

Medical electrical equipment —

Part 2: Particular requirements for safety —

Section 2.33 Specification for magnetic resonance equipment for medical diagnosis

The European Standard EN 60601-2-33:1995 with the inclusion of amendment A11:1997 has the status of a British Standard

ICS 11.040.50

Committees responsible for this British Standard

The preparation of this British Standard was entrusted to Technical Committee CH/84, Magnetic resonance imaging equipment, upon which the following bodies were represented:

- Association of X-ray Equipment Manufacturers (BEAMA Limited)
- British Institute of Radiology
- Department of Health
- Electro Medical Trade Association Limited
- Health and Safety Executive
- Institution of Electrical Engineers
- Institution of Physics and Engineering in Medicine and Biology
- National Radiological Protection Board

This British Standard, having been prepared under the direction of the Health and Environment Sector Board, was published under the authority of the Standards Board and comes into effect on 15 June 1996

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National foreword

This British Standard has been prepared by Technical Committee CH/71 (formerly CH/84) and is the English language version of EN 60601-2-33:1995 *Medical electrical equipment — Part 2: Particular requirements for the safety of magnetic resonance equipment for medical diagnosis*, including amendment A11:1997 published by the European Committee for Electrotechnical Standardization (CENELEC). It was derived by CENELEC from IEC 601-2-33:1995 published by the International Electrotechnical Commission (IEC).

Amendment A11 to IEC 601-2-33:1995 was approved by CENELEC on 1997-03-11. The UK voted against the draft amendment; however in accordance with the CEN/CENELEC Internal Regulations BSI is obliged to implement the approved draft of amendment A11 as an amendment to BS EN 60601-2-33.

The text of CENELEC amendment A11 to IEC 601-2-33:1995 is indicated by a sideline in the margin, and the original IEC text is reproduced in National annex NA

As in the General Standard, the requirements are followed by compliance tests. The numbers of the sections and clauses in this standard refer to the related sections and clauses in the General Standard. Clauses, subclauses or figures that are additional to those of the General Standard are numbered starting from 101; additional appendices are lettered AA, BB, etc, and additional items are lettered aa), bb) etc. The changes from the text of the General Standard are specified by the use of the following words.

“Replacement” means that the clause, subclause or specified paragraph of the General Standard is replaced by the text of this standard.

“Amendment” means that the clause, subclause or specified paragraph of the General Standard is amended as indicated by this text of the standard.

“Addition” means that the text of this standard is additional to the requirements of the General Standard.

A rationale giving guidance for particular subclauses is given in Annex BB. This annex does not form a normative part of the standard.

Cross-references

Publication referred to	Corresponding British Standard
EN 60601-1:1990 (IEC 601-1:1988)	BS 5724 <i>Medical electrical equipment</i> Part 1:1989 <i>General requirements for safety</i>
EN 60601-1-1:1993 (IEC 601-1-1:1992)	BS EN 60601 <i>Medical electrical equipment</i> Part 1: <i>General requirements for safety</i> Section 1.1:1993 <i>Collateral standard. Safety requirements for medical electrical systems</i>
EN 60601-1-2:1993 (IEC 601-1-2:1993)	Section 1.2:1993 <i>Collateral standard. Electromagnetic compatibility. Requirements and tests</i>
EN 60651:1994 (IEC 651:1979)	BS EN 60651:1994 <i>Specification for sound level meters</i>
HD 501 S1 (IEC 788:1984)	BS 6641:1985 <i>Glossary of medical radiology terms</i>
EN 60804:1994 (IEC 804:1985)	BS EN 60804:1994 <i>Specification for integrating-averaging sound level meters</i>
EN 60950:1992 (IEC 950:1991)	BS EN 60950:1992 <i>Specification for safety of information technology equipment, including electrical business equipment</i>

Additional information. The following print types are used in this standard:
Requirements, with which compliance can be tested, and definitions: in roman type.

Explanations, advice, general statements, exceptions and references: in small roman type.

Test procedures: in *italic* type.

Terms defined in clause 2 of BS 5724-1 or in BS 6641: SMALL CAPITALS.

References to IEC page numbers should be ignored.

A British Standard does not purport to include all the necessary provisions of a contract. Users of British Standards are responsible for their correct application.

Compliance with a British Standard does not of itself confer immunity from legal obligations.

Summary of pages

This document comprises a front cover, an inside front cover, pages i to iv, the EN title page, pages 2 to 44, an inside back cover and a back cover.

This standard has been updated (see copyright date) and may have had amendments incorporated. This will be indicated in the amendment table on the inside front cover.

ICS 11.040.50

Descriptors: Medical electrical equipment, magnetic resonance equipment, magnetic resonance examination, safety requirements, protection against electric shock, protection against mechanical hazard, radiation protection, fire protection, environmental conditions

English version

Medical electrical equipment Part 2: Particular requirements for the safety of magnetic resonance equipment for medical diagnosis

(Includes amendment A11:1997)
(IEC 601-2-33:1995, modified)

Appareils électromédicaux
Partie 2: Règles particulières de sécurité
relatives aux appareils à résonance magnétique
pour diagnostic médical
(Inclut l'amendement A11:1997)
(CEI 601-2-33:1995, modifiée)

Medizinische elektrische Geräte
Teil 2: Besondere Festlegungen für die
Sicherheit von medizinischen diagnostischen
Magnetresonanzgeräten
(Enthält Änderung A11:1997)
(IEC 601-2-33:1995, modifiziert)

This European Standard was approved by CENELEC on 1995-09-20; amendment A11 was approved by CENELEC on 1997-03-11. CENELEC members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration.

Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the Central Secretariat or to any CENELEC member.

This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CENELEC member into its own language and notified to the Central Secretariat has the same status as the official versions.

CENELEC members are the national electrotechnical committees of Austria, Belgium, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and United Kingdom.

CENELEC

European Committee for Electrotechnical Standardization
Comité Européen de Normalisation Electrotechnique
Europäisches Komitee für Elektrotechnische Normung

Central Secretariat: rue de Stassart 35, B-1050 Brussels

Foreword

The text of document 62B/240/DIS, future edition 1 of IEC 601-2-33, prepared by SC 62B, Diagnostic imaging equipment, of IEC TC 62, Electrical equipment in medical practice, was submitted to the IEC-CENELEC parallel vote and was approved by CENELEC as EN 60601-2-33 on 1995-09-20.

The following dates were fixed:

- latest date by which the EN has to be implemented at national level by publication of an identical national standard or by endorsement (dop) 1996-07-01
- latest date by which the national standards conflicting with the EN have to be withdrawn (dow) 1996-07-01

Annexes designated “normative” are part of the body of the standard.

Annexes designated “informative” are given for information only.

In this standard, Annex CC and Annex ZA are normative and Annex AA, Annex BB and Annex ZB are informative.

Annex ZA and Annex ZB have been added by CENELEC.

Foreword to amendment A11

This amendment was prepared by the Technical Committee CENELEC TC 62, Electrical equipment in medical practice.

The text of the draft was submitted to the formal vote and was approved by CENELEC as amendment A11 to EN 60601-2-33:1995 on 1997-03-11.

The following dates were fixed:

- latest date by which the amendment has to be implemented at national level by publication of an identical national standard or by endorsement (dop) 1998-03-01
- latest date by which the national standards conflicting with the amendment have to be withdrawn (dow) 1998-06-13

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Introduction

This Particular Standard is written at a moment in which the technical evolution of MAGNETIC RESONANCE EQUIPMENT is in rapid progress and the scientific foundation of its safe use is still expanding.

Extensive rationale is provided for some of the definitions and requirements in order to provide the user of this standard with a reasonably complete access to the source material that was used in support of the considerations during drafting.

The relationship of this Particular Standard with IEC 601-1 (including the amendments) and the Collateral Standards is explained in 1.3.

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 MAGNETIC RESONANCE EQUIPMENT as defined in 2.2.101.

This Standard does not cover MAGNETIC RESONANCE EQUIPMENT intended for use in medical research.

1.2 Object

Replacement:

This Particular Standard establishes requirements for the safety of MAGNETIC RESONANCE EQUIPMENT to provide protection for the PATIENT, the OPERATOR, staff associated with MAGNETIC RESONANCE EQUIPMENT and the general public. It also provides methods for demonstrating compliance with those requirements.

1.3 Particular Standards

Addition:

This Particular Standard amends and supplements a set of IEC publications, hereinafter referred to as “General Standard”, consisting of IEC 601-1:1988, *Medical electrical equipment — Part 1: General requirements for safety*, its amendments 1 and 2 and IEC 601-1-1:1992, *Medical electrical equipment — Part 1: General requirements for safety, 1. Collateral Standard: Safety requirements for medical electrical systems*.

For brevity, IEC 601-1 is referred to in this Particular Standard either as the “General Standard” or as the “General Requirement(s)”, and IEC 601-1-1 as the “Collateral Standard”.

The term “this Standard” covers this Particular Standard, used together with the General Standard and any Collateral Standards.

The numbering of sections, clauses and subclauses of this Particular Standard corresponds with that of the General Standard. The changes to the text of the General Standard are specified by the use of the following words:

“Replacement” means that the clause or subclause of the General Standard is replaced completely by the text of this Particular Standard.

“Addition” means that the text of this Particular Standard is additional to the requirements of the General Standard.

“Amendment” means that the clause or subclause of the General Standard is amended as indicated by the text of this Particular Standard.

Subclauses or figures which are additional to those of the General Standards are numbered starting from 101, additional annexes are lettered AA, BB, etc., and additional items aa), bb), etc.

Clauses and subclauses to which there is a rationale are marked with an asterisk *. These rationales can be found in an informative Annex BB. Annex BB is not part of this Particular Standard and only gives additional information; it can never be the subject of testing.

Where there is no corresponding section, clause or subclause in this Particular Standard, the section, clause or subclause of the General Standard or the Collateral Standard applies without modification.

Where it is intended that any part of the General Standard or the Collateral Standard, although possibly relevant, is not to be applied, a statement to that effect is given in this Particular Standard.

A requirement of this Particular Standard replacing or modifying requirements of the General Standard or the Collateral Standard takes precedence over the corresponding General Requirement(s).

2 Terminology and definitions

This clause of the General Standard applies except as follows:

Additional definitions:

2.2 EQUIPMENT TYPES (classification)

2.2.101

MAGNETIC RESONANCE EQUIPMENT

in medical diagnosis, MEDICAL ELECTRICAL EQUIPMENT which is intended for in-vivo MAGNETIC RESONANCE EXAMINATION

2.2.102

MAGNETIC RESONANCE SYSTEM

ensemble of MAGNETIC RESONANCE EQUIPMENT, ACCESSORIES, energy supplies, and installation facilities

2.10 Operation of EQUIPMENT

2.10.101

NORMAL OPERATING MODE

mode of operation of MAGNETIC RESONANCE EQUIPMENT, in which all operating parameters are within recommended limits for protection against SAFETY HAZARDS during a MAGNETIC RESONANCE EXAMINATION, and in which performance requires only ROUTINE MONITORING to prevent SAFETY HAZARDS to the PATIENT

2.10.102

FIRST LEVEL CONTROLLED OPERATING MODE

mode of operation of MAGNETIC RESONANCE EQUIPMENT in which some operating parameters reach values that may cause undue physiological stress to PATIENTS

2.10.103

SECOND LEVEL CONTROLLED OPERATING MODE

mode of operation of MAGNETIC RESONANCE EQUIPMENT in which some operating parameters reach values that may produce significant risk for PATIENTS

2.10.104

SCAN DURATION*

period of time from the beginning to the end of acquisition of data by the MAGNETIC RESONANCE EQUIPMENT, without OPERATOR intervention

2.10.105

MAGNETIC RESONANCE EXAMINATION*

process of acquiring MAGNETIC RESONANCE data from a PATIENT during one session when the PATIENT is within the magnet's bore

2.11 Mechanical safety

2.11.101

CONTROLLED ACCESS AREA

area to which access is controlled for safety reasons

2.11.102

EMERGENCY FIELD SHUT-DOWN UNIT

MAGNETIC RESONANCE EQUIPMENT equipped with resistive or superconducting magnets, device for de-energization of the magnet in case of an emergency

2.12 Miscellaneous

2.12.101

MAGNETIC RESONANCE*

resonant absorption of electromagnetic energy by an ensemble of atomic nuclei situated in a magnetic field

2.12.102

QUENCH

uncontrolled transition of the electrical conductivity from a superconducting state to normal conductivity of a superconductive coil that is carrying a current, resulting in rapid boil-off of fluid cryogen

2.12.103

SPECIFIC ABSORPTION RATE (SAR)*

radio frequency power absorbed per unit of mass of an object (W/kg)

2.12.104

SPECIFIC ABSORBED ENERGY (SAE)

radio frequency energy absorbed per unit of mass of an object (J/kg)

2.12.105

TIME RATE OF CHANGE OF MAGNETIC FIELD

(dB/dt)*

rate of change of the magnetic flux density with time (T/s)

2.12.106

ROUTINE MONITORING

routine PATIENT monitoring which is carried out by the OPERATOR and staff of the MAGNETIC RESONANCE EQUIPMENT and consisting of audio and/or visual contact, as appropriate with the PATIENT during the MAGNETIC RESONANCE EXAMINATION

2.12.107

MEDICAL SUPERVISION*

management of PATIENTS who may be at risk from some parameters of exposure to the MAGNETIC RESONANCE EQUIPMENT, either because of the medical condition of the PATIENT, the levels of exposure or a combination

3 General requirements

This clause of the General Standard applies except as follows:

3.1 Addition:

A MAGNETIC RESONANCE EQUIPMENT shall not cause a SAFETY HAZARD to the PATIENT, the OPERATOR, staff and the general public.

Compliance is considered to be fulfilled, if the MAGNETIC RESONANCE EQUIPMENT meets the relevant requirements of this Standard.

General safety aspects of MEDICAL ELECTRICAL SYSTEMS are covered by IEC 601-1-1.

6 Identification, marking and documents

This clause of the General Standard applies except as follows:

6.8 ACCOMPANYING DOCUMENTS*

6.8.1 General

Addition:

The ACCOMPANYING DOCUMENTS should provide sufficient information to the USER to enable him to comply with the local regulations and requirements for exposure limits appropriate to the OPERATOR, staff associated with the MAGNETIC RESONANCE EQUIPMENT, and the general public.

6.8.2 INSTRUCTIONS FOR USE*

Addition:

aa)* Pre-screening prior to a MAGNETIC RESONANCE EXAMINATION

INSTRUCTIONS FOR USE shall provide clear recommendations to the USER regarding pre-screening of PATIENTS. This specifically applies to those PATIENTS who could be placed at risk due to their professional activity, past medical history, present medical state and the physical environment of the MAGNETIC RESONANCE EQUIPMENT. These instructions shall indicate the need of a pre-screening programme to identify such PATIENTS at risk, and shall provide recommendations to adequately safeguard these PATIENTS from injury.

The following specific classes of PATIENTS shall be mentioned:

- classes of PATIENTS for whom MAGNETIC RESONANCE EXAMINATIONS are considered to be contraindicated;
- classes of PATIENTS having higher than normal likelihood of needing emergency medical treatment, independent of the physical environment of the MAGNETIC RESONANCE EQUIPMENT;
- classes of PATIENTS having a higher than normal likelihood of needing emergency medical treatment due to the elevated values of the applied fields, when the MAGNETIC RESONANCE EQUIPMENT is capable of operating within the first level CONTROLLED OPERATING MODE as described in clause 51.

bb)* Levels of supervision of PATIENTS

INSTRUCTIONS FOR USE shall provide clear recommendations to the USER to establish a programme for the supervision of PATIENTS appropriate to the classes of PATIENTS described in 6.8.2 aa) and to the modes of operation of the MAGNETIC RESONANCE EQUIPMENT as defined in 2.10 (see also rationale to 2.12.107).

INSTRUCTIONS FOR USE shall:

- include the recommendation that all PATIENTS should receive at least ROUTINE MONITORING;
- if the MAGNETIC RESONANCE EQUIPMENT is capable of operating within the FIRST LEVEL CONTROLLED OPERATING MODE: give recommendation that procedures should be established to ensure that MEDICAL SUPERVISION is provided when entering the FIRST LEVEL CONTROLLED OPERATING MODE;
- if the MAGNETIC RESONANCE EQUIPMENT is provided with a SECOND LEVEL CONTROLLED OPERATING MODE: include notification that operation in the SECOND LEVEL CONTROLLED OPERATING MODE requires approval of investigational human studies protocol according to local requirements (e.g. Ethics Committee, Investigational Review Board, etc.).

cc)* Emergency medical procedures

INSTRUCTIONS FOR USE shall give clear recommendation to the USER, that he shall define and implement specific emergency medical procedures that apply to the PATIENT and that take into account the existence of the magnetic field, so that when during MAGNETIC RESONANCE EXAMINATION the PATIENT feels ill or is injured by external causes, medical treatment can be given as soon as possible.

These instructions shall include recommendations to establish a procedure for removing PATIENTS rapidly from the magnet's influence (if necessary by using the EMERGENCY FIELD SHUT-DOWN UNIT).

dd) Excessive noise

INSTRUCTIONS FOR USE shall state that the A-weighted r.m.s. sound pressure level is measured according to 26 g). INSTRUCTIONS FOR USE shall state that hearing protection shall be required for the safety of the PATIENT if the maximum A-weighted r.m.s. sound pressure level ($L_{Aeq,1h}$) of the EQUIPMENT can exceed 99 dB(A). The hearing protection shall be sufficient to reduce the A-weighted r.m.s. sound pressure level below 99 dB(A).

INSTRUCTIONS FOR USE shall state clearly, that the sound level at the CONTROL PANEL should be limited to comply with local rules.

INSTRUCTIONS FOR USE shall draw attention to the fact that in some countries legislation may exist covering the exposure of employed persons to noise.

A suitable warning sign is specified in ISO 7731.

ee)* CONTROLLED ACCESS AREA

INSTRUCTIONS FOR USE shall state clearly, that it is the responsibility of the user to follow local statutory requirements with respect to access to the CONTROLLED ACCESS AREA.

INSTRUCTIONS FOR USE SHALL indicate the necessity to define and install a CONTROLLED ACCESS AREA around the MAGNETIC RESONANCE EQUIPMENT such that outside this area the magnetic fringe field strength should not exceed 0,5 mT.

Clear specifications shall be given, preferably accompanied by a sketch, on the size and shape of the CONTROLLED ACCESS AREA.

INSTRUCTIONS FOR USE shall indicate the need to establish adequate rules for controlling access to the CONTROLLED ACCESS AREA in terms of the potential risk to PATIENTS and staff within the CONTROLLED ACCESS AREA from the attraction of objects containing iron or other magnetically active materials or from torque on such metallic materials and the potential risk to persons inadvertently entering the area who may be affected by the possible disfunction of their medical implants.

INSTRUCTIONS FOR USE shall give clear recommendations as to how this CONTROLLED ACCESS AREA should be indicated, e.g. by markings on the floor, barriers, signs and other means.

These recommendations shall state, that:

- the CONTROLLED ACCESS AREA should be labelled at all entries by an appropriate warning sign, e.g. “DANGER — HIGH MAGNETIC FIELD”;
- the OPERATOR should be warned by way of appropriate signs of the possible presence of magnetic fields and their attractive force or the torque on ferromagnetic materials that he should exclude loose ferrous objects within that zone (see Annex AA for examples of warning signs and prohibitive signs); and
- access control and labelling of magnetic fringe fields should be carried out by the USER. For safe operation of pacemakers a limit of 0,5 mT should be kept.

For magnetic field strengths less than 0,5 mT no administrative controls are required.

INSTRUCTIONS FOR USE should list EQUIPMENT and tools specified or recommended by the MANUFACTURER for use in the CONTROLLED ACCESS AREA. For all EQUIPMENT, ACCESSORIES or tools listed, a description should be given of special measures that are needed, if any, for its installation as well as special precautions, if any, for their use.

It shall be clearly stated that peripheral equipment, including PATIENT monitoring, life supporting devices and emergency care equipment, which are not specified or recommended for use in the CONTROLLED ACCESS AREA, may be disturbed by the radio frequency field or the magnetic fringe field of the MAGNETIC RESONANCE EQUIPMENT and that this peripheral equipment may also disturb the proper function of the MAGNETIC RESONANCE EQUIPMENT.

ff)* Liquid cryogens and cryogenic gases

For MAGNETIC RESONANCE EQUIPMENT equipped with superconducting magnets, INSTRUCTIONS FOR USE shall, in order to prevent accidents and QUENCH:

- require adequate provisions for supply of liquid cryogen;
- recommend that cryogen refilling should be performed by trained and experienced personnel only;
- provide information on maintenance and inspection of the magnet including the liquid cryogen level(s);
- provide information on the minimum cryogen level(s) required for normal operation;
- require that frequent checks of cryogen level(s) be carried out by the USER;
- give clear information on potential hazards of the use of liquid cryogens as well as information on proper handling of these liquids. This shall include information concerning:
 - the wearing of protective clothing to prevent frostbite;
 - procedures to be performed after gas release;
 - precautions against lack of oxygen;
 - the use of non-magnetic containers for the cryogens that are being supplied;
 - procedures to be followed if flammable materials are found near the cryogen container.

Liquid oxygen may accumulate, or the gaseous oxygen concentration may become high in the vicinity of the cryogen.

gg)* Operating modes

INSTRUCTIONS FOR USE shall provide information concerning the meaning and background of each of the modes of operation, NORMAL OPERATING MODE, FIRST LEVEL CONTROLLED OPERATING MODE, and SECOND LEVEL CONTROLLED OPERATING MODE, as they are defined for dB/dt in **51.102** and for SAR in **51.103**. INSTRUCTIONS FOR USE shall also give the explanation that dB/dt and SAR levels for PATIENTS are based on current scientific literature related to safety, and that the level of exposure and the possible need for physiological monitoring of the PATIENTS shall be a medical judgment as to the PATIENTS potential risk versus benefit.

INSTRUCTIONS FOR USE shall clearly explain the requirements of each operating mode:

- 1) For MAGNETIC RESONANCE EQUIPMENT operating within the NORMAL OPERATING MODE, no specific indication or measure is required to be displayed and only ROUTINE MONITORING is recommended.
- 2) For MAGNETIC RESONANCE SYSTEMS capable of operation in FIRST LEVEL CONTROLLED OPERATING MODE, the properties of the system with respect to displayed indication before entering this mode and to deliberate action when entering this mode, as required in **51.102**, shall be described. Also, MEDICAL SUPERVISION shall be provided as required in **6.8.2 bb**).
- 3) For MAGNETIC RESONANCE EQUIPMENT capable of operating within the SECOND LEVEL CONTROLLED OPERATING MODE, specific security measures shall be provided as required in **51.101.2** to prevent unauthorized operation in the SECOND LEVEL CONTROLLED OPERATING MODE. Operation in the SECOND LEVEL CONTROLLED OPERATING MODE is only permitted under a human studies protocol approved according to local requirements as required in **6.8.2 bb**).

INSTRUCTIONS FOR USE shall recommend that attention should be paid to the safety of PATIENTS in terms of the deliberate action and MEDICAL SUPERVISION which is required for entering the FIRST LEVEL CONTROLLED OPERATING MODE, or in terms of the specific security measures and approval of investigational human studies protocol according to local requirements required for entering the SECOND LEVEL CONTROLLED OPERATING MODE.

Particular information concerning time-varying magnetic fields and radio frequency magnetic fields shall also be provided:

4) Time-varying magnetic field

For MAGNETIC RESONANCE EQUIPMENT that is capable of operation in the FIRST LEVEL CONTROLLED OPERATING MODE or the SECOND LEVEL CONTROLLED OPERATING MODE for dB/dt, the INSTRUCTIONS FOR USE shall:

- a) explain the possible effects on the PATIENTS of the level of dB/dt in each of the operating modes with which the system is provided, paying particular attention to possible effects on the peripheral nervous system and on the heart;
- b) provide information on the values of dB/dt that the MAGNETIC RESONANCE EQUIPMENT is capable of;
- c) explain that the MAGNETIC RESONANCE EQUIPMENT will display an indication of the appropriate operating mode when the value of dB/dt exceeds the levels of the NORMAL OPERATING MODE.

5) Radio frequency magnetic field

INSTRUCTIONS FOR USE shall explain that the definitions of the operating modes for whole-body SAR given in **51.103** assume that the examination room temperature is not more than 24 °C and the relative humidity is not more than 60 % and that for temperatures above 24 °C or relative humidity above 60 %, the limits in the definitions of the operating modes for whole-body SAR shall be reduced as described in the rationale to **51.103**, possibly changing the operating mode for a given value of SAR. The relationship between ambient temperature, relative humidity and SAR shall be described in the INSTRUCTIONS FOR USE.