27th WFHSS CONGRESS - 2026 -

BELGRADE

21ST - 24TH OCTOBER 2026

USDS

World Federation for Hospital Sterilisation Sciences

The IFU Reality Gap: Why Reprocessing Instructions Fail in Practice and What Needs to Change

Name: Dr. Atila Nozari, BSc, MSc, PhD, PMP

Affiliation: Solventum(f.k.a. 3M HealthCare)

27th WFHSS CONGRESS - 2026 -

BELGRADE
21ST - 24TH
OCTOBER 2026

USDS

wfhss World Federation for Hospital Sterilisation Sciences

The IFU Reality Gap

Why validated reprocessing instructions can fail in real-world implementation - and what global sterile-processing systems can do about it?

Validated does not always mean executable in every clinical environment.
Successful reprocessing is a system property.

Instructions for Use (IFU)

BELGRADE
21ST - 24TH
OCTOBER 2026

IFU definition

3.342
instructions for use
IFU
portion of the accompanying information that is essential for the safe and effective intended use of a medical device or accessory directed to the user of the medical device
Note 1 to entry: The instructions for use, or portions thereof, can be located on the display of a medical device or its accessory.
[SOURCE: ISO 20417:2021, 3.11, modified — 'package insert' has been removed, 'use' has been changed to 'intended use', Notes 1, 2, 4 and 5 to entry have been deleted, and Note 3 to entry has become Note 1 to entry.]

3.343
intended use
intended purpose
use for which a product, process or service is intended according to the specifications, instructions and information provided by the manufacturer
Note 1 to entry: The intended medical indication, patient population, part of the body or type of tissue interacted with, user profile, use environment, and operating principle are typical elements of the intended use.
Note 2 to entry: The term "intended use" is used in some jurisdictions while "intended purpose" is used in others.
[SOURCE: ISO/IEC Guide 63:2019, 3.4, modified — "intended purpose" added to term and Note 2 to entry has been added.]

ISO 11139:2018/Amd.1:2024

Aim, analytical questions, and scope

Aim

Investigate the gap between validated Instructions for Use (IFUs) and practical implementation in CSSDs, and identify strategies to improve alignment among manufacturers, standards, regulators and clinical workflows.

Core question

Can representative users, in representative environments, reliably execute the validated process without unsafe adaptation?

Scope

Safe reprocessing is an emergent property of device design, validation, IFU design, human performance, facility capability and postmarket feedback.

Evidence Map

The evidence architecture

No single source proves the whole point; the conclusion emerges by utilizing five evidence streams.

1. Standards

ISO 17664 family
AAMI TIR12
AAMI TIR55
IEC 62366-1
ISO 14971
ISO 13485
....

2. Regulation

FDA reprocessing guidance
FDA human factors
EU MDR
National guidance

3. Clinical data

Duodenoscope contamination
Outbreak reports
Multicentre studies
Meta-analyses

4. Human factors

Comprehension
Task execution
Use error
Instruction design

5. Systems reality

Infrastructure
Inventory
Training
Water/chemistry
Traceability

The IFU is not only a document. It is the visible interface of a reprocessing system.

27th WFHSS CONGRESS - 2026 -

BELGRADE
21ST - 24TH OCTOBER 2026

Manufacturer Workflow

USDS

WFHSS World Federation for Hospital Sterilisation Sciences

A. Design & planning

01
Define intended use and labeling scope

02
Characterize design/reprocessing challenges

03
Map use and processing environments

04
Identify regulatory and standards framework

B. IFU development, risk management & validation

05
Perform risk management

06
Design for reprocessability

07
Define processing workflow and critical tasks

08
Develop draft IFU content

09
Plan validation and verification strategy

10
Execute validation studies

C. Usability, finalization & release

11
Conduct human factors / usability evaluation

12
Revise and finalize IFU

13
Design review, submission, release

D. Lifecycle feedback

14
Post-market surveillance and improvement

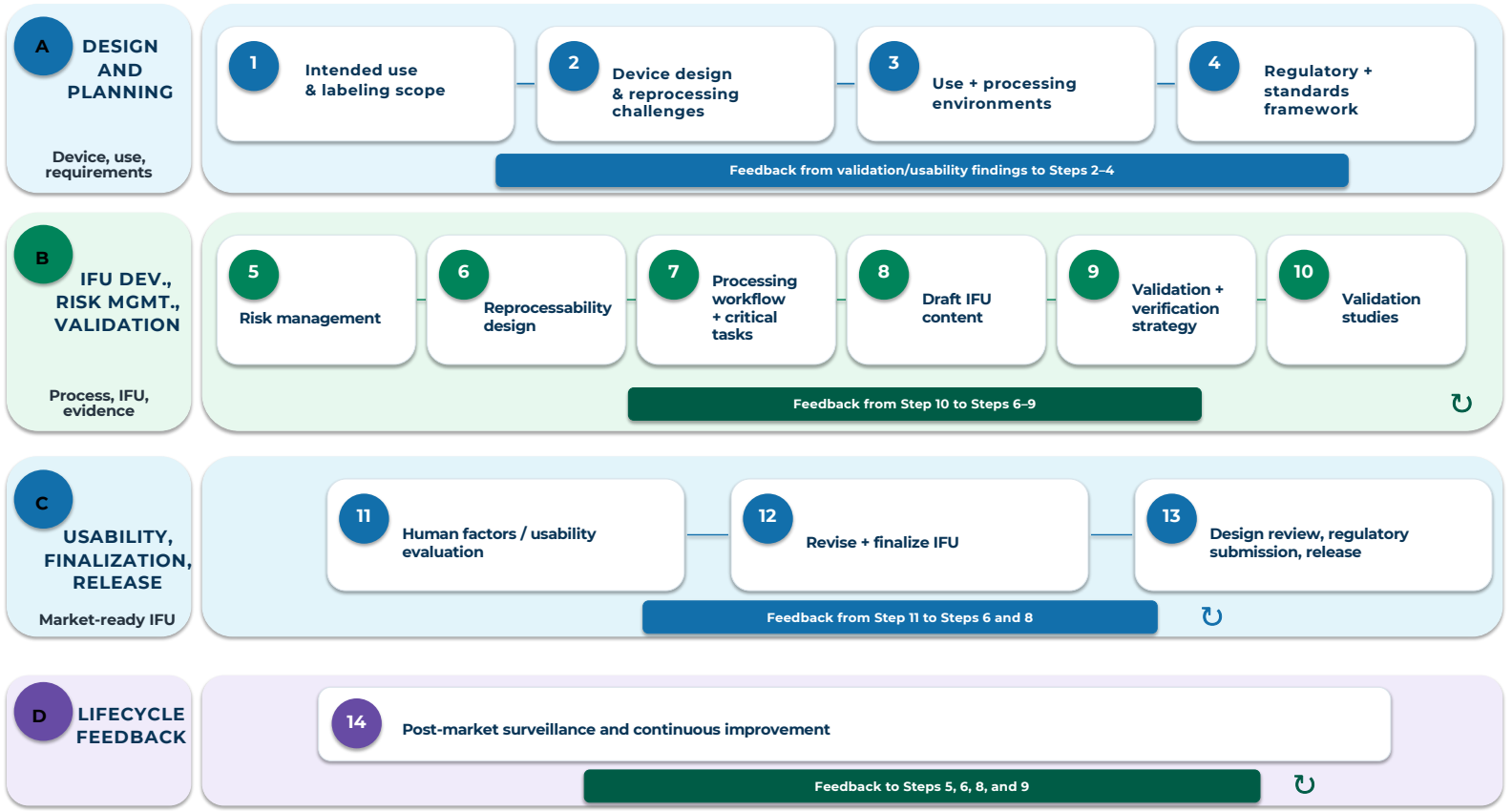
Feedback triggers

- IFU revision
- Revalidation
- Redesign
- Training update
- CAPA / field action
- Standards monitoring

This is simplified.

Actual requirements depend on the device, claims, geography, recognized standards, and regulatory pathway. This workflow is illustrative only

Creating a Reprocessing IFU for a Complex Reusable Medical Device: Manufacturer Workflow



Why this is complex?

- Reflects actual device architecture
- Validated under justified conditions
- Executable by intended users
- Requirements vary by market/standard
- Facility resources may not match assumptions
- Post-market learning may trigger updates

Key takeaway

The IFU is not written in isolation. It is the output of design controls, risk management, validation science, human factors, regulatory requirements, and post-market feedback.

Not a substitute for applicable regulations, recognized standards, or market-specific requirements.

27th WFHSS CONGRESS - 2026 -

BELGRADE
21ST - 24TH
OCTOBER 2026

USDS

wfhss World Federation for Hospital Sterilisation Sciences

From validated process to real-world performance

The IFU is a bridge, not the whole bridge-building process.

Device design → **Validated process** → **IFU design** → **Facility capability** → **Human execution** → **Outcome**

Postmarket learning loop

If performance fails
Do not stop at retraining. Ask whether design, validation assumptions, instructions, resources or workflow need to change.

If performance improves
Capture what changed: IFU format, training, accessories, AER compatibility, device redesign, audit feedback or inventory.

If data are absent
Build surveillance: audits, competency checks, traceability, process indicators, contamination data and use-error reporting.

Created by information form FDA, CDC, WHO, AAMI TIR12, ISO 17664 and IEC 62366-1.

The IFU reality gap: a precise definition

The gap is not a criticism of IFUs. It is a mismatch between system assumptions and system reality.

Validated state

A defined process, performed with specified equipment, parameters, accessories, acceptance criteria and controls, can achieve the intended endpoint under validation conditions.

Reality gap

Executable state

Representative users, in the intended clinical environment, can reliably perform the process as written without unsafe omission, substitution, delay or interpretation.

Working definition aligned with FDA human-factors and reprocessing-validation concepts.

27th WFHSS CONGRESS - 2026 -

BELGRADE
21ST - 24TH
OCTOBER 2026

USDS

World Federation for Hospital Sterilisation Sciences

Why controlled validation can diverge from daily CSSD work

Validation is controlled by design; healthcare delivery is variable by nature.

Validation dimension	Defined/controlled condition	Real-world variable
User	Trained participant or laboratory technician	Different experience levels, turnover, language, fatigue and workload
Equipment/accessories	Specified brushes, connectors, AER/sterilizer and chemistry	Substitutions, availability constraints, legacy equipment, local procurement
Timing	Defined point-of-use and cleaning intervals	Transport delays, procedure volume, emergency cases, after-hours workflows
Environment	Specified water quality, utilities and workspace	Variable water, space, lighting, ergonomics, sink design, drying capability
Device condition	Representative but selected devices	Wear, damage, soil burden variation, loaner devices, mixed generations/models
Information	Controlled IFU version and procedure	Multiple documents, conflicting instructions, local SOPs, updates not yet operationalized

The goal is not to make validation less rigorous - it is to make assumptions more representative and implementation more measurable.

Interpretive framework based on FDA reprocessing validation, CDC core practices, WHO aide-memoire and human-factors concepts.

Global relevance: the same gap appears in different forms

Region / authority	What the evidence or guidance contributes	Relevance to IFU implementation
United States: FDA	Postmarket duodenoscope studies; national infection-prevention guidance; human-factors emphasis	Shows measurable task-execution failures and contamination despite established reprocessing expectations.
Canada: PHO	Best-practice guidance for cleaning, disinfection and sterilization in all healthcare settings	Supports system-wide reprocessing programs, auditing and clear procedures.
European Union: MDR	Defines reprocessing as including cleaning, disinfection, sterilisation, and restoring technical/functional safety	Positions reprocessing as a safety and performance system, not only microbial reduction.
Australia / NSW	AS 5369:2023-aligned health-system resources, DI21/04 advisory and competency frameworks	Highlights traceability, sufficient devices /equipment/ time, competency and complex/loaner device issues.
WHO / global	Frames reprocessing as infrastructure-dependent and sequential with validation/quality control at each step	Explains why resource variability can affect IFU executability internationally.

Sources: FDA 2019; CDC 2024 and disinfection/sterilization recommendations; PHO 2020; EU MDR Medical Device regulation; ACSQHC 2025; NSW CEC 2026; WHO 2022.

27th WFHSS CONGRESS - 2026 -

BELGRADE
21ST - 24TH
OCTOBER 2026

USDS

World Federation for Hospital Sterilisation Sciences

FDA duodenoscope case: why it matters for IFUs

This is not only an endoscope story. It is one of the clearest published demonstrations of IFU executability risk.

5,000+

samples requested

FDA ordered manufacturers to conduct postmarket surveillance cultures for duodenoscopes.

HF

Studies evaluated whether reprocessing user materials supported understanding and adherence.

HCO

high-concern organisms

Microbiological endpoint captured clinically important contamination signal.

PMS

Findings drove IFU changes, design changes and stronger surveillance expectations.

Key interpretation

The strongest lesson is not that duodenoscopes are unique. The lesson is that a validated, written process may still fail at the level of user comprehension, task performance, device condition or real-world environment.

Source: FDA Medical Devices Advisory Committee Executive Summary, Reducing the Risk of Infection from Reprocessed Duodenoscopes, 2019.

27th WFHSS CONGRESS - 2026 -

BELGRADE
21ST - 24TH
OCTOBER 2026

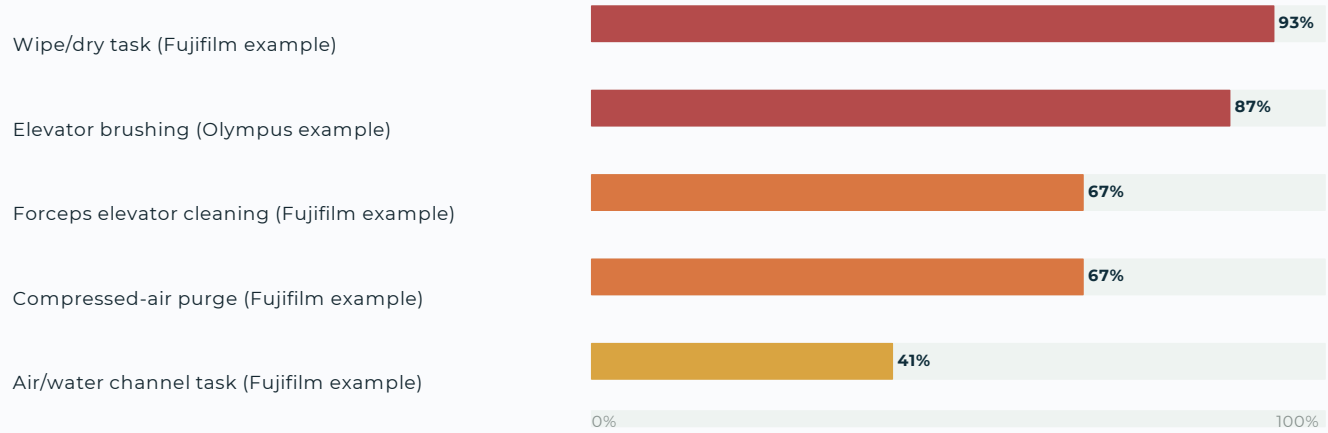
USDS

World Federation for Hospital Sterilisation Sciences

Published human-factors signal: critical IFU task failures

Selected failure rates from FDA-reported duodenoscope reprocessing human-factors studies.

Participants failing selected critical tasks

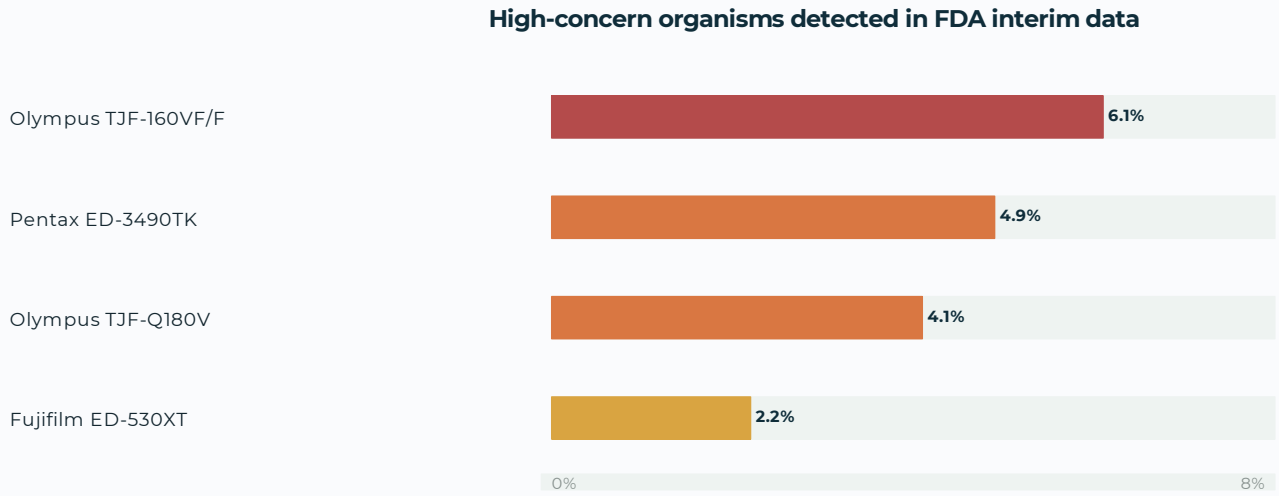


Interpretation: when critical steps are missed by trained participants, the problem should be analyzed as a design + instruction + workflow issue, not only a compliance issue.

Data adapted from FDA 2019 duodenoscope executive summary. Percentages are selected task-level findings from manufacturer human-factors studies.

Published postmarket signal: high-concern organisms after reprocessing

FDA interim postmarket data demonstrated measurable contamination signals across duodenoscope models.



Caution

Contamination data do not identify IFU failure alone. Potential contributors include design complexity, damage, manual-step failures, drying, AER limitations, maintenance and process deviations.

Source: FDA 2019 duodenoscope executive summary, interim sampling/culturing results.

IFU redesign can improve performance: a constructive case

FDA reported a follow-up study after RIFU revision in which performance and understanding improved substantially.

95%

tasks performed appropriately

After revised reprocessing instructions were evaluated in a follow-up study.

99%

tested information understood

Demonstrated comprehension of tested information in the revised materials.

RCA

root-cause analysis

Revision followed analysis of failures and near-misses.

Key message

The solution is not simply more policing of compliance. Better IFU design, human-factors evaluation and feedback loops can measurably improve execution.

Source: FDA 2019 duodenoscope executive summary, Pentax RIFU revision discussion.

27th WFHSS CONGRESS - 2026 -

BELGRADE
21ST - 24TH
OCTOBER 2026

USDS

wfhss World Federation for Hospital Sterilisation Sciences

Systematic-review signal: patient-ready duodenoscope contamination

Meta-analysis data show persistent contamination signals even after reprocessing in published studies.

15	**13,112**	12	**15.25%**
studies	**samples**	**contaminated**	**pooled rate**
Included in Larsen et al. meta-analysis.	Duodenoscope samples in pooled analysis.	Contaminated duodenoscope samples.	95% CI: 11.74-18.75%.

Selected pooled contamination rates

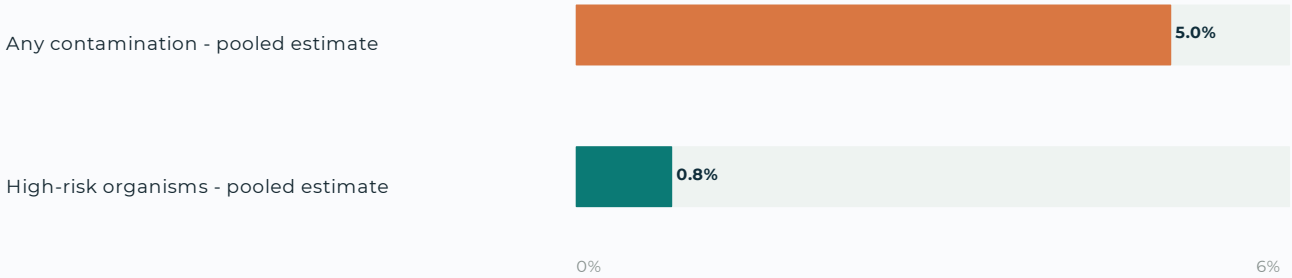


Source: Larsen S et al. EClinicalMedicine. 2020; 25:100451. DOI:10.1016/j.eclinm.2020.100451.

Enhanced reprocessing reduces risk, but may not eliminate it

The literature supports risk reduction, while reinforcing the need for device design and system controls.

Contamination after enhanced surveillance/reprocessing techniques



Interpretation

Enhanced measures can reduce risk, but complex device architecture, manual steps, drying, maintenance and surveillance remain critical. Design changes may be more effective than adding more process burden.

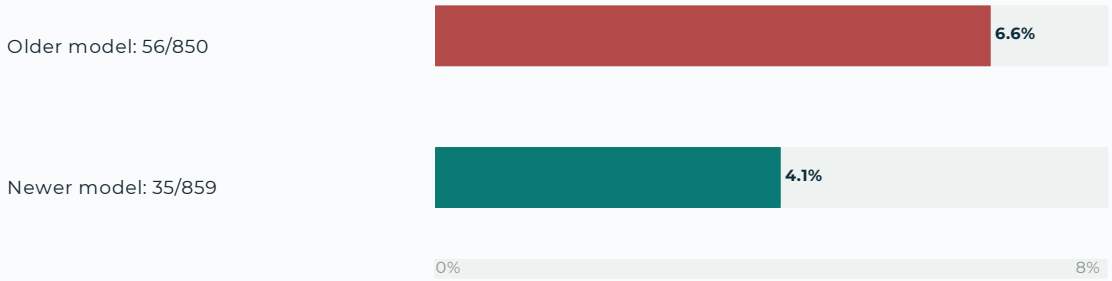
Source: Bomman S et al. Clinical Endoscopy. 2022;55(1):33-40. DOI:10.5946/ce.2021.212.

BELGRADE
21ST - 24TH
OCTOBER 2026

Device design matters: newer vs older model contamination signal

A multicentre clinical study illustrates why design changes can be part of the reprocessing solution.

High-concern organisms after reprocessing



Design implication

A safer IFU is not always a longer IFU. Better device architecture, easier cleaning access, disposable components, inspection points and validated compatible accessories can reduce implementation burden.

Source: Naoaki Okamoto et al ,prospective multicenter clinical duodenoscope contamination study, published 2022 10.1017/ice.2021.525

27th WFHSS CONGRESS - 2026 -

BELGRADE
21ST - 24TH
OCTOBER 2026

USDS

wfhss
World Federation for Hospital Sterilisation Sciences

2025 update: endoscope processing effectiveness reality check

A recent AJIC review reinforces that failures are often found at the level of real-world implementation.

2019-2024
review window

Peer-reviewed articles, FDA adverse-event reports and government reports.

Dozens
outbreaks

The abstract reports dozens of endoscopy-associated outbreaks in the preceding five years.

MDROs
included

Several reported outbreaks involved multidrug-resistant organisms.

Steps
skipped/improper

Investigations commonly found essential processing steps skipped or done improperly.

This recent literature signal that the IFU gap is still active.

Source: Ofstead CL, Smart AG, Hurst L, Lamb LA. Am J Infect Control. 2025;53(7):785-793. DOI:10.1016/j.ajic.2025.04.003.

27th WFHSS CONGRESS - 2026 -

BELGRADE
21ST - 24TH
OCTOBER 2026

USDS

World Federation for Hospital Sterilisation Sciences

2025 update: disposable/single-use designs as risk-control strategy

Recent meta-analysis evidence suggests selected disposable endoscopes may reduce some clinical risks compared with reusable devices.

Relative risk from 2025 meta-analysis



Balanced interpretation

Disposable or single-use designs are not a universal answer. They can reduce selected reprocessing risks, but decisions must also consider performance, access, cost, waste, sustainability and clinical indication.

Source: Hamdar et al. J Hosp Infect. 2025;165:128-142. DOI:10.1016/j.jhin.2025.07.025.

2025 outbreak signal: surveillance still matters

Recent outbreak reports show why postmarket feedback loops must remain active.

What this evidence can support

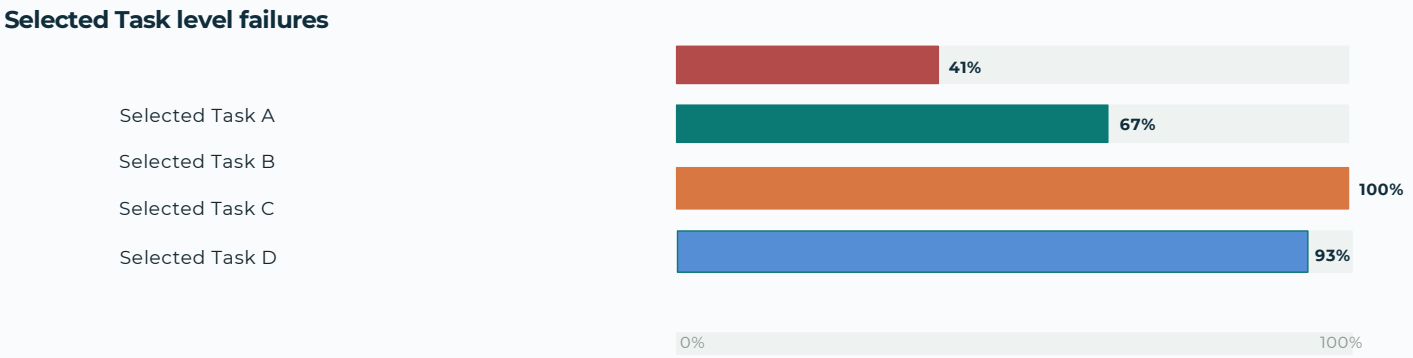
Recent endoscope-associated outbreak reports reinforce the need for vigilance, traceability, microbiological surveillance where appropriate, device inspection, and investigation of reprocessing protocols.

What it cannot support by itself

An outbreak report should not automatically be described as an IFU failure. Causality may involve device damage, organism ecology, protocol deviation, drying, AER limitations, maintenance or healthcare-system factors.

Source: Haak et al. 2025 PubMed-indexed outbreak report 10.1016/j.jhin.2025.01.016; interpret in context with CDC/FDA endoscope guidance.

Task-level failures: why one overall score is not enough



Interpretation

A single score can conceal the critical step that matters most. IFU evaluation should prioritize critical-task analysis, not only page count or overall completion.
.

Source: FDA 522 Postmarket Surveillance Database. Duodenoscope human factors study. Accessed 2026.

CDC: manufacturer instructions must be operationalized

CDC core practices explicitly connect manufacturer IFUs to facility procedures, training and competency.

Availability

Manufacturer instructions should be readily available and used to establish operating procedures and training content.

Location

Instructions should be posted or accessible where reprocessing is performed.

Competency

Personnel should be trained and competency documented initially, when new equipment is introduced and periodically.

CDC converts the IFU from a document into an operating system: procedure + training + competency + periodic verification.

Source: CDC Core Infection Prevention and Control Practices for Safe Healthcare Delivery in All Settings, 2024.

CDC: conflicting instructions and manual steps are recognized risks

CDC recommendations explicitly address instruction conflicts and the need to verify implementation in high-risk areas.

CDC recommendation theme	Why it matters for the IFU reality gap
Compare instrument and sterilizer/AER manufacturer instructions	Conflicting connectors, capping/noncapping, cycle parameters or lumens can create unsafe local interpretation.
Resolve conflicting recommendations by communicating with manufacturers	The facility should not be forced to improvise when instructions conflict.
Conduct infection-control rounds in high-risk reprocessing areas	Implementation should be observed and verified, not assumed.
Review written instructions to ensure they are current and accurate	IFU updates must reach local SOPs, training and competency records.

Practical implication

A global IFU strategy needs a formal conflict-resolution mechanism for device IFU, AER/washer IFU, sterilizer IFU, chemistry IFU and facility SOP.

Source: CDC Recommendations for Disinfection and Sterilization in Healthcare Facilities, Summary Recommendations.

27th WFHSS CONGRESS - 2026 -

BELGRADE
21ST - 24TH
OCTOBER 2026

USDS

WHSS World Federation for Hospital Sterilisation Sciences

WHO: reprocessing is infrastructure-dependent

WHO describes decontamination and reprocessing as complex, sequential and dependent on infrastructure and quality control.

Complex

processes

Not a single step; multiple sequential steps must work together.

Infrastructure

dependent

Requires specific equipment, utilities, facilities and trained personnel.

Validation

at each step

Quality-control procedures such as validation are important at each step.

Global

variability

Resource differences can change executability of the same written IFU.

Interpretation

An IFU may be technically correct yet operationally fragile in settings without the necessary equipment, utilities, accessories, staffing, competency or traceability systems.

Source: WHO. Decontamination and reprocessing of medical devices for health-care facilities: aide-memoire. 2022.

Canada: reprocessing guidance as a system of safe practice

Program scope

Cleaning, disinfection and sterilization apply across healthcare settings and require safe handling, transport and monitoring.

Audit and monitoring

Implementation should be measurable through policies, procedures, audits and quality-assurance processes.

Local translation

Manufacturer instructions must be embedded into local SOPs and training, not treated as separate reference material.

Source: CSA Z314:23 Canadian medical device reprocessing in all health care settings 2023.

Australia 2025: sufficient resources and traceability are part of IFU executability

Australian national advisory language makes operational feasibility explicit.

Australian advisory theme	Why it is important
Classify and reprocess RMDs according to risk	Connects intended use, Spaulding classification and validated processing pathway.
Follow manufacturers instructions and validated disinfectants/processes	Emphasizes the manufacturer IFU as part of compliance and quality control.
Training, competency, validation, routine monitoring and release controls	Shows that execution depends on a managed system, not only individual memory.
Sufficient devices and reprocessing equipment to continue safe care	Acknowledges that timing and inventory affect whether the IFU can be followed.
Traceability and patient recall capability if decontamination fails	Links reprocessing performance to postmarket/patient-safety response.

Source: Australian Commission on Safety and Quality in Health Care, Advisory DI21/04 v2.0, Oct 2025; NSQHS Action 3.17.

NSW: complex and loaner devices increase implementation burden

Recent health-system resources highlight operational complexity beyond the manufacturer document.

Complex devices

Cannulated, lumened or difficult-to-clean RMDs make cleaning and decontamination more challenging and raise the value of classification and validation.

Loaner / consignment

Unfamiliar devices can arrive with limited time, different accessories and new instructions - increasing training and competency burden.

Competency system

NSW competency resources address quality assurance, product definition, process definition, validation, monitoring, release and process effectiveness.

Source: NSW Clinical Excellence Commission reprocessing resources,

Europe: reprocessing includes restoring technical and functional safety

The EU MDR definition reinforces that reprocessing is broader than microbial inactivation.

Cleaning › **Disinfection** › **Sterilisation** › **Related procedures** › **Testing** › **Restoring safety**

Why this matters

A device can be microbiologically processed yet still unsafe if technical or functional performance is not restored or verified.

IFU implication

Processing information should address inspection, maintenance, function checks, packaging, transport and storage where applicable.

Source: European Commission public health page on MDR reprocessing of devices; Regulation (EU) 2017/745 context.

BELGRADE
21ST - 24TH
OCTOBER 2026

ISO 17664 series: the manufacturer information backbone

Standard / document	Primary contribution to the IFU reality gap
ISO 17664-1:2021	Requirements for information supplied by the manufacturer for processing critical and semi-critical medical devices.
ISO 17664-2:2021	Requirements for information for processing non-critical medical devices.
ISO/TS 17664-3:2026	Guidance on cleaning classification categories and product-family/master-product thinking for cleaning validation/instructions.
Supporting QMS/risk standards	ISO 13485 and ISO 14971 provide design-control, QMS and risk-management context, but are not the primary IFU content standards.

Use ISO 17664 as the IFU anchor; use ISO 13485/14971 as the quality and risk-management framework supporting that anchor.

Sources: ISO 17664-1:2021; ISO 17664-2:2021; ISO/TS 17664-3:2026; ISO 13485; ISO 14971.

Human factors: the IFU is part of the user interface

A critical reprocessing step is a use-related safety task. It deserves usability engineering, not only proofreading.

Users

Sterile-processing technicians, nurses, endoscopy staff, OR personnel, biomed/maintenance staff and trainers may all interact with processing information.

Use environments

Decontamination rooms, endoscopy units, OR substerile areas, ambulatory sites and low-resource settings differ in layout, equipment and workload.

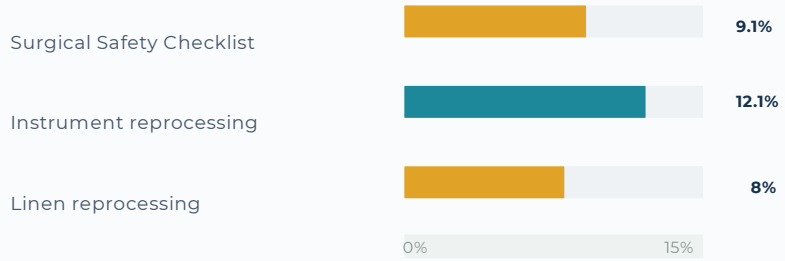
Use errors

Missed channel, wrong brush, skipped drying, incomplete inspection, wrong connector, cycle mismatch, outdated local SOP or unavailable accessory.

Sources: IEC 62366-1:2015+A1:2020; FDA human-factors guidance; FDA 2019 duodenoscope human-factors findings.

Implementation evidence: training plus process mapping

Average weekly compliance improvement



Design implication

Training alone is not enough. The intervention included workshops plus process mapping to identify gaps a closer match to how CSSD implementation problems actually occur.

Source: Nofal et al. World J Surg. 2026;50(1):87–93.

Complexity accumulates across the reprocessing pathway

Each additional conditional step increases cognitive load and the opportunity for drift from the validated process.

Point of use › Transport › Leak test › Manual clean › Rinse › AER/WD › Dry › Inspect › Pack › Sterilize › Store

Complexity driver	Examples
Device geometry	Lumens, elevators, hinges, channels, textured surfaces, sealed joints, disassembly/reassembly.
Conditional logic	If visible soil remains; if using AER model X; if using brush Y; if delayed > time Z; if device is damaged.
Cross-document dependency	Device IFU + chemistry IFU + washer/AER IFU + sterilizer IFU + tray/container IFU + local SOP.
Operational pressure	Emergency turnover, limited inventory, staffing shortages, loaner trays and after-hours cases.

Design based on FDA, CDC, WHO, AAMI TIR12/TIR55 and clinical reprocessing literature.

Facility capability determines whether the IFU is executable

Capability domain	Example IFU dependency	Implementation risk if absent
Equipment	Specific washer-disinfector, AER, sterilizer, drying cabinet	Substitution or manual workaround changes validated conditions.
Accessories	Validated brush size, connector, flushing device, tray or container	Wrong accessory can miss surfaces or channels.
Utilities	Water quality, air quality, steam quality, temperature control	Process endpoint may not be reproducible.
Time / inventory	Defined soak, transport, drying or aeration time	Turnover pressure encourages shortened or skipped steps.
Competency	Initial and periodic task-specific competency	Instructions may be misunderstood or incompletely executed.
Traceability	Device-to-patient/process records	Failures cannot be linked to patients or investigated effectively.

Framework developed from CDC 2024, ACSQHC DI21/04 2025, WHO 2022, AAMI TIR12 and local program-control concepts.

The hidden problem: cross-IFU dependence

Reusable device processing often depends on several manufacturers instructions at once.

Device IFU

Disassembly,
Cleaning,
Inspection,
Packaging,
Cycle compatibility,
Limits on processing.

Washer / AER IFU

Connectors,
Cycle parameters,
Channel irrigation,
Load pattern,
Maintenance.

Chemistry IFU

Dilution,
Temperature,
Contact time,
Compatibility,
Rinse requirements.

Sterilizer IFU

Cycle,
Packaging,
Load configuration,
Drying,
Aeration,
Release requirements.

Container IFU

Weight,
Configuration,
Filter,
Cycle limits,
Drying
Performance.

Failure mode: each document is correct alone, but the combined local pathway is not verified as one executable system.

Source concept supported by CDC recommendation to compare and resolve conflicting manufacturer instructions.

Facility capability mismatch

IFU feasibility depends on local capability.

Required accessory missing	→ Substitution or skipped step
Cycle not available	→ Alternative method or delay
Drying not achievable	→ Residual moisture risk
Inspection criteria vague	→ Variable release decisions
Time/workload pressure	→ Shortcuts and sequencing drift

Loaner and consignment devices: an IFU stress test

Loaner devices compress the learning, verification and execution cycle.



Stress point	Typical risk
Time compression	IFU may be reviewed close to case time; competency may be assumed rather than verified.
Accessory mismatch	Brushes, connectors, trays or containers may not accompany the device or may not be validated locally.
Unfamiliar design	Disassembly/reassembly and inspection may differ from routine devices.
Documentation burden	Traceability, local SOP alignment and release criteria may be incomplete.

Source context: NSW CEC reprocessing/loan-device resources and general reprocessing quality-system expectations.

What should be measured: a high-level IFU implementation dashboard

You cannot manage the IFU reality gap if you only measure final pass/fail release.

Indicator type	Example measures	Why it matters
Structure	IFU availability, accessory availability, equipment compatibility, updated SOPs	Confirms the system is capable before processing starts.
Process	Observed step adherence, manual-cleaning audit, drying audit, inspection completion	Detects drift before adverse outcomes occur.
Competency	Task-specific initial/annual competency; competency after new device introduction	Links IFU changes to human performance.
Outcome	Positive cultures where used, wet packs, BI/CI failures, rejects, nonconformities	Shows final performance signal but often late.
Learning	Root-cause analysis, manufacturer queries, corrective actions, IFU update implementation	Closes the feedback loop.

Dashboard framework; aligned with CDC competency guidance, ISO 13485 QMS concepts and postmarket principles.

A root-cause framework for IFU implementation failures

Avoid shallow conclusions: missed steps usually have upstream causes.

Layer	Root-cause questions
Device design	Was the device inherently difficult to access, clean, inspect, dry or assemble?
Validation assumptions	Were users, equipment, accessories, soil challenge, timing and environment representative enough?
Instruction design	Were steps sequenced, readable, visual, unambiguous and free of conflicting terminology?
Facility capability	Were the required equipment, accessories, utilities, inventory and space available?
Human performance	Were training, competency, staffing, workload and ergonomics adequate?
Feedback loop	Was the issue reported, investigated, corrected and communicated back to the right stakeholder?

Framework developed supports RCA

27th WFHSS CONGRESS - 2026 -

BELGRADE
21ST - 24TH
OCTOBER 2026

USDS

World Federation for Hospital Sterilisation Sciences

Practical scorecard: is this IFU operationally executable?

A high-level screening tool for manufacturers, CSSDs, educators and standards developers.

Domain	Green signal	Red signal
Clarity	Steps are short, sequenced, visual and testable	Long narrative, buried critical warnings, ambiguous terms
Feasibility	Equipment/accessories are common, specified and available	Requires uncommon or unspecified tools, excessive manual work
Compatibility	Device, AER/WD, sterilizer, chemistry and packaging instructions align	Conflicting IFUs or unverified combinations
Human factors	Representative users can execute critical steps with low error rate	High critical-task failure in usability/human-factors testing
Facility readiness	Inventory, time, space, utilities and competency support the process	Turnover pressure or infrastructure makes workarounds likely
Learning loop	Postmarket issues trigger IFU/SOP/training/design updates	Problems handled as one-off retraining only

Scorecard created; apply with local standards, manufacturer guidance and regulatory requirements.

Global examples: same systems problem, different local expression

The IFU reality gap is global, but local risk controls must match local context.

Example source	Observed emphasis	Presenter takeaway
FDA duodenoscope studies	Human-factors failures and contamination signals	Critical steps must be executable, not only validated.
CDC core practices	IFUs available, posted/accessible, used for training and competency	Instructions must be operationalized locally.
WHO aide-memoire	Infrastructure, equipment and validation at each step	Global resource variability affects executability.
Australia DI21/04	Validation, competency, sufficient equipment/devices, traceability	System capability and inventory affect compliance.
NSW CEC resources	Complex/loaner devices, competency, process effectiveness	Unfamiliar devices stress training and workflow.
EU MDR	Reprocessing includes technical/functional safety	Microbial safety plus device function must be considered.

Synthesis of FDA, CDC, WHO, EU, Australian and NSW sources cited throughout the deck.

Recommendations for manufacturers

Manufacturer action should reduce complexity before it reaches the CSSD.

- Treat reprocessing as a design input early, not a labeling activity at the end.
- Use human-factors methods for critical reprocessing steps and user materials.
- Design instructions around observable actions, acceptance criteria and clear decision points.
- Validate not only the microbial/process endpoint but the executability assumptions around users, tools and environment.
- Provide accessory clarity: exact brush/connectors, validated alternatives and what to do when unavailable.
- Use postmarket complaints, contamination investigations and user feedback to revise design and IFUs.

Aligned with AAMI TIR12/TIR55, ISO 17664, FDA reprocessing guidance and IEC 62366-1 concepts.

Recommendations for CSSDs and healthcare facilities

Local implementation should verify capability before routine use.

- Create an IFU intake process for new, loaner and updated devices.
- Verify equipment, accessories, chemistry, packaging, cycle and traceability compatibility before first use.
- Translate IFUs into local SOPs without changing validated parameters or critical steps.
- Document task-specific competency for critical steps and update competency when devices or IFUs change.
- Audit real execution in high-risk areas, including endoscopy and decontamination work zones.
- Escalate conflicts between device, AER/washer, sterilizer, chemistry and container instructions to manufacturers.

Aligned with CDC core practices, CDC disinfection/sterilization recommendations, ACSQHC DI21/04 and PHO guidance.

Recommendations for standards developers, regulators and WFHSS

The global community can make IFU executability a shared quality attribute.

Stakeholder	High-value action
Standards developers	Define clearer expectations for IFU format, critical-step identification, facility capability assumptions and conflict resolution.
Regulators	Continue linking validation, labeling, human factors and postmarket evidence; support transparency of recurring implementation failures.
Professional societies	Develop global education on IFU interpretation, competency, audit methods and escalation pathways.
WFHSS community	Create consensus language for executable IFUs, complex-device readiness and feedback from sterile-processing users.
Researchers	Study actual IFU implementation, not only final contamination outcomes.

Recommendations created from the global evidence base.

Research agenda: what we still need to know

The evidence is strong enough to act, but important measurement gaps remain.

Question	Suggested study approach
Which IFU features predict execution accuracy?	Comparative human-factors studies of format, sequence, graphics, warnings and checklists.
How often do facilities lack a required IFU capability?	Multicentre CSSD capability audits linked to representative device families.
How common are cross-IFU conflicts?	Structured analysis of device + AER/washer + chemistry + sterilizer + container instruction sets.
What interventions reduce critical-step failures?	Before/after studies of IFU redesign, training redesign, accessory kits and workflow changes.
How can postmarket data feed back to standards?	Global reporting taxonomy for IFU implementation problems and reprocessing nonconformities.

Research agenda created from the evidence gaps identified

27th WFHSS CONGRESS - 2026 -

BELGRADE
21ST - 24TH
OCTOBER 2026

USDS

World Federation for Hospital Sterilisation Sciences

Five takeaways

Validated is essential

But not equivalent to executable.

Complexity matters

Device design drives IFU burden.

Human factors matter

Critical steps must be understandable and performable.

Facility capability matters

Equipment, time, accessories and competency determine feasibility.

Learning matters

Postmarket data must feed back into IFUs and design.

The future of IFUs is not longer instructions. It is better alignment between design, validation, instructions, users and real clinical systems.

27th WFHSS CONGRESS - 2026 -

BELGRADE
21ST - 24TH
OCTOBER 2026

USDS

World Federation for Hospital Sterilisation Sciences

Make the validated process executable.

The IFU should not be the end of validation.

It should be the beginning of reliable implementation.

Device design + validation + information design + facility capability + human performance + postmarket learning

Thank you

27th WFHSS CONGRESS - 2026 -

BELGRADE
21ST - 24TH
OCTOBER 2026

USDS

World Federation for Hospital Sterilisation Sciences

References

1. FDA. Reducing the Risk of Infection from Reprocessed Duodenoscopes. Medical Devices Advisory Committee Executive Summary. 2019.
2. CDC. Core Infection Prevention and Control Practices for Safe Healthcare Delivery in All Settings. Updated Apr 12, 2024
3. CDC. Recommendations for Disinfection and Sterilization in Healthcare Facilities: Summary Recommendations.
4. WHO. Decontamination and reprocessing of medical devices for health-care facilities: aide-memoire. 2022.
5. ISO 17664-1:2021. Processing of health care products - Information to be provided by the medical device manufacturer - Part 1
6. ISO 17664-2:2021. Processing of health care products - Information to be provided by the medical device manufacturer - Part 2.
7. ISO/TS 17664-3:2026. Processing of health care products - Information to be provided by the medical device manufacturer - Part 3
8. AAMI TIR12:2020 (R2023). Designing, testing, and labeling medical devices intended for processing by health care facilities.
9. AAMI TIR55:2014 (R2017). Human factors engineering for processing medical devices.
10. IEC 62366-1:2015+A1:2020. Medical devices - Application of usability engineering to medical devices.
11. Larsen S et al. Rate and impact of duodenoscope contamination: A systematic review and meta-analysis. EClinicalMedicine. 2020;25:100451.
12. Bomman S et al. Contamination Rates in Duodenoscopes Reprocessed Using Enhanced Surveillance and Reprocessing Techniques. Clinical Endoscopy. 2022;55(1):33-40.
13. Prospective multicenter clinical study of duodenoscope contamination after reprocessing. 2022; PMC9753065.
14. Ofstead CL et al. Endoscope processing effectiveness: A reality check and call to action. Am J Infect Control. 2025;53(7):785-793.
15. Hamdar et al. Disposable endoscopes and persistent microbial contamination: systematic review/meta-analysis. J Hosp Infect. 2025;165:128-142.
16. Haak et al. Endoscope-associated outbreak report. 2025 PubMed-indexed record.
17. Australian Commission on Safety and Quality in Health Care. Advisory DI21/04: Disinfection requirements for reusable medical devices. Version 2.0. October 2025..
18. Australian Commission on Safety and Quality in Health Care. NSQHS Standard 3, Action 3.17.
19. NSW Clinical Excellence Commission. Reprocessing of reusable medical devices resources. 2026.
20. Public Health Ontario. Cleaning, Disinfection and Sterilization of Medical Equipment/Devices in All Health Care Settings, 3rd ed. 2013.
21. CSA Z314:23 Canadian medical device reprocessing in all health care settings 2023.
22. European Commission. Reprocessing of devices - MDR context, Regulation (EU) 2017/745.. Annex I, §23.4(n), Information in the instructions for use, reusable devices.
23. FDA. Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling. Guidance for Industry and FDA Staff. 2015.
24. ISO 13485:2016; ISO 14971:2019; ISO 15883 series, as supporting QMS, risk and washer-disinfector frameworks.
25. Choi J, Seraphina L, Knudsen K. The Clean and Dirty of Redesigning Reprocessing Instructions for Use. HFES Annual Meeting Proceedings. 2017;6(1):150–153. doi:10.1177/2327857917061032