Rinse water for heat labile endoscopy equipment

Report from a Joint Working Group of the Hospital Infection Society (HIS) and the Public Health Laboratory Service (PHLS)

Summary: The increase in use of endoscopic procedures in diagnosis and surgical treatment has underlined the need for safe cleaning methods for these instruments. While decontamination has been reviewed by several Working Groups in Britain, the problems relating to the prevention of contamination of rinse water and its monitoring procedures have not been addressed previously. This report from the Joint Working Party identifies the problems, and provides guidance on the monitoring and provision of high-quality rinse water.

Keywords: Endoscopy rinse water; monitoring; guidelines.

Introduction and background

The ever-expanding use of endoscopic procedures in diagnosis and surgical treatment of patients has reinforced the need for safe and effective methods of cleaning, disinfection and sterilization of these instruments. In recognition of the relevance and importance of this topic, a Hospital Infection Society Working Party recently issued a report on the decontamination of minimally invasive surgical endoscopes and accessories.1

As the number of patients undergoing endoscopy has increased, the requirements for the safe use of glutaraldehyde and other potentially irritant or sensitizing instrument disinfectants has led to an increased use of automated washer disinfector systems which provide safe containment of hazardous vapour and can remove toxic residues effectively. These automated systems have been shown to be more effective in removing bacteria than manual methods2 but they are not without problems, and the following issues need to be recognized.

1. Many systems are available on the market. Irrespective of whether or not the system has its own wash cycle prior to disinfection, it is recognized that manual precleaning of endoscopes is essential.2,3

2. There is a need to ensure endoscope compatibility with the autodisinfector fittings. Endoscopy staff must follow instructions strictly in order to ensure that all endoscope channels are adequately irrigated with disinfectants. There is a need to ensure endoscopes and washer disinfectors are compatible with the disinfectants used.

3. Automated systems require regular and adequate maintenance which is time consuming and expensive. Furthermore, some parts of the decontamination process (e.g. brushing lumens and wiping insertion tubes) cannot be automated and thus manual cleaning is still an essential prerequisite.

The most significant problem which has not been addressed by the increased use of automated systems...
is that of contaminated rinse water derived from either the internal pipework of the washer disinfector or mains water, as well as intermediate tanks and poorly maintained filters.

Water has to be used in endoscopy to prepare detergent solutions, to clean instruments and to remove traces of disinfectant which could be hazardous to patients and staff.

Unfortunately, tap and mains water are not sterile and therefore have the capacity to recontaminate endoscopes creating the possibility of transmission of infection to patients in whom the endoscope is subsequently used.4±6

There is also the potential problem of contamination of diagnostic samples resulting in false-positive microbiological analysis and subsequent unnecessary treatment of patients, often with expensive and potentially toxic drugs.7±10

Water direct from the rising main is rarely used. The supply usually comes from a storage tank which creates an increased risk of contamination as the water has been standing and is usually not sufficiently chlorinated.

Use of sterile water (e.g. water for irrigation) is one possible means of avoiding such problems, but this is prohibitively expensive and the water would need to be transferred to a sterile container or irrigation system. Even so, washer disinfectors are not closed systems, and contamination seeding from the outside still presents a risk.

The majority of effort has therefore been channelled into trying to make mains water safe for the final, post disinfectant, rinse in endoscope processors.

In spite of widespread use of various processes intended to solve the problem of contaminated rinse water, serious problems have been encountered. Even units which have strictly adhered to the washer disinfector manufacturer’s recommendations for decontamination of filters11 have experienced problems.

In 1998, Phillips et al.12 reported the presence of black pigmented fungi in the pipe work supplying washer disinfectors. Their concerns were reflected by other workers,13,14 and the ability to provide ‘bacteria-free’ water was challenged by Cooke.14

It is thus evident that the production of rinse water of suitable bacterial quality remains a problem, not always recognized by users. The Hospital Infection Society (HIS) Working Party on the decontamination of minimally invasive surgical endoscopes and accessories1 amongst others3,15,16 noted that contaminated rinse water could present a problem to users. Furthermore, there appears to be a lack of clear guidance on how to achieve and monitor the quality of this rinse water. Indeed, there were no standards or guidelines on washer disinfectors until the publication of HTM 2030 in 1995.17

With these comments in mind, the HIS convened a Working Group to review this area and produce recommendations.

**Working method**

A joint HIS/PHLS Working Group was convened, bringing together infection control doctors, scientists with a specific interest/expertise in water microbiology, and infection control officers with an interest in endoscopes.

The remit of the group was as follows:

1. To consider the provision of sterile water for use with endoscopy equipment including a review of currently available methods.
2. To produce guidance on the practical aspects of cleaning and disinfection of processors, including the maintenance and disinfection of rinse water pipework and filters whenever their use is recommended or applicable.

A literature search was carried out, covering the period 1990–2000, using Medline and other medical and nursing databases, cross-referencing relevant key words including endoscopy, contamination and rinse water. Papers of interest found using this methodology were further reviewed by members of the group.

Additional documents from Britain were also considered. These included the Medical Devices Agency Device Bulletin 9607 Decontamination of Endoscopes (November 1996);15 the Health Technical Memorandum 2030, Washer-disinfectors (three volumes: Operational Management, Design Considerations and Validation and Verification);17 an early draft of BSEN ISO 1S883 Washer Disinfectors; British Society of Gastroenterology Endoscopy Committee Report on cleaning and disinfection of equipment for gastrointestinal endoscopy;3 and a draft of the British Thoracic Society’s Guidelines on flexible bronchoscopy.16

A consultation process was undertaken though the HIS’s electronic discussion group and the Society’s website. Members of the Public Health Laboratory Service (PHLS) Water & Environmental Advisory Committee were also invited to comment.
The Mycobacterium Reference Unit (Dulwich) and the Infection Control Nurses Association were asked to comment. Infection control and endoscopy nurses were consulted via the Working Group members.

**Results of literature search**

The literature review identified several reports of problems with contaminated rinse water confirming the Group’s impression that rinse water contamination is a significant problem. Incidents reported included pseudo-outbreaks of infection with *Mycobacteria* spp.,18–20 *Pseudomonas* spp.,21 and *Staphylococcus epidermidis.*22 Although a few incidents were associated with inadequate cleaning, most problems arose from contaminated rinse water or failure to disinfect processors. Choice of disinfectant and contact time appear less problematic. Unfortunately, there were no publications allowing clear evidence-based recommendations to be made.

**Defining the problem**

**Current practices**

The provision of water of high quality can be achieved by a variety of methods. The most popular at present is the use of a two-stage filtration system whereby one or more coarse filters are used to remove large particles and a final filter of bacteria-retentive grade is used to remove micro-organisms. Other systems are in use or under investigation and these include: ultraviolet (UV) light, reverse osmosis, adding bacteriocidal agent (including ozone or superoxide water), and raising the temperature of the rinse water to destroy organisms.

Filtration of water, even if effective in rendering incoming water bacteria free, cannot be relied upon to prevent biofilm accumulation of the internal plumbing of endoscope reprocessors. Whilst filtration aims to sterilize and remove microbial debris, many of these other systems aim to render the water sterile (thus minimizing the risk to patients) but do not remove dead organisms (which may cause false-positive microbiology such as in Ziehl Neelsen or acid-alcohol fast bacilli stains of sputum samples).

A questionnaire survey of selected endoscopy departments within NHS trusts carried out by Rembacken *et al.*23 revealed very disparate practices regarding the microbiological monitoring undertaken, and the expectations of users and providers.

These workers found that there was uncertainty regarding appropriate action to combat biofilm formation and limescale. Many hospitals also found the examination of rinse water for endotoxin as recommended in HTM 2030 to be impractical, due to the cost, impracticability of tests and difficulties in quantitative methods.

A survey of Scope Washer-Disinfector suppliers found a wide range of adequacy of information on routine decontamination and the practicality with which that could be achieved: with some machines, disinfection of the filters and rinse circuits was said to occur on every use; with others, there was said to be a self-disinfectant programme easily operated (i.e. at the press of a button). Other providers indicated that disinfectant had to be added to a water reservoir and flushed through the machine. While some manufacturers declined to comment, on at least one occasion it was stated that modifications were necessary to enable self-disinfection of all pipework, (Hoffman and Parnell, personal communication).

**Rinse water monitoring**

Monitoring was also found to be extremely variable. Although there is guidance in HTM 2030 Validation and Verification (sections 9.213–9.236)17 concerning the commissioning tests and the frequency of monitoring of total viable counts in rinse water, few trusts/hospitals were adhering to these recommendations. This could reflect the significant investment in time and expense required if this recommended guidance is followed.

Microbiological methods also varied, and may not always be appropriate to the detection and identification of all potentially pathogenic organisms, e.g. atypical mycobacteria require longer incubation periods and culture on selective media.

**Recommendations**

In the absence of clear evidence to recommend specific monitoring protocols, HTM 2030 may be a useful starting point on which to base best practice.

A scoring system adapted from the CDC guidelines24 as modified by other UK Working Groups was used25:

**Category I:** Generally consistent findings in a range of evidence derived from well-designed experimental studies.
Category II: Evidence based on a single acceptable study, or a weak or inconsistent finding in some multiple acceptable studies.

Category III: Limited scientific evidence that does not meet all the criteria of 'acceptable studies', or an absence of directly applicable studies of good quality. This includes published or unpublished expert opinion.

This grading system was adapted by other guideline developers in the UK and is commonly used to describe quality and direction of evidence that underpins a guideline recommendation.26

This Working Group recognizes that very few of its recommendations fulfil the criteria required for a Category I guidance.

However, most fall under Categories II and III, and on this basis the Group concluded that:

- Water used in the final rinse cycle of washer disinfectors should be sterile or bacteria-free. As argued by Humphreys and Lee,6 water used only for gastrointestinal tract endoscopes need not be sterile. But many endoscopy departments carry out a variety of procedures, and endoscopes may be processed through the same washer disinfectors.

- Reliance on filtration systems alone is not sufficient to ensure a continued supply of water of the required quality.

- The endoscope washer disinfectors, including all rinse water pathways from bacteria-retaining filters to the drain (including the filters themselves), should be disinfected as part of every processing cycle or daily with an effective agent, either at the start of each working day or preferably at the start of each processing session.

- Weekly monitoring of total viable count is recommended in HTM 2030 but we acknowledge that this may be impractical. The Group advises therefore that microbiological quality of water should be monitored regularly, in agreement with the local microbiology department. If results are plotted against a norm, deviations are easily detectable.

- Trends in water quality should be observed over time, as sudden changes are unlikely. A weekly to monthly programme may be sufficient provided results are regularly reviewed under the guidance of the infection control team(s) (ICT). Such monitoring should include culture on appropriate media with prolonged incubation for mycobacteria. It is recommended that testing should be performed so as to allow the maximum time possible to lapse between disinfection and testing. (See Appendix I for detailed method).

- If after a year there are consistent results, quarterly monitoring may well be sufficient providing there are robust, audited policies, in place and all personnel are aware of these.

- Endotoxin analysis is recommended in HTM 2030, but this Working Party does not believe that routine endotoxin testing is required in the assessment of the quality of rinse water.

Practical steps to achieve the above aims

General measures

- Endoscope and washer disinfecter manufacturers should all give clear, evidence-based advice on these aspects relating to their washers, and these should be provided at the pre-purchase stage.

- Advice relating to these recommendations should be included in the 'scope decontamination' policy and include careful consideration of their endoscope manufacturer and 'scope washers' documentation.

- The policy should be drawn up by a group including the ICT and representatives of all relevant departments, and address all the areas outlined in ‘Provision of bacteria-free water' below.

- There should be regular audit of policy implementation. The policy should be reviewed at two to three yearly intervals.

- Policy contents should be included in induction and ongoing training of relevant staff. Comments from new staff should be encouraged to ensure continued ownership.

- Any new item of relevant equipment such as scopes and scope/washers, changes in building that might affect the efficient running of the service, or changes in the water supply or service, should be discussed with the ICT.

Provision of bacteria-free water

The nature and extent of treatment will depend in part on the quality of the local water supply,
but normally should include at least the following steps:

- The design of the pipework, tanks, valves and pumps to avoid dead legs and areas where microbial growth may proliferate is critical to the maintenance of the system free from microbial contamination. An air gap between the machines and the mains water system is required, in compliance with water regulations.

- All fittings and pipe connections should be pharmaceutical-grade sanitary fittings, or comply with the British Standard BS 6920, part 2. They should also comply with the list of substances, products and processes approved under regulations 25 and 26 for use in connection with the supply of water for drinking, washing, cooking and food production purposes.

- All tanks used for storage of water or aqueous solutions should be designed and constructed to ensure that they are free draining and cleanable.

- The washer-disinfector manufacturer (and filter manufacturer if appropriate) must provide information on cleaning and disinfection procedures, and compatible chemicals for these purposes.

- The system should be disinfected regularly and the machine cleaned and maintained regularly, adhering to the manufacturer’s information.

- The inclusion of the means to disinfect or sterilize filters and the downstream water distribution system between uses and at four-hourly daily intervals. This should preferably be by steam sterilization, but a chemical disinfection process may also be used (see Table I).

An acceptable alternative is to use a demountable system which allows the filters and downstream distribution system to be removed, dried and steam sterilized between sessions. Disinfection after re-assembly to kill dislodged organisms should be carried out.

N.B. HTM 2030 recommends a different disinfectant for reprocessing of endoscopes compared with that used to disinfect the machine to reduce the risk of resistance development.

**Monitoring of water**

- This should begin at the design stage with only properly validated systems coming on to the market.

- Monitoring should take place after maintenance, changes in cycle parameters or on the advice of the infection control doctor.

- It is recommended that maximum time between decontamination and sampling is allowed, i.e. samples to be taken in the morning following the overnight processor decontamination.

It is recommended that the following sites are considered for sampling for microbiological monitoring:

- Rinse water that has been circulating through the washer disinfector to identify any build up of biofilm or
- Rinse bowl prior to discharge to drain.

The most commonly described contaminants are *Pseudomonas* spp., pigmented fungi and *Mycobacterium chelonae*. The minimum recommended incubation period (see Appendix 1) will not be sufficient to allow isolation of this group of organisms. Extended culture incubation will be required, although high total counts may be taken as an indication of contamination.

If any of the samples are found to be contaminated, further exploration of multiple sampling points is advised.

The sample should be taken downstream of any filter or other device, or equipment intended to remove or control microbial contamination in the water supply.

Full details of recommended microbiological processing are provided in Appendix 1. NB. Some washer disinfectors have lockable lids. Washer disinfector manufacturers should design their equipment to facilitate sampling.

**Action to be taken on finding contaminated rinse water (Figure I)**

The Group recommends in the first instance that the entire system is flushed with 1000 ppm of a chlorine-releasing agent. Alternatively, agents such as chlorine dioxide, peracetic acid or superoxidized water may help solve a contamination problem. It is important to check with the manufacturer that the washer disinfecter components are compatible with the intended concentration of disinfectant. The filters should be changed or decontaminated at this stage.
<table>
<thead>
<tr>
<th>UK distributor and telephone number</th>
<th>Autodisinfecto name</th>
<th>Method of providing bacteria-free water</th>
<th>Water processing system if not integral to endoscope reprocessor</th>
</tr>
</thead>
<tbody>
<tr>
<td>AFOS Ltd Manor Estate</td>
<td>ICU (Infection Control Unit) range</td>
<td>Water filtration</td>
<td>AFOS Water Handling Unit 2 micron, 0.6 micron and 0.2 micron filters</td>
</tr>
<tr>
<td>Anlaby HU1 0 6RL 01482 352152</td>
<td>Genesis range</td>
<td>Water filtration/ozone</td>
<td>Genesis water processing unit 5 micron, 1 micron and 1 micron rough particulate filters and a granular activated carbon filter to remove water chemicals and organics. Mains water passes through these filters and then to a processing tank. Low levels of ozone are used to ‘disinfect’ the water. UV light is also used to maintain water quality. 0.2 micron filter positioned as close as possible to the machine. The filter and pipe leading from the filter to the machine are detachable and sterilizable. Can heat disinfect the machine to 95°C.</td>
</tr>
<tr>
<td>BIOQUELL Medical 29-31 Lynx Crescent Weston Super Mare Somerset BS 24 9BP 01934 410575</td>
<td>ICU (Infection Control Unit) range</td>
<td>Water filtration</td>
<td>AFOS Water Handling Unit 2 micron, 0.6 micron and 0.2 micron filters</td>
</tr>
<tr>
<td>DAWMED International (formerly Dawson Medical) Eden Close, Hellaby Rotherham South Yorkshire 01709 7370730</td>
<td>Wassenburg WD 440</td>
<td>Water filtration</td>
<td>Additional pre filtration may be required in order to prolong the life of the integral filter.</td>
</tr>
<tr>
<td>KEYMED Ltd KeyMed House Stock Road Southend on Sea Essex SS2 5QH 01702 616333</td>
<td>OER Olympus Endoscope Reprocessor</td>
<td>Water filtration, Integral 0.2 micron filter</td>
<td>Autoscope water Filtration System. 5 micron, 1 micron and 0.2 micron filters. There is the option for a further additional 0.2 micron filter.</td>
</tr>
<tr>
<td>LABCAIRE System Ltd 175 Kenn Road Clevedon North Somerset BS21 6LH 01275 793000</td>
<td>Autoscope Guardian range</td>
<td>Water filtration</td>
<td>Autoscope Guardian range Water filtration</td>
</tr>
<tr>
<td>LANCER UK Ltd 1 Pembroke Avenue Waterbeach Cambridge CB5 9QR 01223 861665</td>
<td>Fibro-Cleaner</td>
<td>Water filtration</td>
<td>Fibro-Cleaner Water filtration</td>
</tr>
<tr>
<td>MEDISCOPE Ltd 1 Mead Lane Lydney Gloucestershire GL15 5EU 01594 844770</td>
<td>Medivator</td>
<td>Water filtration</td>
<td>Medivator Water filtration</td>
</tr>
<tr>
<td>Company</td>
<td>Address/Contact Information</td>
<td>System Details</td>
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<tr>
<td>STERILOX Technologies</td>
<td>Montrose House Montrose Street Fenton Stoke on Trent Staffordshire SR4 3PB 01782 595969</td>
<td>QED previously supplied by SEE (Specialized Endoscopy Equipment)</td>
<td></td>
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<tr>
<td></td>
<td></td>
<td>Three options</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>1. Water filtration using an external bank of 5 micron (as possible 1 micron) and final 0.2 micron filters.</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>2. For departments using STERILOX (superoxidized water) bacteria-free water (AQUALOX) is produced as an additional product.</td>
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<td></td>
<td></td>
<td>3. The Endoscope Rinse System (ERS). (An ultrafine cartridge which is said to flush micro-organisms away). Bacteria, colloid and pyrogen-free water is produced. Filter life is claimed to be two years. The (ERS) can be used prior to the STERILOX generator in areas where water quality is a severe problem. Further water treatment is required to provide water that is of a suitable quality for the Steris. This will typically involve pre filtration with 10 micron and 5 micron filters.</td>
<td></td>
</tr>
<tr>
<td>STERIS Ltd</td>
<td>Steris House Jays Close Viables Basingstoke Hampshire 0800 252609</td>
<td>Water filtration. 2 Integral filters A&amp;B. 0.2 micron nominal and 0.2 micron absolute.</td>
<td></td>
</tr>
<tr>
<td>VIVENDI WATER SYSTEMS</td>
<td>Process Equipment Group High Street, Lane End High Wycombe, Buckinghamshire HP14 3JH 01494 887700</td>
<td>Has now a typical HTM 2030 System arrangement comprising of softeners and RO to supply water to washer disinfectors.</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Comprises raw water filters, water softener, 5 micron filter, reverse osmosis unit, treated water tank and UV disinfection unit.</td>
<td></td>
</tr>
</tbody>
</table>

N.B. This table lists systems known to be available at the time of printing. Inclusion does not imply endorsement by the authors.
If this fails, other actions to be considered including a second flush with 10 000 ppm chlorine, replacement of as much of the pipework as is practical to remove biofilm and the change to a different disinfectant. This latter action may be particularly helpful if *M. chelonae* is a problem and glutaraldehyde is being used, as these organisms can be aldehyde-resistant whilst remaining sensitive to other agents. It is also worth noting that some oxidizing agents may have a beneficial effect on established biofilm (Sterilox Medical (Europe) Ltd, personal communication).

Routine decontamination schedule should be reviewed to detect any possible failures.

It is also important to ascertain that monitoring is being done according to schedule.

The mains water should also be investigated. If the contamination of this is very high, the local water authority may be able to help. Local estates departments should be involved if the water supply is via a hospital tank, and/or internal plumbing of uncertain quality.

**References**


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**Figure 1** Action to be taken when contaminated rinse water is discovered.
Appendix 1

Procedure for sampling and bacteriological monitoring

Wipe the discharge surfaces of the sampling point thoroughly with 70% isopropanol and allow to evaporate to dryness, or just run through for about 20–30 s (i.e. ‘mid-stream’ rather than ‘first catch’).

Run off not less than 50 mL through the sampling point and discard.

Using aseptic handling techniques, collect not less than 400 mL of sample from each sampling site in a sterile container and close the lid securely. Alternatively, 500 mL in a sodium thiosulphate container may be considered. Label the container with details of the sampling point and the time and date the sample was collected.

The sample should be transferred to the laboratory and tested within 4 h; if this is not possible, the sample should be stored at 2±5°C for not more than 48 h before testing.

Filter a 100 mL aliquot of the sample through a 0.45 μm filter. Aseptically transfer the filter to the surface of a TSA plate and incubate at 35 ± 2°C for 48–72 h. Carry out the test in duplicate.

Also culture a second filtered aliquot on to 7H11 medium at 30°C (for M. chelonae) for one week. Alternatively, to avoid overgrowth by Gram-negative organisms, the use of blood agar with a GC supplement can be considered.

If the possibility of contamination with other AAFBs is identified (e.g. following the growth of an acid-alcohol fast bacillus from a broncho-alveolar lavage), extended culture for other mycobacteria on 7H11 at 37°C may be included.

Examine the filters daily for the length of the incubation period and record the number of colony forming units which are visible.

The microbiological quality of the water should reflect the recommended parameters in 9.22 HTM 2030—for washer-disinfectors in which the product is rinsed after the disinfection stage there should be no recovery of micro-organisms from the rinse water.

All other water services supplied to washer-disinfectors should have less than 100 cfu/100 mL of water after 48–72 h, at temperatures of 35 ± 2°C.

In view of the problems likely to be encountered, it is also recommended that the following measures are included in the routine monitoring programme:

- Machines for processing these endoscopes may be fitted with bacteria-retaining filters, which have a pore size of 0.2 μm.
- Records of viable counts filter changes and processor disinfection should be retained.