Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers

This document is intended to provide guidance in the preparation of a regulatory submission. It does not bind the FDA or the regulated industry in any manner.

Computed Imaging Devices Branch
Division of Reproductive, Abdominal,
Ear, Nose, Throat and Radiological Devices
Office of Device Evaluation

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While this guidance document represents a final document, comments and suggestions may be submitted at any time for Agency consideration by writing Robert A. Phillips, Ph.D., Center for Devices and Radiological Health, HFZ-470, 9200 Corporate Blvd., Rockville, MD 20850. For questions regarding the use or interpretation of this guidance, contact Robert Phillips at 301-594-1212. This guidance replaces *Revised 510(k) Diagnostic Ultrasound Guidance for 1993* that was issued on February 17, 1993 .

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health

Table of Contents

Foreword

This guidance document provides detailed information, checklists and forms recommended for manufacturers seeking marketing clearance of diagnostic ultrasound systems and transducers. This guidance replaces all previous 510(k) guidance documents.

This guidance makes extensive reference to the *Standard for real-time display of thermal and mechanical acoustic output indices on diagnostic ultrasound equipment* (AIUM/NEMA 1996) using the generally recognized shortened name ***Output Display Standard*** or *ODS*. All references to the ***Output Display Standard*** or *ODS* specifically refer to the above mentioned standard.

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In this guideline the following print types are used:

- Requirements: in roman type
- NOTES: in small roman type
- Words in **bold** in the text are defined in section 3

Section 1:

510(k) Diagnostic Ultrasound Checklist

510(k) Number: _____

Device Name: _____

Company Name: _____

Section	Item	Needed? yes / no	Present? yes / no
4	**General Information**		
4.2	**Basic Information:**		
	Cover Letter	☐ / ☐	☐ / ☐
	Contents Page	☐ / ☐	☐ / ☐
	Organizational Aids	☐ / ☐	☐ / ☐
	Manufacturer/U.S. Agent/Importer Information	☐ / ☐	☐ / ☐
	Device Name	☐ / ☐	☐ / ☐
	Common Name	☐ / ☐	☐ / ☐
	Establishment Registration Number	☐ / ☐	☐ / ☐
	Factory Location	☐ / ☐	☐ / ☐
	Sterilization Location	☐ / ☐	☐ / ☐
	Reason for Submission	☐ / ☐	☐ / ☐
	Submission Type (Track 1 or 3)	☐ / ☐	☐ / ☐
	510(k) Special Report Included?	☐ / ☐	☐ / ☐
	510(k) Summary or Statement of Substantial Equivalence	☐ / ☐	☐ / ☐
	510(k) Truthful and Accurate Statement	☐ / ☐	☐ / ☐
4.3	**Indications for Use:**		
	510(k) Indications for Use Form	☐ / ☐	☐ / ☐
	New Indications for Use (probes, Accessories)	☐ / ☐	☐ / ☐
	Previously Cleared Indications for Use	☐ / ☐	☐ / ☐
4.4	**General Device Description:**		
	System Design	☐ / ☐	☐ / ☐
	Transducer Operation	☐ / ☐	☐ / ☐
	Operating Controls	☐ / ☐	☐ / ☐
	New or Unique Features/Technological Characteristics	☐ / ☐	☐ / ☐
	New and Previously Cleared Transducer Summary	☐ / ☐	☐ / ☐
4.5	**Predicate Device Comparison:**		
	Legally Marketed Predicate Device(s)	☐ / ☐	☐ / ☐
	Comparison to Predicate Device(s)	☐ / ☐	☐ / ☐
	Accessories/Kits	☐ / ☐	☐ / ☐
	Labeling and/or Promotional Materials	☐ / ☐	☐ / ☐
4.6	**Acoustic Output Reporting:**		
	Measurement Methodology Certifications	☐ / ☐	☐ / ☐
	Test Methodology Reporting	☐ / ☐	☐ / ☐

Section	Item	Needed? yes / no	Present? yes / no
4.7	**General Clinical Safety & Effectiveness:**		
4.7.1	Clinical Measurement Range and Accuracies:		
	- Doppler Sensitivity	☐ / ☐	☐ / ☐
	- Test Methodology for Accuracies and Sensitivities	☐ / ☐	☐ / ☐
4.7.2	Thermal, Mechanical and Electrical Safety	☐ / ☐	☐ / ☐
4.7.3	Patient Contact Materials:		
	- Previously Cleared or Biocompatibility Data	☐ / ☐	☐ / ☐
	- Material Name/Chemical Composition	☐ / ☐	☐ / ☐
4.7.4	Cleaning, Disinfection and Sterilization:		
	- Legally Marketed Disinfectants / Sterilants	☐ / ☐	☐ / ☐
	- Recommended Procedures for Probe Processing	☐ / ☐	☐ / ☐
	- Level of Required Disinfection/Sterilization (SAL)	☐ / ☐	☐ / ☐
	- Justification for SAL	☐ / ☐	☐ / ☐
	- Information for Components Provided Sterile	☐ / ☐	☐ / ☐
	- Pyrogenicity Claims	☐ / ☐	☐ / ☐
4.7.5	Software/Firmware Information:		
	- Summary Description of Algorithms & Explanations	☐ / ☐	☐ / ☐
	- Software Version Number	☐ / ☐	☐ / ☐
	- Structural Chart	☐ / ☐	☐ / ☐
	- System Hazard Analysis	☐ / ☐	☐ / ☐
	- Specific Hardware / Software Requirements	☐ / ☐	☐ / ☐
	- Summary of Design, Development and Change Processes	☐ / ☐	☐ / ☐
	- Summary of Verification and Validation Processes	☐ / ☐	☐ / ☐
	- Summary of Current Test Results and Future Testing	☐ / ☐	☐ / ☐
4.8	**Labeling:**		
4.8.1	Draft Operator's Manuals / Promotional Materials	☐ / ☐	☐ / ☐
	Description of System and Transducers	☐ / ☐	☐ / ☐
4.8.1.1	Indications for Use, Contraindications, Warning & Precautions	☐ / ☐	☐ / ☐
	Prescription Device Statement	☐ / ☐	☐ / ☐
4.8.1.2	Clinical Instructions for Use	☐ / ☐	☐ / ☐
4.8.1.3	Compatible Accessories and Kits (with Specifications)	☐ / ☐	☐ / ☐
	Probe Sheath Recommendation for Invasive Uses and FDA Latex Alert	☐ / ☐	☐ / ☐
4.8.1.4	Clinical Measurement Accuracies and Ranges	☐ / ☐	☐ / ☐
4.8.1.5	Draft Acoustic Output Tables with Descriptions and Measurement Uncertainties	☐ / ☐	☐ / ☐
4.8.1.6	Care, Cleaning, Disinfection, Sterilization	☐ / ☐	☐ / ☐
4.8.1.7	Special Labeling	☐ / ☐	☐ / ☐
4.8.1.8	Literature References	☐ / ☐	☐ / ☐
5	**Track 1 Specific Information**		
5.1	**Reporting:**		
5.1.1	Mode/Application Possibilities Summary	☐ / ☐	☐ / ☐
	Target Range of Values (MI or $I_{SPPA.3}$ and $I_{SPTA.3}$)	☐ / ☐	☐ / ☐
5.1.3	Fetal Heart Rate Monitor Information	☐ / ☐	☐ / ☐
5.1.4	Temperature Rise for Transcranial	☐ / ☐	☐ / ☐

Section	Item	Needed? yes / no	Present? yes / no
5.2	**Labeling:**		
5.2.1	Draft Acoustic Output Tables	☐ / ☐	☐ / ☐
5.2.2	Explanation of Derated Intensities	☐ / ☐	☐ / ☐
5.2.3	Interactive System Features	☐ / ☐	☐ / ☐
	ALARA Discussion	☐ / ☐	☐ / ☐
6	**Track 3 Specific Information**		
6.1	**Reporting:**		
6.1.1	Operating Mode Possibilities Summary	☐ / ☐	☐ / ☐
6.1.2	Measurement Method Certification	☐ / ☐	☐ / ☐
6.1.4	Description of Defaults	☐ / ☐	☐ / ☐
6.1.5	Justification of TI's>6.0	☐ / ☐	☐ / ☐
6.1.6	**Global maximum** TI, $I_{SPTA.3}$,MI and $I_{PA.3}$@MI_{max} when MI/TI ≤ 1.0	☐ / ☐	☐ / ☐
6.2	**Labeling:**		
6.2.1	Draft Acoustic Output Tables	☐ / ☐	☐ / ☐
6.2.2	Description of Real-Time Display and Controls	☐ / ☐	☐ / ☐
6.2.3	Display Accuracy / Measurement Precision	☐ / ☐	☐ / ☐
6.2.4	**Global maximum** TI, $I_{SPTA.3}$, MI and $I_{PA.3}$@MI_{max} when MI/TI ≤ 1.0	☐ / ☐	☐ / ☐
6.3	**Education Program**	☐ / ☐	☐ / ☐

Section 2:

References

1. AIUM: *Acoustic Output Measurement Standard for Diagnostic Ultrasound Equipment*. American Institute of Ultrasound in Medicine, 14750 Sweitzer Lane suite 100, Laurel MD 20707-5906; 1997 (or latest revision).

2. AIUM: *Medical Ultrasound Safety*, American Institute of Ultrasound in Medicine, 14750 Sweitzer Lane suite 100, Laurel MD 20707-5906; 1994.

3. AIUM/NEMA: *Standard for real-time display of thermal and mechanical acoustic output indices on diagnostic ultrasound equipment*. Revision 2. AIUM/NEMA Standards Publication - UD3; American Institute of Ultrasound in Medicine, 14750 Sweitzer Lane suite 100, Laurel MD 20707-5906 or National Electrical Manufacturers Association, 1300 North 17th Street, Suite 1847, Rosslyn VA 22209, 1996 (or latest revision).

4. Boote EJ, Zagzebski, JA: "Performance Tests of Doppler Ultrasound Equipment with a Tissue and Blood-Mimicking Phantom", J. Ultrasound in Medicine, 7:137-147, 1988.

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6. CDC: Hospital Infections Program, “Creutzfeldt-Jakob Disease: Epidemiology, Risk Factors, and Decontamination”, http://www.cdc.gov/ncidod/diseases/hip/cjd.htm, CDC, Atlanta, GA, 1997.

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10. FDA: “Reviewer Guidance for Computer Controlled Medical Devices Undergoing 510(k) Review”, Food & Drug Administration, 9200 Corporate Blvd., Rockville MD 20850, 1991.

11. FDA: Medical Alert on latex products, “Allergic Reactions to Latex-Containing Medical Devices”, Food & Drug Administration, 9200 Corporate Blvd., Rockville MD 20850, 1991.

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16. IEC: IEC 601-1 - Medical electrical equipment - Part 1: General requirements for safety, International Electrotechnical Commission, Geneva Switzerland, 1995.

17. IEC: IEC 1102--Measurement and characterization of ultrasound fields using hydrophones in the frequency range 0.5 MHz–5 MHz, Amendment 1. International Electrotechnical Commission, Geneva, 1993.

18. ISO: ISO-10993, "Biological Evaluation of Medical Devices Part 1: Evaluation and Testing", 1993.

19. Natrella MG: Experimental Statistics, NBS Handbook 91, National Institute of Standards and Technology, Gaithersburg MD, 1966.

20. NEMA, *Acoustic Output Measurement Standard for Diagnostic Ultrasound Equipment*, UD-2 revision 2, National Electrical Manufacturers Association, 1300 North 17th Street, Suite 1847, Rosslyn VA 22209, 1997 (or latest revision).

21. Preston RC, Bacon DR, Smith RA: “Calibration of medical ultrasonic equipment - procedures and accuracy assessment”, IEEE Transactions on Ultrasonics, Ferroelectrics, and Frequency Control, vol. 35, no. 2, pp. 110-121, 1988.

22. UL: UL-2601 - Standard for Medical Electrical Equipment - Part 1: General Requirements for Safety, Underwriter’s Laboratories, Northbrook IL, 1988.

23. UL: UL 544 - Standard for Medical and Dental Equipment (third edition) , Underwriter’s Laboratories, Northbrook IL, 1994.

24. Zeqiri B, Bond AD: “The influence of waveform distortion on hydrophone spatial averaging corrections - Theory and measurement”, J. Acoust. Soc. Am. 92,1809-1821, 1992.

25. Ziskin MC: “Measurement of Uncertainty In Ultrasonic Exposimetry”, Ultrasonic Exposimetry, M.C. Ziskin and P.A. Lewin, eds. (CRC Press, Boca Raton, FL) pp. 409-443, 1993.

Section 3:

Definitions and Formulae

This section provides precise definitions for the pertinent technical terms used in this document. Unless explicitly noted in this section, the definitions provided are in concurrence with equivalent definitions in the NEMA & AIUM *Acoustic Output Measurement Standards* (NEMA 1997, AIUM 1997), the AIUM/NEMA *Standard for real-time display of thermal and mechanical acoustic output indices on diagnostic ultrasound equipment*. Revision 2 (AIUM/NEMA 1996), IEC 1102 (IEC 1993), IEC 1973 (DRAFT IEC 1997) and the 1985 FDA 510(k) Guide (FDA 1985).

Where used in this Guidance, the terms defined below are in **bold** letters.

3.1 GENERAL DEFINITIONS

510(k) Special Report: A post-clearance report providing production acoustic output values and other information. The **510(k) Special Report** must be submitted prior to shipping the first device (prior to first customer shipment). It may be included with the original 510(k) submission (please note choice in your cover letter). The manufacturer, distributor, or importer should submit the **510(k) Special Report** (Appendix G) as an "add-to-file" and should reference the manufacturer's 510(k) number.

acoustic pressure: The value of the total pressure minus the ambient pressure.

Symbol: p
Unit: Pascal, Pa

autoscan (autoscanning): The electronic or mechanical steering of successive ultrasonic pulses or series of pulses, through at least two dimensions.

bandwidth: The difference between the most widely separated frequencies f_1 and f_2 at which the transmitted **acoustic pressure** spectrum is 71 percent (–3 dB) of its maximum value.

Symbol: BW
Unit: Hertz, Hz

beam axis: A straight line joining the points of maximum **pulse intensity integral** 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.

beam cross-sectional area: The area on the surface of a plane perpendicular to the **beam axis** consisting of all points where the **pulse intensity integral** is greater than 25 percent of the maximum **pulse intensity integral** in that plane. For situations in which the relative **acoustic pressure waveform** does not change significantly across the **beam cross-sectional area**, the **beam cross-sectional area** may be approximated by measuring the area on the surface of a plane perpendicular to the **beam axis** consisting of all points where the **acoustic pressure** is greater than 50 percent of the maximum **acoustic pressure** in the plane.

Symbol: A
Unit: centimeter squared, cm^2

bounded-square output power: **Power** emitted in the **non-autoscanning mode** from the contiguous one square centimeter of the active area of the transducer through which the highest **ultrasonic power** is being transmitted.

Symbol: W_{01x1}
Unit: milliwatt, mW

center frequency: Defined as

$$f_c = (f_1 + f_2)/2$$

where
f_1 and f_2 are frequencies defined in **bandwidth**.

Symbol: f_c
Unit: Hertz, Hz

conventional: (as used with the musculo-skeletal application) Structures located at a depth greater than 1.5 cm.

declaration of conformity: A statement made by the submitter that a particular device was tested and meets the requirements of a recognized standard. It should clearly specify the following:

1. Any element of the standard that was not applicable to the device;
2. If the standard is part of a family of standards which provides collateral and/or particular parts, a statement regarding the collateral and/or particular parts that were met;
3. Any deviations from the standards that were applied;
4. What differences exist, if any, between the tested device(s) and the device to be marketed and a justification of the test results in those areas of difference; and
5. Name and address of any test laboratory or certification body involved and a reference to any accreditations of those organizations.

derating (derating factor, derated): A factor applied to acoustic output parameters intended to account for ultrasonic attenuation of tissue between the source and a particular location in the tissue. As referred to in this document, the average ultrasonic attenuation is assumed to be a 0.3 dB/cm-MHz along the **beam axis** in the body. **Derated** parameters are denoted with a subscript "$_{.3}$".

Symbol: a
Unit: decibel per centimeter - megahertz, dB $cm^{-1}MHz^{-1}$

designated standard mode: Consist of the following specific operating modes: A-mode, B-mode, M-mode, PW Doppler, CW Doppler and Color Doppler.

duty factor: The product of the **pulse duration** and the **pulse repetition frequency** for a pulsed waveform.

entrance beam dimensions: The dimensions of the –12 dB 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.

Symbol: EBD
Unit: centimeter, cm

entrance dimensions of the scan: For **autoscan** systems, 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.

Symbol: EDS
Unit: centimeter, cm

envelope: A smooth curve tangent to and connecting the peaks of successive cycles of a **waveform**.

far field: That region of the field in which the acoustic energy flow proceeds essentially as though coming from a point source located in the vicinity of the **transducer assembly**. (For an unfocused **transducer assembly**, the **far field** is commonly at a distance greater than $S/\pi\lambda$ where S is the **radiating cross-sectional area** and λ is the acoustic **wavelength** in the medium.)

focal surface: The surface which contains the smallest of all **beam cross-sectional areas** of a focusing **transducer assembly**.

Symbol: (none)
Unit: centimeter squared, cm^2

global maximum: The greatest value of a quantity evaluated over all times, over all locations, and over all **operating conditions** for any given operating **mode**.

intensity: The **ultrasonic power** transmitted in the direction of acoustic wave propagation, per unit area normal to this direction, at the point considered. For measurement purposes, this point is restricted to points where it is reasonable to assume that the **acoustic pressure** and particle velocity are in phase, viz., in the **far field** or the area near the **focal surface**.

intensity, instantaneous: The instantaneous **ultrasonic power** transmitted in the direction of acoustic wave propagation, per unit area normal to this direction, at the point considered. It is given in the **far field** by:

$$i = p^2/\rho c$$

where
p is the instantaneous **acoustic pressure**;
ρ is the density of the medium;
c is the speed of sound in the medium.

Symbol: I
Unit: Watt per square-centimeter, W cm^{-2}

intensity, pulse-average: The ratio of the **pulse intensity integral** (energy fluence per pulse) to the **pulse duration**.

Symbol: I_{PA}
Unit: Watt per square-centimeter, W cm^{-2}

intensity, spatial-average temporal-average: For **autoscanning** systems, the **temporal-average intensity** averaged over the **scan cross-sectional area** on a surface specified (may be approximated as the ratio of **ultrasonic power** to the **scan cross-sectional area** or as the mean value of that ratio if it is not the same for each scan); for **non-autoscanning** systems, the **temporal-average intensity** averaged over the **beam cross-sectional area** (may be approximated as the ratio of **ultrasonic power** to the **beam cross-sectional area**.)

Symbol: I_{SATA}
Unit: milliwatt per square-centimeter, mW cm^{-2}

intensity, spatial-peak pulse-average: The value of the **pulse-average intensity** at the point in the acoustic field where the **pulse-average intensity** is a maximum or is a local maximum within a specified region.

Symbol: I_{SPPA}
Unit: Watt per square-centimeter, W cm^{-2}

intensity, spatial-peak temporal-average: The value of the **temporal-average intensity** at the point in the acoustic field where the **temporal-average intensity** is a maximum, or is a local maximum within a specified region.

Symbol: I_{SPTA}
Unit: milliwatt per square-centimeter, mW cm^{-2}

intensity, temporal-average: The time average of **intensity** at a point in space. For **non-autoscan** systems, the average is taken over one or more **pulse repetition periods**. For **autoscan** systems, the **intensity** is averaged over one or more **scan repetition periods** for a specified operating **mode**. For **autoscan mode**s, the average includes contributions from adjacent lines that overlap the point of measurement. For **combined modes** the average includes overlapping lines, from all constituent **discrete operating mode** signals.

Symbol: I_{TA}
Unit: milliwatt per square-centimeter, mW cm^{-2}

intensity, temporal peak: The peak value of the **intensity** at the point considered.

Symbol: I_{TP}
Unit: Watt per square-centimeter, W cm^{-2}

invasive probe: An ultrasound probe that is intended to contact tissue other than intact skin or the surface of the eye. These include transvaginal, transesophageal, transrectal, transurethral, intravascular and intraoperative probes.

mechanical index: 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:

$$MI = p_{r.3}(z_{sp}) \Big/ \left(f_c^{1/2} \right)$$

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

Symbol: *MI*
Unit: Unitless

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

NOTE: Under this definition, FDA considers amplitude Doppler to be a mode.

non-autoscan (**non-autoscanning**): The emission of ultrasonic pulses in a single direction, where scanning in more than one direction would require moving the transducer manually.

operating condition: Any one combination of the possible particular **output control settings** for a **mode**.

output control settings: The settings of the controls affecting the acoustic output of an ultrasound instrument. Such controls would include *but are not limited to* the **power** output control, the focal zone control, and the imaging range control.

Output Display Standard: The *Standard for real-time display of thermal and mechanical acoustic output indices on diagnostic ultrasound equipment*. Revision 2. AIUM/NEMA Standards Publication - UD-3 (AIUM/NEMA 1996).

peak rarefactional pressure; peak negative pressure: Maximum of the modulus of the negative instantaneous **acoustic pressure** in an acoustic field during an acoustic repetition period.

Symbol: p_r or p_-
Unit: megapascal, MPa

power (ultrasonic power): A quantity describing the rate at which acoustic energy travels per unit time in the direction of propagation. Unless stated otherwise, all references to **power** measurements in this standard will be to temporal-average values.

Symbol: W_o
Units: Watts, W

pressure: see **acoustic pressure**.

pulse-average intensity: *see* **intensity**.

Symbol: I_{PA}
Unit: Watt per square-centimeter, W cm^{-2}

pulse duration: 1.25 times the interval between the time when the time integral of **intensity** in an acoustic pulse at a point reaches 10 percent and when it reaches 90 percent of the **pulse intensity integral**.

Symbol: *PD*
Unit: second, s

pulse intensity integral: 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 nonzero. It is equal to the energy fluence per pulse. For a **transducer assembly** operating in a **non-autoscanning mode**, it is equal to the product of **temporal-average intensity** and **pulse repetition period**.

Symbol: *PII*
Unit: Joule per centimeter-squared, J cm^{-2}

pulse repetition frequency: For a pulsed waveform, the number of pulses generated per second.

Symbol: *PRF*
Unit: Hertz, Hz

radiating cross-sectional area: The area of the surface at and parallel to the face of the active transducer element(s) and consisting of all points where the **acoustic pressure** is greater than –12 dB of the maximum **acoustic pressure** in that surface. The area of the active element(s) of the **transducer assembly** may be taken as an approximation for the **radiating cross-sectional area**.

Symbol: *S*
Unit: centimeter squared, cm^2

scan cross-sectional area: for **auto-scanning** systems, the area, on the surface considered, consisting of all points located within the **beam cross-sectional area** of any beam passing through the surface during the scan.

Symbol: (none)
Unit: centimeter squared, cm^2

spatial-average temporal-average intensity: *see* **intensity**.

Symbol: I_{SATA}
Unit: milliwatt per square-centimeter, mW cm^{-2}

spatial-peak pulse-average intensity: *see* **intensity**.

Symbol: I_{SPPA}
Unit: Watt per square-centimeter, W cm^{-2}

spatial-peak temporal-average intensity: *see* **intensity**.

Symbol: I_{SPTA}
Unit: milliwatt per square-centimeter, mW cm^{-2}

superficial: (as used with the musculo-skeletal application) Structures located at a depth of 1.5 cm or less.

temporal-average intensity: *see* **intensity**.

Symbol: I_{TA}
Unit: milliwatt per square-centimeter, mW cm^{-2}

temporal-peak intensity: *see* **intensity**.

Symbol: I_{TP}
Unit: Watt per square-centimeter, W cm^{-2}

thermal index: 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 the **Output Display 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 in the **Output Display Standard** for thermal index categories and formulae.)

Symbol: *TI*
Unit: Unitless

TIS_as: The soft-tissue **thermal index** at surface for **non-autoscanning mode**;

$$TIS\_as = \frac{W_{o1x1} f_c}{210}$$

where
W_{o1x1} is the **bounded-square output power** in milliwatts;
f_c is the **center frequency** in megahertz.

Symbol: *TIS_as*
Unit: Unitless

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.

ultrasonic power: see **power**.

waveform: The graphical characterization of an acoustical or electrical parameter as a function of time.

waveform record: A permanent plot or photograph of a voltage **waveform** for a specific hydrophone when excited under specified conditions.

wavelength: The ratio of the speed of sound in the medium to the **center frequency**.

Symbol: l
Unit: centimeters per cycle, cm $cycle^{-1}$

3.2 LIST OF SYMBOLS

p	=	**acoustic pressure**
BW	=	**bandwidth**
A	=	**beam cross-sectional area**
f_c	=	**center frequency**
a	=	**derating factor**
i	=	**instantaneous intensity**
$\boldsymbol{I_{PA}}$	**=**	**pulse-average intensity**
I_{SATA}	=	**spatial-average temporal-average intensity**
I_{SPPA}	=	**spatial-peak pulse-average intensity**
I_{SPTA}	=	**spatial-peak temporal-average intensity**
I_{TA}	=	**temporal-average intensity**
I_{TP}	=	**temporal-peak intensity**
MI	=	**mechanical index**
$\boldsymbol{p_r}$	**=**	**peak rarefactional pressure**
W_o	=	**power, ultrasonic power**
PD	=	**pulse duration**
PII	=	**pulse intensity integral**
PRF	=	**pulse repetition frequency**
S	=	**radiating cross-sectional area**
TI	=	**thermal index**
TIS_as	=	soft tissue **thermal index** at surface
l	=	**wavelength**

Section 4:
General Information

4.1 INTRODUCTION

This updated guidance is intended to assist the manufacturer in preparing a well organized, concise, and complete 510(k) premarket notification submission to the Center or a third-party reviewing organization. The following are some key elements for consideration:

- The Center will make decisions concerning 510(k) submissions for diagnostic ultrasound devices based on a single submission. The 510(k) submission should contain all the information requested in Sections 4-6 of this Guidance (see 510(k) Diagnostic Ultrasound Screening Checklist, Section 1). All information that requires measurement, calculation, validation, or testing may be derived from prototype devices, unless stated otherwise herein. Information that is provided by reference should supply a specific document number and page.

  Substantial equivalence decisions must be followed by the submission of a post-clearance special report, hereafter referred to as the "**510(k) Special Report**," providing production acoustic output values and other information. The **510(k) Special Report** must be submitted prior to shipping the first device (prior to first customer shipment). It may be included with the original 510(k) submission (please note choice in your cover letter). The manufacturer, distributor, or importer should submit the **510(k) Special Report** (Appendix G) as an "add-to-file" and should reference the manufacturer's 510(k) number.

  The **510(k) Special Report** should contain a list of all transducers cleared under the 510(k). Each transducer should be identified in one of three ways: (1) filed in a previous **510(k) Special Report**, (2) the subject of the current **510(k) Special Report**, or (3) to be filed in a future **510(k) Special Report**. No system or transducer changes or upgrades should be submitted in the **510(k) Special Report** relative to the cleared 510(k) submission. That is, the 510(k) cleared submission and the **510(k) Special Report** should be identical with respect to the ultrasound system and transducers, with the exception of changes in model names or designations, and changes in the final (production) acoustic output values and final labeling.

  Changes in system or transducer model names or designations should be identified clearly in the **510(k) Special Report**, including multiple model names or designations for a single cleared transducer, if applicable. If a transducer has received 510(k) clearance for multiple **modes** or indications for use, and it is intended to market these multiple **modes** or indications for use sequentially, then this intention should be described clearly and completely in the first **510(k) Special Report** filed for that cleared transducer. In this case additional **510(k) Special Reports** need not be filed for the other **modes** or indications for use unless there is a significant change in either the acoustic output tables or the operating instructions regarding acoustic output.

  A **510(k) Special Report** should not be filed to report a single marketed transducer that comprises the combination of two or more cleared transducers. For this situation a new 510(k) application may be submitted, unless use of Appendix E is appropriate. The new 510(k) should consist of new acoustic output tables and labeling unique to the combination with other items included by reference to the previous 510(k)(s).

  510(k) Special Reports that do not conform to the above are unacceptable and will be returned to the submitter.

  NOTE: Acknowledgment of receipt of the 510(k) Special Report does not constitute clearance for marketing of any new device.

A manufacturer may not ship a diagnostic ultrasound device until a 510(k) clearance letter is received from FDA and the **510(k) Special Report** is submitted. If a manufacturer ships a device without first receiving 510(k) clearance and submitting the **510(k) Special Report**, the manufacturer will be in violation of the Food, Drug, and Cosmetic Act. If the **510(k) Special Report** is incomplete or contains unacceptable values (e.g., acoustic output greater than the approved levels), then the 510(k) clearance may not apply to the production units, which then may be considered adulterated or misbranded.

Manufacturers submitting a 510(k) are exempted from submitting an Initial Report under 21 CFR 1002.10 and 1002.12 (Appendix D) for ultrasonic products. Manufacturers are not exempted from the requirements of 21 CFR 1020.10 (Performance Standard for Television Products and subsequent reporting), 21 CFR 1002.20 (Reporting of Accidental Radiation Occurrences), 21 CFR 1003 (Notification of Defects or Failure to Comply) and 21 CFR 1004 (Repurchase, Repair, or Replacement of Electronic Products).

- The 510(k) regulation requires the submission of a new notification for devices already in distribution when the device is significantly changed or modified (21 CFR 807.81(a)(3)). The regulation defines the following changes as significant:

    1. a change that could significantly affect safety or effectiveness, e.g., a significant change in design, materials, energy source, specification or manufacturing; or
    2. a change in intended use.

    The submitter should refer to the CDRH guidance document titled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (FDA, 1997) for guidance in this area.

    The Center will respond to inquiries concerning the need for a new 510(k). These inquiries should be in writing and in sufficient detail so that the Center can make a judgment about the need to submit a 510(k) (See Appendix E).

    NOTE: FDA regulates diagnostic phantoms, QA test objects, and other devices used to test diagnostic ultrasound systems and transducers as Class I Radiologic Quality Assurance Instruments (21 CFR 892.1940). Such devices are exempt from the requirement of 510(k) premarket notification.

- This guidance retains the two-track approach to marketing clearance, Track 1 and Track 3. Track 1 is for devices that do not follow the **Output Display Standard** and therefore have application-specific limits; Track 3 is for devices that conform to the **Output Display Standard**. There is no Track 2.

- Track 1 submissions for devices whose overall acoustic output exceeds application-specific limits (Track 1, Sec. 5) should be supported by laboratory and clinical data demonstrating the need for higher output. These submissions should describe what user-interactive features are provided to enhance user awareness of acoustic output (e.g., on-screen display, power-up default settings, manual override).

- Statistical analyses of measurement or performance data are requested in several sections of the Guidance. See Appendix C for a summary.

4.2 BASIC INFORMATION

The submission should contain a cover letter and a contents page; the major sections of the submission should be tabbed and the numbering scheme should follow this Guidance. The labeling should follow the format provided in Section 4.8.1

NOTE: At the time of writing this guidance, CDRH was in the process of revising the labeling guidance. Submitters should refer to the CDRH web page (www.fda.gov/cdrh) for the latest information.

The submission should contain the following:

4.2.1 Manufacturer's Name:
Address:
Corresponding Official : Title:
Address:
Telephone:

4.2.2 Initial Distributor (if manufacturer is overseas)
Name/Title/Firm:
Address:
Telephone:

4.2.3 Device Name:

4.2.4 Common Name:

4.2.5 Classification
Regulatory Class: II
Review Category: Tier II

	FR Number	Product Code
Ultrasonic Pulsed Doppler Imaging System	892.1550	90-IYN
Ultrasonic Pulsed Echo Imaging System	892.1560	90-IYO
Diagnostic Ultrasound Transducer	892.1570	90-ITX
Other		

4.2.6 Establishment Registration Number:

4.2.7 514 Performance Standards: None

4.2.8 Special Controls: **510(k) Special Report**

4.2.9 Prescription Status: Prescription Device

4.2.10 Manufacturing Location

4.2.11 Sterilization Site(s)

4.2.12 Reason for Submission:

4.2.13 Identification of the TRACK being followed for the submission (Track 1 or Track 3). The cover letter should indicate if the **510(k) Special Report** is included as a separate part of the submission or if it will submitted in the future.

For all 510(k) submissions, as a separate section, you should provide either 1) a “summary of safety and effectiveness” of that information that supports an equivalence determination or 2) a statement that the information supporting an equivalence determination will be made available, by you, upon request (see Appendix F). In addition you should submit a “Truthful and Accurate Statement” and on a separate sheet, the indications for use for your device (see Appendix F and note that the exact wording must be used).

4.3 INDICATIONS FOR USE

Identify all indications for use (new and previously cleared) of the subject device (fill out the indications for use form(s) or equivalent, Appendix F, one for the system and one for each

transducer). Include 510(k) control numbers for the previously cleared indications. This identification should include transducers added under Appendix E and should use different symbols to designate new and old indications. New clinical applications or new **modes** of operation may represent new indications for use and therefore require a new 510(k) (see Appendix E).

4.4 GENERAL DEVICE DESCRIPTION

4.4.1 Provide a general description of the subject device, including (but not limited to) model designation, design, patient contact materials, control panel, and system operation. The following items should be addressed for system operation (as applicable):

4.4.1.1 Describe the transducer operation in each **mode** and **mode** combination, including, but not limited to:

a. the type of transducer (e.g. model designation, mechanical sector, rectangular phased array, curved linear array, annular phased array);

b. size and spacing of element(s), geometrical configuration, total number of elements in the array and array dimensions, as well as the maximum number of active elements for a single pulse, where applicable, and the nominal ultrasonic frequency(ies) of the **transducer assembly**.

4.4.1.2 Describe the operating controls that can cause a change in the radiated field, e.g., gain, **pulse repetition frequency**, transmit focal length, sector angle, image rate, **pulse duration**, depth, and sample volume. For a Track 1 device, describe the operating controls and procedure necessary to change to an application or **mode** that has a higher application-specific acoustic output limit.

4.4.1.3 Describe any unique features or technological characteristics of the subject device. Please refer to Appendix E for examples of the type of information to be submitted.

4.4.1.4 In submissions for a new transducer or a new indication for an existing transducer, provide summary information for all transducers cleared for use with the system, their indications, their **mode**, their **global maximum** output, and the 510(k) control number of the submission(s) where they were cleared.

4.4.1.5 Specify which track is followed in the 510(k) submission. Systems may use transducers that are of different tracks, but a single transducer should be either Track 1 or Track 3 for all applications with a specific model. In some cases, however, exceptions may be considered (e.g., Transcranial Doppler (TCD)).

4.5 PREDICATE DEVICE COMPARISON

4.5.1 Identify comparable predicate device(s) to which the subject device is being claimed substantially equivalent. Identify, if possible, the control number(s) of the 510(k) premarket notifications for the predicate device(s).

4.5.2 The subject device should be compared to the predicate device(s), in terms of key safety and effectiveness features. Discuss the differences and provide supporting data, where applicable. Provide the following (in tabular format wherever possible):

- indication(s) for use;
- general device description (design, patient contact materials, operational characteristics, specifications);
- acoustic output and device settings used;
- general safety and effectiveness; and
- labeling and/or promotional materials (draft documents are acceptable).

4.5.3 Identify any accessories or kits intended for use with the device. For these accessories or kits, provide evidence of the predicate status of the designated comparison device(s); i.e., pre-Amendments or 510(k) control number(s).

4.6 ACOUSTIC OUTPUT REPORTING

Defined in Sections 5 and 6 are the "tracks" a manufacturer of diagnostic ultrasound equipment may follow to demonstrate the substantial equivalence of its ultrasound system with respect to acoustic output. In all cases, the **derated global maximum** acoustic output may not exceed pre-Amendments upper limits; i.e., **derated** $I_{SPTA} \leq 720$ mW/cm^2 and either MI ≤ 1.9 or **derated** $I_{SPPA} \leq 190$ W/cm^2. Note that the **global maximum derated** value is the **global maximum** value *after* derating, and not the **derated** value corresponding to the **global maximum** value measured in water.

In all submissions, the manufacturer should certify that the acoustic output will be or was measured and calculated per the most recent released revision of the *Acoustic Output Measurement Standard for Diagnostic Ultrasound Equipment* (NEMA 1997)**.** Any deviation from the methodologies outlined in NEMA guidance documents should be fully described in terms of the differing methodology used and validating data.

In determining the **global maximum** acoustic output, manufacturers are not expected to include hydrophone measurement uncertainties when reporting **intensity** or MI values, because measurement uncertainties were not included in the guidance levels in the table in Section 5.3. To further clarify this reporting procedure, the uncertainty of the guidance limits is estimated to be +30% for **intensity** and +15% for MI, so a firm does not have to account for its measurement uncertainty as long as that uncertainty does not exceed 30% (or 15%). If the measurement uncertainty does exceed 30% (or 15%), then the guidance values should be reduced accordingly by the amount over 30% (or 15%).

For example, if the **global maximum** hydrophone-determined $I_{SPTA.3}$ was 600 mW/cm^2, and the hydrophone measurement uncertainty for **intensity** was +25%, then the value 600 mW/cm^2 (and not 600 x 1.25 = 750 mW/cm^2) would be compared to 720 mW/cm^2. However, if the hydrophone uncertainty was +35%, then 600 mW/cm^2 would be compared to 720 x (1.30/1.35) = 693 mW/cm^2.

As part of the Device Master Record, Design History File, and Device History Record (21 CFR 820.181, 820.30(j), and 820.184), manufacturers will be responsible for keeping complete documentation of the acoustic output measurement of their transducers. Documentation should include measurement instrumentation & calibration, software, and test results & test protocols. Acoustic output measurements will be performed according to the sampling plan described in the **510(k) Special Report** and compliance will be evaluated as part of Good Manufacturing Practices (GMP's).

4.6.1 Test Methodology Reporting

Provide in the 510(k) either 1) a separate section containing a description of the acoustic output test methodology, or 2) reference to a previously cleared 510(k) or PMA submission that contains an acceptable description of the acoustic output test methodology (include 510(k) or PMA number along with attachment number and/or page numbers). In the latter case, any updates to the test methodology that could affect the comparison with the predicate device should be specifically noted and included in the submission. The test methodology section should contain the following components:

4.6.1.1 Description of measurement instrumentation (e.g., hydrophone type, effective diameter, frequency response, hydrophone amplifier characteristics). Include manufacturers' names and model numbers for commercial devices.

NOTE: With reference to Section 3.3.2 of references AIUM 1997 and NEMA 1997, all measurements of pulsed (i.e., amplitude modulated) **waveforms** that result in reported or labeled acoustic quantities or in output display

indices should be made with a spot-poled membrane hydrophone. Furthermore, the combined ±3 dB frequency response of all components used to condition, amplify, or record the hydrophone **waveform** (but typically excluding the hydrophone itself) should be documented down to at least $f_c/20$. Any deviation from this practice (e.g., due to mechanical interferences) should be described fully in this test methodology section. Non-membrane (e.g., needle-type) hydrophones are acceptable for uses not directly affecting reporting or labeling, such as in quality control measurements.

4.6.1.2 Description of measurement set-up.

4.6.1.3 Description of measurement and calculation procedures, including consistency checks and protocol for assuring that **global maximum** output conditions are identified, especially in **autoscanning** and combined-**mode** situations. This description should include an example calculation of the $I_{SPTA.3}$ in both a **non-autoscanning** and **autoscanning mode**, including a **waveform record** for the **non-autoscanning** case.

4.6.1.4 Description of company protocol for assuring that when either hardware or software changes are made, the effects of these changes on the acoustic output are assessed, and, if necessary, are then measured, documented, and incorporated into the labeling and, if applicable, output display.

4.6.1.5 Description of any procedures used to correct for spatial averaging by the hydrophone, if applicable. See, e.g., (Zeqiri et. al. 1992).

4.6.1.6 Description of calibration procedures for measurement instruments.

4.6.1.7 Assessment of systematic and random uncertainties associated with measurement or calculation of the **ultrasonic power**, **pressure**, **intensities**, and **center frequency**, including a brief description of all relevant error sources considered and an explanation of how the overall uncertainty was determined. See Appendix C, item 2.

4.6.1.8 Description of protocol for assuring substantial equivalence to a predicate device regarding acoustic output (e.g., reject limits in production in comparison to output levels in Section 5.3). If 100% testing is performed, confirm that the test protocol in 4.6.1.3 above is used or describe the correlation between acoustic output and sensitivity or other measurable parameter(s). If 100% testing is not performed, include a description of the statistical sampling plan used to ensure that production units will not exceed the **global maximum** acoustic output limits specified in the guidance. Typically this plan will comprise the one-sided tolerance limit for normal distributions. See Appendix G, Sec. E5. For this plan, provide the values of γ and P. Justify values less than $\gamma = 0.9$ and P=0.9.

4.7 GENERAL CLINICAL SAFETY AND EFFECTIVENESS

4.7.1 Clinical Measurement Accuracy and System Sensitivity

4.7.1.1 Identify and describe the various clinical (biometric) measurements that may be performed with the subject device.

4.7.1.2 For each transducer/**mode** combination, give the accuracy of any measurement (e.g., distance, volume, heart rate, Doppler frequency shift, velocity, indices, etc.) that can be made in that **mode**, and the range over which this accuracy can be expected to be maintained. Describe and justify the test methodology (e.g., laboratory phantom) used to determine each accuracy. With regard to Doppler accuracy, please note that electronic phantom data are not acceptable. One example of an acceptable test is to use a Doppler string phantom, and to provide a plot for each transducer of measured versus actual velocity with error bars for at least ten velocity values over the range of velocity values specified in the labeling.

4.7.1.3 For each probe/**mode** combination, a minimum performance specification of the Doppler sensitivity, where the Doppler sensitivity is defined according to Appendix A, shall be provided in the 510(k). Data validating the specification shall be included in the Device Master Record and submitted in the **510(k) Special Report**. For certain special cases or claims, clinical data or special phantom testing may be more appropriate.

4.7.2 Thermal, Mechanical, and Electrical Safety

4.7.2.1 Provide either a **declaration of conformity** to a CDRH recognized standard, or data showing that your system has been designed to be thermally, electrically, and mechanically safe. You may include descriptions, safety precautions, testing and data to support the electrical and mechanical safety of your device and identify applicable voluntary standards to which the system conforms or supply third party certification that your device meets an acceptable standard. We recognize IEC 60601-1, UL 2601 (future), UL544 (electrical only), CSA C22.2 No. 125 (electrical only), and BSI 5724 (electrical only).

4.7.2.2 Describe the means used to limit the surface heating of **invasive probes** to no more than 43 C in the event of a device malfunction.

4.7.3 Patient Contact Materials

4.7.3.1 Provide the trade name and generic material composition (polyethylene, polycarbonate, silastic, etc.) of all patient contact materials or provide the Master File number that contains the material description.

4.7.3.2 Provide biocompatibility testing results for tests conducted according to the ISO-10993-1 Standard for any patient contact materials. For materials, probes, components and accessories that have been previously cleared for the same or more critical tissue contact, biocompatibility data need not be provided if the sponsor certifies that the patient contact materials are unchanged in formulation and processing from the previously cleared device.

4.7.4 Cleaning, Disinfection, Sterilization, and Pyrogenicity

4.7.4.1 If the transducer is supplied non-sterile or is intended to be reused, provide recommended procedures to clean and disinfect the transducer between uses. These recommended procedures should be validated by you and a summary of your validation procedures provided in the submission (see Appendix B). Alternatively, you may recommend the use of a cleared liquid sterilant or disinfectant product with instructions to follow the labeling.

a. The level of disinfection or sterilization should be appropriate for the intended clinical use. Indicate the target sterility assurance level (SAL) that should be reached by following the recommended procedures.

b. Any recommended disinfecting or sterilizing agents must be registered with the Environmental Protection Agency (EPA) and approved by FDA.

4.7.4.2 For device components or accessories provided sterile to the user, provide the following information:

a. the method of sterilization and a description of the method used to validate the sterilization cycle;

b. the SAL (sterility assurance level) intended (at least 10^{-6}) for the device;

c. a description of the packaging system used to maintain device sterility;

d. if the device is sterilized using ethylene oxide, the maximum levels of residues of ethylene oxide, ethylene chlorohydrin and ethylene glycol; and

e. if the device is radiation sterilized, the radiation dose used to achieve sterility.

4.7.4.3 If the device is labeled pyrogen-free, provide a description of the method (standard method) used to assess pyrogenicity. Sheaths that contact brain tissue must be pyrogen free.

4.7.5 Software/Firmware

Software that governs the operation of diagnostic ultrasound equipment is a minor level of concern, as described in its *Reviewer Guidance For Computer Controlled Medical Devices Undergoing 510(k) Review* (FDA 1991). The rationale for this is the potential for injury possible to a patient in the event of software/firmware failure, both direct (i.e., inappropriate delivery of electrical, thermal, or acoustic energy) and indirect (i.e., inappropriate physician action based on inaccurate diagnostic information), is not likely to be major or life threatening.

Provide a full description of the software/firmware supporting the operation of the subject device per FDA's Reviewer Guidance (FDA 1991), commensurate with the minor level of concern. This guidance applies to original systems, as well as to any software/firmware changes made to already-marketed devices. Changes to software should be revalidated and reverified. FDA recognizes that many of these ultrasound systems have a variety of software modules controlling many different functions, and that the level of concern for a particular module may vary. With appropriate justification, a manufacturer may provide different levels of documentation for different modules.

Your 510(k) submission should provide the following:

1. a summary description of new or altered algorithms and explain why they are suitable for the chosen task;
2. the software version number;
3. a software structural chart;
4. a system hazard analysis;
5. a listing of the specific hardware/software requirements;
6. a summary of the software design and development process including the software change management process;
7. a summary of software verification and validation processes and
8. a summary of what future testing will demonstrate and what has been completed up to the time of the submission.

4.8 LABELING

4.8.1 Provide draft operator's manuals and any promotional materials that describe the system and associated transducers (maintenance manuals, etc. are not necessary). Labeling for all diagnostic ultrasound equipment should comply with 21 CFR 801.109. Manufacturers are encouraged to consult with FDA's manual, "Labeling: Regulatory Requirements for Medical Devices" (FDA 1989). In general labeling should contain:

a) a description of the device indications for use,

b) contraindications,

c) warnings,

d) precautions,

e) adverse effects,

f) instructions for use,

g) summaries of clinical studies and

h) references.

4.8.1.1 Indications for use, contraindications, warnings, and precautions should be clearly stated. This includes (but is not limited to):

a) a precaution to perform a given ultrasound procedure prudently using the principle of ALARA (as low as reasonably achievable);

b) a statement, where applicable, cautioning that the device is "not intended for fetal use" (either in the operator's manual, individual transducer manuals, or on-screen labeling); and

c) a description of the means used to limit the surface heating of **invasive probes** to no more than 43 C in the event of a device malfunction.

At present, you may not promote or market your device for use in the following clinical applications:

- percutaneous umbilical blood sampling (PUBS)
- *in vitro* fertilization (IVF)

Specific diagnostic claims must be supported by appropriate data.

For new clinical or technological changes, it is advisable to check with the Office of Device Evaluation for guidance on the data necessary to support such changes.

4.8.1.2 Clinical instructions for the use of the device should be provided in either the system or transducer operator's manual. Indications for use should be specified.

4.8.1.3 Identify the device's compatible device accessories, kits and components in the operator's manuals. Provide the specifications for these accessories. Where use of probe sheaths is recommended, the user should be referred to FDA's Medical Alert on latex products (FDA 1991).

4.8.1.4 Provide the accuracy of each clinical measurement possible with the device and the range over which this accuracy can be expected to be maintained.

NOTE: The accuracy range possible for Doppler applications cannot exceed the range measured under 4.7.1.2.

4.8.1.5 Provide draft acoustic output labeling in the operator's manual, per Sec. 5.2 (Track 1) or Sec. 6.2 (Track 3).

4.8.1.6 Provide instructions for care of the device between uses, including storage, cleaning, disinfection, and sterilization of all components, as appropriate.

a) Labeling should recommend the use of sterile, when appropriate, market-cleared probe sheaths, for clinical applications of a semi-critical or critical nature (i.e., intraoperative, transrectal, transvaginal, transesophageal, biopsy procedures).

b) When recommending a procedure that uses a cleared liquid disinfecting or sterilizing agent, refer the user to the labeling instructions provided by the manufacturer of that product. At least one recommended procedure should use a cleared agent, if feasible. The ultrasound manufacturer will not need to validate these processes if they refer the user to the manufacturer's instructions.

c) When recommending a procedure other than liquid disinfection or sterilization, detailed instructions should be provided. These procedures should have been

validated and a summary of the validation process and representative data submitted as part of the 510(k) submission.

4.8.1.7 Additional labeling may be necessary to address safety and effectiveness concerns, depending upon the clinical application(s) of the transducer; e.g., transcranial, transesophageal, intraoperative, transvaginal, ophthalmic, or vascular diagnostic systems.

Neurological intraoperative probes (i.e., when the probe makes contact with the dura or any intracranial tissues) should have the following additional labeling. There should be a recommendation to use sterile, pyrogen-free sheaths. In addition, a caution should warn the user of a potential problem in using the probe on patients with Creutzfeld-Jacob disease. If the probe becomes contaminated, it may have to be destroyed since it may not be adequately disinfected (CDC 1997).

4.8.1.8 References to literature should be included, where appropriate.

NOTE: Techniques, methods, and indications given in such literature may represent intended use(s) of the subject device and may need to be supported by clinical data.

Section 5:

Track 1 Specific Information

Track 1 is for diagnostic ultrasound systems that do not conform to the **Output Display Standard** or are not indicated for any fetal Doppler applications (except for fetal heart rate monitors, Section 5.1.3). Track 1 submissions are evaluated in relation to application-specific acoustic output limits. Systems that exceed application-specific limits are evaluated on a case-by-case basis. See Section 5.4 for a logic flow chart.

5.1 TRACK 1 - ACOUSTIC OUTPUT REPORTING

Track 1 reporting is based on application-specific comparisons to pre-Amendments output levels given in Section 5.3. Measurements for each transducer should be made at the highest output setting available for use.

NOTE: For each transducer, the system should operate in such a way that a conscious and deliberate action is required to change to an application or **mode** that has a higher application-specific acoustic output limit. Otherwise, output measurements should be made for the application having the highest application-specific limit. (See Section 4.4.1.2.)

5.1.1 Summarize the **mode**/application possibilities for each system/transducer combination by completing the table given in Section 5.5. For each possible **mode**/application identified, specify the target range of values for the MI or $I_{SPPA.3}$ and $I_{SPTA.3}$ under the **operating conditions** that maximize these quantities, noting that the upper bound must not be greater than the appropriate application specific value listed in Section 5.3. Also provide the engineering basis for the range of values specified (e.g., preliminary or prototype measurements, theoretical calculations, estimates based on measurements of previously cleared transducers).

5.1.2 If the manufacturer wishes to submit the **510(k) Special Report** as part of the 510(k), it should be included as a completely separate section and this election should be noted in the 510(k) cover letter. The **510(k) Special Report** should follow the format described in Appendix G.

5.1.3 This guidance amends Section VI of the "510(k) Guide for Measuring and Reporting Acoustic Output of Diagnostic Ultrasound Medical Devices" (FDA 1985) regarding continuous fetal heart rate (FHR) monitoring with low-**power** unfocused CW Doppler transducers. The pre-1976 I_{SATA} at the transducer face is 20 mW/cm^2 for CW Doppler FHR monitors. A simple conservative approach for pulsed Doppler FHR monitors is to use 20 mW/cm^2 as a limit for the spatial-average pulse-average intensity at the transducer face. For such transducers, two estimates are made:

a) **duty factor** (DF) = **pulse duration** x **pulse repetition frequency**

b) I_{SATA} @ Transducer Face = **Ultrasonic Power** / Area Corresponding to **entrance beam dimensions**

If the I_{SATA} @ Transducer Face / DF is less than 20 mW/cm^2, then the transducer's acoustic output is below pre-Amendments levels for the type of ultrasound transducer, i.e., 20 mW/cm^2. If this value is higher than 20 mW/cm^2, you may consult with CDRH about the appropriate measurements that need to be made.

5.1.4 For any transducer intended for transcranial (cephalic) applications, in which the $I_{SPTA.3}$ exceeds 94 mW/cm^2, provide an estimate of maximum temperature rise (TR) attributable to the use of that transducer for each operating **mode**. Describe the model used to determine the estimation. This model should account for heating of skull bone. An acceptable model for making these estimates can be found in Section 6 of the **Output Display Standard**, entitled "Measurement Methodology for Mechanical and Thermal Indices."

NOTE: When $I_{SPTA.3}$ exceeds 94 mW/cm^2, this application requires special labeling in the form of on-screen precautions about scanning through the eye, burrholes, fontanelles, or foramen magnum.

5.2 TRACK 1 - ACOUSTIC OUTPUT LABELING IN THE OPERATOR'S MANUAL

5.2.1 Provide tables of the **global maximum** acoustic output values for each possible system/transducer/**mode**/application combination, per Sec. 5.5 and 5.6. The tables for the 510(k) submission need not be completed, but the different table formats (e.g., **non-autoscanning mode**, **autoscanning mode**) to be used should be submitted, along with the description of symbols. The labeling (submitted in the **510(k) Special Report**) for the marketed device, however, should contain the full set of complete acoustic output tables, along with the corresponding **operating conditions** and the measurement uncertainties for acoustic quantities (**power**, **pressure**, **intensities**, **center frequency**).

NOTE: Both the MI and the $I_{SPPA.3}$ must be reported in Tables 5-3 and 5-4, although the latter normally will not be used to make SE decisions.

5.2.2 Provide an explanation of how **derated intensities** were derived from **intensities** measured in water.

5.2.3 Provide an explanation of the interactive system features that affect acoustic output (see Section 4.4.1.2). Provide suggestions on how to use these features to follow the ALARA principle. For transducers that exceed application specific acoustic output limits, or for transducers for which more than one application-specific acoustic output limit applies, describe what user-interactive features are provided to enhance user awareness of acoustic output (e.g., on-screen display, power-up default settings, manual override, warnings).

5.3 TRACK 1 - PRE-AMENDMENT ACOUSTIC OUTPUT LEVELS

Table 5-1 lists the highest known acoustic field emissions as recognized by the FDA for pre-Amendments diagnostic ultrasound devices. The **intensity** values are **derated**. The **derating** algorithm is described in Appendix D of the "510(k) Guide for Measuring and Reporting Acoustic Output of Diagnostic Ultrasound Medical Devices" (FDA 1985).

5.4 TRACK 1 - FLOW CHART

A flow chart illustrating the decision tree, with respect to acoustic output, for Track 1 is illustrated in Figure 5-1.

5.5 TRACK 1 - SUMMARY TABLE

A manufacturer following Track 1 should complete Table 5-2 below for each system/transducer combination. For each **mode**/application checked in the table below, the appropriate acoustic output table should be completed. If the acoustic output of an "other" **mode** is the same (within the manufacturer's stated measurement uncertainty) as that of a **designated standard mode**, then only one acoustic output table need be completed for both **modes**. However, the acoustic output table should be identified as applying to both **modes**.

Table 5-1: Pre-Amendments Acoustic Output Levels

use	$I_{SPTA.3}$ (mW/cm^2)	$I_{SPPA.3}$ (W/cm^2)	MI
Peripheral Vessel	720	190	1.9
Cardiac	430	190	1.9
Fetal Imaging & Other*	94	190	1.9
Ophthalmic	17	28	0.23

* Abdominal, Intraoperative, Pediatric, Small Organ (breast, thyroid, testes, etc.), Neonatal Cephalic, Adult Cephalic

$I_{SPTA.3}$ = **Derated Spatial-Peak Temporal-Average Intensity**
$I_{SPPA.3}$ = **Derated Spatial-Peak Pulse-Average Intensity**
MI = **Mechanical Index**

NOTE: for purposes of acoustic output limits:

a) transesophageal for non-cardiac use, intravascular, and musculo-skeletal applications are included in the "Fetal Imaging & Other" category;

b) cardiac use includes transthoracic adult and pediatric uses as well as transesophageal adult and pediatric uses for visualization of the heart;

c) peripheral vessel use included vessels of the neck; and

d) cephalic and transcranial are synonymous.

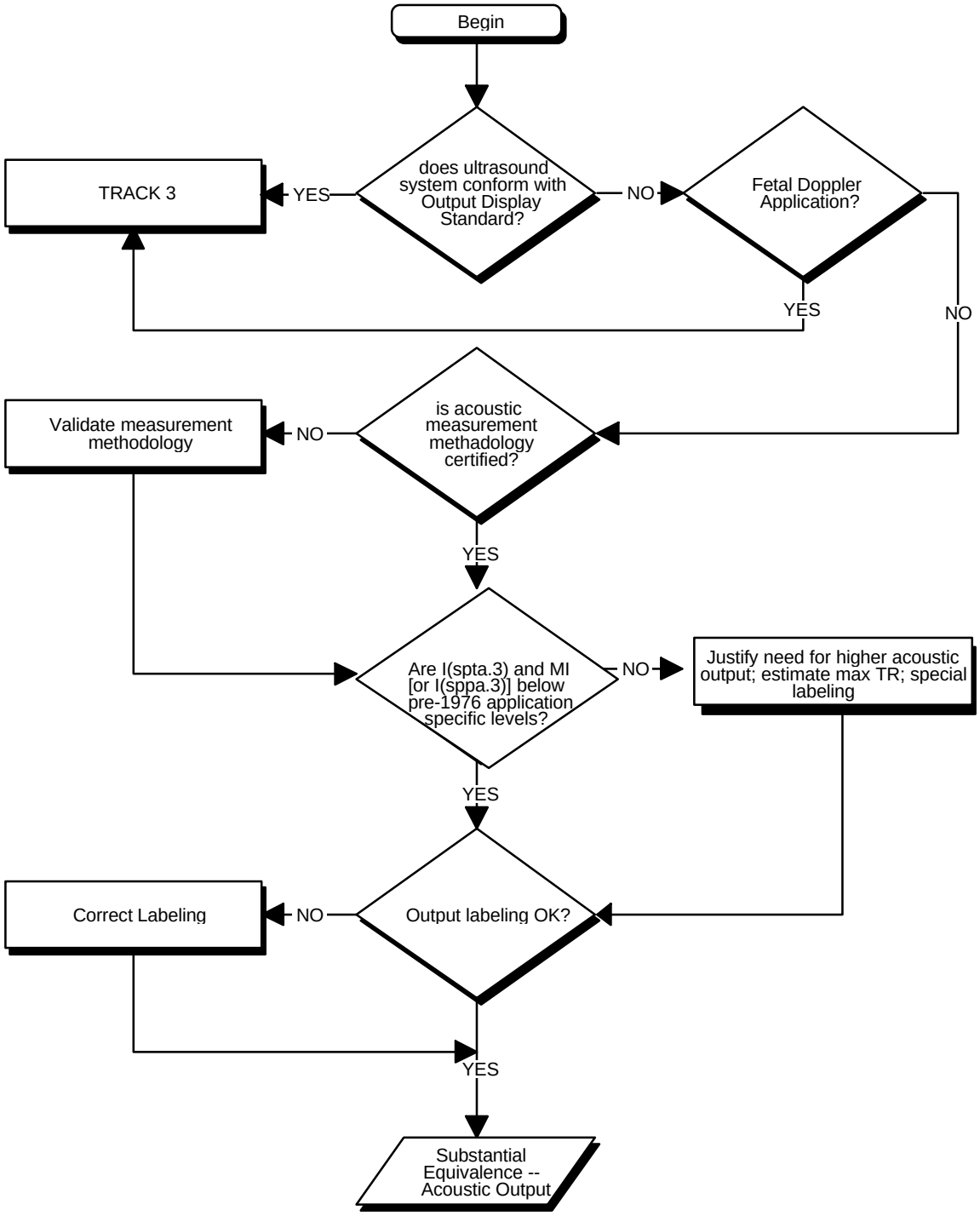
Table 5-2: Track 1 Summary Table

Clinical Application	Operating **Mode**(s) A	B	M	PWD	CWD	CD	Combined (Specify)	Other† (Specify)
Ophthalmic	_____	_____	_____	_____	_____	_____	_____	_____
Fetal Imaging & Other*	_____	_____	_____	_____	_____	_____	_____	_____
Cardiac, Adult & Pediatric	_____	_____	_____	_____	_____	_____	_____	_____
Peripheral Vessel	_____	_____	_____	_____	_____	_____	_____	_____

* Abdominal, Intraoperative, Pediatric, Small Organ (breast, thyroid, testes, etc.), Neonatal Cephalic, Adult Cephalic, Musculo-Skeletal (**conventional**), Musculo-Skeletal (**superficial**)

† Examples may include: Amplitude Doppler, 3-D Imaging, Harmonic Imaging, Tissue Motion Doppler, Color Velocity Imaging.

Figure 5-1: Track 1 Decision Tree Flow Chart



5.6 TRACK 1 - ACOUSTIC OUTPUT REPORTING TABLE

All entries in Table 5-3 should be obtained at the same **operating conditions** that give rise to the **global maximum derated intensity** or MI value in the second row.

These **operating conditions** should be specified.

Symbols used in the table are described below.

$I_{SPTA.3}$ the **derated spatial-peak temporal-average intensity** (milliwatts per square centimeter).

$I_{SPPA.3}$ the **derated spatial-peak pulse-average intensity** (watts per square centimeter). The value of $I_{PA.3}$ at the position of **global maximum** MI ($I_{PA.3}$@MI) may be reported instead of $I_{SPPA.3}$ if the **global maximum** MI is reported.

MI the **Mechanical Index**. The value of MI at the position of $I_{SPPA.3}$, (MI@$I_{SPPA.3}$) may be reported instead of MI (**global maximum** value) if $I_{SPPA.3}$ is $\leq 190 W/cm^2$.

$p_{r.3}$ the **derated peak rarefactional pressure** (megapascals) associated with the transmit pattern giving rise to the value reported under MI.

W_o the **ultrasonic power** (milliwatts). For the **operating condition** giving rise to $I_{SPTA.3}$, W_o is the total time-average **power**; for the **operating condition** subject to reporting under $I_{SPPA.3}$, W_o is the **ultrasonic power** associated with the transmit pattern giving rise to the value reported under $I_{SPPA.3}$.

f_c the **center frequency** (MHz). For MI and $I_{SPPA.3}$, f_c is the **center frequency** associated with the transmit pattern giving rise to the **global maximum** value of the respective parameter. For $I_{SPTA.3}$, for combined **modes** involving beam types of unequal **center frequency**, f_c is defined as the overall range of center frequencies of the respective transmit patterns.

z_{sp} the axial distance at which the reported parameter is measured (centimeters).

x_{-6}, y_{-6} are respectively the in-plane (azimuthal) and out-of-plane (elevational) -6 dB dimensions in the x-y plane where z_{sp} is found (centimeters).

PD the **pulse duration** (microseconds) associated with the transmit pattern giving rise to the reported value of the respective parameter.

PRF the **pulse repetition frequency** (Hz) associated with the transmit pattern giving rise to the reported value of the respective parameter.

EBD the **entrance beam dimensions** for the azimuthal and elevational planes (centimeters).

EDS the **entrance dimensions of the scan** for the azimuthal and elevational planes (centimeters).

Measurement uncertainties for acoustic quantities (**power**, **pressure**, **intensities**, **center frequency**) should be provided.

Table 5-3
Acoustic Output Reporting Table for Track 1
Non-Autoscanning Mode

Transducer Model: _____ **Operating Mode:** _____
Application(s): _____

Acoustic Output			**MI**	**$I_{SPTA.3}$** (mW/cm^2)	**$I_{SPPA.3}$** (W/cm^2)
Global Maximum Value					
Associated Acoustic Parameter	$p_{r.3}$	(MPa)			
	W_o	(mW)			
	f_c	(MHz)			
	z_{sp}	(cm)			
	Beam dimensions	x_{-6} (cm)			
		y_{-6} (cm)			
	PD	(µsec)			
	PRF	(Hz)			
	EBD	Az. (cm)			
		Ele. (cm)			
Operating Control Conditions	Control 1				
	Control 2				
	Control 3				
	Control 4				
	Control n				

Table 5-4
Acoustic Output Reporting Table for Track 1
Autoscanning Mode

Transducer Model: _____ **Operating Mode:** _____
Application(s): _____

Acoustic Output			**MI**	$I_{SPTA.3}$ (mW/cm^2)	$I_{SPPA.3}$ (W/cm^2)
Global Maximum Value					
Associated Acoustic Parameter	$p_{r.3}$ (MPa)				
	W_o (mW)				
	f_c (MHz)				
	z_{sp} (cm)				
	Beam dimensions	x_{-6} (cm)			
		y_{-6} (cm)			
	PD (µsec)				
	PRF (Hz)				
	EDS	Az. (cm)			
		Ele. (cm)			
Operating Control Conditions	Control 1				
	Control 2				
	Control 3				
	Control 4				
	Control n				

Section 6:

Track 3 Specific Information

Track 3 is for diagnostic ultrasound systems that follow the **Output Display Standard**. Systems that include fetal Doppler applications, except for fetal heart rate monitors, should follow Track 3. Track 3 does not apply to systems for which a display would be required but which have fixed acoustic output. Under Track 3, acoustic output will not be evaluated on an application-specific basis, but the **global maximum derated** I_{SPTA} must be ≤ 720 mW/cm^2 and either the **global maximum** MI must be ≤ 1.9 or the **global maximum derated** I_{SPPA} must be ≤ 190 W/cm^2. An exception is for ophthalmic use, in which case the TI = max.(**TIS_as**, TIC), and is not to exceed 1.0; $I_{SPTA.3}$ ≤ 50 mW/cm^2, and MI ≤ 0.23. See Sec. 6.4 for a logic flow chart.

6.1 TRACK 3 - ACOUSTIC OUTPUT REPORTING

The Track 3 approach is based upon conformance with the **Output Display Standard**. This approach eliminates the application-specific comparison of acoustic output to pre-Amendments levels.

6.1.1 Summarize the operating **mode** possibilities for each system/transducer combination by completing the form given in Section 6.5. For each possible transducer/**mode** identified, specify the target range of values for the MI or $I_{SPPA.3}$ and $I_{SPTA.3}$ and an estimated range of TI's, under the **operating conditions** that maximize these quantities, noting that the upper bound must not be greater than the **global maximum** values given at the top of this page. Also provide the engineering basis for the range of values specified (e.g., preliminary or prototype measurements, theoretical calculations, estimates based on measurements of previously cleared transducers).

6.1.2 Provide certification:

1) that the ultrasound system will be designed and marketed in conformance with the **Output Display Standard;**

2) that measurements of acoustic output display indices - the **Thermal Index** (TI) and the **Mechanical Index** (MI) - will be made per Section 6 of the **Output Display Standard** entitled "Measurement Methodology for Mechanical and Thermal Indices" and

3) that information supplied in the 510(k) will be for **global maximum** TI and MI values.

6.1.3 If the manufacturer wishes to submit the **510(k) Special Report** as part of the 510(k), it should be included as a completely separate section and this election should be noted in the 510(k) cover letter. The **510(k) Special Report** should follow the format described in Appendix G.

6.1.4 Specify the default setting levels (e.g.: as a percentage of the maximum levels) and the rationale for selecting these default values. See Section 5 of the **Output Display Standard**.

NOTE: A default setting yielding maximum acoustic output would not be considered appropriate for implementing ALARA.

6.1.5 Provide a justification for any **Thermal Index** that exceeds a value of 6.0.

6.1.6 If no system/transducer combination is capable of exceeding either a TI of 1.0 or an MI of 1.0 in any operating **mode**, then completion of the Track 3 acoustic output tables (Table 6-3) in Sec. 6.6 is not necessary. However, in their place the **global maximum** values of the $I_{SPTA.3}$, TI (TIS, TIB, or TIC), MI, and $I_{PA.3}$ @ MI_{max}, should be specified (see Table 6-1). Details of the calculations should be included in the Device Master Record.

Table 6-1

Track 3 Acoustic Output Reporting Table
(for systems with no probes having **global maximum** index values exceeding 1.0)

Probe Model	$I_{SPTA.3}$	TI type	TI value	MI	$I_{PA.3}@MI_{max}$

6.2 TRACK 3 - ACOUSTIC OUTPUT LABELING IN THE OPERATOR'S MANUAL

6.2.1 Provide tables of the **global maximum** acoustic output indices for each possible system/transducer/**mode** combination, per Sections 6.5 and 6.6. The tables for the 510(k) submission need not be completed, but the different table formats to be used should be submitted, along with the description of symbols. The labeling (submitted in the **510(k) Special Report**) for the marketed device, however, should contain the full set of complete acoustic output tables, along with the corresponding **operating conditions** and the measurement uncertainties for acoustic quantities (**power**, **pressure**, **intensities**, **center frequency**).

Three examples for the Track 3 Acoustic Output Reporting Tables are given in section 6.7, *Track 3 - Reporting Table Examples*. These are provided to illustrate the use of the four footnotes (a, b, c, #).

6.2.2 Provide an explanation of the real-time display features and controls of the system, including default settings (see Sec. 6.1.4). Provide suggestions on how to use these features and controls to follow the ALARA principle.

NOTE: If the intended uses include neonatal cephalic, then the provisions of the **Output Display Standard** are interpreted to mean that all three thermal indices (TIS, TIB, TIC) must be available to be called up by the user, although all three indices are not required to be displayed *simultaneously*. In this regard, please see page 39 in the AIUM publication, "Medical Ultrasound Safety" (AIUM 1994).

6.2.3 Provide the display accuracy and measurement precision. See Sections 4.2, 4.2.1, and 6.4 of the **Output Display Standard** .

6.2.4 If no system/transducer combination in a Track 3 device is capable of exceeding either a TI of 1.0 or an MI of 1.0 in any operating **mode**, then provide the **global maximum** values, for each transducer, of $I_{SPTA.3}$, TI, MI, and $I_{PA.3}$ @ MI_{max}. See Sec. 6.1.6.

6.3 TRACK 3 - EDUCATION PROGRAM

6.3.1 Provide an ALARA education program for the clinical end-user that covers the subjects listed below. ALARA is an acronym for the principle of prudent use of diagnostic ultrasound by obtaining the diagnostic information at an output that is as low as reasonably achievable. This education program should include explanations of:

a) the basic interaction between ultrasound and matter,

b) the possible biological effects,

c) the derivation and meaning of the indices,

d) a recommendation to use and the need for following the ALARA principle in all studies, and

e) clinical examples of specific applications of the ALARA principle.

A document published by the AIUM, "Medical Ultrasound Safety" (AIUM, 1994), is acceptable to FDA as meeting the generic content of the educational program. The manufacturer also should provide information specific to its device regarding ALARA.

6.3.2 Minimum Requirements for Educational Material for Track 3 Devices

6.3.2.1 Bioeffects and Biophysics of Ultrasound Interactions

- Brief description of ultrasound, diagnostic frequencies, energy levels
- Brief description of the change in policy which requires user education
- Short history of ultrasound use and safety record
- Potential hazards at high output levels
- Biological effect mechanisms--Thermal, Mechanical
- Exposure-effect studies (range of outputs)
- Risk versus benefit
- Present state of output levels--higher than historical levels
- Proposed indices as indicators of thermal and mechanical effects

6.3.2.2 Thermal Mechanisms

- Describe thermal bioeffects--temperature rise
- Tissue type (soft, bone, fluid) and relative absorption
- Transducer type (frequency, focusing) and relationship to exposure
- Attenuation, absorption, scattering mechanisms in different tissue types
- Spatial volume of insonified tissue (at focus, or elsewhere)
    - Homogeneity of tissue in insonified volume (effects of layering)
    - oft tissue
    - bone tissue (fetal, skull, other)
    - fluids, gas

6.3.2.3 Nonthermal Mechanisms

- Describe mechanical effects--cavitation & role of bubbles
- Factors which produce cavitation:
    - **pressure** (compressional, **rarefactional**)
    - frequency
    - beam focusing
    - pulsed/continuous
    - standing waves
    - boundaries
    - type of material and ambient conditions
- Types of cavitation:
    - stable and inertial cavitation
    - microstreaming
    - nucleation sites
- Threshold phenomena for different types of tissues
- Bioeffects data on animals (lung hemorrhage, intestinal hemorrhage)

6.3.2.4 Benefits of Ultrasound vs. Risk

- Benefits of use
- Risk of use
- Risk of not using ultrasound
- Increase in risk as acoustic output increases

- Increase in diagnostic information as acoustic output increases
- Increase in responsibility for user at higher output levels
- The ALARA principle
    - controlling energy
    - controlling exposure time
    - controlling scanning technique
    - controlling system setup
    - effects of system capabilities
    - effects of operating **mode** (learn to distinguish)
    - effects of transducer capabilities

6.3.2.5 The **Output Display Standard**

- **Purpose:** To display exposure indices
- **Mechanical Index** (MI)
- **Thermal Index** (TI)
    - Soft Tissue **Thermal Index** (TIS)
    - Bone **Thermal Index** (TIB)
    - Cranial Bone **Thermal Index** (TIC)
    - Thresholds for display of indices
        - (e.g., if system can exceed TI or MI of 1.0)
- System display levels
    - (e.g., minimum TI displayed, minimum MI displayed, display increments)
- Explanation of the meaning of the TI and MI
    - threshold bioeffect levels vary depending on tissue type
    - bioeffect levels vary depending on frequency, **pressure**

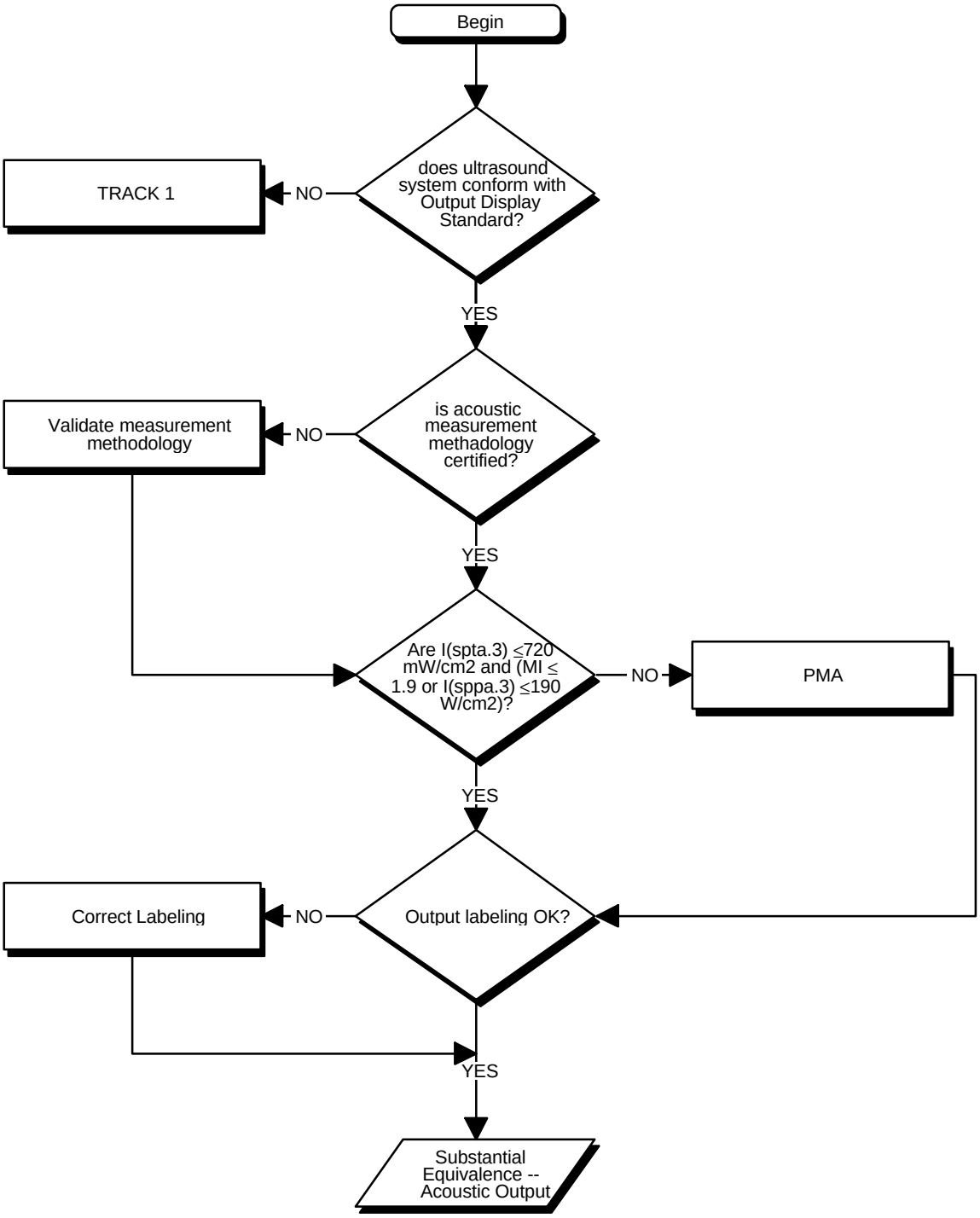
6.3.2.6 Practicing the ALARA Principle

- How to implement ALARA by using the TI and MI indices
- Knowledge of system controls versus acoustic output
    - Overall gain and TGC versus increasing output
    - Dynamic range and post-processing versus increasing output
- Knowledge of system applications versus output
    - selection of appropriate range for task
- Knowledge of transducer effects on output
    - frequency
    - focusing
    - pulse length
    - dwell time (scanned versus unscanned)
- Knowledge of system operating **mode** versus output
    - B **mode**
    - Doppler (spectral, color flow, amplitude Doppler)
    - M **mode**
- Control exposure time
- Use the minimum possible to obtain information
- Clinical application examples--which indices are most important?
    - fetal, cranial
    - fetal, Doppler
    - Adult thyroid
    - Adult carotid Doppler

6.4 TRACK 3 - FLOW CHART

Figure 6-1 is a flow chart illustrating the decision tree, with respect to acoustic output, for Track 3.

Figure 6-1: Track 3 Decision Tree Flow Chart



6.5 TRACK 3 - SUMMARY TABLE

For a Track 3 submission, complete the table below for each transducer/**mode** combination. Indicate with a check the transducer/**mode** combinations for which the **global maximum** displayed MI or TI is greater than 1.0. For each transducer/**mode** combination checked, a Track 3 acoustic output table should be completed. Also, see Sec. 6.2.4.

Table 6-2: Track 3 Summary Table

Operating **Mode**	Transducer Model:					
B-**mode**						
M-**mode**						
Pulsed Doppler						
CW Doppler						
Color Doppler						
Combined (specify)						
Other (specify)*						

*Examples may include: Amplitude Doppler, 3-D Imaging, Harmonic Imaging, Tissue Motion Doppler, Color Velocity Imaging.

For reporting purposes, the following **mode** definitions and reporting rules apply:

B **Mode**: No other **modes** active.
Only MI (when > 1.0) need be reported for this **mode**.

M **Mode**: May include simultaneous B **mode**.

PW Dop./CW Dop.: In duplex **modes**, report largest displayed TIS (scanned or non-scanned) if > 1.0.

Color Flow: May include simultaneous Color Flow M-**mode**, B-**mode** and M **mode**. In combined **modes**, report largest displayed TIS (scanned or non-scanned) if > 1.0.

Combined **modes**: Need only be reported as a separate **mode** if the largest formulation of TIS, TIB or TIC (if there is an applicable intended use; e.g., transcranial or neonatal cephalic) is greater than the corresponding value reported for all constituent **modes**.

TIC need not be reported if the probe is not intended for transcranial or neonatal cephalic use.

If the acoustic output of an “other” **mode** is the same (within the manufacturer’s stated measurement uncertainty) as that of a **designated standard mode**, then only one acoustic output table need be completed for both **modes**. However, the acoustic output table should be identified as applying to both **modes**.

6.6 TRACK 3 - ACOUSTIC OUTPUT REPORTING TABLE

All entries in Table 6-3 should be obtained at the same **operating conditions** that give rise to the **global maximum** Index Value in the second row.

These **operating conditions** should be specified.

Symbols used in the table are described below.

MI the **Mechanical Index**.

TIS_{scan} the Soft Tissue **Thermal Index** in an **auto-scanning mode**.

$TIS_{non\text{-}scan}$ the Soft Tissue **Thermal Index** in a **non-autoscanning mode**.

TIB the Bone **Thermal Index**.

TIC the Cranial **Thermal Index**.

A_{aprt} the area of the active aperture (square centimeters).

$p_{r.3}$ the **derated peak rarefactional pressure** associated with the transmit pattern giving rise to the value reported under MI (megapascals).

W_o the **ultrasonic power**, except for TIS_{scan}, in which case it is the **ultrasonic power** passing through a one centimeter window (milliwatts).

$W_{.3}(z_1)$ the **derated ultrasonic power** at axial distance z_1 (milliwatts).

$I_{TA.3}(z_1)$ the **derated spatial-peak temporal-average intensity** at axial distance z_1 (milliwatts per square centimeter).

z_1 the axial distance corresponding to the location of $\max[\min(W_{.3}(z), I_{TA.3}(z) \times 1\ cm^2)]$, where $z \geq z_{bp}$ (centimeters).

z_{bp} $1.69\sqrt{A_{aprt}}$ (centimeters).

z_{sp} For MI, the axial distance at which $p_{r.3}$ is measured
for TIB, the axial distance at which TIB is a **global maximum** (i.e., $z_{sp} = z_{B.3}$) (centimeters).

$d_{eq}(z)$ the equivalent beam diameter as a function of axial distance z, and is equal to $[(4/\pi)(W_o/I_{TA}(z))]^{0.5}$ where $I_{TA}(z)$ is the **temporal-average intensity** as a function of z (centimeters).

f_c the **center frequency** (MHz). For MI, f_c is the **center frequency** associated with the transmit pattern giving rise to the **global maximum** reported value of MI. For TI, for combined **modes** involving transmit patterns of unequal **center frequency**, f_c is defined as the overall range of center frequencies of the respective transmit patterns.

Dim. of A_{aprt} the active aperture dimensions for the azimuthal (x) and elevational (y) planes (centimeters).

PD the **pulse duration** (microseconds) associated with the transmit pattern giving rise to the reported value of MI.

PRF the **pulse repetition frequency** associated with the transmit pattern giving rise to the reported value of MI (Hz).

$p_r@PII_{max}$ the **peak rarefactional pressure** at the point where the free-field, spatial-peak **pulse intensity integral** is a maximum (megapascals). See Section 6.2.4.1 of the **Output**

Display Standard, entitled "Measurement Methodology for Mechanical and Thermal Indices".

$d_{eq}@PII_{max}$ the equivalent beam diameter at the point where the free-field, spatial-peak **pulse intensity integral** is a maximum (centimeters). See Section 6.2.5.1 of the **Output Display Standard**, entitled "Measurement Methodology for Mechanical and Thermal Indices".

FL the focal length, or azimuthal (x) and elevational (y) lengths, if different (centimeters).

$I_{PA.3}@MI_{max}$ the **derated pulse-average intensity** at the point of **global maximum** reported MI (Watts per square centimeter).

Measurement uncertainties for acoustic quantities (**power**, **pressure**, **intensities**, **center frequency**) should be provided.

Table 6-3: Track 3 - Acoustic Output Reporting Table

Acoustic Output Reporting Table for Track 3
(provide data where **global maximum** displayed index exceeds 1.0)

Transducer Model: _____ **Operating Mode:** _____

Index Label			**MI**	**TIS**			**TIB**	**TIC**
				scan	**non- scan**		non-scan	
					A_{aprt}≤1	**A_{aprt}>1**		
Global Maximum Index Value								
Assoc Acoustic Parameter	$p_{r.3}$	(MPa)						
	W_o	(mW)						
	min of[$W_{.3}(z_1)$, $I_{TA.3}(z_1)$]	(mW)						
	z_1	(cm)						
	z_{bp}	(cm)						
	z_{sp}	(cm)						
	$d_{eq}(z_{sp})$	(cm)						
	f_c	(MHz)						
	Dim of A_{aprt}	X (cm)						
		Y (cm)						
Other Information	PD	(μsec)						
	PRF	(Hz)						
	p_r@PII_{max}	(MPa)						
	d_{eq}@PII_{max}	(cm)						
	Focal Length	FL_x (cm)						
		FL_y (cm)						
	$I_{PA.3}$ @MI_{max}	(W/cm^2)						
Operating Control Conditions	Control 1							
	Control 2							
	Control 3							
	Control n							

Notes:

(a) This index is not required for this operating **mode**;
see section 4.1.3.1 of the **Output Display Standard** (NEMA UD-3).
(b) This probe is not intended for transcranial or neonatal cephalic uses.
(c) This formulation for TIS is less than that for an alternate formulation in this **mode**.
No data are reported for this **operating condition** since the **global maximum** index value is not reported for the reason listed.

6.7 TRACK 3 - EXAMPLES OF ACOUSTIC OUTPUT REPORTING TABLES

The next three pages contain example output tables to illustrate the use of the four footnotes (a, b, c, #). A check mark (✓) indicates that the box should be filled in with the appropriate value; a dash (-) means that no value is required because of either scan/non-scan or aperture size considerations.

With regard to the third example, color flow and M-**mode**, the use of footnote c) is shown. Note that if the M-**mode** TIS were greater than the color flow TIS, then footnote c) would appear under TIS(scan), and the M-**mode** TIS value would be listed in the appropriate TIS(non-scan) box. Therefore, it is important to list under "Operating **Mode**" all included modes for proper interpretation of the tabulated values.

Acoustic Output Reporting Table for Track 3
(provide data where **global maximum** displayed index exceeds 1.0)

Transducer Model: _____ **Operating Mode:** B-mode

Index Label			MI	TIS			TIB	TIC
				scan	non- scan		non-scan	
					$A_{aprt} \leq 1$	$A_{aprt} > 1$		
Global Maximum Index Value			1.5	(a)	-	-	-	(a)
Assoc Acoustic Parameter	$p_{r.3}$	(MPa)	✓					
	W_o	(mW)		#	-		-	#
	min of $[W_{.3}(z_1), I_{TA.3}(z_1)]$	(mW)				-		
	z_1	(cm)				-		
	z_{bp}	(cm)				-		
	z_{sp}	(cm)	✓				-	
	$d_{eq}(z_{sp})$	(cm)					-	
	f_c	(MHz)	✓	#	-	-	-	#
	Dim of A_{aprt}	X (cm)		#	-	-	-	#
		Y (cm)		#	-	-	-	#
Other Information	PD	(µsec)	✓					
	PRF	(Hz)	✓					
	$p_r@PII_{max}$	(MPa)	✓					
	$d_{eq}@PII_{max}$	(cm)					-	
	Focal Length	FL_x (cm)		#	-	-		#
		FL_y (cm)		#	-	-		#
	$I_{PA.3}$ @MI_{max}	(W/cm^2)	✓					
Operating Control Conditions	Control 1							
	Control 2							
	Control 3							
	Control n							

Notes:

(a) This index is not required for this operating **mode**;
see section 4.1.3.1 of the **Output Display Standard** (NEMA UD-3).

(b) This probe is not intended for transcranial or neonatal cephalic uses.

(c) This formulation for TIS is less than that for an alternate formulation in this **mode**.

\# No data are reported for this **operating condition** since the **global maximum** index value is not reported for the reason listed.

Acoustic Output Reporting Table for Track 3
(provide data where **global maximum** displayed index exceeds 1.0)

Transducer Model: _____ **Operating Mode:** Pulsed Doppler

Index Label			MI	TIS			TIB	TIC
				scan	non- scan		non-scan	
					$A_{aprt} \leq 1$	$A_{aprt} > 1$		
Global Maximum Index Value			(a)	-	-	<1	2.0	<1
Assoc Acoustic Parameter	$p_{r.3}$	(MPa)	#					
	W_o	(mW)		-	-		✓	#
	min of [$W_{.3}(z_1)$, $I_{TA.3}(z_1)$]	(mW)				#		
	z_1	(cm)				#		
	z_{bp}	(cm)				#		
	z_{sp}	(cm)	#				✓	
	$d_{eq}(z_{sp})$	(cm)					✓	
	f_c	(MHz)	#	-	-	#	✓	#
	Dim of A_{aprt}	X (cm)		-	-	#	✓	#
		Y (cm)		-	-	#	✓	#
Other Information	PD	(μsec)	#					
	PRF	(Hz)	#					
	$p_r@PII_{max}$	(MPa)	#					
	$d_{eq}@PII_{max}$	(cm)					✓	
	Focal	FL_x (cm)		-	-	#		#
	Length	FL_y (cm)		-	-	#		#
	$I_{PA.3}$ @MI_{max}	(W/cm^2)	#					
Operating Control Conditions	Control 1							
	Control 2							
	Control 3							
	Control n							

Notes:

(a) This index is not required for this operating **mode**;
see section 4.1.3.1 of the **Output Display Standard** (NEMA UD-3).

(b) This probe is not intended for transcranial or neonatal cephalic uses.

(c) This formulation for TIS is less than that for an alternate formulation in this **mode**.

\# No data are reported for this **operating condition** since the **global maximum** index value is not reported for the reason listed.

Acoustic Output Reporting Table for Track 3
(provide data where **global maximum** displayed index exceeds 1.0)

Transducer Model: _____ **Operating Mode:** Color Flow (inc. M-mode)

Index Label				MI	TIS			TIB	TIC
					scan	non- scan		non-scan	
						$A_{aprt} \leq 1$	$A_{aprt} > 1$		
Global Maximum Index Value				(a)	2.0	-	(c)	3.0	(b)
Assoc Acoustic Parameter	$p_{r.3}$		(MPa)	#					
	W_o		(mW)		✓	-		✓	#
	min of $[W_{.3}(z_1), I_{TA.3}(z_1)]$		(mW)				#		
	z_1		(cm)				#		
	z_{bp}		(cm)				#		
	z_{sp}		(cm)	#				✓	
	$d_{eq}(z_{sp})$		(cm)					✓	
	f_c		(MHz)	#	✓	-	#	✓	#
	Dim of A_{aprt}	X	(cm)		✓	-	#	✓	#
		Y	(cm)		✓	-	#	✓	#
Other Information	PD		(µsec)	#					
	PRF		(Hz)	#					
	p_r@PII_{max}		(MPa)	#					
	d_{eq}@PII_{max}		(cm)					✓	
	Focal	FL_x	(cm)		✓	-	#		#
	Length	FL_y	(cm)		✓	-	#		#
	$I_{PA.3}$ @MI_{max}		(W/cm^2)	#					
Operating Control Conditions	Control 1								
	Control 2								
	Control 3								
	Control n								

Notes:

(a) This index is not required for this operating **mode**;
see section 4.1.3.1 of the **Output Display Standard** (NEMA UD-3).

(b) This probe is not intended for transcranial or neonatal cephalic uses.

(c) This formulation for TIS is less than that for an alternate formulation in this **mode**.

\# No data are reported for this **operating condition** since the **global maximum** index value is not reported for the reason listed.

Appendix A:

Doppler Sensitivity

As specified in Section. 4.7.1.3, transducers that may operate in Doppler **modes** should be tested for sensitivity and the results of this testing should be reported in the 510(k) or **510(k) Special Report**.

Doppler sensitivity is defined as the minimum detectable Doppler signal, for a given **center frequency** and **ultrasonic power**, reflected from flowing blood-equivalent scatterers deep within tissue. A measure of Doppler sensitivity is the maximum tissue depth at which a Doppler signal of known strength is detectable by a given Doppler instrument. The deeper in the body that a signal can be detected, the more sensitive the device is said to be.

An alternative definition of sensitivity is a measure of the signal-to-noise ratio of the detected Doppler signal reflected by blood-equivalent scatterers at different depths in tissue, or a tissue-equivalent material, for a specific Doppler shift frequency and **ultrasonic power**.

Suggested guide for sensitivity measurements:

A.1 Test Materials

For measuring Doppler sensitivity, the use of a physiologically relevant test method is recommended. The method should include the following materials:

a) A phantom with uniformly attenuating tissue-equivalent medium (with attenuation of approximately 0.5 dB/cm-MHz), in which a simulated blood vessel is embedded at a sloping angle, or several different simulated vessels are embedded at different depths (string phantoms and electronic phantoms are not recommended);

b) A blood-mimicking fluid of known properties (i.e., fluid type, particle type and size, concentration, backscatter **intensity**, viscosity, etc.); this fluid and its scatterers should resemble human blood as closely as possible in particle size and backscatter levels (Boote et al. 1988); and

c) A means to vary fluid flow in the vessel; e.g., pump, gravity feed, etc.

The simulated test vessel should have a cross-sectional diameter no larger than 5 mm. The test vessel should either be sloping in a tissue mimicking matrix, or several simulated vessels could be placed horizontally, at different depths in the phantom. The use of amorphous (slurry-like) tissue mimicking material could be used to make this configuration easier to obtain. Additional measurements using larger diameter vessels (e.g., 10 mm and 15 mm) would be useful, but not required.

A.2 Methods

A suggested measurement procedure is described below. Reasonable variations and/or improvements in this procedure are acceptable.

a) With **ultrasonic power** set at maximum for a given transducer, obtain a clean Doppler flow signal from the blood-mimicking fluid at zero depth, for a velocity in the middle of the instrument's velocity range. Measure the maximum depth at which the Doppler signal can be detected both on the Doppler display and by the audible Doppler signal. Since the phantom attenuation is known in dB/cm-MHz, the maximum depth of penetration can be expressed in decibels. Record the maximum depth of penetration (in both distance and dB) for midrange velocity, v_2.

b) Repeat these measurements for the minimum and maximum detectable velocities in the Doppler velocity range for the Doppler instrument. The first value to measure is the maximum depth at which the lowest velocity will be detected and record this value

as v_1. Proceed to find the maximum depth at which the maximum system velocity is detected and record that value as v_3.

c) For a more quantitative measurement, the user may consider the use of an RMS voltmeter to measure the output Doppler signal (Boote et al. 1988). Plot the signal-to-noise ratio versus depth in the tissue-mimicking material for each selected velocity setting (low, medium, high), indicating the noise-equivalent cutoff. The cutoff point defines the maximum sensitivity for the given transducer and acoustic output setting configuration.

Appendix B:

Cleaning and Disinfection

Cleaning and disinfection is a two step process: a cleaning step followed by a disinfection step. Many manufacturers try to merge these two steps. This is incorrect.

CLEANING

Cleaning is intended to remove all foreign matter (blood, tissue, protein, scanning gel, etc.) from the device. The device is first cleaned with a compatible detergent then rinsed to remove residue. Enzyme cleaners and special baths may be used where appropriate. Disinfection solutions are not intended to be cleaning agents. Reusable devices should be designed to allow adequate cleaning. If adequate cleaning cannot be achieved, subsequent disinfection procedures are likely to be ineffective.

DISINFECTION OR STERILIZATION

The level of disinfection required for a device is dictated by the type of tissue it will contact during use. Non-critical, semi-critical, and critical are the classifications, based on the degree of risk of infection involved in the use of the device. For this guidance, non-critical applications are those where the device contacts only intact skin; semi-critical applications are those where the device contacts mucus membranes; critical applications are those where the device contacts blood, compromised tissue, or is used in a sterile field.

Ultrasound probes used for non-critical applications need only be cleaned and low-level disinfected between patient use. Probes used in semi-critical applications should be high-level disinfected and the use of a sheath is recommended. Devices used in critical applications should be high-level disinfected, at a minimum, and must be used with a sterile sheath.

There are several special situations:

1. Neurosurgical use: Operative devices that contact brain tissue should not be sterilized using liquid sterilants. The residue left on the probe is neuro-toxic. These probes should be used with a sheath that is pyrogen-free.

   NOTE: If the probe is used on a patient with Creutzfeld-Jacob Disease and the sheath breaks, the probe may be destroyed by the disinfection procedures (see CDC, 1997).

2. Endoscopic probes should normally be used with a sterile sheath. Rectal and transvaginal probes may be used with a sheath that is surgically clean.

3. Because biological indicators cannot be used with liquid sterilants, liquid sterilization should only be recommended for situations in which ETO gas or heat sterilization are not compatible with the device.

For further information see CDRH's document titled "Labeling Reusable Medical Devices for Reprocessing In Health Care Facilities" (FDA 1996).

Appendix C:

Statistical Reporting

Summary of Statistical Reporting in the 510(k) and 510(k) Special Report

There are five areas of the submission in which a statistical analysis of measurement or performance data may be necessary.

1. Specification of clinical measurement accuracy. See, Sections 4.7.1.2 and 4.8.1.4 of this guidance.

2. Specification of measurement uncertainties for acoustic quantities (**power**, **pressure**, **intensities**, **center frequency**). See Section 5.2.1 (Track 1), Section 6.2.1 (Track 3), and Appendix G, Section E2, of this guidance. In this regard, a good description of the various potential sources of random and systematic uncertainties for hydrophone measurements can be found in (Preston et al. 1988).

3. Specification of statistical sampling plan used to insure that the acoustic outputs of production units do not exceed appropriate pre-Amendments output levels in Section 5.3 (Track 1). See Section 4.6.1.8, Section E5 of Appendix G, Section 5.1.2 (Track 1), and Section 6.1.3 (Track 3) of this guidance.

4. Specification of display accuracy, as defined in Section 2.1 and required in Section 4.2.1 of the **Output Display Standard**. See Section 6.2.3 (Track 3) of this guidance.

5. Specification of measurement precision of **center frequency**, **ultrasonic power**, and **peak rarefactional pressure**, as described in Section 6.4 of the **Output Display Standard**. See Section 6.2.3 (Track 3) of this guidance.

Appendix D:

Exemption from Reporting Under 21 CFR 1002

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

FEB 24 1986

TO: All Diagnostic Ultrasound Manufacturers and Importers

SUBJECT: Exemption from Reporting under 21 CFR 1002

Background

All electronic products that emit radiation, including ultrasound, are subject to the requirements of the Radiation Control for Health and Safety Act of 1968 (RCHSA). Section 1002 of Title 21 of the Code of Federal Regulations (21 CFR 1002) requires that manufacturers and importers of ultrasonic equipment file initial and model change reports on the radiation safety and testing of their products prior to introduction into commerce. In addition, diagnostic ultrasound products are subject to the requirements of Section 510(k) of the Food, Drug and Cosmetic Act. Since information required to be submitted under the RCHSA is very similar to that required to be submitted in 510(k) notifications, some manufacturers have requested relief from this duplication.

Policy

Under the authority of 21 CFR 1002.50(b), all manufacturers and importers of diagnostic ultrasound products are hereby exempted from initial and model change report requirements under 21 CFR 1002.10 and 1002.12. This exemption will not apply if the firm fails to comply with the requirements for 510(k) notifications. The Center for Devices and Radiological Health reserves the right to withdraw this exemption from any firm if it finds, through inspections under the Good Manufacturing Practice (GMP) requirements of 21 CFR 820 or through other means, that any of their products fail to conform to the product description in the 510(k) notice.

Manufacturers are not exempt from the requirements of 21 CFR 1002.20 (Reporting of Accidental Radiation Occurrences) nor the requirements of 21 CFR 1003 (Notification of Defects or Failure to Comply) and 1004 (Repurchase, Repair, or Replacement of Electronic Products).

Invitation to Comment

All questions or comments may be directed to Ms. Joanne Barron, Chief, Microwave/Acoustics Products Section, FDA (HFZ-312), 8757 Georgia Avenue, Silver Spring, MD 20910; telephone (301) 427-7187.

John C. Villforth
Director
Center for Devices
and Radiological Health

Appendix E:

Deciding if System and Transducer Modifications Require Additional 510(k) Premarket Notifications or Add-To-Files

See Center guidance "Deciding When to Submit a 510(k) for a Change to an Existing Device" (FDA, 1997).

A. The addition or modification of transducers to a particular system will not require a new 510(k) if all of the following conditions are met:

   1. The system is already the subject of a submitted and cleared 510(k);

   2. Indication(s) for use and **mode**(s) of operation are unchanged;

   3. Acoustic output of each new or modified transducer is below the limits in the enclosed tables for the respective indication(s) (Track 1) or are below $I_{SPTA.3}$ = 720 mW/cm^2 and either MI =1.9 or $I_{SPPA.3}$ =190 W/ cm^2 (Track 3). For Track 3 ophthalmic applications TI = max.(**TIS_as**, TIC), and is not to exceed 1.0, $I_{SPTA.3} \leq$ 50 mW/cm^2 and MI $\leq$ 0.23.

   4. Acoustic output is measured according to the 510(k) Guide and recorded according to the procedures in the 510(k) Guide; these procedures are included in the Device Master Record or Design History File, and the results are included in the Device History Record, as part of Good Manufacturing Practices (GMP's) for that device. This condition should be met for changes that affect the output of any transducer intended for use with the system. In addition, the Master Record should adequately document minor changes not affecting the indications for use or acoustic output. These files will be reviewed periodically under inspection authority of the Food, Drug, and Cosmetic Act. If measurement technology different from that defined in the 510(k) Guide is used to document acoustic output, a 510(k) premarket notification will be necessary.

B. Modifications to a diagnostic ultrasound system that has a previously cleared 510(k) will not require a new 510(k) if the indications for use and the ultrasound generator, transducer(s), controls, and signal processing technologies are unchanged; no system functions are added; no significant new clinical information is provided; no significant claims of added effectiveness are made; and the clinical application/**mode** of operation does not provide a significant new interpretation of existing information. CDRH still reserves its discretion to require a 510(k) in selected situations.

C. A device that enters the market using the process described above cannot be used as a predicate for a future submission.

D. New Indications for Use

   New clinical applications or new **modes** of operation may represent new indications for use and therefore require a new 510(k). Several examples of recent new clinical applications/modes of operation and the data necessary for a 510(k) follow. Generally, a new indication will need the following information:

   1. A description of the new application/**mode** including clinical use and theory of operation;

   2. A discussion of any new means of operation necessary to use the new application/**mode**;

   3. A discussion of the acoustic output consequences (TI, MI, $I_{SPTA\ 3}$, etc.) resulting from use of the new application/**mode**; and

   4. A demonstration of the clinical utility of the new application; and

   5. A demonstration clinical study and interpretation by a qualified physician for the new clinical application that demonstrates the competency of the device to perform the new

task and a discussion of the minimum performance requirements necessary for a device to properly perform the new task.

Examples of new clinical applications or **modes** of operation that may need new 510(k)'s are: 3-D imaging, Power or Amplitude Doppler Imaging, and Musculo-Skeletal (**superficial**) Imaging.

Example 1 -- Three-Dimensional Imaging, Reconstruction, and Volume Computation

For devices that display three-dimensional ultrasound data, the manufacturer should submit their data collection and data display method(s). If the system uses lenses or other techniques that simulate three-dimensions, this should be stated clearly and the labeling should state that no three-dimensional volume data are collected or displayed. Conversely, if the system is a true 3-dimensional system that collects data stored in a 3-dimensional array and reconstructs and/or renders the final 3-D image, then these reconstruction and rendering methods should be described. The manufacturer should clearly state if a three-dimensional array is created from original data or if several 2-dimensional arrays are interpolated to construct a three-dimensional data volume. A description (simplified flow chart) of the sampling and reconstruction algorithm should be included.

A demonstration of device reconstruction accuracy can be demonstrated by submitting 3-D reconstruction data from an appropriate phantom. The phantom should be tissue-mimicking and should include geometrically-regular objects (e.g., spheres, ellipses, cylinders, cones) whose dimensions are known and whose positions can be tested at different depths within a test volume. The objects in the phantom should include small sizes and low contrast levels such that they demonstrate the device reconstruction resolution limits. Note that the reconstruction resolution is different from the system resolution.

The measurement data should demonstrate that object(s) of known dimensions and contrast can be accurately reproduced in a three-dimensional image. The image measurements and relative dimensions of the object(s) should correspond to those of the original object for a range of object sizes. If the manufacturer claims volume computation capability, data should be supplied that compute the volume for a range of reconstructed test objects, within the phantom, of known size (from largest to smallest), giving the calculated volume and associated error compared to the known object volume. This computation should also be performed for objects of low contrast, to demonstrate how the system error is affected by ill-defined contours.

If the manufacturer claims a specific level of reconstruction resolution, this should be demonstrated by data and images of the smallest objects the system can reconstruct for each of several low contrast levels.

Example 2-- Amplitude Doppler

The filing of a 510(k) submission is required for any diagnostic ultrasound system adding amplitude Doppler **mode**.

The following information should be supplied:

1) a concise technological description of your version of the amplitude Doppler modality (include trade name and summary description of algorithms used);

2) a detailed comparison between the subject and predicate modalities (i.e. intended use, algorithms, technological characteristics, performance specifications, general claims) with all differences highlighted;

3) acoustic output reporting associated with amplitude Doppler **mode**;

4) the results of the measured Doppler sensitivities of the system/transducer combination for several depths;

5) a discussion of the basis for any claim of improved imaging or reduction of an artifact;

6) software information consistent with section 4.7.5; and

7) adequate descriptive information and instructions for use in the product labeling, including a discussion of any new artifacts.

Example 3-- Musculo-Skeletal (superficial) Imaging

Recent advances in data processing have allowed ultrasound devices to easily image areas that heretofore have been difficult. Imaging of **superficial** tendons, ligaments, and muscles is one such example.

Musculo-Skeletal imaging has been performed for some time. It was limited to deep structures and had limited resolution. The advent of high definition imaging has now allowed the imaging of **superficial** structures (1.5 cm or less). For purposes of clarity, we are calling the older imaging "musculo-skeletal (**conventional**)" and the newer method "musculo-skeletal (**superficial**)." We regard the new method as a new clinical application and subject to a 510(k) submission.

Appendix F:

Administrative Forms

510(k) Summary/Statement Certification

Re: K_____

CHECK ONLY ONE:

☐ 1. **510(k) Summary**. Attached is a summary of safety and effectiveness information upon which an equivalence determination could be based.

☐ 2. **510(k) Statement**. I certify that, in my capacity as

_____

of _____(company),

I will make available all information included in this premarket notification on safety and effectiveness within 30 days of request by any person if the device described in the premarket notification submission is determined to be substantially equivalent. The information I agree to make available will be a duplicate of the premarket notification submission, including any adverse safety and effectiveness information, but excluding all patient identifiers, and trade secret and confidential commercial information, as defined in 21 CFR 20.61.

_____

[Signature]*

_____

[Typed or Printed Name]

_____

[Date]

* Must be signed by a responsible person of the firm required to submit the premarket notification (e.g., not a consultant for the 510(k) submitter).

PREMARKET NOTIFICATION TRUTHFUL AND ACCURATE STATEMENT
(as required by 21 CFR 807.87(j))

I certify that, in my capacity as _____ of _____(company name), I believe, to the best of my knowledge, that all data and information submitted in this premarket notification are truthful and accurate and that no material fact has been omitted.

_____ _____
(Signature)* *(Date)*

_____ _____
(Typed Name) *(510(k) number)*

* Must be signed by a responsible person of the firm required to submit the premarket notification (e.g., not a consultant for the 510(k) submitter).

Diagnostic Ultrasound Indications for Use Form

Fill out one form for each ultrasound system and each transducer.

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	**Mode** of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal										
Abdominal										
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric										
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (specify)										

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments:_____

_____

_____

_____

_____

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

Appendix G:

Format and Content of Diagnostic Ultrasound ***510(k) Special Report***

U.S. Department of Health and Human Services
Public Health Service
Food and Drug Administration
Center for Devices and Radiological Health
Rockville, Maryland 20857

General Information

Purpose:

Manufacturers and importers of diagnostic ultrasound equipment are subject to the requirements promulgated under Subchapter C - Electronic Product Radiation Control of the Food, Drug, and Cosmetic Act (formerly the Radiation Control for Health and Safety Act), as well as the medical device requirements under the Medical Device Amendments and the Safe Medical Devices Act. Applicable radiation reporting regulations are contained in Title 21 CFR, Part 1002.

Currently, manufacturers are exempt from reporting under Part 1002 of the regulations if the 510(k) requirements are met. This guide is intended to assist manufacturers in providing final measurement data and product labeling information, based on their production devices, following 510(k) clearance.

Use of this Guide:

Use the format in this appendix for filing reports in the future. Retain a copy of all completed reports in your Device Master Record.

Submission of Reports:

The report should reference your 510(k) number and be submitted, in duplicate, to:

Food and Drug Administration
Center for Devices and
Radiological Health
Document Mail Center, HFZ 401
9200 Corporate Blvd.
Rockville, Maryland 20850

The **510(k) Special Report** should contain a list of all transducers cleared under the 510(k). Each transducer should be identified in one of three ways: (1) filed in a previous **510(k) Special Report**, (2) the subject of the current **510(k) Special Report**, or (3) to be filed in a future **510(k) Special Report**. No system or transducer changes or upgrades should be submitted in the **510(k) Special Report** relative to the cleared 510(k) submission. That is, the 510(k) cleared submission and the **510(k) Special Report** should be identical with respect to the ultrasound system and transducers, with the exception of changes in model names or designations, and changes in the final (production) acoustic output values and final labeling.

Changes in system or transducer model names or designations should be identified clearly in the **510(k) Special Report**, including multiple model names or designations for a single cleared transducer, if applicable. If a transducer has received 510(k) clearance for multiple **modes** or indications for use, and it is intended to market these multiple **modes** or indications for use sequentially, then this intention should be described clearly and completely in the first **510(k) Special Report** filed for that cleared transducer. In this case additional **510(k) Special Reports** need not be filed for the other **modes** or indications for use unless there is a significant change in either the acoustic output tables or the operating instructions regarding acoustic output.

A **510(k) Special Report** should not be filed to report a single marketed transducer that comprises the combination of two or more cleared transducers. For this situation a new 510(k) application may be submitted, unless use of Appendix E is appropriate. The new 510(k) should consist of new acoustic output tables and labeling unique to the combination with other items included by reference to the previous 510(k)(s).

510(k) Special Reports that do not conform to the above are unacceptable and will be returned.

NOTE: Acknowledgment of receipt of the 510(k) Special Report does not constitute clearance for marketing of any new device.

FOI Notice:

The acoustic output forms submitted as part of this report may be subject to public disclosure in accordance with the Freedom of Information Act, 5 U.S.C. 552, and any other applicable statute or agency regulation.

A. REPORT IDENTIFICATION:

A1. Date of **510(k) Special Report**:

A2. Date and Control Number of 510(k) Notice:

B. IDENTIFICATION OF FIRM

B1. Manufacturer's Name:
Address:

Corresponding Official:
Title:
Address:

Signature:
Telephone:

B2. Initial Distributor (if manufacturer is overseas)
Name/Title/Firm:
Address:
Telephone:

B3. Factory Location.

C. LABELING/USER INFORMATION

C1. Provide a copy of all labeling pages that have significant changes in content from that submitted in the 510(k) submission and certify that no other significant content changes have occurred; i.e., do not include pages that have changes only in format or pagination.

C2. Provide the **global maximum derated** I_{SPTA} **intensity** values and **Mechanical Index** (or **derated** I_{SPPA} **intensity**) values obtained from production units, as determined according to Section E5 below. For Track 1, provide this information for each system/transducer/**mode**/application combination (i.e., one set of values for each of the items checked in Section 5.5, Table 5-2 of your 510(k) submission). For Track 3, provide this information for each system/transducer/**mode** combination.

D. DOPPLER SENSITIVITY

Provide data validating the Doppler sensitivity specification (see Section 4.7.1.3), if not provided in the original submission.

E. GMP TEST PLAN

E1. Provide the number of units tested and percentage of production lot:

E2. Provide measurement uncertainties for acoustic quantities (**power**, **pressure**, **intensities**, and **center frequency**):

E3. Describe the **operating conditions** used to obtain the measured acoustic output:

E4. Did the **operating conditions** result in maximizing output? If not, please explain and provide reasons for equivalence:

E5. Provide the statistical plan and protocol used to ensure that the appropriate **intensity** and index values are not exceeded [$I_{SPTA.3}$ values for Track 1 (see Table 5.1); $I_{SPTA.3}$ = 720 mW/cm^2 (50 for ophthalmic) for Track 3; for Track 3 ophthalmic, Max(**TIS_as**, TIC)≤1; MI = 1.9 (0.23 for ophthalmic) for both tracks]:

Firms are not required to conduct 100% sampling. If however, testing is performed on all devices to be shipped and it is assured that the acoustic output of each device tested will not exceed maximum specified levels following the guidelines described in Section 4.6, paragraphs 3 and 4, then the process for determining the measurement uncertainty shall be provided in the 510(k) and the data establishing the measurement uncertainty shall be available for inspection under GMP.

If 100 percent sampling is not done, then the sampling plan should provide reasonable statistical assurance that production units will not exceed the maximum acoustic output levels specified in the guidance. This should be accomplished by following a statistical technique known as "one-sided tolerance for normal distributions" - see section 2-5 on page 2-13 and Table A-7 on page T-14 of (Natrella 1966). In applying this technique, the sample size should be not less than three units. This procedure has the following formulation:

$$L \geq X + Ks$$

where:

- L is the $I_{SPTA.3}$ or MI (or $I_{SPPA.3}$) limit
- X is the mean of the measured values
- s is the standard deviation of the measured values
- K is a value found in Table A-7, and is a function of γ (confidence level), P (the proportion of the distribution less than (X + Ks)), and n (sample size).

The choice of γ, P, and n is at the manufacturer's discretion. However, the choice of γ, P, and n should be documented and justified in the GMP process and the Device Master Record. The values of X, s, γ, P, and n should be provided in this appendix.

An example of applying this procedure to a population of ultrasound transducers is given in (Ziskin 1993), with the substitution of Table A-7 from (Natrella 1966) in place of Table 2 provided in the Ziskin reference.

NOTE: In computing the standard deviation s, the hydrophone measurement uncertainty does not have to be taken into account if it is less than + 30% for **intensity** or + 15% for MI. However, if the hydrophone measurement uncertainty exceeds these values, then the guidance levels should be reduced accordingly, as described in Section 4.6, paragraphs 3 and 4.

NOTE: Another reference for the one sided tolerance tables is Hahn et al. 1991. See Tables A.12c and d, on pages 314 and 315. In these tables, $\gamma = 1-\alpha$.