IEC/TR 60977

Edition 2.0 2008-07

TECHNICAL REPORT

RAPPORT TECHNIQUE

Medical electrical equipment – Medical electron accelerators – Guidelines for functional performance characteristics

Appareils électromédicaux – Accélérateurs médicaux d'électrons – Lignes directrices pour les caractéristiques des performances fonctionnelles

IEC Central Office
3, rue de Varembé
CH-1211 Geneva 20
Switzerland
Email: inmail@iec.ch
Web: www.iec.ch

About the IEC

The International Electrotechnical Commission (IEC) is the leading global organization that prepares and publishes International Standards for all electrical, electronic and related technologies.

About IEC publications

The technical content of IEC publications is kept under constant review by the IEC. Please make sure that you have the latest edition, a corrigenda or an amendment might have been published.

- Catalogue of IEC publications: www.iec.ch/searchpub

The IEC on-line Catalogue enables you to search by a variety of criteria (reference number, text, technical committee,…). It also gives information on projects, withdrawn and replaced publications.

- IEC Just Published: www.iec.ch/online_news/justpub

Stay up to date on all new IEC publications. Just Published details twice a month all new publications released. Available on-line and also by email.

- Electropedia: www.electropedia.org

The world's leading online dictionary of electronic and electrical terms containing more than 20 000 terms and definitions in English and French, with equivalent terms in additional languages. Also known as the International Electrotechnical Vocabulary online.

- Customer Service Centre: www.iec.ch/webstore/custserv

If you wish to give us your feedback on this publication or need further assistance, please visit the Customer Service Centre FAQ or contact us:
Email: csc@iec.ch
Tel.: +41 22 919 02 11
Fax: +41 22 919 03 00

A propos de la CEI

La Commission Electrotechnique Internationale (CEI) est la première organisation mondiale qui élabore et publie des normes internationales pour tout ce qui a trait à l'électricité, à l'électronique et aux technologies apparentées.

A propos des publications CEI

Le contenu technique des publications de la CEI est constamment revu. Veuillez vous assurer que vous possédez l'édition la plus récente, un corrigendum ou amendement peut avoir été publié.

- Catalogue des publications de la CEI: www.iec.ch/searchpub/cur_fut-f.htm

Le Catalogue en-ligne de la CEI vous permet d'effectuer des recherches en utilisant différents critères (numéro de référence, texte, comité d'études,…). Il donne aussi des informations sur les projets et les publications retirées ou remplacées.

- Just Published CEI: www.iec.ch/online_news/justpub

Restez informé sur les nouvelles publications de la CEI. Just Published détaille deux fois par mois les nouvelles publications parues. Disponible en-ligne et aussi par email.

- Electropedia: www.electropedia.org

Le premier dictionnaire en ligne au monde de termes électroniques et électriques. Il contient plus de 20 000 termes et définitions en anglais et en français, ainsi que les termes équivalents dans les langues additionnelles. Egalement appelé Vocabulaire Electrotechnique International en ligne.

- Service Clients: www.iec.ch/webstore/custserv/custserv_entry-f.htm

Si vous désirez nous donner des commentaires sur cette publication ou si vous avez des questions, visitez le FAQ du Service clients ou contactez-nous:
Email: csc@iec.ch
Tél.: +41 22 919 02 11
Fax: +41 22 919 03 00

IEC/TR 60977

Edition 2.0 2008-07

TECHNICAL REPORT

RAPPORT TECHNIQUE

Medical electrical equipment – Medical electron accelerators – Guidelines for functional performance characteristics

Appareils électromédicaux – Accélérateurs médicaux d'électrons – Lignes directrices pour les caractéristiques des performances fonctionnelles

INTERNATIONAL ELECTROTECHNICAL COMMISSION

COMMISSION ELECTROTECHNIQUE INTERNATIONALE

PRICE CODE
CODE PRIX XB

ICS 11.040.50 ISBN 2-8318-9893-5

CONTENTS

INTERNATIONAL ELECTROTECHNICAL COMMISSION

MEDICAL ELECTRICAL EQUIPMENT – MEDICAL ELECTRON ACCELERATORS – GUIDELINES FOR FUNCTIONAL PERFORMANCE CHARACTERISTICS

FOREWORD

1) The International Electrotechnical Commission (IEC) is a worldwide organization for standardization comprising all national electrotechnical committees (IEC National Committees). The object of IEC is to promote international co-operation on all questions concerning standardization in the electrical and electronic fields. To this end and in addition to other activities, IEC publishes International Standards, Technical Specifications, Technical Reports, Publicly Available Specifications (PAS) and Guides (hereafter referred to as "IEC Publication(s)"). Their preparation is entrusted to technical committees; any IEC National Committee interested in the subject dealt with may participate in this preparatory work. International, governmental and non-governmental organizations liaising with the IEC also participate in this preparation. IEC collaborates closely with the International Organization for Standardization (ISO) in accordance with conditions determined by agreement between the two organizations.
2) The formal decisions or agreements of IEC on technical matters express, as nearly as possible, an international consensus of opinion on the relevant subjects since each technical committee has representation from all interested IEC National Committees.
3) IEC Publications have the form of recommendations for international use and are accepted by IEC National Committees in that sense. While all reasonable efforts are made to ensure that the technical content of IEC Publications is accurate, IEC cannot be held responsible for the way in which they are used or for any misinterpretation by any end user.
4) In order to promote international uniformity, IEC National Committees undertake to apply IEC Publications transparently to the maximum extent possible in their national and regional publications. Any divergence between any IEC Publication and the corresponding national or regional publication shall be clearly indicated in the latter.
5) IEC provides no marking procedure to indicate its approval and cannot be rendered responsible for any equipment declared to be in conformity with an IEC Publication.
6) All users should ensure that they have the latest edition of this publication.
7) No liability shall attach to IEC or its directors, employees, servants or agents including individual experts and members of its technical committees and IEC National Committees for any personal injury, property damage or other damage of any nature whatsoever, whether direct or indirect, or for costs (including legal fees) and expenses arising out of the publication, use of, or reliance upon, this IEC Publication or any other IEC Publications.
8) Attention is drawn to the Normative references cited in this publication. Use of the referenced publications is indispensable for the correct application of this publication.
9) Attention is drawn to the possibility that some of the elements of this IEC Publication may be the subject of patent rights. IEC shall not be held responsible for identifying any or all such patent rights.

The main task of IEC technical committees is to prepare International Standards. However, a technical committee may propose the publication of a technical report when it has collected data of a different kind from that which is normally published as an International Standard, for example "state of the art".

IEC 60977, which is a technical report, has been prepared by subcommittee 62C: Equipment for radiotherapy, nuclear medicine and radiation dosimetry, of IEC technical committee 62: Electrical equipment in medical practice.

This second edition cancels and replaces the first edition published in 1989 and its Amendment 1 (2000). It constitutes a technical revision.

This second edition likewise follows on the issue of a second edition to the disclosure standard IEC 60976 in 2007. It includes the addition of performance guidelines relating to several relatively new technologies introduced within the last few years, including dynamic beam delivery techniques, such as moving beam radiotherapy, INTENSITY MODULATED RADIATION THERAPY (IMRT), IMAGE GUIDED RADIOTHERAPY (IGRT), and PROGRAMMABLE WEDGE

FIELDS (PWF). Also included are STEREOTACTIC RADIOTHERAPY (SRT)/STEREOTACTIC RADIOSURGERY (SRS) and the use of certain ELECTRONIC IMAGING DEVICES (EIDs).

The text of this technical report is based on the following documents:

Enquiry draft	Report on voting
62C/424/DTR	62C/439/RVC

Full information on the voting for the approval of this technical report can be found in the report on voting indicated in the above table.

This publication has been drafted in accordance with the ISO/IEC Directives, Part 2.

The committee has decided that the contents of this publication will remain unchanged until the maintenance result date indicated on the IEC web site under "http://webstore.iec.ch" in the data related to the specific publication. At this date, the publication will be

- reconfirmed,
- withdrawn,
- replaced by a revised edition, or
- amended.

INTRODUCTION

The guidelines given in this report are recommendations both to manufacturers and to USERS. They provide guidance to MANUFACTURERS on the needs of USERS 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 60601-1 [1)] is a general standard for the safety of medical electrical equipment. It is supplemented by IEC 60601-2-1, a standard which lays down particular requirements for MEDICAL ELECTRON ACCELERATORS in the range of 1 MeV to 50 MeV. In addition, IEC 60976 second edition has been issued as a disclosure standard. It 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 60976. It is repeated herein as 3.1, 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 3.2.

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 60976.

Subclause 4.2 contains a summary of suggested test methods for machine acceptance. These are consistent with the test methods of IEC 60976 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.

Subclause 4.3 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.

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 5.2 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 5.3. The manufacturer may recommend different intervals or additional or different tests, depending on the special requirements of the MEDICAL ELECTRON ACCELERATOR in question.

Since the issue in 1989 of IEC 60977, a first amendment was published in 2000 to address the introduction and increasing use of multi-element BEAM LIMITING DEVICES (multi-element BLDS) for determining the shape of the RADIATION FIELD, with or without the use of back-up BLDS. This publication followed from the issue of the corresponding amendment to the disclosure standard itself, IEC 60976:1989, in 2000. The performance issues addressed in these first amendments were mainly associated with the applications of multi-element BLDs to

---

1) See Bibliography.

static RADIATION FIELDS. This second edition likewise follows on the issue of a second edition to the disclosure standard IEC 60976 in 2007. It includes the addition of performance guidelines relating to several relatively new technologies introduced within the last few years, including dynamic beam delivery techniques, such as moving beam radiotherapy, INTENSITY MODULATED RADIATION THERAPY (IMRT), IMAGE GUIDED RADIOTHERAPY (IGRT), and PROGRAMMABLE WEDGE FIELDS (PWF). Also included are STEREOTACTIC RADIOTHERAPY (SRT)/STEREOTACTIC RADIOSURGERY (SRS) and the use of certain ELECTRONIC IMAGING DEVICES (EIDs).

In recognition of the diversity of equipment produced by manufacturers in each of these technologies, this second edition, as with the first, has specified performance guidelines that are as basic and generic as possible.

MEDICAL ELECTRICAL EQUIPMENT – MEDICAL ELECTRON ACCELERATORS – GUIDELINES FOR FUNCTIONAL PERFORMANCE CHARACTERISTICS

1 Scope

This technical report applies to medical ELECTRON ACCELERATORS when used, for therapy purposes, in human medical practice.

This technical report applies to medical 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.

2 Normative references

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

IEC 60601-2-1:1998, *Medical electrical equipment – Part 2-1: Particular requirements for the safety of electron accelerators in the range 1 MeV to 50 MeV*
Amendment 1 (2002)

IEC 60976:2007, *Medical electrical equipment – Medical electron accelerators – Functional performance characteristics*

3 General, type tests

3.1 Format of Annex A of the disclosure standard with suggested functional performance values

The purpose of this subclause 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 60976:2007. 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 60976. 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 60976 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 subcommittee 62C, a set of suggested values of functional performance was agreed upon with respect to the standardized statements of IEC 60976:2007. These suggested values are shown in parentheses for each relevant clause. For Clauses 7 and 8, 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 "+/-" where they represent permissible deviations in more than one direction from a desired point or value. The "+/-" 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.

Where a functional performance value is required for a square RADIATION FIELD of specified dimensions, and the equipment is unable to provide these dimensions, then the required performance information may be provided for a square RADIATION FIELD nearest in size to that prescribed.

FORMAT FOR PRESENTATION OF FUNCTIONAL PERFORMANCES VALUES

Manufacturer _____

MEDICAL ELECTRON ACCELERATOR type designation _____

Date _____ Location _____

Clause	Abbreviation of statement in disclosure standard
5.2	**Available NOMINAL ENERGIES and ABSORBED DOSE RATES**

X-radiation mode*:

NOMINAL ENERGY ____ MV ____ ____ ____ ____ ____ Gy/min, 10 cm × 10 cm RADIATION FIELD

NOMINAL ENERGY ____ MV ____ ____ ____ ____ ____ Gy/min, 10 cm × 10 cm RADIATION FIELD

NOMINAL ENERGY ____ MV ____ ____ ____ ____ ____ Gy/min, 10 cm × 10 cm RADIATION FIELD

NOMINAL ENERGY ____ MV ____ ____ ____ ____ ____ Gy/min, maximum RADIATION FIELD

NOMINAL ENERGY ____ MV ____ ____ ____ ____ ____ Gy/min, maximum RADIATION FIELD

NOMINAL ENERGY ____ MV ____ ____ ____ ____ ____ Gy/min, maximum RADIATION FIELD

* Where SRT/SRS modes are available, the following information shall also be provided for the applicable NOMINAL ENERGIES and X-RADIATION FIELDS

Clause	Abbreviation of statement in disclosure standard	Values declared (suggested)
	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.

Clause	Abbreviation of statement in disclosure standard	Values declared (suggested)
5.3	**Available RADIATION FIELDS (at NORMAL TREATMENT DISTANCE)**	
	X-RADIATION mode:	
	Minimum square ______ cm × ______ cm	
	Maximum square ______ cm × ______ cm (Fully flattened RADIATION FIELD, square corners)	
	Maximum with clipped comers ______ cm × ______ cm Diagonals ______ cm × ______ cm	
	If SRT/SRS is provided, available RADIATION FIELD sizes shall be given	
	ELECTRON RADIATION mode:	
	Minimum square ______ cm × ______ cm	
	Maximum square ______ cm × ______ cm	
	Other rectangular ______ cm × ______ cm, ______ cm × ______ cm,… ______ cm × ______ cm,	
	______ cm × ______ cm, ______ cm × ______ cm,… ______ cm × ______ cm,	
	______ cm × ______ cm,	
	Adjustable RADIATION FIELD range ______ cm × ______ cm to ______ cm × ______ cm	

Clause	Abbreviation of statement in disclosure standard	Values declared (suggested)

Unless otherwise stated, all functional performance values, related to the selection of specific RADIATION FIELD sizes, are to be the result of selection of RADIATION FIELD size by the adjustable BLD system (jaws). Unless otherwise stated, all RADIATION FIELDS are symmetrically placed about the REFERENCE AXIS.

For a multi-element BLD, the following information shall be provided.

X-RADIATION mode:

Adjustable RADIATION FIELD range:

square corners from:____ cm × ____ cm to: ____ cm × ____ cm

maximum with clipped corners ____ cm × ____ cm diagonals: ____ cm × ____ cm

Maximum offset of centre of RADIATION FIELD in relation to the REFERENCE AXIS: ____ mm

ELECTRON RADIATION mode (if applicable):

Adjustable RADIATION FIELD range:

square corners from:____ cm × ____ cm to: ____ cm × ____ cm

maximum with clipped corners ____ cm × ____ cm diagonals: ____ cm × ____ cm

Maximum offset of centre of RADIATION FIELD in relation to the REFERENCE AXIS: ____ mm

5.4 NORMAL TREATMENT DISTANCE

X-RADIATION mode: _____ cm

ELECTRON RADIATION mode: _____ cm

5.5 Available wedge X-ray fields:

Designation	NOMINAL ENERGY	Maximum RADIATION FIELD	WEDGE ANGLE	Related isodose value	WEDGE FILTER FACTOR
_____	_____ MV	____ cm × ____ cm	_____ °	_____ %	_____
_____	_____ MV	____ cm × ____ cm	_____ °	_____ %	_____
_____	_____ MV	____ cm × ____ cm	_____ °	_____ %	_____
_____	_____ MV	____ cm × ____ cm	_____ °	_____ %	_____
_____	_____ MV	____ cm × ____ cm	_____ °	_____ %	_____
_____	_____ MV	____ cm × ____ cm	_____ °	_____ %	_____

Clause	Abbreviation of statement in disclosure standard	Values declared (suggested)
5.6	**Available FLATTENING FILTERS**	
	X-RAY FIELD FLATTENING FILTERS:	
	Designation — NOMINAL ENERGY	Maximum square RADIATION FIELD (square corners)
	———— ——————— MV	——— cm × ——— cm
	———— ——————— MV	——— cm × ——— cm
	———— ——————— MV	——— cm × ——— cm
	ELECTRON FIELD-FLATTENING FILTERS:	
	Designation — NOMINAL ENERGY	Maximum square RADIATION FIELD (square corners)
	———— ——— MeV to ——— MeV	——— cm × ——— cm
	———— ——— MeV to ——— MeV	——— cm × ——— cm
	———— ——— MeV to ——— MeV	——— cm × ——— cm
	———— ——— MeV to ——— MeV	——— cm × ——— cm
5.7	**Availability**	
	Time necessary to reach the READY STATE from the STAND-BY STATE	——— min
5.8	**Influencing quantities**	
	Environmental conditions:	
	Ambient temperature	——— °C to ——— °C
	Relative humidity	——— % to ——— %
	Atmospheric pressure	——— Pa to ——— Pa
	Maximum period of continuous operation: (possibly influencing the functional performance characteristics)	———min
5.11	**Dimensions, clearances, within the RADIATION HEAD, and in the region RADIATION HEAD to ISOCENTRE, of BEAM LIMITING DEVICES**	
	Equipment layout drawing	

Clause	Abbreviation of statement in disclosure standard	Values declared (suggested)
5.12	**IMRT**	
	Smallest number of DOSE MONITOR UNITS	_____
	Largest number of DOSE MONITOR UNITS	_____
7	**DOSE MONITORING SYSTEM**	
	Range of ABSORBED DOSE over which the standard is met...	_____ to _____ Gy
	Range of ABSORBED DOSE RATES over which the standard is met...	_____ to _____ Gy/min
7.2	**Reproducibility**	
	Maximum coefficients of variation of ratio *R* of	
	a) the number of DOSE MONITOR UNITS and ABSORBED DOSE for X-RADIATION	_____ % (0,5)
	b) the number of DOSE MONITOR UNITS and ABSORBED DOSE for ELECTRON RADIATION	_____ % (0,5)
7.3	**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 _____ _____ _____ MV	
	of _____ Gy to _____ Gy at _____ Gy/min to _____ Gy/min...	
	Declared deviation ± _____ ± _____ ± _____ % (2)	
	ELECTRON RADIATION NOMINAL ENERGY _____ _____ _____ _____ _____ _____ _____ MeV	
	of _____ Gy to _____ Gy at _____ Gy/min to _____ Gy/min...	
	Declared deviation ± _____ ± _____ ± _____ ± _____ ± _____ ± _____ ± _____ % (2)	
7.4	**Dependence on angular positions**	
	Maximum difference between the maximum and minimum values of $\overline{R}$ over the full angular ranges of the GANTRY and BEAM LIMITING SYSTEM...	