# **HTM 01-06: Decontamination of Flexible Endoscopes – Expanded FRCPath Notes**

## **Part A: Policy and Management**

**Purpose**: Establishes national framework for safe decontamination of flexible endoscopes (GI scopes, bronchoscopes).

**Drivers**:

* HCAI Code of Practice (Health & Social Care Act 2008).
* MHRA safety alerts after incidents of inadequate endoscope cleaning.
* Risks: bacterial, viral, and **prion (vCJD/CJD)** transmission.

**Essential Quality Requirements (EQR)**:

* Legal minimum standards (CE-marked equipment, validated processes, trained staff, water quality, record-keeping).

**Best Practice**:

* Going beyond EQR: separate clean/dirty rooms, centralised units, validated controlled environment storage, computerised traceability.

**Prion risks**:

* Bedside clean immediately after use.
* Avoid reuse after contact with high-risk tissue unless sterilisation validated.

### **Decontamination Process – Techniques and Conditions**

1. **Bedside pre-clean**
   1. Performed *immediately after procedure*.
   2. Flush lumens with water or multi-enzyme detergent.
   3. Wipe external surfaces, remove gross soiling.
   4. Keep moist (humid environment, not desiccated). Prevents biofilm and protein fixation.
2. **Manual cleaning**
   1. Performed in dedicated sink with **low-foaming detergent**.
   2. Use **single-use brushes** for lumens/valves; actuate valves to ensure detergent access.
   3. Soak/immerse fully; rinse thoroughly.
   4. Critical conditions: correct detergent concentration, contact time, fluid flow through all channels, brushing technique.
3. **Automated cleaning (EWD)**
   1. Enclosed locked chamber prevents interruption.
   2. Sprays/pulsed flow contact all surfaces.
   3. **All lumens connected** to machine; flow monitoring by internal sensors.
   4. Reproducible and validated.
4. **Automated disinfection**
   1. Low-temp **chemical disinfectant** (glutaraldehyde, OPA, peracetic acid, etc).
   2. **Single-use** strongly preferred; reuse = risk of reduced activity.
   3. Conditions: correct concentration, contact time, temperature; absence of protein/detergent residues (these inactivate disinfectant).
5. **Rinsing**
   1. Rinse with **treated water** (reverse osmosis or equivalent).
   2. Water quality requirements: low TVC, TOC, conductivity, free of *Pseudomonas/Legionella*.
6. **Drying and storage**
   1. External and internal drying critical.
   2. **Controlled environment cabinets (BS EN 16442)** validated to maintain microbiological safety.
   3. If not in such cabinets → must be reused within **3 hours**.
   4. Some sealed cassette systems validated for up to 7 days.

### **Tracking & Audit**

* **Track-and-trace systems mandatory**:
  + Auto-identification (barcodes/GS1/RFID).
  + Must link **patient ↔ scope ↔ cycle ↔ operator**.
* **Audit trail must include**:
  + Endoscope ID.
  + Patient ID.
  + Staff member (operator).
  + Date/time, cycle data, EWD ID.
  + Results of periodic testing/validation.
* **Audit**:
  + Local self-audit (unit-level checks).
  + External audits by inspectors (CQC).
  + Failures → incident reporting and corrective action.

## **Part E: Testing Methods**

**Purpose**: Provides detailed methodology for the tests referenced in Part D, harmonised with BS EN ISO 15883-4.

**Test Categories**:

1. **Automatic control tests**
   1. Verify correct function of cycle controls.
   2. Parameters (time, flow, pressure, detergent dosing) compared against independent calibrated instruments.
2. **Cleaning efficacy tests**
   1. **Process challenge devices (PCDs)** used to simulate worst-case soils.
   2. Test soils (protein, carbohydrate, blood surrogates) applied to devices.
   3. Acceptance = complete removal to below defined threshold.
   4. Residual protein detection: sensitive assays required (ninhydrin obsolete). Alternative methods: fluorometric/biochemical with detection limits <1 µg.
3. **Microbiological tests**
   1. **Rinse-water**: tested for total viable counts (TVC), endotoxin, conductivity, TOC.
   2. Some microbiological cultures may take up to 28 days; interim risk assessment needed.
   3. Endotoxin test (LAL assay) may be applied to detect Gram-negative contamination.
4. **Chemical residual tests**
   1. Detect carry-over of detergents/disinfectants (e.g. aldehydes, peracetic acid).
   2. Colourimetric or analytical chemical assays.
   3. Must confirm below harmful thresholds.
5. **Thermometric tests**
   1. Used if thermal disinfection/self-disinfection steps included.
   2. Multiple probes placed in chamber and lumens to confirm target temperatures reached for required time.
6. **Test instrumentation**
   1. All measurement equipment (flow meters, pressure gauges, probes) must be **calibrated and traceable** to national standards.

**Acceptance thresholds** (examples – exam recall):

* **Protein residues**: as low as reasonably achievable, typically <1 µg/cm².
* **Water TVC**: <10 CFU/100 mL for final rinse.
* **Endotoxin**: <0.25 EU/mL (if scopes for sterile body sites).
* **Chemical residues**: below toxicological thresholds (compound-specific).

**Documentation**:

* Test results → validation reports.
* Signed by CP(D), reviewed by AE(D), microbiologist endorses microbiology tests.
* Records stored for life of the EWD.

✅ **FRCPath exam angle**:

* Be able to **list and describe the decontamination steps and their conditions**.
* Know the **validation and revalidation test categories**.
* Recall **tracking & audit requirements** (linking patient to scope).
* Highlight **microbiological relevance**: preventing *Pseudomonas*, *Mycobacterium*, and **prion transmission**.