Experiment Proposal

Experiment number GP2024004

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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 SEM measurements

MRF Instrument	**SEM with correlative AFM**	**Days requested:** 5
Access Route	Direct Access	**Previous GP Number:** no
Science Areas	Engineering	**DOI:** -
Sponsored Grant	None	**Sponsor:** -
Grant Title	-	**Grant Number:** -
Start Date	-	**Finish Date:** -
Similar Submission?	-	
Industrial Links	-	

Non-Technical Abstract

We propose a 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 single-event effects, and 3D neutron imaging - to be performed at ChipIr and IMAT beamlines at ISIS Facility (UK); the ECs will be assessed before and after neutron irradiation using the SEM correlative AFM operating at the Unit UniTOV. The SEM images will be collected before and after neutron-induced SEEs test to reveal the possible presence in the ECs of damages caused by the neutron irradiation tests. These results will be complemented with a 3D reconstruction analysis to be obtained using the X-ray tomography (XCT) instrument operating at the Unit CNR-IPCB and at IMAT, to be requested in a distinct proposal. The final goal is to study both the resilience of ECs in the medical device against atmospheric neutrons as well as a full characterisation of the materials containing ECs.

Publications -

Instruments	**ChipIR**	**Days Requested:** 3
Access Route	Direct Access	**Previous RB Number:** No
Science Areas		**DOI:**
Sponsored Grant	None	**Sponsor:**
Grant Title	-	**Grant Number:**
Start Date	-	**Finish Date:**
Similar Submission?		
Industrial Links		

Sample record sheet

Principal contact	Dr Triestino Minniti, University of Rome Tor Vergata, ITALY		
MRF Instrument	**SEM with correlative AFM**	**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	-	-

Characterisation of the degree of damage by neutron induced single-event effects on Heartmate 3 Ventricular Assist Device by means of SEM measurements.

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.

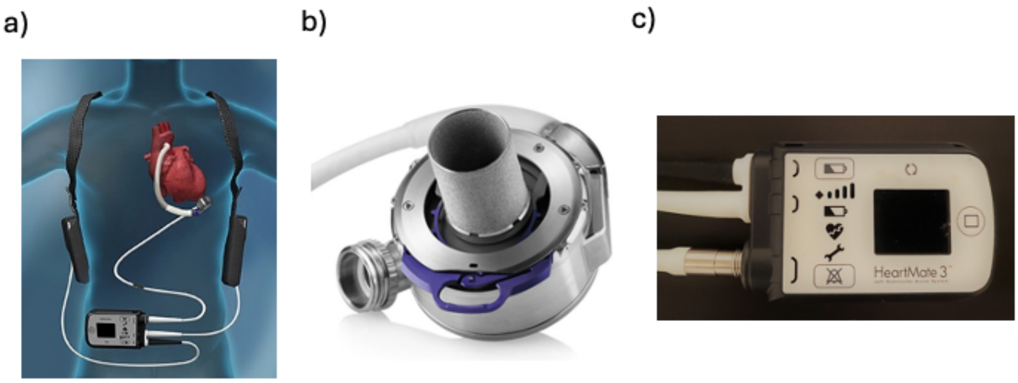

Figure 1: Heartmate III VAD devices. a) image of the full LVAD system, b) its centrifugal flow pump and c) its external controller.

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 scanning electron microscopy (SEM with correlative AFM), X-ray computed topography (XCT) and neutron tomography measurements which are stored within the housing of the HeartMate 3 pump before and after accelerated neutron tests to induce SEEs and 3D neutron imaging. We aim to perform the latter measurements using the IMAT and ChipIr beamlines at the ISIS neutron and muon source (UK). 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 measure the cross-sectional SEM images 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 with the SEM with correlative AFM operating at IM@IT Unit UniTOV. The electronic components studied before neutron-induced SEEs will be used as gold reference to which infer the impact of neutron irradiation. Cross-sectional SEM images will be compared with the 3D reconstruction of the samples obtained performing distinct X-ray and neutron tomography experiments which will be requested in separate proposals to the X-Ray Tomography instrument operating at IM@IT Unit CNR-IPCB and the IMAT beamline at ISIS. This comparison is especially important in the case of electronic components showing neutron-induced damage, that we will allow us to benchmark XCT results as an independent method for non-destructively assess damaged electronic components of the HeartMate 3 VAD system with SEM images.

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 neutron beamlines will be acquired using a field of view and magnification which depends on the size of the samples. We predict n. 6 image per sample. Hence, after discussion with the instrument scientist, we request 5 days of beamtime on SEM 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.