ISIS@MACH ITALIA

Science and Technology Facilities Council
ISIS Neutron and Muon Source

Experiment Proposal

Experiment number GP2024003

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Experiment title	Characterisation of the degree of damage by neutron induced single-event effects on Heartmate 3 Ventricular Assist Device by means of X-Ray tomography
MRF Instrument	**XRD TOMOGRAPHY**
Access Route	Direct Access
Science Areas	Medicine
Sponsored Grant	None
Grant Title	-
Start Date	-
Similar Submission?	-
Industrial Links	-
Non-Technical Abstract	We propose multilevel characterisations of Electronic Components (ECs) located within the housing of an artificial heart. These include: a) MeV and thermal neutron tests - before and after neutron-induced SEEs, and 3D neutron imaging - to be performed at ChipIr and IMAT beamlines at ISIS Facility (UK); the 3D reconstruction analysis before and after neutron neutron-induced SEEs, using X-ray tomography (XCT) instrument operating at the at Unit CNR-IPCB and at IMAT. The 3D analysis aims at revealing the possible presence of damages caused by the neutron irradiation tests in the ECs. The results will be compared with cross-sectional SEM images to be obtained using the SEM with correlative AFM instrument operating at the Unit UniTOV, to be requested in a distinct proposal. The final goal is to study both the resilience of the electronic components of the medical device against atmospheric neutrons as well as a full characterisation of the materials components containing the ECs.
Publications	-

Days requested: 5
Previous GP Number: No
DOI: No
Sponsor: -
Grant Number: -
Finish Date: -

Instruments	**IMAT**
Access Route	Direct Access
Science Areas	**DOI:** No
Sponsored Grant	None
Grant Title	-
Start Date	-
Similar Submission?	
Industrial Links	

Days Requested: 3
Previous RB Number: No
Sponsor:
Grant Number:
Finish Date:

Sample record sheet

Principal contact Dr Triestino Minniti, University of Rome Tor Vergata, ITALY
MRF Instrument **XRD TOMOGRAPHY** **Days Requested:** 5
Special requirements:

SAMPLE

Material	Si	-	-
Formula	Si	-	-
Forms	Solid		
Volume	0.004 cc		
Weight	10 mg		
Container or substrate	-	-	-
Storage Requirements	-	-	-

SAMPLE ENVIROMENT

Temperature Range	- K	-	-
Pressure Range	- mbar	-	-
Magnetic field range	- T	-	-
Standard equipment	-	-	-
Special equipment	-	-	-

SAFETY

Prep lab needed	Yes	-	-
Sample Prep Hazards	-	-	-
Special equip. reqs	-	-	-
Sensitivity to air	No	-	-
Sensitivity to vapour	No	-	-
Experiment Hazards	-	-	-
Equipment Hazards	-	-	-
Biological hazards	-	-	-
Radioactive Hazards	-	-	-
Additional Hazards	-	-	-
Additional Details	-	-	-
Sample will be	Disposed by IS	-	-

1. Background and Context

Given the increasing shortage of donor organs, implantable mechanical circulatory support (MCS) systems for ventricular assist device (VAD) therapy have emerged as an essential element of treatment [1–3]. These devices are installed permanently in many patients, and fewer are now undergoing heart transplantation (Htx). Patients supported by VADs can be discharged from intensive care units or hospitals because VADs are mostly intracorporeal and improve quality of life compared with short-term devices. Using VADs as destination therapy is now an acceptable as well as a feasible therapy for the patients of end-stage heart failure who cannot qualify for Htx. The most widely implanted left ventricular assist device, the Heartmate II (Abbott) [4], is an axial continuous-flow pump which requires thoracoabdominal placement, and where all control circuitry and electronics are hosted in the external controller.

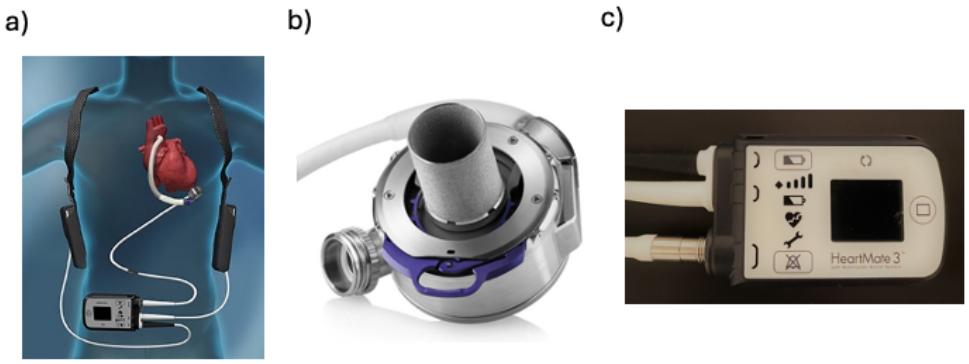

Figure 1: Heartmate III VAD devices. a) image of the full LVAD system, b) its centrifugal flow pump and c) its external controller.

Despite improved survival and quality of life with the Heartmate II, long-term success with this device remains partially limited by adverse effects, including infections, neurologic complications and pump thromboses [5]. The HeartMate 3 ventricular assist system (Figure 1 panel a)) is a centrifugal flow pump (panel b)) engineered to optimize fluid dynamics and developed with wider blood-flow passages with the intent to avert thrombogenesis. CE approval for usage was granted in 2015 following a clinical trial completed on 27 November 2014. Compared to the Heartmate II, this new device has some electronics stored within the housing of the pump as well as the external controller shown in panel c) of Figure 1. This structural change in the new HeartMate 3 model can potentially lead to unexpected failures due to single-event effects (SEEs) triggered by atmospheric neutrons, that of course can cause catastrophic consequence for a life-critical device like a VAD. At sea-level neutron flux is of the order of 21 neutrons for cm^{-2} h^{-1} and with energies E_n>1 MeV, but it varies with altitude increasing from sea level to about 15 km by almost a factor of 1000. Single-event effects trigger by atmospheric neutrons are not new in semiconductor devices and ICs [6], and extensive measurement campaigns where nowadays included in R&D to verify that components are resilient to such particles.

For this reason, the aim of this proposal is to characterise the electronics components by means of X-ray computed topography (XCT), scanning electron microscopy (SEM with correlative AFM) and neutron tomography measurements which are stored within the housing of the HeartMate 3 pump before and after accelerated neutron tests to induce SEE. The neutron measurements will be envisaged two separate proposals to IMAT and ChipIr beamlines at the ISIS facility. Furthermore, failure in time (FIT) test of the device will be done before and during the neutron irradiation at ChipIr to verify their resilience to neutron irradiation.

2. Proposed experiment

We aim to perform XC of all the electronic components stored within the housing of the HeartMate 3 pump and controller, some of which will be dismantle from the VAD device, before and after neutron-induced SEEs. The electronic components studied before neutron-induced SEEs will be used as gold reference to which infer the impact of neutron irradiation. 3D reconstruction of XCT data will be compared with cross-sectional SEM images of the samples and neutron 3D data which will be requested in separate proposals to the SEM with correlative AFM instrument operating at the Unit UniTOV and the IMAT beamline at ISIS Facility. This comparison is especially important in the case of electronic components showing neutron-induced damage, that we will allow us to benchmark SEM images as an independent method for non-destructively assess damaged electronic components of the HeartMate 3 VAD system with XCT results.

3. Justification of experimental time requested.

The electronic components stored within the housing of the HeartMate 3 pump and controller before and after neutron-induced SEEs and 3D neutron imaging on ChipIr and IMAT beamlines will be acquired using a field of view and magnification which depends on the size of the samples. We request n. 2 XCT scans with different spatial resolution (one full scan and one detailed scan) per sample. Hence, after discussion with the instrument scientist, we request 5 days of beamtime which account also for setup time, and eventual beam loss time.

References

1. Kirklin, J.K. et al. J. Hear. Lung Transplant. 2015, 34, 1495–1504.
2. De Bya, T.M.M.H. et al. Second report. Eur. J. Cardiothorac. Surg. 2018, 53, 309–316.
3. Kirklin, J.K. et al., Heart Lung Transplant. 2018, 37, 685–691.
4. Slaughter, M.S. et al. Advanced Heart Failure Treated with Continuous-Flow Left Ventricular Assist Device. N. Engl. J. Med. 2009, 361, 2241–2251.
5. Stulak J.M., et al., J. Thorac. Cardiovasc Surg. 151 (2016), pp. 177-189.
6. F. W. Sexton, IEEE Transactions on Nuclear Science, vol. 50, no. 3, pp. 603-621.