

INTERNATIONAL STANDARD

IEC 60601-2-33

2002

AMENDMENT 1
2005-08

Amendment 1

Medical electrical equipment –

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

© IEC 2005 Droits de reproduction réservés — Copyright - all rights reserved

International Electrotechnical Commission, 3, rue de Varembé, PO Box 131, CH-1211 Geneva 20, Switzerland
Telephone: +41 22 919 02 11 Telefax: +41 22 919 03 00 E-mail: inmail@iec.ch Web: www.iec.ch



Commission Electrotechnique Internationale
International Electrotechnical Commission
Международная Электротехническая Комиссия

FOREWORD

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

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

FDIS	Report on voting
62B/573/FDIS	62B/586/RVD

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

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

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- withdrawn,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

Page 13

6.8.2 INSTRUCTIONS FOR USE

Replace, on page 18, the existing item pp) by the following:

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.

Add, on page 18, the following new item ss):

* 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.

Page 19

6.8.3 Technical description

Replace, on page 20, the existing item cc) by the following:

* 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.

Page 45

Annex BB – Guidance and rationale for particular subclauses

Add, on page 57, a rationale for subclause item 6.8.2 ss) as follows:

Concerning **6.8.2 ss)**

In addition to the information given in Clause 6.8.2 cc) on emergency medical procedures and clause 6.8.2 ff) on liquid and gaseous cryogens, this item provides information pertinent to emergencies present in the event that magnet helium gas escapes from the magnet into the examination room or other adjacent rooms during a QUENCH. This situation may be present when the venting system of the superconducting magnet fails either in part or fully during a magnet QUENCH. In this case, hazards may be present for the personnel involved. The information provided here will be useful for the OPERATOR in establishing an emergency plan adapted to local requirements.

While a QUENCH as such is a rare event, the additional failure of a venting system of the magnet is even more unlikely. Although thousands of MR SYSTEMS are in operation, there have been only a few reports to date regarding accidents or near accidents involving personal injuries in relationship to a QUENCH. Nevertheless, the MANUFACTURERS are required to point out the potential hazard of the combined event and to provide information pertinent to this type of emergency. Note that the information covers the highly unlikely, yet possibly serious event of a malfunctioning venting system at the time of a quench of the superconducting magnet.

What is a QUENCH?

During a QUENCH, the magnet loses its super-conductivity. The magnetic field ramps down in a matter of seconds – typically lasting approximately 20 seconds. The magnet begins to warm up. Liquid helium boils off at a rate of 500 to 1 500 l within a few minutes and expands quickly. The exact boil-off rate amount depends on the fill level as well as the field strength of the magnet. A 3 T magnet may have a higher boil-off rate than a 1,5 T magnet. One litre of liquid helium translates into approximately 700 l of gaseous helium. During maximum conditions this means approximately 1 000 m³ of gas. A manual QUENCH may be initiated by activating the Emergency field shut down unit. Another source for quenching is when the helium fill level decreases to a point where the magnet begins to warm up. In rare instances, a spontaneous QUENCH may be observed that cannot be explained by the presence of obvious causes.

Hissing or whistling noises caused by the quickly escaping stream of cold helium gas may accompany a QUENCH. Plumes of white fog sink to the floor mainly from the upper part of the magnet from the vicinity of the QUENCH line due to condensation of both water vapour and air. The stream of helium gas diminishes in a matter of minutes. Air near the non-insulated components of the magnet and the QUENCH line condenses into liquid air and drips to the floor.

Risks associated with a failing venting system

The purpose of the venting system of the superconducting magnet is to securely exhaust gaseous helium to the outside. The main element of this system is a conduit that is designed to transport the escaping helium gas to a safe open area. The possibility of a QUENCH should be taken into careful consideration during the design of both the magnet and the venting system of the superconducting magnet. As a result, a QUENCH should be completely harmless to personnel. Also, neither the magnet nor the MR installations as such should be subject to damage during a QUENCH.