AS/NZS IEC 60601.2.62:2022
IEC 60601-2-62:2013

Australian/New Zealand Standard™

Medical electrical equipment

Part 2.62: Particular requirements for the basic safety and essential performance of high intensity therapeutic ultrasound (HITU) equipment

AS/NZS IEC 60601.2.62:2022

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Preface

This Standard was prepared by the Joint Standards Australia/Standards New Zealand Committee HE-003, Medical Electrical Equipment.

The objective of this document is to specify safety requirements additional to those in the general standard (AS/NZS IEC 60601.1) for high intensity therapeutic ultrasound equipment. It adds or replaces clauses listed in AS/NZS IEC 60601.1 that are specific for high intensity therapeutic ultrasound equipment.

This document applies to the basic safety and essential performance of high intensity therapeutic ultrasound equipment.

This document can also be applied to —

(a) therapeutic equipment for thrombolysis through exposure to high-intensity therapeutic ultrasound;

(b) therapeutic equipment for the treatment of occluding feeding vessels through exposure to high-intensity focused ultrasound; and

(c) equipment intended to be used for relieving cancer pain due to bone metastases.

Hazards inherent in the intended physiological function of ME equipment or ME systems within the scope of this document are not covered by specific requirements in this document except in Clauses 7.2.13 and 8.4.1 of AS/NZS IEC 60601.1.

This document does not apply to —

(i) ultrasound equipment intended to be used for physiotherapy, refer to AS 60601.2.5 and AS/NZS 4713:2002;

(ii) ultrasound equipment intended to be used for lithotripsy, refer to AS/NZS 60601.2.36;

(iii) ultrasound equipment intended to be used for dedicated hyperthermia devices; or

(iv) ultrasound equipment intended to be used for phacoemulsification.

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