DHF Impact and Actions Recommendation – ISO 7199:2024

Gap Assessment: ISO 7199:2017 versus ISO 7199:2024

Document Type: Design History File (DHF) Impact Analysis

Standard Reference: ISO 7199:2024 – Sterile, single-use, extracorporeal blood-gas exchangers

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1. Executive Summary

ISO 7199:2024 retains the core design and safety framework of the 2017 edition, but introduces several substantive changes affecting biological safety references, blood pathway and air-handling validation for pulsatile devices, connector standards, gas-transfer testing parameters, flow-rate retesting expectations, blood volume testing conditions, and broader documentation practices. The attached comparison concludes that organizations should prioritize revalidation of pulsatile-mode performance, connector compliance, blood volume methods, gas-transfer protocols, and filter flow/air-handling evidence, while also updating DHF traceability, risk files, and technical documentation.

Key Impact Areas for DHF:

- Biological safety documentation updates, especially the streamlined biocompatibility reference structure.
- New or expanded dynamic/pulsatile testing for blood pathway integrity and air-handling capability.
- Connector validation transition to ISO 80369-7:2021 and added fast-coupling compatibility considerations.
- Refined gas-transfer performance testing parameters and sampling intervals.
- Retesting expectations for blood volume and integral arterial filter flow when blood-related artifacts affect results.
- Optional lifecycle pre-conditioning steps that strengthen stress-based DHF evidence.

This document maps the attached ISO 7199:2024 versus 2017 gap assessment into a DHF impact-and-actions plan using the same implementation style as the attached DHF template reference. [cite:2]

2. Key Changes Summary

2.1 Biological safety and biocompatibility documentation

Change: Core sterility and non-pyrogenicity expectations remain unchanged, with verification still relying on recognized sterilization and pyrogen standards. However, the 2024 edition removes the explicit ISO 10993-7 reference from the biocompatibility verification clause and retains ISO 10993-1 as the central framework, shifting the emphasis toward a more risk-based biological evaluation structure.

DHF Impact:

- Biological evaluation files should be reviewed to ensure the rationale remains robust even though the explicit ISO 10993-7 citation has been removed from the clause text.
- DHF biological sections should show that finished-device biocompatibility remains justified through ISO 10993-1-based planning, testing, or documented review.
- Residual chemical or process-related evaluations that were historically tied to ISO 10993-7 should be retained where scientifically relevant, but the primary compliance mapping should align to the updated clause language.

Recommended Actions:

Action	Timeline	Owner	Priority
Review biological evaluation plan/report against ISO 7199:2024 biocompatibility wording	4 weeks	Biological Safety / Regulatory	High
Update DHF biocompatibility traceability to ISO 10993-1-centered justification	4 weeks	Quality/Regulatory	High
Document any retained ISO 10993-7 evidence as supporting rationale where applicable	5 weeks	Toxicology / Regulatory	Medium

2.2 Blood pathway integrity and pulsatile validation

Change: The static blood pathway integrity requirement remains unchanged, but ISO 7199:2024 adds pulsatile-mode worst-case dynamic testing for applicable blood-gas exchangers. This is a significant DHF impact for products intended for pulsatile use because static pressure evidence alone is no longer sufficient.

DHF Impact:

- Pulsatile devices require new verification protocols and reports covering dynamic worst-case pressure/leak conditions.
- Existing static integrity reports remain useful but are not complete evidence for pulsatile variants.
- Risk management should explicitly distinguish between non-pulsatile and pulsatile use conditions where applicable.

Recommended Actions:

Action	Timeline	Owner	Priority
Identify product variants intended for pulsatile operation	2 weeks	Design Engineering / Clinical	Critical
Develop pulsatile worst-case blood pathway integrity protocol per 2024 requirement	4 weeks	Test Engineering	Critical
Execute dynamic integrity revalidation for applicable devices	8 weeks	Test Engineering	High
Update risk management file to include pulsatile leak/integrity hazards and controls	6 weeks	Quality/Risk Manager	High

2.3 Blood volume testing refinements

Change: ISO 7199:2024 prefers anticoagulated whole blood for blood volume testing rather than the 2017 blood/water option, and adds clarification on variable/pressure evaluation and drainage. The acceptance intent is unchanged, but the test medium and execution details are more clinically realistic.

DHF Impact:

- Existing blood volume data generated with water-only approaches may need gap assessment or revalidation.
- Verification protocols should be revised to reflect the preferred whole-blood approach and drainage clarifications.
- Design outputs and IFU claims tied to pathway volume should be checked against the updated verification method.

Recommended Actions:

Action	Timeline	Owner	Priority

Review current blood volume validation data for water-versus-blood method dependency	3 weeks	Test Engineering / Quality	High
Update blood volume test protocol to 2024 preferred test conditions	4 weeks	Test Engineering	High
Revalidate blood volume claims where current evidence does not reflect the updated method	8 weeks	Test Engineering	High

2.4 Connector requirements and interoperability

Change: ISO 7199:2024 expands connector expectations beyond the blood pathway to include gas and heat-exchanger fluid pathways, mandates ISO 80369-7:2021 performance testing, and adds compatibility with female fast couplings. This is one of the most consequential design-control changes in the 2024 edition.

DHF Impact:

- Connector drawings, specifications, and supplier evidence must be updated to ISO 80369-7:2021 alignment.
- Verification plans must now cover broader connector scope across blood, gas, and heat-exchanger interfaces.
- Supplier qualification and incoming inspection records may require rework if they still rely only on legacy connector evidence.

Recommended Actions:

Action	Timeline	Owner	Priority
Update connector design specifications and drawings to ISO 80369-7:2021 criteria	4 weeks	Design Engineering	Critical
Obtain updated supplier declarations and test evidence for all relevant connector types	4 weeks	Procurement / Supplier Quality	Critical
Revise connector validation protocols to include gas and heat-exchanger pathway applicability	6 weeks	Test Engineering	High
Confirm compatibility with female fast couplings where applicable	6 weeks	Design Engineering / Verification	High

2.5 Gas transfer performance refinements