

AS/NZS 4434.2:1996
IEC 977:1989

AS/NZS 4434.2

Australian/New Zealand Standard[®]

**Medical electrical equipment—
Medical electron accelerators**

**Part 2: Periodic function
performance testing**

[IEC title: Medical electrical equipment—Medical electron accelerators
in the range 1 MeV to 50 MeV—Guidelines for functional performance
characteristics]

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AS/NZS 4434.2:1996

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Australasian College of Physical Scientists and Engineers in Medicine
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 Australian Chamber of Commerce and Industry
 Australian Dental Association
 Australian Dental Industry Association
 Australian Institute of Radiography
 Australian Radiation Laboratory
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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 977:1989, *Medical electrical equipment—Medical electron accelerators in the range 1 MeV to 50 MeV—Guidelines for functional performance characteristics*.

This Standard is issued in conjunction with AS/NZS 4434.1, *Medical electrical equipment—Medical electron accelerators, Part 1: Functional performance characteristics*. This Standard's title has been amended to clarify their relationship.

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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 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:

<i>Reference to International Standard or other publication</i>		<i>Australian/New Zealand Standard</i>	
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	—	
976	Medical electrical equipment— Medical electron accelerators— Functional performance characteristics	4434 4434.1	Medical electrical equipment— Medical electron accelerators Part 12: Functional performance characteristics

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Medical electrical equipment—Medical electron accelerators

Part 2: Periodic function performance testing

SECTION ONE — INTRODUCTION

The guidelines given in this report are recommendations both to manufacturers and to USERS. They provide guidance to manufacturers on the needs of radiotherapists in respect of the performance of ELECTRON ACCELERATORS and they provide guidance to USERS wishing to check the manufacturer's declared performance characteristics, to carry out acceptance tests and to check periodically the performance throughout the life of the equipment.

IEC Publication 601-1 (1977) is a general standard for the safety of medical electrical equipment*. It is supplemented by IEC Publication 601-2-1, a standard which lays down particular requirements for MEDICAL ELECTRON ACCELERATORS in the range of 1 MeV to 50 MeV, titled Section One: General; Section Two: Radiation safety for equipment; Section Three: Electrical and mechanical safety for equipment. In addition, IEC Publication 976 has been issued as a disclosure standard. It is a standard which standardizes methods of declaring the MEDICAL ELECTRON ACCELERATOR functional performance characteristics. It standardizes the type test conditions and type test methods to which manufacturers' declared values of functional performance relate.

A format for the presentation of functional performance values is contained in IEC Publication 976 as Appendix B. It is repeated herein as 2.1, with the addition of a set of suggested values which reflects the need for precision in RADIOTHERAPY and the knowledge of what is reliably achievable technically. A corresponding rationale for the suggested values is presented in 2.2.

In order to check whether each individual machine at the time of installation performs in a manner consistent with the set of functional performance values declared by the manufacturer based upon his type test data, it is customary to perform a series of acceptance tests at the USER's site before the machine is put into full medical use. Because of limitations of time and test equipment, this series of acceptance tests is usually less extensive than the type tests specified in the disclosure standard, IEC Publication 976.

3.1 contains a summary of suggested test methods for machine acceptance. These are consistent with the test methods of IEC Publication 976 but have been presented in a form which may be more suitable for use in hospitals. For reasons of economy and time, the USER may prefer to have a more limited but still standardized test performed at the time of installation of the equipment.

3.2 contains a set of suggested acceptance (commissioning) test conditions. It should be emphasized that these test conditions are presented only as examples and that a quite different set of test conditions may still be needed for the purpose of displaying the functional performance characteristics of the individual machine.

* The second edition has been published in 1988.

During the working life of the MEDICAL ELECTRON ACCELERATOR, periodic tests are usually conducted by the USER to check whether the functional performance of the machine is satisfactory. Because the available machine time is limited, a highly abbreviated set of test conditions is essential. Individual tests should not be repeated any more or less frequently than can be justified by experience with the particular machine or machine type. A set of suggested periodic test methods is presented in 4.1 and a list of suggested periodic tests during the working life of the MEDICAL ELECTRON ACCELERATOR and suggested intervals between such tests is presented in 4.2. The manufacturer may recommend different intervals or additional or different tests, depending on the special requirements of the MEDICAL ELECTRON ACCELERATOR in question.

SECTION TWO — GENERAL, TYPE TESTS

2.1 Format of Appendix B of the disclosure standard with suggested functional performance values

Introduction

The purpose of 2.1 is to provide a suggested format for the presentation of functional performance values corresponding to the standardized statements of functional performance in the disclosure standard, IEC Publication 976. USERS of MEDICAL ELECTRON ACCELERATORS may find this format useful in getting information from the manufacturer on the expected performance, in recording acceptance test values measured at the time of installation and in periodic testing of performance during the working life of the machine. Manufacturers may find it useful in declaring the functional performance values for their particular types of MEDICAL ELECTRON ACCELERATORS in response to IEC Publication 976. Although the manufacturer may use his own set of type test methods in developing functional performance data, he should make sure that the functional performance values which he declares would be met if the test methods of IEC Publication 976 were used. It is not suggested that a manufacturer should provide information to USERS from his type test in any greater detail than a simple declaration of these functional performance values.

As a result of extensive deliberations by Working Group 1 of IEC Sub-Committee 62C, a set of suggested values of functional performance was agreed upon with respect to the standardized statements of IEC Publication 976. These suggested values are shown in parentheses for each relevant clause. For Clauses 6 and 7, the suggested tolerance values are given only for NOMINAL ENERGIES in the range from 3 MeV to 50 MeV, since this range covers most of the practice with MEDICAL ELECTRON ACCELERATORS.

Tolerances are designated $\pm$ where they represent permissible deviations in more than one direction from a desired point or value. The $\pm$ designation is not used where the tolerance represents permissible deviation in any one direction between two points or values. The abbreviations "maxi" and "mini" are used for "maximum" and "minimum", respectively.

In addition to declaring functional performance values, for which this format is suitable, IEC Publication 976 also calls for the following other items to be provided in the ACCOMPANYING DOCUMENTS:

Clause	Item
3.6	Influencing quantities
6.1.3.1	Isodose charts for X-RADIATION, information to the USER
6.2.4.1	Isodose charts for ELECTRON RADIATION, information to the USER
7.1.5.1	X-RAY FIELDS with WEDGE FILTER, information to the USER

IEC Publication 601-2-1 also calls for certain information to be provided in the ACCOMPANYING DOCUMENTS.

FORMAT FOR PRESENTATION OF FUNCTIONAL PERFORMANCES VALUES

Manufacturer _____

MEDICAL ELECTRON ACCELERATOR Type Designation _____

Date _____ Location _____

Clause Abbreviation of Statement in Disclosure Standard

3.1 Available NOMINAL ENERGIES and ABSORBED DOSE RATES

X-RADIATION mode:

NOMINAL ENERGY	_____ MeV	_____	_____	_____ Gy/min, 10 cm × 10 cm RADIATION FIELD
NOMINAL ENERGY	_____ MeV	_____	_____	_____ Gy/min, 10 cm × 10 cm RADIATION FIELD
NOMINAL ENERGY	_____ MeV	_____	_____	_____ Gy/min, 10 cm × 10 cm RADIATION FIELD
NOMINAL ENERGY	_____ MeV	_____	_____	_____ Gy/min, maximum RADIATION FIELD
NOMINAL ENERGY	_____ MeV	_____	_____	_____ Gy/min, maximum RADIATION FIELD
NOMINAL ENERGY	_____ MeV	_____	_____	_____ Gy/min, maximum RADIATION FIELD

ELECTRON RADIATION mode:

NOMINAL ENERGY	_____ MeV	_____	_____ Gy/min*
NOMINAL ENERGY	_____ MeV	_____	_____ Gy/min*
NOMINAL ENERGY	_____ MeV	_____	_____ Gy/min*
NOMINAL ENERGY	_____ MeV	_____	_____ Gy/min*
NOMINAL ENERGY	_____ MeV	_____	_____ Gy/min*
NOMINAL ENERGY	_____ MeV	_____	_____ Gy/min*
NOMINAL ENERGY	_____ MeV	_____	_____ Gy/min*

* The same ABSORBED DOSE RATE applies for both 10 cm × 10 cm and maximum RADIATION FIELD in ELECTRON RADIATION mode.

Values
declared (suggested)

Abbreviation of Statement in Disclosure Standard

Clause

3.2 Available RADIATION FIELDS (at NORMAL TREATMENT DISTANCE)

X-RADIATION mode:

Minimum square _____ cm x _____ cm
Maximum square _____ cm x _____ cm (Fully flattened RADIATION FIELD, square corners)
Maximum with clipped corners _____ cm x _____ cm Diagonals _____ cm x _____ cm

ELECTRON RADIATION mode:

Minimum square _____ cm x _____ cm
Maximum square _____ cm x _____ cm
Other rectangular _____ cm x _____ cm, _____ cm x _____ cm, _____ cm, _____ cm, _____ cm, _____ cm, _____ cm, _____ cm

Adjustable RADIATION FIELD range

_____ cm x _____ cm to _____ cm x _____ cm

3.3

NORMAL TREATMENT DISTANCE

X-RADIATION mode:

ELECTRON RADIATION mode:

_____ cm
_____ cm

3.4

Available FILTERS

X-RAY FIELD FLATTENING FILTERS:

Designation	NOMINAL ENERGY	Maximum square RADIATION FIELD (square corners)
_____	_____ MeV	_____ cm x _____ cm
_____	_____ MeV	_____ cm x _____ cm
_____	_____ MeV	_____ cm x _____ cm

ELECTRON FIELD-FLATTENING FILTERS:

Designation	NOMINAL ENERGY range	Maximum square RADIATION FIELD
_____	_____ MeV to _____ MeV	_____ cm x _____ cm
_____	_____ MeV to _____ MeV	_____ cm x _____ cm

Clause

Abbreviation of Statement in Disclosure Standard

_____ MeV to _____ MeV _____ cm x _____ cm
 _____ MeV to _____ MeV _____ cm x _____ cm

Values

declared (suggested)

X-RAY WEDGE FILTERS:

Designation	NOMINAL ENERGY	Maximum RADIATION FIELD	WEDGE FILTER ANGLE	Related isodose value	WEDGE FILTER FACTOR
_____	_____ MeV	_____ cm x _____ cm	_____ °	_____ %	_____ %
_____	_____ MeV	_____ cm x _____ cm	_____ °	_____ %	_____ %
_____	_____ MeV	_____ cm x _____ cm	_____ °	_____ %	_____ %
_____	_____ MeV	_____ cm x _____ cm	_____ °	_____ %	_____ %
_____	_____ MeV	_____ cm x _____ cm	_____ °	_____ %	_____ %
_____	_____ MeV	_____ cm x _____ cm	_____ °	_____ %	_____ %

3.5

Availability

Time necessary to reach the READY STATE from the STAND-BY STATE...

_____ min

3.6

Influencing quantities

Environmental conditions:

Ambient temperature

Relative humidity

Atmospheric pressure

Maximum period of continuous operation:

(possibly influencing the functional performance characteristics)

_____ °C to _____ °C

_____ % to _____ %

_____ Pa to _____ Pa

_____ h

5

DOSE MONITORING SYSTEM

Range of ABSORBED DOSE over which the standard is met...

Range of ABSORBED DOSE RATES over which the standard is met...

_____ to _____ Gy

_____ to _____ Gy/min

5.1

*Reproducibility*Maximum coefficients of variation of ratio *R* of

a) the number of DOSE MONITOR UNITS and ABSORBED DOSE for X-RADIATION

_____ % (0,5)

Values
declared (suggested)
_____% (0,5)

Clause Abbreviation of Statement in Disclosure Standard
b) the number of DOSE MONITOR UNITS and ABSORBED DOSE for ELECTRON RADIATION

The average of a number of determinations of $\bar{R}$ is defined as $\bar{R}$ in the following.

5.2 Proportionality

Maximum deviation of the measured ABSORBED DOSE from the value given by multiplying the measured value U of DOSE MONITOR UNITS by the proportionality factor S over the following ranges of ABSORBED DOSE and ABSORBED DOSE RATES:

X-RADIATION NOMINAL ENERGY	_____ MeV	
of _____ Gy to _____ Gy at _____ Gy/min to _____ Gy/min...		
Declared deviation $\pm$ _____ $\pm$ _____ %		(2)
ELECTRON RADIATION NOMINAL ENERGY	_____ MeV	
of _____ Gy to _____ Gy at _____ Gy/min to _____ Gy/min...		
Declared deviation $\pm$ _____ $\pm$ _____ %		(2)

5.3 Dependence on angular positions

Maximum difference between the maximum and minimum values of $\bar{R}$ over the full angular ranges of the GANTRY and BEAM LIMITING SYSTEM...

X-RADIATION		(3)
Declared maximum difference...	_____ %	
ELECTRON RADIATION		(3)
Declared maximum difference...	_____ %	

5.4 Dependence on GANTRY rotation

As the GANTRY moves, the maximum deviation of $\bar{R}$ from the arithmetic mean of the maximum and minimum values of $\bar{R}$ determined in Sub-clause 5.3

X-RADIATION		(2)
Declared maximum deviation...	_____ %	

Clause	Abbreviation of Statement in Disclosure Standard	Values declared (suggested)
	ELECTRON RADIATION	
	Declared maximum deviation ...	_____ % (2)
5.5	<i>Dependence on the shape of the RADIATION FIELD</i>	
	Maximum difference of $\bar{R}$ between 5 cm × 20 cm and 20 cm × 5 cm fields (or maximum if less than 20 cm)...	
	X-RADIATION	
	Declared maximum difference ...	_____ %
	ELECTRON RADIATION	
	Declared maximum difference ...	_____ %
5.6	<i>Stability of calibration</i>	
5.6.1	<i>Stability after high ABSORBED DOSE delivered</i>	
	X-RADIATION	
	Maximum difference of $\bar{R}$ between beginning and end of ...	
	a) IRRADIATION of 100 Gy at NORMAL TREATMENT DISTANCE...	_____ % (2)
	b) or a period of 30 minutes at maximum nominal ABSORBED DOSE RATE, whichever results in the shorter period...	_____ % (2)
	ELECTRON RADIATION	
	Maximum difference of $\bar{R}$ between beginning and end of ...	
	a) IRRADIATION of 100 Gy at NORMAL TREATMENT DISTANCE...	_____ % (2)
	b) or a period of 30 minutes at maximum nominal ABSORBED DOSE RATE, whichever results in the shorter period...	_____ % (2)
5.6.2	<i>Stability throughout the day</i>	
	Maximum difference of $\bar{R}$ between beginning and end of 8 hours of successive 4 Gy IRRADIATIONS followed by 10 minutes without IRRADIATION...	
	X-RADIATION	_____ % (2)
	ELECTRON RADIATION	_____ % (2)

Clause	Abbreviation of Statement in Disclosure Standard	Values declared (suggested)
5.6.3	Stability throughout the week Maximum difference between the highest and lowest values of $\bar{R}$ measured immediately following switch-on on 5 consecutive days... X-RADIATION ELECTRON RADIATION	(2) (2)
5.7	Stability in MOVING BEAM RADIOTHERAPY X-RADIATION Where GANTRY angular range TERMINATES IRRADIATION the maximum difference between the reading of DOSE MONITOR UNITS and the value calculated by multiplying preset DOSE MONITOR UNITS per unit angle by preset angular range of GANTRY rotation... Where the DOSE MONITOR SYSTEM TERMINATES IRRADIATION the maximum difference in degrees between the GANTRY rotation angular range traversed and the angular range calculated by dividing preset DOSE MONITOR UNITS by the value of preset DOSE MONITOR UNITS per unit angle... ELECTRON RADIATION Where GANTRY angular range TERMINATES IRRADIATION the maximum difference between the reading of DOSE MONITOR UNITS and the value calculated by multiplying preset DOSE MONITOR UNITS per unit angle by preset angular range of GANTRY rotation... Where the DOSE MONITOR SYSTEM TERMINATES IRRADIATION, the maximum difference in degrees between the GANTRY rotation angular range traversed and the angular range calculated by dividing preset DOSE MONITOR UNITS by the value of preset DOSE MONITOR UNITS per unit angle...	(5) (3) (5) (3)
6	Depth ABSORBED DOSE characteristics	
6.1	X-RADIATION NOMINAL X-RAY ENERGY (of electrons striking the X-ray TARGET)... DEPTH OF DOSE MAXIMUM for 10 cm × 10 cm RADIATION FIELD... DEPTH OF DOSE MAXIMUM for maximum RADIATION FIELD... PENETRATIVE QUALITY (10 cm × 10 cm RADIATION FIELD)	MeV cm cm cm

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Clause	Abbreviation of Statement in Disclosure Standard	Values declared (suggested)
6.2.2	Stability of PENETRATIVE QUALITY Maximum variation of PENETRATIVE QUALITY of ELECTRON RADIATION with angular position of the GANTRY and usable range of nominal ABSORBED DOSE RATES...	mm (2) % (1)
7	Uniformity of RADIATION FIELDS (see Figure 4 for flattened area)	
7.1	X-RADIATION	
7.1.1	Flatness of square X-RAY FIELDS NOMINAL ENERGY Maximum ratio of maximum ABSORBED DOSE anywhere in the RADIATION FIELD to minimum ABSORBED DOSE in flattened area of RADIATION FIELD both at STANDARD MEASUREMENT DEPTH... 5 cm × 5 cm to 30 cm × 30 cm... greater than 30 cm × 30 cm to maximum square...	MeV % (106) % (110)
7.1.2	Deviation of dose distribution of square X-RAY FIELDS with angular positions Maximum variation in the ratio of ABSORBED DOSE at a point in the flattened area to ABSORBED DOSE on the RADIATION BEAM AXIS both at STANDARD MEASUREMENT DEPTH for all angular positions of the GANTRY and BEAM LIMITING SYSTEM...	 % (3) % (4)
7.1.3	Symmetry of square X-RAY FIELDS Maximum ratio of ABSORBED DOSES at points symmetrically displaced from the AXIS OF THE BEAM and within the flattened area at STANDARD MEASUREMENT DEPTH...	% (103)
7.1.4	Maximum ratio of ABSORBED DOSE NOMINAL ENERGY Maximum ratio of ABSORBED DOSE in the RADIATION FIELD to ABSORBED DOSE on the RADIATION BEAM AXIS in the plane at the DEPTH OF DOSE MAXIMUM... 5 cm × 5 cm to 30 cm × 30 cm... greater than 30 cm × 30 cm to maximum square...	MeV % (107) % (109)

Clause	Abbreviation of Statement in Disclosure Standard	Values	
		declared	(suggested)
7.1.5	X-RAY FIELDS WITH WEDGE FILTERS (see Sub-clause 3.4)		
	NOMINAL ENERGY	_____	MeV
	Maximum deviation of WEDGE FILTER FACTOR...	_____	% (2)
	Maximum deviation of WEDGE FILTER ANGLE...	_____	deg (2)
7.2	ELECTRON RADIATION		
7.2.1	Flatness of ELECTRON FIELDS		
	Maximum distance between 80% isodose contours and edge of GEOMETRICAL FIELD projection at base depth...		
	along major axes...	_____	mm (15)
	Maximum distance between 90% isodose contours and edge of GEOMETRICAL FIELD projection at STANDARD MEASUREMENT DEPTH...		
	along major axes...	_____	mm (10)
	along bisectors of corners...	_____	mm (20)
	Ratio of the highest ABSORBED DOSE anywhere in the RADIATION FIELD at STANDARD MEASUREMENT DEPTH to the ABSORBED DOSE on the RADIATION BEAM AXIS at the DEPTH OF DOSE MAXIMUM...	_____	%
7.2.2	Deviation of dose distribution of ELECTRON FIELDS with angular positions		
	Maximum variation in the ratio of ABSORBED DOSE at any point in the flattened area confined by the line 1 cm inside the 90% isodose contour at STANDARD MEASUREMENT DEPTH to the ABSORBED DOSE on the RADIATION BEAM AXIS at the same depth for all angular positions of the GANTRY and BEAM LIMITING SYSTEM...	_____	% (3)
7.2.3	Symmetry of ELECTRON FIELDS		
	Maximum ratio of ABSORBED DOSES at points symmetrically displaced from the RADIATION BEAM AXIS and more than 1 cm inside the 90% isodose contour at STANDARD MEASUREMENT DEPTH...	_____	% (105)

Clause	Abbreviation of Statement in Disclosure Standard	Values declared _____	Values (suggested) _____
7.2.4	Maximum ratio of ABSORBED DOSE Maximum ratio of ABSORBED DOSE in the RADIATION FIELD at 0,5 mm depth to ABSORBED DOSE on the RADIATION BEAM AXIS at DEPTH OF DOSE MAXIMUM ...	%	(109)
7.3	Penumbra of RADIATION FIELDS Maximum distance along major axes between points of 80% and 20% of the ABSORBED DOSE on the RADIATION BEAM AXIS, all measurements being in the plane at STANDARD MEASUREMENT DEPTH	5 cm × 5 cm _____ _____ Maximum square field	10 cm × 10 cm _____ _____ mm mm
8	Indication of RADIATION FIELDS		
8.1	X-RADIATION		
8.1.1	Numerical field-indication Maximum difference between the numerical RADIATION FIELD-indication and the dimensions of the RADIATION FIELD at NORMAL TREATMENT DISTANCE... 5 cm × 5 cm to 20 cm × 20 cm ... Greater than 20 cm × 20 cm to maximum square...	mm _____ % _____ mm _____ % _____ (3) (1,5) (5) (1,5)	
8.1.2	LIGHT FIELD-INDICATOR Maximum distance along the major axes between the LIGHT FIELD edge and the RADIATION FIELD edge at NORMAL TREATMENT DISTANCE in mm or percent of dimensions of the RADIATION FIELD... 5 cm × 5 cm to 20 cm × 20 cm ... Greater than 20 cm × 20 cm to maximum square...	mm _____ % _____ mm _____ % _____ (2) (1) (3) (1)	