AS/NZS 4434.1:1996
IEC 976:1989

Australian/New Zealand Standard®

Medical electrical equipment—Medical electron accelerators

Part 1: Functional performance characteristics

[IEC title: Medical electrical equipment—Medical electron accelerators—Functional performance characteristics]

This Joint Australian/New Zealand Standard was prepared by Joint Technical Committee HT/23, Medical Diagnostic Imaging Equipment. It was approved on behalf of the Council of Standards Australia on 16 September 1996 and on behalf of the Council of Standards New Zealand on 26 July 1996. It was published on 5 November 1996.

The following interests are represented on Committee HT/23:

Australasian College of Physical Scientists and Engineers in Medicine
Australian Academy of Dento-Maxillo-Facial Radiologists
Australian Chamber of Commerce and Industry
Australian Dental Association
Australian Dental Industry Association
Australian Institute of Radiography
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PREFACE

This Standard was prepared by the Joint Standards Australia/Standards New Zealand Committee, HT/23, on Medical Diagnostic Imaging Equipment, as a Joint Standard.

This Standard is identical with and has been reproduced from IEC 976:1989, *Medical electrical equipment—Medical electron accelerators—Functional performance characteristics*.

Under arrangements made between Standards Australia/Standards New Zealand and the IEC, as well as certain other Standards organizations, users of this Standard are advised that the number of this Standard is not reproduced on each page; its identity is shown only on the cover.

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 words '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/New Zealand Standards:

Reference to International Standard or other publication		*Australian/New Zealand Standard*	
IEC		AS/NZS	
601	Medical electrical equipment	3200	Approval and test specification—Medical electrical equipment
601-1	Part 1: General requirements for safety	3200.1.0	General requirements for safety
601-2-1	Part 2: Particular requirements for medical electron accelerators in the range 1 MeV to 50 MeV. Section One—General. Section Two—Radiation safety for equipment	—	
788	Medical radiology—Terminology	—	
977	Medical electrical equipment—Medical electron accelerators in the range 1 MeV to 50 MeV—Guidelines for functional performance characteristics	4434	Medical electrical equipment—Medical electron accelerators
		4434.2	Part 2: Periodic function performance testing

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Part 1:
Functional performance characteristics

INTRODUCTION

Standards containing safety requirements for MEDICAL ELECTRON ACCELERATORS have been published by the IEC, details of which will be found in the Preface.

The present standard specifies methods of test and methods of disclosure of functional performance of ELECTRON ACCELERATORS intended for RADIOTHERAPY. It permits a direct comparison between the performance data of equipment of different manufacture.

Since this standard does not contain safety requirements it has not been numbered in the IEC 601 publication series. It describes aspects of functional performance of ELECTRON ACCELERATORS and the way in which they should be presented. It also includes test methods and conditions suitable for type tests. These test methods are suggested test methods and alternative methods may be equally appropriate, but the specified functional performance characteristics of the MEDICAL ELECTRON ACCELERATORS shall be related to these test methods and conditions. Tests specified in this standard are not necessarily appropriate for ensuring that any individual ELECTRON ACCELERATOR conforms with the declared functional performance during the course of its working lifetime. Guidance on the values which may be expected are given in the Report, IEC Publication 977.

1 **Scope and object**

1.1 *Scope*

1.1.1 This standard applies to MEDICAL ELECTRON ACCELERATORS when used, for therapy purposes, in human medical practice.

1.1.2 This standard applies to ELECTRON ACCELERATORS which deliver a RADIATION BEAM of either X-RADIATION OR ELECTRON RADIATION with NOMINAL ENERGIES in the range 1 MeV to 50 MeV at maximum ABSORBED DOSE RATES between 0,001 Gy s^{-1} and 1 Gy s^{-1} at 1 m from the RADIATION SOURCE and at NORMAL TREATMENT DISTANCES between 50 cm and 200 cm from the RADIATION SOURCE.

1.1.3 The present standard describes a set of measurements requiring two to three months' work to complete. It specifies test procedures to be performed by the manufacturer at the design and construction stage of a MEDICAL ELECTRON ACCELERATOR but does not specify acceptance tests to be performed after installation at the purchaser's site. The accompanying report, IEC Publication 977, however, does suggest that many of the test procedures are appropriate for acceptance tests.

1.1.4 The measurement conditions described in the present standard differ from those currently in use. This applies particularly to the PHANTOM position for measurements and the measurement of distances from the ISOCENTRE. These new conditions should be substituted for and not be added to present methods.

1.2 *Object*

This standard specifies test procedures for the determination and disclosure of functional performance characteristics, knowledge of which is deemed necessary for proper application

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