THE
NATIONAL INFECTION PREVENTION & CONTROL
GUIDELINES
FOR
ENDOSCOPY CENTRES

2023

FOREWORD

The National Infection Prevention and Control Committee (NIPC) was appointed by the Singapore Ministry of Health in 2014 and charged with a number of tasks including consolidation of national guidelines to guide healthcare facilities in developing policies to meet national standards.

It is with pleasure that we present this first edition of 'National Infection Prevention and Control Guidelines for Endoscopy Centres'. The intent of this document is to provide evidence-based guidance for the prevention of healthcare-associated infections (HAIs) in both inpatient and standalone endoscopy centres. This set of guidelines was designed for use by those responsible for infection prevention in these settings e.g. infection prevention and control (IPC) professional, clinic manager, nurse.

The recommendations in this guideline were developed by reviewing best available evidence and consulting with experts in the field and key stakeholders. Proper reprocessing of endoscopes and accessories continues to be a critical step in ensuring safe and successful treatment of patients. It is strongly recommended that facilities have in place a reliable and high-quality system for endoscope reprocessing to minimise infection risks to patients. We understand that several facilities may not be able to implement several recommendations in this guideline immediately, such as the design specifications, due to infrastructural and resource constraints (e.g. limited number of scopes etc.) but we would strongly encourage for facilities to work towards implementing them in the next couple of years or when there are plans for major renovations. In the meantime, facilities should implement close gap measures if unable to fulfil these recommendations (e.g. ensure traceability of instruments and recall policy must be in place if unable to quarantine scopes while awaiting culture results etc.).

We welcome any feedback that will help improve the guideline moving forward. For any comments or feedback, please reach out to NIPC_Sec@moh.gov.sg.

Yours sincerely,
Prof Dale Fisher
Chairperson
National Infection Prevention and Control Committee (NIPC)

ACKNOWLEDGEMENT

The National Infection and Prevention Guidelines for Endoscope Reprocessing has been endorsed by the National Infection Prevention and Control Committee (NIPC). The composition of the NIPC is provided in Table 0.1.

Table 0.1: Composition of NIPC

S/N	Name	Role	Designation
1	Prof Dale Fisher (Chairperson)	Chairperson	Senior Consultant, Division of Infectious Diseases, University Medicine Cluster, NUH
2	Adj A/Prof Brenda Ang	Member	Clinical Director, Department of Infection Prevention and Control, TTSH & NCID
3	A/Prof Ling Moi Lin	Member	Director, Infection Prevention and Epidemiology, SGH
4	Adj Asst Prof Kalisvar Marimuthu	Member	Senior Consultant, Department of Infectious Diseases, TTSH & NCID
5	Adj Asst Prof Surinder Pada	Member	Director and Senior Consultant, Infectious Diseases, NTFGH
6	Dr Louisa Sun	Member	Consultant, Infectious Diseases, AH
7	Dr Tan Si Huei	Member	Senior Consultant, Laboratory Medicine, CGH
8	A/Prof Thoon Koh Cheng	Member	Head and Senior consultant, Infectious Disease Service and Infection Control Committee Chair, KKH
9	Ms Sharon Wong	Member	Senior Nurse Clinician, Infection Prevention and Control, SKH
MOH Representatives and NIPC Secretariat			
10	Dr Kok Mun Foong	MOH Representative *(Former)*	Director, Patient Safety and Quality Improvement Division, MOH
11	Dr Albert Ty	MOH Representative	Director-Designate, Patient Safety and Quality Improvement Division, MOH
12	Dr Adelina Young	MOH Representative *(Former)*	Deputy Director, Patient Safety and Quality Improvement Division, MOH
13	Ms Luisa Tan	Secretariat *(Former)*	Assistant Director, Patient Safety and Quality Improvement Division, MOH
14	Ms Wang Xiaojie	Secretariat	Assistant Director, Patient Safety and Quality Improvement Division, MOH
15	Ms Ong Xin Yi	Secretariat	Senior Manager, Patient Safety and Quality Improvement Division, MOH

MOH would like to acknowledge A/Prof Ling Moi Lin (Director, Infection Prevention and Epidemiology, Singapore General Hospital) for leading the group of experts in the writing of the guidelines. The members of the expert workgroup who contributed in their individual capacity to the drafting of the National Infection Prevention and Control Guidelines for Endoscopy Centres are listed in Table 0.2.

Table 0.2: Composition of the Expert Workgroup (in alphabetical order)

Name	Designation
A/Prof Ling Moi Lin	Director, Infection Prevention & Epidemiology, SGH
Adj A/Prof Brenda Ang	Clinical Director, Department of Infection Prevention and Control, TTSH
Ms Chang Pin Sun	Assistant Director Nursing, Major Operating Theatre/Short Stay Unit, SGH
Tan Hwei Hian Christina	Assistant Director of Nursing, Nursing Service, TTSH
Ms Chua Puay Hoon	Senior Nurse Manager, Endoscopy Centre, SGH
Dr Ho Wen Wei Christopher	Consultant, Gastroenterology, Hepatology and Nutrition Service, Department of Paediatrics, KKH
Ms Rosidah bte Idris	Nurse Clinician, Nursing Informatics *(Current)*, Endoscopy Centre *(Former)*, NTFGH
Dr Somani Jyoti	Director, Epidemiology Unit, Deputy Chair, Infection Control Committee, Senior Consultant, Infectious Diseases, NUH.
Dr Surendra Kumar Mantoo	Senior Consultant and Chairman Endo-centre Committee, KTPH
Ms Ng Siok Peng	Deputy Director, Operating Theatre Services (Nursing), SKH
Ms Ong Siok Hoon	Nurse Clinician, Operating Theatre Services, KKH
Adj Asst Prof Surinder Pada	Director and Senior Consultant, Infectious Diseases, NTFGH
Ms See Ling Ling	Nurse Clinician, Endoscopy Centre, NUH
Ms Norhayati Binte Mohd Shariff	Nurse Clinician, Endoscopy Centre, CGH
Dr Tan Si Huei	Senior Consultant, Laboratory Medicine, CGH
Ms Serene Tay Bee Hwa	Nurse Clinician, Endoscopy Centre/Perioperative Services, KTPH
Ms Sharon Wong	Senior Nurse Clinician, Infection Prevention and Control, SKH

CONTENTS

ABBREVIATIONS AND GLOSSARY

ABHR	Alcohol Based Hand Rub
ACH	Air Changes per Hour
ACMV	Air-Conditioning and Mechanical Ventilation
AER	Automatic Endoscope Reprocessors
APIC	Association for Professionals in Infection Control and Epidemiology
CDC	Centers for Disease Control and Prevention
CSSU	Central Sterile Supplies Unit
EPDM	Ethylene Propylene Diene Monomer
ERCP	Endoscopic Retrograde Cholangiopancreatography
FTE	Full-time Equivalent
HAI	Healthcare-associated infection
HCW	Healthcare Workers
HEPA	High Efficiency Particulate Air
HLD	High-Level Disinfection
IFU	Instruction For Use
IPC	Infection Prevention and Control
MDRO	Multi-Drug Resistant Organism
MOH	Ministry of Health, Singapore
NIPC	National Infection Prevention and Control Committee
NSI	Needle-Stick Injury
PEP	Post Exposure Prophylaxis
PPE	Personal Protective Equipment
QUATs	Quaternary Ammonium Compounds
RO	Reverse Osmosis

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Chapter 1 Design Specifications for the Endoscopy Unit

1.1 Introduction

The aim of an endoscopy facility is to provide high quality diagnostic and therapeutic endoscopy services. As reprocessing is a complex process requiring stringent compliance to minimise the risk of disease transmission, it is strongly recommended that, wherever possible, reprocessing of endoscopes should be performed in a centralised area that complies with the physical and human resource requirements for reprocessing.

Centralised reprocessing areas can be either located in the Endoscopy Unit or in the Central Sterile Supplies Unit (CSSU). Where there is more than one location (i.e. decentralised), a central administration is recommended for streamlined activities and standardised workflow.

Decisions related to reprocessing of endoscopes should be made in consultation with the institution's Infection Prevention & Control (IPC) committee together with individuals responsible for purchasing, maintaining, occupational health and safety, and the end-users of the equipment / device. The objectives of planning or designing the unit are to:

a) Minimise the risk of infection and contamination for staff, patients, and the public;
b) Ensure protection from chemicals used during reprocessing of endoscopes;
c) Ensure protection from cross-contamination of potentially infectious material, blood and / or body fluids.

This document describes IPC-related specifications for areas where reprocessing of endoscopes is done in healthcare facilities and should be taken into consideration when setting up a new endoscopy unit or when planning for future renovations of existing units.

1.2 Types of Procedures

Common endoscopic procedures include respiratory procedures (bronchoscopy, endobronchial ultrasound (EBUS) and pleuroscopy) and gastrointestinal procedures (gastroscopy, endoscopic retrograde cholangiopancreatography (ERCP) and colonoscopy). In some centres, they may also be used for urological procedures (cystoscopy).

1.3 Location

Endoscopy units may be sited in acute hospitals or as a stand-alone facility as most endoscopic procedures are carried out in an ambulatory setting. Having dedicated endoscopy units allows for greater convenience for patients, streamlines processes, and enables efficient and effective utilisation of resources by scheduling groups of similar procedures together.

Ideally, the unit is to be located away from public waiting area or high traffic public corridor. Access to the endoscopy unit is restricted to only patients and staff working in the department.

1.4 Size

The size of an endoscopy unit is dependent on the type of procedures and the projected workload. Certain procedures will require radiology support and lead lined wall. Endoscopic procedure rooms will vary in size, and for more complex procedures such as endoscopic retrograde cholangiopancreatography (ERCP), greater space is required for specialised equipment and possibly additional staff. Other factors to consider would be requirement for anaesthetic support and necessary machines.

The size and design of the reprocessing area depend on:

a) Workload (number of patients and procedures);
b) Number and types of endoscopes reprocessed in area;
c) Number and types of automatic endoscope reprocessors (AERs), storage and / or drying cabinets.

The endoscopy unit may need to factor in the requirement for bronchoscopy or change in type of procedures as well as any increase in workload caused by the introduction of new referral guidelines, increase in screening programs or change in population patient profile.

Each area within the endoscopy unit should have a designated flow for the safe physical movement of dirty endoscopes that do not cross-contaminate clean endoscopes coming out of the cleaning process and their storage. Table 1.1 presents the design parameters for the endoscopy unit. The main goal is to ensure immediate reprocessing of used endoscopes, irrespective of the distance between the procedure room and the reprocessing area.

It is the responsibility of the clinical service provider to ensure that adequate facilities for proper reprocessing are available.

Table 1.1: Recommended Design Parameters for Endoscopy Unit

Area	Pressure relationship to adjacent areas	Minimum air changes of outdoor air per hour	Minimum total air change per hour	Relative humidity (%)	Temperature (^{0}C)
Reprocessing area	Negative*	2	10	No requirement	No requirement
Gastrointestinal endoscopy procedure room	No requirement	2	6	40-60	21-24
Bronchoscopy procedure room	Negative	2	12	40-60	21-24

Note: *There should be a minimal pressure difference of 2.5 Pa to the adjacent area (Reference: Guidelines for design and construction of hospitals. The Facility Guidelines Institute. 2018 edition)

1.5 Safety features

Lighting, ventilation, and fume extraction are used to minimise the risks from chemical vapours generated during the reprocessing. Separation into dirty and clean reprocessing rooms reduces the risks for re-contamination of reprocessed equipment and reduces risk of environmental contamination. The spread of contaminated aerosols, droplets and dust particles is further minimised by using negative pressure ventilation only for bronchoscopy room. Besides the Air-Conditioning and Mechanical Ventilation (ACMV) specifications described in Table 1.1, attention should also be paid to the location of exhausts for appropriate discharge of smell and toxic chemical vapours.

1.6 Layout

The key zones for functional areas are:

a) Public areas;
b) Consultation / preparation areas;
c) Procedural areas;
d) Clinical support areas;
e) Administration, staff welfare, training, educational and research areas.

The patient's journey through the endoscopy unit can be separated into the following areas:

a) Entrance / Exit;

b) Reception and waiting;
c) Preparation for the procedure;
d) Procedure;
e) Recovery and discharge.

The reprocessing room should be designed to provide a one-way traffic flow of contaminated items to cleaned items to the automatic endoscope reprocessors (AERs). Entrance to the reprocessing room from the procedure room is permitted. Exit from the clean area of the reprocessing room into the procedure room is also permitted. A minimum clearance of 2 metres should be provided between the decontamination area and the clean work area.

1.6.1 Entrance / Exit

If the endoscopy unit is in a hospital, then ideally, there should be separate entrances and exits for inpatients and outpatients. Inpatient entrances should be wide enough to allow for passage of patients in beds or trolleys. Outpatient entrances should be accessible for disabled or wheelchair patients. Entrances and exits should be clearly signposted. The width of the entrance and corridors should be broad enough to allow for the transportation of beds, stretchers and wheelchairs and allow for beds to turn around in corridors.

1.6.2 Reception and waiting area

The reception area accommodates the initial processing and admission of all scheduled and unscheduled patients. It should be spacious enough to avoid a sense of overcrowding and provide an open, friendly facility. Patients' escorts and staff must be able to talk and exchange information with ease.

The reception desk should be adjacent to the general administrative office and close to the main waiting area. The administrative office should be large enough to accommodate administrative staff, as well as storage of the necessary health records. There should be adequate telephone, fax and internet facilities for communication, booking and audit activities.

Staff will be managing the assessment and preparation of patients prior to their procedures. The staff base should thus be sited for easy access to patient records and nursing assessment forms as well as to oversee the patient changing rooms and sub-wait areas.

1.6.3 Preparation for procedure

Changing rooms are required where a patient can undress in privacy and put on appropriate scrub suit. Intake rooms (or cubicles) are needed for patients to give their medical history, allow baseline observations to be carried out and enable confidential discussions with the staff; for example, taking informed consent.

Patient preparation rooms should be adjacent to the main waiting area and be provided with toilet facilities. There should be easy access from the patient preparation rooms to the endoscopy rooms. The number of patient preparation rooms will depend on the throughput of the endoscopy rooms. Ideally, one patient preparation room for each endoscopy room will be adequate, with an additional one containing a trolley for non-ambulatory patients. However, a shared preparation room may be considered where there is space constraint.

Pressure on the number of patient preparation rooms resulting from fast throughput of patients will be relieved by the inclusion of a sub-wait area. Two separate entrance / exit doors should be provided to allow for the entry of clean instruments and for the removal of used endoscopes at the end of the procedure.

With respect to space requirements, the following are specifications for the area (The Facility Guidelines Institute, FGI):

a) Patient Bays: a minimum clear floor area of 9 m^2 shall be provided for each patient in a lounge chair or stretcher;
b) Cubicles: each station shall have a minimum clear floor area of 9 m^2;
c) Single-bed rooms: a minimum clear floor area of 9 m^2 shall be provided in each room.

With respect to space requirements on clearance (FGI):

a) Patient Bays minimum clearance: a minimum clearance of 2 metres shall be provided between the sides of patient beds / stretchers; 1.2 metres between the sides of patient beds / stretchers and adjacent walls or partitions; and 1.2 metres between the foot of the bed and the cubicle curtain;
b) Patient Bays aisle: an aisle with a minimum clearance of 2.4 metres independent of the foot clearance between patient stations or other fixed objects shall be provided;
c) Cubicles and Single-bed rooms: a minimum clearance of 2 metres shall be provided between the sides and foot of lounge chairs / stretchers and adjacent walks or partitions.

Handwash stations should be evenly distributed for use. The patient's toilet should be separate from that for public use and be directly accessible by patients.

1.6.4 Procedure

The room should be laid out into two main areas, the endoscopy area and the assistant area. Each procedure room shall have a minimum clear floor area of 16.7 m^2. Room arrangement shall permit a minimum clearance of 2 metres at each side, head, and foot of the stretcher / table.

The endoscopy area should include hand hygiene facilities and a small office workstation where the endoscopist may sit to dictate, write, or enter endoscopy findings or post-procedure instructions.

The assistant area should include a work surface with inset sink, and units for the storage of endoscope accessories, small quantities of clean and sterile supplies and drugs, including the temporary storage of controlled drugs. There should be direct access from the assistant area to the endoscope cleaning room to facilitate the reprocessing of endoscopic equipment. The inset sink should be at least 2 metres away from where drug preparation is being done. If not possible, then a splashguard should be erected to separate sink from work surface.

The endoscopy procedure room should be purpose-designed to accommodate, but not be limited to, the following:

a) Endoscopy stack and video monitor(s);
b) Endoscope cabinet with clean endoscopes and accessory equipment such as endoscopy biopsy forceps, snares, injectors to allow for endoscopes to hang without coiling, preventing damage to either end of the scope, and properly ventilated with temperature controls, preferably a pass-through type, located between decontamination / sterilising areas and operating/procedure room;
c) Monitoring equipment to allow continuous monitoring of patient condition during procedures;
d) Anaesthetic equipment and medication to provide procedural sedation;
e) Diathermy and / or argon plasma coagulation equipment;
f) Imaging equipment, such as image intensifier or C-Arm X-Ray screening unit, depending on procedures to be performed; imaging equipment should be portable or installed in room.

There should be considerations for the special requirements of imaging and laser equipment, if required. Lead lining of designated rooms should be included.

The procedure room for endoscopy will require access to the clinical scrub-up area, clean-up, and decontamination area for timely processing of endoscopes and their storage.

The width and height of the doorways to operating / procedure should ensure that transportation of equipment is not impeded, and the patient trolley / bed movement is not hampered, with a minimum clear opening of 1.5 metres. The doors should be automated with sensors.

All scrub-up / gowning areas / rooms should be located with close access to the procedure rooms. To avoid contamination, the door(s) between adjacent procedure room and scrub-up room should have a non-contact mechanism for operation. The scrub-up / gowning room should be sized to accommodate several staff scrubbing, gowning, and moving simultaneously without any risk of contamination from each other or surrounding fixtures. The fixtures in the scrub-up / gowning room should meet the following requirements:

a) The chemical and stain resistant stainless-steel trough and fixtures should be wall mounted for hand and arm washing;
b) Efficient drainage in the trough should be provided to avoid spills onto the floor during the scrub-up procedures;
c) The rim of the scrub trough should not have an internal lip as dirty water may drain from the elbows into the sink. Debris may also be potentially trapped under rims with internal lips which cause risk of infection. The wall surface behind the trough should be a single waterproof surface.

A reliable and adequate source for oxygen is required. Sources may include in-wall or free-standing oxygen. In some units, carbon dioxide may be used for insufflation of the gastrointestinal lumen. A suction source for the equipment and patient must be present either in-wall or portable. An uninterruptible power source supplied either by a generator or battery source is required.

The purpose of a secondary power source is to allow completion of the current procedure in the event the primary power source malfunctions. There should be adequate space in the endoscopy procedure room, especially for fluoroscopic or other portable devices or carts. Planning for general anaesthesia should focus on providing adequate space for

anaesthesia staff and equipment at the head of the bed and for storage of anaesthesia equipment.

1.6.5 Others: Recovery and discharge

There should be sufficient space for equipment to monitor patients e.g. pulse oximeter, sphygmomanometer, and ECG machines. All rooms should have facilities for piped oxygen and suction and adequate electrical socket outlets for ancillary equipment.

If an image intensifier is to be used, space must be allowed to manoeuvre and position the equipment. There should be adequate space to store lead aprons worn by staff.

Puncture resistant containers for biohazardous materials and sharps should be located at immediate care areas to facilitate safe disposal of used sharps. If special therapeutic procedures are planned, specific room features may be required, such as leaded walls when flat table fluoroscopy is utilised.

A room designated for bronchoscopy should be engineered to have negative pressure with 12 Air Changes per Hour (ACH). 100% exhaust, no recirculation (ASHRAE Standard 170) air flow to other rooms is recommended to be relatively negative and 6 ACH for odour control as well as to contain leakage of anaesthetic gases.

1.6.6 Support areas for staff

A staff rest area is provided with a handwash station. Tables and chairs are to be placed with safe distancing measures considered for mask down activities.

A staff changing area with private changing rooms shall be provided for staff. It should include the following:

a) Lockers;
b) Toilets;
c) Shower facilities;
d) Handwashing stations;
e) Space for changing clothes;
f) Provision for separate storage of clean and soiled surgical attire.

1.6.7 Support areas for patients

A patient toilet room(s) shall be readily accessible to procedure room(s) and pre- and post- procedure patient care area(s). An area shall be provided for patients to change from street clothing into patient gowns. Provision should be made for securing patients' personal items.

1.6.8 Storage of Supplies

Clean surgical equipment should be stored in appropriate places with demonstrable regular checks on the integrity of the equipment, relative humidity (< 60%) and temperature (< 25°C).

Sterile supply items such as intravenous (IV) solutions should be protected from splash contamination during environmental cleaning (20 - 25 cm off the floor), damage from compression (stacking only ridged containers), and water damage (no storage under sinks).

1.6.9 Endoscope reprocessing room and storage

Endoscope and instrument reprocessing is a multi-step procedure which involves the following:

a) Decontamination/ intake of dirty scopes/ instruments as soon as the procedure is complete;
b) Reprocessing of scopes in the reprocessing room;
c) Packaging and storage of clean scopes, for reuse in the procedure room(s).

An endoscope reprocessing room and storage area should have a 'dirty' area where used equipment can be manually cleaned and tested, and a separate 'clean' area where equipment can be disinfected and stored. These areas may be separated by 'pass through' AER.

Depending on local policy, endoscope accessories may be sterilised, and suction bottles may be automatically emptied, washed, and disinfected. Alternatively, these items may be sent to the Sterile Services Unit (SSU) for reprocessing. The 'dirty' area should be equipped with separate sinks of adequate size for cleaning and rinsing i.e. double bowl sinks at least 0.5 metres high and double drainers. Ideally, the sinks should be height-adjustable i.e. ergonomically correct for staff use. Handwash facilities should also be provided. There should be separate dedicated handwash basins in 'dirty' and 'clean' work areas. An eyewash station is required and should be installed to prevent potential hazards to the eye due to contact with a biological or chemical agent.

A leak tester will be required to allow checking the integrity of endoscopes before reprocessing and sinks should be supplied with washing hoses to allow adequate rinsing.

The ‘clean’ area of the endoscope reprocessing room should contain the AERs, the number of which will be dictated by the volume and throughput of the unit. The area should include storage areas for the decontamination solutions and appropriate personal protective equipment. This area should have negative pressure and adequate ventilation fulfilling the local health and safety ventilation requirements required for the specific decontamination solutions in use and adequate handwashing facilities. The clean area should be adjacent to the storage area for flexible endoscopes and reusable accessories. There should be adequate space allocated for purpose-designed drying cabinets, if used.

The ‘dirty’ area and ‘clean’ storage area in the endoscope cleaning room should have separate direct access from the other rooms, preventing cross-over of ‘dirty’ and ‘clean’ endoscopes. ‘Clean’ and ‘dirty’ utility rooms are ideally placed with easy access from both the preparation and recovery areas. The ‘dirty’ utility area should be fitted with a sluice sink, a sink unit with drainer, a hand-wash basin, a work surface, cupboards, and shelves. There should be a minimum gap of 1 m between the decontamination and work areas.

Storage for clean scopes should be located in a clean room, within a HEPA filtered cabinet with doors to hang scopes vertically without bending or placed horizontally with attachments for continual drying of the endoscopes. The cabinet must be at least 2 metres away from any sink and should be located such that staff do not have to cross through the decontamination area to access the clean scopes. Space and utility connections should be made available for AERs, sonic cleansers and sterilisers.

Space should be allocated for the following cleaning and disinfection equipment to be installed:

a) Sinks for soaking, disinfection, and rinsing, sufficiently sized to prevent tight coiling of the endoscope which may damage the fibre-optic cables in the instrument;
b) Ultrasonic cleaner for accessory equipment used in procedures;
c) Equipment for manual cleaning steps e.g. brushes, cleaning adapters, endoscope leak test units;
d) Automated endoscope cleaning/ disinfecting machines (AERs);
e) Compressed air with suitable technical specifications for drying of endoscopic equipment after cleaning;

f) Handwash basin;
g) Safety eyewash facility;
h) Stainless steel benches with space to accommodate the length of the endoscopes;
i) Appropriate storage of process chemicals;
j) Storage facilities for endoscopes, ideally storage cabinets with/without drying function;
k) Documentation and traceability equipment.

1.6.10 Recovery areas

Various arrangements for patient recovery may be in place in different institutions. When the number of procedures is small to moderate, all the patients may be in a single location post-procedure. For endoscopy units with greater volumes of patients and procedures, having a design that allows for a 2-stage recovery may be more efficient.

Units with a two-stage process: where the first allows for close monitoring immediately post-procedure and the second, a less intensively supervised area which allows patients to wait for their escorts and receive refreshment.

With respect to space requirement, a minimum clear floor area of (9 square meters) should be provided for each bay or cubicle.

Each patient care station shall have the following minimum clearance:
a) A minimum clearance of 2 metres between patient stretchers or beds;
b) A minimum clearance of 1.2 metres between patient stretchers or beds and adjacent walls or other fixed elements at the stretcher / bed's sides and foot;
c) A minimum clearance of 1.2 metres from the foot of the stretcher or bed to a closed cubicle curtain.

Hand hygiene facilities should be evenly distributed and there should be a uniform distance from two patient care stations farthest from a general handwash station.

In the absence of an isolation room, patients with multidrug resistant organisms (MDROs) at recovery area may be managed through observation of good hand hygiene practices and appropriate use of gown and gloves.

Patient's toilet should be separate from public use and be directly accessible by patients.

1.7 Radiation Protection

The systems and processes that are put in place for radiation protection and provision of storage for radioactive sources and waste under clinical support areas should be in accordance with the Radiation Protection Act (Cap.262) and its Regulations. Plans and specifications of the areas that require radiation protection will require assessment by Radiation Protection and Nuclear Science Department (RPNSD), National Environment Agency of Singapore.

1.8 Recommendations

1. It is strongly recommended that, wherever possible, reprocessing of endoscopes should be performed in a centralised area that complies with the physical and human resource requirements for reprocessing. [BIII]
2. Decisions related to reprocessing of endoscopes should be made in consultation with the institution's Infection Prevention & Control (IPC) Committee together with individuals responsible for purchasing the equipment / device, maintaining the equipment / device, occupational health and safety and the end-users of the equipment / device. [AII]
3. Each area within the endoscopy unit should have a designated flow for the safe physical movement of dirty endoscopes that does not cross-contaminate clean endoscopes coming out of the cleaning process and their storage. [AII]

1.9 References

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Chapter 2 Water Quality

2.1 Introduction

Water is used in the Endoscopy Unit for various purposes:

a) Initial rinse-water;
b) Intermediate rinse-water (not a critical factor if disinfectant and cleaning agents are compatible);
c) Final rinse-water; and
d) Diluent for chemicals.

2.2 Water hardness

Hard water (>200 mg/L $CaCO_3$ equivalent) used in final rinse in the AER cycle may cause deposits on the endoscope. These deposits will act as potential focus for soiling and recontamination of the endoscope. It may also seriously impair the optical system of the endoscope. However, the water in Singapore is not hard.

2.3 Temperature

Water at too high temperature during the initial flushing stage may lead to the coagulation of proteins and may “fix” proteinaceous soil to the surface in parts of the endoscope. Refer to manufacturer’s Instruction for Use (IFU) on optimal temperature setting required for the detergent and disinfectant used.

2.4 Chloride concentration

Water used in the cleaning and disinfection of flexible endoscopes should have a chloride concentration between 0 and 120 mg/L chlorine to avoid the risk of corrosion on steel and plastic components of the endoscope.

2.5 Microbial contamination

Water supply to AER should be treated using filtration, deionisation, or reverse osmosis (RO). A 0.2µm filter is adequate to remove common microbial pathogens. Deionised water may become contaminated with microorganisms and the resin column colonised with bacteria; hence it should be further decontaminated (i.e. either by heating or filtration etc) if used for final rinse of products intended for invasive use. RO is performed under pressure through a semi-permeable membrane against an osmotic gradient. The process will also

remove a high proportion of organic material, bacterial endotoxins, and microorganisms. Some RO units are fitted with a final 0.2µm filter to control bacterial numbers.

Legionella species may be found in contaminated water in association with other organisms and the presence of biofilm. However, they are rarely found in the filtered rinse water and its detection is not routinely required.

Biofilm is a layer of growth that forms due to organisms sticking to solid surfaces. The removal of biofilm takes considerable effort and may require the use of aggressive chemical agents and physical friction. *Pseudomonas aeruginosa* has been reported to colonise taps in handwash basins and sinks used for cleaning or general tasks, therefore regular microbiological sampling of rinse water is required to determine the risk for *Pseudomonas aeruginosa* and atypical *Mycobacterium* species contamination.

2.6 Recommendations

1. Regular microbiological sampling of the rinse water is required to determine the risk for *Pseudomonas aeruginosa* and atypical *Mycobacterium* species contamination. Refer to Chapter 6 on Microbiological Surveillance for further details. [AI]
2. Water used for cleaning and disinfection should be treated using filtration, deionization, or reverse osmosis (RO). A 0.2 µm filter is required to remove common microbial pathogens. [AII]

2.7 References

Chapter 2 Water quality and water treatment. In Health Technical Memorandum 01-06: Decontamination of flexible endoscopes Part B: Design and installation. 2016.

Chapter 3 Personnel

3.1 Introduction

The reprocessing and handling of reusable flexible endoscopes (RFE) is a multi-step, highly complex activity which includes pre-cleaning, leak testing, manual cleaning, rinsing after cleaning, visual inspection, high level disinfection (HLD), rinse after HLD, drying, storage and documentation.

Compliance with accepted guidelines for the reprocessing of endoscopes between patients is critical to the safety of use. Hence, it requires that personnel are trained and competent in standards and practices. Ensuring consistent effective endoscope reprocessing and safety is a multidisciplinary effort involving clinical, reprocessing staff, infection prevention personnel, and management.

There should be a trained and certified supervisor who oversees the process of reprocessing instruments in the institution.

3.2 Objectives

Reprocessing personnel should:

a) Understand the rationale and importance of each step in reprocessing;
b) Have ready access to the manufacturer's instructions for use (IFU);
c) Be able to read, comprehend and implement the manufacturer's instructions on the proper cleaning and high-level disinfection of gastrointestinal endoscopes and accessories (CDC, 2017);
d) Demonstrate competency on the proper use of the equipment such as AER and chemicals used for endoscope reprocessing;
e) Complete hospital reprocessing training programme, with documented competency for new models of endoscopes, accessories, valves and automatic endoscope reprocessors as soon as they are introduced in the facility (AAMI, 2015; CDC, 2017);
f) Complete all endoscope reprocessing steps meticulously and efficiently, maintaining, strict adherence to reprocessing guidelines;
g) Comply with methods of tracking and documentation required for each phase of reprocessing as outlined by the facility;

h) Immediately report any breaches in reprocessing according to facility policies and protocols;
i) Understand the safety hazards of endoscope reprocessing and take appropriate action to protect oneself and others;
j) Follow manufacturers' guidelines for maintenance, repair and replacement of endoscopes and equipment used for reprocessing (e.g. AER) including loaner equipment;
k) Keep up to date information related to endoscopy reprocessing, as well as manufacturer's instruction for use and institutional policies;
l) Temporary personnel and/or staff who are not deemed competent should not be allowed to clean or disinfect the scopes in either manual or automated reprocessing systems until competency has been established. Only trained personnel whose competency has been established are allowed to re-process endoscopes.

Supervisors overseeing department / area involved in reprocessing of flexible endoscopes should contribute to the effectiveness and safety of endoscope reprocessing. The role of the supervisor of the endoscopy unit is to ensure that staff involved in reprocessing of endoscopes fulfil the following criteria:

a) Experienced to reprocess scopes and able to adequately train and evaluate the competency of staff (CDC, 2017);
b) Compliance with the manufacturer's validated IFU for reprocessing (Alfan & Olson, 2016);
c) Follow manufacturers' guidelines for maintenance, repair and replacement of endoscopes and equipment use for reprocessing (e.g. AER) (CDC,2017);
d) Verify that there is documentation of compatibility between each endoscope, AER and method of HLD (Armellino, 2016);
e) Reprocessing guidelines and related competencies are reviewed and updated to ensure compliance with current standards and manufacturers' guidelines;
f) Consult with individuals responsible for infection prevention and when considering modification to the reprocessing guidelines and when purchasing new reprocessing equipment (CDC, 2017);
g) Collaborate with IPC and quality personnel to assess risk of disease transmission in the reprocessing environment;
h) Collaborate with IPC to ensure institutional policies are consistent with national, international guidelines and manufacturers' instructions for use;

i) Collaborate with vendor, biomedical engineer (BME), and facilities engineer (FE) for sharing of their technical expertise and ensure reprocessing equipment are periodically maintained and in good working condition;
j) Ensure FE / BME engineer are responsible for commissioning of all new / loan / trial equipment and ensure that it complies with international safety standards and its performance meets the manufacturer's performance specifications;
k) Establish policies and procedures detailing the facility's response to a reprocessing breach or failure (CDC, 2017);
l) Provide timely corrective action for patient safety issues related to reprocessing (Kanamori *et al*., 2016);
m) Assess the number and category of personnel who will be responsible for endoscope reprocessing;
n) Ensure all staff involved in endoscope reprocessing are identified, trained, and demonstrate initial and continued competency based on the manufacturer's IFU (Armellino, 2016);
o) Ensure availability of adequate staff to support meticulous and timely reprocessing;
p) Allow adequate time for endoscope reprocessing to ensure adherence to all reprocessing steps recommended by the manufacturer (CDC, 2017);
q) Observe staff for adherence to policies and guidelines, possibly using a checklist for endoscope reprocessing areas (JCI,2014);
r) Monitor adequate documentation at all stages of reprocessing (CDC, 2017);
s) Promote a culture of safety so that staff can be free to communicate concerns.

3.3 Education and Training

Institutions with any centralised and decentralised reprocessing unit(s) must have:
a) Documented comprehensive training programme(s) for staff involved in reprocessing of endoscopes;
b) Relevant competency-based training programme appropriate to their role;
c) Differentiated training programmes for staff at entry (basic) level and supervisor/managerial (advanced) level;
d) Continuing education programmes are in place to ensure continuous knowledge and skills upgrading.

Education programme for reprocessing personnel should encompass the following component:

a) Mechanisms of disease transmission and their precaution (SGNA, 2016);
b) Personal protective equipment (ASGE,2014);
c) Reprocessing procedures for endoscopes and accessory equipment including loan endoscopes (ASGE,2014; SGNA,2016);
d) Maintenance of a safe work environment (CDC,2017; Petersen *et al*.,2017);
e) Safe handling of high-level disinfectants (CDC,2017; Ling *et al*.,2018);
f) Waste management (CDC,2017; ASGE,2014);
g) Type and design of endoscopes used, and the procedures performed in the facility (ASGE,2014);
h) Manufacturers' specific instruction for endoscopes care (SGNA,2016);
i) Decontamination, cleaning, and sterilization of reusable accessories that breach the mucosal barrier (SGNA,2016).

A competency assessment framework should be in place to evaluate staff competency annually. Ideally, this should be centralised. Any decentralised facility should have a list of competencies applicable to high-level disinfection reprocessing of endoscopes. Competency assessment to re-certify staff should be clearly documented with information on the staff assessed, date, competency assessed, method and frequency of assessment. On-going competency assessment is important to assure safe practice and continuous performance improvement.

3.4 Audit

Regular internal audits of competency and reprocessing activities should be conducted:

a) At least annually to refine / update training programmes (Petersen *et al*.,2017);
b) To assess compliance with guidelines (Lukejohn *et al*.,2017; Van Wicklin et al.,2016); and
c) To identify lack of knowledge and skill for early practice correction (Petersen *et al*.,2017; ESGENA,2018).

3.5 Recommendations

1. It is strongly recommended that the reprocessing personnel are only allowed to perform scope reprocessing independently after completion of hospital

reprocessing training programme and are assessed to be competent. (SGNA,2016). [AII]

2. Department should ensure annual on-going competency and assessment for reprocessing personnel to maintain safe practice and continuous performance improvement (Einreichen, A.,2018). Department should keep a register of staff training records and competency. [AII]

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Chapter 4 Procurement

4.1 Introduction

In recent years, endoscope reprocessing has been a key hot topic in IPC, largely due to a number of publicised outbreaks due to increasing scope complexity and reprocessing. As per Spaulding classification [1], gastrointestinal endoscopes are considered semi-critical medical devices and require at least High-Level Disinfection (HLD) after each use. Bronchoscopes should ideally be sterilised.

Use of Automated Endoscope Reprocessors (AERs) has increased in popularity as they can be used as a HLD machine for flexible endoscopes. They can be used to replace some manual steps in reprocessing and can be programmed to handle complex multistage processes as shown in Table 4.1.

AERs are also associated with increased consistency and compliance with endoscope reprocessing guidelines and inversely associated with skipped steps during reprocessing. They allow for record keeping regime and can be used as an effective form of manual or computer-based instrument tracking and tracing that can be interfaced with patient records.

In addition to patient safety benefits, AERs also minimise exposure of endoscopy or sterile processing department personnel to HLDs or chemical sterilant and reduce work related repetitive movements that can potentially cause bodily injury. Table 4.1 below illustrates some steps that could be considered for automation using an AER that might be considered during the purchasing process.

Table 4.1 Endoscope reprocessing steps

Steps	Purpose	Can be performed by AER
Precleaning	• Begins in the procedure room immediately after procedure and before disconnecting the endoscope from the power source • Precleaning removes bioburden before it has an opportunity to dry	No
Leak testing	• Detects damage to the interior or exterior of the endoscope	Yes

[1] Spaulding classification is a strategy for reprocessing contaminated medical devices. The system classifies a medical device as critical, semi-critical, or non-critical on the basis of risk to patient safety from contamination on a device. The system also established three levels of germicidal activity (sterilization, high-level disinfection, and low-level disinfection) for strategies with the three classes of medical devices (critical, semi-critical, and non-critical).

Steps	Purpose	Can be performed by AER
	• Leak testing is done before immersion of the endoscope in reprocessing solutions to minimize damage to parts of the endoscope not designed for fluid exposure	
Manual cleaning	• Ensures removal of retained bioburden • Retained bioburden may inactivate or interfere with the capability of the HLD solution to effectively kill or inactivate microorganisms	No*
Rinse after cleaning	• Removes residual debris and detergent	Yes
Visual inspection	• Ensures the endoscope is visually clean before proceeding to HLD • Manual cleaning and rinse after cleaning should be repeated if visual inspection fails	No
HLD	• Destroys all viable microorganisms but not necessarily all bacterial spores	Yes
Rinse after HLD	• Prevents exposure and potential injury of skin and mucous membranes from chemical residue	Yes
Drying	• Prevents growth of waterborne pathogens	Yes

**Manual cleaning is required even if AER manufacturers claim that manual cleaning is unnecessary.*

It is vital that appropriate procedures are followed for the acquisition, maintenance, and validation of decontamination equipment. Before such an exercise can be undertaken, there are some factors that should first be considered to help with the ultimate decision of which AER will work best for your institution and how many you may need.

4.2 Specifications

4.2.1 Number of AERs

The number of the AER machines needed in each location should be based on the assessment of throughput and workload.

Throughput capacity is in turn affected by:

a) The number of operational hours per week for the department in which AERs are located;
b) The machine utilisation factor expressed as a percentage of the number of operational hours. The following should be taken note of whilst carrying out this exercise:
    i. Delivery schedules from clinical areas, if separate from the decontamination area;

ii. Peak throughput dependent on list scheduling;
iii. Staff availability for loading and unloading;
iv. Start-up and shutdown time each day;
v. Planned and breakdown maintenance time;
vi. Routine, periodic and annual testing;
vii. First morning run to decontaminate endoscopes stored overnight;
viii. Self-decontamination runs.

Throughput time is the shortest practicable turnaround time required to maintain an effective clinical service; this time is affected by four key factors:

a) AER cycle time;
    i. Single versus dual scope capability
    ii. Single basin or separate basins for independent cycle. Dependant on scope inventory and procedure load.
b) AER capacity and design configuration;
c) Manual cleaning time;
d) Machine availability.

Workload estimates come from historical records of operational activity or based on proposed workloads. An approximate assessment of the workload can be determined from the actual, or expected, weekly caseload.

Downtime is the total time that machines are unavailable for routine use. This needs to be calculated as time is required for carrying out the machine disinfection procedure, routine servicing, maintenance, and for compliance with the recommended testing regime.

4.2.2 Type of AERs

The type of AER machine procured should be based on the needs of the department and constitute a number of factors as listed below:

a) Scope mix — the most common types of scopes used should be identified.
b) Compatibility to common AER types - Procure AERs that are designed specifically to reprocess scopes that are most commonly found in the departments.

The model of AER should also have been approved by HSA at the point of tender process. The AER compliant with the EN ISO 15883 standard series should;

a) Provide a standardised and validated reprocessing cycle in a closed environment;
b) Document the process steps automatically (via a printer or electronically);
c) Provide a reliable and reproducible reprocessing;
d) Minimise staff contact with chemicals and contaminated equipment;
e) Minimise contamination of the environment;
f) Facilitate the work involved for personnel;
g) Lower the risk of damage to endoscope.

4.2.3 Cost and budget

Budget limitations should be considered; look at overall costs per cycle, including expenditures for service, support, energy, training, disinfectants, and other consumables.

Required chemicals for the AER play a critical role. Increased efficiencies can be realised when using disinfectants that:

a) Are close to room temperature;
b) Have a shorter contact time, allowing for a quicker turnaround time;
c) Demonstrate cost-effectiveness when considering costs of disinfection per cycle;
d) Have documented microbial efficacy against full spectrum of clinically relevant microorganisms.

Servicing requirements also add to potential cost and efficiency. Consider:

a) Typical service schedule for that model;
b) Determine yearly maintenance and servicing fees that would be expected;
c) How quickly service can be provided for the unit;
d) Mobility of AER; useful feature as it allows the unit to be moved to prevent disruption of workflow within the endoscopy unit.

Training needed and the support required is a very important component to consider when procuring an AER. Things to consider include:

a) Onsite visits;
b) Repeat visits provided when new staff hired;
c) Remote support provided to help troubleshoot issues or answer questions;
d) Available training tools e.g. videos or competency checklists.

Footprint of the AER is important when deciding what type of AER to purchase. Factors that need to be considered include the following issues relating to:

a) Workflow:
   i. Room set up: single room with dirty and clean workflow or separate clean and dirty rooms; single versus double door AER;
   ii. Single-door AERs that are loaded and unloaded from the same side;
   iii. Double-door (or pass-through) AERs allow dirty flexible endoscopes to load on one side and be processed. The clean, disinfected instruments are unloaded on the other side of the unit. This type of AER allows endoscopy decontamination to pass through a dividing wall and provide clean and dirty areas with separate entrances and air supplies;
   iv. Space for access to the AER chamber; allows staff to easily operate the AER without risk to themselves, AER and endoscope and allows service engineers to carry out maintenance and testing.

b) Environmental limitations:
   i. Power supply needed;
   ii. Plumbing requirements including filtration (i.e. hard or soft water) issues;
   iii. Storage for concentrated chemical in secure chemical cabinet;
   iv. Compressed air.

4.3 Tender process

Consult with the AER manufacturer and other relevant manufacturer's IFU, especially the intended flexible endoscope to be reprocessed, on compatibility of endoscopes with a specific AER or chemical. See example in Annex A.

The AER should have a manufacturer validated IFU for cleaning and processing. Validation by the manufacturer provides objective evidence that the requirements for the specific intended use of the product or device can be consistently fulfilled. There should be an opportunity for pre-purchase evaluation of the AER; ensuring that the facility has the capability to comply with the manufacturer's IFU. Verification of the manufacturer's IFU is important since these may vary widely. Some parts may have unique requirements that may not be achievable within the facility.

Data supplied by purchaser:

a) Water-supply test results prior to any tender actions (these tests may include hardness, total organic carbon (TOC), total viable count (TVC), and conductivity.
b) Outline of the unit's layout: configuration – single- or double-door/lid.

c) Role of an endoscope dryer, if required.
d) Specification for the performance qualification (PQ) test.
e) The tracking and traceability system to be used, including print-out of cycle data, should be traceable to the patient.
f) Cleaning and disinfection chemicals, if possible (if not detailed in the manufacturer's type-test data).
g) Method of adjudication should problems arise.
h) Breakdown of endoscope numbers per day that can be processed including cycle times: for example, allow for 60% AER usage time; 40% maintenance and testing.

Data to be supplied by the manufacturer / agent:

a) Floor area required for AER(s) and water treatment plant, plus dimensions, weight, clearance, and access requirements.
b) If water treatment plant is required, who to supply and install specification of final rinse-water standard to be adopted.
c) Engineering details for the proposed machines: drainage, water, electricity, sound, ventilation, air supply, and floor loading.
d) Pre-tender site inspection by manufacturers: site improvement work that may be required; -access clearance and access for maintenance and repair.
e) Type-test list and results
1. Price breakdown of AER and associated equipment (for example, connectors, endoscope cradles): running costs including electric power, recommended detergent, disinfectant, water volume and treatment (for example, filters, reverse osmosis).

4.4 Delivery of an AER

The delivery path of the machine through the building to where it is to be installed should be worked out in details, also the services needed to be in place so that the machine can be operated without delay.

The manufacturer should take steps to dry the internal surfaces of an AER before leaving the factory after final tests to limit the growth of biofilm during delivery / storage.

Storing or delayed delivery of an AER may be unavoidable. Water remaining in the machine after its factory testing will allow biofilm to develop within pipework. If delays have occurred since the date of manufacture, and it was not dried before delivery, arrangements

should be made to have a replacement pipe set fitted to the machine and a self-disinfection cycle run before it is tested and used. A new AER should be delivered with replacement pipework, which can be fitted before commissioning.

A works test sheet should accompany an AER when it is delivered to site. It is important that test results are compatible with national guidelines and found acceptable, otherwise it will be more difficult to resolve problems if the machine is allowed to be installed and connected.

4.5 Commissioning

The efficacy and the efficiency of the procured AER should be validated based on the manufacturers commissioning documents and guidelines.

Refer to Table 4.2 for Checklist for AER commissioning.

Key factors in determining the cleaning efficacy of the process include:

a) Concentration of detergent;
b) Confirmation that process fluids come into contact with and flows across all surfaces of the endoscope, internal and external;
c) Compatibility of the AER to the endoscope;
d) Temperature of the cleaning process;
e) Type of wash process (for example, soak or spray);
f) Pressure of water jets, if used;
g) Orientation of endoscope in an AER to give good chemical access to all external surfaces;
h) Pressure and/or flow of detergent down all lumens to be cleaned;
i) Contact time;
j) Water quality.

Key factors in determining the microbial efficacy of the process include:

a) Assurance that the load is clean;
b) Formulation and type of disinfectant(s) used;
c) Concentration of the disinfectant;
d) Microbial quality of the final rinse-water;
e) Temperature at which the cleaning agent and disinfectant are used;
f) Contact time with the endoscope;
g) Quality and temperature of water used to dilute (if applicable) disinfectant;

h) Confirmation of disinfectant flow across all surfaces, internal and external, of the endoscope;

i) Absence of inhibitory materials, such as residual soiling and residual chemicals from the cleaning stage;

j) Pressure and flow down lumens;

k) Scope orientation;

l) Absence of fissures and holes in the endoscope and its lumens.

Table 4.2: Checklist for AER commissioning

Item	Pointers
Water supply	• Hardness, conductivity, total organic carbon (TOC) and total viable count (TVC) • Level of residual chlorine (as it can destroy reverse osmosis membrane) • Pressure, temperature and flow of water supply • Conduct audit of water supply system from point of entry to hospital to point of use
Drains	• Position of the drain in the floor of a room will, to a degree, dictate where the AER can be sited. To move drain can be major issue. • Drains from AER should be sealed within the room and vented to the outside to prevent noxious gases entering the work area. • Check that the drainpipe diameter is sufficient to carry effluent when all equipment is operating.
Ventilation	• Check ventilation (air changes per hour) in the decontamination room for the purpose of staff comfort • Check whether ventilation is to be provided in the chemical storage area.
Electrical services	• Check the electrical services required by AER. • Three-phase supply • All AER functioning • Are the electrical shut-off switches conveniently sited
Throughput/workload	• From throughput, calculate the number of AERs needed. • Timeout for weekly testing should be subtracted from the number of AER cycles available • Allow for quarterly testing of up to one day, and annual testing of up to 3 days per AER. Total time for testing and maintenance may be as much as 40% of the operational time.
Air supply	• In accordance with manufacturer's recommendations

4.6 Recommendations

1. The type of AER to be procured should take into account the needs of the department and the available resources. [BI]

4.7 References

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Annex A: Example of equipment specifications[2]

Equipment Specification	Comply (Yes /No)	Offer's Specification / Vendor's Comments
1 General Requirements		
1.1 Automated endoscope reprocessor (hereinafter called "AER") designed to disinfect/sterilise endoscopes so that they are safe for immediate reuse.		
1.2 The Specialist Centre shall include: (a) Endoscopy Centre		
1.3 The AER shall be compatible for all flexible fiber optic and video endoscope (for example: bronchoscopes, colonoscopes, cystoscopes, duodenoscopes, enteroscopes, gastroscopes, rhinoscope and Transesophageal probe aka TEE probe)		
1.4 Vendor shall provide quotations for the following offer: (a) Single Basin (b) Double Basin		
1.5 The AER shall comprise, but not limited to the following programmable processes: (a) Wash Cycle; (b) Disinfecting cycle; (c) Sterilizing cycle; (d) Rinse cycle; (e) Air-purging cycles; (f) Alcohol flush (g) Others (Vendor to specify).		
1.6 The AER shall be equipped with, but not limited to the following: (a) Two separate basins (with lid fitted with rubber layer for better seal) in which the endoscopes are reprocessed; or single basin that can accommodate two scopes at one time.		

[2] This table serves as a reference only and some elements may not apply depending on the type of AER.

Equipment Specification	Comply (Yes /No)	Offer's Specification / Vendor's Comments
(b) Each basin cycle shall be individually controlled, monitored and processed. (c) Channel tubing with adapters/connectors that irrigate all of the endoscope's channels; (d) All endoscope channels shall be independently monitored and processed; (e) Every cycle shall have continuous endoscope leakage and blockage; (f) Built-in heater for automatic drying (preferably); (g) Both hand and foot Pedal to open lid; (h) Timing mechanism to control the time of the reprocessing phases; (i) Liquid and air pumps; (j) Reservoir for the Liquid Chemical Germicidal (LCG); (k) Heater to raise temperature of the LCG (if required); (l) Built-in printer (for hard-copy printout) or system memory for documentation of disinfection / sterilization cycles; (m) Screen to display real-time of current cycle stages in progress. (n) Water filtration systems; (o) Capable of auto-disinfect; (p) Audio and visual alarm for any device/stages' failure; (q) Screen or print out display of the failure (r) Others (Vendor to specify).		
1.7 The AER shall incorporate microprocessor-based design capable of controlling and monitoring system operations.		
1.8 The AER shall be able to use all type of HSA / FDA approved and recommended LCG agent for disinfection / sterilization of the endoscope.		

Equipment Specification	Comply (Yes /No)	Offer's Specification / Vendor's Comments
1.9 The AER shall be able to regularly self-disinfect or self-sterilise according to the manufacturer's recommendations through programmed cycles. 1.10 The AER shall provide documentation of the disinfection / sterilization cycle indicating all the necessary parameters have been met or that the cycle has been automatically cancelled or aborted by the user and the reason why. 1.11 The AER shall be able to (a) Store and transmit data (e.g via thumb drive) (b) Generate usage report. 1.12 The AER can scan, identify and store the following data: (a) Scope (b) Patient (c) Basin (d) Operator (e) Cycle report 1.13 The AER shall be: (a) Floor standing (b) The latest model and design; (c) User friendly – easy to operate; (d) Modular in design, with flexibility of upgrading or installing additional features when required; (e) Easy to clean and maintain; (f) Protect against ingress of water and dust. 1.14 All materials used for the construction of the AER shall be: (a) Rust proof; (b) Resistant to corrosion by saline and detergents; (c) Fire retardant.		

Equipment Specification	Comply (Yes /No)	Offer's Specification / Vendor's Comments
1.15 The AER shall be preferably using the single use sterilant on every cycle.		
1.16 EPDM (Ethylene Propylene Diene Monomer), M-class rubber shall be used for all pipes joints and gaskets.		
1.17 The Vendor shall connect the AER discharge to the available floor trap and fully comply with National Environment Agency of Singapore standards such that the necessary ventilation and facilities are in place to prevent the discharge from contaminating the user and environment. (HLD treatment before discharge).		
1.18 The Vendor shall specify the location, size and requirement of the drainage point and other special requirement, such as water supply. The Vendor shall work and liaise closely with the Main Contractor for such installation plan.		
1.19 The Vendor shall ensure that the temperature of water discharge to the sewer shall not exceed 45°C. There shall be a cooling measure prior before the water is discharged to the sewer.		
1.20 The Vendor shall provide the necessary measure if the quality (pressure and low rate) of the incoming water supply does not meet the AER requirement. Vendor shall replace/repair at no cost to the Company for future failure of the AER related to the quality of the water if the latter is not addressed during installation.		
1.21 The Vendor shall interface, programme and organize his works and liaise closely with the Main Contractor and/or his Specialist Nominated Sub-Contractors and afford whatever assistance that may be necessary to ensure the satisfactory and timely sequencing and completion of all works on the site from planning, delivery, installation and commissioning.		

Equipment Specification			Comply (Yes /No)	Offer's Specification / Vendor's Comments
1.22	The Vendor shall comply fully with the specifications and drawings and all costs to be incurred, pertaining to the compliance to these requirements, are deemed to be included in the proposal offer. In addition, there shall be no additional time implication with such requirements.			
1.23	The Vendor shall state all major technical specifications of the AER proposed.			
1.24	The Vendor shall ensure that the AER they proposed can be used under local climatic conditions in terms of temperature and humidity.			
2	**Electrical Requirements**			
2.1	The AER shall operate directly on the Company's existing electrical switched socket of rating 230 VAC ± 10 %, 50 ± 2 Hz, 13 amperes single phase AC supply. Vendor to specify if otherwise.			
2.2	Power cord(s) shall be fitted with fused and molded BS 1363A 3-pin plug and the length of the power cord shall be more than 3 metres.			
2.3	The AER shall be protected from transient power disruption during use. The transient power disruption shall not affect the AER's performance.			
3	**Functional and Technical Requirements**			
3.1	Disinfect or Sterilise	:	At least high-level disinfection	
3.2	Detergent loading	:	Automatic	

Equipment Specification			Comply (Yes /No)	Offer's Specification / Vendor's Comments
3.3	Type of documentation	:	Paper printout or System memory	
3.4	Auto disinfection			
3.5	Vendor to specify the following parameters:			
	(a) Chamber size, L x W x H, cm	:		
	(b) Power consumption, kW	:		
	(c) Number of scopes per cycle	:		
	(d) Automated leak detection	:		
	(e) Number of channel adapters	:		
3.6	Vendor shall specify the programmable cycle time of the AER with regards to each process:			
	(a) Wash cycle	:		
	(b) Disinfect/Sterilise cycle	:		
	(c) Rinse cycle	:		
	(d) Alcohol flush cycle	:		
	(e) Dry cycle	:		
3.7	Vendor shall specify the type of Germicidal Agents use:			
	(a) Type	:		
	(b) Single use	:		
	(c) Temperature range, in degrees	:		
3.8	Vendor shall specify the water requirements:			
	(a) Temperature requirements, in degrees	:		
	(b) Filtration system	:	<0.2 µm filtration	
	(c) Filter change indicator	:		
3.9	Vendor shall specify the type of scopes that are compatible with the AER.			
3.10	The AER shall			

Equipment Specification	Comply (Yes /No)	Offer's Specification / Vendor's Comments
(a) Only be operated with authorize card i.e. swipe of ID card.		
(b) Not allow the users to skip or omit any required phase (e.g., by setting the timer to 0 min).		
(c) Not allow the operator to abort the reprocessing protocol before completion of all phases without a clear warning.		
3.11 The AER shall remove the majority of rinse water in the endoscope's channels (e.g. with forced air) after the post-liquid chemical germicide (LCG) water rinse.		
3.12 The AER shall eliminate direct personnel exposure to the LCG and minimize its release into the environment, preferably with an enclosed mechanism (e.g., a fluid-transfer pump) during the filling of the LCG reservoir.		
3.13 The AER shall inform the user when its LCG reservoir is filled with an adequate supply of LCG (e.g., by ensuring that the LCG level is clearly visible). If the LCG fluid level is inadequate, the AER shall cancel the process and provide a clear warning (e.g., with an audible alarm).		
3.14 The AER shall automatically monitor LCG concentration during reprocessing to avoid using LCG below its recommended concentration.		
3.15 Vendor shall specify the dimension of the AER: (a) Overall size, L x W x H, cm (b) Weight, kg		
4 Safety Requirements		
4.1 The AER shall incorporate a self-diagnostic program that will activate and indicate any types of defects each time the AER is powered on.		

Equipment Specification	Comply (Yes /No)	Offer's Specification / Vendor's Comments
4.2 The AER shall be designed in such a way that the heater will automatically cut off in the event of overheating.		
4.3 The AER shall incorporate an automatic safety cycle selection lock to avoid accidental setting changes. 4.4 Vendor shall specify all other safety features and alarm conditions available in the AER proposed. **5 Standards** 5.1 The AER shall comply with the following standards, including the latest revisions/amendments/collaterals: (a) IEC 60601-1 Medical electrical equipment – Part 1: General requirements for safety. (b) IEC 60601-1-2 Medical electrical equipment – Part 1: General requirements for safety. Part 2: Collateral standard: electromagnetic compatibility – requirements and tests. (c) Other equivalent international safety and quality standards (The Vendor to specify). 5.2 The AER shall conform to the requirements of the European Pre-Standards per EN 15883-1-4 and to the standards EN 61010-1, EN 61010-2-045, EN 60204- 1 and to the standard ISO 14937 for sterilizing agents. 5.3 The Vendor shall furnish test certificates from international recognised testing bodies, attesting to compliance with the above standards/requirements or equivalent international standards. **6 Standard Accessories**		

Equipment Specification			Comply (Yes /No)	Offer's Specification / Vendor's Comments
6.1	All standard accessories necessary for the required functions and proper operation of the AER shall be listed with itemised pricing and included in the base price. These shall include but not limited to the following:			
	(a)	Trolley for placing clean or dirty scope :	2 nos.	
	(b)	Tray for placing clean or dirty scope :	8 nos.	
	(c)	Different type of adapters and tubing for scope channels (e.g. OGD, Colon, etc.) :	2 sets each	
	(d)	3 – 6 months' worth of single shot sterilant and its minimum effective concentration strip		
	(e)	3 – 6 months' worth of detergent		
	(f)	Manual Handheld scope leakage tester		
	(g)	Automatic Individual leak tester machine, dry preferably		
	(h)	Scope flushing machine		
	(i)	Basket / soft wire mesh bag to place accessories in basin.		
	(j)	12 – 24 months' supply of various range of filters for each AER.		
	(k)	All essential accessories required for the full-function operation of the AER		
7	**Optional Accessories**			
7.1	The Vendor shall quote separately, with itemised pricing, for all optional accessories or capabilities/upgrades available with the AER. These shall include but not limited to the following:			
	(a)	LCG		
8	**Training**			
8.1	Vendor shall provide on-site:			
	(a)	Operation and applications training for the user(s) to ensure they are fully familiar with the function and operation of the System;		

Equipment Specification	Comply (Yes /No)	Offer's Specification / Vendor's Comments
(b) Application and technical training for BME staff to ensure they are able to maintain the System.		
8.2 Vendor shall perform follow-up (repeat) in-service training at no additional charge to Hospital at Hospital's request for the first year after equipment installation. 8.3 The cost of the above training shall be included in the base price. **9 On-site Comprehensive Warranty and after Warranty Support** 9.1 Vendor shall provide on-site comprehensive warranty, at no extra cost for a period of not less than 24 months starting from the date of successful commissioning of the System by the Hospital. The on-site comprehensive warranty shall include manufacturer-recommended preventive maintenance/calibration (subject to a minimum frequency of once a year), unlimited breakdown services and repairs, all replacement parts (exclude consumable), labour, transport, extended time beyond the office hours, etc. 9.2 The Frequency of Preventive Maintenance (PM) during the warranty period. _____ times / year (Vendor to Specify) (The frequency of Preventive Maintenance during the warranty period shall be in accordance with the manufacturer's recommendation.) 9.3 Vendor shall guarantee a response time of two (2) hour or less by telephone and four (4) hours or less on site for the duration of the warranty.		

Equipment Specification		Comply (Yes /No)	Offer's Specification / Vendor's Comments
9.4	Vendor shall ensure uptime of 95% during the warranty coverage.		
10	**Documentation / Manuals**		
10.1	The following documents shall be included in the base price of the System: (a) One set of ORIGINAL operator's manual in hard copy and another set in softcopy (CD); (b) One set of ORIGINAL service manual complete with wiring/circuit diagrams and parts list in softcopy (CD); (c) Factory certification (in summary) of equipment quality-assurance. (d) Commissioning test results (for each equipment proposed) at point of successful commissioning		
11	**Term Contract** Vendor shall offer a term contract that will expire on DD/MM/YYYY, for the offered model and accessories.		

Chapter 5 Reprocessing of Flexible Endoscopes

5.1 Introduction

Endoscope reprocessing should be performed in an area designated only for reprocessing activities and is physically located such that they are away from areas where patient care and endoscope procedures are performed.

Appropriate personal protective equipment (PPE) should be made available, and this include surgical mask with eye protection or goggles, fluid resistant gown, and general-purpose utility gloves that extend beyond the cuff of the gown.

The design of any reprocessing area should incorporate the following considerations:

a) Adequate space for reprocessing activities;
b) Maintain ventilation with negative pressure and minimum airflow exchange rate of ten per hour;
c) Workflow pattern with no cross-contamination of clean and dirty sinks (minimum of two sinks in the dirty area for each endoscope. One sink for leak testing and manual cleaning and the other only for rinsing);
d) Work surfaces and lighting;
e) Electrical support and water;
f) Easy access to hand washing and eye washing facility separate from reprocessing sink;
g) Medical air-drying facilities;
h) Proper storage cabinets for flexible endoscopes.

Filtered water (minimum 0.2 µm) must be available and should meet the specifications outlined by the manufacturer's instructions for the device and reprocessing equipment.

Ensure emergency spill kit is available for specific chemicals being used.

Endoscope reprocessing will need to be done with staff wearing appropriate PPE as follows:

a) Scrub wear or uniform;
b) Hair cover;
c) Gloves - long enough to prevent contact with contaminated water (mid-length). Thickness and durability should be sufficient to prevent easily torn;

d) Gown - fluid resistant material with arms completely covered;
e) Full face protection - full length face shield or combination of mask and eye protection should be worn.

Compliance with the guidelines for reprocessing of flexible endoscope between patients is important to the safety of patient care and care of device.

Reprocessing personnel must be familiar with the work processes and should be responsible for each endoscope that they reprocessed.

Reprocessing personnel must also be competent in the usage of AERs and high-level disinfectants. In addition, they should also be able to ensure that mechanical devices used to assist in the manual cleaning process are compatible with a particular endoscope and use the equipment and products according to the manufacturer's instructions.

Validated manufacturer's instructions for each endoscope must be readily available and accessible for all reprocessing personnel.

Reprocessing personnel must complete the yearly flexible endoscopy reprocessing competency assessment as required by the department.

Endoscope reprocessing includes the following steps:
a) Pre-Cleaning;
b) Leak Testing;
c) Manual Cleaning;
d) Visual Inspection;
e) Manual or automated reprocessing;
f) Drying;
g) Storage.

5.2 Pre-Cleaning

a) Pre-cleaning must be done in the procedure room immediately after the removal of the insertion tube from the patient and prior to disconnecting the endoscope from the power source. It should be performed at point of use, before bioburden has an opportunity to dry and before complete decontamination.
b) Pre-cleaning of each device should be based on the manufacturer's instructions.

c) Wipe the insertion tube with a soft, lint-free cloth or sponge saturated with hospital approved cleaning solution. The soft, lint-free cloth or sponge should be single use and disposed immediately after use.
d) Ensure endoscope control knobs are in the free and unlocked position
e) Air and water channel cleaning adapters may be needed and should be used according to the manufacturer's instructions.
f) Place the distal end of the endoscope into the appropriate detergent solution, and suction detergent solution through the endoscope as per manufacturer's instructions.
g) Flush the air, water, and other channels (auxiliary water or elevator channel), alternating with cleaning solution and air, finishing with air.
h) Detach the endoscope from the light source and suction pump.
i) Attach protective video caps where applicable.
j) Visually inspect the endoscope for damage.

5.3 Transporting soiled endoscope

a) A dedicated cart is required to transport the endoscope if the AER is a distance away.
b) All soiled endoscopes should be wrapped in a leak proof drape and placed in covered lid container or cart before transported it to a reprocessing area within department or to other departments within hospital.
c) Coil the soiled endoscope in large loops without kinks.
d) Label the transport cart and container with biohazard legend.
e) Transport the soiled endoscope to the reprocessing area as soon as possible or within an hour after use.
f) No other instruments or sharps should be placed in the container with endoscope.
g) Clean and disinfect transport carts after each use with hospital approved disinfectant.

5.4 Leak Testing

a) Perform a leak test after each use and before use of a new, repaired and or loaned endoscope.
b) Leak testing must be done in accordance with the endoscope and leak testing equipment manufacturers' instructions for use (automated or manual leak test).
    i. For mechanical (wet) leak testing:
        - Remove all port covers and function valves.
        - Attach the leak tester and pressurize the endoscope to the recommended pressure.

- Do not add detergent to water before or during leak testing as the detergent will obscure bubbles and a leak may be missed.
- With the pressurized endoscope completely submerged, manipulate all moving parts; angulate the bending section of the distal end and observing for bubbles.
- Check the insertion tube, distal bending section, and universal cord for bubbles coming from the interior of the endoscope.
- Maintain pressure and inspect the endoscope for a minimum of 30 seconds.
- Remove the endoscope from the sink leak tester and turn off the leak tester.
- Disconnect the leak tester from the video cap and allow the endoscope to depressurize. Ensure that the video cap is secure and has not loosened with the removal of the leak tester.

ii. For automated endoscope (dry) leak tester:

- Do not place endoscope in water while testing.
- Automated endoscope leak tester should be grounded in accordance with applicable electrical and safety regulations.
- Attach all channel adaptors to the automated leak tester in accordance with the manufacturer's instructions.
- Start the leak tester and allow it to complete all cycles or phases.
- Remove the endoscope from the connection tubing of the automated leak tester before turning off the leak tester.

d) Continue with the reprocessing steps when the test is complete unless a leak is detected.

e) When an endoscope fails a leak test, remove it from service and send for repair or replacement. Do not proceed to reprocess as it might damage the scope. Care should be taken to prevent environmental contamination during the handling and transportation of the scope.

5.5 Manual Cleaning

Manual cleaning includes brushing, rinsing and exposure of all external and internal components to a low-foaming detergent compatible to the endoscope. It is critical prior to automated high-level disinfection or sterilization to remove any microbial burden from the endoscope that may interfere with the effectiveness of high-level disinfection or sterilization capability. Manual cleaning and thorough brushing of channels should be done and in accordance with the manufacturer's instructions.

Use medical-grade low-foaming, neutral pH detergent formulated for endoscopes that may or may not contain enzymes. Cleaning solution and dilution should be used based on the manufacturer's instructions. Too diluted or concentrated solutions will not be effective as solutions that are mixed to the exact strength required. The use of engraved or permanent markings on the inner surfaces of sink is easily reproducible for accurate detergent dilution.

All soiled endoscopes should not be allowed to submerge in detergent solution for long periods; instead manufacturer's instructions are to be followed. Reprocessing of the endoscope should commence within an hour after pre-cleaning.

Manual cleaning includes the following steps:

a) Fill the sink with freshly diluted appropriate detergent solution at a specified concentration and ensure video cap is secured (if applicable) before fully submerge the endoscope.
b) Use a freshly prepared cleaning solution compatible with the endoscope and do not add other products to the cleaning solution unless recommended by the manufacturer.
c) Place the endoscope in the solution. Keeping it below the fluid's surface level at all times.
d) Clean the endoscope's exterior surfaces with a single-use lint-free cloth or sponge.
e) Clean all valve cylinder openings and forceps elevator with a cleaning brush. Endoscope valves need to be actuated to ensure all internal lumens are cleansed.
f) Brush all channels according to the endoscope manufacturer's IFU until there is no visible debris seen.
g) Use a disposable brush if available. If using a reusable brush, ensure the brush is routinely cleaned and disinfected per each endoscope use.
h) Use a brush size compatible to each channel of endoscope.
i) All internal and external surfaces of the endoscope and its removable parts must be thoroughly cleaned and all auxiliary channel or other channels (even if not used) must be brushed and flushed according to the manufacturer's IFU.
j) Specialty endoscopes that include elevators (endoscopic ultrasound gastro-videoscope, and duodenoscopes) requires the elevators to be raised and lowered throughout the manual cleaning process to allow brushing of surfaces that may be obscured by the raiser bridge.

k) Non-lumen endoscope or probes that does not allow water submersion should also be cleaned and disinfected.
l) Attach a model specific cleaning adapter flush channel and allow for adequate solution contact time according to solution manufacturer's IFU.
m) If an automatic flushing system is used, ensure that it is compatible with the endoscope and follow manufacturer's IFU.
n) Flush all channels with detergent, filtered water (if not sent to AER) and air as recommended by manufacturer.
o) Rinse exterior surfaces with filtered water (if not sent to AER) until all cleaning solution is visibly removed.
p) All steps should be completed sequentially and within the manufacturer's recommended time frame.

Delay reprocessing protocol should be followed as per manufacturer's recommendation for endoscopes that manual cleaning is not able to be carried out within 1 hour. E.g.: for normal GI scopes, to soak in the detergent for not more than 10 hours and bronchoscopes to soak not more than 1 hour.

Clean, brush and rinse reusable parts, accessories, and cleaning implements. Discard all single-use parts, accessories, and cleaning implements, if any. Once an endoscope has been cleaned, it should not be placed on a surface where a soiled endoscope was placed.

5.6 Visual Inspection

All endoscopes and reusable accessories must be visually inspected during all stages of handling and reprocessing. Visual inspection must be done in an environment that has adequate lighting to assist in visual inspection. Use additional illuminators and magnification to help to inspect and evaluate endoscopes and accessories for:

a) Cleanliness;
b) Missing parts;
c) Clarity of lenses;
d) Integrity of seals and gaskets;
e) Physical or chemical damage;
f) Moisture;
g) Function.

Repeat manual cleaning steps if determined not to be visually clean. Remove defective endoscopes, accessories and equipment from service and send them for repair or discard them.

5.7 Disinfection of Endoscopes

Spaulding classification system is universally used to determine the type of disinfection or sterilisation that is required for the medical devices. HLD is the destruction of all vegetative microorganisms, mycobacterium, small non-lipid viruses, fungal spores, and some bacterial spores. Sterilisation is a process by which all forms of microbial life, including bacteria, viruses, spores, and fungi are completely destroyed. Most flexible endoscopes undergo HLD, and some endoscopes are sterilised. HLD can be performed manually or by using AER. AER is the preferred method as it standardises the disinfection process and decrease personnel exposure to chemical disinfectant.

5.7.1 Manual Endoscope Disinfection

5.7.1.1 Manual disinfection process

a) Endoscopes must be purged with air and externally dried prior to immersion to minimize diluting the high level-disinfectant.
b) Completely immerse the endoscope and all removable parts in a basin of high-level disinfectant /sterilant.
c) The basin must be of a size to accommodate the endoscope without undue coiling (AAMI, 2015).
d) To prevent damage, the endoscope should not be soaked with other sharps instruments that could potentially damage the endoscopes.
e) Flush disinfectant into all channels of the endoscopes until it can be seen exiting the opposite end of endoscope channel or according to manufacturer recommendation.
f) All channels must be filled with the chemical so that no air pockets remain within the channels. Complete microbial destruction cannot occur unless all surfaces are in complete contact with the chemical (FDA, 2009).
g) Cover the soaking basin with a tight-fitting lid to minimize chemical vapor exposure. Exposure to chemical vapours may present a health hazard.
h) The reprocessing area must have engineering controls to ensure good air quality.
i) Soak the endoscopes in high level disinfectant / sterilant for the time / and temperature required to achieve HLD as per manufacturer’s instruction.

j) Use a timer to verify soaking time. Do not exceed the manufacturer's recommendation time for soaking, such as leave the scope overnight.
k) Purge all channels completely with air before removing endoscope from the high-level disinfectant / sterilant. Purging the channels preserves the concentration and volume of the chemical and prevent exposure from dripping and spillage.

5.7.1.2 Rinsing after Manual Disinfection

a) Thoroughly rinse all surfaces and removal parts and flush all channels of the endoscope and its removable parts with sterile water according to the disinfectant and endoscope manufacturers' recommendations. Rinsing prevents exposure and potential injury of skin and mucous membranes from chemical residue.

5.7.2 Automated Endoscope Reprocessor (AER)

AER standardises the disinfection process and decrease personnel exposure to chemical disinfectant.

5.7.2.1 Using the AER

a) Follow both the endoscope and AER manufacturers' instruction program for HLD or sterilisation.
b) Position endoscopes and accessories within the AER in a manner that ensures contact of the processing solutions with all surfaces of the endoscope.
c) Ensure all connectors between the endoscope and AER are connected correctly.
d) Use cleaning, disinfectant and sterilant solutions and chemical recommended by the endoscope and AER manufacturers.
e) Set AER for the appropriate time and temperature according to the mode of reprocessing.
f) Start the machine and allow it to complete all cycles / phases. If cycles / phases are interrupted, HLD cannot be ensured, and the full cycle must be repeated.
g) Use a test strip to monitor solution potency as recommended by the AER manufacturer.
h) All endoscopes that have completed reprocessing should be removed from AER as soon as possible.

5.7.2.2 Transportation of Processed Endoscope

a) Processed endoscopes should be protected from recontamination.

b) New pair of clean gloves should be donned when handling and transporting processed endoscopes at all times. All processed endoscopes should be wrapped in a clean / sterile leak proof drape and placed in covered lid container or cart during transportation either within procedure rooms or to other departments within hospital. Label the container and transport cart with clean legend / signage.
c) A dedicated cart is required to transport the reprocessed endoscope if the storage cabinet is a distance away.
d) A clean endoscope that is sent for repair to vendor (outside hospital) should be transported in an endoscope carrier bag.

5.8 Drying

a) Drying is a critical element in reprocessing. Moisture allows microorganisms to survive and multiply; therefore, all channels and the surface of endoscope must be thoroughly dried before storage.
b) To ensure that endoscopes are thoroughly dried, they must be flushed with 70% or 90% ethyl or isopropyl alcohol prior to being dried with pressurised, filtered air by AER or manually.
c) Following the manufacturer's instructions for specific AER, endoscope model and channel.
d) Flush all channels with alcohol until the alcohol can be seen exiting the opposite end of each channel if required.
e) Remove all channel adaptors.
f) Purge all channels with air.
g) Use compressed air that have been filtered to remove microorganisms.
h) Avoid the use of excessively high air pressure that can damage the internal channels of flexible endoscopes.
i) Dry the exterior of the endoscopes with a soft, lint free towel.

5.9 Storage

a) Wear clean gloves when handling and transporting the processed endoscope to and from the storage cabinet.
b) Reprocessed endoscopes should be stored in an endoscopic storage cabinet designed with high efficiency particulate air (HEPA) filter also known as "controlled environment storage cabinets" with specification details:

    i. Storage cabinet must have sufficient height, width, and depth to allow endoscopes to be hung vertically or for horizontal storage.

ii. Storage cabinet with HEPA filters that provides positive air pressure and circulation, and controlled temperature and humidity.
iii. It provides microbial free air that is blown through the endoscope channels and around the scope body to ensure they remain dry.
iv. Quality control and filter replacement of the storage cabinet is done according to the manufacturer's IFU.

c) Endoscopes should be stored so they do not touch one another or the bottom or sides of the storage cabinet. All caps, buttons and valves should be removed prior storage.
d) Endoscope storage cabinet should be configured according to hospital infection control guidelines or up to 7 days' storage after effective processing and stored according to manufacturer instructions. This applies to lumen endoscopes storage shelf-life.
e) As per Gastroenterology Association of Australia guidelines, the endoscopes need to be disinfected after storage time has elapsed in the storage cabinet.
f) After an endoscope has been removed from the storage cabinet, it must be used as soon as possible and not longer than 3 hours and should not be returned into the storage cabinet without being processed in an AER, even if it has not been used. (Reference: 2020 Guidance on Decontamination of Equipment for Gastrointestinal Endoscopy, British Society of Gastroenterology)
g) Each facility should determine a method of documentation and traceability to the endoscope and reusable accessories.
h) The contents of each storage cabinet, the date and time of each endoscope are put in, and the expiry date and time must be recorded.
i) Documentation and traceability of the processed endoscope include the following:
    i. Date and time;
    ii. Identity of the endoscope and accessories;
    iii. Method and verification of cleaning and results of cleaning verification testing;
    iv. Results of AER efficacy testing;
    v. Identity of the personnel performing the processing.

5.10 Recommendations

1. All staff involved in flexible endoscope reprocessing must understand and be familiar with the work process to ensure they are safe for patient use. These

recommendations apply to all settings where endoscope procedures are performed and where endoscopes are reprocessed.

a) Pre-Cleaning:
   - Pre-clean flexible endoscopes and reusable accessories by following the device's IFU.
   - Perform pre-cleaning immediately following completion of procedure to prevent the formation of biofilm.

b) Transporting:
   - Coil the soiled endoscope in large loops without kinks and place it in a closed, leak proved and puncture resistant container to prevent the damage of the endoscope.
   - Transport the soiled endoscope to the reprocessing area as soon as possible or to ensure manual cleaning can be carried out within an hour after use.

c) Leak Testing:
   - Perform leak testing according to IFU, after each use and prior of manual cleaning.

d) Manual Cleaning:
   - Perform meticulous manual cleaning including brushing and flushing channels and ports consistent with IFU to remove residual organic material. Incomplete removal of organic material will reduce the effectiveness of manual or automated reprocessing.

e) Visual Inspection:
   - Visual inspection of the endoscope provides additional assurance that the device and its accessories are clean and free from defects.

f) Manual or Automated Reprocessing
   - Reprocess the endoscope in accordance with the IFU to help to ensure effective disinfection occurs

g) Storage:
   - Reprocessed endoscopes must be stored in a HEPA filtered storage cabinet with positive air pressure and circulation.
   - Storage cabinet must have sufficient height, width and depth to allow endoscopes to be hung vertically or for horizontal storage.
   - Endoscopes removed from the storage cabinet must be used within 3 hours.

- Documentation and traceability are essential for quality assurance purposes in the event a recall is necessary. [AII]

5.11 References

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Chapter 6 Quality Assurance and Microbiological Surveillance

6.1 Quality Assurance

Quality assurance is essential in ensuring the practices meets safety and effectiveness of endoscope reprocessing. It provides evidence (manual or electronic) of correct reprocessing and in case of suspicious infection, the data could aid in the investigation. There should be documentation in place on monitoring with documentation at all stages of the reprocessing process. Documentations may include, but not limited to the following:

a) Procedure date and time;
b) Patient's name and medical record number;
c) Endoscopist's name;
d) Endoscope model and serial number /other identifier;
e) AER (if used) model and serial number/ other identifier;
f) Names of personnel who processed the Endoscope.

Other documentation essential for infection control includes information and audits on the following:

a) Timing of reprocessing activities;
b) Equipment performance and maintenance records;
c) Records verifying high level disinfectants are tested and replaced appropriately;
d) Identification of staff who check and release the scope for use on next patient.

The audit is to determine if the personnel adhere to the procedures and it if meets quality requirements.

6.2 Microbiological Surveillance

Microbiological surveillance culture of endoscopes and AER is a quality control measure widely performed by many healthcare institutions. It provides a representative sample of quality from various samples location of endoscopes and AER.

Microbiological cultures can help in monitoring the effectiveness of cleaning and disinfection process of endoscopes. It can provide early detection of endoscope internal channel and AER defects in the detection of pathogens. The culture is performed on scheduled intervals as a quality monitoring of the effectiveness of disinfection process.

6.2.1 Microbiological surveillance of Automated Endoscopy Reprocessor (AER)

Microbiological surveillance of the AER is done on water samples taken from AER after the waterline disinfection and sent to the laboratory to test for presence of bacterial growth including atypical mycobacteria. Following waterline disinfection, microbiological surveillance of AERs should be performed every month. In addition, waterline disinfection and microbiological surveillance of AERs should be performed after bacteria filter change and newly purchased AER or according to manufacturer's guideline.

All methods of sample collection must comply with the manufacturer's instructions.

6.2.3 Microbiological surveillance of Endoscope

The healthcare facility should have a policy to state the frequency of testing according to manufacturer's recommendation. This should be discussed with the facility's IPC team and should include risk assessment and mitigation plans.

There are various guidelines on the frequency of microbiological surveillance testing ranging from 4 weeks to 1 year (See Table 6.1). It is strongly recommended that therapeutic scopes, duodenoscope, linear ultrasonic endoscope, bronchoscope, cystoscope, and AER are tested monthly. Diagnostic endoscopes should be tested at least every 3-monthly.

Testing should be conducted in the following scenarios:

a) Routine quality assurance of endoscopes;
b) Endoscopes on loan (within 72 hours of receipt);
c) There is a clinical suspicion of cross-infection related to endoscope;
d) Positive surveillance culture occurs;
e) New AER before use;
f) Testing for AER in situation if construction or works are made to the plumping of the endoscopy reprocessing area.

For endoscopes that have been reprocessed through a chemical sterilisation cycle; microbiological culture testing should be performed every 3 months.

Table 6.1: Sampling Methods and Sites and Frequency of Microbiological Surveillance Culturing Site by Different Guidelines (Shin & Kim, 2015)

Guidelines (year)	Sampling method	Sampling site	Surveillance frequency
APIC (2000)	Flushing, brushing	Suction/biopsy, air/water, elevator, and carbon dioxide channel	Routine test not recommended

ESGE-ESGENA (2008)	Anterograde flush: channels Swabs: outer surfaces Liquid samples: water bottles	All channels Outer surfaces Connected water bottle	No longer than 3 months
BSG (2008)	For atypical mycobacteria Rinse water: AER	AER	Annual
Canada (2010)	Anterograde flush	Suction/biopsy and air/water channels	Routine test not recommended
GESA-GENCA (2010)	Flush-brush-flush: channels Anterograde sampling supported by retrograde sampling Flushing with filter: AER Liquid samples: water bottles	All channels AER Water for manual rinsing or water supply to AER	AER, duodenoscopes: every 4 weeks Other GI endoscopes: every 3 months
ASGE (2011)			Routine test not recommended
UMCG (2011)	Retrograde flushing	Suction/biopsy and air/water channels	Therapeutic gastro/ duodenoscopes: monthly Diagnostic endoscopes: every 3 months
CDC (2015)	Brush: distal end of the duodenoscope Anterograde flush: channels	Instrument channels and distal end of the duodenoscope	Routine test not recommended

APIC, Association for Professionals in Infection Control and Epidemiology; ESGE-ESGENA, European Society of Gastrointestinal Endoscopy and European Society of Gastroenterology and Endoscopy Nurses and Associates; BSG, British Society of Gastroenterology; GESA-GENCA, Gastroenterological Society of Australia and Gastroenterological Nurses College of Australia; ASGE, American Society for Gastrointestinal Endoscopy; UMCG, University Medical Center Groningen; CDC, Centers for Disease Control and Prevention.

The microbiological culture test results may take up to a period of 28 days before it is available (prolonged culture is required for detection of environmental mycobacteria in AER samples). Rapidly growing *Mycobacterium* species may take up to 10-14 days. If there are concerns for slower growing Nontuberculous Mycobacteria (NTM) then the samples should be kept for a longer duration (i.e. up to 28 days).

It is recommended that endoscopes are quarantined until a negative result is available, if possible. If this is not possible (due to resource constraints), then there should be risk assessments and action plans in place in the event of positive culture result, such as a recall policy.

6.2.3 Microbiological sampling methodology & sample collection process for endoscopes

There are various sampling methods for collection of samples from endoscope channels. Some techniques of sampling include:

a) A swab-rinse technique should be used for sampling the exterior surfaces and the distal opening of the suction-biopsy channel port;
b) A flush-brush-flush technique should be used for adequate sampling of the interior surface of endoscope channels, it should be performed with rinsing through the channel with a sterile fluid and using a sterile cleaning brush to obtain samples from the biopsy port;
c) A simple flush through technique may be considered when brushing of the channel lumens is impossible, but it is less efficient.
d) Sample may be collected after HLD.

Refer to Table 6.1: Sampling Methods and Sites and Frequency of Microbiological Surveillance Culturing Site by Different Guidelines.

Personnel must refer to the endoscope's instructions for use and be familiar with the channel configuration.

The sampling process must be performed with staff in appropriate PPE as per sterile procedure and with aseptic techniques. Where possible, 2 staff are required to conduct sampling from channels: 1 staff person (the sampler) maintains aseptic handling and conducts brushing steps, while the second staff person (the facilitator) opens packages and handles the unsampled portions of the endoscope.

Samples should be obtained from (if applicable):

a) Biopsy Lumen;
b) Suction lumen;
c) Air lumen;
d) Auxillary Lumen.

Duodenoscopes or some other complex models of endoscope may have different channel or elevator recess areas.

6.2.4 Laboratory testing protocol

The primary focus in laboratory testing is for detection of the most relevant organisms of concern and it is not intended to be used for certification of sterility.

There are various international laboratory protocols where either a filtration or a centrifugation method is performed. Individual laboratories should evaluate and select the most appropriate method for their facility, based on the needs and resources of the facility.

AER final rinse water testing is to be done once a month using the following protocol where collection is not less than 200 ml per sample. (see Annex B for detailed method).

6.2.5 Interpretation of microbiological sampling and follow-up actions

Endoscopes that have been subjected to microbiological sampling should ideally be quarantined until results are back from the laboratory. The Microbiologist overseeing the culturing should report findings to both the Endoscopy Centre and IPC team to review the reports in a timely manner. When culture results are significant and / or exceed acceptable limits, the IPC team should be informed to ensure contact tracing is initiated, and senior management informed, where necessary. Each institution should have a policy describing response to positive cultures and recall process.

The principle used is the presence of microbes that indicate inadequate reprocessing (See Table 6.2 for Interpretative guide to microbiological surveillance culture results of endoscopes).

The presence of oral and gut flora signifies the possibility of the endoscope to have undergone inadequate reprocessing. The affected endoscope should undergo repeat reprocessing, endoscope quarantined until results confirm that the endoscope is safe for next patient use.

The presence of skin flora indicates possible contamination from staff skin flora during handling of the endoscope during sampling. It is safe to release the endoscope for next use.

The presence of environmental flora suggests possible contamination from an environmental source e.g. water source. An affected endoscope should be subjected to a repeat reprocessing and quarantined until results confirm that the endoscope is safe for next patient use. It should prompt investigations on water source and filters used.

Where microbial count is done by the laboratory using a reference international protocol, the interpretative guide for specific counts should be followed as per protocol designed.

Table 6.2: Interpretative guide to microbiological surveillance culture results of endoscopes

Category	Micro-organism	Actions to be taken
Oral and gut flora	Gut *Enterobacterales (Klebsiella* species, *Escherichia coli*, etc); Non-fermenters (*Pseudomonas aeruginosa*, *Acinetobacter* species, *Stenotrophomonas maltophilia*); *Enterococcus* species, *Staphylococcus aureus, Candida* species~~)~~ Oral *Moraxella* species, *Rothia* species, *Streptococcus* species	1. Reprocess scopes 2. Send off repeat cultures 3. Quarantine scopes till results are back
Skin flora	Coagulase-negative *Staphylococcus*), *Bacillus* species, *Micrococcus* species	1. Release scope for use
Environment flora	Non fermenters (e.g. *Pseudomonas aeruginosa*, *Pseudomonas* species) and atypical *Mycobacteria*	1. Reprocess scopes 2. Send off repeat cultures 3. Quarantine scopes till results are back 4. Check for possible causes e.g. check filter, check water source, etc.

Refer to Table 6.3 for interpretative guide in reading the microbiological surveillance culture results of the AER final rinse water. There should not be any *P. aeruginosa* or mycobacteria in the rinse water tested.

Table 6.3: Interpretative guide for AER final rinse water microbiological surveillance culture results

Number of bacteria (CFU/ 100 mls)	Interpretation
<1 (No bacterial growth)	Satisfactory
1-9* Low-moderate virulence bacteria	Acceptable: bacterial numbers are under reasonable level of control. 1-9 CFU/100 mls on a regular basis should trigger a review of reprocessing practices, sampling and culture procedure
1-9 High virulence bacteria	Risk assessment required to investigate potential problems.
10 -100	Risk assessment required to investigate potential problems.
> 100	Risk assessment required including consideration for taking AER out of service until water quality improved

Note: High virulence bacteria are organisms that are more often associated with disease, e.g. *Enterobacterales, Pseudomonas aeruginosa, Staphylococcus aureus,* beta-haemolytic *Streptococcus,* Enterococci*.* Low virulence bacteria are organisms that are less often associated with disease, the presence of which may have been introduced from contamination during sample collection. Examples include skin-flora contamination (e.g. *Micrococcus species,* coagulase-negative *Staphylococcus, Corynebacterium species)* or environmental contamination *(Bacillus species).*

6.3 Recommendations

1. There should be documentation (manual or electronic) of a complete reprocessing cycle. [AII]
2. It is recommended that endoscopes are quarantined until a negative result is available, if possible. If this is not possible (due to resource constraints), then there should be risk assessments and action plans in place in the event of positive culture result, such as a recall policy [AI]
3. Microbiological sampling of endoscopes and AER rinse water are done regularly to verify that adequate reprocessing is done. [AI]
4. Each institution should have a policy describing response to positive cultures response and recall process. [AI]

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Annex B: Laboratory testing protocols

I. Testing of luminal samples from endoscopes and AER final rinse samples

A. Filtration method

1) Filter 100 mls through a ≤0.45µmm membrane filter.
2) Aseptically transfer filter onto the surface R2A agar, Yeast Extract Agar, Tryptone Soy Agar plate, or other equivalent/ suitable media and incubate at 30 +/- 2°C for 5 – 7 days.
3) Filter a further 100 mls through a ≤0.45µmm membrane filter.
4) Aseptically transfer this second filter onto the surface a blood agar plate and incubate at 35- 37°C for 5-7 days.
5) Examine the agar plates after 48 hours' incubation and at 5-7 days.
6) Record the number of colony-forming units/100mls that are visible.
7) Identify the bacteria to the extent necessary to distinguish high-virulence bacteria from low/moderate-virulence bacteria.
8) Bacterial susceptibility testing is not routinely required but may be performed as indicated e.g. to determine the presence of multi-drug resistant *Enterobacterales* or as part of an outbreak investigation.

B. Centrifugation method

1) Centrifuge 50 mls x 2 tubes for 10-15 minutes at approximately 3000 - 5000 rpm.
2) Discard the supernatant from each tube and re-suspend the residual cells from the first tube in a suitable solution to approximately 0.1 mls.
3) Transfer this suspension into the second tube to re-suspend the sample in the second tube.
4) Inoculate the entire volume (0.1mls) of this final suspension onto R2A agar, Yeast Extract Agar, Tryptone Soy Agar, or other equivalent/ suitable media and incubate at 30 +/- 2°C for 5 – 7 days.
5) Repeat steps 1-3.
6) Inoculate the entire volume (0.1mls) of this final suspension onto a blood agar plate and incubate at 35- 37°C for 5-7 days.
7) Examine the agar plates after 48 hours' incubation and at 5-7 days.

8) Record the number of colony-forming units/ 100mls that are visible.
9) Identify the bacteria to the extent necessary to distinguish high-virulence bacteria from low/moderate-virulence bacteria.
10) Bacterial susceptibility testing is not routinely required but may be performed as indicated e.g. to determine the presence of multi-drug resistant *Enterobacterales* or as part of outbreak investigation.

The method described above will not culture all bacteria, including fastidious bacteria e.g. *Haemophilus* species that could potentially contaminated luminal scopes. The culture conditions may need to be revised e.g. if bronchoscopes are sampled, the substitution of chocolate agar for the blood agar plate may be considered.

II. Testing of AER final rinse samples for environmental mycobacteria

A. Filtration method

1) Filter 100 mls through a ≤0.45µm membrane filter.
2) Aseptically transfer filter to the surface of a Middlebrook 7H10 agar plate, or other equivalent/ suitable media and incubate at 30 +/- 2°C for 10 – 14 days, up to 28 days may be required.
3) Examine the agar plate weekly.
4) There should be no recovery of mycobacteria.
5) If growth of mycobacterial species is observed, the cultures should be transferred to a reference laboratory for mycobacterial identification

B. Centrifugation method

1) Centrifuge 50 mls x 2 tubes for 10-15 minutes at approximately 3000- 5000 rpm.
2) Discard the supernatant from each tube and re-suspend the residual cells from the first tube in a suitable solution to approximately 0.1 mls.
3) Transfer this suspension into the second tube to re-suspend the sample in the second tube.
4) Inoculate the entire volume (0.1mls) of this final suspension onto Middlebrook 7H10 agar plate, or other equivalent/ suitable media and incubate at 30 +/- 2°C for 10 – 14 days, up to 28 days may be required.
5) Examine the agar plate weekly and record number of colony-forming units that are visible.
6) There should be no recovery of mycobacteria.
7) If growth of mycobacterial species is observed, the cultures should be transferred to a reference laboratory for mycobacterial identification.

Chapter 7 Maintenance of AER

7.1 Routine monitoring of AER

The investment of AER in the department needs to be safeguarded. Ensure that only trained and designated staff operate the AER and that a comprehensive instruction manual on daily start up and shutdown, weekly and monthly routines is available in the reprocessing area. Audits are also useful tools to ensure staff are compliant (See Annex C for example of an audit tool).

Routine monitoring of the AER verifies that the flexible endoscopes had undergone high-level disinfection process effectively. Routine monitoring of the AER involves the assessment of physical parameters of the high-level disinfection parameters of the leakage testing, cleaning cycle, rinsing cycle and exposure time of the high-level disinfectant on the flexible endoscope and lastly the rinsing cycle.

To achieve consistency and efficiency of the AER, follow the manufacturer's instruction for use of the AER which should include the following:

a) Ensure that the endoscope had been leak tested and manually cleaned prior to placement in AER.
b) Ensure that the endoscope and endoscope components to be reprocessed are compatible with the AER used.
c) Ensure that channel connectors and caps for both the AER and the endoscope are compatible.
d) Completely immerse the endoscope and endoscope components in the high-level disinfectant and ensure all channels are perfused.
e) Do not open or stop the AER once started; if an AER cycle is interrupted, high-level disinfection cannot be assured; and
f) Implement and document preventive maintenance program(s) for the AER(s).
g) Water-line disinfection, filter change and daily maintenance of the machine should be carried out at regular basis as per manufacturers' recommendation.

To ensure efficacy of the AER performance, a thorough evaluation of all the high-level disinfection processes is carried out at regular intervals as per the manufacturer's instruction and as per individual institution protocol.

Monitor the efficacy of the high-level disinfectant use with test strip if available from the product manufacturer.

7.2 Recommendations

1. Ensure that manufacturer's instructions for installation, operation, cleaning, and preventive maintenance of the AER are followed. [BII]
2. A preventive maintenance program for AER shall be implemented and documented. [BI]
3. Ensure that only trained and designated staff with clearly defined responsibilities can operate the AER [BI]
4. An assigned staff is responsible for the monitoring the performance of the AER to ensure it is operating in conformance to the manufacturer's recommendation. [BI]
5. A well-informed instruction manual on daily starts up and shutdown, weekly and monthly routine are available in the reprocessing area. [BII]

b. Routine audits and adhoc audits carried out are also useful tools to ensure staff are in compliance. [BI]

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Annex C: Example of AER Audit tool

INFECTION CONTROL AUDIT - AER

Department / Ward: _____

Date: _____

SN	Elements	Compliance			Remarks
		Met	Not Met	NA	
Automated Endoscope Reprocessor (AER)					
1	High level disinfectant (HLD) concentration is checked each day with an appropriate chemical test strip according to manufacturer's recommendations.				
2	The HLD is discarded and changed if the concentration is less than the minimum effective concentration (MEC).				
3	Pre-cleaned endoscope and accessories are loaded immediately in the Automated Endoscope Reprocessor (AER).				
4	The AER channel attachments are appropriate to the scope being reprocessed.				
5	The endoscope connectors/adapters are attached to the AER.				
6	The endoscope is completely immersed in HLD solution for the recommended time and temperature in the AER.				
7	The endoscope is removed promptly after the final cycle has been completed.				
8	A channel air flush followed by a 70% ethanol and a forced-air purge is done (A medical grade air supply is recommended).				
9	The scheduled microbiological surveillance culture is performed and result acknowledged by Endoscopy Centre management				

AUDIT FINDINGS

SN	Non Compliance	Follow-up Action	Completion Date	Gaps Closed Y / N

SN	Observations / Comments	Follow-up Action

Name of Auditor:	Name of Auditor:	Name of SNM / SNC:
Signature:	Signature:	Signature:
Date:	Date:	Date:

Chapter 8 Documentation

8.1 Introduction

Documentation is the storage of all relevant records arose from endoscopes related activities, such as procedure, reprocessing, preventive maintenance, microbiological surveillance, repair, and inventory.

Documentation prospectively ensures that staff are following the correct processes, and the equipment, solutions are functioning correctly at the time of reprocessing each endoscope.

These documentations also allow retrospective investigation into possible transmission of infection or source of contamination.

8.2 List of Documentation

List of records to be included but are not limited to the following:

Activity	Data required
Procedure	Date and time of procedure Patient unique identifiers Endoscope unique identifiers Staff unique identifiers on their roles
Reprocessing	Date and time of reprocessing Endoscope unique identifier Automated Endoscope Reprocessor (AER) unique identifier Staff unique identifiers performing: • Leak testing • Manual cleaning • Loading of endoscope into AER • Manual disinfection • Minimum effective concentration (MEC) /minimum recommended concentration (MRC) testing • Unloading of the endoscopes from AER • Storage of the endoscopes in drying cabinet

	• Removal of the endoscopes from drying cabinet Date chemical changed or topped up Batch number of chemicals used MEC /MRC result
Preventive maintenance (PM)	Date of PM Endoscope/ Equipment unique identifier Proof of PM completed
Microbiological surveillance (MS)	Date of MS Endoscope /AER unique identifier Result of MS Follow up actions when applicable
Repair	Date of repair Endoscope/ Equipment unique identifier Outcome of repair
Inventory	Information of endoscopes and equipment: • Manufacturer name • Model number • Unique identifier • Purchased date • Status
Audit	Date of audit Audit findings Follow up actions when applicable Auditor unique identifier Acknowledger unique identifier

8.3 Recommendations

1. Each facility should establish:
   a) Its own documentation standard that meets its own particular needs as the requirements may vary depending upon the methods and products used for endoscope reprocessing;
   b) Its documentation method that can be seamlessly integrated into the existing hospital information technology (IT) environment;
   c) Backup plan for planned and unplanned downtime if electronic documentation system is used;
   d) Documentation retention policy. [BII]

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Chapter 9 Traceability of Flexible Endoscopes

9.1 Introduction

Traceability of flexible endoscopes is becoming increasingly important with the emergence of new transmissible diseases and pandemics. It is recommended that healthcare systems completely trace and track the use of each individual scope, reusable tools and any implants to each procedure, patient, provider, and the related processes which were used to clean and sterilise each endoscope.

Traceability of a flexible endoscope should be able to track the complete cycle of a unique endoscope through the steps of a compliant pre-procedural decontamination, intra-procedural recording of a unique endoscope to a unique patient and a compliant post-procedural decontamination process before the endoscope is returned to the drying or storage cabinet. This whole cycle is a complex chain that involves multiple healthcare workers, expensive and delicate equipment, and several small tools and components.

9.2 Traceability systems

A computerised system for tracking and traceability is a key component of such a quality system and should cover all endoscopes processed, including those placed in quarantine and sent off for refurbishment. A quality computerised system should be able to always maintain a full decontamination and usage history. Archiving of data and obtaining historical usage and decontamination reports are simplified with a computerised system.

If a computerised system is not available, a manual system should be in place to track and trace all the available data on the decontamination cycle and usage history of an individual endoscope. A print-out of all the available data on endoscope decontamination and use should be made available and sent out with the used decontaminated endoscope to provide information for the next user. Archiving of data and audits can be time consuming and challenging with manual systems.

9.3 Traceability cycle

A quality traceability cycle should record the following:

A. Pre-procedure phase

i. Each endoscope in the unit should have a unique identifier which can be preferably bar code scanned or less preferably manually read and linked at each step of decontamination cycle.

ii. To ensure patient safety, it should be possible to identify that an endoscope has been through a compliant decontamination cycle prior to being used on a patient.

iii. Movement of endoscopes should be recorded (e.g. checking into and out of storage or drying cabinets)

iv. On removal from a drying or storage cabinet, each individual endoscope should have its barcode scanned by the reprocessing staff and linked with individual identifier of the reprocessing staff before subjecting the endoscope to automated endoscopy reprocessing (AER).

v. On completion of AER, the reprocessing staff pack the ready endoscope in a marked clean endoscopy tray and transfer the endoscope to the procedure room for use on a patient.

B. Intra-procedure phase

i. Clean endoscope should be removed from the marked clean endoscopy tray and have its barcode scanned to link it to the patient and the procedurist in the endoscopy documentation system.

ii. If a second or a third endoscope is required, the same entry linking system should be used.

iii. After completion of the procedure, a pre-cleaning should be performed before putting the used endoscope in a marked endoscopy tray.

C. Post-procedure phase

i. Used endoscopes in the marked dirty tray should be transferred directly to the decontamination room.

ii. Each individual used endoscope should be linked to the individual reprocessing staff via a bar code scanning system.

iii. Endoscope should go through manual washing including visual inspection and manual leak test and decontamination.

iv. After manual washing and cleaning, the endoscope should be subject to AER by the same reprocessing staff.

v. After completion of AER, the clean endoscope can be placed in the marked endoscopy tray or stored in the drying or storage cabinet. The storage should be recorded.

9.4 Audit in traceability

a) The system should allow for verification that the uniquely identified endoscope has been through a compliant decontamination cycle prior to being used on a patient.
b) The system should be able to highlight any non-compliant processes within the AER, manual washing, or drying/storage cabinet.
c) A computerised system should allow generation of historical decontamination and usage reports in a timely manner.
d) A backup of the traceability chain should be available and stored in a secure off-site system.
e) Traceability chain should be maintained when an endoscope is transferred to other sites within the hospital.

9.5 Recommendations

1. A quality traceability system should ensure that flexible endoscopes are effectively and accurately traced through manual wash, through an AER, through a drying cabinet and finally to use on a patient. [BI]
2. Traceability reports should allow for verification that the uniquely identified endoscope has been through a compliant decontamination cycle prior to being used on a patient. [BI]
3. Computerised traceability is a key component of such a quality system which can link the use of an individual endoscope to a particular patient, reprocessing operator and the procedurist. [BI]
4. A backup of the traceability chain should be available and stored in a secure off-site system. [BI]

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