Health Canada Santé Canada

June 7, 2006

NOTICE

Our file number: 06-113050-982

Please note that none of the content has changed in the following guidance document **GUIDANCE FOR INDUSTRY - Device Licence Applications for Ultrasound Diagnostic Systems and Transducers.**

The *Guidance for Industry - Preparing Device Licence Applications for Ultrasound Diagnostic Systems and Transducers* requires a correction to the year and revision of the following two standards:

Change	Location	Nature of Change
1	Entire Document	original standard AIUM/NEMA UD2-1998, Revision 2 *Acoustic Output Measurement Standard for Diagnostic Ultrasound Equipment.* revised standard AIUM/NEMA UD2-**2004**, Revision **3** *Acoustic Output Measurement Standard for Diagnostic Ultrasound Equipment.*
2	Entire Document	original standard AIUM/NEMA UD3-1998, Revision 1 *Standard for Real-Time Display of Thermal and Mechanical Acoustic Output Indices on Diagnostic Ultrasound Equipment.* revised standard AIUM/NEMA UD3-**2004**, Revision **2** *Standard for Real-Time Display of Thermal and Mechanical Acoustic Output Indices on Diagnostic Ultrasound Equipment.*

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Health Canada Santé Canada

July 18, 2005

NOTICE

Our file number: 05-114684-13

Please find attached the finalized *Guidance for Industry - Device Licence Applications for Ultrasound Diagnostic Systems and Transducers.* This guidance document will supercede the previous *Guidance for Manufacturers Preparing Device Licence Applications for Ultrasound Diagnostic Systems and Transducers (June 3, 2002).*

The *Medical Device Regulations* set out the requirements governing the sale, importation and advertisement of medical devices. The goal of the Regulations is to ensure that medical devices distributed in Canada are safe and effective and meet quality standards.

This guidance document entitled *Guidance for Industry - Preparing Device Licence Applications for Ultrasound Diagnostic Systems and Transducers* sets out the Therapeutic Products Directorate's guidance for industry on this subject. This guidance document is to be used specifically in the preparation of new Ultrasound Diagnostic Systems and Transducers device licence applications.

The changes made to the guidance document reflect changes to the current interpretation of the materials required to demonstrate safety and effectiveness of diagnostic ultrasound systems. Specifically, the following items should be considered when preparing an application for licensing:

- Data validating Doppler sensitivity is now required.
- Global acoustic output limits for systems in conformance with the AIUM/NEMA 1998 Standard *for Real-Time Display of Thermal and Mechanical Acoustic Output Indices on Diagnostic Ultrasound Equipment* has been specified.
- It is recommended that the user's manual make reference to *Health Canada's Guidelines for the Safe Use of Diagnostic Ultrasound* for the application of the ALARA principle in imaging.

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This final guidance does not address device-specific issues related to "significant change" and applications for device licence amendments. Manufacturers are directed to the general guidance on this matter entitled *Guidance for the Interpretation of Significant Change*. The Therapeutic Products Directorate may, in the future, consider the development of device-specific Significant Change guidance documents if the need arises. This guidance document is available on the website and can be accessed in the MEDICAL DEVICE GUIDANCE DOCUMENTS section.

Should you have any questions or comments regarding the content of the guidance, please contact:

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Medical Devices Bureau
Therapeutic Products Directorate
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Health Canada
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Health Canada Santé Canada

GUIDANCE FOR INDUSTRY

Device Licence Applications for Ultrasound Diagnostic Systems and Transducers

Published by authority of the
Minister of Health

Date Adopted	2002/06/01
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Health Products and Food Branch

Canada

Our mission is to help the people of Canada maintain and improve their health. *Health Canada*	The Health Products and Food Branch's mandate is to take an integrated approach to the management of the risks and benefits to health related to health products and food by: • Minimizing health risk factors to Canadians while maximizing the safety provided by the regulatory system for health products and food; and, • Promoting conditions that enable Canadians to make healthy choices and providing information so that they can make informed decisions about their health. *Health Products and Food Branch*

Également disponible en français sous le titre: Demande d'homologation d'instrument relative à des systèmes de diagnostic à ultrasons et à des transducteurs

Document Change Log

Change	Location	Nature of Change
1	Entire Document	Minor editorial and style changes. Updated URLs.
2	File name	File name changed from "ultrasound_e.wpd" to "draft_ ultrasound_e.wpd".
3	1.0 BACKGROUND INFORMATION 1.2 Section 32(3)(b): Design Philosophy, Transducer Operation 1.2.2 Operating Controls	Sentence rewritten Original sentence "For devices not conforming to the AIUM/NEMA 1998 *Standard for Real-Time Display of Thermal and Mechanical Acoustic Output Indices on Diagnostic Ultrasound Equipment* (here after in this Guidance Document referred to as the "Output Display Standard") describe the operating controls and procedures necessary to change to an application or mode that has a high application specific acoustic output limit." Revised sentence "For devices not conforming to the AIUM/NEMA 1998 *Standard for Real-Time Display of Thermal and Mechanical Acoustic Output Indices on Diagnostic Ultrasound Equipment* (hereafter in this Guidance Document referred to as the "Output Display Standard") describe the operating controls and procedures necessary to change to an application or mode that has a **higher** application specific acoustic output limit."
4	2.0 SUMMARY OF SAFETY AND EFFECTIVENESS STUDIES 2.3 Section 32(3)(f): Summary of Studies 2.3.1 Clinical Measurement Accuracy and System Sensitivity	Paragraph removed "For each probe/mode combination in which quantitative claims regarding Doppler sensitivity are made in the product labeling, a minimum performance specification for the Doppler sensitivity should be provided and the methodology justified. Data validating the specification shall be included in the submission and the Device Master Record. For certain special cases or claims, clinical data or special phantom testing may be more appropriate."
5	2.0 SUMMARY OF SAFETY AND EFFECTIVENESS STUDIES 2.3 Section 32(3)(f): Summary of Studies 2.3.2 Performance Specifications	Paragraph rewritten Original paragraph "For each transducer/mode combination in which quantitative claims regarding Doppler sensitivity are made in the product labelling, minimum performance specification of the Doppler sensitivity is be provided and the methodology justified. For certain special cases or claims, clinical data or special phantom testing may be more appropriate"

		Revised paragraph "For each transducer/mode combination in which quantitative claims regarding Doppler sensitivity are made in the product labelling, a minimum performance specification of the Doppler sensitivity is to be provided and the methodology justified. **Data validating the specification shall be included in the submission**. For certain special cases or claims, clinical data or special phantom testing may be more appropriate."
6	2.0 SUMMARY OF SAFETY AND EFFECTIVENESS STUDIES 2.3 Section 32(3)(f): Summary of Studies 2.3.3 Accepted Acoustic Output Levels For Systems Not in Compliance with the "Output Display Standard"	Sentence added "For Fetal Heart Rate Monitors, the maximum attainable value of **spatial average, temporal average intensity** at the transducer face should be less than 20 mW/cm^2 for continuous wave devices and the maximum attainable value of the **spatial average, pulse average intensity** at the transducer face should be less than 20 mW/cm^2 for pulsed devices." Sentence removed "Acoustic output should not exceed the following upper limits: i.e., global maximum derated $I_{SPTA.3}$=720 mW/cm^2 and either MI=1.9 or $I_{SPPA.3}$=190 W/cm^2."
7	2.0 SUMMARY OF SAFETY AND EFFECTIVENESS STUDIES 2.3 Section 32(3)(f): Summary of Studies 2.3.3 Accepted Acoustic Output Levels For Systems in Compliance with the "Output Display Standard" First paragraph, Third paragraph Fifth paragraph	Sentence added "Acoustic output should not exceed the following upper limits: $I_{SPTA.3}$=720 mW/cm^2 and either MI=1.9 or $I_{SPPA.3}$=190 W/cm^2." Sentence rewritten Original sentence "For these devices that comply with the "Output Display Standard", refer to Section 3.2.4 on Labelling of this guidance document." Revised sentence "For these devices that comply with the "Output Display Standard", refer to Section **3.1.4** on Labelling of this guidance document." Sentence rewritten Original sentence "For each possible transducer/mode identified, specify the maximum estimated MI and TI (TIS and TIC, each as applicable)."

		Revised sentence "For each possible transducer/mode identified, specify the maximum estimated $I_{SPTA.3}$, MI or $I_{SPPA.3}$ and TI (TIS, TIB and TIC, each as applicable)."
8	2.0 SUMMARY OF SAFETY AND EFFECTIVENESS STUDIES 2.3 Section 32(3)(f): Summary of Studies 2.3.7 Low Output Systems	Revised sentence Original sentence Alternatively, the global maximum values of the $I_{SPTA.3}$ of the TI (TIS, TIB or TIC) and MI and $I_{PA.3}$ @ MI_{max} should be specified. Revised sentence However, in their place the global maximum values of the $I_{SPTA.3}$ of the TI (TIS, TIB or TIC) and MI and $I_{PA.3}$ @ MI_{max} should be specified.
9	3.0 SECTION 32(3)(g):LABELLING 3.1 Acoustic Output Labelling in the Operator's Manual First paragraph	Sentence rewritten Original sentence "Draft labelling of the operator's manual showing estimated global acoustic output indices for each possible system/transducer/mode combination as per Appendix 1: Tables A-2, may be provided with the initial medical device licence application." Revised sentence "Draft labelling of the operator's manual showing estimated global acoustic output indices for each possible system/transducer/mode combination as per **Appendix 2: Tables A-2 and A-2-1**, may be provided with the initial medical device licence application."
10	3.0 SECTION 32(3)(g):LABELLING 3.1 Acoustic Output Labelling in the Operator's Manual 3.1.1 Real Time Features First paragraph	Sentence added "It is recommended that these include, but not be limited to, a reference to Health Canada's Guidelines for the Safe Use of Diagnostic Ultrasound, particularly sections 2 and 3. The document is available on the website.
11	3.0 SECTION 32(3)(g): LABELLING 3.1 Acoustic Output Labelling in the Operator's Manual 3.1.3 Low Output Systems	Revised sentence Original sentence Alternatively, the global maximum values of the $I_{SPTA.3}$ of the TI (TIS, TIB or TIC) and MI and $I_{PA.3}$ @ MI_{max1} should be specified as shown in Appendix 1: Table A-1. Revised sentence However, in their place the global maximum values of the $I_{SPTA.3}$ of the TI (TIS, TIB or TIC) and MI and $I_{PA.3}$ @ MI_{max1} should be specified as shown in Appendix 1:

		Table A-1.
12	3.0 SECTION 32(3)(g):LABELLING 3.2 Section 32(3)(g): General Labelling Information 3.2.2 Additional Labelling	Sentence rewritten Original sentence "If the transducer becomes contaminated, it may have be destroyed since it may not be adequately disinfected." Revised sentence "If the transducer becomes contaminated, it may have **to** be destroyed since it may not be adequately disinfected."
13	4.0 SECTION 32(3)(j): QUALITY SYSTEM CERTIFICATION	Sentence removed "This section of the Regulations will not come into force until January 1, 2003." Paragraph rewritten Original paragraph "Section 32(3)(j) requires a signed attestation by a senior official of the manufacturing firm or copy of the certification that the device is designed and manufactured under an appropriate quality system. This system must satisfy the Canadian Standards Association criteria in CAN/CSA - ISO 13485-98, *Medical Devices - Particular Requirements for the Application of ISO 9001*, as amended from time to time. This attestation must be based on the results of an audit by an organization that performs quality system audits." Revised paragraph "Section 32(3)(j) requires a copy of a quality system certificate certifying that the quality system under which the device is designed and manufactured satisfies National Standard of Canada CAN/CSA- ISO 13485-98, *Quality systems* - Medical devices - *Particular requirements for the application of ISO 9001*, as amended from time to time."
14	5.0 MEDICAL DEVICE LICENCE ISSUANCE First paragraph	Sentence rewritten Original sentence "In the case where final global acoustic output indices (Section 3.2) are provided in the initial medical device licence application, and it is determined that the ultrasound system/transducer meet the safety and effectiveness requirements of the Regulations, a medical device licence will be issued." Revised sentence

		"In the case where the final global acoustic output indices (**Sections 2.3.3 and 3.1**) are provided in the initial medical device licence application, and it is determined that the ultrasound system/transducer meet the safety and effectiveness requirements of the Regulations, a medical device licence will be issued."
	Second paragraph	Sentence rewritten Original sentence "In the case where estimated global acoustic output indices (Section 3.2) are provided in the initial medical device licence application, and it is determined that the ultrasound system/transducer meet the safety and effectiveness requirements of the Regulations, a medical device licence with conditions will be issued." Revised sentence "In the case where the estimated global acoustic output indices (**Sections 2.3.3 and 3.1**) are provided in the initial medical device licence application, and it is determined that the ultrasound system/transducer meet the safety and effectiveness requirements of the Regulations, a medical device licence with conditions will be issued."
15	Appendix 4: List of Standards	Sentence rewritten Original sentence "For a complete list of TPD Recognized Medical Device Standards, refer to the *Policy on Recognition and Use of Standards under the Medical Devices Regulations* (dated April 2002) posted on the website at: Revised sentence "For a complete list of TPD Recognized Medical Device Standards, refer to the *Policy on Recognition and Use of Standards under the Medical Devices Regulations* (dated **January 2004**) posted on the website. Original sentence 1.AIUM/NEMA UD2-1998, Revision 2 2.AIUM/NEMA UD3-1998, Revision 1 Revised sentence 1.AIUM/NEMA UD2-2004, Revision 2 2.AIUM/NEMA UD3-2004, Revision 1
16	Appendix 5: Device Specific Definitions	Definition added

		"INTENSITY, SPATIAL-AVERAGE PULSE-AVERAGE: the spatial average, temporal average intensity at the face of the transducer divided by the duty factor, where the duty factor is the product of the pulse duration and the pulse repetition frequency. Symbol: I_{SAPA} Unit: milliwatt per square-centimetre, mW cm^{-2} " "SPATIAL-AVERAGE PULSE-AVERAGE INTENSITY: see intensity. Symbol: I_{SAPA} Unit: milliwatt per square-centimetre, mW cm^{-2} "
17	Appendix 5: List of Symbols	Symbol added "I_{SAPA}=Spatial-average pulse-average intensity"

FOREWORD

Guidance documents are meant to provide assistance to industry and health care professionals on **how** to comply with the policies and governing statutes and regulations. They also serve to provide review and compliance guidance to staff, thereby ensuring that mandates are implemented in a fair, consistent and effective manner.

Guidance documents are administrative instruments not having force of law and, as such, allow for flexibility in approach. Alternate approaches to the principles and practices described in this document ***may be*** acceptable provided they are supported by adequate scientific justification. Alternate approaches should be discussed in advance with the relevant program area to avoid the possible finding that applicable statutory or regulatory requirements have not been met.

As a corollary to the above, it is equally important to note that Health Canada reserves the right to request information or material, or define conditions not specifically described in this guidance, in order to allow the Department to adequately assess the safety, efficacy or quality of a therapeutic product. Health Canada is committed to ensuring that such requests are justifiable and that decisions are clearly documented.

This document should be read in conjunction with the accompanying notice and the relevant sections of other applicable guidances.

TABLE OF CONTENTS

PURPOSE

This guidance document is intended to assist manufacturers and sponsors in preparing a premarket device licence application for Class III or IV ultrasound diagnostic systems and transducers.

BACKGROUND

The importation, advertising and sale of medical devices is regulated by the *Food and Drugs Act* and the *Medical Device Regulations*. The Sections 10 to 20 provide for the general safety and effectiveness requirements for all medical devices.

Section 32(3) and 32(4) of the Regulations outline specific evidence required for Class III and Class IV applications in order to meet the safety and effectiveness requirements. All Class III and Class IV medical devices require a review of submitted evidence of safety and effectiveness before the device can be recommended for licensing.

A new device licence application for a Class III or a Class IV medical device will contain a premarket review document in addition to the general requirements of Section 32(1). The premarket review document contains the evidence to support the requirements of Section 32(3) or 32(4), depending on the risk classification of the device. Portions of the review submission may reference application files previously submitted by the manufacturer.

A licence will be issued after a review of the information included in the medical device licence application has determined that the medical device conforms to the safety and effectiveness requirements.

Section 35(1) of the *Medical Devices Regulations*, provides a provision for ADDITIONAL INFORMATION or documentation from the manufacturer where the evidence submitted in support of the licence application requirements of Section 32 is insufficient to determine whether the device meets the safety and effectiveness requirements of Section 10 to 20.

A copy of the *Medical Devices Regulations* is available on The Department of Justice Canada website.

SCOPE

This document is intended to be a device specific premarket guidance on the preparation of a new device licence application for Class III and Class IV ultrasound diagnostic systems and transducers. For ultrasound systems and transducers, this device-specific guidance document replaces the general premarket medical device guidance documents entitled *Preparation of a*

Premarket Review Document for Class III and Class IV Device Licence Applications.

This guidance document does not address issues related to significant change, applications for medical device licence amendments or the general process and procedures of device licensing.

For guidance on significant change, refer to the *Guidance for the Interpretation of Significant Change*.

For guidance on general processes and procedures, refer to the general guidance documents such as *How to Complete the Application for a New Medical Device Licence, Guidance on the Interpretation of Section 28 to 31: Licence Application Type* and *Guidance for the Labelling of Medical Devices under Section 21 to 23 of the Medical Devices Regulations.*

PRESENTATION OF THE REVIEW DOCUMENT

Manufacturers and/or device sponsors are advised to follow the structure below when submitting an application for a device licence. Sections that are not applicable must be clearly indicated and accompanied by a rationale.

Elements of Class III Device Licence Application

A licence application for a Class III medical device must contain evidence in support of the requirements of Section 32(3) of the *Medical Devices Regulations*. These requirements are grouped into four general sections. These sections must be easily identifiable in every licence application for a Class III medical device. The following format is advised:

Device Licence Application Form
Executive Summary
Table of Contents

1 Background Information
- 1.1 Device Description
- 1.2 Design Philosophy
- 1.3 Marketing History

2 Summary of Safety and Effectiveness Studies
- 2.1 List of Standards
- 2.2 Method of Sterilization
- 2.3 Summary of Studies
- 2.4 Bibliography

3 Labelling
4 Quality System Requirements

Health Canada will accept information as provided to another regulatory authority's prescribed format [for example (eg.) United States Food and Drug Administration (FDA) 510(k) applications] provided that the information is appropriately indexed to Section 32(3) of *Medical Devices Regulation* requirements using the above suggested format.

Elements of Class IV Device Licence Application

Ultrasound diagnostic systems and transducers are generally classified as Class III devices. Devices, such as transducers, intended to be used in direct contact with the central nervous system or the central cardiovascular system are an exception. Application of classification Rule 1(2), these surgically invasive devices are considered to be Class IV devices.

In addition to the requirements of Class III, device licence applications for Class IV central nervous system or cardiovascular system surgically invasive ultrasound diagnostic devices would require the following information:

i. Section 32(4)(d): a risk assessment comprising of an analysis and evaluation of the risks, and the risk reduction measures adopted to satisfy the safety and effectiveness requirements.
ii. Section 32(4)(e): a quality plan setting out the specific quality practices, resources and sequence of activities relevant to the device
iii. Section 32(4)(f): the specifications of the materials used in the manufacture and packaging of the device (not required if previously licensed)
iv. Section 32(4)(g): the manufacturing process of the device
v. Section 32(4)(i): detailed information on all studies on which the manufacturer relies to ensure that the device meets the safety and effectiveness requirements, including:
    a. pre-clinical (not required if previously licensed)
    b. process validation studies
    c. software validation studies (not required for transducers)
    d. literature studies (not required for established technology)

1.0 BACKGROUND INFORMATION

1.1 Section 32(3)(a): Device Description

Provide a general description of the subject device, including but not limited to the model, designation, design, patient contact materials, operating controls, and system operation. Components or accessories that can be sold separately and used with other medical devices, systems or units must be identified.

1.1.1 Indications for Use

Identify all indications for use of the subject device (fill out the indications for use form(s) or equivalent (refer to Table 1 below).

Table 1: Diagnostic Ultrasound Indications for Use

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

Clinical Application		Mode of Operation						
General	Specific	B	M	PWD	CWD	Colour Doppler	Combined (Specify)	Other* (Specify)
Ophthalmic	Ophthalmic	-	-	-	-	-	-	-
Fetal Imaging & Other	Fetal	-	-	-	-	-	-	-
	Abdominal	-	-	-	-	-	-	-
	Intra-operative (Specify)	-	-	-	-	-	-	-
	Intra-operative (Neuro)	-	-	-	-	-	-	-
	Laparoscopic	-	-	-	-	-	-	-
	Pediatric	-	-	-	-	-	-	-
	Small Organ (Specify)	-	-	-	-	-	-	-
	Neonatal Cephalic	-	-	-	-	-	-	-
	Adult Cephalic	-	-	-	-	-	-	-
	Trans-rectal	-	-	-	-	-	-	-
	Trans-vaginal	-	-	-	-	-	-	-
	Trans-urethral	-	-	-	-	-	-	-
	Trans-esoph. (Non-Card.)	-	-	-	-	-	-	-
	Musculo-skel (conventional)	-	-	-	-	-	-	-
	Musculo-skel (superficial)	-	-	-	-	-	-	-
	Intra-luminal	-	-	-	-	-	-	-
	Other (Specify)	-	-	-	-	-	-	-
	Cardiac Adult	-	-	-	-	-	-	-
Cardiac	Cardiac Pediatric	-	-	-	-	-	-	-
	Trans-Esoph. (Cardiac)	-	-	-	-	-	-	-
	Other (Specify)	-	-	-	-	-	-	-

Peripheral Vessel	Peripheral vessel	-	-	-	-	-	-	-
	Other (Specify)	-	-	-	-	-	-	-

*Examples may include: A-mode, Amplitude Doppler, 3-D Imaging, Harmonic Imaging, Tissue Motion Doppler, Colour Velocity Imaging
Additional Comments: _____

A separate form should be filled in for the system and for each transducer. It is not necessary to fill out a form for a previously submitted/licensed transducer. In a submission for a new mode or a new indication for use on an existing system(s), a form for the system(s) and each transducer having the new mode or indication for use must be filled out.

1.2 Section 32(3)(b): Design Philosophy, Transducer Operation

1.2.1 Description of the transducer operation in each mode and mode combination including, but not limited to:

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

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

1.2.2 Operating Controls

Describe the operating controls that can cause a change in the radiated field, e.g. gain, pulse repetition frequency, transmit focal length, sector angle, image rate, pulse duration, depth, and sample volume.

For devices not conforming to the AIUM/NEMA 2004 *Standard for Real-Time Display of Thermal and Mechanical Acoustic Output Indices on Diagnostic Ultrasound Equipment* (hereafter in this Guidance Document referred to as the "**Output Display Standard**") describe the operating controls and procedures necessary to change to an application or mode that has a higher application specific acoustic output limit.

1.2.3 Unique Features

Describe any unique features or technological characteristics of the subject device.

1.3 Section 32(3)(c): Marketing History

Provide the following:

i. List of countries where the device is currently being sold.
ii. How many units have been sold worldwide?
iii. Summary of reported problems, number reported and corrective action. (e.g. modifications to the same device, software fixes)
iv. Summary of the recalls and any corrective actions as a result of the recall.

2.0 SUMMARY OF SAFETY AND EFFECTIVENESS STUDIES

Section 32(3)(f) of the *Medical Devices Regulations* requires a summary of all studies that the manufacturer relies on to ensure that the device meets the safety and effectiveness requirements of Section 10 to 20.

For devices based on established technology, information to demonstrate that the specifications and performance are equivalent to previously licensed devices is acceptable.

2.1 Section 32(3)(d): List of Standards

Manufacturers may choose to demonstrate conformance to a recognized standard or they may elect to address the relevant safety and effectiveness issues in another manner. Conformance with recognized standards is voluntary for manufacturers. If a standard is recognized, a manufacturer applying for a device licence to which that standard applies must either:

a) meet the standard; or
b) meet an equivalent or a better standard; or
c) provide alternate evidence of safety or efficacy.

In the case of "b" and "c", detailed information must be submitted with the device licence application.

Manufacturers are directed to the Therapeutic Products Directorate's (TPD) *Guidance Document - Recognition and Use of Standards under the Medical Devices Regulations* for further information on the use of standards and for the TPD list of recognized medical device standards. The guidance document may be found on the website.

The *List of Recognized Standards for Medical Devices* may also be found on the website. For a partial list of recognized standards that are applicable to ultrasound systems and transducers, refer to Appendix 4 of this document.

2.2 Section 32(3)(e): Method of Sterilization

In the case of a Class III device sold in a sterile condition, the applicant is requested to provide a description of the sterilization method used and the packaging used to maintain sterility. This must include the type of sterilization process, the level of sterility assurance and an attestation or certification that the process has been properly validated.

2.2.1 Components Provided Sterile

For device components provided sterile to the user (e.g. single use, disposable components), provide the following information:

i. The method of sterilization and a description of the method used to validate the sterilization cycle;
ii. The SAL (Sterility Assurance Level) intended for the device (at least 10^{-6});
iii. A description of the packaging system used to maintain device sterility;
iv. If the device is sterilized using ethylene oxide, the maximum levels of residues of ethylene oxide, ethylene chlorohydrin and ethylene glycol;
v. If the device is radiation sterilized, the radiation dose used to achieve sterility.

For device accessories, the above information is also applicable if the accessory is included in the same Class III or Class IV device licence application.

2.2.2 Pyrogenicity

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

2.3 Section 32(3)(f): Summary of Studies

2.3.1 Clinical Measurement Accuracy and System Sensitivity

For each transducer/mode combination, give the accuracy of any measurement (e.g. distance, volume, heart rate, Doppler frequency shift, velocity, indices etc.) that can be made in that mode, and the range over which this accuracy can be expected to be maintained. Describe and justify the test methodology (e.g. laboratory and/or electronic phantom) used to determine each accuracy.

2.3.2 Performance Specifications

For each transducer/mode combination in which quantitative claims regarding Doppler sensitivity are made in the product labelling, a minimum performance specification of the Doppler sensitivity is to be provided and the methodology justified. Data validating the specification shall be included in the submission. For certain special cases or claims, clinical data or special phantom testing may be more appropriate.

2.3.3 Accepted Acoustic Output Levels

For Systems Not in Compliance with the "Output Display Standard"

The global maximum derated acoustic output limits, given in Table 2-1, are deemed to be acceptable for devices that do not comply with the "Output Display Standard" (also known as the AIUM/NEMA 2004 *Standard for Real-Time Display of Thermal and Mechanical Acoustic Output Indices on Diagnostic Ultrasound Equipment*).

Table 2-1: Accepted Acoustic Output Levels

Devices that do not conform with the "Output Display Standard"

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

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

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

NOTE: for purposes of acoustic output limits:

i. trans-esophageal for non-cardiac use, intravascular, and musculo-skeletal applications are included in the "Fetal Imaging and Other" category;
ii. cardiac use includes transthoracic adult and pediatric uses as well as trans esophageal adult and pediatric uses for visualization of the heart;
iii. peripheral vessel use includes vessels of the neck; and

iv. cephalic and transcranial are synonymous.

For Fetal Heart Rate Monitors, the maximum attainable value of **spatial average, temporal average intensity** at the transducer face should be less than 20 mW/cm^2 for continuous wave devices and the maximum attainable value of the **spatial average, pulse average intensity** at the transducer face should be less than 20 mW/cm^2 for pulsed devices.

For Systems in Compliance with the "Output Display Standard"

Acoustic output should not exceed the following upper limits: $I_{SPTA.3}$=720 mW/cm^2 and either MI=1.9 or $I_{SPPA.3}$=190 W/cm^2.

Devices that comply with the "Output Display Standard" must also comply with the AIUM 2004 *Acoustic Output Labelling Standard for Diagnostic Ultrasound Equipment: A Standard for How Manufacturers should Specify Acoustic Output Data*.

For these devices that comply with the "Output Display Standard", refer to Section 3.1.4 on Labelling of this guidance document. The related Acoustic Reporting Tables are given in Appendix 3.

For ophthalmic applications in conformance with the "Output Display Standard", the upper limits are TI=max. (TIS_as, TIC) and is not to exceed 1.0, $I_{SPTA.3}$= 50mW/cm^2 and MI=0.23.

Summarize the operating mode possibilities for each system/transducer combination by completing Table A-2 in Appendix 2. For each possible transducer/mode identified, specify the maximum estimated $I_{SPTA.3}$, MI or $I_{SPPA.3}$ and TI (TIS, TIB and TIC, each as applicable). Provide a justification of the method of estimation (e.g. preliminary or prototype measurements, theoretical calculations, estimates based on measurements of previously licensed transducers).

2.3.4 Certifications

Provide the following certifications:

i. That the ultrasound system will be designed and marketed in conformance with the "Output Display Standard";

ii. That the measurements of acoustic output display indices - Thermal Index (TI) and the Mechanical Index (MI), will be in conformance with the requirements of Section 6 entitled, "Measurement Methodology for Mechanical and Thermal Indices" of the *Standard for Real-Time Display of Thermal and Mechanical*

Acoustic Output Indices on Diagnostic Ultrasound Equipment (AIUM/NEMA 2004) or "Output Display Standard".

In all submissions, the applicant shall provide evidence that the acoustic output will be, or was measured, calculated and derated as per the most recently released revision of the *Acoustic Output Measurement Standard for Diagnostic Ultrasound* Equipment (AIUM/NEMA UD 2-2004) and the *Standard for Real-Time Display of Thermal and Mechanical Acoustic Output Indices on Diagnostic Ultrasound Equipment* (AIUM/NEMA UD3-2004). Any deviation from the methodologies outlined in these references shall be fully described in terms of the differing methodology used and validating data.

2.3.5 Default Settings

Specify the default setting levels [that is (i.e.) as a percentage of the maximum levels] and the rationale for selecting these default values. Refer to Section 5 of the "Output Display Standard".

2.3.6 Thermal Index

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

2.3.7 Low Output Systems

If no system/transducer combination is capable of exceeding either a TI of 1.0 or and MI of 1.0 in any operating mode, then completion of the Acoustic Output Reporting Tables (Appendix 3) is not necessary. However, in their place the global maximum values of the $I_{SPTA.3}$ of the TI (TIS, TIB or TIC) and MI and $I_{PA.3}$ @ MI_{max} should be specified.

2.3.8 Thermal, Mechanical and Electrical Safety

Provide either a declaration of conformity to a recognized standard, or data showing that their system is designed to be thermally, electrically and mechanically safe. This may be provided in the form of descriptions, safety precautions, testing and data to support the electrical and mechanical safety of the device. Applicable voluntary recognized standards must be identified to which the system is specified to conform with or the applicant shall include a third party certification to demonstrate that the device meets an acceptable standard.

2.3.9 Patient Contact Material

2.3.9.1 Identification and Composition

Provide the trade name and generic material composition (polyethylene, polycarbonate, silastic, etc.) of all patient contact materials or provide previously filed device licence number that contains the material description.

2.3.9.2 Biocompatibility

Provide either a declaration of conformity to applicable ISO 10993 or equivalent standards or provide biocompatibility testing results for tests conducted according to the ISO-10993-1, Biological Evaluation of Medical Devices Part 1: Evaluation and Testing or equivalent standard for any patient contact materials.

For materials, transducers, components and accessories that have been previously approved for the same or more critical tissue contact, biocompatibility is not required if the applicant certifies that the patient contact materials are unchanged in formulation and processing from the previously licensed device. Device licence numbers shall be provided.

2.3.10 Section 20: Software/Firmware

Provide either a declaration of conformity to IEC 60601-1-4 or equivalent standard or provide a description of the software/firmware supporting the operation of the subject device as per the following guidance. This applies to new systems and to software/firmware changes made to devices with extensive marketing history and history of safe use (marketing history) in other countries. Significant changes to software must be validated and verified.

The Therapeutic Products Directorate recognizes that many of ultrasound systems have a variety of software modules controlling different functions and that the level of concern for a particular module may vary. An applicant may provide different levels of documentation for different modules, providing appropriate justification is given. Applications shall include the following:

i. A summary description of new and altered algorithms and an explanation why they are considered suitable for the task;
ii. The software version number;
iii. A software structural chart;
iv. A system hazard analysis;

v. A listing of the specific hardware/software requirements;
vi. A summary of the software design and development process, including the software change management process; and
vii. A summary of the software verification and validation processes.

2.4 Section 32(3)(i): Bibliography

To facilitate the review process, the applicant is requested to provide a bibliography of relevant reports dealing with the use of the device for new technology and new indications. Inclusion of abstracts and reprints may facilitate the review process. For established technology, a rationale for not including references must be provided.

3.0 SECTION 32(3)(g): LABELLING

A copy of device labelling is required to be submitted for Class III and Class IV device licence application under Section 32(3)(g) and Section 32(4)(o) of the Regulations, respectively.

"Final draft device labelling" may be submitted to meet these requirements.

Labelling includes device labels, package inserts, product brochures, operator's manuals, promotional material that describe the system and associated transducers. Maintenance manuals are not a required component of the final draft device labelling.

Graphics and ink colours are not required for the "final draft device labelling". Final product labelling shall not differ in the content or context of the "final draft device labelling" submitted with the device licence application.

All final product labelling shall comply with the Labelling Requirements (Section 21 to 23) of the Regulations.

3.1 Acoustic Output Labelling in the Operator's Manual

Draft labelling of the operator's manual showing estimated global acoustic output indices for each possible system/transducer/mode combination as per Appendix 2: Tables A-2 and A-2-1, may be provided with the initial medical device licence application. However, final acoustic output indices values are required to be submitted prior to the first sale of the device as per Appendix 3: Tables A-3, A-3-1, A-3-2 and A-3-3.

The acoustic output reporting table may also be found in the AIUM labelling standard (AIUM 1998). Manufacturers are advised to use the format of the tables in the submission.

3.1.1 Real Time Features

Provide an explanation of the real-time display features and controls of the system, including default setting (refer to Section 4.2.2 of the "Output Display Standard"). Suggestions on how to use these features and controls to follow the ALARA principle should be provided. It is recommended that these include, but not be limited to, a reference to *Health Canada's Guidelines for the Safe Use of Diagnostic Ultrasound*, particularly sections 2 and 3.

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

3.1.2 Display Accuracy and Measurement Precision

Provide the display accuracy and measurement precision. Refer to Sections 4.2, 4.2.1, and 6.4 of the "Output Display Standard".

3.1.3 Low Output Systems

If no system/transducer combination is capable of exceeding either a TI of 1.0 or and MI of 1.0 in any operating mode, then completion of the Acoustic Output Reporting Tables (Appendix 3) is not necessary. However, in their place the global maximum values of the $I_{SPTA\,.\,3}$ of the TI (TIS, TIB or TIC) and MI and $I_{PA\,.\,3}$ @ MI_{max1} should be specified as shown in Appendix 1: Table A-1.

3.1.4 Acoustic Output Reporting Tables

Appendix 3 contains an example output table. Note the use of the four footnotes: a,b,c,#. The Operating Mode (B-mode, Pulsed Doppler, and/or Colour Flow (incl. M-Mode)) should be stated, and applicable data provided.

Summarize the operating mode possibilities for each system/transducer combination by completing Table A-2. For each possible transducer/mode identified specify the target range of values for the MI or $I_{SPPA\,.3}$ and $I_{SPTA\,.3}$ and an estimated range of TI's under the operating conditions that maximize these quantities, noting that the upper bound must not be greater than the global maximum values. Also provide the engineering basis for the range of values specified (e.g. preliminary or prototype measurements, theoretical calculations, estimates based on measurements of previously licensed transducers).

3.2 Section 32(3)(g): General Labelling Information

3.2.1 Re-use Instructions

Provide instructions for care of the device between uses, including storage, cleaning, disinfection and sterilization of all components, as appropriate. Labelling should recommend the use of sterile, when appropriate and licensed transducer sheaths, for clinical applications of a semi-critical or critical nature (i.e. intra operative, transrectal, transvaginal, trans-esophageal, biopsy procedures).

When recommending a procedure that uses a clear liquid disinfection or sterilizing agent refer the user to the labelling instructions provided by the manufacturer of that product.

When recommending a procedure other than liquid disinfection or sterilization, detailed instructions are to be provided. These procedures are validated and a summary of the validation process and representative data submitted as part of the application.

3.2.2 Additional Labelling

Additional labelling may be necessary to address safety and effectiveness concerns, depending upon the clinical application(s) of the transducer: e.g. transcranial, trans-esophageal, intra operative, transvaginal, ophthalmic or vascular diagnostic systems.

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

4.0 SECTION 32(3)(j): QUALITY SYSTEM CERTIFICATION

Section 32(3)(j) requires a a copy of a quality system certificate certifying that the quality system under which the device is designed and manufactured satisfies National Standard of Canada CAN/CSA- ISO 13485:03, *Medical devices - Quality management systems - Requirements for regulatory purposes*, as amended from time to time.

5.0 MEDICAL DEVICE LICENCE ISSUANCE

In the case where the final global acoustic output indices (Sections 2.3.3 and 3.1) are provided in the initial medical device licence application, and it is determined that the ultrasound

system/transducer meet the safety and effectiveness requirements of the Regulations, a medical device licence will be issued.

In the case where the estimated global acoustic output indices (Sections 2.3.3 and 3.1) are provided in the initial medical device licence application, and it is determined that the ultrasound system/transducer meet the safety and effectiveness requirements of the Regulations, a medical device licence with conditions will be issued. A licence with conditions sets out terms to ensure that the device continues to meet the safety and effectiveness requirements. In this case, and specifically for ultrasound systems and transducers, the licence is granted on the condition that prior to the first sale of the device, the final global acoustic output indices based on production line devices (as per Appendix 3: tables A-3. A-3-1, A-3-2, A-3-3) must be submitted. Once this information is provided, sale of the ultrasound system and/or transducer may commence. If the information is complete and contains acceptable acoustic output values (i.e. the device continues to meet the safety and effectiveness requirements) then the licence will be amended to remove this condition.

Appendix 1:

Table A-1: Low Output Summary Table

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

System: _____

Transducer Model	$I_{spta .3}$	TI Type	TI Value	MI	Ipa .3@MI_{max}
Model A					
Model B					
Model C					

Additional Comments:

_____
_____
_____
_____

Appendix 2: Operating Modes and Acoustic Output Estimates

This approach is based upon conformance with the "Output Display Standard".

Table A-2: Output Range Summary Table

For devices that comply with the "Output Display Standard", the information submitted in this table format will provide information on the specifications and parameters to determine applicability of standards.

System: _____ Transducer: _____

	Mode of Operation						
Global Maximum Output Levels (est.)	B	M	PWD	CWD	Colour 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 may include: A-mode, Amplitude Doppler, 3-D Imaging, Harmonic Imaging, Tissue Motion Doppler, Colour Velocity Imaging

Notes:

- Include one table for each transducer.
- Please provide an explanation of the method(s) used to arrive at the estimates.
- Information is only required for applicable modes (e.g. MI information is not required for transducers that only support Doppler modes).

Additional Comments:

_____
_____
_____
_____

Table A-2-1: Transducer/Mode Combination Summary Table

Complete Table A-2-1 below for each transducer/mode combination. Indicate with a check the transducer/mode combinations for which the global maximum displayed MI or TI is greater than 1.0. For each transducer/mode combination checked, and acoustic output table should be completed (Table A-3).

System: _____

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

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

Additional Comments:_____
_____
_____

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

B **Mode**:	No other modes active. Only MI (when > 1.0) need be reported for this **mode**.
M **Mode**:	May include simultaneous B **mode**.
PW Dop./CW Dop.:	In duplex **modes**, report largest displayed TIS (scanned or non-scanned) if > 1.0.
Colour Flow:	May include simultaneous Colour Flow M-mode, B-mode and M mode. In combined **modes**, report largest displayed TIS (scanned or non-scanned) if > 1.0.
Combined **modes**:	Need only be reported as a separate **mode** if the largest formulation of TIS, TIB or TIC (if there is an applicable intended use; e.g. transcranial or neonatal cephalic) is greater than the corresponding value reported for all constituent **modes**.

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

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

Appendix 3: Acoustic Output Reporting Table

Z_1	where $z^3 z_{bp}$ (centimetres)
US	where z Z_{bm} (centimetres)
$D_{eq}(z)$	(4/p)

All entries in Table A-3 should be obtained at the same operating conditions that give rise to the global maximum Index Value in the second row. These operating conditions should be specified. Measurement uncertainties for acoustic quantities (power, pressure, intensities, center frequency) should be provided.

Symbols used in the table are described below.

MI	the **Mechanical Index**.
TIS_{scan}	the Soft Tissue **Thermal Index** in an **auto-scanning mode**.
$TIS_{non\text{-}scan}$	the Soft Tissue **Thermal Index** in a **non-autoscanning mode**.
TIB	the Bone **Thermal Index**.
TIC	the Cranial **Thermal Index**.
A_{aprt}	the area of the active aperture (square centimetres). See Radiation Cross Sectional Area definition.
$p_{r.3}$	the **derated peak rarefactional pressure** associated with the transmit pattern giving rise to the value reported under MI (megapascals).
W_o	the **ultrasonic power**, except for TIS_{scan}, in which case it is the **ultrasonic power** passing through a one-centimetre window (milliwatts).
$W_{.3}(z_1)$	the **derated ultrasonic power** at axial distance z_1 (milliwatts).
$I_{TA.3}(z_1)$	the **derated spatial-peak temporal-average intensity** at axial distance z_1 (milliwatts per square centimetre).
z_1	the axial distance corresponding to the location of max[min($W_{.3}(z)$, $I_{TA.3}(z)$ x 1 cm^2)], where $z \geq z_{bp}$ (centimetres).
z_{bp}	$1.69\sqrt{A_{aprt}}$ (centimetres).
z_{sp}	For MI, the axial distance at which $p_{r.3}$ is measured for TIB, the axial distance at which TIB is a **global maximum** (i.e., $z_{sp} = z_{B.3}$) (centimetres). (The AIUM Acoustic Output Measurement Standard and NEMA UD-2 Standard allow MI to be measured at position of max Pii.3.).
$d_{eq}(z)$	the equivalent beam diameter as a function of axial distance z, and is equal to $\sqrt{(4/\pi)\,(W_o / I_{TA}(z))}^{0.5}$ where $I_{TA}(z)$ is the **temporal-average intensity** as a function of z (centimetres).

f_c	the **center frequency** (MHz). For MI, f_c is the **center frequency** associated with the transmit pattern giving rise to the **global maximum** reported value of MI. For TI, for combined modes involving transmit patterns of unequal center frequency, f_c is defined as the overall ranges of **center frequencies** of the respective transmit patterns.
Dim. of A_{aprt}	the active aperture dimensions for the azimuthal (x) and elevational (y) planes (centimetres).
PD	the **pulse duration** (microseconds) associated with the transmit pattern giving rise to the reported value of MI.
PRF	the **pulse repetition frequency** associated with the transmit pattern giving rise to the reported value of MI (Hz).
$p_r@PII_{max}$	the **peak rarefactional pressure** at the point where the free-field, spatial-peak **pulse intensity integral** is a maximum (megapascals). See Section 6.2.4.1 of the **"Output Display Standard"**, entitled "Measurement Methodology for Mechanical and Thermal Indices".
$d_{eq}@PII_{max}$	the equivalent beam diameter at the point where the free-field, spatial-peak **pulse intensity integral** is a maximum (centimetres). See Section 6.2.5.1 of the **"Output Display Standard"**, entitled "Measurement Methodology for Mechanical and Thermal Indices".
FL	the focal length, or azimuthal (x) and elevational (y) lengths, if different (centimetres).
$I_{PA.3}@MI_{max}$	the **derated pulse-average intensity** at the point of **global maximum** reported MI (Watts per square centimetre).

All entries in Table A-3 should be obtained at the same operating conditions that give rise to the global maximum Index Value in the second row. These operating conditions should be specified. Measurement uncertainties for acoustic quantities (power, pressure, intensities, center frequency) should be provided.

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

$$= \frac{W_{o1x1} f_c}{210/f_c}$$

where

W_{o1x1} is the bounded-square output power in milliwatts;
$_c$ is the center frequency in Megahertz.

Symbol: TIS_as
Unit: Unitless

Appendix 3: Table A-3: Acoustic Output Reporting Table

(provide data where global maximum displayed index exceeds 1.0)

Note: See section 4.1.3.1 of the "Output Display Standard"

Transducer Model: _____ Operating Mode: _____

Index Label			MI	TIS			TIB	TIC
				scan	non - scan		non-scan	
					$A_{aprt} \leq 1$	$A_{aprt} > 1$		
Global Maximum Index Value								
Assoc Acoustic Parameter	$p_{r.3}$	(MPa)						
	W_o	(mW)						
	min of $[W_3(z_1), I_{TA.3}(z_1)]$	(mW)						
	z_1	(cm)						
	z_{bp}	(cm)						
	z_{sp}	(cm)						
	$d_{eq}(z_{sp})$	(cm)						
	f_c	(MHz)						
	Dim of A_{aprt}	X (cm)						
		Y (cm)						
Other Information	PD	(μsec)						
	PRF	(Hz)						
	p_r@PII_{max}	(MPa)						
	d_{eq}@PII_{max}	(cm)						
	Focal Length	FL_x (cm)						
		FL_y (cm)						
	$I_{PA.3}$ @MI_{max}	(W/cm²)						
Operating Control Conditions	Control 1							
	Control 2							
	Control 3							
	Control n							

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

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

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

Table A-3-1: Acoustic Output Reporting Table (B-mode

(provide data where global maximum displayed index exceeds 1.0)

Note: See section 4.1.3.1 of the "Output Display Standard".

Transducer Model: Operating Mode: B-mode

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

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

Table A-3-2: Acoustic Output Reporting Table (Pulsed Doppler)

(provide data where global maximum displayed index exceeds 1.0)
Note: See section 4.1.3.1 of the Output Display Standard.

Transducer Model: _____ Operating Mode: Pulsed Doppler

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

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

Table A-3-3: Acoustic Output Reporting Table (Colour Flow M-Mode)

(provide data where global maximum displayed index exceeds 1.0)
Note: See section 4.1.3.1 of the "Output Display Standard".

Transducer Model: _____ Operating Mode: Colour Flow (M-mode)

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

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

Appendix 4: List of Standards

The following is a partial list of recognized standards that are available for use in diagnostic ultrasound submissions. For a complete list of TPD Recognized Medical Device Standards, refer to the *List of Recognized Standards for Medical Devices* posted on the website.

1. **AIUM 1998**
   Acoustic Output Labelling Standard for Diagnostic Ultrasound Equipment: A Standard for How Manufacturers Should Specify Acoustic Output Data

2. **AIUM/NEMA UD2-2004**, **Revision 3**
   Acoustic Output Measurement Standard for Diagnostic Ultrasound Equipment.

3. **AIUM/NEMA UD3-2004**, **Revision 2**
   Standard for Real-Time Display of Thermal and Mechanical Acoustic Output Indices on Diagnostic Ultrasound Equipment.

4. **IEC 60601-1**
   Medical Electrical Equipment - Part 1: General Requirements for Safety 2nd edition

5. **IEC 60601-1-am1**
   Medical Electrical Equipment - Part 1: General Requirements for Safety Amendment No.1

6. **IEC 60601-1-am2**
   Medical Electrical Equipment - Part 1: General Requirements for Safety Amendment No.2

7. **IEC 60601-1-1**
   Medical Electrical Equipment - Part 1: General Requirements for Safety - Section 1: Collateral Standard: Safety Requirements for Medical Electrical Systems

8. **IEC 60601-1-2**
   Medical Electrical Equipment - Part 1: General Requirements for Safety - Section 2: Collateral Standard: Programmable Electrical Medical Systems

9. **IEC 60601-1-4**
   Medical Electrical Equipment - Part 1: General Requirements for Safety - Section 4: Collateral Standard: Programmable Electrical Medical Systems

10. **ISO-10993-1**,
Biological Evaluation of Medical Devices Part 1: Evaluation and Testing, (ISO 1993)

11. **IEC 60601-2-37 Ed. 1.0**
Medical Electrical Equipment - Part 2-37: Particular Requirements for the Safety of Ultrasonic Medical Diagnostic and Monitoring Equipment

12. **ISO 14971-1-2000**
Medical Devices - Application of Risk Management to Medical Devices

Note: This guidance makes extensive reference to the *Standard for Real-Time Display of Thermal and Mechanical Acoustic Output Indices on Diagnostic Ultrasound Equipment* using the generally recognized shortened name "**Output Display Standard**". All references to the **"Output Display Standard"** specifically refer to the above-mentioned standard.

Appendix 5:

General Definitions

CONTRAINDICATIONS describe situations where the device should not be used because the risk of use clearly outweighs any reasonably foreseeable benefits.

CONTROL MECHANISM is a means of verifying or checking that the specifications or outputs of the device meet a standard or predetermined result. They are mechanisms put in place to maintain on-going control or regulate the output of a device.

INDICATIONS FOR USE is the general description of the disease(s) or condition(s) the device will diagnose, treat, prevent or mitigate, including where applicable a description of the patient population for which the device is intended. The indications include all the labelled patient uses of the device, for example: the condition(s) or disease(s) to be prevented, mitigated, treated or diagnosed, part of the body or type of tissue applied to or interfaced with, frequency of use, physiological purpose and patient population. Indications for use are generally found in the indications section of the labelling, but indications may also be inferred from other parts of the labelling such as the precautions, warnings, bibliography or directions for use sections. In some instances, intended use is determined by a manufacturer's and/or distributor's statements or may be shown by the circumstances surrounding the distribution of the article.

OPERATING PRINCIPLES are the means by which a device produces or brings about a desired or appropriate effect. They are the means whereby a device is able to have a certain influence on a person or its surroundings.

PRECAUTIONS describe any special care to be exercised by practitioner or patient for the safe and effective use of a device. This definition includes limitations stated for *in vitro* diagnostic devices (IVDDs).

WARNINGS describe serious adverse reactions and potential safety hazards that can occur in the proper use, or the misuse, of a device, along with consequent restrictions in use and mitigating steps to take if problems occur.

Device Specific Definitions

ACOUSTIC PRESSURE: The value of the total pressure minus the ambient pressure.
Symbol: P
Unit: Pascal, Pa

ALARA: As low as reasonably achievable.

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

BANDWIDTH: The difference between the most widely separated frequencies f_1 and f_2 at which the transmitted acoustic pressure spectrum is 71 percent (-3 dB) of its maximum value.
Symbol: BW
Unit: Hertz, Hz

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

BEAM CROSS-SECTIONAL AREA: The area on the surface of a plane perpendicular to the beam axis consisting of all points where the pulse intensity integral is greater than 25 percent of the maximum pulse intensity integral in that plane. For situations in which the relative acoustic pressure waveform does not change significantly across the beam cross-sectional area, the beam cross-sectional area may be approximated by measuring the area on the surface of a plane perpendicular to the beam axis consisting of all points where the acoustic pressure is greater than 50 percent of the maximum acoustic pressure in the plane.
Symbol: A
Unit: centimetre squared, cm^2

BOUNDED-SQUARE OUTPUT POWER: Power emitted in the non-autoscanning mode form the contiguous one square centimetre of the active area of the transduce through which the highest ultrasonic power is being transmitted.
Symbol: W_{01X1}
Unit: milliwatt, mW
center frequency: defined as

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

where

f_1 and f_2 are frequencies defined in bandwidth

Symbol: f_c
Unit: Hertz, Hz

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

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

(1) Any element of the standard that was not applicable to the device;

(2) If the standard is part of a family of standards which provides collateral and/or particular parts, a statement regarding the collateral and/or particular parts that were met;

(3) Any deviations from the standards that were applied;

(4) What differences exist, if any, between the tested device(s) and the device to be marketed and a justification of the test results in those areas of difference; and

(5) Name and address of any test laboratory or certification body involved and a reference to any accreditations of those organisations.

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

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

DESIGNATED STANDARD MODE: consist of the following specific operating modes: A-mode, B-mode, M-mode, PW Doppler, CW Doppler and Colour 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 -12dB beam width where the beam enters the patient. For contact transducers, these dimension can be taken as the dimensions of the radiating element, if so stated.
Symbol: EBD
Unit: centimetre, 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: centimetre, 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 the $S/\pi\lambda$ where S is the radiating cross-sectional area and L 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: centimetre squared, cm^2

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

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

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

$$I = p^2/rc$$

where

p is the instantaneous acoustic pressure;
r is the density of the medium;
c is the speed of sound in the medium.

Symbol: I

Unit: Watt per square-centimetre, 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-centimetre, W cm^{-2}

INTENSITY, SPATIAL-AVERAGE PULSE-AVERAGE: the spatial average, temporal average intensity at the face of the transducer divided by the duty factor, where the duty factor is the product of the pulse duration and the pulse repetition frequency.
Symbol: I_{SAPA}
Unit: milliwatt per square-centimetre, mW 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-centimetre, 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-centimetre, W cm^{-2}

INTENSITY, SPATIAL-PEAK TEMPORAL-AVERAGE: the value of the temporal-average intensity at the point in the acoustic field where the temporal-average intensity is a maximum, or is a local maximum within a specified region.
Symbol: I_{SPTA}
Unit: milliwatt per square-centimetre, 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 modes, 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-centimetre, mW cm^{-2}

INTENSITY, TEMPORAL PEAK: the peak value of the intensity at the point considered.
Symbol: I_{TP}
Unit: Watt per square-centimetre, W cm^{-2}

INVASIVE TRANSDUCER: An ultrasound transducer that is intended to contact tissue other than intact skin or the surface of the eye. These include transvaginal, trans-esophageal, transrectal, transurethral, intravascular and intraoperative transducers.

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

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

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 require moving the transducer manually.

OPERATING CONDITION: Any one combination of the possible particular output control settings for a mode.

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

OUTPUT DISPLAY STANDARD: The Standard for real-time display of thermal and mechanical acoustic output indices on the diagnostic ultrasound equipment. Revision 1. AIUM/NEMA Standards Publication (AIUM/NEMA 1998b).

PEAK RAREFACTIONAL PRESSURE; PEAK NEGATIVE PRESSURE: Maximum of the modulus of the negative instantaneous acoustic pressure in an acoustic field during an acoustic repetition period.
Symbol: P_r or P_-
Unit: megapascal, Mpa

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

PRESSURE: See acoustic pressure.

PULSE-AVERAGE INTENSITY: See intensity
Symbol: I_{PA}
Unit: Watt per square-centimetre, 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 non-zero. 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 centimetre-squared, J cm^{-2}

PULSE REPETITION FREQUENCY: for pulsed waveform, the number of pulses generated per second.
Symbol: PRF
Unit: Hertz, Hz

RADIATING CROSS-SECTIONAL AREA (A_{aprt}): the area of the surface at and parallel to the face of the active transducer element(s) and consisting of all points where the acoustic pressure is greater than -12 dB of the maximum acoustic pressure in that surface. The area of the active element(s) of the transducer assembly may be taken as an approximation for the radiating cross-sectional area.
Symbol: S
Unit: centimetre 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: centimetre squared, cm^2

SPATIAL-AVERAGE PULSE-AVERAGE INTENSITY: see intensity.
Symbol: I_{SAPA}
Unit: milliwatt per square-centimetre, mW cm^{-2}

SPATIAL-AVERAGE TEMPORAL-AVERAGE INTENSITY: see intensity.
Symbol: I_{SATA}
Unit: milliwatt per square-centimetre, mW cm^{-2}

SPATIAL-PEAK PULSE-AVERAGE INTENSITY: see intensity.
Symbol: I_{SPPA}
Unit: Watt per square-centimetre, W cm^{-2}

SPATIAL-PEAK TEMPORAL-AVERAGE INTENSITY: see intensity.
Symbol: I_{SPTA}
Unit: milliwatt per square-centimetre, mW cm^{-2}

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

TEMPORAL-AVERAGE INTENSITY: see intensity.
Symbol: I_{TA}
Unit: milliwatt per square-centimetre, mW cm^{-2}

TEMPORAL-PEAK INTENSITY: see intensity.
Symbol: I_{TP}
Unit: Watt per square-centimetre, W cm^{-2}

THERMAL INDEX: A quantity related to calculated or estimated temperature rise under certain defined assumptions. The thermal index is the ratio of total acoustic power to the acoustic power required to raise tissue temperature by 1C under defined assumption. In the calculation of all thermal indices in the "Output Display Standard", the average ultrasonic attenuation is assumed to be 0.3 dB/cm-MHz along the beam axis in the body. (See Tables 2-1, 2-2, 2-3, and 2.4 in the "Output Display Standard" for thermal index categories and formulae).
Symbol: TI

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

$$= \frac{W_{o1x1} f_c}{210/f_c}$$

where

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

Symbol: TIS_as
Unit: Unitless

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

UTRASONIC 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:
Unit: centimetres per cycle, cm cycle^{-1}

Mechanical Index, MI = $p_{r.3}(Z_{sp})/f_c^{1/2}$

Wavelength $\lambda = v/f$

List of Symbols

P	=	Acoustic Pressure
BW	=	Bandwidth
A	=	Beam cross-sectional area
f_c	=	Center frequency
a	=	Derating Factor
I	=	Instantaneous Intensity
I_{PA}	=	Pulse-average intensity
I_{SAPA}	=	Spatial-average pulse-average intensity
I_{SATA}	=	Spatial-average temporal-average intensity
I_{SPPA}	=	Spatial-peak pulse-average intensity
I_{SPTA}	=	Spatial-peak temporal-average intensity
I_{TA}	=	Temporal-average intensity
I_{TP}	=	Temporal-peak intensity
MI	=	Mechanical index
P_r	=	Peak rarefactional pressure
W_O	=	Power, ultrasonic power
PD	=	Pulse duration
PII	=	Pulse intensity integral
PRF	=	Pulse repetition frequency
S	=	Radiating cross-sectional area
TI	=	Thermal Index
TIS_as	=	Soft tissue thermal index at surface
λ	=	Wavelength