

Credibility Decision Record — COU2 (VAD)

Decision Record

Field	Value
Context of Use	COU2: Ventricular Assist Device (VAD)
Device Class	Class III
Model Risk Level	5 (Very High)
Decision	NOT ACCEPTED
Decision Date	April 2, 2019
Criteria Set	ASME V&V 40-2018

Rationale

The computational model is NOT accepted for COU2 (VAD use) based on the following assessment:

- 1. Insufficient validation rigor for MRL 5:** While the PIV velocity comparison and hemolysis MIH comparison demonstrate reasonable agreement, the level of validation evidence does not meet the extensive requirements for Model Risk Level 5. The 15.8% MIH discrepancy is acceptable for relative ranking (COU1) but insufficient for absolute prediction of long-term cumulative hemolysis in VAD patients.
- 2. Uncertainty quantification performed but insufficient:** Monte Carlo propagation of dimensional tolerances (200 samples) provides initial UQ, but the 95% confidence interval on predicted MIH spans a factor of 2.5x, which is too wide for VAD safety decisions. Additional UQ on blood model parameters, boundary conditions, and turbulence model uncertainty is required.
- 3. Blood model limitations:** The Newtonian assumption, while acceptable for CPB (COU1, short-term), introduces unquantified bias for long-term VAD use where sub-lethal damage accumulation and non-Newtonian effects at lower shear rates become significant.
- 4. Missing credibility factors:** Several V&V; 40 credibility factors assessed as adequate for MRL 2 do not meet MRL 5 requirements. Specifically: test sample representativeness, equivalency of input parameters between model and comparator, and relevance of validation activities to the intended long-term COU require additional evidence.

Required Actions for Acceptance

To achieve acceptance for COU2, the following must be addressed: (a) expanded UQ covering all significant uncertainty sources, (b) non-Newtonian blood model comparison study, (c) long-term hemolysis correlation validation against clinical data, (d) formal assessment of all 13 V&V; 40 credibility factors at MRL 5 rigor.