves.

Controls Which Directly Affect the Intensity

DIRECT CONTROLS

- the Application
- the POWER

This category includes two system controls:

- the application selection, which establishes the appropriate range of intensities (see maximum output section); the application also establishes the indices to be displayed;
- the POWER control, which allows an increase or decrease in the output intensity within the range of the selected application. This parameter will affect both the MI and the TI values.

Controls Which Indirectly Affect the Intensity

INDIRECT CONTROLS

- PRF
- Focal Point
- Frequency
- CFM Process
- Sample Volume

This category includes controls, which change several aspects of the transmitted ultrasonic field rather than the intensity. Intensity is affected because of the field variations. Each mode has its own pulse repetition frequency (PRF) and intensity level; moreover, for each mode, a number of parameters will indirectly affect the transmitted field.

> **Note**
>
> The TI index display depends on the application and on the mode.

2D

The MI may increase whenever the PRF is decreased, i.e. when the field of view is increased.

MyLab allows the user to set the transmit focal point which will affect both indices by varying the beam profile. Generally, higher MI's and TI's will occur with closer focal points. If more than one transmit focal point is activated, MI and TI values will each correspond to the zone with the largest value. In addition, all system probes can image at two frequencies; both indices are usually different, depending on the probe bandwidth.

TEI

The same controls described for 2D affect the acoustic output. Because the tissue response is a non-linear phenomenon, this modality usually **requires higher acoustic outputs** than conventional imaging. While using this mode, the **MI** is your primary concern; a deeper transmit focal point helps to keep the MI value as low as possible.

M-Mode

In M-Mode, the transmitted field is only affected by the transmit focal point and the frequency. If M-Mode is displayed with 2D and the 2D is updated, the system may show the latter mode MI (and TI if available) if higher.

2D-CFM

The MI is primarily dependent on 2D settings, i.e. the depth (which will determine the 2D and color PRF) and the transmit focal point. The MI may also be increased by a decrease in the color PRF.

The TI may be increased by increasing the color CFM. Increasing the color frame rate may increase the TI while decreasing the MI. Finally, probes can provide color at two frequencies; the outcome in terms of transmitted field is marginal and largely unpredictable.

TVM

This mode optimizes CFM settings in order to image the movement of tissue, thus the same controls described for 2D-CFM affect the acoustic outputs.

Pulsed Wave Doppler

In PW, the sample volume depth automatically sets the Doppler PRF and the focal point. Deeper sample volumes will cause lower PRF; the MI may, however, not increase since the focal point is far, while the TI is generally reduced. The TI may, however, change if the sample volume size is varied. This factor accounts generally for a MI modification.

TV

TV Doppler optimizes your settings to analyse tissue motion.

Finally, most probes provide Doppler at two frequencies; the outcome in terms of transmitted field is marginal and largely unpredictable.

Continuous Wave Doppler

In CW, the only "variable" factor is the Doppler frequency. As stated before, most probes provide Doppler at two frequencies; the outcome in terms of transmitted field is marginal and largely unpredictable. The user can vary the spectral velocity range; this does NOT, however, change the system's PRF.

> **Note**
>
> In Doppler modes, if the tracings are displayed with an updated 2D, the 2D values are used if higher than the Doppler indices.

Implementing ALARA with **MyLab**

Prudent use implies that during an exam the user should use for the shortest time the least amount of acoustic output to obtain the necessary clinical information for diagnostic purposes. In other words, the goal is to keep the TI and the MI indices as low as possible for the shortest time while obtaining the necessary clinical information.

This section does not cover the patient and technique factors, which may influence the indices such as the patient body size, the tissue perfusion characteristics, the presence or the absence of fluid, etc.

ALARA Guidelines

- Select the appropriate Application when you enter the patient data.
- Depending on the patient characteristics and the type of exam (see Intended Use Section) select the appropriate probe and frequency.

Use the system capabilities to preset the **MyLab** system to default each mode according to your needs or specific applications; this will reduce the need for real-time interactions and help to obtain useful images quickly thus reducing ultrasound exposure.

GS
See the "Getting Started" manual for your system controls.

- Start scanning with a low output level and optimize the focusing, the gains and all other system adjustments; if this is not adequate for diagnostic purposes, then increase the output level. In cardiac studies, use Tissue Enhancement Imaging if acoustic noise is affecting the images' readability.
- Use the output display feature to guide your settings; remember that the indices do not consider TIME exposure: the higher your indices, the shorter the patient exposure should be.

Which Index When

In cardiac, vascular, abdominal and small parts examinations, MI is the primary concern in imaging modes, while the TIS is the principle index in Doppler.

In **cardiac**, **vascular** and general purpose (**abdominal**, **small parts, musculoskeletal**) exams, the system displays the TIS in addition to the MI. In imaging and CFM modes, the primary concern is in keeping the "cavitation" predictor as low as possible. You can minimize the MI by reducing the power to the lowest possible level, and adjusting the TGC and general gain controls. Use the transmit focal point to enhance resolution and sensitivity in the area of interest: this

may increase the MI, but because of the enhanced sensitivity, you may be able to reduce the transmit power, thus reducing the MI. Decreasing the imaging depth as low as possible may allow the system to increase the PRF and thus reduce the MI.

In Doppler modes, if you are working with a 2D + Doppler display, the MI will show the 2D value (because it is higher than the Doppler one) and the Doppler TIS; the latter parameter should be your primary concern: the MI value reflects the energy to which the patient is exposed only for a minimal time, i.e. between every sweep. You may want however to remember that whenever varying the Doppler speed: increasing the speed will cause the 2D to be refreshed more often. You may eventually freeze the 2D or switch to a full screen mode; however, this will probably increase the time to actually find the desired signal, and therefore the exposure time.

In OB, the TIB should be considered when scanning a second or third trimester fetus, while the TIS is more reliable for earlier exams.

In **OB** exams, this system displays both the MI and the TIB in imaging and CFM modes. While the MI will remain your primary concern in those modes, you should also consider the TIB in imaging a second or third trimester fetus as a conservative estimate of the actual temperature rise. In PW Doppler, the latter value is the primary parameter to consider for second or third trimesters pregnancies while the TIS is a more reliable indicator for earlier exams. The general guidelines already expressed for the previous exams remain valid.

The TIB is a better predictor during neonatal head studies, while the TIC is more significant in adult transcranial studies.

For **Neonatal Head** studies, the MI and the TIB may be significant in imaging and CFM modes, while the MI and both TIS and TIB are displayed for Doppler modes. Because of the chance of focusing near the base of the skull, the TIB should be conservatively considered the ideal thermal index. As usual the MI is the primary concern in imaging modes, and the TIB in Doppler. The general guidelines expressed above are valid. In **Adult Cephalic**, because of the skull, the TIC is considered the most significant index for this application. The general guidelines expressed above are valid.

Acoustic Output Tables

According to the IEC61157 and EN 60601-2-37, the acoustic output tables give the acoustic output data for each probe in every operating mode. These tables are in the **MyLab** "Getting Started" manual.

Glossary and Definition of Terms

"In Situ" Intensities Calculations

The intensity measurements made in water in the laboratory must be derated to reflect the effects of attenuation.

When determining the possible effects of the ultrasound beam on tissue, the intensity encountered at the tissue site must be calculated. Because of attenuation of the beam within the body, the intensity at the tissue site ("in situ") may be 10 to 100 times less than if it was measured at the same location in water. The amount of attenuation from experience by an ultrasound beam as it travels through the body tissue is determined by three factors:

1. Type of tissue along the beam path
2. Frequency of the ultrasound energy
3. Distance covered by the beam

In order to achieve a conservative approximation of attenuation due to these three factors, the FDA requires the application of the following formula:

$$\mathbf{I_d = I_w \exp(-0.23\ a\ f\ z)}$$

- I_d is the estimated "in situ" intensity at the tissue site
- I_w is the intensity measured in water at a distance "z", measured in cm
- a is the attenuation coefficient[7] expressed in dB/cm/MHz
- f = acoustic frequency in MHz of the ultrasound beam

Definition of Terms

The **acoustic intensity** generated by an ultrasound probe is usually described as follows:

Ispta

The Spatial Peak Time Average Intensity is an ultrasound intensity averaged over time at the point in the acoustic field where the pulse average intensity is at maximum.

Isppa

The Spatial Peak Pulse Average Intensity is an ultrasound intensity averaged over the pulse transmission time at a point in the acoustic field where the pulse average intensity is at maximum.

Imax

The Maximum Intensity is an average intensity during the half-cycle with the greatest amplitude during the pulse.

[7] As per the FDA, this coefficient is equal to 0.3 dB/cm/MHz

Mechanical Index

The Mechanical Index is defined as the peak rarefactional pressure in MPa (derated by a tissue attenuation coefficient of 0.3 dB/cm/MHz) divided by the square root of the probe central frequency in MHz.

Thermal Index

The Thermal Index is the ratio between the acoustic power and the power required to raise tissue temperature by 1°C, estimated on thermal models.

Peak Rarefactional Pressure

The peak rarefactional pressure (p_r in MPa) is the temporal peak rarefactional pressure amplitude at a specified point.

Pulse Intensity Integral

The Pulse Intensity Integral (PII) is the time integral of instantaneous velocity for any specific point and for any specific pulse, integrated over the time in which the envelope of acoustic pressure or the envelope of hydrophone signal for the specific pulse is non-zero. It is equal to the energy fluence per pulse.

Indices Equations

Parameter	Equation
Soft Tissue at Surface TIS(scanned[8]) TIB (scanned[6])	$\frac{W_{01}}{\frac{210}{f_c}}$
Large Aperture ($A_{aprt} > 1\ cm^2$) TIS (unscanned[9])	$\frac{\max\limits_{z>zbp}\left[\min\left(W_{.3}(z); I_{TA.3}(z)x1cm^2\right)\right]}{\frac{210}{f_c}}$
Small Aperture ($A_{aprt} \leq 1\ cm^2$) TIS (unscanned[7])	$\frac{W_0}{\frac{210}{f_c}}$
Bone at Focus TIB (unscanned[7])	$\min\left\{\frac{\sqrt{W_{.3}(z_{B.3})I_{TA.3}(z_{B.3})}}{50}; \frac{w_{.3}(z_{B.3})}{4.4}\right\}$ where $z_{B.3}$ is the depth that maximizes $W_{.3}(z)I_{TA.3}(z)$, or, equivalently, the depth of $I_{SPTAB.3}$.
Bone at Surface TIC	$\frac{W_0}{40D_{eq}}$
Mechanical Index (MI)	$\frac{p_{r.3}(z_{sp})}{\sqrt{f_c}}$ where $p_{r.3}(z_{sp})$ is the peak rarefactional pressure (in MPa) derated by 0.3 $dBcm^{-1}MHz^{-1}$ to the point on the beam axis z_{sp} where pulse intensity integral (PII.3) is maximum, and f_c is the center frequency (in MHz).

[8] The scanned mode (or autoscanning) is the electronic or mechanical steering of successive ultrasonic pulses or series of pulses, through at least two dimensions.

[9] The unscanned mode (or nonautoscanning) is the emission of ultrasonic pulses in a single direction, where scanning in more than one direction would require moving the transducer assembly manually.

Symbols Used in Indices Equations

Symbol	Definition
A_{aprt} (cm^2)	Active aperture area
$d_{eq}(z)$ (cm)	Equivalent beam diameter $\sqrt{\frac{4W_{.3}(z)}{\pi I_{TA.3}(z)}}$
D_{eq} (cm)	Equivalent aperture diameter $\sqrt{\frac{4A_{aprt}}{\pi}}$
f_c (MHz)	Center frequency.
$I_{SPTAB.3}$ (mW/cm^2)	Equivalent to the spatial peak temporal average derated (0.6 $dBcm^{-1}MHz^{-1}$) intensity
$I_{TA.3}$ (z) (mW/cm^2)	Temporal average intensity derated to depth z
W_0 (mW)	Time average acoustic power at source
W_{01} (mW)	Time average acoustic power at the source emitted from the central centimeter of the active aperture
$W_{.3}$ (z) (mW)	Time average acoustic power derated to depth z
$\frac{W}{X}$ (mW/cm)	Acoustic power per unit linear length (for example of a linear array)
z (cm)	Depth from the surface along the beam axis
z_{bp} (cm)	Break point depth (minimum depth for intensity measurements in the TIS(unscanned) models) $z_{bp} = 1.5D_{eq}$
$z_{B.3}$ (cm)	Depth of the maximum temperature rise in the bone at focus model
$p_{r.3}(z_{sp})$	Peak rarefactional pressure (in MPa) derated by 0.3 $dBcm^{-1}MHz^{-1}$ to the point on the beam axis z_{sp} where pulse intensity integral (PII.3) is maximum

Chapter 3

3 - Devices Standards

Medical Device Directive

This system complies with the Medical Device Directive (MDD) 93/42/EEC, according to which ESAOTE has classified this device as a Class IIa device.

Note for U.S. Customers

U.S. Federal Law restricts these devices to sale, distribution and use by or on the order of a physician.

Medical Electrical Equipment Standard

As defined in EN60601-1 (IEC Standard 60601-1, Safety of Medical Electrical Equipment), **MyLab** models are classified as Class I, with applied parts of type B or BF (probes), and of Type CF (ECG).

These devices also comply with the EN 60601-2-37 (IEC 60601-2-37) "Particular requirements for the safety of ultrasonic medical diagnostic and monitoring equipment".

Electromagnetic Compatibility

GS

Each **MyLab** model complies with the EN60601-1-2 (Electromagnetic Compatibility). Refer to the **MyLab** "Getting Started" manual for the electromagnetic emissions classification of the devices and electromagnetic immunity compliance levels.

Biocompatibility

The probe and electrode material that is in contact with patients, complies with the applicable requirements of EN ISO 10993-1, according to their intended use. No negative reactions to these materials have been reported.

Standards Summary Table

Standard	Title
EN60601-1	Medical Electrical Equipment – General requirements for Safety
EN60601-2-37	Medical Electrical Equipment – Particular requirements for the safety of ultrasonic medical diagnostic and monitoring equipment
EN60601-1-2	Medical Electrical Equipment – General requirements for Safety – Electromagnetic compatibility – Requirements and Test
EN60601-1-1	Medical Electrical Equipment – General requirements for Safety - Safety requirements for medical electrical systems - requirements and tests
EN ISO 10993-1	Biological evaluation of medical devices – Guidance on selection of tests
EN61157	Requirements for the declaration of the acoustic output of medical diagnostic ultrasonic equipment
AIUM/NEMA UD-3	Standard for Real Time Display of Thermal and Mechanical Acoustic Output Indices on Diagnostic Ultrasound Equipment

Acoustic Output

MyLab acoustic output complies with the requirements of FDA Track 3 guidance.

Peripherals Standard Requirements

When peripherals are connected to an ultrasound system, they become part of a medical system. Therefore they must comply with the below mentioned standards to maintain the overall system conformity.

Safety

Your device must:

meet the EN60601-1 OR in accordance with EN60601-1-1:
- **the device must meet the applicable safety standards for its category;**
- **the device must be powered through an isolation transformer designed for medical applications**

If your configuration is equipped with the cart, the isolation transformer requirement is fulfilled by powering the device through one of the cart's insulated plugs.

Electromagnetic Compatibility

Your peripheral device must:

- meet the EN55011 or 55022 emission limits, according to the environment where the system is used;
- meet the EN50082-1 or EN61000-6-1 immunity requirements