Summary of Verification and Validation (V&V) Activities

V&V Activity	Description	Result
Test fluid characterization	Blood analog fluid (BAF), used as the test fluid in the MCL, was prepared to mimic the viscous behavior of blood. BAF characterization involved fluid viscosity and density measurements. Please refer to document, 'Preparation of Blood Analog Fluid (BAF)'.	Dynamic viscosity: 3.95 mPa·s Density: 1.095 g/cm^3 **Acceptable**. BAF properties closely match those of blood.
Pressure transducer calibration	The LV, LA, and Ao pressure transducers were calibrated using a graduated (in mmHg) cylindrical tube containing a 0-100 mmHg range of heights of fluid column. Please refer to document, 'Pressure Transducer Calibration'.	Water: | Ao	LV	LA
60 mV/mmHg	59 mV/mmHg	58 mV/mmHg | BAF: | Ao	LV	LA
60.1 mV/mmHg	59.6 mV/mmHg	57 mV/mmHg | This is a **characterization only** test that is meant to verify the precision and reproducibility of the pressure sensors.
Flow sensor calibration	The CO (EP688) and Ao (ME-25PXN) flow sensors were calibrated using a traditional timed volumetric fluid collection method. Please refer to document, 'Flow Sensor Calibration'.	Water: EP688 – N/A (*can only be used with BAF*) ME-25PXN – 50 mV/L/min (sensor gain: 85%) BAF: EP688 – 100 mV/L/min ME-25PXN – 50 mV/L/min (sensor gain: 98%) This is a **characterization only** test that is meant to verify the precision and reproducibility of the flow sensors.
Frequency response filter characterization	The filter frequency response on the pressure amplifier and flowmeter	Recommended filter for pressure:

	modules were characterized using a simplified flow loop. Please refer to document, 'Filter Frequency Response Characterization'.	Pressure amplifier – 30 Hz low-pass filter (for LV, LA, and Ao pressure transducer channels) Recommended filter for flow: T402 flowmeter – 10 Hz filter (for ME-25PXN flow sensor) FM501 flowmeter – 30 Hz pulsatile frequency response (for EP688 flow probe) This is a **characterization only** test that is meant to ensure measurement accuracy.
MCL simulations of the recommended target test conditions	The MCL was used to simulate the pathophysiologic hemodynamics corresponding to the pre-defined five target test conditions. Qualitative pressure and flow pulses and quantitative cardiac indices were computed and compared against the target values for validation purposes. Please refer to documents: 'Mock Circulatory Loop (MCL) Simulations of the Target Test Conditions', D'Souza et al., JBME, 2023	Detailed test results are reported and discussed in D'Souza et al., JBME, 2023. The absolute difference between the target and simulated hemodynamics range between 3 – 9 mmHg for the SAP, 2 – 12 mmHg for the DAP, 0.3 – 1 L/min for the mean CO, and 0.001 – 0.01 s for the cardiac cycle time. **Acceptable**. The simulated hemodynamics closely matched the set target values.
MCL repeatability testing	The repeatability of the MCL test system was characterized by conducting ten replicate (or trial) tests at one of the recommended test conditions, cardiogenic shock, and by keeping all MCL inputs constant among the ten replicate tests. Please refer to documents: 'Mock Circulatory Loop (MCL) Repeatability Testing', D'Souza et al., JBME, 2023, Contarino et al., ASAIO Journal, 2023.	Detailed test results are reported and discussed in D'Souza et al., JBME, 2023 (sub-section: MCL Repeatability Testing) and Contarino et al., ASAIO Journal, 2023. The maximum uncertainty (95% CI) in the pressure and CO pulses are: Ao pressure = 1.4 mmHg, LV pressure = 10.2 mmHg, LA pressure = 11.57 mmHg, and CO = 1.17 L/min.

		Acceptable. Low uncertainty values demonstrate repeatability of the test system.