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Quality of the final rinse water for endoscope washer disinfectors

A literature review

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Abstract

Quality of the final rinse water for endoscope washer disinfectors

After the disinfection stage in an endoscope washer disinfector (EWD), the flexible endoscope shall be rinsed with water to remove the disinfectant. The water that is used for this final rinse shall be free from micro-organisms and the content of chemical contaminants like limestone shall be limited. A variety of water treatment systems are available, which are effective if properly designed, installed and maintained. Limiting values and test methods for the determinants mentioned above are given in literature, international standards and national guidance documents. The manufacturers of the EWD, the endoscope and process chemicals may give additional requirements and guidance in their instructions for use. Users of washer disinfectors for flexible endoscopes shall establish a test regime to monitor the quality of the final rinse water and a procedure that comes into action whenever test results show that the specifications are not met.

Bacteria in the final rinse water may lead to the formation of a persistent and hard to remove biofilm in the endoscope washer disinfector, re-contamination of the disinfected endoscope, contamination of tissue samples taken through the biopsy channel or fatal infections in the patient. Bacteria that remain in moist environment of the washer disinfector at the end of the operating cycle may proliferate and form a biofilm. Mature biofilms release bacteria which will sustain the contamination of the washer disinfector and also re-contaminate the final rinse water, which may subsequently re-contaminate the disinfected endoscope. This cycle is hard to break out of, which makes it very important to prevent the formation of biofilms.

Potable water does not necessarily meet the specifications for final rinse water in EWDs and should be treated before use. Design flaws in water treatment systems should be avoided. For example, leaving stagnant water in the system in which micro-organisms will grow into numbers higher than the bioburden in the potable water that is used to feed the water treatment systems. To remove the microbial contamination, water filters are the most popular. Systems using (combinations of) UV light, low concentrations of disinfectant and heat, may be equally effective. Since these systems give a reduction of the bioburden and not an absolute removal of all micro-organisms, the efficacy depends on the bioburden of the water. These systems shall be designed after establishment of the bioburden.

All water treatment systems shall be meticulously maintained in accordance with the instructions of the manufacturer of the system. Maintenance should include daily self-disinfection the EWD including the water treatment systems and the down stream pipe work that is connected to it.

Key words:
water, water quality, endoscope, reprocessor, washer disinfector, flexible endoscope

Samenvatting

Kwaliteit van het laatste spoelwater voor endoscopenwasmachines

Na de desinfectie met een chemisch ontsmettingsmiddel in een endoscopenwasmachine wordt de flexibele endoscoop met water nagespoeld om het ontsmettingsmiddel te verwijderen. Het water dat wordt gebruikt voor deze laatste spoeling moet vrij zijn van micro-organismen en het gehalte aan chemische contaminanten, zoals ketelsteen, moet beperkt zijn. Verschillende waterbehandelingssystemen zijn beschikbaar, die effectief zijn mits zij goed zijn ontworpen en conform de specificaties geïnstalleerd zijn en onderhouden worden. Grenswaarden en testmethoden voor de genoemde determinanten worden gegeven in de literatuur, internationale normen en nationale richtlijnen. De fabrikanten van de endoscopenwasmachine, de endoscoop en de proceschemicaliën kunnen in hun gebruikshandleiding aanvullende eisen en richtlijnen geven. Gebruikers van endoscopenwasmachines moeten een testregime opstellen om de kwaliteit van het laatste spoelwater te monitoren en een procedure beschikbaar hebben waarin staat beschreven hoe men moet handelen wanneer blijkt dat het water niet aan de specificaties voldoet.

Bacteriën in het laatste spoelwater kunnen leiden tot de vorming van een moeilijk te verwijderen biofilm in de endoscopenwasmachine, herbesmetting van de gedesinfecteerde endoscoop, vervuiling van weefselmonsters genomen via het biopsiekanaal of dodelijke infecties bij de patiënt.
Bacteriën die aan het eind van het proces in de vochtige omgeving van de endoscopenwasmachine achterblijven kunnen een biofilm vormen. Uit volgroeide biofilms komen bacteriën los die zich door de wasmachine verspreiden en zo de besmetting van de wasmachine in stand houden, het laatste spoelwater opnieuw besmetten en via het laatste spoelwater de gedesinfecteerde endoscoop. Deze cyclus is moeilijk te doorbreken en het is daarom van belang dat de vorming van biofilms wordt voorkomen.

Er mag niet vanuit worden gegaan dat drinkwater aan de specificaties voor het laatste spoelwater in endoscopenwasmachine voldoet. Drinkwater moet voor gebruik behandeld worden. Ontwerpfouten in waterbehandelingssystemen moeten voorkomen worden. Bijvoorbeeld, de aanwezigheid van langdurig stilstaand water waardoor micro-organismen tot grote aantallen kunnen uitgroeien. Hierdoor kunnen in behandeld water veel meer bacteriën aanwezig zijn dan het drinkwater waarmee de waterbehandelingssystemen worden gevoed.
Om de microbiële contaminatie uit het water te verwijderen worden waterfilters het meest toegepast. Systemen die werken met (combinaties van) UV-licht, lage concentraties van een desinfectans en hitte, kunnen even doeltreffend zijn. Aangezien deze systemen de bioburden reduceren en niet een absolute verwijdering van alle micro-organismen geven, hangt de effectiviteit echter af van de bioburden in het water. In het ontwerp van dergelijke systemen moet hiermee rekening worden gehouden.

Ieder waterbehandelingssysteem moet nauwgezet onderhouden worden in overeenstemming met de instructies van de fabrikant van het systeem. Onderdeel van het onderhoud is de dagelijkse zelfdesinfectie van de endoscopenwasmachine, inclusief de waterbehandelingssystemen en de leidingen die het water naar de wasmachine voeren.

Trefwoorden:
water, waterkwaliteit, endoscopenwasmachine, desinfector, flexibele endoscoop.

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Interviewing them and the documentation they supplied gave us an insight into the design of water treatment systems, and the specifics on maintaining and monitoring the performance of these systems.

Acronyms

AAMI	Association for the Advancement of Medical Instrumentation
CFU	Colony Forming Unit
DoH	Department of Health (United Kingdom)
EWD	Endoscope Washer Disinfector
FDA	Food and Drug Administration
EU	Endotoxines Unit
ERCP	Endoscopic Retrograde Cholangio Pancreatography
IGZ	The Netherlands Health Care Inspectorate
MAUDE	Manufacturer and User Facility Device Experience Database
NTM	Non-tuberculous mycobacteria
RIVM	Dutch National Institute for Public Health and the Environment
UF	Ultra Filtration
WIP	Dutch Working Group for Infection Prevention

1 Introduction

1.1 Background

The RIVM survey into the quality of the cleaning and disinfection of flexible endoscopes (RIVM 2008) indicated that the quality control of the water used in automated endoscope reprocessors (EWDs) leaves room for improvement and may, in a number of hospitals, actually be insufficient to prevent problems with bacterial contamination. The data from the survey indicated that:

- About half of the hospitals that stated to periodically validate the EWDs, included testing of the water quality in the validation program.
- Less then 5% of the hospitals routinely monitored the quality of the water used in the EWD.
- Only one of the six EWD suppliers that were active on the Dutch market at the time of the study gave the recommendation to periodically monitor the microbial quality of the final rinse water.

The fact that relative little effort is put in the validation and routine monitoring of the quality of the water used in EWDs may indicate that the quality of the water is not of particular importance or that the importance is not realized by the users of the EWDs.

In the period from 2004 to 2008, the Netherlands Health Care Inspectorate (IGZ) received three adverse event notifications concerning water quality. In two instances the problems involved water filters. Since the results of the RIVM study show that routine monitoring is hardly performed, it is unclear whether the low number of reported incidents is the result of not discovering problems or that there are in fact few problems.

1.2 Goal of the study

IGZ requested RIVM to perform a study into the different aspects of the quality control of water used in EWDs to establish the potential influence of water quality on the safety of reprocessed flexible endoscopes. The study should answer the following questions regarding the quality of the water that is used in EWDs, especially the final rinse water that is used to remove residues of the chemical disinfectant as the final stage of the reprocessing cycle.

- What problems are identified as a result of the use of water of insufficient quality in an EWD?
- What are the requirements for the quality of the final rinse water in EWDs and is this required quality related to the medical procedure in which the endoscope is to be used (ERCP, bronchoscopy, colonoscopy)?
- What are the requirements for potable water (in the Netherlands) and is the quality of potable water sufficient for this water to be used as final rinse water in EWDs?
- What are the options to treat potable water to improve the quality to the required level and what are the advantages and disadvantages of these treatment methods?
- Should water treatment equipment be included the self-disinfection cycle of the EWD?
- Does literature provide pragmatic and validated procedures to monitor the water quality?
- Does literature provide a procedure to take the appropriate measures, when the water quality does not meet the requirements?

The answers to the questions shall include recommendations that may help the users of EWDs to establish the specifications for the water, the water treatment systems and routine monitoring of the water quality.

2 Methods

2.1 Literature

The literature database Scopus was searched using (combinations of) the following terms: endoscope washer, biofilm, flexible endoscope, water, tap water, water filter, self-disinfection, outbreak, rinse water and water disinfection. The abstracts of the publications as provided by Scopus were screened for the relevance for this study.

2.2 Standards and guidelines

The following standards and guidelines were consulted:
- Health Technical Memorandum 01-01: Decontamination of reusable medical devices Part D – Washer-disinfectors and ultrasonic cleaners (DoH 2009)
- International standard for endoscope washer disinfectors (ISO15883-4 2008)
- Hygienic requirements for the reprocessing of flexible endoscopes and endoscopic accessories (translated; original paper in German) (RKI 2002)
- Dutch guideline on Infection prevention for Hemodialysis, Dutch Working Group for Infection Prevention (translated; original paper in Dutch) (WIP 1997)
- European Pharmacopeia (EP 2009)

2.3 Suppliers

Suppliers of EWDs, water treatment equipment and filtration equipment were contacted to discuss whether problems with water filters (contaminated final rinse water) are inherent to the technology of water filtration or that the problems arise from sub optimal application of the filtration technology.

3 Results

3.1 Introduction

A continuous supply of water of the specified chemical and microbial quality is essential for the correct functioning of the EWD in the different stages of the reprocessing cycle. Water which is too hard or has too high a concentration of dissolved solids can impair the activity of detergents (or require the use of increased quantities) and can cause deposits, scaling or corrosion of items being processed. Water containing high numbers of micro organisms may recontaminate disinfected items. The required water quality may vary for each stage of the reprocessing cycle. (DoH 2009)

Typically the reprocessing cycle in an EWD includes the following stages:
- *Leak testing* of the endoscope; to ensure that the endoscope is sealed, preventing ingress of fluids and subsequent contamination and damage of the interior of the endoscope.
- *Cleaning*; to remove blood, mucus and other patient's material from the endoscope channels and the exterior of the endoscope, using a detergent.
- *Disinfecting*; to kill the pathogenic micro-organisms that remain in the channels and on the exterior of the endoscope, using a chemical disinfectant.
- *Final rinsing*; to remove toxic residues of the disinfectant from the channels and the exterior of the endoscope, using so called 'bacteria free' or 'sterile' water to prevent recontamination of the disinfected endoscope.
- *Purging the rinse water*; from the endoscope channels; to prevent spillage of water when the endoscope is removed from the EWD and to facilitate drying of the endoscope, by blowing filtered air through the channels.

A final step for the reprocessing of flexible endoscopes, when it is not immediately used after reprocessing, is drying and storage, preferably under optimised conditions in a drying cabinet. Additionally EWDs should be equipped with a self-disinfection cycle that is designed to disinfect the fluid pathways in the EWD including those parts that during normal use do not come into contact with the disinfectant. (ISO15883-4 2008)

The information in this report is divided into six sections:
- Requirements for the quality of the water used in EWDs
- Potable water from the public drinking water supply
- Water treatment
- Self-disinfection of the EWD and water treatment system
- Monitoring of the water quality
- Endoscope drying

Each section describes the keys issues on the subject. For a number of subjects detailed information is given in the annexes which present summaries from the publications that were consulted for this report. These summaries are taken from the original papers and represent the findings and opinions of the authors of the publications. They are intended for the interested reader who wishes to learn more about the particular subject.
A full reference list in given in clause 5 (References), including bibliographic details, which will enable the reader to obtain a copy of the original publication.

3.2 Requirements for the quality of the water used in EWDs

This report deals with two aspects of water quality; chemical and microbial. Both aspects need to be specified, controlled and monitored. Looking at the incident reports over the years, a number of problems with EWDs have a microbial root cause. Therefore, this report deals with both quality aspects, but focuses on the microbial quality and related issues.

3.2.1 Chemical quality

Depending on the quality of the materials of the EWD that come into contact with the water during any stage of the reprocessing cycle, the quality of the materials of the endoscope that is processed and the requirements for the detergent and disinfectant, the respective manufacturers may each specify maximum values for the determinants. Typical determinants and suggested maximum values are given in table 1. The requirements set by the respective manufactures may deviate from these.
The user of the EWD shall verify that all requirements are met. Where EWDs are not fitted with integral water treatment systems, the user of the EWD shall follow the requirements given by the manufacturers of the EWD, the endoscope and the process chemicals. Where the EWD is provided with an integral water treatment system, the user shall verify that the water quality produced by the system is compatible with the endoscope and the process chemicals.

3.2.1.1 Hardness

Water hardness is caused by the presence of dissolved salts of calcium, magnesium and strontium. When the water is heated or evaporates the salts come out of solution and deposit as hard mineral layers (lime scale). The deposition of lime scale within pipes and/or around the edges of spray nozzles can impair the performance of the EWD. Moreover, the presence of hardness in water seriously impairs the efficiency of most detergents and disinfectants.
Using hard water in the thermal self-disinfection of the EWD and in the final rinse stages of the reprocessing cycle is one of the major causes of white powdery deposits on endoscopes and on the surfaces of the EWD washing chamber. These are not only unattractive and unwelcome but also attract soiling, which may cause possible recontamination of the processed endoscopes. Such deposits can seriously impair the utility of the optical system of the flexible endoscope.
(DoH 2009)

3.2.1.2 Ionic contaminants

Ionic contaminants may consist of e.g. heavy metals, halides, phosphates and silicates. To avoid the risk of corrosion, water used in the cleaning should have a chloride concentration less than 120 mg/l and, when used for disinfection and final rinse, less than 10 mg/l. Moreover, chloride concentrations higher than 240 mg/l can cause pitting on bare metal parts of the endoscopes. Tarnishing of stainless steel parts, shown by blue, brown or iridescent surface coloration, occurs when heavy metal ions, such as iron, manganese or copper, are present. (DoH 2009)

3.2.1.3 Bacterial endotoxins

Bacterial endotoxins are thermostable compounds derived from the cell walls of bacteria. When introduced into the human body, endotoxins can cause a fever-like reaction and other adverse effects. They are not inactivated at the temperatures used for disinfection.
There is no general agreement on the need for endotoxin free rinse water. Some doubt the necessity (Humphreys and Lee 1999; Richards, Spencer et al. 2002), while others give the clear recommendation that water used for the final rinsing in an EWD, where there is a significant risk of residual water remaining in or on the reprocessed endoscopes, should not contain more than 0.25 EU/ml when the endoscopes are used surgically invasive. (DoH 2009)

Although from the reference documents it does not become clear whether ERCP or taking a tissue sample through the endoscope qualifies as 'surgically invasive', the presence of bacterial endotoxins does not seem to be of major concern. In case of doubt, the user of the EWD should verify with the medical staff whether there is a need for control of the endotoxin level on the processed endoscopes.

3.2.2 Microbial quality

The literature search performed indicated that there are extensive amounts of literature available on the microbial quality of the water used in EWDs and the associated problems. The text provided in the clauses below gives a summary of that information. More elaborate information from the individual sources is given in the annexes, where also the references are given.

3.2.2.1 Contaminated final rinse water

Three types of problems may arise when the final rinse water is contaminated with micro-organisms:

1. The endoscope gets contaminated with the bacteria that were present in the rinse water, leading to infection of the next patient or even an outbreak in the patient population.
2. Tissue samples taken through a contaminated biopsy channel of the endoscope may lead to faults in the diagnosis.
3. A biofilm is formed in the fluid pathways and the washing chamber of the EWD.

3.2.2.2 Infections and diagnostic confusion

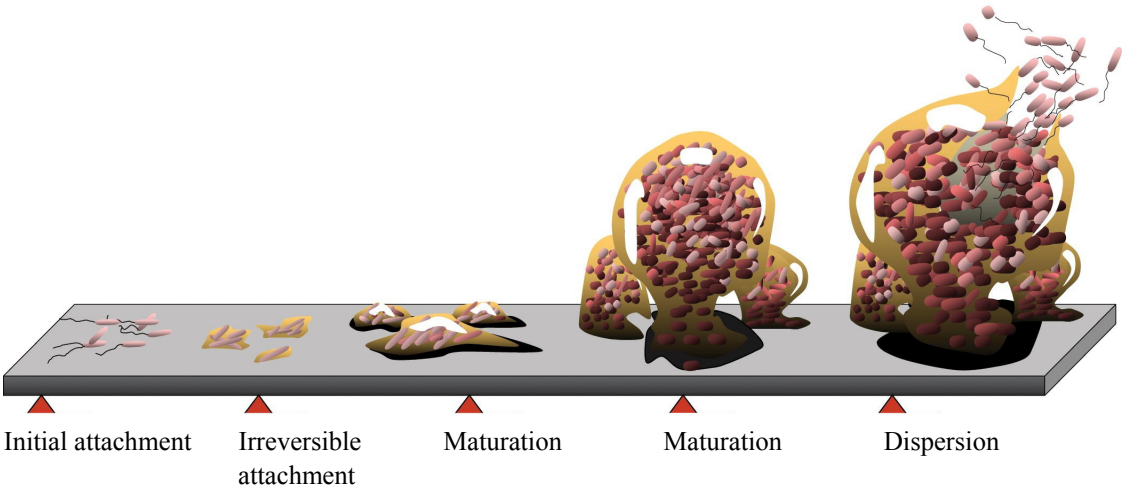
Endoscopy related outbreaks are described from the year 1974 onwards. In the early years outbreaks were related to inappropriate cleaning and disinfection procedures, like omitting to disinfect the air and water channel of endoscopes. With the introduction of EWDs, it still occurred that channels were not flushed, simply because the design of the EWD did not provide connectors for all channels e.g. the forceps raiser channel in ERCP endoscopes.
Over the years it became apparent that environmental bacteria in the final rinse water may re-contaminate the disinfected endoscope and may lead to (pseudo-) infections and even patient deaths. Numerous reports have been published about incidents involving *Pseudomonas aeruginosa*, *Escherichia coli, Mycobacterium chelonae* and *Legionella pneumophila*. These are all bacteria species that proliferate in water systems feeding the EWD. Pseudomonas bacteremia is clearly linked to ERCP, especially in combination with malignant biliary obstruction as co morbidity. Bronchoscopes that are contaminated with environmental mycobacteria (e.g. *Mycobacterium chelonae*) caused (pseudo-) infections and contamination of clinical specimens, leading to unnecessary treatment and delayed diagnosis.

Summaries of the literature on outbreaks and diagnostic confusion are given in annex 1.

3.2.2.3 Formation of biofilms

Due to design restrictions of the EWD, not all internal surfaces are adequately disinfected during normal operation. Bacteria that remain in the EWD can proliferate and start to form a biofilm after a few hours. Biofilms, once formed, are hard to control. As illustrated by figure 1, the structure of the biofilm effectively shields the embedded bacteria and fungi from the presence of a disinfectant. The embedded bacteria are deprived of nutrition, slowing down their metabolism and increasing the resistance against disinfectants. Mature biofilms release bacteria, which not only sustain the contamination in the EWD, but also re-contaminate the final rinse water that circulates in the EWD. Literature describes several cases where this led to (pseudo)infection of patients with *P. aeruginosa* and *M. chelonea* or contamination of diagnostic samples. In this respect, biofilms close the circle. Even when the initial source of contamination has been irradicated, remaining biofilms can continue to recontaminate the EWD. The choice of an effective cleaning agent (or a

specifically designed combination of agents), regular (daily) self-disinfection of the EWD, maintenance and disinfection of the water treatment system, the use of soft water and the selection of biofilm antagonistic materials for the fluid pathways can help to control or even prevent the formation of biofilms.



Summaries of the literature on biofilms are given in annex 2.

Fig. 1 Five stages of biofilm development (Monroe 2007)

3.2.3 Requirements for the microbial quality

Post disinfection rinsing of flexible endoscopes is a necessary procedure to remove residues of the disinfectant, to prevent that the patient or staff is injured by disinfectant residues. The general view is that the water should be of a quality that is not increasing the bioburden of the endoscopes and that it shall not present a hazard to the patient, either through infection or by leading to erroneous diagnosis. Practically, this means that the final rinse water should be bacteria free. Some question the necessity for a bacteria free endoscope for investigations in the gastrointestinal tract. However, many endoscopy departments carry out a variety of procedures. The endoscopes used for different procedures may be processed through the same washer disinfectors, making it impractical and unsafe to maintain specifications for the final rinse water that vary with the application of the endoscope. Moreover, microbial contamination of the final rinse water may also lead to the formation of biofilm in the EWD, being the source of persistent contamination of the EWD and the endoscopes processed in it.

The requirements from the international standard on endoscope washer disinfectors (ISO15883-4 2008) are in line with the general view as presented in literature and could be considered to be the baseline requirements for the microbial quality of the final rinse water:
The final rinse water shall meet the following requirements for microbiological quality:

1. There are fewer than 10 cfu per 100 ml sample of final rinse water;
2. The water is free from *Legionellae spp.*, *Pseudomonas aeruginosa* and mycobacteria.

The standard also gives requirements on how to produce this quality of water; the rinse water will be:

1. Maintained in a dedicated reservoir at a temperature not less than 65 °C for the time demonstrated to achieve disinfection of the incoming supply or,
2. Disinfected immediately prior to use or,
3. Filtered to remove suspended particles of a size greater than 0,2 µm or,

4. Sterile, in a closed container, with a connection to the WD designed and constructed to provide aseptic transfer.

Detailed information from literature on the microbial quality of the final rinse water is given in annex 3.

3.3 Potable water from the public drinking water supply

3.3.1 Chemical quality

Table 1 shows the maximum permitted values for ionic contamination and some other determinants for water intended for human consumption supplied from a distribution network, according to Dutch decree on Drinking water quality (Waterleidingwet 1960) as compared with the maximum permitted values for final rinse water used in EWDs (DoH 2009).
The data in table 1 indicate that untreated tap water may not be suitable as the final rinse water used in EWDs because the maximum permitted values for conductivity (ionic contaminants), total hardness and chloride are much higher than is permitted for final rinse water. Other determinants such as phosphate, silicate and bacterial endotoxins are not controlled during the production of drinking water and as a consequence may vary unpredictably over time.

Determinant and unit	*Maximum permitted values*		
	Drinking water (indicator values for production control)	*Final rinse water in EWDs*	*Other reprocessing steps in EWDs*
Appearance	Clear, colourless	Clear, colourless	–
Degree of acidity (pH)	7.0 to 9.5	5.5 to 8.0	–
Conductivity at 20°C (uS/cm)	1250	30	–
Total dissolved solids (mg/100ml)	-	4	–
Total hardness, $CaCO_3$ (mg/l)	100 - 250	50	50
Chloride, Cl (mg/l)	150	10	120
Heavy metals, determined as Lead, Pb (mg/l)	0.10	10	–
Iron, Fe (mg/l)	0.2	2	–
Phosphate, P_2O_5 (mg/l)	-	0.2	–
Silicate, SiO_2 (mg/l)	-	0.2	2
Bacterial endotoxins (EU/ml)	-	0.25	–

Table 1 Chemical quality indicators for water intended for human consumption (Waterleidingwet 1960) and the maximum permitted values for determinants of the water used in EWDs (DoH 2009).

3.3.2 Microbial quality

The Dutch decree on Drinking water quality requires that micro-organisms should not occur in drinking water in a concentration that could jeopardise public health; see table 2.
For certain micro-organisms, such as viruses and protozoa (including *Cryptosporidium* and *Giardia*), it is not possible to measure the concentration at the very low levels at which exposure is relevant to the health of the user. Based on the number of these micro-organisms in the raw water supply and the efficacy of the different purification steps, a quantitative risk assessment shall be done by the producer. Drinking water is not routinely tested for mycobacteria and pseudomonas. (Waterleidingwet 1960)

Potable water from the public supply has a low microbial content and should be free from pathogenic organisms, other than those which might cause opportunistic infections in immunologically compromised patients. If stored in tanks or cisterns, the microbial content can increase considerably. Attention is drawn to the requirement under the code of practice for control of legionella that water in intercepting tanks must be stored below 20°C or above 55°C. Water stored at 60°C or above may be assumed not to have a proliferating microbial population. (DoH 2009)
In practice one may find that hot water has a higher colonization rate than cold water. This is a result of decreasing hot water temperatures from 70°C to 55°C or lower as a measure against the risk of sustaining burns and increasing energy costs. *M. avium* and *M. xenopi* are isolated more frequently from hospital hot water sources, which reflect the optimal growth temperature of these organisms, whereas *M. kansasii* is isolated more frequently from cold water sources. (Phillips and Von Reyn 2001)

Parameter	*Parametric value (number/100 ml)*
Escherichia coli	0
Enterococci	0
Cryptosporidium	Risk assessment
(Entero)virussen	Risk assessment
Giardia	Risk assessment
Aeromonas	1000
Clostridium perfringens (including spores)	0 This parameter need not be measured unless the water originates from or is influenced by surface water.
Coliform bacteria	0
Total CFU at 22 °C	10000 Geometric annual average, No abnormal change
Legionella spp	10

Table 2 Microbiological quality standards for water intended for human consumption supplied from a distribution network according to Dutch decree on Drinking water quality (Waterleidingwet 1960)

The data in table 2 indicate that untreated tap water is not necessarily suitable as final rinse water to be used in EWDs, because the maximum permitted colony count is higher than the requirement for the final rinse water in EWDs. It may contain microbes including *Pseudomonas spp.*, *Legionalla spp*. and mycobacteria, which have been connected to outbreaks of (pseudo)infections and diagnostic confusion. Furthermore, it is undesirable that waterborne bacteria are allowed in the EWD, especially for the final rinse of the endoscope because they are likely to proliferate in the water that remains in the EWD and form biofilms which create additional problems and create associated problems. See also clause 3.2.2.

3.4 Water treatment

In order to achieve the required water quality the following general provisions shall be met:
1. The water softener shall be run to a minimum volume of out-flow to prevent stagnant water in the system. This volume should be specified by the manufacturer of the water treatment plant. The output from the water treatment system could be to a water tank and the volume demanded each time additional water is fed to the tank should exceed the minimum flow (DoH 2009) or;
   a constant flow of water through the water treatment system should be maintained by recirculation. (Jong 1994)
2. The water treatment system shall be maintained, disinfected or replaced per instruction of the manufacturer of the system. (WIP 1997)

3. Where the water treatment system is a part of the EWD, the manufacturer shall provide guidance on the frequency of the disinfection of the water treatment equipment (ISO15883-4 2008)

3.4.1 Water treatment; chemical

Three methods of water treatment are commonly used for water supply in EWDs (DoH 2009):
1. Water softeners;
2. Water de-ionizers;
3. Reverse osmosis (RO).

The water treatment systems have their limitations. The water that is provided by each system can not be used for every application. Table 3 gives the suitable applications of the water provided by a certain water treatment system.

Type of water	*Possible application the EWD*
Potable	Flushing/washing
Soft potable Hardness < 50 mg/l $CaCO_3$	Cleaning with detergent or enzymatic cleaners
De-ionized	Rinsing after cleaning
Reverse osmosis (RO)	Diluent for chemical disinfection Thermal selfdisinfection
RO or soft potable water, which is filtered, recirculated, heated and/or UV-disinfected	Post-disinfection rinsing (final rinsing)
Sterile purified water	Post-disinfection rinsing (final rinsing)
Note: This table shows suitable applications for the various qualities of water commonly available. Although water of lower quality may be used, this will normally require additional chemical additives and may cause some impairment of the WD performance. Although higher quality of water will be more expensive to produce, it is not practical to use a range of water qualities. Therefore, one or possibly two types of water quality will be used.	

Table 3 Possible applications of the water provided by a variety of water treatment systems (DoH 2009)

3.4.1.1 Water softeners

Water softeners, or base-exchange softeners, consist of an ion-exchange column containing a strong cation resin in the form of sodium hydroxide. Calcium and magnesium ions in the water are replaced by sodium ions. The column may be regenerated by treatment with a solution of common salt (sodium chloride). The concentration of dissolved solids in the water is not reduced by this process. The remaining sodium salts do not, like calcium salts, form hard deposits to foul heat exchangers or spray nozzles. But if used as the final rinse they will leave white deposits on the load items as they dry. The process is simple to operate with an automated in-line system, it will handle water with varying levels of hardness, and is simple and safe to regenerate. The down sides are that after regeneration high levels of chloride ions might be present in the initial output from the softener, which should be run to waste. Base-exchange softeners can cause a significant increase in the microbial content of the water, which should be taken into account when establishing the operational parameters of the microbial water treatment systems. (DoH 2009)

3.4.1.2 De-ionizers

De-ionization or demineralization systems can remove virtually all the dissolved ionic material by ion-exchange using a combination of cation and anion exchange resins. These can be combined in a single column (mixed bed) or be operated in separate columns. Anions are replaced with hydroxyl-ions (OH^-) and cations are replaced with hydronium-ions (H_3O^+), which instantly

combine to form water. Regeneration requires the use of strong acid (hydrochloric acid) and strong alkali (sodium hydroxide).
De-ionized water might be heavily contaminated with micro-organisms and will be colonized rapidly because the chloride ions that control microbial growth, naturally present from the source or added to the water as a preservative, have been removed. De-ionized water should not be used for the final rinse of flexible endoscopes without further decontamination by heating, filtration, chemical disinfection etc. (DoH 2009)

The most advanced form of demineralisation is the electrical de-ionizator (EDI). In addition to ion exchange resins, an electric field is generated that produces H_3O^+ and OH^- -ions, which continuously regenerate the ion exchange resin. Splitting of water in these ions generates extreme pH values, which at both limits are bactericidal; ph 2 at one electrode, ph 12 at the other). Water obtained through electro-deionization has a conductivity typically lower than 0.05 µS /cm. (Offerman 2007)

3.4.1.3 Reverse osmosis

Reversed osmosis (RO) treatment plants remove dissolved contaminants from water by passing the water, under pressure, through a semi-permeable membrane. The process will remove organic material, bacterial endotoxins and micro-organisms, as well as dissolved ionic material. When appropriate measures are taken to maintain the microbial quality of the water during storage and distribution, the water is endotoxin-free and has a negligible microbial population. (DoH 2009)
A well maintained RO system and frequent disinfection of the entire flow path produces water with $<10^2$ CFU/ml and <0.25 IU/ml of endotoxin. Adding a step of ultrafiltration can make the water ultrapure ($<10^{-1}$ CFU/ml and <0.03 IU/ml of endotoxin). One additional step of controlled ultra filtration provides sterile and pyrogen-free fluids ($<10^{-6}$ CFU/ml and <0.03 IU/ml of endotoxin). (Ledebo and Nystrand 1999)

Nevertheless, several publications show that the microbial quality of the water from RO equipment may be hard to maintain:

1. The passage of some germs cannot be excluded even when using a system configuration with absolute reliability. In any case, the subsequent distribution system must be, if it is not operated hot, kept free from germs by addition of ozone. (Feigenwinter and Wirz 2000)
2. The reduction or disappearance of available chlorine appears to be associated with microbial contamination of UF water, RO water and distilled water. (Oie, Oomaki et al. 1998)
3. Microbiological tests on reverse osmosis water revealed a bacteriological contamination level exceeding the accepted limits for potable water. This contamination persisted despite repeated disinfection of the network with peracetic acid. (Netzer, Combeau et al. 2008)

A possible explanation may be that the contamination found in RO water sheds from the biofilm that is inevitably growing on the RO membrane and continuously contaminates the purified water. Disinfection of the RO membrane itself is problematic as it can usually only be done by chemical means. Biofilm is better removed by a high concentration of disinfectant during a short contact time. RO membranes are usually not resistant to high concentrations and therefore only low levels of disinfectant and consequent long contact times of several hours are needed. When these long contact times are not respected, the biofilm may not be entirely destroyed, leaving the contamination effectively in place. (Offerman 2007)
As with other water treatment systems the users of reverse osmosis water treatment systems should be aware of the increase of the bioburden in the water as a result of the water treatment. The possible increase of the bioburden should be taken into account when establishing the operational parameters of the microbial water treatment systems.

3.4.2 Water treatment; microbial

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. For this method, 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, either as a single system or in combination. These include:

- Ultraviolet (UV) light,
- Adding a bactericidal agent (e.g. peracetic acid, ozone and active chlorine generated from sodium chloride through electrolyses),
- Raising the temperature above 60°C.

Whilst filtration aims to remove micro-organisms and other debris, the other systems do not remove inactivated organisms which may cause false-positive test results, such as in Ziehl-Neelsen or acid-alcohol fast bacilli stains of sputum samples.

Filtration excepted, which aims at removal of all micro-organisms, water treatment systems give a reduction of the number of micro-organisms rather than total removal. As a consequence, the end result will depend on the initial contamination of the water before it enters the water treatment system. Water provided by water softeners, de-ionizers and RO equipment is likely to be contaminated with bacteria, even at higher levels than found in potable water from the public drinking water supply. Especially after a period of rest, e.g. after the weekend, the contamination of the water that was left to rest in a water softener, de-mineralisation plant or RO-equipment may be heavily contaminated. Under those circumstances, the efficacy of the following microbial treatment method may be insufficient to render the water free of micro-organisms. As a consequence the out flowing water lines will be contaminated and a biofilm is likely to grow. Once a biofilm has developed in the water line between the microbial water treatment unit and the washing chamber, this biofilm may become a continuous and difficult to eradicate source of contamination.

Water filters, although considered an absolute way of removing microbes, may not always be effective. Essential is the choice of filters, filter housings, correct installation of the filters and a continuous flow through the filter so that the filter is not left in static water. The filters, filter housings and associated pipe work should be maintained in accordance with the instructions of the manufacturer. This may include periodic disinfection of the water filters and the associated pipework. Ideally, the filters and the pipework are included in the self-disinfection cycle of the EWD. Sterilisation of water filters as a means to prevent growth through the filtration material should be followed by an integrity test, e.g. bubble point test, pressure hold test, forward flow test. Before the integrity test is performed, the filter material shall be thoroughly wetted. This may take a long time when the filter material is dried out during the sterilisation process. The instructions of the manufacturer of the filter should be followed meticulously or the results of the integrity test may not be valid.

For more detailed information on microbial water treatment see the literature summary in annex 4.

3.4.3 Problems with microbial water treatment systems

Despite the use of microbial water treatment systems that should render the final rinse water free from viable micro-organisms, numerous publications are available describing incidents where the water was found to be contaminated. Design failures like positioning the bacterial filter before the ion exchanger instead of down flow and the use of microbial objectionable tubing material to transport the water were observed in the early years of EWD utilization. Another error is the use of an unsuitable micro-organism to test the filter efficacy. The size of the test organism might not be representative for the types or condition of the micro-organisms in practice. Nutrition deprived conditions make micro-organisms much smaller than the laboratory cultivated test species. The

susceptibility of the microbial species for the chemical disinfectant used for the decontamination of the water treatment system should also be considered. The well nourished conditions of the micro-organisms that are used for disinfectant testing, may not be representative for the nutrient deprived conditions in real life. Besides bacteria, also fungi can be a problem. This should be considered when choosing the microbial water treatment system.

Some authors indicate that filtration should not be the only measure to control the microbial load of the rinse water, but should be followed by storage at elevated temperature, or under ozone (both may prove to be impracticable for use in EWDs), or irradiation with UV-light. Stagnant water in any part of the water treatment system must be avoided at all times, by the use of circulation pumps. Omitting the periodic disinfection procedure of the filters and associated pipe work may lead to an initial small contamination of the system that after time may prove impossible to eradicate because it has developed into a biofilm. Once the contamination has advanced beyond the filters into the pipework, exchange of the filters is no longer an effective measure. Therefore, prevention of contamination through effective maintenance is of utmost importance.

The maintenance procedures of the water treatment system prescribed by the manufacturer of that system should be followed precisely. Monitoring the differential pressure over the filter alone is not a proven method to show that the filter continues to be effective. Microbiological monitoring of the filtered water remains a more accurate and reliable method for establishing the end of life of the filter.

More detailed information on problems with microbial water treatment in given the literature summary in annex 5.

3.5 Self-disinfection of the EWD and water treatment system

During use the EWD may become contaminated with micro-organisms that survive the normal disinfection procedure. Design restrictions preclude that all of the fluid pathways are effectively disinfected during the normal cycle; e.g. the piping between water treatment system and the wash chamber, dead volumes in pipes (those parts that are not purged by the usual flow of liquids during the operation cycle). During periods of rest, biofilms are easily formed in these parts. Contamination may come from debris from the endoscope, from the handling during maintenance or repairs where parts of the machine and pipe work have been dismantled, failing water treatment system, or from contaminated cleaner or disinfectant. Prolonged and not-validated reuse of disinfectant solution where the concentration dropped below the minimum effective concentration, has been proven as the cause of mycobacteria proliferation in EWDs. This was the main reason that the reuse of the disinfectant was abandoned in the Netherlands.
Although there is no agreement on the exact frequency for performing self-disinfection, the general view is that it should be done very frequently, e.g. daily. The water treatment system and all associated pipe work should be included in the self-disinfection cycle. When using a chemical disinfectant it should be chosen with caution. The user must verify that it is effective against all types of micro-organisms that may be present in the EWD and water treatment system, taking into account the nutrient deprived conditions in the EWD and the consequent increased resistance against disinfectants.

Summaries from literature on EWD self-disinfection and the disinfection of water treatment systems are given in annex 6.

3.6 Monitoring

3.6.1 Chemical quality; final rinse water

The methods of analysis recommended to detect chemical contaminants at low concentrations with a high level of accuracy, require the use of a laboratory with appropriate expertise, facilities and experience. Some tests can be carried out on-site, using simple hand held test equipment. These may lack the precision and sensitivity of the laboratory tests. However, they are useful, in providing evidence of any gross failure and the results are available immediately, making them of diagnostic value during a fault finding exercise. Recourse to more precise analysis might be needed in the event of a dispute between two parties. Before adopting any test method, care should be taken to ensure that the test provides the required accuracy and sensitivity. When using the equipment, the users' instructions as provided by the manufacturer of the equipment should be followed meticulously. (DoH 2009)

Tests suitable for use on-site fall into three main categories:
1. Instrumental tests using portable instruments designed for on-site use, for example portable pH meters, ion selective electrodes, etc.;
2. Spectrophotometric tests based on measurement of the absorbance of a coloured reaction product; measurement can be visual or photometric and can be against a precalibrated coloured disc or against standard reference solutions;
3. Titrimetric tests that may be carried out using standard laboratory equipment or with commercially available apparatus designed for field use; the latter is usually much simpler to use.

Laboratory tests for the determinants in table 1 are specified in the Health Technical Memorandum 2030, Washer-disinfectors, validation and verification. (DoH 2009)

3.6.2 Microbial status; final rinse water

As indicated in the previous paragraphs, the quality of the final rinse water is important to prevent microbial contamination of the processed endoscopes and subsequent infection of patients. Periodic monitoring of the quality of the final rinse water is therefore justified.

The frequency, at which the microbial test on the final rinse water must be performed, could be established by starting with weekly testing. If the tests show consistent acceptable results after a period of weekly testing, one could convert to monthly testing and after a year of finding consistent test results, quarterly testing. The microbial status of the final rinse water should also be tested after repairs and/or maintenance of the water treatment system and associated pipework. Routine monitoring of the quality of the rinse water implies that the user of the EWD must have an action plan in case the number or type of micro-organisms found in the final rinse water exceeds the requirements. A "go/no-go system" in which the EWD is taken out of use whenever the number or type of micro-organisms in the final rinse water are found to be outside the specifications, may be clear and simple, but unnecessary strict. In many cases low numbers of bacteria in the final rinse water are undesirable, but not necessarily a cause for immediate alarm. Therefore an action plan could consist of a series of action levels of increased severity, ranging from 'no action', through 'investigation of potential problems' to the ultimate step of 'taking the EWD out of use until the problems are solved'.

For all tests, the water should be sampled from the washing chamber of the EWD at the end of a standard cycle. Samples may need to be taken from additional points in the supply when trying to identify the cause of a non-conformity. For the purpose of trouble shooting it may be helpful also

to determine the types of micro-organisms in the drinking water supply that is feeding the water treatment system. If the micro-organisms that are found in the final rinse water are identical to those in the drinking water supply, the cause of the contamination of the final rinse water may be found in the water treatment system.

The culturing method that is employed (type of culture medium, incubation time and temperature) must be suited for the type of micro-organisms that may be present in the water.
The culture media and incubation times should be matched to the micro-organisms whose presence must be detected in the rinse water, eg mycobacteria, legionella and fungi.

Further considerations for the development of a test regime are given in annex 7. Annex 9 presents further suggestions on actions to be taken when the final rinse water is microbial contaminated. Procedures to test the microbial quality of water are given in annex 10.

3.6.3 Microbial status; EWD after self-disinfection

The efficacy of the self-disinfection shall be verified by routine monitoring of:
- The temperature in parts of the pipework of the EWD and the water treatment system, when the self-disinfection is done with moist heat (hot water) and the time during which the surfaces are in contact with the moist heat.
- The concentration of the chemical disinfectant that is used to perform the self-disinfection, the contact time and the temperature during the self-disinfection.
- The absence of micro-organisms in the final rinse water taken from the EWD at the end of a normal operation cycle.
- The absence of biofilms in the pipework of EWD by taking swabs from positions where biofilms are likely to develop, e.g. positions in the washing chamber or pipework where water collects that is not drained, and those parts of the pipework that are not disinfected during the normal operating cycle.

(ISO15883-4)

3.6.4 Microbial status; processed endoscopes

The value of the testing of absence of micro-organisms in and on flexible endoscopes is a subject of debate. Proof that regular microbial monitoring of processed endoscopes reduces the risk for patients is lacking.
On the other hand, cases have been reported in which damage to the internal channels of the endoscope was discovered by flushing the channels and culturing the rinse fluid. If micro-organisms are recovered, the type of organisms can indicate the cause of the problem. If patient's micro-organisms are found in or on the endoscope this may indicate shortcomings in the reprocessing procedure, whereas waterborne bacteria may indicate problems with the water treatment.

Microbiological monitoring of endoscopes is warranted where clinical or epidemiologic data suggest endoscopy related transmission of infection. Anyhow, the sampling of the endoscope should not be limited to flushing of the channels, but should include swabbing of difficult to reach outer surfaces and brushing or 'sponging' of the biopsy and suction channel. Aseptic techniques shall be used to prevent environmental contamination of the sample. A channel separator shall be positioned in the air/water valve to separate the water and air channel to enable separate sampling of both channels. The full length of the channels shall be flushed from the proximal end (connector) towards the distal end.

Annex 8 provides more information on the views on monitoring the microbial status of the processed endoscopes.

3.7 Endoscope drying

The water that is used to remove the disinfectant that is used during endoscope reprocessing may not be bacteria free so that at the end of the process low levels of bacteria may be present in the endoscope. When the endoscope remains wet after the reprocessing, these bacteria start to grow to numbers that may be harmful to the patient or interfere with diagnostics; see clause 3.2.2.. The danger of biofilm formation is always present.
Endoscopes that are dried and stored in a drying cabinet do not contain sufficient moisture to promote the proliferation of bacteria. Reprocessing of these endoscopes before the next use is not necessary. A processed endoscope that has not been dried may be used within a period of four hours. After this period it shall be reprocessed, before the next use.

In a single publication, the drying of the endoscopes channels after purging the channels with alcohol is suggested as an alternative for using bacteria free final rinse water. This view is not generally shared.

Annex 11 provides additional information on the drying of processed endoscopes.

4 Discussion and conclusions

This report provides a comprehensive review of the potential influence of the quality of the final rinse water used in endoscope washer disinfectors on the safety of reprocessed flexible endoscopes. In a systematic way, it clearly shows why control of the final rinse water quality should be included in validation and routine monitoring of the functioning of the EWD.

4.1 Discussion

In the introduction to this report the goals of the study were presented in a number of questions. The study provides answers to these questions which are discussed below.

What problems are identified as a result of the use of water of insufficient quality in an EWD?
Chemical contaminants like calcium and other minerals that are present in the water may interfere with the detergents and disinfectants used in the processes. When the water is heated and evaporates the dissolved substances may settle on the surfaces of fluid pathways inside the EWD and on the endoscope. In time, these may impair the proper functioning and may act as seeding ground for further build up of contaminants. Therefore the amount of chemical contaminants in the water should be limited for every process step, not only in final rinse water.
Microbial contamination of the final rinse water, i.e. the water that is used to rinse off the disinfectant at the end of the cycle, may leave bacteria, fungi and protozoa on the endoscope and inside the endoscope's channels. These micro-organisms may lead to serious, even lethal infections in patients, diagnostic confusion and consequently unnecessary medical treatment. Fatal incidents involving the use of ERCP endoscopes that proved to be contaminated with *Pseudomonas aeruginosa* are described in literature. Micro-organisms that remain in the EWD may proliferate, cluster and form persistent biofilms. Bacteria that shed from these biofilms contaminate the final rinse water, which may lead to re-contamination of the disinfected endoscope, which may subsequently lead to diagnostic confusion or serious deterioration of the patient's health. The resistance of the micro-organisms that live in the biofilms to the disinfectant that is used in the reprocessing cycle is increased dramatically. Once a biofilm is formed it is difficult to completely remove it, which makes prevention essential.
Considering the widespread use of flexible endoscopes, the number of incidents reported in literature and to the Netherlands Health Care Inspectorate is low. This might indicate that not many problems occur, problems are not discovered or problems are not reported.

What are the requirements for the quality of the final rinse water in EWDs and is this required quality related to the medical procedure in which the endoscope is to be used (ERCP, bronchoscopy, colonoscopy)?
Suggestions for maximum allowable levels of relevant chemical contaminants are given in literature and are copied into this report. The generic terms for water of the correct quality for use in EWDs are demineralised water or reversed osmosis water. The manufacturers of the EWDs, endoscopes and process chemicals may give more specific requirements which should be given in the instructions for use.
The general view is that the final rinse water shall be of a microbial quality that will not increase the bioburden of the disinfected endoscope. In practice this means that the final rinse water shall be sterile or bacteria free. The international standard for endoscope washer disinfectors requires that the overall contamination is less than 10 cfu/100 ml and that the water is free from *Legionella spp*., *Ps. aeruginosa* and mycobacteria. This can be considered a practical value for 'bacteria free water'. Although the requirements could be tailored taking into account the use of the endoscope (ERCP, bronchoscopy, colonoscopy) and focusing on particular groups of micro-organisms that

could pose a problem in a particular application of the endoscope, this is not recommended practice. Many endoscopy departments in hospitals perform a variety of procedures and the endoscopes may be processed through the same washer disinfectors.
There seems to be no consensus on a general requirement for the maximum level of endotoxins in the final rinse water. When there is a considerable risk of water remaining on or in the endoscope after reprocessing and the endoscope is used surgically invasive, the level of endotoxins may be an issue that is to be discussed with the medical staff.

What are the requirements for potable water (in the Netherlands) and is the quality of potable water sufficient for this water to be used as rinse water in EWDs?
The requirements for potable water are given in the Dutch decree on Drinking water quality and aim at providing safe drinking water that will not jeopardize public health. For a number of chemical and microbial contaminants, the acceptable levels exceed the levels required for final rinse water in EWDs. Thus, the quality of untreated tap water is considered insufficient to meet the requirements for final rinse water. Untreated tap water shall not be used as final rinse water.

What are the options to treat potable water to improve the quality to the required level and what are the advantages and disadvantages of these treatment methods?
Three basic techniques are in use to lower the hardness of the water, lower the ionic contamination and remove other dissolved contaminants. Each technique has its advantages and disadvantages, but all may give an increase of the bioburden in the water. This should be taken into account when designing the microbial water treatment system.
The microbial water treatment system shall remove or kill all micro-organisms that are present in the water after the water softener and subsequent demineralisation steps. The design of the microbial water treatment system shall cater for the fact that the water that is fed to the system may be contaminated at a much higher level than potable water, especially when water remains stagnant in the chemical water treatment system for periods of time, e.g. overnight and over the weekend.
A number of options are available to remove microbial contamination from water. A multi-stage water filter is mostly used, aiming at absolute removal of all micro-organisms from the water. A variety of problems are described that are inherent to the improper use of water filters. Ensuring a supply of water of specified quality starts with a proper design of the treatment system. The choice of filter and filter housing and proper installation and maintenance are essential. Water filters are available in a variety of qualities and capacities. Advice shall be sought from the manufacturer/distributor when choosing the filter. The filter chosen shall be capable to render the water free of all relevant micro-organisms. Depending on the quality of the inflowing water it may be necessary to install pre-filters. The filter housing shall match the filter and shall be installed as prescribed by the manufacturer. The design of the filter system shall allow for a continuous flow of water through the filters, to prevent stagnant water in the filters. The recirculating water shall be continuously disinfected, e.g. by UV radiation.
Other water treatment systems such as UV radiation, addition of a disinfectant and thermal treatment, establish a reduction of the number of micro-organisms. Whether or not the treatment is sufficient to render the water free of micro-organisms depends on the efficacy of the treatment and the initial bioburden. At high levels of contamination, the treatment may not be sufficient. When using disinfectants to treat the final rinse water, one must always bear in mind that this disinfectant, albeit in low concentration, will remain on the surfaces of the processed endoscope and in its channels and may come into contact with the patient where it may cause adverse effects.

Should water treatment equipment be included the self-disinfection cycle of the EWD?
All water treatment systems shall be meticulously maintained per instructions of the manufacturer of the water treatment systems. Several occasions have been reported in literature in which the formation of biofilm in the EWD was the source of post disinfection recontamination of flexible

endoscopes. Once a biofilm is formed in any part of the EWD it may be hard to remove. To prevent the formation of a biofilm, the EWD shall be fitted with a self-disinfection cycle that will disinfect all internal pipe work, the washing chamber and the microbial water treatment system. Thermal disinfection is preferred over chemical disinfection. The self-disinfection cycle shall be run after each working day, before the first use after the weekend and after work on the EWD or the microbial water treatment system. In modern EWDs, the self-disinfection process can be programmed to run automatically, which facilitates frequent performance of the self-disinfection cycle.
It is common practice to periodically sterilize the water filters. This procedure will however not eradicate the micro-organisms in the fluid pathways downstream of the water filter and may not be effective in the prevention of the development of biofilms in the EWD, again indicating the need for self-disinfection.

Does literature provide pragmatic and validated procedures to monitor the water quality?
Close monitoring of the efficacy of both the chemical and microbial water treatment systems and the self-disinfection cycle of the EWD is necessary to establish that a continuous supply of water of specified quality is fed to the EWD and that the EWD remains free of biofilms.
Pragmatic test methods for the chemical determinants and the microbial contamination are described in literature. The frequency at which the tests shall be performed shall be established by experience, starting at a high frequency, e.g. once per week. Based on the results the test frequency can be decreased to biweekly, monthly and finally quarterly.

Does literature provide a procedure to take the appropriate measures, when the water quality does not meet the requirements?
A procedure shall be available describing the actions to take when the tests show that the parameters are outside the established specifications. A framework for a stratified action plan is provided in literature in which the actions taken may depend on the extent of the deviation from the specified values and may range from ‘no action’ through ‘investigation of potential problems’ to ‘discontinuation of the EWD’.

4.2 Conclusion

“Water, water everywhere nor any a sterile drop to rinse your endoscope”
From the dramatic title of the paper by Dr. McKay one might expect that it is impossible to obtain an acceptable quality of final rinse water in endoscope reprocessing. Although the requirements for the quality of the water are quite stringent, the literature review learns that the demands are not impossible to meet, maintain or verify, as long as the necessary preconditions for the design, maintenance and monitoring are met. Failing to meet the necessary requirements for the final rinse water may lead to recontaminated endoscopes being used on patients. Subsequent misdiagnosis, unnecessary medical treatment, infections, even lethal infection may subvert the patient’s health. The following recommendations are intended to give guidance to healthcare facilities in design review, maintenance and verification of water treatment systems for endoscope washer disinfectors.

Recommendations:
- The water that is used for the final rinse of disinfected flexible endoscopes shall be free from chemical contaminants in quantities that may deposit on the endoscope or on the internal surfaces of the endoscope washer disinfector.
- When the endoscope is used in surgically invasive procedures additional requirements for the limits of endotoxins may be set by the physician.

- The water shall be free from micro-organisms. The limiting value given in the international standard for endoscope washer disinfectors is 10 cfu/100ml and non detectable numbers of pseudomonas, legionella and mycobacteria.
- The limits for the level of chemical and microbial contaminants in water from the public drinking water supply are higher than those set for the final rinse water in endoscope reprocessing. Untreated drinking water shall not be used for endoscope reprocessing.
- Where water is left stagnant in the chemical water treatment system, the microbial water treatment system must be designed to cope with very high levels of microbial contamination. Nevertheless, stagnant water in the water treatment system should prevented by ensuring a continuous flow of water through the system. Where water is re-circulated, measures shall be taken for inline disinfection of the water.
- To prevent the formation of biofilm, all the fluid pathways in the washer disinfector, including the pipework from the microbial water treatment system and where possible the water treatment system itself shall be disinfected through self-disinfection.
- The self-disinfection cycle shall be run at the end of each working day, before the start of the working day after the weekend or holiday period and after work has been done on the washer disinfector or microbial water treatment system.
- The materials used in the construction shall be suitable for water treatment and shall have surface characteristics that will not aid the attachment and proliferation of micro-organisms.
- The water treatment systems shall be installed to the recommendations of the manufacturer.
- Maintenance shall be performed meticulously. Any replacement parts shall meet the specifications of the original parts, as prescribed by the manufacturer of the system.
- The quality of the final rinse water as it is circulating in the washer disinfector shall be monitored for the level of chemical determinants and the absence of micro-organisms. A test regime shall be established, starting with weekly testing. Based on the test results the test frequency can be reduced step by step to quarterly testing.
- An action plan must be prepared in case the test results show that the specifications of the final rinse water are not met. This could be a stratified plan with different action levels depending on the test results.

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Annex 1 Outbreaks and diagnostic confusion

Note: This summary is intended for the reader who wishes to learn more from the original sources. The summaries are ordered by the year of publication. The summaries are taken from the papers and represent the findings and opinions of the authors of those publications. A full reference list in given under "References" including full bibliographic details, which will enable any library to obtain a copy of the referenced publication.

Several reports identify cross-contamination with environmental mycobacteria via EWD. In a large outbreak, *Mycobacterium chelonae* was isolated from bronchial washings, brushings or sputum in 72 patients. Two patients developed clinical disease and one patient died. (Pappas, Schaaff et al. 1983)

In a 6-week period, three out of 50 patients developed Pseudomonas aeruginosa septicaemia following Endoscopic Retrograde Cholangiopancreatography (ERCP). Pseudomonas aeruginosa serotype 10 was isolated from each of the patients and from the endoscope. The outbreak was related to inadequate disinfection of the air and water channel of the endoscope. Following the introduction of a modified decontamination technique, which involved rinsing the air and water channel with glutaraldehyde, no further cases of pseudomonas infection occurred, and the organism could not be isolated from the instrument. (Cryan, Falkiner et al. 1984)

Siegman described two cases of pseudomonas bacteremia after ERCP endoscopy in 1985, due to a contaminated instrument. The two patients who encountered bacteremia had malignant obstruction, which is recognized as a risk factor for septic complications. The author recommended (1988) a thorough mechanical cleaning, followed by immersion in an effective disinfectant for an adequate period of time. Adequate rinsing with sterile water followed by effective drying was stated to be equally important. In addition, endoscopic equipment should be routinely cultured to assure the efficiency of the method employed. Septicemia from a contaminated endoscope may only be prevented by proper disinfection and meticulous everyday care of the endoscopic apparatus. (Siegman-Igra, Spinrad et al. 1988)

Classen described a situation where seven out of 167 patients developed an infection within five days after ERCP. All the pseudomonas isolates that were available for testing were of the same serotype as the *P. aeruginosa* recovered from the ERCP endoscopes, several other endoscopes and the equipment used to clean endoscopes. Each of the patients in the outbreak received the first scheduled ERCP of that day. The mean duration between the cleaning of the endoscope and its subsequent use was significantly longer in the cases than in matched controls, a factor that may have permitted contaminating organisms to achieve high numbers in the inadequately cleaned endoscope. (Classen, Jacobson et al. 1988)

Devière found that the most commonly isolated bacteria from blood and bile cultures, taken from patients who developed septicemia after ERCP, were *P. aeruginosa* and *E. coli*. *P. aeruginosa* was observed mainly in patients after previous diagnostic ERCP. The contamination was associated with problems in the disinfection of the endoscopes. (Deviere, Motte et al. 1990)

Misdiagnosis of tuberculosis has been reported due to contamination of the instruments with environmental mycobacteria from the rinse water, which subsequently contaminated bronchial washings sent for culture. (Nye, Chadha et al. 1990)

Gubler described a pseudoepidemic due to nontuberculous mycobacteria contaminating the water tank of a machine used to clean and disinfect fiberoptic endoscopes. Forty-six bronchoscopies

performed on 41 patients during a six-month period yielded 16 specimens positive for acid-fast bacilli (AFB). One specimen showed *Mycobacterium avium* complex from an AIDS patient and another, *M. tuberculosis* from a patient with active cavitary tuberculosis. In four patients, only the smears showed AFB; subsequent cultures remained negative. Of the rest, seven contained *M. chelonal* and three *M. gordonae*, all in patients with no clinical signs of mycobacterial disease. Four patients in the beginning of the pseudoepidemic were treated for presumed tuberculosis until negative culture results were available. Control of the 'outbreak' was achieved by regular disinfection of the implicated water tank in the cleaning machine. Contamination of bronchoscopes with nontuberculous mycobacteria could lead to unnecessary diagnostic and therapeutic interventions. (Gubler, Salfinger et al. 1992)

Struelens described the isolation of multiply-resistant *Citrobacter freundii* and *Pseudomonas aeruginosa* in the bile specimens from several patients after endoscopic retrograde cholangiopancreatography (ERCP), two months after modification of the disinfection procedure. Microbiologic sampling of the endoscopes processed in the EWD disclosed heavy contamination in 93 out of 113 instruments. The isolated bacteria (*P. aeruginosa, Enterobacteriacea*, and other gram-negative organisms) paralleled the organisms isolated from the patients with bacteremia. Contamination with *P. aeruginosa* and other non-fermentative bacteria was found in tap water from a sink in the endoscopy suite, in tap water feeding the EWD and in nearly half of the surface and water samples taken from the EWD. These microorganisms were also recovered from scale deposits in the endoscope holding tank, from the water hoses, spigots, and irrigation tubing connected to endoscope channel ports, and from the interior part of the water filter. Filtered water collected during the rinse cycle also showed contamination with these organisms (10^2 to 10^5 CFU/mL). Furthermore, the EWD was not designed to flush the endoscopes' forceps raiser channel, a blind channel that contains the elevator wire. On sampling this channel in three processed instruments, massive (greater than 10^6 CFU/mL) contamination with *P. aeruginosa*, *K. pneumoniae, E. coli, Morganella morganii,* and *C. freundii* was found. (Struelens, Rost et al. 1993)

Contamination of bronchoalveolar lavage specimens by environmental mycobacteria in hospital water supplies may lead to diagnostic confusion, particularly in immunocompromised patients. Mycobacteria from the hospital water supplies may become concentrated in the tubing of bronchoscope disinfecting machines. It is very difficult to eradicate these organisms once contamination of the EWD has occurred. (Brown, Hellyar et al. 1993)

Fifteen patients had positive cultures for *Mycobacterium abscessus* without evidence of infection following endoscopy. Retrospective cohort studies of patients undergoing endoscopy and microbiologic sampling of the environment were performed to examine potential nosocomial transmission and to identify the source and risk factors for *M. abscessus* pseudoinfection. *M. abscessus* was recovered from the EWD holding tanks, the inlet water feeding the EWD, and a flexible bronchoscope. Endoscopes were reprocessed in an EWD, where they were flushed with a detergent, disinfected with 2% glutaaraldehyde, rinsed with tap water, and then flushed with 70% isopropyl alcohol and forced-air dried in the EWD or using pressurized air canisters. Procedure and log book review revealed that the EWD was disinfected every 14 days, even though the manufacturer's manual recommended EWD disinfection every 7 days or 40 cycles, whichever came first. Maloney concluded that users should carefully adhere to the manufacturer's protocol for EWD disinfection and be aware that colonization of the EWD holding tanks, which may not be reversible, despite the use of the manufacturer's recommended disinfection protocol, could occur. Active surveillance should be maintained, and if infection or pseudoinfection are suspected, cultures of tap water, EWD washer tanks, and endoscopes should be obtained to assess possible EWD contamination. In previous outbreaks involving washer contamination, terminal rinsing with alcohol and air drying of endoscopes was initially effective in ending outbreaks. However, in

some instances, active surveillance identified new or recurrent contamination, and use of the EWD was discontinued. (Maloney, Welbel et al. 1994)

During bronchoscopy, the potential exists for contamination of bronchoscopes and microbiological specimens. Patients may also be cross infected with acid fast bacilli (AFB). During a five month period, 12 bronchial wash specimens of 65 patients undergoing bronchoscopy, one bronchoscope and an EWD were contaminated with the AFB, *Mycobacterium chelonae*. To identify the source of contamination, samples for AFB culture were taken from three bronchoscopes, the EWD and water taps. To eradicate *M. chelonae* contamination, the bronchoscopes were soaked in 2% glutaraldehyde overnight and flushed with 70% alcohol. Disinfection procedures were altered by using sterile water in cleaning. The use of the EWD was discontinued. (Campagnaro, Teichtahl et al. 1994)

The association of mycobacterial incidents with the use of automatic washer/disinfectors (17 out of 18 incidents), together with Department of Health warnings of build-up of biofilm within these chemical-process machines was reason to audit local practice for compliance with national guidelines. The use of tap water rather than sterile water for rinsing the disinfected bronchoscope was one of the discrepancies between recommended and local practice. Other shortcomings included the lack of specification of detergent/cleaning agent, inadequate contact time for chemical disinfection and. Other procedural anomalies associated with mycobacterial contamination included failure to adhere to manufacturers' instructions to dismantle valves prior to cleaning and to autoclave valves and accessories. (Uttley 1994)

Mycobacterium xenopi typically accounts for less than 0.3% of all clinical mycobacterial isolates. Over a 37-months period, 21 (35%) of 60 mycobacterial isolates were identified as *M. xenopi*. A study was conducted to elucidate aspects of the bronchoscopy procedure associated with *M. xenopi* isolation. Bronchoscope cleaning procedures were reviewed, and samples from the hospital water systems were cultured. Four isolates were from three patients with disease attributable to *M. xenopi.* Of the other isolates, specimens obtained by bronchoscopy were more likely to yield *M. xenopi* than were specimens obtained by other routes. Bronchoscopes were disinfected in a 0.13% glutaraldehyde-phenate solution and were then rinsed in tap water. Water from the hot water tank supplying this area yielded *M. xenopi*. Mycobacteria were cultured from bronchoscopes after disinfection. *M. xenopi* in the tap water appears to have contaminated the bronchoscopes during cleaning. Adequate disinfection of contaminated bronchoscopes and careful collection of specimens to avoid contamination with contaminated water are essential, both for limiting diagnostic confusion caused by mycobacterial pseudoinfections and for reducing risks of disease transmission. (Bennett, Peterson et al. 1994)

An unusual increase in the frequency of isolation of *Mycobacterium chelonae* from specimens of bronchial washings was found. A total of 123 patients underwent fibreoptic bronchoscopy. Seventy six patients had bronchial washing for bacteriological study and cytological examination. Acid-fast bacilli were found in 21 patients, in 18 of whom *M. chelonae* were isolated from bronchial washing cultures. Eight patients were treated as mycobacterial infected, because of the presence of unexplained pulmonary lesion, positive acid-fast stain and culture for *M. chelonae*. Diagnosis of lung cancer was delayed in one patient because of the initial negative cytological study and positive bacterial culture. (Wang, Liaw et al. 1995)

A contaminated bronchoscope may introduce mycobacteria into specimens causing diagnostic confusion, infect the patient with mycobacteria, or be a vehicle for cross-infection. Bronchoscopes are difficult to disinfect adequately if they are not properly cleaned, which may include stripping down channel valves. Bronchoscope washers have also contributed to the problem when

glutaraldehyde becomes too dilute as a result of non-validated reuse or they become heavily contaminated with environmental mycobacteria. (Reeves and Brown 1995)

The discontinuation of using tapwater in the cleaning process resulted in complete eradication of contamination events, with no further events occurring in the following 12 months. Insertion of bacterial filters into the water supply, with the addition of a more sophisticated semiautomatic cleaning machine involving an ultrasound cycle in addition to conventional cleaning methods currently used, will help reduce or eradicate contamination events with *M. chelonae* in bronchoscopy units (Kiely, Sheehan et al. 1995)

The study of Griffith showed a decrease of susceptibility of the micro-organisms that survive the disinfection stage of the process. Two EWD isolates of *M. chelonae* var. *chelonae* proved very tolerant to 2% glutaraldehyde with little or no loss of viability during an one hour period of exposure to the disinfectant. However, unlike Van Klingeren and Pullen, see annex 2, no cross resistance to peracetic acid was found. This disinfectant, along with higher concentrations of a chlorine releasing agent and 70% alcohol, was very effective in inactivating these organisms, even when dried onto carriers with 10% serum present. (Griffiths, Babb et al. 1997)

An investigation of a pseudoepidemic of *Legionella pneumophila* serogroup 6 contaminating bronchoalveolar lavage specimens, traced the source to contaminated tap water used to rinse disinfected bronchoscopes. The problem recurred despite plumbing changes and the installation of filters in the endoscopy unit water system because of inadequate maintenance of the filters. (Mitchell, Hicks et al. 1997)

Several outbreaks have been described in which non-tuberculous mycobacteria (NTM) in hospital water supplies have resulted in respiratory tract colonization. *M. chelonae* pulmonary infection occurred in 2 patients after the use of a colonized bronchoscope. Endoscopes, especially bronchoscopes, are frequently the cause of pseudo-outbreaks of NTM. Bronchoscope suction valves and channels are difficult to clean and disinfect, and they can become colonized with mycobacteria, which may lead to the transmission of disease to previously uninfected patients. Damage to the suction channel is hard to detect, and it predisposes to NTM colonization and subsequent contamination of specimens. EWDs also result in contaminated sputum specimens, typically by NTM colonization of water-holding tanks or water inlet hoses. Manual washing could decrease the risk of bronchoscope colonization, yet a pseudo-outbreak still occurred after *M. xenopi*–contaminated water was used in the manual disinfection of bronchoscopes in one hospital. Avoiding the use of tap water during endoscope cleaning helped to resolve a bronchoscope-associated *M. chelonae* pseudo-outbreak. Contamination of clinical specimens by NTM had resulted in unnecessary therapy directed against *M. tuberculosis* and delayed diagnosis of malignancy. (Phillips and Von Reyn 2001)

A literature review identified several reports of problems with contaminated rinse water. Incidents reported included pseudo-outbreaks of infection with *Mycobacteria* spp., *Pseudomonas* spp. and *Staphylococcus epidermidis*. Although a few incidents were associated with inadequate cleaning, most problems arose from contaminated rinse water or failure to disinfect the EWD. Choice of disinfectant and contact time appears less problematic except for the selfdisinfection of the EWD, where doubt arises about the efficacy against fungi. (Richards, Spencer et al. 2002)

On the basis of a thorough review of the FDA's databases and the hemodialyzer and endoscope reprocessing literature, as well as several other sources, Muscarella concludes that routinely sampling of the rinse water used during endoscope reprocessing is important to reduce the risk of patient infection from waterborne, gram-negative bacteria following endoscopy, even though this practice is not recommended by either the CDC or AAMI. Gramnegative bacteria (and

mycobacteria) have caused several outbreaks, pseudo-outbreaks, and patient deaths following endoscopy (see Introduction: final rinse water). In particular, rinse water used during endoscope reprocessing has been found to be contaminated with these and other microorganisms and has been identified as the cause of outbreaks. In addition to forming in the hydraulic pathways of hemodialysis equipment, biofilm complexes containing *P. aeruginosa* and other gram-negative bacteria have been identified in the internal components of EWDs and have been linked to patient injury and death. Further, as reported in the FDA's database, more than a dozen outbreaks and at least five patient deaths have been linked to bronchoscopes or EWDs contaminated with gram-negative bacteria (and other opportunistic microorganisms). (Muscarella 2002)

Willis reviewed the literature and found a number of reports of outbreaks and pseudo-outbreaks amongst patients following endoscopy procedures, which were subsequently traced to improperly functioning EWDs or contaminated rinse water. The source of a pseudo-epidemic of *Legionella pneumophila* was identified as contaminated tap water used to rinse disinfected bronchoscopes, an outbreak of multidrug-resistant *Pseudomonas aeruginosa* was attributed to a contaminated washer-disinfector that had not been adequately maintained during the year since it was purchased and two cases of pseudo-infection with *Mycobacterium chelonae* were associated with contaminated rinse water in a EWD used to disinfect bronchoscopes. Pseudo-infections may lead to misdiagnosis and inappropriate treatment of patients, which may be both costly and unpleasant for the patient. (Willis 2005)

Waterborne nosocomial infections caused by mycobacteria include wound infections, post-injection abscesses, surgery related outbreaks, and infection after bronchoscopy or dialysis. The following sources can be distinguished:
- rinsing with contaminated tap water of surgical devices and endoscopes/bronchoscopes after disinfection;
- contaminated ice and ice machines;
- inhalation of aerosols during showering. (Vaerewijck, Huys et al. 2005)

Seoane-Valquez performed an analysis of the characteristics of exogenous endoscopy-related infections, pseudoinfections, and toxic reactions that have occurred worldwide during the period 1974 - 2004. The literature review identified 140 outbreaks, reported in 134 scientific articles. Exogenous endoscopy-related infections are considered to be rare. However the available information on endoscopy-related infections, pseudoinfections, and toxic reactions remains very limited, and focuses primarily on the experience in the United States. Endoscopy-related infections and toxic reactions are very difficult to identify unless they occur in clusters. Washer contamination was the second most common cause of contamination in the United States (13.0%), while contaminated water was the second most common cause of contamination in other countries (14.1 %). A total of 14 endoscopy-related deaths were described in nine reports in the United States, representing 1.9% of contaminated patients. (Seoane-Vazquez, Rodriguez-Monguio et al. 2007)

Annex 2 Biofilms

Note: This summary is intended for the reader who wishes to learn more from the original sources. The summaries are ordered by the year of publication. The summaries are taken from the papers and represent the findings and opinions of the authors of those publications. A full reference list in given under "References" including full bibliographic details, which will enable any library to obtain a copy of the referenced publication.

Alvarado reports the heavy contamination (10^5 CFU/ml) of the suction channel of upper gastrointestinal endoscopes after cleaning and disinfection in an EWD, with *P. aeruginosa*. The contamination originated from a flaw in the design of the EWD. The detergent holding tank, inlet water hose, and air vents could not be reliably disinfected and contained heavy biofilms that recontaminated the EWD after it had been disinfected. In three endoscopy centers post-endoscopy infections by EWD associated *P. aeruginosa* had been confirmed by demonstrating concordance between isolates from contaminated machines or endoscopes and from infected patients. (Alvarado, Stolz et al. 1991)

Aggressive infection control measures on the disinfecting machine, including use of sterile water in the wash and rinse cycles, increasing the 2% alkaline glutaraldehyde exposure time, frequent replacement of the glutaraldehyde, and disinfection of the machine, failed to eradicate *M. chelonae*, presumably because of the presence of a biofilm inside the machine. Rinsing the scopes with 70% alcohol after automated disinfection eliminated the outbreak strain. This study demonstrates that automated bronchoscope disinfecting machines may become heavily contaminated with mycobacteria that resist usual disinfection, resulting in a source of bronchoscope contamination. (Fraser, Jones et al. 1992)

Contamination of broncho-alveolar lavage specimens by environmental mycobacteria in hospital water supplies may lead to diagnostic confusion, particularly in immunocompromised patients. Mycobacteria may become concentrated in biofilms in the tubing of bronchoscope disinfecting machines. It is very difficult to eradicate these organisms once contamination has occurred. (Brown, Hellyar et al. 1993)

Another problem is the decrease of susceptibility of the micro-organisms that survive the disinfection stage of the process. Van Klingeren and Pullen showed that machine associated isolates of *M. chelonae var. abscessus* were far more tolerant to 2% glutaraldehyde than a laboratory strain of *M. chelonae* and *M. terrae*, the official test organism for mycobactericidal testing in Germany and the Netherlands. (Van Klingeren and Pullen 1993)

The association of mycobacterial incidents with the use of automatic washer/disinfectors (17 of 18 incidents) together with Department of Health warnings of build-up of biofilm within these chemical-process machines gives further cause for concern. (Uttley 1994)

The presence of biofilm in EWDs may protect *M. chelonae*, present within the matrix. These will be more difficult to access with the disinfectant than free floating bacteria. Regular cleaning, disinfection and maintenance of the washer disinfector and the water delivery system will prevent the formation of biofilm and increase the effectiveness of the machine self-disinfect cycle. The use of softened water and the selection of biofilm antagonistic materials should further reduce this risk. (Griffiths, Babb et al. 1997)

Micro-organisms present in the water are able to grow in a dental unit when there are favorable conditions to grow. In contrast to the drinking water piping system which is often made of copper and therefore has antibacterial properties, the material of the internal piping of a unit often made

from plastic. When the plastic pipes of a new unit is filled with water, within a very short time (eight hours) a biofilm is created in which rapid multiplication of micro-organisms occurs. The growth rate is further increased if a boiler is installed in the unit to keep the cooling / rinse / spray water at a temperature comfortable for the patient (often around 30°C). Another factor that contributes to a significant growth of micro-organisms in the piping of the unit is an unfavorable ratio between the wall surface and the contents of the pipes. This together with the low flow rate of a unit (only a few liters of water per day) contributes significantly to the internal contamination of the dental unit. Regular cleaning, or a continuous disinfection is therefore required. (Feilzer 1999)

Nontuberculous mycobacteria may occur naturally and grow in tap water and cause nosocomial infections, particularly in immuno compromised persons. These mycobacteria may be more resistant to disinfectants than *M. tuberculosis* and may require longer exposure times for killing. The ability of bacteria to form biofilms is an important factor in the pathogenesis of endoscopy-related infections, particularly as biofilms interfere with disinfection and may thus present a persistent microbial reservoir. Biofilms consist of colonies of organisms forming structures to maximize growth potential. Strategies aimed at decreasing biofilm formation and viability will have an important role in endoscope disinfection because biofilms have been found to adhere to the internal channels of endoscopes. This finding emphasizes the importance of thorough mechanical cleaning to enable the action of disinfectants and prevent the spreading of micro-organisms between patients. (Alvarado and Reichelderfer 2000)

M. chelonae, *M. mesophilicum*, gram-negative bacteria, and various molds grew from endoscopes, EWDs, and glutaraldehyde from the EWDs but not from unopened glutaraldehyde. The endoscopy department regularly monitored the pH of glutaraldehyde, and the logs contained no deficiencies. The above sources remained positive for the same organisms after a glutaaraldehyde cleaning cycle of the EWDs. DNA fingerprinting of the *M. chelonae* found in the different locations revealed that they were clonally related. The automated washers were contaminated with a biofilm that rendered them resistant to decontamination. The washers then contaminated the endoscopes and bronchoscopes they were used to disinfect. (Kressel and Kidd 2001)

EWDs may become contaminated due to the development of a biofilm on their internal pipe-work with consequent bacterial growth. The growth of micro-organisms within the machine will result in the production of contaminated rinse water, with possible subsequent recontamination of disinfected endoscopes during the final rinse cycle of the machine. This can result in the transmission of infection to patients on whom the endoscope is subsequently used. In addition there is the problem of pseudo-infection with organisms such as *M. chelonae* where diagnostic samples may be contaminated with bacteria derived solely from the rinse water. There are two main sources of micro-organisms in drinking water distribution systems, a) bacteria present in the water after the initial treatment, and b) bacteria seeded into the water from biofilms present within the distribution system. It is often difficult to differentiate between the two. Biofilms consist of cells immobilized on a surface and frequently embedded in an organic polymer matrix of microbial origin, and it is now clear that life within a biofilm is the dominant mode of existence for many micro-organisms. Drinking water biofilms may harbour pathogenic micro-organisms along with non-pathogenic species. These non-pathogenic species, which constitute the natural microflora, provide a community structure for colonization and play a major role in biofilm formation. Biofilms may protect bacteria from detrimental environmental factors such as changes in oxygen concentration and redox potential allowing survival in difficult conditions. They also make the bacteria less susceptible to biocides. The resistance to biocides can be due, in the case of peroxygens and halogens, to reaction of the biocide with the exopolysaccharide or limited diffusion of the biocide through the exopolysaccharide. In addition, cells deep within biofilms grow much more slowly than cells at the surface and are metabolically dormant, which again

reduces the effectiveness of biocides. Biofilms function as a reservoir for pathogens and the number of pathogens that has been shown experimentally to benefit from a biofilm mode of existence is growing. Examples now include *E. coli,* Campylobacter species, *Cryptosporidium parvum*, *Pseudomonas aeruginosa*, *Aeromonas hydrophila*, and *Candida albicans*. Mycobacteria are also known to be widely present in biofilms found in water distribution systems, and *Mycobacterium chelonei* has been known to colonize EWDs for many years. The presence of a variety of fungi in the pipe work supplying EWDs has also been noted. This bacterial and mycobacterial contamination has been shown to persist despite the use of apparently adequate disinfection methods.
The HTM 2030 standard differentiates rinse water, which must show no bacterial growth, from other waters used in the processing of endoscopes in which the presence of bacteria up to 100 cfu/100mL is considered acceptable. Thus the majority of effort has been concentrated upon ensuring sterile water for the final rinse. However, even with widespread use of processes such as water filters and UV disinfection, problems have been encountered in the provision of rinse water of suitable bacterial quality. This is likely to relate in part to the widespread nature of biofilms and the difficulty in their removal. Organisms attached to stainless steel surfaces require 10-100 times the manufacturers recommended in use concentrations of biocide to be effective.
Incorporation of biocidal substances into surfaces causes only minor delays to the formation of biofilms for example the incorporation of silver slows initial colonization by *Legionella pneumophila* biofilms but after 28 days no difference is seen between test and control surfaces. Incorporation of antibiotics has also been used in some medical devices, but this may lead to problems with antibiotic resistance, and has not been shown to be uniformly effective. (MacKay, Leanord et al. 2002)

It was observed that ethanol rinsing and drying of the endoscopes contributed to recontamination. The investigations of Sciortino to resolve this issue led to the observation that when new endoscopes were used, they were not recontaminated by an ethanol rinse. This led to the conclusion that the internal channels of older endoscopes were not being adequately cleaned to remove biofilms. It is possible that the ethanol rinse acted as an organic solvent that flushed out adherent biofilm within the channel and the aerosol recontaminated the endoscopes when air was forced through the channel. Hence, older endoscopes gave higher readings than new ones at this step. (Sciortino Jr, Xia et al. 2004)

Mycobacteria have the capacity to produce or live in biofilms in aquatic environments. Biofilms, consisting of single or multiple bacterial species, can function as a reservoir of opportunistic and true human pathogens. Bacteria, including mycobacteria, embedded in a biofilm are more protected against antimicrobial agents than planktonic cells. Restricted penetration of the antimicrobials into the biofilm, decreased growth rate, and expression of possible biofilm-specific resistance genes are mechanisms which, alone or in combination, explain biofilm survival in a number of cases.
General measures to control biofilm development are focussed on nutrient control (cleaning and rinsing), control of contamination from materials and equipment, control of hydraulic problems, cross-connection control and backflow prevention, disinfectant residuals and corrosion control. In a model distribution system, it was demonstrated that reducing the biodegradable organic material in the water, control of corrosion of pipe material, maintenance of an effective disinfectant residual, and management of hot water temperatures can decrease the occurrence of *M. avium*. Removal of nutrients and maintenance of a chlorine residual may be considered as the most important measures to minimize biofilm formation in drinking water systems. (Vaerewijck, Huys et al. 2005)

With regard to potential action on biofilms, peroxyacetic acid is considered to be a superior disinfectant compared with glutaraldehyde. However, although peroxyacetic acid is known to be a

very good biocide, previous studies performed on haemodialysis systems have shown that it has low efficacy for biofilm removal. This has been confirmed in situ following experimental contamination of actual dialysis machines, suggesting that biofilm removal should be attempted with cleaning agents rather than disinfectants. The anti-biofilm efficacy of a cleaning agent should be related to its ability to detach biofilm from a surface. A new anti-biofilm procedure, has been developed recently for the disinfection of haemodialysis machines. This procedure provides complete detachment of biofilm due to sequential and synergetic action of two detachment promoting agents: a complex enzymatic mixture (substance A) and a specific alkaline detergent solution (substance B). The Pronetron agents can be used for preventive maintenance (preventing the development of a biofilm) based on the use of a detergent solution alone, and corrective maintenance (removal of an existing biofilm) based on enzymatic treatment followed immediately by treatment with an enriched detergent solution. (Marion, Freney et al. 2006)

Flow in pipes can be used to minimize attachment of bacteria to a minimum. Flow of liquid along a surface is laminar. Due to friction a stationary layer of water molecules is present along the solid surface of the pipe. A smooth looking polished stainless steel surface, mechanical and electro-polished is still a rough structure for micro-organisms, where several micro-organisms can be stacked together. Even with turbulent flow growth of micro-organisms remains possible. Under the condition of a high flow rate the thickness of the biofilm will be limited to 5 to 10 microns. In case of pure laminar flow, with little or no flow along the surface, the biofilm is able to grow to a thickness of more than 200 microns. (Offerman 2007)

Annex 3 Microbial quality of final rinse water

Note: This summary is intended for the reader who wishes to learn more from the original sources. The summaries are ordered by the year of publication. The summaries are taken from the papers and represent the findings and opinions of the authors of those publications. A full reference list in given under "References" including full bibliographic details, which will enable any library to obtain a copy of the referenced publication.

In 1995, Health Technical Memorandum (HTM) 2030 was produced by NHS Estates, providing guidance on operational management, design considerations and validation requirements of washer disinfectors. This document states that the final rinse water used for invasive endoscopes should be sterile, and for non-invasive endoscopes 'it is preferable that it is sterile'. It suggests that weekly microbiological checks should be carried out, and that there should be no recovery of microorganisms from duplicate samples of 100 ml of rinse water. In addition, annual samples should be tested to ensure absence of environmental mycobacteria in 100 ml of water. A joint working group of the Hospital Infection Society and the Public Health Laboratory Service issued guidelines relating to the prevention of contamination of endoscope rinse water. This document is in agreement with HTM 2030 that final rinse water should be bacteria-free, but suggests that a weekly to monthly programme of monitoring with regular review of results may be adequate.

Bacteria-free water is only essential for the rinsing of endoscopes used in endoscopic retrograde choledocho-pancreatography (ERCP). Endoscopy per se is not performed in a sterile body cavity and therefore high level disinfection rather than sterilization is usually adequate. Without relatively expensive water treatment units or the use of filters which require careful maintenance and monitoring, most endoscopy units will have difficulty in achieving sterile rinse water. Ensuring that rinse water is endotoxin free is likely to be even more difficult to achieve and monitor. Drinking water is likely to be endotoxin positive from time to time and furthermore, the normal flora of the gastrointestinal tract is not endotoxin-free. (Humphreys and Lee 1999)

The purpose of the cleaning and disinfection process is to remove soiling and reduce the microbial contamination to an acceptable level for the intended use of the items to be processed. The water used at each stage of the WD process cycle should not increase the bioburden of the load items. For endoscope disinfection, where the disinfected endoscopes are intended to be used without further decontamination processing, post-disinfection rinsing is necessary to prevent toxic effects of residual chemicals. Chemical colitis mimicking pseudomembranous colitis, caused by 3% hydrogen peroxide and glutaraldehyde, has been reported. (Alvarado and Reichelderfer 2000)

Ordinary tap water may contain microbes, including *Legionellae spp*, *Pseudomonas spp* and mycobacteria. In several reports, contaminated rinse water was the suspected source of *P. aeruginosa* transmission to patients through previously disinfected endoscopes. For these reasons, rinsing should be done with sterile water. If sterile water is not used, an alcohol rinse followed by complete drying by purging air through the channels is essential. Only sterile water should be used for endoscopes that pass through sterile tissues. (Alvarado and Reichelderfer 2000)

If endoscopes are processed by immersion in disinfectants, harmful residues must be removed by thorough rinsing. Sterile or bacteria free water is essential for rinsing all invasive endoscopes and accessories to prevent recontamination. (Babb, Ayliffe et al. 2000)

Following disinfection, a sterile water rinse followed by forced-air drying or a tap water rinse followed by forced-air drying and a 70% alcohol rinse must be used to prevent recontamination. (Weber and Rutala 2001)

Many of the agents used for the decontamination of endoscopes and accessories deposit toxic residues that must be adequately rinsed off before the endoscope can be used. Tap water may contain microbes including *Pseudomonas spp* and *Mycobacterium spp* and there are many reports of procedure-acquired infection and pseudo-infection with these organisms via contaminated rinse water. (MDA 2002)

Instruments used for other procedures such as endoscopic retrograde cholangio pancreatography (ERCP), which enter sterile sites, require sterilization or at least high-level disinfection with rinsing in sterile or bacteria-free water prior to re-use. (Humphreys, McGrath et al. 2002)

For rinsing off disinfectant residuals fresh water, bacteria free water must be used. The use of non-sterile tap water or distilled water is not sufficient because they often contaminated with eg *Pseudomonas spp*, *Legionella spp* and atypical mycobacteria. With this water satisfactory disinfected endoscopes can become recontaminated. When the channels of the endoscope are insufficiently dried, the number of bacteria may increase during storage. For the final rinse water must be used of at least potable quality and free from pathogenic micro-organisms. Microbiologically impeccable rinse water can be produced in large quantities by sterile filtration. The guideline of the Association for Professionals in Infection Control and Epidemiology (Alvarado and Reichelderfer 2000) recommends the use of sterile water, for the final rinse. Endoscopes used in areas of the body that are normally free form micro-organisms (eg intra-operative endoscopy, cholangioscopy), are to be sterilized with gas in a packaging to maintain sterility up to the moment of use. (RKI 2002)

We agree with Humphries and Lee (Humphreys and Lee 1999) that the need for bacteria free water in general gastrointestinal endoscopy is questionable, however the problem of contamination of channels used for the introduction of instruments in ERCP and bronchoscopy is real and can lead to serious consequences. But many endoscopy departments carry out a variety of procedures, and endoscopes may be processed through the same washer disinfectors. (Richards, Spencer et al. 2002)

After high-level disinfection, rinse the endoscope and flush the channels with sterile, filtered, or tap water to remove the disinfectant/sterilant. Discard the rinse water after each use/cycle. Flush the channels with 70% to 90% ethyl or isopropyl alcohol and dry using forced air. The final drying steps greatly reduce the possibility of recontamination of the endoscope by waterborne microorganisms. (Nelson, Jarvis et al. 2003)

The final rinse water shall meet the following requirements for microbiological quality
a) there are fewer than 10 cfu per 100 ml sample of final rinse water;
b) the water is free from legionellae, *Pseudomonas aeruginosa* and mycobacteria. (ISO15883-4 2008)

The nature and extent of the microbial population in the final rinse water should not present a potential hazard to the patient, either through infection or by leading to erroneous diagnosis. Appropriate treatment to control or reduce the microbial contamination in water is required. (DoH 2009)

Annex 4 Microbial water treatment

Note: This summary is intended for the reader who wishes to learn more from the original sources. The summaries are ordered by the year of publication. The summaries are taken from the papers and represent the findings and opinions of the authors of those publications. A full reference list in given under "References" including full bibliographic details, which will enable any library to obtain a copy of the referenced publication.

Filtration
Water filters cannot be used indefinitely:
- The pores in the filter material become clogged with particles and bacteria. The capacity of the filter may be specified as the retention value; the number of particles or bacteria that will be retained per cm^2 of filter material. A 0.2 µm filter should have a retention value of at least 10^7 cfu/cm^2.
- When the pores become clogged the pressure difference over the filter material increases, causing the material to deform. As a result the shape and size of the pores may alter and the smaller particles and micro-organisms that were captured earlier may be released and still pass through the filter.
- Filter may tear and rupture during use. The integrity of the filter should be tested before it is used again, e.g. after sterilisation.
- Bacteria that are trapped in the filter material may change their shape (e.g. as a consequence of cell division) and penetrate deeper and deeper into the filter, until they 'grow through' the filter. The decaying bacteria in the filter may release unwanted pyrogens into the filtered water. Membrane filters should not be used for more than a working day. (Zuidema J 1999)

Developments led to various features of modern sterilizing grade filter elements including steam sterilization resistance up to 134°C, minimal extractables, mechanical resistance of pulsations at five bar differential pressure, low adsorptivity, optimized flow rates to reduce costs and processing times, and integrity testable filters using common non-destructive tests (e.g. diffusive flow, pressure decay, or bubble point). All major filter manufacturers offer validation services, which support any re-validation effort. (Jornitz, Soelkner et al. 2002)

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. The system should be disinfected regularly and the machine cleaned and maintained regularly, adhering to the manufacturer's information. The water treatment system shall be fitted with means to disinfect or sterilize filters and the downstream water distribution system between uses and at four-hourly daily intervals. This should preferably be done by steam sterilization, but a chemical disinfection process may also be used.
An 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. (Richards, Spencer et al. 2002)

It is generally assumed, and confirmed, that filters with a 0.1 - 0.45 µm pore size can retain bacteria. In contrast to this assumption, we have regularly observed the passage of a significant fraction of natural freshwater bacterial communities through 0.45, 0.22, and 0.1 µm pore size filters. In all instances, the dominant microbial populations comprised slender spirillum-shaped *Hylemonella gracilis* strains, suggesting shape-dependent selection during the filtration process. Filtration of ten water samples representing a broad range of water types revealed that a high percentage of the natural aquatic microbial communities pass through 0.45 µm pore size filters. On average, 50% filterability was recorded. A considerable percentage (0.03-3%) of the communities was recorded to be able to pass through 0.22 µm pore size filters. Furthermore, a

small yet significant percentage (0.003-0.2%) of the communities can even pass through 0.1 µm pore size filters. In fact, a considerable fraction of the bacterial communities in surface and drinking water is able to pass through filters with 0.22 µm and even 0.1 µm pore sizes. Spirillum-shaped bacteria are commonly distributed in natural aquatic environments, even including some pathogenic bacteria, e.g., *Leptospira* and *Treponema*. The isolation of *Leptospira biflexa* in deionized water, which was sterilized by filtration through 0.22 µm pore size membrane filters was reported. The ability of *Treponema pallidum* escaping the entrapment of 0.22 µm filters was demonstrated earlier. Our observations suggested that spirillum-shaped bacterial cells cultivated with natural assimilable organic carbon are much more meaningful candidates for filtration efficiency testing than *B. diminuta* cultivated with a laboratory medium making them "fat and large". (Wang, Hammes et al. 2007)

When water is treated by filtration, e.g. through a 0.22 µm filter to remove microbial contaminants, rigorous controls are needed to ensure that the system works effectively. These should include:

- either maintaining the pressure drop across the filter throughout its working life, a decrease in differential pressure being cause for rejection of the process cycle and a change of filter, or a bubble point test before and after each process cycle (see BS 1752:1983);
- a continuous recirculation system so that the filter is not left wet in static water;
- treatment of the circulating water to ensure that proliferation of microbial contamination is inhibited either by use of elevated temperature (e.g. >60°C) or by the use of UV irradiation (UVC wavelength 260 nm ± 10 nm; >2J.m^{-2}).

Verification of purification by filtration should be made by relevant total viable count and conductivity tests. (DoH 2009)

UV irradiation

Martiny established that UVA and UVB light is able to disinfect flowing water. UVA gives a 5 log reduction at a energy density of 50 - 190 J.m^{-2} or 140 - 750 J.m^{-2} for UVB. A 7 log reduction is established at 190 - 550 J.m^{-2} for UVA and at 650 - 1610 J. m^{-2} for UVB. (Martiny 1991)

The circulation of contaminated water in the water treatment unit leads to a contamination of each part of the hydraulic system in such a way that even if the system is, then, supplied with non contaminated water, the water produced is always contaminated. Irradiation with UV light is able to reduce the contamination level of the water circulating in the system but this is not sufficient to ensure the production of non contaminated rinse water. In conclusion, those first data show that:

- The hydraulic system parts located before the UV unit are rapidly contaminated by the bacteria present in the water supply, and the contamination at those points increase slowly day after day,
- The UV unit reduces the number of viable bacteria presents in the water but some of them are not destroyed and contaminate the water treatment unit after the UV lamp,
- A significant contamination of the water produced by the system is observed after 2 days.

(Desbuquois and Pineau 2001)

Connecting structures in the DNA of micro-organisms are broken down under the influence of UV light with a wavelength of 254 nm. As a result of the damage to the DNA, micro-organism will not die but cell division is hindered. For proper operation sufficient UV power must be available and the thickness of the irradiated water film should be limited. Usually, the UV lamp is placed behind the water softener, so that the UV light renders the bacteria that grow in the softener harmless. One can also argue that the UV lamp must be placed for the softener so fewer bacteria enter and grow in the softener. (Offerman 2007)

Addition of peracetic acid

With an addition of peracetic acid at the water inlet level (just after the flow meter) which permits to maintain a peracetic acid concentration in the system of about 30 ppm, the water produced at the water outlet during the ten test days, is always free from bacterial contamination (less than 1 cfu/10 ml). Furthermore, according to those data, running one empty cycle each morning should permit to eliminate the small bacterial contamination observed for some parts of the system, located before the UV disinfection unit. (Desbuquois and Pineau 2001)

Whilst peracetic acid is an effective bactericide, one should be aware that it may, in the low concentrations for the disinfection of rinse water may not be equally effective against fungi. Appropriate monitoring of the water quality should be applied. (Phillips, McEwan et al. 1998)

Ozonization
The piping between the water treatment system and the dialysis machines can be disinfected using ozone. The required ozone is generated from water through electrolysis. When the disinfection treatment with ozone is ready, the ozone can be removed from the water by irradiation with UV light. (Offerman 2007)

Super oxidized water
A low dose of Sterilox super oxidized water (hypochlorous acid) may give sufficient residual of active chlorine to keep the microbial load in the final rinse water at consistent low levels. With the market introduction in the Netherlands of the Sterilox system this was one of the proposed applications.

Thermal disinfection
Although an effective disinfection method, thermal disinfection of the final rinse water is not generally applied by the manufacturers of the EWDs (that are in use in the Netherlands). In the EWD of one manufacturer the water is heated to approximately 90°C and cooled to an appropriate temperature before it comes into contact with the flexible endoscopes. (BHT 2009)

Hot water should be distributed such that a temperature of at least 55°C is achieved within one minute at the outlets. It may be expected that the heat and flush method to eradicate Legionella spp. will also result in a dramatic reduction of environmental mycobacteria (EM) (E.g. *M. avium, M. kansasii, and M. xenopi*), taking into account that several species do not tolerate temperatures >60°C for several minutes. Drawbacks of the latter method include the risk of scalding and the fact that it is time consuming. (Vaerewijck, Huys et al. 2005)

An alternative method for making sterile pyrogen free water is the Sterile Water for injection Field Technology (SWIFT). This technology is based on the supplier's patented hydrothermal processing concept to achieve rapid depyrogeneration and sterilization of water with minimum space and energy requirements. Unlike the distillation and RO methods, which physically remove endotoxins from water, the supplier's technology ensures pyrogen-free by a final heat treatment step to inactive pyrogens. Six logs of endotoxin inactivation in water was achieved at temperatures greater than 250°C and sufficient pressures to prevent water from boiling with a contact time of less than one minute. The high-pressure approach also allows the process to be more compact and heat recovery more efficient than the conventional stills. (Li and Renard 2008)

Annex 5 Problems with microbial water treatment

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The samples taken from the water containing piping system of seven washer-disinfectors located at the university clinics, were bacteriologically examined. The results showed systemic contamination of the tubes of all tested machines. The well known positive effect of ion-exchangers on bacterial growth was not the only reason for the high degree of microbial contaminations. As the result of the use of bacteriological objectionable tube materials, partial bacterial growth was detected on the inner sides of the water tubes. Recontamination of the processed goods is possible by the final rinse water. Preceding sterile filtration showed no effect as the filters were installed upstream of the ion exchanger. (Kolch, Krizek et al. 1993)

It is believed that L-form organisms can be present in pharmaceutical water systems. Bacteria that are reduced in size may also be present in such nutrient-deficient environments. L-form bacteria are present in sera. L-form bacteria cannot be removed from sera by filtration through 0.2 µm or 0.1 µm rated membranes. These organisms were also found in sera prefiltered using 0.04 µm rated membranes. Ultrafilters of 300,000 daltons seemed serviceable. Given the failure of 0.2 µm or of 0.1 µm rated filters, or even lower ratings, to remove L-form organisms from a liquid medium (albeit from sera), there is no reason to expect their removal by double-filter systems. Nevertheless, the European regulatory authorities have established their position. Whatever the merits of filtration, the existence of waterborne organisms can probably be eliminated by the use of hot water storage (~80 °C) or by storing the water under ozone. (Jornitz and Meltzer 1998)

Cooke describes a situation in which the water filtration system installed could not reliably provide bacteria free water. The water filtration system consisted of a holding tank, booster pump, three pre-filtration filters (5 µm, 0.2 µm unpleated filter membranes plus 0.2 µm absolute filter) and a final hollow fibre 0.2 µm (bacterial-rated) filter membrane for each of the four EWDs. Mains water was not softened. Weekly chemical disinfection of the water filtration system was recommended by the manufacturer of the filter system to ensure that the system remained bacteria-free and the life of the final filter could be extended.
The disinfection procedure consisted of adding a mixture of 1% hydrogen peroxide and 0.1% peracetic acid solution to the holding tank at the end of the week, the disinfectant being left within the system until the following Monday. During this period, disinfectant was continuously re-circulated through the water filtration system including the duct between the final filter and the outlet tap of each machine. This water treatment system disinfection was, contrary to the manufacture’s instructions, only performed on two occasions during the first three months of the study.
Infrequent chemical disinfection of the water filtration system or failure to regularly replace filters may result in build-up of bacteria on the final filters causing bacterial growth through the filter and recontamination of the water supply. Final filter change made no difference to the water quality. Bacterial build-up may also occur when water is allowed to stagnate if an endoscopy unit is not operational at weekends. To avoid this problem, water was continuously re-circulated by the booster pump when the EWD was not in use.
Knowledge of the hardness and microbiological quality of the mains water supply are important factors when deciding upon a suitable filtration system. In our case, prior awareness of the poor bacteriological quality of the water supply may have influenced the filtration system chosen. Use

of a water-softener and the fitting of true bacterial 0.2 um final filters, rather than particulate 0.2 um filters with a bacterial rating, need to be considered. Ultra-violet radiation of filtered water is another option, though costly and inadequately evaluated for EWDs. The suitability of current commercial filter housings and O-rings also needs to be addressed. Despite the limitations of the system installed, it was reassuring that there were no episodes of mycobacterial contamination of bronchoscopes. (Cooke, Whymant-Morris et al. 1998)

The water supply is processed by passing mains water through UPVC pipes across a series of three filters (1 µm, 0.4 µm and 0.2 µm) prior to exposure to an ultraviolet (UV) light source. Decontamination of the water line is performed daily by feeding a 5% dilution of a disinfectant consisting of 0.1% w/w peracetic acid and 1% w/w hydrogen peroxide) to the water using a dosage pump. The solution fills the pipe-work from the pump through to the machine baths and remains in situ from the end of one working day to the beginning of the next, when it is flushed away to drain. In May 1998, staff reported black debris in the machine baths. It is possible that fungi such as *Phialophora* sp. are more resistant to peracetic acid and survived, then entrapped bacteria. Only total aerobic bacterial counts were used as a measure of the water quality and the presence of the predominant fungal growth was not detected. It is unlikely that the UV light contributed significantly to the degradation or inactivation the peracetic acid over the period it was exposed, but it may have added heat to the system to encourage growth. How long the biofilm had been present is unknown but the density of growth suggested that this was not an acute problem. It is possible that the concentration of the disinfectant/cleaner recommended is inadequate for the microbial challenge in these systems or that some environmental strains may grow in acidic medium. (Phillips, McEwan et al. 1998)

Cheesbrough described a similar fungal contamination of the water treatment system. Investigations detected *Exophilia jeanselmii* at very low counts (1-2 cfu/100 ml) from the hospital mains water but much higher counts in the post-filtration rinse water. Filter replacement, irrigation of the filter housing and washer/disinfector with a oxidizing disinfectant and increasing the frequency of the self-disinfection of the system with the peracetic acid and hydrogen peroxide mixture to nightly had no impact. However, once the filters were removed, the level of colonization with *E. jeanselmii* fell over a period of two months to the very low level previously observed in mains water.
Apparently, the filters employed, their housing unit and pipework, provided a niche in which this fungus could replicate and in this sessile state was not susceptible to the disinfectant, despite in-vitro sensitivity. Black colonies were regularly visible to the naked eye on filters when these were changed approximately every 3 weeks. On examination of the filters particles of glass fibre from the upstream filters were found on microscopic examination of the final 0.2 µm polypropylene backed filter. It is of interest to note that the 2 µm and 0.6 µm filters have a glass fibre supporting matrix and that the black fungus mentioned in previous correspondence was associated with water tank glass fibre matrix exposed by loss of gel coat. Our experience with a water module in which a similar combination of filters are all exposed to 10% of peracetic acid based disinfectant on a daily basis has only yielded one low level growth of *E. jeanselmii* on weekly surveillance over a 6-month period (11 cfu/100 ml). The problem of providing bacteria-free water at reasonable cost remains.
(Cheesbrough and Barkess-Jones 1999)

The change of water filters should be accompanied by disinfection of the pipework from the filter housing into the machine to remove any contamination. The manufacturer further emphasises the importance of proper maintenance of the filter system, including systematic system disinfection and planned monitoring of the quality of the water output. It is possible to produce a quality of water suitable for the rinsing of endoscopes. This is a process constantly carried out within the pharmaceutical industry. However, a rigorous protocol is required to ensure the continuing

production of water at the required quality and if this is followed, it is not ‘an impossible dream’ to produce bacteria free water. (Curtis, Cooke et al. 1999)

Manufacturers that equip their EWDs with a water filtration system typically recommend that the bacterial filter be replaced once a differential pressure across its membrane reaches a preset value (e.g. 25 psi during flow conditions), or when an automatic diagnostic cycle or alarm is activated. This differential pressure is typically measured using two pressure gauges or sensors. One is located proximal to the bacterial filter, the other distal to it. As the bacterial filter collects and retains microbial and other debris, its resistance, as measured by the difference in pressure across the two gauges, increases. Although a common practice, using a differential pressure as a method for testing the integrity of the bacterial filter may be inexact, and data showing it is a reliable indicator of a filter’s effectiveness are lacking. Several articles have established that bacterial filters can fail unexpectedly and allow bacteria to pass. The extent to which a bacterial filter can fail and permit bacterial “leakage” before achieving the preset pressure differential (or before activation of a diagnostic alarm) is unclear. Instead of reliance on a pressure differential measurement, microbiologically sampling the filtered rinse water may be a more accurate and reliable method for assessing when a bacterial filter is failing and requires replacement. (Muscarella 2002)

Because tap water may contain low levels of microorganisms some have suggested that only sterile water (which may be prohibitively expensive) or filtered water be used. The suggestion to use only sterile water or filtered water is not consistent with published guidelines that allow tap water followed by an alcohol rinse and forced air-drying or the scientific literature. In addition, there has been no evidence of disease transmission when tap water followed by an alcohol rinse and forced air-drying has been used.
EWDs produce filtered water via passage through a bacterial filter (e.g. 0.2 μm). Filtered rinse water was identified as a source of bacterial contamination in a study that cultured the accessory and suction channels of endoscopes and the internal chambers of EWDs between 1996 and 2001 and reported that 8.7% of samples collected between 1996 and 1998 had bacterial growth with 54% being *Pseudomonas spp*. Following the introduction of a system of hot water flushing of the piping (60°C for 60 min daily), the frequency of positive cultures fell to approximately 2% with only rare isolation of >10 cfu/ml. (Rutala and Weber 2004)

Annex 6 Self-disinfection

Note: This summary is intended for the reader who wishes to learn more from the original sources. The summaries are ordered by the year of publication. The summaries are taken from the papers and represent the findings and opinions of the authors of those publications. A full reference list in given under "References" including full bibliographic details, which will enable any library to obtain a copy of the referenced publication.

The water delivery system to the EWD may also become contaminated with atypical mycobacteria and requires similar treatment as the EWD. We would advise that if bacteria-retaining filters are used, these are steam sterilized or chemically disinfected together with any fluid pathways not accessed during the machine self-disinfect cycle. Water treatment with UV light in the absence of bacteria-retaining filters is unlikely to be effective as the presence of dead mycobacteria may also lead to a positive lab test (ZN-stain) and misdiagnosis of tuberculosis. (Griffiths, Babb et al. 1997)

Decontamination of the water line is performed daily by disinfectant solution that contains a mixture of peracetic acid hydrogen peroxide. The solution fills the pipe-work from the pump through to the machine baths and remains in situ from the end of one list to the beginning of the next when it is flushed away to drain. The machine is not used from Thursday evening to Monday morning and for a fortnight over the Christmas and local trade holidays. During these periods, it is disinfected the weekend prior to reuse. Staff reported black debris in the machine baths. There was no obvious blackening of the filters although floating particles of black debris were visible in the filter housings. The rubber seals in the filter housings were intact. Changing the filters made no difference to the problem. Water samples yielded total viable counts of 40, 50 and 2 cfu/mL at 22°C, 30°C and 37°C respectively from one bath and 50, 90 and 0 cfu/mL respectively from the other. Microscopic examination of the black debris revealed a tangled mass of fungal hyphae and the machine was taken out of use.
Culture of the debris yielded a complex mixture of organisms including *Pseudomonas aeruginosa* and *Stenotvophomonas maltophilia*, but was composed predominantly of a black pigmented *Phialophora sp.* The black debris (biofilm) was clearly visible along the water pathway to the washer disinfector. The whole of the external water pipeline was renewed as were the filters and housings. The internal pipe work of the machine was treated with another disinfectant. Two stainless steel elbows situated after the inlet valves on the machine were replaced. Culture of one of these yielded *Phialophora sp.* No such organisms were found on culture of the water supply. Several points are raised by this experience. The regular maintenance and decontamination of the pipework and filters did not prevent buildup of biofilm in the system. It is possible that fungi such as *Phialophora sp.* are more resistant to peracetic acid and survived, then entrapped bacteria. Only total aerobic bacterial counts were used as a measure of the water quality and the presence of the predominant fungal growth was not detected. In common with others, we found it was impossible to achieve consistently low (<10 cfu/mL) counts over a prolonged period. Presumably, the mass of the bacteria was contained within the bulk of the biofilm, which would explain the unremarkable total aerobic counts seen in the face of such gross contamination of the pipe-work. (Phillips, McEwan et al. 1998)

If used, EWDs and other processing equipment should be disinfected on a regular basis, i.e., between patients or at the start of each session. This will prevent biofilm formation and recontamination of instruments during rinsing. Disinfection should include the water treatment system, if present. (Babb, Ayliffe et al. 2000)

Between 1996 and 2001, weekly samples were obtained from accessory and suction channels of endoscopes as well as the internal chambers of automated washing machines. Samples were processed for routine bacterial and mycobacterial culture. Bacteria were isolated in 8.7% of

samples collected between 1996 and 1998. Of 36 positive samples, 20 (54%) were *Pseudomonas sp.* Analysis of rinse water from pipework downstream from filters demonstrated high growth of *Pseudomonas sp,* suggesting biofilm within piping was contaminating rinse water. A system of hot water flushing of pipework was developed that maintains a temperature above 60°C for 60 minutes on a daily basis. This resulted in a consistently low level of bacterial contamination.
The risk associated with bacterial contamination of rinse water and endoscopes is probably negligible for EGD and colonoscopy. This is not the case for ERCP, in which introduction of certain pathogens, such as *Pseudomonas sp,* into the pancreaticobiliary tree may be catastrophic. The reason for this isolated incident was not identified, but it serves as a reminder of the importance of ongoing vigilant surveillance. (Pang, Perry et al. 2002)

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. (Richards, Spencer et al. 2002)

Contamination of the inner fluid paths of the EWD may result from the contamination that is still present on the endoscope after pre-cleaning, but may also come from using contaminated cleaner solution and the use of rinse water that is not bacteria free. Tunuguntla found as many a 50.000 cfu/ml of *Pseudomonas* in the endoscope cleaner and up to 3000 cfu/ml is the store water that was used to process the endoscopes. Monitoring of the reprocessed endoscopes was performed by flushing the biopsy channel of the endoscopes with 30 ml of sterile water. All but two endoscopes were culture positive with *Pseudomonas* species with cfu/ml ranging between 20000 and 75000. (Tunuguntla and Sullivan 2004)

A self-disinfection cycle shall be provided to ensure that the WD does not become a focus for contamination of the load and to provide a means of disinfecting the WD after interventions for maintenance, repairs or testing. The self-disinfection process is intended also to deal with the situation where the WD has become contaminated. The self-disinfection cycle shall ensure that a WD that has become contaminated through failure of the water treatment equipment can be effectively disinfected. The piping used to convey rinse water to the endoscope, if contaminated, can easily develop a layer of biofilm containing many micro-organisms in a state in which they are highly resistant to chemical disinfection.
Compliance shall be verified by testing. The performance shall be deemed to be satisfactory if the microbial count is 10 cfu/100 ml or fewer in the final rinse water of the first operating cycle that is performed after carrying out a self-disinfection cycle.
A WD in which the normal operating cycle provides for disinfection of the chamber and all piping and tanks which come into contact with the water or solutions used for cleaning, disinfecting and rinsing the load shall be deemed to meet this requirement without the provision of an additional self-disinfection cycle. (ISO15883-4 2008)

The manufacturer shall provide details of the parts of the WD subjected to the self-disinfection cycle and whether this cycle includes the water treatment equipment. The self-disinfection cycle shall provide for disinfection of the chamber and all liquid transport systems. When the water treatment equipment is a part of the WD, the water treatment system shall be designed and constructed so that it can be periodically submitted to a disinfection procedure. Guidance on the minimum frequency with which the equipment shall be disinfected shall be stated by the WD manufacturer according to the information supplied by the purchaser for the quality of the water supply and the manufacturer of the water treatment equipment.
The disinfection of the water treatment equipment can be carried out during a self-disinfection cycle. The actual frequency should be decided by the user based upon known, e.g. seasonal, variations in the quality of water supplied to the WD and the operational history of the water

treatment equipment. The disinfection method shall not cause any damage to, nor impair the efficacy of, the treatment equipment. The efficacy of the water equipment disinfection procedure to provide self-disinfection shall be deemed to have been established if less than 10 cfu are recovered from each of two 100 ml samples and other controlling parameters have been achieved. (ISO15883-4 2008)

Thermal disinfection using moist heat is the preferred method. Thermal disinfection systems shall be evaluated by thermometric monitoring of the system with sensors placed at those parts of the system specified by the WD manufacturer as representative of the lowest temperatures in the system. During the thermal self-disinfection cycle of the WD, all the parts of the heating system and the associated pipework, via which the water or the steam reach the WD tank, shall be subjected to a temperature of 80°C during 10 minutes (or a process with an equivalent efficacy). (ISO15883-4 2008)

If the use of thermal disinfection is not possible, a disinfectant different from that used for disinfecting the endoscope should be used. The use of the same disinfectant carries the risk of allowing organisms resistant to that particular disinfectant to proliferate.
For chemical disinfection systems a microbiological test shall be required. The test shall be designed to ensure that the self-disinfection cycle will disinfect contaminated pipework by evaluating the effect of the cycle against a biofilm containing Pseudomonas aeruginosa. The capability of the WD to provide self-disinfection shall be deemed to have been established if the required microbial reduction factor has been achieved. (ISO15883-4 2008)

The WD manufacturer shall specify the planned preventive maintenance required on the piping that is part of the WD and is used to convey final rinse water to the endoscope. This shall include the frequency at which such piping should be replaced. (ISO15883-4 2008)

Annex 7 Monitoring of the microbial quality of final rinse water

Note: This summary is intended for the reader who wishes to learn more from the original sources. The summaries are ordered by the year of publication. The summaries are taken from the papers and represent the findings and opinions of the authors of those publications. A full reference list in given under "References" including full bibliographic details, which will enable any library to obtain a copy of the referenced publication.

Microbiological guidelines on standard methods for monitoring the quality of filtered water for endoscopy machines are urgently required since valid comparisons between different systems cannot be currently made. Until manufacturers can reliably demonstrate that bacteria-free water can be produced for EWDs, we recommend that the bacterial monitoring of filtered water is included in the commissioning of any new EWDs. If filtered water is non-sterile, the advice of a specialist company should be sought. (Cooke, Whymant-Morris et al. 1998)

Weekly monitoring of total viable count is recommended in HTM 2030 (DoH 2009) but this may be impractical. Richards (Richards, Spencer et al. 2002) advises therefore that microbiological quality of water should be monitored regularly, starting with weekly tests and based on the results work towards a educated test regime. 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. 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. 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.
Monitoring of the quality of the final rinse water should take place after maintenance, changes in cycle parameters or on the advice of the infection control doctor in case an outbreak is suspected. 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 microbiological methods 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. (Richards, Spencer et al. 2002)

The extent to which a bacterial filter can fail and permit bacterial "leakage" before achieving the preset pressure differential (or before activation of a diagnostic alarm) is unclear. Instead of reliance on a pressure differential measurement, microbiologically sampling the filtered rinse water may be a more accurate and reliable method for assessing when a bacterial filter is failing and requires replacement. (Muscarella 2002)

Despite the documented reports of patient infections and deaths following endoscopy, periodic microbiologic sampling of the rinse water used during endoscope reprocessing is not yet routinely recommended. Muscarella recommends microbiological sampling of the rinse water used during endoscope reprocessing at least once a month. Depending on several factors, including the status of the patient's immune system, even a few bacteria in the rinse water can be problematic. Whereas unlikely to pose a nosocomial infection risk if used immediately, endoscopes contaminated with just a few bacteria after rinsing can pose a serious infection risk if stored wet

for several hours and in a moist environment. An inadequately dried endoscope contaminated with only one or two viable bacteria can, after 8 hours of storage, be contaminated with tens of thousands of bacteria, which could pose a risk of serious patient infection.
Muscarella recommends sampling at least three sites:

- the tap water supply prior to the bacterial filter (which reveals whether the tap water is contaminated with "background" bacteria);
- the filtered water immediately after the bacterial filter (which helps to determine not only whether the filter is failing, but also whether the filter's housing may contain a biofilm and require decontamination); and
- the rinse water in the EWD's basin (which aids in evaluating whether the EWD's internal components may contain a biofilm. (Muscarella 2002)

Several unanswered water sampling questions that warrant consideration:

- To what extent might routine sampling of the rinse water used during endoscope reprocessing reduce the risk of patient infection?
- If the rinse water's bacterial count exceeds a few (e.g. 5 to 10) colony-forming units per milliliter, to what extent does this microbial concentration place the patient at risk for a gram negative bacterial infection between patient procedures? (Before storage, no bacteria in the endoscope are permissible.)
- Under what conditions might sampling the rinse water less than once a month be acceptable?
- Under what conditions might sampling the rinse water more than once a month be necessary?
- If there are no bacteria in the rinse water, is a terminal flush of the endoscope's channels with 70% alcohol, followed by forced air drying, still necessary?
- Will the water test kits used for testing hemodialyzer rinse water prove to be reliable for testing for gram-negative bacteria in the rinse water used to reprocess endoscopes?
- What if the water test kit yields no growth after 2 to 3 days? Could the water sample still be contaminated with gram-negative bacteria (i.e. a false-negative)? How prone are water test kits to yielding false-positive results?
- What are the limitations of these water test kits, in addition to their inability to yield atypical bacteria for culture?
- Under what conditions (if any) might removing the endoscope from service be warranted, pending the results of the water test kit?
- To what extent are these water test kits likely to be more reliable indicators of microbial contamination than a pressure differential across two pressure gauges?

(Muscarella 2002)

Although each drinking water distribution system (DWDS) harbours its own mycobacterial flora, environmental mycobacteria (EM) are generally not included as a parameter in standard microbiological analysis. Most EM are virtually never covered by the heterotrophic plate count because plates are usually incubated at 20°C, 22°C, 30°C or 37°C for 48h, 72h or 7d (depending on the international standard followed), and the composition of the routine media such as R2A agar and plate count agar differs from those usually used to cultivate mycobacteria. (Vaerewijck, Huys et al. 2005)

Most findings regarding filterable bacteria hitherto, including standard filter challenging tests, have relied on the heterotrophic plate count (HPC) method, or equivalent techniques, for enumeration and isolation of filterable bacteria. The shortcomings of this method for detection of natural bacteria are well documented. It has been repeatedly observed that less than 1% of the bacterio-planktonic cells in aquatic samples can form a colony on agar surfaces, despite the fact that most bacterial cells in the environment exhibit metabolic activity. (Wang, Hammes et al. 2007)

Annex 8 Monitoring of the microbial status of processed endoscopes

Note: This summary is intended for the reader who wishes to learn more from the original sources. The summaries are ordered by the year of publication. The summaries are taken from the papers and represent the findings and opinions of the authors of those publications. A full reference list in given under "References" including full bibliographic details, which will enable any library to obtain a copy of the referenced publication.

Without dismantling the endoscope to collect microbiologic samples from all of its inner surfaces, the validity of the data used to evaluate effectiveness (or ineffectiveness) of either process may be questioned (Muscarella 1996).

The regular use of a disinfectant may select and thereby encourage the proliferation of mycobacteria, or other micro-organisms, of increasing resistance to the agents used. We would therefore recommend sampling at periodic intervals or should a problem occur. (Bradley and Babb 1990)
Samples should be taken from the lumens and external surfaces of the instrument after processing and from the washer disinfector and rinse water. (Griffiths, Babb et al. 1997)

Focused microbiologic testing is warranted if clinical or epidemiologic findings suggest endoscopy-related transmission of infection. Culturing should be based on the epidemiologic data and follow a plan that specifies the specimens to be obtained for culture and the action to be taken on the basis of the results. Aliquots of sterile, non-bacteriostatic, saline solution flushed through the suction and biopsy, air, water, elevator, and carbon dioxide channels may be quantitatively cultured to determine the adequacy of disinfection. However, few organisms will be obtained from flushings alone. Brushing of the suction and biopsy channel with a sterile brush is more likely to release viable organisms attached to the inner lumen of the channel and is a more sensitive sampling technique (Alvarado and Reichelderfer 2000).

The following procedures are currently in microbiological tests endoscope used:
- Flushing of endoscope channels and subsequent culturing of the collected fluids
- Swabbing of endoscope outer surfaces, parts of the endoscope that are difficult to access by cleaning and disinfection fluids (eg distal end of the endoscope, elevator of ERCP scopes
- "Spounge test" (pulling a piece of foam through the biopsy channel and subsequent culturing of the foam). (RKI 2002)

The quality of reprocessing gastroscopes, colonoscopes and duodenoscopes in daily routine of 25 endoscopy departments in hospitals and 30 doctors with their own practices was evaluated by microbiological testing in the HYGEA interventional study. In 2 test periods, endoscopes ready for use in patients were found contaminated at high rates (period 1: 49% of 152 endoscopes; period 2: 39% of 154 endoscopes). Culture of bacterial fecal flora (*E. coli*, coliform enterobacteriaceae, enterococci) was interpreted indicating failure of cleaning procedure and disinfection of endoscopes. Detection of *Pseudomonas spp*. (especially *P. aeruginosa*) and other non-fermenting rods - indicating microbial insufficient final rinsing and incomplete drying of the endoscope or a contaminated flushing equipment for the air/water channel - pointed out endoscope recontamination during reprocessing or afterwards.
(Bader, Blumenstock et al. 2002)

Moses reports a study in which one duodenoscope proved to be persistently culture positive and was found to have a damaged biopsy channel. This indicates that periodic sampling of the endoscopes may be useful to detect such anomalies. (Moses and Lee 2003)

A major difference between RKI Guideline (RKI 2002) and Multi-Society Guideline (Nelson, Jarvis et al. 2003) consists in the valuation of the monitoring of the endoscope treatment by microbiological quality control. There are no data demonstrating that regular microbiological monitoring of the endoscope treatment reduces the risk of infection for the patient. However by checking the outcome of the cleaning and disinfection procedure, damage to the endoscope (eg cracks in the endoscope channels) can be recognized, which would remain undetected if one would only focus on the quality of the process until an infectious outbreak occurs. The authors of the Multi-Society Guideline hold the microbiological checks for an "unresolved issue". Also the updated guidelines of the European Society of Gastrointestinal Endoscopy, clearly support the microbiological control of the endoscope treatment. (Leiß, Bader et al. 2008)

Annex 9 Action to take on finding contaminated rinse water

Note: This summary is intended for the reader who wishes to learn more from the original sources. The summaries are ordered by the year of publication. The summaries are taken from the papers and represent the findings and opinions of the authors of those publications. A full reference list in given under “References” including full bibliographic details, which will enable any library to obtain a copy of the referenced publication.

Richards 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 disinfector components are compatible with the intended concentration of disinfectant. The filters should be changed or decontaminated at this stage. 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. 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.

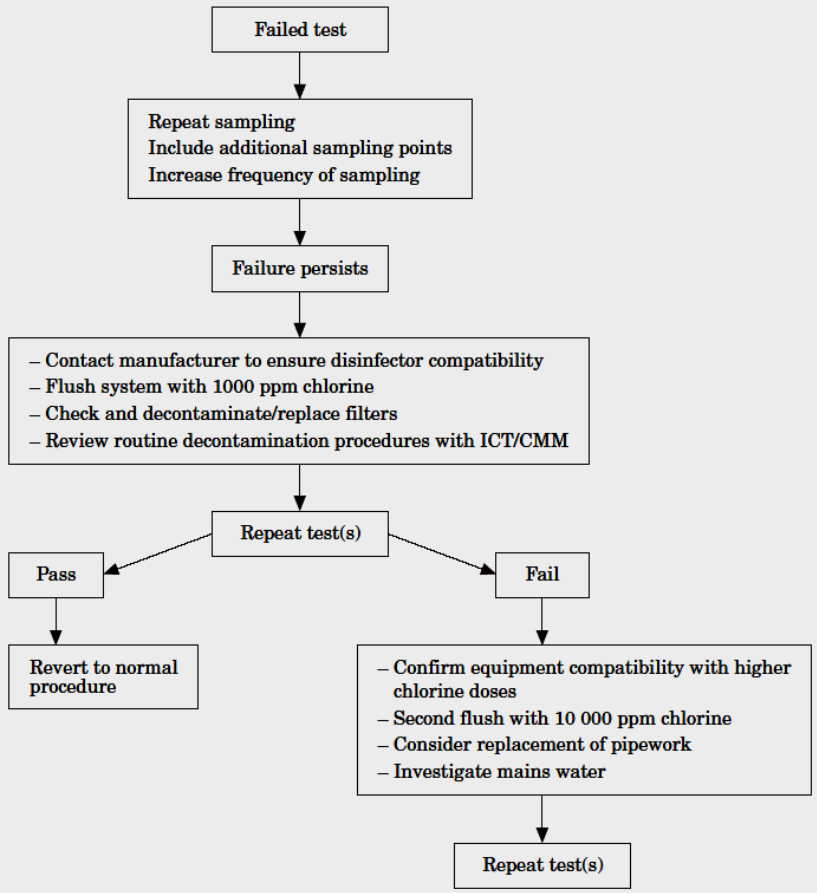

Figure 1 Action to be taken when contaminated rinse water is discovered.

(Richards, Spencer et al. 2002)

Whilst the recommendation for the bacterial quality of final rinse water is that bacteria should be absent in 100 ml, it is unclear at what level of contamination the machines should be considered unfit for use. It is, therefore, important that action levels and remedial actions are clearly identified, in order to avoid unnecessary expenditure of time and money on inappropriate responses to microbiology results. Whilst there is a clear need for guidance on the expected quality of final rinse water, it appears that current guidelines may be unhelpfully rigid, leaving endoscopy staff unclear about how urgently to react to even low numbers of bacteria in water samples. The guidelines issued by the joint working group of the Hospital Infection Society and the Public Health Laboratory Service (Richards, Spencer et al. 2002) give detailed guidance on remedial actions to be taken on finding contaminated rinse water, but do not identify a level of bacteria above which the washer-disinfector should be taken out of use. Thus, it is tempting for staff to repeatedly carry out remedial actions and re-test water samples whilst still using the washer-disinfector. It is suggested by Muscarella (Muscarella 2002) that low numbers of bacteria remaining on an endoscope after washing may become problematic if the endoscope is subsequently stored wet and in a moist environment for several hours, but that a few bacteria per millilitre of final rinse water may be considered acceptable if the endoscope is dried thoroughly using 70% alcohol followed by forced air after cleaning and before storage. As part of our local investigations of elevated bacterial numbers in rinse water, Infection Control teams checked microbiological records for patients on whom affected endoscopes may have been used. None of these checks revealed any cases of nosocomial infection likely to be due to endoscopy rinse-water

contaminants. Therefore, in most instances, it seems reasonable to view low numbers of bacteria in final rinse water as undesirable but not necessarily a cause for immediate alarm. We would suggest that guidelines consisting of a series of action levels of increasing severity would be of more practical use to hospital staff than the current single guideline of 'bacteria-free' water. The table shows an example of how action levels might be set; these reflect the current policies of local Infection Control teams that have been developed from their experiences to date. However, it should be noted that there are certain situations where a more stringent interpretation of results may be appropriate, such as bronchoscopy of immunosuppressed patients. It is considered that *Mycobacterium spp*. are undesirable in any numbers. However, results should be addressed by means of a risk assessment, with presence of mycobacteria in water used to rinse bronchoscopes being viewed as more significant than in rinse water for other types of endoscope. (Willis 2005)

Table. *Example of how future guidelines might be produced consisting of a series of action levels of increasing severity*

Aerobic colony count in 100 ml	Interpretation/action
0	Satisfactory
1–9 (achieved on a regular basis)	Acceptable – indicates that bacterial numbers are under a reasonable level of control
10–100	Unsatisfactory – investigate potential problems and super-chlorinate
>100	Unacceptable – take washer-disinfector out of use until water quality improved

(Willis 2005)

Annex 10 Water quality; test procedures

Method 1: (DoH 2009)

Introduction
The following test will only detect the presence of mesophyllic aerobic bacteria which do not have specialized nutritional requirements. If particular micro-organisms are of concern (such as mycobacteria and legionalla) other recovery conditions (growth medium, incubation temperature, etc.) should be used as appropriate. The advice of the microbiologist should be sought. The following test should be carried out by the qualified personnel.
Note: Microbiological enumeration tests and alternative methods for control of microbiological quality are described in the EP.

Apparatus:
- Sterile single use containers 250 ml;
- Sterile filter membranes (47 mm diameter, ≤ 0.45 µm pore size);
- Suction filtration apparatus;
- Incubator set at 35ºC ± 2ºC;
- Tryptone soya agar plates;

Note: The medium should have been demonstrated as capable of recovering an inoculum of 10–100 cells of *Pseudomonas aeruginosa*.
- Isopropanol 70% and non-woven wipes.

Method: sample collection
- Wipe the discharge surfaces of the sampling point thoroughly with 70% isopropanol and allow to evaporate to dryness.
- Run off not less than 50 ml through the sampling point and discard.
- Take the sample downstream of any filter or other device or equipment intended to remove or control microbial contamination in the water supply. The washing chamber may be a suitable site to take the sample from.
- Using aseptic handling techniques collect not less than 200 ml of sample in the sterile container and close the lid securely. Label the container with details of the sampling point and the time and date the sample was collected.
- Transfer the sample to the laboratory for testing within 4 h; if this is not possible the sample should be stored at 2ºC to 5ºC for not more than 48 h before testing.

Method: 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 35ºC ± 2ºC for 48 h to 72 h. Carry out the test in duplicate.
- Examine the filters daily and record the number of colony forming units which are visible.

Method 2: (Richards, Spencer et al. 2002)

- 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 50ml through the sampling point and discard. Using aseptic handling techniques, collect not less than 400ml of sample from each sampling site in a sterile container and close the lid securely. Alternatively, 500ml 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 100ml aliquot of the sample through a 0.45 mm 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.

Method 3: (Willis 2005):

Water samples
Samples of 400–500 ml were collected from washer-disinfector outlets into sterile bottles containing sodium thiosulphate to neutralize any residual chlorine in the water. They were then transported to the laboratory in cold boxes maintained between 2 and 8 °C and were tested on the day of collection.

Determination of aerobic colony count
A membrane filtration technique was used. Duplicate aliquots of 100 ml were filtered through sterilized funnels, using a membrane of pore size 0.45 mm. Following filtration, membranes were placed on yeast extract agar plates and incubated at 37°C for 48 h. The total number of colonies on each membrane was then counted.
If presumptive *P. aeruginosa* colonies were identified, their presence was reported. These were identified as blue/green, oxidase-positive colonies that fluoresced under ultra-violet light.

Detection of environmental mycobacteria
A single 100-ml aliquot of water was filtered onto a membrane as described above. The membrane was placed on a Middlebrook (7H11) agar plate and incubated at 30°C for 7 days. Following incubation, suspect colonies were counted and the identity confirmed by performing an acid-fast stain. Acid-fast bacilli were considered to be *Mycobacterium spp.*

Annex 11 Drying of endoscopes

Note: This summary is intended for the reader who wishes to learn more from the original sources. The summaries are ordered by the year of publication. The summaries are taken from the papers and represent the findings and opinions of the authors of those publications. A full reference list in given under “References” including full bibliographic details, which will enable any library to obtain a copy of the referenced publication.

For endoscopes that have been properly cleaned, disinfected, and stored there appears to be no benefit to an additional reprocessing cycle before use. If a well designed EWD is used of which the process parameters are regularly checked, and the endoscope is stored in a drying cabinet, re-disinfection before use of the endoscope is not necessary. When the endoscope is not stored in a drying cabinet, or one has doubts about the dryness of the endoscope, the general view is that it shall be reprocessed after four hours. This period of four hours is not based on clinical research or infection data. Fact is that after a latency time bacterial growth starts and after four hours it has reached a level that warrants the reprocessing of the endoscope before use. This applies to all types of endoscope, the simple bronchoscope and the ERCP-scoop alike. (WIP 2003)

There has been some controversy regarding the need for reprocessing immediately before the first procedure of the day of an endoscope that has been appropriately reprocessed and stored previously. Although there are little or no data supporting this practice, the British Society of Gastroenterology, the European Society of Gastrointestinal Endoscopy, and the Association of Perioperative Registered Nurses all recommend that endoscopes undergo a reprocessing cycle before the first patient of the day. The US Multi-Society guidelines, based on current evidence (or more accurately, the lack of evidence that this practice provides a clinical benefit), do not recommend this practice for endoscopes that have undergone appropriate cleaning, disinfection, and storage. In one of the few studies performed to specifically address this issue, a variety of endoscopes was cultured immediately after disinfection and storage, and subsequently every other day for 5 days. Only four out of 135 cultures were positive, all of which were skin contaminants. To minimize the possibility that this contamination was an artifact introduced by the repeated sampling procedure, in the second part of the study, 10 endoscopes were cultured after storage for 5 days; all cultures were negative. Although a small study, it does suggest that endoscopes that have been appropriately reprocessed and stored do not need an additional reprocessing cycle prior to use. This confirms the findings of an earlier study suggesting that an additional reprocessing cycle for endoscopes is unnecessary even after storage for up to 1 week. (Nelson 2005)

To prevent microbial growth or transmission in a moist environment, the insertion tube and channels should be thoroughly dried. Rinsing channels with 70% alcohol and directing compressed air through the damp lumens will facilitate drying. Fatal infections with waterborne *P. aeruginosa* learned that the organism was able to proliferate in the channels of the endoscope. To control the outbreak, the investigators adopted a procedure of suctioning 70% alcohol through all channels, followed by compressed air to completely dry the instrument. Drying with alcohol and compressed air should be done between each patient use when tap water is used to rinse the endoscope channels and before storage whether tap water or sterile water is used. This greatly reduces the possibility of recontamination of the endoscope by waterborne micro-organisms. (Alvarado and Reichelderfer 2000)

Water is used to remove the disinfectants used during endoscope reprocessing. Contamination by waterborne bacteria was considered a factor in several outbreaks of endoscope and washer contamination. Delivery of bacteria-free water for endoscope decontamination is considered a complex and expensive undertaking that requires routine microbiological monitoring of the water. Nevertheless, monitoring of the rinse water used during the reprocessing of endoscopes remains controversial. Drying the endoscope after every reprocessing cycle is considered an alternative to reduce the transmission of waterborne micro-organisms. (Seoane-Vazquez and Rodriguez-Monguio 2008)

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