Water for re-processing

Requirements

Design

Monitoring

1

Instrument Washer Disinfector - ISO 15883 parts 1* and 2		
Determinant and unit Maximum permitted values	**Final rinse water**	**Other stages (See Note 2)**
Degree of acidity (pH)	5.5 to 8.0	
Conductivity at 25ºC (µS/cm)	≤30	
Total hardness, CaCO3 (mg/L)	≤10	150
Chloride, Cl (mg/L)	≤10	120
Iron, Fe (mg/L)	≤0.2	
Phosphate, P2O5 (mg/L)	≤0.2	
Silicate, SiO2 (mg/L)	≤1	
Total viable count (TVC) (See Note 1)	≤100/100ml	
Bacterial endotoxins (EU/mL)	≤0.25	

**ISO 15883-1 is the umbrella (i.e. horizontal) standard that applies to all WDs. Specific or altered requirements are given in each of its subsequent parts (i.e. vertical standards) for different types of WD.*

Note 1. For TVC, test methodology should be in accordance with ISO 15883-1 and the HTM 01-01 series.
Note 2: This quality of water may be suitable for use in the final rinse of washer-disinfectors within the scopes of ISO 15883-3, ISO 15883-6 and ISO 15883-7.

AS/NZS 4187:2014 + AMDT 2:2019

2

Thermolabile Endoscope Washer Disinfector ISO 15883 parts 1* and 4		
Determinant and unit Maximum permitted values	**Final rinse water**	**Other stages**
Total viable count (TVC) (See Note 1)	≤10/100ml	In accordance with WD manufacturer's recommendations
Pseudomonas aeruginosa	Not detected/100 mL	
(Atypical) Mycobacterium sp.	Not detected/100 mL	
Chemical purity	In accordance with WD manufacturer's recommendations	
Bacterial endotoxins (EU/mL)	≤30 EU/mL	

**ISO 15883-1 is the umbrella (i.e. horizontal) standard that applies to all WDs. Specific or altered requirements are given in each of its subsequent parts (i.e. vertical standards) for different types of WD.*

AS/NZS 4187:2014 + AMDT 2:2019

3

Feed water to a dedicated steam generator — for Steam Sterilizers

Determinant and unit	Maximum permitted values
Evaporative residue	≤10 mg/L
Silicates (molybdate reactive)	≤1.0 mg/L
Iron	≤0.2 mg/L
Cadmium	≤0.005 mg/L
Lead	≤0.05 mg/L
Heavy metals excluding Iron, cadmium, lead	≤0.1 mg/L
Chloride	≤0.5 mg/L
Phosphates (molybdite reactive)	≤0.5 mg/L
Conductivity at 20°C	≤5 µs/cm
pH	5–7.5
Appearance	Colourless, clear without sediment
Hardness	≤0.02 mmol/L equivalent to ≤2 mg CaCO3/L

AS/NZS 4187:2014 + AMDT 2:2019

4

Where are these requirements coming from

5

Guidance for Industry

Pyrogen and Endotoxins Testing: Questions and Answers

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)
Center for Biologics Evaluation and Research (CBER)
Center for Veterinary Medicine (CVM)
Center for Devices and Radiological Health (CDRH)
Office of Regulatory Affairs (ORA)

June 2012
Compliance

https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-pyrogen-and-endotoxins-testing-questions-and-answers

6

11. What are the endotoxins limits for medical devices?

The Center for Devices and Radiological Health (CDRH) has adopted the USP Endotoxin Reference Standard and limits for medical device extracts expressed in EU/mL. USP Chapter <161> Transfusion and Infusion Assemblies and Similar Medical Devices provides the limits for medical devices within its scope. The endotoxins limit for a medical device is dependent on the intended use of the device and what the device contacts (e.g., blood, the cardiovascular system, cerebrospinal fluid, intrathecal routes of administration, permanently implanted devices, and devices implanted subcutaneously).[27]

For medical devices, using the extraction volume recommendations described below, the limit is 0.5 EU/mL or 20 EU/device for products that directly or indirectly contact the cardiovascular system and lymphatic system. For devices in contact with cerebrospinal fluid, the limit is 0.06 EU/mL or 2.15 EU/device. For devices that are in direct or indirect contact with the intraocular environment, a lower endotoxins limit may apply. Please contact the appropriate review division for specific recommendations.

7

Cleaning – Mechanical Method: **Manual Cleaning**

extracted from DePuy IFU 'Processing Synthes Reusable Medical Devices'

Equipment: various sized soft-bristled brushes, lint-free cloths, syringes, pipettes and/or water jet, neutral enzymatic cleaner or neutral detergent with a pH between 7 and 9.

1. Disassemble device, if device is able to be disassembled, prior to cleaning. Refer to technique guide or other supplemental information for specific device disassembly and/or reassembly instructions.
2. Rinse soiled device under running cold tap water for a minimum of two minutes. Use a soft-bristled brush to assist in the removal of gross soil and debris.
3. Soak device in a neutral pH enzymatic cleaner or detergent solution for a minimum of ten minutes. Follow the enzymatic cleaner or detergent manufacturer's instructions for use for correct exposure time, temperature, water quality and concentration.
4. Rinse device with cold water for a minimum of two minutes. Use a syringe, pipette, or water jet to flush lumens, channels and other hard to reach areas.
5. Manually clean device for a minimum of five minutes in a freshly prepared neutral pH enzymatic cleaner or detergent solution. Use a soft-bristled brush to remove soil and debris. Actuate joints, handles and other movable device features to expose all areas to the detergent solution, if applicable. Clean device under water to prevent aerosolization of contaminants. *Note: fresh solution is a newly- made, clean solution.*
6. Rinse device thoroughly with deionized (DI) or purified (PURW) water for a minimum of two minutes. Use a syringe, pipette or water jet to flush lumens and channels. Actuate joints, handles and other moveable device features in order to rinse thoroughly under running water, if applicable.
7. Visually inspect device. Repeat the manual cleaning procedure (steps 2- 6) until no visible soil remains on device.
8. Perform a final rinse on device using DI or PURW water.
9. Dry device using a clean, soft, lint-free cloth or clean compressed air.

http://synthes.vo.llnwd.net/o16/LLNWMB8/IFUs/JJMDC/DPS/CMF/DJ1305I.pdf

8

Cleaning – Mechanical Method: **Mechanical Washer**

extracted from DePuy IFU 'Processing Synthes Reusable Medical Devices'

Process device using the following cycle parameters:

Cycle	Minimum Time (minutes)	Minimum Temperature/Water	Type of Detergent
Pre-wash	2	Cold tap water	N/A
Wash I	2	Cold to warm tap water	Neutral enzymatic pH between 7 and 9
Wash II	5	Warm tap water (>40°C)	Detergent with pH between 7 and 9
Rinse	2	Warm DI or PURW (>40°C)	N/A
Dry	40	90°C	N/A

http://synthes.vo.llnwd.net/o16/LLNWMB8/IFUs/JJMDC/DPS/CMF/DJ1305I.pdf

9

Cleaning – Mechanical Method: **Ultrasonic**

extracted from DePuy IFU 'Processing Synthes Reusable Medical Devices'

Pre-clean method (Pre-clean method must be performed prior to ultrasonic mechanical method listed below.)

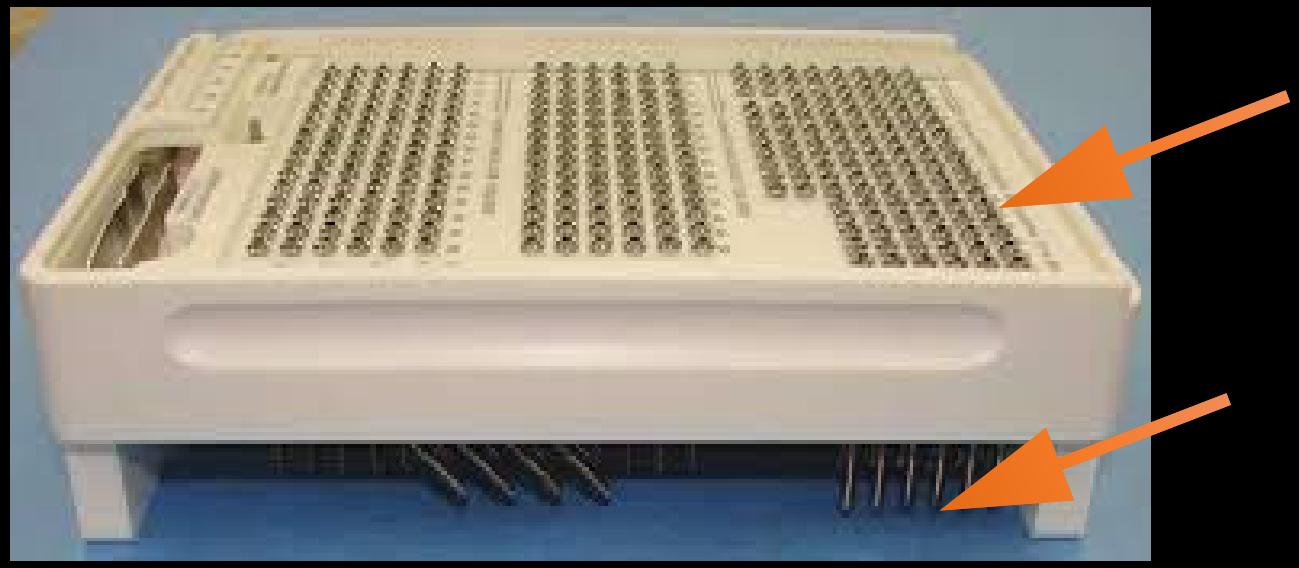
1. Disassemble device, if device is able to be disassembled, prior to cleaning. Refer to technique guide or other supplemental information for specific device disassembly and/or reassembly instructions.
2. Rinse soiled device under running cold tap water for a minimum of two minutes. Use a soft-bristled brush to assist in the removal of gross soil and debris.
3. Soak device in a neutral pH enzymatic cleaner or detergent solution for a minimum of ten minutes. Follow the enzymatic cleaner or detergent manufacturer's instructions for use for correct exposure time, temperature, water quality and concentration.
4. Rinse device with cold water for a minimum of two minutes. Use a syringe, pipette, or water jet to flush lumens, channels and other hard to reach areas.
5. Manually clean device for a minimum of five minutes in a freshly prepared neutral pH enzymatic cleaner or detergent solution. Use a soft-bristled brush to remove soil and debris. Actuate joints, handles and other movable device features to expose all areas to the detergent solution, if applicable. Clean device under water to prevent aerosolization of contaminants. *Note: fresh solution is a newly- made, clean solution.*
6. Rinse device thoroughly using cold or warm tap water for a minimum of two minutes. Use a syringe, pipette or water jet to flush lumens and channels. Actuate joints, handles and other moveable device features in order to rinse thoroughly under running water, if applicable.
7. Visually inspect device. Repeat steps 2- 6 until no visible soil remains on device.

Ultrasonic process: (Pre-cleaning steps 1 -7 should occur prior to this step.)

8. Prepare a fresh detergent solution using a neutral pH enzymatic cleaner or detergent. Follow the enzymatic cleaner or detergent manufacturer's instructions for use for correct exposure time, temperature, water quality and concentration. *Note: fresh solution is a newly- made, clean solution.*
9. Clean Synthes device ultrasonically for a minimum of 15 minutes, using a minimum frequency of 40 KHz.
10. Rinse device thoroughly with deionized (DI) or purified (PURW) water for a minimum of two minutes. Use a syringe, pipette or water jet to flush lumens and channels. Actuate joints, handles and other moveable device features in order to rinse thoroughly under running water, if applicable.
11. Visually inspect device. Repeat steps 2- 10 until no visible soil remains on device.
12. Perform a final rinse on device using DI or PURW water for a minimum of 15 seconds.
13. Dry device using a clean, soft, lint-free cloth or clean compressed air.

http://synthes.vo.llnwd.net/o16/LLNWMB8/IFUs/JJMDC/DPS/CMF/DJ1305I.pdf

10



Consider the result of residual contamination on an implantable screw that is re-processed in a screw caddie in a vertical orientation. Residue will tend to accumulate and concentrate around the under side of the screw head at the contact point of the caddie, and at the point/tip of the screw.

11


RICHARD WOLF
spirit of excellence
Manual
Reprocessing
of
RICHARD WOLF
Heat-Stable Instruments
GA-J020 / en / 2014-05 V17.0 / PDI 13-6891

12

Water Quality can affect instrument life

extracted from 'Reprocessing of Richard Wolf Heat-Stable Instruments'

The water quality used for product reprocessing has a great influence on the preservation of value.

Depending on the water hardness and temperature, differing drinking water qualities (types and concentrations of ingredients) can cause difficult-to-dissolve hardness deposits, corrosion and discoloration on the products.

The concentration of the water ingredients varies depending on the source and type of drinking water treatment. When water evaporates these ingredients remain in the form of a salt crust. Amongst these ingredients chlorides are particularly critical.

☞ ***IMPORTANT!***

Excessive chloride concentrations cause pitting corrosion on stainless steel!

To avoid this when machine-cleaning products, we recommend using fully demineralized water of a defined water quality in accordance with DIN EN 285, Appendix B for the final rinsing.

https://www.richard-wolf.com/mam/data/Typo3/Sonstige_Downloads/Aufbereitung/Thermostabile%20Instrumente/GA-J020-en.pdf

13

EN 285 – Sterilization – Steam Sterilizers

Annex B
(informative)

Steam supply; suggested maximum values of contaminants in feed water and condensate

Table B.1 — Contaminants in feed water supplied to a dedicated steam generator

Determinand	Feed water
Residue on evaporation	≤ 10 mg/l
Silicate (SiO_2)	≤ 1 mg/l
Iron	≤ 0,2 mg/l
Cadmium	≤ 0,005 mg/l
Lead	≤ 0,05 mg/l
Rest of heavy metals except iron, cadmium, lead	≤ 0,1 mg/l
Chloride (Cl^-)	≤ 2 mg/l
Phosphate (P_2O_5)	≤ 0,5 mg/l
Conductivity (at 25 °C)	≤ 5 µS/cm
pH value (degree of acidity)	5 to 7,5
Appearance	Colourless clean without sediment
Hardness (Σ Ions of alkaline earth)	≤ 0,02 mmol/l
NOTE Compliance should be tested in accordance with acknowledged analytical methods.	

Table B.2 — Contaminants in condensate from steam supply to the sterilizer measured at the sterilizer inlet

Determinand	Condensate
Silicate (SiO_2)	≤ 0,1 mg/ l
Iron	≤ 0,1 mg/ l
Cadmium	≤ 0,005 mg/l
Lead	≤ 0,05 mg/l
Rest of heavy metals except iron, cadmium, lead	≤ 0,1 mg/l
Chloride (Cl^-)	≤ 0,1 mg/l
Phosphate (P_2O_5)	≤ 0,1 mg/l
Conductivity (at 25 °C)	≤ 3 µS/cm
pH value (degree of acidity)	5 to 7
Appearance	Colourless clean without sediment
Hardness (Σ Ions of alkaline earth)	≤ 0,02 mmol/l
NOTE A method by which a sample of condensate can be taken is given in 22.4.	

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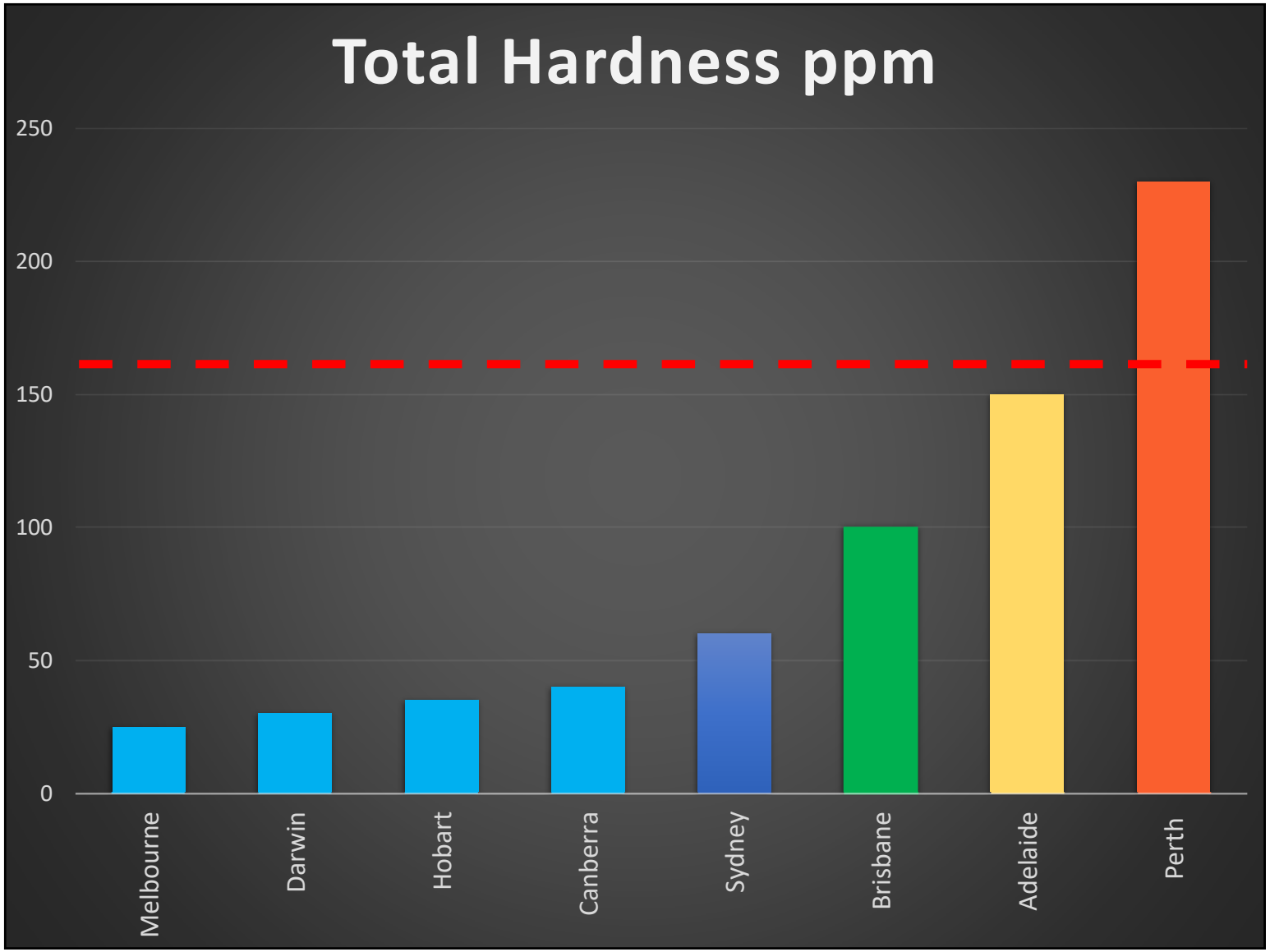
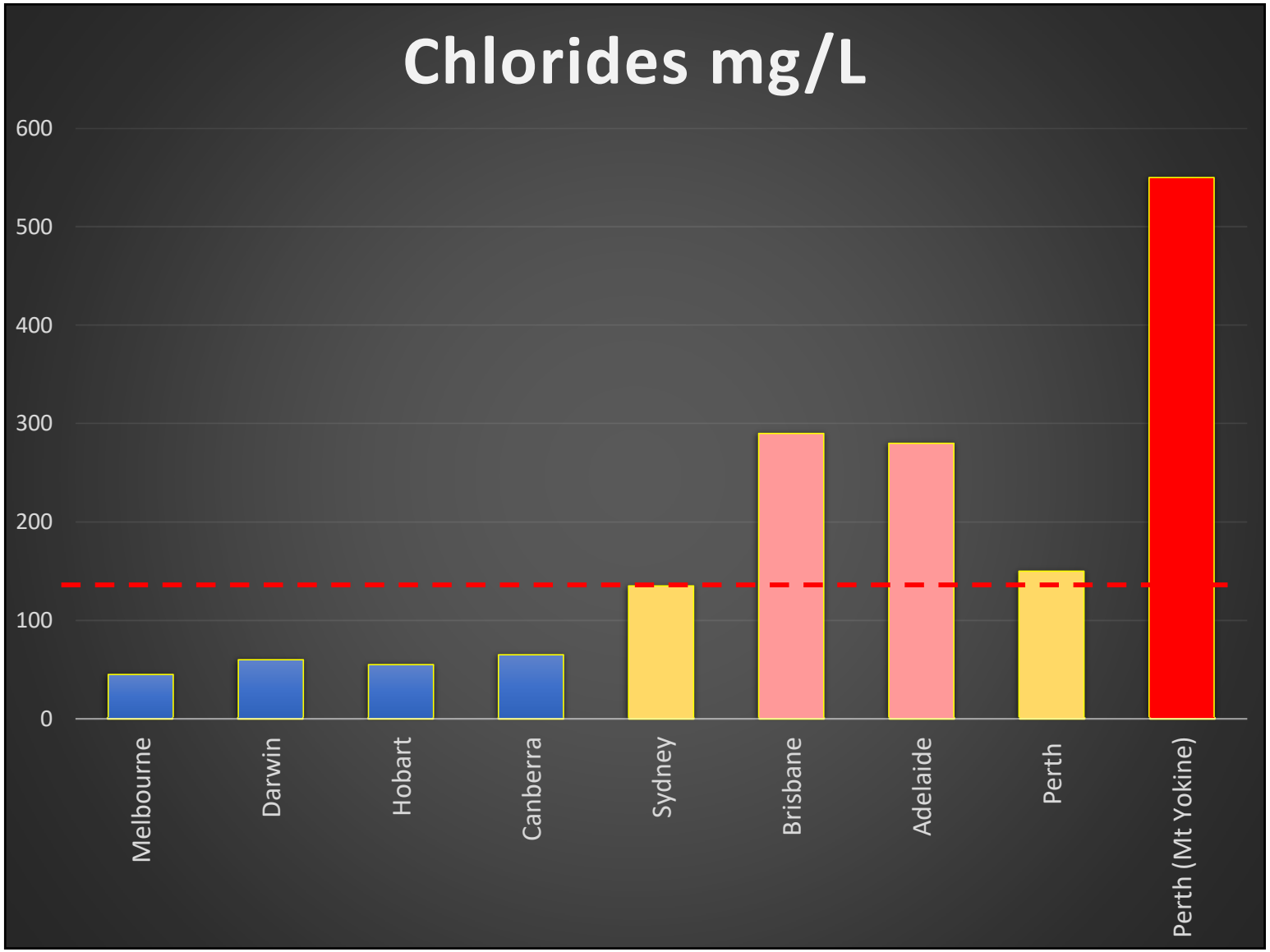

Total Hardness ppm
250
200
150
100
50
0
Melbourne
Darwin
Hobart
Canberra
Sydney
Brisbane
Adelaide
Perth

15


Chlorides mg/L
600
500
400
300
200
100
0
Melbourne
Darwin
Hobart
Canberra
Sydney
Brisbane
Adelaide
Perth
Perth (Mt Yokine)

16

Sources of Chloride Ions

- River/stream beds with salt-containing minerals
- Irrigation water returned to streams
- Mixing of seawater with freshwater
- Chlorinated drinking water
- Water softener regeneration

17

So what do I need ?

18

RMDs

WHAT PRODUCT DO I HAVE THAT NEEDS RE-PROCESSING?

WHAT DOES THE MANUFACTURER RECOMMEND?

WHAT WILL THE DEVICE BE USED FOR?

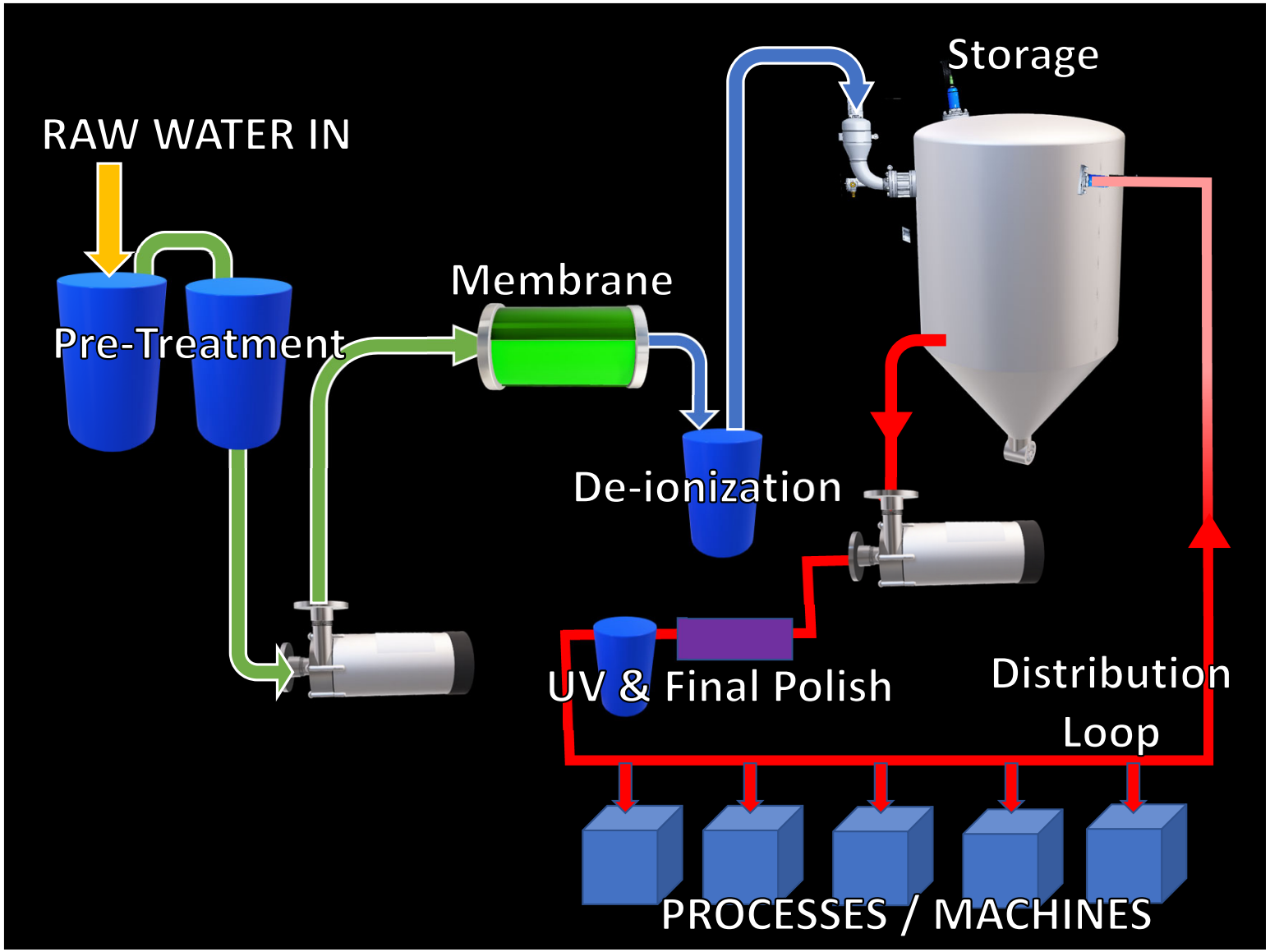
WHAT OTHER REQUIREMENTS NEED TO CONSIDERED?

19

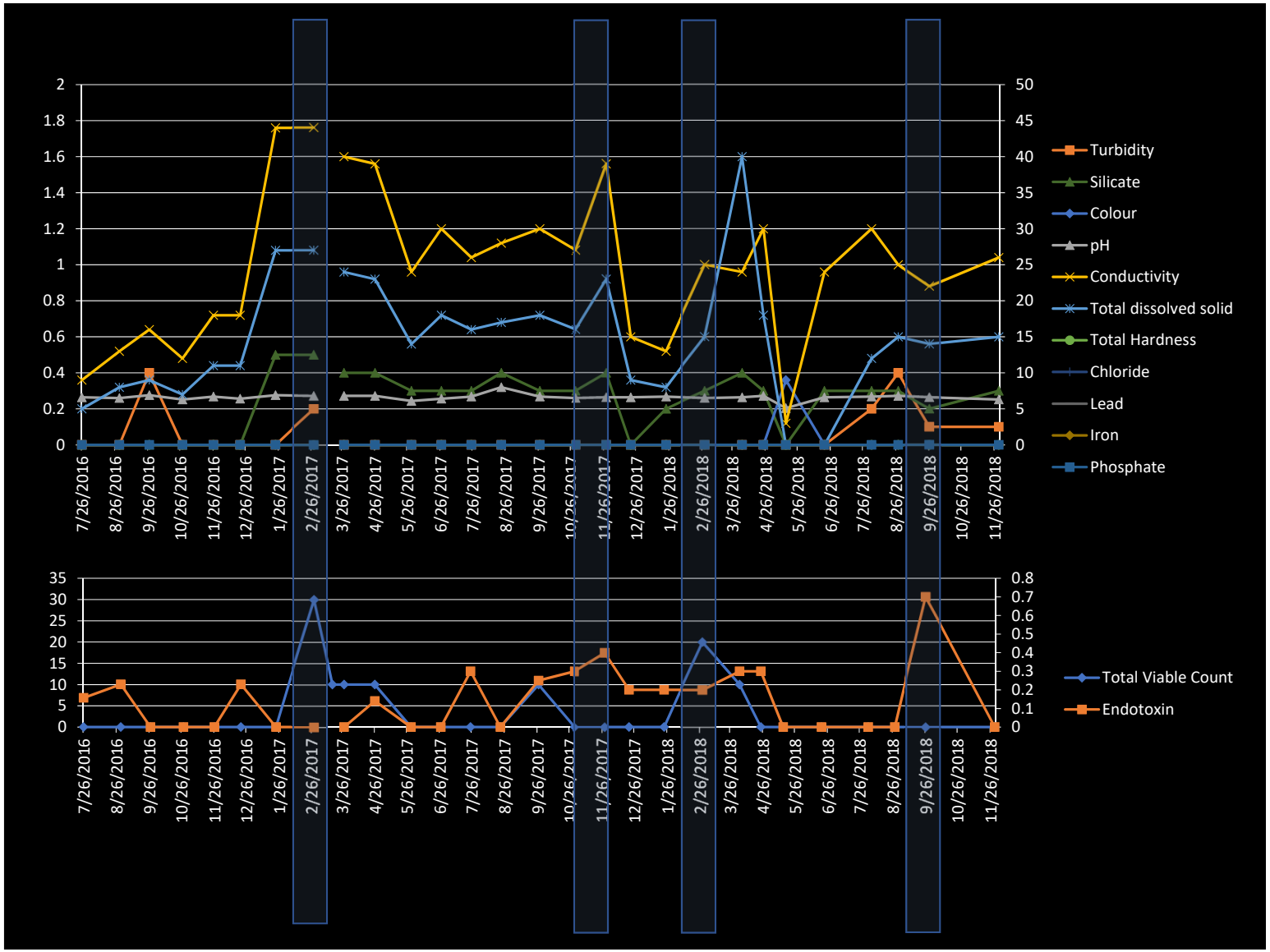
Do I Need Water Treatment

Process	Raw Water	Filtered	Softened	Pure	Ultra Pure
Manual Wash	✓	✓	✓	✗	✗
Manual Rinse	✗	✗	✗	✓	✓
Ultrasonic Wash	✓	✓	✓	✗	✗
Ultrasonic Rinse	✗	✗	✗	✓	✓
WD Wash	✓	✓	✓	✗	✗
WD Rinse	✗	✗	✗	✓	✓
AER Wash	✗	✓	✓	✗	✗
AER Rinse	✗	✓	✓	✓	✓
Steam Feedwater	✗	✗	✗	✗	✓

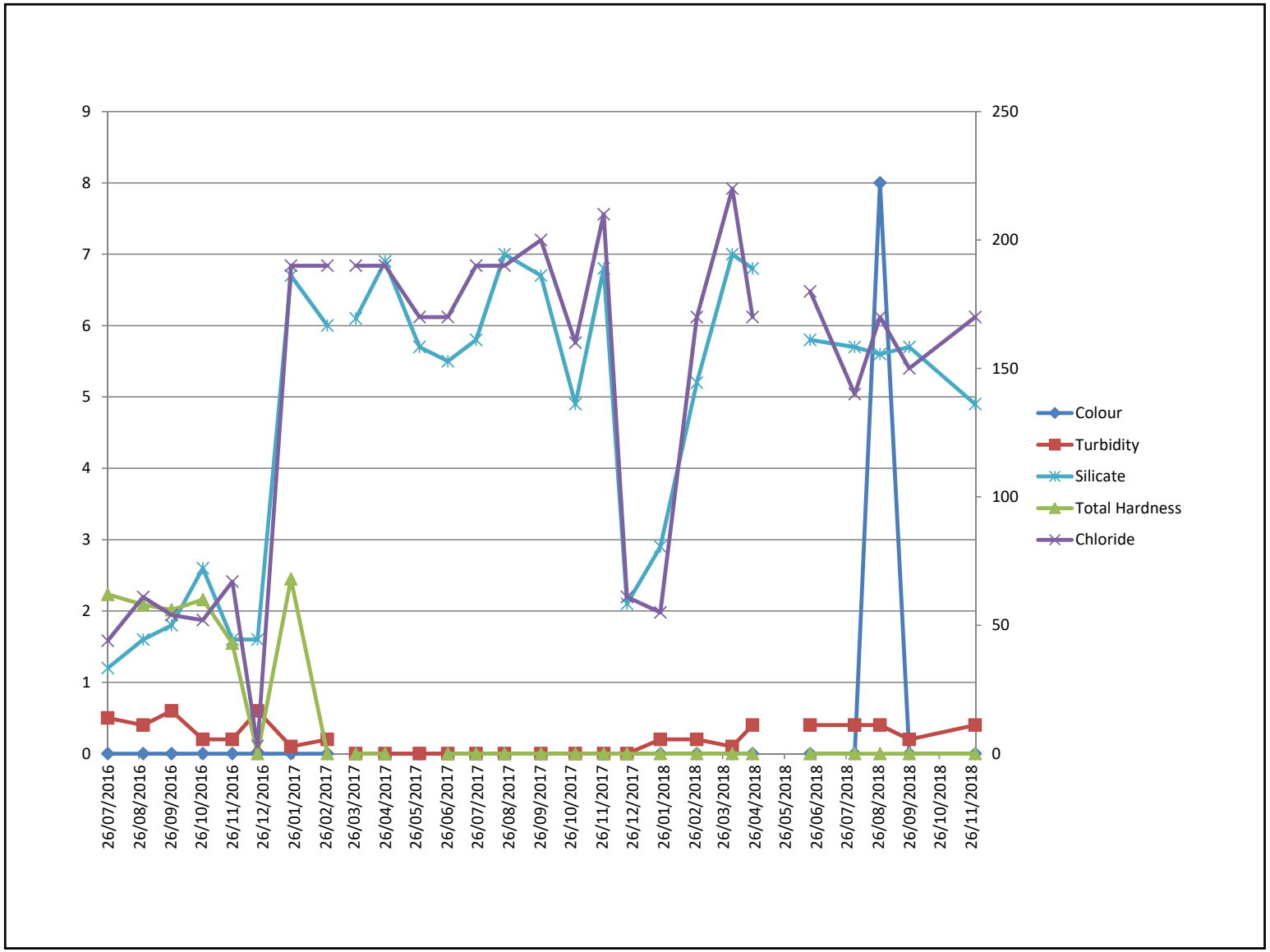
20


Storage
RAW WATER IN
Membrane
Pre-Treatment
De-ionization
UV & Final Polish
Distribution
Loop
PROCESSES / MACHINES

21


Turbidity
Silicate
Colour
pH
Conductivity
Total dissolved solid
Total Hardness
Chloride
Lead
Iron
Phosphate
Total Viable Count
Endotoxin

22


9
8
7
6
5
4
3
2
1
0
250
200
150
100
50
0
26/07/2016
26/08/2016
26/09/2016
26/10/2016
26/11/2016
26/12/2016
26/01/2017
26/02/2017
26/03/2017
26/04/2017
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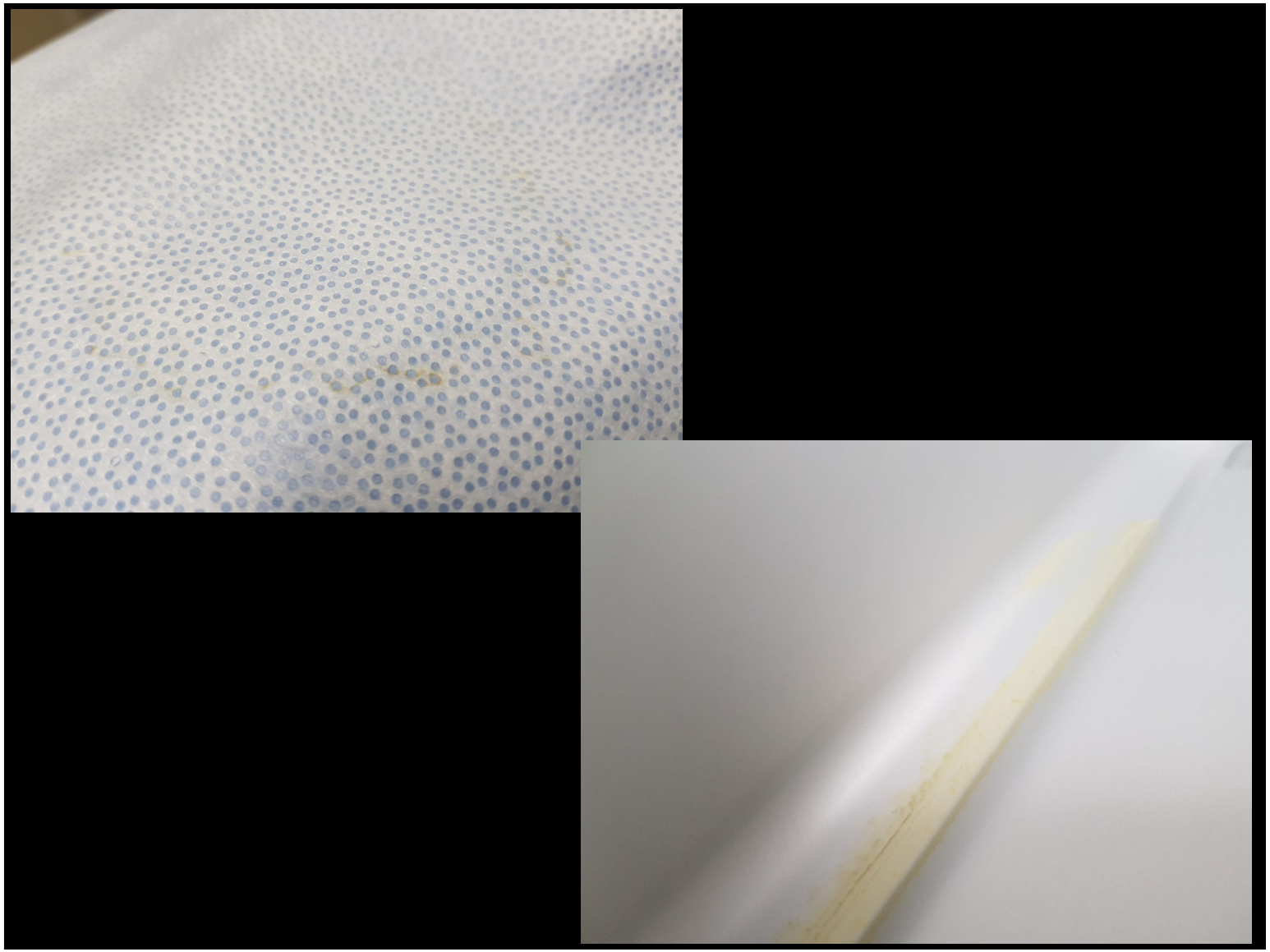
26/09/2017
26/10/2017
26/11/2017
26/12/2017
26/01/2018
26/02/2018
26/03/2018
26/04/2018
26/05/2018
26/06/2018
26/07/2018
26/08/2018
26/09/2018
26/10/2018
26/11/2018
Colour
Turbidity
Silicate
Total Hardness
Chloride

23



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General design principles

- Configuration
- Materials
- Operating Temperature
- Operating Hours
- Service Criticality
- Remediation
- Testing

25

References

European Standards 2015. EVS-EN 285:2009 + 2015 *Sterilization – Steam Sterilizers – Large Sterilizers.*

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Standards Australia 2014. AS/NZS 4187:2014 + AMDT 2:2019 *Reprocessing of reusable medical devices in health service organisations.*

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