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Australian/New Zealand Standard™

Medical electrical equipment

Part 2.65: Particular requirements for the basic safety and essential performance of dental intra-oral X-ray equipment

AS/NZS IEC 60601.2.65:2022

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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 requirements for the basic safety and essential performance of dental intra-oral X-ray equipment and its main components, hereafter also called ME equipment.

The scope of this document is restricted to X-ray equipment where the X-ray tube assembly contains the high-voltage transformer assembly.

Dental extra-oral X-ray equipment is excluded from the scope of this document.

NOTE 1 The X-ray generator in dental intra-oral X-ray equipment always comprises an X-ray monoblock assembly. Therefore, in this particular document the concept of X-ray tube assembly is replaced by that of X-ray monoblock assembly.

NOTE 2 Main components may be for instance the X-ray monoblock assembly and an electronic X-ray image receptor.

ME equipment and ME systems in the scope of AS/NZS 60601.2.63, AS/NZS IEC 60601.2.44, AS 60601.2.54, AS/NZS IEC 60601.2.45 or AS/NZS 60601.2.43 are excluded from the scope of this particular document. The scope of this document also excludes radiotherapy simulators and equipment for bone or tissue absorption densitometry. Excluded from the scope is also ME equipment intended to be used for dental radioscopy.

All requirements addressing integrated X-ray tube assemblies are covered by this particular standard. Therefore AS/NZS IEC 60601.2.28 does not apply to ME equipment in the scope of this document.

The particular requirements of this document refer to IEC 60601-1, which has been adopted as AS/NZS IEC 60601.1, *Medical electrical equipment, Part 1: General requirements for basic safety and essential performance*. Reference to these general requirements is essential for the application of this document.

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