ESAOTE

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SAFETY AND STANDARDS

OPERATOR MANUAL

Doc # 29B05EN03

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.**

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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

CAUTIONS

Observe these precautions to prevent damage to your system

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

- 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 take 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.

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[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

Observe the following warnings for maximum safety

GS

Warnings

- 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 "Operator Manual CD" 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** (**A**s **L**ow **A**s **R**easonably **A**chievable) 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

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[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.

TI

Relates to temperature rise

The Thermal Index

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.

In combined modes (ex.: 2D+Doppler), the indices will show the highest value between the two modes.

The Output Display

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.

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[5] Includes Neonatal Head studies

[6] Only when TIB≠TIS

MAXIMUM OUTPUT

- MI < 1.9
- Ispta<720 mW/cm²

Maximum Acoustic Output

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.

DIRECT CONTROLS

- the Application
- the POWER

Controls Which Directly Affect the Intensity

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.

INDIRECT CONTROLS

- PRF
- Focal Point
- Frequency
- CFM Process
- Sample Volume

Controls Which Indirectly Affect the Intensity

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 located in the **MyLab** Operator Manual CD.

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:

$$I_d = I_w \exp(-0.23\ a\ f\ z)$$

- 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.

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[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])	$\dfrac{W_{01}}{\dfrac{210}{f_c}}$
Large Aperture (A_{aprt}> 1 cm^2) TIS (unscanned[9])	$\dfrac{\max\limits_{z>zbp}\left[\min\left(W_{.3}(z); I_{TA.3}(z)x1cm^2\right)\right]}{\dfrac{210}{f_c}}$
Small Aperture (A_{aprt}≤ 1 cm^2) TIS (unscanned[7])	$\dfrac{W_0}{\dfrac{210}{f_c}}$
Bone at Focus TIB (unscanned[7])	$\min\left\{\dfrac{\sqrt{W_{.3}(z_{B.3})I_{TA.3}(z_{B.3})}}{50}; \dfrac{w_{.3}(z_{B.3})}{4.4}\right\}$ 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	$\dfrac{W_0}{40D_{eq}}$
Mechanical Index (MI)	$\dfrac{p_{r.3}(z_{sp})}{\sqrt{f_c}}$ 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