

Summary of Verification and Validation (V&V) Activities

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Summary of Verification and Validation (V&V) Activities

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. Acceptable. BAF properties closely match those of blood.	V&V Activity	Description	Result		
mimic the viscous behavior of blood. BAF characterization involved fluid viscosity and density measurements. Please refer to document, 'Preparation of Blood Analog Fluid (BAF)'. 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'. Please refer to document, 'Pressure Transducer 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'. BAF: Ao LV LA 60.1 59.6 57 mV/mmHg mV/mmHg mV/mmHg This is a characterization only test that is meant to verify the precision and reproducibility of the pressure sensors. Water: EP688 – N/A (*can only be used with BAF) ME-25PXN – 50 mV/L/min (sensor gain: 85%) Please refer to document, 'Flow Sensor Calibration'. BAF: EP688 – 100 mV/L/min (sensor gain: 85%)	Test fluid	Blood analog fluid (BAF), used as the	Dynamic viscosity: 3.95 mPa·s		
BAF characterization involved fluid viscosity and density measurements. Please refer to document, 'Preparation of Blood Analog Fluid (BAF)'. The LV, LA, and Ao pressure transducer calibration agraduated (in mmHg) cylindrical tube containing a 0-100 mmHg range of heights of fluid column. Please refer to document, 'Pressure Transducer Calibration'. Please refer to document, 'Pressure Transducer Calibration'. The CO (EP688) and Ao (ME-25PXN) flow sensors were calibrated using a traditional timed volumetric fluid collection method. 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'. BAF: EP688 – N/A (*can only be used with BAF) ME-25PXN – 50 mV/L/min (sensor gain: 85%) BAF: EP688 – 100 mV/L/min (sensor gain: Pe688 – 100 mV/L/min (sensor gain: Pe68	characterization	test fluid in the MCL, was prepared to	Density: 1.095 g/cm ³		
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Pressure transducer 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'. Ao		Please refer to document,			
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containing a 0-100 mmHg range of heights of fluid column. Please refer to document, 'Pressure Transducer Calibration'. 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'. End a limit wor/mmHg mV/mmHg mV/mmHg This is a characterization only test that is meant to verify the precision and reproducibility of the pressure sensors. 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: ME-25PXN – 50 mV/L/min (sensor gain	transducer	transducers were calibrated using a	Ao	LV	LA
heights of fluid column. Please refer to document, 'Pressure Transducer Calibration'. 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'. BAF: Ao LV LA 60.1 59.6 57 mV/mmHg mV/mmHg mV/mmHg 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: 9588 – 100	calibration	graduated (in mmHg) cylindrical tube	60	59	58
Please refer to document, 'Pressure Transducer Calibration'. Ao		containing a 0-100 mmHg range of	mV/mmHg	mV/mmHg	mV/mmHg
Please refer to document, 'Pressure Transducer Calibration'. Ao		heights of fluid column.		l	
Transducer Calibration'. Transducer Calibration'. 60.1 59.6 57 mV/mmHg mV			BAF:		
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Sensor Calibration'. BAF: EP688 – 100 mV/L/min ME-25PXN – 50 mV/L/min (sensor gain:			85%)		
EP688 – 100 mV/L/min ME-25PXN – 50 mV/L/min (sensor gain:		,			
ME-25PXN – 50 mV/L/min (sensor gain:		Sensor Calibration'.	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		
98%)					
This is a characterization only test that					
reproducibility of the flow sensors.					



Frequency	The filter frequency response on the	Recommended filter for pressure:	
response filter	pressure amplifier and flowmeter		
characterization	modules were characterized using a	Pressure amplifier – 30 Hz low-pass	
	simplified flow loop.	filter (for LV, LA, and Ao pressure	
		transducer channels)	
	Please refer to document, 'Filter		
	Frequency Response Characterization'.	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	The MCL was used to simulate the	Detailed test results are reported and	
of the	pathophysiologic hemodynamics	discussed in <u>D'Souza et al., JBME, 2024</u> .	
recommended	corresponding to the pre-defined five		
target test	target test conditions. Qualitative	The absolute difference between the	
conditions	pressure and flow pulses and	target and simulated hemodynamics	
	quantitative cardiac indices were	range between 3 – 9 mmHg for the SAP,	
	computed and compared against the	2 – 12 mmHg for the DAP, 0.3 – 1 L/min	
	target values for validation purposes.	for the mean CO, and 0.001 – 0.01 s for	
		the cardiac cycle time.	
	Please refer to documents: 'USER		
	MANUAL: Mock Circulatory Loop	Acceptable. The simulated	
	(MCL) Setup and Testing', D'Souza et	hemodynamics closely matched the set	
	al., JBME, 2024	target values.	
MCL	The repeatability of the MCL test	Detailed test results are reported and	
repeatability	system was characterized by	discussed in <u>D'Souza et al., JBME, 2024</u>	
testing	conducting ten replicate (or trial) tests	(sub-section: MCL Repeatability	
	at one of the recommended test	Testing) and Contarino et al., ASAIO	
	conditions, cardiogenic shock, and by	Journal, 2023.	
	keeping all MCL inputs constant among		
	the ten replicate tests.	The maximum uncertainty (95% CI) in	
		the pressure and CO pulses are: Ao	
	Please refer to documents: 'Mock	pressure = 1.4 mmHg, LV pressure =	
	Circulatory Loop (MCL) Repeatability		



Testing', D'Souza et al., JBME, 2024, Contarino et al., ASAIO Journal, 2023.	10.2 mmHg, LA pressure = 11.57 mmHg, and CO = 1.17 L/min.	
	Acceptable . Low uncertainty values demonstrate repeatability of the test system.	