

Compact, Lightweight , high field, next generation magnetic resonance imaging scanners.

Voxelgrids Innovations Pvt. Ltd.

Environmental and Health Risk Management Plan

1. Environmental Impact and risk mitigation

Risks	Project Specific Risk	Potential Impact	Mitigation Steps
Air Pollution	Minimal Risk. Assembly of MRI scanners do not involve any manufacturing processes that generate air pollution. However, the use of electricity backup generators indeed cause air pollution.	This is subject to the quality of electricity supply that is available at our facility from the electricity board. Use of diesel-electric generators will potentially cause air pollution.	We will not run heavy machinery at our site and the pre-dominant assembly process do not require large amounts of power. Hence, the level of pollution is expected to be minimized.
Water Pollution and Waste water treatment	Minimal Risk. Assembly of MRI scanners do not involve any manufacturing processes that generate water pollution. However, standard use of any facility where manpower is used will generate typical levels of water pollution.	No project specific impact. This will be at levels like any typical office space or industrial facility.	All water used in the facility, other than for drinking, is water that is treated and recycled. Therefore, the levels of pollution are minimized. We will comply with the requisite state regulations for waste water management.
Chemical waste	Minimal Risk. Not applicable as no chemicals will be used in our assembly/ manufacturing processes.	Not applicable as no chemicals will be used in our assembly/ manufacturing processes.	Not applicable as no chemicals will be used in our assembly/ manufacturing processes.
Biological Waste	Minimal Risk. Not applicable as no biological waste is generated during the	Not applicable as no biological waste is generated during the	Not applicable as no biological waste is generated during the

	assembly of MRI scanners.	assembly of MRI scanners.	assembly of MRI scanners.
Heavy metals	Minimal Risk. All components that use metals and alloys such as Niobium, Titanium, Iron, steel etc. will be manufactured at authorized vendors and only assembled at our site. Waste generated will be minimal such as wires etc.	Environmental pollution. If sheathed metal wires are burned, it would release dioxins and other harmful VOCs	All metallic waste will be appropriately disposed through authorized disposal agencies.
Electronics Waste	Minimal Risk. PCBs, electronic components, LCD screens etc. which fail quality control testing. No manufacturing of such components will be undertaken.	Can lead to environmental pollution and dumping.	QC-failed material will be returned to vendor or disposed appropriately.
Radiation Waste	Not applicable as no radiation waste is generated during the assembly of MRI scanners.	Not applicable as no radiation waste is generated during the assembly of MRI scanners.	Not applicable as no radiation waste is generated during the assembly of MRI scanners.
Destruction/ alteration of surrounding ecosystem	Not applicable as we will operate in facilities that have been established in designated industrial zones within city limits.	Not applicable as we will operate in facilities that have been established in designated industrial zones within city limits.	We will ensure compliance with local regulations.
Humidity	Moderate Risk. Excessive humidity can result in condensation of water on the scanner parts that are exposed to the environment	This can cause an electric shock to the operator or patient.	Sensors are installed in the operating area to ensure scanner shut down in case of excess humidity.
Ambient temperatures	Moderate Risk. Scanners must be assembled and operated in areas	Absence of the same can cause a shutdown of the scanner magnet	The scanners are always operated in areas where temperatures are controlled between 18-25 degree Celsius as

	where temperatures are controlled	thus harming operations	recommended by IEC. This is ensured during assembly site set up.
Liquid and gaseous cryogens	Minimal Risk. Our scanners do not employ liquid cryogens. It uses 25 litres of helium gas that flows inside a closed loop	If helium gas leaks, it displaces oxygen thus causing a potential suffocation hazard	The level of helium gas is too low to cause any such harm under any scenario. Any fall in helium gas levels results in an automatic shutdown of the scanner, thus preventing helium gas circulation.
Biocompatibility	Minimal Risk. Scanner surfaces must use paints that are biocompatible with human skin	Absence of compatibility will cause rashes and irritation to human skin	Only biocompatible paints will be used with scanner covers.

2. Occupational Health and Safety and risk mitigation

Risks	Project Specific Risk	Potential Impact	Mitigation Steps
Heat Hazards	Moderate Risk. Parts in direct contact with patients can heat up.	Cause skin burns	Design must satisfy IEC (International Electrotechnical Commission) standards on temperature rise. This is verified by the Notified Body. Personal protective equipment will be provided as per requirements during the assembly/ testing process.
Chemical hazards, including fire and explosions	Moderate Risk. Operations in an oxygen risk environment.	Can cause fire and explosion	Design must satisfy IEC standards in an oxygen rich environment. This is verified by the Notified Body. Personal protective equipment will be provided as per requirements during the assembly/ testing process.

Pathogenic and biological hazards	Not applicable as MRI is a non-invasive imaging modality with no in vitro functions.	Not applicable as MRI is a non-invasive imaging modality with no in vitro functions.	Not applicable as MRI is a non-invasive imaging modality with no in vitro functions.
Radiological hazards	Not applicable as MRI is a non-ionizing imaging modality. No other radiation sources are used in any process.	Not applicable as MRI is a non-ionizing imaging modality.	Not applicable as MRI is a non-ionizing imaging modality.
Noise	Moderate Risk. Scanner acoustics can be very loud.	Temporary / permanent hearing loss.	Design must satisfy IEC standards on acoustic noise. This is verified by the Notified Body. Personal protective equipment will be provided as per requirements during the assembly/ testing process.
Process safety	Moderate Risk. Process errors during assembly of MRIs. Errors in managing patients during scans	QC failure of instrument or accident. Wrong Imaging process could be executed	User documentation must satisfy IEC standards on processes to be followed. This is verified by the Notified Body. Personal protective equipment will be provided as per requirements during the assembly/ testing process.
Leakage currents	Moderate Risk. Earth leakage current, touch leakage current and patient leakage currents.	Can cause electric shock to the operator and patient.	These currents are measured at every part of the scanner's surface that can come into contact with the operator and patient to ensure that the current limits, if any, are below the limits specified by the IEC. Personal protective equipment will be provided as per requirements during the

			assembly/ testing process.
Water spillage	Moderate Risk. Water coolant that flows through all the scanner's sub-systems could leak	This can cause shock and can also cause a chemical spill as the water coolant contains biocides and anti-corrosive inhibitors	Spillage is contained by introducing emergency shut down mechanisms at every point where there is a connection to a water hose. These mechanisms ensure an immediate shut down of the water supply in the event of a leak. Personal protective equipment will be provided as per requirements during the assembly/ testing process.
Controlled access area	Moderate Risk. There is a certain limit beyond which unauthorized personnel must not be allowed near the scanner.	In the absence of adequate screening, such personnel could be harmed if they have body implants or are carrying metallic equipment.	Controlled access to the area where scanner is built and operated. Clear markings will be provided everywhere so that the 'No Go' zone is clear to all concerned. Personal protective equipment will be provided as per requirements during the assembly/ testing process.
Fire prevention	Moderate Risk. Scanner covers can catch fire if they experience excess heat from any leakage currents that flow through it.	This is a fire hazard	The scanner covers are checked for flammability and used only if they pass this IEC specified tests. Personal protective equipment will be provided as per requirements during the assembly/ testing process.
Radiation hazard	Minimal Risk. The scanner employs a laser light for landmarking the	Direct exposure of the eye to this laser light can cause damage.	The operator and patient must be instructed to close their eyes when the laser light is on. This protocol is in line with

	location that needs to be scanned		IEC recommendations and will be mentioned on the machine. Personal protective equipment will be provided as per requirements during the assembly/ testing process.
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3. Community Health and Safety and risk mitigation

Risks	Project Specific Risk	Potential Impact	Mitigation Steps
Safety Transportation Management System (for transport of hazardous material)	Not applicable as our operations do not involve the transportation of hazardous material. Though the machine itself is not hazardous, product safety on the mobile platform during transport is a safety concern.	Not applicable as our operations do not involve the transportation of hazardous material. Scanners can be damaged during transport.	Not applicable as our operations do not involve the transportation of hazardous material. For safety of scanner on mobile truck/ platform, 1. A speed governor will be installed in the mobile truck 2. Physically strong to support up to 3 tons 3. Walls of the truck designed to prevent scanner noise to affective the outside surroundings.
Emergency preparedness and participation of local authorities and potentially affected communities	Not applicable as our operations do not involve the use of chemical, biological or radiological products in anyway and does not generate any such waste.	Not applicable as our operations do not involve the use of chemical, biological or radiological products in anyway and does not generate any such waste.	Fire extinguishers will be available. Emergency exits will be properly marked at the facility. Emergency contact numbers will be listed in the company.

In case your organization already has **EHS guideline**, please summarise the same. If not, please describe the impact because of hazardous material, release of chemicals, biologicals, management of catastrophic events like fire/explosion.

