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INTERNATIONAL STANDARD

colour inside

Medical electrical equipment – Dosimetric instruments used for non-invasive measurement of X-ray tube voltage in diagnostic radiology

INTERNATIONAL
ELECTROTECHNICAL
COMMISSION

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

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MEDICAL ELECTRICAL EQUIPMENT – DOSIMETRIC INSTRUMENTS USED FOR NON-INVASIVE MEASUREMENT OF X-RAY TUBE VOLTAGE IN DIAGNOSTIC RADIOLOGY

FOREWORD

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IEC 61676 has been prepared by subcommittee 62C: Equipment for radiotherapy, nuclear medicine and radiation dosimetry, of IEC technical committee 62: Medical equipment, software, and systems. It is an International Standard.

This second edition of IEC 61676 cancels and replaces first edition published in 2002, Amendment 1:2008. This edition constitutes a technical revision.

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Draft	Report on voting
62C/830/CDV	62C/866/RVC

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

The language used for the development of this International Standard is English.

This document was drafted in accordance with ISO/IEC Directives, Part 2, and developed in accordance with ISO/IEC Directives, Part 1 and ISO/IEC Directives, IEC Supplement, available at www.iec.ch/members_experts/refdocs. The main document types developed by IEC are described in greater detail at www.iec.ch/standardsdev/publications.

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– requirements, compliance with which can be tested, and definitions: in roman type;
– notes, explanations, advice, general statements and exceptions: in small roman type;
– *test specifications: in italic type*;
– TERMS USED THROUGHOUT THIS DOCUMENT THAT HAVE BEEN DEFINED IN CLAUSE 3 OR IN IEC 60601-1 AND ITS COLLATERAL STANDARDS: IN SMALL CAPITALS.

The committee has decided that the contents of this document will remain unchanged until the stability date indicated on the IEC website under webstore.iec.ch in the data related to the specific document. At this date, the document will be

- reconfirmed,
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NOTE The committee knows this second edition of the document does still not address all problems associated with non-invasive high voltage measurements. For mammography only molybdenum filtration is considered in conjunction with a molybdenum anode although in addition tungsten and rhodium anodes with other filtrations are in use like rhodium, aluminium, copper, silver or titanium. At the time when this document was drafted there were not enough data available in the literature to define realistic limits of variation for these types of INFLUENCE QUANTITIES. On the other hand, the committee was informed that several international projects were started to examine the general behaviour of non-invasive X-ray multimeters of the main MANUFACTURERS. Results from these studies were to be expected within about 5 years. Therefore, the committee decided to set a short stability time for the second edition and update the document as soon as the results from these new examinations will be available.

The contents of the corrigendum 1 (2024-01) have been included in this copy.

INTRODUCTION

The result of a measurement of the X-RAY TUBE VOLTAGE by means of invasive or non-invasive instruments is normally expressed in the form of one single number for the value of the tube voltage, irrespective of whether the tube voltage is constant potential or shows a time dependent waveform. Non-invasive instruments for the measurement of the X-RAY TUBE VOLTAGE on the market usually indicate the "MEAN PEAK VOLTAGE". But the quantity "MEAN PEAK VOLTAGE" is not unambiguously defined and ~~may~~ can be any mean of all voltage peaks. It is impossible to establish test procedures for the performance requirements of non-invasive instruments for the measurement of the X-RAY TUBE VOLTAGE without the definition of the quantity under consideration. Therefore, this document is based on a quantity ~~recently proposed in the literature[1] to be~~ called "PRACTICAL PEAK VOLTAGE". The PRACTICAL PEAK VOLTAGE is unambiguously defined and applicable to any waveform. This quantity is related to the spectral distribution of the emitted X-RADIATION and the image properties. X-RAY GENERATORS operating at the same value of the PRACTICAL PEAK VOLTAGE produce the same low-level contrast in the RADIOGRAMS, even when the waveforms of the tube voltages are different. Detailed information on this concept is provided in Annex B. An example for the calculation of the PRACTICAL PEAK VOLTAGE in the case of a "falling load" waveform is also given in Annex B.

~~As a result of introducing a new quantity, the problem arises that this standard has been written for instruments which were not explicitly designed for the measurement of the PRACTICAL PEAK VOLTAGE. However, from preliminary results of a trial type test of a non-invasive instrument currently on the market, it can be expected that future instruments and most instruments on the market will be able to fulfil the requirements stated in this standard without insurmountable difficulties. For the most critical requirements on voltage waveform and frequency dependence of the RESPONSE, it turned out from these investigations that it is even easier to comply with the standard by using the PRACTICAL PEAK VOLTAGE as the measurement quantity.~~

The CALIBRATION and adjustment of the X-RAY TUBE VOLTAGE of an X-RAY GENERATOR is generally performed by the MANUFACTURER using a direct INVASIVE MEASUREMENT. Instruments utilising NON-INVASIVE MEASUREMENTS can also be used to check the CALIBRATION or to adjust the X-RAY TUBE VOLTAGE. These instruments are ~~required~~ used to have uncertainties of the voltage measurement comparable with the INVASIVE MEASUREMENT. One of the most important parameters of diagnostic X-RAY EQUIPMENT is the voltage applied to the X-RAY TUBE, because both the image quality in diagnostic radiology and the DOSE received by the PATIENT undergoing radiological examinations are dependent on the X-RAY TUBE VOLTAGE. An overall uncertainty below ±5 % is ~~required~~ applicable, and this value serves as a guide for the LIMITS OF VARIATION for the effects of INFLUENCE QUANTITIES.

~~[1] See annex B.~~

MEDICAL ELECTRICAL EQUIPMENT – DOSIMETRIC INSTRUMENTS USED FOR NON-INVASIVE MEASUREMENT OF X-RAY TUBE VOLTAGE IN DIAGNOSTIC RADIOLOGY

1 Scope ~~and object~~

This document specifies the performance requirements of instruments as used in the NON-INVASIVE MEASUREMENT of X-RAY TUBE VOLTAGE up to 150 kV and the relevant compliance tests. This document also describes the method for CALIBRATION and gives guidance for estimating the uncertainty in measurements performed under conditions different from those during CALIBRATION.

Applications for such measurement are found in diagnostic RADIOLOGY including mammography, COMPUTED TOMOGRAPHY (CT), dental radiology and RADIOSCOPY. This document is not concerned with the safety aspect of such instruments. The requirements for electrical safety applying to them are contained in IEC 61010-1.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements 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 60417, *Graphical symbols for use on equipment*, available at http://www.graphical-symbols.info/equipment

IEC 60601-1:2005, *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance*
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IEC TR 60788:~~1984~~2004, ~~*Medical radiology – Terminology*~~ *Medical electrical equipment – Glossary of defined terms*

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IEC 61010-1~~:2001~~, *Safety requirements for electrical equipment for measurement, control, and laboratory use – Part 1: General requirements*

IEC 61187~~:1993~~, *Electrical and electronic measuring equipment – Documentation*

~~ISO:1993, International vocabulary of basic and general terms in metrology (ISBN 92-67-01075-1)~~

ISO 7000:~~1989~~2019, *Graphical symbols for use on equipment –~~ Index and synopsis~~ Registered symbol*

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Edition 2.0 2023-03

INTERNATIONAL STANDARD

NORME INTERNATIONALE

Medical electrical equipment – Dosimetric instruments used for non-invasive measurement of X-ray tube voltage in diagnostic radiology

Appareils électromédicaux – Appareils de dosimétrie pour le mesurage non invasif de la tension du tube radiogène dans la radiologie de diagnostic

IEC 61676:2023-03(en-fr)

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SOMMAIRE

COMMISSION ÉLECTROTECHNIQUE INTERNATIONALE

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APPAREILS ÉLECTROMÉDICAUX – APPAREILS DE DOSIMÉTRIE POUR LE MESURAGE NON INVASIF DE LA TENSION DU TUBE RADIOGÈNE DANS LA RADIOLOGIE DE DIAGNOSTIC

AVANT-PROPOS

1) La Commission Électrotechnique Internationale (IEC) est une organisation mondiale de normalisation composée de l'ensemble des comités électrotechniques nationaux (Comités nationaux de l'IEC). L'IEC a pour objet de favoriser la coopération internationale pour toutes les questions de normalisation dans les domaines de l'électricité et de l'électronique. À cet effet, l'IEC – entre autres activités – publie des Normes internationales, des Spécifications techniques, des Rapports techniques, des Spécifications accessibles au public (PAS) et des Guides (ci-après dénommés "Publication(s) de l'IEC"). Leur élaboration est confiée à des comités d'études, aux travaux desquels tout Comité national intéressé par le sujet traité peut participer. Les organisations internationales, gouvernementales et non gouvernementales, en liaison avec l'IEC, participent également aux travaux. L'IEC collabore étroitement avec l'Organisation Internationale de Normalisation (ISO), selon des conditions fixées par accord entre les deux organisations.
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L'IEC 61676 a été établie par le sous-comité 62C: Equipements médicaux, logiciels et systèmes pour la radiothérapie, la médecine nucléaire et la radiodosimétrie, du comité d'études 62 de l'IEC: Équipement médical, logiciels et systèmes médicaux. Il s'agit d'une Norme internationale.

Cette seconde édition de l'IEC 61676 annule et remplace la première édition parue en 2002 et l'Amendement 1:2008. Cette édition constitue une révision technique.

Elle comprend une évaluation de l'INCERTITUDE TYPE COMPOSEE pour les performances d'un appareil hypothétique pour le MESURAGE NON INVASIF de la haute tension du tube (à l'Annexe A) qui remplace l'Annexe A de l'édition 1.1 intitulée "Critères de performances recommandés pour le diviseur invasif".

Le texte de ce document est issu des documents suivants:

Projet	Rapport de vote
62C/830/CDV	62C/866/RVC

Le rapport de vote indiqué dans le tableau ci-dessus donne toute information sur le vote ayant abouti à son approbation.

La langue employée pour l'élaboration de cette Norme internationale est l'anglais.

Ce document a été rédigé selon les directives ISO/IEC, Partie 2, il a été développé selon les directives ISO/IEC, Partie 1 et les directives ISO/IEC, Supplément IEC, disponibles sous www.iec.ch/members_experts/refdocs. Les principaux types de documents développés par l'IEC sont décrits plus en détail sous www.iec.ch/standardsdev/publications.

Dans le présent document, les caractères d'imprimerie suivants sont utilisés:

– exigences dont la conformité peut être vérifiée par essai, et définitions: caractères romains;
– notes, explications, conseils, propos généraux et exceptions: petits caractères romains;
– *spécifications d'essai: caractères italiques*;
– TERMES UTILISES DANS LE PRESENT DOCUMENT QUI SONT DEFINIS A L'ARTICLE 3 OU DANS L'IEC 60601-1 ET SES NORMES COLLATERALES: PETITES MAJUSCULES.

Le comité a décidé que le contenu de ce document ne sera pas modifié avant la date de stabilité indiquée sur le site web de l'IEC sous webstore.iec.ch dans les données relatives au document recherché. À cette date, le document sera

- reconduit,
- supprimé,
- remplacé par une édition révisée, ou
- amendé.

NOTE Le comité est conscient que cette deuxième édition du présent document ne traite toujours pas de tous les problèmes associés aux mesurages non invasifs à haute tension. Pour la mammographie, seule la filtration en molybdène en association avec une anode en molybdène est prise en considération, bien qu'en complément, des anodes en tungstène et en rhodium avec d'autres filtrations sont utilisées telles que celles en rhodium, en aluminium, en cuivre, en argent ou en titane. Au moment de la rédaction du présent document, il n'existait pas assez de données disponibles dans les ouvrages de référence pour définir des limites de variation réalistes pour ces types de GRANDEURS D'INFLUENCE. D'un autre côté, le comité a été informé du fait que plusieurs projets internationaux ont été mis en œuvre pour examiner le comportement général des multimètres à rayons X non invasifs des principaux FABRICANTS. Les résultats de ces études sont attendus dans les 5 prochaines années environ. Ainsi, le comité a décidé d'établir une courte période de stabilité pour cette deuxième édition et de mettre le présent document à jour dès que les résultats de ces nouvelles études seront disponibles.

Le contenu du corrigendum 1 (2024-01) a été pris en considération dans cet exemplaire.

INTRODUCTION

Le résultat d'un mesurage de la TENSION DU TUBE RADIOGENE au moyen d'appareils invasifs ou non invasifs est habituellement exprimé sous la forme d'un seul nombre pour la valeur de la tension du tube, que la tension du tube soit constante ou qu'elle présente une forme d'onde en fonction du temps. Les appareils non invasifs pour le mesurage de la TENSION DU TUBE RADIOGENE sur le marché indiquent généralement la "TENSION DE CRETE MOYENNE". Mais la grandeur "TENSION DE CRETE MOYENNE" n'est pas clairement définie et peut être une moyenne quelconque de toutes les crêtes de tension. Il est impossible d'établir des procédures d'essai pour les exigences de performance des appareils non invasifs pour le mesurage de la TENSION DU TUBE RADIOGENE sans la définition de la grandeur à l'étude. De ce fait, le présent document est fondé sur une grandeur dénommée "TENSION DE CRETE PRATIQUE". La TENSION DE CRETE PRATIQUE est définie de façon claire et est applicable à toute forme d'onde. Cette grandeur est liée à la répartition spectrale du RAYONNEMENT X émis et aux propriétés de l'image. Les GENERATEURS A RAYONS X qui fonctionnent à une même valeur de la TENSION DE CRETE PRATIQUE produisent le même contraste de bas niveau dans les RADIOGRAMMES, même lorsque les formes d'onde des tensions du tube sont différentes. L'Annex B fournit des informations détaillées sur ce concept. Un exemple de calcul de la TENSION DE CRETE PRATIQUE dans le cas d'une forme d'onde "à charge décroissante" est également fourni dans l'Annex B.

L'ETALONNAGE et le réglage de la TENSION DU TUBE RADIOGENE d'un GENERATEUR A RAYONS X sont généralement réalisés par le FABRICANT en utilisant un MESURAGE INVASIF direct. Des appareils utilisant des MESURAGES NON INVASIFS peuvent également être employés pour vérifier l'ETALONNAGE ou régler la TENSION DU TUBE RADIOGENE. Ces appareils présentent des incertitudes de mesure de la tension comparables à celles du MESURAGE INVASIF. Un des paramètres les plus importants des APPAREILS A RAYONNEMENT X de diagnostic est la tension appliquée au TUBE RADIOGENE, du fait que la qualité d'image dans la radiologie de diagnostic et la DOSE reçue par le PATIENT qui subit les examens radiologiques dépendent de la TENSION DU TUBE RADIOGENE. Une incertitude globale inférieure à ±5 % est applicable, et cette valeur sert de guide pour les LIMITES DE VARIATION pour les effets des GRANDEURS D'INFLUENCE.

APPAREILS ÉLECTROMÉDICAUX – APPAREILS DE DOSIMÉTRIE POUR LE MESURAGE NON INVASIF DE LA TENSION DU TUBE RADIOGÈNE DANS LA RADIOLOGIE DE DIAGNOSTIC

1 Domaine d'application

Le présent document spécifie les exigences de performance des appareils utilisés dans le MESURAGE NON INVASIF de la TENSION DU TUBE RADIOGENE jusqu'à 150 kV et les essais de conformité applicables. Le présent document décrit également la méthode d'ETALONNAGE et donne des recommandations pour l'estimation de l'incertitude des mesurages réalisés dans des conditions différentes de celles rencontrées au cours de l'ETALONNAGE.

Les applications pour un tel mesurage se rencontrent dans la RADIOLOGIE de diagnostic y compris la mammographie, la TOMODENSITOMETRIE, la radiologie dentaire et la RADIOSCOPIE. Le présent document ne traite pas des aspects sécurité de tels appareils. Les exigences pour la sécurité électrique s'appliquant à ceux-ci figurent dans l'IEC 61010-1.

2 Références normatives

Les documents suivants sont cités dans le texte de sorte qu'ils constituent, pour tout ou partie de leur contenu, des exigences du présent document. Pour les références datées, seule l'édition citée s'applique. Pour les références non datées, la dernière édition du document de référence s'applique (y compris les éventuels amendements).

IEC 60417, *Graphical symbols for use on equipment,* disponible sous http://www.graphical-symbols.info/equipment (disponible en anglais seulement)

IEC 60601-1:2005, *Appareils électromédicaux – Partie 1: Exigences générales pour la sécurité de base et les performances essentielles*
IEC 60601-1:2005/AMD1:2012
IEC 60601-1:2005/AMD2:2020

IEC TR 60788:2004, *Medical electrical equipment – Glossary of defined terms* (disponible en anglais seulement)

IEC 61000-4-2, *Compatibilité électromagnétique (CEM) – Partie 4-2: Techniques d'essai et de mesure – Essai d'immunité aux décharges électrostatiques*

IEC 61000-4-3, *Compatibilité électromagnétique (CEM) – Partie 4-3: Techniques d'essai et de mesure – Essai d'immunité aux champs électromagnétiques rayonnés aux fréquences radioélectriques*

IEC 61000-4-4, *Compatibilité électromagnétique (CEM) – Partie 4-4: Techniques d'essai et de mesure – Essais d'immunité aux transitoires électriques rapides en salves*

IEC 61000-4-5, *Compatibilité électromagnétique (CEM) – Partie 4-5: Techniques d'essai et de mesure – Essai d'immunité aux ondes de choc*

IEC 61000-4-6, *Compatibilité électromagnétique (CEM) – Partie 4-6: Techniques d'essai et de mesure – Immunité aux perturbations conduites, induites par les champs radioélectriques*

IEC 61000-4-11, *Compatibilité électromagnétique (CEM) – Partie 4-11: Techniques d'essai et de mesure – Essais d'immunité aux creux de tension, coupures brèves et variations de tension pour les appareils à courant d'entrée inférieur ou égal à 16 A par phase*

IEC 61010-1, *Règles de sécurité pour appareils électriques de mesurage, de régulation et de laboratoire – Partie 1: Exigences générales*

IEC 61187, *Équipements de mesures électriques et électroniques – Documentation*

ISO 7000:2019, *Symboles graphiques utilisables sur le matériel – Symboles enregistrés*