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INTERNATIONAL STANDARD

AMENDMENT 2

Medical electrical equipment – Part 2-65: Particular requirements for the basic safety and essential performance of dental intra-oral X-ray equipment

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FOREWORD

This second amendment has been prepared by subcommittee 62B: Diagnostic imaging equipment, of IEC technical committee 62: Electrical equipment in medical practice.

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

FDIS	Report on voting
62B/1233/FDIS	62B/1238/RVD

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

The committee has decided that the contents of this amendment and the base publication will remain unchanged until the stability date indicated on the IEC website under "http://webstore.iec.ch" in the data related to the specific publication. At this date, the publication will be

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- withdrawn,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

201.7.9.1 General

Add, under Addition, after the existing second paragraph, the following new text and new note:

If a test or a QUALITY CONTROL PROCEDURE recommended by the MANUFACTURER requires a device-specific arrangement (including a tool, a phantom, a special software or a software setting); that is only available from the MANUFACTURER, the MANUFACTURER shall provide this arrangement for the RESPONSIBLE ORGANIZATION.

NOTE 102 The intention is to perform these QUALITY CONTROL PROCEDURES and tests using only the supplied information.

203.5.2.4.5 Deterministic effects

Add, after the note of this subclause, the following new subclause:

203.5.2.4.6 RISK to OPERATORS

Addition:

NOTE OPERATORS of HAND-HELD ME EQUIPMENT are assumed to be in the SIGNIFICANT ZONE OF OCCUPANCY when the ME equipment is hand-held during LOADING.

203.6.2.1 Normal initiation and termination of the IRRADIATION

Add, under Addition, after the first paragraph, the following new paragraph and new note:

HAND-HELD ME EQUIPMENT shall have a means to prevent unauthorized initiation of IRRADIATION.

NOTE Example may be a physical key or password.

203.8.5.4 Positioning of the PATIENT and restriction of the irradiated area

Add, under Replacement, after the note, the following new text:

The MANUFACTURER of an INTRA-ORAL image receptor shall make available ACCESSORIES that may be used to hold the INTRA-ORAL X-RAY IMAGE RECEPTOR and align the X-ray beam with the INTRA-ORAL X-RAY IMAGE RECEPTOR during LOADING.

203.12.2 Mounting OF X-RAY SOURCE ASSEMBLIES and X-RAY IMAGING ARRANGEMENTS

Replace, under Replacement, the introductory paragraph of the list with the following:

For DENTAL INTRA-ORAL X-RAY SOURCE ASSEMBLIES intended to be HAND-HELD during LOADING in NORMAL USE, the following information shall be provided with the ACCOMPANYING DOCUMENTS:

203.12.4 LEAKAGE RADIATION in the LOADING STATE

Add, under Replacement, before the first paragraph, the following new text:

1) DENTAL INTRA-ORAL X-RAY SOURCE ASSEMBLIES intended to be HAND-HELD during LOADING in NORMAL USE

In the LOADING STATE, the AIR KERMA due to LEAKAGE RADIATION from X-RAY SOURCE ASSEMBLIES, at any point on the outer surface of the equipment, when operated at the NOMINAL X-RAY TUBE VOLTAGE under conditions of LOADING corresponding to the reference LOADING conditions, shall not exceed 0,05 mGy in one hour.

Compliance is checked by the following test procedure:

a) block the RADIATION APERTURE sufficiently to ensure that measurements of LEAKAGE RADIATION are not affected by RADIATION passing through it. Make and fit any cover used for this purpose to be as close as practicable to the RADIATION APERTURE and not to overlap it to an extent greater than is required for effective blocking;

b) for LOADING during the test

1) use the NOMINAL X-RAY TUBE VOLTAGE for the X-RAY SOURCE ASSEMBLY under test;

2) use a convenient value of CURRENT TIME PRODUCT;

3) do not use LOADINGS so as to cause any specified ratings to be exceeded during the test;

c) determine, if necessary by making measurements, how the determination of LEAKAGE RADIATION will be affected by the settings and configurations specified for the NORMAL USE of the assembly under test. For the test itself, adopt the combination appearing to be the least favourable with regard to compliance;

d) with the appropriate LOADING FACTORS applied, make a sufficient number of measurements to determine the maximum AIR KERMA over the entire surface of the equipment;

e) normalize the MEASURED VALUES at the LOADING FACTORS actually used, to values of AIR KERMA in one hour corresponding to the reference conditions of LOADING stated in the ACCOMPANYING DOCUMENTS, in accordance with 12.3 of the collateral standard;

f) compliance is achieved if no MEASURED VALUE obtained by the test procedure exceeds the required limit.

2) DENTAL INTRA-ORAL X-RAY SOURCE ASSEMBLIES not intended to be HAND-HELD during LOADING in NORMAL USE

Delete the existing Note 101.

203.13.3 Protection by distance

Add, at the end of this subclause, before the compliance statement, the following new paragraph:

The ACCOMPANYING DOCUMENTS shall include a statement drawing the attention of the RESPONSIBLE ORGANISATION indicating that the HAND-HELD operation of the equipment increases the OPERATOR radiation exposure due to the proximity.

Add, at the end of 201.13.3, before Additional subclause, the following new subclause:

203.13.4 Designated SIGNIFICANT ZONES OF OCCUPANCY

Addition:

A HAND-HELD ME EQUIPMENT shall instead provide the profile(s) of STRAY RADIATION with respect to the location of FOCAL SPOT and the orientation of the X-ray BEAM AXIS of the HAND-HELD ME EQUIPMENT.

203.13.101 Protection against stray radiation for HAND-HELD ME EQUIPMENT

Replace the entire subclause with the following:

203.13.101 Protection against stray radiation for HAND-HELD ME EQUIPMENT

HAND-HELD ME EQUIPMENT shall include a means to protect the OPERATOR from STRAY RADIATION with a shield which cannot be removed and contains a minimum of 0,25 mm lead equivalence at a NOMINAL X-RAY TUBE VOLTAGE of 70 kV.

The MANUFACTURER of HAND-HELD ME EQUIPMENT shall make available a means to provide support such that it can be operated without being HAND-HELD. When the device is operated with such means, it shall be possible to operate the device with a second irradiation switch, whether attached or remote, that gives the OPERATOR the option to stand at least 2 m from the X-RAY SOURCE ASSEMBLY.

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