# The importance of water quality in sterilization practice

**Wayne Spencer**

# Water Quality

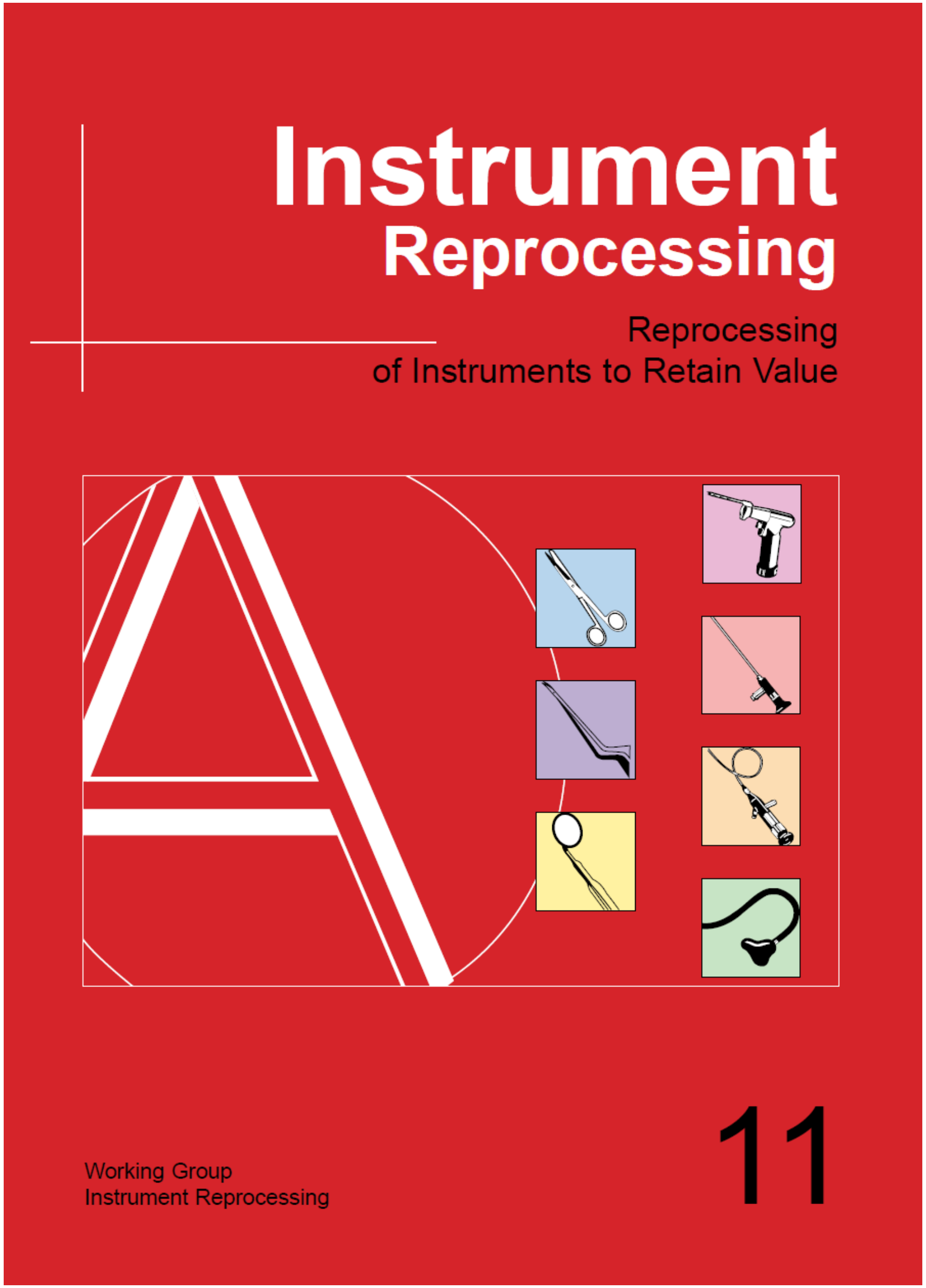
- Important for the following:
  - Raw water source for steam generation
  - Washer disinfectors – cleaning
  - Washer disinfectors – thermal disinfection
  - Flexible endoscopes – diluting disinfectant
  - Flexible endoscopes – post-disinfection rinsing

# Water - Considerations

- At each stage the water quality should be compatible with:
  - the materials of construction of the Sterilizer/WD/Boiler/Steam Generator
  - the load items to be processed
  - any chemical additive used
  - the requirements of that particular process

# Water - Properties

- Hardness
- Ionic/Organic contamination
- Microbial Contamination
- Bacterial endotoxins
- Temperature




## Use correct water quality!

Unfavorable water composition can have an adverse effect both on the reprocessing procedure and on the appearance of the instruments and materials.

Available in English and Chinese:
https://en.a-k-i.org/rote-broschuere

# Chemical Purity – The Patient

- Metals: Many of these are toxic (some are cumulative poisons) and therefore their presence is undesirable. Of particular concern include cadmium, lead, mercury and other heavy metals.
- Organic compounds: Many of these are biologically active and therefore undesirable. The chief compounds of concern are filming amines and other chemicals that may be used in boiler treatment.
- Pyrogens: These are bacterial endotoxins, predominantly derived from Gram-negative bacteria, which can cause severe reactions when administered intravenously.
- Particulate material: Solid particles can lead to a number of adverse effects if injected into the body.

# Chemical Purity – The Patient

## TASS (Toxic Anterior Segment Syndrome)

- Acute inflammatory response - introduction of foreign material into the anterior chamber of the eye
- Associated with:
  - Contaminated solutions (BSS),
  - Detergent residues,
  - Endotoxins from overgrowth of gram-negative bacilli in ultrasonic cleaners,
  - Foreign matter,
  - Preservatives,
  - Degradation of brass on surgical instruments sterilized with gas plasma
  - Impurities of autoclave steam

*"Most cases of TASS appear to result from inadequate instrument cleaning and sterilization"*

Nick Mamalis, MD, *Toxic Anterior Segment Syndrome* Journal of Cataract and Refractive Surgery 2006; 32:324-333.

# Chemical Purity – The Instruments, Boiler And Chamber

- Alkaline earth metals cause “hardness” which can lead to build-up of lime scale on load items, in the sterilizer/washer chamber and in pipework. Most problems are caused by calcium and magnesium, and to a lesser extent strontium.
- Iron, whether in metallic or ionic form, is corrosive to stainless steel.
- Chlorides in the presence of oxygen lead to pitting corrosion and (to a lesser extent) crevice corrosion in stainless steel. The effects can be controlled by limiting the amount of oxygen in the feedwater.
- Phosphates and silicates act to concentrate chloride ions and so promote their corrosive effects.

# Chemical Purity – Contamination

- Contaminants in final rinse water of washer-disinfectors
- Contaminants present in the water supply from which the steam is generated;
- Contaminants arising from treatment of the boiler feedwater;
- Contaminants arising in the distribution system carrying steam to the sterilizer.

# Hardness – The Forgotten Requirement?

- Hard water is high in dissolved minerals, specifically calcium and magnesium
- Released if the water is heated to form lime scale!
- UK Ministry of Health Report on Water Softening[1] – identified that 0.5 mm of hard scale increases fuel costs by 9.4%. Similar evidence is cited in more recent studies[2]: 0.8mm scale increases fuel costs by 10%
- In washers it impairs detergent use
- Hardness deposits act as a focus for soiling and recontamination of the item in use
- May seriously impair the utility of an endoscope, particularly the optical system

[1] Ministry of Health, Water Softening, Report of the Sub-committee of the Central Advisory Water Committee, 1949
[2] Federal Technology Alert – Non-Chemical Technologies for Scale & Hardness Control, US Department of Energy

# Why Is Hardness Important?

- Using hard water in the final rinse stages of a washer cycle or in a boiler/steam generator is one of the major cause of deposits on instrumentation
- They act as a focus for soiling and recontamination of the item in use
- May seriously impair the utility of an endoscope, particularly the optical system
- Increase energy costs

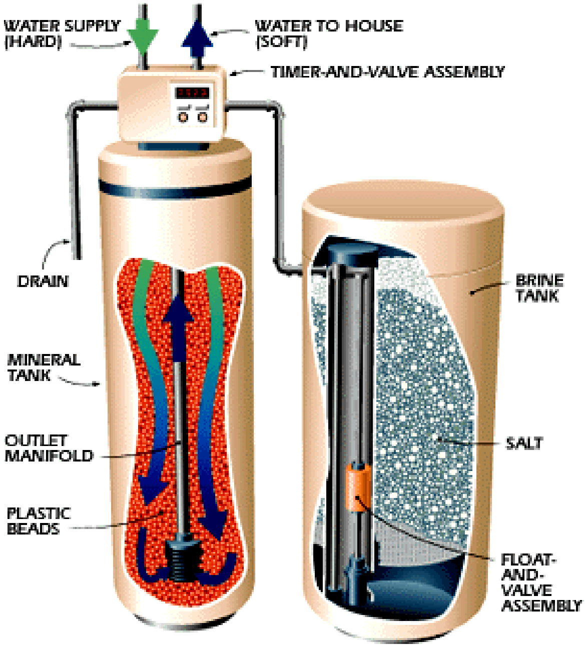
| Application | Requirement |
|---|---|
| Initial flush | Hardness less than 200 mg/L $CaCO_3$ |
| Intermediate flush | Hardness less than 200 mg/L $CaCO_3$ |
| Water for diluting disinfectants and detergents | Hardness less than 50 mg/L $CaCO_3$ |
| Final rinse-water (see also Table 1 in 'Water system' in the 'Testing methods' volume) | Hardness less than 50 mg/L $CaCO_3$<br>TOC less than 1 mg/L<br>Conductivity less than 40 µS/cm, unless disinfectant added |

# Why Is Hardness Important For RO?

- Fouling of the membrane resulting in less membrane space for the water to pass through, leading to:
  - More pressure being required
  - Higher energy use
  - Increase of the cleaning frequency
  - Shorter life span of the membranes

# Curing the Hardness Problem

- Softeners have tanks filled with food-grade resin beads that are dosed with sodium ions (salt and water mix - brine)
- As the water passes through the tanks the resin beads attract and hold on to the magnesium and calcium minerals and 'exchange' the sodium ions
- This process makes the water soft
- Needs regular regeneration to wash away remaining magnesium and calcium salts and redose with sodium salts (brine)



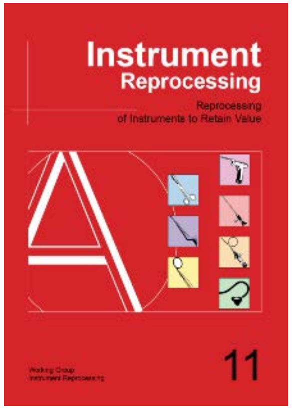
***Ionic and mineral contamination:***

- Create cosmetic changes as a minimum
- May lead to more serious damage such as corrosion

**Silicates**
Silicic acid and silicates may cause white-gray, yellowish brown or bluish purple discolorations even at low concentrations.

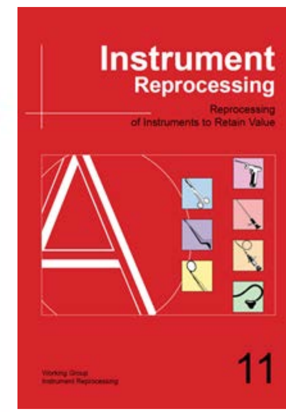
**Chlorides**
Chlorides dissolved in the water are particularly critical substances, as they tend to cause pitting even on stainless steel instruments if present in higher concentrations.
The danger of chloride-induced pitting generally rises with:

- An increase in the chloride content,
- An increase in temperature,
- Declining pH value,
- Increasing exposure time,
- Insufficient drying,
- Concentration of chloride resulting from adherence of dry residues to instrument surfaces after evaporation.

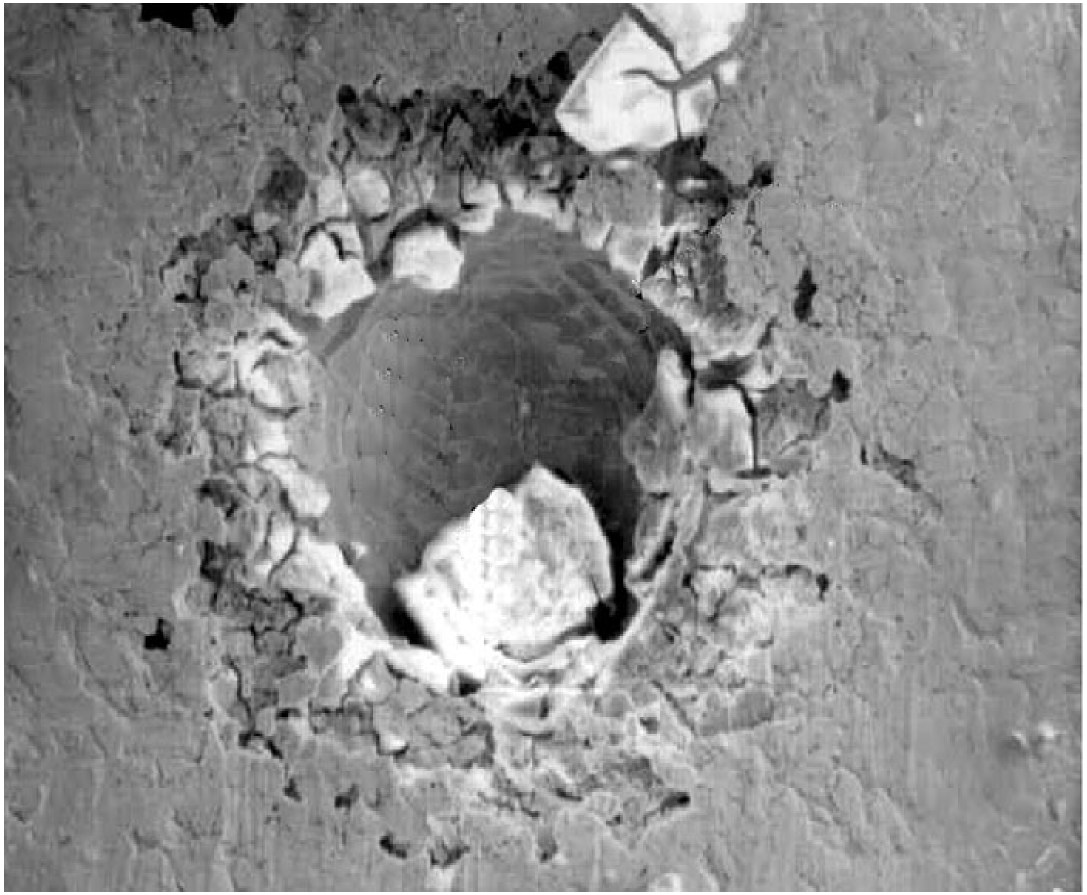


Titanium oxide discoloration occurs mostly on reflective surfaces over large surfaces, yellow-brown to blue-violet, sometimes with a shimmering appearance, in the wash chamber or over the entire surface of the instrument during machine-cleaning.

Typical silicate discoloration occurs, regardless of the nature of the surface, over large surfaces, yellow-brown to blue-violet in the cleaning & disinfection process, or in spots, droplet-shaped with pronounced condensation stain-like appearance during the steam sterilization process.

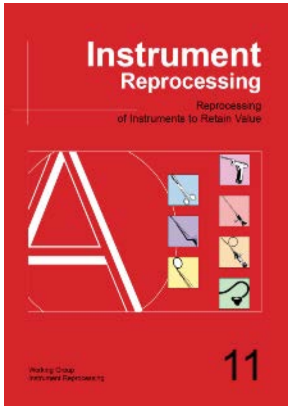


# Water



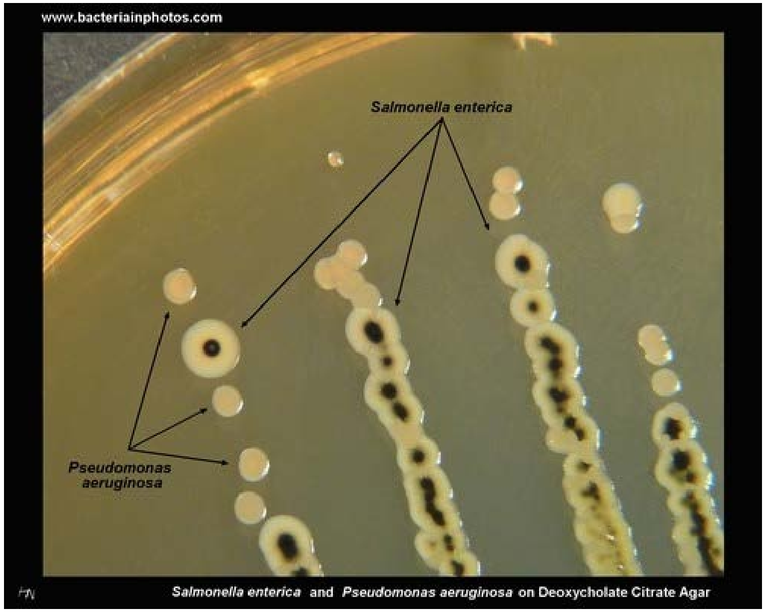
The water constituents may cause the following problems:

| | |
|---|---|
| Minerals causing water hardness (calcium and magnesium salts) | Scaling, lime deposits due to calcium and magnesium salts, corrosion potential |
| Heavy and nonferrous metals, e.g. iron, manganese, copper | Brown-red deposits, secondary rust |
| Silicates, silicic acid | White-grey, colored appearance, thin scaling |
| Chlorides | Pitting |
| Evaporation residue | Spotting and scaling |



# Microbiological contamination

- Contravenes the purpose of decontamination
- Critical where water is used as a final rinse and there is no following sterilization process



# Microbiological contamination

- This will be removed by some purification methods

- Weekly TVC limits of post-disinfection rinse water (e.g. for WD's in which a product is rinsed <u>after</u> the disinfection stage):
  - 10cfu/100ml in ISO15883 Part 4

- Annual TVC limits of thermal disinfection rinse water:
  - 100cfu/100ml

# Biofilm Build Up

- Can happen in most machine designs somewhere
- Sometimes present in the machine on delivery
- Chemical self-disinfect machines and water systems are more prone to it than thermal systems
- Engineer out dead-legs and hiding places
- Interface between the Washer and water treatment system is often a problem
- While most bacteria are trapped within a biofilm, the biofilm will constantly generate bacteria that are released as free-floating individual cells (planktonic forms), and parts of the biofilm may slough off in clumps
- Hyperchlorination is not effective against established biofilms. Consider replacing affected parts
- Additional ultrafiltration may be needed near point of use in low temperature water systems

# Bacterial Endotoxins

- Can create toxic shock and a serious patient reaction
- Impact still being debated with some thinking it is of little affect on most people at much higher levels than specified
- Limits originate from standards for Water For Injection (WFI)
- It is difficult to remove endotoxins from products once present. It is far better to keep finished products and components relatively endotoxin-free rather than have to remove it once present (FDA Advice).
- This may be removed by purification or may need additional endotoxin filtration
- In ISO 15883 = National Guidelines

# Temperature

- To feed steam generation systems
  - At a high enough temperature to prevent non-condensable gases forming (80-90 °C)
- For Sterilizers
  - Because of the effect of temperature on the performance of the vacuum system, the water temperature should not
  - exceed 15 °C
- For Washer-disinfectors
  - removal of gross soling pre-wash stages <45°C to preclude the occurrence of protein coagulation
  - For main wash and thermal rinse stages, too low extends cycle time due to need to heat water

# Standards for Chemical Purity of Steam

ISO 17665 Part 1:

- Contaminates contained within the sterilizing agent shall not impair the safety of the product for its intended use
- Refers to EN285 steam quality

# Chemical Purity – ISO 17665 Part 2

**Table A.1 — Contaminants in condensate measured at the steam inlet to the sterilizer to be considered in relationship to the corrosion of materials**

| Determinand | Condensate |
|---|---|
| Silicate ($SiO_2$) | u 0.1 mg/l |
| Iron | u 0.1 mg/l |
| Cadmium | u 0.005 mg/l |
| Lead | u 0.05 mg/l |
| Rest of heavy metals except iron, cadmium, lead | u 0.1 mg/l |
| Chloride ($Cl^-$) | u 0.1 mg/l |
| Phosphate ($P_2O_5$) | u 0.1 mg/l |
| Conductivity (at 25 °C) | u 3 µS/cm |
| pH value (degree of acidity) | 5 to 7 |
| Appearance | Colorless clean without sediment |
| Hardness (Σ ions of alkaline earth) | u 0.02 mmol/l |
| NOTE A method by which a sample of condensate can be taken is given in subclause 22.4 of EN 285:2006. | |

# Chemical Purity – ISO 17665 Part 2

**Table A.2 — Contaminants in condensate from steam used by the sterilizer to be considered in relation to contamination of the load**

| Determinand | Clean steam condensate |
|---|---|
| Acidity or alkalinity | R[a] |
| Ammonium ($NH_4$) | u 0.2 mg/l |
| Calcium and magnesium | R[a] (mg/l) |
| Heavy metals | u 0.1 mg/l |
| Chloride ($Cl^-$) | u 0.5 mg/l |
| Nitrate ($NO_3$) | u 0.2 mg/l |
| Sulphate ($SO_4$) | R[a] (mg/l) |
| Oxidizable substances | R[a] |
| Residue on evaporation | u 30 mg/l |
| Silicate ($SiO_2$) | u 0.1 mg/l |
| Phosphate ($P_2O_5$) | u 0.1 mg/l |
| Conductivity (25 °C) | u 35 µS/cm |
| Bacterial endotoxins | u 0.25 EU/ml |
| Appearance | Clear, colorless |

[a] Reagent test specified in European Pharmacopoeia.

NOTE A method by which a sample of condensate can be taken is given in subclause 22.4 of EN 285:2006.

# Chemical Purity – A Comparison

| | |
|---|---|
| Silicate | ≤0.1 mg/L (corrosion) |
| Heavy metals | ≤0.1 mg/L (corrosion and load) |
| Cadmium | ≤0.005 mg/L (corrosion) |
| Lead | ≤0.05 mg/L (corrosion) |
| Chloride | ≤0.1 mg/L (corrosion), ≤0.5 mg/L (load) |
| Phosphate | ≤0.1 mg/L (corrosion and load) |
| Conductivity | ≤3 µS/cm (corrosion), ≤35 µS/cm (load) |
| pH | 5–7 (corrosion) |
| Hardness | ≤0.02 mmol/L (corrosion) |
| Appearance | clear, colourless, no sediment (corrosion), clear and colourless (load) |
| Endotoxins | ≤0.25 EU/mL (load) |
| Ammonium | ≤0.2 mg/L (load) |
| Nitrate | ≤0.2 mg/L (load) |
| Sulphate | Ra (load) |
| Oxidisable Sub | Ra (load) |
| Evap Residue | ≤30 mg/L (load) |
| Calcium & magnesium | Ra (load) |

NOTE: This table is a combination of tables A1 (re: corrosion)

# Water Purity – ISO 15883

- Tests for chemical purity shall include tests for those determinands known to influence the efficacy of the process.
- NOTE This can include, but is not limited to, tests to determine the value of the following:
  - conductivity;
  - pH;
  - oxidizable substances
  - total hardness (salts of $Ca2+$, $Mg2+$, $Sr2+$ expressed as mmol $CaCO3$)
  - total dissolved solids (TDS) determined as evaporative residue
  - inorganic phosphate [Pi] and inorganic silicate [$SiO2$
  - chloride [$Cl-$]

# UK HTM 01-01 Instrument Washer

| Determinant and Unit | Maximum permitted values | |
|---|---|---|
| | Final rinse | Other processes |
| Appearance | Clear, colourless | - |
| Degree of acidity [pH] | 5.5 to 8.0 | - |
| Conductivity at 25ºC [uS/cm] | 30 | - |
| Total dissolved solids [mg/100ml] | 4 | - |
| Total hardness, $CaCO_3$ [mg/l] | 50 | 50 |
| Chloride, Cl [mg/l] | 10 | 120 |
| Heavy metals, determined as Lead, Pb [mg/l] | 10 | - |
| Iron, Fe [mg/l] | 2 | - |
| Phosphate,$P_2O_5$ [mg/l] | 0.2 | - |
| Silicate, $SiO_2$ [mg/l] | 0.2 | 2 |
| Total Viable Count at 22ºC<br>at 37ºC<br>[cfu/100ml] | 100<br>100 | -<br>- |
| Bacterial endotoxins [EU/ml] | 0.25 | - |

# ISO TS 5111



**ISO/WD TS 5111:202X(X)**

ISO TC 198

Secretariat: AAMI

**Sterilization of health care products – Quality of water for sterilizers, sterilization and washer-disinfectors**

WD

**Warning for WDs and CDs**

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Recipients of this draft are invited to submit, with their comments, notification of any relevant patent rights of which they are aware and to provide supporting documentation.

# ISO TS 5111

**Table B.2 – Examples of recommendations for quality of final rinse water used in a WD**

| **Criterion** | **AS/NZS 4187:2014 +A2:2019** | **ISO 15883-4: 2018** | **AAMI ST 108** | **HTM 01-01/HTM 01-06** | **DGKH, DGSV and AKI Guideline** | |
|---|---|---|---|---|---|---|
| | | | | | **Softened water** | **Demineralized water** |
| pH | 5,5 – 8,0 | a) | 5,0 – 7,5 | 5,5 – 8,0 | 5 – 8 | 5 to 7,5 |
| Conductivity at 20 °C | ≤ 30 µS/cm | a) | < 10 µS/cm | ≤ 30 µS/cm | Not specified | ≤15 µS/cm |
| Total hardness | ≤ 10 mg /l $CaCO_3$ | a) | <1 mg /l $CaCO_3$ | < 50 mg/l $CaCO_3$[b)] | < 0,5 mmol $CaO_3$/l (< 3°dH) | ≤ 0,02 mmol/l |
| Residue on evaporation | Not specified | Not specified | Not specified | <40 mg/l | < 500 mg/l | ≤ 10 mg/l |
| Chloride | ≤ 10 mg/l | a) | <1 mg/l | < 10 mg/l | < 100 mg/ or < 50 mg/l[b)] | ≤ 0,5 mg/l |
| Iron | ≤ 0,2 mg/l | a) | <0,1 mg/l | < 2 mg/l | Not specified | ≤ 0,2 mg/l |
| Phosphates (molybdate reactive) | ≤ 0,2 mg/ l | a) | <1 mg/l | ≤ 0,2 mg/ l | Not specified | ≤ 0,5 mg/l |
| Silicates (molybdate reactive) | ≤ 1,0 mg/l | a) | <1 mg/l | ≤ 0,2 mg/ l | Not specified | ≤ 1 mg/l |
| Total viable count | ≤ 100 CFU/ 100 ml | ≤ 10 CFU/100 ml | <10 CFU/ml | ≤ 100 CFU/ 100 ml | Not specified | Not specified |
| Bacterial endotoxin | ≤0,25 EU/ml | a) | <10 EU/ml | ≤ 0,25 EU/ml | Not specified | Not specified |

# Getting Good Quality Feed/Rinse Water

***Purification methods:***

- Softening – removal of deposits from hard water
- Filtration – removes impurities from the water
- Ion Exchange – using beads to remove organic material
- Reverse Osmosis – membrane technology filtration
- Distillation – boiling to remove impurities

# So After Softening?

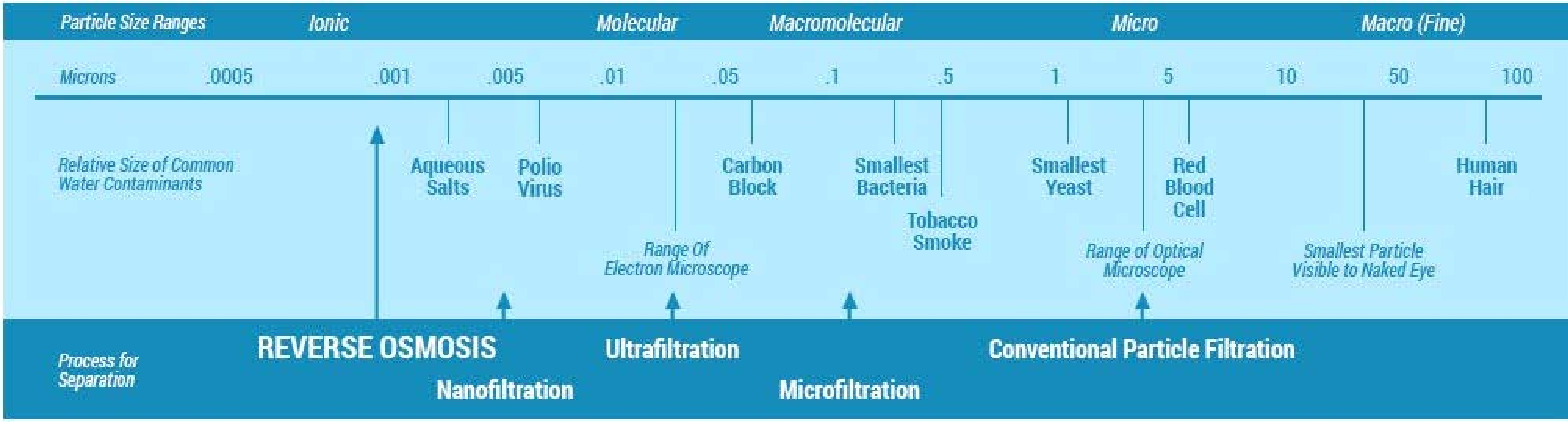
**Purification methods:**

- Demineralisation – may lead to microbe pass-through
- Reverse Osmosis – preferred method due to balance of cost versus performance
- Distillation – expensive and unnecessary

Get good quality washer rinse water and then use the same/similar treatment system to supply water for steam generation!

# Osmosis System Removal

Below are the various particulate removal thresholds for various water purification methods.




## TYPICAL REJECTION CHARACTERISTICS OF R.O. MEMBRANES

Elements and the Percent R.O. Membranes will remove

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| **Sodium** | 85 – 94% | **Iron** | 94 – 98% | **Lead** | 94 – 98% | **Manganese** | 94 – 98% |
| **Sulfate** | 96 – 98% | **Zinc** | 95 – 98% | **Arsenic** | 95 – 98% | **Cadmium** | 95 – 98% |
| **Calcium** | 94 – 98% | **Mercury** | 95 – 98% | **Magnesium** | 95 – 98% | **Barium** | 95 – 98% |
| **Potassium** | 85 – 95% | **Selenium** | 94 – 96% | **Nickel** | 84 – 92% | **Cyanide** | 84 – 92% |
| **Nitrate** | 60 – 75% | **Phosphate** | 96 – 98% | **Fluoride** | 85 – 92% | **Chloride** | 85 – 92% |

% may vary based on membrane type water pressure, temperature & TDS

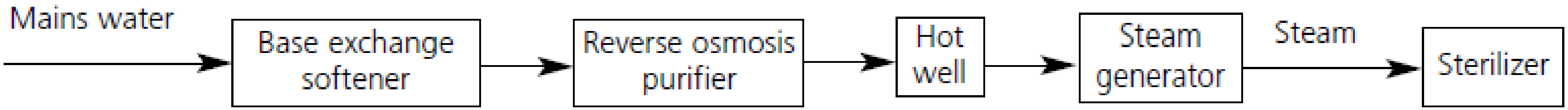
# Getting Good Quality Steam

- Feedwater should be as free as possible of contaminants (using RO is advised)
- The boiler should be designed to prevent water droplets being carried over into the steam
- The boiler should be operated to prevent foaming and priming
- The distribution system carrying steam from the boiler to the sterilizer should be resistant to corrosion

# Getting Good Quality Steam

- A boiler system designed and operated to provide minimal carry-over of entrained water droplets will be able to maintain a low level of contaminants in the steam even where the quality of feedwater is poor
- However, if the feedwater is of low quality, even small deviations from optimum operating conditions may result in large amounts of contaminants being carried over

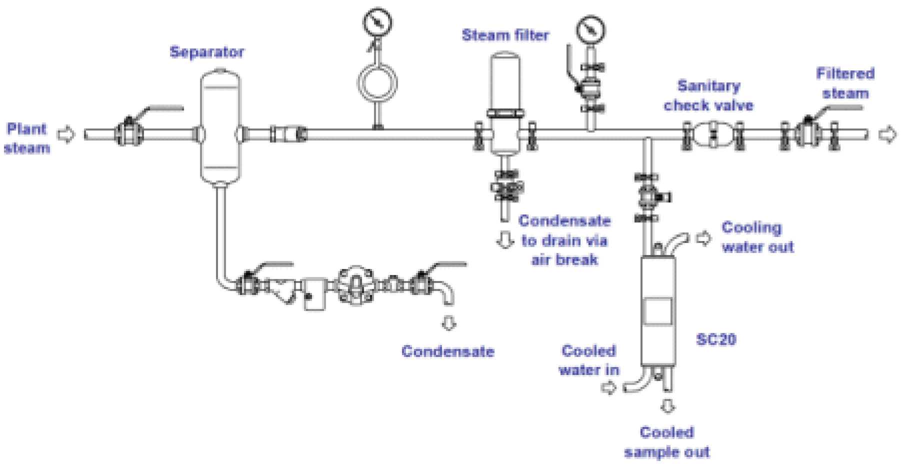
# Getting Good Quality Steam



# Getting Clean Steam

- A dedicated system must therefore:
  - minimise the amount of non-condensable gases and other contaminants in the boiler feedwater
  - prevent liquid water leaving the boiler and being delivered in the steam
  - prevent microbial growth in any storage tank or pipework
  - be constructed from materials resistant to corrosion and particle shedding, such as low-carbon stainless steel (type 316L)
- The capacity of the generator should be sufficient to meet both maximum and minimum demands while still maintaining the requirements for dryness and non-condensable gases
- Requires a means of separating entrained water droplets from the steam before it is delivered to the sterilizer

# Steam Supply Components That Can Assist With Clean Steam - Steam Filters



# Decontamination Water Control

- Have a policy and….. Use it, not ignore it!
- Trend test results
- Integrate with the hospitals water group – do not sit in isolation!
- When failures are experienced - Full documentation must be kept – who did what and when!
- Look at the system as a whole – water supply, RO plant, filters, washer-disinfector, steam generators and BEHAVIOUR!
- Avoid over-reaction - Water is transient and failures can be one off!

# Chemical Purity

## Remember:

With Steam – The water you put in affects the quality of the what you get out!