INTERNATIONAL STANDARD

IEC 60601-2-43

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Medical electrical equipment –

Part 2-43: Particular requirements for the safety of X-ray equipment for interventional procedures

Appareils électromédicaux –

Partie 2-43: Règles particulières de sécurité pour les appareils radiologiques lors d'interventions

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

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MEDICAL ELECTRICAL EQUIPMENT –

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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.
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International Standard IEC 60601-2-43 has been prepared by subcommittee 62B: Diagnostic imaging equipment, of IEC technical committee 62: Electrical equipment in medical practice.

The text of this Particular Standard is based on the following documents:

FDIS	Report of voting
62B/401/FDIS	62B/408/RVD

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

Annexes AA, EE and FF form an integral part of this standard.

Annexes BB, CC and DD are for information only.

In this Particular Standard, the following print types are used:

– requirements, compliance with which can be tested and definitions: roman type;
– notes, explanations, advice, introductions, general statements, exceptions and references: smaller type;
– *test specifications: italic type;*
– TERMS USED THROUGHOUT THIS PARTICULAR STANDARD WHICH HAVE BEEN DEFINED IN CLAUSE 2 OF THE GENERAL STANDARD, IN IEC 60788 OR IN THIS STANDARD: SMALL CAPITALS.

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

The committee has decided that the contents of this publication will remain unchanged until 2005. At this date, the publication will be

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- withdrawn;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

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

INTRODUCTION

In recent years, there have been major developments in the use of X-RAY EQUIPMENT for RADIOSCOPICALLY GUIDED INTERVENTIONAL PROCEDURES. These procedures may involve prolonged IRRADIATIONS and may subject PATIENTS and OPERATORS to higher levels of risk than those which normally prevail.

A consequence is the occurrence of deterministic injury when procedures involve the delivery of substantial amounts of RADIATION to localized areas on the PATIENT. Another consequence is the large contribution to the stochastic risk for the RADIATION induced cancers etc. collectively to the PATIENT.

This Particular Standard deals with these additional risks and thereby complements the General Standard with special provisions for this particular domain. Interventional procedures of the type envisaged are well established in clinical fields such as:

– invasive cardiology;

– interventional RADIOLOGY;

– interventional neuroradiology.

These procedures also include many newly developing and emerging applications in a wide range of medical and surgical specialities.

NOTE Attention is drawn to the existence of legislation in some countries concerning RADIOLOGICAL PROTECTION, which may not align with the provisions of this standard.

MEDICAL ELECTRICAL EQUIPMENT –

Part 2-43: Particular requirements for the safety of X-ray equipment for interventional procedures

SECTION 1: GENERAL

The clauses and subclauses of this section of the General Standard apply, except as follows:

1 Scope and object

This clause of the General Standard applies, except as follows:

1.1 Scope

Addition:

This Particular Standard applies to X-RAY EQUIPMENT declared by the MANUFACTURER to be suitable for prolonged RADIOSCOPICALLY GUIDED INTERVENTIONAL PROCEDURES. Its scope excludes, in particular:

– equipment for RADIOTHERAPY;
– equipment for COMPUTED TOMOGRAPHY;
– ACCESSORIES intended to be introduced into the PATIENT;
– mammographic X-RAY EQUIPMENT.

NOTE 1 Examples of prolonged RADIOSCOPICALLY GUIDED INTERVENTIONAL PROCEDURES, for which the use of EQUIPMENT complying with this standard is recommended, are given in annex BB.

NOTE 2 The particular requirements of this standard are not essential for EQUIPMENT used in all RADIOSCOPICALLY GUIDED INTERVENTIONAL PROCEDURES. Examples of procedures, for which the use of EQUIPMENT complying with this standard is considered not to be essential, are given in annex BB.

EQUIPMENT declared by the MANUFACTURER to be suitable for RADIOSCOPICALLY GUIDED INTERVENTIONAL PROCEDURES, which does not include a PATIENT SUPPORT as part of the system, is exempt from the PATIENT SUPPORT provisions of this standard.