Marketing Clearance of Diagnostic Ultrasound Systems and Transducers

Guidance for Industry and Food and Drug Administration Staff

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

Preface

Public Comment

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Table of Contents

1 Introduction 1
2 Background 1
2.1 Safety of diagnostic ultrasound technology 1
2.2 Enforcement policy for modifications to legally marketed devices 2
2.3 Relevant Standards 2
2.4 Preservation of existing 510(k) pathway and two-track approach, and use of Output Display Standard, International Electrotechnical Commission (IEC) 60601-2-37 3
2.5 Radiation control 4
3 Scope 4
4 Definitions 5
5 Policy 6
5.1 Modifying a Legally Marketed Device 6
5.1.1 Overview 6
5.1.2 Compliance Policy 6
5.1.3 Examples of modifications for which FDA does not intend to enforce compliance with the 510(k) requirement 11
5.2 510(k) Submissions 12
5.2.1 Indications for use 12
5.2.2 Device description 12
5.2.3 Predicate device comparison 13
5.2.4 Acoustic output 14
5.2.5 General clinical safety and effectiveness 17
5.2.6 Labeling 21
5.2.7 Track 1 recommendations 24
5.2.8 Track 3 recommendations 28
5.3 Additional Considerations 32
Appendix A List of Symbols Used in this Guidance 33
Appendix B Format and Content of Acoustic Output Measurement and Labeling Records Maintained in the Design History File 42
Appendix C Non-OEM Replacement Transducers and Remanufactured Transducers 45
Appendix D Reprocessed “Single-Use Only” Transducers 47

Appendix E Cleaning, Disinfection, and Sterilization 49
Appendix F Acoustic Output Reporting Examples 51
Appendix G Statistical Analyses 61

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Guidance for Industry and Food and Drug Administration Staff

This guidance represents the current thinking of the Food and Drug Administration (FDA or Agency) on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. To discuss an alternative approach, contact the FDA staff or Office responsible for this guidance as listed on the title page.

1 Introduction

This guidance document provides detailed recommendations for 510(k) submissions for diagnostic ultrasound systems and transducers. In addition to outlining regulatory approaches for certain diagnostic ultrasound devices, this guidance document describes the types of modifications to a diagnostic ultrasound device for which FDA does not intend to enforce the requirement for a new premarket notification (510(k)).

In general, FDA's guidance documents 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 guidance means that something is suggested or recommended, but not required.

2 Background

2.1 Safety of diagnostic ultrasound technology

Exposure of tissues to intense levels of ultrasound that are well above the levels found in typical diagnostic ultrasound devices can have significant biological effects. Therefore, determinations of substantial equivalence have been made in part by comparing the appropriate acoustic output levels of new devices to those of predicate devices of this type that were on the market prior to May 28, 1976, the date of the Medical Device Amendments to the Federal Food, Drug, and Cosmetic Act (FD&C Act or the Act), which are known as "preamendments devices." The

maximum acoustic output exposure levels of these preamendments devices are given in Table 3 of Section 5.2.7 of this guidance. The levels are derated using a general attenuation coefficient for tissues, to permit a more accurate comparison between transducers of different frequencies and focal lengths. For further information on regulatory acoustic output comparisons, see O'Brien et al., *Acoustic Output Upper Limit Proposition: Should upper limits be retained*, J. Ultrasound Med. 1335, 21, 1335-41 (2002); ME Stratmeyer, *FDA Model for Regulatory Purposes*, Ultrasound in Med. & Biol. 15, 35-36 (1989); and GR Harris, *Early Hydrophone Work and Measurement of Output Exposure Limits at the U.S. Food and Drug Administration,* in Ultrasound in Med. & Biol., BIOLOGICAL EFFECTS OF ULTRASOUNDS; DEVELOPMENT OF SAFETY GUIDELINES, PART 1: PERSONAL HISTORIES 26, 930-932 (W.L. Nyborg ed., 2000).

Because some 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 (JS Abramowicz, *Benefits and risks of ultrasound in pregnancy*, Seminars in Perinatology, 37, 295-300, (2013)), prudent use has been advocated by national and international bodies concerned with medical ultrasound use and safety. In the United States, the American Institute of Ultrasound in Medicine (AIUM) has endorsed the prudent use, as reflected in its official statements.[1] Two mechanisms have been recommended to help clinical users employ the concept of prudent use: (1) providing the maximum levels of acoustic output in the device labeling and (2) incorporating an acoustic output display on the device. This guidance recognizes both of these mechanisms as potential methods of informing users about the acoustic output of their device for the purpose of implementing the principle of As Low As Reasonably Achievable (ALARA).

2.2 Enforcement policy for modifications to legally marketed devices

This guidance describes an enforcement policy for modifications to legally marketed devices that utilize the factors set forth in section 5.1.2 below.

2.3 Relevant Standards

FDA-recognized standards may be used to help demonstrate substantial equivalence in 510(k) submissions. For more information regarding use of consensus standards, see FDA's guidance entitled "Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices."[2] For the current edition of the FDA-recognized consensus standards referenced in this document, see the FDA Recognized Consensus Standards Database.[3]

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[1] Available at https://www.aium.org/press/viewRelease.aspx?id=102

[2] Available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/appropriate-use-voluntary-consensus-standards-premarket-submissions-medical-devices

[3] Available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

2.4 Preservation of existing 510(k) pathway and two-track approach, and use of Output Display Standard, International Electrotechnical Commission (IEC) 60601-2-37

This guidance document retains a two-track approach, 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. Please note that for historical reasons, there is no Track 2.

Track 1 recommendations are for devices that do not conform to the Output Display Standard in IEC 60601-2-37 (IEC 60601-2-37 *Medical electrical equipment - Part 2-37: Particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment*) and that follow FDA's recommendations for application-specific acoustic output levels. The acoustic output information should be included in the operator's manual. A tabular format (e.g., Examples 2 and 3 in Appendix F of this guidance) may be useful for this purpose.

Track 3 recommendations are for devices that conform to the Output Display Standard in IEC 60601-2-37. The system should incorporate the output display according to IEC 60601-2-37, and the labeling should include acoustic output information. A tabular format such as shown in the example Acoustic output reporting table of IEC 60601-2-37 may be a useful example for this purpose. Also, please note that information similar to that provided in IEC 60601-2-37 *Acoustic output table intended for 3rd parties,* should be provided to 3rd parties (including the FDA) to allow independent verification of the calculations of the Thermal Index (TI) and Mechanical Index (MI) values for each operating mode. Section 5.2.4.1 of this guidance recommends the basic elements of the acoustic output test methodology that should be described in the design history file and/or 510(k) submission.

The term "Output Display Standard" now refers only to the CDRH-recognized IEC standard, IEC 60601-2-37. Previously, the AIUM/NEMA standard (NEMA UD 3- *Standard for Real-Time Display of Thermal and Mechanical Acoustic Output Indices on Diagnostic Ultrasound Equipment*) was included when the term Output Display Standard was used. Since 2008, the AIUM has withdrawn its equivalent standard, *Standard for real-time display of thermal and mechanical acoustic output indices on diagnostic ultrasound* equipment. Please see the guidance entitled **"**Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices" for detailed information on the use of consensus standards in your regulatory submissions.[4]

[4] Available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/appropriate-use-voluntary-consensus-standards-premarket-submissions-medical-devices

2.5 Radiation control

It is important to note that independent from the pathways described in this guidance for a new or modified ultrasound device, manufacturers must continue to meet the following electronic product radiation control requirements:[5]

- 21 CFR 1020.10 Television Receivers with Cathode Ray Tubes (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.

3 Scope

The following table provides a listing of the classifications containing diagnostic ultrasound systems and transducers affected by this document:

Table 1: Diagnostic Ultrasound Classifications

Device Area	CFR #	Name	Covered by Section 5.1 Modifications Policy?
Radiology	892.1550*	Ultrasonic pulsed doppler imaging system	Yes
Radiology	892.1560	Ultrasonic pulsed echo imaging system	Yes
Radiology	892.1570	Diagnostic ultrasonic transducer	Yes
Cardiovascular	870.1200	Diagnostic intravascular catheter	No
Cardiovascular	870.2100	Cardiovascular blood flowmeter	No

[5] FDA amended the Electronic Product Radiation Control (EPRC) reporting requirements in 21 CFR 1002.1, for diagnostic ultrasound devices, to remove reporting and recordkeeping requirements under 21 CFR 1002.10, 21 CFR 1002.11, 21 CFR 1002.12, and 21 CFR 1002.13 (88 FR 3638 available at https://www.federalregister.gov/documents/2023/01/20/2023-00922/radiological-health-regulations-amendments-to-records-and-reports-for-radiation-emitting-electronic)

Cardiovascular	870.2330	Echocardiograph	No
Cardiovascular	870.2880	Ultrasonic transducer	No
Cardiovascular	870.2890	Vessel occlusion transducer	No
Ob/Gyn	884.2660	Fetal ultrasonic monitor and accessories	No
Ob/Gyn	884.2730	Home uterine activity monitor	No
Ob/Gyn	884.2740	Perinatal monitoring system and accessories	No
Ob/Gyn	884.2960	Obstetric ultrasonic transducer and accessories	No
Radiology	892.1540	Nonfetal ultrasonic monitor	No

*Certain reusable devices within these regulations are subject to 82 FR 26807 (June 9, 2017) and are therefore not within the scope of devices covered by the Section 5.1 modifications policy. (See Sections 5.1.2 and 5.1.2.1.)

Note that the recommendations described in Section 5.2 regarding the content of 510(k) submissions apply to device types denoted in the table above that are not covered by the enforcement policy for modifications to legally marketed devices described in Section 5.1. If you have any questions as to whether your device is covered by the optional modifications pathway described in this guidance, please contact the appropriate review team in the Office of Product Evaluation and Quality (OPEQ) in FDA.

4 Definitions

The definitions and formulae for certain technical terms used in this document are provided in Appendix A. Unless explicitly noted in this section, the definitions and symbols provided are in concurrence with equivalent definitions and symbols in IEC 62359 *Ultrasonics - Field characterization - Test methods for the determination of thermal and mechanical indices related to medical diagnostic ultrasonic fields*. At the manufacturer's discretion, equivalent symbols from IEC 60601-2-37 can be used in the labeling, but all symbols in the labeling should be defined in your submission.

5 Policy

5.1 Modifying a Legally Marketed Device

5.1.1 Overview

This section describes the Agency's enforcement policy for certain modified ultrasound and transducer devices (see Section 3; "Scope") that utilize the factors set forth in Section **0**. Section 5.1.35.1.3 below provides some examples of modifications that may have led to 510(k) submissions in the past, but for which FDA does not intend to enforce compliance with the 510(k) requirement[6] because the device modifications fall within the circumstances described in Section 5.1.2.

After a 510(k) is cleared, certain modifications may trigger the requirement for another 510(k) submission. See "Deciding When to Submit a 510(k) for a Change to an Existing Device,"[7] "Deciding When to Submit a 510(k) for a Software Change to an Existing Device,"[8] and "The Abbreviated 510(k) Program."[9]

5.1.2 Compliance Policy

FDA does not intend to enforce compliance with the 510(k) requirement for certain modified ultrasound and transducer devices (that have already obtained an initial 510(k) clearance) when all of the following apply:

1. The intended use of the modified device is not changed (see Section 5.1.2.1 for details);
2. The device is not a reusable device subject to the requirement for the submission of reprocessing labeling and validation data (see Section 5.1.2.1 for details);
3. The modes of operation for the modified device are well-established (see Section 5.1.2.2 for details);
4. The modifications do not lead to acoustic outputs that exceed the recommended maximum acoustic output levels (see Section 5.1.2.3 for details);
5. The modifications do not result in a range of ultrasound interrogation parameters outside a well-known range (see Section 5.1.2.4 for details);
6. The modifications do not utilize novel mechanical or thermal effects for imaging or measurements (see Section 0 for details);
7. The measurements and analyses are clearly described and the user can adjust the associated control parameters (see Section 5.1.2.6 for details);
8. Transducer element check is performed (see Section 5.1.2.7 for details);

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[6] 21 CFR 807.81(a)(3)
[7] Available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/deciding-when-submit-510k-change-existing-device
[8] Available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/deciding-when-submit-510k-software-change-existing-device
[9] Available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/abbreviated-510k-program

9. Transducer surface temperature falls within a well-defined range (see Section 5.1.2.8 for details); and
10. Appropriate transducer covers are recommended to users (see Section 5.1.2.9 for details).

5.1.2.1 Regarding the intended use of the device:

5.1.2.1.1 The modified device is indicated to obtain ultrasound images of or signals from the body;

5.1.2.1.2 The device's classification is listed in Table 1 of Section 3 of this guidance as falling within the Section 5.1 modifications policy;

5.1.2.1.3 The device is not a reusable ultrasound bronchoscope (product code PSV) subject to the requirement for the premarket submission of validated reprocessing data and instructions [82 FR 26807 (June 9, 2017)];

5.1.2.1.4 The modifications do not introduce or affect intracardiac or intravascular imaging, performed using catheter-based transducers;

5.1.2.1.5 The modifications introduce a new clinical application only if the clinical application has been cleared in another model, manufactured by the same manufacturer, with the same technological characteristics and indications for use as those of the subject device, and within the circumstances defined in Section 5.1.2;

5.1.2.1.6 The modifications do not introduce or affect indications that are disease- or treatment-specific, and/or provide features, or labeling relevant to a disease or treatment;

5.1.2.1.7 The modifications do not involve the marketing of the device for use with a drug or contrast agent and do not affect any existing drug or contrast agent indication;

5.1.2.1.8 The device is indicated for prescription use only; and

5.1.2.1.9 The modifications do not introduce sterile use where previously not indicated, and do not affect previously indicated sterile uses.

5.1.2.2 Regarding the modes of operation of the device: The modifications do not introduce or affect modes of operation other than the well-established ultrasound modes described in Table 2, below.

Table 2: Well-established ultrasound modes of operation

Mode of Operation	Description
A-mode	Signal visualization mode, based on ultrasound reflection data in a single line of interrogation
B-mode (2D, extended field of view 2D, and 3D)	Imaging mode, producing gray-scale ultrasound images, based on ultrasound reflection
M-mode	Signal visualization mode, based on ultrasound reflection data, depicted as a function of time
Doppler	Characterization of movement, based on the Doppler frequency shift
CW (Continuous Wave)	Audio signal, indicating movement in a line of interrogation
Color Doppler	Color-coded imaging, showing movement with respect to the transducer axial direction
Spectral Doppler or Pulsed Wave (PW)	Spectral signal, quantification of movement in user-defined sample volumes
Power Doppler	Color-coded imaging, showing movement with no direction information
Combination Doppler	Any combination of the above Doppler modes
Speckle-tracking	Any form of characterization of movement in the image based on spatial displacement of speckle, including strain imaging
Tissue Harmonic Imaging	Gray-scale imaging based on the harmonics of the frequency of interrogation
Combination Modes	Combination of the above modes of operation, superimposed on the display

Note 1: The modes of operation listed above in Table 2 are for ultrasound-based tissue interrogations that utilize longitudinal waves.

Note 2: Any modification that introduces or affects modes of operation other than the modes listed above in Table 2 is outside the scope of the compliance policy described in Section 5.1.2. Examples of modes not included in Table 2 are shear wave elastography, acoustic attenuation mapping, transmission based imaging, and sound speed measurement.

5.1.2.3 Regarding the acoustic output of the device: The modifications do not lead to acoustic outputs that exceed the recommended maximum acoustic output levels specified in Table 3 of Section 5.2.7 (Track 1) or Section 5.2.8 (Track 3).

5.1.2.4 Regarding the ultrasound interrogation parameters: The modifications do not result in a range of ultrasound interrogation parameters outside the ranges specified below:[10]

Center frequency (f_c)	1 – 20 MHz
Peak rarefactional pressure (p_r)	0 – 7 MPa
Number of Cycles in Pulse	1 – 100
Pulse repetition frequency (PRF)	100 Hz – 20 kHz

Note 1: Restriction on number of cycles does not apply to CW Doppler and coded excitation.

5.1.2.5 Regarding novel ultrasound effects: The modifications do not use ultrasound energy to produce novel mechanical or thermal effects beyond those known to occur for the imaging modes described in Table 2 of Section 5.1.2.2 above (e.g., acoustic radiation force impulse imaging produces novel mechanical effects at levels above those associated with imaging methods listed in Table 2). Also, the modifications do not affect any cleared use of ultrasound energy to produce mechanical or thermal effects on tissue for the purpose of tissue interrogation. In cases where the level of thermal or mechanical effects could be increased as a result of a certain modification, please consult the Office of Radiological Health (OHT8), Center for Devices and Radiological Health, FDA.

5.1.2.6 Regarding modifications to measurement and processing features:

[10] FDA derived these parameter ranges from previously cleared and preamendments devices.

5.1.2.6.1 Other than radio frequency (RF) signal processing (including all the steps necessary to convert RF data into displayable data), the image processing is reversible or the original image is available to the user;

5.1.2.6.2 The user or facility is able to edit or adjust user-activated post-processing applications that are used for measurements (e.g., segmentation and registration);

5.1.2.6.3 Where possible, the user or facility should be able to edit assumed values, parameters, or thresholds in equations or algorithms used to generate additional outputs based on measurements of anatomical dimensions, tissue velocity, or pixel intensity. For example, the user should be able to adjust sensitivity (thresholds) in spectral Doppler for measurement of resistance index (RI). The equations or algorithms and assumptions are provided in the operator's manual when appropriate (such as when it does not reveal proprietary information). Manufacturers may choose to limit users' initial abilities to make such edits, for example, by requiring users to call a customer support line to obtain a password. In instances that editing capability is not provided for the user, such as due to the potential for corruption of the original image, the manufacturer should provide the justification for such exclusion in the Design History File.

For equations or algorithms that require fixed assumptions in order to be reduced to readily solvable forms, the equations or algorithms and any assumptions necessary to reduce the equations or algorithms should be provided in the operator's manual when appropriate (such as when it does not reveal proprietary information); and,

5.1.2.6.4 The labeling provides complete information about processing or compression algorithms used when appropriate (such as when it does not reveal proprietary information). This includes, but is not limited to, algorithms that perform spatial compounding, frequency compounding, other speckle reduction, and phase aberration correction. The labeling provides the name of the algorithm and a citation if it is published in an archival format or a complete description of the method if it is not.

5.1.2.7 Regarding transducer element check: Device manufacturers implement appropriate integrated tests of transducer performance each time a transducer is connected to the main system or activated. The transducer performance test should be accessible by competent technical personnel, such as operators or service personnel. While the FDA appreciates that different performance specifications may be necessary for transducers based on the application and system configuration, each device should include some level of testing. For example, an impedance check of each transducer element may provide a preliminary evaluation of the element integrity and function. Device manufacturers implement methods to communicate the results of the transducer performance tests to the operators, and identify regions of the image that have been compromised by transducer

malfunction. This integrated test feature would also generate a report on the performance of the probe under test for documentation, generally including a list of elements or smallest available patches of elements that have been compromised. This integrated test should also be available to the operators to initiate any time when a particular probe is suspected of failure. As described in AIUM: *Routine Quality Assurance for Diagnostic Ultrasound Equipment*, American Institute of Ultrasound in Medicine, Laurel, MD, 2008 (AIUM 2008), transducer element checks are important to ensure proper performance of the transducer for acquiring images or signals that provide the intended information for the users. Such proper performance is critically dependent on the integrity of the piezoelectric transducer elements in terms of their mechanical and electrical configuration, and the subsequent transduction function.

5.1.2.8 Regarding the transducer surface temperature: The specifications in IEC 60601-2-37 regarding protection against excessive temperatures and other hazards from the transducer assembly at the patient contact surface are met.

5.1.2.9 Regarding endocavity use and appropriate transducer covers: If the device is for endocavity use, the labeling includes validated cleaning/disinfecting instructions and identifies the appropriate sleeves, if available. Please see Appendix E of this guidance for information on reprocessing of all types of transducers, including those for endocavity use.

5.1.3 Examples of modifications for which FDA does not intend to enforce compliance with the 510(k) requirement

The following are examples of device modifications for which FDA does not intend to enforce compliance with the 510(k) requirement (assuming the factors outlined in Section 5.1.2 have been used):

5.1.3.1 Adding Continuous-Wave (CW) and Pulsed-Wave (PW) Doppler interrogation methods to the modes of operation of the device.

5.1.3.2 Adding an algorithm that measures the volume of an organ based on scientifically well-established image segmentation and volume calculation methods. As described in Section 5.1.2.6.4, the scientific basis of the algorithm should be disclosed to the users for optimal usage of the measurement.

5.1.3.3 Adding a new transducer with similar indications for use and similar acoustic output as one already cleared in the system. As described in Section 5.1.2.1.5, the new transducer may have a new clinical application, if the particular clinical application (e.g., indication) has been cleared for another transducer, manufactured by the same manufacturer.

5.1.3.4 Adding a B-mode noise reduction filter for general imaging use to a system. The characteristics of the algorithm used for the noise reduction are defined in Section 5.1.2.6.

Notwithstanding this compliance policy, manufacturers must continue to update Design History Files and other records as appropriate (21 CFR 820.30(j)).

5.2 510(k) Submissions

This section applies to new or modified devices that are not covered by the enforcement policy described in Section 5.1.2.

5.2.1 Indications for use

Previous versions of this guidance recommended that manufacturers provide extensive documentation of individual transducer functions on the Indications for Use (IFU) form. Though this transducer function information should still be made available in the operator's manual, FDA is no longer recommending transducer function tables be included on the IFU form. General purpose diagnostic ultrasound systems are intended to provide images of or signals from the inside of the body, and FDA recommends that they be indicated for such use accordingly. However, all modes of operation and the clinical applications of the device should be specified in the IFU statement. Also, the operator qualifications (e.g., appropriately trained healthcare professional) and device use settings (e.g., hospital or home use) should be specified in the IFU statement. Specialized systems may necessitate more specific indications for providing images of or signals from the inside of a specific organ.

Highly specialized systems, systems with unique specific indications, and systems that provide novel quantitative information may have a new intended use or may raise different safety or effectiveness questions. These devices may require a Premarket Approval (PMA) application as set forth in Section 515 of the FD&C Act and part 814 (21 CFR part 814) of the regulations or a De Novo request for classification under Section 513(f)(2) of the FD&C Act.

5.2.2 Device description

5.2.2.1 In your 510(k) submission, 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):

5.2.2.1.1 You should describe each transducer and its operation in each mode and mode combination, including, but not limited to: (1) the transducer model designation and type (e.g., mechanical sector, rectangular phased array, curved linear array, annular phased array), (2) the size and spacing of element(s), (3) geometrical configuration, (4) total number of elements in the array, (5) array dimensions, (6) the maximum number of active elements for a single pulse, if applicable, and (7) the nominal ultrasonic frequency or frequencies of the transducer assembly.

5.2.2.1.2 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, you should 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 3 of Section 5.2.7).

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

5.2.2.1.4 You should specify which track is followed in the 510(k) submission (see Section 5.2.4). Systems can use transducers that are of Track 1 or 3, but a single transducer should be either exclusively Track 1 (Section 5.2.7) or Track 3 (Section 5.2.8) for all applications with a specific model. Exceptions may be considered in some cases (e.g., Transcranial Doppler (TCD)). For consideration of a potential exception, please contact the Office of Radiological Health (OHT8), Center for Devices and Radiological Health, FDA.

5.2.3 Predicate device comparison

5.2.3.1 A 21 CFR 807.92 compliant 510(k) summary must identify comparable predicate device(s) to which the subject device is being claimed to be substantially equivalent (21 CFR 807.92(a)(3)). Whenever possible, you should identify the 510(k) numbers for the predicate device(s).

5.2.3.2 You should compare the subject device to the predicate device(s) in terms of key technological 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):

5.2.3.2.1 indication(s) for use;

5.2.3.2.2 general device description (i.e., design, patient contact materials, operational characteristics, and specifications);

5.2.3.2.3 acoustic output and device settings used;

5.2.3.2.4 general safety and effectiveness information; and

5.2.3.2.5 proposed and/or final labels, labeling, and promotional materials.

5.2.3.3 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) (generally 510(k) number(s) or preamendments device status. *See* FDA's guidance entitled "Preamendment Status."[11]

5.2.4 Acoustic output

Defined in Sections 5.2.7 and 5.2.8 are the "Tracks" a manufacturer of diagnostic ultrasound equipment can follow to demonstrate the substantial equivalence of its ultrasound system with respect to acoustic output. The derated global maximum acoustic output should not exceed preamendments acoustic output exposure levels (see Table 3 of Section 5.2.7) unless the device is operating under conditionally increased output (see below); 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 5.2.8. 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. Also, note that 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.

Some studies suggest that acoustic output beyond preamendments acoustic output exposure levels may be warranted under certain conditions (Nightingale KR, Church CC, Harris GR, Wear KA, Bailey MR, Carson PL, Jiang H, Sandstrum KL, Szabo TL, and Ziskin MC, *Conditionally increased acoustic pressures in nonfetal diagnostic ultrasound examinations without contrast agents: a preliminary assessment*, J. Ultrasound Med., 34, 1-41, 2015). If the manufacturer wishes to include the capability for conditionally increased output beyond preamendments acoustic output levels or the ophthalmic levels listed in Section 5.2.8 in a 510(k) submission, discussion of the planned submission through a pre-submission[12] is recommended.

The manufacturer should indicate that the acoustic output exposure levels were measured, calculated, and derated following the most recently released revision of the FDA-recognized consensus standard IEC 62359, along with a declaration of conformity. Alternatively, the measurement procedure should be fully described**.** Any deviation from the methodologies outlined in the IEC 62359 standard document should be fully described in terms of the differing methodology used and be supported with validating data.

Note that pursuant to Section 514(c) of the Act, a person can use a standard recognized by FDA to meet a premarket submission statutory requirement or other requirement under the Act to which such standard is applicable and submit a declaration of conformity to FDA to certify the device is in conformity with the standard.

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[11] Available at https://www.fda.gov/medical-devices/quality-and-compliance-medical-devices/preamendment-status

[12] See guidance entitled "Requests for Feedback on Medical Device Submissions: The Pre-Submission Program and Meetings with Food and Drug Administration Staff" available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/requests-feedback-and-meetings-medical-device-submissions-q-submission-program

In determining the global maximum acoustic output, manufacturers are not expected to include hydrophone measurement uncertainties. The uncertainties of the acoustic output exposure levels in Table 3 of Section 5.2.7 are estimated to be ±30% for intensities and ±15% for MI, so a manufacturer may not have to account for its measurement uncertainty as long as that uncertainty does not exceed ±30% (or ±15%). However, if the measurement uncertainty does exceed ±30% (or ±15%), then the preamendments acoustic output exposure levels in Table 3 should be reduced accordingly by the excess 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. Because measurement uncertainty typically increases with increasing frequency, this example calculation is more likely to be applicable for high frequency applications (> 20 MHz) (Nagle SM, Sundar G, Schafer ME, Harris GR, Vaezy S, Gessert JM, Howard SM, Moore MK, Eaton RM, *Challenges and regulatory considerations in the acoustic measurement of high frequency (> 20 MHz) ultrasound*, J. Ultrasound Med., 32, 1897-1911, 2013).

Manufacturers must comply with 21 CFR 820.30(j) Design History File, and it 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, you should include documentation of the acoustic output measurement of your transducers, including measurement instrumentation, calibration, software, test results, and test protocols.

5.2.4.1 Acoustic output test methodology: You should provide in your 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, approved PMA, or De Novo request that contains a description of the acoustic output test methodology (you should include a 510(k), De Novo, or PMA number, along with the attachment number and/or page numbers). If you refer to a prior submission, 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.

5.2.4.1.1 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: We recommend that all measurements of pulsed (e.g., amplitude modulated) waveforms that result in reported or labeled acoustic quantities or in output display indices be made with a spot-poled membrane or capsule hydrophone. This recommendation applies unless it can be demonstrated that a non-membrane (e.g., needle-type) hydrophone provides 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, such as deconvolution (IEC 62127-1 *Ultrasonics -- Hydrophones -- Part 1: Measurement and characterization of medical ultrasonic fields up to 40 MHz*, and IEC 62127-2 *Ultrasonics -- Hydrophones -- Part 2: Calibration for ultrasonic fields up to 40 MHz*). 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 $f_c/20$, where f_c is center frequency. This spectral resolution is necessary to allow a full review of the frequency response of the system. Any deviation from this practice (e.g., due to mechanical interferences) should be described fully in this test methodology section. Non-membrane hydrophones are appropriate for continuous wave measurements (when reflections are a concern) and uses not directly affecting reporting or labeling, such as in quality control measurements.

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

5.2.4.1.3 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 5.2.7.1.2 and 5.2.7.2.5), the example calculation should include I_{SATA} instead of $I_{SPTA.3}$.

5.2.4.1.4 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.

5.2.4.1.5 You should describe any procedures used to correct for spatial averaging by the hydrophone, if applicable (*see* Zeqiri et al., *The Influence of Waveform Distortion on Hydrophone Spatial Averaging Corrections-Theory and Measurement*, 92 J. Acoust. Soc. Am. 1809, 1809-21, 1992).

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

5.2.4.1.7 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 G, Section 2).

5.2.4.1.8 You should describe the protocol for assuring that the specifications for acoustic output exposure levels are within the global maximum acoustic output exposure levels specified in Sections 5.2.7 (Track 1) or 5.2.8 (Track 3). If the test protocol described in Section 5.2.4.1.3 is not used on all devices, you should describe the correlation between acoustic output and sensitivity or other measurable parameter(s). If 100% testing is not 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 B, Section (B)(5)). This plan can be described by providing the values of γ (or, equivalently, $1-\alpha$) and P. You should 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 this guidance (see Appendix G for a summary).

5.2.5 General clinical safety and effectiveness

5.2.5.1 Clinical measurement accuracy and system sensitivity

5.2.5.1.1 You should identify and describe the various clinical (biometric) measurements that the users may perform using the subject device.

5.2.5.1.2 For each transducer/mode combination, you should provide the accuracy of any measurement (e.g., distance, volume, heart rate, Doppler frequency shift, velocity, indices) 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 over the range of velocity values specified in the labeling. Simulated or electronic data should not be used because they generally do not include the transducer as part of the test system.

5.2.5.1.3 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 (DHF). The justification for the methodology and an

analysis of uncertainty should also be included in the DHF. 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 DHF (21 CFR 820.30(g), (j)).

5.2.5.2 Thermal, mechanical, and electrical safety

Diagnostic ultrasound devices are medical electrical equipment and therefore may expose the operator and patient to hazards associated with the use of electrical energy or may fail to operate properly in the presence of electromagnetic disturbance.

5.2.5.2.1 Your device should be tested to demonstrate that it is thermally, electrically, and mechanically safe, and that it performs as anticipated in their intended use environment. We recommend that this testing be performed as described in the currently FDA-recognized versions of the following standards for medical electrical equipment safety and electromagnetic compatibility:

- **ANSI AAMI** ES60601-1 *Medical electrical equipment—Part 1: General requirements for basic safety and essential performance*.
- IEC 60601-1-2 *Medical electrical equipment—Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic disturbances –Requirements and tests*.

If submitting a declaration of conformity, the FDA guidance document "Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices"[13] provides the information on the mechanisms of declaring the conformance to the consensus standard. For additional information on providing electromagnetic compatibility information in a premarket submission, please see FDA's guidance, "Electromagnetic Compatibility (EMC) of Medical Devices."[14]

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

5.2.5.3 Patient-contacting materials

[13] Available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/appropriate-use-voluntary-consensus-standards-premarket-submissions-medical-devices
[14] Available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/electromagnetic-compatibility-emc-medical-devices

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

5.2.5.3.2 You should provide, for any patient contact materials, biocompatibility evaluation of the device, conducted as described in ISO 10993-1: *Biological evaluation of medical devices –Part 1: Evaluation and testing within a risk management process*, and FDA's guidance entitled "Use of International Standard ISO-10993, 'Biological Evaluation of Medical Devices Part-1: Evaluation and Testing within a risk management process."[15] For materials, probes, components, and accessories that have been previously cleared for identical type and duration of contact, biocompatibility data need not be provided if you indicate that the patient contact materials are unchanged in formulation and processing method from a previously cleared device.

5.2.5.4 Cleaning, disinfection, sterilization, and pyrogenicity

5.2.5.4.1 If the transducer is supplied sterile, you should provide information on the sterilization process, according to the FDA guidance document "Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling."[16] See also the guidance entitled "Submission and Review of Sterility Information in Premarket Notification (510(k)) Submissions for Devices Labeled as Sterile."[17] We recommend the device be sterilized with a sterility assurance level (SAL) of 10^{-6}.

5.2.5.4.2 If the transducer is supplied non-sterile or is intended to be reprocessed between patient use, you should provide written recommended procedures on how to clean, disinfect, and/or sterilize the transducer between uses. 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 chemical sterilant/high level disinfectant for the high level disinfection of transducers used as semi-critical devices (see FDA's guidance entitled "Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling."[18] For sterilization, which should be

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[15] Available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/use-international-standard-iso-10993-1-biological-evaluation-medical-devices-part-1-evaluation-and

[16] Available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/reprocessing-medical-devices-health-care-settings-validation-methods-and-labeling

[17] Available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/submission-and-review-sterility-information-premarket-notification-510k-submissions-devices-labeled

[18] Available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/reprocessing-medical-devices-health-care-settings-validation-methods-and-labeling

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 E.

5.2.5.4.3 If the device is labeled non-pyrogenic, you should provide the results of pyrogenicity testing recommended in the FDA guidance document entitled "Submission and Review of Sterility Information in Premarket Notification (510(k)) Submissions for Devices Labeled as Sterile."[19]

5.2.5.5 Software

FDA's guidance entitled "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices"[20] provides the recommendations for software documentation in premarket submissions. According to this guidance document, the level of software documentation should be based on the device's Level of Concern (LOC). A full description of the software/firmware supporting the operation of the subject device, commensurate with the appropriate LOC, as defined in the software guidance document cited above, should be provided. Please note that changes to the device's software must be validated and a risk analysis performed in accordance with 21 CFR 820.30(g). You must also perform verification, review, and approval of design changes before their implementation in accordance with 21 CFR 820.30(i). The information provided to comply with 21 CFR 820.30(g) and 21 CFR 820.30(i) must be documented in the DHF in accordance with 21 CFR 820.30(j).

When appropriate, you should provide information on the cybersecurity aspects of your device. For more information on this topic, please see FDA's guidance "Content of Premarket Submissions for Management of Cybersecurity in Medical Devices."[21]

If the device includes off-the-shelf software, you should provide the additional information as recommended in the FDA documents titled "Off-the-Shelf Software Use in Medical Devices"[22] and "Cybersecurity for Networked Medical Devices Containing Off-The-Shelf (OTS) Software,"[23] which provide additional information regarding medical devices utilizing off-the-shelf software.

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[19] Available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/submission-and-review-sterility-information-premarket-notification-510k-submissions-devices-labeled

[20] Available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-content-premarket-submissions-software-contained-medical-devices

[21] Available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/content-premarket-submissions-management-cybersecurity-medical-devices-0

[22] Available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/shelf-software-use-medical-devices

[23] Available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/cybersecurity-networked-medical-devices-containing-shelf-ots-software

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.

5.2.5.6 Transducer element check

Device manufacturers should implement appropriate integrated tests of transducer performance each time a transducer is connected to the main system or activated. The transducer performance test should be accessible by competent technical personnel, such as operators or service personnel. While the FDA appreciates that different performance specifications for transducers based on the application and system configuration, each device should include some level of testing. For example, an impedance check of each transducer element may provide a preliminary evaluation of the element integrity and function. Device manufacturers implement methods to communicate the results of the transducer performance tests to the operators, and identify regions of the image that have been compromised by transducer malfunction. This integrated test feature would also generate a report on the performance of the probe under test for documentation, generally including listing the integrity of elements or smallest available patches of elements. This integrated test should also be available to the operators to initiate any time when a particular probe is suspected of failure. As described in AIUM: *Routine Quality Assurance for Diagnostic Ultrasound Equipment*, American Institute of Ultrasound in Medicine, Laurel, MD, 2008 (AIUM 2008), transducer element checks are important to ensure proper performance of the transducer for acquiring images or signals that provide the intended information for the users. Such proper performance is critically dependent on the integrity of the piezoelectric transducer elements in terms of their mechanical and electrical configuration, and the subsequent transduction function.

5.2.6 Labeling

Labeling must be sufficient to describe the device, its intended use, and the directions for its use 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 21 CFR Part 801.

5.2.6.1 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. In general, labeling for these devices should include:

- A description of the device;
- Indications for use;
- Contraindications;

- Warnings;
- Precautions;
- Adverse effects;
- Instructions for use;
- Summaries of clinical studies; and
- References.

5.2.6.1.1 You should include an indications for use statement, contraindications, warnings, precautions, and a prescription device statement, where appropriate. This should include:

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

5.2.6.1.1.2 for Track 1 systems (see also Table 3 of Section 5.2.7 and Section 5.2.7.2.4), a caution (when applicable) that the device is not intended for fetal use either in the operator's manual, individual transducer manuals, or on equipment labeling;

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

5.2.6.1.1.4 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 and that, for details, to see the specific package insert for the contrast agent being used; and

5.2.6.1.1.5 appropriate data supporting specific diagnostic claims.

5.2.6.1.2 You should provide clinical instructions for the use of the device in either the system or transducer operator's manual. Information for use must be specified for prescription devices in accordance with 21 CFR 801.109(c).

5.2.6.1.3 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.

5.2.6.1.4 You should provide the accuracy of each clinical measurement capability using 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 Section 5.2.5.1.2.

5.2.6.1.5 You should provide draft acoustic output labeling in the operator's manual, following Section 5.2.7.2 (Track 1) or Section 5.2.8.2 (Track 3).

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

5.2.6.1.6.1 For clinical applications of a semi-critical or critical 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 E, special situation 2).

5.2.6.1.6.2 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.

5.2.6.1.6.3 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 FDA's guidance entitled "Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling,"[24] which provides recommendations for the formulation and scientific validation of reprocessing instructions for reusable medical devices, as well as the recommended information you should provide in your 510(k) submission.

5.2.6.1.7 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 (e.g., probes that make contact with the

[24] Available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/reprocessing-medical-devices-health-care-settings-validation-methods-and-labeling

dura matter or any intracranial tissues) should have the following additional labeling:

5.2.6.1.7.1 a recommendation to use sterile, non-pyrogenic sheaths; and

5.2.6.1.7.2 a caution, warning the user of the potential problem in using the probe on patients with known or suspected Creutzfeldt Jakob disease (CJD). The probe sheath should not be relied upon to prevent contamination of the probe. A transducer exposed to central nervous system tissue from known or suspected CJD or variant CJD (vCJD) should be destroyed since it may not be possible to sterilize it.[25]

5.2.6.1.8 You should provide information regarding repair of the systems and transducers, and provide instructions to the users on repair and maintenance of the systems and transducers, especially when they are not functioning as designed and intended. For example, the manufacturer may provide instructions for the users that all repair work should be performed by the Original Equipment Manufacturer (OEM). Also, the manufacturer may provide instructions to the users to contact the manufacturer to obtain a list of third-party repair organizations that are qualified to repair its transducers.

5.2.6.1.9 References to literature should be included when appropriate.

5.2.7 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 5.2.7.1.2). Track 1 submissions are evaluated in relation to application-specific preamendments acoustic output exposure levels. Table 3 (below) 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 should be evaluated on a case-by-case basis.

Table 3: 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

[25] For additional information on this topic, see "Infection Control" located at https://www.cdc.gov/prions/cjd/infection-control.html

Use	$I_{SPTA.3}$ (mW/cm^2)	$I_{SPPA.3}$ (W/cm^2) or MI	
Cardiac	430	190	1.9
Fetal Imaging & Other[26]	94	190	1.9
Ophthalmic	17	28	0.23

For the purposes of acoustic output exposure levels:

- transesophageal and intravascular for non-cardiac use and musculoskeletal applications should be included in the "Fetal Imaging & Other" category;
- cardiac use should include transthoracic adult and pediatric uses as well as intravascular and transesophageal adult and pediatric uses for visualization of the heart and coronary vessels; peripheral vessel use should include vessels of the neck; and
- cephalic and transcranial should be synonymous.

Note 1: Transcranial Doppler is considered to be in the "Peripheral Vessel" category unless measurements are performed through the eye, in which case it is considered in the "Ophthalmic" category.

5.2.7.1 Track 1 acoustic output: Track 1 is based on application-specific comparisons to preamendments acoustic output exposure levels given in Table 3. Measurements 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 should be necessary 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 5.2.7.1.1.1).

5.2.7.1.1 Your submission should include the information described below:

5.2.7.1.1.1 For each system/transducer combination, you should specify for each mode/application combination (as stated in the Indications for Use), the range of values for the $I_{SPTA.3}$ and for the MI or $I_{SPPA.3}$ under the operating conditions that

[26] The "Fetal & Other" category includes abdominal, intraoperative, pediatric, small organ (breast, thyroid, testes, etc.), neonatal cephalic, and adult cephalic use.

maximize these quantities. A tabular format is desirable (see Example 1 in Appendix F).

NOTE: The upper bound of the acoustic output values should not be greater than the appropriate application-specific value listed in Table 3. When system/transducer or mode/application combinations have the same design range for a given output quantity, a single range can be listed for those combinations.

5.2.7.1.1.2 A description of how you intend to meet the specification(s) in Section 5.2.7.1.1.1.

5.2.7.1.1.3 The engineering basis for the range of values specified in Section 5.2.7.1.1.1 (e.g., preliminary or prototype measurements, theoretical calculations, estimates based on measurements of previously cleared transducers, or acoustic output exposure levels).

5.2.7.1.2 For continuous-wave fetal heart rate (FHR) monitors with low-power unfocused CW Doppler transducers, a single maximum acoustic output exposure level for the spatial-average temporal-average intensity (I_{SATA}) at the transducer face of 20 mW/cm^2 should be used to evaluate the acoustic output of the device. This intensity may be estimated by dividing the ultrasonic power by the area corresponding to the entrance beam dimensions. A conservative approach for pulsed Doppler FHR monitors should be to use 20 mW/cm^2 as a guide for the maximum spatial-average pulse-average intensity (I_{SAPA}) at the transducer face. For such transducers, two estimates should be made:

(1) duty factor (DF) = pulse duration x pulse repetition frequency

(2) 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 acoustic output 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 should consult with the review division about the appropriate measurements you should make.

5.2.7.1.3 Track 1 submissions for devices whose overall acoustic output exceeds application-specific levels should be supported by laboratory and clinical data demonstrating safety and the need for such 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 example/model for making these estimates can be found in IEC 62359. When the $I_{SPTA.3}$ exceeds 94 mW/cm^2 for this application, we recommend labeling in the form of on-screen precautions about scanning through the eye, burr-holes, fontanels, or foramen magnum.

5.2.7.2 Track 1 acoustic output labeling

5.2.7.2.1 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. 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). The global maximum values of MI and spatial-peak intensities in the Track 1 acoustic output labeling should be statistical maximum values (see Appendix B, Section (B)(5)).

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

5.2.7.2.3 You should provide an explanation of the interactive system features that affect acoustic output (see Section 5.2.2.1.2). 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 3 of Section 5.2.7 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, and warnings.

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

5.2.7.2.5 For unfocused fetal heart rate monitors, (see Section 5.2.7.1.2), you should provide the following information instead of that recommended in Sections 5.2.7.2.1 and 5.2.7.2.2: I_{SATA} at the transducer face, entrance

beam dimensions, center frequency, pulse duration and pulse repetition frequency (if applicable), 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 B, Section (B)(5)).

5.2.7.3 Track 1 example acoustic output formats:

For each mode/application combination identified in Section 5.2.7.1.1.1, 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 and 3 in Appendix F 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 Examples 2 and 3 in Appendix F 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.

5.2.8 Track 3 recommendations

If you follow the Output Display Standard (IEC 60601-2-37), 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 should 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 should be for ophthalmic use, in which case, the TI = Max (TIS_as, TIC) should be ≤ 1; $I_{SPTA.3} \leq 50$ mW/cm^2; and MI ≤ 0.23. A device with fixed acoustic output should be Track 1, unless Section 5.2.8.1.5 applies.

5.2.8.1 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 acoustic output exposure levels.

5.2.8.1.1 Your submission should include the information described below:

5.2.8.1.1.1 For each system/transducer combination, we recommend you specify for each mode (as stated in the Indications for Use), the range of values for the $I_{SPTA.3}$, and the MI or $I_{SPPA.3}$, and the range of TIs under the operating conditions that maximize these quantities. A tabular format is desirable; see the example given in Example 4 in Appendix F.

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

5.2.8.1.1.2 A description of how the specification(s) in Section 5.2.8.1.1.1 is(are) met.

5.2.8.1.1.3 The engineering basis for the range of values specified in Section 5.2.8.1.1.1 (e.g., preliminary or prototype measurements, theoretical calculations, estimates based on measurements of previously cleared transducers, or acoustic output exposure levels).

5.2.8.1.2 You should:

5.2.8.1.2.1 Indicate that the measurements made to determine the acoustic output display indices - the TI and the MI - follow IEC 62359; and

5.2.8.1.2.2 indicate that information supplied in the 510(k) is for global maximum TI and MI values.

5.2.8.1.3 You should specify the default setting acoustic output exposure levels (e.g., as a percentage of the maximum levels) and the rationale for selecting such default values (*see* the clause *Accidental selection of excessive output values*, IEC 60601-2-37).

NOTE: Default settings should consider the ALARA principle.

5.2.8.1.4 You should explain the reason for any TI that exceeds a value of 6.0.

5.2.8.1.5 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 5.2.8.2.4). You should also include the details of the calculations in the DHF.

5.2.8.2 Track 3 acoustic output labeling

5.2.8.2.1 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; see Section 5.2.8.3. The labeling in your 510(k) should contain the acoustic output quantities you intend to include. The labeling also should include a description of any symbols used. In addition, the labeling should include the corresponding

operating conditions, and the measurement uncertainties for acoustic quantities (e.g., power, pressure, intensities, center frequency).

5.2.8.2.2 You should provide an explanation of the real-time display features and controls of the system, including default settings (*see* the clause *Accuracy of controls and instruments and protection against hazardous outputs* of IEC 60601-2-37). 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 should be 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 may not have to be displayed simultaneously. In this regard, please see page 49 in the AIUM publication, *Medical Ultrasound Safety, Third Edition* (AIUM 2014).

5.2.8.2.3 You should provide the display accuracy (*see* the clause *Accuracy of controls and instruments and protection against hazardous outputs* of IEC 60601-2-37).

5.2.8.2.4 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 5 in Appendix F. You should explain the meaning of and describe the uncertainties associated with these values.

5.2.8.3 Track 3 acoustic output formats:

Example 6 in Appendix F shows an example of a recommended tabular format for presenting the transducer/mode combinations for which the global maximum displayed MI or TI is greater than 1.0. For Example 6 in Appendix F, the following mode definitions and conventions are applied:

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:	Should 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 6 in Appendix F, 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 of an Acoustic output reporting table given in IEC 60601-2-37). All symbols used should be defined.

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 also be provided.

5.2.8.4 Track 3 education program for the clinical end user

5.2.8.4.1 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:

5.2.8.4.1.1 The basic interaction between ultrasound and matter;

5.2.8.4.1.2 The possible biological effects;

5.2.8.4.1.3 The deviation and meaning of the indices;

5.2.8.4.1.4 A recommendation to use and follow the ALARA principle in all studies; and

5.2.8.4.1.5 Clinical examples of specific applications of the ALARA principle.

A document published by the AIUM (*Medical Ultrasound Safety, Third Edition*, American Institute of Ultrasound in Medicine, 2014. Laurel, Maryland), includes the generic content of the educational program. You should also provide information specific to your device regarding ALARA.

5.3 Additional Considerations

The FDA Reauthorization Act (FDARA) was signed into law on August 18, 2017. Of importance to diagnostic ultrasound devices is Section 706, entitled "Fostering Innovation in Medical Imaging."

Section 706 added section 520(p) to the FD&C Act and specifies that, under certain circumstances, regulatory submissions for imaging medical devices (e.g., ultrasound imaging systems and transducers) may include certain new uses of an approved contrast agent (imaging drug) that are different from those described in the approved drug labeling. Such new uses of contrast agents, which would be evaluated based on safety and effectiveness information submitted in the device premarket application, could include, for example, different routes of drug administration, anatomical regions, or patient populations as long as FDA determines that the differences do not adversely affect the safety and effectiveness of the contrast agent when used with the device. Manufacturers interested in pursuing new uses of an approved contrast agent are strongly urged to submit a pre-submission to discuss the potential application with FDA.[27]

[27] See guidance entitled "Requests for Feedback on Medical Device Submissions: The Pre-Submission Program and Meetings with Food and Drug Administration Staff" available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/requests-feedback-and-meetings-medical-device-submissions-q-submission-program

Appendix A List of Symbols Used in this Guidance

p	≡	**acoustic pressure**
BW	≡	**bandwidth**
A	≡	**beam cross-sectional area**
P_{1x1}	≡	**bounded-square output power**
f_c	≡	**center frequency**
a	≡	**derating factor**
EBD	≡	**entrance beam dimensions**
EDS	≡	**entrance dimensions of the scan**
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**
MI	≡	**mechanical index**
p_r	≡	**peak rarefactional pressure**
P_o	≡	**power, ultrasonic power**
PD	≡	**pulse duration**
PII	≡	**pulse intensity integral**
PRF	≡	**pulse repetition frequency**
S	≡	**radiating cross-sectional area**
TI	≡	**thermal index**

TIB ≡ **thermal index bone**

TIC ≡ **thermal index cranium**

TIS_as ≡ **soft tissue thermal index at surface**

λ ≡ **wavelength**

The following definitions are provided for the technical terms used in this document.

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: The maximum value of the **power** emitted from any one-centimeter square region of the active area of the transducer, the one-centimeter square region having 1 cm dimensions in the x- and y-directions. See the definition of bounded power, and the Schematic diagram of the different planes and lines in an ultrasonic field in IEC 62359.
Symbol: P_{1x1}

Unit: watt, W

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

declaration of conformity: A document that declares that a product is in conformance with the provisions of a recognized standard pursuant to Section 514(c) of the FD&C Act. Information on such declarations is available in FDA's guidance entitled "Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices."[28]

derated peak rarefactional pressure: The value of p_r derated by 0.3 dB cm^{-1} MHz^{-1} to account for the acoustic attenuation in soft tissues.
Symbol: $p_{r.3}$
Unit: megapascal, MPa

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 $dBcm^{-1}MHz^{-1}$ 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 (DHF): Documentation established and maintained by the manufacturer for each type of medical device. The 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. *See* 21 CFR 820.30(j).

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.

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[28] Available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/appropriate-use-voluntary-consensus-standards-premarket-submissions-medical-devices.

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 overall **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; and
> 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, derated spatial-peak pulse-average: The value of I_{SPPA} derated by 0.3 dB cm^{-1} MHz^{-1} to account for the acoustic attenuation in soft tissues.
Symbol: $I_{SPPA.3}$
Unit: milliwatt 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}
Units: milliwatts per square-centimeter, mW cm^{-2}

intensity, derated spatial-peak temporal-average intensity: The value of I_{SPTA} derated by 0.3 dB cm^{-1} MHz^{-1} to account for the acoustic attenuation in soft tissues.
Symbol: $I_{SPTA.3}$
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}

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

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

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

Symbol: *MI*
Unit: Unitless

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

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: IEC 60601-2-37 "*Medical electrical equipment - Part 2-37: Particular requirements for the safety of ultrasonic medical diagnostic and monitoring equipment*," (IEC 60601-2-37).

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. For the **operating condition**

giving rise to $I_{SPTA.3}$, P_o is the total time-average **power**; for the **operating condition** subject to reporting under $I_{SPPA.3}$, P_o is the **ultrasonic power** associated with the transmit pattern giving rise to the value reported under $I_{SPPA.3}$.
Symbol: P_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 minus 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}

temporal-average intensity: See **intensity**.
Symbol: I_{TA}
Unit: milliwatt per square-centimeter, mW cm^{-2}

thermal index (TI): A quantity related to calculated or estimated temperature rise under certain defined assumptions. The thermal index is the ratio of total acoustic **power** to the acoustic **power** required to raise tissue temperature by 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 1, 2, A.1, and A.2 in IEC 62359 for thermal index categories, models, and formulae.)
Symbol: *TI*
Unit: Unitless

TIS_{as}: The soft-tissue **thermal index** at surface for **non-autoscanning mode**:

$$TIS_{as} = \frac{P_{1x1} f_c}{210}$$

$$TIS_{as} = \frac{P_{1x1} f_c}{210}$$

where
P_{1x1} 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}

Appendix B 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 (DHF).

Recommended records:

A. LABELING/USER INFORMATION

The DHF should contain:

1. a copy of all labeling, including acoustic output information following Sections 5.2.7.2 and 5.2.8.2 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 B.5 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 5.2.7.1.1.1 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 5.2.8.1.1.1 of this guidance).

B. GMP TEST PLAN

The DHF 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 3 of Section 5.2.7); $I_{SPTA.3}$ = 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; I_{SATA} or I_{SAPA} = 20 mW/cm^2 for Doppler FHR monitors (see Section 5.2.7.1.2)].

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 5.2.7 (Track 1) and 5.2.8 (Track 3) of this 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 MG: Experimental Statistics, NBS Handbook 91, National Institute of Standards and Technology, Gaithersburg MD, 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 3 in Section 5.2.7);
- X is the mean of the measured values;
- s is the standard deviation of the measured values; and
- 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 DHF. 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.

An example of applying this procedure to a population of ultrasound transducers is given in 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, 1993and Ziskin MC: *Specification of acoustic output level and measurement uncertainty in ultrasound exposimetry*, IEEE Trans. Ultrasonics, Ferroelectrics, and Frequency Control, 50, 1023-34, 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 5.2.7 (Track 1) or Section 5.2.8 (Track 3) should be reduced accordingly as described in Section 5.2.4, paragraph 4.

C. STATISTICAL TECHNIQUES

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

Appendix C Non-OEM Replacement Transducers and Remanufactured Transducers

Non-original equipment manufacturer (OEM) replacement transducers are generally those that are manufactured by a party other than the OEM and are intended to replace a transducer originally provided by the system manufacturer. Transducers may be remanufactured by the OEM, or entities other than the OEM. FDA considers transducers that are processed, conditioned, renovated, repackaged, restored, or subjected to any modification that significantly changes its performance or safety specifications, or intended use to be remanufactured.[29] Examples of actions that could be considered remanufacturing are changing the acoustic stack, electrical component, or patient-contact material.

Like new OEM transducers, non-OEM replacement transducers and remanufactured transducers are new medical devices. As such, they are subject to the 510(k) premarket notification regulations (21 CFR 807.81). They are required 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, biocompatibility testing, and labeling for diagnostic ultrasound replacement transducers:

1. In making the acoustic output comparison between the replacement and the OEM transducers, three or more transducers of each type should be used. The use of a single OEM generator may be appropriate if it operates within the OEM's specifications.
2. Acoustic output comparisons in the basic modes of M, B, and pulsed Doppler may be appropriate, but worst-case (i.e., maximum output) conditions should be identified and reported.
3. New acoustic output information (see Sections 5.2.7.2 and 5.2.8.2) should be provided in the transducer operator's manual whether or not you can demonstrate that the acoustic outputs of the replacement or remanufactured and OEM transducers agree within the limits of the measurement uncertainty. Moreover, if the outputs do not agree, the manufacturer should demonstrate that means have been incorporated into the replacement transducer to ensure the accuracy of the acoustic output real-time display indices, as well as the accuracy of any clinical measurement performed using the transducer. 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 5.2.4.1 of this guidance.

[29] 21 CFR 820.3(w).

All patient contact materials that are changed during the remanufacturing process should be tested for biocompatibility (see Section 5.2.5.3).

Appendix D 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 under 21 CFR 807.81. See FDA's guidances entitled "Frequently-Asked-Questions about the Reprocessing and Reuse of Single-Use Devices by Third-Party and Hospital Reprocessors"[30] and "Frequently-Asked-Questions about the Reprocessing and Reuse of Single-Use Devices by Third-Party and Hospital Reprocessors - Three Additional Questions."[31] The reprocessor should conduct functional testing, as well as validation of cleaning and sterilization. For the 510(k) submission, reprocessors should address the following points in addition to providing the other information recommended in the body of this guidance.

1. You should provide a detailed discussion of how you confirm that the diagnostic ultrasound performance characteristics (e.g., 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 describe the acoustic output test methodology following Section 5.2.4.1 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 OEM transducers for this comparison.

3. You should describe the testing to be performed to verify that the repeated reprocessing procedures are not adversely affecting the acoustic output and imaging performance of the transducer, as recommended in the guidance entitled "Medical Device User Fee and Modernization Act of 2002, Validation Data in Premarket Notification Submissions (510(k)s) for Reprocessed Single-Use Medical Devices"[32] (Validation Data guidance).

4. If the maximum number of reprocessing cycles for the transducer is not specified by the OEM, 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.

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[30] Available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/frequently-asked-questions-about-reprocessing-and-reuse-single-use-devices-third-party-and-hospital

[31] Available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/frequently-asked-questions-about-reprocessing-and-reuse-single-use-devices-third-party-and-hospital-0

[32] Available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/medical-device-user-fee-and-modernization-act-2002-validation-data-premarket-notification

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. This can be addressed by referring to the Validation Data guidance.

Appendix E Cleaning, Disinfection, and Sterilization

Reusable devices should contain clear instructions for cleaning and for disinfection and/or sterilization. The recommended cleaning, disinfection, and sterilization procedures should be validated by the probe manufacturer. Guidance on providing label reprocessing instructions and conducting reprocessing validation testing can be found in the guidance entitled "Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling."[33]

According to the FDA guidance document cited above, ultrasound probes that are non-critical devices should be cleaned and undergo low-level disinfection between patient uses. Probes used in semi-critical applications should undergo sterilization between uses whenever feasible, but high-level disinfection is minimally acceptable. In addition, the use of a sterile 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 for each use. 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 undergo sterilization or at least receive high level disinfection after use even if a sheath was used. Probes used for critical applications should be cleaned and undergo sterilization 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.

In addition, there are several special situations:

1. Neurosurgical use: Probes that contact brain tissue and cerebrospinal fluid should be used with a single-use, sterile, non-pyrogenic sheath because any disinfectant/sterilant residue left on the probe may be neurotoxic and any residual endotoxin is pyrogenic (i.e., causes fevers). NOTE: If the probe is used on a patient with known or suspected Creutzfeldt-Jakob Disease (CJD), the probe should be destroyed. For more information on CJD and infection control, see https://www.cdc.gov/prions/cjd/infection-control.html.[34]

2. Endoscopic, rectal, and transvaginal probes should be used with a single-use sterile sheath. If these probes are used to assist biopsy procedures, all of the biopsy accessories should be sterile for the procedure and any reusable biopsy accessories should be reprocessed 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.

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[33] Available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/reprocessing-medical-devices-health-care-settings-validation-methods-and-labeling

[34] For additional information on this topic, see "Infection Control" located at https://www.cdc.gov/prions/cjd/infection-control.html

3. Due to the inherent limitations of using liquid chemicals for sterilizing medical devices, liquid chemical sterilization should be limited to only critical and semi-critical devices that are heat-sensitive and incompatible with other sterilization methods.

Appendix F Acoustic Output Reporting Examples

Example 1

TRACK 1 SUMMARY

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.

Example 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)			
	P_o	(mW)			
	f_c	(MHz)			
	z_{sp} Note 1	(cm)			
	Beam dimensions	x_{-6} Note 2 (cm)			
		y_{-6} Note 2 (cm)			
	PD	(μsec)			
	PRF	(Hz)			
	EBD	Az. (cm)			

		Ele. (cm)			
Operating Control Conditions	Control 1				
	Control 2				
	Control 3				
	•••		•••	•••	•••

Note 1: z_{sp} is the axial distance at which the reported parameter is measured in centimeters.

Note 2: x_{-6}, y_{-6}, respectively, the in-plane (azimuthal) and out-of-plane (elevational) -6 dB dimensions in the x-y plane where z_{sp} is found in centimeters.

Example 3

Acoustic Output Format for Track 1

Autoscanning Mode

System: **Operating Mode:**

Transducer Model: **Application(s):**

Acoustic Output			**MI**	**ISPTA.3** (mW/cm^2)	**ISPPA.3** (W/cm^2)
Global Maximum Value					
Associated Acoustic Parameter	$p_{r.3}$	(MPa)			
	P_o	(mW)			
	f_c	(MHz)			
	z_{sp} Note 1	(cm)			
	Beam dimensions	x_{-6} Note 2 (cm)			
		y_{-6} Note 2 (cm)			
	PD	(μsec)			
	PRF	(Hz)			
	EDS	Az. (cm)			

		Ele. (cm)			
Operating Control Conditions	Control 1				
	Control 2				
	Control 3				
	•••		•••	•••	•••

Note 1: z_{sp} is the axial distance at which the reported parameter is measured in centimeters.

Note 2: x_{-6}, y_{-6}, respectively, the in-plane (azimuthal) and out-of-plane (elevational) -6 dB dimensions in the x-y plane where z_{sp} is found in centimeters

Example 4

Track 3 Output Range Summary Format

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 5

TRACK 3 SUMMARY

(for systems with no probes having global maximum index values exceeding 1.0)

System: _____

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

Example 6

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**: Should 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**.

Appendix G Statistical Analyses

There are four areas of the submission in which a statistical analysis of measurement or performance data should be conducted and provided.

1. Description of clinical measurement accuracy (see Sections 5.2.5.1.2 and 5.2.6.1.4).

2. Description of measurement uncertainties for acoustic quantities (**power**, **pressure**, **intensities**, **center frequency**) (see Section 5.2.7.2.4 (Track 1) and Section 5.2.8.2.1 (Track 3)). 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 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 (see also Ziskin 2003).

3. Description of statistical sampling plan used to ensure that the specifications for acoustic output exposure levels are meaningful (see Section 5.2.4.1.8 and Ziskin 2003).

4. Description of display accuracy, as specified in the clause *Accuracy of controls and instruments and protection against hazardous outputs* of IEC 60601-2-37 (see Section 5.2.8.2.3).