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

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## COMMITTEE DRAFT FOR VOTE (CDV) PROJET DE COMITÉ POUR VOTE (CDV)

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Titre :

Title : IEC 60601-2-33 Ed. 2 Am.1: Particular requirements for the safety of magnetic resonance equipment for medical diagnosis

Note d'introduction

Introductory note  
IEC 60601-2-33 Ed. 2.0 was published in May 2002. This edition was expected to remain unchanged until June 2005. However, an amendment is required to provide for the users of the standard a technically more in-depth text for the safety requirement of MR equipment in case of a quench (see the rationale for an early amendment of IEC 60601-2-33 Ed. 2.0 given in Annex A).  
The amendment is planned to be published by October 2004 as asked in SMB/2610/QP, 2003-08.

<b>ATTENTION</b>	<b>ATTENTION</b>
<b>CDV soumis en parallèle au vote (CEI) et à l'enquête (CENELEC)</b>	<b>Parallel IEC CDV/CENELEC Enquiry</b>

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**INTERNATIONAL ELECTROTECHNICAL COMMISSION**

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**MEDICAL ELECTRICAL EQUIPMENT –****Part 2-33 Ed.2 Amendment 1:  
Particular requirements for the safety  
of magnetic resonance equipment for medical diagnosis****FOREWORD**

This amendment to International Standard IEC 60601-2-33 Ed.2 has been prepared by subcommittee 62B: Diagnostic imaging equipment, of IEC technical committee 62: Electrical equipment in medical practice.

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

FDIS	Report on voting

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

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

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

- requirements, compliance with which can be tested, and definitions: in roman type
- notes, explanations, advice, introductions, general statements, exceptions, and references: in smaller type
- *test specifications: in italic type*
- TERMS USED THROUGHOUT THIS PARTICULAR STANDARD THAT HAVE BEEN DEFINED IN CLAUSE 2 AND IEC 60601-1: IN SMALL CAPITALS.

The committee has decided that the contents of this publication may remain unchanged until December 2006. At or before this date, the publication will be

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

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

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

***“Replace in the Particular Standard”***: means that the clause or subclause of the Particular Standard is replaced completely by the text of this Amendment.

***“Add to the Particular Standard”***: means that the text of this Amendment is additional to the requirements of the Particular Standard.

***“Change the Particular Standard”***: means that the clause or subclause of the Particular Standard is changed as indicated by the text of this Amendment.

## **6.8.2 INSTRUCTIONS FOR USE**

***Replace in the Particular Standard Clause 6.8.2 pp) by:***

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 clause under

- cc) Emergency medical procedures
- ee) CONTROLLED ACCESS AREA
- mm) EMERGENCY FIELD SHUT DOWN UNIT
- nn) Fire precautions
- ss) Emergency actions in case of a QUENCH.

***Add to the Particular Standard in clause 6.8.2 ss)***

ss) Emergency actions in case of a QUENCH

The INSTRUCTIONS FOR USE shall include instructions how to identify a QUENCH and how to act in case of a QUENCH, especially when the venting system of the superconducting magnet system fails.

***Replace in the Particular Standard Clause 6.8.3 cc) by:***

## **6.8.3 Technical Description**

cc) Provisions to control safety in case 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 case 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 state 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 in case of failure of the venting system 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 for 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 a safety emergency plan for the case of a QUENCH, including the situation whereby the venting system for the superconducting magnet fails to function adequately
- state the need for possible extra control measures for a 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 at a safe place (such as at low level in the examination room or directly connected to the air-condition of the examination room), or is 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: Fore the examination room configuration solutions demonstrated by simulation or test that are acceptable include:

- Configurations in which the RF door opens outwards
- Configurations where the RF door opens inwards, if these include extra precautions to prevent PRESSURE build up. This can be realized by
  - an extra examination room ventilator system, which can be switched on in case of a QUENCH,
  - or a PRESSURE-equalizing opening in the wall or ceiling of the examination room, venting towards an open area,
  - or a possibility to open outwards or slide by the observation window in the examination room as a PRESSURE equalizing means,
  - 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.

***Add to the particular standard in Annex BB clause 6.8.2 ss)***

**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 clause 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 are only a few reports to date regarding accidents or near accidents that involve 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 1500 litres 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 3T magnet may have a higher boil-off rate than a 1.5 T magnet. One litre of liquid helium translates into approximately 700 litres of gaseous helium. During maximum conditions this means approximately 1000 m<sup>3</sup> gas. A QUENCH may be released by pressing the magnet's "emergency shut-down" switch. Another source for quenching is a helium fill level that 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.

However, when upon a quench the venting system fails, an emergency situation arises. Helium is lighter than air, non-poisonous and non-flammable. However, since it displaces oxygen, the risk of suffocation exists. Cryogenic helium escaping into the ambient air leads to white clouds caused by condensation. These clouds will adversely affect visibility.

Persons may be rendered unconscious by the amount of helium entering their respiratory system. Depending on the helium concentration present in the air, a few breaths may suffice to result in unconsciousness.

In addition, escaping helium is extremely cold, possibly causing hypothermia and frostbite. The latter results in injuries resembling burns (cryogenic burns) after the skin is exposed to normal temperature levels. Skin contact with cold parts or liquid air may also lead to frostbite.

A variety of failures of the venting system of the superconducting magnet is conceivable. For instance, the following may occur:

- Small leaks: Smaller amounts of helium gas are exhausted to the outside via the heating and air conditioning system and replaced by fresh air. This is not a critical situation as long as the heating and air conditioning system functions as required.
- Leakages are the result of constructional errors and need to be removed.
- The venting system of the superconducting magnet fails in part: Only part of the helium gas is exhausted to the outside via the integrated venting system. Larger amounts of helium are present in the examination room. The heating and air conditioning system cannot remove the helium due to its volume. Large clouds form that adversely effects

visibility. Additionally, the PRESSURE in the room increases. Depending on the size of the leakage, hazardous conditions may be present for the personnel involved.

- Total failure: The venting system of the superconducting magnet fails completely, e.g. through blockage or breaks in the line. The entire amount of gas is exhausted into the examination room. If the requirements and recommendations previously mentioned are not followed there is an increased potential for loss of life in the case of a complete cryogen vent failure.
- Up to 1000 m<sup>3</sup> gas are blown into the room, which frequently has a volume of less than 100 m<sup>3</sup>.

*Add the rational in Annex BB for clause 6.8.3 cc)*

Concerning 6.8.3 cc)

### **Examination room configuration**

A number of examination room features are suggested in the standard. For the examination room features a clear distinction is made between the helium venting system for the superconducting magnet needed in case of a QUENCH and the PATIENT ventilation system needed for daily air refreshment for the PATIENTS. The examination room features try to maximise the time available to remove a PATIENT from the system in case of a QUENCH associated with a failing venting system of the superconducting magnet. These features will help increase the time available to remove a patient to an average time of a few minutes. In general the operation of the PATIENT ventilation system should be monitored carefully. Some PATIENT ventilation systems bring fresh conditioned air from the top of the examination room to the PATIENT. In case of a QUENCH associated with a failing venting system of the superconducting magnet this is very unfavourable for the PATIENT and the operation of the PATIENT ventilation system should be stopped, preferably automatic via the detection of the QUENCH by a sensor. Also an automated warning to the OPERATOR can be considered in all situations. When remodelling of the examination room is performed, the integrity of the RF-shielding has to be tested again.

### **Door of the examination room opens inwards - constructional safety measures**

The most unfavourable situation for the examination room is when the door of the examination room opens inwards. In this situation, slight overpressure due to helium gas leakage may make opening of the door rather difficult. Depending on the ventilation system for the room, overpressure may be present for a considerable length of time. Installation of a provision in the examination room to allow air breathing in this situation, may help to enlarge the time available to allow for pressure equalization in the room.

To address this situation the following alternatives are available:

- The door is reconfigured so that it opens to the outside into the control room.
- The door is replaced with an RF-sealed sliding door. It should be ensured that the door closes in a way that allows it to move away from the frame in case of overpressure, that is, it facilitates opening the door.
- The stationary observation window is replaced by a window opening into the control room or by an RF-sealed sliding window.
- Panels are installed in the examination room wall, door or ceiling that can be unlocked and opened to the outside in case of emergency or allow for continual pressure equalization to interstitial space. These panels require an RF-sealed installation. After opening the panel, the outlet should measure at least 60 x 60 cm<sup>2</sup>. When using rectangular panels, the shorter side should measure a minimum of 60 cm in length. Also, easy removal of the panel by a single person has to be ensured. In addition, a minimum distance of 1 meter to the next wall needs to be observed. The panel should be installed as far as possible toward the top of the room to allow escape of the low-density helium.



- The examination room MANUFACTURER can provide you with additional RF-sealed room openings that lead directly to the outside. However, these openings are also conduits for noise generated outside the examination room. Again, these openings should be installed toward the top as far as possible to allow escape of the low-density helium. To maintain unobstructed flow through a pipe, the diameter of a long line has to be appropriate.

For doors moved via auxiliary drives (e.g. electrical or pneumatic), manual operation has to be ensured as well.

An outside window should be in the vicinity to allow venting exhausted gas to the outside.

If included in the installation, the observation window may be pushed in. The window usually includes wiring for the RF-shielding that needs to be worked through as well. However, the resulting glass splinters may injure rescue personnel. Depending on the construction and the thickness of the window, the OPERATOR has to provide suitable tools for breaking the window.

## **Maintenance**

### Checking the exhaust system and room venting

The installation of the room venting system and the cryogen venting system for the superconducting magnet has to adhere to the requirements and should be checked by trained personnel. Both systems have to be visually inspected at regular intervals to determine inappropriate changes.

In particular:

- Design changes inside and outside the shielded examination room
- Inappropriate changes
- Damage to the thermal insulation of the exhaust line
- Damage to the exhaust line
- Obstructed exit, e.g. presence of bird nests (is the protective grid still intact?)
- Damage to protective rain covers (these are regularly required for vertically exiting QUENCH lines. Depending on the design, they are also frequently in place for horizontal exits).
- Is the exhaust to the outside changed after the system was handed over to the customer, endangering anyone by the exhausted gas? This may involve, for example, windows installed at a later date, exits and entrances put in place for heating and air conditioning systems, new buildings or temporarily installed containers and any other foreign debris or construction matter that could negatively influence the performance of the venting system..
- Is the heating and air conditioning system or venting system of the room changed, e.g. by adding additional venting inlets or outlets in adjacent rooms?
- Are additional MR SYSTEMS installed?
- Is the same QUENCH line used for additional MR SYSTEMS?

Since each system is subject to either changes or remodelling of the building during its operating life, the OPERATOR needs to be thoroughly familiar with the importance of the QUENCH line and the venting system. For this reason, we recommend frequent visual inspections (e.g. with respect to constructional changes in the vicinity of the QUENCH line, severe weather-related changes such as ice, snow or sand). In case of questionable system functionality, please contact your venting system installation contractor..

## **Emergency plan**