ESGE

EUROPEAN SOCIETY OF GASTROINTESTINAL ENDOSCOPY

ESGENA

EUROPEAN SOCIETY OF GASTROINTESTINAL ENDOSCOPY NURSES AND ASSOCIATES

GUIDELINES

Check List for Purchase of Washer Disinfectors for Flexible Endoscopes

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Introduction

Endoscopic procedures are now well established in the diagnosis and therapy of gastrointestinal diseases. In addition to procedure related risks, the risk of infections due to endoscopic procedures has to be taken into consideration. Endoscopy associated infections are as follows :

- endogenous infections
- exogenous infections caused by inadequately reprocessed equipment. (Endoscopes and accessories can be vehicles for pathogenic or facultative-pathogenic germs which are transmitted from previous patients)
- risk of infection to staff working in endoscopy

During the last 10 years, the reprocessing of gastrointestinal endoscopes has become more and more standardised, facilitated by the increasing number of protocols that have been established for manual and automated cleaning and disinfection of endoscopes and accessories. National gastroenterology and endoscopy societies, national official bodies for infection control as well as working parties at European level have developed a variety of recommendations for manual and automated reprocessing of endoscopes. Since the eighties, a large number of endoscope washer disinfectors have come onto the market. These machines differ greatly in technology, systems and components as well as in the chemicals and disinfectants used in the machines.
The enclosed check list should raise awareness in endoscopy staff (nurses and endoscopists) and service providers to the need for staff protection measures with regard to automated reprocessing, necessary structural requirements, the diversity of components and different standardised systems available in machines.
The check list should help in the decision making when purchasing automated washer disinfectors. It should be an instrument for comparing advantages and disadvantages of machines and systems. Furthermore it should help to identify individual requirements of the respective endoscopy department regarding an automated reprocessing system.

Key points in the shaded boxes highlight important and essential aspects which have to be taken into account. Further considerations follow below.

Knowledge is not static and new evidence and research is constantly affecting and changing practice. New techniques and developments will have to be evaluated and proved before adopting into standardised systems.

Index :

This guide is split into 2 parts. The first part facilitates assessment of the existing environment and the service requirements, the second assessment of the machines under consideration. Finally, in an addendum, some points for consideration are added for those departments who would like to use the machines for the reprocessing of rigid endoscopes.

1. Structural (Departmental Requirements)

1.1. To evaluate the needs of the endoscopy department and the number of machines which are necessary for the respective endoscopy department:

Key points to evaluate the service commitment of the endoscopy department:
- How many endoscopic interventions are performed in the endoscopy department per year?
- How many endoscopic procedures are on each list per day (average)?
- What type of procedures are offered in the department and with which frequency?

Interventions	No	Yes	Number of procedures per list	Number of endoscopes available per list
OGD - diagnostic				
- therapeutic				
Colonoscopy - diagnostic				
- therapeutic				
ERCP - diagnostic				
- therapeutic				
Percutaneous Interventions - diagnostic				
- therapeutic				
Bronchoscopy - diagnostic				
- therapeutic				
Paediatric endoscopy - diagnostic				
- therapeutic				
Others				

Key points:
- How many procedure rooms does the endoscopy department have?

Is simultaneous working in different endoscopy suits possible? *Yes *No
In how many rooms ?
- How many reprocessing rooms does the endoscopy department have?
- How much staff is available for reprocessing endoscopes and equipment?
- How much time is scheduled for reprocessing a flexible endoscope?

1.2. To evaluate the compatibility requirements to reprocess the excising equipment in the endoscopy department:

- Should the machine be able to reprocess flexible endoscopes from various companies?

Key points:

- How many endoscopes are available in the endoscopy department?
- What different kinds of endoscopes are available in the endoscopy department? (different types, number of scopes, from which manufacturer)

Kind of endoscope	Number of scopes	From which companies
Gastroscopes		
Duodenoscopes		
Colonoscopes		
Bronchoscopes		
Paediatric endoscopes		
Others		

1.3. Survey of the reprocessing room / area and to evaluate necessary installations and investments

A purposely designed room for cleaning and disinfection, separate from procedure rooms, is of utmost importance for patient and staff, in order to

- protect from chemicals used in cleaning and disinfection procedures (e.g. toxic/allergic reactions, vapour of glutaraldehyde)
- protect from cross contamination with potentially infectious material, blood and body fluid.
- minimise the potential risk of infection and contamination.

Key points:

- Is a reprocessing room available which is separate from procedure rooms ? * Yes * No
- Size of the room ?
- How many reprocessing rooms are available (only for larger units)?
- How many machines are necessary for each reprocessing room and / or for the whole endoscopy unit? (calculate with information from 1.1.: needs of endoscopy department)
- Available space for a new machine?

Further aspects:

- Have any machines already been installed ? * Yes * No

If so, which type and manufacturer?

- Which supplies have already been installed and with which capacity?

Type of Supplies	Existing Machine(s)	Available for new machine	Potential for new machine
Cold water:			
Warm water			
De-ionised water:			
Filtered water			
Drainage			
Ventilation system:			
Electricity: (watt)			
Other			

- Which noise level does the existing machine(s) have ? noise level : _____dB(A)

(Compare it with the national recommended noise level (see DIN IEC 704)

1.4. To evaluate the national requirements which have to be followed

Key points:
Which national regulations, recommendations and guidelines have to be followed regarding:
* health and safety of staff at work?
* control of substances hazardous to health?
* personal protective equipment at work?
* electronic compatibility?
* water supply?
* ventilation systems?
* noise level of machines?
* staff training?
* micro-biological surveillance?

2. Requirements of the Automated Washer Disinfector

2.1. Design of the proposed machine

Key points:
- Name of manufacturer, marketing agent(s), country of origin
- Does the machine machine meet the respective national guidelines and recommendations
* Yes * No
- Price of the washer disinfector and its accessories, including
-Capital investment
Annual cost
- depreciation
- revenue costs per cycle (chemicals, water, electrical power, filters, etc.)
- maintenance (servicing/repair) costs
- Which manufacturer and type of endoscopes can be reprocessed in the machine?
_____ (check against assessment in part 1)
- Description of construction and instrumentation * Yes * No
- Details of guarantee/warranty
- Is a maintenance/service contract available * Yes * No
- Planned preventative maintenance requirements * Yes * No
- What kind of training for staff is offered by the manufacturer?
- How many endoscopes can be reprocessed in one cycle?
- Is the machine fixed or portable? * fixed * portable
- What specification has the machine? (check against assessment in part 1)
- dimensions / size
- services required (plumbing) * Yes * No
- water supplies
(warm, cold, de-ionised or distilled water, water quality etc)
- exhaust air extraction * Yes * No
- drainage connection
- electric supplies watt ____
- Noise level : _____dB(A)
(Compare it with the national recommended noise level (see DIN IEC 704)
- What loading system is used for the endoscopes ?
* front loading system
* top loading system
* baskets
* immersion trays

* tanks
* pressure chamber with tubes
* etc.
• What material is the: washer chamber _____and the outside panelling of the machine_____ (e.g. polished chrome nickel steel, plastic, temperature and chemical resistant etc.)

2.2. System of the machine

Key points: Due to their construction, endoscopes have to be treated either chemically or thermo-chemically.
• Which system is available in the considered machine?
* chemical - cold reprocessing or
* thermo-chemical reprocessing
• Does the washer disinfector provide a standardised reprocessing cycle including the following steps?
- leakage testing * Yes * No
- cleaning/detergent cycle * Yes * No
(Ask manufacturer whether a pre-cleaning, by means of brushing the endoscope before putting it into the machine, is recommended or not ? - ESGE/ESGENA guidelines recommend routine brushing before disinfection)
- rinsing / neutralisation of detergents * Yes * No
- disinfection * Yes * No
- rinsing / neutralisation of disinfectant* Yes * No
- alcohol flush * Yes * No
- drying * Yes * No

• What types of endoscopes can be reprocessed in the machine?
• Are the channels irrigated singly or collectively ? * singly * collectively
• What type of adapters / connectors are necessary for the existing endoscopes used in the department?
Are they supplied by the manufacturer of the machine? * Yes * No
• How many endoscopes can be reprocessed in one cycle
* one endoscope
* two endoscopes in one basket, immersion tray or tank
¦ two endoscopes synchronously
¦ two endoscopes asynchronously in two separate baskets, immersion trays or tanks

2.3. Reprocessing cycle

Key points:
• How long is the duration of the optimal reprocessing cycle, including all reprocessing steps recommended by the manufacturer?
• What time does the machine need for each single step of the reprocessing cycle (leakage test, cleaning, disinfection, neutralisation, drying
• Are the cycles pre-programmed? * Yes * No
• Can the operation sequence be varied:
by the manufacurer * Yes * No
by the endoscopy staff * Yes * No
• What type of programmes are available on the machines?
Are there any optional extras?

• Has the machine a pre-cleaning cycle before the disinfection cycle? * Yes * No
• Can supplementary drying be chosen separately, e.g. at the end of the list prior to storage of the endoscopes? * Yes * No

• Satisfy yourself that all channel irrigation is achieved (suction, biopsy, air, water, elevator, etc.) * Yes * No
• Are all external surfaces processed * Yes * No
• Does the machine loading suit your department's working routines and is convenient to you?

2.4. Chemicals

Key points:
• What type of agents / chemicals are compatible with the machine?
- cleaner ?
- disinfectant(s) ?
• Are the chemicals compatible with the endoscopes, used in the endoscopy department? (Ask endoscope manufacturer) * Yes * No
• Has the micro-biological efficacy of the chemicals been tested? (Ask manufacturer and microbiologist) * Yes * No
• What hazards to staff and equipment are already known?

Consider ALL possible disinfectants separately as times, expiry and hazards etc. may vary with each product:
• How much of the chemicals are needed - for each cycle/to fill container in the machine?
- cleaner
- disinfectant
• What is the live time of the activated chemicals ?
• Frequency of chemicals exchange ?
• Are the chemicals ready for use? * Yes * No
• Ask the manufacturer and clarify details concerning
- advice for handling to minimise the hazard when changing chemicals
- conditions storage of chemicals (size of containers, room, temperature, etc.)

2.5. Water Quality

Key points:
• What is the volume of water used per cycle?
• What water quality is required for the machine?
• Is "decontaminated" water used for the last rinsing phase?
• How is the rinsing water produced ?
* UV-filter
* boiler
* bacteria retaining water filters between water pipe a machine
• Is fresh rinsing water used for each cycle ?
• What methods and / or constructions are used to prevent a recontamination of
- the endoscopes
- the inner chamber of the machine
- all water pipes of the machine

2.6. Control Systems

Key points: The efficiency of the cleaning and disinfection procedure depends partially on the water pressure and water volume, the concentration of agents, temperature and duration of various cycles and patency of endoscope channels. In case of any deviations of process parameters or interruption for technical reasons, the machine must stop working. A visual and audible alarm shall be given to the user. In case of interruptions for technical reasons, the entire programme must be repeated completely.

- What fail safe / control systems are available in the machine to check:

- the water volume and pressure
- the volume-controlled dosage system for the cleaner and disinfectant
- temperature
- duration of various cycles
- leakage test of endoscopes
- adequate irrigation of all channels
- changing of chemicals required

- Does the machine interrupt the reprocessing cycle in case of deviation of technical parameters? * Yes * No
- Which signals are available?

- acoustic signal * Yes * No
- optical signal (lamps or digital) * Yes * No
- are the underlying causes identified on digital display/print-out * Yes * No

- Is the flow of liquids adjusted to the individual construction of the endoscope (see which types of endoscopes can be reprocessed in the machine)
- During the reprocessing cycle, the complete disinfection of all components immersed in rinse agents and / or circulating water (e.g. ducts, valves, pumps, regenerative devices, etc.). are ensured?
- Attention must be paid to prevent the escape of toxic vapour

- during filling of the machine with disinfectant
- while the machine is operating
- in case it is necessary to open the machine
    - o in case of interruptions for technical reasons
    - o in case of leakage of endoscope
    - o in case of obtaining water samples from the last rinsing water for micro-biological tests
    - o when changing the cleaner/disinfectant containers.

- Is a cycle indicator fitted? * Yes * No
- Is a cycle counter fitted ? * Yes * No
- Is the equipment capable of self-disinfection? * Yes * No

2.7. Staff protection

Key points: Protective measurers for the personnel must be followed during all phases of the reprocessing cycle and during change of chemicals. Protective clothing should be put on before starting the reprocessing, including chemically resistant gloves, protective glasses / visor, protective face masks and special examination gown or coat (long-sleeved, moisture-resistant) or plastic aprons

- What facilities are provided to reduce staff exposure to aldehyde vapour or other chemical agent (e.g. peracetic acid) whilst filling, using and emptying the machine?
- How can the machine be opened and closed?
- How is contamination of the exterior surfaces of the appliance avoided / excluding during loading and unloading the machine?
- What is the noise level of the machine (Ask manufacturer for the dB(A) - level)

2.8. Hygiene and infection control

Key points:
- Is the procedure / system approved by an independently validated standard ?
- Does the machine meet all national requirements?
- Does the machine have a specific programme to collect the last rinsing water for micro-biological tests?
- After the machine has not been used for about 12 hours, a safety programme should be istigated, including

- complete check of technical parameters
- complete disinfection of water transport systems and the inner chamber of the machine

2.9. Documentation

Key points: To fulfill the legal requirements of providing evidence of adequate reprocessing of equipment, the machine should provide a printout of how the endoscope was reprocessed and with the relevant patient details.
- Is machine generated documentation of procedure related data available? * Yes * No
- What data are documented? * reprocessed endoscope (type and identity number)

* date
* duration of cycle
* amount of water
* chemicals
* temperature
* pressure
* interruptions of cycle and faults
* patient ID
* etc.?

- How are process data documented? (printer, bar code, PC, etc.?.)

Addendum:

Rigid Endoscopes

Some machines also enable the reprocessing of rigid endoscopes and accessories. Rigid endoscopes are used in gastroenterological endoscopy in form of
- procto-rectoscopes and accessories
- rigid laparoscopes and accessories

International and national guidelines recommend that all endoscopic equipment used for percutaneous interventions must be sterile. If rigid laparoscopes and accessories are cleaned in a washer disinfector, sterilisation must follow. ALL heat tolerant equipment must be autoclaved.

Flexible Endoscopic Accessories

Some machines also offer cleaning and disinfection of flexible endoscopic accessories. THIS DOES NOT NEGATE THE NEED FOR STERILISATION.
The following steps must be followed before machine disinfection:
☐ disconnecting and dismantling accessories as far as possible
☐ pre-cleaning
☐ ultrasonic cleaning
☐ neutralisation

After cleaning and disinfection in the washer disinfector, accessories must be dried completely and sterilised (recommendation: steam autoclave, pre-vacuum, 134oC, 5 minutes or equivalent cycles / in line with national regulations)

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