

Medical electrical equipment —

Part 2-33: Particular requirements for the safety of magnetic resonance equipment for medical diagnosis

ICS 11.040.55

National foreword

This British Standard is the UK implementation of EN 60601-2-33:2002+A2:2008. It is identical with IEC 60601-2-33:2002, incorporating amendment 2:2007. It supersedes BS EN 60601-2-33:2002+A1:2005 which will be withdrawn on 1 February 2011.

The start and finish of text introduced or altered by amendment is indicated in the text by tags. Tags indicating changes to IEC text carry the number of the IEC amendment. For example, text altered by IEC amendment 1 is indicated by A1 A1.

The UK participation in its preparation was entrusted by Technical Committee CH/62, Electromedical equipment in medical practice, to Subcommittee CH/62/2, Diagnostic imaging equipment.

A list of organizations represented on this subcommittee can be obtained on request to its secretary.

This publication does not purport to include all the necessary provisions of a contract. Users are responsible for its correct application.

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EN 60601-2-33:2002+A2

March 2008

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Supersedes EN 60601-2-33:1995 +A11:1997

English version

Medical electrical equipment
Part 2-33: Particular requirements for the safety of magnetic resonance
equipment for medical diagnosis
(IEC 60601-2-33:2002)

Appareils électromédicaux
Partie 2-33: Règles particulières
de sécurité relatives aux appareils
à résonance magnétique
pour diagnostic médical
(CEI 60601-2-33:2002)

Medizinische elektrische Geräte
Teil 2-33: Besondere Festlegungen für die
Sicherheit von Magnetresonanzgeräten
für die medizinische Diagnostik
(IEC 60601-2-33:2002)

This European Standard was approved by CENELEC on 2002-07-01. 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 amendment 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.

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CENELEC

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

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Foreword

The text of document 62B/462/FDIS, future edition 2 of IEC 60601-2-33, 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 2002-07-01.

This European Standard supersedes EN 60601-2-33:1995 + A11:1997.

The following dates were fixed:

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with the EN have to be withdrawn (dow) 2005-07-01

Annexes designated "normative" are part of the body of the standard.

Annexes designated "informative" are given for information only.

In this standard, annex ZA is normative and annexes AA, BB and ZB are informative.

Annexes ZA and ZB have been added by CENELEC.

In this standard, the following print types are used:

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

Endorsement notice

The text of the International Standard IEC 60601-2-33:2002 was approved by CENELEC as a European Standard without any modification.

Foreword to amendment A1

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Foreword to amendment A2

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Endorsement notice

The text of amendment 2:2007 to the International Standard IEC 60601-2-33:2002 was approved by CENELEC as an amendment to the European Standard without any modification.

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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.

This International Standard addresses technical aspects of the medical diagnostic MR SYSTEM and the MR EQUIPMENT therein, related to the safety of PATIENTS examined with this system, the safety of the MR WORKER involved with its operation and the safety of the MR WORKER involved with the development, manufacturing, installation, and servicing of the MR SYSTEM. Where limits of electromagnetic fields (EMF) exposure of PATIENTS and MR WORKER are stated, these limits do not imply that such levels of exposure can be assumed to be acceptable for workers in other professional settings and for the population at large. The limits provide a sensible balance between risks for the PATIENTS and MR WORKERS and benefits for the PATIENTS.

The introduced EMF exposure limits required in this standard for an MR WORKER are equal to those allowed for PATIENTS. All exposure levels allowed for a PATIENT and for an MR WORKER protect them against negative instantaneous and long-term health effects.

Subjective short-term physiological and sensory effects are expected for the exposure to static magnetic fields only, these influence the well being of the MR WORKER marginally and only during or shortly after exposure.

For the exposure to GRADIENT OUTPUT and RF transmit fields, normally no short-term physiological and sensory effects are expected for MR WORKERS.

In addition no experimental or theoretical basis for cumulative biological effects in humans, resulting from exposure at the allowed levels has been generally accepted.

Organisational aspects of safety are the task of the USER. This task includes adequate training of staff, rules of access to the MR SYSTEM, qualification of staff for decisions that are related to safety, definition of medical responsibility and specific requirements for personnel following from that responsibility when the PATIENT is in or near the MR SYSTEM.

Examples of such organisational aspects are:

- operation in first controlled mode;
- emergency procedures for resuscitation of the PATIENT who is in the MR SYSTEM,
- emergency procedures after a QUENCH of the superconductive magnet when present;
- set-up and maintenance of a protocol for screening the PATIENT for contraindications or for conditions that may affect acceptable exposure;
- rules for ROUTINE MONITORING and for MEDICAL SUPERVISION of the PATIENT during the exam.
- rules to minimize and to limit the exposure of MR WORKERS.

Extensive rationale is provided in Annex BB 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 60601-1 (including its amendments) and the Collateral Standards is explained in 1.3.

MEDICAL ELECTRICAL EQUIPMENT –

Part 2-33: Particular requirements for the safety of magnetic resonance equipment for medical diagnosis

SECTION ONE: 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 and MAGNETIC RESONANCE SYSTEMS as defined in 2.2.102.

This Standard does not cover the application of MAGNETIC RESONANCE EQUIPMENT beyond the INTENDED USE.

1.2 Object

Replacement:

A2 This particular standard establishes requirements for the safety of MR EQUIPMENT to provide protection for the PATIENT and the MR WORKER.

NOTE This standard presumes that the MR WORKERS are properly screened medically, and properly trained and instructed in their duties. **A2**

It establishes requirements to provide information to 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 the "General Standard", consisting of

IEC 60601-1:1988, *Medical electrical equipment – Part 1: General requirements for safety*, and its amendments 1 (1991) and 2 (1995),

IEC 60601-1-1:2000, *Medical electrical equipment – Part 1-1: General requirements for safety – Collateral Standard: Safety requirements for medical electrical systems*, and

IEC 60601-1-4:1996, *Medical electrical equipment – Part 1: General requirement for safety – 4. Collateral Standard: Programmable electronic medical systems*.

For brevity, IEC 60601-1 is referred to in this Particular Standard either as the "General Standard" or as the "General Requirement(s)", and IEC 60601-1-1 and IEC 60601-1-4 as "Collateral Standards".

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 Standard are numbered starting from 101, additional annexes are lettered AA, BB, etc., and additional items aa), bb), etc.

Clauses and subclauses for which there is a rationale are marked with an asterisk *. These rationales can be found in informative annex BB. Annex BB does not form an integral 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 of a specified 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 a specified 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 (MR EQUIPMENT)

MEDICAL ELECTRICAL EQUIPMENT which is intended for in-vivo MAGNETIC RESONANCE EXAMINATION of a PATIENT. The MR EQUIPMENT comprises all parts in hardware and software from the SUPPLY MAINS to the display monitor. The MR EQUIPMENT is a Programmable Electrical Medical System (PEMS)

2.2.102

MAGNETIC RESONANCE SYSTEM (MR SYSTEM)

ensemble of MR EQUIPMENT, ACCESSORIES including means for display, control, energy supplies, and the CONTROLLED ACCESS AREA, where provided

2.2.103

WHOLE BODY MAGNETIC RESONANCE EQUIPMENT (WHOLE BODY MR EQUIPMENT)

MR EQUIPMENT of sufficient size to allow whole body MR-EXAMINATION and partial body MR-EXAMINATION of adult PATIENTS. It may be equipped with VOLUME RF TRANSMIT COILS, LOCAL RF TRANSMIT COILS and with a SPECIAL PURPOSE GRADIENT SYSTEM

2.2.104

WOLE BODY MAGNET

magnet suitable for use in WHOLE BODY MR EQUIPMENT

2.2.105

TRANSVERSE FIELD MAGNET

magnet for which the field is at right angles to the axial direction of the PATIENT

2.2.106

WHOLE BODY GRADIENT SYSTEM

a gradient system suitable for use in WHOLE BODY MR EQUIPMENT

2.2.107

SPECIAL PURPOSE GRADIENT SYSTEM

a gradient system suitable for use in MR EQUIPMENT for a special purpose.

An example of a SPECIAL PURPOSE GRADIENT SYSTEM is a gradient system that can be incorporated in MR EQUIPMENT to allow special examination of the head of the PATIENT

2.2.108

GRADIENT UNIT

all gradient coils and amplifiers that together generate a magnetic field gradient along one of the axes of the coordinate system of the MR EQUIPMENT

2.2.109

VOLUME RF TRANSMIT COIL

an RF transmit coil suitable for use in MR EQUIPMENT that produces a homogeneous RF field over an extended volume encompassed by the coil. The VOLUME RF TRANSMIT COIL can be a WHOLE BODY RF TRANSMIT COIL, a HEAD RF TRANSMIT COIL or a RF transmit coil designed for homogeneous exposure of a specific part of the body. A single loop coil enclosing the body or a part of the body is considered to be a VOLUME RF TRANSMIT COIL (example: single loop wrist coil)

2.2.110

WHOLE BODY RF TRANSMIT COIL

A VOLUME RF TRANSMIT COIL of sufficient size for whole body examinations of adult PATIENTS

2.2.111

HEAD RF TRANSMIT COIL

a VOLUME RF TRANSMIT COIL suitable for use in MR EQUIPMENT for a MAGNETIC RESONANCE EXAMINATION of the head of PATIENTS

2.2.112

LOCAL RF TRANSMIT COIL

an RF transmit coil other than a VOLUME RF TRANSMIT COIL. The LOCAL RF TRANSMIT COIL can be a coil for spectroscopy

2.10 Operation of equipment

2.10.101

NORMAL OPERATING MODE

mode of operation of the MR EQUIPMENT in which none of the outputs have a value that may cause physiological stress to PATIENTS

2.10.102

FIRST LEVEL CONTROLLED OPERATING MODE

mode of operation of the MR EQUIPMENT in which one or more outputs reach a value that may cause physiological stress to PATIENTS which needs to be controlled by MEDICAL SUPERVISION

2.10.103

SECOND LEVEL CONTROLLED OPERATING MODE

mode of operation of the MR EQUIPMENT in which one or more outputs reach a value that may produce significant risk for PATIENTS, for which explicit ethical approval is required (i.e. a human studies protocol approved to local requirements)

*** 2.10.104**

MAGNETIC RESONANCE EXAMINATION (MR EXAMINATION)

process of acquiring data by MAGNETIC RESONANCE from a PATIENT

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

device for de-energizing a superconducting or resistive magnet in case of an emergency situation

2.11.103

QUENCH

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

2.12 Miscellaneous

*** 2.12.101**

MAGNETIC RESONANCE (MR)

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

2.12.102

ROUTINE MONITORING

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

*** 2.12.103**

MEDICAL SUPERVISION

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

2.12.104**COMPLIANCE VOLUME**

area of PATIENT accessible space in which compliance of GRADIENT OUTPUT is inspected

In MR EQUIPMENT with a cylindrical WHOLE BODY MAGNET, the COMPLIANCE VOLUME is a cylinder with its axis coinciding with the magnet axis and with a radius of 0,20 m.

In MR EQUIPMENT with a TRANSVERSE FIELD MAGNET and a WHOLE BODY GRADIENT SYSTEM, the COMPLIANCE VOLUME is a volume bound by planes parallel to the magnet poles and separated by a distance that is either the largest dimension of the accessible space between the poles of the magnet, or 0,40 m, whichever is less.

In all other MR EQUIPMENT the COMPLIANCE VOLUME is the volume where any part of a PATIENT body can be properly located according to the intended use of the MR EQUIPMENT.

2.12.105**MAXIMUM GRADIENT SLEW RATE**

the rate of change of the gradient obtained by switching the GRADIENT UNIT between its maximum specified gradient strengths $G_{+\max}$ and $G_{-\max}$ in the shortest possible ramp time obtainable under normal scan conditions

2.12.106**SEARCH COIL**

a small diameter coil used in a compliance test to measure GRADIENT OUTPUT

A2 2.12.107**MR WORKER**

person that because of his/her profession has to enter the CONTROLLED ACCESS AREA or equivalent of the MAGNETIC RESONANCE SYSTEM

NOTE Other persons like MR volunteers and PATIENT carers are not covered by this definition, however OPERATORS and staff are included in this definition (see rationale) **A2**

2.101 Output*** 2.101.1****SPECIFIC ABSORPTION RATE (SAR)**

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

2.101.2**WHOLE BODY SAR**

SAR averaged over the total mass of the PATIENTS body and over a specified time

2.101.3**PARTIAL BODY SAR**

SAR averaged over the mass of the PATIENTS body that is exposed by the VOLUME RF TRANSMIT COIL and over a specified time

2.101.4**HEAD SAR**

SAR averaged over the mass of the PATIENTS head and over a specified time

2.101.5**LOCAL SAR**

SAR averaged over any 10 g of tissue of the PATIENT body and over a specified time

2.101.6**TIME RATE OF CHANGE OF THE MAGNETIC FIELD (dB/dt)**

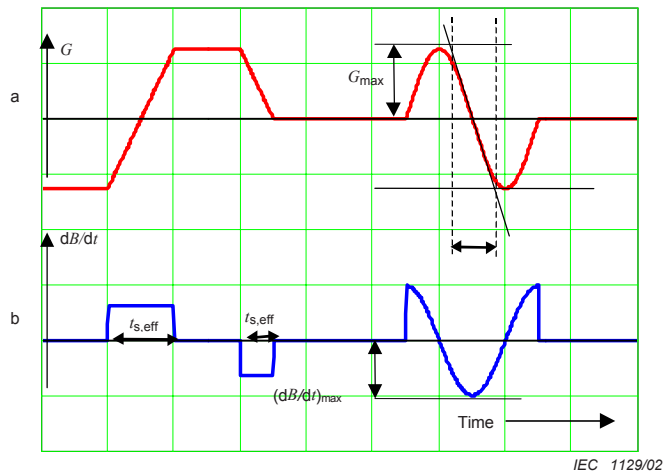
rate of change of the magnetic flux density with time (T/s)

2.101.7**GRADIENT OUTPUT**

parameter characterizing the gradient performance such as rate of change of the magnitude of the magnetic field, or electric field induced by one or more GRADIENT UNITS under specified conditions and at a specified position

2.101.8**EFFECTIVE STIMULUS DURATION ($t_{s,eff}$)**

duration of any period of the monotonic increasing or decreasing gradient, used to describe its limits for cardiac or peripheral nerve stimulation. It is defined as the ratio of the peak-to-peak field variation and the maximum value of the time derivative of the gradient in that period

**Graph a**

G magnetic field gradient

G_{max} maximum of gradient

Graph b

dB/dt time rate of change of magnetic field

$(dB/dt)_{max}$ maximum of time rate of change of magnetic field

$t_{s,eff}$ effective stimulus duration

Three periods of monotonic change of the gradient G are shown in graph a. The corresponding gradient output dB/dt is shown in graph b and the effective stimulus duration $t_{s,eff}$ is indicated.

Figure 101 – Gradient waveform and EFFECTIVE STIMULUS DURATION

Table 101 – List of symbols

Symbol	SI-Unit	Definition
B_0	T	Static magnetic field
B_1	T	Magnetic induction of the radio frequency magnetic field
dB/dt	T/s	TIME RATE OF CHANGE OF THE MAGNETIC FIELD (dB/dt)
E	V/m	Electric field induced by gradient switching
G	T/m	Magnetic field gradient
$L01$	V/m or T/s	Limit of the GRADIENT OUTPUT for the NORMAL OPERATING MODE
$L12$	V/m or T/s	Limit of the GRADIENT OUTPUT for the FIRST LEVEL CONTROLLED OPERATING MODE
O	depending on context	GRADIENT OUTPUT
O_i	depending on context	GRADIENT OUTPUT per GRADIENT UNIT
rb	V/m or T/s	Rheobase
SAR	W/kg	SPECIFIC ABSORPTION RATE (SAR)
$t_{s,eff}$	ms	EFFECTIVE STIMULUS DURATION
t_{SAR}	min	Averaging time for the determination of SAR
T	°C	Temperature
w_i	none	Weight factor per GRADIENT UNIT relating the GRADIENT OUTPUT of that unit to the limit

3 General requirements

This clause of the General Standard applies except as follows:

3.1 Addition:

The MR EQUIPMENT shall not cause an unacceptable SAFETY HAZARD to the PATIENT, the OPERATOR, staff and the general public.

Compliance is considered to be fulfilled, when the MR EQUIPMENT meets the relevant requirements of this Standard.

General safety aspects of MEDICAL ELECTRICAL SYSTEMS are covered by IEC 60601-1-1.

Compliance to IEC 60601-1-4 requires identification of hazards, assessment of their risks, and appropriate verification and validation of risk controls. Demonstration of compliance to the requirements of this standard shall be included as part of these processes and retained by the MANUFACTURER as a permanent record. All tests shall include, in sufficient detail for the test to be exactly repeatable, a test protocol, all input data and the expected result.

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 facility, and the general public.

* 6.8.2 INSTRUCTIONS FOR USE

Addition:

* aa) Pre-screening of the PATIENT and MR WORKER

INSTRUCTIONS FOR USE shall provide clear recommendations to the USER regarding pre-screening of PATIENTS and MR WORKERS. This specifically applies to those PATIENTS and MR WORKERS who could be placed at risk due to their professional activity, past medical history, present medical state and/or the physical environment of the MR EQUIPMENT. These instructions shall indicate the need for a pre-screening program to identify such PATIENTS and MR WORKERS at risk, and shall provide recommendations to adequately safeguard these PATIENTS and MR WORKERS from injury. For the MR WORKER especially the risk due to the past professional activity, which may have caused accidental implantation of ferromagnetic materials, shall be considered. 

The following specific classes of PATIENTS shall be mentioned:

- classes of PATIENTS for whom MR 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 MR 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 MR EQUIPMENT is capable of operating within the FIRST LEVEL CONTROLLED OPERATING MODE as described in clause 51.

* bb) MEDICAL SUPERVISION OF PATIENTS

INSTRUCTIONS FOR USE shall provide clear recommendations to the USER to establish a programme for the supervision appropriate to the classes of PATIENTS described in 6.8.2 aa) and to the controlled modes of operation of the MR EQUIPMENT as defined in 2.10 (see also rationale to 2.12.103).

INSTRUCTIONS FOR USE shall:

- include the recommendation that all PATIENTS should receive at least ROUTINE MONITORING;
- if the MR 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 MR 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.).

In addition it shall be stated that the local approval should specifically state limits for gradient output, SAR and static field strength.

* cc) Emergency medical procedures

INSTRUCTIONS FOR USE shall give clear recommendation to the USER to 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 if during MR 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).

* A₂ dd) Exposure of the PATIENT and MR WORKER to excessive acoustic noise A₂

For MR EQUIPMENT that are capable of producing more than an A-weighted r.m.s. sound pressure level ($L_{Aeq, 1h}$) of 99 dB(A), the INSTRUCTIONS FOR USE:

- shall state that the A-weighted r.m.s. sound pressure level is measured according to 26 e) and 26 g);
- shall state that hearing protection shall be used for the safety of the PATIENT and that this hearing protection shall be sufficient to reduce the A-weighted r.m.s. sound pressure level below 99 dB(A);
- shall state that special attention and special training for the OPERATOR is required for proper positioning of the hearing protection, especially when the standard ear cuffs cannot be applied, or no protection at all can be applied, as for neonates and premature infants;
- shall draw attention to a warning that due to increased anxiety, accepted sound pressure levels may still be of concern to pregnant women and the foetus, to newborns, infants and young children and to the elderly;
- shall state clearly the sound level at the CONTROL PANEL for the safety of the OPERATOR and staff;
- shall draw attention to the possibility that anaesthetised PATIENTS can have less than normal protection against high sound pressure, so that ear protection for these PATIENTS should not be omitted even at moderate sound levels;
- A₂ – shall draw attention to the fact that in some countries legislation may exist covering the exposure of MR WORKERS to noise.
- shall state that for tasks in the CONTROLLED ACCESS AREA during scanning, the MR WORKER shall wear adequate hearing protection to reach compliance with the rules for protection of workers to noise. A₂

NOTE A suitable warning sign is specified in ISO 7731.

* ee) CONTROLLED ACCESS AREA

When the installation of a CONTROLLED ACCESS AREA is required for the MR EQUIPMENT (see 6.8.3.aa) and 36.101), the 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;
- shall specify, preferably accompanied by a sketch, the size and shape of the CONTROLLED ACCESS AREA;
- 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 dysfunction of their medical implants such as pacemakers;

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

- shall 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 their installation as well as special precautions, if any, for their use;
- shall state clearly that peripheral equipment, including PATIENT monitoring, life supporting devices and emergency care equipment, which is 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 MR EQUIPMENT and that this peripheral equipment may also disturb the proper functioning of the MR EQUIPMENT.

* ff) Liquid and gaseous cryogenics

For MR 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 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 cryogen 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 cryogen that are being supplied;
 - procedures to be followed if flammable materials are found near the cryogen container.

NOTE 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 mode of operation: NORMAL OPERATING MODE, FIRST LEVEL CONTROLLED OPERATING MODE, and SECOND LEVEL CONTROLLED OPERATING MODE, as they are defined in 51.101. The INSTRUCTIONS FOR USE shall also give the explanation that GRADIENT OUTPUT and SAR levels for PATIENTS are based on current scientific literature related to safety, and that the level of exposure, the decision of leaving the NORMAL OPERATING MODE and the possible need for physiological monitoring of the PATIENTS shall be a medical judgement as to the PATIENTS' potential risk versus benefit.

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

- For MR EQUIPMENT operating within the NORMAL OPERATING MODE, no specific indication or measure is required to be displayed and only ROUTINE MONITORING is recommended.
- For MR EQUIPMENT capable of operation in FIRST LEVEL CONTROLLED OPERATING MODE, the properties of the MR EQUIPMENT with respect to displayed indication before entering this mode and to deliberate action when entering this mode, as required in 51.101.3, shall be described. Also, MEDICAL SUPERVISION shall be recommended as required in 6.8.2 bb).
- For MR EQUIPMENT capable of operating within the SECOND LEVEL CONTROLLED OPERATING MODE, specific security measures shall be provided as required in 51.101.4 to prevent unauthorised 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.

* A_2 hh) Exposure of the PATIENT and MR WORKER to the static magnetic field A_2

For MR EQUIPMENT that is capable of operation in the FIRST LEVEL CONTROLLED OPERATING MODE or the SECOND LEVEL CONTROLLED OPERATING MODE for static magnetic field, the INSTRUCTIONS FOR USE shall:

- A_2 – explain the possible effects that PATIENTS and MR WORKERS may experience when the static magnetic field is above the level of NORMAL OPERATION MODE, paying particular attention to the effects that may be experienced if the PATIENT or MR WORKER'S head is moved rapidly while inside or close to the MR EQUIPMENT, including dizziness, vertigo, and a metallic taste in the mouth; A_2
- recommend that the PATIENT remains still while in the region of high static magnetic field;
- provide information on the values of B_0 which the MR EQUIPMENT is capable of.
- A_2 – explain that when the main static magnetic field is higher than 2 T and not exceeding 4 T, the MR SYSTEM is continuously operating in the FIRST LEVEL CONTROLLED OPERATION MODE and therefore ensure that MEDICAL SUPERVISION is provided for all PATIENTS
- explain that adequate training shall be given to MR WORKERS to minimise adverse health effects arising from the high static magnetic field. Explain the health effects related to the increased static magnetic fields and explain the possible changes in the MR compatibility of the tools and accessories used by the MR WORKER, as a function of the value of the static magnetic field.
- explain that when the main static magnetic field is higher than 4 T, the MR system is continuously operating in the SECOND LEVEL CONTROLLED OPERATION MODE and therefore ensure that MEDICAL SUPERVISION is provided for all PATIENTS. Explain that in this situation MR WORKERS shall not be allowed to access the MR EQUIPMENT without local approval as required. A_2

ii) Exposure of the PATIENT to time varying magnetic fields

For MR EQUIPMENT that is capable of operation at levels of GRADIENT OUTPUT above the NORMAL OPERATING MODE, the INSTRUCTIONS FOR USE shall draw attention to risk factors, which may increase the potential for peripheral nerve stimulation for the PATIENT and they shall describe ways for the USER to mitigate these risk factors. The INSTRUCTIONS FOR USE shall: 

- explain the possible effects on the PATIENTS of the level of GRADIENT OUTPUT in each of the operating modes with which the MR EQUIPMENT is provided, paying particular attention to possible effects on the peripheral nervous system and on the heart;
- provide information on the GRADIENT OUTPUT of which the MR EQUIPMENT is capable in each operating mode;
- explain that the MR EQUIPMENT will display an indication of the appropriate operating mode when the value of GRADIENT OUTPUT exceeds the limits of the NORMAL OPERATING MODE;
- describe the gradient system as either a WHOLE BODY GRADIENT SYSTEM or as a SPECIAL PURPOSE GRADIENT SYSTEM and describe the volume in which the GRADIENT OUTPUT is in compliance.

jj) Exposure of the PATIENT to radio frequency magnetic fields

The INSTRUCTIONS FOR USE shall draw attention to risk factors, which may increase the potential for local excessive RF heating of the PATIENT and they shall describe ways for the USER to mitigate these risk factors. These factors include: 

- the presence of conductive (metallic) objects or implants within the sensitivity region of the RF transmit coil. All clothing containing metallic thread or components and all other metallic objects such as watches, coins, etc. must be removed from the PATIENT;
- the use of medicinal products in transdermal patches which may cause burns to the underlying skin;
- the fact that skin-to-skin contact may form a conductive loop through part of the body, e.g., inner thigh-to-thigh, calf-to-calf, hand-to-hand, hand-to-body, ankle-to-ankle contact;
- the presence of damp clothing;
- the placement of the body or extremities against the RF transmit coil surface;
- the contact between PATIENT and RF receive coil cable and the routing of the RF coil cable in proximity to RF transmit coil;
- the formation of loops with RF receive coil cables and ECG leads;
- the use of incompatible ECG electrodes and leads. Inform the OPERATOR to only use MR compatible ECG leads and electrodes, such as provided or specified by the MANUFACTURER of the MR EQUIPMENT. Inform the OPERATOR to always use electrodes that have not passed their expiration date.
- the scanning of sedated or unconscious PATIENTS, or PATIENTS with loss of feeling in any body part, e.g., paralysis of arms or legs, and who would therefore not be able to alert the OPERATOR as to excessive heating and associated tissue damage;
- the presence of unconnected receive coils or electric cables that remain in the RF transmit coil during the examination.

For MR EQUIPMENT that is capable of operation at SAR levels above the NORMAL OPERATING MODE, the INSTRUCTIONS FOR USE shall:

- explain the possible effects of elevated values of the different types of SAR that are limited by the MR EQUIPMENT as required in 51.103;

- explain the possible effects of the SAR on the PATIENTS in each of the operating modes provided by the MR EQUIPMENT, paying particular attention to the safety of PATIENTS who may have reduced thermal regulatory capabilities and increased sensitivity to raised body temperature (e.g. febrile and cardiac decompensated PATIENTS, those with compromised ability to perspire, and pregnant women). In addition, information describing the importance of environmental controls and the effect of ambient temperature on PATIENT core temperature rise shall be provided, along with recommendations for environmental conditions for the PATIENT;
- provide information on the values of each type of SAR the MR EQUIPMENT is capable of;
- state the accuracy of the predicted value of the different types of SAR;
- explain that the limits for 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 %. In addition, the INSTRUCTIONS FOR USE shall explain how the SAR is controlled outside these environmental specifications. This explanation may
 - specify that the MR EQUIPMENT shall not be used when the temperature is greater than 24 °C or the humidity is greater than 60 %, or
 - explain that the limits of the operating modes for SAR are being automatically reduced according to 51.103.2 (only for MR EQUIPMENT that has the capability to measure the temperature and humidity);
- draw attention to means to reduce the risk from high SAR scanning, such as the need for breaks for the PATIENT to cool down, light clothing for the PATIENT and adequate ventilation of the PATIENT space.

* kk) Occupational exposure

A2 The INSTRUCTIONS FOR USE shall draw attention to the fact that MR WORKERS can be exposed to the electromagnetic fields (EMF) emitted by the MR EQUIPMENT. They shall provide sufficient information relating to the risks from these exposures to enable safe working procedures for the MR WORKER. The relevant requirements of 6.8.2 ii) and jj) for the PATIENT shall also apply for the MR WORKER. This information shall also include

- specification of areas to which access by the MR WORKER is restricted, if any;
- the actual levels of the exposure in all areas accessible to the MR WORKER, expressed in proper units for the static magnetic field (see 6.8.2 hh) and 51.104), the GRADIENT OUTPUT (see 6.8.2.ii) and 51.102) and the RF transmit field (see 6.8.2 jj) and 51.103) generated by the MR EQUIPMENT;
- instructions that the MR WORKER shall be informed and trained sufficiently so that they can perform all their tasks safely in a way that minimizes their exposure to EMF emitted by the MR EQUIPMENT;
- a statement that there is a possibility that mild peripheral nerve stimulation (PNS) may be induced in the PATIENT and MR WORKER when exposed to the gradients in the FIRST LEVEL CONTROLLED OPERATION MODE;.

The risk factors associated with the expected exposure levels for the MR WORKER shall be explained. A description of ways for the MR WORKER to mitigate these risk factors shall be given.

Known factors to draw attention to are the following:

- The possible physiological effect of exposure to RF radiation is heating. Exposure to RF radiation can be minimised by keeping sufficient distance away from the transmit RF coil or by reducing time of exposure during scanning;
- The possible physiological effect of exposure to the GRADIENT OUTPUT is peripheral nerve stimulation for the person exposed. Exposure to GRADIENT OUTPUT can be minimised by keeping sufficient distance away from the gradient coils during scanning. **A2**

- A₂** – The possible physiological effects of exposure to the static magnetic field are dizziness, vertigo, and a metallic taste in the mouth of the person exposed. Exposure to the static magnetic field can be minimised by staying away from the magnet (not just during scanning but all the time) and by avoiding rapid movements of the head while in the static magnetic field.

The INSTRUCTIONS FOR USE may state that, it is generally accepted that no published evidence supporting the occurrence of cumulative and/or long-term effects after exposure to EMF emitted by the MR EQUIPMENT exists.

The INSTRUCTIONS FOR USE shall state that extra precaution is advisable for pregnant MR WORKERS, although there is no currently available epidemiological evidence for any negative health effects. Local regulations may apply.

The INSTRUCTIONS FOR USE shall state that the limits for MR WORKERS may not be applicable when an MR WORKER is pregnant. It may be required in some countries that the 'member of the public' limit be applied to the foetus.

The INSTRUCTIONS FOR USE shall state that in some countries legislation may exist covering occupational limits for exposure to EMF, that are lower than the limits for MR WORKER given in this standard. **A₂**

* II) Auxiliary EQUIPMENT

The USER shall be made aware that any application of physiological monitoring and sensing devices to the PATIENT should be made under the USER'S direction and is the USER'S responsibility.

INSTRUCTIONS FOR USE shall warn the USER that the use of auxiliary equipment, such as physiological monitoring and gating equipment and RF transmit coils, which has not been specifically tested and approved for use in the environment of the MR EQUIPMENT may result in burns or other injuries to the PATIENT. INSTRUCTIONS FOR USE shall further warn the USER that even auxiliary devices labelled as compatible with MR EQUIPMENT or MR SYSTEMS may be capable of causing injury if the MANUFACTURERS instructions, especially with respect to electrically conducting lead positioning, are not followed.

mm) EMERGENCY FIELD SHUT DOWN UNIT

INSTRUCTIONS FOR USE shall indicate when and how the EMERGENCY FIELD SHUT-DOWN UNIT should be operated in the event of an emergency. Examples of situations which would require emergency field shut-down shall be provided.

NOTE Permanent magnets cannot be de-energised in case of emergency.

nn) Fire precautions

INSTRUCTIONS FOR USE shall recommend to the USER that fire precautions should be discussed with the local fire department, that emergency procedures should be established and that it is the USER'S responsibility to take the necessary initiatives.

oo) Artefacts

INSTRUCTIONS FOR USE shall alert the USER to the fact that image artefacts may occur as a result of technological and physiological factors (e.g. magnet homogeneity, gradient linearity, truncation, aliasing, motion, flow, chemical shift, susceptibility variations, etc.). The effects of these factors (e.g. image non-uniformity, geometric distortion, ghosts, wraparound etc.) on the image shall be described. Methods of correcting or mitigating such effects (e.g. changing bandwidth, gradient moment nulling, pre-saturation, etc.) shall also be discussed.

[A1] pp) Recommended training

INSTRUCTIONS FOR USE shall recommend that training is needed for physicians and the OPERATOR to operate the MR EQUIPMENT safely and effectively. This training shall include emergency procedures, including those for the issues described in this subclause under

- cc) Emergency medical procedures
- ee) CONTROLLED ACCESS AREA
- mm) EMERGENCY FIELD SHUT DOWN UNIT
- nn) Fire precautions
- ss) Emergency actions in the event of a QUENCH. **[A1]**

qq) Quality assurance

INSTRUCTIONS FOR USE shall describe the quality assurance procedures recommended for the USER, including a description of all of the phantoms to be used.

rr) Maintenance

INSTRUCTIONS FOR USE shall include the recommended maintenance schedules for the MR EQUIPMENT. Items that should be performed by service personnel shall be identified.

[A1]* ss) Emergency actions in case of a QUENCH

The INSTRUCTIONS FOR USE shall include instructions on how to identify a QUENCH and how to act in the event of a QUENCH, especially when the venting system of the superconducting magnet system fails. **[A1]**

6.8.3 Technical description

Addition:

aa) CONTROLLED ACCESS AREA

For MR EQUIPMENT that generates a stray field exceeding 0,5 mT outside its permanently attached cover, and/or an electromagnetic interference level that does not comply with IEC 60601-1-2, the technical description

- shall indicate the necessity to define and permanently install a CONTROLLED ACCESS AREA around the MR EQUIPMENT such that outside this area
 - 1) the magnetic fringe field strength shall not exceed 0,5 mT, and
 - 2) the electromagnetic interference level complies with IEC 60601-1-2:2001;
- shall give clear recommendations as to how this CONTROLLED ACCESS AREA shall be delimited, e.g. by markings on the floor, barriers and/or other means to allow the responsible staff to adequately control access to this area by unauthorised persons;
- shall state that the CONTROLLED ACCESS AREA should be labelled at all entries by appropriate warning signs, including an indication of the presence of magnetic fields and their attractive force or the torque on ferromagnetic materials (see annex AA for examples of warning signs and prohibitive signs).

When the MR EQUIPMENT is designed for installation in a room in which audiovisual contact with the PATIENT is likely to be limited, the technical descriptions shall specify provisions in the design of the room and in the EQUIPMENT to enable audio and visual contact with the PATIENT during the MR EXAMINATION. The audio visual contact shall be sufficient to allow ROUTINE MONITORING and MEDICAL SUPERVISION of the PATIENT.

* bb) Compatibility technical specification sheet

In addition to the INSTRUCTIONS FOR USE for MR EQUIPMENT a compatibility technical specification sheet shall be provided with sufficient information to enable testing the proper operation of peripheral equipment. The compatibility technical specification sheet (product data sheet) shall describe a number of parameters which characterise the MR EQUIPMENT. The parameter list includes:

- Magnet: type, field strength, bore dimension, cryogen types and boil-off rates, spatial distribution of surrounding field in plots relating to a typical installation of the MR EQUIPMENT.
 - The plots shall represent three suitable orthogonal planes through the iso-center to illustrate maximum spatial extent of iso-magnetic contours.
 - Each plot shall contain at least the iso-magnetic contours with values of 0,5 mT, 1 mT, 3 mT, 5 mT, 10 mT, 20 mT, 40 mT, and 200 mT as well as a distance scale and a superimposed outline of the magnet.
 - The position where the spatial gradient of the main magnetic field is a maximum, and the values of B_0 and the spatial gradient of B_0 at that location. At this location the force on a saturated ferromagnetic object resulting from the spatial gradient of the main magnetic field is maximum.
 - The position where the product of the magnitude of the magnetic field B_0 and the spatial gradient of B_0 is a maximum and the value of B_0 and the spatial gradient of B_0 at that location. At this location, the force on a diamagnetic or paramagnetic object, or a ferromagnetic material below its magnetic saturation point, is a maximum.
- A2

 • For MR equipment that is capable of operation in the FIRST LEVEL CONTROLLED OPERATION MODE or the SECOND LEVEL CONTROLLED OPERATION MODE for the static magnetic field, a plot representing the 0,5 T, 1 T, 1,5 T, 2 T, 3 T and the 4 T iso-magnetic contours at positions accessible to and relevant for the MR WORKER shall be included if the static magnetic field in the iso-centre exceeds any of these values.
- Gradient system: type, amplitude, rise time, slew rate, and spatial distribution of the maximum magnitude values of the vector sum of all three GRADIENT OUTPUTS at the positions accessible to and relevant for the MR WORKER during scanning.
- RF system: types of RF transmit coil, amplifier peak r.m.s. power, applied maximum transmit RF magnetic field and bandwidth, spatial distribution of the maximum transmit RF magnetic field at the positions accessible to and relevant for the MR WORKER during scanning.

A2
- Compatibility protocols:

The MANUFACTURER of MR EQUIPMENT shall suggest protocols, which can be run routinely on the MR EQUIPMENT, and enable the MANUFACTURER of peripheral equipment to test the functionality of its equipment. The protocols are designed to run the MR EQUIPMENT with high transmit RF field or high gradient slew rates and amplitudes so that the MANUFACTURER of peripheral equipment can investigate the influence of the MR EQUIPMENT on its peripheral equipment. The tests are not intended for estimation of the possible effect of the peripheral equipment on the resulting image quality of the MR EQUIPMENT and are no guarantee that the peripheral equipment will function properly.
- PATIENT space: size, ventilation, communication, and lighting.
- PATIENT SUPPORT: dimensions, positioning, accuracy and maximum load.

A1)* cc) Safety provisions in the event of a quench

For MR EQUIPMENT equipped with superconducting magnets, the ACCOMPANYING DOCUMENTS shall

- state the requirements for a venting system for the superconducting magnet which connects the cryostat of the magnet to the outside atmosphere and which is designed to withstand a QUENCH and to protect nearby persons in the event of a QUENCH;
- provide guidelines for the construction (dimensions, position, assembly and material to be applied) of the venting system for the superconducting magnet inside and outside the examination room;
- recommend a preventive maintenance program, which states that regular checks of the adequateness of the function of the venting system for the superconducting magnet are to be made;
- state requirements for the design of the examination room to increase safety of the patient and other persons inside and outside the examination room in the event of failure of the venting system during a quench. The suggested design shall address the issues of reducing pressure build-up, temperature decrease and oxygen depletion during a quench. A number of acceptable solutions for such provisions, demonstrated to be effective by simulation or test, shall be listed, so that even when the venting system of the superconducting magnet fails to work adequately, the chance of a hazard for the PATIENT or other persons inside as well as outside the examination room, as caused by PRESSURE build-up, temperatures decrease or oxygen depletion during the QUENCH, is reduced considerably;
- state the need for the USER to establish an emergency plan for a quench, including a situation in which the venting system for the superconducting magnet fails to function adequately;
- state the need for possible extra control measures for the PATIENT ventilation system in order not to expose the PATIENT to additional helium transported to the PATIENT via the PATIENT ventilation system. The PATIENT ventilation system should have its inlet opening in a safe place (such as at a low level in the examination room or directly connected to the air-conditioning of the examination room), or be connected to a QUENCH detector, so that the PATIENT ventilation system can be automatically controlled when a QUENCH occurs and will not transport helium to the PATIENT inside the scanner.

NOTE 1 The venting system for the superconducting magnet is considered to be the cryogenic vent pipe and all the extra components necessary to safely accommodate a QUENCH.

NOTE 2 Examination room configurations demonstrated by simulation or test that are acceptable include:

- configurations in which the RF door opens outwards or is a sliding RF door;
- configurations in which the RF door opens inwards, if these include extra precautions to prevent PRESSURE build up. This can be realized by one of the following
 - an extra examination room ventilator system, which can be switched on (possibly automatically via an oxygen monitor in the ceiling of the examination room to detect the escape of helium gas) in the event of a QUENCH; or
 - an opening in the wall or ceiling of the examination room, venting towards an open area; or
 - a possibility of opening the observation window in the examination room outward or by sliding; or
 - a second independent venting system for the superconducting magnet that remains operational in case the regular venting system for the superconducting magnet is obstructed; or
 - equivalent methods demonstrated to be effective by simulation or test. **A1**

dd) Decay characteristics of magnetic field

For MR EQUIPMENT comprised of superconducting magnets or resistive magnets, the technical description shall provide decay characteristics of the magnet in case of a QUENCH or of an emergency field shut-down to enable the USER to implement adequate life supporting and other safety procedures. These characteristics shall indicate the time from activation of the EMERGENCY FIELD SHUT-DOWN UNIT to the moment at which the field strength in the centre of the magnet has fallen to 20 mT.

In the technical description, guidance shall be given regarding where and how to install the actuator of the EMERGENCY SHUT DOWN UNIT.

ee) Type of gradient system

The gradient system shall be labelled in the technical description by the MANUFACTURER either as a WHOLE BODY GRADIENT SYSTEM or as a SPECIAL PURPOSE GRADIENT SYSTEM.

SECTION TWO: ENVIRONMENTAL CONDITIONS

This section of the General Standard applies.

SECTION THREE: PROTECTION AGAINST ELECTRICAL SHOCK HAZARDS

This section of the General Standard applies.

SECTION FOUR: PROTECTION AGAINST MECHANICAL HAZARDS

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

*** 26 Vibration and noise**

This clause of the General Standard applies except as follows:

Replacement:

The MR EQUIPMENT shall not produce noise having an unweighted peak sound pressure level (L_P) higher than 140 dB referenced to 20 μ Pa in any accessible area.

Method of measurement of acoustic noise to demonstrate compliance with the given requirement and for assessment of the level related to the given requirement:

- a) *The sound pressure level shall be measured in terms of r.m.s. and peak value. Without a PATIENT on the PATIENT SUPPORT, position the microphone at the magnet isocentre, move the microphone parallel to the PATIENT SUPPORT along the PATIENT axis to locate the noisiest location and make the test there.*

The microphone shall not be placed inside a head coil unless that head coil is placed over the PATIENT'S head for all MAGNETIC RESONANCE EXAMINATIONS.

- b) *The sound level meter shall be placed sufficiently far from the magnet isocentre so that its accuracy is not affected by the magnetic fringe field. This often requires the use of an extension cable between the meter and the microphone. The microphone shall be omnidirectional and insensitive to magnetic fields, or calibrated to account for the magnetic field.*

Care shall be taken to ensure that environmental effects (e.g. electromagnetic interference, pulsed gradient fields) are avoided or adequately compensated.

- c) *The sound level meter shall comply with IEC 60651, type 0 or type 1, and/or IEC 60804, type 0 or type 1.*
- d) *Measurements shall be taken with normal eddy current compensation as for standard clinical use.*
- e) *Measurements shall be made using the MR EQUIPMENT in the mode producing the worst case situation acoustically. This can be done either by using maximum amplitude bipolar gradient waveform (see figure 102) applied simultaneously to all three gradient axes or the clinical scan condition producing the maximum acoustic noise.*

When the maximum gradient waveforms are used, the transition times t_1 , t_2 , t_3 , and t_4 shall be the minimum that the MR EQUIPMENT is capable of generating under any conditions allowed for clinical use. The amplitudes, A_{+max} and A_{-max} , are defined as the maximum gradient strength that can be generated by the MR EQUIPMENT under normal gradient operating conditions. The on-time of the pulse, t_{on} , shall be the minimum that will allow the current wave-form to attain the maximum current demanded by the wave form.

The cycle time, T_R , shall be the shortest allowed by the gradient system duty cycle limits.

- f) Using the "max hold" function, measure the unweighted peak sound pressure level L_P (according to 3.1 of ISO 1999) using the following sound level meter settings and conditions:

detector: peak
 time weighting: not applicable
 frequency weighting: no weighting
 measurement period: ≥ 20 s

- g) Measure the A-weighted r.m.s. sound pressure $L_{Aeq, 1 h}$ (according to 3.5 of ISO 1999) using the following sound level meter settings and conditions:

detector: r.m.s.
 time weighting: fast or slow
 frequency weighting: A-weighting
 measurement duration: ≥ 20 s

- h) Record the values measured.

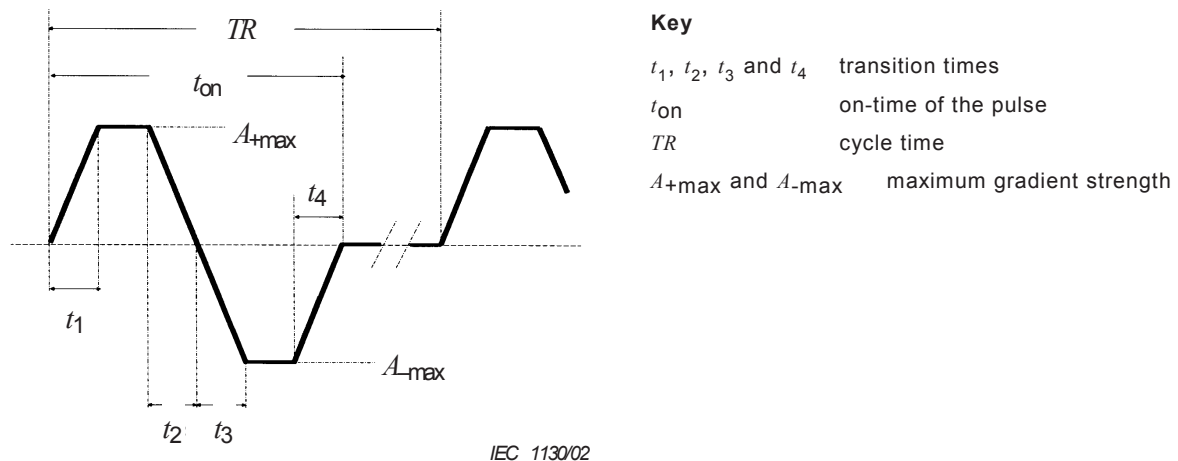


Figure 102 – Gradient output waveform for performing measurements of acoustic noise

SECTION FIVE: PROTECTION AGAINST HAZARDS FROM UNWANTED OR EXCESSIVE RADIATION

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

* 36 Electromagnetic compatibility

This clause of the General Standard applies except as follows:

Addition:

Outside the CONTROLLED ACCESS AREA the magnetic stray field shall be smaller than 0,5 mT and the electromagnetic interference level shall comply with Collateral Standard IEC 60601-1-2.

Inside the CONTROLLED ACCESS AREA the requirements as stated under 6.8.2 ee) are applicable.

NOTE 1 For electromagnetic compatibility purposes the CONTROLLED ACCESS AREA, when installed, is considered to be part of the MR SYSTEM.

NOTE 2 Inside the CONTROLLED ACCESS AREA, special interface requirements may be set by the MANUFACTURER of the MR EQUIPMENT.

SECTION SIX: PROTECTION AGAINST HAZARDS OF IGNITION OF FLAMMABLE ANAESTHETIC MIXTURES

This section of the General Standard applies.

SECTION SEVEN: PROTECTION AGAINST EXCESSIVE TEMPERATURES AND OTHER SAFETY HAZARDS

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

45 PRESSURE VESSELS and parts subject to PRESSURE

This clause of the General Standard applies with the following addition:

Addition:

45.101 If the helium vessel is designed as a PRESSURE VESSEL, then it shall be tested in compliance with clause 45 of IEC 60601-1, or with national regulations.

49 Interruption of the power supply

This clause of the General Standard applies except as follows:

Addition:

49.101 EMERGENCY FIELD SHUT-DOWN UNIT

MR EQUIPMENT comprised of a superconducting magnet or resistive magnet shall be provided with an EMERGENCY SHUT DOWN UNIT.

NOTE 1 Such an emergency situation is, for example, the entrapment of persons in the magnetic field resulting from ferromagnetic objects.

NOTE 2 Requirements on the provision in the INSTRUCTIONS FOR USE of information concerning the EMERGENCY SHUT DOWN UNIT are given in 6.8.2 mm).

NOTE 3 Information on the magnetic field decay characteristics during emergency field shut-down are required in 6.8.3 dd) for the ACCOMPANYING DOCUMENTS.

49.102 Scan interruption

A facility shall be provided to allow the OPERATOR to immediately stop the scan by interrupting the power to the gradient system and that to the RF transmit coil (see IEC 60601-1-2).

SECTION EIGHT: ACCURACY OF OPERATING DATA AND PROTECTION AGAINST HAZARDOUS OUTPUT

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

*** 51 Protection against hazardous output**

This clause of the General Standard applies except as follows:

51.1 Intentional exceeding of safety limits

This subclause does not apply.

51.2 Indication of parameters relevant to safety

This subclause does not apply.

51.4 Accidental selection of excessive output values

This subclause does not apply.

Addition:

51.101 Operating modes

When during its operation one or more of the outputs of the MR EQUIPMENT reach a level that may cause undue physiological stress to the PATIENT, the USER must decide whether or not this operation is in the interest of the PATIENT. In this clause, requirements on the design of the MR EQUIPMENT are given that can help the USER to make that decision. The requirements in this clause describe three levels of operation of MR EQUIPMENT that are specified with respect to the USER interface and information given to the OPERATOR (51.101) and with respect to the values of output permitted (51.102 – 51.104).

The requirements of this subclause shall apply separately for all operating modes, and more specifically for the operating modes for the GRADIENT OUTPUT, the SPECIFIC ABSORPTION RATES (SAR) and the static magnetic field.

Demonstration of compliance with the requirements of this subclause relating to operating modes, (i.e. the means for control, the deliberate action required and the information and indications provided) shall be checked by inspection. The methods of measurement to demonstrate compliance with the operating mode limits contained in 51.102 and 51.103 are described in 51.105.1 through 51.105.3.

51.101.1 All operating modes

MR EQUIPMENT shall comply with the following requirements:

- a) Means (control) shall be provided in order to ensure, that the limit(s) of the (selected) operating mode cannot be exceeded. This control shall be independent of OPERATOR input (as to PATIENT size, mass or position) or shall be checked by the MR EQUIPMENT in order to detect any OPERATOR input error.
- b) A reset to the NORMAL OPERATING MODE with respect to SAR and dB/dt shall be performed automatically with change of the PATIENT.
-  c) The MR EQUIPMENT shall provide information upon request about the relevant SAR and relevant GRADIENT OUTPUT. 

51.101.2 NORMAL OPERATING MODE

For MR EQUIPMENT that is not capable of operation at levels above the NORMAL OPERATING MODE as specified in 51.102 and 51.103, no specific indication of the operating mode or the maximum GRADIENT OUTPUT or predicted value of SAR is required to be displayed at the CONTROL PANEL.

51.101.3 FIRST LEVEL CONTROLLED OPERATING MODE

MR EQUIPMENT that allows the operation in the FIRST LEVEL CONTROLLED OPERATING MODE as specified in 51.102 and 51.103 shall comply with the following requirements:

-  a) Before the start of each scan, an indication of the operating mode defined by the value of the GRADIENT OUTPUT which will actually be applied during the scan and the value of the SAR which will actually be applied during the scan, and a prediction of these values (upon request) shall be displayed at the CONTROL PANEL. The value for the GRADIENT OUTPUT shall be expressed as the percentage of the upper level of the FIRST LEVEL CONTROLLED OPERATION MODE (L12) for the scan applied. 

- b) If the value of the GRADIENT OUTPUT or SAR that controls the scan is such as to enter the FIRST LEVEL CONTROLLED OPERATING MODE, the attention of the OPERATOR shall be drawn to this condition by a clear indication on the CONTROL CONSOLE. A record of the operating mode or equivalent data shall be an integral part of the image data.
- c) A deliberate action of the operator shall be necessary in order to enter the first level controlled operating mode.

51.101.4 SECOND LEVEL CONTROLLED OPERATING MODE

MR EQUIPMENT not intended for normal use in the hospital, which allows the operation in the SECOND LEVEL CONTROLLED OPERATING MODE for values of the GRADIENT OUTPUT or SAR as specified in 51.102 and 51.103, shall comply with the following requirements:

- a) A specific security measure that prevents access to the SECOND LEVEL CONTROLLED OPERATING MODE must be deactivated before entering the SECOND LEVEL CONTROLLED OPERATING MODE. The specific security measure shall be designed so that the SECOND LEVEL CONTROLLED OPERATING MODE may be accessed only under the authorisation of the medically responsible person acting under the authority of a human studies protocol approved according to local requirements. The specific security measure shall involve a key-lock, a combination lock, a software password, or other protective device.
-  b) Before the start of each scan, an indication of the operating mode defined by the value of the GRADIENT OUTPUT which will actually be applied during the scan and the value of the SAR which will actually be applied during the scan, and a prediction of these values (upon request) shall be displayed at the CONTROL PANEL. The value for the GRADIENT OUTPUT shall be expressed as the percentage of the upper level of the FIRST LEVEL CONTROLLED OPERATION MODE (L12) for the scan applied. 
- c) A record of the GRADIENT OUTPUT or SAR that controls the scan values and the equivalent data shall be an integral part of the image data.
- d) An indication to the OPERATOR shall be included that the operating conditions are potentially hazardous and that these conditions should not be applied for normal clinical use.
- e) The MR EQUIPMENT shall provide means to set adjustable limits (in the SECOND LEVEL CONTROLLED OPERATING MODE) of GRADIENT OUTPUT or different types of SAR which cannot be adjusted by the OPERATOR, unless authorised.

* 51.102 Protection against excessive low frequency field variations produced by the gradient system

Low frequency field variations produced by the gradient system are in this standard the variations for which the concern is to prevent cardiac or peripheral nerve stimulation (PNS) (EFFECTIVE STIMULUS DURATION >20 µs).

51.102.1 Objectives for limitation of GRADIENT OUTPUT

 The MR EQUIPMENT shall be designed to automatically control the GRADIENT OUTPUT so that cardiac stimulation in the PATIENT and in the MR WORKER at any operating mode is prevented.

The MR EQUIPMENT shall be designed to automatically control the GRADIENT OUTPUT so that the occurrence of intolerable peripheral nerve stimulation (PNS) in the PATIENT and in the MR WORKER in any operating mode is minimised. 

NOTE MR EQUIPMENT that meet the requirements given in the following sub-clauses are considered to satisfy these objectives when balanced against their diagnostic efficacy.

For this Particular Standard it is understood that

- PNS is the sensation of an activation of the nervous system due to gradient switching,
- threshold PNS is the onset of sensation,
- painful PNS is the level tolerable to the PATIENT when properly informed and motivated,

- intolerable PNS is the level at which the PATIENT will ask the scan procedure to be terminated immediately,
- cardiac stimulation is the induction of an ectopic beat or other cardiac arrhythmia.

The MR EQUIPMENT shall minimize the occurrence of painful PNS in the NORMAL OPERATING MODE.

51.102.2 Limits for GRADIENT OUTPUT

A2 In this subclause, limits for the PATIENT and the MR WORKER are expressed either as the electric field E induced in the PATIENT or the MR WORKER by the changing magnetic field of the gradients, or by dB/dt , the time rate of change of that field. **A2**

Test conditions used to demonstrate compliance to these limits are defined in 51.105.2.

A2 NOTE MR WORKER exposure limits are the same as for the PATIENTS. Compliance with the GRADIENT OUTPUT limits for PATIENTS therefore automatically implies compliance for the MR WORKERS. **A2**

51.102.2.1 Limits related to prevention of cardiac stimulation

To protect against cardiac stimulation in each operating mode, the GRADIENT OUTPUT of all GRADIENT UNITS shall satisfy:

$$E < \frac{2}{\left\{ 1 - \exp\left(-\frac{t_{s,eff}}{3}\right) \right\}}$$

where

$t_{s,eff}$ (ms) is the EFFECTIVE STIMULUS DURATION ;

E (V/m) is the electric field induced by GRADIENT SWITCHING.

For MR EQUIPMENT provided with WHOLE BODY GRADIENT SYSTEMS, this limit may be replaced by:

$$dB / dt < \frac{20}{\left\{ 1 - \exp\left(-\frac{t_{s,eff}}{3}\right) \right\}}$$

where

dB/dt (T/s) is the rate of change of the magnetic field during GRADIENT SWITCHING ;

$t_{s,eff}$ (ms) is the EFFECTIVE STIMULUS DURATION.

51.102.2.2 Limits related to peripheral nerve stimulation (PNS)

Limits of GRADIENT OUTPUT either shall be based on the results of an experimental study of human subjects as described in section a) of this subclause or shall have values as stated in section b) of this subclause.

a) Directly determined limits

Limits related to minimising PNS for any given type of gradient system may be based on direct determination from a study on human volunteers and are as follows:

- for operation in the NORMAL OPERATING MODE, the gradient system shall operate at a level that does not exceed 80 % of the directly determined mean threshold PNS, and
- for operation in the FIRST LEVEL CONTROLLED OPERATING MODE, the gradient system shall operate at a level that does not exceed 100 % of the directly determined mean threshold PNS.

In addition the study may be used to derive weight factors for each GRADIENT UNIT, suitable for use in the control of the GRADIENT OUTPUT (see 51.102.2.3)

The manner in which the direct determined threshold PNS and weight factors are obtained from the human volunteer study shall comply with the conditions stated in 51.105.2

These limits and weight factors shall not be applied to other types of gradient systems, unless such types are shown to be of sufficiently similar design.

b) Default values

When no direct determination of limits is obtained, the GRADIENT OUTPUT limits for the NORMAL OPERATING MODE (*L01*) and the FIRST LEVEL CONTROLLED OPERATING MODE (*L12*) shall, depending on the label (as defined in 6.8.3 ee) not be larger than the values stated below:

$$L12 = 1,0 \, rb(1 + 0,36 / t_{s,eff}), \quad (t_{s,eff} \text{ in ms})$$

$$L01 = 0,8 \, rb(1 + 0,36 / t_{s,eff}), \quad (t_{s,eff} \text{ in ms})$$

where

$t_{s,eff}$ (ms) is the EFFECTIVE STIMULUS DURATION and

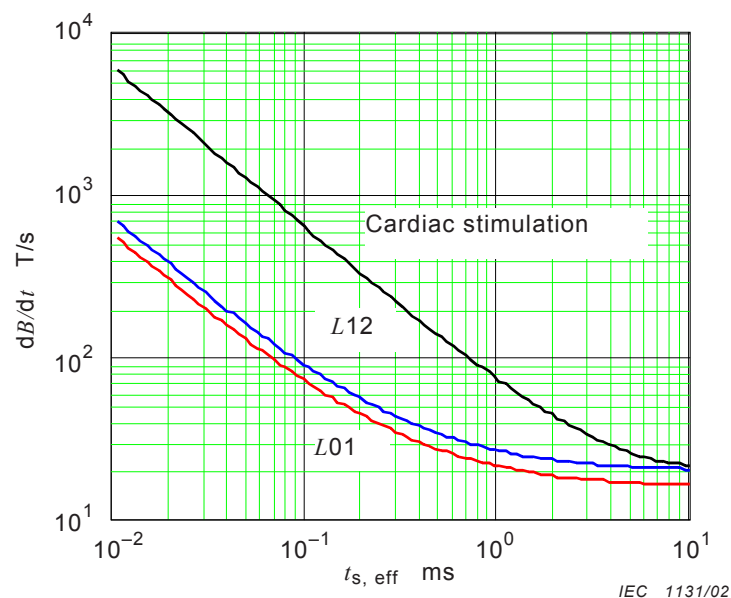
rb (here in T/s) is the rheobase given in Table 102.

$L01$ and $L12$ as well as rb shall either be expressed as the electric field E (V/m) induced or as the TIME RATE OF CHANGE OF THE MAGNETIC FIELD dB/dt (T/s).

Table 102 – Rheobase values per type of gradient system

Type of gradient system	rb expressed as E (V/m)	rb expressed as dB/dt (T/s)
WHOLE BODY GRADIENT SYSTEM	2,2	20
SPECIAL PURPOSE GRADIENT SYSTEM	2,2	Not applicable

Figure 103 gives a graphical presentation of the limits for GRADIENT OUTPUT for a WHOLE BODY GRADIENT SYSTEM related to cardiac stimulation and peripheral nerve stimulation, expressed in dB/dt , as a function of the EFFECTIVE STIMULUS DURATION.



Limits for peripheral nerve stimulation of GRADIENT OUTPUT for the NORMAL OPERATING MODE (*L01*) and the FIRST LEVEL CONTROLLED OPERATING MODE (*L12*) in WHOLE BODY GRADIENTS, expressed as dB/dt (T/s) versus t_s (ms). The limit of 51.102.2.1 for cardiac stimulation is shown for comparison.

Figure 103 – Limits for cardiac and peripheral nerve stimulation

51.102.2.3 Control of GRADIENT OUTPUT

The MR EQUIPMENT shall control the GRADIENT OUTPUT O of the gradient system so that it does not exceed the limits for peripheral nerve stimulation. O shall either be obtained by weighted quadratic addition from O_i , the maximum GRADIENT OUTPUT of each GRADIENT UNIT i , or by properly validated alternative summation rules.

The equation expressing weighted quadratic addition shall be:

$$O = \sqrt{\sum (w_i O_i)^2}$$

where w_i is the weight factor per GRADIENT UNIT.

Weight factors for E -fields are always equal to one, weight factors for dB/dt are stated in table 103. Values of weight factors derived by direct determination or other properly validated means may be used.

Table 103 – Weight factors for summation of the maximum output O_i per GRADIENT UNIT

Type of gradient system		Weight factors		
		w_{AP}^a	w_{LR}^a	w_{HF}^a
WHOLE BODY GRADIENT SYSTEM	Default values	1,0	1,0	1,0
	Cylinder magnets	1,0	0,8	0,7
	Empirical determination	1,0	b	b
SPECIAL PURPOSE GRADIENT SYSTEM	Default values	1,0	1,0	1,0
	Empirical determination	1,0	b	b
NOTE Weight factors for the E field are always equal to one.				
^a w_{AP} , w_{LR} , w_{HF} : Weighting factors allowed per GRADIENT UNIT, depending on the orientation of the direction of the GRADIENT UNITS with respect to the PATIENT coordinate system with axes AP (anterio-posterior), LR (left to right) and HF (head to feet).				
^b Values of weight factors derived by direct determination or other properly validated means may be used.				

* 51.103 Protection against excessive radio frequency energy

51.103.1 Limits for temperature

The MR EQUIPMENT shall limit body core temperature rise and limit spatially localised temperatures in the body of the PATIENT to values given in table 104 by limiting pulse sequence parameters and by limiting radio frequency power. **A2** Allowed values for the temperature rise of the MR WORKER caused by the MR EQUIPMENT are equal to the values for the PATIENT as defined in Table 104 for the NORMAL OPERATING MODE and the FIRST LEVEL CONTROLLED OPERATING MODE. **A2**

Table 104 – Temperature limits

Operating mode ↓	Rise of body core temperature °C	Spatially localised temperature limits		
		Head °C	Torso °C	Extremities °C
NORMAL	0,5	38	39	40
FIRST LEVEL CONTROLLED	1	38	39	40
SECOND LEVEL CONTROLLED	>1	>38	>39	>40

Compliance to the limits to temperature and temperature rise may be reached by limiting the SPECIFIC ABSORPTION RATE (SAR) as specified in 51.103.2.

NOTE The requirements regarding protection against radio frequency power assume that the MANUFACTURER'S recommendations regarding the control of environmental temperature, humidity and other conditions are met.