Water quality requirements for surgical instrument reprocessing

Paper 2: The reprocessing of Stainless Steel Instruments

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1.Introduction

This is the second paper in a series of 4 investigating water quality requirements for the reprocessing of surgical instruments. This paper focuses on stainless steel instruments. It must be read in conjunction with paper 1, which provides background information to the project and a table comparing SMTL test results for water quality with HTM2030 requirements. Newer Welsh HTM guidance has been published since this work was commissioned. The papers presented here are reference documents that investigate the evidence for water quality recommendations.

Most reusable surgical instruments are made of stainless steel which is mechanically strong and tolerant to reasonably harsh environments due to the chromium content which gives it corrosion resistant properties. A protective surface layer (known as the passivation layer) forms on the exposed steel surface when the metal comes in to contact with the oxygen in the environment and 'self-passivates' to form a chromium-rich oxide surface which is resistant to corrosion.

Stainless steel comes in a range of grades. British standard (BS EN ISO 7153 Surgical instruments-Metallic materials-Part 1:Stainless steel (1991)) categorises stainless steel into alphabetically labelled groups and provides examples of the types of instruments and parts that each grade should be used for. The type of stainless steel used for many surgical instruments is 'martensitic' (grades A-I, K and R), a strong and hard steel containing carbon and chromium with moderate corrosion resistant properties (see www.bssa.org.uk for more information). Austenitic alloys (grades M-O) contain chromium and nickel, and tend to have better corrosion resistance, particularly to chloride. However, they are unsuitable for high strength and cutting applications required for many surgical instruments[1]

The quality of stainless steel instruments can vary in terms of the steel composition (which can affect aspects such as hardness and corrosion resistance) and how the instrument is forged (which can also affect the accuracy of the instrument design or 'pattern') (Coole 2009)[2]. Quality issues such as these can impact the performance of the device following repeated reprocessing.

As well as the quality of the instrument, it has been suggested that stainless steel instrument damage during reprocessing can be due to other factors including the quality of water used in the washer

1 Communication with Peter Mitchell, B Braun

2 Author of paper is Director of Surgical Holdings, a UK manufacturer of specialised surgical instruments

disinfector, detergents, additives and the quality of steam used in the sterilizer (Hooper 2003). However, there is a danger of focusing on minor defects which may be related to water or instrument quality. As one of the consultees noted,

> '*overemphasis on minor defects (such as surface discolouration) has the potential to expect a perfection which is both unrealistic and unaffordable, particularly as the ability to focus down to sub-microscopic details becomes greater'* [3].

2. Impact of water quality characteristics on stainless steel instruments

2.1 Water hardness

Water hardness is variable throughout the UK and is usually specific to the geographical area where the water is sourced (Shah and Bernardo 2002, Fisher 2003). Reprocessing stainless steel instruments with hard water may lead to lime scale deposition on the instruments, the washer disinfector or the water pipes, which can reduce the effectiveness of cleaning products, make microorganisms more difficult to remove (AAMI 2008, p8, section 3.2.3.5) and even lead to corrosion of the instrument underneath the deposit (Proper Maintenance of Instruments (PMI), 2009, p17).

Wales is mainly a soft water area and therefore water hardness is not usually an issue for most Welsh CSSD departments. Rinse water results usually fall within the limits stipulated in HTM2030. The 'Welsh Water Supply (water quality) Regulations 2010 (no. 994, W.99)' do not specify hardness requirements for potable water.

One participant in the consultation process stated that they had experienced no problems with calcium or magnesium but rather with manganese due to their source of water coming from boreholes in local sandstone, which illustrates the difficulty of legislating for all circumstances[4].

Even if water hardness levels are not an issue for stainless steel instrument quality, machines may 'scale up' as a result of hard water and Health Boards may feel that it is appropriate to address this by installing a water softener, for example. A small number of hospitals have reported problems due to the scaling up of machines which may have been due to geographical location as well as changes in water supply[5]. In addition, hardness levels can have an effect on the performance of process chemicals. The recently published WHTM 01/01 part D recommends a maximum value of 210 mg/L $CaCO_3$ because of this.

Recommendation 1: The hardness levels of rinse water is not considered to affect patients. No limits are therefore recommended in this document for water hardness. However, testing for water hardness is useful for trend monitoring and may provide helpful information about changes in local water conditions. In addition, although the focus of this document is the effects of water quality on surgical instruments, high levels of water hardness may lead to the scaling of washer-disinfector machines which may be detrimental. The decision about whether and how often to test for water hardness is a local decision.

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3 Communication with Craig Macintosh, Principal Clinical Scientist, Wirral University Teaching Hospitals NHS Foundation Trust.

4 Communication with Craig Macintosh

5 Information supplied by member of NHS Wales Shared Services Partnership

Criticality: water hardness is a non-critical parameter

Evidence:

1. SMTL test results clearly show that Welsh water hardness levels are within HTM limits.

2. The opinion of the Welsh water group is that hardness has not traditionally been a problem for stainless steel instruments and therefore no hardness limits should be specified.

After consultation, no data or evidence was provided to support a specific hardness limit. This recommendation will be reviewed and revised if data becomes available to support a particular limit.

2.2 Total dissolved solids (including silicates, phosphates, heavy metals, iron)

There is a correlation between water conductivity and the concentration of dissolved salts it contains. High concentrations of dissolved salts can produce a high conductivity levels and indicate impurities in the water. Conductivity is a simple test that can be carried out regularly and can be helpful in identifying unusual trends (this test is specified in the WHTM 01/01 D guidance). However, conductivity alone provides limited information and unexpected results indicate that other parameters should be investigated.

Fisher (2003) reported that, in his experience, silicate was responsible for the scaling of steam sterilisers rather than for the corrosion of instruments in washer-disinfectors. He therefore argued that the limits described in the document for washer-disinfectors could be relaxed if instrument corrosion was the major issue of concern.

The PMI document (2009) states that discolouration of stainless steel instruments can occur due to silicates, iron, copper or manganese but that this is harmless and does not cause corrosion of devices.

A surgical instrument manufacturer has stated that silicate can discolour instruments but that it was not detrimental to instrument quality (personal communication).

PMI (2009) states that most chemicals in water used for instrument processing have no harmful effects on surgical instrumentation. The main exception to this is chloride (PMI 2009, p14) (see section 1.3).

European standard EN15883[6] does not provide limits for total dissolved solids. The AAMI document states that 'excessive TDS are corrosive and can lead to spotting'. It recommends a TDS limit of <500 mg/l $CaCO^3$ in potable water which is misleading as $CaCO^3$ is only part of TDS and tends to define water hardness rather than TDS (AAMI, Table 1 2008). The Welsh water data have

6 Part 1 (General requirements, terms and definitions and tests) and Part 2 (Requirements and tests for washer-disinfectors employing thermal disinfection for surgical instruments, anaesthetic equipment, bowls, dishes, receivers, utensils, glassware) are relevant to stainless steel instrument reprocessing.

TDS values between 140-200 mg/l, which falls well within the AAMI limit.

Recommendation 2: Most dissolved chemicals have no harmful effects on surgical instruments and there is no evidence suggesting that they are harmful to patients. We recommend that as long as 'potable quality' water is being supplied, no limit for silicates, phosphates, heavy metals or iron are necessary.[7]

Criticality: Total dissolved solids is a non-critical parameter

Evidence:

1. PMI (2009) states total dissolved solids cause discolouration but not corrosion of instruments – expert opinion and some case studies with photographic evidence available

2. Fisher (2003) states that silica is 'not a corrosive issue' – expert opinion

2.3 Chloride levels

The main group of chemicals the PMI document (2009) raises concerns about are halides (of which chloride is a member). Chloride can damage the passive (protective chromium oxide) layer of stainless steel which can range from small black spots to large corrosive holes, depending on the concentration of chloride present. Experience has shown that any corrosion related to chloride levels will be detected by engineers in the steel sterilizer chamber before any corrosion is identified on instruments[8].

Some studies have investigated the effect of body fluids on stainless steel implants by immersing the metal in 0.9% sodium chloride solution to mimic the body's environment. One study reported that corrosion occurred with increasing temperature, once the 'critical pitting temperature' had been reached which in this case was 70ºC (no time scale was mentioned) (Ornhagen et al., 1996). Another observed that corrosion occurred when implants had been immersed in solution for 14 days (Grimsdottir et al., 1992). However, the chloride concentration and exposure time in these studies are greater than those seen in surgical instrument reprocessing.

PMI (2009) states that if chloride levels are less than 120mg/l, the probability of instrument damage is low at room temperature. The chance of corrosion increases with factors such as increased temperature, insufficient drying and particularly the presence of residues on the dried instrument (PMI 2009). Rinse aid can help prevent this by enabling water to run off the instruments rather than slowly drying on them. The AAMI document recommends that potable water has less than 250 mg/l chloride and that chloride concentrations below 120mg/ml avoid corrosion, although it does not cite any specific evidence for this (AAMI, 2008, section 5.2.2.2(d)). HTM2030 states a maximum chloride concentration of 10mg/l. Some (but not all) Welsh water test results failed this limit but all were at or below 50mg/l . A chloride limit of 50 mg/l is an appropriate compromise as it

7 WHTM 01/01 D recommends that these variables are only tested in the event of operational problems.
8 Personal communication with the NHS Wales Shared Services Partnership

appears to be an achievable limit which has not been associated with reports of chloride corrosion in Wales[9] and is lower than the concentrations known to cause corrosion (i.e. >120 mg/l).

The 'Proper Maintenance of instruments' document recommends the use of fully demineralised water for the final rinse of instruments (PMI, 2009, section 7). The reasons given are that demineralised water prevents spotting, staining, deposits and corrosion. If instruments are being visually inspected prior to use, which is routine in most CSSD/HSDU facilities, and chloride levels monitored, then the use of demineralised rinse water is unnecessary.

Recommendation 3: High chloride levels can damage surgical steel instruments but the concentrations observed in Welsh water used for reprocessing has not historically caused instrument problems. As a result of this we recommend that the limit for chloride be relaxed from 10mg/l to 50mg/l. Relaxation of this limit assumes that visual checking of instruments is being performed**.**

Criticality: Chloride is a semi-critical parameter as high levels can damage instruments which may be detrimental to patients

Evidence:

1. PMI (2009) : <120 mg/l does not cause corrosion at room temperature. Chance of corrosion increases with temperature and dried residues (expert opinion and photographic evidence).

2. SMTL test results show that the chloride concentration of final rinse water in Wales is 5.5-50 mg/l (primary evidence based on well designed experiments).

3. AAMI document recommends that potable water has less than 250 mg/l chloride and that chloride concentrations below 120mg/ml avoid corrosion (guidance document written by experts in the field – although no evidence for these recommendations are cited in the document)

4. Chloride corrosion of instruments has not been observed as a problem by CSSD managers and NHS Wales Shared Services Partnership – expert opinion

Please note: we have taken advice on the recommendation and the general consensus is that as long as appropriate instrument checking is being undertaken this relaxation in limit is considered to be acceptable

2.4 pH

Stainless steel can withstand a wide range of pH, and would certainly be unaffected by the usual pH

9 Personal communication with the NHS Wales Shared Services Partnership

range of mains water, therefore the pH of rinse water is unlikely to be an issue for patients. The AAMI document states that water that is either too acidic (pH less than 6) or too alkaline (pH greater than 9) can cause pitting and staining of instruments and shorten their useful lives (AAMI, 2008). Extremes in pH are not an issue in mains water and all Welsh CSSD rinse water samples fall well within the pH limits set in the HTM2030 Instruments are often exposed to extremes in pH during the cleaning process as some detergents are very alkaline. Therefore, the pH of rinse water appears to be inconsequential when compared to this.

Recommendation 4: The pH of water in the Welsh NHS falls within the range stated in the present HTM2030 (pH 5.5-8) and it is proposed that this range is kept.

Criticality: pH is a non-critical parameter

Evidence:

1. SMTL test results show that extremes of pH have not been observed within the Welsh NHS (primary evidence)

2. AAMI (2008) - Extremes of pH can damage surgical instruments (Based on expert opinion)

2.5 Endotoxin levels

Biofilm formation is common in pipework and hence it can be difficult to eliminate bacteria from the water system (Phillips et al., 1998). Gram negative bacteria can produce high levels of endotoxin (ET) after their inactivation. These endotoxins can cause pyrexia in humans (and can contribute to shock). Studies have shown that increasing the concentration of intravenously administered endotoxin results in a dose-related inflammatory response in human subjects (Suffredini et al 1999). Most studies are based on intravenous administration, and it is difficult to relate this to acceptable ET levels in rinse water, their subsequent deposition on surgical instruments and the effect that these residual endotoxins may have on patients.

The United States Pharmacopoeia (USP) and FDA[10] guidelines state that non-intrathecal injections have a limit of 5 endotoxin units per Kg (EU/Kg) and intrathecal injections have a limit of 0.2 EU/Kg (maximum dose in an hour). Therefore a 70 Kg adult should tolerate up to 350 EU intravenously over the course of an hour without any adverse effects.

Approximately 70% of ET results for Welsh NHS rinse water over the last 5 years have been under 20 EU per ml. The AAMI document states that a limit of 100 EU/ml in rinse water is unlikely to stimulate adverse patient reactions (AAMI, 2008, section 3.2.3.2). However, the HTM2030 stipulates that final rinse water in a washer-disinfectors should contain no more than 0.25 endotoxin units per ml (EU/ml) of endotoxin.

A recent study investigated the necessity for such a limit by measuring the ET concentration on instruments at different stages of reprocessing: after washing-disinfection, clean room handling and steam sterilisation (Steeves and Steeves 2006). Instruments were either spiked with endotoxin or depyrogenated (ET removed) before reprocessing. When ET-spiked instruments were directly

[10] FDA websie www.fda.gov/ICECI/Inspections/InspectionGuides/InspectionTechnical guides/ucm072918.htm

placed in the steam steriliser without being handled, levels were considerably reduced (from approximately 4000 EU per instrument to an average of 237 EU per device) although not eliminated. Results showed that depyrogenated instruments were contaminated with ET after handling by HSDU staff in the clean room after washing-disinfection had taken place, but that subsequent steam sterilisation virtually eliminated this ET, probably because the steam rinses ET off when it condenses.

These results indicate that testing rinse water from washer-disinfectors is not a useful indicator of final ET contamination of instruments, as contamination can occur after this stage of reprocessing. The authors described the rinse water limit of 0.25 EU/ml (the same limit used for water for injection) as 'unnecessarily stringent' because steam sterilisation reduced endotoxins at the final reprocessing stage (Steeves and Steeves 2006).

A similar study contaminated stainless steel instruments with high levels of endotoxins (Flocard et al 2006) and also contaminated the water feeding the steam sterilizer. The authors found that following reprocessing in these conditions, instruments possessed no more contamination than negative controls. Their conclusion was that 'there is no danger in using contaminated water' (p 102)

It has been suggested that, rather than testing rinse water for endotoxins, it may be more appropriate to measure the ET load on individual devices after processing and sterilisation, when they are ready for use, and check for compliance with the USP limit of 20 EU per device. This value is extrapolated from the USP limit on intravenous administration (350 EU for a 70 kg adult) and is more conservative in order to take into account the non-specific adsorption of ET on the surface of the instrument. SMTL have been performing this test for most Trusts/Health Boards in Wales for over 10 years on a quarterly basis, during which period less than 20 EU were detected in almost all (> 99 %) cases. It therefore appears that the routes for endotoxin contamination in Wales (water levels and inspection/packing staff) do not contribute significantly to levels on sterilised instruments. As endotoxin levels on 'ready to use' instruments appear to be more relevant than levels in rinse water, the handler should ensure good hand hygiene to minimise contamination. Testing of endotoxin levels on 'ready to use' instruments is a more useful indicator than the testing of rinse water.

Recommendation 5: Endotoxin level in rinse water is not a good predictor of endotoxin level on instruments after packing and sterilisation. Limited evidence indicates that most ET is removed during steam sterilisation, and few instruments fail the USP limit of 20 EU/device. We therefore recommend that if potable water is being used for final rinse, the requirement for endotoxin testing of final rinse water is removed and instead, the testing of ET load on 'ready to use' instruments is performed. We recommend applying the USP limit of <=20 EU per device. The measurement of ET levels on instruments addresses concerns that users have with regards to patient safety rather than ET levels in rinse water, which have been shown to be unrelated.

Criticality: Endotoxin level is a critical parameter as a high load of ET on an instrument could be a major risk to patient health. However, evidence suggests that the loads detected on autoclaved instruments are very low

Evidence: -

1. Steeves and Steeves 2006- handling instruments contaminates them with ET, steam sterilisation which follows this significantly reduces it. (primary research – well designed laboratory research)

2. Flocard et al 2006- ET contaminated steam sterilizer does not lead to contamination of instruments. (primary research -well designed laboratory studies).

3. AAMI (2008) – rinse water containing less than 100 EU/ml is unlikely to have a detrimental effect on patients (Based on expert opinion)

4. SMTL test results – over the last 5 years, the majority of rinse water results have been less than 20 EU/ml (primary research)

5. USP recommend a limit of 20 EU/device. (Based on expert opinion)

2.6 Bacterial contamination/TVCs

The contamination of instruments with viable microbes is one of the main concerns surrounding patient safety, due to the risk of infection following surgery. However, because terminal sterilisation with an autoclave takes place after the final rinse, the relevance of testing rinse water for bacteria has been questioned.

The European standard BS EN ISO 15883 part 1 ('Washer-disinfectors', published in 2009) states that 'rinse water used in final stage after disinfection shall be of potable quality or better' (section 5.3.2.5).

The AAMI document places a limit of 200 cfu/ml on potable, softened and de-ionised water (table 1, section 4). De-ionised water is considered acceptable (although high-purity water is recommended) for the final rinse of 'critical' devices (i.e. devices which directly contact the bloodstream or sterile areas of the body) if there is no endotoxin issue (table 1, AAMI). Specific recommendations for critical devices that have been terminally sterilised such as stainless steel instruments, are not provided in the AAMI guidance. However, the document does comment that using the highest disinfection level water available may be unnecessary and it is acknowledged that stainless steel instruments have 'different water quality issues' to other critical devices that cannot be steam sterilized (section 4.1). The conclusion drawn from the AAMI guidance is that a cfu limit of 200 cfu/ml for rinse water for stainless steel instruments is acceptable.

This seems reasonable as the validation of sterilisers is based on the 'Overkill' approach (Lewis 2002). The 'overkill' approach is a sterilisation cycle based on a 'worst case scenario'. The usual acceptance of sterility is based on a sterility assurance level (SAL) value of 10^{-6} (where there would be a one in a million chance of finding one viable micro-organism on an instrument). An 'overkill' cycle is a calculation for heat stable loads based on a theoretical contamination with10^{6} resistant organisms achieving a SAL of 10^{-6} . This therefore gives a 12-log reduction in viable organisms.

Autoclaves commonly use steam heated within the range of 121–134 °C. To achieve sterility, a holding time of at least 15 minutes at 121 °C or 3 minutes at 134 °C is required. CSSDs in Wales tend to sterilise using 134-137 ºC for 3 to 3.5 minutes. This is in line with recommendations in HTM 2020 (Sterilization part 2, 1995) and more recently in ISO 17665. ISO 17665 specifies requirements for the development, validation and routine control of a moist heat sterilization process for medical devices. ISO 17665 - Part 1 (2006) provides general guidelines on steam sterilization requirements and operations whereas part 2 (2009) aims to describe these guidelines more specifically through the use of examples and further explanation.

It is clear that the standard UK sterilisation cycle can eliminate high challenges of microbial contamination. Therefore, residual contamination from rinse water should not pose any significant problems when assuring the sterility of instruments. Whilst there is the potential for the dead micro-organisms to leave residual endotoxin on the instruments, the risks appear to be low or negligible as discussed in the previous section.

Therefore, the bioburden levels stipulated in HTM2030 (0 cfu in 100 ml) are thought to be unnecessarily stringent for instruments undergoing final sterilisation. In the light of the AAMI recommended limit of 200 cfu/ml and the fact that the data collected by SMTL reveals that Welsh water has cfu levels much lower than this, a limit of 50 cfu/ml appears reasonable.

Recommendation 6: Due to the terminal sterilisation process undergone by these instruments current limits can be relaxed to less than 50 cfu per ml (5000 cfu per 100 ml).

Criticality: The TVC level is a critical parameter as viable CFUs on an instrument would be a major risk to patient health. However, terminal sterilisation of instruments means that the actual risk from this source is extremely low.

Evidence:

1. AAMI (2008) Suggests a 200 cfu/ml limit for potable and de-ionised water. (Based on expert opinion).

2. Lewis (2002) -Lewis's validation paper discussing the 'overkill' approach calculates the conditions required to achieve the appropriate 'sterility assurance level' for stainless steel instruments (based on strong theoretical rationale and previous validation work by author).

3. HTM2020 (1995) states temperature and length of cycle required in order to achieve desired level of sterility (based on expert opinion).

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