

Australian/New Zealand Standard

Requirements for the declaration of the acoustic output of medical diagnostic ultrasonic equipment

AS/NZS 4194:1994

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PREFACE

This Standard was prepared by the Joint Standards Australia/Standards New Zealand Committee HT/17 on Ultrasonic Medical Equipment, and issued as a Joint Standard under the terms of the Active Cooperation Agreement between Standards Australia and Standards New Zealand.

This Standard is identical with and has been reproduced from IEC 1157:1992, *Requirements for the declaration of the acoustic output of medical diagnostic ultrasonic equipment*.

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For the purpose of this Standard, the IEC text should be modified as follows:

- (a) *Terminology* The words ‘this Australian/New Zealand Standard’ should replace the word ‘this International Standard’ wherever they appear.
- (b) *Decimal marker* Substitute a full point for a comma where it appears as a decimal marker.
- (c) *References* The references to international Standards should be replaced by references to the following Australian or Joint Australian/New Zealand Standards:

<i>Reference to International Standard or other publication</i>	<i>Australian or Joint Australian/New Zealand Standard</i>
IEC	—
469 Pulse techniques and apparatus	
469 Part 1: Pulse terms and definitions	
854 Methods of measuring the performance of ultrasonic pulse-echo diagnostic equipment	—
1102 Measurement and characterization of ultrasonic fields using hydrophones in the frequency range 0,5 MHz to 15 MHz	—
1161 Ultrasonic power measurement in liquids in the frequency range 0,5 MHz to 25 MHz	—

The terms ‘normative’ and ‘informative’ have been used in this Standard to define the application of the annex to which they apply. A ‘normative’ annex is an integral part of a Standard, whereas an ‘informative’ annex is only for information and guidance.

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Australian/New Zealand Standard
Requirements for the declaration of the acoustic output of medical
diagnostic ultrasonic equipment

1 Scope

This International Standard is applicable to medical diagnostic ultrasonic equipment.

It establishes requirements for the declaration of the acoustic output information:

- to be presented in technical data sheets supplied to prospective purchasers of equipment by manufacturers;
- to be declared in the accompanying literature/manual supplied by manufacturers;
- as background information to be made available on request to interested parties by manufacturers.

It also gives exemption conditions for equipment generating low acoustic output levels.

2 Normative references

The following normative documents contain provisions which, through reference in this text, constitute provisions of this International Standard. At the time of publication, the editions indicated were valid. All normative documents are subject to revision, and parties to agreements based on this International Standard are encouraged to investigate the possibility of applying the most recent editions of the normative documents indicated below. Members of IEC and ISO maintain registers of currently valid International Standards.

IEC 469-1: 1987, *Pulse techniques and apparatus. Part 1: Pulse terms and definitions.*

IEC 854: 1986, *Methods of measuring the performance of ultrasonic pulse-echo diagnostic equipment.*

IEC 1102: 1991, *Measurement and characterization of ultrasonic fields using hydrophones in the frequency range 0,5 MHz to 15 MHz.*

IEC 1161: 1992, *Ultrasonic power measurement in liquids in the frequency range 0,5 MHz to 25 MHz.*

3 Definitions and symbols

For the purpose of this International Standard, the following definitions apply.

Figures 1 to 4 illustrate some of the defined parameters given below.

3.1 accompanying literature: Operating and instruction manual provided by the **manufacturer** with each piece of **medical diagnostic ultrasonic equipment**.

3.2 acoustic initialization fraction: Ratio of the **peak-negative acoustic pressure** when a **system** is in **initialization mode** to the maximum value of the **peak-negative acoustic pressure** for any **system** settings of a specified mode of operation. This ratio is determined from measurements made at the position which yields the maximum **pulse-pressure-squared integral** (or maximum mean square acoustic pressure for continuous wave [cw] **systems**). The ratio is usually expressed as a percentage.

NOTE - The mode of operation of a **system** in **initialization mode** may be different from the specified mode of operation.

3.3 acoustic output freeze: A condition of a **system** for which the acoustic output is disabled when there is no active updating of ultrasonic echo information.

3.4 acoustic power-up fraction: Ratio of the **peak-negative acoustic pressure** when the **system** is in **power-up mode** to the maximum value of the **peak-negative acoustic pressure** for any **system** settings of a specified mode of operation. This ratio is determined from measurements made at the position which yields the maximum **pulse-pressure-squared integral** (or maximum mean square acoustic pressure for continuous wave [cw] **systems**). The ratio is usually expressed as a percentage.

NOTE - The mode of operation of a **system** in **power-up mode** may be different from the specified mode of operation.

3.5 bandwidth: Difference in the frequencies f_1 and f_2 at which the amplitude of the spectrum of the acoustic pressure first becomes 3 dB lower than the peak amplitude.

3.6 combined-operating mode: Mode of operation of a **system** which combines more than one **discrete-operating mode**.

NOTE - Examples of **combined-operating modes** are real-time B-mode combined with M-mode (B+M), real-time B-mode combined with pulsed Doppler (B+D), colour M-mode (cM), real-time B-mode combined with M-mode and pulsed Doppler (B+M+D), real-time B-mode combined with real-time flow-mapping Doppler (B+rD), i.e. flow-mapping in which different types of acoustic pulses are used to generate the Doppler information and the imaging information.

3.7 discrete-operating mode: Mode of operation of **medical diagnostic ultrasonic equipment** in which the purpose of the excitation of the ultrasonic transducer or ultrasonic transducer element group is to utilize only one diagnostic methodology.

NOTE - Examples of **discrete-operating modes** are A-mode (A), M-mode (M), static B-mode (sB), real-time B-mode (B), acoustic wave Doppler (cwD), pulsed Doppler (D), static flow-mapping (sD) and real-time flow-mapping Doppler (rD) using only one type of acoustic pulse.

3.8 inclusive mode: **Combined-operating mode** having acoustic output levels (p_- and I_{spta}) less than those corresponding to a specified **discrete-operating mode**.

3.9 initialization mode: A defined state of a **system** corresponding to the mode of operation and system settings when a new patient procedure is initiated.

3.10 manufacturer: A company that makes, markets or distributes **medical diagnostic ultrasonic equipment**.

3.11 medical diagnostic ultrasonic equipment (or system): Combination of the **ultrasound instrument console** and the **transducer assembly** making up a complete diagnostic **system**.

3.12 non-scanning mode: A mode of operation of a **system** that involves a sequence of ultrasonic pulses which give rise to **ultrasonic scan lines** that follow the same acoustic path.

NOTE - The sequence of pulses is not necessarily made up of identical pulses, such as in multiple focal-zone systems.

3.13 output beam area: Area of the ultrasonic beam derived from the **output beam dimensions**.

Unit: centimetre squared, cm^2 .

3.14 output beam dimensions: Dimensions of the ultrasonic beam (**-6 dB pulse beam-width**) in a specified direction normal to the **beam alignment axis** and at the **transducer output face**.

Unit: millimetre, mm.

3.15 output beam intensity: Temporal-average power output divided by the **output beam area**.

Symbol: I_{ob}

Unit: milliwatt per centimetre squared, mW/cm^2 .

3.16 patient entry plane: Plane perpendicular to the **beam alignment axis**, or the axis of symmetry of the **scan plane** for an automatic scanner, which passes through the point on said axis at which the ultrasound enters the patient.

See figure 1.

3.17 power-up mode: A defined state of a **system** corresponding to the mode of operation and **system** settings automatically established when power to the **system** is first turned on. If the defined state is user dependent, **power-up mode** is referred to as “not applicable” (abbreviated n/a).

NOTE - The defined state would normally be one of the discrete- or combined-operating modes.

3.18 pulse beam-width: Distance between two points, on a specified surface and in a specified direction passing through the point of the maximum **pulse-pressure-squared integral** (ppsi) in that surface, at which the ppsi is a specified fraction of the maximum value of the ppsi

in the surface. The two points are farthest from and on opposite sides of the point of maximum ppsi. If the position of the specified surface is not given, then it passes through the point of spatial-peak temporal-peak acoustic pressure in the whole acoustic field.

The specified levels are 0,25 and 0,01 for the **−6 dB** and **−20 dB pulse beam-widths** respectively.

NOTES

1 For continuous wave **systems**, the term **pulse-pressure-squared integral** (ppsi) is replaced everywhere in the above definition by mean square acoustic pressure.

2 The specified surface is usually a plane perpendicular to the **beam-alignment axis** but can be a cylinder for ultrasonic transducers with cylindrical active elements or a sphere for ultrasonic transducers with spherical active elements.

Symbol: w_{pb6} , w_{pb20}

Unit: millimetre, mm.

3.19 reference direction: For **systems** with scanning modes, the direction normal to the **beam-alignment axis** for an **ultrasonic scan line** and in the **scan plane**. For **systems** with only non-scanning modes, the direction normal to the **beam-alignment axis** and parallel to the direction of maximum **−6 dB pulse beam-width**.

3.20 scan direction: For **systems** with scanning modes, the direction in the **scan plane** and perpendicular to a specified **ultrasonic scan line**.

3.21 scanning mode: A mode of operation of a **system** that involves a sequence of ultrasonic pulses which give rise to **ultrasonic scan lines** that do not follow the same acoustic path.

NOTE - The sequence of pulses is not necessarily made up of identical pulses, such as in multiple focal-zone **systems**.

3.22 transducer assembly: Those parts of **medical diagnostic ultrasonic equipment** comprising the ultrasonic transducer and/or ultrasonic transducer element group together with any integral components, such as an acoustic lens, integral stand-off etc. The **transducer assembly** is usually separable from the **ultrasound instrument console**.

3.23 transducer output face: External surface of a **transducer assembly** which is either directly in contact with the patient or is in contact with a water or liquid path to the patient.

See figures 1 and 2.

3.24 transducer stand-off distance: Shortest distance between the **transducer output face** and the **patient entry plane**.

The term “contact” is used to connote direct contact between the **transducer output face** and the patient, with the **transducer stand-off distance** equal to zero.

Symbol: l_{ts}

Unit: millimetre, mm.

See figure 1

3.25 transducer to transducer-output-face distance: The distance along the **beam-alignment axis** between the surface containing the active face of the ultrasonic transducer or ultrasonic transducer element group and the **transducer output face**.

Symbol: l_{tt}

Unit: millimetre, mm.

See figures 1 and 2.

3.26 type testing values: For acoustical output parameters, the maximum probable acoustical output levels for a specified **system**.

3.27 ultrasonic scan line: For automatic scanning **systems**, the **beam-alignment axis** either for a particular ultrasonic transducer element group, or for a single or multiple excitation of an ultrasonic transducer or of an ultrasonic transducer element group.

See figure 3.

NOTE - Here, an **ultrasonic scan line** refers to the path of acoustic pulses and not to a line on an image on the display screen of a **system**.

3.28 ultrasound instrument console: Electronic unit to which the **transducer assembly** is attached.

The following definitions are identical to or conform to those given in IEC 1102.

3.29 acoustic pulse waveform: Temporal waveform of the instantaneous acoustic pressure at a specified position in an acoustic field and displayed over a period sufficiently long to include all significant acoustic information in a single pulse or tone-burst, or in one or more cycles in a continuous wave.

See also 2.3.1 of IEC 469-1 and 3.2 of IEC 1102.

3.30 arithmetic-mean acoustic-working frequency: The arithmetic mean of the frequencies f_1 and f_2 at which the amplitude of the spectrum of the acoustic signal, i.e. the output of a hydrophone placed in an acoustic field at a specified position, first becomes 3 dB lower than the peak amplitude.

Conforms to 3.4.2 of IEC 1102.