

Ultra-low-field portable MRI and Extracorporeal Membrane Oxygenation (ECMO):

Preclinical Safety Testing

Jin Kook Kang, MD^{1*}, Eric Etchill, MD^{1*}, Kate Verdi, MD¹, Ana K. Velez, MD¹, Sean Kearney, BS¹, Jeffrey Dodd-o, MD², Errol Bush, MD³, Samantha By, PhD⁴, Eddy Boskamp⁴, PhD, Christopher Wilcox, DO, MS¹, Chun Woo Choi, MD¹, Bo Soo Kim, MD^{1,5}, Glenn J. R. Whitman, MD¹, Sung-Min Cho, DO, MHS^{1,6#}

Institutions / Affiliations

1. Division of Cardiac Surgery, Department of Surgery, Johns Hopkins Hospital, Baltimore, MD.
2. Division of Cardiac Anesthesiology, Department of Anesthesiology and Critical Care Medicine, Johns Hopkins University School of Medicine, Baltimore MD
3. Division of Thoracic Surgery, Department of Surgery, Johns Hopkins Hospital, Baltimore, MD.
4. Hyperfine, Inc., Guilford, CT.
5. Division of Pulmonary and Critical Care Medicine, Department of Medicine, Johns Hopkins University School of Medicine, Baltimore, MD.
6. Division of Neurosciences Critical Care, Department of Neurology, Neurosurgery, Anesthesiology and Critical Care Medicine, Johns Hopkins Hospital, Baltimore, MD.

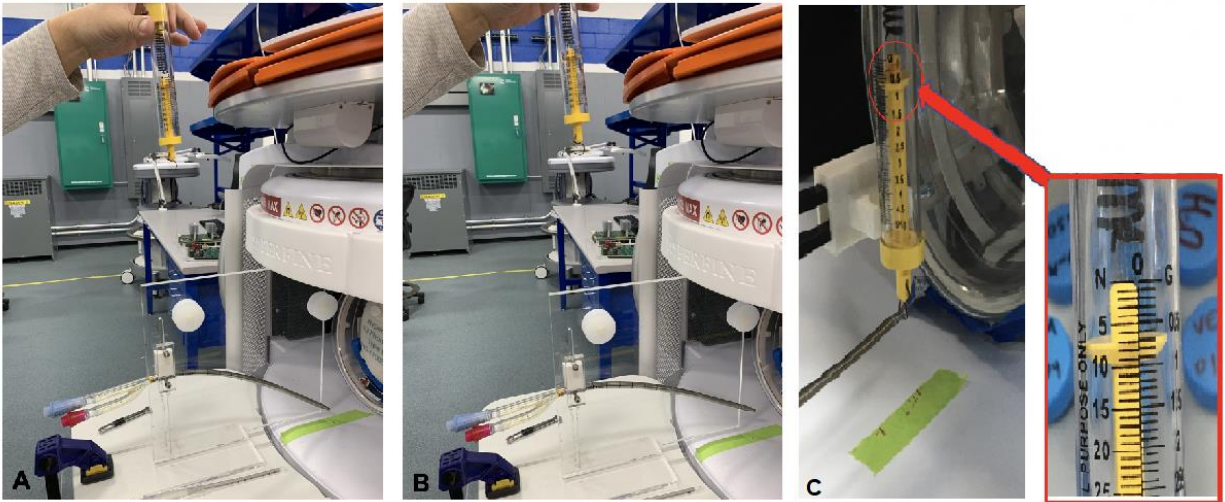
Supplemental Content

1. Supplemental Figure 1 -----	2
2. Supplemental Figure 2 -----	3
3. Supplemental Figure 3 -----	3
4. Supplemental Figure 4 -----	4
5. Supplemental Table 1 -----	5
6. Supplemental Figure Legends -----	6

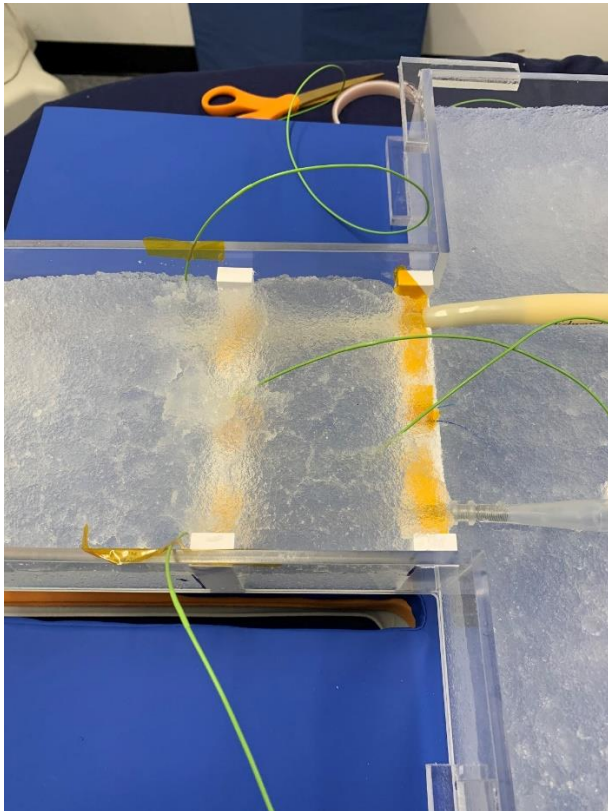
Supplemental Figure 1: Fixture with a cannula attached to ULF-pMRI scanner (spring gauge unattached).



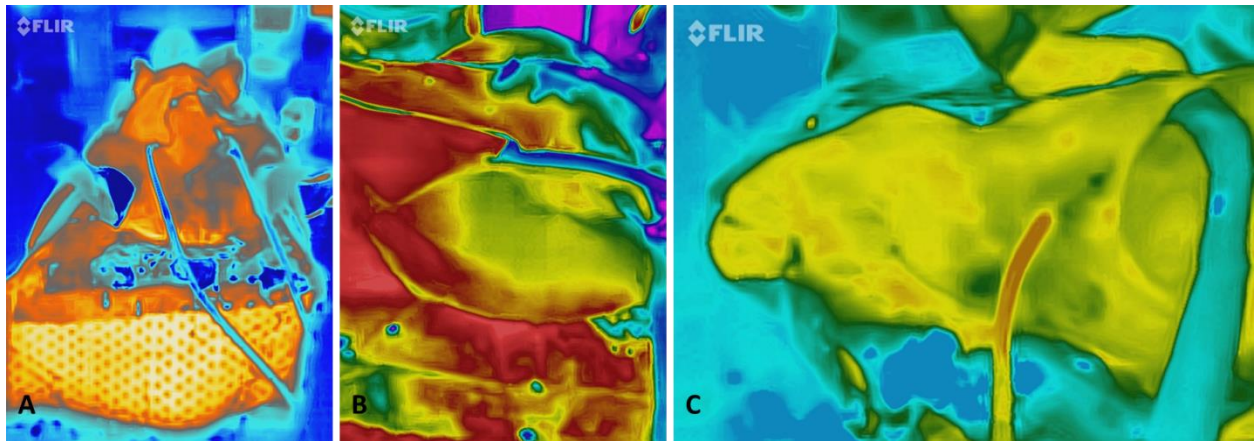
Supplemental Figure 2: Different configurations for displacement force measurement at position where (A) maximum force and (B) neutral force were recorded; (C) measurement with plastic spring gauge.



Supplemental Figure 3: Phantom device for heat testing.



Supplemental Figure 4: Thermal images of the pigs with ECMO cannulation during overall scanning process (A), close-up of femoral cannulation site (B), and jugular cannulation site (B).



Supplemental Table 1. Risks identified and testing performed to mitigate the associated risk.

Risk	Risk Description	Testing
Displacement Force	Static magnetic field-induced displacement force (F2503-13 section X1.2.1.1) on ferromagnetic components of the ECMO device and associated components (magnetic tip and/or coils of wire inside the cannula). It should be noted that the risks of Swoop compared to conventional MRI are expected to be greatly reduced.	Performed on identified components of the ECMO intervention guided by ASTM F2052
Heating	The electrically conductive and possibly ferromagnetic tip and/or the coils of wire inside the cannula may cause radiofrequency (F2503-13 section X1.2.1.3) or gradient field induced (F2503-13 section X1.2.1.4) heating. It should be noted that the risks of Swoop compared to conventional MRI are expected to be greatly reduced.	Tests as guided by ASTM standard F2182 for RF heating were performed. F2182 outlines less than 2°C over 15 min of exposure at 1.5 T/64-MHz or 3 T/128-MHz frequencies inside a gelled-saline filled phantom.
Malfunction	The ECMO device may have magnetic components, and therefore, in close proximity to the static magnetic field of the Hyperfine system, may malfunction (see F2503-13 section X1.2.1.5). Other causes of malfunction could be from RF or gradient fields. It should be noted that the risks of Swoop compared to conventional MRI are expected to be greatly reduced.	Tests were performed on the ECMO pumps guided by ISO/TS 10974 Ed2 using a saline phantom.

ECMO: extracorporeal membrane oxygenation, ASTM: American Society for Testing and Materials, MRI: magnetic resonance imaging, RF: radiofrequency

Supplemental Figure Legends.

Supplemental Figure 1: Fixture with a cannula attached to ULF-pMRI scanner (spring gauge unattached).

Supplemental Figure 2: Different configurations for displacement force measurement at position where (A) maximum force and (B) neutral force were recorded; (C) measurement with plastic spring gauge.

Supplemental Figure 3: Phantom device for heat testing.

Supplemental Figure 4: Thermal images of the pigs with ECMO cannulation during overall scanning process (A), close-up of femoral cannulation site (B), and jugular cannulation site (B).