Standard operating procedure (SOP) · EQP-SOP-002 · Version 1.1 · Approved by the ASF Expert Committee

Supports: 2B.10

At a glance

- Clean the endoscope at the point of use, before it dries, following the manufacturer's instructions.
- Leak-test and disinfect (or sterilise) to the documented standard before each use.
- Store the endoscope dry and hanging, in a cabinet that protects it.
- Record each reprocessing cycle and test against the device ID.
- Do not use an endoscope that has not completed the full cycle.
- Stop and get help straight away if: a reprocessing step is missed, a leak test fails, or the record cannot be linked to the device and patient.

1. Purpose

To make sure each endoscope is cleaned, tested and reprocessed to a documented standard before every use, and that every use can be traced to the device and the cycle [EC].

2. Scope

Applies to	Endoscopy and reprocessing staff, and all staff who handle endoscopes
Locations	Endoscopy suites, reprocessing rooms and storage at the facility
When	After every use, before every use, and during storage
Does not apply to	Non-endoscopic instruments, covered by the instrument reprocessing SOP (SOP-039)

3. Definitions

Term	Meaning
Endoscope	A flexible instrument used to look inside the body
Reprocessing	Cleaning, leak test, disinfection or sterilisation, drying and storage

Leak test	A test that checks the endoscope channels are not damaged

4. Background

Endoscopes are complex to clean and have a documented risk of transmitting infection when reprocessing fails. Criterion 2B.10 asks for a documented standard and a record linking each use to its device and cycle. The generic procedure (SOP-030) is adapted here.

5. Responsibilities

Role	Responsibility	Competence
Endoscopy lead	Owns the standard; approves products and staff; reviews records	Endoscopy competence
Reprocessing staff	Carry out each step; record each cycle	Trained and assessed
Infection prevention lead	Audits the process and advises on problems	Infection prevention
Biomedical engineer	Maintains and repairs endoscopes and washers	Biomedical engineering

6. Materials and equipment

Item	Requirement	Condition
Endoscope washer-disinfector or manual cleaning kit	As the manufacturer requires	Validated, serviced
Leak tester	Calibrated as the manufacturer sets	Working
Approved detergent and disinfectant	Per the product label and the standard	In date
Drying cabinet and storage cabinet	Clean, dry, ventilated	Working
Reprocessing log (EQP-REG-002)	Current	Available at the reprocessing room

7. Safety

- Wear gloves, eye protection and a gown during manual cleaning.
- Keep the endoscope wet and cleaned until reprocessing starts. Do not let blood or tissue dry on it.
- Handle sharp or fragile parts with care.

8. Before you start

- Check the endoscope is recorded on the inventory and is due for use.
- Check the washer, leak tester and products are in date and working.

9. Procedure

Step 1. Pre-clean at the point of use.

- Wipe the insertion tube and flush the channels at the point of use, before the material dries.
- Record the time of use on the log.

Key point: Dried material is very hard to remove and can protect organisms.

Step 2. Transport to reprocessing.

- Transport the endoscope in a sealed, labelled container to the reprocessing room.
- Record the transfer.

Key point: Transport is a point where damage and contamination occur.

Step 3. Leak test.

- Carry out a leak test before cleaning, as the manufacturer requires.
- If the test fails, stop and take the endoscope out of use. Report to the endoscopy lead.

Key point: A leaking endoscope may carry contamination inside.

Step 4. Clean and disinfect.

- Clean the endoscope using the manual or automated method, following the manufacturer’s steps.
- Brush and flush all channels as set.

- Disinfect or sterilise to the level set by the standard, with the contact time on the label.
- Record the cycle, the product batch and the operator.

Key point: Each step is necessary. A missed channel can remain contaminated.

Step 5. Dry and store.

- Dry the channels with filtered air, then store the endoscope hanging in a clean cabinet.
- Do not store wet.
- Record the storage time.

Key point: Wet storage allows growth of organisms.

Step 6. Link the record to the device and the next use.

- Record the device ID, the cycle, the test result and the release for use on EQP-REG-002.
- Do not use an endoscope whose cycle record is missing or incomplete.

Key point: The link is what allows any patient exposed to be traced.

10. Decision points

- If a cycle is incomplete, repeat it. If the endoscope has been used without a complete cycle, the endoscopy lead decides on patient notification and follow-up (EC).

11. Special situations

Situation	Action
Endoscope with a suspected fault or damage	Take out of use, label it, report to biomedical engineering.

12. Escalation

- A failed leak test, a missed cycle, or an endoscope used without reprocessing is reported as an incident at once.

13. Monitoring

Measure	Target	Frequency	Owner	If not met
Cycles recorded with device ID and test result	100%	Weekly audit of 10 cycles	Endoscopy lead	Retrain; repeat audit within 7 days
Endoscopes used only after full cycle (audit)	100%	Monthly	Infection prevention lead	Immediate review of the endoscope and the patients
Staff competence assessed	100%	Yearly	Endoscopy lead	Retrain

14. Records

Record	Kept in	Retention
EQP-REG-002 Reprocessing and Test Log	Endoscopy file	the period set by the facility’s records policy years, or as the national rules require (EC)
Incident report (INC-POL-001)	Incident log	the period set by the facility’s records policy years

15. Training

- Reprocessing staff are trained, and assessed by observation before working alone (EC).
- Annual refresher and reassessment (EC).

16. Related documents

ID	Title	Use
EQP-REG-002	Reprocessing and Test Log	Used in step 6
SOP-030	Endoscope Reprocessing Procedure (generic)	Basis for this standard
SOP-039	Instrument Processing and Reprocessing Procedure (generic)	Other instruments
SOP-037	Infection Prevention and Control Procedure (generic)	Hand hygiene after handling

17. Evidence

Reference	Note
E-009	ASF Expert Committee consensus. Products, contact times, and sterilisation level must be confirmed against the endoscope manufacturer’s instructions and national infection prevention guidance before approval.

18. Change history

Version	Date	What changed	Approval
1.0	the date of approval	First version	Approved by the ASF Expert Committee
1.1	the date of approval	Internal quality review: corrected cross-references, status wording and document control	Approved by the ASF Expert Committee

E-learning for this document

- **Gastroenterology & Endoscopy Safety Standards** (AMB-22)

References

- Accréditation Sans Frontières (2026). ASF Expert Committee consensus on Standard 1. (E-009)

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