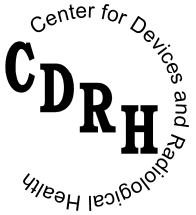
Guidance for Industry and FDA Staff

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

Document issued on: September 9, 2008

This document supersedes "Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers," dated September 30, 1997.

For questions regarding this document contact Robert Phillips, Ph.D. at 240-276-3666 or Gerald Harris, Ph.D. at 301-796-2508, by email at Robert.Phillips1@FDA.HHS.GOV or Gerald.Harris@FDA.HHS.GOV, or write them at Robert Phillips, Ph.D., CDRH/FDA, 9200 Corporate Blvd., Rockville MD 20850 or Gerald Harris, Ph.D., CDRH/FDA, Building 62, Room 2104, 10903 New Hampshire Ave., Silver Spring MD 20993.



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

Radiological Devices Branch
Division of Reproductive, Abdominal, and Radiological Devices
Office of Device Evaluation

Division of Solid and Fluid Mechanics
Office of Science and Engineering Laboratories

Preface

Public Comment

Written comments and suggestions may be submitted at any time for Agency consideration to the Division of Dockets Management, Food and Drug Administration, 5630 Fishers Lane, Room 1061, (HFA-305), Rockville, MD, 20852. When submitting comments, please refer to the exact title of this guidance document. Comments may not be acted upon by the Agency until the document is next revised or updated.

Additional Copies

Additional copies are available from the Internet at: http://www.fda.gov/cdrh/ode/guidance/560.html. You may also send an e-mail request to dsmica@fda.hhs.gov to receive an electronic copy of the guidance or send a fax request to 240-276-3151 to receive a hard copy. Please use the document number (**560**) to identify the guidance you are requesting.

Note: Where used in this guidance, defined terms are in **bold** letters.

Table of Contents

Guidance for Industry and FDA Staff

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

This guidance represents the Food and Drug Administration's (FDA's) current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the FDA staff responsible for implementing this guidance. If you cannot identify the appropriate FDA staff, call the appropriate number listed on the title page of this guidance.

Introduction

This guidance document provides detailed information recommended for manufacturers seeking marketing clearance of diagnostic ultrasound systems and transducers. This guidance replaces "Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers," dated September 30, 1997 (the 1997 guidance).

The 1997 guidance stated that any substantial equivalence decision should be followed by submission of a 510(k) Special Report prior to shipping the device. This new guidance document no longer recommends the submission of a 510(k) Special Report if the manufacturer maintains acoustic output measurements and labeling records in their **Design History File**[1] (see Appendix A of this guidance document). Appendix A contains suggestions for documenting this information. Also refer to: CDRH Device Advice, Quality System http://www.fda.gov/cdrh/devadvice/pma/quality_system.html and 21 CFR Part 820--Quality System Regulation, Subpart C--Design Controls; Sec. 820.30(j) **Design History File**.

This guidance also adds appendices addressing non-OEM (original equipment manufacturer) replacement transducers (Appendix B) and reprocessed "single-use only" transducers (Appendix C) and revises recommended labeling for cleaning and disinfecting transducers (Appendix D).

[1] Bolded words in the text are defined in Section 4 of the guidance.

NOTE: This guidance refers to many voluntary standards and other guidances. An attempt has been made to list the most current versions, but submitters should refer to the latest version of guidances and voluntary standards (see individual standards documents and the CDRH web page http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm on recognized standards) when preparing their submissions. Contact the Radiological Devices Branch (RADB) if questions of applicability arise.

The Least Burdensome Approach

The issues identified in this guidance document represent those that we believe should be addressed before your device can be marketed. In developing the guidance, we carefully considered the relevant statutory criteria for Agency decision-making. We also considered the burden that may be incurred in your attempt to follow the guidance and address the issues we have identified. We believe that we have considered the least burdensome approach to resolving the issues presented in the guidance document. If, however, you believe that there is a less burdensome way to address the issues, you should follow the procedures outlined in the "A Suggested Approach to Resolving Least Burdensome Issues" document. It is available on our Center web page at http://www.fda.gov/cdrh/modact/leastburdensome.html.

FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidances means that something is suggested or recommended, but not required.

Section 1. General Information

1.1 INTRODUCTION

This guidance supplements other FDA documents regarding the specific content requirements of a premarket notification submission. You should also refer to 21 CFR 807.87; the guidance, "Format for Traditional and Abbreviated 510(k)s," http://www.fda.gov/cdrh/ode/guidance/1567.html; and CDRH Device Advice, Premarket Notification 510(k), http://www.fda.gov/cdrh/devadvice/314.html. We recommend that you tab the major sections of your submission and that the numbering scheme of your submission follow or refer to the Section numbers in this guidance. Section 6 in this guidance contains an illustrative list for FDA reviewers diagnostic ultrasound 510(k) submissions..

Section 402(j)(5)(B) of the Public Health Service Act, as amended by Title VIII of the Food and Drug Administration Amendments Act of 2007 (FDAAA), requires that certifications be submitted with new applications/submissions to FDA. If you have questions on the Certification Form or the new requirements for the clinical trials databank under the Food and Drug Administration Amendments Act of 2007, Title VIII, Section 801, please contact: FDAAAclinicaltrials@fda.hhs.gov. Additional information about Title VIII and a link to Form 3674 may be found at: http://www.fda.gov/cdrh/news/121307.html.

The application of this document is limited to the devices described below.

Device	21 CFR section	Product Code
Ultrasonic Pulsed Doppler Imaging System	892.1550	IYN
Ultrasonic Pulsed Echo Imaging System	892.1560	IYO
Diagnostic Ultrasound Transducer	892.1570	ITX
Endoscope and Accessories	876.1500	ODG
Diagnostic Intravascular Catheter	870.1200	OBJ
Fetal Doppler Ultrasound	884.2660	LXE
Fetal Doppler Ultrasound Monitor	884.2660	MAA
Echocardiograph	870.2330	DXK
Cardiovascular Blood Flowmeter	870.2100	DPW
Intravascular Ultrasound Catheter	870.1200	OBJ

NOTE: FDA regulates diagnostic phantoms, quality assurance (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, subject to the limitations of section 892.9. Section 892.1940 also exempts radiological QA devices from good manufacturing practice regulations (21 CFR Part 820) except for those related to records (21 CFR 820.180) and complaint files (21 CFR 820.198).

In addition to submitting a premarket notification [510(k)] for a new ultrasound device, manufacturers must also meet the following electronic product radiation control requirements:

- 21 CFR 1020.10 (Performance Standard for Ionizing Radiation Emitting Products - Television Receivers) for ultrasound products incorporating a cathode-ray-tube display;
- 21 CFR 1002.20 (Reporting of Accidental Radiation Occurrences);
- 21 CFR Part 1003 (Notification of Defects or Failure to Comply); and
- 21 CFR Part 1004 (Repurchase, Repairs, or Replacement of Electronic Products).

Diagnostic ultrasound manufacturers are not required to submit abbreviated radiation safety reports as indicated in Table 1 of 21 CFR 1002.1. This guidance does not change the policy established by a notice to industry, dated February 24, 1986, exempting such products from reporting so long as a 510(k) is submitted.

You should refer to the CDRH guidance document titled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (http://www.fda.gov/cdrh/ode/510kmod.pdf) for guidance on when a change or modification to an already cleared device requires submission of a new 510(k). Further information can be found in Appendix E.

This guidance retains the two-track approach of the 1997 guidance, in which FDA's recommendations for the information you should include in your 510(k) submission depend on whether your device follows Track 1 or Track 3.[2] The Track 1 recommendations are for devices that do not conform the **Output Display Standard**. Track 3 recommendations are for devices that conform to the **Output Display Standard**.

Please note: Instead of conforming to the **Output Display Standard,** Track 1 devices follow FDA recommendations for application-specific acoustic output exposure levels (see Table 2-1).

Although the term **Output Display Standard** is a generally recognized shortened name for the *Standard for real-time display of thermal and mechanical acoustic output indices on diagnostic ultrasound equipment (*AIUM/NEMA 2004a), for the purposes of this guidance, the term refers to one of two standards, AIUM/NEMA 2004a and *Medical electrical equipment - Part 2-37: Particular requirements for the safety of ultrasonic medical*

[2] For historical reasons, there is no Track 2.

diagnostic and monitoring equipment (IEC 2007). Both are FDA-recognized standards[3] and conformance with either allows you to follow Track 3 for your device. If you choose to follow the **Output Display Standard** (Track 3), you should provide a **declaration of conformity** to the one of those standards (see FDA-3654 Standards Data Report form at http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3654.pdf).

See also Appendix F for a flow chart to aid in determining which Track to follow, and what the recommendations are for each Track with respect to acoustic output. In either case, you should clearly identify the Track being followed for your submission.

1.1.1 Abbreviated 510(k)s

An Abbreviated 510(k) submission must include the required elements identified in 21 CFR 807.87, including the proposed labeling for the device sufficient to describe the device, its intended use, and the directions for its use. In an Abbreviated 510(k), we recommend that you include a descriptive summary report of appropriate supporting data within the meaning of 21 CFR 807.87(f) or (g). The report should describe how this guidance document was used during the device development and testing and should briefly describe the methods or tests used and a summary of the test data or description of the acceptance criteria applied to address the risks identified in this document, as well as any additional risks specific to your device. This section suggests information to fulfill some of the requirements of section 807.87 and identifies other items that we recommend you include in an Abbreviated 510(k).

Coversheet

The coversheet should prominently identify the submission as an Abbreviated 510(k) and cite the title of this guidance document.

Proposed labeling

Proposed labeling must be sufficient to describe the device, its intended use, and the directions for its use (21 CFR 807.87(e)). (Please refer to Section 1.8 for specific information that should be included in the labeling for devices of the type covered by this guidance document.)

Summary report[4]

In accordance with 21 CFR 807.87, your summary report should contain:

---

[3] (see **"**Recognition and Use of Consensus Standards" at (http://www.fda.gov/cdrh/osel/guidance/321.pdf)

[4] An abbreviated 510(k) summary report is intended to explain how a device-specific guidance document was used during development and testing of your device. This is not the 510(k) summary described in 21 CFR 807.92, which may be submitted to satisfy 21 CFR 807.87(h). For additional information on abbreviated 510(k) summary reports, see section 9 of **Format for Traditional and Abbreviated 510(k)s** at http://www.fda.gov/cdrh/ode/guidance/1567.html.

Description of the device and its intended use

We recommend that you describe the performance specifications and, when appropriate, include detailed, labeled drawings of the device. (Please refer to Section 1.4 for specific information that we recommend you include in the device description for devices of the type covered by this guidance document.) You should also submit an "indications for use" enclosure. (See Appendix G for an example of a recommended format.)

Description of device design requirements

You must include a brief description of the device design requirements. (21 CFR 807.87(g).

Identification of the risk analysis method

We recommend that you identify the risk analysis method(s) you used to assess the risk profile, in general, as well as the specific device's design and the results of this analysis. (Please refer to Section 1.2 for the risks to health generally associated with the use of this device that FDA has identified.)

Discussion of the device characteristics

We recommend that you discuss the device characteristics that address the risks identified in this guidance document, as well as any additional risks identified in your risk analysis.

Description of the performance aspects

We recommend that you include a brief description of the test method(s) you have used or intend to use to address each performance aspect identified in Sections 1-3 of this class II special controls guidance document. If you follow a suggested test method, you may cite the method rather than describing it. If you modify a suggested test method, you may cite the method but should provide sufficient information to explain the nature of and reason for the modification. For each test, you may either (1) briefly present the data resulting from the test in clear and concise form, such as a table, or (2) describe the acceptance criteria that you will apply to your test results[5]. (See also 21 CFR 820.30, Subpart C - Design Controls for the Quality System Regulation.)

[2] If FDA makes a substantial equivalence determination based on acceptance criteria, the subject device should be tested and shown to meet these acceptance criteria before being introduced into interstate commerce. If the finished device does not meet the acceptance criteria and, thus, differs from the device described in the cleared 510(k), FDA recommends that submitters apply the same criteria used to assess modifications to legally marketed devices (21 CFR 807.81(a)(3)) to determine whether marketing of the finished device requires clearance of a new 510(k).

Reliance on standards

If any part of the device design or testing relies on a recognized standard, we recommend that you include either:

- a statement that testing will be conducted and meet specified acceptance criteria before the device is marketed or
- a **declaration of conformity** to the standard.[6]

Because a **declaration of conformity** is based on results from testing, you cannot properly submit a **declaration of conformity** until you have completed the testing the standard describes. For more information, please refer to section 514(c)(1)(B) of Federal Food, Drug, and Cosmetics Act (the Act) and the FDA guidance, Use of Standards in Substantial Equivalence Determinations**,** http://www.fda.gov/cdrh/ode/guidance/1131.html.

If it is not clear how you have addressed the risks identified by FDA or additional risks identified through your risk analysis, we may request additional information about aspects of the device's performance characteristics. We may also request additional information if we need it to assess the adequacy of your acceptance criteria. Under 21 CFR 807.87(l), we may request any additional information that is necessary to reach a determination regarding substantial equivalence. Also, if you choose to use a standard in the submission of any new 510(k) (Traditional, Abbreviated or Special [see http://www.fda.gov/cdrh/ode/parad510.pdf]), you should fill out a standards form (Form 3654) for each standard referenced and submit it with your 510(k). Information on this form may be found at http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3654.pdf.

As an alternative to submitting an Abbreviated 510(k), you can submit a Traditional 510(k) that provides all of the information and data required under 21 CFR 807.87 and described in this guidance. A Traditional 510(k) should include all of your methods, data, acceptance criteria, and conclusions. Manufacturers considering certain modifications to their own cleared devices should consider submitting a Special 510(k).

1.2 RISK ASSESSMENT

Diagnostic ultrasound has an excellent safety record over its several decades of use. However, exposure of tissues to intense levels of ultrasound, well above those levels found with diagnostic ultrasound devices, can have significant destructive effects. Therefore, determinations of substantial equivalence in terms of safety for diagnostic devices are made in part by comparing the appropriate acoustic output levels of new devices to those of predicate devices; i.e., devices on the market prior to May 28, 1976, the date of the Medical Device Amendments to the Federal Food, Drug, and Cosmetic Act. These Preamendments acoustic output exposure levels are given in Table 2-1 of this guidance. The levels are

[6] See http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3654.pdf

derated to permit a more accurate comparison between transducers having different frequencies and focal lengths.[7]

Furthermore, because laboratory studies have shown the potential for both thermal and mechanical bioeffects at diagnostic acoustic output levels, and because of the particular concern for fetal exposures (Stratmeyer 2003), prudent use has been advocated by national and international bodies concerned with medical ultrasound use and safety (AIUM 1994, Barnett et al. 2000, BMUS/BIR 2000, Health Canada 2001, Nyborg, 2002, NCRP 2002). Two mechanisms have been advanced to help clinical users employ this concept: providing the maximum levels of acoustic output in the device labeling (AIUM 2008) and incorporating an acoustic output display on the device (AIUM 1994, IEC 2007, AIUM/NEMA 2004a). This guidance recognizes both of these mechanisms. For devices that follow the Track 1 recommendations (Section 2), acoustic output information should be included in the Operator's Manual. A tabular format such as shown in Examples 2-2 and 2-3 may be useful for this purpose. For devices that follow the Track 3 recommendations (Section 3), the system should incorporate the output display according to AIUM/NEMA 2004a or IEC 2007, and the labeling should include acoustic output information. A tabular format such as shown in Example 3-4 may be useful for this purpose. Although the completed examples need not accompany the 510(k) submission, Section 1.6.1 suggests the basic elements of the acoustic output test methodology that should be described in the submission.

1.3 INDICATIONS FOR USE

We recommend that you use this section to provide the indications for use (IFU) statement, which is a document used to identify and describe the specific indications for use for the system(s) and transducers included in the 510(k) submission.

Your IFU statement should be exactly the same as the indications for use described throughout your 510(k) submission, including the indications for use in the device labeling. Diagnostic ultrasound devices are generally indicated as "prescription use only."

We recommend that your IFU statement contain the clinical applications (see "Guidance for Industry: General/Specific Intended Use," (http://www.fda.gov/cdrh/modact/genspec.pdf)) and modes of operation applicable to each application for the system and for each transducer. We believe that a tabular format is desirable for presenting this information. An example is provided in Appendix G.

General imaging and Doppler IFUs for ultrasound devices have usually been cleared through the 510(k) process. However, individual devices may not follow this pattern. For example,

[7] For further information on regulatory acoustic output comparisons, see O'Brien et al. 2002, Harris 2000, and Stratmeyer 1989.

devices with unique specific indications or that provide novel quantitative information may be found to have a new intended use or raise new types of questions of safety and effectiveness. These devices may require a PMA.

1.4 General Device Description

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

1.4.1.1 You should describe the transducer and its operation in each **mode** and **mode** combination, including, but not limited to:

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

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, if applicable, and the nominal ultrasonic frequency(ies) of the **transducer assembly**.

1.4.1.2 You should describe the operating controls that can cause a change in the radiated field, e.g., output, **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 procedures necessary to change to an application or **mode** that has a higher application-specific acoustic output level (see Table 2-1).

1.4.1.3 You should describe any unique features or technological characteristics of the subject device.

1.4.1.4 You should 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)).

1.5 Predicate Device Comparison

1.5.1 You should identify comparable predicate device(s) to which the subject device is being claimed to be substantially equivalent. Identify, if possible, the 510(k) numbers for the predicate device(s).

1.5.2 You should compare the subject device to the predicate device(s) in terms of key safety and effectiveness features. We recommend you also discuss the differences and provide supporting data, if applicable. In addition, you should provide the following (tabular format is desirable):

- 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).

1.5.3 You should identify any accessories or kits intended for use with the device. For accessories or kits, you should provide evidence of the predicate status of the designated comparison device(s); i.e., Preamendments status (see CDRH Device Advice, Preamendments Devices, (http://www.fda.gov/cdrh/devadvice/314.html#preamend)) or 510(k) number(s).

1.6 ACOUSTIC OUTPUT

Defined in Sections 2 and 3 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. See Appendix F for a decision flow chart. In all cases, the **derated global maximum** acoustic output should not exceed Preamendments acoustic output exposure levels (see Table 2-1); 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 the exception for ophthalmic use in Section 3. Also 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 indicate that the acoustic output exposure levels will be or were measured, calculated, and derated following the most recently released revision of the *Acoustic Output Measurement Standard for Diagnostic Ultrasound Equipment* (AIUM/NEMA 2004b) or the measurement procedure should be fully described**.** Any deviation from the methodologies outlined in the AIUM/NEMA standard document should be fully described in terms of the differing methodology used and be supported with 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 acoustic output exposure levels in Table 2-1. To further clarify this procedure, the uncertainty of the acoustic output exposure levels in Table 2-1 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 Preamendments acoustic output exposure levels in Table 2-1 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.

Manufacturers must comply with 21 CFR 820.30(j) **Design History File**. Your **Design History File** must contain or reference the records necessary to demonstrate that the design was developed in accordance with the approved design plan and the requirements of 21 CFR Part 820. Accordingly, include documentation of the acoustic output measurement of your transducers including measurement instrumentation, calibration, software, test results, and test protocols.

1.6.1 Test Methodology

You should provide in the 510(k), either 1) a separate section containing a description of the acoustic output test methodology or 2) a reference to a previously cleared 510(k) submission or approved PMA application that contains an acceptable description of the acoustic output test methodology (you should include 510(k) or PMA number, along with the attachment number and/or page numbers). If you refer to a 510(k) or PMA, 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 components discussed below.

1.6.1.1 You should include descriptions of measurement instrumentation (e.g., hydrophone type, effective diameter, frequency response, hydrophone amplifier characteristics). If you use any commercial devices, you should include manufacturers' names and model numbers.

NOTE: With reference to Section 3.3.2 of AIUM/NEMA 2004b, it is recommended that all measurements of pulsed (i.e., amplitude modulated) **waveforms** that result in reported or labeled acoustic quantities or in output display indices be made with a spot-poled membrane hydrophone. This recommendation applies unless it can be demonstrated that a non-membrane (e.g., needle-type) hydrophone gives a result equivalent to (or better than) a membrane hydrophone, whether due to the nature of the pulse or field being measured, special hydrophone designs, or the use of correction factors or procedures. 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 hydrophones are acceptable for continuous wave measurements and uses not directly affecting reporting or labeling, such as in quality control measurements.

1.6.1.2 You should provide a description of the measurement set-up.

1.6.1.3 You should include descriptions of the 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.

NOTE: For Doppler fetal heart rate monitors (see Sections 2.1.2 and 2.2.5), the example calculation should include I_{SATA} instead of $I_{SPTA.3}$.

1.6.1.4 You should describe your procedures 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.

1.6.1.5 You should describe any procedures used to correct for spatial averaging by the hydrophone, if applicable. See e.g., Zeqiri, et al. 1992.

1.6.1.6 You should describe the calibration procedures for measurement instruments, including how often calibrations or spot checks are performed.

1.6.1.7 You should describe the procedures used for assessment of Type A (random) and Type B (systematic) uncertainties associated with measurement or calculation of the **ultrasonic power**, **pressure**, **intensities**, and **center frequency**. In addition, you should include a brief description of all relevant error sources considered and an explanation of how the overall uncertainty was determined. See Appendix H, item 2.

1.6.1.8 You should describe the protocol for assuring that the specifications for acoustic output exposure levels will not exceed the **global maximum** acoustic output exposure levels specified in Sections 2 (Track 1) or Section 3 (Track 3). If the test protocol described in 1.6.1.3 is not used on all devices, you should describe the correlation between acoustic output and sensitivity or other measurable parameter(s). If 100% testing will not be performed, you should describe the statistical sampling plan used to ensure that the specifications for acoustic output exposure levels are meaningful. We recommend that this plan comprise the one-sided tolerance limit for normal distributions. See Appendix A, Section B5. This plan can be described simply by providing the values of γ (or, equivalently, $1-\alpha$) and P. Please justify values less than $\gamma = 0.9$ and P=0.9.

Note: Statistical analyses of measurement or performance data are requested in several sections of the guidance. See Appendix H for a summary.

1.7 GENERAL CLINICAL SAFETY AND EFFECTIVENESS

1.7.1 Clinical Measurement Accuracy and System Sensitivity

1.7.1.1 You should identify and describe the various clinical (biometric) measurements that may be performed with the subject device.

1.7.1.2 For each transducer/**mode** combination, you should provide 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. You should describe and justify the test methodology (e.g., laboratory phantom) used to determine each accuracy. With regard to Doppler accuracy, you should 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. Please note that electronic phantom data should not be used because it generally does not include the transducer as part of the test system.

1.7.1.3 For each probe/**mode** combination in which quantitative claims regarding Doppler sensitivity are made in the product labeling, you should provide a minimum performance specification of the Doppler sensitivity in the **Design History File.** The justification for the methodology and an analysis of uncertainty should also be included in the **Design History File**. The results of the design validation, including identification of the design methods, the date, and the individuals performing the validation, must be documented in the Design History File (21 CFR 820.30(g), (j)).

1.7.2 Thermal, Mechanical, and Electrical Safety

1.7.2.1 Please provide either a **declaration of conformity** to an FDA-recognized standard or data showing that your system has been tested 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 the FDA recognized standards to which the system conforms.

1.7.2.2 You should describe the means used to limit the surface heating of **invasive probes** in the event of a device malfunction. Please state and scientifically justify your temperature limits.

1.7.3 Patient-Contacting Materials

1.7.3.1 Please provide the trade name, generic material composition (e.g., polyethylene, polycarbonate), and manufacturer of all patient-contacting materials or provide the Master File number that contains the material description.

1.7.3.2 You should provide biocompatibility testing results for tests conducted as described in ISO 10993-1:2003, “Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing,” and the guidance entitled "Use of International

Standard ISO-10993, "Biological Evaluation of Medical Devices Part-1: Evaluation and Testing," (http://www.fda.gov/cdrh/g951.html) 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 you indicate that the patient contact materials are unchanged in formulation and processing from a previously cleared device.

1.7.4 Cleaning, Disinfection, Sterilization, and Pyrogenicity

1.7.4.1 If the transducer is supplied non-sterile or is intended to be reused between patients, you should provide clearly written recommended procedures on how to clean, disinfect, and sterilize the transducer between uses if necessary. These recommended procedures should be validated by you and a summary of your validation procedures provided in the submission. The level of disinfection or sterilization should be appropriate for the intended clinical use. You should determine which types of disinfectants are compatible with your products. You may recommend the use of an FDA-cleared liquid sterilant/high level disinfectant for the high level disinfection of transducers used as semi-critical devices (see "Content and Format of Premarket Notification [510(k)] Submissions for Liquid Chemical Sterilants/High Level Disinfectants," (http://www.fda.gov/cdrh/ode/397.html). For sterilization, which should be used for transducers in contact with the bloodstream or normally sterile tissues, you should recommend the use of an appropriate sterilization process, which you should validate for use with your transducers. See Appendix D for more information.

1.7.4.2 For device components or accessories provided sterile to the user, FDA recommends that you provide sterilization information in your 510(k) as described in the "Updated 510(k) Sterility Review Guidance K90-1," (http://www.fda.gov/cdrh/ode/guidance/361.html). We recommend the device be sterilized with a sterility assurance level (SAL) of 1×10^{-6}.

1.7.4.3 If the device is labeled pyrogen-free, you should provide a description of the method (standard method) used to assess pyrogenicity. FDA recommends the following endotoxin endpoint: 0.5 EU/ml for general medical devices (e.g. blood contacting) and 0.06 EU/ml for devices that contact cerebrospinal fluid. These endpoints assume an extraction methodology described in "Guideline on Validation of the Limulus Amebocyte Lysate (LAL) Test as an End-Product Endotoxin Test," (http://www.fda.gov/cder/guidance/old005fn.pdf).

1.7.5 Software/Firmware

Applications that contain software that governs the operation of diagnostic ultrasound equipment have usually been submitted with minor level of concern as described in "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices" (the Software guidance)

(http://www.fda.gov/cdrh/ode/guidance/337.pdf). The rationale for this level of concern was that the potential for injury possible to a patient in the event of software/firmware failure, both directly (i.e., inappropriate delivery of electrical, thermal, or acoustic energy) and indirectly (i.e., inappropriate physician action based on inaccurate diagnostic information), is not likely to be major or life threatening. This is an outdated interpretation. The Software guidance places software "where a failure or latent flaw could indirectly result in minor injury to the patient or operator through incorrect or delayed information or through the action of a care provider" into the moderate risk category.

We recommend that you provide a full description of the software/firmware supporting the operation of the subject device following the Software guidance, commensurate with the appropriate level of concern. This recommendation applies to original systems as well as to any software/firmware changes made to already-marketed devices. New or unusual indications, applications, or technological characteristics may result in a higher level of concern. Changes to software must be revalidated and reverified in accordance with Design Controls, 21 CFR 820.30(g)(i), and documented in the Design History File 21 CFR 820.30(j). 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.

We recommend that your 510(k) submission also provide a summary description of new or altered algorithms and an explanation of why they are suitable for the chosen task.

1.8 LABELING

Labeling must provide sufficient detail to satisfy the requirements of 21 CFR 807.87(e). The following information will assist you in meeting the requirements of 21 CFR Part 801. Although final labeling is not required for 510(k) clearance, final labeling must comply with the requirements of 21 CFR Part 801 before a medical device is introduced into interstate commerce. In addition, final labeling for prescription medical devices must comply with 21 CFR 801.109. Labeling recommendations in this guidance are consistent with the requirements of Part 801.

1.8.1 You should provide draft operator's manuals and any labeling materials that describe the system and associated transducers (maintenance manuals are not necessary). Labeling for all prescription diagnostic ultrasound equipment must comply with 21 CFR 801.109. Manufacturers are encouraged to consult CDRH Device Advice, Labeling Requirements (http://www.fda.gov/cdrh/devadvice/33.html) for labeling advice. In general, labeling contains:

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.

1.8.1.1 Provide clearly stated indications for use, contraindications, warnings, precautions, and a prescription device statement where appropriate. This includes (but is not limited to):

a. a precaution to perform the ultrasound procedure prudently using the principle of **ALARA (As Low As Reasonably Achievable**);

b. for Track 1 systems, a caution when applicable (see also Table 2-1 and Section 2.2.4) that the device is not intended for fetal use (either in the operator's manual, individual transducer manuals, or on equipment labeling);

c. a description of the warnings, displays, or other system responses of the device to fault conditions;

d. a caution that cardiac rhythm disturbances during perfusion studies using gas ultrasound contrast agents have been observed in the diagnostic range of **Mechanical Index** (MI) values. See the specific package insert for the contrast agent being used for details; and

e. appropriate data supporting specific diagnostic claims.

1.8.1.2 Provide clinical instructions for the use of the device in either the system or transducer operator's manual. Indications for use must be specified for prescription devices (21 CFR 801.109(c)).

1.8.1.3 You should identify the device's compatible device accessories, kits, and components in the operator's manual(s). You should also provide the specifications for these accessories. When use of probe sheaths is recommended, the probe labeling should discuss the natural rubber safety issues described in 21 CFR 801.437, User Labeling for Devices that Contain Natural Rubber.

1.8.1.4 You should 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 given for Doppler applications should not exceed the range measured under 1.7.1.2.

1.8.1.5 You should provide draft acoustic output labeling in the operator's manual, following Section 2.2 (Track 1) or Section 3.2 (Track 3).

1.8.1.6 You should provide instructions for care of the device between uses, including storage, cleaning, disinfection, and sterilization of all components, as appropriate.

a. For clinical applications of a semi-critical or critical[8] nature (e.g., intraoperative, transrectal, transvaginal, transesophageal, or biopsy procedures), labeling should recommend, when appropriate, the use of sterile, legally marketed probe sheaths. Note that the use of sheaths does not change the type of reprocessing that is recommended after each use (see Appendix D, special situation 2).

b. When recommending a procedure that uses a legally marketed liquid disinfecting or sterilizing agent, either your labeling should reference the labeling provided by the agent's manufacturer or your instructions should be consistent with the agent's labeling.

c. For a reusable device, when recommending any procedure, such as cleaning, low level disinfection, high level disinfection, or sterilization, you should provide detailed instructions to the user. You should validate these procedures. Please see "Labeling Reusable Medical Devices for Reprocessing in Health Care Facilities: FDA Reviewer Guidance" (http://www.fda.gov/cdrh/ode/198.pdf), which describes the information you should provide in your 510(k) submission.

1.8.1.7 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., probes that make contact with the dura or any intracranial tissues) should have the following additional labeling:

a. a recommendation to use sterile, pyrogen-free sheaths; and

b. a caution, warning the user of a potential problem in using the probe on patients with known or suspected Creutzfeldt-Jakob disease (CJD). The probe sheath cannot be relied upon to prevent contamination of the probe. A transducer exposed to central nervous system tissue from known or suspected CJD or vCJD should be destroyed since it may not be possible to sterilize it. (See http://www.cdc.gov/ncidod/qa_cjd_infection_control.htm).

[8] The terms "critical device" and "semi-critical device" generally refer to devices that during use contact normally sterile tissue or body spaces (critical), and those that during use contact mucous membranes or non-intact skin (semi-critical).

1.8.1.8 References to literature should be included when appropriate.

1.9 CARDIOVASCULAR APPLICATIONS

Ultrasound systems intended for specific cardiovascular applications include intravascular ultrasound (IVUS) catheters, associated software, and imaging systems. For cardiovascular applications, these devices are reviewed by the Cardiac Electrophysiology and Monitoring Branch (CEMB) in the Division of Cardiovascular Devices (DCD), Office of Device Evaluation, CDRH. For specific questions related to devices that feature cardiovascular applications, please contact the CEMB Branch Chief at (240) 276-4095.

This section is not intended to provide a comprehensive discussion of the requirements of ultrasound systems for cardiovascular applications, but to provide some basic recommendations to aid a sponsor in the preparation of a 510(k) application for a cardiovascular application.

Indications for Use

Your submission should describe the specific indications for use for which the device is intended (e.g., visualization of cardiac and vessel anatomy and physiology).

Device Description

For IVUS catheters, the submission should contain a full characterization of the device description, including:

- dimensions (catheter size, length);
- materials of use;
- device design;
- mechanical properties (e.g., deflectability); and
- mechanism of action, including properties of use.

Regarding any software, the submission should provide a full description of the algorithm (or methodology) employed by the software in its generation of any diagnostic or visual information. The submission should also include evidence that demonstrates the accuracy of the algorithms employed and that supports the instructions for use.

Performance Testing

For IVUS catheters, the submission should contain appropriate mechanical and electrical testing including the following:

- tensile strength;
- torsional strength;
- deflection; and
- buckling force.

Section 2. Track 1 Recommendations

Track 1 recommendations are for diagnostic ultrasound systems that do not follow the **Output Display Standard** or are not indicated for any fetal Doppler applications (except for fetal heart rate monitors, Section 2.1.2). Track 1 submissions are evaluated in relation to application-specific Preamendments acoustic output exposure levels. Table 2-1 lists the highest known acoustic field emissions for Preamendments diagnostic ultrasound devices. The values are **derated**. Systems that exceed these application-specific acoustic output exposure levels are evaluated on a case-by-case basis.

Table 2-1: Preamendments Acoustic Output Exposure Levels

Use	$I_{SPTA.3}$(mW/cm^2)	$I_{SPPA.3}$(W/cm^2) or 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 exposure levels:

a. transesophageal and intravascular for non-cardiac use, and musculo-skeletal applications should be included in the category, Fetal Imaging & Other;
b. cardiac use includes transthoracic adult and pediatric uses as well as intravascular and transesophageal adult and pediatric uses for visualization of the heart and coronary vessels;
c. peripheral vessel use includes vessels of the neck; and
d. cephalic and transcranial are synonymous.

2.1 Track 1 - Acoustic Output

Track 1 is based on application-specific comparisons to Preamendments acoustic output exposure levels given in Table 2-1. Measurements or estimates of acoustic output 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 exposure level. Otherwise, output measurements should be made for the application having the highest application-specific acoustic output exposure levels. (See Section 1.4.1.2.)

2.1.1 Your submission should include the information described below.

a. For each system/transducer combination, we recommend you specify for each mode/application combination (as stated in the Indications for Use), the target range of values for the $I_{SPTA.3}$ and for the MI or $I_{SPPA.3}$ under the operating conditions that maximize these quantities. A tabular format is desirable; see the example given in Example 2-1.

NOTE: The upper bound should not be greater than the appropriate application specific value listed in Table 2-1. When system/transducer or mode/application combinations have the same design target range for a given output quantity, a single range can be listed for those combinations.

b. A description of how the specification(s) in 2.1.1.a will be met.

c. The engineering basis for the range of values specified in 2.1.1.a (e.g., preliminary or prototype measurements, theoretical calculations, estimates based on measurements of previously cleared transducers, or acoustic output exposure levels).

NOTE: If you specify upper bounds that the device will not exceed in place of the target range of values recommended in 2.1.1.a, you should explain how you addressed the recommendations in 2.1.1.b and 2.1.1.c.

2.1.2 For continuous-wave fetal heart rate (FHR) monitors with low-**power** unfocused CW Doppler transducers, there is a single acoustic output exposure level for the spatial-average temporal-average intensity (I_{SATA}) at the transducer face of 20 mW/cm^2. This intensity may be estimated by dividing the **ultrasonic power** by the area corresponding to the **entrance beam dimensions**. A simple conservative approach for pulsed Doppler FHR monitors is to use 20 mW/cm^2 as a guide for the maximum spatial-average pulse-average intensity at the transducer face. For such transducers, two estimates should be 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 Preamendments exposure 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 the Radiological Devices Branch about the appropriate measurements that you should make.

2.1.3 Track 1 submissions for devices whose overall acoustic output exceeds application specific limits should be supported by laboratory and clinical data demonstrating safety and the need for higher output. In these submissions, you should describe what

user interactive features are provided to enhance user awareness of acoustic output (e.g., on screen display, power up default settings, or manual override).

For example, for any transducer intended for transcranial (cephalic) applications in which the $I_{SPTA.3}$ exceeds 94 mW/cm^2, you should provide an estimate of maximum temperature rise (TR) attributable to the use of that transducer for each operating **mode**. You should 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 AIUM/NEMA 2004a, or in IEC 2005. When the $I_{SPTA.3}$ exceeds 94 mW/cm^2 for this application, we recommend special labeling in the form of on-screen precautions about scanning through the eye, burr-holes, fontanels, or foramen magnum.

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

2.2.1 In the operator's manual, you should provide **global maximum** acoustic output values for each possible system/transducer/**mode**/application combination. A tabular format is desirable for this information. An example of this format is provided in Section 2.3 and also in the AIUM labeling standard (AIUM 2008). The proposed labeling in your 510(k) should contain the acoustic output quantities you plan to include but not necessarily the values of these quantities, and also a description of any symbols used. In addition, the labeling should include the corresponding **operating conditions**, and the measurement uncertainties for acoustic quantities (**power**, **pressure**, **intensities**, **center frequency**). The **global maximum** values of MI and spatial-peak intensities in the Track 1 acoustic output labeling should be statistical maximum values. See Appendix A, Section B5.

2.2.2 You should provide an explanation of how **derated** acoustic output exposure quantities were derived from exposure quantities measured in water.

2.2.3 You should provide an explanation of the interactive system features that affect acoustic output (see Section 1.4.1.2). You should also provide instructions on how to use these features to follow the **ALARA** principle. For transducers that exceed application specific acoustic output exposure levels in Table 2-1 or for transducers for which more than one application-specific acoustic output exposure level applies, you should describe what user-interactive features are provided to enhance user awareness of acoustic output. For example these features could include an on-screen display, power-up default settings, manual override, or warnings.

2.2.4 When abdominal Doppler is indicated, you should clearly state that this indication does not include fetal Doppler.

2.2.5 For unfocused fetal heart rate monitors, (see Section 2.1.2) you should provide the following information instead of that recommended in Sections 2.2.1 and 2.2.2: I_{SATA} at the transducer face, entrance beam dimensions, **center frequency**, pulse duration and pulse repetition frequency (if pulsed), and measurement uncertainties for I_{SATA}, **ultrasonic power**, and **center frequency**. The reported I_{SATA} at the transducer face

should be the statistical maximum of the global maximum value. See Appendix A, Section B5.

Example 2-1
TRACK 1 SUMMARY (ref. 2.1.1)

System: _____ Transducer: _____

		Mode of Operation						
Clinical Application	Global Maximum Output Level (est.)	B	M	PWD	CWD	Color Doppler	Combined (Specify)	Other* (Specify)
Ophthalmic	max $I_{SPTA.3}$							
	min $I_{SPTA.3}$							
	max MI (or $I_{SPPA.3}$)							
	min MI (or $I_{SPPA.3}$)							
Fetal Imaging & Other	max $I_{SPTA.3}$							
	min $I_{SPTA.3}$							
	max MI (or $I_{SPPA.3}$)							
	min MI (or $I_{SPPA.3}$)							
Cardiac	max $I_{SPTA.3}$							
	min $I_{SPTA.3}$							
	max MI (or $I_{SPPA.3}$)							
	min MI (or $I_{SPPA.3}$)							
Peripheral Vessel	max $I_{SPTA.3}$							
	min $I_{SPTA.3}$							
	max MI (or $I_{SPPA.3}$)							
	min MI (or $I_{SPPA.3}$)							

*Examples of other modes of operation include: A-mode, Amplitude Doppler, 3-D Imaging, Harmonic Imaging, Tissue Motion Doppler, and Color Velocity Imaging

N.B. The information should be provided separately for each system and transducer.

2.3 TRACK 1 – EXAMPLE ACOUSTIC OUTPUT FORMATS

For each mode/application combination identified in Section 2.1.1.a, we recommend that you provide the acoustic output (MI, $I_{SPTA.3}$, $I_{SPPA.3}$) and associated acoustic parameters and operating control conditions. A tabular format is desirable; see Examples 2-2 and 2-3 for **non-autoscanning** and **autoscanning modes**, respectively. 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 one acoustic output description can apply for both **modes**. However, the acoustic output description should be identified as applying to both **modes**.

All entries in Example 2-2 and Example 2-3 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. Measurement uncertainties for acoustic quantities (**power**, **pressure**, **intensities**, **center frequency**) should be provided.

Symbols used in the two examples 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).

Example 2-2
Acoustic Output Format for Track 1
Non-Autoscanning Mode

System: _____ **Operating Mode:** _____
Transducer Model: _____ **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				
	•••		•••	•••	•••

Example 2-3
Acoustic Output Format for Track 1
Autoscanning Mode

System: _____ **Operating Mode:** _____
Transducer Model: _____ **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				
	•••		•••	•••	•••

Section 3. Track 3 Recommendations

If you follow the **Output Display Standard** (AIUM/NEMA 2004a or IEC 2007), FDA considers your device a Track 3 device. Systems that include fetal Doppler applications, except for fetal heart rate monitors, should follow Track 3. Under Track 3, acoustic output will not be evaluated on an application-specific basis, but the **global maximum derated** I_{SPTA} should be ≤ 720 mW/cm^2, and either the **global maximum** MI should be ≤ 1.9 or the **global maximum derated** I_{SPPA} should be ≤ 190 W/cm^2. An exception is for ophthalmic use, in which case, the TI = Max(**TIS_as**, TIC) should be ≤1; $I_{SPTA.3}$ ≤ 50 mW/cm^2; and MI ≤ 0.23. FDA considers a device with fixed acoustic output to be Track 1, unless Section 3.1.5 applies.

3.1 TRACK 3 - ACOUSTIC OUTPUT

The Track 3 approach applies to systems that follow the **Output Display Standard**. This approach eliminates the application-specific comparison of acoustic output to Preamendments exposure levels.

3.1.1 Your submission should include the information described below.

a. For each system/transducer combination, we recommend you specify for each mode (as stated in the Indications for Use), the target range of values for the $I_{SPTA.3}$, and the MI or $I_{SPPA.3}$, and an estimated range of TI's under the operating conditions that maximize these quantities. A tabular format is desirable; see the example given in Example 3-1.

   NOTE: Where system/transducer or transducer/mode combinations have the same design target range for a given output quantity, only a single range can be listed for those combinations.

b. A description of how the specification(s) in 3.1.1.a will be met.

c. The engineering basis for the range of values specified in 3.1.1.a (e.g., preliminary or prototype measurements, theoretical calculations, estimates based on measurements of previously cleared transducers, or acoustic output exposure levels).

NOTE: If you specify upper bounds that the device will not exceed in place of the target range of values recommended in 3.1.1.a, you should explain how you addressed the recommendations in 3.1.1.b and 3.1.1.c.

3.1.2 You should indicate:

a. that measurements of acoustic output display indices - the **Thermal Index** (TI) and the **Mechanical Index** (MI) - will be made following Section 6 of AIUM/NEMA 2004a, or IEC 2005; and

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

3.1.3 You should specify the default setting acoustic output exposure levels (e.g., as a percentage of the maximum levels) and the rationale for selecting these default values. See Section 5 of AIUM/NEMA 2004a or Clause 201.12.4.3 of IEC 2007.

NOTE: A default setting that uses the maximum acoustic output for implementing **ALARA** is not considered good practice. The reason is that the user must then take action to make the device operate at a potentially safer output, rather than having to take an action to make the situation potentially less safe if the default had been set at a lower output.

3.1.4 You should explain the reason for any **Thermal Index** that exceeds a value of 6.0.

3.1.5 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**, you should submit the **global maximum** values of the $I_{SPTA.3}$, TI (TIS, TIB, or TIC), MI, and $I_{PA.3}$ @ MI_{max}, (see Section 3.2.4). You should also include the details of the calculations in the **Design History File**.

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

3.2.1 In the operator's manual, you should provide **global maximum** acoustic output values for each possible system/transducer/**mode** combination. A tabular format is desirable for this information. Examples of this format are provided in Section 3.3, and also in the AIUM labeling standard (AIUM 2008). The labeling in your 510(k) should contain the acoustic output quantities you plan to include, but not necessarily the values of these quantities. The labeling should also include a description of any symbols used. In addition, the labeling should include the corresponding **operating conditions**, and the measurement uncertainties for acoustic quantities (**power**, **pressure**, **intensities**, **center frequency**).

3.2.2 You should provide an explanation of the real-time display features and controls of the system, including default settings (see Section 4.2 of AIUM/NEMA 2004a or Clause 201.7 of IEC 2007). You should provide instructions 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) should be available to be called up by the user, although all three indices do not have to be displayed simultaneously. In this regard, please see page 39 in the AIUM publication, "Medical Ultrasound Safety" (AIUM 1994).

3.2.3 You should provide the display accuracy (see Section 4.2.1 of AIUM/NEMA 2004a or Clause 201.7.2.101 of IEC 2007).

3.2.4 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**, you should provide the

mean of the **global maximum** values (when taken over a number of units), for each transducer, of $I_{SPTA.3}$, TI (TIS, TIB, or TIC), MI, and $I_{PA.3}$ @ MI_{max}. See Example 3-2. You should explain the meaning of and describe the uncertainties associated with these values.

Example 3-1
Track 3 Output Range Summary Format
(see 3.1.1.a)

System: _____
Transducer: _____

	Mode of Operation						
Global Maximum Output Levels (est.)	B	M	PWD	CWD	Color Doppler	Combined (Specify)	Other* (Specify)
max $I_{SPTA.3}$							
min $I_{SPTA.3}$							
max MI (or $I_{SPPA.3}$)							
min MI (or $I_{SPPA.3}$)							
max TIS							
min TIS							
max TIB							
min TIB							
max TIC							
min TIC							

* Examples of other modes of operation may include: A-mode, Amplitude Doppler, 3-D Imaging, Harmonic Imaging, Tissue Motion Doppler, and Color Velocity Imaging

N.B. The information should be provided separately for each system and transducer.

Example 3-2
TRACK 3 SUMMARY
(for systems with no probes having global maximum index values exceeding 1.0)
(see 3.1.5 and 3.2.4)

System: _____

Transducer Model	$I_{SPTA.3}$	TI Type	TI Value	MI	$I_{PA.3}@MI_{max}$
Model A					
Model B					
Model C					
•••	•••	•••	•••	•••	•••

3.3 TRACK 3 - EXAMPLE ACOUSTIC OUTPUT FORMATS

Example 3-3 shows an example of a tabular format for presenting the transducer/**mode** combinations for which the **global maximum** displayed MI or TI is greater than 1.0.

Example 3-3
Track 3 Transducer/Mode Combination Summary Format

System: _____

	Mode of Operation						
Transducer Model	B	M	PWD	CWD	Color Doppler	Combined (Specify)	Other* (Specify)

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

In Example 3-3, the following **mode** definitions and conventions apply:

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**.

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 one acoustic output description can apply for both **modes**. However, the acoustic output description should be identified as applying to both **modes**.

For each of these transducer/**mode** combinations identified in Example 3-3, we recommend that you provide acoustic output information. This should include **global maximum** index values, associated acoustic and transducer parameters, and relevant operating control conditions. A tabular format is desirable; see the example given in Example 3-4.

All values that you report should be obtained at the same **operating conditions** that give rise to the **global maximum** Displayed Index Value. These **operating conditions** should be specified. Measurement uncertainties for acoustic quantities (**power**, **pressure**, **intensities**, **center frequency**) should be provided.

Symbols used in Example 3-4 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}	the axial distance at which TIB is a **global maximum** (i.e., $z_{sp} = z_{B.3}$) (centimeters).
$z@PII_{.3max}$	the axial distance corresponding to the maximum of the derated spatial-peak **pulse intensity integral** (megapascals).

$d_{eq}(z)$	the equivalent beam diameter as a function of axial distance z. It 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).

NOTE: Some of the symbols used in IEC 2007 are different from those above, which are taken from AIUM/NEMA 2004a, AIUM/NEMA 2004b, and AIUM 2008. These differences are tabulated in AIUM 2008. In such cases either symbol is acceptable, but all symbols should be defined in the labeling.

Example 3-4: Track 3 - Acoustic Output Format

Acoustic Output Table for Track 3

(We recommend you include data where **global maximum** displayed index exceeds 1.0.)

System: _____

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

Index Label			MI	TIS			TIB	TIC
				scan	non- scan		non-scan	
					$A_{aprt} \leq 1$	$A_{aprt} > 1$		
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)						
	$z@PII_{.3max}$	(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							
	•••		•••	•••	•••	•••	•••	•••

NOTE 1 Data need not be included for more than one of the three situations related to TIS.

NOTE 2 Information need not be provided regarding TIC for any **transducer assembly** not intended for transcranial or neonatal cephalic uses.

NOTE 3 Data need not be included for TIS, TIB or TIC if your device meets Section 4.1.2.1 of AIUM/NEMA 2004a or Clause 201.12.4.2a of IEC 2007.

NOTE 4 Data related to MI need not be included if your device meets Section 4.1.2.4 of AIUM/NEMA 2004a or Clause 201.12.4.2b of IEC 2007.

NOTE 5 Example Track 3 Acoustic Output Tables for B-mode, Pulsed Doppler mode, and combined Color Flow/M-mode can be found in AIUM 2008.

3.4 TRACK 3 - EDUCATION PROGRAM FOR THE CLINICAL END-USER

3.4.1 **ALARA** Education Program

You should 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 to follow the **ALARA** principle in all studies, and

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

You may wish to provide a document published by the AIUM, "Medical Ultrasound Safety" (AIUM 1994), to meet the generic content of the educational program. You should also provide information specific to your device regarding **ALARA**.

3.4.2 Recommended information for Educational Material for Track 3 Devices.

3.4.2.1 Bioeffects and Biophysics of Ultrasound Interactions.

You should provide the following:

- brief description of ultrasound, diagnostic frequencies, acoustic output exposure levels;
- brief description of the change in policy that 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; and
- indices as indicators of thermal and mechanical effects.

3.4.2.2 Thermal Mechanisms.

You should provide the following:

- description of thermal bioeffects--temperature rise;
- tissue type (soft, bone, fluid) and relative absorption;
- transducer type (frequency, focusing) and relationship to exposure;
- attenuation, absorption, and scattering mechanisms in different tissue types; and
- spatial volume of insonified tissue (at focus, or elsewhere), including:
    - homogeneity of tissue in insonified volume (effects of layering);
    - soft tissue;
    - bone tissue (fetal, skull, other); and
    - fluids, gas.

3.4.2.3 Nonthermal Mechanisms.

You should provide the following:

- description of mechanical effects--cavitation and role of bubbles;
- factors that produce cavitation, including:
    - pressure (compressional, rarefactional);
    - frequency;
    - beam focusing;
    - pulsed/continuous;
    - standing waves;
    - boundaries; and
    - type of material and ambient conditions.
- types of cavitation, including:
    - stable and inertial cavitation;
    - microstreaming; and
    - nucleation sites.
- threshold phenomena for different types of tissues; and
- bioeffects data on animals (lung hemorrhage, intestinal hemorrhage).

3.4.2.4 Benefits of Ultrasound vs. Risk.

You should provide the following:

- 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 acoustic output exposure levels; and
- the **ALARA** principle, including:
    - controlling energy;
    - controlling exposure time;
    - controlling scanning technique;
    - controlling system setup;
    - effects of system capabilities;
    - effects of operating mode (learn to distinguish); and
    - effects of transducer capabilities.

3.4.2.5 The **Output Display Indices**.

You should provide the following:

- purpose, e.g., display exposure indices;
- **Mechanical Index** (MI);
- **Thermal Index** (TI):
    - soft tissue **Thermal Index** (TIS);
    - bone **Thermal Index** (TIB);
    - cranial bone **Thermal Index** (TIC); and
    - thresholds for display of indices (e.g., whether the system can exceed TI or MI of 1.0).
- system display levels (e.g., minimum TI displayed, minimum MI displayed, display increments); and
- explanation of the meaning of the TI and MI, including:
    - threshold bioeffect levels vary depending on tissue type and
    - bioeffect levels vary depending on frequency and **pressure**

3.4.2.6 Practicing the **ALARA** Principle.

You should address the following:

- how to implement **ALARA** by using the TI and MI indices;
- effects of system controls on acoustic output:

  - Overall gain and TGC versus increasing output and
  - Dynamic range and post-processing versus increasing output.
- relationship of system applications to output;
  - selection of appropriate range for task
- effect of transducer parameters on output:
  - frequency;
  - focusing;
  - pulse length; and
  - dwell time (scanned versus unscanned).
- effect of system operating **modes** on output:
  - B mode;
  - Doppler (spectral, color flow, amplitude Doppler); and
  - M mode.
- means of controlling exposure time;
- whether the device uses the lowest possible output to obtain diagnostic information; and
- examples of clinical applications.

Section 4. 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 AIUM/NEMA 2004a, AIUM/NEMA 2004b. Where used in this guidance, the terms defined below are in **bold** letters.

4.1 General Definitions

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

Symbol: *p*
Unit: Pascal, Pa

ALARA: As low as reasonably achievable.

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**. Calculated according to regression rules, this line extends 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 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 document that declares that a product is in conformance with the provisions of a recognized standard (See FDA-3654 Standards Data Report form at http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3654.pdf).

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 $cm^{-1}MHz^{-1}$

Design History File: Documentation established and maintained by the manufacturer for each type of medical device. The Design History File shall contain or reference the records necessary to demonstrate that the design was developed in accordance with the approved design plan and the requirements of 21 CFR Part 820 - Quality System Regulation. See CDRH Device Advice, Quality System (http://www.fda.gov/cdrh/devadvice/pma/quality_system.html) and 21 CFR 820.30(j) Design History File.

designated standard mode: Consists 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:

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

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**.**

non-autoscan (**non-autoscanning**): The emission of ultrasonic pulses in a single direction, where scanning in more than one direction would necessitate 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 may 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 1," AIUM/NEMA Standards Publication (AIUM/NEMA 2004a) or IEC 60601-2-37 "Medical electrical equipment - Part 2-37: Particular requirements for the safety of ultrasonic medical diagnostic and monitoring equipment," (IEC 2007).

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 guidance 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 1ºC 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, 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: λ
Unit: centimeters per cycle, cm cycle^{-1}

4.2 LIST OF SYMBOLS

p	=	**acoustic pressure**
BW	=	**bandwidth**
A	=	**beam cross-sectional area**
f_c	=	**center frequency**
a	=	**derating factor**
i	=	**instantaneous intensity**
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**
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
λ = **wavelength**

Section 5. References

AIUM: Medical Ultrasound Safety, American Institute of Ultrasound in Medicine, Laurel, MD, 1994. NOTE: As of this writing an update of this publication is being finalized by the AIUM.

AIUM: Acoustic Output Labeling Standard for Diagnostic Ultrasound Equipment: A Standard for How Manufacturers Should Specify Acoustic Output Data, Revision 1, American Institute of Ultrasound in Medicine, Laurel, MD, 2008.

AIUM/NEMA: Standard For Real-Time Display of Thermal and Mechanical Acoustic Output Indices On Diagnostic Ultrasound Equipment, Revision 2. NEMA Standards Publication UD 3-2004; American Institute of Ultrasound in Medicine, Laurel MD; National Electrical Manufacturers Association, Rosslyn, VA; 2004a.

AIUM/NEMA: Acoustic Output Measurement Standard for Diagnostic Ultrasound Equipment, Revision 3. NEMA Standards Publication UD 2-2004; American Institute of Ultrasound in Medicine, Laurel, MD; National Electrical Manufacturers Association, Rosslyn, VA; 2004b.

Barnett SB, Ter Haar GR, Ziskin MC, Rott H-D, Duck FA, Maeda K: "International recommendations and guidelines for the safe use of diagnostic ultrasound in medicine," Ultrasound in Med. & Biol., 26, 355-366, 2000.

BMUS/BIR: "The Safe Use of Ultrasound in Medical Diagnosis," The British Medical Ultrasound Society and The British Institute of Radiology, ter Haar G and Duck FA, eds. (BIR, 36 Portland Place, London, W1N 4AT, UK) 2000.

Hahn GJ, Meeker WQ: Statistical Intervals, A Guide for Practitioners (John Wiley and Sons, New York NY), ISBN # 0-471-88769-2, 1991.

Harris GR: "Early hydrophone work and measurement of output exposure limits at the U.S. Food and Drug Administration," in "Biological effects of ultrasound: Development of safety guidelines, Part 1: Personal histories," W.L. Nyborg, Ed., Ultrasound in Med. & Biol., 26, 930-932, 2000.

Health Canada: "Guidelines for the safe use of diagnostic ultrasound," Cat. H46-2/01-255E, Ministry of Public Works and Government Services Canada, 2001.

IEC: IEC 60601-1, Medical Electrical Equipment - Part 1: General Requirements for Safety, International Electrotechnical Commission, 2004.

IEC: IEC 62359, Ultrasonics – Field characterization – Test methods for the determination of thermal and mechanical indices related to medical diagnostic ultrasonic fields, International Electrotechnical Commission, 2005.

References

IEC: IEC 60601-2-37, Medical electrical equipment - Part 2-37: Particular requirements for the safety of ultrasonic medical diagnostic and monitoring equipment, International Electrotechnical Commission, 2007.

ISO: ISO-10993-1, Biological Evaluation of Medical Devices Part 1: Evaluation and Testing, 2003.

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

NCRP: "Exposure Criteria for Medical Diagnostic Ultrasound: II. Criteria Based on all Known Mechanisms," NCRP Report No. 140, National Council on Radiation Protection and Measurements, 7910 Woodmont Ave., Suite 400, Bethesda, MD 20814, 2002.

Nyborg WL: "Lauriston S. Taylor Lecture: Assuring the safety of medical diagnostic ultrasound," Health Physics, 82, 578-587, 2002.

O'Brien WD, Abbott JA, Stratmeyer ME, Harris GR, Schafer ME, Siddiqi TA, Merritt CRB, Duck FA, Bendick PJ: "Acoustic output upper limit proposition: Should upper limits be retained?" J. Ultrasound Med., 21, 1335-1341, 2002.

Preston RC, Bacon DR, Smith RA: "Calibration of medical ultrasonic equipment - procedures and accuracy assessment," IEEE Trans. Ultrasonics, Ferroelectrics, and Frequency Control, 35, 110-121, 1988.

Stratmeyer ME: "FDA model for regulatory purposes," Ultrasound in Med. & Biol., 15, Supplement 1, 35-36, 1989.

Stratmeyer ME: "Ultrasound-induced fetal bioeffects," Proceedings of Ultrasonics World Congress, ISBN #2-9521105-0-6, 1145-1147, September, 2003.

UL: UL-60601-1 - Medical Electrical Equipment, Part 1: General Requirements for Safety, Underwriter's Laboratories, Northbrook IL, 2003.

UL: UL 544 - Standard for Medical and Dental Equipment, Underwriter's Laboratories, Northbrook IL, 1998.

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.

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.

Ziskin MC: "Specification of acoustic output level and measurement uncertainty in ultrasound exposimetry," IEEE Trans. Ultrasonics, Ferroelectrics, and Frequency Control, 50, 1023-34, 2003.

Section 6. Illustrative List for FDA Reviewers of Diagnostic Ultrasound 510(k) Submissions

510(k) Number: _____

Device Name: _____

Company Name: _____

Section	Item	Needed? yes / no	Present? yes / no
	Administrative Information:		
	MDUFMA Cover Sheet	☐ / ☐	☐ / ☐
	CDRH Premarket Review Cover Sheet	☐ / ☐	☐ / ☐
	510(k) Cover Letter	☐ / ☐	☐ / ☐
	Indications for Use Statement	☐ / ☐	☐ / ☐
	510(k) Summary or Statement	☐ / ☐	☐ / ☐
	Truthful and Accuracy Statement	☐ / ☐	☐ / ☐
	Financial Certification or Disclosure	☐ / ☐	☐ / ☐
	Declarations of Conformity and Summary Reports	☐ / ☐	☐ / ☐
	Standards Form FDA-3654	☐ / ☐	☐ / ☐
	Clinical Trials Form FDA-3674	☐ / ☐	☐ / ☐
	Executive Summary	☐ / ☐	☐ / ☐
	Reason for Submission	☐ / ☐	☐ / ☐
	Submission Type (Track 1 or 3)	☐ / ☐	☐ / ☐
1.3	**Indications for Use:**		
	510(k) Indications for Use Form	☐ / ☐	☐ / ☐
	New Indications for Use (Probes, Accessories)	☐ / ☐	☐ / ☐
	Previously Cleared Indications for Use	☐ / ☐	☐ / ☐
1.4	**General Device Description:**		
	System Design	☐ / ☐	☐ / ☐
	Transducer Operation	☐ / ☐	☐ / ☐
	Operating Controls	☐ / ☐	☐ / ☐
	New or Unique Features/Technological Characteristics	☐ / ☐	☐ / ☐
1.5	**Predicate Device Comparison:**		
	Legally Marketed Predicate Device(s)	☐ / ☐	☐ / ☐
	Comparison to Predicate Device(s)	☐ / ☐	☐ / ☐
	Accessories/Kits	☐ / ☐	☐ / ☐
	Labeling and/or Promotional Materials	☐ / ☐	☐ / ☐
1.6	**Acoustic Output Reporting:**		
	Measurement Methodology Certifications	☐ / ☐	☐ / ☐
	Test Methodology Reporting Per Section 1.6.1	☐ / ☐	☐ / ☐
1.7	**General Clinical Safety & Effectiveness:**		
1.7.1	Clinical Measurement Range and Accuracies:		
	- Test Methodology for Accuracies and Sensitivities	☐ / ☐	☐ / ☐
	- Doppler Sensitivity (for quantitative claims)	☐ / ☐	☐ / ☐

1.7.2	Thermal, Mechanical and Electrical Safety	☐ / ☐	☐ / ☐
1.7.3	Patient Contact Materials:		
	- Material Name/Chemical Composition	☐ / ☐	☐ / ☐
	- Previously Cleared or Biocompatibility Data	☐ / ☐	☐ / ☐
1.7.4	Cleaning, Disinfection, Sterilization, and Pyrogenicity:		
	- Legally Marketed Disinfectants / Sterilants	☐ / ☐	☐ / ☐
	- Recommended Procedures for Probe Processing	☐ / ☐	☐ / ☐
	- Level of Required Disinfection/Sterilization (SAL)	☐ / ☐	☐ / ☐
	- Information for Components Provided Sterile	☐ / ☐	☐ / ☐
	- Pyrogenicity Claims	☐ / ☐	☐ / ☐
1.7.5	Software/Firmware Information (Moderate LOC):		
	- Summary Description of Algorithms & Explanations	☐ / ☐	☐ / ☐
	- Software Description	☐ / ☐	☐ / ☐
	- Software Version Number	☐ / ☐	☐ / ☐
	- Device Hazard Analysis	☐ / ☐	☐ / ☐
	- Software Requirements Specification (SRS)	☐ / ☐	☐ / ☐
	- Architecture Design Chart	☐ / ☐	☐ / ☐
	- Software Design Specifications (SDS)	☐ / ☐	☐ / ☐
	- Traceability Analysis	☐ / ☐	☐ / ☐
	- Software Development Environment Description	☐ / ☐	☐ / ☐
	- Verification and Validation Documentation	☐ / ☐	☐ / ☐
	- Revision Level History	☐ / ☐	☐ / ☐
	- Unresolved Anomalies (Bugs and Defects)	☐ / ☐	☐ / ☐
1.8	**Labeling:**		
1.8.1	Draft Operator's Manuals / Promotional Materials	☐ / ☐	☐ / ☐
	Description of System and Transducers	☐ / ☐	☐ / ☐
1.8.1.1	Indications for Use, Contraindications, Warning & Precautions	☐ / ☐	☐ / ☐
	Prescription Device Statement	☐ / ☐	☐ / ☐
1.8.1.2	Clinical Instructions for Use	☐ / ☐	☐ / ☐
1.8.1.3	Compatible Accessories and Kits (with Specifications)	☐ / ☐	☐ / ☐
	Probe Sheath Recommendation for Invasive Uses and FDA Latex Alert	☐ / ☐	☐ / ☐
1.8.1.4	Clinical Measurement Accuracies and Ranges	☐ / ☐	☐ / ☐
1.8.1.5	Draft Acoustic Output Labeling with Descriptions and Measurement Uncertainties	☐ / ☐	☐ / ☐
1.8.1.6	Care, Cleaning, Disinfection, Sterilization	☐ / ☐	☐ / ☐
1.8.1.7	Special Labeling	☐ / ☐	☐ / ☐
1.8.1.8	Literature References	☐ / ☐	☐ / ☐
2	**Track 1 Specific Information**		
2.1	**Acoustic Output Reporting:**		
2.1.1	Mode/Application Possibilities Summary	☐ / ☐	☐ / ☐
	Target Range of Values (MI or $I_{SPPA.3}$ and $I_{SPTA.3}$)	☐ / ☐	☐ / ☐
2.1.2	Fetal Heart Rate Monitor Information	☐ / ☐	☐ / ☐
2.1.3	Temperature Rise for Transcranial	☐ / ☐	☐ / ☐
2.2	**Acoustic Output Labeling:**		
2.2.1	Draft Acoustic Output Labeling Formats	☐ / ☐	☐ / ☐
2.2.2	Explanation of Derated Acoustic Output Quantities	☐ / ☐	☐ / ☐
2.2.3	Interactive System Features	☐ / ☐	☐ / ☐
	ALARA Discussion	☐ / ☐	☐ / ☐
2.2.4	Abdominal Doppler Contraindication	☐ / ☐	☐ / ☐
2.2.5	Fetal Heart Rate Monitoring	☐ / ☐	☐ / ☐

3 Track 3 Specific Information

3.1 Acoustic Output Reporting:

3.1.1	Operating Mode Possibilities Summary	☐ / ☐	☐ / ☐
3.1.2	Output Display and Measurement Method Certification	☐ / ☐	☐ / ☐
3.1.3	Description of Defaults	☐ / ☐	☐ / ☐
3.1.4	Justification of TI's>6.0	☐ / ☐	☐ / ☐
3.1.5	**Global maximum** TI, $I_{SPTA.3}$,MI and $I_{PA.3}$@MI_{max} when MI/TI ≤ 1.0	☐ / ☐	☐ / ☐

3.2 Acoustic Output Labeling:

3.2.1	Draft Acoustic Output Labeling Formats	☐ / ☐	☐ / ☐
3.2.2	Description of Real-Time Display and Controls	☐ / ☐	☐ / ☐
3.2.3	Display Accuracy	☐ / ☐	☐ / ☐
3.2.4	**Global maximum** TI, $I_{SPTA.3}$, MI and $I_{PA.3}$@MI_{max} when MI/TI ≤ 1.0	☐ / ☐	☐ / ☐

3.3	**Education Program**	☐ / ☐	☐ / ☐

Appendix A: Suggested Format and Content of Acoustic Output Measurement and Labeling Records Maintained in the Design History File

General Information

This appendix is intended to assist manufacturers in documenting the final measurement data and product labeling information, based on their production devices. This information should be maintained in the **Design History File**.

Suggested records:

A. LABELING/USER INFORMATION

The Design History File should contain:

1. a copy of all labeling, including acoustic output information following Sections 2.2 and 3.2 of this guidance and
2. 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 B5 below. For Track 1, you should document this information for each system/transducer/**mode**/application combination (i.e., one set of values for each applicable mode/application combination identified under Section 2.1.1.a of this guidance). For Track 3, you should document this information for each system/transducer/**mode** combination (i.e., one set of values for each applicable mode identified under Section 3.1.1.a of this guidance).

B. GMP TEST PLAN

The **Design History File** should contain:

1. the number of units tested and percentage of production lot if applicable;
2. measurement uncertainties for acoustic quantities (**power**, **pressure**, **intensities**, and **center frequency**);
3. the **operating conditions** used to obtain the measured acoustic output;
4. a statement explaining whether the **operating conditions** result in maximizing output, and if not, a justification for equivalence; and
5. 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 2-1); $I_{SPTA.3}$ = 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].

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 exposure levels specified in Sections 2 (Track 1) and 3 (Track 3) of the guidance. We recommend that the statistical technique known as "one-sided tolerance for normal distributions" be used. See Hahn et al. 1991, Section 2.4 (pages 34-36), Sections 4.6.3 and 4.6.4 (pages 60-61), and Table A.12d (page 315), or see Natrella 1966, Section 2-5 (page 2-13) and Table A-7 (page T-14). This procedure has the following formulation:

$$L \geq X + Ks$$

where:

- L is the relevant $I_{SPTA.3}$ or MI (or $I_{SPPA.3}$) Preamendments acoustic output exposure level (see Table 2-1)
- X is the mean of the measured values
- s is the standard deviation of the measured values
- K is the tolerance coefficient and is a function of the confidence level (notated $(1 - \alpha)$ in Hahn et al. 1991 and γ in Natrella 1966), the proportion (P) of the distribution less than (X + Ks), and the sample size (n).

The choices for γ (or, equivalently, $1 - \alpha$), P, and n are at the manufacturer's discretion. However, the choices for γ, P, and n should be documented and justified in the GMP process and the **Design History File**. The values of X and s also should be documented.

For this statistical procedure to be valid, the sample size n should not be less than three. Also, please note that, if the above one-sided tolerance inequality is not met for an initial (and presumably low) sample size, you should not simply increase n to achieve a lower tolerance coefficient value (K) and continue the test. Such a sequential testing approach is invalid.

An example of applying this procedure to a population of ultrasound transducers is given in Ziskin 1993 and Ziskin 2003. However, please note that Table 2 in Ziskin 1993 is incorrect and should be replaced by either Table A-7 in Natrella 1966, Table A.12d in Hahn et al. 1991, or Table II in Ziskin 2003.

NOTE: In computing the standard deviation s, the hydrophone measurement uncertainty should not 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 acoustic output exposure levels in Section 2 (Track 1) or Section 3 (Track 6) should be reduced accordingly as described in Section 1.6, paragraphs 3 and 4.

C. STATISTICAL TECHNIQUES

For ongoing testing of production units, statistical techniques must conform to 21 CFR 820.250.

Appendix B: Non-OEM Replacement Transducers

These transducers are generally those that are manufactured by a party other than the original equipment manufacturer (OEM) and are intended to replace a transducer originally provided by the system manufacturer. They can be either new transducers or original equipment transducers that have been modified or remanufactured.

Like new OEM transducers, non-OEM, reprocessed, and remanufactured transducers are new medical devices. As such, they are subject to the 510(k) premarket notification regulations (21 CFR 807.81). They need to have a cleared 510(k) prior to being marketed.

In addition to the information recommended in the body of this guidance, we recommend the following in regard to acoustic output testing and labeling for diagnostic ultrasound replacement transducers:

1. In making the acoustic output comparison between the replacement and OEM transducers, three or more transducers of each type should be used. The use of a single OEM generator is acceptable if it operates within the OEM manufacturer's specifications.

2. Acoustic output comparisons in the basic modes of M, B, and pulsed Doppler are acceptable, but worst-case (i.e., maximum output) conditions should be identified and reported.

3. New acoustic output information (following Sections 2.2 and 3.2) should be provided in the transducer operator's manual whether or not you can demonstrate that the acoustic outputs of the replacement and OEM transducers agree within the limits of the measurement uncertainty. Moreover, if the outputs do not agree the sponsor should demonstrate that means have been incorporated into the replacement transducer to ensure the accuracy of the acoustic output real-time display indices. Furthermore, if the outputs do not agree, then the transducers should not be referred to as "replacement." Instead the transducers should be referred to as "similar to" and the differences should be noted.

4. The acoustic output measurement methodology should be completely described following Section 1.6.1 of this guidance.

Appendix C: Reprocessed "Single-Use Only" Transducers

Reprocessed single-use only transducers are ultrasound transducers that are intended by the OEM to be single-use devices (SUDs), but after such single-use they are reprocessed for use on another patient or in another procedure on the same patient. Reprocessing of SUDs requires a registered reprocessor to submit a 510(k) to the FDA for premarket clearance. See "Frequently-Asked-Questions about the Reprocessing and Reuse of Single-Use Devices by Third-Party and Hospital Reprocessors," (http://www.fda.gov/cdrh/ohip/guidance/1333.pdf) and "Frequently-Asked-Questions about the Reprocessing and Reuse of Single-Use Devices by Third-Party and Hospital Reprocessors; Three Additional Questions," (http://www.fda.gov/cdrh/ohip/guidance/1427.pdf). The reprocessor should conduct functional testing, as well as validation of cleaning and of sterilization. For the 510(k) submission, reprocessors should address the following points in addition to providing all of the information requested in the body of this guidance.

1. You should provide a detailed discussion of how you confirm that the diagnostic ultrasound performance characteristics (i.e., image quality, acoustic output) and physical integrity of the reprocessed transducer (when used with each compatible OEM system) are substantially equivalent to the original OEM device following transducer reprocessing for the maximum recommended number of cycles.

2. You should completely describe the acoustic output test methodology following Section 1.6.1 of this guidance. You should furnish final acoustic output test results for the last recommended reprocessing cycle. You should compare these results to those for the OEM device. We recommend that you measure three or more reprocessed and OEM transducers for this comparison.

3. You should describe the testing that will be performed to verify that the repeated reprocessing procedures are not adversely affecting the acoustic output and imaging performance of the transducer, following "Validation Data in Premarket Notification Submissions (510(k)s) for Reprocessed Single-Use Medical Devices" (Validation Data guidance) (http://www.fda.gov/cdrh/ode/guidance/1216.html).

4. If the maximum number of reprocessing cycles for the transducer is not specified, then you should test each transducer (100% sampling) for acoustic performance characteristics following each reprocessing cycle. All results should be documented and compared to the original OEM device specifications.

5. You should describe the method that you as the reprocessor use to keep track of the number of reprocessing cycles that an individual transducer has undergone. Again, this is better addressed by referring to the Validation Data guidance.

Appendix D: Cleaning, Disinfection, and Sterilization

Reusable devices should contain clear instructions for cleaning and sterilization or disinfection. The recommended cleaning and sterilization procedures should be validated by the manufacturer. Guidance on this subject is "Labeling Reusable Medical Devices for Reprocessing in Health Care Facilities," (http://www.fda.gov/cdrh/ode/198.pdf).

Ultrasound probes that are non-critical devices only need to be cleaned and low-level disinfected between patient uses. Probes used in semi-critical applications should be sterilized between uses whenever feasible, but high level disinfection is minimally acceptable. In addition, the use of a sheath is recommended for every semi-critical use of the probe. Critical devices should be sterilized and the use of a sterile sheath is recommended. Please note that the use of sheaths does not change the type of processing that is recommended for the transducer. After use, the single-use sheath should be removed and discarded. The probe used in a semi-critical application should be cleaned and sterilized or at least receive high level disinfection after use even if a sheath was used. Probes used for critical applications should be cleaned and sterilized after use even if a sterile sheath was used. Sheaths can fail during use and the level of resulting contamination may not be easily visible.

For devices and accessories that can be terminally sterilized, a validated method of sterilization should be specified. The validation method used should be described. The SAL should be stated. The critical sterilization cycle parameters for each sterilization method should be provided clearly to the users along with a description of any equipment and accessories needed for sterilization of the medical device.

For steam sterilization, you should indicate whether the recommended cycle(s) are pre-vacuum or gravity cycles and state the cycle temperature and time and the recommended drying time.

For ethylene oxide gas sterilization, you should state the EO concentration recommendations, the cycle time and temperature, and the humidity needed for the sterilization process, as well as the minimum holding or exposure time in the sterilant and the aeration time needed to remove ethylene oxide residues on the device. Cycle parameters provided to users should be consistent with the validated cycles provided in sterilizers used in health care facilities.

If a non-traditional sterilization method is recommended, you should identify the exact sterilizer make and model validated as well as the critical cycle parameters of time and temperature and any post-sterilization instructions needed.

In addition, there are several special situations:

1. Neurosurgical use: Probes that contact brain tissue and cerebrospinal fluid should always be used with a sterile, endotoxin-free sheath because the disinfectant/sterilant residue left on the probe is neuro-toxic and endotoxin is pyrogenic (e.g., cause fevers). NOTE: If the probe is used on a patient with known or suspected

Creutzfeldt-Jakob Disease (CJD) the probe should be destroyed. (see http://www.cdc.gov/ncidod/qa_cjd_infection_control.htm)

2. Endoscopic, rectal, and transvaginal probes should normally be used with a sterile sheath. If these probes are used to assist biopsy procedures, all of the biopsy accessories should be sterile for the procedure and should be cleaned and resterilized after each use. If the transducer probe itself has a built-in channel for the needle guide, that channel could create a risk for contamination of the biopsy needle during use unless the channel is thoroughly cleaned and the probe is sterilized before use on another patient.

3. Due to the inherent limitation of using liquid chemicals for sterilizing medical devices, liquid chemical use should be limited to reprocessing only critical and semi-critical devices that are heat-sensitive and incompatible with other sterilization methods, such as ETO gas or heat sterilization.

   For further information see CDRH's document titled "Labeling Reusable Medical Devices for Reprocessing in Health Care Facilities: FDA Reviewer Guidance." (http://www.fda.gov/cdrh/ode/198.pdf). Also, the following documents should be consulted:

   - ANSI/AAMI ST 35: 2003. Safe handling and biological decontamination of reusable medical devices in health care facilities and in nonclinical settings. Association for the Advancement of Medical Instrumentation. Arlington, VA.
   - ANSI/AAMI ST 81: 2004. Sterilization of medical devices-Information to be provided by the manufacturer for the processing of resterilizable medical devices. Association for the Advancement of Medical Instrumentation. Arlington, VA.
   - ANSI/AAMI/ISO 11607-1:2006. Packaging for terminally sterilized medical devices-Part 1: Requirements for materials, sterile barrier systems, and packaging. Association for the Advancement of Medical Instrumentation. Arlington, VA
   - ANSI/AAMI/ISO 11607-2: 2006 Validation requirements for forming, sealing and assembly processes 1ed. Association for the Advancement of Medical Instrumentation. Arlington, VA
   - ANSI/AAMI/ISO 10993: Biological evaluation of medical devices. Association for the Advancement of Medical Instrumentation. Arlington, VA.
   - U.S. Food and Drug Administration. Guideline on validation of the Limulus amebocyte lysate test as an end-product endotoxin test for human and animal parenteral drugs, biological products, and medical devices. http://www.fda.gov/cder/guidance/old005fn.pdf

- U.S. Food and Drug Administration. Guidance on the Content and Format of Premarket Notification [510(k)] Submissions for Liquid Chemical Sterilants and High Level Disinfectants. http://www.fda.gov/cdrh/ode/397.pdf
- U.S. Food and Drug Administration. Labeling Reusable Medical Devices for Reprocessing in Health Care Facilities. http://www.fda.gov/cdrh/ode/198.pdf
- AAMI TIR 12: 2004. Designing, Testing, and Labeling Reusable Medical Devices for Reprocessing in Health Care Facilities: A Guide for Device Manufacturers. Association for the Advancement of Medical Instrumentation. Arlington, VA.
- AAMI TIR 30: 2003. A compendium of processes, materials, test methods, and acceptance criteria for cleaning reusable medical devices. Association for the Advancement of Medical Instrumentation. Arlington, VA.

Appendix E: Deciding if System or Transducer Modifications Require a New 510(k) Premarket Notification

In addition to the recommendations below, please refer to the guidance "Deciding When to Submit a 510(k) for a Change to an Existing Device" (http://www.fda.gov/cdrh/ode/510kmod.pdf) and "The New 510(k) Paradigm, Alternate Approaches to Demonstrate Substantial Equivalence in Premarket Notifications" (http://www.fda.gov/cdrh/ode/parad510.pdf).

A. Addition or Modification of Transducers

We believe that the addition or modification of transducers to a particular system will need a new 510(k) except when 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 of the system or transducer are unchanged;
3. Acoustic output of each new or modified transducer is below the Preamendments acoustic output exposure level in Table 2-1 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; and
4. Acoustic output is measured and recorded according to the procedures in this 510(k) guidance; these procedures are included in the **Design History File**, and the results are included in the **Design History File**, 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 **Design History File** should adequately document minor changes not affecting the indications for use or acoustic output. These files may be reviewed during FDA quality system inspections. If measurement technology different from that defined in this guidance is used to document acoustic output, a 510(k) premarket notification may be necessary.

B. Modifications to Previously Cleared Diagnostic Ultrasound Systems

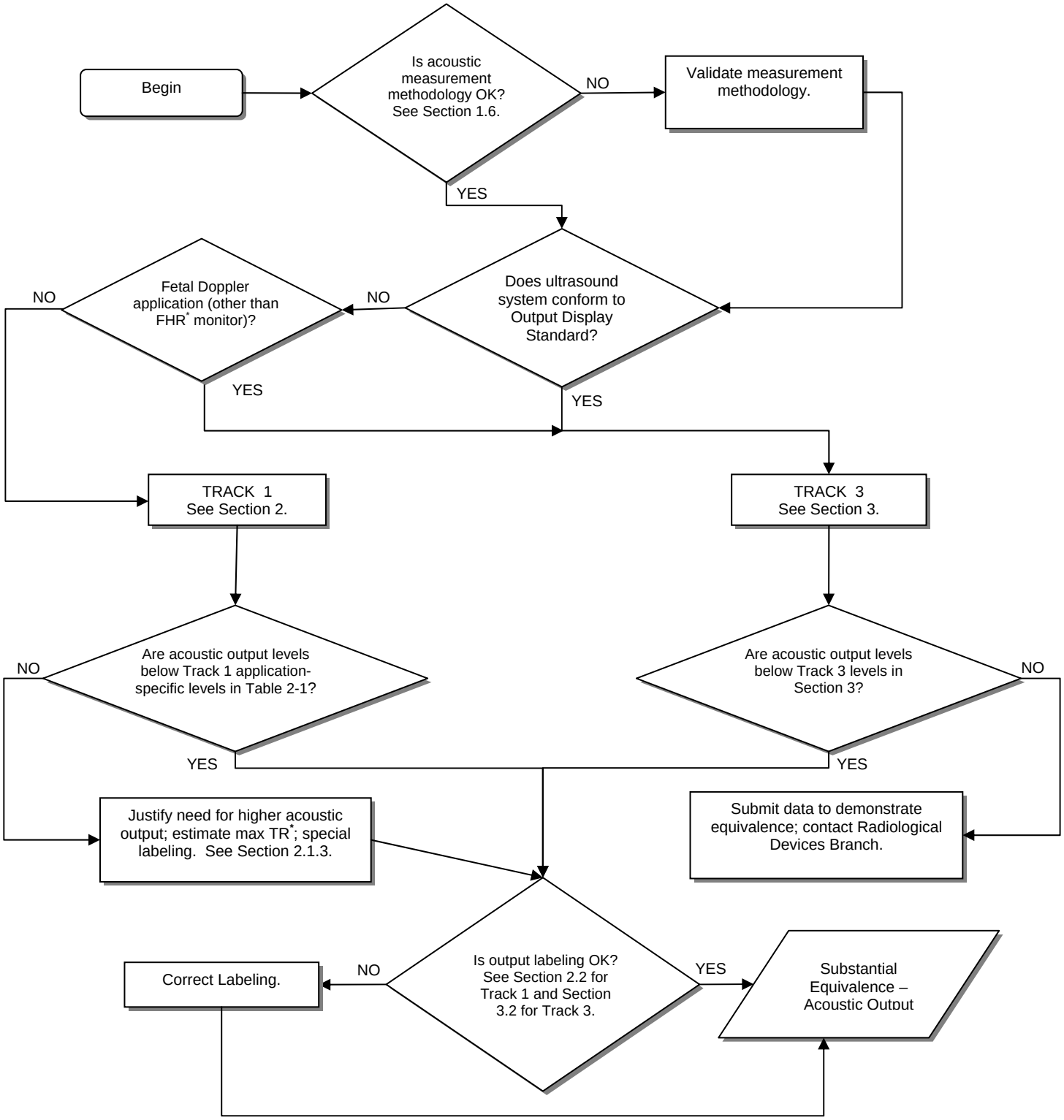
Modifications to a diagnostic ultrasound system that has a previously cleared 510(k) generally will not require a new 510(k) if the Track (1 or 3), indication for use, and the ultrasound generator, controls, and signal processing technologies are unchanged; no system functions are added; no significant new clinical information is provided; and the

clinical application/**mode** of operation does not provide a significant new interpretation of existing information.

C. New Indications for Use

We believe that new clinical applications or new **modes** of operation may represent new indications for use and, therefore, need a new 510(k). An example format for providing the indications for use is given in Appendix G.

Appendix F: Decision Flow Chart for Tracks 1 and 3



* FHR = fetal heart rate; TR = temperature rise

Appendix G: Example Diagnostic Ultrasound Indications For Use Format

System: _____
Transducer: _____

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

Clinical Application		Mode of Operation						
General (Track 1 Only)	Specific (Tracks 1 & 3)	B	M	PWD	CWD	Color Doppler	Combined (Specify)	Other* (Specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal							
	Intra-operative (Specify)							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric							
	Small Organ (Specify)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skeletal (**Conventional**)							
	Musculo-skeletal (**Superficial**)							
	Intravascular							
	Other (Specify)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Intravascular (Cardiac)							
	Trans-esoph. (Cardiac)							
	Intra-cardiac							
	Other (Specify)							
Peripheral Vessel	Peripheral vessel							
	Other (Specify)							

N = new indication; P = previously cleared by FDA; E = added under this appendix
* Examples of other modes of operation may include: A-mode, Amplitude Doppler, 3-D Imaging, Harmonic Imaging, Tissue Motion Doppler, and Color Velocity Imaging

Appendix H: Statistical Analyses

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

1. Description of clinical measurement accuracy. See Sections 1.7.1.2 and 1.8.1.4 of this guidance.
2. Description of measurement uncertainties for acoustic quantities (**power**, **pressure**, **intensities**, **center frequency**). See Section 2.2.1 (Track 1) and Section 3.2.1 (Track 3) of this guidance. In this regard, a good description of the various potential sources of Type A (random) and Type B (systematic) uncertainties for hydrophone measurements can be found in Preston et al. 1988. Also see Ziskin 2003.
3. Description of statistical sampling plan used to ensure that the specifications for acoustic output exposure levels are meaningful. See Section 1.6.1.8 and Ziskin 2003.
4. Description of display accuracy, as specified in Section 4.2.1 of AIUM/NEMA 2004a or Clause 201.7.2.101 of IEC 2007. See Section 3.2.3 (Track 3) of this guidance.