# INTERNATIONAL STANDARD

# IEC 61676

First edition
2002-09

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

*Appareils électromédicaux –*
*Instruments de dosimétrie pour la mesure non invasive de la tension du tube radiogène dans la radiologie de diagnostic*



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# CONTENTS

FOREWORD ..... 3
INTRODUCTION ..... 5

1 Scope and object ..... 6
2 Normative references ..... 6
3 Terminology and definitions ..... 7
4 General performance requirements for measurement of PRACTICAL PEAK VOLTAGE measurements ..... 10
4.1 Quantity to be measured ..... 10
4.2 Limits of PERFORMANCE CHARACTERISTICS ..... 10
4.3 LIMITS OF VARIATION for effects of INFLUENCE QUANTITIES ..... 13
4.4 Performance test procedures ..... 15
5 Special instrumental requirements and marking ..... 21
5.1 Requirements for the complete instruments ..... 21
5.2 General ..... 21
5.3 Display ..... 22
5.4 Range of measurement ..... 22
5.5 Connectors and cables ..... 22
6 ACCOMPANYING DOCUMENTS ..... 22
6.1 General ..... 22
6.2 Information provided ..... 22
6.3 Instrument description ..... 22
6.4 Detector ..... 22
6.5 Delay time ..... 22
6.6 Measurement window ..... 22
6.7 Data outlet ..... 23
6.8 Transport and storage ..... 23

Annex A (informative) Recommended performance criteria for the invasive divider ..... 24
Annex B (informative) Additional information on PRACTICAL PEAK VOLTAGE ..... 25
Annex C (informative) Glossary of defined terms ..... 32

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

1) The IEC (International Electrotechnical Commission) is a worldwide organization for standardization comprising all national electrotechnical committees (IEC National Committees). The object of the IEC is to promote international co-operation on all questions concerning standardization in the electrical and electronic fields. To this end and in addition to other activities, the IEC publishes International Standards. Their preparation is entrusted to technical committees; any IEC National Committee interested in the subject dealt with may participate in this preparatory work. International, governmental and non-governmental organizations liaising with the IEC also participate in this preparation. The IEC collaborates closely with the International Organization for Standardization (ISO) in accordance with conditions determined by agreement between the two organizations.
2) The formal decisions or agreements of the IEC on technical matters express, as nearly as possible, an international consensus of opinion on the relevant subjects since each technical committee has representation from all interested National Committees.
3) The documents produced have the form of recommendations for international use and are published in the form of standards, technical specifications, technical reports or guides and they are accepted by the National Committees in that sense.
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5) The IEC provides no marking procedure to indicate its approval and cannot be rendered responsible for any equipment declared to be in conformity with one of its standards.
6) Attention is drawn to the possibility that some of the elements of this International Standard may be the subject of patent rights. The IEC shall not be held responsible for identifying any or all such patent rights.

International Standard IEC 61676 has been prepared by subcommittee SC 62C: Equipment for radiotherapy, nuclear medicine and radiation dosimetry, of IEC Technical Committee 62: Electrical equipment in medical practice.

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

| FDIS | Report on voting |
|---|---|
| 62C/340/FDIS | 62C/344/RVD |

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

This publication has been drafted in accordance with the ISO/IEC Directives, Part 3.

Annexes A, B and C are for information only.

In this standard 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 STANDARD 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 publication will remain unchanged until 2004. At this date, the publication will be

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

A bilingual version of this publication may be issued at a later date.

NOTE The committee is aware of the fact that this standard does not address all problems associated with non-invasive high voltage measurements. In particular one influence quantity concerning the target condition is not dealt with at all. Before this can be done, a substantial amount of measurements is still necessary to improve the physical understanding of this influence quantity. On the other hand, for the reasons described in the introduction there is an urgent need to publish this standard in order to assure that non-invasive measurements are comparable to each other within tolerable uncertainties, regardless of differences in X-RAY GENERATOR, waveform or other influence quantities (except target condition), which is not the case for the time being. The committee has decided to revise this standard as soon as sufficient knowledge on the outstanding items is 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 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 Standard 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 will 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 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, and this value serves as a guide for the LIMITS OF VARIATION for the effects of INFLUENCE QUANTITIES.



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

IEC 60417 (all parts), *Graphical symbols for use on equipment*

IEC 60788:1984, *Medical radiology – Terminology*

IEC 61000-4-2:1995, *Electromagnetic compatibility (EMC) – Part 4: Testing and measurement techniques – Section 2: 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: Testing and measurement techniques – Section 4: Electrical fast transient/burst immunity test.* Basic EMC Publication

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

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

IEC 61000-4-11:1994, *Electromagnetic compatibility (EMC) – Part 4: Testing and measurement techniques – Section 11: Voltage dips, short interruptions and voltage variations immunity tests.* 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 7000:1989, *Graphical symbols for use on equipment – Index and synopsis*

## 3 Terminology and definitions

For the purposes of this standard the following definitions 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.

**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. The maximum (minimum) effective INDICATED VALUE is the highest (lowest) in this range

**3.3**
**INDICATED VALUE**
the 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 affect the performance of an instrument (e.g. ambient temperature etc.) and any property of the X-RAY EQUIPMENT under test that needs to 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 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**
the maximum VARIATION of a PERFORMANCE CHARACTERISTIC $y$, permitted by this standard. 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. 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. The unit of this quantity is the volt (V)

**3.11**
**MEASURED VALUE**
the 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 The CONVENTIONAL TRUE VALUE will usually be the value determined by the working standard with which the instrument under test is being compared

**3.12**
**MINIMUM EFFECTIVE RANGE**
the MINIMUM EFFECTIVE RANGE is the 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**
the VOLTAGE RIPPLE at the X-RAY TUBE, $r$, is expressed as a percentage of the peak voltage, $U_{max}$, over a specified time interval. This is expressed by the equation:

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

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)**

The PRACTICAL PEAK VOLTAGE $\hat{U}$ is defined as:

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

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. The unit of the quantity PRACTICAL PEAK VOLTAGE is the volt (V)

NOTE 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 will be 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 (of use)**

the range of values of an INFLUENCE QUANTITY or INSTRUMENT PARAMETER within which the instrument will operate within the LIMITS OF VARIATION. Its limits are the maximum and minimum RATED values.

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 standard

**3.18**
**REFERENCE CONDITIONS**

conditions 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**

the ratio of the INTRINSIC ERROR to the CONVENTIONAL TRUE VALUE

**3.21**
**RESPONSE**

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

**3.22**
**STANDARD TEST CONDITIONS**

conditions under which all INFLUENCE QUANTITIES and INSTRUMENT PARAMETERS have their STANDARD TEST VALUES

**3.23**
**STANDARD TEST VALUES**
a value, values, or a range of values of an INFLUENCE QUANTITY or INSTRUMENT PARAMETER, which is/are permitted when carrying out calibrations or tests on another INFLUENCE QUANTITY or INSTRUMENT PARAMETER

**3.24**
**VARIATION**
The 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 . 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 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 kV to 150 kV) | W | 100 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 equation:

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

where $\hat{U}_{meas}$ is the MEASURED VALUE of PRACTICAL PEAK VOLTAGE and $\hat{U}_{true}$ 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 4.2.2.1 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 equation:

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

where $\hat{U}_{meas}$ is the MEASURED VALUE of PRACTICAL PEAK VOLTAGE and $\hat{U}_{true}$ 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 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 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 4.2.3 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 kV or ±0,5 % whichever is greater

*Compliance with performance requirement 4.2.4 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 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.

*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 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:

$$\left|(R / R_{\text{ref}}) - 1\right| \cdot 100\,\% \leq L$$

**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:<br>Diagnostic<br><br><br><br>Mammography | Constant potential, 2-, 6-, 12-pulse and medium frequency generators [a]<br><br>Constant potential | Constant potential | Constant potential, ripple less than 4 % | <br><br><br><br>0,5 | 2,0 | 4.4.2 |
| Anode angle:<br>Diagnostic<br>Mammography | 6° to 18°<br>15° to 24° | 12°<br>20° | REFERENCE VALUE ± 2°<br>REFERENCE VALUE ± 2° | 0,5 | 0,5 | 4.4.3 |
| Filtration:<br>Diagnostic<br>Mammography<br>CT<br>Dental | 2,5 to 3,5 mm Al [b]<br>25 to 35 µm Mo [c]<br>4 to 8 mm Al<br>1 to 2 mm Al | 3,0 mm Al<br>30 µm Mo<br>6 mm Al<br>1,5 mm Al | REFERENCE VALUE ± 5 %<br>REFERENCE VALUE ± 5 %<br>REFERENCE VALUE ± 5 %<br>REFERENCE VALUE ± 5 % | 0,5 | 1,5<br><br>1,5<br>1,5 | 4.4.4 |
| Dose rate:<br>Diagnostic<br>Mammography<br>CT<br>Dental<br>Fluoroscopic | 20 to 200 mGy/s<br>25 to 150 mGy/s<br>20 to 200 mGy/s<br>5 to 50 mGy/s<br>1 to 10 mGy/s | As stated byMfg. | REFERENCE VALUE ± 20 % | 0,5 | 0,5<br>0,5<br>0,5<br>0,5 | 4.4.5 |
| Irradiation time:<br>Diagnostic<br>Other | 10 to 1000 ms<br>200 to 1000 ms | 100 ms<br>500 ms | REFERENCE VALUE ± 20 %<br>REFERENCE VALUE ± 20 % | | 0,5<br>0,5 | 4.4.6 |
| Field size:<br>Rated Range<br><br>Large Field | Length and width stated by Mfg. [d] + 30 % – 10 %<br>30 cm by 30 cm | As stated by Mfg.<br>30 cm by 30 cm | REFERENCE VALUE ± 2 %<br><br>REFERENCE VALUE ± 2 % | | 0,5<br><br>2,0 | 4.4.7.1<br><br>4.4.7.2 |
| Detector-Focal distance | 32 to 60 cm or as stated by Mfg | 40 cm or as stated by Mfg | REFERENCE VALUE ± 1 % | | 0,5 | 4.4.8 |
| Angle of incidence<br>Rotation | ± 5°<br>± 180° | 0°<br>0° | REFERENCE VALUE ± 1°<br>REFERENCE VALUE ± 1° | | 0,5<br>0,5 | 4.4.9<br>4.4.10 |
| Temperature<br>Relative humidity | 15 to 35°C<br>≤ 80 % (max 20 g/m$^3$) | 20°C<br>50 % | REFERENCE VALUE ± 2°C<br>30 TO 75 % | | 1,0 | 4.4.11 |
| Power supply<br>Line voltage and frequency<br>Batteries<br>Rechargeable batteries | 115 or 230 V + 10 % – 15 %<br>50 or 60 Hz<br>As stated by Mfg.<br>Fresh to Low | 115/230 V<br>50/60 Hz<br>As stated<br>Fresh, mains disconnected | REFERENCE VALUE ± 1 %<br><br>REFERENCE VALUE ± 1 %<br>REFERENCE VALUE ± 1 % | | 0,5<br><br>0,5<br>0,5 | 4.4.12.1<br><br>4.4.12.2<br>4.4.12.3 |
| Electromagnetic compatibility | IEC 61000-4-(2 to 6, 11) | Without any disturbance | Insignificant | | 1,0 | 4.4.13 |

[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 50kHz are treated as constant potential generators.

[b] Filtration outside of MINIMUM RATED RANGE may 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.

[d] Mfg. = Manufacturer

### 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 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 | 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

VOLTAGE RIPPLE ( % ) 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 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 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 be compared with those obtained by an invasive high voltage divider system. If the detector focus distance or the radiation quality must 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 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 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

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.

##### 4.4.7.1 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.*

##### 4.4.7.2 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 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 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 be made by exposing the instrument to X-RADIATIONS at the test value indicated in table 3, or the MANUFACTURER may 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 be made by IRRADIATION at the test value indicated in table 3, or the MANUFACTURER may 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 d.c. 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 be made by IRRADIATION at the test value indicated in table 3, or the MANUFACTURER may 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 compromise the instrument shield, or batteries may not be at chassis ground. In these cases, the MANUFACTURER shall provide 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 be made by IRRADIATION at the test value indicated in table 3, or the MANUFACTURER may 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 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 be made by IRRADIATION at the test value indicated in table 3, or the MANUFACTURER may 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 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.

##### 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 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 and 1 000 MHz with a field strength of 10 V/m may 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 be made by IRRADIATION at the test value indicated in table 3, or the MANUFACTURER may 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 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 be made by IRRADIATION at the test value indicated in table 3, or the MANUFACTURER may 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 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.

#### 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 be made by IRRIADIATION at the test value indicated in table 3, or the MANUFACTURER may 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 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.



## 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 standard must have a digital display. The display must 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 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 describe in the accompanying documents whether this signal is proportional to voltage or dose rate and information must 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 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 B
(informative)

## Additional information on PRACTICAL PEAK VOLTAGE

### B.1 Introduction

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 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]

### 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:

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

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

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

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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.

where

a = –8,646855E-03
b = +8,170361E-01
c = –2,327793E+01

and for the voltage region of 36 kV $< U_i \leq$ 150 kV, by

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

where

d = +4,310644E-10

e = –1,662009E-07

f = +2,308190E-05

g = +1,030820E-05

h = –1,747153E-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 $U_i \leq$ 50 kV the formula and the values for the parameters k to o as given below are to be used.

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

where

k = –2,142352E-06

l = +2,566291E-04

m = –1,968138E-02

n = +8,506836E-01

o = –1,514362E+01

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