

# List of CDS Related Guidance

Processing Requirements for Thermolabile Flexible Endoscopes





# CDS Related Guidance

## Processing Requirements for Thermolabile Flexible Endoscopes

United Kingdom



Procedure Room	Decontamination Area		
Precleaning	Manual Cleaning*	Manual Disinfection or EWD	Drying/Storage/Sterilization
<p><b>Immediately</b> after finishing patient’s procedure</p> <p>Flush/suck all channels with low-foaming neutral <b>detergent or water</b> until runs clear</p> <p>For <b>transfer</b>, keep the endoscope <b>moist/humid</b> (e.g. plastic-lined tray, foam spray) until start of manual cleaning</p>	<p>Perform <b>manual cleaning no more than three hours</b> after the endoscope was used</p> <p>For use with flexible endoscopes, <b>neutral</b> or <b>neutral enzymatic</b> detergents are normally recommended; <b>alkaline</b> detergents should be used with caution and under the manufacturer’s stated conditions</p> <p>Ensure all channels come into contact with detergent, while aspirating detergent from a separate container/sink</p> <p>Brushes must be single-use</p>	<p>In principle EWD processing; manual disinfection is unacceptable</p> <p>Manual cleaning should be completed and the <b>EWD cycle commenced within three hours</b> of completion of the endoscopic procedure</p> <p>Mainly <b>PAA</b>-based disinfectants (no GDA), but also <b>superoxidized water</b> (Sterilox) or <b>CIO<sub>2</sub></b> (Tristel)</p> <p>Spectrum of antimicrobial activity: bactericidal, mycobactericidal, fungicidal, virucidal, and killing some bacterial spores</p>	<p>Use the endoscope within <b>three hours</b> after removal from the EWD or store in a validated storage system and, if not used, repeat the entire reprocessing cycle incl. manual (brush) cleaning</p> <p><b>Drying:</b> drying or blowing is an integral part of the cycle; alcohol flush at the end of a cycle to aid drying is discouraged, because it is a protein fixative</p> <p><b>Storage:</b></p> <p>a) storage in a cabinet that keeps the endoscopes secure and away from unintentional contact with contaminated surfaces, but that does not dry them; if <b>more than three hours</b> elapse between decontamination and use of an endoscope, the endoscope should be decontaminated before it is reused</p> <p>b) drying and storage in “controlled-environment storage cabinets” (EN 16442)</p> <p><b>Sterilization:</b> EtO sterilization is uncommon; instead, alternative methods such as H<sub>2</sub>O<sub>2</sub> sterilization</p>

<p><b>Legend:</b></p> <p>EWD – endoscope washer-disinfector (chemo-thermal mechanical/automatic cleaning and disinfection)</p> <p>GDA – glutardialdehyde</p>	<p>PAA – peracetic acid</p> <p>CIO<sub>2</sub> – chlorine dioxide</p> <p>LCS – liquid chemical sterilization</p> <p>EtO – ethylene oxide</p>	<p>LTSF – low-temperature steam formaldehyde</p> <p>H<sub>2</sub>O<sub>2</sub> – hydrogen peroxide</p> <p>OR – operating room</p> <p>EHEF – European Hygiene Experts Forum</p>
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\*Mandatory, even in the case of EWD processing

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Remarks	Source
GI scopes incl. duodenoscopes classified as semicritical medical devices (UK definition: endoscopes that enter sterile body cavities via contaminated body cavities) require all manual (pre-) cleaning steps and EWD	Report of a Working Party of the British Society of Gastroenterology Endoscopy Committee: BSG Guidance for Decontamination of Equipment for Gastrointestinal Endoscopy <b>(update 2020)</b>  <a href="https://www.bsg.org.uk/clinical-resource/guidance-on-decontamination-of-equipment-for-gastrointestinal-endoscopy/">https://www.bsg.org.uk/clinical-resource/guidance-on-decontamination-of-equipment-for-gastrointestinal-endoscopy/</a>
Endoscopes entering sterile body cavities (critical devices) need to be sterile – e.g. choledochoscope, devices used for NOTES, CYF, URF, nephroscopes – and require all manual (pre-) cleaning steps, EWD, and sterilization	Health Technical Memorandum 01-06: Management and decontamination of flexible endoscopes; Part A: policy and management and Part C: operational management <b>(2016)</b>  <a href="https://www.england.nhs.uk/wp-content/uploads/2021/05/HTM0106_PartA.pdf">https://www.england.nhs.uk/wp-content/uploads/2021/05/HTM0106_PartA.pdf</a>
Endoscope and its detachable components (e. g. A/W- and S-valves) are kept together as a traceable unique set throughout the life cycle	<a href="https://www.england.nhs.uk/wp-content/uploads/2021/05/HTM0106_PartC.pdf">https://www.england.nhs.uk/wp-content/uploads/2021/05/HTM0106_PartC.pdf</a>

As medical knowledge is constantly growing, technical modifications or changes of the product design, product specifications, accessories and service offerings may be required. This quick reference guide is a mere summary of some important procedure steps and/or product information. It is not meant to replace the instructions for use. Any user of this product must at all times observe all mandatory information for the product, found, in particular, on the labels and the instructions for use.