

# Credibility Decision Record — COU1 (CPB)

## Decision Record

Field	Value
Context of Use	COU1: Cardiopulmonary Bypass (CPB)
Device Class	Class II
Model Risk Level	2 (Medium)
Decision	ACCEPTED
Decision Date	April 2, 2019
Criteria Set	ASME V&V 40-2018

## Rationale

The computational model is accepted for COU1 (CPB use) based on the following evidence:

- Mesh convergence:** Grid Convergence Index (GCI) of 0.9% on the fine mesh demonstrates adequate spatial discretization. Richardson extrapolation confirms asymptotic convergence.
- PIV velocity validation:** Average relative error of  $11\% \pm 9\%$  (90% confidence) between CFD predictions and PIV measurements of centerline velocity. Maximum relative error of 54% occurs near the inlet ( $x = 0.067$  m) where flow development effects are strongest. Agreement improves downstream where hemolysis-relevant shear stresses are highest.
- Hemolysis comparison:** CFD-predicted MIH values agree with in vitro measurements within 15.8% across all tested configurations. The model correctly ranks pump configurations by hemolysis severity, which is the primary requirement for this COU.
- Dimensional sensitivity:** The model identifies impeller-housing gap and volute cutwater gap as the dominant contributors to hemolysis variation, consistent with engineering expectations.

## Limitations and Caveats

No formal uncertainty quantification was performed for COU1. The Newtonian blood assumption limits applicability to shear rates above  $100 \text{ s}^{-1}$ . The model should not be used for absolute hemolysis prediction; it is accepted for relative ranking of dimensional configurations only.