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REDLINE VERSION

INTERNATIONAL STANDARD

colour inside

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

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CONTENTS

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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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This redline version of the official IEC Standard allows the user to identify the changes made to the previous edition IEC 61676:2002+AMD1:2008 CSV. A vertical bar appears in the margin wherever a change has been made. Additions are in green text, deletions are in strikethrough red text.

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.

It includes an assessment of the COMBINED STANDARD UNCERTAINTY for the performance of a hypothetical instrument for the non-invasive measurement of the tube high voltage (in Annex A) which replaces Annex A of the edition 1.1 titled "Recommended performance criteria for the invasive divider".

The text of this document is based on the following documents:

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.

In this document the following print types are used:

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- withdrawn,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

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.

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*

IEC 61000-4-2~~:1995~~, *Electromagnetic compatibility (EMC) – Part 4-2: Testing and measurement techniques – Electrostatic discharge immunity test*~~. Basic EMC Publication~~

IEC 61000-4-3~~:2000~~, *Electromagnetic compatibility (EMC) – Part 4-3: Testing and measurement techniques – Radiated, radio-frequency, electromagnetic field immunity test*~~. Basic EMC Publication~~

IEC 61000-4-4~~:1995~~, *Electromagnetic compatibility (EMC) – Part 4-4: Testing and measurement techniques – Electrical fast transient/burst immunity test*~~. Basic EMC Publication~~

IEC 61000-4-5~~:1995~~, *Electromagnetic compatibility (EMC) – Part 4-5: Testing and measurement techniques – Surge immunity test*~~. Basic EMC Publication~~

IEC 61000-4-6~~:1996~~, *Electromagnetic compatibility (EMC) – Part 4-6: Testing and measurement techniques – Immunity to conducted disturbances, induced by radio-frequency fields*~~. Basic EMC Publication~~

IEC 61000-4-11:1994, *Electromagnetic compatibility (EMC) – Part 4-11: Testing and measurement techniques – Voltage dips, short interruptions and voltage variations immunity tests for equipment with input current up to 16 A per phase*. Basic EMC Publication

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 7000:19892019, *Graphical symbols for use on equipment – Index and synopsis Registered symbol*

3 Terminology Terms and definitions

For the purposes of this document, the terms and definitions given in IEC 60601-1:2005, IEC TR 60788:2004 and the following apply.

The definitions given in this standard are generally in agreement with those in IEC 60788 and the ISO *International vocabulary of basic and general terms in metrology*. Any terms not defined in this subclause have the meanings defined in the above publications or are assumed to be in general scientific usage.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

- IEC Electropedia: available at http://www.electropedia.org/
- ISO Online browsing platform: available at http://www.iso.org/obp

NOTE 1 An Index of defined terms is to be found at the end of the document.

NOTE 2 A searchable IEC Glossary can be found at std.iec.ch.

3.1
CORRECTION FACTOR
dimensionless multiplier which corrects the INDICATED VALUE of an instrument from its value when operated under particular conditions to its value when operated under stated REFERENCE CONDITIONS

3.2
EFFECTIVE RANGE
range of INDICATED VALUES for which an instrument complies with a stated performance

Note 1 to entry: The maximum (minimum) effective INDICATED VALUE is the highest (lowest) in this range.

3.3
INDICATED VALUE
value of quantity derived from the scale reading of an instrument together with any scale factors indicated on the control panel of the instrument

3.4
INFLUENCE QUANTITY
any external quantity that may can affect the performance of an instrument (e.g., ambient temperature etc.) and any property of the X-RAY EQUIPMENT under test that needs to shall be taken into account in using the instrument for NON-INVASIVE MEASUREMENT of X-RAY TUBE

VOLTAGE (e.g., range of X-RAY TUBE VOLTAGE, ANODE ANGLE, anode material, TOTAL FILTRATION, etc.)

3.5
INSTRUMENT PARAMETER
any internal property of an instrument that ~~may~~ can affect the performance of the instrument

3.6
INTRINSIC ERROR
deviation of the MEASURED VALUE (i.e., the INDICATED VALUE, corrected to REFERENCE CONDITIONS) from the CONVENTIONAL TRUE VALUE under STANDARD TEST CONDITIONS

3.7
INVASIVE MEASUREMENT
measurement of the X-RAY TUBE VOLTAGE by external connection of a suitable meter or a high resistance divider

3.8
LIMITS OF VARIATION
maximum VARIATION of a PERFORMANCE CHARACTERISTIC y, permitted by this document

Note 1 to entry: If the LIMITS OF VARIATION are stated as $\pm L$ % the VARIATION $\Delta y / y$, expressed as a percentage, shall remain in the range from $-L$ % to $+L$ %.

3.9
MAXIMUM PEAK VOLTAGE
maximum value of the X-RAY TUBE VOLTAGE in a specified time interval

Note 1 to entry: The unit of this quantity is the volt (V).

3.10
MEAN PEAK VOLTAGE
mean value of all X-RAY TUBE VOLTAGE peaks during a specified time interval

Note 1 to entry: The unit of this quantity is the volt (V).

3.11
MEASURED VALUE
best estimate of the CONVENTIONAL TRUE VALUE of a quantity, being derived from the INDICATED VALUE of an instrument together with the application of all relevant CORRECTION FACTORS

Note 1 to entry: The CONVENTIONAL TRUE VALUE is usually the value determined by the working standard with which the instrument under test is being compared.

3.12
MINIMUM EFFECTIVE RANGE
smallest permitted range of INDICATED VALUES for which an instrument complies with a stated performance

3.13
NON-INVASIVE MEASUREMENT
measurement of X-RAY TUBE VOLTAGE by analysis of the emitted RADIATION

3.14
PERFORMANCE CHARACTERISTIC
one of the quantities used to define the performance of an instrument (e.g., RESPONSE)

3.15
VOLTAGE RIPPLE
VOLTAGE at the X-RAY TUBE, r, expressed as a percentage of the peak voltage, U_{max}, over a specified time interval

Note 1 to entry: The VOLTAGE RIPPLE is expressed by the formula:

$$r = \frac{U_{max} - U_{min}}{U_{max}} \times 100 \ \%$$

where U_{max} is the highest voltage in the interval, and U_{min} is the lowest voltage in the interval.

3.16
PRACTICAL PEAK VOLTAGE
PPV

$$\frac{\int_{U_{min}}^{U_{max}} p(U) \times w(U) \times U dU}{\int_{U_{min}}^{U_{max}} p(U) \times w(U) \times dU} \text{ with} \int_{U_{min}}^{U_{max}} p(U) dU = 1$$

where $p(U)$ is the distribution function for the voltage U and $w(U)$ is a weighting function, U_{max} is the highest voltage in the interval, and U_{min} is the lowest voltage in the interval

Note 1 to entry: The unit of the quantity PRACTICAL PEAK VOLTAGE is the volt (V).

Note 2 to entry: Additional information on the PRACTICAL PEAK VOLTAGE, the weighting function $w(U)$ and the distribution function $p(U)$ is provided in Annex B. Using this weighting function $w(U)$ the PRACTICAL PEAK VOLTAGE is defined as the constant potential which produces the same AIR KERMA contrast behind a specified PHANTOM as the non-DC voltage under test.

3.17
RATED RANGE
RATED RANGE OF USE
range of values of an INFLUENCE QUANTITY or INSTRUMENT PARAMETER within which the instrument will operate within the LIMITS OF VARIATION

Note 1 to entry: The limits of rated range are the maximum and minimum RATED values.

Note 2 to entry: The MINIMUM RATED RANGE is the least range of an INFLUENCE QUANTITY or INSTRUMENT PARAMETER within which the instrument shall operate within the specified LIMITS OF VARIATION in order to comply with this document.

3.18
REFERENCE CONDITION
condition under which all INFLUENCE QUANTITIES and INSTRUMENT PARAMETERS have their REFERENCE VALUES

3.19
REFERENCE VALUE
particular value of an INFLUENCE QUANTITY (or INSTRUMENT PARAMETER) chosen for the purposes of reference i.e., the value of an INFLUENCE QUANTITY (or INSTRUMENT PARAMETER) at which the CORRECTION FACTOR for dependence on that INFLUENCE QUANTITY (or INSTRUMENT PARAMETER) is unity

3.20
RELATIVE INTRINSIC ERROR
ratio of the INTRINSIC ERROR to the CONVENTIONAL TRUE VALUE

3.21
RESPONSE
quotient of the INDICATED VALUE divided by the CONVENTIONAL TRUE VALUE

3.22
STANDARD TEST CONDITION
condition under which all INFLUENCE QUANTITIES and INSTRUMENT PARAMETERS have their STANDARD TEST VALUES

3.23
STANDARD TEST VALUE
value or a range of values of an INFLUENCE QUANTITY or INSTRUMENT PARAMETER, which is permitted when carrying out CALIBRATIONS or tests on another INFLUENCE QUANTITY or INSTRUMENT PARAMETER

3.24
VARIATION
relative difference $\Delta y / y$, between the values of a PERFORMANCE CHARACTERISTIC y, when one INFLUENCE QUANTITY or INSTRUMENT PARAMETER assumes successively two specified values, the other INFLUENCE QUANTITIES and INSTRUMENT PARAMETERS being kept constant at the STANDARD TEST VALUES, unless other values are specified

3.25
X-RAY TUBE VOLTAGE
potential difference applied to an X-RAY TUBE between the anode and the cathode

Note 1 to entry: The unit of this quantity is the volt (V).

4 General performance requirements for measurement of PRACTICAL PEAK VOLTAGE measurements

4.1 Quantity to be measured

The quantity to be measured is the PRACTICAL PEAK VOLTAGE.

NOTE Additional quantities ~~may~~ can be displayed.

The MINIMUM EFFECTIVE RANGES of PRACTICAL PEAK VOLTAGE shall be as listed in Table 1 for the relevant X-RAY applications.

Table 1 – Minimum effective ranges

Application	Nominal anode material	MINIMUM EFFECTIVE RANGE
Mammography 20 kV to 50 kV	Mo a)	24 kV to 35 kV
Diagnostic 40 kV to 150 kV	W	60 kV to 120 kV
CT ~~80~~ 70 kV to 150 kV	W	~~100~~ 80 kV to 140 kV
Dental 40 kV to 110 kV	W	60 kV to 90 kV
Fluoroscopic 40 kV to 130 kV	W	60 kV to 120 kV

a) For mammography anode materials other than Mo, the MINIMUM EFFECTIVE RANGE of PPV shall be at least 10 kV.

4.2 Limits of PERFORMANCE CHARACTERISTICS

4.2.1 Limits

All values of the limits of PERFORMANCE CHARACTERISTICS stated in this subclause do not contain the uncertainty of the test equipment.

4.2.2 Maximum error

4.2.2.1 Maximum RELATIVE INTRINSIC ERROR for voltages above 50 kV

The RELATIVE INTRINSIC ERROR, I, of PRACTICAL PEAK VOLTAGE, $\hat{U}$, measurements made under STANDARD TEST CONDITIONS, shall not be greater than ±2 % over the EFFECTIVE RANGE of voltages. This is expressed by the formula:

$$|I| = \left| \frac{\hat{U}_{\text{meas}} - \hat{U}_{\text{true}}}{\hat{U}_{\text{true}}} \right| \leq 0{,}02$$

where $\hat{U}_{\text{meas}}$ is the MEASURED VALUE of PRACTICAL PEAK VOLTAGE and $\hat{U}_{\text{true}}$ is the TRUE VALUE of the PRACTICAL PEAK VOLTAGE. The voltages for the MINIMUM EFFECTIVE RANGE are listed in Table 1.

The compliance test for performance requirement for this subclause is listed under 4.2.2.2.

4.2.2.2 Maximum INTRINSIC ERROR for voltages below 50 kV

The maximum INTRINSIC ERROR, E, of PRACTICAL PEAK VOLTAGE, $\hat{U}$, measurements made under STANDARD TEST CONDITIONS shall not be greater than ±1 kV over the EFFECTIVE RANGE of voltages. This is expressed by the formula:

$$|E| = \left| \hat{U}_{\text{meas}} - \hat{U}_{\text{true}} \right| \leq 1{,}0 \text{ kV}$$

where $\hat{U}_{\text{meas}}$ is the MEASURED VALUE of PRACTICAL PEAK VOLTAGE and $\hat{U}_{\text{true}}$ is the CONVENTIONAL TRUE VALUE of the PRACTICAL PEAK VOLTAGE. The voltages for the MINIMUM EFFECTIVE RANGE are listed in Table 1.

Compliance with performance requirements 4.2.2.1 and 4.2.2.2 shall be checked by measuring the RELATIVE INTRINSIC ERROR above 50 kV or the INTRINSIC ERROR below 50 kV over the EFFECTIVE RANGE of voltages for each application claimed. STANDARD TEST CONDITIONS are listed in Table 2 for each application. The end points of the EFFECTIVE RANGE ~~must~~ shall be checked. For mammography, the nominal step between measurements shall be no greater than 2 kV. For all other applications the nominal step between measurements shall be no greater than 5 kV for voltages below 100 kV, and no greater than 10 kV for voltages above 100 kV.

If more than one instrument configuration can be utilised to measure a span of voltages, then that span of voltages shall be measured utilising all relevant instrument configurations. As a minimum the end points and enough interim points shall be measured to meet the minimum step requirements given above. An example could be the use of different absorber pairs to provide overlapping voltage spans. In the case of different absorber pairs, if the first measured from 40 kV to 80 kV, and the second from 60 kV to 120 kV, then the overlapping span would be from 60 kV to 80 kV. At a minimum, measurements would be made utilising each absorber pair at 60 kV, 65 kV, 70 kV, 75 kV, and 80 kV.

4.2.3 Over and under range indications

The instrument ~~must~~ shall clearly indicate when it is displaying a reading outside its EFFECTIVE RANGE of PRACTICAL PEAK VOLTAGE.

Conditions above and below the EFFECTIVE RANGE of PRACTICAL PEAK VOLTAGE shall be tested and it shall be demonstrated that if the instrument displays a reading it will be clearly indicated to the user that the reading might not meet the accuracy of the instrument.

If more than one instrument configuration can be utilised to measure a span of voltages, then over and under range conditions shall be checked for all relevant instrument configurations. An example could be the use of different absorber pairs to provide overlapping voltage spans. In the case of different absorber pairs, if the first measured from 40 kV to 80 kV, and the second from 60 kV to 120 kV, then over and under range indications would be checked below 40 kV and above 80 kV for the first absorber pair, and below 60 kV and above 120 kV for the second absorber pair. (The instrument's refusal to make a reading under these conditions is an acceptable result.)

Compliance with performance requirement of this subclause shall be verified at the lowest limit of the RATED RANGE of dose rates. All other INFLUENCE QUANTITIES shall be at STANDARD TEST CONDITIONS as listed in Table 2.

4.2.4 Repeatability

When a measurement is repeated with the same instrument under unaltered conditions, the COEFFICIENT OF VARIATION ~~of the individual measurement~~ shall not exceed ±0,5 % or the standard deviation shall not exceed 0,5 kV ~~or ±0,5 %~~, whichever is greater.

Compliance with performance requirement of this subclause shall be checked by determining the COEFFICIENT OF VARIATION of ten consecutive measurements taken at the lowest limit of the RATED RANGE of dose rates. All other INFLUENCE QUANTITIES shall be at STANDARD TEST CONDITIONS as listed in Table 2 for each application. The end points of the EFFECTIVE RANGE and one point near the middle of the EFFECTIVE RANGE ~~must~~ shall be checked. The test shall be conducted a second time with the dose rate also within STANDARD TEST CONDITIONS.

If more than one instrument configuration can be utilised to measure a span of voltages, then the end points of that span of voltages shall be measured utilising all relevant instrument configurations. An example could be the use of different absorber pairs to provide overlapping voltage spans. In the case of different absorber pairs, if the first measured from 40 kV to 80 kV, and the second from 60 kV to 120 kV, then the overlapping span would be from 60 kV to 80 kV. At a minimum, measurements would be made utilising each absorber pair at 60 kV and 80 kV.

4.2.5 Long term stability

The design and construction shall be such that the instrument RESPONSE does not change by more than ±2,0 % for voltages above 50 kV ~~or by more than ±1,0 kV for voltages below 50 kV~~ over a period of one year. For voltages below 50 kV, the difference between the INDICATED VALUE and CONVENTIONAL TRUE VALUE shall not change by more than ±1,0 kV over a period of one year.

Compliance with this performance requirement shall be checked by retaining a representative instrument, stored under STANDARD TEST CONDITIONS of temperature and relative humidity and by measuring the RELATIVE INTRINSIC ERROR above 50 kV or the INTRINSIC ERROR below 50 kV at a minimum of two voltages, one near the top and one near the bottom of the EFFECTIVE RANGE.

If more than one instrument configuration can be utilised to measure a span of voltages, then the end points of that span of voltages shall be measured utilising all relevant instrument configurations. An example could be the use of different absorber pairs to provide overlapping voltage spans. In the case of different absorber pairs, if the first measured from 40 kV to 80 kV, *and the second from 60 kV to 120 kV, then the overlapping span would be from 60 kV to 80 kV. At a minimum, measurements would be made utilising each absorber pair at 60 kV and 80 kV.*

These measurements shall be made at a minimum of one-month intervals over a period of not less than six months. Linear regression analysis shall be used to extrapolate these readings to obtain the change in RESPONSE over one full year.

4.3 LIMITS OF VARIATION for effects of INFLUENCE QUANTITIES

4.3.1 INFLUENCE QUANTITIES

Quantities which ~~may~~ can influence the performance of the instrument are given in Table 2.

4.3.2 MINIMUM RATED RANGE of use

The MINIMUM RATED RANGE of use for each of the INFLUENCE QUANTITIES involved is given in Table 2.

4.3.3 REFERENCE CONDITIONS

The REFERENCE CONDITIONS for each particular INFLUENCE QUANTITY are given in Table 2. For those INFLUENCE QUANTITIES that can be controlled, the REFERENCE VALUE should be the value used during the CALIBRATION of the equipment.

4.3.4 STANDARD TEST CONDITIONS

The STANDARD TEST CONDITIONS stated in Table 2 shall be met during the test procedure except for the INFLUENCE QUANTITY being tested.

4.3.5 LIMITS OF VARIATION

The LIMITS OF VARIATION $\pm L$ for each particular INFLUENCE QUANTITY are given in Table 2. For any change of an INFLUENCE QUANTITY within its RATED RANGE the change of the RESPONSE of the instrument shall be such that the following relationship is fulfilled:

$$\left| \frac{R}{R_{\text{ref}}} - 1 \right| \times 100\ \% \leq L$$

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

Influence quantity	Minimum rated range of use	REFERENCE CONDITIONS	STANDARD TEST CONDITIONS	± E kV	± L %	Sub-clause
Voltage waveform and frequency:						4.4.2
Diagnostic	Constant potential, 2-, 6-, 12-pulse and medium frequency generators [a]	Constant potential	Constant potential, ripple less than 4 %		2,0	
Mammography	Constant potential			0,5		
Anode angle:						4.4.3
Diagnostic	6° to 18°	12°	REFERENCE VALUE ±2°		0,5	
Mammography	15° to 24°	20°	REFERENCE VALUE ±2°	0,5		
Filtration:						4.4.4
Diagnostic	2,5 mm Al to 3,5 mm Al [b]	3,0 mm Al	REFERENCE VALUE ±5 %		1,5	
Mammography	25 µm Mo to 35 µm Mo [c]	30 µm Mo	REFERENCE VALUE ±5 %	0,5		
CT	4 mm Al to 8 mm Al	6 mm Al	REFERENCE VALUE ±5 %		1,5	
Dental	1 mm Al to 2 mm Al	1,5 mm Al	REFERENCE VALUE ±5 %		1,5	
Dose rate:		As stated by MANUFACTURER	REFERENCE VALUE ±20 %	0,5		4.4.5
Diagnostic	20 mGy/s to 200 mGy/s				0,5	
Mammography	25 mGy/s to 150 mGy/s				0,5	
CT	20 mGy/s to 200 mGy/s				0,5	
Dental	5 mGy/s to 50 mGy/s				0,5	
Fluoroscopic	1 mGy/s to 10 mGy/s					
Irradiation time:						4.4.6
Diagnostic	10 ms to 1 000 ms	100 ms	REFERENCE VALUE ±20 %		0,5	
Other	200 ms to 1 000 ms	500 ms	REFERENCE VALUE ±20 %		0,5	
Field size:						
Rated range	Length and width stated by MANUFACTURER + 30 % to 10 %	As stated by MANUFACTURER.	REFERENCE VALUE ±2 %		0,5	4.4.7.1
Large field	30 cm by 30 cm	30 cm by 30 cm	REFERENCE VALUE ±2 %		2,0	4.4.7.2
Detector-focal distance	32 cm to 60 cm or as stated by MANUFACTURER	40 cm or as stated by MANUFACTURER	REFERENCE VALUE ±1 %		0,5	4.4.8
Angle of incidence	±5°	0°	REFERENCE VALUE ±1°		0,5	4.4.9
Rotation	±10°	0°	REFERENCE VALUE ±1°		0,5	4.4.10.1
	±180°	0°	REFERENCE VALUE ±1°		0,5	4.4.10.2
Temperature	15 °C to 35 °C	20 °C	REFERENCE VALUE ±2 °C		1,0	4.4.11
Relative humidity	≤ 80 % (max 20 g/m³)	50 %	30 % to 75 %			
Power supply						
Line voltage and frequency	115 V or 230 V + 10 % to 15 %	115 V/230 V	REFERENCE VALUE ±1 %		0,5	4.4.12.1

Influence quantity	Minimum rated range of use	REFERENCE CONDITIONS	STANDARD TEST CONDITIONS	± E kV	± L %	Sub-clause
Batteries	50 Hz or 60 Hz	50 Hz/60 Hz as stated	REFERENCE VALUE ±1 %		0,5	4.4.12.2
Rechargeable batteries	As stated by MANUFACTURER. Fresh to low	Fresh, mains disconnected	REFERENCE VALUE ±1 %		0,5	4.4.12.3
Electromagnetic compatibility	IEC 61000-4-2 IEC 61000-4-3 IEC 61000-4-4 IEC 61000-4-5 IEC 61000-4-6 IEC 61000-4-11	Without any disturbance	Insignificant		1,0	4.4.13
Additional tungsten filtration (tube aging)	0 µm to 10 µm W	3 µm W	0 µm W to 3 µm W		2,0	4.4.14

[a] Frequency range f = 50 Hz to 50 kHz, VOLTAGE RIPPLE (%) from 0 to (50 – 10log f), e.g., 0 % to 20 % at 1 000 Hz, 0 % to 3 % at 50 kHz. All frequencies above 50 kHz are treated as constant potential generators.

[b] Filtration outside of MINIMUM RATED RANGE ~~may~~ can be met by applying corrections.

[c] X-ray generator with a molybdenum anode, a beryllium window, and no added filtration other than the 30 µm Mo.

4.4 Performance test procedures

4.4.1 General remarks

Performance tests for a particular INFLUENCE QUANTITY shall be carried out in such a way that the pertaining INFLUENCE QUANTITY is varied within the RATED RANGE of use and that STANDARD TEST CONDITIONS are used for all other INFLUENCE QUANTITIES. If not otherwise stated, the TEST VALUE for the quantity to be measured, i.e., voltage, is taken from Table 3. Unless otherwise specified by the MANUFACTURER of the instrument, the measuring unit shall be placed on a radiographic table or a surface whose X-RAY scatter characteristics are similar to a radiographic table.

For those INFLUENCE QUANTITIES which ~~may~~ can have an impact on the voltage behaviour of the X-RAY unit used for test purposes, i.e., voltage waveform and frequency, dose rate and IRRADIATION TIME, a high voltage divider system shall be used as a reference. This reference shall have a CALIBRATION which is traceable to a national standard. The dependence of the voltage divider and its read-out system on voltage waveform and frequency over the range stated in Table 2 shall be less than 0,5 %.

For those INFLUENCE QUANTITIES which introduce a change in the intensity and the spectral composition of the RADIATION beam emitted from the X-RAY source assembly, i.e., voltage waveform and frequency, ANODE ANGLE, filtration and dose rate, performance tests shall be made at the minimum test points as indicated in Table 3 in order to show compliance over the EFFECTIVE RANGE of voltages unless otherwise stated. For those instruments having ranges exceeding the minimum ranges additional performance tests shall be run at the lower and upper values.

If more than one instrument configuration can be utilised to measure any of the above specified test points, then each of those points shall be measured utilising all relevant instrument configurations. An example could be the use of different absorber pairs to provide overlapping voltage spans. In the case of different absorber pairs, if the first measured from 40 kV to 90 kV, and the second from 60 kV to 120 kV, then the overlapping span would be from 60 kV to 90 kV. At a minimum, if this were a diagnostic application, measurements would be made utilising each absorber pair at 60 kV and at 80 kV. If this were a dental application, measurements would be made utilising each absorber pair at 60 kV, 75 kV and at 90 kV.

Table 3 – Minimum test points and test values of PRACTICAL PEAK VOLTAGE for INFLUENCE QUANTITIES

Application	Minimum test points kV	Test value kV
Mammography	24, 28, 30, 35	30
Diagnostic	60, 80, 100, 120	80
CT	80, 100, 120, 140	120
Dental	60, 75, 90	60
Fluoroscopic	60, 80, 100, 120	80

4.4.2 Dependence of instrument RESPONSE on voltage waveform and frequency

The MINIMUM RATED RANGE of frequency is between 50 Hz and 50 kHz. The MINIMUM RATED RANGE of VOLTAGE RIPPLE is defined as

$$\text{VOLTAGE RIPPLE}\ (\%)\ \text{from 0 to}\ (50 - 10 \log f)$$

where f is the frequency expressed in Hz.

Over the RATED RANGE of voltage waveform and frequency, the LIMITS OF VARIATION of RESPONSE shall not be greater than stated in Table 2.

For each application, except of mammography, compliance with this performance requirement shall be checked by measuring the RESPONSE of the instrument with the detector of the instrument exposed to RADIATION produced by an X-RAY tube, which is supplied with high voltage of the following waveforms: a) single- or two-pulse with pulse duration of 8 ms to 10 ms per pulse; b) DC with a ripple of 0,5 kHz to 1 kHz and of magnitude between 20 % to 25 %, c) DC with a ripple of 5 kHz to 15 kHz and of magnitude between 8 % to 15 %; the measured RESPONSE ~~has to~~ shall be compared with the RESPONSE under REFERENCE CONDITIONS; d) DC with ripple less than 4 %. A high voltage divider system shall be used in each case a) to d) to obtain the CONVENTIONAL TRUE VALUE for the PRACTICAL PEAK VOLTAGE from the waveform of the high voltage supplied to the X-RAY TUBE. Tests shall be made at the test value indicated in Table 3 for each application. If the rated range contains waveforms which are not included in the MINIMUM RATED RANGE stated in Table 2 (e.g., higher frequency and/or greater ripple), additional tests at the limits of the rated range shall be performed.

For mammography, compliance ~~has~~ shall only ~~to~~ be checked if the rated range stated for the mammography application range includes voltage waveforms other than constant potential. In this case compliance shall be checked in the same way as described above for each additional waveform.

4.4.3 Dependence of instrument RESPONSE on ANODE ANGLE

The MINIMUM RATED RANGE of ANODE ANGLE of X-RAY tubes is given in Table 2. Over the RATED RANGE of ANODE ANGLE, the LIMITS OF VARIATION of the RESPONSE shall not be greater than stated in Table 2.

Compliance test for this performance requirement is not necessary because the change in the spectral photon distribution of the X-RADIATION due to changes in the ANODE ANGLE within its rated range is less than the change of spectral photon distribution due to changes in filtration.

4.4.4 Dependence of instrument RESPONSE on FILTRATION

The MINIMUM RATED RANGE of filtration of X-RAY tubes is given in Table 2 for different applications. Over the RATED RANGE of FILTRATION, the LIMITS OF VARIATION of RESPONSE shall not be greater than stated in Table 2.

Compliance with this performance requirement shall be checked by measuring the RESPONSE of the instrument with the detector of the instrument exposed to the minimum and the maximum rated filtration and compared with a reference set of readings at reference filtration. Tests shall be made at the minimum test points indicated in Table 3 and in 4.4.1 to show compliance over the EFFECTIVE RANGE of voltages.

4.4.5 Dependence of instrument RESPONSE on dose rate

The MINIMUM RATED RANGE of dose rate is given in Table 2 for different applications. Over the RATED RANGE of dose rate, the LIMITS OF VARIATION of RESPONSE shall not be greater than stated in Table 2.

Compliance with this performance requirement shall be checked by measuring the RESPONSE of the instrument with the detector of the instrument exposed to the minimum and the maximum rated dose rate and at least three measurement points per decade over the rated range of dose rate. The measurements ~~have to~~ shall be compared with those obtained by an invasive high voltage divider system. If the detector focus distance or the RADIATION QUALITY ~~must~~ shall be changed to provide the necessary dose rates, measurements shall overlap at the dose rate values where these changes are performed. In this case a CORRECTION FACTOR (see note) ~~may~~ can be used to compensate possible VARIATIONS of RESPONSE due to the change of distance and/or RADIATION QUALITY. This CORRECTION FACTOR is the quotient of the MEASURED VALUE after the change of the measurement conditions and the value before the change, both values measured at the same dose rate.

NOTE This CORRECTION FACTOR is only used during the compliance test and ~~shall compensate~~ compensates the changes in RESPONSE of the instrument which are due to the changes in the test conditions only (deviation from STANDARD TEST CONDITIONS) and not due to changes in the dose rate. The CORRECTION FACTOR assures that the readings of the instrument under different measurement conditions are the same for the same dose rate in the overlapping region.

4.4.6 Dependence of instrument RESPONSE on IRRADIATION TIME

The MINIMUM RATED RANGE of IRRADIATION TIME is stated in Table 2. Over the RATED RANGE of IRRADIATION TIME, the LIMITS OF VARIATION of RESPONSE shall not be greater than that stated in Table 2.

Compliance with this performance requirement shall be checked by measuring the RESPONSE of the instrument with the detector of the instrument exposed to the minimum and the maximum rated IRRADIATION TIME and compared with a reference set of readings at reference IRRADIATION TIME. A high voltage divider system shall be used to control and – if necessary – to correct the high voltage of the X-RAY GENERATOR when IRRADIATION TIMES are selected which are different from REFERENCE CONDITIONS. Tests shall be made at the test value indicated in Table 3 for each application.

4.4.7 Dependence of instrument RESPONSE on field size

4.4.7.1 General

The ACCOMPANYING DOCUMENTS shall state the nominal value and the RATED RANGE of field size. The MINIMUM RATED RANGE of field size is given in Table 2.

4.4.7.2 Dependence of instrument RESPONSE on field size variations over the RATED RANGE

Over the RATED RANGE of field size, the LIMITS OF VARIATION of RESPONSE shall not be greater than stated in Table 2.

Compliance with this performance requirement shall be checked by measuring the RESPONSE of the instrument with the detector of the instrument exposed to the minimum and the maximum RATED FIELD SIZE and compared with a reference set of readings at nominal field size.

4.4.7.3 Dependence of instrument RESPONSE on large field size

When exposed to a field of 30 cm by 30 cm, the LIMITS OF VARIATION of RESPONSE shall not be greater than stated in Table 2.

Compliance with this performance requirement shall be checked by measuring the RESPONSE of the instrument with the detector of the instrument exposed to an X-RAY FIELD of 30 cm by 30 cm and compared with a reference set of readings at nominal field size.

4.4.8 Dependence of instrument RESPONSE on focus-to-detector distance

The MINIMUM RATED RANGE of distance from the FOCAL SPOT of the X-RAY TUBE to the detector is given in Table 2. Over the RATED RANGE of distance, the LIMITS OF VARIATION of RESPONSE shall not be greater than stated in Table 2.

Compliance with this performance requirement shall be checked by measuring the RESPONSE of the instrument with the detector of the instrument exposed to the minimum and the maximum rated distance from the FOCAL SPOT and compared with a reference set of readings at reference distance. During the test, the field size and the dose rate to the detector shall always be the same. Tests shall be made at the test value indicated in Table 3 for each application.

4.4.9 Dependence of instrument RESPONSE on angle of incidence of RADIATION

The MINIMUM RATED RANGE of angle of incidence from the normal direction of incidence is given in Table 2. Over the RATED RANGE of angle of incidence, the LIMITS OF VARIATION of RESPONSE shall not be greater than stated in Table 2.

Compliance with this performance requirement shall be checked by measuring the RESPONSE of the instrument with the detector of the instrument tilted to the outmost boundaries of the RATED RANGE of angle of incidence in two perpendicular directions from a position perpendicular to the axis of the beam and compared with a reference set of readings at perpendicular incidence. Tests shall be made at the test value indicated in Table 3 for each application.

4.4.10 Dependence of instrument RESPONSE on angle of detector rotation with respect to the X-RAY TUBE axis

4.4.10.1 Dependence of instrument RESPONSE for instruments stated by the MANUFACTURER to have a preferred direction of alignment

If there is a preferred direction of alignment it ~~must~~ shall be stated by the MANUFACTURER. When the detector is rotated by ±10° from the preferred direction, the LIMITS OF VARIATION of RESPONSE shall not be greater than stated in Table 2.

Compliance with this performance requirement shall be checked by measuring the RESPONSE of the instrument with the detector of the instrument rotated first by +10° then by –10° from the preferred direction in the plane perpendicular to the incident X-RAY BEAM and compared to a reference set of readings at the preferred direction. Tests shall be made at the test value indicated in Table 3 for each application.

4.4.10.2 Dependence of instrument RESPONSE for instruments stated by the MANUFACTURER to have no preferred direction of alignment

If there is no preferred direction of alignment it ~~must~~ shall be stated by the MANUFACTURER. When the detector is rotated through 180°, LIMITS OF VARIATION of RESPONSE shall not be greater than stated in Table 2.

Compliance with this performance requirement shall be checked by measuring the RESPONSE of the instrument when the detector of the instrument is rotated by 45°, 90°, 135°, and 180° from the original orientation in the plane perpendicular to the incident X-RAY BEAM and compared to a reference set of readings at the original (0°) direction. Tests shall be made at the test value indicated in Table 3 for each application.

4.4.11 Dependence of instrument RESPONSE on temperature and humidity

The LIMITS OF VARIATION of the instrument RESPONSE shall be not greater than the value given in Table 2, for all possible temperature and humidity conditions within the RATED RANGES of temperature and humidity.

Compliance with this performance requirement shall be checked by carrying out the following test. The instrument shall be exposed to varying temperature and air humidities. At least three measurements shall be performed, one under each of the following climatic conditions:

temperature	*relative humidity*
20 °C	*50 %*
15 °C	*80 %*
35 °C	*50 %*

The instrument shall be exposed to each different temperature and humidity condition for at least 24 h before the instrument is tested. Tests ~~may~~ can be made by exposing the instrument to X-RADIATIONS at the test value indicated in Table 3, or the MANUFACTURER ~~may~~ can provide a means to electrically simulate the signal by using stable reference currents to demonstrate the proper operation of the instrument without IRRADIATION.

4.4.12 Dependence of instrument RESPONSE on operating voltage

4.4.12.1 For mains-operated instruments the LIMIT OF VARIATION of RESPONSE due to VARIATION of the operating voltage between the limits found in Table 2 of the nominal voltage shall not be greater than stated in Table 2, over the RATED RANGE of mains voltage stated by the MANUFACTURER.

Compliance with this performance requirement shall be checked by taking two sets of readings with the voltage of the SUPPLY MAINS adjusted to the upper and lower boundaries of the RATED RANGE of operating voltage stated by the MANUFACTURER and compared with a reference set of readings at nominal operating voltage. Tests ~~may~~ can be made by IRRADIATION at the test value indicated in Table 3, or the MANUFACTURER ~~may~~ can provide a means to electrically simulate the signal by using stable reference currents to demonstrate the proper operation of the instrument without IRRADIATION.

4.4.12.2 Over the rated range of battery voltage, the LIMIT OF VARIATION of RESPONSE shall not be greater than stated in Table 2. For battery-operated instruments, a low battery condition shall be indicated if the instrument is operating when the battery voltage is outside the rated range stated by the MANUFACTURER. Furthermore, the instrument shall not display a measurement if the battery voltage is outside the rated range.

Compliance with this performance requirement shall be checked as follows: the batteries shall be replaced by a stable DC power supply producing a voltage equivalent to the voltage produced by a set of fresh batteries of the type specified by the MANUFACTURER. A set of reference readings shall be taken, and the voltage decreased until the battery power indicator *begins to show "low battery" condition. A second set of readings shall then be taken and compared with the REFERENCE VALUE. Tests ~~may~~ can be made by IRRADIATION at the test value indicated in Table 3, or the MANUFACTURER ~~may~~ can provide a means to electrically simulate the signal by using stable reference currents to demonstrate the proper operation of the instrument without IRRADIATION.*

NOTE In some instruments, connection to an external supply with a cable ~~may~~ can compromise the instrument shield, or batteries ~~may~~ are possibly not ~~be~~ at chassis ground. In these cases, the MANUFACTURER ~~shall provide~~ provides proper guidance on the test method.

4.4.12.3 For mains rechargeable, battery-operated instruments in addition to the requirements on battery powered instruments, the LIMIT OF VARIATION of RESPONSE shall not be greater than stated in Table 2 when the instrument is operated under the following conditions:

– mains disconnected, battery fresh;
– mains connected, battery fresh;
– mains connected, battery low.

Compliance with this performance requirement shall be checked as follows: the reference reading shall be taken with the mains disconnected and a set of fresh batteries of the type specified by the MANUFACTURER fitted. The mains shall then be connected, and a second set of readings taken and compared with the reference reading. Finally, a set of used batteries which are just spent enough to cause the "battery low" indication to show shall be fitted, and with the mains connected a third set of readings shall be taken and compared with the reference reading. Tests ~~may~~ can be made by IRRADIATION at the test value indicated in Table 3, or the MANUFACTURER ~~may~~ can provide a means to electrically simulate the signal by using stable reference currents to demonstrate the stability of the instrument without IRRADIATION.

4.4.13 Dependence of instrument RESPONSE on electromagnetic compatibility

4.4.13.1 Electrostatic discharge

The maximum spurious indications (both transient and permanent) of the display or data output due to electrostatic discharge shall not exceed the limits given in Table 2.

Compliance with this performance requirement shall be checked by observing and recording the indications of the display and any data output terminals while discharging a suitable test generator as described in IEC 61000-4-2 at least five times to those various external parts of the complete equipment which ~~may~~ can be touched by the OPERATOR during a normal measurement (i.e., not to those parts that are normally exposed in the RADIATION beam). The electrostatic discharge shall be equivalent to that from a capacitor of 150 pF charged to a voltage of 6 kV and discharged through a resistor of 330 Ω (severity level 3 for contact discharge as described in IEC 61000-4-2). When instruments with insulated surfaces are tested, the air discharge method with a voltage of 8 kV (severity level 3) shall be used. Tests ~~may~~ can be made by IRRADIATION at the test value indicated in Table 3, or the MANUFACTURER ~~may~~ can provide a means to electrically simulate the signal by using stable reference currents to demonstrate the stability of the instrument without IRRADIATION. In that case the X-RAY DETECTORS ~~must~~ shall remain connected in the circuit as they provide a possible path for electrical disturbances to enter the instrument.

NOTE Complete "latch-up" of the instrument which would not lead to an incorrect value being indicated is ~~allowed~~ possible.

4.4.13.2 Radiated electromagnetic fields

The maximum spurious indications (both transient and permanent) of the display or data output terminals due to electromagnetic fields shall be less than the limits given in Table 2.

Compliance with this performance requirement shall be checked by observing and recording the indications of the display and any data output terminals while measurements are performed, both with and without the presence of the radio-frequency field around the complete equipment.

The electromagnetic field strength shall be 3 V/m in the frequency range of 80 MHz to ~~1~~ 6 GHz in steps of 1 % (severity level 2 as described in IEC 61000-4-3). For battery-operated instruments~~, for which the requirements of 6.8.3 and 6.8.4 do not apply~~, tests at 27 MHz shall also be performed. To reduce the number of measurements needed to show compliance with this requirement, tests at frequencies 27, 80, 90, 100, 110, 120, 130, 140, 150, 160, 180, 200, 220, 240, 260, 290, 320, 350, 380, 420, 460, 510, 560, 620, 680, 750, 820, 900, 1 000, 2 000, 3 000, 4 000, 5 000, and 6 000 MHz with a field strength of 10 V/m ~~may~~ can be performed in one orientation only. If any change of the RESPONSE greater than one-third of the limits given in Table 2 is observed at one of these given frequencies, additional tests in the range of ± 5 % around this frequency in steps of 1 % and with a field strength of 3 V/m shall be carried out with the instrument in all three orientations as described in IEC 61000-4-3. Tests ~~may~~ can be made by IRRADIATION at the test value indicated in Table 3, or the MANUFACTURER ~~may~~ can provide a means to electrically simulate the signal by using stable reference currents to demonstrate the stability of the instrument without IRRADIATION. In that case the X-RAY DETECTORS ~~must~~ shall remain connected in the circuit as they provide a possible path for electrical disturbances to enter the instrument.

4.4.13.3 Conducted disturbances induced by bursts and radio frequencies

The maximum spurious indications (both transient and permanent) of the display or data output terminals due to conducted disturbances induced by bursts and radio frequencies shall be less than the limits given in Table 2.

For mains-operated instruments, compliance shall be checked by observing and recording the indications of the display and any data output terminals both with and without the presence of conducted disturbances induced by bursts (IEC 61000-4-4) and conducted disturbances induced by radio-frequency fields (IEC 61000-4-6). The severity level shall in both cases be level 3 as described in these documents. Tests ~~may~~ can be made by IRRADIATION at the test value indicated in Table 3, or the MANUFACTURER ~~may~~ can provide a means to electrically simulate the signal by using stable reference currents to demonstrate the stability of the instrument without IRRADIATION. In that case the X-RAY DETECTORS ~~must~~ shall remain connected in the circuit as they provide a possible path for electrical disturbances to enter the instrument.

NOTE Complete "latch-up" of the instrument which would not lead to an incorrect value being indicated is ~~allowed~~ possible.

4.4.13.4 Voltage dips, short interruptions and voltage variations

The maximum spurious indications (both transient and permanent) of the display or data output terminals due to voltage dips, short interruptions and voltage VARIATIONS shall be less than the limits given in Table 2.

For mains-operated instruments compliance with this performance requirement shall be checked by observing and recording the indications of the display and any data output terminals while measurements are performed on the most sensitive range, both with and without the presence of conducted disturbances induced by voltage dips, short interruptions and voltage VARIATIONS as described in IEC 61000-4-11. Tests ~~may~~ can be made by IRRADIATION at the test value indicated in Table 3, or the MANUFACTURER ~~may~~ can provide a means to electrically simulate the signal by using stable reference currents to demonstrate the stability of the instrument without IRRADIATION. In that case the X-RAY detectors ~~must~~ shall remain connected in the circuit as they provide a possible path for electrical disturbances to enter the instrument.

4.4.13.5 Surges

The maximum spurious indications (both transient and permanent) of the display or data output due to surges shall be less than the limits given in Table 2.

For mains-operated instruments compliance shall be checked by observing and recording the indications of the display and any data output terminals while measurements are performed on the most sensitive range (if the ranges are selectable), both with and without the presence of *disturbances induced by surges (IEC 61000-4-5). The severity level shall be level 3 as described in this document.*

NOTE Complete "latch-up" of the instrument which would not lead to an incorrect value being indicated is ~~allowed~~ possible.

4.4.14 Additional tungsten filtration (tube aging)

Over the RATED RANGE of additional tungsten filtration, the LIMITS OF VARIATION of RESPONSE shall not be greater than stated in Table 2.

NOTE The higher the age of an X-RAY TUBE, the anode roughens more and more depending on the cumulative heat load during its total operation time. The roughening of the anode results in a hardening of the spectral photon distribution, which can be simulated by additional tungsten filtration, where zero filtration represents a new tube, and 10 µm W an X-RAY TUBE near the end of its lifetime, respectively.

Before performing this test, it should be proved that the X-RAY TUBE used for this test is of moderate age, corresponding to an additional filtration of 0 µm W to 3 µm W as required for the STANDARD TEST CONDITIONS. This can be shown under the following conditions: 70 kV tube voltage and 3,0 mm Al total filtration, by measuring the Al-HALF-VALUE LAYER (HVL) which should be less than the values in Table 4, depending on the anode angle of the tube.

Table 4 – Maximum HALF-VALUE LAYER (HVL) depending on anode angle

Anode angle (°)	6	8	10	12	14	16	18
HVL (mm Al)	3,23	3,07	2,98	2,91	2,86	2,83	2,80

Compliance with the performance requirement shall now be checked by measuring the RESPONSE of the instrument with the detector of the instrument exposed to the minimum and the maximum rated additional tungsten filtration and compared with a reference set of readings at reference filtration (with 3 µm additional tungsten filtration). Tests shall be made at the minimum test points indicated in Table 3 and in 4.4.1 to show compliance over the EFFECTIVE RANGE of voltages.

5 Special instrumental requirements and marking

5.1 Requirements for the complete instruments

The MANUFACTURER shall state for all INFLUENCE QUANTITIES the range of use. With regard to electric safety the requirements of IEC 61010-1 shall be fulfilled.

5.2 General

All electrical connections, controls and display shall be clearly indicated with relation to their function. Where appropriate, symbols from IEC 60417 and ISO 7000 shall be used. Permanent markings shall include

- identification of the MANUFACTURER;
- model number and serial number of the instrument.

In addition, during use it shall be clearly indicated

- when the instrument is not ready to take a measurement;
- the range of measurement;
- the result of measurement, including units, whether the measurement is out of range, and what corrections are applied if any;
- other warnings such as "low battery".

The state of all OPERATOR programmable instrument settings shall be retrievable.

5.3 Display

Instruments which comply with this document ~~must~~ shall have a digital display. The display ~~must~~ shall show the unit of quantity measured. Within the whole EFFECTIVE RANGE of INDICATED VALUES the resolution of the reading shall be at least 0,5 %.

5.4 Range of measurement

If an instrument's measurement range consists of two or more partial ranges of measurement, the partial ranges ~~must~~ shall overlap at their boundaries. Requirement 4.2.2 shall be applied to each of the partial ranges if the instrument does not switch automatically to the next range.

5.5 Connectors and cables

Connectors and cables shall be clearly marked or of different design to avoid improper connections.

6 ACCOMPANYING DOCUMENTS

6.1 General

The ACCOMPANYING DOCUMENTS shall comply with IEC 61187~~:1993~~.

6.2 Information provided

The MANUFACTURER shall provide adequate information describing the correct use of the instrument.

6.3 Instrument description

The ACCOMPANYING DOCUMENTS shall contain a description of the instrument, including its type number, MANUFACTURER, and range of intended use.

6.4 Detector

The MANUFACTURER shall state the type of detector(s) and the physical principle used to determine the PRACTICAL PEAK VOLTAGE.

6.5 Delay time

The MANUFACTURER shall state whether the instrument has a delay time function and if it can be modified by the OPERATOR.

6.6 Measurement window

The MANUFACTURER shall state the period over which the instrument samples the waveform.

6.7 Data outlet

The MANUFACTURER shall state whether a detector unit has the ability to provide data for further evaluation by recorder or computer. The MANUFACTURER ~~must~~ shall describe in the ACCOMPANYING DOCUMENTS whether this signal is proportional to voltage or dose rate and information ~~must~~ shall be given about the time constant and resolution.

6.8 Transport and storage

The MANUFACTURER shall state any special requirements for transport and storage. All components of the complete instrument ~~must~~ shall be designed for transport and storage in the range of temperature from −20 °C to +50 °C.

Annex A
(informative)

Recommended performance criteria for the invasive divider

A.1 General

An invasive divider used to determine the value of the high voltage applied to the X-RAY TUBE must be well characterized over the range X-RAY TUBE VOLTAGES and VOLTAGE WAVEFORMS used during performance testing of non-invasive high-voltage meters. The invasive divider should be connected between the X-RAY GENERATOR and the X-RAY TUBE and be used for all high-voltage determinations which may be required for the computation of PRACTICAL PEAK VOLTAGE (PPV). The invasive divider should be frequency compensated and calibrated for DC accuracy and frequency RESPONSE by a NATIONAL LABORATORY.

A.2 Electrical rating (MAXIMUM PEAK VOLTAGES)

- Anode to cathode: ≥150 kVp
- Anode to ground: ≥80 kVp
- Cathode to ground: ≥80 kVp
- Direct Current voltage division ratio: ≥10:000:1
- Division ratio accuracy: ±1 %
- Voltage divider load: ≥100 MΩ to ground
- Frequency RESPONSE: ±1 dB from 0 kHz to 100 kHz
- Duty cycle: continuous

Use of CORRECTION FACTORS will allow ±0,5 % accuracy.

Annex A
(informative)

Combined standard uncertainty

The COMBINED STANDARD UNCERTAINTY for the performance of a hypothetical instrument for the NON-INVASIVE MEASUREMENT of the tube high voltage operating at the maximum limits of PERFORMANCE CHARACTERISTICS according to Clause 4 and LIMITS OF VARIATION L for the effects of INFLUENCE QUANTITIES according to Table 2 was estimated. The uncertainty components and the results are shown in Table A.1.

Table A.1 – Example for assessment of the COMBINED STANDARD UNCERTAINTY – Instruments used for NON-INVASIVE MEASUREMENT of X-RAY TUBE VOLTAGE

INFLUENCE QUANTITY or PERFORMANCE CHARACTERISTIC	Subclause	$\pm L$ %	Relative standard uncertainty %
Voltage waveform and frequency [a]	4.4.2	2,0	1,15
Anode angle [a]	4.4.3	0,5	0,289
Filtration [a]	4.4.4	1,5	0,866
Dose rate [a]	4.4.5	0,5	0,289
Irradiation time [a]	4.4.6	0,5	0,289
Field size: Rated range [a]	4.4.7.2	0,5	0,289
Field size: large [a]	4.4.7.3	2,0	1,15
Detector-Focal distance [a]	4.4.8	0,5	0,289
Angle of incidence [a]	4.4.9	0,5	0,289
Rotation [a]	4.4.10	0,5	0,289
Temperature and relative humidity [a]	4.4.11	1,0	0,577
Power supply [a]	4.4.12	0,5	0,289
Electromagnetic compatibility [a]	4.4.13	1,0	0,577
Additional tungsten filtration (tube aging) [a]	4.4.14	2,0	1,15
COMBINED STANDARD UNCERTAINTY for PERFORMANCE CHARACTERISTICS, k = 1 [b]			2,5
COMBINED STANDARD UNCERTAINTY for PERFORMANCE CHARACTERISTICS, k = 2 [c]			4,9
CALIBRATION		2,0	1,15
COMBINED STANDARD UNCERTAINTY, k = 2			5,4

[a] Uniform probability distribution, symmetric limits $\pm L$, i.e. relative uncertainty = $L/\sqrt{3}$.

[b] Root-mean-square of relative uncertainties.

[c] Root-mean-square of relative uncertainties, multiplied by 2.

Annex B
(informative)

Additional information on practical peak voltage

B.1 ~~Introduction~~ Overview

The PRACTICAL PEAK VOLTAGE is based on the concept that the RADIATION generated by a high voltage of any waveform produces the same AIR KERMA contrast behind a specified PHANTOM as a RADIATION generated by an equivalent constant potential. The constant potential producing the same contrast as the waveform under test is defined as PRACTICAL PEAK VOLTAGE.

For the determination of the PRACTICAL PEAK VOLTAGE for a specified waveform, the X-RAY spectrum produced by an X-RAY TUBE supplied with this non-constant potential ~~has to~~ shall be calculated. Using this spectrum, the ratio of AIR KERMA behind a PHANTOM and the AIR KERMA behind the PHANTOM plus a contrast material can then be calculated (for the application range "conventional diagnostic" a PHANTOM of 10 cm PMMA and a contrast material of 1,0 mm Al is used). Then, in a corresponding way, a constant potential giving the same AIR KERMA ratio for the same contrast configuration can be found. This is the PRACTICAL PEAK VOLTAGE for the given waveform. This complex procedure is only necessary for the correct determination of the quantity PRACTICAL PEAK VOLTAGE. For practical use it can be substituted for all waveforms by a simplified formalism described below~~.[2]~~ [1].[3]

B.2 Simplified formalism for the determination of the PRACTICAL PEAK VOLTAGE $\hat{U}$

For a given probability distribution $p(U_\text{i})$ for the occurrence of a value of the voltage in the interval $[U_\text{i} - \Delta U/2, U_\text{i} + \Delta U/2]$, the PRACTICAL PEAK VOLTAGE $\hat{U}$ can be directly calculated by:

$$\hat{U} = \frac{\sum_{i=1}^{n} \mathrm{p}(U_\text{i}) \times w(U_\text{i}) \times U_\text{i}}{\sum_{i=1}^{n} \mathrm{p}(U_\text{i}) \times w(U_\text{i})} \quad \text{(B.1)}$$

When U_i is in units of kV, the weighting function $w(U_\text{i})$ can be approximated with sufficient accuracy by the following formulas:

in the voltage region of U_i < 20 kV, by

$$w(U_\text{i}) = 0 \quad \text{(B.2)}$$

in the voltage region of 20 kV ≤ U_i < 36 kV, by

~~[2] Detailed information about the whole concept and the computational methods can be found in KRAMER, H-M., SELBACH H-J., ILES, WJ. The PRACTICAL PEAK VOLTAGE of diagnostic X-RAY generators. *British Journal of Radiology*, 1998, 77, p.200-209.~~

[3] Numbers in square brackets refer to the Bibliography.

$$w(U_\mathrm{i}) = \exp\left\{a \times U_\mathrm{i}^2 + b \times U_\mathrm{i} + c\right\} \tag{B.3}$$

where

a = ~~−8,646855E-03~~ $-8{,}646\,855 \times 10^{-03}$

b = ~~+8,170361E-01~~ $+8{,}170\,361 \times 10^{-01}$

c = ~~−2,327793E+01~~ $-2{,}327\,793 \times 10^{01}$

and for the voltage region of 36 kV < U_i ≤ 150 kV, by

$$w(U_\mathrm{i}) = d \times U_\mathrm{i}^4 + e \times U_\mathrm{i}^3 + f \times U_\mathrm{i}^2 + g \times U_\mathrm{i} + h \tag{B.4}$$

where

d = ~~+4,310644E-10~~ $+4{,}310\,644 \times 10^{-10}$

e = ~~−1,662009E-07~~ $-1{,}662\,009 \times 10^{-07}$

f = ~~+2,308190E-05~~ $+2{,}308\,190 \times 10^{-05}$

g = ~~+1,030820E-05~~ $+1{,}030\,820 \times 10^{-05}$

h = ~~−1,747153E-02~~ $-1{,}747\,153 \times 10^{-02}$

For the definition (see 3.16) the formula for $\hat{U}$ is generalized by using integral expressions instead of the summations, which however does not affect the values for the weighting function.

The above formula and the given values for the parameters a to h are valid for the application ranges "conventional diagnostic", "CT", "dental" and "fluoroscopic".

For mammography in the voltage region of U_i ≤ 50 kV the formula and the values for the parameters k to o as given below are to be used.

$$w(U_\mathrm{i}) = \exp\left\{k \times U_\mathrm{i}^4 + l \times U_\mathrm{i}^3 + m \times U_\mathrm{i}^2 + n \times U_\mathrm{i} + o\right\} \tag{B.5}$$

where

k = ~~−2,142352E-06~~ $-2{,}142\,352 \times 10^{-06}$

l = ~~+2,566291E-04~~ $+2{,}566\,291 \times 10^{-04}$

m = ~~−1,968138E-02~~ $-1{,}968\,138 \times 10^{-02}$

n = ~~+8,506836E-01~~ $+8{,}506\,836 \times 10^{-01}$

o = ~~−1,514362E+01~~ $-1{,}514\,362 \times 10^{+01}$

NOTE This formula is defined only for waveforms containing no voltage peaks greater than 50 kV.

Figure B.1 and Figure B.2 show two examples of determination of the PRACTICAL PEAK VOLTAGE (straight line) for two extremely different waveforms using the formalism given above.

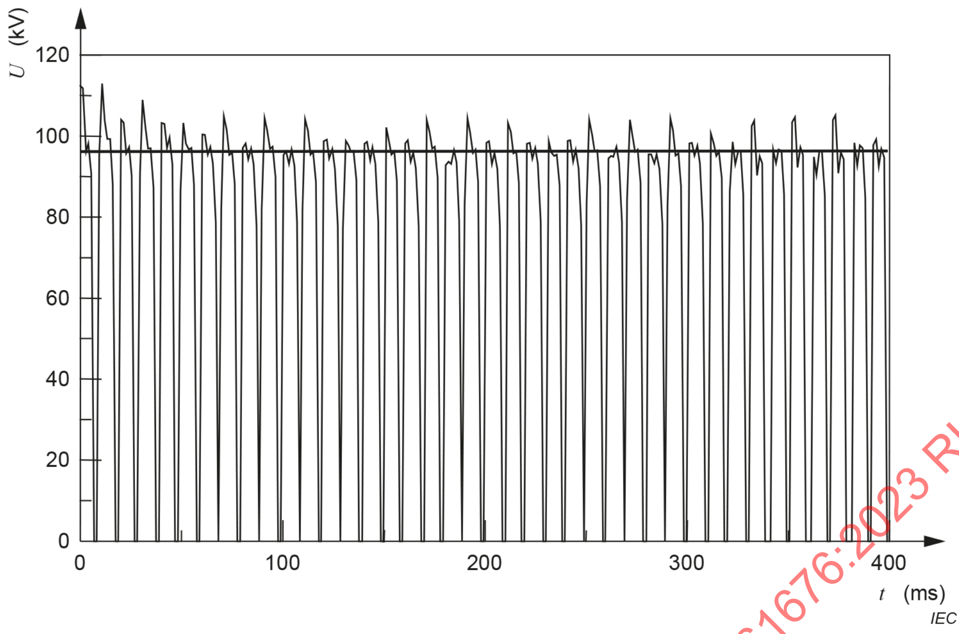

Figure B.1 – Example of a waveform of a two-pulse generator

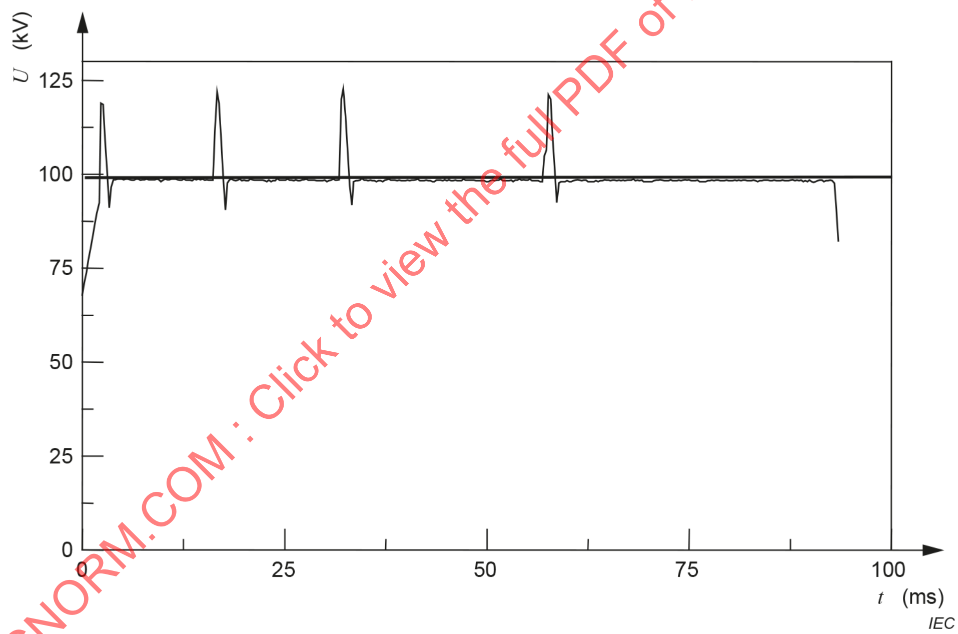

Figure B.2 – Example of a waveform of a constant-voltage generator

The following example (see Figure B.3) shows for the case of a falling load waveform how the simplified formalism for the determination of the PRACTICAL PEAK VOLTAGE $\hat{U}$ ~~is to~~ shall be used. The number of the samples taken is reduced to 20, to show only the principle of the calculation. The values of the 20 samples are listed in ~~table B.4~~ Table B.1.

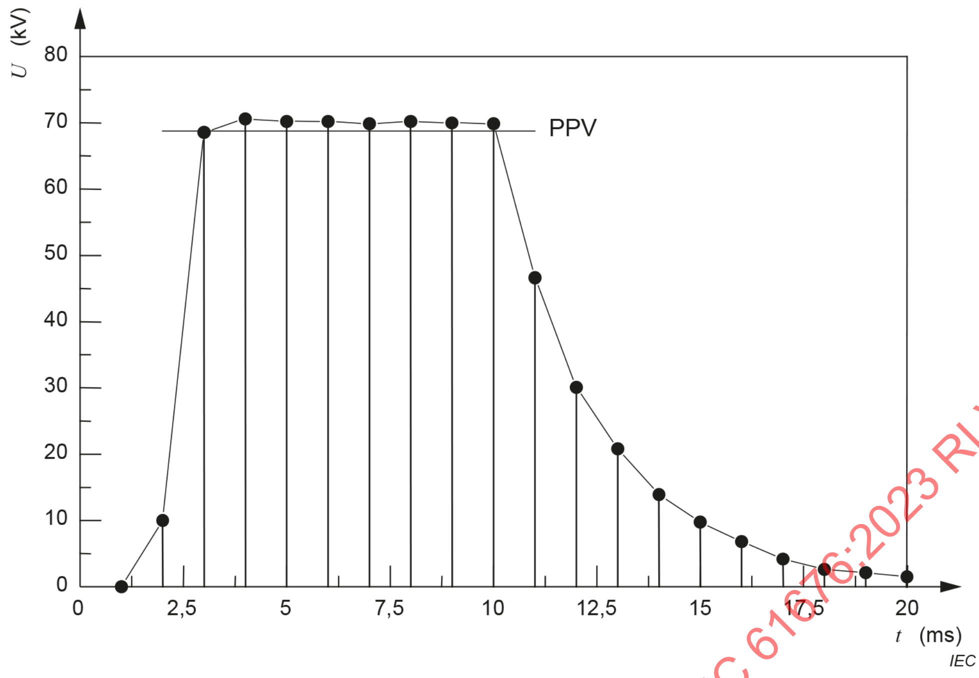

Figure B.3 – Example of falling load waveform

Table B.1 – Values of 20 samples of the falling load waveform in Figure B.3

Sample No. i	Sample value U_i/kV
1	0,00
2	10,00
3	68,60
4	70,60
5	70,20
6	70,20
7	69,90
8	70,20
9	70,00
10	69,90
11	46,60
12	30,10
13	20,80
14	13,90
15	9,80
16	6,80
17	4,20
18	2,60
19	2,10
20	1,50

With an interval of ΔU = 0,1 kV one obtains from the voltage samples in Table B.1 the voltage bins $U_i - \Delta U/2$ to $U_i + \Delta U/2$ and the probability distribution $p(U_i)$ as given in columns 2 and 3 of Table B.2. Using the indicated formulas (column 4) the values for $w(U_i)$, $p(U_i) \times w(U_i) \times U_i$ and $p(U_i) \times w(U_i)$ can be calculated. The quotient of the sum of the two last columns gives the PRACTICAL PEAK VOLTAGE (Formula (B.6)).

Table B.2 – Voltage bins, probability and weighting factors for the 20 samples of the falling load waveform in Figure B.3

U_i	$U_i - \Delta U/2$ to $U_i + \Delta U/2$	$p(U_i)$	Formula	$w(U_i)$	$p(U_i) \times w(U_i) \times U_i$	$p(U_i) \times w(U_i)$
kV	kV					
< 20	< 20,05	9	(B.2)	~~0,0000E + 00~~ 0,000 0 × 10^{+00}	~~0,0000E + 00~~ 0,000 0 × 10^{+00}	~~0,0000E + 00~~ 0,000 0 × 10^{+00}
20,80	20,75 to 20,85	1	(B.3)	~~4,4299E – 05~~ 4,429 9 × 10^{-05}	~~9,2141E – 04~~ 9,214 1 × 10^{-04}	~~4,4299E – 05~~ 4,429 9 × 10^{-05}
30,10	30,05 to 30,15	1	(B.3)	~~1,4747E – 03~~ 1,474 7 × 10^{-03}	~~4,4389E – 02~~ 4,438 9 × 10^{-02}	~~1,4747E – 03~~ 1,474 7 × 10^{-03}
46,60	46,55 to 46,65	1	(B.4)	~~1,8347E – 02~~ 1,834 7 × 10^{-02}	~~8,5495E – 01~~ 8,549 5 × 10^{-01}	~~1,8347E – 02~~ 1,834 7 × 10^{-02}
68,60	68,55 to 68,65	1	(B.4)	~~4,7750E – 02~~ 4,775 0 × 10^{-02}	~~3,2757E + 00~~ 3,275 7 × 10^{+00}	~~4,7750E – 02~~ 4,775 0 × 10^{-02}
69,90	69,85 to 69,95	2	(B.4)	~~4,9555E – 02~~ 4,955 5 × 10^{-02}	~~6,9278E + 00~~ 6,927 8 × 10^{+00}	~~9,9110E – 02~~ 9,911 0 × 10^{-02}
70,00	69,95 to 70,05	1	(B.4)	~~4,9694E – 02~~ 4,969 4 × 10^{-02}	~~3,4786E + 00~~ 3,478 6 × 10^{+00}	~~4,9694E – 02~~ 4,969 4 × 10^{-02}
70,20	70,15 to 70,25	3	(B.4)	~~4,9972E – 02~~ 4,997 2 × 10^{-02}	~~1,0524E + 01~~ 1,052 4 × 10^{+01}	~~1,4992E – 01~~ 1,499 2 × 10^{-01}
70,60	70,55 to 70,65	1	(B.4)	~~5,0529E – 02~~ 5,052 9 × 10^{-02}	~~3,5673E + 00~~ 3,567 3 × 10^{+00}	~~5,0529E – 02~~ 5,052 9 × 10^{-02}
		∑ = 20			~~∑ = 2,8674E + 01~~ ∑ = 2,867 4 × 10^{+01}	~~∑ = 4,1686E – 01~~ ∑ = 4,168 6 × 10^{-01}

$$\hat{U} = \frac{28{,}674\ 1}{0{,}416\ 86} = 68{,}78 \text{ kV} \qquad \text{(B.6)}$$

If, as in most cases, the sampling rate is constant, which means that the samples are taken in equal time intervals, the probability distribution can be set to 1 for all samples, and Formula (B.1) reduces to the simple formula:

$$\hat{U} = \frac{\sum_{i=1}^{n} w(U_i) \times U_i}{\sum_{i=1}^{n} w(U_i)} \qquad \text{(B.7)}$$

and the PRACTICAL PEAK VOLTAGE can be calculated as shown in Table B.3 and Formula (B.8).

Table B.3 – Weighting factors for the 20 equally spaced samples of the falling load waveform in figure B.3

i	U_i kV	Formula	$w(U_i)$	$w(U_i) \times U_i$
1	0,00	(B.2)	~~0,0000E + 00~~ 0,000 0 × 10^{+00}	~~0,0000E + 00~~ 0,00 00 × 10^{+00}
2	10,00	(B.2)	~~0,0000E + 00~~ 0,000 0 × 10^{+00}	~~0,0000E + 00~~ 0,000 0 × 10^{+00}
3	68,60	(B.4)	~~4,7750E – 02~~ 4,775 0 × 10^{-02}	~~3,2757E + 00~~ 3,275 7 × 10^{+00}
4	70,60	(B.4)	~~5,0529E – 02~~ 5,052 9 × 10^{-02}	~~3,5673E + 00~~ 3,567 3 × 10^{+00}
5	70,20	(B.4)	~~4,9972E – 02~~ 4,997 2 × 10^{-02}	~~3,5081E + 00~~ 3,508 1 × 10^{+00}
6	70,22	(B.4)	~~5,0000E – 02~~ 5,000 0 × 10^{-02}	~~3,5110E + 00~~ 3,511 0 × 10^{+00}
7	69,90	(B.4)	~~4,9555E – 02~~ 4,955 5 × 10^{-02}	~~3,4639E + 00~~ 3,463 9 × 10^{+00}
8	70,18	(B.4)	~~4,9945E – 02~~ 4,994 5 × 10^{-02}	~~3,5051E + 00~~ 3,505 1 × 10^{+00}
9	70,00	(B.4)	~~4,9694E – 02~~ 4,969 4 × 10^{-02}	~~3,4786E + 00~~ 3,478 6 × 10^{+00}
10	69,90	(B.4)	~~4,9555E – 02~~ 4,955 5 × 10^{-02}	~~3,4639E + 00~~ 3,463 9 × 10^{+00}
11	46,60	(B.4)	~~1,8347E – 02~~ 1,834 7 × 10^{-02}	~~8,5495E – 01~~ 8,549 5 × 10^{-01}
12	30,10	(B.3)	~~1,4747E – 03~~ 1,474 7 × 10^{-03}	~~4,4389E – 02~~ 4,438 9 × 10^{-02}
13	20,80	(B.3)	~~4,4299E – 05~~ 4,429 9 × 10^{-05}	~~9,2141E – 04~~ 9,214 1 × 10^{-04}
14	13,90	(B.2)	~~0,0000E + 00~~ 0,000 0 × 10^{+00}	~~0,0000E + 00~~ 0,000 0 × 10^{+00}
15	9,80	(B.2)	~~0,0000E + 00~~ 0,000 0 × 10^{+00}	~~0,0000E + 00~~ 0,000 0 × 10^{+00}
16	6,80	(B.2)	~~0,0000E + 00~~ 0,000 0 × 10^{+00}	~~0,0000E + 00~~ 0,000 0 × 10^{+00}
17	4,20	(B.2)	~~0,0000E + 00~~ 0,000 0 × 10^{+00}	~~0,0000E + 00~~ 0,000 0 × 10^{+00}
18	2,60	(B.2)	~~0,0000E + 00~~ 0,000 0 × 10^{+00}	~~0,0000E + 00~~ 0,000 0 × 10^{+00}
19	2,10	(B.2)	~~0,0000E + 00~~ 0,000 0 × 10^{+00}	~~0,0000E + 00~~ 0,000 0 × 10^{+00}

20	1,50	(B.2)	~~0,0000E + 00~~ 0,000 0 × 10^{+00}	~~0,0000E + 00~~ 0,000 0 × 10^{+00}
			~~∑ = 4,1687E – 01~~ ∑ = 4,1687 x 10^{-01}	~~∑ = 2,8674E + 01~~ ∑ = 2,8674 x 10^{+01}

$$\hat{U} = \frac{28{,}674}{0{,}416\ 87} = 68{,}78\ \text{kV} \quad (B.8)$$

Annex C
(informative)

Glossary of defined terms

Reference Number	Standard IEC 61676 Term	Paragraph in IEC 61676 (#) is number of occurrences
3.1	CORRECTION FACTOR	3.11, 3.19, 4.4.5(4)*, A.2*
3.2	EFFECTIVE RANGE	4.2.2.1 (3), 4.2.2.2(2), 4.2.3, 4.2.4(2), 4.2.5
3.3	INDICATED VALUE	3.1, 3.2, 3.6, 3.11, 3.12, 3.21, 5.1.2*
3.4	INFLUENCE QUANTITY	3.17(2), 3.19(3), 3.23(2), 3.24, 4.3.3, 4.3.4, 4.3.5(2), Table 2(2), 4.4.1(2)
3.5	INSTRUMENT PARAMETER	3.17(2), 3.18, 3.19(3), 3.22, 3.23(3), 3.24(2)
3.6	INTRINSIC ERROR	3.20, 4.2.2.2(4), 4.2.5, Table 2
3.7	INVASIVE MEASUREMENT	Introduction (2)
3.8	LIMITS OF VARIATION	Introduction, 3.17(2), 4.3*, 4.3.5(2), table2, 4.4.2, 4.4.3, 4.4.4, 4.4.5, 4.4.6, 4.4.7.1, 4.4.7.2, 4.4.8, 4.4.9, 4.4.10.1, 4.4.10.2, 4.4.11
3.9	MAXIMUM PEAK VOLTAGE	A2
3.10	MEAN PEAK VOLTAGE	3.10
3.11	MEASURED VALUE	3.6, 4.2.2.1, 4.2.2.2, 4.4.5
3.12	MINIMUM EFFECTIVE RANGE	4.1.1(2), Table 1, NOTE 1*, 4.2.2.1, 4.2.2.2
3.13	NON-INVASIVE MEASUREMENT	Title, Introduction, Title sec.1), 1, 3.4*
3.14	PERFORMANCE CHARACTERISTIC	Index*, 3.8, 3.24, 4.2*, 4.2.1
3.15	VOLTAGE RIPPLE	3.8, 3.24, 4.2, 4.2.1, 3.15, table 2 NOTE 1, 4.4.2(2)
3.16	PRACTICAL PEAK VOLTAGE	4.1.1(2), 4.2.2.1(3), 4.2.2.2(2), 4.2.3(2), Table 3, 4.4.2, 6.1.4, A1, B.1(6), B.2(4), NOTE 2
3.17	RATED RANGE (OF USE)	4.2.3, 4.2.4, 4.3.2, 4.3.5, table 2(4), 4.4.1, 4.4.2(2), 4.4.3(2), 4.4.4(2), 4.4.5(3), 4.4.6(2), 4.4.7(2), 4.4.7.1(2), 4.4.8(2), 4.4.9)2), 4.4.11, 4.4.12(2), 4.4.12.2(3)
3.18	REFERENCE CONDITIONS	3.1, 3.6, 4.3.3(2), Table 2(2), 4.4.2*, 4.4.6
3.19	REFERENCE VALUE	3.1.8, 4.3.3, Table 2(18), 4.4.12.2
3.20	RELATIVE INTRINSIC ERROR	4.2.2.1(2), 4.2.2.2, 4.2.5
3.21	RESPONSE	Introduction, 3.1.4, 4.2.5(2), 4.3.5, 4.4.2(4), 4.4.3(2), 4.4.4(3), 4.4.5(5), 4.4.6(3), 4.4.7, 4.4.7.1(2), 4.4.7.2(3), 4.4.8(2), 4.4.9(3), 4.4.10, 4.4.10.1(3), 4.4.10.2(3), 4.4.11(2), 4.4.12, 4.4.12.1, 4.4.12.2*, 4.4.12.3, 4.4.13, 4.4.13.2, A.1, A.2
3.22	STANDARD TEST CONDITIONS	3.6, 4.2.2.1, 4.2.2.2(2), 4.2.3, 4.2.4(2), 4.2.5, 4.3.4(2), table 2(2), 4.4.1, 4.4.5 NOTE
3.23	STANDARD TEST VALUES	3.22, 3.24
3.24	VARIATION	Introduction, 2, 3.8, 3.17(2), 4.4.5, 4.4.7.1, 4.4.12.1, 4.4.13.4(3)
3.25	X-RAY TUBE VOLTAGE	Title, Introduction (6), Title1, 1, 3.4(2), 3.7, 3.9, 3.10, 3.13, A.1

Bibliography

[1] KRAMER, H-M., SELBACH H-J., ILES, WJ. The practical peak voltage of diagnostic X-ray generators. *British Journal of Radiology*, 1998, 77, p.200-209

[2] IEC 60580:2019, *Medical electrical equipment – Dose area product meters*

[3] IEC 60731:2011, *Medical electrical equipment – Dosimeters with ionization chambers as used in radiotherapy*

[4] ISO/IEC Guide 98-3:2008, *Uncertainty of measurement – Part 3: Guide to the expression of uncertainty in measurement (GUM:1995)*

[5] ISO/IEC Guide 99:2007, *International vocabulary of metrology – Basic and general concepts and associated terms (VIM)*

Index of defined terms

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

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.

It includes an assessment of the COMBINED STANDARD UNCERTAINTY for the performance of a hypothetical instrument for the non-invasive measurement of the tube high voltage (in Annex A) which replaces Annex A of the edition 1.1 titled "Recommended performance criteria for the invasive divider".

The text of this document is based on the following documents:

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.

In this document the following print types are used:

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

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.

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 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 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.

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 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 applicable, and this value serves as a guide for the LIMITS OF VARIATION for the effects of INFLUENCE QUANTITIES.

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

1 Scope

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 60788:2004, *Medical electrical equipment – Glossary of defined terms*

IEC 61000-4-2, *Electromagnetic compatibility (EMC) – Part 4-2: Testing and measurement techniques – Electrostatic discharge immunity test*

IEC 61000-4-3, *Electromagnetic compatibility (EMC) – Part 4-3: Testing and measurement techniques – Radiated, radio-frequency, electromagnetic field immunity test*

IEC 61000-4-4, *Electromagnetic compatibility (EMC) – Part 4-4: Testing and measurement techniques – Electrical fast transient/burst immunity test*

IEC 61000-4-5, *Electromagnetic compatibility (EMC) – Part 4-5: Testing and measurement techniques – Surge immunity test*

IEC 61000-4-6, *Electromagnetic compatibility (EMC) – Part 4-6: Testing and measurement techniques – Immunity to conducted disturbances, induced by radio-frequency fields*

IEC 61000-4-11, *Electromagnetic compatibility (EMC) – Part 4-11: Testing and measurement techniques – Voltage dips, short interruptions and voltage variations immunity tests for equipment with input current up to 16 A per phase*

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

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

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

3 Terms and definitions

For the purposes of this document, the terms and definitions given in IEC 60601-1:2005, IEC TR 60788:2004 and the following apply.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

- IEC Electropedia: available at http://www.electropedia.org/
- ISO Online browsing platform: available at http://www.iso.org/obp

NOTE 1 An Index of defined terms is to be found at the end of the document.

NOTE 2 A searchable IEC Glossary can be found at std.iec.ch.

3.1
CORRECTION FACTOR
dimensionless multiplier which corrects the INDICATED VALUE of an instrument from its value when operated under particular conditions to its value when operated under stated REFERENCE CONDITIONS

3.2
EFFECTIVE RANGE
range of INDICATED VALUES for which an instrument complies with a stated performance

Note 1 to entry: The maximum (minimum) effective INDICATED VALUE is the highest (lowest) in this range.

3.3
INDICATED VALUE
value of quantity derived from the scale reading of an instrument together with any scale factors indicated on the control panel of the instrument

3.4
INFLUENCE QUANTITY
any external quantity that can affect the performance of an instrument (e.g., ambient temperature etc.) and any property of the X-RAY EQUIPMENT under test that shall be taken into account in using the instrument for NON-INVASIVE MEASUREMENT of X-RAY TUBE VOLTAGE (e.g., range of X-RAY TUBE VOLTAGE, ANODE ANGLE, anode material, TOTAL FILTRATION, etc.)

3.5
INSTRUMENT PARAMETER
any internal property of an instrument that can affect the performance of the instrument

3.6
INTRINSIC ERROR
deviation of the MEASURED VALUE (i.e., the INDICATED VALUE, corrected to REFERENCE CONDITIONS) from the CONVENTIONAL TRUE VALUE under STANDARD TEST CONDITIONS

3.7
INVASIVE MEASUREMENT
measurement of the X-RAY TUBE VOLTAGE by external connection of a suitable meter or a high resistance divider

3.8
LIMITS OF VARIATION
maximum VARIATION of a PERFORMANCE CHARACTERISTIC y, permitted by this document

Note 1 to entry: If the LIMITS OF VARIATION are stated as $\pm L$ % the VARIATION $\Delta y / y$, expressed as a percentage, shall remain in the range from $-L$ % to $+L$ %.

3.9
MAXIMUM PEAK VOLTAGE
maximum value of the X-RAY TUBE VOLTAGE in a specified time interval

Note 1 to entry: The unit of this quantity is the volt (V).

3.10
MEAN PEAK VOLTAGE
mean value of all X-RAY TUBE VOLTAGE peaks during a specified time interval

Note 1 to entry: The unit of this quantity is the volt (V).

3.11
MEASURED VALUE
best estimate of the CONVENTIONAL TRUE VALUE of a quantity, being derived from the INDICATED VALUE of an instrument together with the application of all relevant CORRECTION FACTORS

Note 1 to entry: The CONVENTIONAL TRUE VALUE is usually the value determined by the working standard with which the instrument under test is being compared.

3.12
MINIMUM EFFECTIVE RANGE
smallest permitted range of INDICATED VALUES for which an instrument complies with a stated performance

3.13
NON-INVASIVE MEASUREMENT
measurement of X-RAY TUBE VOLTAGE by analysis of the emitted RADIATION

3.14
PERFORMANCE CHARACTERISTIC
one of the quantities used to define the performance of an instrument (e.g., RESPONSE)

3.15
VOLTAGE RIPPLE
VOLTAGE at the X-RAY TUBE, r, expressed as a percentage of the peak voltage, U_{max}, over a specified time interval

Note 1 to entry: The VOLTAGE RIPPLE is expressed by the formula:

$$r = \frac{U_{max} - U_{min}}{U_{max}} \times 100 \text{ \%}$$

where U_{max} is the highest voltage in the interval, and U_{min} is the lowest voltage in the interval.

3.16
PRACTICAL PEAK VOLTAGE
PPV

$$\frac{\int_{U_{\text{min}}}^{U_{\text{max}}} p(U) \times w(U) \times U dU}{\int_{U_{\text{min}}}^{U_{\text{max}}} p(U) \times w(U) \times dU} \text{ with} \int_{U_{\text{min}}}^{U_{\text{max}}} p(U) dU = 1$$

where $p(U)$ is the distribution function for the voltage U and $w(U)$ is a weighting function, U_{max} is the highest voltage in the interval, and U_{min} is the lowest voltage in the interval

Note 1 to entry: The unit of the quantity PRACTICAL PEAK VOLTAGE is the volt (V).

Note 2 to entry: Additional information on the PRACTICAL PEAK VOLTAGE, the weighting function $w(U)$ and the distribution function $p(U)$ is provided in Annex B. Using this weighting function $w(U)$ the PRACTICAL PEAK VOLTAGE is defined as the constant potential which produces the same AIR KERMA contrast behind a specified PHANTOM as the non-DC voltage under test.

3.17
RATED RANGE
RATED RANGE OF USE
range of values of an INFLUENCE QUANTITY or INSTRUMENT PARAMETER within which the instrument will operate within the LIMITS OF VARIATION

Note 1 to entry: The limits of rated range are the maximum and minimum RATED values.

Note 2 to entry: The MINIMUM RATED RANGE is the least range of an INFLUENCE QUANTITY or INSTRUMENT PARAMETER within which the instrument shall operate within the specified LIMITS OF VARIATION in order to comply with this document.

3.18
REFERENCE CONDITION
condition under which all INFLUENCE QUANTITIES and INSTRUMENT PARAMETERS have their REFERENCE VALUES

3.19
REFERENCE VALUE
particular value of an INFLUENCE QUANTITY (or INSTRUMENT PARAMETER) chosen for the purposes of reference i.e., the value of an INFLUENCE QUANTITY (or INSTRUMENT PARAMETER) at which the CORRECTION FACTOR for dependence on that INFLUENCE QUANTITY (or INSTRUMENT PARAMETER) is unity

3.20
RELATIVE INTRINSIC ERROR
ratio of the INTRINSIC ERROR to the CONVENTIONAL TRUE VALUE

3.21
RESPONSE
quotient of the INDICATED VALUE divided by the CONVENTIONAL TRUE VALUE

3.22
STANDARD TEST CONDITION
condition under which all INFLUENCE QUANTITIES and INSTRUMENT PARAMETERS have their STANDARD TEST VALUES

3.23
STANDARD TEST VALUE
value or a range of values of an INFLUENCE QUANTITY or INSTRUMENT PARAMETER, which is permitted when carrying out CALIBRATIONS or tests on another INFLUENCE QUANTITY or INSTRUMENT PARAMETER

3.24
VARIATION
relative difference $\Delta y / y$, between the values of a PERFORMANCE CHARACTERISTIC y, when one INFLUENCE QUANTITY or INSTRUMENT PARAMETER assumes successively two specified values, the other INFLUENCE QUANTITIES and INSTRUMENT PARAMETERS being kept constant at the STANDARD TEST VALUES, unless other values are specified

3.25
X-RAY TUBE VOLTAGE
potential difference applied to an X-RAY TUBE between the anode and the cathode

Note 1 to entry: The unit of this quantity is the volt (V).

4 General performance requirements for measurement of PRACTICAL PEAK VOLTAGE measurements

4.1 Quantity to be measured

The quantity to be measured is the PRACTICAL PEAK VOLTAGE.

NOTE Additional quantities can be displayed.

The MINIMUM EFFECTIVE RANGES of PRACTICAL PEAK VOLTAGE shall be as listed in Table 1 for the relevant X-RAY applications.

Table 1 – Minimum effective ranges

Application	Nominal anode material	MINIMUM EFFECTIVE RANGE
Mammography 20 kV to 50 kV	Mo [a)]	24 kV to 35 kV
Diagnostic 40 kV to 150 kV	W	60 kV to 120 kV
CT 70 kV to 150 kV	W	80 kV to 140 kV
Dental 40 kV to 110 kV	W	60 kV to 90 kV
Fluoroscopic 40 kV to 130 kV	W	60 kV to 120 kV

a) For mammography anode materials other than Mo, the MINIMUM EFFECTIVE RANGE of PPV shall be at least 10 kV.

4.2 Limits of PERFORMANCE CHARACTERISTICS

4.2.1 Limits

All values of the limits of PERFORMANCE CHARACTERISTICS stated in this subclause do not contain the uncertainty of the test equipment.

4.2.2 Maximum error

4.2.2.1 Maximum RELATIVE INTRINSIC ERROR for voltages above 50 kV

The RELATIVE INTRINSIC ERROR, I, of PRACTICAL PEAK VOLTAGE, $\hat{U}$, measurements made under STANDARD TEST CONDITIONS, shall not be greater than ±2 % over the EFFECTIVE RANGE of voltages. This is expressed by the formula:

$$|I| = \left| \frac{\hat{U}_{\text{meas}} - \hat{U}_{\text{true}}}{\hat{U}_{\text{true}}} \right| \leq 0{,}02$$

where $\hat{U}_{\text{meas}}$ is the MEASURED VALUE of PRACTICAL PEAK VOLTAGE and $\hat{U}_{\text{true}}$ is the TRUE VALUE of the PRACTICAL PEAK VOLTAGE. The voltages for the MINIMUM EFFECTIVE RANGE are listed in Table 1.

The compliance test for performance requirement for this subclause is listed under 4.2.2.2.

4.2.2.2 Maximum INTRINSIC ERROR for voltages below 50 kV

The maximum INTRINSIC ERROR, E, of PRACTICAL PEAK VOLTAGE, $\hat{U}$, measurements made under STANDARD TEST CONDITIONS shall not be greater than ±1 kV over the EFFECTIVE RANGE of voltages. This is expressed by the formula:

$$|E| = \left| \hat{U}_{\text{meas}} - \hat{U}_{\text{true}} \right| \leq 1{,}0 \text{ kV}$$

where $\hat{U}_{\text{meas}}$ is the MEASURED VALUE of PRACTICAL PEAK VOLTAGE and $\hat{U}_{\text{true}}$ is the CONVENTIONAL TRUE VALUE of the PRACTICAL PEAK VOLTAGE. The voltages for the MINIMUM EFFECTIVE RANGE are listed in Table 1.

Compliance with performance requirements 4.2.2.1 and 4.2.2.2 shall be checked by measuring the RELATIVE INTRINSIC ERROR above 50 kV or the INTRINSIC ERROR below 50 kV over the EFFECTIVE RANGE of voltages for each application claimed. STANDARD TEST CONDITIONS are listed in Table 2 for each application. The end points of the EFFECTIVE RANGE shall be checked. For mammography, the nominal step between measurements shall be no greater than 2 kV. For all other applications the nominal step between measurements shall be no greater than 5 kV for voltages below 100 kV, and no greater than 10 kV for voltages above 100 kV.

If more than one instrument configuration can be utilised to measure a span of voltages, then that span of voltages shall be measured utilising all relevant instrument configurations. As a minimum the end points and enough interim points shall be measured to meet the minimum step requirements given above. An example could be the use of different absorber pairs to provide overlapping voltage spans. In the case of different absorber pairs, if the first measured from 40 kV to 80 kV, and the second from 60 kV to 120 kV, then the overlapping span would be from 60 kV to 80 kV. At a minimum, measurements would be made utilising each absorber pair at 60 kV, 65 kV, 70 kV, 75 kV, and 80 kV.

4.2.3 Over and under range indications

The instrument shall clearly indicate when it is displaying a reading outside its EFFECTIVE RANGE of PRACTICAL PEAK VOLTAGE.

Conditions above and below the EFFECTIVE RANGE of PRACTICAL PEAK VOLTAGE shall be tested and it shall be demonstrated that if the instrument displays a reading it will be clearly indicated to the user that the reading might not meet the accuracy of the instrument.

If more than one instrument configuration can be utilised to measure a span of voltages, then over and under range conditions shall be checked for all relevant instrument configurations. An example could be the use of different absorber pairs to provide overlapping voltage spans. In the case of different absorber pairs, if the first measured from 40 kV to 80 kV, and the second from 60 kV to 120 kV, then over and under range indications would be checked below 40 kV and above 80 kV for the first absorber pair, and below 60 kV and above 120 kV for the second absorber pair. (The instrument's refusal to make a reading under these conditions is an acceptable result.)

Compliance with performance requirement of this subclause shall be verified at the lowest limit of the RATED RANGE of dose rates. All other INFLUENCE QUANTITIES shall be at STANDARD TEST CONDITIONS as listed in Table 2.

4.2.4 Repeatability

When a measurement is repeated with the same instrument under unaltered conditions, the COEFFICIENT OF VARIATION shall not exceed ±0,5 % or the standard deviation shall not exceed 0,5 kV, whichever is greater.

Compliance with performance requirement of this subclause shall be checked by determining the COEFFICIENT OF VARIATION of ten consecutive measurements taken at the lowest limit of the RATED RANGE of dose rates. All other INFLUENCE QUANTITIES shall be at STANDARD TEST CONDITIONS as listed in Table 2 for each application. The end points of the EFFECTIVE RANGE and one point near the middle of the EFFECTIVE RANGE shall be checked. The test shall be conducted a second time with the dose rate also within STANDARD TEST CONDITIONS.

If more than one instrument configuration can be utilised to measure a span of voltages, then the end points of that span of voltages shall be measured utilising all relevant instrument configurations. An example could be the use of different absorber pairs to provide overlapping voltage spans. In the case of different absorber pairs, if the first measured from 40 kV to 80 kV, and the second from 60 kV to 120 kV, then the overlapping span would be from 60 kV to 80 kV. At a minimum, measurements would be made utilising each absorber pair at 60 kV and 80 kV.

4.2.5 Long term stability

The design and construction shall be such that the instrument RESPONSE does not change by more than ±2,0 % for voltages above 50 kV over a period of one year. For voltages below 50 kV, the difference between the INDICATED VALUE and CONVENTIONAL TRUE VALUE shall not change by more than ±1,0 kV over a period of one year.

Compliance with this performance requirement shall be checked by retaining a representative instrument, stored under STANDARD TEST CONDITIONS of temperature and relative humidity and by measuring the RELATIVE INTRINSIC ERROR above 50 kV or the INTRINSIC ERROR below 50 kV at a minimum of two voltages, one near the top and one near the bottom of the EFFECTIVE RANGE.

If more than one instrument configuration can be utilised to measure a span of voltages, then the end points of that span of voltages shall be measured utilising all relevant instrument configurations. An example could be the use of different absorber pairs to provide overlapping voltage spans. In the case of different absorber pairs, if the first measured from 40 kV to 80 kV, and the second from 60 kV to 120 kV, then the overlapping span would be from 60 kV to 80 kV. At a minimum, measurements would be made utilising each absorber pair at 60 kV and 80 kV.

These measurements shall be made at a minimum of one-month intervals over a period of not less than six months. Linear regression analysis shall be used to extrapolate these readings to obtain the change in RESPONSE over one full year.

4.3 LIMITS OF VARIATION for effects of INFLUENCE QUANTITIES

4.3.1 INFLUENCE QUANTITIES

Quantities which can influence the performance of the instrument are given in Table 2.

4.3.2 MINIMUM RATED RANGE of use

The MINIMUM RATED RANGE of use for each of the INFLUENCE QUANTITIES involved is given in Table 2.

4.3.3 REFERENCE CONDITIONS

The REFERENCE CONDITIONS for each particular INFLUENCE QUANTITY are given in Table 2. For those INFLUENCE QUANTITIES that can be controlled, the REFERENCE VALUE should be the value used during the CALIBRATION of the equipment.

4.3.4 STANDARD TEST CONDITIONS

The STANDARD TEST CONDITIONS stated in Table 2 shall be met during the test procedure except for the INFLUENCE QUANTITY being tested.

4.3.5 LIMITS OF VARIATION

The LIMITS OF VARIATION $\pm L$ for each particular INFLUENCE QUANTITY are given in Table 2. For any change of an INFLUENCE QUANTITY within its RATED RANGE the change of the RESPONSE of the instrument shall be such that the following relationship is fulfilled:

$$\left| \frac{R}{R_{\mathrm{ref}}} - 1 \right| \times 100\ \% \leq L$$

Table 2 – Minimum RATED RANGE OF USE, REFERENCE CONDITIONS, STANDARD TEST CONDITIONS, LIMITS OF VARIATION ($\pm L$) and INTRINSIC ERROR (E) over the EFFECTIVE RANGE of use, for the pertaining INFLUENCE QUANTITY

Influence quantity	Minimum rated range of use	REFERENCE CONDITIONS	STANDARD TEST CONDITIONS	$\pm E$ kV	$\pm L$ %	Sub-clause
Voltage waveform and frequency:						4.4.2
Diagnostic	Constant potential, 2-, 6-, 12-pulse and medium frequency generators [a]	Constant potential	Constant potential, ripple less than 4 %		2,0	
Mammography	Constant potential			0,5		
Anode angle:						4.4.3
Diagnostic	6° to 18°	12°	REFERENCE VALUE ±2°		0,5	
Mammography	15° to 24°	20°	REFERENCE VALUE ±2°	0,5		
Filtration:						4.4.4
Diagnostic	2,5 mm Al to 3,5 mm Al [b]	3,0 mm Al	REFERENCE VALUE ±5 %		1,5	
Mammography	25 µm Mo to 35 µm Mo [c]	30 µm Mo	REFERENCE VALUE ±5 %	0,5		
CT	4 mm Al to 8 mm Al	6 mm Al	REFERENCE VALUE ±5 %		1,5	
Dental	1 mm Al to 2 mm Al	1,5 mm Al	REFERENCE VALUE ±5 %		1,5	
Dose rate:		As stated by MANUFACTURER	REFERENCE VALUE ±20 %	0,5		4.4.5
Diagnostic	20 mGy/s to 200 mGy/s				0,5	
Mammography	25 mGy/s to 150 mGy/s				0,5	
CT	20 mGy/s to 200 mGy/s				0,5	
Dental	5 mGy/s to 50 mGy/s				0,5	
Fluoroscopic	1 mGy/s to 10 mGy/s					
Irradiation time:						4.4.6
Diagnostic	10 ms to 1 000 ms	100 ms	REFERENCE VALUE ±20 %		0,5	
Other	200 ms to 1 000 ms	500 ms	REFERENCE VALUE ±20 %		0,5	

Influence quantity	Minimum rated range of use	REFERENCE CONDITIONS	STANDARD TEST CONDITIONS	± E kV	± L %	Sub-clause
Field size:						
Rated range	Length and width stated by MANUFACTURER + 30 % to 10 %	As stated by MANUFACTURER.	REFERENCE VALUE ±2 %		0,5	4.4.7.1
Large field	30 cm by 30 cm	30 cm by 30 cm	REFERENCE VALUE ±2 %		2,0	4.4.7.2
Detector-focal distance	32 cm to 60 cm or as stated by MANUFACTURER	40 cm or as stated by MANUFACTURER	REFERENCE VALUE ±1 %		0,5	4.4.8
Angle of incidence	±5°	0°	REFERENCE VALUE ±1°		0,5	4.4.9
Rotation	±10°	0°	REFERENCE VALUE ±1°		0,5	4.4.10.1
	±180°	0°	REFERENCE VALUE ±1°		0,5	4.4.10.2
Temperature	15 °C to 35 °C	20 °C	REFERENCE VALUE ±2 °C		1,0	4.4.11
Relative humidity	≤ 80 % (max 20 g/m^3)	50 %	30 % to 75 %			
Power supply						
Line voltage and frequency	115 V or 230 V + 10 % to 15 %	115 V/230 V	REFERENCE VALUE ±1 %		0,5	4.4.12.1
Batteries	50 Hz or 60 Hz	50 Hz/60 Hz as stated	REFERENCE VALUE ±1 %		0,5	4.4.12.2
Rechargeable batteries	As stated by MANUFACTURER. Fresh to low	Fresh, mains disconnected	REFERENCE VALUE ±1 %		0,5	4.4.12.3
Electromagnetic compatibility	IEC 61000-4-2 IEC 61000-4-3 IEC 61000-4-4 IEC 61000-4-5 IEC 61000-4-6 IEC 61000-4-11	Without any disturbance	Insignificant		1,0	4.4.13
Additional tungsten filtration (tube aging)	0 µm to 10 µm W	3 µm W	0 µm W to 3 µm W		2,0	4.4.14

[a] Frequency range f = 50 Hz to 50 kHz, VOLTAGE RIPPLE (%) from 0 to (50 – 10log f), e.g., 0 % to 20 % at 1 000 Hz, 0 % to 3 % at 50 kHz. All frequencies above 50 kHz are treated as constant potential generators.

[b] Filtration outside of MINIMUM RATED RANGE can be met by applying corrections.

[c] X-ray generator with a molybdenum anode, a beryllium window, and no added filtration other than the 30 µm Mo.

4.4 Performance test procedures

4.4.1 General remarks

Performance tests for a particular INFLUENCE QUANTITY shall be carried out in such a way that the pertaining INFLUENCE QUANTITY is varied within the RATED RANGE of use and that STANDARD TEST CONDITIONS are used for all other INFLUENCE QUANTITIES. If not otherwise stated, the TEST VALUE for the quantity to be measured, i.e., voltage, is taken from Table 3. Unless otherwise specified by the MANUFACTURER of the instrument, the measuring unit shall be placed on a radiographic table or a surface whose X-RAY scatter characteristics are similar to a radiographic table.

For those INFLUENCE QUANTITIES which can have an impact on the voltage behaviour of the X-RAY unit used for test purposes, i.e., voltage waveform and frequency, dose rate and IRRADIATION TIME, a high voltage divider system shall be used as a reference. This reference shall have a CALIBRATION which is traceable to a national standard. The dependence of the voltage divider and its read-out system on voltage waveform and frequency over the range stated in Table 2 shall be less than 0,5 %.

For those INFLUENCE QUANTITIES which introduce a change in the intensity and the spectral composition of the RADIATION beam emitted from the X-RAY source assembly, i.e., voltage waveform and frequency, ANODE ANGLE, filtration and dose rate, performance tests shall be made at the minimum test points as indicated in Table 3 in order to show compliance over the EFFECTIVE RANGE of voltages unless otherwise stated. For those instruments having ranges exceeding the minimum ranges additional performance tests shall be run at the lower and upper values.

If more than one instrument configuration can be utilised to measure any of the above specified test points, then each of those points shall be measured utilising all relevant instrument configurations. An example could be the use of different absorber pairs to provide overlapping voltage spans. In the case of different absorber pairs, if the first measured from 40 kV to 90 kV, and the second from 60 kV to 120 kV, then the overlapping span would be from 60 kV to 90 kV. At a minimum, if this were a diagnostic application, measurements would be made utilising each absorber pair at 60 kV and at 80 kV. If this were a dental application, measurements would be made utilising each absorber pair at 60 kV, 75 kV and at 90 kV.

Table 3 – Minimum test points and test values of PRACTICAL PEAK VOLTAGE for INFLUENCE QUANTITIES

Application	Minimum test points kV	Test value kV
Mammography	24, 28, 30, 35	30
Diagnostic	60, 80, 100, 120	80
CT	80, 100, 120, 140	120
Dental	60, 75, 90	60
Fluoroscopic	60, 80, 100, 120	80

4.4.2 Dependence of instrument RESPONSE on voltage waveform and frequency

The MINIMUM RATED RANGE of frequency is between 50 Hz and 50 kHz. The MINIMUM RATED RANGE of VOLTAGE RIPPLE is defined as

$$\text{VOLTAGE RIPPLE } (\ \%\ ) \text{ from 0 to } (\ 50 - 10 \log f\ )$$

where f is the frequency expressed in Hz.

Over the RATED RANGE of voltage waveform and frequency, the LIMITS OF VARIATION of RESPONSE shall not be greater than stated in Table 2.

For each application, except of mammography, compliance with this performance requirement shall be checked by measuring the RESPONSE of the instrument with the detector of the instrument exposed to RADIATION produced by an X-RAY tube, which is supplied with high voltage of the following waveforms: a) single- or two-pulse with pulse duration of 8 ms to 10 ms per pulse; b) DC with a ripple of 0,5 kHz to 1 kHz and of magnitude between 20 % to 25 %, c) DC with a ripple of 5 kHz to 15 kHz and of magnitude between 8 % to 15 %; the measured RESPONSE shall be compared with the RESPONSE under REFERENCE CONDITIONS; d) DC with ripple less than 4 %. A high voltage divider system shall be used in each case a) to d) to obtain the CONVENTIONAL TRUE VALUE for the PRACTICAL PEAK VOLTAGE from the waveform of the high voltage supplied to the X-RAY TUBE. Tests shall be made at the test value indicated in Table 3 for each application. If the rated range contains waveforms which are not included in the MINIMUM RATED RANGE stated in Table 2 (e.g., higher frequency and/or greater ripple), additional tests at the limits of the rated range shall be performed.

For mammography, compliance shall only be checked if the rated range stated for the mammography application range includes voltage waveforms other than constant potential. In this case compliance shall be checked in the same way as described above for each additional waveform.

4.4.3 Dependence of instrument RESPONSE on ANODE ANGLE

The MINIMUM RATED RANGE of ANODE ANGLE of X-RAY tubes is given in Table 2. Over the RATED RANGE of ANODE ANGLE, the LIMITS OF VARIATION of the RESPONSE shall not be greater than stated in Table 2.

Compliance test for this performance requirement is not necessary because the change in the spectral photon distribution of the X-RADIATION due to changes in the ANODE ANGLE within its rated range is less than the change of spectral photon distribution due to changes in filtration.

4.4.4 Dependence of instrument RESPONSE on FILTRATION

The MINIMUM RATED RANGE of filtration of X-RAY tubes is given in Table 2 for different applications. Over the RATED RANGE of FILTRATION, the LIMITS OF VARIATION of RESPONSE shall not be greater than stated in Table 2.

Compliance with this performance requirement shall be checked by measuring the RESPONSE of the instrument with the detector of the instrument exposed to the minimum and the maximum rated filtration and compared with a reference set of readings at reference filtration. Tests shall be made at the minimum test points indicated in Table 3 and in 4.4.1 to show compliance over the EFFECTIVE RANGE of voltages.

4.4.5 Dependence of instrument RESPONSE on dose rate

The MINIMUM RATED RANGE of dose rate is given in Table 2 for different applications. Over the RATED RANGE of dose rate, the LIMITS OF VARIATION of RESPONSE shall not be greater than stated in Table 2.

Compliance with this performance requirement shall be checked by measuring the RESPONSE of the instrument with the detector of the instrument exposed to the minimum and the maximum rated dose rate and at least three measurement points per decade over the rated range of dose rate. The measurements shall be compared with those obtained by an invasive high voltage divider system. If the detector focus distance or the RADIATION QUALITY shall be changed to provide the necessary dose rates, measurements shall overlap at the dose rate values where these changes are performed. In this case a CORRECTION FACTOR (see note) can be used to compensate possible VARIATIONS of RESPONSE due to the change of distance and/or RADIATION QUALITY. This CORRECTION FACTOR is the quotient of the MEASURED VALUE after the change of the measurement conditions and the value before the change, both values measured at the same dose rate.

NOTE This CORRECTION FACTOR is only used during the compliance test and compensates the changes in RESPONSE of the instrument which are due to the changes in the test conditions only (deviation from STANDARD TEST CONDITIONS) and not due to changes in the dose rate. The CORRECTION FACTOR assures that the readings of the instrument under different measurement conditions are the same for the same dose rate in the overlapping region.

4.4.6 Dependence of instrument RESPONSE on IRRADIATION TIME

The MINIMUM RATED RANGE of IRRADIATION TIME is stated in Table 2. Over the RATED RANGE of IRRADIATION TIME, the LIMITS OF VARIATION of RESPONSE shall not be greater than that stated in Table 2.

Compliance with this performance requirement shall be checked by measuring the RESPONSE of the instrument with the detector of the instrument exposed to the minimum and the maximum rated IRRADIATION TIME and compared with a reference set of readings at reference IRRADIATION TIME. A high voltage divider system shall be used to control and – if necessary – to correct the high voltage of the X-RAY GENERATOR when IRRADIATION TIMES are selected which are different from REFERENCE CONDITIONS. Tests shall be made at the test value indicated in Table 3 for each application.

4.4.7 Dependence of instrument RESPONSE on field size

4.4.7.1 General

The ACCOMPANYING DOCUMENTS shall state the nominal value and the RATED RANGE of field size. The MINIMUM RATED RANGE of field size is given in Table 2.

4.4.7.2 Dependence of instrument RESPONSE on field size variations over the RATED RANGE

Over the RATED RANGE of field size, the LIMITS OF VARIATION of RESPONSE shall not be greater than stated in Table 2.

Compliance with this performance requirement shall be checked by measuring the RESPONSE of the instrument with the detector of the instrument exposed to the minimum and the maximum RATED FIELD SIZE and compared with a reference set of readings at nominal field size.

4.4.7.3 Dependence of instrument RESPONSE on large field size

When exposed to a field of 30 cm by 30 cm, the LIMITS OF VARIATION of RESPONSE shall not be greater than stated in Table 2.

Compliance with this performance requirement shall be checked by measuring the RESPONSE of the instrument with the detector of the instrument exposed to an X-RAY FIELD of 30 cm by 30 cm and compared with a reference set of readings at nominal field size.

4.4.8 Dependence of instrument RESPONSE on focus-to-detector distance

The MINIMUM RATED RANGE of distance from the FOCAL SPOT of the X-RAY TUBE to the detector is given in Table 2. Over the RATED RANGE of distance, the LIMITS OF VARIATION of RESPONSE shall not be greater than stated in Table 2.

Compliance with this performance requirement shall be checked by measuring the RESPONSE of the instrument with the detector of the instrument exposed to the minimum and the maximum rated distance from the FOCAL SPOT and compared with a reference set of readings at reference distance. During the test, the field size and the dose rate to the detector shall always be the same. Tests shall be made at the test value indicated in Table 3 for each application.

4.4.9 Dependence of instrument RESPONSE on angle of incidence of RADIATION

The MINIMUM RATED RANGE of angle of incidence from the normal direction of incidence is given in Table 2. Over the RATED RANGE of angle of incidence, the LIMITS OF VARIATION of RESPONSE shall not be greater than stated in Table 2.

Compliance with this performance requirement shall be checked by measuring the RESPONSE of the instrument with the detector of the instrument tilted to the outmost boundaries of the RATED RANGE of angle of incidence in two perpendicular directions from a position perpendicular to the axis of the beam and compared with a reference set of readings at perpendicular incidence. Tests shall be made at the test value indicated in Table 3 for each application.

4.4.10 Dependence of instrument RESPONSE on angle of detector rotation with respect to the X-RAY TUBE axis

4.4.10.1 Dependence of instrument RESPONSE for instruments stated by the MANUFACTURER to have a preferred direction of alignment

If there is a preferred direction of alignment it shall be stated by the MANUFACTURER. When the detector is rotated by ±10° from the preferred direction, the LIMITS OF VARIATION of RESPONSE shall not be greater than stated in Table 2.

Compliance with this performance requirement shall be checked by measuring the RESPONSE of the instrument with the detector of the instrument rotated first by +10° then by –10° from the preferred direction in the plane perpendicular to the incident X-RAY BEAM and compared to a reference set of readings at the preferred direction. Tests shall be made at the test value indicated in Table 3 for each application.

4.4.10.2 Dependence of instrument RESPONSE for instruments stated by the MANUFACTURER to have no preferred direction of alignment

If there is no preferred direction of alignment it shall be stated by the MANUFACTURER. When the detector is rotated through 180°, LIMITS OF VARIATION of RESPONSE shall not be greater than stated in Table 2.

Compliance with this performance requirement shall be checked by measuring the RESPONSE of the instrument when the detector of the instrument is rotated by 45°, 90°, 135°, and 180° from the original orientation in the plane perpendicular to the incident X-RAY BEAM and compared to a reference set of readings at the original (0°) direction. Tests shall be made at the test value indicated in Table 3 for each application.

4.4.11 Dependence of instrument RESPONSE on temperature and humidity

The LIMITS OF VARIATION of the instrument RESPONSE shall be not greater than the value given in Table 2, for all possible temperature and humidity conditions within the RATED RANGES of temperature and humidity.

Compliance with this performance requirement shall be checked by carrying out the following test. The instrument shall be exposed to varying temperature and air humidities. At least three measurements shall be performed, one under each of the following climatic conditions:

temperature	*relative humidity*
20 °C	*50 %*
15 °C	*80 %*
35 °C	*50 %*

The instrument shall be exposed to each different temperature and humidity condition for at least 24 h before the instrument is tested. Tests can be made by exposing the instrument to X-RADIATIONS at the test value indicated in Table 3, or the MANUFACTURER can provide a means to electrically simulate the signal by using stable reference currents to demonstrate the proper operation of the instrument without IRRADIATION.

4.4.12 Dependence of instrument RESPONSE on operating voltage

4.4.12.1 For mains-operated instruments the LIMIT OF VARIATION of RESPONSE due to VARIATION of the operating voltage between the limits found in Table 2 of the nominal voltage shall not be greater than stated in Table 2, over the RATED RANGE of mains voltage stated by the MANUFACTURER.

Compliance with this performance requirement shall be checked by taking two sets of readings with the voltage of the SUPPLY MAINS adjusted to the upper and lower boundaries of the RATED RANGE of operating voltage stated by the MANUFACTURER and compared with a reference set of readings at nominal operating voltage. Tests can be made by IRRADIATION at the test value indicated in Table 3, or the MANUFACTURER can provide a means to electrically simulate the signal by using stable reference currents to demonstrate the proper operation of the instrument without IRRADIATION.

4.4.12.2 Over the rated range of battery voltage, the LIMIT OF VARIATION of RESPONSE shall not be greater than stated in Table 2. For battery-operated instruments, a low battery condition shall be indicated if the instrument is operating when the battery voltage is outside the rated range stated by the MANUFACTURER. Furthermore, the instrument shall not display a measurement if the battery voltage is outside the rated range.

Compliance with this performance requirement shall be checked as follows: the batteries shall be replaced by a stable DC power supply producing a voltage equivalent to the voltage produced by a set of fresh batteries of the type specified by the MANUFACTURER. A set of reference readings shall be taken, and the voltage decreased until the battery power indicator begins to show "low battery" condition. A second set of readings shall then be taken and compared with the REFERENCE VALUE. Tests can be made by IRRADIATION at the test value indicated in Table 3, or the MANUFACTURER can provide a means to electrically simulate the signal by using stable reference currents to demonstrate the proper operation of the instrument without IRRADIATION.

NOTE In some instruments, connection to an external supply with a cable can compromise the instrument shield, or batteries are possibly not at chassis ground. In these cases, the MANUFACTURER provides proper guidance on the test method.

4.4.12.3 For mains rechargeable, battery-operated instruments in addition to the requirements on battery powered instruments, the LIMIT OF VARIATION of RESPONSE shall not be greater than stated in Table 2 when the instrument is operated under the following conditions:

– mains disconnected, battery fresh;
– mains connected, battery fresh;
– mains connected, battery low.

Compliance with this performance requirement shall be checked as follows: the reference reading shall be taken with the mains disconnected and a set of fresh batteries of the type specified by the MANUFACTURER fitted. The mains shall then be connected, and a second set of readings taken and compared with the reference reading. Finally, a set of used batteries which are just spent enough to cause the "battery low" indication to show shall be fitted, and with the mains connected a third set of readings shall be taken and compared with the reference reading. Tests can be made by IRRADIATION at the test value indicated in Table 3, or the MANUFACTURER can provide a means to electrically simulate the signal by using stable reference currents to demonstrate the stability of the instrument without IRRADIATION.

4.4.13 Dependence of instrument RESPONSE on electromagnetic compatibility

4.4.13.1 Electrostatic discharge

The maximum spurious indications (both transient and permanent) of the display or data output due to electrostatic discharge shall not exceed the limits given in Table 2.

Compliance with this performance requirement shall be checked by observing and recording the indications of the display and any data output terminals while discharging a suitable test generator as described in IEC 61000-4-2 at least five times to those various external parts of the complete equipment which can be touched by the OPERATOR during a normal measurement (i.e., not to those parts that are normally exposed in the RADIATION beam). The electrostatic discharge shall be equivalent to that from a capacitor of 150 pF charged to a voltage of 6 kV and discharged through a resistor of 330 Ω (severity level 3 for contact discharge as described in IEC 61000-4-2). When instruments with insulated surfaces are tested, the air discharge method with a voltage of 8 kV (severity level 3) shall be used. Tests can be made by IRRADIATION at the test value indicated in Table 3, or the MANUFACTURER can provide a means to electrically simulate the signal by using stable reference currents to demonstrate the stability of the instrument without IRRADIATION. In that case the X-RAY DETECTORS shall remain connected in the circuit as they provide a possible path for electrical disturbances to enter the instrument.

NOTE Complete "latch-up" of the instrument which would not lead to an incorrect value being indicated is possible.

4.4.13.2 Radiated electromagnetic fields

The maximum spurious indications (both transient and permanent) of the display or data output terminals due to electromagnetic fields shall be less than the limits given in Table 2.

Compliance with this performance requirement shall be checked by observing and recording the indications of the display and any data output terminals while measurements are performed, both with and without the presence of the radio-frequency field around the complete equipment.

The electromagnetic field strength shall be 3 V/m in the frequency range of 80 MHz to 6 GHz in steps of 1 % (severity level 2 as described in IEC 61000-4-3). For battery-operated instruments, tests at 27 MHz shall also be performed. To reduce the number of measurements needed to show compliance with this requirement, tests at frequencies 27, 80, 90, 100, 110, 120, 130, 140, 150, 160, 180, 200, 220, 240, 260, 290, 320, 350, 380, 420, 460, 510, 560, 620, 680, 750, 820, 900, 1 000, 2 000, 3 000, 4 000, 5 000, and 6 000 MHz with a field strength of 10 V/m can be performed in one orientation only. If any change of the RESPONSE greater than one-third of the limits given in Table 2 is observed at one of these given frequencies, additional tests in the range of ± 5 % around this frequency in steps of 1 % and with a field strength of 3 V/m shall be carried out with the instrument in all three orientations as described in IEC 61000-4-3. Tests can be made by IRRADIATION at the test value indicated in Table 3, or the MANUFACTURER can provide a means to electrically simulate the signal by using stable reference currents to demonstrate the stability of the instrument without IRRADIATION. In that case the X-RAY DETECTORS shall remain connected in the circuit as they provide a possible path for electrical disturbances to enter the instrument.

4.4.13.3 Conducted disturbances induced by bursts and radio frequencies

The maximum spurious indications (both transient and permanent) of the display or data output terminals due to conducted disturbances induced by bursts and radio frequencies shall be less than the limits given in Table 2.

For mains-operated instruments, compliance shall be checked by observing and recording the indications of the display and any data output terminals both with and without the presence of conducted disturbances induced by bursts (IEC 61000-4-4) and conducted disturbances induced by radio-frequency fields (IEC 61000-4-6). The severity level shall in both cases be level 3 as described in these documents. Tests can be made by IRRADIATION at the test value indicated in Table 3, or the MANUFACTURER can provide a means to electrically simulate the signal by using stable reference currents to demonstrate the stability of the instrument without IRRADIATION. In that case the X-RAY DETECTORS shall remain connected in the circuit as they provide a possible path for electrical disturbances to enter the instrument.

NOTE Complete "latch-up" of the instrument which would not lead to an incorrect value being indicated is possible.

4.4.13.4 Voltage dips, short interruptions and voltage variations

The maximum spurious indications (both transient and permanent) of the display or data output terminals due to voltage dips, short interruptions and voltage VARIATIONS shall be less than the limits given in Table 2.

For mains-operated instruments compliance with this performance requirement shall be checked by observing and recording the indications of the display and any data output terminals while measurements are performed on the most sensitive range, both with and without the presence of conducted disturbances induced by voltage dips, short interruptions and voltage VARIATIONS as described in IEC 61000-4-11. Tests can be made by IRRADIATION at the test value indicated in Table 3, or the MANUFACTURER can provide a means to electrically simulate the signal by using stable reference currents to demonstrate the stability of the instrument without IRRADIATION. In that case the X-RAY detectors shall remain connected in the circuit as they provide a possible path for electrical disturbances to enter the instrument.

4.4.13.5 Surges

The maximum spurious indications (both transient and permanent) of the display or data output due to surges shall be less than the limits given in Table 2.

For mains-operated instruments compliance shall be checked by observing and recording the indications of the display and any data output terminals while measurements are performed on the most sensitive range (if the ranges are selectable), both with and without the presence of disturbances induced by surges (IEC 61000-4-5). The severity level shall be level 3 as described in this document.

NOTE Complete "latch-up" of the instrument which would not lead to an incorrect value being indicated is possible.

4.4.14 Additional tungsten filtration (tube aging)

Over the RATED RANGE of additional tungsten filtration, the LIMITS OF VARIATION of RESPONSE shall not be greater than stated in Table 2.

NOTE The higher the age of an X-RAY TUBE, the anode roughens more and more depending on the cumulative heat load during its total operation time. The roughening of the anode results in a hardening of the spectral photon distribution, which can be simulated by additional tungsten filtration, where zero filtration represents a new tube, and 10 µm W an X-RAY TUBE near the end of its lifetime, respectively.

Before performing this test, it should be proved that the X-RAY TUBE used for this test is of moderate age, corresponding to an additional filtration of 0 µm W to 3 µm W as required for the STANDARD TEST CONDITIONS. This can be shown under the following conditions: 70 kV tube voltage and 3,0 mm Al total filtration, by measuring the Al-HALF-VALUE LAYER (HVL) which should be less than the values in Table 4, depending on the anode angle of the tube.

Table 4 – Maximum HALF-VALUE LAYER (HVL) depending on anode angle

Anode angle (°)	6	8	10	12	14	16	18
HVL (mm Al)	3,23	3,07	2,98	2,91	2,86	2,83	2,80

Compliance with the performance requirement shall now be checked by measuring the RESPONSE of the instrument with the detector of the instrument exposed to the minimum and the maximum rated additional tungsten filtration and compared with a reference set of readings at reference filtration (with 3 µm additional tungsten filtration). Tests shall be made at the minimum test points indicated in Table 3 and in 4.4.1 to show compliance over the EFFECTIVE RANGE of voltages.

5 Special instrumental requirements and marking

5.1 Requirements for the complete instruments

The MANUFACTURER shall state for all INFLUENCE QUANTITIES the range of use. With regard to electric safety the requirements of IEC 61010-1 shall be fulfilled.

5.2 General

All electrical connections, controls and display shall be clearly indicated with relation to their function. Where appropriate, symbols from IEC 60417 and ISO 7000 shall be used. Permanent markings shall include

- identification of the MANUFACTURER;
- model number and serial number of the instrument.

In addition, during use it shall be clearly indicated

- when the instrument is not ready to take a measurement;
- the range of measurement;
- the result of measurement, including units, whether the measurement is out of range, and what corrections are applied if any;
- other warnings such as "low battery".

The state of all OPERATOR programmable instrument settings shall be retrievable.

5.3 Display

Instruments which comply with this document shall have a digital display. The display shall show the unit of quantity measured. Within the whole EFFECTIVE RANGE of INDICATED VALUEs the resolution of the reading shall be at least 0,5 %.

5.4 Range of measurement

If an instrument’s measurement range consists of two or more partial ranges of measurement, the partial ranges shall overlap at their boundaries. Requirement 4.2.2 shall be applied to each of the partial ranges if the instrument does not switch automatically to the next range.

5.5 Connectors and cables

Connectors and cables shall be clearly marked or of different design to avoid improper connections.

6 ACCOMPANYING DOCUMENTS

6.1 General

The ACCOMPANYING DOCUMENTS shall comply with IEC 61187.

6.2 Information provided

The MANUFACTURER shall provide adequate information describing the correct use of the instrument.

6.3 Instrument description

The ACCOMPANYING DOCUMENTS shall contain a description of the instrument, including its type number, MANUFACTURER, and range of intended use.

6.4 Detector

The MANUFACTURER shall state the type of detector(s) and the physical principle used to determine the PRACTICAL PEAK VOLTAGE.

6.5 Delay time

The MANUFACTURER shall state whether the instrument has a delay time function and if it can be modified by the OPERATOR.

6.6 Measurement window

The MANUFACTURER shall state the period over which the instrument samples the waveform.

6.7 Data outlet

The MANUFACTURER shall state whether a detector unit has the ability to provide data for further evaluation by recorder or computer. The MANUFACTURER shall describe in the ACCOMPANYING DOCUMENTS whether this signal is proportional to voltage or dose rate and information shall be given about the time constant and resolution.

6.8 Transport and storage

The MANUFACTURER shall state any special requirements for transport and storage. All components of the complete instrument shall be designed for transport and storage in the range of temperature from −20 °C to +50 °C.

Annex A
(informative)

COMBINED STANDARD UNCERTAINTY

The COMBINED STANDARD UNCERTAINTY for the performance of a hypothetical instrument for the NON-INVASIVE MEASUREMENT of the tube high voltage operating at the maximum limits of PERFORMANCE CHARACTERISTICS according to Clause 4 and LIMITS OF VARIATION L for the effects of INFLUENCE QUANTITIES according to Table 2 was estimated. The uncertainty components and the results are shown in Table A.1.

Table A.1 – Example for assessment of the COMBINED STANDARD UNCERTAINTY – Instruments used for NON-INVASIVE MEASUREMENT of X-RAY TUBE VOLTAGE

INFLUENCE QUANTITY or PERFORMANCE CHARACTERISTIC	Subclause	$\pm L$ %	Relative standard uncertainty %
Voltage waveform and frequency [a]	4.4.2	2,0	1,15
Anode angle [a]	4.4.3	0,5	0,289
Filtration [a]	4.4.4	1,5	0,866
Dose rate [a]	4.4.5	0,5	0,289
Irradiation time [a]	4.4.6	0,5	0,289
Field size: Rated range [a]	4.4.7.2	0,5	0,289
Field size: large [a]	4.4.7.3	2,0	1,15
Detector-Focal distance [a]	4.4.8	0,5	0,289
Angle of incidence [a]	4.4.9	0,5	0,289
Rotation [a]	4.4.10	0,5	0,289
Temperature and relative humidity [a]	4.4.11	1,0	0,577
Power supply [a]	4.4.12	0,5	0,289
Electromagnetic compatibility [a]	4.4.13	1,0	0,577
Additional tungsten filtration (tube aging) [a]	4.4.14	2,0	1,15
COMBINED STANDARD UNCERTAINTY for PERFORMANCE CHARACTERISTICS, k = 1 [b]			2,5
COMBINED STANDARD UNCERTAINTY for PERFORMANCE CHARACTERISTICS, k = 2 [c]			4,9
CALIBRATION		2,0	1,15
COMBINED STANDARD UNCERTAINTY, k = 2			5,4

[a] Uniform probability distribution, symmetric limits $\pm L$, i.e. relative uncertainty = $L/\sqrt{3}$.

[b] Root-mean-square of relative uncertainties.

[c] Root-mean-square of relative uncertainties, multiplied by 2.

Annex B
(informative)

Additional information on PRACTICAL PEAK VOLTAGE

B.1 Overview

The PRACTICAL PEAK VOLTAGE is based on the concept that the RADIATION generated by a high voltage of any waveform produces the same AIR KERMA contrast behind a specified PHANTOM as a RADIATION generated by an equivalent constant potential. The constant potential producing the same contrast as the waveform under test is defined as PRACTICAL PEAK VOLTAGE.

For the determination of the PRACTICAL PEAK VOLTAGE for a specified waveform, the X-RAY spectrum produced by an X-RAY TUBE supplied with this non-constant potential shall be calculated. Using this spectrum, the ratio of AIR KERMA behind a PHANTOM and the AIR KERMA behind the PHANTOM plus a contrast material can then be calculated (for the application range "conventional diagnostic" a PHANTOM of 10 cm PMMA and a contrast material of 1,0 mm Al is used). Then, in a corresponding way, a constant potential giving the same AIR KERMA ratio for the same contrast configuration can be found. This is the PRACTICAL PEAK VOLTAGE for the given waveform. This complex procedure is only necessary for the correct determination of the quantity PRACTICAL PEAK VOLTAGE. For practical use it can be substituted for all waveforms by a simplified formalism described below [1].[1]

B.2 Simplified formalism for the determination of the PRACTICAL PEAK VOLTAGE $\hat{U}$

For a given probability distribution $p(U_i)$ for the occurrence of a value of the voltage in the interval $[U_i - \Delta U/2, U_i + \Delta U/2]$, the PRACTICAL PEAK VOLTAGE $\hat{U}$ can be directly calculated by:

$$\hat{U} = \frac{\sum_{i=1}^{n} p(U_i) \times w(U_i) \times U_i}{\sum_{i=1}^{n} p(U_i) \times w(U_i)} \qquad \text{(B.1)}$$

When U_i is in units of kV, the weighting function $w(U_i)$ can be approximated with sufficient accuracy by the following formulas:

in the voltage region of U_i < 20 kV, by

$$w(U_i) = 0 \qquad \text{(B.2)}$$

in the voltage region of 20 kV ≤ U_i < 36 kV, by

$$w(U_i) = \exp\left\{a \times U_i^2 + b \times U_i + c\right\} \qquad \text{(B.3)}$$

[1] Numbers in square brackets refer to the Bibliography.

where

a = −8,646 855 × 10^{-03}

b = +8,170 361 × 10^{-01}

c = −2,327 793 × 10^{01}

and for the voltage region of 36 kV < U_i ≤ 150 kV, by

$$w(U_i) = d \times U_i^4 + e \times U_i^3 + f \times U_i^2 + g \times U_i + h \quad \text{(B.4)}$$

where

d = +4,310 644 × 10^{-10}

e = −1,662 009 × 10^{-07}

f = +2,308 190 × 10^{-05}

g = +1,030 820 × 10^{-05}

h = −1,747 153 × 10^{-02}

For the definition (see 3.16) the formula for $\hat{U}$ is generalized by using integral expressions instead of the summations, which however does not affect the values for the weighting function.

The above formula and the given values for the parameters a to h are valid for the application ranges "conventional diagnostic", "CT", "dental" and "fluoroscopic".

For mammography in the voltage region of U_i ≤ 50 kV the formula and the values for the parameters k to o as given below are to be used.

$$w(U_i) = \exp\left\{ k \times U_i^4 + l \times U_i^3 + m \times U_i^2 + n \times U_i + o \right\} \quad \text{(B.5)}$$

where

k = −2,142 352 × 10^{-06}

l = +2,566 291 × 10^{-04}

m = −1,968 138 × 10^{-02}

n = +8,506 836 × 10^{-01}

o = −1,514 362 × 10^{+01}

NOTE This formula is defined only for waveforms containing no voltage peaks greater than 50 kV.

Figure B.1 and Figure B.2 show two examples of determination of the PRACTICAL PEAK VOLTAGE (straight line) for two extremely different waveforms using the formalism given above.

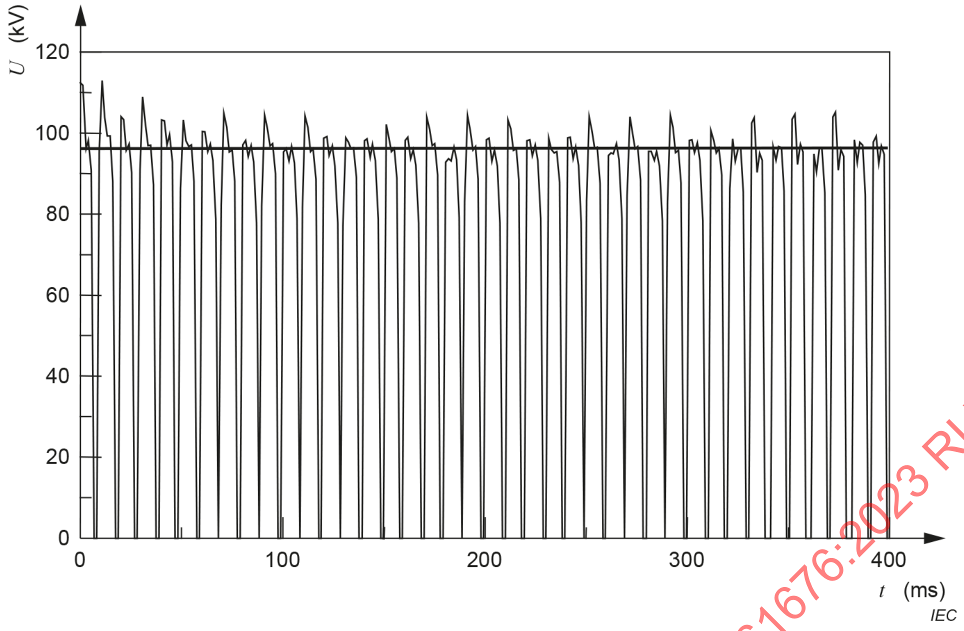

Figure B.1 – Example of a waveform of a two-pulse generator

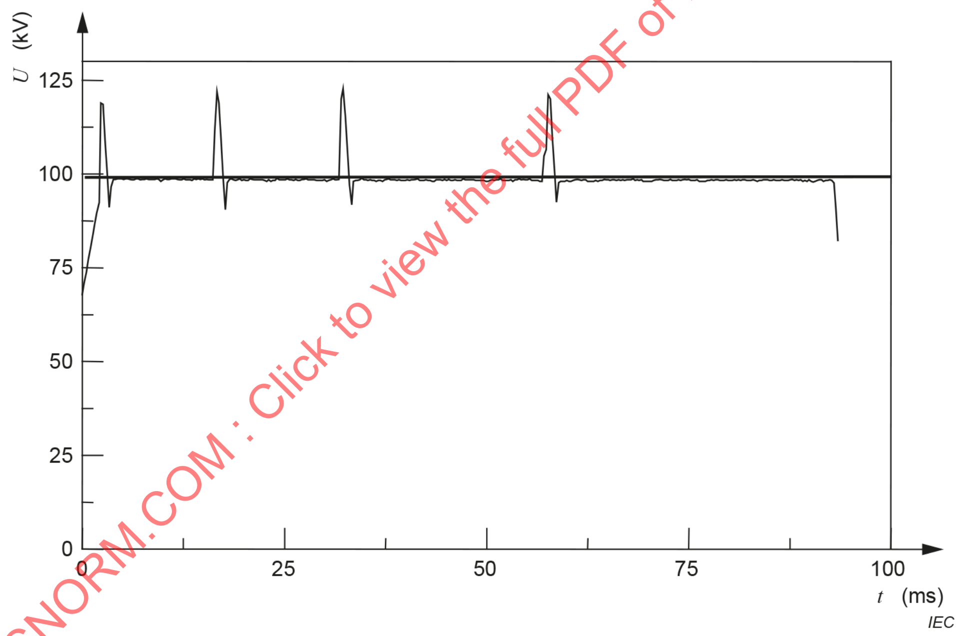

Figure B.2 – Example of a waveform of a constant-voltage generator

The following example (see Figure B.3) shows for the case of a falling load waveform how the simplified formalism for the determination of the PRACTICAL PEAK VOLTAGE $\hat{U}$ shall be used. The number of the samples taken is reduced to 20, to show only the principle of the calculation. The values of the 20 samples are listed in Table B.1.

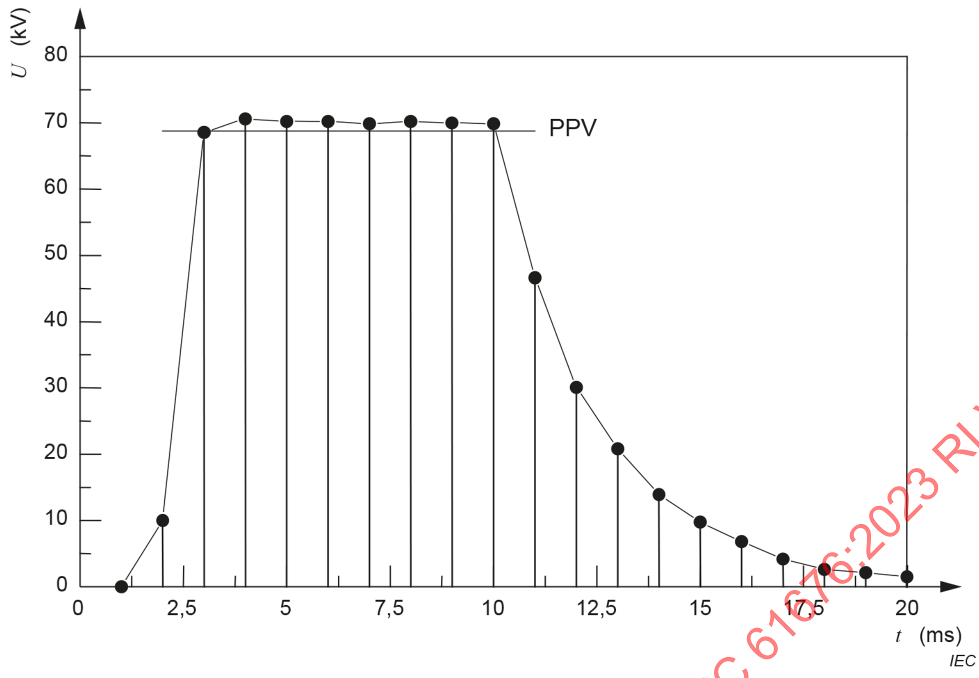

Figure B.3 – Example of falling load waveform

Table B.1 – Values of 20 samples of the falling load waveform in Figure B.3

Sample No. i	**Sample value** U_i/kV
1	0,00
2	10,00
3	68,60
4	70,60
5	70,20
6	70,20
7	69,90
8	70,20
9	70,00
10	69,90
11	46,60
12	30,10
13	20,80
14	13,90
15	9,80
16	6,80
17	4,20
18	2,60
19	2,10
20	1,50

With an interval of ΔU = 0,1 kV one obtains from the voltage samples in Table B.1 the voltage bins $U_i - \Delta U/2$ to $U_i + \Delta U/2$ and the probability distribution $p(U_i)$ as given in columns 2 and 3 of Table B.2. Using the indicated formulas (column 4) the values for $w(U_i)$, $p(U_i) \times w(U_i) \times U_i$ and $p(U_i) \times w(U_i)$ can be calculated. The quotient of the sum of the two last columns gives the PRACTICAL PEAK VOLTAGE (Formula (B.6)).

Table B.2 – Voltage bins, probability and weighting factors for the 20 samples of the falling load waveform in Figure B.3

U_i	$U_i - \Delta U/2$ to $U_i + \Delta U/2$	$p(U_i)$	Formula	$w(U_i)$	$p(U_i) \times w(U_i) \times U_i$	$p(U_i) \times w(U_i)$
kV	kV					
< 20	< 20,05	9	(B.2)	$0{,}000\,0 \times 10^{+00}$	$0{,}000\,0 \times 10^{+00}$	$0{,}000\,0 \times 10^{+00}$
20,80	20,75 to 20,85	1	(B.3)	$4{,}429\,9 \times 10^{-05}$	$9{,}214\,1 \times 10^{-04}$	$4{,}429\,9 \times 10^{-05}$
30,10	30,05 to 30,15	1	(B.3)	$1{,}474\,7 \times 10^{-03}$	$4{,}438\,9 \times 10^{-02}$	$1{,}474\,7 \times 10^{-03}$
46,60	46,55 to 46,65	1	(B.4)	$1{,}834\,7 \times 10^{-02}$	$8{,}549\,5 \times 10^{-01}$	$1{,}834\,7 \times 10^{-02}$
68,60	68,55 to 68,65	1	(B.4)	$4{,}775\,0 \times 10^{-02}$	$3{,}275\,7 \times 10^{+00}$	$4{,}775\,0 \times 10^{-02}$
69,90	69,85 to 69,95	2	(B.4)	$4{,}955\,5 \times 10^{-02}$	$6{,}927\,8 \times 10^{+00}$	$9{,}911\,0 \times 10^{-02}$
70,00	69,95 to 70,05	1	(B.4)	$4{,}969\,4 \times 10^{-02}$	$3{,}478\,6 \times 10^{+00}$	$4{,}969\,4 \times 10^{-02}$
70,20	70,15 to 70,25	3	(B.4)	$4{,}997\,2 \times 10^{-02}$	$1{,}052\,4 \times 10^{+01}$	$1{,}499\,2 \times 10^{-01}$
70,60	70,55 to 70,65	1	(B.4)	$5{,}052\,9 \times 10^{-02}$	$3{,}567\,3 \times 10^{+00}$	$5{,}052\,9 \times 10^{-02}$
		$\sum = 20$			$\sum = 2{,}867\,4 \times 10^{+01}$	$\sum = 4{,}168\,6 \times 10^{-01}$

$$\hat{U} = \frac{28{,}674\,1}{0{,}416\,86} = 68{,}78 \text{ kV} \tag{B.6}$$

If, as in most cases, the sampling rate is constant, which means that the samples are taken in equal time intervals, the probability distribution can be set to 1 for all samples, and Formula (B.1) reduces to the simple formula:

$$\hat{U} = \frac{\sum_{i=1}^{n} w(U_i) \times U_i}{\sum_{i=1}^{n} w(U_i)} \tag{B.7}$$

and the PRACTICAL PEAK VOLTAGE can be calculated as shown in Table B.3 and Formula (B.8).

Table B.3 – Weighting factors for the 20 equally spaced samples of the falling load waveform in Figure B.3

i	U_i kV	Formula	$w(U_i)$	$w(U_i) \times U_i$
1	0,00	(B.2)	$0,000\ 0 \times 10^{+00}$	$0,00\ 00 \times 10^{+00}$
2	10,00	(B.2)	$0,000\ 0 \times 10^{+00}$	$0,000\ 0 \times 10^{+00}$
3	68,60	(B.4)	$4,775\ 0 \times 10^{-02}$	$3,275\ 7 \times 10^{+00}$
4	70,60	(B.4)	$5,052\ 9 \times 10^{-02}$	$3,567\ 3 \times 10^{+00}$
5	70,20	(B.4)	$4,997\ 2 \times 10^{-02}$	$3,508\ 1 \times 10^{+00}$
6	70,22	(B.4)	$5,000\ 0 \times 10^{-02}$	$3,511\ 0 \times 10^{+00}$
7	69,90	(B.4)	$4,955\ 5 \times 10^{-02}$	$3,463\ 9 \times 10^{+00}$
8	70,18	(B.4)	$4,994\ 5 \times 10^{-02}$	$3,505\ 1 \times 10^{+00}$
9	70,00	(B.4)	$4,969\ 4 \times 10^{-02}$	$3,478\ 6 \times 10^{+00}$
10	69,90	(B.4)	$4,955\ 5 \times 10^{-02}$	$3,463\ 9 \times 10^{+00}$
11	46,60	(B.4)	$1,834\ 7 \times 10^{-02}$	$8,549\ 5 \times 10^{-01}$
12	30,10	(B.3)	$1,474\ 7 \times 10^{-03}$	$4,438\ 9 \times 10^{-02}$
13	20,80	(B.3)	$4,429\ 9 \times 10^{-05}$	$9,214\ 1 \times 10^{-04}$
14	13,90	(B.2)	$0,000\ 0 \times 10^{+00}$	$0,000\ 0 \times 10^{+00}$
15	9,80	(B.2)	$0,000\ 0 \times 10^{+00}$	$0,000\ 0 \times 10^{+00}$
16	6,80	(B.2)	$0,000\ 0 \times 10^{+00}$	$0,000\ 0 \times 10^{+00}$
17	4,20	(B.2)	$0,000\ 0 \times 10^{+00}$	$0,000\ 0 \times 10^{+00}$
18	2,60	(B.2)	$0,000\ 0 \times 10^{+00}$	$0,000\ 0 \times 10^{+00}$
19	2,10	(B.2)	$0,000\ 0 \times 10^{+00}$	$0,000\ 0 \times 10^{+00}$
20	1,50	(B.2)	$0,000\ 0 \times 10^{+00}$	$0,000\ 0 \times 10^{+00}$
			$\sum = 4,1687 \times 10^{-01}$	$\sum = 2,8674 \times 10^{+01}$

$$\hat{U} = \frac{28,674}{0,416\ 87} = 68,78\ \text{kV} \quad \text{(B.8)}$$

Bibliography

[1] KRAMER, H-M., SELBACH H-J., ILES, WJ. The practical peak voltage of diagnostic X-ray generators. *British Journal of Radiology*, 1998, 77, p.200-209

[2] IEC 60580:2019, *Medical electrical equipment – Dose area product meters*

[3] IEC 60731:2011, *Medical electrical equipment – Dosimeters with ionization chambers as used in radiotherapy*

[4] ISO/IEC Guide 98-3:2008, *Uncertainty of measurement – Part 3: Guide to the expression of uncertainty in measurement (GUM:1995)*

[5] ISO/IEC Guide 99:2007, *International vocabulary of metrology – Basic and general concepts and associated terms (VIM)*

Index of defined terms

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

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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.

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- 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.

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*

3 Termes et définitions

Pour les besoins du présent document, les termes et définitions donnés dans l'IEC 60601-1:2005, l'IEC TR 60788:2004, ainsi que les suivants s'appliquent.

L'ISO et l'IEC tiennent à jour des bases de données terminologiques destinées à être utilisées en normalisation, consultables aux adresses suivantes:

- IEC Electropedia: disponible à l'adresse http://www.electropedia.org/
- ISO Online browsing platform: disponible à l'adresse http://www.iso.org/obp

NOTE 1 Un Index des termes définis se trouve à la fin du présent document.

NOTE 2 Un glossaire interactif de l'IEC peut être consulté à l'adresse std.iec.ch.

3.1
FACTEUR DE CORRECTION
multiplicateur sans dimension qui corrige la VALEUR INDIQUEE d'un appareil à partir de sa valeur lors d'un fonctionnement dans des conditions particulières en sa valeur lors du fonctionnement dans des CONDITIONS DE REFERENCE indiquées

3.2
PLAGE EFFICACE
plage des VALEURS INDIQUEES pour lesquelles un appareil est conforme à la performance indiquée

Note 1 à l'article: La VALEUR INDIQUEE efficace maximale (ou minimale) est la plus élevée (ou la plus faible) de cette plage.

3.3
VALEUR INDIQUEE
valeur de grandeur déduite de l'échelle de lecture d'un appareil conjointement avec tout facteur d'échelle indiqué sur le panneau de commande de l'appareil

3.4
GRANDEUR D'INFLUENCE
toute grandeur externe qui peut altérer la performance d'un appareil (par exemple, la température ambiante, etc.) et toute propriété de l'APPAREIL A RAYONNEMENT X en essai qu'il est nécessaire de prendre en compte en utilisant l'appareil pour le MESURAGE NON INVASIF de la TENSION DU TUBE RADIOGENE (par exemple, la plage de la TENSION DU TUBE RADIOGENE, de la PENTE D'ANODE, le matériau de l'anode, la FILTRATION TOTALE, etc.)

3.5
PARAMETRE D'APPAREIL
toute propriété interne d'un appareil qui peut altérer la performance de l'appareil

3.6
ERREUR INTRINSEQUE
écart de la VALEUR MESUREE (c'est-à-dire, la VALEUR INDIQUEE, corrigée en CONDITIONS DE REFERENCE) de la VALEUR VRAIE CONVENTIONNELLE dans les CONDITIONS D'ESSAI NORMALISEES

3.7
MESURAGE INVASIF
mesurage de la TENSION DU TUBE RADIOGENE par raccordement externe d'un appareil de mesure adapté ou d'un diviseur haute résistance

3.8
LIMITES DE VARIATION
VARIATION maximale d'une CARACTERISTIQUE DE PERFORMANCE y, autorisée par le présent document

Note 1 à l'article: Lorsque les LIMITES DE VARIATION sont indiquées en tant que $\pm L$ % la VARIATION $\Delta y/y$, exprimée en pourcentage, doivent demeurer dans la plage comprise entre $-L$ % et $+L$ %.

3.9
TENSION DE CRETE MAXIMALE
valeur maximale de la TENSION DU TUBE RADIOGENE dans un intervalle de temps spécifié

Note 1 à l'article: L'unité de cette grandeur est le volt (V).

3.10
TENSION DE CRETE MOYENNE
valeur moyenne de toutes les crêtes de TENSION DU TUBE RADIOGENE au cours d'un intervalle de temps spécifié

Note 1 à l'article: L'unité de cette grandeur est le volt (V).

3.11
VALEUR MESUREE
meilleure estimation de la VALEUR VRAIE CONVENTIONNELLE d'une grandeur, déduite de la VALEUR INDIQUEE d'un appareil ainsi que de l'application de tous les FACTEURS DE CORRECTION applicables

Note 1 à l'article: La VALEUR VRAIE CONVENTIONNELLE est habituellement la valeur déterminée par la norme avec laquelle l'appareil en essai est comparé.

3.12
PLAGE EFFICACE MINIMALE
plus petite plage admise des VALEURS INDIQUEES pour lesquelles un appareil est conforme à la performance indiquée

3.13
MESURAGE NON INVASIF
mesurage de la TENSION DU TUBE RADIOGENE par analyse du RAYONNEMENT émis

3.14
CARACTERISTIQUE DE PERFORMANCE
une des grandeurs utilisées pour définir la performance d'un appareil (par exemple, REPONSE)

3.15
ONDULATION DE LA TENSION
TENSION au niveau du TUBE RADIOGENE, r, exprimée en pourcentage de la tension de crête, U_{max}, sur un intervalle de temps spécifié

Note 1 à l'article: Elle est exprimée par la formule suivante:

$$r = \frac{U_{\text{max}} - U_{\text{min}}}{U_{\text{max}}} \times 100 \ \%$$

où U_{max} est la tension la plus élevée dans l'intervalle, et U_{min} est la tension la plus basse dans l'intervalle.

3.16
TENSION DE CRETE PRATIQUE
TCP

$$\frac{\int_{U_{\text{min}}}^{U_{\text{max}}} p(U) \times w(U) \times U dU}{\int_{U_{\text{min}}}^{U_{\text{max}}} p(U) \times w(U) \times dU} \text{avec} \int_{U_{\text{min}}}^{U_{\text{max}}} p(U) dU = 1$$

où $p(U)$ est la fonction de répartition pour la tension U et $w(U)$ est une fonction de pondération, U_{max} est la tension la plus élevée dans l'intervalle, et U_{min} est la tension la plus basse dans l'intervalle

Note 1 à l'article: L'unité de la grandeur TENSION DE CRETE PRATIQUE est le volt (V).

Note 2 à l'article: Des informations supplémentaires sur la TENSION DE CRETE PRATIQUE, la fonction de pondération $w(U)$ et la fonction de répartition $p(U)$ sont fournies dans l'Annex B. En utilisant cette fonction de pondération $w(U)$, la TENSION DE CRETE PRATIQUE est définie comme le potentiel constant qui produit le même contraste de KERMA DANS L'AIR derrière un FANTOME spécifié que la tension à courant non continu en essai.

3.17
PLAGE ASSIGNEE
PLAGE ASSIGNEE d'utilisation
plage de valeurs d'une GRANDEUR D'INFLUENCE ou d'un PARAMETRE D'APPAREIL dans laquelle l'appareil fonctionne dans les LIMITES DE VARIATION

Note 1 à l'article: Ses limites sont les valeurs ASSIGNEES maximales et minimales.

Note 2 à l'article: La PLAGE ASSIGNEE MINIMALE est la plus petite plage d'une GRANDEUR D'INFLUENCE ou d'un PARAMETRE D'APPAREIL dans laquelle l'appareil doit fonctionner dans les LIMITES DE VARIATION spécifiées afin d'être conforme au présent document.

3.18
CONDITION DE REFERENCE
condition dans lesquelles toutes les GRANDEURS D'INFLUENCE et tous les PARAMETRES D'APPAREIL ont leurs VALEURS DE REFERENCE

3.19
VALEUR DE REFERENCE
valeur particulière d'une GRANDEUR D'INFLUENCE (ou d'un PARAMETRE D'APPAREIL) choisie comme référence, c'est-à-dire la valeur d'une GRANDEUR D'INFLUENCE (ou d'un PARAMETRE D'APPAREIL) à laquelle le FACTEUR DE CORRECTION pour dépendance par rapport à cette GRANDEUR D'INFLUENCE (ou ce PARAMETRE D'APPAREIL) est l'unité

3.20
ERREUR INTRINSEQUE RELATIVE
rapport de l'ERREUR INTRINSEQUE à la VALEUR VRAIE CONVENTIONNELLE

3.21
REPONSE
quotient de la VALEUR INDIQUEE divisée par la VALEUR VRAIE CONVENTIONNELLE

3.22
CONDITION D'ESSAI NORMALISEE
condition dans laquelle toutes les GRANDEURS D'INFLUENCE et tous les PARAMETRES D'APPAREIL ont leurs VALEURS D'ESSAI NORMALISEES

3.23
VALEUR D'ESSAI NORMALISEE
valeur ou plage de valeurs d'une GRANDEUR D'INFLUENCE ou d'un PARAMETRE D'APPAREIL, qui est/sont admises lors de la réalisation d'ETALONNAGES ou d'essais d'une autre GRANDEUR D'INFLUENCE ou d'un autre PARAMETRE D'APPAREIL

3.24
VARIATION
différence relative $\Delta y/y$, entre les valeurs d'une CARACTERISTIQUE DE PERFORMANCE y, lorsqu'une GRANDEUR D'INFLUENCE (ou un PARAMETRE D'APPAREIL) prend successivement pour hypothèse deux valeurs spécifiées, les autres GRANDEURS D'INFLUENCE (et PARAMETRES D'APPAREIL) étant maintenues constantes aux VALEURS D'ESSAI NORMALISEES (à moins que d'autres valeurs ne soient spécifiées)

3.25
TENSION DU TUBE RADIOGENE
différence de potentiel appliquée à un TUBE RADIOGENE entre l'anode et la cathode

Note 1 à l'article: L'unité de cette grandeur est le volt (V).

4 Exigences générales de performance pour le mesurage de la TENSION DE CRETE PRATIQUE

4.1 Grandeur à mesurer

La grandeur à mesurer est la TENSION DE CRETE PRATIQUE.

NOTE Des grandeurs supplémentaires peuvent être affichées.

Les PLAGES EFFICACES MINIMALES de la TENSION DE CRETE PRATIQUE doivent correspondre à celles énumérées dans le Tableau 1 pour les applications de RAYONNEMENT X correspondantes.

Tableau 1 – Plages efficaces minimales

Application	Matériau d'anode nominal	PLAGE EFFICACE MINIMALE
Mammographie (20 kV à 50 kV)	Mo [a]	24 kV à 35 kV
Diagnostic (40 kV à 150 kV)	W	60 kV à 120 kV
Tomodensitométrie (70 kV à 150 kV)	W	80 kV à 140 kV
Dentaire (40 kV à 110 kV)	W	60 kV à 90 kV
Radioscopique (40 kV à 130 kV)	W	60 kV à 120 kV

[a] Pour les matériaux d'anode utilisés en mammographie autres que le Mo, la PLAGE EFFICACE MINIMALE de TCP doit être d'au moins 10 kV.

4.2 Limites des CARACTÉRISTIQUES DE PERFORMANCE

4.2.1 Limites

Aucune valeur des limites des CARACTERISTIQUES DE PERFORMANCE indiquées dans ce paragraphe ne contient l'incertitude du matériel d'essai.

4.2.2 Erreur maximale

4.2.2.1 ERREUR INTRINSEQUE RELATIVE maximale pour les tensions supérieures à 50 kV

L'ERREUR INTRINSEQUE RELATIVE, I, des mesurages de la TENSION DE CRETE PRATIQUE, $\hat{U}$, effectués dans des CONDITIONS D'ESSAI NORMALISEES, ne doit pas être supérieure à ±2 % sur la PLAGE EFFICACE de tensions. Ceci est exprimé par la formule suivante :

$$|I| = \left| \frac{\hat{U}_{\text{meas}} - \hat{U}_{\text{true}}}{\hat{U}_{\text{true}}} \right| \leq 0{,}02$$

où $\hat{U}_{\text{meas}}$ est la VALEUR MESUREE de la TENSION DE CRETE PRATIQUE et $\hat{U}_{\text{true}}$ est la VALEUR VRAIE de la TENSION DE CRETE PRATIQUE. Les tensions pour la PLAGE EFFICACE MINIMALE sont énumérées dans le Tableau 1.

L'essai de conformité pour l'exigence de performance du présent paragraphe figure au 4.2.2.2.

4.2.2.2 ERREUR INTRINSEQUE maximale pour les tensions inférieures à 50 kV

L'ERREUR INTRINSEQUE maximale, E, des mesurages de la TENSION DE CRETE PRATIQUE, $\hat{U}$, effectués dans des CONDITIONS D'ESSAI NORMALISEES, ne doit pas être supérieure à ±1 kV sur la PLAGE EFFICACE de tensions. Ceci est exprimé par la formule suivante :

$$|E| = \left| \hat{U}_{\text{meas}} - \hat{U}_{\text{true}} \right| \leq 1{,}0 \text{ kV}$$

où $\hat{U}_{\text{meas}}$ est la VALEUR MESUREE de la TENSION DE CRETE PRATIQUE et $\hat{U}_{\text{true}}$ est la VALEUR VRAIE CONVENTIONNELLE de la TENSION DE CRETE PRATIQUE. Les tensions pour la PLAGE EFFICACE MINIMALE sont énumérées dans le Tableau 1.

La conformité aux exigences de performance de 4.2.2.1 et de 4.2.2.2 doit être vérifiée en mesurant l'ERREUR INTRINSEQUE RELATIVE supérieure à 50 kV ou l'ERREUR INTRINSEQUE inférieure à 50 kV sur la PLAGE EFFICACE de tensions pour chaque application déclarée. Les CONDITIONS D'ESSAI NORMALISEES sont énumérées dans le Tableau 2 pour chaque application. Les points aux limites de la PLAGE EFFICACE doivent être vérifiés. Pour la mammographie, le pas nominal entre les mesurages ne doit pas être supérieur à 2 kV. Pour toutes les autres applications, le pas nominal entre les mesurages ne doit pas être supérieur à 5 kV pour des tensions inférieures à 100 kV ni supérieur à 10 kV pour des tensions supérieures à 100 kV.

Lorsque plus d'une configuration d'appareil peut être utilisée pour mesurer une étendue de tensions, alors cette étendue de tensions doit être mesurée en utilisant toutes les configurations d'appareils correspondantes. Au minimum, les points aux limites et les points intermédiaires suffisants doivent être mesurés pour satisfaire aux exigences de pas minimales données ci-dessus. À titre d'exemple, différentes paires d'absorbeurs peuvent être utilisées pour fournir le chevauchement d'étendues de tensions. Dans le cas de paires d'absorbeurs différentes, si la première étendue mesurée est comprise entre 40 kV et 80 kV, et la seconde entre 60 kV et 120 kV, alors l'étendue de chevauchement est comprise entre 60 kV et 80 kV. Au minimum, les mesurages sont effectués en utilisant chaque paire d'absorbeur à 60 kV, 65 kV, 70 kV, 75 kV, et 80 kV.

4.2.3 Indications supérieures et inférieures à la plage

L'appareil doit clairement indiquer le cas où il affiche une lecture en dehors de sa PLAGE EFFICACE de TENSION DE CRETE PRATIQUE.

Les conditions au-dessus et en dessous de la PLAGE EFFICACE de la TENSION DE CRETE PRATIQUE doivent être soumises à l'essai et il faut démontrer que lorsque l'appareil affiche une lecture, il est clairement indiqué à l'utilisateur que la lecture peut ne pas satisfaire à l'exactitude de l'appareil.

Lorsque plus d'une configuration d'appareil peut être utilisée pour mesurer une étendue de tensions, alors les conditions dans les plages supérieures et inférieures doivent être vérifiées pour toutes les configurations d'appareils correspondantes. À titre d'exemple, différentes paires d'absorbeurs peuvent être utilisées pour fournir le chevauchement d'étendues de tensions. Dans le cas de différentes paires d'absorbeurs, lorsque la première étendue mesurée est comprise entre 40 kV et 80 kV, et la seconde entre 60 kV et 120 kV, alors les indications dans les plages supérieures et inférieures sont vérifiées en dessous de 40 kV et au-dessus de 80 kV pour la première paire d'absorbeurs, et en dessous de 60 kV et au-dessus de 120 kV pour la deuxième paire d'absorbeurs. (Le refus de l'appareil d'effectuer une lecture dans ces conditions est un résultat acceptable.)

La conformité à l'exigence de performance du présent paragraphe doit être vérifiée à la limite inférieure de la PLAGE ASSIGNEE des débits de dose. Toutes les autres GRANDEURS D'INFLUENCE doivent être aux CONDITIONS D'ESSAI NORMALISEES comme cela est énuméré dans le Tableau 2.

4.2.4 Répétabilité

Lorsqu'un mesurage est répété avec le même appareil dans des conditions inchangées, le COEFFICIENT DE VARIATION du mesurage individuel ne doit pas dépasser ±0,5 % ou l'écart-type ne doit pas dépasser 0,5 kV, en prenant celle des deux valeurs qui est la plus élevée.

La conformité à l'exigence de performance du présent paragraphe doit être vérifiée en déterminant le COEFFICIENT DE VARIATION de dix mesurages consécutifs pris à la limite inférieure de la PLAGE ASSIGNEE des débits de dose. Toutes les autres GRANDEURS D'INFLUENCE doivent correspondre aux CONDITIONS D'ESSAI NORMALISEES comme cela est énuméré dans le Tableau 2 pour chaque application. Les points aux limites de la PLAGE EFFICACE et un point proche du milieu de la PLAGE EFFICACE doivent être vérifiés. L'essai doit être réalisé une seconde fois avec le débit de dose également dans des CONDITIONS D'ESSAI NORMALISEES.

Lorsque plus d'une configuration d'appareils peut être utilisée pour mesurer une étendue de tensions, alors les points aux limites de cette étendue de tensions doivent être mesurés en utilisant toutes les configurations d'appareils correspondantes. À titre d'exemple, différentes paires d'absorbeurs peuvent être utilisées pour fournir le chevauchement d'étendues de tensions. Dans le cas de paires d'absorbeurs différentes, lorsque la première étendue mesurée est comprise entre 40 kV et 80 kV, et la seconde entre 60 kV et 120 kV, alors l'étendue de chevauchement est comprise entre 60 kV et 80 kV. Au minimum, les mesurages sont effectués en utilisant chaque paire d'absorbeurs à 60 kV et à 80 kV.

4.2.5 Stabilité à long terme

La conception et la construction doivent être telles que la REPONSE de l'appareil ne varie pas de plus de ±2,0 % pour des tensions supérieures à 50 kV sur une période d'un an. Pour des tensions inférieures à 50 kV, la différence entre la VALEUR INDIQUEE et la VALEUR VRAIE CONVENTIONNELLE ne doit pas varier de plus de ±1,0 kV sur une période d'un an.

La conformité à cette exigence de performance doit être vérifiée en maintenant un appareil représentatif stocké dans des CONDITIONS D'ESSAI NORMALISEES de température et d'humidité relative et en mesurant l'ERREUR INTRINSEQUE RELATIVE supérieure à 50 kV ou l'ERREUR INTRINSEQUE inférieure à 50 kV au moins pour deux tensions, l'une proche du niveau supérieur et l'autre proche du niveau inférieur de la PLAGE EFFICACE.

Lorsque plus d'une configuration d'appareils peut être utilisée pour mesurer une étendue de tensions, alors les points aux limites de cette étendue de tensions doivent être mesurés en utilisant toutes les configurations d'appareils correspondantes. À titre d'exemple, différentes paires d'absorbeurs peuvent être utilisées pour fournir le chevauchement d'étendues de tensions. Dans le cas de paires d'absorbeurs différentes, lorsque la première étendue mesurée est comprise entre 40 kV et 80 kV, et la seconde entre 60 kV et 120 kV, alors l'étendue de chevauchement est comprise entre 60 kV et 80 kV. Au minimum, les mesurages sont effectués en utilisant chaque paire d'absorbeurs à 60 kV et à 80 kV.

Ces mesurages doivent être effectués à au moins un mois d'intervalle sur une période dont la durée ne peut être inférieure à six mois. Une analyse de régression linéaire doit être utilisée pour extrapoler ces lectures afin d'obtenir la modification de REPONSE sur une année complète.

4.3 LIMITES DE VARIATION des effets de GRANDEURS D'INFLUENCE

4.3.1 GRANDEURS D'INFLUENCE

Les grandeurs qui peuvent influencer la performance de l'appareil sont données dans le Tableau 2.

4.3.2 PLAGE ASSIGNÉE MINIMALE d'utilisation

La PLAGE ASSIGNEE MINIMALE d'utilisation pour chacune des GRANDEURS D'INFLUENCE concernées est fournie dans le Tableau 2.

4.3.3 CONDITIONS DE RÉFÉRENCE

Les CONDITIONS DE REFERENCE pour chaque GRANDEUR D'INFLUENCE particulière sont données dans le Tableau 2. Pour les GRANDEURS D'INFLUENCE qui peuvent être commandées, il convient que la VALEUR DE REFERENCE soit la valeur utilisée pendant l'ETALONNAGE du matériel.

4.3.4 CONDITIONS D'ESSAI NORMALISÉES

Les CONDITIONS D'ESSAI NORMALISEES indiquées dans le Tableau 2, doivent être satisfaites pendant la procédure d'essai sauf pour la GRANDEUR D'INFLUENCE soumise à l'essai.

4.3.5 LIMITES DE VARIATION

Les LIMITES DE VARIATION $\pm L$ pour chaque GRANDEUR D'INFLUENCE particulière sont données dans le Tableau 2. Pour toute modification d'une GRANDEUR D'INFLUENCE dans sa PLAGE ASSIGNEE, la modification de la REPONSE de l'appareil doit être telle que la relation suivante soit remplie:

$$\left| \frac{R}{R_{\text{ref}}} - 1 \right| \times 100\ \% \le L$$

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

GRANDEUR D'INFLUENCE	PLAGE ASSIGNÉE MINIMALE d'utilisation	CONDITIONS DE RÉFÉRENCE	CONDITIONS D'ESSAI NORMALISÉES	± E kV	± L %	Para-graphe
Fréquence et forme d'onde de la tension:						
Diagnostic	Potentiel constant, fréquence moyenne et d'impulsions 2-, 6-, 12 générateurs [a]	Potentiel constant	Potentiel constant, ondulation inférieure à 4 %		2,0	4.4.2
Mammographie	Potentiel constant			0,5		
Pente d'anode:						
Diagnostic	6° à 18°	12°	VALEUR DE RÉFÉRENCE ±2°		0,5	4.4.3
Mammographie	15° à 24°	20°	VALEUR DE RÉFÉRENCE ±2°	0,5		
Filtration:						
Diagnostic	2,5 mm Al à 3,5 mm Al [b]	3,0 mm Al	VALEUR DE RÉFÉRENCE ±5 %		1,5	4.4.4
Mammographie	25 µm Mo à 35 µm Mo [c]	30 µm Mo	VALEUR DE RÉFÉRENCE ±5 %	0,5		
Tomodensitométrie	4 mm Al à 8 mm Al	6 mm Al	VALEUR DE RÉFÉRENCE ±5 %		1,5	
Dentaire	1 mm Al à 2 mm Al	1,5 mm Al	VALEUR DE RÉFÉRENCE ±5 %		1,5	
Débit de dose:						
Diagnostic	20 mGy/s à 200 mGy/s	Comme cela est indiqué par le FABRICANT	VALEUR DE RÉFÉRENCE ±20 %	0,5	0,5	4.4.5
Mammographie	25 mGy/s à 150 mGy/s				0,5	
Tomodensitométrie	20 mGy/s à 200 mGy/s				0,5	
Dentaire	5 mGy/s à 50 mGy/s				0,5	
Radioscopique	1 mGy/s à 10 mGy/s					
Temps d'irradiation						
Diagnostic	10 ms à 1 000 ms	100 ms	VALEUR DE RÉFÉRENCE ±20 %		0,5	4.4.6
Autre	200 ms à 1 000 ms	500 ms	VALEUR DE RÉFÉRENCE ±20 %		0,5	
Taille de champ:						
Plage assignée	Longueur et largeur indiquées par le FABRICANT + 30 % à 10 %	Comme cela est indiqué par le FABRICANT.	VALEUR DE RÉFÉRENCE ±2 %		0,5	4.4.7.1
Champ large	30 cm sur 30 cm	30 cm sur 30 cm	VALEUR DE RÉFÉRENCE ±2 %		2,0	4.4.7.2
Distance focale-Détecteur	32 cm à 60 cm ou comme cela est indiqué par le FABRICANT	40 cm ou comme cela est indiqué par le FABRICANT	VALEUR DE RÉFÉRENCE ±1 %		0,5	4.4.8

GRANDEUR D'INFLUENCE	PLAGE ASSIGNÉE MINIMALE d'utilisation	CONDITIONS DE RÉFÉRENCE	CONDITIONS D'ESSAI NORMALISÉES	± E kV	± L %	Para-graphe
Angle d'incidence Rotation	±5°	0°	VALEUR DE RÉFÉRENCE ±1°		0,5	4.4.9
	±10°	0°	VALEUR DE RÉFÉRENCE ±1°		0,5	4.4.10.1
	±180°	0°	VALEUR DE RÉFÉRENCE ±1°		0,5	4.4.10.2
Température	15 °C à 35 °C	20 °C	VALEUR DE RÉFÉRENCE ±2 °C		1,0	4.4.11
Humidité relative	≤ 80 % (max 20 g/m^3 au plus)	50 %	30 % à 75 %			
Alimentation						
Tension de secteur et fréquence	115 V ou 230 V + 10 % à 15 %	115 V/230 V	VALEUR DE RÉFÉRENCE ±1 %		0,5	4.4.12.1
Batteries	50 Hz ou 60 Hz	50 Hz/60 Hz comme cela est indiqué	VALEUR DE RÉFÉRENCE ±1 %		0,5	4.4.12.2
Batteries rechargeables	Comme cela est indiqué par le FABRICANT. Neuve à faible	Neuve, Déconnexion du réseau	VALEUR DE RÉFÉRENCE ±1 %		0,5	4.4.12.3
Compatibilité électromagnétique	IEC 61000-4-2 IEC 61000-4-3 IEC 61000-4-4 IEC 61000-4-5 IEC 61000-4-6 IEC 61000-4-11	Sans aucune perturbation	Non significative		1,0	4.4.13
Filtration en tungstène supplémentaire (vieillissement du tube)	0 µm à 10 µm W	3 µm W	0 µm W à 3 µm W		2,0	4.4.14

[a] La plage de fréquences f = 50 Hz à 50 kHz, ONDULATION DE LA TENSION (%) de 0 à (50 – 10log f), par exemple 0 % à 20 % à 1 000 Hz, 0 % à 3 % à 50 kHz. Toutes les fréquences supérieures à 50 kHz sont traitées comme des générateurs de potentiel constant.

[b] La filtration en dehors de la PLAGE ASSIGNEE MINIMALE peut être établie en appliquant des corrections.

[c] Le GENERATEUR RADIOLOGIQUE à rayons X avec une anode en molybdène, une fenêtre en béryllium, et aucune FILTRATION ADDITIONNELLE autre que les 30 µm de Mo.

4.4 Procédures d'essai de performance

4.4.1 Remarques générales

Les essais de performance pour une GRANDEUR D'INFLUENCE particulière doivent être effectués de manière que la GRANDEUR D'INFLUENCE correspondante soit modifiée sur la PLAGE ASSIGNEE d'utilisation et que les CONDITIONS D'ESSAI NORMALISEES soient utilisées pour toutes les autres GRANDEURS D'INFLUENCE. Sauf indication contraire, la VALEUR D'ESSAI pour la grandeur à mesurer, c'est-à-dire la tension, est tirée du Tableau 3. Sauf spécification contraire du FABRICANT de l'appareil, l'appareil de mesure doit être placé sur une table radiographique ou sur une surface dont les caractéristiques de diffusion de RAYONS X sont similaires à celles d'une table radiographique.