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NEMA STANDARDS PUBLICATION

NEMA UD 3

STANDARD FOR REAL-TIME DISPLAY OF THERMAL AND MECHANICAL ACOUSTIC OUTPUT INDICES ON DIAGNOSTIC ULTRASOUND EQUIPMENT

REVISION 1

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NEMA Standards Publication UD 3-1998

Standard for Real-Time Display of Thermal and Mechanical Acoustic Output Indices on Diagnostic Ultrasound Equipment

Revision 1

Published by:

American Institute of Ultrasound in Medicine
National Electrical Manufacturers Association

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The NEMA Office is located at 1300 N. 17th Street, Suite 1847, Rosslyn, VA 22209.

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Preface

This is the first significant revision of the 1992 Standard for Real-Time Display of Thermal and Mechanical Acoustic Output Indices on Diagnostic Ultrasound Equipment, also known as the Output Display Standard, or ODS. The 1996 "Second Printing" of the ODS included typographical and editorial corrections.

The most significant change in this revision is in Section 4.1.1. Here, the display resolution for the Mechanical Index has been changed to increments of no more than 0.2 over the entire range of display. Other changes were made to make the document compatible with the revised *Acoustic Output Measurement Standard for Diagnostic Ultrasound Equipment*, designated AIUM AOMS-1998 and NEMA Standard UD 2-1998.

Special thanks for this revision go to the Output Standards Subcommittee, a joint AIUM/NEMA task group formed by the AIUM Technical Standards Committee. The current co-chairs are Gerald Harris and Charles Hottinger. The previous chair was Peter Lewin, and subcommittee members are John Abbott, Paul Carson, Peter Edmonds, Charles Grossman, Peter Lewin, Michael MacDonald, Ernest Madsen, Kurt Sandstrom, Mark Schafer, Kai Thomenius, Doug Worth, Junru Wu, James Zagzebski, and Marvin Ziskin.

Peter Lewin
Chair, AIUM Technical Standards Committee

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Foreword

Since June 1976, the American Institute of Ultrasound in Medicine (AIUM) and the National Electrical Manufacturers Association (NEMA) have worked cooperatively on regulatory issues of mutual interest. One category of cooperative activities has included the development of the voluntary standards, including *Safety Standard for Diagnostic Ultrasound Equipment, Acoustic Output Measurement Standard for Diagnostic Ultrasound Equipment,* and *Standard Methods for Measuring Performance of Pulse-Echo Ultrasound Imaging Equipment.*

The *Standard for Real-Time Display of Thermal and Mechanical Acoustic Output Indices on Diagnostic Ultrasound Equipment* continues this productive cooperation. But more importantly, this standard came about from the broad-based efforts of professional societies, manufacturers' organizations, manufacturers, governments, and consumer groups. User input has been considered in the development of this standards publication. The organizations involved in the standard's development are listed as follows, and all had a vital role in its development:

PROFESSIONAL ORGANIZATIONS

American Academy of Neurology
American Academy of Ophthalmology
American Association of Physicists in Medicine
American College of Cardiology
American College of Obstetricians & Gynecologists
American Medical Association
American College of Osteopathic Obstetrics & Gynecology
American College of Radiology
American Institute of Ultrasound in Medicine
American Registry of Diagnostic Medical Sonographers
American Society of Echocardiography
International Perinatal Doppler Society
National Council on Radiation Protection and Measurements
Society of Diagnostic Medical Sonographers
Society of Pediatric Echocardiography
Society of Perinatal Obstetricians
Society of Radiologists in Ultrasound
Society of Vascular Surgeons
Society of Vascular Technologists
World Federation for Ultrasound in Medicine & Biology

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MANUFACTURERS' ORGANIZATIONS

Electronic Industries Association Japan
National Electrical Manufacturers Association

MANUFACTURERS' GROUPS

Acoustic Imaging Corporation
Acuson
Advanced Technology Laboratories, Inc.
Diasonics, Inc.
Elscint, Ltd.
General Electric Medical Systems
Hewlett Packard Company
Hitachi Medical Systems America, Inc.
Interspec Incorporated
Medasonics, Inc.
Philips Ultrasound
Siemens Quantum, Inc.
Sonic Technologies
Toshiba America Medical Systems
Yokogawa Medical Systems

GOVERNMENTS

Bureau of Radiation and Medical Devices
Health and Welfare, Canada

Center for Devices and Radiological Health
Food and Drug Administration, USA

CONSUMER GROUPS

International Childbirth Education Association
National Women's Health Network

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Scope

This voluntary standard applies to diagnostic ultrasound **equipment** that is intended for use on humans, and is capable of exceeding a **thermal index** of 1.0, or a **mechanical index** of 1.0.

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Section 1
REFERENCED PUBLICATIONS

1.1 GENERAL

This Standards Publication is classified as an AIUM Standard and as a NEMA Standard, unless otherwise indicated, and establishes definitions and aspects of **indication/ display** and **operator** control features relevant to **acoustic output** levels of diagnostic ultrasound **equipment.**

1.2 REFERENCED PUBLICATIONS

In this publication, reference is made to the standard listed below. Copies are available from the indicated sources.

Acoustic Output Measurement Standard for Diagnostic Ultrasound Equipment

(AOMS-1998) American Institute of Ultrasound in Medicine (AIUM)
14750 Sweitzer Lane, Suite 100
Laurel, MD 20707-5906
(301) 498-4100
FAX: (301) 498-4450

(NEMA UD 2-1998) National Electrical Manufacturers Association (NEMA)
1300 N. 17th Street, Suite 1847
Rosslyn, VA 22209

Standards are available through Global Engineering Documents
1-800-854-7179
FAX: 303-397-2740

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Section 2
DEFINITIONS AND FORMULAE

For the purposes of this standard, the following terms are defined in specific language which either replaces or supplements, as appropriate, the corresponding definitions in the AIUM/NEMA *Acoustic Output Measurement Standard for Diagnostic Ultrasound Equipment*, referenced as NEMA Standard UD 2-1998 or as AIUM Standard AOMS-1998. Unless explicitly defined in this section, all other terms retain the definitions as described in the corresponding Section 1 of AIUM Standard AOMS-1998 or NEMA Standard UD 2-1998. For terms not covered in this document, consult the 1997 AIUM *Recommended Ultrasound Terminology.*

Where used in this standard, the terms defined below and the terms defined in Section 1 of the AIUM Standard AOMS-1998 and NEMA Standard UD 2-1998 are in bold letters.

2.1 GENERAL DEFINITIONS

acoustic output: The ultrasound emitted from the **transducer assembly** into the body. In normal usage, this ultrasound is directed into the body of the patient being examined. For most cases, this **acoustic output** is estimated by measurements in a water medium, with a **derating factor** included.

active aperture: The aperture defined by the **entrance beam dimensions** for **unscanned** cases or **entrance dimensions of the scan** for **scanned** cases defined in Section 1 of NEMA Standard UD 2-1998 or AIUM Standard AOMS-1998. In cases with nonuniform excitation of the transducer elements in contact with the skin, the area (in cm^2) of the **active aperture** at the beam entrance shall be taken as the maximum dimensions at which the rms excitation voltage, v_{arms} per unit transducer area exceeds –12 dB, relative to the spatial maximum v_{arms} per unit transducer area. This definition for nonuniform excitation is intended to cover phased arrays, linear, and curved arrays in both **scanned** and **unscanned** modes. This definition is also applicable to annular array-based mechanical probes in both **scanned** and **unscanned** modes.

beam axis: A straight line joining the points of maximum **pulse intensity integral** (PII), measured at several different distances in the far field. This line, calculated according to regression rules, is to be extended back to the **transducer assembly** surface.

bone thermal index (TIB): The **thermal index** for applications, such as fetal (second and third trimester) or neonatal cephalic (through the fontanelle), in which the ultrasound beam passes through soft tissue and a focal region is in the immediate vicinity of bone. (See Tables 2–1, 2–2, 2–3, and 2–4 for **thermal index** categories and formulae.)

center frequency (fc): $(f_1 + f_2)/2$, where f_1 and f_2 are frequencies defined in **bandwidth.**

center frequency for j^{th} transmit pattern ($f_c(j)$ in MHz): The **center frequency**, as defined in the NEMA Standard UD 2-1998 or in AIUM Standard AOMS-1998, for the j^{th} transmit pattern, except that the subject acoustic waveform is measured at the point of free-field spatial-maximum **pulse intensity integral** (PII), and the **transmit pattern** is operated at its **maximum drive voltage amplitude.**

cranial bone thermal index (TIC): The **thermal index** for applications, such as pediatric and adult cranial applications, in which the ultrasound beam passes through bone near the beam entrance into the body. (See Tables 2–1, 2–2, 2–3, and 2–4 for **thermal index** categories and formulae.)

combined mode (combined operating mode): Any combination of two or more of the **discrete operating modes** operating simultaneously.

default setting: A system control state which is pre-set by the manufacturer or **operator.**

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derating factor: A multiplicative factor applied to **acoustic output** parameters intended to account for ultrasonic attenuation of tissue between the source and a particular location in the tissue. In the calculation of all **mechanical** and **thermal indices** in this standard, the average ultrasonic attenuation is assumed to be 0.3 dB/cm–MHz along the **beam axis** in the body.

discrete operating mode: One of the following system operations: A-Mode, M-Mode, static B-Mode, real-time B-Mode, CW Doppler, pulsed Doppler, static flow mapping, real-time flow mapping, or any other single display format for presenting clinical information.

display accuracy: As used in this standard, is a manufacturer's specification of how closely the displayed index values correspond to actual index values, i.e., values computed using formulae and values of **acoustic output** quantities measured per methodology as specified in this standard.

drive voltage amplitude (v_a): The temporal-peak amplitude of an electrical drive **waveform** applied to a transducer or array of transducer elements.

entrance beam dimensions: The dimensions of the –12dB **beam width** where the beam enters the patient. For contact transducers, these dimensions can be taken as the dimensions of the radiating element, if so stated.

entrance dimensions of the scan: For autoscan systems, are the dimensions of the area of the surface through which the scanned ultrasound beams enter the patient, consisting of all points located within the –12 dB **beam width** of any beam passing through that surface during the scan.

equipment: The combination of a specific **ultrasound console** and a specific **transducer assembly**.

full software control of acoustic output: The means by which the **equipment** establishes values of the **acoustic output** quantities independent of direct **operator** control.

indication/display: The means by which the **operator** is informed of **equipment** operation or characteristics. These means may include either dynamic displays or on-**equipment** labeling.

indication/display increment: The discrete range step between adjacent displayed levels.

maximum drive voltage amplitude (v_{mj}): The largest **drive voltage amplitude** that is applied to any element in the j^{th} **transmit pattern** in any operating condition allowed in clinical use by a specific system including both hardware and software configurations.

mechanical index (MI) formula: The spatial-peak value of the **peak rarefactional pressure**, derated by 0.3 dB/cm–MHz at each point along the **beam axis**, divided by the square root of **the center frequency**, that is:

$$MI = \frac{p_{r.3}(z_{sp})}{\sqrt{f_c}} \qquad (2.1\text{–}1)$$

where:

$p_{r.3}$ (z_{sp}) is the **peak rarefactional pressure** (in MPa) derated by 0.3 dB/cm–MHz to the point on the **beam axis**, z_{sp}, **pulse intensity integral** ($PII_{.3}$) is maximum, and f_c is the **center frequency** (in MHz).

To make the **mechanical index** unitless, the righthand side of equation 2.1–1 is multiplied by [(1 MHz)$^{0.5}$/(1 MPa)].

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For **combined modes**, the **mechanical index** for the **discrete operating mode** with the largest derated **peak rarefactional pressure** is reported.

operator: The person who performs the ultrasound examination.

NOTE—The physician is always responsible for the ultrasound examination, but is not the only person who performs examinations.

operator control feature: The means by which the **operator** may modify the operation of the **equipment**.

peak rarefactional pressure (p_r in MPa): The temporal peak rarefactional pressure amplitude at a specified point.

prudent use statement: An affirmation of the principle advising the use of **acoustic output** levels and exposure times, as low as reasonably achievable (ALARA principle), while acquiring necessary clinical information.

pulse intensity integral (PII): The time integral of instantaneous intensity, for any specific point and pulse, integrated over the time in which the envelope of acoustic pressure or hydrophone signal for the specific pulse is non-zero. It is equal to the **energy fluence** per pulse. For a **transducer assembly** operating in a nonautoscanning mode, it is equal to the product of temporal average intensity and **pulse repetition period**.

scanned mode (auto-scanning): The electronic or mechanical steering of successive ultrasonic pulses or series of pulses, through at least two dimensions.

soft tissue thermal index (TIS): The **thermal index** related to soft tissues. (See Tables 2–1, 2–2, 2–3, and 2–4 for **thermal index** categories and formulae.)

system control feature: A means by which the **equipment** automatically modifies its operation.

thermal index (TI): A quantity related to calculated or estimated temperature rise under certain defined assumptions. The **thermal index** is the ratio of total acoustic **power** to the acoustic **power** required to raise tissue temperature by 1°C under defined assumptions. In the calculation of all **thermal indices** in this standard, the average ultrasonic attenuation is assumed to be 0.3 dB/cm–MHz along the **beam axis** in the body. (See Tables 2–1, 2–2, 2–3, and 2–4 for **thermal index** categories and formulae.)

transducer assembly: The transducer(s), the transducer housing (probe), any associated electronic circuitry and any liquids contained in the housing, and the integral cable which connects the transducer probe to an **ultrasound console**.

transmit pattern (j): The combination, denoted by the index j, of a specific set of transducer beam-forming characteristics (determined by the transmit aperture size, apodization shape, and relative timing/phase delay pattern across the aperture resulting in a specific focal length and direction), and an electrical drive **waveform** of specific fixed shape but variable amplitude.

unscanned mode (nonautoscanning): The emission of ultrasonic pulses in a single direction, where scanning in more than one direction would require moving the **transducer assembly** manually.

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Table 2–1
CROSS-REFERENCE—TI CATEGORIES TO TI FORMULAE

Thermal Index Category	Thermal Index Formulae	
	Scanned Mode	Unscanned Mode
TIS (Soft Tissue)	A. Soft Tissue at Surface	B. Large Aperture C. Small Aperture
TIB (Bone at Focus)	A. Soft Tissue at Surface	D. Bone at Focus
TIC (Bone at Surface)	E. Bone at Surface	

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Table 2–2
TI FORMULAE

Name	Formula
A. Soft Tissue at Surface TIS (scanned) TIB (scanned) (see Section A5.1.1 of this standard)	$TI = \frac{W_{01}}{\left(\frac{210}{f_c}\right)}$
B. Large Aperture ($A_{aprt} > 1\ cm^2$) TIS (unscanned) (see Section A5.1.2 of this standard)	$TI = \frac{\max\limits_{z > z_{bp}} [\min[W_{.3}(z),\ I_{TA.3}(z) \times 1\ cm^2]]}{\left(\frac{210}{f_c}\right)}$
C. Small Aperture ($A_{aprt} \leq 1\ cm^2$) TIS (unscanned) (see Section A5.1.3 of this standard)	$TI = \frac{W_0}{\left(\frac{210}{f_c}\right)}$
D. Bone at Focus TIB (unscanned) (see Section A5.1.4 of this standard)	$TI = \min\left[\frac{\sqrt{W_{.3}(z_{B.3}) I_{TA.3}(z_{B.3})}}{50}, \frac{W_{.3}(z_{B.3})}{4.4}\right]$ where $z_{B.3}$ is the depth that maximizes $W_{.3}(z)I_{TA.3}(z)$, or, equivalently, the depth of $I_{SPTAB.3}$
E. Bone at Surface TIC (see Section A5.1.5 of this standard)	$TI = \frac{W_0}{40 D_{eq}}$

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Table 2–3
DEFINITION OF SYMBOLS USED IN THERMAL INDEX FORMULAE

Symbol	Definition
A_{aprt} (cm^2)	Active aperture area
$d_{eq}(z)$ (cm) (See Section A5.1.4 of this standard)	Equivalent beam diameter $d_{eq}(z) = \sqrt{\frac{4W_{.3}(z)}{\pi I_{TA.3}(z)}}$
D_{eq} (cm) (See Section A5.1.5 of this standard)	Equivalent aperture diameter $D_{eq} = \sqrt{\frac{4}{p} A_{aprt}}$
f_c (MHz)	Center frequency
$I_{SPTAB.3}$ (mW/cm^2)	Equivalent to the spatial peak temporal average derated (0.6 dB/cm–MHz) intensity. (N.B.: 0.6 derating is used for notational simplicity in the TIB(unscanned) model. See Appendix A for derivation.)
$I_{TA.3}(z)$ (mW/cm^2)	Temporal average intensity derated to depth z
W_0 (mW)	Time average acoustic power at the source
W_{01} (mW)	Time average acoustic power at the source emitted from the central one centimeter of the active aperture
$W_{.3}(z)$ (mW)	Time average acoustic power derated to depth z
$\frac{W}{X}$ (mW/cm)	A symbol that denotes acoustic power per unit length in the scan direction, e.g., 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 for the TIS(unscanned) model) $z_{bp} = 1.5D_{eq}$
$z_{B.3}$ (cm)	Depth of the maximum temperature rise in the bone at focus model.

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Table 2–4
COMBINATION MODES*

TI categories	Combined TI
TIS small aperture ($A \leq 1\ cm^2$) TIC	Σ (TI values for all modes)
TIS large aperture ($A > 1\ cm^2$) TIB	Max [Σ (TI values for scanned modes), Σ (TI values for unscanned modes)]

*See Section A6.1 of this Standard for the method of combining results.

When multiple modes are used simultaneously, the TI contribution of each **discrete operating mode** is calculated separately and then combined to determine the TI value for the **combined mode**.

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Section 3
RATIONALE

3.1 CLINICAL PURPOSE

This standard specifies aspects of **indication/display** and **operator control features** relevant to **acoustic output** levels. These features are intended to provide information to clinical **operators** at the time of the patient examination such that exposure of the patient to ultrasound may be reasonably minimized, while diagnostic information and ease of use are maximized. In addition, the standard is also intended as a foundation for an **operator's** education program to be implemented by the medical community relevant to these issues. This information will assist the **operator** in making informed patient risk/benefit decisions.

3.2 REGULATORY PURPOSE

This standard provides a uniform approach in presenting **acoustic output** information by all manufacturers. The premise behind the standard is that ultrasound **acoustic output** levels should be used at a level that is as low as practical while providing adequate diagnostic information. In this way, this voluntary standard, in conjunction with an effective educational program, is intended to serve as one means for compliance with relevant requirements under the FDA 510(k) process. A regulatory guidance document describing the 510(k) clearance process for diagnostic ultrasound **equipment** can be obtained from the FDA.

3.2.1 Purpose of Voluntary Standards

In accordance with such common standards development practices as those recommended by the American National Standards Institute (ANSI), a voluntary standard "recommends to the manufacturer the information that should be provided with or on the product."

3.3 RATIONALE FOR CHOICE OF INDICATION/DISPLAY PARAMETER

The relationship of various **acoustic output** parameters (e.g., acoustic intensity, pressure, power, etc.) to biological endpoints is not well understood at the present time. Evidence to date indicates that thermal and cavitation mechanisms may be relevant for potential bioeffects.

3.3.1 Rationale for Thermal Indices

Soft tissue, cranial bone, and **bone thermal indices** are selected as values to be displayed as indicators of the thermal mechanism.

3.3.2 Rationale for Mechanical Index

A **mechanical index** is selected as the value to be displayed as an indicator related to mechanical effects, such as cavitation.

3.4 RATIONALE REGARDING DIVERSIFICATION OF EQUIPMENT TYPES

The introduction and use of new technologies, allowing further improvements in safety and effectiveness, are to be encouraged. Similarly, unnecessarily restrictive limitations on new options usable with existing **equipment** are to be minimized. This will allow useful diversification of types of ultrasound devices utilizing different technologies or for different applications.

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Section 4
INFORMATION TO BE PROVIDED TO OPERATORS

The **equipment** and its **operator's** instruction manual shall provide the following information regarding the **acoustic output** and **operator control feature** and **system control feature** relevant to **acoustic output.**

4.1 ON-EQUIPMENT ACOUSTIC OUTPUT INDICATION/DISPLAY

The **equipment** shall indicate to the **operator** a **thermal index** and a **mechanical index**, according to the specifications of Sections 4.1.2 and 4.1.3 of this standard.

4.1.1 Resolution

4.1.1.1 Thermal Index

The **indication/display** for each **thermal index** shall be at the choice of the manufacturer, but shall be in increments of no more than 0.2 for values of indices of 1.0 or less, and no more than 1.0 for values greater than 1.0.

4.1.1.2 Mechanical Index

The **indication/display** for the **mechanical index** shall be at the choice of the manufacturer, but shall be in increments of no more than 0.2 over the entire range of display.

4.1.2 Values of Indices to be Displayed

4.1.2.1 Equipment Not Requiring Display of Thermal Indices

If the diagnostic ultrasound **equipment** is not capable of exceeding either a **soft tissue thermal index** of 1.0 or a **bone thermal index** of 1.0, then it need not display any **thermal index.**

4.1.2.2 Minimum Value of Any Thermal Index to be Displayed

If the diagnostic ultrasound **equipment** is capable of exceeding a **thermal index** of 1.0, then the **thermal index** corresponding to the **operating condition** chosen by the **operator** shall be displayed when it equals or exceeds a value of 0.4.

4.1.2.3 Display of Both TIS and TIB

If the diagnostic ultrasound **equipment** is capable of exceeding a **bone thermal index** or **soft tissue thermal index** value of 1.0, then the system shall allow the **operator** to display both a **soft tissue thermal index (TIS)**, and a **bone thermal index (TIB)**, but the diagnostic ultrasound **equipment** need not be capable of displaying both indices simultaneously.

4.1.2.4 Equipment Not Requiring Display of the Mechanical Index

If the diagnostic ultrasound **equipment** is not capable of exceeding a **mechanical index** of 1.0, then it need not display values of the **mechanical index.**

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4.1.2.5 Minimum Value of Mechanical Index to be Displayed

If the diagnostic ultrasound **equipment** is capable of exceeding a **mechanical index** of 1.0, then the **mechanical index** corresponding to the **operating condition** chosen by the **operator** shall be displayed when it equals or exceeds a value of 0.4.

4.1.2.6 Display of TIC

If the diagnostic ultrasound **equipment** is intended solely for adult cephalic applications, then the **thermal index** display need only include the **cranial bone thermal index**.

4.1.3 Other Conditions on Display of Indices

4.1.3.1 Multi-Mode Equipment that is Capable of Real-Time (B-Mode) Imaging

For multi-mode diagnostic ultrasound **equipment** that is capable of real-time (B-mode) imaging, a **thermal index** need not be displayed in real-time (B-mode), and the **mechanical index** need not be displayed if any other mode(s) is (are) active.

The intention in this approach is to present the most relevant information in a compact format. The **thermal index** is unlikely to be high in real-time (B-mode) mode. For other modes, it is unnecessary to display the **mechanical index** since it typically does not differ by more than a factor of two from that for the real-time (B-mode) mode, with which the **operator** should be familiar.

4.1.3.2 Equipment that is not Capable of Real-Time (B-Mode) Imaging

For diagnostic ultrasound **equipment** that is not capable of real-time (B-mode) imaging, the diagnostic ultrasound **equipment** shall allow the **operator** to display both a **thermal index** and a **mechanical index**, but the diagnostic ultrasound **equipment** need not be capable of displaying both indices simultaneously.

4.1.3.3 Visibility of Indication/Display

The **indication/display** shall be clearly visible from the **operator's** position, shall clearly indicate the full name or abbreviation of the index (indices) displayed as given in Section 2.1, but may otherwise be in a format and at a location on the **equipment** of the manufacturer's choice.

4.2 INFORMATION REQUIRED IN OPERATOR'S MANUAL

The **operator's** instruction manual shall contain the information listed below in Sections 4.2.1—4.2.3 of this standard. This information shall be identified and provided in a separate section of the **operator's** instruction manual or in a separate manual devoted only to this information.

4.2.1 Meaning of Indices, Display Accuracy, and Precision

Descriptions of the meaning of **thermal** and **mechanical indices** and **display accuracy** and precision, as described in Section 6 of this standard, and of **acoustic output** and **indication/display**, including the contributions of **combined modes**, shall be included in the **operator's** instruction manual.

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4.2.2 Discussion of Operator Control Features

Descriptions of **operator control features** affecting displayed **thermal** and **mechanical indices** (e.g., description of **operator** controls which directly affect **thermal** and **mechanical indices**, description of controls which have only an indirect effect, specification of **default settings**) shall be included in the **operator's** instruction manual.

4.2.3 Prudent Use Statement

A **prudent use statement** shall be included in the **operator's** instruction manual.

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Section 5
DEFAULT SETTINGS

5.1 EQUIPMENT DESIGNS ALLOWING FOR FULL SOFTWARE CONTROL OF ACOUSTIC OUTPUT

For diagnostic ultrasound **equipment** in which the design allows **full software control of acoustic output**, the **equipment** shall switch to an appropriate **default setting** upon power up, entry of new patient ID data or change from a nonfetal to a fetal application. These **default setting** levels are established by the manufacturer, but may be reconfigured by the **operator**.

5.2 EQUIPMENT DESIGNS NOT ALLOWING FOR FULL SOFTWARE CONTROL OF ACOUSTIC OUTPUT

For diagnostic ultrasound **equipment** in which the design does not allow **full software control of acoustic output**, the **equipment** shall provide upon power up, entry of new patient ID data, or change from a nonfetal to a fetal application, a reminder to the **operator** to check (and reset or change, if appropriate) the **acoustic output** and index displayed.

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Section 6
MEASUREMENT METHODOLOGY FOR MECHANICAL AND THERMAL INDICES

6.1 GENERAL

The following measurement methodologies for determining the **mechanical index** and the various **thermal indices** referenced in this standard are based on methods described in *Acoustic Output Measurement Standard for Diagnostic Ultrasound Equipment*, referenced as NEMA Standard UD 2-1998 or AIUM Standard AOMS-1998. The basic equations employed in these measurements are listed in Section 2 of this standard and are described in Appendix A "Summary of the Thermal Indices Formulae" and Appendix B "Mechanical Index Rationale" of this standard. See Figure 6–1.

The measurement techniques described for determining the values of the various indices may be replaced by simpler approaches where conditions warrant. However, such simplifying assumptions may only be made for those conditions where they can be demonstrated to be equivalent to the methods of this standard.

6.2 INDEX MEASUREMENTS IN UNSCANNED MODES

6.2.1 Measurement of Center Frequency $f_c(j)$ in Unscanned Modes

6.2.1.1 Selection of Maximum Drive Voltage (Set $v_a = v_{mj}$)

For the subject **transmit pattern** (j), set the **drive voltage amplitude** (v_a) to the **maximum drive voltage amplitude** (v_{mj}), resulting in the maximum free-field **pulse intensity integral** ($PII(j,v_{mj})$), that is achievable by the **operator**.

6.2.1.2 Determination of the Beam Axis

The alignment and determination procedures described in NEMA Standard UD 2-1998 or AIUM Standard AOMS-1998, Sections 5.3.2 and 5.4.3, shall be performed.

6.2.1.3 Location of Maximum Pulse Intensity Integral (Maximum $PII(j,v_{mj})$ in Water)

The location of the maximum **pulse intensity integral** (maximum $PII(j,v_{mj})$ in water) shall be determined according to the procedure described in NEMA Standard UD 2-1998 or AIUM Standard AOMS-1998 Section 5.4.4; this location is denoted as z_{mjPII}.

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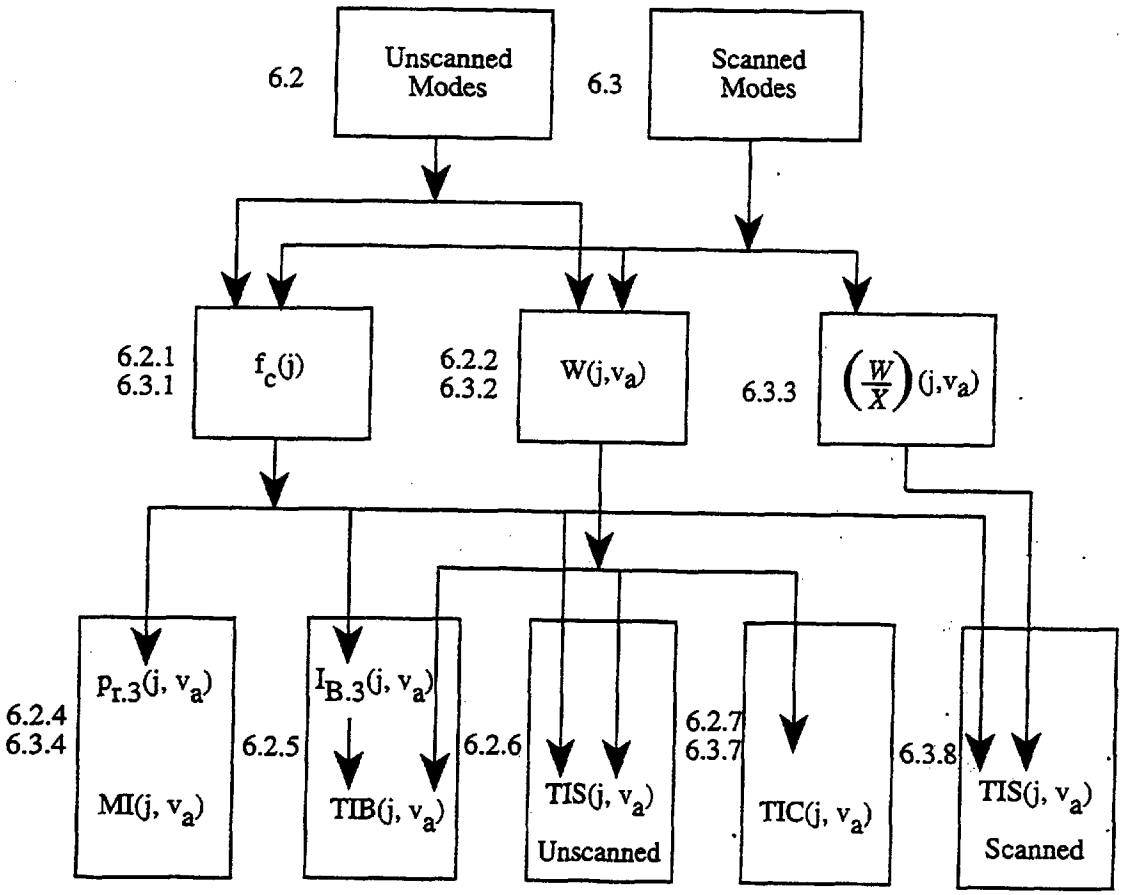


Figure 6–1
OUTLINE OF MEASUREMENT METHODOLOGY

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6.2.1.4 Verification of Maximum PII(j,v_{mj})

The location of the maximum **pulse intensity integral** (maximum PII(j,v_{mj}) in water), located at $z_{mjPII.}$, shall be verified according to the procedure described in NEMA-Standard UD 2-1998 or in AIUM Standard AOMS-1998, Section 5.4.5.

6.2.1.5 Measurement of Center Frequency f_c(j) at z_{mjPII}

The **center frequency** f_c(j) shall be measured using the procedure described in NEMA Standard UD 2-1998 or in AIUM Standard AOMS-1998, Section 5.4.9.2.

6.2.2 Measurement of Acoustic Power (W(j, v_a)) in Unscanned Modes

6.2.2.1 General Comments

The measurement method shall provide acoustic **power** W(j, v_a) measurements consistent with those of a calibrated radiation force balance measurement. The measurement method of acoustic **power** shall be traceable to NIST (National Institute of Standards and Technology, Washington, D.C.) or other comparable national standards laboratories.

Where acoustic **power** is determined using a radiation force balance, the radiation force balance shall be calibrated using a **reference source** transducer with acoustic **power** traceable to a national standards laboratory. Where acoustic **power** is determined using hydrophone planar scanning methods, the **working hydrophone** sensitivity shall be determined using a **reference source** transducer or **reference hydrophone** traceable to a national standards laboratory. The entire planar scanning system accuracy shall be verified using a **reference source** transducer for which the acoustic **power** is traceable to a national standards laboratory.

6.2.2.2 Radiation Force Balance Measurements of Acoustic Power

6.2.2.2.1 Calibrating the Radiation Force Balance System

The requirements of NEMA Standard UD 2-1998 or of AIUM Standard AOMS-1998, Sections 4.4.1—4.4.5, shall apply over the range of expected acoustic **powers**.

6.2.2.2.1.1 Verification Procedure

The intent of this section is to verify that the radiation force balance (RFB) **acoustic output power** (W_m) is linearly proportional to the input acoustic **power** (W_r), over the range of expected device **acoustic outputs**.

Couple the **reference source** to the radiation force balance and drive the **reference source** at its calibrated **acoustic output,** according to the directions of NEMA Standard UD 2-1998 or in AIUM Standard AOMS-1998, Section 4.4.3. The **reference source acoustic output power** (W_{rmax}) should be equal to or greater than the maximum total acoustic **power** anticipated in future diagnostic ultrasound **equipment** characterization measurements. For each calibration frequency, adjust the **reference source** drive level to decrease the source **acoustic output power** in approximately 0.1 Wrmax steps from W_{rmax} to 0.1 W_{rmax}. For each step (i), measure W_r(i) and record the **drive voltage amplitude** v_a(i).

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6.2.2.2.1.2 Linearity Requirements

The best-fit straight line and the percent error E(i) of each measured $W_r(i)$ from the best-fit straight line shall be calculated for the data set $[W_r(i), v_a^2(i)]$ using the method of least squares. The force balance response shall be considered linear if abs [E(i)] = 20% for all E(i) at each of the calibration frequencies. Otherwise, the **acoustic output** response is considered nonlinear.

If the **acoustic output** is found to be nonlinear, then the radiation force balance should be either repaired, adjusted, or recalibrated or the **reference source** should be recalibrated at the national standards laboratory before the radiation force balance is used to characterize diagnostic ultrasound **equipment**. For the case where response is linear for low **drive voltage amplitude** levels but deviates from linear response at high **drive voltage amplitude** levels (saturation effects), a linear response function may be derived by deleting the higher **drive voltage amplitude** level points, one at a time, and recalculating the best-fit line until the **acoustic output** linearity requirements are met.

6.2.2.2.2 Radiation Force Balance Methods

While making radiation force balance (RFB) measurements, care should be taken to ensure that the radiation force balance target intercepts the total **acoustic output power** emitted by **the source transducer**. The **source transducer** and RFB target should be positioned so that the effective **beam cross-sectional area's** dimensions are less than the corresponding RFB target dimensions, and the beam is centered on the RFB target. Also, tests should be performed to detect nonlinear response due to the saturation of the water medium.

6.2.2.2.2.1 Aperture Considerations

a. Aperture dimensions less than or equal to 75% of the radiation force balance target dimensions:

   For transmit aperture dimensions less than or equal to 75% of the corresponding radiation force balance target dimensions, the transducer-target separation distance shall be the smaller of 1 cm or one-half the distance to the focal point, where the focal point is defined as the position of maximum PII on the **beam axis** with the diagnostic ultrasound **equipment** operating at the **maximum drive voltage amplitude** (v_{mj}), for the **transmit pattern** (j) being tested, and such that the **acoustic output** linearity requirements of Section 6.2.2.2.2.2b of this standard are met.

b. Aperture dimensions greater than 75% of the radiation force balance target dimensions:

   For transmit aperture greater than 75% of the corresponding radiation force balance target dimensions, the transducer-target separation distance shall be selected so that the **beam cross-sectional area's** major and minor dimensions are less than 75% of the corresponding radiation force balance target dimensions, and such that the **acoustic output** linearity requirements of Section 6.2.2.2.2.2b of this standard are met.

   Absorbing targets with dimensions on the order of 3/4" to 1" wide are recommended. This size permits small transducer-target distances. Targets with larger dimensions often cause unacceptably noisy measurements. For large aperture transducers, increase the transducer target distance or use a collimator (see references in NEMA Standard UD 2-1998 or in AIUM Standard AOMS-1998, Section 3.6.1) to meet the requirements specified in Section 6.2.2.2.2.2b of this standard.

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6.2.2.2.2.2 Focused Beam Power Measurement Linearity Test

a. Measurement procedure:

For each discrete **transmit pattern** (j), the acoustic **power** data shall be measured over the range of **drive voltage amplitudes** (v_a) that can be applied to the **transmit pattern**. A constant **pulse repetition frequency** shall be used for the entire set of measurements. Data shall be taken for at least 10 equally spaced **drive voltage amplitude** squared intervals over the entire voltage range, and acoustic **power** vs. v_a^2 shall be plotted to determine **acoustic output** linearity per the criteria outlined in Section 6.2.2.2.2.2b of this standard.

b. Linearity requirements:

The best-fit straight line and the percent error E(i) of each measured $W_r(i)$ from the best-fit straight line shall be calculated for the data set $[W_r(i), v_a^2(i)]$ using the method of least squares. The radiation force balance response shall be considered linear if abs [E(i)] = 20% for all E(i). Otherwise, the **acoustic output** response is considered nonlinear.

For the case where **acoustic output** response is linear for low **drive voltage amplitude** levels, but deviates from linear response at high **drive voltage amplitude** levels (saturation effects), a linear response function may be derived by deleting the higher **drive voltage amplitude** level points, one at a time, and recalculating the best-fit line until the **acoustic output** linearity requirements are met.

c. Determining the causes of nonlinearity:

The following techniques may be used to determine the cause(s) of **nonlinear acoustic output** response:

1. If possible, defocus the beam, leaving all other **transmit pattern** parameters unchanged, and repeat the above linearity test.

2. Decrease the transducer-target distance and repeat the linearity test. Increase the radiation force balance target diameter, if necessary, to keep the beam dimensions < 3/4 of the corresponding target dimensions.

3. Calculate the **nonlinearity propagation parameter** σ_m (as defined in NEMA Standard UD 2-1998, Section 2 and Appendix B or in AIUM Standard AOMS-1998, Section 1 and Appendix B). If $\sigma_m > 0.5$, then it is likely that nonlinear loss may have occurred.

If the **nonlinearity propagation parameter** $\sigma_m > 0.5$ and defocusing and/or decreasing transducer-target distance results in linear response, then nonlinearity is caused by the acoustic **power** measurement setup as described in Section 6.2.2.2.2.2d of this standard.

If **nonlinearity propagation parameter** $\sigma_m < 0.5$ and nonlinearity persists after the beam is defocused and/or the target distance is decreased, then given linear response with a **reference source**, nonlinearity is most likely caused by the system/transducer combination.

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d. Nonlinear response due to acoustic power measurement setup:

If it is determined, according to Section 6.2.2.2.2.2c of this standard, that **acoustic output** nonlinear response is due to the acoustic **power** measurement **equipment**, then either:

1. The acoustic **power** measurement setup shall be adjusted and the radiation force balance calibration and linearity shall be rechecked per the procedures in Sections 6.2.2.2.1 and 6.2.2.2.2.2 of this standard; or

2. A linear response correction function shall be derived by extrapolating from the lower **drive voltage amplitude** data points per the procedure recommended in Section 6.2.2.2.2.2b of this standard. This function shall be used to generate reference data in determining acoustic **power** at higher **drive voltage amplitudes**.

e. Nonlinear response due to the system/transducer combination:

If it is determined, according to Section 6.2.2.2.2.2c of this standard, that the **acoustic output** nonlinear response is due to nonlinearities resulting from the system/transducer combination and/or duty cycle or voltage limitations, then the system acoustic **power** calculation routine should model the **acoustic output** nonlinear effects, according to the procedure recommended in Section 6.2.2.2.2.2b of this standard.

6.2.3 (Reserved for Future Use)

6.2.4 Measurement of Mechanical Index MI(j, v_a) for Unscanned Modes

For the rationale of the **mechanical index**, see Appendix B of this standard.

6.2.4.1 Determination of the Beam Axis

With the **drive voltage amplitude** maximized such that $v_a = v_{mj}$, repeat, if necessary, the alignment procedure specified in Section 6.2.1.2 of this standard. The spatial-peak **pulse intensity integral** ($PII(j,v_{mj})$) shall be verified to be maximized locally in all coordinate directions.

6.2.4.2 Location of the Spatial Maximum Pulse Intensity Integral $PII_{.3}(j,v_{mj})$

With the **drive voltage amplitude** maximized, such that $v_a = v_{mj}$ and the **center frequency** $f_c(j)$ measured as in Section 6.2.1 of this standard, the spatial maximum of $PII_{.3}(j,v_{mj})$ shall be determined by equating it to the maximum with respect to z of the following expression:

$$\text{spatial maximum } PII_{.3}(j,v_{mj}) = \max \text{ on } z \text{ of } \left(PII(j,v_{mj},z)\, 10^{-0.03 f_c(j) z}\right) \left(\frac{mJ}{cm^2}\right) \qquad (6.2.4.2\text{–}1)$$

where z is the (one way) distance in cm along the **beam axis** from the **transducer assembly** to the measurement point. The location of the maximum derated **pulse intensity integral** (spatial maximum $PII_{.3}(j,v_{mj})$) shall be determined according to the procedure described in NEMA Standard UD-2 1998 or AIUM Standard AOMS-1998, Section 5.4.12; this location is denoted as $z_{mjPII.3}$.

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An equivalent expression for the spatial maximum $PII_{.3}(j,v_{mj})$ is given by the following:

$$\text{spatial maximum } PII_{.3}(j,v_{mj}) = PII(j,v_{mj},z_{mjPII.3})10^{-0.03f_C(j)z_{mjPII.3}} \left(\frac{mJ}{cm^2}\right) \qquad (6.2.4.2\text{–}2)$$

6.2.4.3 Verification of $z_{mjPII.3}$, Location of Spatial Maximum $PII_{.3}(j,v_{mj})$ and $p_{r.3}(j,v_{mj})$

With the **drive voltage amplitude** maximized such that $v_a = v_{mj}$, the location, denoted by $z_{mjPII.3}$, of the spatial maximum derated **pulse intensity integral** (spatial-maximum $PII_{.3}(j,v_{mj})$) shall be verified according to the procedure described in NEMA Standard UD 2-1998 or in AIUM Standard AOMS-1998, Section 5.4.13.

6.2.4.4 Calculation of $p_{r.3}(j,v_a)$ at $z_{mjPII.3}$

The temporal maximum $p_{r.3}(j,v_a)$ at $z_{mjPII.3}$ shall be calculated by:

$$p_{r.3}(j,v_a) = \frac{V_r\, 10^{-0.015f_C(j)z_{mjPII.3}}}{M_L(f_C(j))} \text{ (MPa)} \qquad (6.2.4.4\text{–}1)$$

where V_r is the magnitude of the hydrophone's output voltage (in volts) corresponding to the temporal **peak rarefactional pressure** $p_r(j,v_a)$ at $z_{mjPII.3}$ (the point of spatial maximum $PII_{.3}(j,va)$), and the hydrophone's **end-of-cable loaded sensitivity** $M_L(f_c(j))$, is expressed in V/MPa.

6.2.4.5 Calculation of $MI(j,v_a)$ at $z_{mjPII.3}$

The **mechanical index** $MI(j,v_a)$ for the **transmit pattern** (j) and **drive voltage amplitude** (v_a) under test shall be calculated by:

$$MI(j,v_a) = \frac{p_{r.3}(j,v_a)}{\sqrt{f_C(j)}} \text{ (unitless)} \qquad (6.2.4.5\text{–}1)$$

where the temporal maximum $p_{r.3}(j, v_a)$ (expressed in MPa) shall be determined, as in Section 6.2.4.4 of this standard. At $z_{mjPII.3}$, the point of spatial maximum $PII_{.3}(j,v_{mj})$ and fc(j) is expressed in MHz.

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Since, by definition in Equation 6.2.4.4–1 of this standard, it is assumed that the location of spatial maximum $PII_{.3}(j,v_a)$ above does not change significantly with **drive voltage amplitude** v_a, Equation 6.2.4.5–1 of this standard is equivalent to:

$$MI(j,v_a) = \frac{p_r(j,v_a,z_{mjPII.3})10^{-0.015f_c(j)z_{mjPII.3}}}{\sqrt{f_c(j)}} \text{ (unitless)} \qquad (6.2.4.5\text{–}2)$$

6.2.5 Measurement of Bone Thermal Index TIB(j, v_a) for Unscanned Modes

For the rationale of the **bone thermal index**, see Appendix A of this standard. As discussed in the rationale for determination of **bone thermal index**, the assumed **derating factor** in the homogeneous tissue model is 0.3 dB/cm–MHz. However, in the methodology described in this section, the location of TIB (j,v_a) occurs at the point where the **pulse intensity integral** with an attenuation factor of 0.6 dB/cm–MHz is found, that is, at $PII.6(j,v_{mj})$ which is denoted as $PII_{B.3}(j,v_{mj})$, and this location is denoted as $z_{mjPIIB.3}$.

6.2.5.1 Determination of the Beam Axis

With the **drive voltage amplitude** maximized such that $v_a = v_{mj}$, repeat, if necessary, the alignment procedure accomplished in Section 6.2.1.2 of this standard. The spatial-peak **pulse intensity integral** $(PII(j,v_{mj}))$ shall be verified to be maximized locally in all coordinate directions.

6.2.5.2 Determination of the Location of $PII_{B.3}(j,v_{mj})$

With the **drive voltage amplitude** maximized such that $v_a = v_{mj}$, the **center frequency** $f_c(j)$, as outlined in Section 6.2.1 of this standard, shall be measured, and the spatial maximum of **the pulse intensity integral** (the spatial maximum of $PII_{B.3}(j,v_{mj})$) shall be determined by equating it to the maximum with respect to z of the following expression:

$$\text{spatial maximum } PII_{B.3}(j,v_{mj}) = \max \text{ on z of } (PII(j,v_{mj},z)10^{-2(0.03f_c(j)z)}) \left(\frac{mJ}{cm^2}\right) \qquad (6.2.5.2\text{–}1)$$

where z is the (one way) distance in cm along the **beam axis** from the **transducer assembly** to the measurement point. The location of the maximum derated **pulse intensity integral** (spatial maximum $PII_{B.3}(j,v_{mj})$) shall be determined according to the procedure described in NEMA Standard UD 2-1998 or AIUM Standard AOMS-1998, Section 5.4.12; this location is denoted as $z_{mjPIIB.3}$.

An equivalent expression for the spatial maximum $PII_{B.3}(j,v_{mj})$ is given by the following:

$$\text{spatial maximum } PII_{B.3}(j,v_{mj}) = PII(j,v_{mj},z_{mjPIIB.3})10^{-2(0.03f_c(j)z}mjPIIB.3) \left(\frac{mJ}{cm^2}\right) \qquad (6.2.5.2\text{–}2)$$

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6.2.5.3 Verification of $z_{mjPIIB.3}$, the Location of the Spatial Maximum $PII_{B.3}(j,v_{mj})$

With the **drive voltage amplitude** maximized such that $v_a = v_{mj}$, the location, denoted by $z_{mjPIIB.3}$, of the spatial maximum derated **pulse intensity integral** (spatial maximum $PII_{B.3}(j,v_{mj})$) shall be verified according to the procedure described in NEMA Standard UD 2-1998 or in AIUM Standard AOMS-1998, Section 5.4.13.

6.2.5.4 Calculation of $I_{SPTAB.3}(j,v_a)$ at $z_{mjPIIB.3}$

The **spatial-peak temporal-average intensity**, given by $I_{SPTAB.3}(j,v_a)$, at the location $z_{mjPIIB.3}$, shall be calculated by:

$$I_{SPTAB.3}(j,v_a) = PII_{B.3}(j,v_a)\ PRF\left(\frac{mW}{cm^2}\right) \qquad (6.2.5.4\text{–}1)$$

where $PII_{B.3}(j,v_a)$ (the maximum **pulse intensity integral**) is determined as in Section 6.2.5.2 of this standard, and where PRF is the **pulse repetition frequency**.

Equivalently, this is expressed as:

$$I_{SPTAB.3}(j,v_a) = I_{TA}(j,v_a,z_{mjPIIB.3})10^{-2(0.03f_{C(j)}z_{mjPIIB.3})}\left(\frac{mW}{cm^2}\right) \qquad (6.2.5.4\text{–}2)$$

where $I_{TA}(j,v_a,z_{mjPIIB.3})$ is the **temporal average intensity** for the **transmit pattern** (j), with **drive voltage amplitude** v_a, measured at location $z_{mjPIIB.3}$, as defined in Section 6.2.5.2 of this standard.

6.2.5.5 Calculation of $TIB(j,v_a)$ at $z_{mjPIIB.3}$

The **bone thermal index** $TIB(j,v_a)$ at $z_{mjPIIB.3}$, for cases where the insonified bone is near the focus, is calculated as the following:

$$TIB(j,v_a) = \min\left(\frac{\sqrt{W(j,v_a)I_{SPTAB.3}(j,v_a)}}{50}; \frac{W_{.3}(j,v_a,z_{mjPIIB.3})}{4.4}\right) \text{(unitless)} \qquad (6.2.5.5\text{–}1)$$

where $W(j,v_a)$ in mW is determined as in Section 6.2.2 of this standard, and $I_{SPTAB.3}(j,v_a)$ in $\frac{mW}{cm^2}$ is determined as in Section 6.2.5.4 of this standard.

Since it is assumed in Equation 6.2.5.5–1 of this standard that the location of the spatial maximum $PII_{B.3}(j,v_a)$ does not change significantly with **drive voltage amplitude** v_a, the first min. term on the right hand side can be rewritten and then Equation 6.2.5.5–1 of this standard is equivalent to:

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$$TIB(j,v_a)=\min\left(\frac{\sqrt{W(j,v_a)I_{TA}(j,v_a,z_{mjPIIB.3})}}{50}10-0.03f_c(j)z_{mjPIIB.3}\,;\frac{W_{.3}(j,v_a,z_{mjPIIB.3})}{4.4}\right) \quad (6.2.5.5\text{–}2)$$

6.2.6 Measurement of Soft Tissue Thermal Index (TIS(j, v_a)) for Unscanned Modes

For the rationale of the **soft tissue thermal index**, see Appendix A of this standard.

6.2.6.1 Selection of Maximum Drive Voltage Amplitude

For the subject **transmit pattern** (j), if necessary, reset the **drive voltage amplitude** (v_a) to the **maximum drive voltage amplitude** (v_{mj}), following the procedure in Section 6.2.1.1 of this standard.

6.2.6.2 Measurement of Active Aperture at Beam Entrance

The area of the **active aperture** for **transmit pattern** (j) at the beam entrance is denoted as $A_{aprt}(j)$. If the **active aperture** satisfies the condition

$$A_{aprt}(j) = 1\ cm^2 \quad (6.2.6.2\text{–}1)$$

then $TIS(j,v_a)$ shall be calculated following the procedures described beginning at Section 6.2.6.20 of this standard. Otherwise, $TIS(j,v_a)$ shall be calculated according to the procedures immediately following.

6.2.6.3 – 6.2.6.9 (Reserved for Future Use)

6.2.6.10 Determination of the Beam Axis for $A_{aprt}(j) > 1\ cm^2$

If necessary, the alignment and determination procedures described in NEMA Standard UD 2-1998 or in AIUM Standard AOMS-1998, Sections 5.3.2 and 5.4.3, shall be repeated.

6.2.6.11 Determination of the Break Point Depth z_{bp}

The break point depth z_{bp} shall be calculated as:

$$z_{bp} = 1.5\sqrt{\frac{4}{\pi}A_{aprt}(j)} = 1.69\sqrt{A_{aprt}(j)}\ (cm) \quad (6.2.6.11\text{–}1)$$

6.2.6.12 Calculation of the Total Acoustic Power $W(j,v_{mj})$

Following the procedures in Section 6.2.2 of this standard, measure $W(j,v_{mj})$, the total acoustic **power** for the **transmit pattern** (j) under test, at the corresponding maximum **drive voltage amplitude** (v_{mj}).

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6.2.6.13 Determination of z_{1j}

The depth z_{1j} shall be measured as the depth at which the following expression is maximized over z where $z \geq z_{bp}$:

z_{1j} = z where $z \geq z_{bp}$ and where the minimum of $\{W_{.3}(j,v_{mj},z)$; $I_{TA.3}(j,v_{mj},z) \times 1cm^2\}$ is maximized (cm) where $W_{.3}(j,v_{mj},z)$ is in mW and $I_{TA.3}(j,v_{mj},z)$ is in $\frac{mW}{cm^2}$. (6.2.6.13-1)

6.2.6.14 Determination of $TIS(j,v_a)$ for $A_{aprt}(j) > 1\ cm^2$

$TIS(j,v_a)$ shall be calculated as:

$$TIS(j,v_a) = \frac{\max_{z>z_{bp}} [\min[W_{.3}(j,v_a,z_{1j}) ; I_{TA.3}(j,v_a,z_{1j}) \times 1cm^2]]}{\left(\frac{210}{f_c(j)}\right)} \text{(unitless)}$$

where $W_{.3}(j,v_a,z_{1j})$ is in mW, $I_{TA.3}(j,v_a,z_{1j})$ is in $\frac{mW}{cm^2}$, and $f_c(j)$ is in MHz.

6.2.6.15 – 6.2.6.19 (Reserved for Future Use)

6.2.6.20 Calculation of $TIS(j,v_a)$ for $A_{aprt}(j) = 1\ cm^2$

If the **active aperture**, as defined in Section 6.2.6.2 of this standard, satisfies the following condition:

$$A_{aprt}(j) = 1\ cm^2 \quad (6.2.6.20\text{–}1)$$

then $TIS(j,v_a)$ is calculated according to the following expression:

$$TIS(j,v_a) = \frac{W(j,v_a)}{\left(\frac{210}{f_c(j)}\right)} \text{(unitless)} \quad (6.2.6.20\text{–}2)$$

where $W(j,v_a)$ is in mW and $f_c(j)$ is in MHz.

6.2.7 Measurement of Cranial Bone Thermal Index $TIC(j,v_a)$ for Unscanned Modes

For the rationale of the **cranial bone thermal index**, see Appendix A of this standard.

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6.2.7.1 Calculation of TIC(j,v_a) for Unscanned Mode

For the **transmit pattern** (j), with **drive voltage amplitude** v_a, the **cranial bone thermal index** shall be estimated as:

$$TIC(j,v_a) = \frac{W(j,v_a)}{40\sqrt{\frac{4}{\pi}A_{aprt}(j)}} = \frac{W(j,v_a)}{45.1\sqrt{A_{aprt}(j)}} \text{ (unitless)} \qquad (6.2.7.1\text{–}1)$$

where $W(j,v_a)$ is the acoustic **power** (in mW), as measured in Section 6.2.2 of this standard, and $A_{aprt}(j)$ is the area (in cm^2) of the **active aperture** at the beam entrance for **transmit pattern** (j).

6.2.7.1.1 Estimation of $A_{aprt}(j)$ for Nonuniform Excitation of the Transducer Elements in Contact with the Skin

In cases with nonuniform excitation of the transducer elements in contact with the skin, $A_{aprt}(j)$, the area (in cm^2) of the **active aperture** at the beam entrance for **transmit pattern** (j), shall be taken as the maximum dimensions at which the rms excitation voltage, v_{arms} per unit transducer area, exceeds –12 dB of the spatial maximum v_{arms} per unit transducer area.

The rationale for the choice of –12 dB in the definition of $A_{aprt}(j)$ relates to the amount of acoustic **power** emitted by the transducer segments within the **active aperture**. With typical apodization functions (e.g., Hamming, Hanning, or Blackman) which may be used to create the nonuniform excitation, 98–99% of the acoustic **power** is emitted from the A_{aprt} aperture when defined with the –12 dB limit. Use of a definition based on –6 dB would cover the aperture area, which emits only 91–92% of the total acoustic **power**. Furthermore, a –12 dB level is desirable for defining the beam area because **spatial-average temporal-average intensities** based on this level have been shown to give approximately the same heating at the center of the beam for relatively diverse beam profiles, such as cylindrical, sinc, $J_1(x)/x$, and Gaussian functions.

6.3 INDEX MEASUREMENTS IN SCANNED MODES

The information in this section primarily deals with the exceptions that must be made for **scanned** modes from the procedures in Section 6.2 of this standard developed for **unscanned** modes. Further exceptions are Section 6.3.3 of this standard (concerning the acoustic **power** per unit length, $(\frac{W}{X})$, and Section 6.3.8 of this standard (dealing exclusively with TIS for **scanned** modes), which have no equivalents in Section 6.2 of this standard and deal exclusively with methods which do not apply to **unscanned** modes.

6.3.1 Measurement of Center Frequency $f_c(j)$ for Scanned Modes

The procedures in Section 6.2.1 of this standard shall be performed, except that in a combination **scanned** mode with more than one type of **transmit pattern** (j) employed during the scan period, the **center frequency** fc(j) shall be considered separately for different **transmit patterns** as appropriate in calculating the index of interest.

6.3.2 Measurement of Acoustic Power ($W(j,v_a)$) in Scanned Modes

The procedures in Section 6.2.2 of this standard shall be performed, except as follows:

a. In a combination **scanned** mode with more than one type of **transmit pattern** (j) employed during the scan period, the acoustic **power** shall be considered separately for different **transmit patterns**, when necessary to permit accurate measurement of acoustic **power** and appropriate calculation of the indices of interest.

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b. When performing these measurements with the beam scan arrested (when possible), the measured **acoustic output power** shall be corrected to compensate for any beam-former related output variability, dependent on beam scan angle and/or linear position. Hydrophone measurements of acoustic **power** shall be performed only with the beam scan arrested.

   In phased arrays, **acoustic output power** is often increased for non-normal scan angles because of decreased element (reception) sensitivity off axis.

c. When performing these measurements with the beam scan operating, the radiation force balance target and source shall be positioned such that the effective **beam cross-sectional area** intercepts the target over the entire extent of the beam. For angularly scanning sources, the measured output shall be corrected to compensate for any radiation force balance directivity if the maximum beam angle perpendicular to the target plane exceeds 10°.

   The measured radiation force is proportional to the cosine of the half angle of the sector, the angle that the direction of wave propagation deviates from the direction for which the radiation force balance is calibrated. At a 10° half angle, the maximum acoustic **power** error is 1.5%.

6.3.3 Measurement of Acoustic Power per Unit Length $\frac{W}{X}(j,v_a)$ in Scanned Modes

The acoustic **power** transmitted through the 1 cm linear length of the active array which transmits the most acoustic power shall be measured.

The following sections describe windowing techniques using a 1 cm wide slit absorber, a 1 cm wide radiation force balance target, or electronic masking techniques.

6.3.3.1 Creating a 1 cm Azimuthal Wide Window Using a Mask of Absorbing Material or a 1 cm Wide Radiation Force Balance Target

When an absorbing mask or radiation force balance target is used to limit the azimuthal (image plane) aperture, its geometry and composition shall be such as to detect all forward emissions from a 1 cm wide strip immediately in front of the scanhead and not to detect emissions from outside that 1 cm wide strip within the requirements of Section 6.3.3 of this standard.

The two techniques in this Section have somewhat different sources of error. Agreement of the two methods of defining the apertures should give reasonable confidence that the aperture is defined accurately. Use of an absorbing mask or limited width radiation force balance absorber to limit detection to a 1 cm linear length at the front surface of the active scan aperture is recommended for mechanical sector probes, or third party testing of all probes.

6.3.3.1.1 One cm Aperture in a Mask

When a mask is used, its geometry and composition shall be such as to eliminate transmitted acoustic **power**, except that emitted by the designated 1 cm length of the active array, to allow passage of all forward emissions from that 1 cm length and to agree with the accuracy and other requirements of Section 6.3.3.3 of this standard.

The scanhead front surface shall be coplanar with the mask surfaces, as illustrated in Figure 6–2. This requirement maintains consistency with Section 6.3.3.1.2 of this standard. The ultrasonic attenuation of the mask shall be at least 30 dB and its window's inside walls shall be lined with a material of at least 90% reflectance to prevent loss by the walls. The length of the slit shall be at least twice the elevation dimension of the transducer under test.

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As a check of these two requirements, acoustic **power** measurements should be made with two mask thicknesses. The measurements should be made in a scanning mode on each scanhead/system under measurement, and should agree within 10%.

Figure 6–2 is a sketch of a suggested geometry. A material with a maximum attenuation coefficient and minimum impedance mismatch with water is recommended. Materials are available commercially, which are well matched to water (reflection coefficient $\leq$ –30 dB) and have a loss in the range of 45 dB/cm at 3.5 MHz. Additional attenuation can be provided by sandwiching a stainless steel, closed pore foam or other high or low impedance reflector between two layers of the ultrasonic attenuating material.

For measurement of the acoustic **power** per unit length, the mask slit should be aligned with respect to the transducer under test and its imaging plane as illustrated in Figure 6–3. With mechanical sector scanners and curvilinear arrays, lateral positioning is critical. Scanhead probe holders and jigs will be helpful in this regard. It is anticipated that **beam axis** alignment within ± 5° of the normal to the mask plane and target plane and scan plane alignment within ± 5° of the normal to the sides of the slit are sufficient for the purposes of this test (see Figure 6–3).

6.3.3.1.2 One cm Wide Radiation Force Balance Target

As an alternative to the use of an aperture-limiting mask, the measurement of the acoustic **power** per unit length may be made using a 1 cm wide radiation force target. When the 1 cm wide radiation force balance target is used, it must be placed immediately in front of the scanhead, and its geometry and composition shall be such that it detects all and only the acoustic emissions from a 1 cm wide strip of the scanhead.

To meet the accuracy requirements of Section 6.3.3.3 and the linearity requirements of Section 6.2.2.3.2.2 of this standard, the target to transducer distance should be less than 10λ [$\lambda = 1.5/f_c$ where f_c is expressed in MHz] or 3 mm, whichever is greater.

As a check of target performance, acoustic **power** measurements should be made with two target thicknesses. The measurements should be made in a scanning mode on each scanhead/system under measurement, and should agree within 10%.

To minimize measurement errors due to reverberations, caution must be used to ensure that reflected acoustic energy does not reflect back onto the target. Further, the orientation of the target's long axis should remain perpendicular to the scan plane, as illustrated in Figure 6–4.

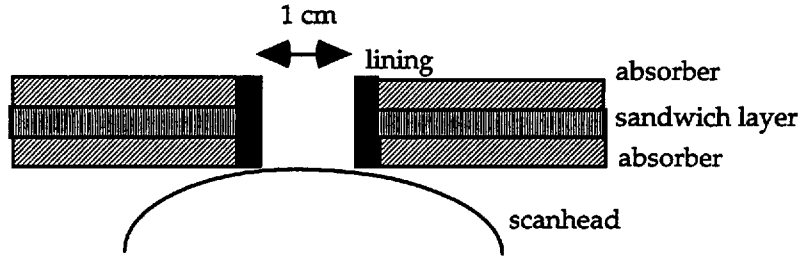


Figure 6–2
SUGGESTED 1 CM WIDE APERTURE MASK

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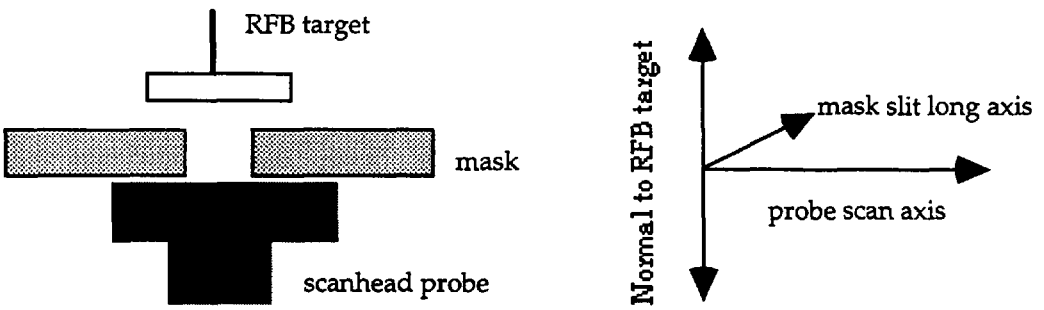


Figure 6–3
SUGGESTED ORIENTATION OF PROBE, MASK SLIT, AND RFB TARGET

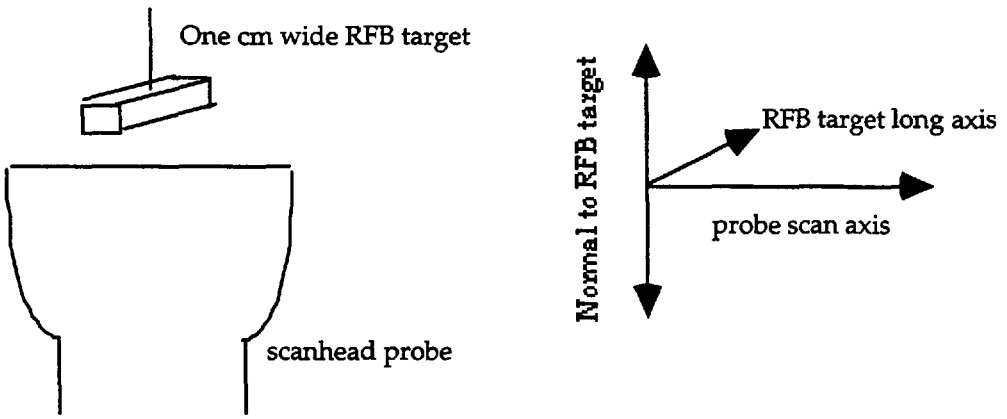


Figure 6–4
SUGGESTED ORIENTATION OF PROBE AND 1 CM WIDE TARGET FOR W_{01} MEASUREMENT

6.3.3.2 Creating a 1 cm Azimuthal Wide Window Using Electronic Control Means

Where the diagnostic ultrasound **equipment** control scheme and transducer geometry allow, masking a 1 cm linear length aperture may be accomplished electronically by de-energizing the aperture outside this area, provided that the acoustic **power** emitted within the 1 cm linear length aperture is not affected by the electronic masking.

Electronic means for masking the active aperture for a 1 cm linear length aperture is recommended where feasible with electronically controllable linear arrays (sequenced, phased, or combination).

6.3.3.3 Measurement of $\frac{W}{X}(j,v_a)$

While using the methods of Sections 6.3.3.1 or 6.3.3.2 to mask all the acoustic **power**, except that originating within a 1 cm azimuthal linear length of the **scanned active aperture**, the remaining acoustic

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power transmitted shall be measured according to the procedures in NEMA Standard UD 2-1998 or in AIUM Standard AOMS-1998, Section 5.6.

In locating the mask used in either Sections 6.3.3.1 or 6.3.3.2 of this standard, the 1 cm linear length aperture emitting the largest amount of acoustic **power**, resulting in the largest measured value of $\frac{W}{X}(j,v_a)$, shall be exposed.

The acoustic **power** accuracy from the 1 cm linear length aperture shall be verified as allowing forward passage of all the acoustic **power** from the central 1 cm linear length aperture of the transducer within ±20%.

6.3.4 Measurement of Mechanical Index MI(j, v_a) for Scanned Modes

The procedures in Section 6.2.4 of this standard shall be performed, except as follows: In a combination **scanned** mode with more than one type of **transmit pattern** (j) employed during the scan period, only the **center frequency** pertaining to the particular combination of **transmit pattern** and **drive voltage amplitude** resulting in the largest $p_{r.3}(j,v_a)$ shall be considered in the calculation of $MI(j,v_a)$.

6.3.5 (Reserved for Future Use)

6.3.6 Measurement of Bone Thermal Index TIB(j,v_a) for Scanned Modes

Refer to Chart A–1 in Appendix A.

6.3.7 Measurement of Cranial Thermal Index TIC(j,v_a) for Scanned Modes

For the **transmit pattern** (j), with **drive voltage amplitude** (v_a), in a **scanned** mode the **cranial bone thermal index** shall be estimated as:

$$TIC(j,v_a) = \frac{W(j,v_a)}{40\sqrt{\frac{4}{\pi}A_{aprt}(j)}} = \frac{W(j,v_a)}{45.1\sqrt{A_{aprt}(j)}}$$

where $W(j,v_a)$ is the acoustic **power** (in mW), as measured in Section 6.3.2 of this standard, and $A_{apr_t}(j))$ is the area (in cm^2) of the total **active aperture** during the scan period at the entrance to the body for **transmit pattern** (j).

6.3.7.1 Estimation of the Scanning $a_{aprt}(j)$ for Nonuniform Excitation of the Transducer Elements in Contact with the Skin

In a manner similar to that in Section 6.2.7.1.1 of this standard, for nonuniform excitation of the transducer elements in contact with the skin, $A_{aprt}(j)$, the area (in cm^2) of the **active aperture** at the beam entrance for scanning **transmit pattern** (j), shall be taken as the maximum dimensions at which the rms excitation voltage, v_{arms}, per unit transducer area, exceeds –12 dB relative to the spatial maximum v_{arms} per unit transducer area.

The rationale for the choice of –12 dB in the definition of $A_{aprt}(j)$ is based on the rationale for the **unscanned** case, Section 6.2.7.1.1 of this standard. In addition, with the **scanned** case, the area of **active aperture** is modified by the nature of the scanning process in some types of arrays. To fully capture the relevant size of the **scanned active aperture**, the –12 dB definition is needed.

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6.3.8 Measurement of Soft Tissue Thermal Index TIS(j, v_a) for Scanned Modes

For the **transmit pattern** (j), with **drive voltage amplitude** v_a, in a **scanned** mode, the **soft tissue thermal index** shall be estimated as:

$$TIS(j,v_a) = \frac{\frac{W}{X}(j,v_a)}{\left(\frac{210}{f_c(j)}\right)} \text{ (unitless)} \qquad (6.3.8\text{–}1)$$

where $\frac{W}{X}(j,v_a)$ is the acoustic **power** per unit length (in $\frac{mW}{cm}$) over an azimuthal 1 cm linear length at the scan entrance as measured in Section 6.3.2 of this standard, and $f_c(j)$ is the **center frequency** (in MHz) as measured in Section 6.3.1 of this standard.

6.4 MEASUREMENT PROCEDURE FOR ASSESSMENT OF PRECISION

6.4.1 Measurement of Precision of Center Frequency, f_c

The measurement precision of the **center frequency** (f_c) shall be determined according to the statistical procedures in Appendix A of NEMA Standard UD 2-1998 or of AIUM Standard AOMS-1998 and reported, as required in Section 4.2.1 of this standard, as the percentage of the standard deviation of f_c relative to its mean. The measurement of the **center frequency** f_c shall be determined according to Section 6.2.1 of this standard using a standard test transducer/driver combination for the following conditions:

Beam Size (d_{-6})	2 mm
Aperture Size	19 mm (dia)
Nominal p_r	1 MPa
Nominal f_c	3.5 MHz
Pulse duration	2 μs
Independent trials	10

6.4.2 Measurement of Precision of Acoustic Power, W

The measurement precision of the acoustic **power** (W) shall be determined according to the statistical procedures in Appendix A of NEMA Standard UD 2-1998 or of AIUM Standard AOMS-1998 and reported, as required in Section 4.2.1 of this standard, as the percentage of the standard deviation of W relative to its mean. The measurement of the acoustic **power** (W) shall be determined according to Section 6.2.2 of this standard using a standard test transducer/driver combination for the following conditions:

Beam Size (d_{-6})	2 mm
Aperture Size	19 mm (dia)
Nominal Power	20 mW
Duty Cycle	20%
Frequency	3.5 MHz
Independent trials	10

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6.4.3 Measurement of Precision of Peak Rarefactional Pressure, p_r

The measurement precision of the **peak rarefactional pressure** (p_r) shall be determined according to the statistical procedures in Appendix A of NEMA Standard UD 2-1998 or of AIUM Standard AOMS-1998 and reported, as required in Section 4.2.1 of this standard, as the percentage of the standard deviation of p_r relative to its mean. The measurement of the **peak rarefactional pressure** (p_r) shall be determined according to Section 6.2.4 of this standard using a standard test transducer/driver combination for the following conditions:

Beam Size (d_{-6})	2 mm
Aperture Size	19 mm (dia)
Nominal p_r	1 MPa
Nominal f_c	3.5 MHz
Pulse duration	2 μs
Independent trials	10

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Appendix A
SUMMARY OF THERMAL INDEX FORMULAE

A1.1 INTRODUCTION

This is a summary of the formulae for **thermal indices** specified in the Output Display Standard. The indices are intended to allow **operators** to implement ALARA using an indicator related to a potential bioeffect. The formulae provide index values that relate to predicted tissue temperature rise for the assumed tissue models. The indices are rough approximations due to the difficulty of modeling the complex and varied thermal characteristics of human tissues, the need to allow for the complexity of modern auto-scanning diagnostic ultrasound **equipment**, and the need to keep measurement requirements feasible.

This summary includes a brief description of the **thermal index** (TI) models, the measurements and calculations required for their implementation, and suggestions for ways the TI might be displayed. The derivations, evaluations, and underlying rationale for these indices are included in a series of documents evaluated or developed by the Thermal Index Working Group (TIWG) of the Output Display Standard Committee and in official minutes thereof. The earliest and most complete rationale, derivations, and supporting data are presented in NCRP Report 113, entitled *Exposure Criteria for Medical Diagnostic Ultrasound I. Criteria Based on Thermal Mechanisms.*[1]

A2.1 THERMAL INDEX CONCEPT

The **thermal index**, as defined by TIWG, is:

$$TI = \frac{W_0}{W_{deg}} \qquad \text{(A2.1–1)}$$

where W_0 = time-averaged acoustic power of the source or other Power Parameter as described in section A5.

W_{deg} = estimated power necessary to raise the target tissue one degree C, based on Thermal Models described in section A5.

When displayed on a diagnostic ultrasound imaging system, the TI provides the **operator** the estimated potential for ultrasonic temperature increase of soft tissue or bone. The **operator** uses this information to implement the ALARA (As Low As Reasonably Achievable) principle.

A3.1 MEASUREMENT PARAMETERS

Present **acoustic output** measurement parameters, such as:

a. W_0 = Source acoustic power,
b. I_{TA} = Axial temporal average intensity, and
c. I_{SPTA} = Spatial peak of I_{TA},

are not individually suitable as indicators or estimates of ultrasound-induced temperature increase. However, combinations of these parameters can be used to calculate indices which approximate the potential for soft tissue or bone temperature increase. Three key concepts of these calculations are:

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a. Derated acoustic power and intensity;
b. Equivalent beam area; and
c. Location of the maximum temperature rise.

Derated acoustic power and intensity, as functions of depth, are straightforward applications of the **derating factor** equal to 0.3dB/cm–MHz. Derated powers and intensities are denoted by subscripts indicating the value of **derating factor**. Parameters without the **derating factor** subscripts refer to nonderated values measured in water. Thus, the beam **power** at a distance z is written:

$$W_{.3}(z) = W_0^{-0.03 f_{cz}} \quad \text{(A3.1–1)}$$

and the derated **spatial-peak, temporal-average intensity** is written:

$$I_{SPTA.3}(z) = I_{SPTA}(z) \times 10^{-0.03 f_{cz}} \quad \text{(A3.1–2)}$$

Equivalent beam area, A_{eq}, is defined:

$$A_{eq}(z) = \frac{W_{.3}(z)}{I_{TA.3}(z)} = \frac{W_0}{I_{TA}(z)} \quad \text{(A3.1–3)}$$

A related equivalent beam diameter, d_{eq}, is defined:

$$d_{eq}(z) = \sqrt{\frac{4}{p} A_{eq}(z)} \quad \text{(A3.1–4)}$$

or 0.1 cm (whichever is greater).

A minimum beamwidth of one millimeter (0.1 cm) is assumed because of the practical difficulty of holding a small beam steady on one bone location.

The location of the maximum temperature increase depends on the imaging conditions. The maximum temperature increase is near the surface if the ultrasound beam passes through bone near the surface or if the mode automatically scans the ultrasound beam. For **unscanned** modes with bone in a focal region, the maximum temperature increase is at the focal region. For **unscanned** modes in soft tissue, the maximum temperature increase may be at the surface or at a deeper location. The interaction between acoustic beam dimensions and the cooling effect of perfusion determines the depth of maximum temperature increase. A low perfusion rate is assumed with a heat perfusion length of one centimeter, suggesting a critical depth, z_1, where the beam area is one square centimeter.

A4.1 THERMAL INDEX CATEGORIES

Because of the difficulties of anticipating and thermally modeling the many possible ultrasound scan planes of the human body, the TIWG proposed practical, simplified models based on average conditions.

Three user-selectable **thermal index** categories correspond to different anatomical combinations of soft tissue and bone encountered in imaging applications (refer to Chart A–1). Each category uses one or more TI models which are selected automatically, based on system information, including transducer aperture or acoustic beam dimensions and the imaging mode.

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Chart A–1
THERMAL INDEX CATEGORIES AND MODELS

Thermal Index Category	Thermal Index Formulae	
	Scanned Mode	**Unscanned Mode**
TIS (Soft Tissue)	A. Soft Tissue at Surface	B. Large Aperture C. Small Aperture
TIB (Bone at Focus)	A. Soft Tissue at Surface	D. Bone at Focus
TIC (Bone at Surface)	E. Bone at Surface	

The **soft tissue thermal index (TIS)** is based on three soft tissue models. Two models cover small and large aperture cases for **unscanned** modes, such as Doppler and M-mode. One model covers **scanned** modes, such as color flow mapping.

The **bone thermal index (TIB)** uses for **unscanned** modes a model in which bone is located in a focal region (such as may occur in second and third trimester fetal applications). For **scanned** modes, the soft tissue model is used because the temperature increase at the surface is usually greater than or about the same as with the bone at the focus.

The **cranial bone thermal index (TIC)** is based on a model with bone located close to the surface (such as in adult cranial applications). The cranial bone model is used with both **unscanned** and **scanned** modes.

A5.1 THERMAL INDEX MODELS

A5.1.1 Soft Tissue at Surface [TIS(scanned), TIB(scanned)]

For **scanned** modes (e.g., B-mode and color flow), the maximum temperature increase occurs at or near the surface where the ultrasound enters the body. Tissue attenuation does not have to be considered. Temperature increase is determined by power per unit length $\left(\frac{W}{X}\right)$ in the scan direction. If the scan width of the active aperture is longer than the heat perfusion length of one centimeter, then the source power is measured by a force balance using an intermediary absorbing mask with a one centimeter window in the scan direction. **Power** from the central one centimeter of the radiating or active aperture is measured (see Figure A–1). For **active apertures** having a scan width less than one centimeter, no mask is necessary. The result of these **power** measurements, designated W_{01}, is the Power Parameter used in the numerator of the TI formula (see Equation A2.1–1).

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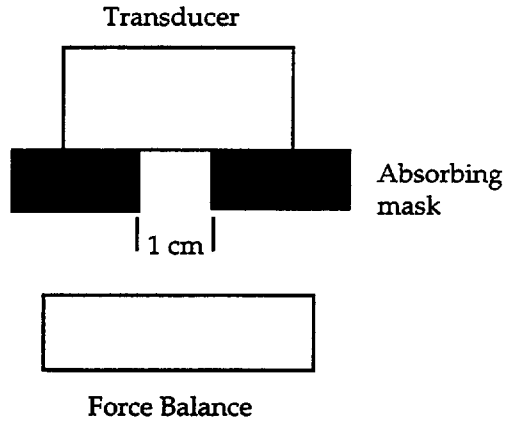


Figure A–1
POWER PER UNIT LENGTH MEASUREMENT WITH A MASK

The **power** required to raise the temperature one degree Celsius is approximated by the formula (see Equation A2.1–1):

$$W_{deg} = \frac{210}{f_c} \text{ (mW)} \qquad \text{(A5.1.1–1)}$$

This W_{deg} formula is shared by all three soft tissue models.

Combining the Power Parameter and the thermal model yields the soft tissue, **scanned** mode, **thermal index** formula (see Model A in Chart A–1):

$$TI = \frac{W_{01}}{\left(\frac{210}{f_c}\right)} \qquad \text{(A5.1.1–2)}$$

A5.1.2 Soft Tissue, Unscanned, Large Aperture [TIS(unscanned)]

The perfusion assumption (one centimeter heat perfusion length) is critical to determining the location of maximum temperature increase. Theory for a heated cylinder suggests that if the beam area is less than one square centimeter, the *power* in the beam controls the temperature rise. If the beam area is greater than one square centimeter, *intensity* controls the temperature rise. In other words, the Power Parameter for narrow beams ($A_{eq} \leq 1$ cm^2) is derated **power**, and for broad beams ($A_{eq} > 1$ cm^2) it is $I_{TA.3} \times 1$ cm^2. Thus, for any location on the **beam axis**, the Local Power Parameter (LPP) is:

$$LPP(z) = \min [W_{.3}(z), I_{TA.3}(z) \times 1\text{cm}^2] \qquad \text{(A5.1.2–1)}$$

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To avoid inaccuracies introduced by attempting to measure intensities in the acoustic near field, a break-point depth, z_{bp}, is defined equal to one-and-a-half times the equivalent aperture diameter.

$$z_{bp} = 1.5D_{eq} \text{ (cm)} \qquad \text{(A5.1.2–2)}$$

Thus,

$$z_{bp} = 1.5\sqrt{\frac{4}{p}A_{aprt}} = 1.69\sqrt{A_{aprt}} \text{ (cm)} \qquad \text{(A5.1.2–3)}$$

For purposes of this standard, the maximum temperature increase is assumed to be at the location at or beyond z_{bp} that maximizes LPP(z). Thus, the Power Parameter (PP) for the beam is given by:

$$PP = \max_{z>z_{bp}} [LPP(z)] = \max_{z>z_{bp}} [\min[W_{.3}(z), I_{TA.3}(z) \times 1\text{cm}^2]] \text{ (mW)} \qquad \text{(A5.1.2–4)}$$

The PP location, i.e., the location that satisfies Equation A.5.1.2–4, is denoted z_1 in Section 6.2.6.13 of this standard.

Model B (see Chart A–1), the Large Aperture model, describes a transducer for which the entrance area is greater than one square centimeter. Figures A–2A, A–2B, A–2C, and A–2D show examples of possible locations and values of PP for Model B. These figures show examples of possible relationships between intensity ($I_{TA.3} \times 1$ cm^2) and power ($W_{.3}$) curves. For depths less than the break-point depth ($z < z_{bp}$), the curves are shown as dotted lines; values within this region are not considered. The local power parameter, LPP, shown by a double thickness line, is the lesser of the intensity or the power curve, per equation A.5.1.2–1.

It is helpful to consider what these curves indicate about beam focusing. The equivalent beam area, A_{eq}, is the ratio of $W_{.3}$ to $I_{TA.3}$. In regions where the intensity curve is below (less than) the power curve, the equivalent beam area is greater than one square centimeter. Where the intensity curve is above (greater than) the power curve, the equivalent beam area is less than one square centimeter. The equivalent beam area is one square centimeter where the curves intersect.

Figure A–2A might represent a focused transducer with a very large aperture. It shows a focused beam for which the equivalent beam area first decreases to one square centimeter, that is, the curves intersect at a depth greater than the break-point. (Curve intersections in the near-field are ignored.) The maximum value of the Local Power Parameter, LPP, is found at this intersection. The power value, $W_{.3}$, at the intersection is the Power Parameter PP, and the location is denoted z_1.

Figure A–2B might represent a focused transducer with somewhat smaller aperture (but still greater than one square centimeter). At the break-point depth, the equivalent beam area is already less than one square centimeter. The maximum value of the Local Power Parameter, LPP, is the derated power at the break-point depth, and z_1 is the break-point depth.

Figure A–2C might represent a focused transducer with a weak ($A_{eq} > 1$ cm^2) focus just beyond the break-point depth. This local intensity maximum may result from the elevation focus of a rectangular aperture transducer or, perhaps, a near-field effect beyond the break-point depth. In this example, the location, z_1, of the LPP maximum is at the weak focus; the value of the Power Parameter is $I_{TA.3} \times 1$ cm^2.

Figure A–2D represents a weakly focused transducer; the equivalent beam diameter always exceeds one square centimeter. Such a transducer is unlikely in diagnostic ultrasound applications. The example is provided for the sake of complete understanding of the model. The LPP is the intensity curve. The PP is

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the maximum value of the $I_{TA.3}$, i.e., the $I_{SPTA.3}$, and z_1 is at the location of the $I_{SPTA.3}$. (In this example, the $I_{SPTA.3}$ is located at a depth deeper than the break-point.)

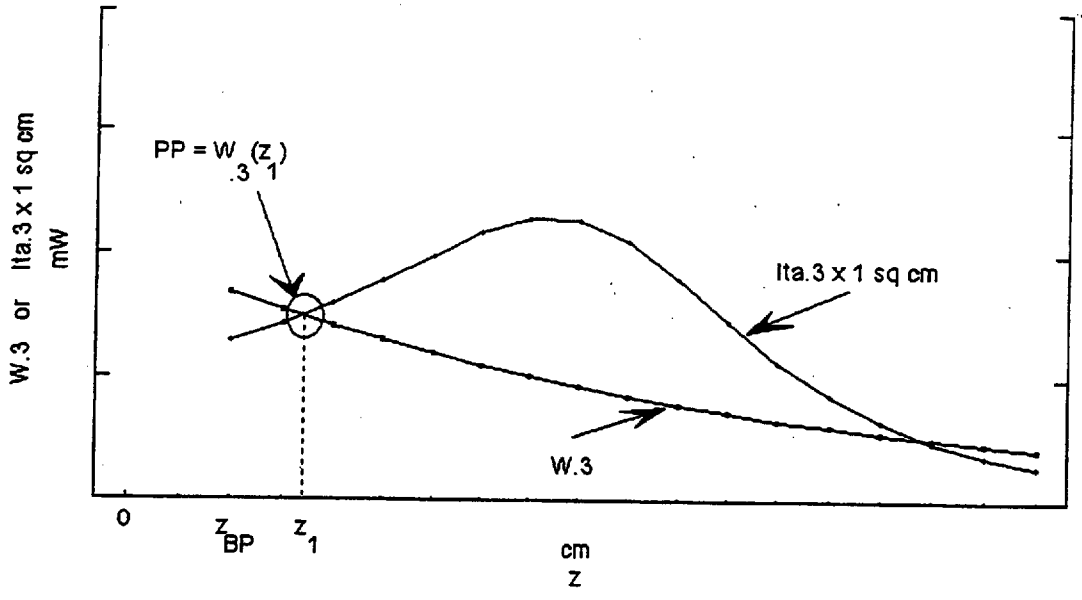


Figure A–2A

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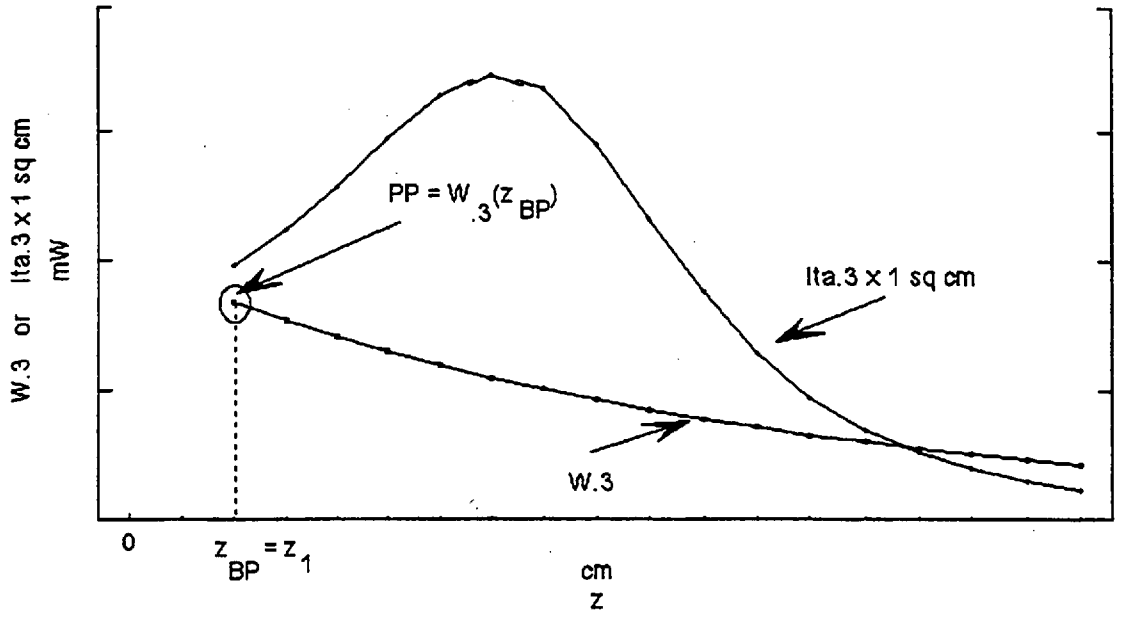


Figure A–2B

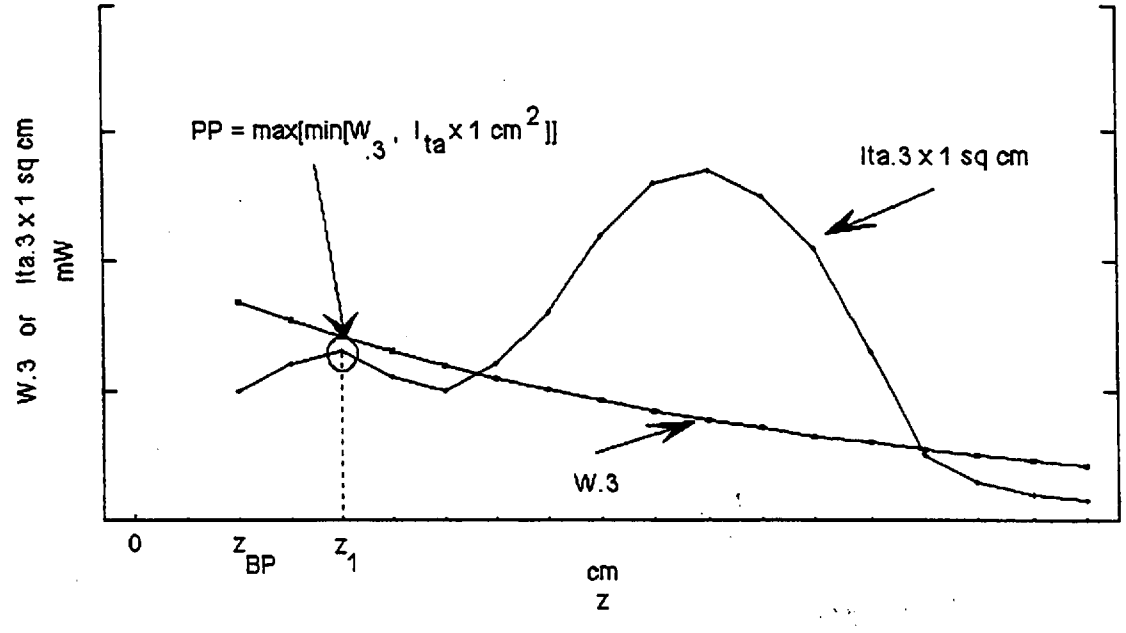


Figure A–2C

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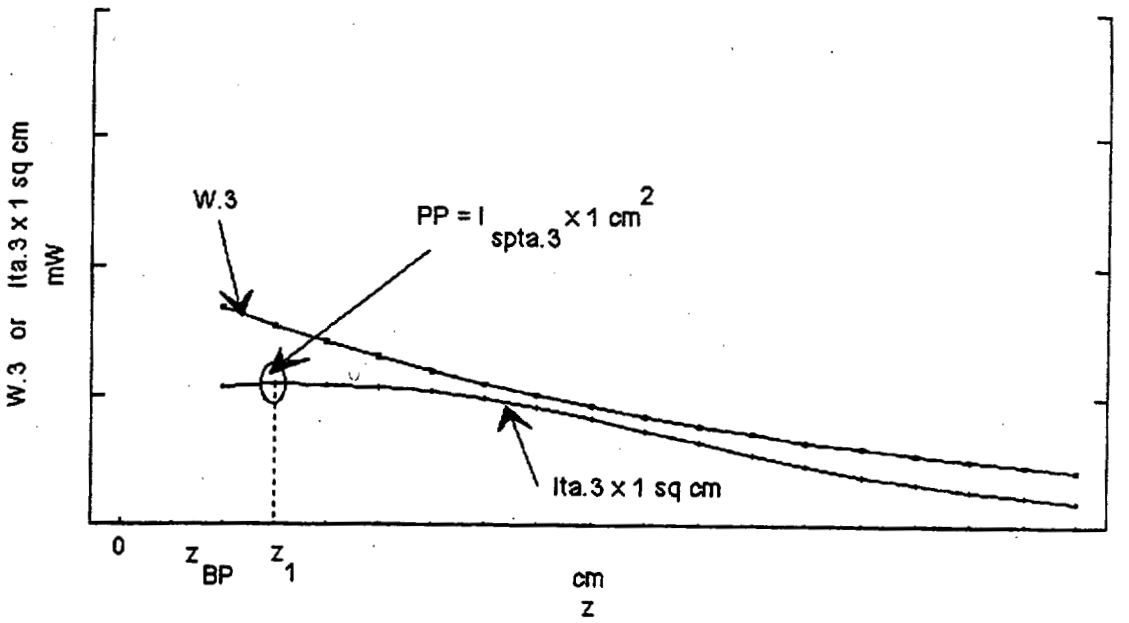


Figure A–2D

Combining the Model B Power Parameter with the soft tissue W_{deg} yields the Model B **thermal index** formula denoted TIS in Equation 6.2.6.14–1 of this standard:

$$TI = \frac{\max_{z > z_{bp}} [\min[W_{.3}(z), I_{TA.3}(z) \times 1\,cm^2]]}{\left(\frac{210}{f_c}\right)} \qquad (A_{aprt} > 1\ cm^2) \qquad \text{(A5.1.2–5)}$$

A5.1.3 Soft Tissue, Unscanned, Small Aperture [TIS(unscanned)]

Model C (see Chart A–1), the Small Aperture model, describes a transducer for which the aperture area is less than one square centimeter. In this case, power controls the temperature increase. The location of maximum power and, hence, the assumed maximum temperature increase is at the surface. The Power Parameter for Model C is the source acoustic power, W_o.

Thus, the Model C **thermal index** formula is denoted TIS in Equation 6.2.6.20–2 of this standard:

$$TI = \frac{W_o}{\left(\frac{210}{f_c}\right)} \qquad (A_{aprt} = 1\ cm^2) \qquad \text{(A5.1.3–1)}$$

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A5.1.4 Bone at Focus [TIB(unscanned)]

For Model D, the **unscanned** case with bone in the focal region, the location of the maximum temperature increase is at the surface of the bone. It is assumed that the bone surface is located at an axial distance, $z_{B.3}$, the depth at which the TIB expression is a maximum. The **derating factor** is 0.3 dB/cm–MHz. The Power Parameter is $W_{.3}(z_{B.3})$, the source power derated to the depth $z_{B.3}$.

The estimated **power** necessary to raise bone one degree Celsius at an axial distance of $z_{B.3}$ is proportional to the equivalent beam diameter at z, or 0.1 cm, whichever is greater; i.e.:

$$W_{deg} = \max[40K_{bs}d_{eq}(z_{B.3}),\ 4K_{bs}] \qquad \text{(A5.1.4–1)}$$

where $d_{eq}(z_{B.3})$ is in centimeters and K_{bs} is a beam shape factor that accounts for the radial non-uniformity of the beam intensity distribution, and is found from:

$$I_{SPTA} = (K_{bs})^2 \frac{W0}{A_{-6}} \qquad \text{(A5.1.4–2)}$$

where A_{-6} is the **beam cross-sectional area** at the location of the I_{SPTA}.

For a uniform beam, $K_{bs} = 1$, but for other beams, $K_{bs} = 1.1$ is a more reasonable value. Therefore, equation A5.1.4–1 becomes:

$$W_{deg} = \max[44d_{eq}(z_{B.3}),\ 4.4] \qquad \text{(A5.1.4–3)}$$

$$= \max\left[44\sqrt{\frac{4}{\pi}A_{eq}(z_{B.3})},4.4\right] \qquad \text{(A5.1.4–4)}$$

$$= \max\left[50\sqrt{\frac{W_{.3}(z_{B.3})}{I_{TA.3}(z_{B.3})}},4.4\right] \qquad \text{(A5.1.4–5)}$$

The TIB(**unscanned**) formula is (see Model D in Chart A–1):

$$\text{TIB(unscanned)} = \frac{W_{.3}(z_{B.3})}{\max\left[50\sqrt{\frac{W_{.3}(z_{B.3})}{I_{TA.3}(z_{B.3})}},4.4\right]} \qquad \text{(A5.1.4–6)}$$

$$= \min\left[\frac{\sqrt{W_{.3}(z_{B.3})I_{TA.3}(z_{B.3})}}{50}, \frac{W_{.3}(z_{B.3})}{4.4}\right] \qquad \text{(A5.1.4–7)}$$

$$= \min\left[\frac{\sqrt{W_0 I_{TA}(z_{B.3})} \times (10^{-0.03 f_c z_{B.3}})}{50}, \frac{W_{.3}(z_{B.3})}{4.4}\right] \qquad \text{(A5.1.4–8)}$$

The location, $z_{B.3}$, is the depth that maximizes the expression:

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$$W_{.3}(z)I_{TA.3}(z)$$

$$= W_0 I_{TA}(z) \times (10^{-0.03fc^z})^2 \qquad \text{(A5.1.4–9)}$$

$$= W_0 I_{TA}(z) \times 10^{-(0.06fc^z)} \qquad \text{(A5.1.4–10)}$$

$$= W_0 I_{TA.6}(z) \qquad \text{(A5.1.4–11)}$$

The spatial maximum of $I_{TA.6}(z)$ is the $I_{SPTA.6}$. Thus, it is mathematically accurate and occasionally convenient for notation to say that $z_{B.3}$ is the location of the $I_{SPTA.6}$, or $z_{SP.6}$. The notation $z_{B.3}$ was developed to indicate the **derating factor** is 0.3 dB/cm–MHz, not 0.6 dB/cm–MHz.

A5.1.5 Bone at Surface [TIC]

Like the focal bone case (Model D), the location of the maximum temperature increase for the cranial case is at the bone. Since the bone is located at the surface, or beam entrance, there is no attenuation calculation. The Power Parameter is W_o.

The thermal model for Bone at Surface is conceptually the same as for the Bone at Focus, with the equivalent beam diameter at the surface replacing the minimum equivalent beam diameter. The thermal model, appropriate for both **scanned** and **unscanned** modes, is:

$$W_{deg} = 40D_{eq} \quad \left(40\sqrt{\frac{4}{p}A_{aprt}}\right) \qquad \text{(A5.1.5–1)}$$

Thus, the **thermal index** formula for Model E (see Chart A–1), the Bone at Surface model, is (see Equation 6.2.7.1–1 of this standard):

$$TIC = \frac{W_0}{40D_{eq}} \qquad \left(\frac{W_0}{40\sqrt{\frac{4}{p}A_{aprt}}}\right) \qquad \text{(A.5.1.5–2)}$$

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A6.1 COMBINATION MODES

When multiple modes are used simultaneously, the contribution of each discrete mode is calculated separately and then combined to determine the total estimated temperature rise at the location of the maximum temperature rise.

The location of maximum temperature increase is near the surface for models A, C, and E, but at deeper depths for models B and D. The combined TI for multiple modes is the greater of either the sum of discrete mode TI contributions heating the surface or the sum of discrete mode TI contributions heating at depths.

Chart A–2 summarizes the combination formulae for each of the TI categories.

Chart A–2
TI FOR COMBINATION MODES

TI categories/models	Combining discrete mode TI values
TIC, TIS small aperture (Models A, C, or E)	TI @ surface = Σ (TI values for all modes)
TIB, TIS large aperture (Models A, B, or D)	Max(TI @ surface, TI @ depth)= Max [Σ (TI values for scanned modes), Σ (TI values for unscanned modes)]

A7.1 DISPLAY OF THE THERMAL INDEX

The **thermal index** display should help the user to use ALARA with systems having the potential for significant tissue temperature rise. TI values less than one are displayed to help in implementing the ALARA principle. TI values equal to or greater than one, alert the informed user to proceed with more caution.

For diagnostic ultrasound **equipment,** which can produce **thermal indices** greater than one in any mode, the **equipment** must be capable of displaying a TI. However, the TI need not be displayed below 0.4.

To facilitate ALARA, display increments shall not exceed 0.2 for TI less than one, and shall not exceed one for TI greater than one. These requirements are met by a display with increments of 0.4, 0.6, 0.8, 1, 2, 3, 4, and so on. In many cases, it is not expected that the TI values can estimate temperature increase to within a factor of two. Nevertheless, the ODS Committee decided that finer display increments are helpful in applying ALARA even though the increments may seem to imply an accuracy which does not always exist.

Several options for implementing the display are possible. For example, both the bone and soft tissue TI might be displayed simultaneously. Alternatively, a switch for changing from a soft tissue TI display to a bone TI display may be supplied.

An extensive training and educational program is necessary to implement **thermal indices** and to explain the implications of their use as well as the physical basis of the thermal models. Manufacturers will contribute by supplying information that will enable the **operator** to apply the ALARA principle, with the **thermal** and **mechanical indices** as aids, on their diagnostic ultrasound **equipment.**

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A8.1 MEASUREMENTS

Chart A–3 summarizes the measurements that must be made to validate **thermal indices.**

Chart A–3
MEASUREMENTS FOR VALIDATING TI MODELS

Model	Measurements	Derived parameters
A. Soft Tissue at Surface	f_c [MHz] W_{01} [mW]	
B. Soft Tissue, Unscanned, Large Aperture	A_{aprt} [cm^2] f_c [MHz] W_0 [mW] $I_{TA}(z>z_{bp})$ [mW/cm^2]	z_{bp} [cm] $W_{.3}(z>z_{bp})$ [mW] $I_{TA.3}(z>z_{bp})$ [mW/cm^2]
C. Soft Tissue, Unscanned, Small Aperture	f_c [MHz] W_0 [mW]	
D. Bone at a Focal Region	f_c [MHz] W_0 [mW] $I_{TA}(z_{B.3})$ [mW/cm^2]	$W_{.3}(z_{B.3})$ [mW] $I_{TA.3}(z_{B.3})$ [mW/cm^2] $z_{B.3}$ [cm]
E. Bone at Surface	A_{aprt} [cm^2] W_0 [mW]	D_{eq} [cm]

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Appendix B
MECHANICAL INDEX RATIONALE

B1.1 PURPOSE

The AIUM Bioeffects Committee describes two fundamental mechanisms by which ultrasound may induce bioeffects, heating, and mechanical mechanisms.[2] The **mechanical index** is intended to estimate the potential for mechanical bioeffects. Examples of mechanical effects are motion (or streaming) around compressible gas bubbles as ultrasound pressure waves pass through tissues, or energy released in the collapse, via cavitation, of transient gas bubbles.

There have been no adverse mechanical bioeffects observed in humans from exposure to ultrasound output levels typical of diagnostic ultrasound imaging. However, several concerns led to the decision to include a **mechanical index** in the Output Display Standard:

a. In lithotripsy, mechanical bioeffects are induced by ultrasound with peak pressures in the same range as are sometimes used in diagnostic imaging, albeit at markedly different frequencies.

b. *In vitro* experiments and observations with lower organisms have demonstrated the possibility of cavitation at ultrasound peak pressures and frequencies in ranges in which some diagnostic imaging systems can operate.

c. Lung hemorrhage has been demonstrated in mice exposed to levels of pulsed ultrasound similar to those used in diagnostic imaging systems. (Although this has been demonstrated in adult mice, similar effects have not been found in fetuses.)

No clear conclusion has been drawn on the relevance of these laboratory studies to human exposure to diagnostic ultrasound.

However, the results raise sufficient concern that the Output Display Committee believed the display of a **mechanical index**, and the related educational material, would raise in users' minds an appropriate awareness of the possibility of mechanical effects, and of conditions under which the possibility was more likely. With a **mechanical index,** users could apply the ALARA principle to keep the potential for mechanical bioeffects "as low as reasonably achievable" while obtaining diagnostically adequate images.

B2.1 DISPLAY REQUIREMENTS

The Output Display Committee decided the **mechanical index** need only be displayed during B-mode imaging. However, if a transducer does not provide B-mode, then the **mechanical index** for Doppler mode must be available to the user.

In B-mode imaging, thermal bioeffect concerns are usually low, but the peak pressures may be relatively high compared to other modes. In B-mode, the concern about the potential for mechanical bioeffects was present while concern about thermal bioeffects was negligible. The Output Display Committee agreed that if B-mode is available, display of the **mechanical index** will be mandatory only for pure B-mode imaging. The potential for mechanical bioeffects might be equivalent in other modes. In particular, pulsed Doppler with longer duty cycles or high peak pressures might be of equal or greater concern. However, when real-time (B-mode) imaging is available, the MI in B-mode can provide the operator with some information as to the maximum MI likely to be encountered in a Doppler mode.

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For transducers that do not allow B-mode imaging, the **mechanical index** must be available in Doppler mode. Clinical users expressed a strong demand to display only a single index, and that the single index should reflect the bioeffect of greater concern. Thus, this standard does not require simultaneous display of the **thermal** and **mechanical indices**. Rather, this standard simply requires that, when B-mode is not available, the user be able to choose which index is displayed.

B3.1 FORMULA

The conditions that affect the likelihood of mechanical effects are not yet well understood. It is generally agreed that the likelihood increases as peak pressure increases, but decreases as the ultrasound frequency increases. Further, it is generally believed to be a threshold effect, that is, no effect occurs unless a certain output level is exceeded.

The relationship, p^2/f = constant, was proposed by Apfel and Holland[3] as an estimate of threshold conditions. The Output Display Committee used the square root of the proposed relationship. The **mechanical index** is defined as (see Equation 6.2.4.5–1 of this standard):

$$MI = \frac{p_{r.3}(z_{sp})}{\sqrt{f_c}} \qquad \text{(B3.1–1)}$$

where $p_{r.3}(z_{SP})$ = the **peak rarefactional pressure** (MPa), derated by 0.3dB/cm–MHz to the point on the **beam axis**, z_{SP}, where $PII_{.3}$ is maximum,

and f_c = **center frequency** (MHz)

To make the **mechanical index** unitless, the MI is multiplied by $[(1\ MHz)^{0.5}/(1\ MPa)]$.

The choice of a homogeneous tissue model and the **derating factor** of 0.3 dB/cm–MHz is a compromise. Other attenuation models were proposed, such as fixed distance models, like those proposed by NCRP for fetal cases, and homogeneous tissue attenuation factors of 0.5 dB/cm–MHz which are more representative of many radiological and cardiac imaging applications. However, using more than one attenuation model would entail an increase in **equipment** complexity and need for user input to select appropriate attenuation schemes.

The Output Display Committee did not believe that the extra complexity in attenuation modeling was justified given the level of understanding of the conditions required to produce mechanical bioeffects. With the simple, compromise attenuation model, the **mechanical index** is simple to implement and use and, most importantly, sufficient to allow users to implement the ALARA principle and to motivate education of users with regard to potential mechanical bioeffects.

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