

Environmental and Health Risk Management Plan (EHRMP)

Carditek Medical Devices Private Limited

Proposal entitled: Real time High frequency ECGs as a tool in the evaluation of chest pain presenting to the emergency room

- i. Brief description of the proposed activity:
- a. design of PCB and IOMT services for a wearable high frequency ECG
 - b. There is no known health risk. The device only collects cardiac ECG waves that are emanating from the body, and does not pump in any waves into the body
 - c. The battery used is a very small 3.2 volt 800 mah li po and device has already been tested for current leakage , there is no danger to the user
 - d. An adhesive is applied **only** in case of long term usage and is the only consumable
- By this device , wires and electrode patches which are used in regular ecg monitoring has been eliminated , thus this is an environmentally aware green product
- ii. List of environments related regulatory clearances required for the activity.
- We don't manufacture** - we only work on medical device design and development, therefore we do not required CPCB

		Yes	No	Details	Proposed Plan
Institutional Arrangement					
1.	Is there a designated full-time staff for Environment Health and Safety (EHS) issues?		No	One of our Current staff is handling EHS issues	Planning to recruit a full time staff to manage EHS issues in the coming months The concerned staff will be trained on the Environment Health and Safety (EHS) and will comply with the norms and EHS requirements
2.	Does the EHS staff handle the following?				
	Occupational Health and Safety		No		The Full time EHS staff will handle the details in the future.
	Waste Management		No		
List of consents and		No			

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	regulatory clearances				Necessary Compliance requirements will be taken if required We will comply to Environment Management Framework compliance for Innovate in India Project
	Record keeping of accidents and procedures		No		
	EHS trainings for staff		No		
	Environment Management Framework compliance for Innovate in India Project		No		
3.	Is there a reporting structure in place regarding EHS issues?		No		We will develop the architecture for managing the EHS issues SOPs and formats to record any incidents and EHS issues will be structured as a part of EHS policy.
4.	Are regular EHS training provided to staff?	Yes		Every new employee will undergo one day EHS training	Training calendars shall be prepared for employees. Training will be provided as and when required to all the existing as well as newly recruited staffs
5.	Institutional Bio-Safety Committee (IBSC)		No		If required in future, we will establish IBSC and take necessary action and approvals whenever required.
6.	Ethics Committee (EC)	Yes		Internal ethics committee is constituted	Code of conduct and ethics policy will be put in place soon with periodic review meetings in place.
General Occupational Health and Safety					
7.	Are there Standard Operating Procedures for accidents, hazards, and other emergencies (chemical		No		We will implement in near future

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	spills, heat hazards, fire hazards, radioactive hazards etc.)?				SOPs and formats to record any accidents, hazards, and other emergencies will be structured
8.	Are the following in place?			All the basic emergency first aid tools are in office All are located at strategic locations for easy accessibility	Will have chemical spill kits when needed. Sufficient number of first aid kits, eye washers, chemical spill kits will always be maintained. Register will be maintained for ensuring provisions of such requisites.
	Chemical spill kits		No		
	Eye wash	Yes			
	Shower stations	yes			
	First Aid Kit	yes			
	Fire Extinguishers	yes			
	Register of accidents and injuries	yes			
9.	Are proper signage and storage systems in place?			The Emergency safety flyers with all the relevant contact number are displayed in all the working area All details are printed on a sheet with visible fonts size and placed located at strategic locations for easy accessibility and readability	Facilities will be upgraded with the activities increased.
	Display of Material Safety Data Sheet (MSDS) where relevant	Yes			
	Display of emergency numbers and procedures (Person to Contact, Doctor, Ambulance, Fire Emergency, Police) displayed in all critical places	Yes			
	Signage across the facility (labs, storage, hazardous areas, etc.)	Yes			
	Are flammable materials appropriately stored to prevent fire hazards?	Yes			

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10.	Are smoke detectors, fire alarms, automatic safety/shutoff systems, overflow preventers, etc. in place and regularly maintained?		No		We will install them as and when we require Facilities will be maintained and upgraded with the activities increased.
11.	Are there control measures for VOC, air emissions, high operating temperatures, pathogens/vectors etc. in place?		No		We will install them as and when we require Preventive measures with all precautions will be put in place as and when required during the project.
12.	Are regular mock drills conducted for emergency preparedness and safety?	Yes		Every new employee will undergo training	Will ensure that this process will be regularly followed. Mock drills are conducted will be documented.
13.	Are staff provided with OHS training?	Yes		Every new employee will undergo training	Will ensure that this training is incorporated as a regular process. All the staff will be provided with trainings including newly joined staff
Biomedical Waste (BMW)					
14.	Is there generation of biomedical waste (as described in Bio-Medical Waste Management Rules, 2016) in the grantee?		No	No Biomedical waste is generated in our activity	Necessary rules will be followed when required. Biomedical waste will be sent to PCB authorized

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					facility.
15.	Is there trained staff to handle biomedical waste in the grantee?		No	No Biomedical waste is generated in our activity	We will train the staff when required.
16.	Has the grantee obtained authorization from the State Pollution Control Board /Pollution Control Committee?		No	No Biomedical waste is generated in our activity	Necessary Authorizations will be taken if required
17.	Is the biomedical waste segregated at point of generation in the facility and stored in suitable containers?		No	No Biomedical waste is generated in our activity	We will arrange biomedical waste management as and when required
18.	Is the barcode system for the segregated waste in place?		No	No Biomedical waste is generated in our activity	We will arrange bar code system when needed
19.	Is the biomedical waste being sent to an authorized common BMW facility?		No	No Biomedical waste is generated in our activity	At present we do not handle biomedical waste. In future if we handle BMW then we will send the BMW to authorised centers
20.	Does the grantee have an in-house BMW treatment facility?		No	No Biomedical waste is generated in our activity	In future when we are dealing with biomedical waste, we will arrange an in-house treatment facility.
	Is the treatment facility owned (individual)?		No		
	Is the treatment facility a shared facility in an industrial park?		No		
21.	Are lab waste, microbiological waste and chemical liquid waste pre-treated before storing and sending to treatment		No	No Biomedical waste is generated in our activity	In future when we are dealing with biomedical waste, we will arrange for pre-treatment

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	facilities according to guidelines prescribed in BWM, 2016 regulations?				
22.	Is the liquid waste checked for active cells before sending it to the treatment plant?		No	No Biomedical waste is generated in our activity	We do not generate any liquid waste
23.	Are necessary waste pre-treatment equipment in place?		No	No Biomedical waste is generated in our activity	At present we don't generate any harmful waste, in future we will take necessary action to follow the SPCB norms
	Does the equipment adhere to prescribed norms by the State Pollution Control Board (SPCB)?		No		
24.	Are chlorinated plastic gloves and bags phased out in the grantee?		No	No Biomedical waste is generated in our activity	We don't use chlorinated plastic gloves
25.	Are grantee's personnel involved in handling BMW provided with regular training?		No	No Biomedical waste is generated in our activity	We will provide training when required
26.	Are medical examination provided to personnel involved in BMW waste handling and are they provided with relevant immunization like Hepatitis B and Tetanus?		No	No Biomedical waste is generated in our activity	We will conduct medical examination and immunization when required
27.	Is a daily register for biomedical waste maintained, including accident reporting record?		No	No Biomedical waste is generated in our activity	All the daily register and records will be maintained when required
28.	Are annual reports on BWM submitted to SPCB as per required form (see Bio-Medical Waste Rules 2016)?		No	No Biomedical waste is generated in our activity	Necessary Authorizations will be taken if required
Hazardous Waste (HW)					

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29.	Is there generation of hazardous waste (as per Hazardous Waste Rules, 2016) in the grantee?		No	No Hazardous waste is generated in our activity	Disposed of hazardous waste will be done as an when required according to Hazardous Waste Rules, 2016Bio
30.	Is there trained staff in the facility to identify and handle hazardous waste?		No	No Hazardous waste is generated in our activity	We will provide required training at the time requirement
31.	Does the grantee have authorization from SPCB for hazardous waste?		No	No Hazardous waste is generated in our activity	Necessary Authorizations will be taken if required
32.	Is there a secure location for storage of HW with proper signage?		No	No Hazardous waste is generated in our activity	We will arrange proper storage facilities when required
	Are hazardous waste stored for more than 90 days in the grantee's premises?		No		
33.	Is the hazardous being sent to an authorized disposal facility or user?	Yes		All the electronics wastes like battery are disposed in the government authorized disposal bins (Post Office)	Will continue to dispose of the hazardous wastes to authorized disposal facility throughout the Project
	Is the disposal facility in house?		No		
	Is the disposal facility external/outsourced?	Yes			
34.	Is a register maintained on production and treatment, and a manifest system followed for transport of hazardous waste from the grantee to treatment facility?		No	No Hazardous waste is generated in our activity	We will maintain the register when required
E-Waste and Batteries					
35.	Does the grantee generate e-waste, produce or manufacture electrical and electronic equipment?	Yes		Old Batteries are the main source of e-waste, they will packed and disposed in government authorized e-waste disposable bins	The list of authorized centres will be obtained from PCB and disposal of the e-waste will be done as per E-waste Management Rules

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36.	Has the grantee obtained SPCB authorization on e-waste?		No		Necessary Authorizations will be taken if required
37.	Does the grantee channelize the e-waste to authorized recycling or disposal facilities?		No		Will select an authorized vendor authorized and listed by the PCB to channelize any e-waste generated in future.
38.	Does the manufacturing grantee have an Extended Producer Responsibility system and EPR-authorization in place?		No		
39.	Does the grantee practice reduction in the usage of hazardous substances in the manufacture of electrical and electronic equipment and its parts?		No		Will be implemented in coming years
40.	Does the grantee provide detailed information on the constituents of the equipment and their components/spares and declaration of conformation to Reduction in Hazardous Substances in the product user documentation?		No		Will be implemented in coming years
41.	Does the grantee maintain a record of collection, storage, sale and transport of e-waste?		No		Will be implemented in coming years
42.	Does the grantee submit annual reports on e-waste to SPCB?		No		Will be implemented in coming years
43.	Is there accident reporting and records in place?		No		Will be implemented in coming years
44.	Are PPEs available to staff?	Yes		We had disposable	The stock status of PPE

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				PPE for all the staff	will be regularly monitored and procurement will be done in time to avoid any situation of stock out.
45.	Is the grantee involved in manufacture of batteries?		No		At present we are purchasing off the shelf battery and in future also we will use CE Certified Off the shelf battery
46.	Does the grantee generate battery waste?	Yes		can, in small quantities after a couple of years	Battery waste generated will be sent to authorized Recycler
47.	Does the grantee deposit the battery waste to a registered recycler/dealer/manufacturer /reconditioned/collection center?	Yes		We dispose the old batteries in government authorised e-waste bin	We Will dispose then e waste bin
48.	In case of manufacturing, does the grantee comply with Battery Management Rules 2000 and ensure collection of old batteries?		No		Will be implemented in the coming years
Community Health and Safety and risk mitigation					
49.	Safety Transportation Management System (for transport of hazardous material)		No	Not required for our activity	
50.	Emergency preparedness and participation of local authorities and potentially affected communities		No		Will develop the emergency preparedness plan if required .
Others					
51.	Does the grantee use any radioactive materials (isotopes tracers, radiation equipment, etc.)?		No		we don't use radioactive material
	Does the grantee have appropriate radioactive		No		If we use, then we will arrange for proper storage

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	material and waste storage and disposal systems in place?				and disposal
	Are radioactive warning signs in place?		No		Will be implemented if required
52.	Is the lab/room air regularly checked for microbial contamination?		No		Will be implemented if needed Periodic checks will be done if required
53.	Are there any odor control measures in place?	Yes		air fresheners is arranged	Periodic checks will be done.
54.	Are fume hoods and exhausts regularly checked and maintained?		No	Not applicable as we don't use any hazardous or toxic fumes, vapors or dusts	Periodic checks will be done.
55.	Does the grantee use DG set > 15 KVA?		No	At present we are not using any DG	
	Does the grantee have consent for DG > 15 KVA?		No		
	Are emissions from boilers and DG sets regularly monitored to be within the prescribed norms?		No		
56.	Does the grantee have a proper disposal process for solid and plastic waste in compliance to Solid Waste Management Rules, 2016 and Plastic Waste Management Rules, 2016?		No		Necessary compliance will be taken when required It will be ensured that segregation rules are followed. This will be maintained and monitored
57.	Is wastewater treated separately by the grantee? (Liquid waste from laboratory, chemicals, fluids, solvents, medium and		No		Will be implemented when needed

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	cultures, coolants, etc.)				
	Are there sludge management and cut off drains in place for wastewater?		No		Will be implemented when needed
58.	Are necessary provisions for noise cancellation in place?	Yes		Proper grounding of the office bundling is taken care	Preventive measures will be taken for reducing noise levels
59.	Are there any settlements, water bodies, cultivated land, or any other eco-sensitive areas near the grantee's premises?		No	We are situated in a commercial area	
60.	Are there any buffers, fire vehicle routes in the grantee's premises?	Yes		We are situated in a commercial area therefore we have access for all lids of help during emergency	Will ensure cleared for fire safety including vehicle routes

Notwithstanding the above other risk (relevant to the project activities) that will be identified in the course shall be addressed as per standard mitigation monitoring parameters and manner of records keeping shall be in accordance to the recommendations of the project monitoring committee on subject experts engaged by BIRAC.