the cyclotron resonance of calcium ions. Such a combination of electric and magnetic fields may occur near power lines. In a 1,5 T magnet, a 576 kHz orthogonal electric field is required for cyclotron resonance. The resonant frequency in the MR EQUIPMENT is more than two orders of magnitude higher than the cyclotron resonance frequency for calcium for the same magnet. There is no electric field near the cyclotron resonance frequency in MR EQUIPMENT, since electromagnetic shielding is used. These shields protect the environment from MR signals and prevent environmental signals from degrading MR images.

Chemical reaction rates, equilibrium, and concentrations might be altered if some or all of the reactants or products had magnetic moments which significantly modified reaction thermodynamics [16], [17], [24], [39], [40], [41]. However, up to 4 T, thermodynamic considerations indicate that the effects should be nearly immeasurable [24].

Other possible mechanisms for static magnetic field bioeffects have been proposed. For example, proton tunnelling in DNA due to changes in potential height caused by the static magnetic field [40]. Other mechanisms have been discussed in excellent reviews [16], [24], [37], [40], [42], [43], [44], [45], [46].

- **Static fields: mechanisms for occupational concerns**

As discussed above, in the presence of static magnetic fields, ferromagnetic materials may experience translational forces towards regions of higher magnetic field strength [24]. Ferromagnetic objects may also experience torque tending to align their magnetic moments with the static magnetic field [24]. Moving, electrically conductive objects may experience forces and torque in static magnetic fields due to Lenz's law [24].

Flow potentials [22] may be induced in conductive fluids (such as blood) moving through static magnetic fields. Flow-induced potentials cause artefacts on electrocardiogram (EKG) recordings [23]. Rapid head motion may induce voltages in the semi-circular canals of the inner ear sufficient to exceed the vertigo perception threshold [24]. Theoretical predictions of flow-induced blood pressure elevation apparently influenced occupational safety standards. However, the magnitude of this effect turns out to be extremely small [79].

Flow potential-induced electric fields may produce elevated T-wave artefacts on electro-cardiograms. These electric fields E may be derived from Equation (AA.4) (see Figure AA.1):

$$V = \frac{F\,D}{q} = v\,B\,D\sin(\theta) \qquad \text{(AA.4)}$$

This electric field is orthogonal to the plane containing the flow velocity vector and the static magnetic field. The highest flow velocity coincides in time with the T-wave on an EKG. For example, assume that the peak blood velocity is 0,6 m/s [40], the flow and static field make an angle of 30°, and the artery diameter = 0,02 m, then the induced voltage is 9 mV for a static magnetic field of 1,5 T. Contrast this result with typical EKG "R" wave amplitudes which are on the order of 10 mV. The resulting "T-swells" disappear with the static magnetic field. T-swells appear to have no biological significance. Whether chronic induction of such voltages is of concern is not certain. However, evidence to date, suggests there are no safety issues up to at least 7 T.

Note that in most high field MR EQUIPMENT, the PATIENTS are aligned parallel to the static magnetic field. Peak blood flow velocities occur in the aorta [80]. Assuming the aorta is nearly aligned with the static magnetic field, then for typical MR EQUIPMENT the induced electric field should be small. Next, consider a worker standing in the gap of a magnet. For this case, θ is approximately equal to 90°, and the induced electric field is larger. Reilly [81] has estimated that an electric field of 6,2 V/m is needed to produce cardiac stimulation in the most sensitive population percentile for gradient ramp times >>3 ms. For gradient ramp times of 600 μs (more typical of MR EQUIPMENT), cardiac stimulation in the most sensitive population percentile

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rises to about 31 V/m. Cardiac stimulation in the most sensitive population percentile requires static magnetic fields to be at least 10 T (ramp times >>3 ms), but more typically about 52 T (for ramp times of 600 μs). It would be prudent to conduct experimental cardiac safety studies before building open magnets for MR EQUIPMENT with extremely high fields.

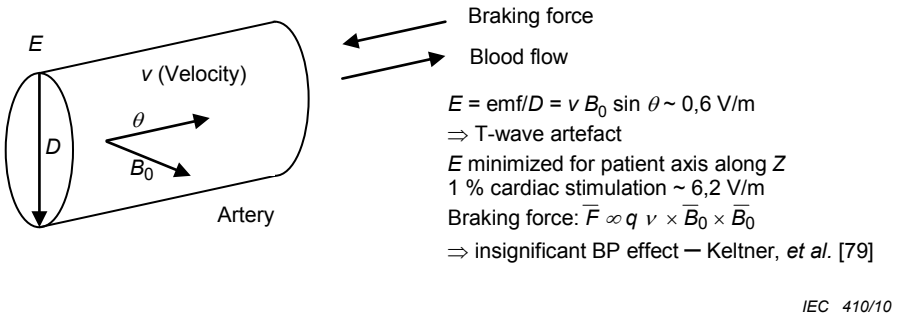

Figure AA.1 – Static magnetic fields: flow potentials and retardation

Blood flowing in a static magnetic field generates a flow potential proportional to the velocity, static magnetic field, and the sine of the angle between them. A braking force which opposes blood flow is also created, but its magnitude is physiologically insignificant up to at least 5 T.

The induced electric field will create a flow of charged particles along the electric field. These charged particles moving orthogonally to the magnetic field will experience a force which opposes blood flow [22] (see Figure AA.1). Apparently, this force was thought to be of concern since it might lead to an increase in blood pressure. However, Keltner, *et al.* [79] showed both theoretically and experimentally that this effect is of no concern.

Conclusions

Up to at least 8 T, no adverse health effects of the static magnetic field have been reported provided no ferromagnetic materials are permitted that could become projectiles. MR scanners of up to 8 T should be safe for both MR WORKERS and PATIENTS.

Concerning 201.7.9.2.101 k) – Occupational exposure to EMF

Limits for the protection of workers for exposure to electromagnetic fields are introduced in the European Directive 2013/35/EU [130] which was adopted by the Council and the European parliament in June 2013. The limits introduced are based on the International Commission on Non-Ionizing Radiation Protection (ICNIRP) guidelines. A derogation regarding exposure limits for MR WORKERS is provided in Article 10 of the Directive. Applicable conditions for safe working practices are to be established and include documented working procedures, as well as specific information and training measures for MR WORKERS exposed to electromagnetic fields during MRI-related activities. This standard (IEC 60601-2-33) provides the basis for implementation of safe working practices.

Upper limits for electromagnetic exposure for the MR WORKER are introduced in this standard, based on RISK MANAGEMENT specifically applied to the exposure to electromagnetic fields for the MR WORKER.

– Exposure to static magnetic fields for the MR WORKER is covered by the rationale of 201.7.9.2.101 h).

– dB/dt values due to motion in the static magnetic stray field should be less than 3 T/s to minimize physiological effects (see 201.12.4.104). Information on the speed of motion related to this dB/dt value can be provided for both translational and rotational movement. The maximum translational movement can be calculated by dividing the SPATIAL FIELD GRADIENT by dB/dt. The maximum rotational movement can be calculated from the static magnetic stray field.

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- The limits in the range of a few Hz to about 100 kHz for the MR WORKER are based on thresholds for peripheral nerve and muscle stimulation and cardiac muscle stimulation and are low enough to avoid all such physiological effects. There are no peer-reviewed published reports of gradient-induced magneto-phosphenes.
- Since minimal peripheral nerve stimulation could be accepted for the MR WORKER under some circumstances, it may be required to give extra instructions to the MR WORKER to avoid an exposure to the GRADIENT OUTPUT. A prediction of the expected GRADIENT OUTPUT is displayed (on request) on the CONTROL PANEL and can be used to either avoid exposure by creating sufficient distance from the scanner during scanning or by reducing the value of the GRADIENT OUTPUT. Since the stray field of the gradient coil drops off rapidly outside the coil and by geometrical considerations, exposure of the MR WORKER can be assumed to be most likely at the level of NORMAL OPERATING MODE and peripheral nerve stimulation is not expected for the MR WORKER.

For pregnant MR WORKERS extra precaution is advisable. It is advisable for a pregnant MR WORKER not to stay in the scan room during scanning to avoid unnecessary exposure to gradient and radiofrequency electromagnetic fields and noise levels. Local regulations may apply.

Instructions for use are required to state that the limits for workers may not be applicable when a MR WORKER is pregnant. It may be required that the 'member of the public' limit may be applied to the foetus in some countries.

The RISK MANAGEMENT approach is also applied for the exposure to the GRADIENT OUTPUT EMF generated by MR SYSTEMS when balancing the probability of RISK of ionizing radiation versus MR [133]. The cumulative effect of exposure to ionizing radiation has been studied extensively.

Workers exposed to ionizing radiation with energy ≥ 12,4 eV (or (2×10^{-18}) J) are regulated by limits recommended by such groups as the National Council on Radiation Protection and Measurements (NCRP) and the International Commission on Radiation Protection (ICRP). To illustrate the difference between that type of radiation and the frequency range of the EMF in an MR SYSTEM (1 kHz – 1 GHz), the following: An MR scanner would need a magnetic field strength of $(7{,}04 \times 10^{7})$ T (the resonant frequency for protons would be $(3{,}0 \times 10^{15})$ Hz) to reach this threshold level (five orders of magnitude above the field strengths of any current scanners). At 4 T the energy in any MR photons (assuming the system is capable of radiating) would be a factor of $(1{,}8 \times 10^{7})$ below the 12,4 eV threshold. In fact, the energy of any 4 T photons would be a factor of $(3{,}4 \times 10^{5})$ below the threshold energy needed to break hydrogen-hydrogen bonding in water (the weakest of all bonds) [135]. So, in MR biological interactions similar to radiation damage by ionizing radiation from single photons are not possible. This reasoning suggests that it can be concluded that cumulative effects on the molecular level from EMF exposure from MR will be absent. To the working group's knowledge, there are no peer reviewed published studies up to the present day that show any of these cumulative effects.

In the United States the annual occupational exposure limit [137] for ionizing radiation (10 CFR 20 subpart C) is 0,05 Sv (5 rem), while the general public may not be exposed to more than 0,001 Sv (0,1 rem). The threshold for observable effects from ionizing radiation is about 0,05 Sv. A PATIENT receiving a head computed tomography (CT) scan is estimated to receive up to 0,03 Sv. The RISK of dying from cancer from an exposure to 0,01 Sv (1 rem) has been estimated at 0,0005. In contrast, there is no known RISK of dying from EMF exposures generated by MR EQUIPMENT provided OPERATORs comply with IEC 60601-2-33 (2002).

In conclusion, RISKS to MR WORKERS exposed to the possible EMF generated by MR SYSTEMS appear to be very low. Workers exposed to ionizing radiation appear to be at higher, but still acceptable RISK levels.

The probability of cardiac stimulation under the 2nd edition of the IEC 60601-2-33 limits is close to zero, as shown in the rationale of subclause 201.12.4.102 (4). Reilly [85] determined

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that cardiac fibrillation thresholds follow a lognormal distribution with the threshold for the most sensitive percentile about half the value for the median. In addition, Reilly estimated that for a given animal the median cardiac stimulation threshold is about 40% of the cardiac fibrillation level. Reilly estimated that the rate of change of the magnetic field, $(dB/dt)_{1\%\ cardiac}$, which may stimulate hearts in the most sensitive percentile of the population, is related to the total gradient ramp duration, d, and to a time constant, τ, and may be expressed by the following equation:

$$\left(\frac{dB}{dt}\right)_{1\%\,cardiac} = \frac{60}{1-\exp\left(\frac{-d}{\tau}\right)} .$$

Reilly used a value of 3 ms for τ. Bourland et al [90] found that thresholds for canine cardiac stimulation when adjusted for the relative ratio between humans and dogs agreed well with Reilly's estimates extrapolated to the cardiac mean. In the IEC rationale it was shown that Reilly's estimates indicate the probability of cardiac excitation at the mean peripheral nerve stimulation limit is on the order of 10^{-9}. Schaefer [136] found similar estimates. So, cardiac stimulation is extremely unlikely at the IEC 60601-2-33, 2nd edition (2002) limits.

- **Peripheral nerve stimulation versus magneto phosphenes for the GRADIENT OUTPUT**

Specifically for the frequency range relevant for the GRADIENT OUTPUT, the 1 kHz to 10 kHz range, the ICNIRP limits are based on extrapolations of the effects related to evoked potentials in the retina, which can result in visual stimulations (visual phosphenes). There is no evidence that such visual stimulation constitutes an adverse effect or leads to any long-term HARM. These effects are observed at somewhat lower frequencies than relevant for MR. Since retinal tissue can be compared with brain tissue (the central nervous system), these effects are used by ICNIRP as a model for effects in the central nervous system and are extrapolated to the somewhat higher frequency range. In addition, these ICNIRP guidelines include a large safety margin and resulted in an exposure limit expressed as 10 mA/m^2. A recent review of this effect was organized by the NRPB in 2004 and confirmed the 10 mA/m^2 (including a factor 10 safety margin). At somewhat higher frequencies the electric current densities generated by the GRADIENT OUTPUT in the PATIENT is much higher and is known to generate Peripheral Nerve Stimulation at the frequencies and waveforms relevant for MR. The visual stimulations seem not to be the relevant physiologic effect for the somewhat higher frequencies and specific gradient waveforms applied for MR (and are never reported in relation to the GRADIENT OUTPUT of MR EQUIPMENT). For MR PATIENTS limits are based on Peripheral Nerve Stimulation effects. This observation is confirmed by the ICNIRP in a recent publication [132], specifically addressing exposure limits for MR PATIENTS. The PNS limits have never been reported to result in unsafe situations in medical practice.

For the kHz frequency range, ICNIRP has formulated action values expressed as electric field strength of 610 V/m. This value is much higher than the values for the electric field generated in a human body by the GRADIENT OUTPUT. The exposure limits for the current densities are 10 mA/m^2 at 1 kHz and 10 A/m^2 at 1 MHz. Between 100 kHz and 1 MHz a body SAR limit of 0,4 W/kg has to be satisfied. The 610 V/m action value is derived from the electrical LF/RF current, which is driven from the electric field in an almost empty space. Inside the human body the E-field is much lower due to the electrical conductivity $\sigma \approx 1$ S/m. Assuming a large capacitor of length L and cross section A with a much thinner slice LB (human body) of a complex dielectric permittivity ε_r ($\varepsilon_r = \varepsilon' + i\varepsilon'' = \varepsilon' + i\sigma/\varepsilon_0\omega$) the overall capacitancy is given by

$$\frac{1}{C} = \frac{L - LB}{\varepsilon_0 A} + \frac{LB}{\varepsilon_r \varepsilon_0 A}$$

Since $|\varepsilon_r| >> 1$ (for the considered frequency range) and $LB << L$ the capacitancy C is not affected by the physical presence of the human body. Hence, the current I through the capacitor is given by

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$$I = \frac{\omega \varepsilon_0 A}{L} U'$$

and the current density J is given by

$$J = \omega \varepsilon_0 E$$

(I, J are amplitudes only and U is the potential in Volts and E is the electric field in V/m)

At 1 kHz and E = 610 V/m one obtains a current density of 33 μA/m^2 and at 1 MHz a current density of 33 mA/m^2, respectively. These values are much lower than the exposure limits!

Let us consider SAR values. The SAR is given by

$SAR = \frac{1}{\sigma \rho} J^2$, where ρ is the tissue density..

For $\sigma \approx$ 1S/m and ρ = 10^3 kg/m^3 one obtains a SAR of 10^{-7} W/kg at 1 kHz and 0,1 W/kg at 1 MHz assuming the exposure limits of 0,01 mA/m^2 at 1 kHz and 10 A/m^2 at 1 MHz, respectively.

Concerning 201.7.9.2.101 l) – Auxiliary EQUIPMENT

Care should be taken in the selection of monitoring/sensing devices to ensure that they are specifically intended for use with MR EQUIPMENT (e.g. high resistance ECG leads). Electrically conducting materials, except those which have to make electrical contact with the PATIENT (e.g. ECG electrodes), should be electrically insulated from the PATIENT. All conducting materials should be thermally insulated from the PATIENT. The MANUFACTURER'S instruction for arranging monitoring leads (e.g. to avoid closed loops) and other cables near the PATIENT are required to be followed. The purpose of all these measures is to minimise the likelihood of induced currents because of coupling to the RF transmit coil, with the concomitant RISK of burns to the PATIENT.

Concerning 201.7.9.2.101 s) – Emergency actions in case of a QUENCH

In addition to the information given in item cc) of 201.7.9.2.101 on emergency medical procedures and item f) of 201.7.9.2.101 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 RESPONSIBLE ORGANIZATION 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.

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- **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 s. The magnet begins to warm up. Liquid helium boils off at a rate of 500 l 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 810 l of gaseous helium. During maximum conditions this means approximately 1 000 m^3 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 installation as such should be subject to damage during a QUENCH.

An emergency situation will arise if a QUENCH venting system fails. Helium is lighter than air, and is 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 lack of oxygen 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 are 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.

These leakages are the result of constructional errors that need to be corrected.

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, which 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

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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 1 000 m^3 of gas are blown into the room, which frequently has a volume of less than 100 m^3.

Concerning 201.7.9.2.101 t) – Scanning of PATIENTS with active or passive implants

Reference is given to the IEC 62570:2014, which formulates the definitions of MR safe, MR conditional and MR unsafe devices and describes how these markings are to be interpreted and handled by both the implant MANUFACTURER and the OPERATOR planning to scan a PATIENT with a specific type of implant.

The following is a sample text describing the responsibility for scanning of PATIENTS with MR conditional labelled implants:

"In general, MR examinations are contraindicated for PATIENTS with electronic or electrically conductive implants or metals, especially those containing ferromagnetic material.

However, certain implantable medical devices have been cleared, approved and/or licensed by the competent governmental authorities and/or labelled by the manufacturer as "MR conditional" or "MR safe". For such devices, the general contraindications as stated above may not be applicable in their entirety.

It is the responsibility of the implant manufacturer to declare an implant as "MR conditional" or "MR safe", if appropriate, and to define the conditions (constraints) for safe MR scanning. The MR OPERATOR must be aware of any such conditions for MR scanning. It is the obligation of the MR OPERATOR to assure that these conditions are strictly adhered to.

To obtain these specific conditions, the OPERATOR is advised to refer to the labelling of the implant or to contact the implant manufacturer. The MR manufacturer does not assume responsibility for the operation of the MR when scanning PATIENTS with any implantable medical device. Especially the MR manufacturer is not responsible for controlling technical parameters of the MR SYSTEM other than those defined by the NORMAL OPERATING MODE or the FIRST LEVEL CONTROLLED OPERATING MODE, the FPO (if available) and the data provided in the compatibility technical datasheet, such as SPATIAL FIELD GRADIENT."

Concerning 201.7.9.2.101 u) – Scanning of pregnant PATIENTS

Pregnant women may be compromised in their ability to dissipate heat. In this context, it is worth noting that heat loss from the embryo and foetus across the placental barrier may be less efficient than heat dissipation in other well vascularised tissues. Elevated body temperature is known to be teratogenic to a number of mammalian species including primates, and has been implicated in central nervous system and facial defects in children whose mothers developed prolonged severe hyperthermia (>39 °C), especially during the first trimester of pregnancy [109][110]. In these cases it is desirable to limit rises in body temperature to less than 0,5 °C [106]. Furthermore, a detailed numerical study [141] of SPECIFIC ABSORPTION RATE and temperature increase calculations within pregnant woman models exposed to MAGNETIC RESONANCE imaging showed that in the FIRST LEVEL CONTROLLED OPERATING MODE foetus temperature exceeds or approaches 38 °C for frequencies, 64 MHz and 128 MHz. Based on the results of this study, local foetus heating should be minimised by using NORMAL OPERATING MODE sequences which minimize the whole body SPECIFIC ABSORPTION RATE in the mother.

Concerning 201.7.9.3.101 b) – Compatibility technical specification sheet

The summary specification sheet is often referred to as the product data sheet. Specific information on this sheet can help the RESPONSIBLE ORGANIZATION to assess the compatibility of peripheral equipment with the specific MR EQUIPMENT. The compatibility of peripheral

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equipment relates to both MANUFACTURERS, and only when both MANUFACTURERS issue a compatibility statement does the RESPONSIBLE ORGANIZATION have no further concern. In all other situations the RESPONSIBLE ORGANIZATION is required to ensure that both types of equipment do not disturb the proper functioning of the other.

It is very important to realise that the system configuration of the MR EQUIPMENT can affect the proper operation of peripheral equipment and vice versa. For instance the installation of stronger gradient systems on the MR EQUIPMENT may affect the functionality of peripheral equipment, like a physiological monitoring and sensing device applied near the magnet bore. Therefore in case of an upgrade of the MR EQUIPMENT the RESPONSIBLE ORGANIZATION should inform the MANUFACTURER of the peripheral equipment to assure the safety and performance of the equipment [83].

Concerning 201.7.9.3.101 c) – Safety provisions in the event of a QUENCH

- **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 the event 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 the event 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 automatically via the detection of the QUENCH by a sensor. Also, an automated warning to the OPERATOR can be considered in all situations. The fitting of an oxygen monitor, wired to audible and visual alarms, in the ceiling of the examination room to give an early warning of the escape of helium gas is recommended. 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 extremely 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 for persons present in the examination room during the QUENCH in this situation may help to increase 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, and thus 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 fixed 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 interstitional space. These panels require an RF-sealed installation. After opening the panel, the outlet should measure at least (60 × 60) cm^2. 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

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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 additional RF-sealed room openings (metal grids) that lead directly to the outside. However, these openings are also conduits for acoustic noise generated outside the examination room. Again, these openings should be installed as far as possible toward the top 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.
– An oxygen detector and alarm can be hardwired to an emergency air extraction system to turn on automatically to maximum air extraction power when in alarm mode due to a too low oxygen level.

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

If included in the installation, the observation window may be broken although this may be difficult to accomplish. 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**

A preventive maintenance program should include the following actions.

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).
– Has the exhaust to the outside been changed after the system was handed over to the customer thus subjecting others to 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.
– Has the heating and air conditioning system or venting system of the room been changed, e.g. by adding additional venting inlets or outlets in adjacent rooms?
– Were 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, the venting system installation contractor should be contacted.

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- **Emergency plan**

The following recommendations are designed to help the OPERATOR in establishing an emergency plan that should include the following:

– layout of the MR-suite with respect to windows, escape routes both for personnel or for venting exhaust gas to the outside, emergency manual switches on the PATIENT support for fast PATIENT removal;

– availability of emergency personnel (e.g. ambulance personnel, on-site fire emergency response teams and on and off-site security);

– instructions and information provided to fire departments and police departments (to be provided before an actual emergency as described in the operating manual), including the need for an extra check whether the magnetic field is still present or not;

– rescue exercises performed with the respective personnel;

– operating personnel should be trained in overseeing the evacuation of the MR suite and adjacent rooms;

– Personnel should only return to the MR suite after the situation is back to normal, that is, noises have stopped and vision is no longer obstructed. For safety reasons, all rooms should be thoroughly aired; windows and doors to the outside should be open. Usually the air conditioning system will provide for effective air exchange.

If persons are present in the magnet room, consider the following.

– **Standard scenario:** the QUENCH line works as planned. The PATIENT can be easily removed. Contact with cryogenic parts is prohibited.

– **Small leaks:** these would lead to small clouds of fog that clearly remain above head level and are visibly removed by the heating and air conditioning system. White fog-like clouds may sink to the floor. These clouds consist of cold air and do not lead to oxygen depletion. In this case, overpressure is not present. There is no RISK of suffocation for either PATIENT or personnel. The PATIENT can be removed, either immediately or after a few minutes depending on the PATIENT'S reaction to the situation. Contact with cryogenic parts is prohibited.

– **Partial or complete failure of the QUENCH line:** large fog-like clouds are present that may impair visibility. PRESSURE in the examination room will increase. All persons inside the room or entering to help with rescue are in danger. During a complete failure of the venting system of the superconducting magnet inside the examination room, the examination room would be quickly filled with cryogenic helium gas.

As a rule, rescue personnel should not work alone, but rather in groups of two or more persons.

Usually, the strongest gas flow occurs within the first few minutes and will subsequently subside. However, the course of gas flow is not fully predictable, since at the time of occurrence the type of error in the QUENCH line is generally not fully known.

Prior to opening the door to the examination room, all available doors and windows should be opened to ensure sufficient ventilation. All personnel in the vicinity of the system who are not needed for rescue activities should leave prior to the rescue of the PATIENT in the examination room. When opening the door, possible overpressure in the room should be factored in as follows:

If the door opens outward in the direction of the control room, the door may fly open due to overpressure. The OPERATOR should be aware of this possibility so injuries caused by the unexpected opening of the door can be avoided.

– If the door opens inward in the direction of the examination room, it may be impossible to open it due to the overpressure in the room. In this case, existing windows and emergency flaps should be opened. The overpressure may lead to windows or flaps swinging unexpectedly. If there are no emergency openings, the observation window may be

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smashed. However, the resulting glass splinters may injure rescue personnel. Depending on the construction and the thickness of the window, the RESPONSIBLE ORGANIZATION has to provide suitable tools for breaking the window.

After opening the door to the examination room, the helium gas may escape to adjacent rooms, endangering the safety of the rescue personnel. It is possible to check the oxygen levels in the air with an oxygen monitor. A gas mask does not protect against oxygen displacement by the helium gas. An air tank is necessary in order to remain in a facility subject to escaping helium. In addition to the RISK of suffocation there is also the additional RISK of hypothermia or frostbite.

Since the helium gas warms up quickly and spreads downward from the ceiling, a rescue worker standing upright is exposed to greater danger than a PATIENT lying on the PATIENT SUPPORT. There may be more air nearer to the floor. A rescue worker may gain time by going down on hands and knees to take breaths of air.

After the PATIENT has been removed from the examination room, no personnel should be present in the vicinity of the MR SYSTEM until the QUENCH has been stopped and ventilation has been ensured.

After a QUENCH, the service procedure as described in the ACCOMPANYING DOCUMENTS has to be performed. The maintenance personnel should be informed immediately to put the MR SYSTEM back into operation.

Concerning 201.8.7.3 – Allowable values

Application of leakage current test requirements from the general standard are to be clarified for surface coils. The allowable values for the leakage current as formulated in subclause 8.7.3 e) of the general standard cannot be measured for all situations. On the MR EQUIPMENT, PATIENT limits for leakage current and PATIENT auxiliary currents under NORMAL and SINGLE FAULT CONDITIONS do not apply for frequencies above 1 MHz. Regardless the waveform and frequency, the HAZARDS related to leakage currents are controlled via the requirements formulated for the local SAR as formulated in subclause 201.12.4.103.2 of this standard.

Concerning 201.9.6.2.1 – Audible acoustic energy

The high rates of change of current passing through the gradient coils in a static magnetic field produce vibrations in the audible frequency range. These are often manifested as loud "knocking" sounds.

Sudden hearing loss can be caused by short very loud noises, such as these knocks, in which the relevant safety parameter is the peak sound pressure level, measured in dB relative to 20 μPa.

The limit on peak sound pressure level of 140 dB has been taken from current internationally accepted values. It is difficult to predict under what circumstances the MR EQUIPMENT will produce the worst case situation with respect to acoustic noise production. It may very well happen that due to the frequency response characteristics of the MR EQUIPMENT the worst case acoustic noise situation is found for a clinical protocol (which by coincidence stimulates the MR EQUIPMENT at a mechanical resonance frequency and consequently produces more acoustic noise).

See also rationale 201.7.9.2.101 d).

Concerning 201.12.4 – Protection against hazardous output

The time varying (gradient) field, radio frequency field and static magnetic field generated by MR EQUIPMENT may influence physiological functions to an extent that safety measures

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