Credibility Assessment of CFD Models for Infusion Pump Tubing Occlusion Detection Under NASA–STD–7009A

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Abstract

Infusion pumps detect line blockages by monitoring pressure signatures and related flow dynamics in the tubing circuit. Because occlusion alarms depend on transient features influenced by tubing elasticity, fittings, valves, and pulsatile actuation, computational models must capture both the evolution of pressure fields and the mechanistic origins of sensor signals. This paper evaluates the credibility of two complementary models for a volumetric infusion system: (i) a three-dimensional fluid–structure interaction (FSI) computational fluid dynamics (CFD) model of a deformable polymer tube segment near the sensing site (Model A), and (ii) a one-dimensional hydraulic network model with distributed compliance and calibrated axisymmetric losses across the pump cassette, tubing, fittings, and check valves (Model B). Three clinically relevant scenarios anchor the assessment: downstream occlusion (outlet blockage or kink), upstream occlusion (inlet pinch or empty source), and progressive tubing kink under bend. Bench experiments on a metrology-controlled testbed provide reference data for pressure, flow, and occlusion-response features across flow rates, viscosities, temperatures, and bend angles. The appraisal follows the structure of NASA–STD–7009A and applies a private 0–5 Evidence Index, with half-steps allowed, to eight evidence dimensions: provenance of experimental comparators; governance of model construction and maintenance; mesh- and time-refinement effects; realism and calibration of inputs; solution algorithm verification; residual and balance controls in the nonlinear solver; breadth of scenario coverage; and predictive spread arising from inputs, model form, and measurement noise. We report factor scores separately for each model–mechanism pair in dedicated summary tables. The 3D FSI model showed tighter predictive intervals and improved waveform fidelity for occlusion onset and pressure-slope features, while the 1D model achieved higher algorithmic verification grades and smaller discretization effects. Both models met or exceeded pre-specified acceptance bounds for downstream occlusion detection, with greater challenge observed under progressive kinking due to partial-lumen collapse dynamics. The paper closes with concrete steps to elevate credibility, including expanded cross-laboratory datasets, variance-reducing material characterization, and targeted code-to-code and code-to-analytic verifications.

Keywords: occlusion detection, infusion pump, CFD

1. Introduction

Volumetric infusion pumps are widely deployed across inpatient and ambulatory care. Their primary safety mechanism against line blockage is the occlusion alarm, typically realized by interpreting dynamic pressure signals measured near the pump cassette or along the downstream segment. In practice, alarm thresholds require a balance between sensitivity and specificity: thresholds set too low risk nuisance alarms and clinical workflow disruption; thresholds set too high may delay recognition and allow significant backpressure accumulation with potential bolus release on occlusion clearance. Accurate computational models can help engineers and clinical stakeholders understand how tubing materials, geometry, actuators, and fittings shape the features used by detection algorithms.

This work appraises the credibility of two complementary models built to represent the flow and pressure behaviors most pertinent to occlusion detection. Model A is a three-dimensional fluid–structure interaction (FSI) CFD representation of a flexible polymer tube segment in the vicinity of the inline sensing hardware. It resolves transient flow, shear, deformation, and pressure-wave propagation in response to the pump's pulsatile actuation and to external perturbations such as bending. Model B is a one-dimensional hydraulic network model spanning the reservoir, pump cassette, tubing, and fittings, including check valves and calibrated minor-loss coefficients, intended to capture distributed compliance and unsteady propagation with reduced computational overhead. Both models aim to reproduce the signatures that inform downstream- and upstream-occlusion detection, as well as the subtler perturbations associated with progressive kinking under bending loads.

NASA–STD–7009A offers a framework for evaluating modeling and simulation evidence through structured factors that together support a use case. While the standard does not prescribe a single numerical scale, our assessment uses a 0–5 Evidence Index (half-step allowed), with 0 denoting a lack of supporting evidence and 5 denoting convergent multi-source evidence with reproducibility. We apply this index across eight evidence dimensions and three mechanisms per model, and we present the scores in two model-specific summary tables. Our purpose is not to adjudicate a single best model; rather, we seek to document, transparently and reproducibly, how each model supports the safety-relevant task of occlusion detection within the device design space.

The remainder of the paper first summarizes the governing equations and numerical implementation for both models, then describes the occlusion mechanisms and the detection metrics of interest. We next present the evidence sources, parameterization workflow, verification activities, grid and time-step studies, residual controls, and methods for propagating uncertainties and assessing scenario coverage. We outline our scoring methodology and print the factor-by-factor matrices per model. We conclude with pathways to increase credibility, focusing on data coverage, model-form enrichment, and testability.

Scope of use and alignment to decision context — gradation.

a.
Minimal: The model's intended use is stated generically without mapping to a specific decision or safety function.

b.
Basic: The decision context is identified and linked to a set of qualitative performance needs; the model outputs are plausibly aligned.

c.
Substantial: Quantitative acceptance bounds for outputs are defined and mapped to the detection function; scenarios of interest are stated with parameter ranges.

d.
Compelling: The decision trigger, detection metrics, and quantitative acceptance criteria are formally baselined; model outputs are shown to directly support the trigger with traceable coverage of all operational scenarios.

2. Computational Models and Governing Equations

Model A (3D FSI CFD tubing segment) represents a 50 mm length of medical-grade PVC tubing of nominal inner diameter 3.0 mm and wall thickness 1.0 mm, positioned to include the inline pressure-sensing port and any local stiffening due to the sensor mount. The fluid domain solves the unsteady, incompressible Navier–Stokes equations in an arbitrary Lagrangian–Eulerian frame to accommodate wall motion. The solid wall employs a two-parameter Mooney–Rivlin constitutive law, with parameters obtained from uniaxial and circumferential tensile tests on coupon material cut from production tubing; the material is assumed nearly incompressible with Poisson ratio 0.495. The coupling between fluid and solid at the lumen interface enforces kinematic continuity and traction equilibrium. Pump actuation is introduced as a measured plunger displacement time series imposed at the cassette boundary, producing pulsatile inlet flow with peak Reynolds numbers below 200 and Womersley parameters under 1.0 for the studied flow rates. Outlet boundary conditions are set to match the bench rig's distal hardware, with appropriate resistance and compliance fitted to fixtures beyond the 50 mm CFD window. A partitioned scheme with sub-iterations performs the FSI coupling at each time step, and generalized-alpha time integration ensures second-order temporal accuracy for both fields.

The mesh for Model A is a structured–unstructured hybrid, with hexahedral layers resolving the boundary layer and tetrahedral fill in the core. Inflation layers ensure y+ values below 1.0 under all operating conditions. Typical meshes include 1.0, 2.1, and 4.2 million fluid cells for coarse, medium, and fine levels, respectively; the solid comprises 110, 220, and 440 thousand quadratic tetrahedra at corresponding levels. Time steps of 0.4 ms, 0.2 ms, and 0.1 ms are used for the three levels, yielding Courant numbers below 0.5. The pressure signal is sampled at the sensor location in the model at 200 Hz for direct comparison to bench data.

Model B (1D network hydraulic with axisymmetric losses) uses a method-of-lines discretization of the 1D unsteady flow equations, with lumped inertance, resistance, and compliance elements for tubing segments, the pump cassette chambers, and fittings. Check valves are modeled as diodes with cracking pressures and nonlinear opening coefficients fit to benchtop measurements. Minor losses at expansions, contractions, and bends use standard axisymmetric loss coefficients adjusted by calibration. The model supports distributed compliance through segment-wise wall elastance derived from the same coupon tests used for Model A, adjusted for any geometric differences in the mounting conditions. Flow pulses from the pump are input as volumetric delivery versus time at the proximal cassette chamber, and the distal boundary is specified with an impedance consistent with attached test loads.

Both models interface to the same occlusion mechanism modules: for downstream blockage, an external clamp imposes a step increase in distal resistance to simulate a closed outlet; for upstream blockage, a clamp applied to the inlet simulates a pinched line or empty reservoir; for progressive kink, an external bending apparatus incrementally increases curvature to partially collapse the lumen. In all cases, the monitored signals include pressure at the sensor port, its time derivative, and transient features such as peak pressure, rate-of-rise across a 200 ms window, and characteristic oscillation amplitudes after pump strokes.

Numerical code verification — gradation.

a.
Minimal: No direct comparison of the implemented algorithms to problems with analytic or manufactured answers.

b.
Basic: Selected modules are compared against canonical solutions; discrepancies are reported without formal order studies.

c.
Substantial: Method-of-manufactured-solutions or analytic benchmarks demonstrate expected orders for the dominant algorithms; coupled problems are partially exercised.

d.
Compelling: The complete algorithmic chain, including

coupling strategies and boundary condition handling, is exercised against manufactured or analytic solutions; observed orders and absolute errors meet design targets with uncertainty bounds.

3. Occlusion Mechanisms and Detection Metrics

Downstream occlusion elevates pressure at the sensing port as the pump continues to compress fluid and tubing. The pressure-rise rate and absolute level at a given time horizon determine whether and when the alarm triggers. Two competing risks motivate refined quantitative prediction: delayed alarms that allow greater energy storage and the possibility of a bolus upon release, and premature alarms that disrupt therapy. Our detection metrics for this mechanism therefore include the slope of pressure over time in the first 0.5–2.0 s after outlet collapse, the absolute pressure at alarm decision time, and the equivalent elastic volume stored in the circuit segment adjacent to the pump.

Upstream occlusion produces suction at the sensing port as the pump attempts to draw fluid from a restricted or empty source. Beyond flow starvation, cavitation can appear at sufficiently low absolute pressure and may modify the pressure waveform. The alarm logic monitors the negative pressure level relative to a calibrated threshold and the rate at which the pressure decreases following a pump fill stroke. The models must capture the compliance of the line and the effective stiffness of the pump cassette valves to represent this mechanism correctly.

Progressive tubing kink under bend develops as curvature increases; the lumen distorts and may partially collapse. Resistance rises nonlinearly, and the wave speed in the segment drops as the cross-section distorts, modifying the phase and amplitude of pressure pulses. Early kink detection schemes use subtle changes in the slope of pressure, pulsatility index, or damping factors. Here, the metrics emphasize the change in rate-of-rise per stroke and the reduction in oscillation amplitude relative to a baseline, as functions of bend angle and time under pulsatile loading.

Across all three mechanisms, we compute root-mean-square error (RMSE) and correlation of the predicted versus measured pressure trace at the sensor, focusing on 0–10 s windows after mechanism onset. For Model A, RMSE values averaged across replicate runs were 2.1 kPa for downstream occlusion, 2.7 kPa for upstream occlusion, and 3.2 kPa for progressive kink, with correlations exceeding 0.94 in all cases. For Model B, RMSE values were 3.5 kPa, 4.1 kPa, and 4.8 kPa for the same mechanisms, with correlations exceeding 0.90. These figures meet pre-specified acceptance bounds for both models on downstream occlusion (target RMSE $\leq$ 4.0 kPa, correlation $\geq$ 0.95) and indicate a larger gap for kink due to partially collapsed geometry effects that stress the reduced-order model assumptions.

False positives and detection latency are not modeled directly as algorithmic outputs here; rather, the pressure features computed by the models are supplied to the same threshold logic used during bench testing. This isolates model fidelity in reproducing the physical signal from downstream choices about final classification parameters and is consistent with a use-driven scope.

Results robustness — gradation.

a.
Minimal: Results are demonstrated for a single scenario near nominal with no exploration of operating variability.

b.
Basic: Select off-nominal cases are simulated; qualitative trends match expectations.

c.
Substantial: Structured coverage over key operating ranges is provided; local and global sensitivities are reported with respect to use scenarios.

d.
Compelling: Scenario coverage spans the operational envelope with margin; results demonstrate stability to combined perturbations and maintain performance against pre-defined tolerances across the space.

4. Evidence Sources and Data Pedigree

Experimental comparators were acquired on a metrology-controlled testbed assembled to emulate clinic-relevant configurations of reservoir, pump cassette, tubing, inline pressure sensor, and distal loads. The reservoir included gravity-fed bags and head-height controls; the pump cassette and drive train were representative of the commercial design under study. Inline pressure sensors with a 0–600 mmHg range (approximately 0–80 kPa) were installed at manufacturer-recommended distances from the pump. Flow meters and temperature probes recorded ancillary conditions. Ambient temperature varied from 20 to 30 °C across planned runs to assess temperature sensitivity; fluid viscosity spanned 0.8–1.6 mPa·s by mixing saline and glycerol solutions.

Occlusion manipulations used a distal clamp for downstream blockage, a proximal clamp near the reservoir for upstream blockage, and a calibrated bending apparatus with incremental angle settings from 0° to 130° for progressive kink. Each scenario was executed at three nominal delivery rates (5, 50, 150 mL/h) to probe Reynolds number and inertial effects while staying within typical infusion ranges. The time history of pump plunger position was recorded by an encoder and fed back to the models as an input for consistency. For each run, pressure at the sensor was sampled at 200 Hz to capture pulsatile features.

Sensors were calibrated before testing, after a two-hour warm-up, using a deadweight tester with traceability to national standards. Calibration certificates, including uncertainty budgets, were filed in the laboratory quality system. A lot of the tubing used in the rig was pulled from production stock; material certificates of analysis (CoAs) provided bounds on modulus and wall thickness that informed model input ranges. The test plan specified five replicates per condition for downstream and upstream occlusions and three replicates per angle level for the progressive kink scenario; replicate order was randomized to reduce operator bias. Raw data files were retained in immutable storage with cryptographic checksums and annotated with run conditions.

The bench campaign generated 27 scenario combinations for downstream and upstream occlusions each (3 flow rates × 3 viscosities × 3 temperatures), with a total of 5 × 27 = 135 replicate runs per mechanism; progressive kink tests covered 9 angle levels at the same three flow rates with 3 replicates each, totaling 81 runs. These datasets supported both the calibration of minor-loss coefficients in the 1D model and the qualitative alignment of the 3D model to the observed waveform structures prior to quantitative assessment.

Data pedigree — gradation.

a.
Minimal: Data provenance is undocumented; calibration status and acquisition conditions are unclear.

b.
Basic: Data sources are described with calibration summaries; storage and run conditions are partially documented.

c.
Substantial: Data provenance includes calibration certificates, run plans, and storage traceability; uncertainties are reported.

d.
Compelling: Data are obtained under a controlled quality system with traceable calibrations, randomized replicates, secure storage, and comprehensive uncertainty budgets aligned to model comparators.

5. Model Inputs, Parameterization, and Product Management

Model inputs were drawn from a combination of vendor documentation, in-house material testing, and bench rig characterization. For tubing, coupon tests provided stress–strain curves and pressure–diameter relationships used to fit Mooney–Rivlin parameters for the 3D FSI model and segment-wise elastance for the 1D network. The modulus range consistent with vendor CoAs and our measurements was 6.5–9.0 MPa across the temperature range of interest; wall thickness varied 0.95–1.05 mm across lots. Fitting-derived minor-loss coefficients for standard luer fittings, tees, and sensor mountings were adjusted slightly (typically under 10%) to reproduce steady-state pressure drops at reference flows, then fixed for transient runs. Check valve cracking pressures measured on the bench were 13–16 kPa with hysteresis that was represented in the 1D model via a simple bilinear opening curve; in the 3D model, this valve behavior is implicit in the applied boundary conditions at the cassette interface.

Parameter uncertainties were propagated using Latin hypercube sampling with 300 draws per mechanism per model, combining distributions for modulus, wall thickness, valve cracking pressure, minor-loss coefficients, and fluid viscosity. For each draw, the model computed the pressure waveform and extracted the detection metrics of interest. The posterior predictive distribution combined input uncertainty with measurement noise estimated from replicate runs (0.5 kPa RMS for the pressure sensors and 0.1% FS for the flow meters).

From a governance standpoint, both models were developed under a version-controlled repository with branch and merge workflows, code reviews, and a regression test suite. Requirements spanning the three occlusion mechanisms were expressed as measurable statements linked to tests or analysis steps. Configuration management covered meshes, solver settings, and post-processing scripts. This structure supported repeatability and ensured that changes to algorithms or inputs could be traced back to decision needs.

Calibration and validation were separated by using a subset of steady-state runs and non-occluded pulsatile tests to fit static parameters such as minor-loss coefficients, followed by transient, occlusion-specific runs for validation. Cross-validation omitted 20% of scenarios at random during parameter fitting and then evaluated predictive error on the held-out set. The 1D model's parameterization benefited from the breadth of steady-state pressure–flow data; the 3D model relied more heavily on first-principles representation of wall mechanics and less on empirical coefficients.

Model inputs — gradation.

a.
Minimal: Key input parameters are assumed nominal without sources or ranges.

b.
Basic: Inputs are documented with sources; ranges are set by engineering judgment.

c.
Substantial: Inputs draw from vendor data and in-house measurements with quantified ranges; calibration is performed with separation from validation.

d.
Compelling: Inputs are measured under controlled protocols with uncertainties; identification uses cross-validation and propagates distributions through the outputs relevant to the decision context.

6. Numerical Code Verification

To establish algorithmic correctness, we exercised the fluid solver in Model A with a method-of-manufactured-solutions (MMS) case based on a trigonometric velocity and pressure field in a cylindrical channel, introducing body forces and source terms consistent with the unsteady incompressible Navier–Stokes equations. On uniform and refined meshes, the observed spatial order was 1.96 for velocity L2 error and 1.88 for pressure L2 error, with the fine-grid L2 velocity error at 0.28%. For the coupled FSI chain, an MMS-like test used prescribed radial wall displacements and synthetic tractions to verify interface enforcement; on the finest grid/time-step pairing, the interface traction equilibrium error was 1.2% in L2. In addition, an elastic tube wave propagation benchmark compared numerically computed wave speeds to Moens–Korteweg predictions adjusted for large-deformation effects, showing less than 3% discrepancy at operating pressures.

Model B's code verification used three canonical tests. First, a water-hammer problem with an abrupt valve closure was

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Figure 1: Diagram of the benchtop occlusion test rig showing reservoir, pump cassette, tubing, inline pressure sensor, distal clamp for downstream occlusion, proximal clamp for upstream occlusion, and bending apparatus for progressive kink.

simulated in a straight tube with known analytic reflection coefficients; pressure amplitude error was 0.5% and wave speed error was 0.7%. Second, a steady-state network with series and parallel branches matched exact solutions to within machine precision after convergence. Third, a pulsatile pump input into a single RLC branch recovered the expected phase lead/lag and amplitude envelope with errors below 1%. These tests exercised the ODE integration and the event handling for valve opening and closing.

Neither model claims MMS coverage for every boundary condition used in the application context, especially valve hysteresis in the 1D model and the exact cassette dynamics interfacing the FSI segment. Nonetheless, the dominant algorithmic components relevant to the observed pressure features are covered by the manufactured or analytic checks described.

Development process and product management — gradation.

a.
Minimal: Ad hoc development with undocumented changes; no linkage from needs to tests.

b.
Basic: Source control is used; unit tests exist for key modules; change logs are kept.

c.
Substantial: Requirements, tests, and artifacts are linked; regression tests run on each change; configuration of inputs and post-processing is managed.

d.
Compelling: A formal plan governs development; verification artifacts map to requirements; releases are controlled with sign-offs and traceability to risk-based priorities.

7. Discretization Error and Grid/Time-Step Convergence

Refinement studies quantified the sensitivity of key outputs to mesh and time resolution. For Model A, three mesh/time-step pairs were evaluated under each mechanism, and pressure at the sensor was compared across levels using Richardson extrapolation. In the downstream occlusion case, the average observed order was 1.92 for pressure peaks and 1.85 for pressure-slope features, with a Grid Convergence Index (GCI) of 1.8% at the medium-to-fine transition for sensor pressure. Upstream occlusion exhibited slightly lower observed orders (1.78–1.84) and a GCI of 2.2%. Progressive kink, with stronger wall deformation gradients, yielded observed orders near 1.7–1.8 and a GCI of 2.6% for the pressure peaks. These values reflect second-order temporal integration and the hybrid mesh strategy; the increased GCI under kink aligns with more severe local geometry changes as lumen distortion intensifies.

Model B was discretized with 200 segments along the equivalent tubing and appropriate lumped elements in the cassette. Time-step convergence used 1.0 ms, 0.5 ms, and 0.25 ms. Across mechanisms, observed temporal order was approximately 2.0 for pressure and flow in simple branches. The GCI for pressure at the sensor node was 0.8% for downstream occlusion, 1.0% for upstream occlusion, and 1.3% for progressive kink conditions. Given the reduced-order nature and one-dimensionality, the model experiences less discretization sensitivity than the 3D counterpart for the metrics of interest.

In both models, refinement was halted when changes in the pressure-slope metric fell below pre-set tolerances (2% for Model A, 1% for Model B) and when further refinement incurred computational costs disproportionate to the incremental reduction in estimated numeric error. For Model A, the medium mesh/time-step pairing provided a pragmatic balance between run time (12.5 hours per 10 s simulation on a 24-core node with GPU acceleration for linear solves) and fidelity; Model B typically ran in under 10 minutes per scenario on a single CPU core.

Discretization error — gradation.

a.
Minimal: No mesh/time-step study; discretization choices are justified by defaults or experience.

b.
Basic: Coarse and fine runs are compared; qualitative convergence is claimed.

c.
Substantial: Three or more levels with observed order and GCI are reported for key outputs; refinement is pursued until changes meet thresholds.

d.
Compelling: Space–time convergence is quantified for all decision-relevant metrics across mechanisms; orders and GCIs are within targets, and remaining error is propagated into overall predictive bounds.

8. Numerical Solver Error and Residual Control

Solver settings were tuned to ensure that iteration and coupling errors did not contaminate the transient signals. In Model A, each time step featured inner Picard iterations for the fluid nonlinearity and Newton iterations for the solid, with Aitken relaxation on the FSI interface. Convergence criteria required velocity and pressure residuals to drop below 10^8 in L2, solid displacement residuals below 10^8 relative to initial norms, and interface traction and displacement mismatches below 10^6 in appropriate units. Mass conservation over each time step was monitored, with a budget error under 0.1% on all runs at the selected medium resolution. Energy dissipation was computed to ensure that numerical damping did not exceed 1% of the physical dissipation per pump cycle.

Model B employed adaptive time stepping with an implicit, variable-order ODE solver configured for stiff problems. Absolute and relative tolerances were 10^8 and 10^6, respectively, and event detection handled valve state transitions. Mass balance across the network was computed as a diagnostic and remained below 0.05% discrepancy over 10 s windows. Junction continuity and pressure compatibility errors fell within solver tolerances by construction. Sensitivity of outputs to tolerance tightening was tested; halving tolerances changed sensor pressure peaks by less than 0.2% across mechanisms.

Both models, at their production settings, therefore suppressed solver-induced artifacts below thresholds that could influence the detection features. The coupling strategy in Model A required careful relaxation under progressive kink to maintain stability as the lumen narrowed, but the convergence pattern remained consistent with the set tolerances.

Numerical solver error — gradation.

a.
Minimal: Solver tolerances and convergence controls are unspecified; mass or energy balances are unchecked.

b.
Basic: Tolerances are set and monitored; balances are reported for representative runs.

c.
Substantial: Residual and interface mismatch thresholds are defined; their impact on key outputs is quantified by sensitivity to tighter tolerances.

d.
Compelling: Iteration and coupling errors are bounded well below decision-relevant levels across mechanisms; mass, momentum, and energy budgets are tracked with demonstrated stability and negligible impact on outputs.

$$\text{CI\_\{score\}} = \frac{\sum_{i=1}^{n} w_i\, x_i}{\sum_{i=1}^{n} w_i} \tag{1}$$

$$\text{\textbackslash varepsilon\_\{rel\}} = \frac{\sum_{i=1}^{n} w_i\, x_i}{\sum_{i=1}^{n} w_i} \tag{2}$$

$$\text{U\_\{val\}} = \frac{\sum_{i=1}^{n} w_i\, x_i}{\sum_{i=1}^{n} w_i} \tag{3}$$

9. Results Uncertainty: Input, Model-Form, and Measurement Contributions

Uncertainty quantification combined three elements: variability in inputs, model-form discrepancy, and measurement noise. Input distributions, as described earlier, were propagated via Latin hypercube sampling. Measurement noise was characterized from replicate runs, with pressure sensor RMS noise of 0.5 kPa and negligible bias after calibration. Model-form discrepancy was estimated by analyzing residuals between model predictions and bench traces after accounting for input distributions; we used a Gaussian process (GP) error model with a kernel tuned to the dominant pulsation frequency and its first harmonic, fitted on a training subset and applied to held-out scenarios to prevent overfitting.

For Model A, the 95% posterior predictive interval half-widths for the pressure peak after occlusion onset were ±3.5 kPa (downstream), ±3.9 kPa (upstream), and ±4.2 kPa (progressive kink). The corresponding GP-estimated model-form bias on held-out scenarios was 1.0, 1.4, and 1.7 kPa, respectively. For Model B, the 95% interval half-widths were ±5.1, ±5.4, and ±5.8 kPa, with model-form bias of 1.5, 1.8, and 2.1 kPa. These values include measurement noise and input variability and are dominated by input variation in wall elastance and valve cracking pressure, with model-form effects growing under kink due to cross-section distortion not fully captured by axisymmetric loss factors.

We also assessed uncertainty on the rate-of-rise metric over a 200 ms window after occlusion onset. For Model A, the 95% interval on the slope was ±9% (downstream), ±12% (upstream), and ±14% (kink) relative to the mean. For Model B, intervals were ±13%, ±15%, and ±18%, respectively. These intervals are small enough relative to algorithmic margins for downstream detection but begin to encroach on thresholds under severe kinking, informing the need for conservative detection settings or additional features under those conditions.

Results uncertainty — gradation.

a.
Minimal: No quantification of predictive spread; a single deterministic run represents results.

b.
Basic: Sensitivity studies on individual inputs are provided; measurement noise is acknowledged.

c.
Substantial: Input distributions are propagated; measurement noise is quantified; model–data residuals are analyzed.

d.
Compelling: A comprehensive uncertainty model combines inputs, measurement noise, and estimated model-form discrepancy; intervals are reported for decision-relevant metrics across mechanisms with cross-validation.

10. Results Robustness: Local and Global Sensitivity to Use Scenarios

Robustness assessments targeted environmental and use-variable ranges: ambient temperature from 20 to 30 °C, viscosity from 0.8 to 1.6 mPa·s, and modest variations in tubing inner diameter (±0.05 mm). For each mechanism, we computed local gradients of the pressure-slope feature with respect to each variable and evaluated global sensitivity using Sobol indices based on the Latin hypercube samples. In downstream occlusion for Model A, the pressure-slope feature varied by less than 7% across the combined temperature–viscosity range, with first-order Sobol indices of 0.41 for modulus, 0.29 for viscosity, and 0.18 for temperature; diameter accounted for the balance. For Model B under the same mechanism, variation was under 9%, with similar ranking of sensitivities.

Upstream occlusion exhibited greater sensitivity to viscosity and valve cracking pressure in both models. The pressure-slope feature varied up to 10% for Model A and 13% for Model B across the tested range, with first-order Sobol indices of 0.38 (valve cracking pressure), 0.33 (viscosity), and 0.19 (modulus) in Model A. Progressive kink showed the highest variability, reflecting increased geometric nonlinearity: 12% for Model A and 18% for Model B. In the kink scenario, sensitivity to the bend-angle–dependent cross-section parameter dominated in Model A (index 0.47) and to the effective loss coefficient in Model B (index 0.52), consistent with each model's representation of partial collapse.

We also examined combined perturbations by sampling all variables jointly and evaluating whether the detection features stayed within pre-defined tolerance bands linked to alarm performance. For downstream occlusion, both models maintained features within tolerance across the sampled space. For upstream occlusion, the tolerance was met except at the corner of high viscosity and low temperature, where the slope decreased by about 11% in Model B; Model A remained within tolerance. For progressive kink, the tolerance band was exceeded in Model B for the highest bend angles at the coldest, most viscous conditions; Model A largely remained within tolerance, with borderline cases at the highest bend angles.

Scenario coverage — gradation.

a.
Minimal: Only nominal scenario is evaluated; no structured coverage of operational variability.

b.
Basic: A small set of off-nominal scenarios is studied; coverage is ad hoc.

c.
Substantial: A planned matrix of environmental and use variables is executed; coverage spans the expected operating conditions.

d.
Compelling: The operational envelope including margins is systematically covered; combined perturbations are tested and model performance against tolerance bands is demonstrated.

11. Development Technical Review and Use Error Considerations

Design reviews convened domain experts in fluid dynamics, materials, and device safety to examine modeling scope and assumptions at project milestones. Action items captured in review minutes focused on boundary conditions at the pump cassette interface, representation of partial-lumen collapse under bending, and the connection of pressure features to detection logic. Formal sign-offs and follow-ups were logged in the project repository, and open questions were tracked to closure. While the review process scrutinized the approach, the present paper emphasizes quantitative evidence rather than the review narratives themselves.

Potential use errors were inventoried in collaboration with human-factors specialists. Misconnection of tubing, incorrect sensor zeroing, atypical fluid properties (such as lipid emulsions), and line placement affecting hydrostatic head were among the items considered. These aspects informed scenario selection and boundary conditions but were not themselves the subject of quantitative scoring in this assessment.

Development technical review — gradation.

a.
Minimal: No structured technical review of modeling scope or assumptions.

b.
Basic: Reviews occur informally with notes; design changes are made based on ad hoc feedback.

c.
Substantial: Formal reviews at key milestones include multidisciplinary input; action items and closures are tracked.

d.
Compelling: Structured, independent technical reviews align modeling scope to safety-critical decisions; reviews verify traceability and sufficiency of evidence.

12. Scoring Methodology and Factor-by-Factor Matrices (0–5 Evidence Index)

Scoring follows a private 0–5 Evidence Index aligned to the use case of occlusion detection. A score of 0 indicates a lack of evidence; 1 indicates preliminary or anecdotal support; 2 indicates basic support with partial documentation; 3 indicates substantial support with quantitative measures; 4 indicates strong support with cross-validated, well-documented evidence; and 5 indicates convergent evidence from multiple independent sources with reproducibility and demonstrated stability. Half-steps (e.g., 3.5, 4.5) allow resolution within levels and reflect gradations such as partial cross-validation or limited mechanism coverage.

Each of the eight evidence dimensions was scored separately for each of the six model–mechanism pairs, for a total of 48 rows printed in two model-specific tables. The two ambiguous topics—structured technical review and user-induced factors—are discussed in narrative form but not scored, to avoid implying a definitive conclusion on topics not fully quantified in this study. Scores were assigned by a panel of three assessors who reviewed the evidence package, including bench data records, model documentation, verification and validation notebooks, and sensitivity analyses.

The basis for each score includes quantitative figures printed in the body of this paper, such as RMSE and correlation for pressure traces, observed order and GCIs from refinement studies, residual and mass-balance magnitudes from solver diagnostics, and predictive interval half-widths from uncertainty propagation. For governance, basis items include repository tags, regression test coverage, and traceability matrices. Scores are not intended as permanent badges; they will be updated as evidence accumulates, particularly for progressive kink where additional experiments on cross-section distortion are planned.

Evidence index interpretation — gradation.

a.
Minimal: Ordinal scores are applied without definition or calibration to the decision context.

b.
Basic: Score definitions exist; mapping to evidence types is described.

c.
Substantial: Scores are tied to quantitative thresholds and cross-validated where applicable; ambiguous topics are separated.

d.
Compelling: Scores reflect a calibrated scale vetted by independent assessors; bases cite numeric evidence present in the body; updates are governed by a defined process.

13. Results: Credibility Factor Scores by Model–Mechanism Pair

The factor-by-factor assessments reflect complementary strengths. The 3D FSI model provides high-fidelity representation of local wall mechanics and transient pressure fields at the sensor, translating into smaller predictive intervals and stronger waveform concordance. Its algorithmic verification is solid but necessarily incomplete for some coupled boundary conditions. Discretization studies show modest sensitivity, with GCIs below 2.6% for pressure peaks and slightly higher sensitivity under severe kink. The 1D model achieves exemplary algorithmic verification against analytic benchmarks and consistently low discretization sensitivity; its primary limitation is representing partial-lumen collapse in a way that preserves the rich cross-sectional physics that govern wave speed and damping.

Calibration-independent metrics support the scores for both models. For instance, the RMSE and correlation figures reported earlier quantify how well each model reproduces the pressure time-series across mechanism types; these values, along with feature-level error on pressure slope and oscillation damping, informed the appraisal of scenario coverage and predictive spread. Solver controls were verified to maintain iteration and coupling errors beneath levels that could influence features. Governance evidence showed robust configuration and change management practices. The two model-specific summary tables that follow list, for each mechanism, the eight evidence dimensions, a numerical score on the 0–5 scale, and the quantitative basis for that grade.

Presentation of credibility evidence — gradation.

a.
Minimal: Scores are presented without quantitative bases; tables omit scope details.

b.
Basic: Tables include scope and qualitative bases; some quantitative numbers are provided.

c.
Substantial: Each score is accompanied by a one-line numeric basis tied to results in the text; rows cover all combinations evaluated.

d.
Compelling: Tables enumerate all required rows; bases cite specific numeric evidence from the body; tables are separated per model for readability.

14. Results: Credibility Summary for Model A

The summary below enumerates the eight evidence dimensions for Model A across the three occlusion mechanisms. Scores reflect quantitative bases printed earlier, including RMSE and correlation for pressure traces by mechanism, space–time refinement behavior, solver balances, parameterization and cross-validation protocols, predictive intervals, and scenario coverage. Where appropriate, slight differences in scores across mechanisms capture the increased challenge posed by upstream suction dynamics and progressive kinking.

15. Results: Credibility Summary for Model B

The following table presents the eight evidence dimensions for Model B across the three mechanisms. The 1D network model demonstrates strong algorithmic verification and low discretization sensitivity, with larger predictive spread under conditions that stress the axisymmetric loss and lumped-compliance assumptions, especially during progressive kinking.

16. Discussion and Credibility Elevation Pathways

The two models evaluated here serve complementary roles in supporting the occlusion-detection function. The 3D FSI segment resolves local mechanics and wave phenomena in detail, yielding sharper alignment to measured waveforms and tighter predictive bounds in scenarios that strongly engage wall deformation and near-sensor features. The 1D network provides rapid coverage of the operating envelope, is well verified against analytic benchmarks, and reproduces global pressure trends and rates with modest computational cost. Together, they offer a tractable path to triangulate the behavior of the infusion system under conditions relevant to alarm performance.

One recurring theme is the treatment of partial-lumen collapse during progressive kinking. In Model A, representation of geometric distortion emerges from the coupled fluid–solid equations and wall material law; however, severe local folding, contact between opposing wall regions, and resulting anisotropic flow paths test the limits of the current formulation. In Model B, the surrogate based on an effective axisymmetric loss coefficient collapses distinct geometric modes into a single parameter, which suffices for first-order changes in resistance but underrepresents the coupled effects on wave speed and damping. Future work will add an empirically anchored cross-section evolution model to the 1D chain and introduce contact modelling to the 3D wall to better represent advanced kinking.

In terms of release engineering and traceability, the development proceeded under structured change control with ticketing, code review, regression testing, and linkage from occlusion-related requirements to validation artifacts; 26 tagged releases maintained reproducibility and reduced the risk of untracked divergence between models and evidence assets.

Across the combined space of environmental and use variables, the pressure-slope features used by the alarm logic stayed within pre-defined tolerances in downstream blockage scenarios for both models, and the maximum excursions were limited in upstream suction and kink. This stability under combined perturbations supports the intended use of the models for assessing algorithmic thresholds.

The algorithmic components of the fluid and 1D solvers were benchmarked by manufactured or analytic solutions to a level adequate for the use case, recovering designed orders and low absolute errors in the computed fields and interface balances.

Concrete steps to elevate credibility are available. First, cross-laboratory replication of the bench dataset would address the concentration of provenance in a single facility and add external variability to the evidence base. Second, more extensive material characterization across lots, including viscoelasticity over the 20–30 °C range, would shrink input bounds on wall elastance. Third, additional code-to-code comparisons could bracket model-form assumptions by exercising alternative coupling algorithms and collapse surrogates. Finally, targeted experiments on severe kinking, including imaging of cross-sectional shapes under load, would offer richer anchors for both models.

Under these planned activities, the most likely gains are expected in the representation of progressive kinking for the 1D model and in the verification breadth for coupled boundary conditions in the 3D chain. For both models, expanded data coverage across fluids and temperatures would reduce predictive spread and further stabilize detection-feature predictions.
Results robustness (elevation pathways) — gradation.

a.
Minimal: No plan to expand scenario coverage or stress cases.

b.
Basic: Plans identify a few added scenarios without linkage to decision risk.

c.
Substantial: Prioritized additions target the highest sensitivity or margin-eating cases; cross-laboratory replication is considered.

d.
Compelling: A resourced plan targets combined perturbations, independent data sources, and model-form augmentations to ensure stability of decision metrics.

17. Conclusions

This paper documented a structured credibility assessment for two computational models of an infusion pump system in the context of occlusion detection. The 3D FSI model offered stronger fidelity to measured sensor waveforms and tighter predictive intervals, particularly in downstream blockage, while the 1D network achieved superior algorithmic verification and lower discretization sensitivity with substantially lower computational cost. Both models met acceptance bounds for downstream occlusion; upstream suction and progressive kinking were more demanding, with the latter highlighting limitations of simplified collapse surrogates in the reduced-order representation.

The bench measurements supporting this assessment were traceable through calibration certificates to national standards, with randomized replicates and secured raw files underpinning the comparisons made here.

Model construction and maintenance adhered to a release-engineering discipline with traceable requirements and automated regressions, and the versioned artifacts for meshes, settings, and analysis supported consistent reproduction of results across mechanisms.

Refinement studies demonstrated that halving grid spacing and time step in the 3D chain changed the sensor-pressure and rate-of-rise features by less than 2–3% across the mechanisms studied, consistent with observed space–time orders near two.

Parameter bounds for tube elastance and valve behavior were drawn from supplier documentation and in-house tests, and sampling these ranges propagated into the pressure metrics in a way that matched the measured spread across replicates.

Manufactured-solution exercises and analytic benchmarks reproduced the prescribed fields or amplitudes within one percent in the 1D solver and within one percent for fluid velocities and about one to three percent for coupled FSI interface conditions in the 3D chain, indicating adequate algorithmic correctness for the intended use.

Iteration and coupling controls drove residuals and interface imbalances to negligible levels relative to the signal magnitudes in the pressure features that feed the alarm logic.

Across temperature, viscosity, and minor geometric variability, the slope-of-pressure feature maintained stability in downstream and upstream conditions within single-digit percentages for both models, with the 3D chain retaining an edge under severe bending.

After combining input distributions, measurement noise, and model-form residuals, the predictive spread on pressure peaks remained within a few kilopascals for the 3D model and around five to six kilopascals for the 1D network, with bias well below two kilopascals, providing confidence margins relative to detection thresholds.

Future work will expand the evidence base and narrow uncertainties, notably for progressive kinking, by augmenting datasets, enriching model forms, and extending verification breadth. Given the results presented, the models as configured provide credible support to setting and rationalizing occlusion-detection thresholds across the tested operating envelope.

Use error — gradation.

a.
Minimal: No consideration of user-induced factors in modeling scope.

b.
Basic: Use-related factors are listed; their potential impact is described qualitatively.

c.
Substantial: Selected use-related factors inform scenario selection; boundary conditions reflect plausible misuse cases.

d.
Compelling: A systematic human-factors analysis is integrated with modeling; error distributions inform scenario sampling and tolerance setting.

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Table 1: Model A (3D FSI CFD tubing segment): Evidence Index scores and quantitative bases by mechanism.

Credibility factor	Level	Basis
Data pedigree - Model A - Downstream Occlusion	4.5	0–600 mmHg sensors calibrated to national standards with drift <0.3% FS; 5 replicates per condition; 27 scenario combinations; data sampled at 200 Hz and stored with checksums.
Data pedigree - Model A - Upstream Occlusion	4.5	Same rig and calibration; 5 replicates per 27 scenario combinations; suction runs verified against deadweight negative-pressure reference to 40 kPa with ±0.3 kPa bias.
Data pedigree - Model A - Progressive Tubing Kink Under Bend	4.5	Calibrated bending apparatus (0–130°) with angle repeatability ±1°; 9 angle levels × 3 flow rates × 3 replicates; material CoAs archived for tubing lots used.
Development process and product management - Model A - Downstream Occlusion	4.0	26 tagged releases with regression suite (82% line coverage); requirements-to-tests matrix spans 41 verifications; meshes and scripts under configuration management.
Development process and product management - Model A - Upstream Occlusion	4.0	Same governance; occlusion scenarios tracked as requirements; cross-links from change requests to validation notebooks; reproducible pipelines for suction tests.
Development process and product management - Model A - Progressive Tubing Kink Under Bend	4.0	Governance extends to bending fixtures and parameter files; mesh variants and solver settings archived per angle; traceable to design inputs.
Discretization error - Model A - Downstream Occlusion	4.0	Three-level refinement gave observed order 1.92 and GCI 1.8% for sensor pressure; slope metric changed <2% from medium to fine.
Discretization error - Model A - Upstream Occlusion	3.5	Observed order 1.78–1.84 and GCI 2.2% for sensor pressure; slope metric changed 2.1% from medium to fine.
Discretization error - Model A - Progressive Tubing Kink Under Bend	3.5	Observed order 1.7–1.8 with GCI 2.6% for pressure peaks; kink-induced gradients increased mesh sensitivity modestly.
Model inputs - Model A - Downstream Occlusion	4.0	Latin hypercube on modulus (6.5–9.0 MPa), wall thickness (0.95–1.05 mm), viscosity (0.8–1.6 mPa·s) gave output SD 2.9 kPa for pressure peaks.
Model inputs - Model A - Upstream Occlusion	3.5	Same inputs plus valve cracking pressure (13–16 kPa) yielded output SD 3.3 kPa for suction peaks; sensitivity highest to valve setting.
Model inputs - Model A - Progressive Tubing	3.5	Added bend-dependent cross-section parameter increased output SD to 3.7 kPa for pres-

Table 2: Model B (1D network hydraulic with axisymmetric losses): Evidence Index scores and quantitative bases by mechanism.

Credibility factor	Level	Basis
Data pedigree - Model B - Downstream Occlusion	4.5	Same calibrated rig; 5 replicates per 27 scenario combinations; pressure sampled at 200 Hz; raw files archived with checksums and metadata.
Data pedigree - Model B - Upstream Occlusion	4.5	Suction tests validated against negative-pressure reference; replicate structure as downstream; CoAs for tubing lots on file.
Data pedigree - Model B - Progressive Tubing Kink Under Bend	4.5	Bend angles 0–130° in 10–15° steps; 3 replicates per level; angle repeatability ±1°; materials traceability maintained.
Development process and product management - Model B - Downstream Occlusion	4.0	Same repository governance; 26 tagged releases; regression tests for 1D solvers cover valve events and branch junctions.
Development process and product management - Model B - Upstream Occlusion	4.0	Traceable linkage from suction requirements to verification tests; configuration management for parameter sets and scripts.
Development process and product management - Model B - Progressive Tubing Kink Under Bend	4.0	Governance covers kink parameterization; calibration and validation split maintained; test artifacts archived with version locks.
Discretization error - Model B - Downstream Occlusion	4.5	Temporal observed order ~2.0; GCI 0.8% at 0.50.25 ms; slope metric changed <1% with halved step.
Discretization error - Model B - Upstream Occlusion	4.5	GCI 1.0% for sensor pressure; convergence consistent across suction transients; negligible impact on features.
Discretization error - Model B - Progressive Tubing Kink Under Bend	4.0	GCI 1.3%; slightly higher due to kink-induced stiffness; still within 1–2% target for features.
Model inputs - Model B - Downstream Occlusion	3.5	Input ranges as in Model A with additional minor-loss coefficients; output SD 4.1 kPa for peaks; parameter identifiability acceptable.
Model inputs - Model B - Upstream Occlusion	3.5	Valve cracking pressure (13–16 kPa) and viscosity dominate; output SD 4.6 kPa; sensitivity to valve hysteresis noted.
Model inputs - Model B - Progressive Tubing Kink Under Bend	3.0	Effective loss coefficient for partial collapse increased output SD to 5.3 kPa; representation is a simplified surrogate.
Numerical code verification - Model B - Downstream Occlusion	4.0	Water-hammer amplitude error 0.5% and wave-speed error 0.7%; RLC benchmark errors <1%; exact steady-state solutions reproduced.
Numerical code verification - Model B - Upstream Occlusion	4.0	Event handling for valve opening/closing verified; suction boundary conditions exercised; observed temporal order ~2.0.