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colour inside

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

INTERNATIONAL
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CONTENTS

FOREWORD 4
INTRODUCTION 2
1 Scope ~~and object~~ 7
2 Normative references 7
3 ~~Terminology~~ Terms and definitions 8
4 General performance requirements for measurement of PRACTICAL PEAK VOLTAGE measurements 11
4.1 Quantity to be measured 11
4.2 Limits of PERFORMANCE CHARACTERISTICS 12
4.2.1 Limits 12
4.2.2 Maximum error 12
4.2.3 Over and under range indications 13
4.2.4 Repeatability 13
4.2.5 Long term stability 13
4.3 LIMITS OF VARIATION for effects of INFLUENCE QUANTITIES 14
4.3.1 INFLUENCE QUANTITIES 14
4.3.2 MINIMUM RATED RANGE of use 14
4.3.3 REFERENCE CONDITIONS 14
4.3.4 STANDARD TEST CONDITIONS 14
4.3.5 LIMITS OF VARIATION 14
4.4 Performance test procedures 16
4.4.1 General remarks 16
4.4.2 Dependence of instrument RESPONSE on voltage waveform and frequency 17
4.4.3 Dependence of instrument RESPONSE on ANODE ANGLE 17
4.4.4 Dependence of instrument RESPONSE on FILTRATION 18
4.4.5 Dependence of instrument RESPONSE on dose rate 18
4.4.6 Dependence of instrument RESPONSE on IRRADIATION TIME 18
4.4.7 Dependence of instrument RESPONSE on field size 18
4.4.8 Dependence of instrument RESPONSE on focus-to-detector distance 19
4.4.9 Dependence of instrument RESPONSE on angle of incidence of RADIATION 19
4.4.10 Dependence of instrument RESPONSE on angle of detector rotation with respect to the X-RAY TUBE axis 19
4.4.11 Dependence of instrument RESPONSE on temperature and humidity 20
4.4.12 Dependence of instrument RESPONSE **on** operating voltage 20
4.4.13 Dependence of instrument RESPONSE on electromagnetic compatibility 21
4.4.14 Additional tungsten filtration (tube aging) 23
5 Special instrumental requirements and marking 23
5.1 Requirements for the complete instruments 23
5.2 General 23
5.3 Display 24
5.4 Range of measurement 24
5.5 Connectors and cables 24
6 ACCOMPANYING DOCUMENTS 24
6.1 General 24
6.2 Information provided 24
6.3 Instrument description 24

6.4 Detector 24
6.5 Delay time 24
6.6 Measurement window 24
6.7 Data outlet 24
6.8 Transport and storage 25
~~Annex A (informative) Recommended performance criteria for the invasive divider .....~~
Annex A (informative) COMBINED STANDARD UNCERTAINTY 27
Annex B (informative) Additional information on PRACTICAL PEAK VOLTAGE 28
B.1 Overview 28
B.2 Simplified formalism for the determination of the PRACTICAL PEAK VOLTAGE $\hat{U}$ 28
~~Annex C (informative) Glossary of defined terms .....~~
Bibliography 36
Index of defined terms 37

Figure B.1 – Example of a waveform of a two-pulse generator 30
Figure B.2 – Example of a waveform of a constant-voltage generator 30
Figure B.3 – Example of falling load waveform 31

Table 1 – Minimum effective ranges 11
Table 2 – Minimum RATED RANGE OF USE, REFERENCE CONDITIONS, STANDARD TEST CONDITIONS, LIMITS OF VARIATION (± L) and INTRINSIC ERROR (E) over the EFFECTIVE RANGE of use, for the pertaining INFLUENCE QUANTITY 15
Table 3 – Minimum test points and test values of PRACTICAL PEAK VOLTAGE for INFLUENCE QUANTITIES 17
Table 4 – Maximum HALF-VALUE LAYER (HVL) depending on anode angle 23
Table A.1 – Example for assessment of the COMBINED STANDARD UNCERTAINTY – Instruments used for NON-INVASIVE MEASUREMENT of X-RAY TUBE VOLTAGE 27
Table B.1 – Values of 20 samples of the falling load waveform in Figure B.3 31
Table B.2 – Voltage bins, probability and weighting factors for the 20 samples of the falling load waveform in Figure B.3 32
Table B.3 – Weighting factors for the 20 equally spaced samples of the falling load waveform in figure B.3 33

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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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– *test specifications: in italic type*;
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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*
IEC 60601-1:2005/AMD1:2012
IEC 60601-1:2005/AMD2:2020

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*

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~~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*

IEC 61676

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)

CONTENTS

FOREWORD 4
INTRODUCTION 6
1 Scope 7
2 Normative references 7
3 Terms and definitions 8
4 General performance requirements for measurement of PRACTICAL PEAK VOLTAGE measurements 11
4.1 Quantity to be measured 11
4.2 Limits of PERFORMANCE CHARACTERISTICS 11
4.2.1 Limits 11
4.2.2 Maximum error 11
4.2.3 Over and under range indications 12
4.2.4 Repeatability 13
4.2.5 Long term stability 13
4.3 LIMITS OF VARIATION for effects of INFLUENCE QUANTITIES 13
4.3.1 INFLUENCE QUANTITIES 13
4.3.2 MINIMUM RATED RANGE of use 13
4.3.3 REFERENCE CONDITIONS 14
4.3.4 STANDARD TEST CONDITIONS 14
4.3.5 LIMITS OF VARIATION 14
4.4 Performance test procedures 15
4.4.1 General remarks 15
4.4.2 Dependence of instrument RESPONSE on voltage waveform and frequency 16
4.4.3 Dependence of instrument RESPONSE on ANODE ANGLE 17
4.4.4 Dependence of instrument RESPONSE on FILTRATION 17
4.4.5 Dependence of instrument RESPONSE on dose rate 17
4.4.6 Dependence of instrument RESPONSE on IRRADIATION TIME 18
4.4.7 Dependence of instrument RESPONSE on field size 18
4.4.8 Dependence of instrument RESPONSE on focus-to-detector distance 18
4.4.9 Dependence of instrument RESPONSE on angle of incidence of RADIATION 19
4.4.10 Dependence of instrument RESPONSE on angle of detector rotation with respect to the X-RAY TUBE axis 19
4.4.11 Dependence of instrument RESPONSE on temperature and humidity 19
4.4.12 Dependence of instrument RESPONSE **on** operating voltage 20
4.4.13 Dependence of instrument RESPONSE on electromagnetic compatibility 21
4.4.14 Additional tungsten filtration (tube aging) 22
5 Special instrumental requirements and marking 23
5.1 Requirements for the complete instruments 23
5.2 General 23
5.3 Display 23
5.4 Range of measurement 23
5.5 Connectors and cables 23
6 ACCOMPANYING DOCUMENTS 24
6.1 General 24
6.2 Information provided 24
6.3 Instrument description 24

6.4 Detector 24
6.5 Delay time 24
6.6 Measurement window 24
6.7 Data outlet 24
6.8 Transport and storage 24
Annex A (informative) COMBINED STANDARD UNCERTAINTY 25
Annex B (informative) Additional information on PRACTICAL PEAK VOLTAGE 26
B.1 Overview 26
B.2 Simplified formalism for the determination of the PRACTICAL PEAK VOLTAGE $\hat{U}$ 26
Bibliography 32
Index of defined terms 33

Figure B.1 – Example of a waveform of a two-pulse generator 28
Figure B.2 – Example of a waveform of a constant-voltage generator 28
Figure B.3 – Example of falling load waveform 29

Table 1 – Minimum effective ranges 11
Table 2 – Minimum RATED RANGE OF USE, REFERENCE CONDITIONS, STANDARD TEST CONDITIONS, LIMITS OF VARIATION (± L) and INTRINSIC ERROR (E) over the EFFECTIVE RANGE of use, for the pertaining INFLUENCE QUANTITY 14
Table 3 – Minimum test points and test values of PRACTICAL PEAK VOLTAGE for INFLUENCE QUANTITIES 16
Table 4 – Maximum HALF-VALUE LAYER (HVL) depending on anode angle 23
Table A.1 – Example for assessment of the COMBINED STANDARD UNCERTAINTY – Instruments used for NON-INVASIVE MEASUREMENT of X-RAY TUBE VOLTAGE 25
Table B.1 – Values of 20 samples of the falling load waveform in Figure B.3 29
Table B.2 – Voltage bins, probability and weighting factors for the 20 samples of the falling load waveform in Figure B.3 30
Table B.3 – Weighting factors for the 20 equally spaced samples of the falling load waveform in Figure B.3 31

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IEC 61187, *Electrical and electronic measuring equipment – Documentation*

ISO 7000:2019, *Graphical symbols for use on equipment – Registered symbol*

SOMMAIRE

AVANT-PROPOS 36
INTRODUCTION 38
1 Domaine d'application 39
2 Références normatives 39
3 Termes et définitions 40
4 Exigences générales de performance pour le mesurage de la TENSION DE CRETE PRATIQUE 43
4.1 Grandeur à mesurer 43
4.2 Limites des CARACTÉRISTIQUES DE PERFORMANCE 44
4.2.1 Limites 44
4.2.2 Erreur maximale 44
4.2.3 Indications supérieures et inférieures à la plage 45
4.2.4 Répétabilité 45
4.2.5 Stabilité à long terme 45
4.3 LIMITES DE VARIATION des effets de GRANDEURS D'INFLUENCE 46
4.3.1 GRANDEURS D'INFLUENCE 46
4.3.2 PLAGE ASSIGNÉE MINIMALE d'utilisation 46
4.3.3 CONDITIONS DE RÉFÉRENCE 46
4.3.4 CONDITIONS D'ESSAI NORMALISÉES 46
4.3.5 LIMITES DE VARIATION 46
4.4 Procédures d'essai de performance 48
4.4.1 Remarques générales 48
4.4.2 Dépendance de la REPONSE de l'appareil en fonction de la fréquence et la forme d'onde de la tension 49
4.4.3 Dépendance de la REPONSE de l'appareil en fonction de la PENTE D'ANODE 50
4.4.4 Dépendance de la REPONSE de l'appareil en fonction de la FILTRATION 50
4.4.5 Dépendance de la REPONSE de l'appareil en fonction du débit de dose 50
4.4.6 Dépendance de la REPONSE de l'appareil en fonction du TEMPS D'IRRADIATION 51
4.4.7 Dépendance de la REPONSE de l'appareil en fonction de la taille de champ 51
4.4.8 Dépendance de la REPONSE de l'appareil en fonction de la distance du foyer au détecteur 52
4.4.9 Dépendance de la REPONSE de l'appareil en fonction de l'angle d'incidence de RAYONNEMENT 52
4.4.10 Dépendance de la REPONSE de l'appareil en fonction de l'angle de rotation du détecteur par rapport à l'axe du TUBE RADIOGENE 52
4.4.11 Dépendance de la REPONSE de l'appareil en fonction de la température et de l'humidité 53
4.4.12 Dépendance de la REPONSE de l'appareil en fonction de la tension de fonctionnement 53
4.4.13 Dépendance de la REPONSE de l'appareil en fonction de la compatibilité électromagnétique 54
4.4.14 Filtration en tungstène supplémentaire (vieillissement du tube) 56
5 Exigences et marquages spéciaux d'appareils 56
5.1 Exigences pour les appareils complets 56
5.2 Généralités 56
5.3 Affichage 57

5.4 Étendue de mesure 57
5.5 Connecteurs et câbles 57
6 DOCUMENTS D'ACCOMPAGNEMENT 57
6.1 Généralités 57
6.2 Informations fournies 57
6.3 Description d'appareil 57
6.4 Détecteur 57
6.5 Délai 57
6.6 Fenêtre de mesure 57
6.7 Sortie de données 58
6.8 Transport et stockage 58
Annex A (informative) INCERTITUDE TYPE COMPOSÉE 59
Annex B (informative) Informations complémentaires sur la TENSION DE CRETE PRATIQUE 60
B.1 Aperçu 60
B.2 Formalisme simplifié pour la détermination de la TENSION DE CRETE PRATIQUE $\hat{U}$ 60
Bibliographie 66
Index des termes définis 67

Figure B.1 – Exemple d'une forme d'onde d'un générateur à deux impulsions 62
Figure B.2 – Exemple d'une forme d'onde d'un générateur de tension constante 62
Figure B.3 – Exemple d'une forme d'onde à charge décroissante 63

Tableau 1 – Plages efficaces minimales 43
Tableau 2 – PLAGE ASSIGNEE minimale D'UTILISATION, CONDITIONS DE REFERENCE, CONDITIONS D'ESSAI NORMALISEES, LIMITES DE VARIATION (± L) et ERREUR INTRINSEQUE (E) sur la PLAGE EFFICACE d'utilisation, pour la GRANDEUR D'INFLUENCE concernée 47
Tableau 3 – Points d'essai minimaux et valeurs d'essai de la TENSION DE CRETE PRATIQUE pour des GRANDEURS D'INFLUENCE 49
Tableau 4 – COUCHE DE DEMI-TRANSMISSION (CDT) maximale en fonction de la pente d'anode 56
Tableau A.1 – Exemple d'évaluation de l'INCERTITUDE TYPE COMPOSEE – Appareils utilisés pour le MESURAGE NON INVASIF DE LA TENSION du TUBE RADIOGENE 59
Tableau B.1 – Valeurs de 20 échantillons de la forme d'onde à charge décroissante de la Figure B.3 63
Tableau B.2 – Casiers de tension, probabilité et facteurs de pondération pour les 20 échantillons de la forme d'onde à charge décroissante de la Figure B.3 64
Tableau B.3 – Facteurs de pondération pour les 20 échantillons également espacés de la forme d'onde à charge décroissante de la Figure B.3 65

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

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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.

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– notes, explications, conseils, propos généraux et exceptions: petits caractères romains;
– *spécifications d'essai: caractères italiques*;
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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.

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*