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AS/NZS IEC 60601.2.45:2015
IEC 60601-2-45, Ed.3.1 (2015)

Australian/New Zealand Standard™

Medical electrical equipment

Part 2.45: Particular requirements for basic safety and essential performance of mammographic X-ray equipment and mammographic stereotactic devices

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Australian and New Zealand College of Anaesthetists
Australian Dental Association
Australian Society of Anaesthetists
Canterbury District Health Board
College of Biomedical Engineering Engineers Australia
Department of Defence
Engineers Australia
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PREFACE

This Standard was prepared by the Joint Standards Australia/Standards New Zealand Committee HE-003, Medical Electrical Equipment, to supersede AS/NZS 3200.2.45:1999, *Medical electrical equipment,* Part 2.45: *Particular requirements for safety—Mammographic X-ray equipment and mammographic stereotactic devices*.

The objective of this Standard is to establish particular basic safety and essential performance requirements for mammographic X-ray equipment and mammographic stereotactic devices, to ensure safety, to provide methods for demonstrating compliance with those requirements, and to provide guidance for risk management.

The objective of this revision is to adopt the current edition of IEC 60601-2-45.

The requirements of this Standard supplement the general requirements specified in AS/NZS IEC 60601.1. This Standard is intended to be read in conjunction with AS/NZS IEC 60601.1:2015, which is an identical adoption of IEC 60601-1, Ed.3.1 (2012) and is referred to in the source text as 'the general standard'.

This Standard is identical with, and has been reproduced from IEC 60601-2-45, Ed.3.1 (2015), *Medical electrical equipment,* Part 2-45: *Particular requirements for basic safety and essential performance of mammographic X-ray equipment and mammographic stereotactic devices*. This edition 3.1 incorporates Amendment 1 (2015). The text affected by Amendment 1 is indicated by marginal bars, redline and strikeout.

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(a) In the source text 'this International Standard' should read 'this Australian/New Zealand Standard'.

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The term 'informative' has been used in this Standard to define the application of the annex to which it applies. An 'informative' annex is only for information and guidance.

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