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Purification processes to meet **AS/NZS 4187:2014 Amdt:2**

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Reprocessing of Reusable Medical Devices (RMDs) is a multiple-step process of cleaning, disinfecting, and sterilising. All these processes are critical in validating the re-use of medical devices on patients; not only to reduce the risk of acquiring Healthcare Associated Infections (HAIs) but also to reduce the potential outbreaks of infection associated with their re-use.

AS/NZS 4187:2014 Amdt:2 stipulates the feed water quality parameters for each level of decontamination in the reprocessing of RMDs and references external guidance documents that may be useful in selecting the appropriate processes to achieve the set limits.

Internationally recognised standards, such as EN285:2015, ISO17665-2:2009, CFPP 01-01. Part C etc., all emphasise the importance of water quality to feed steam generators, as well as condensate quality. ISO17665-2:2009 sets limits on pyrogen or bacterial endotoxin which is critical for the protection of patients and staff, the focus of other standards is primarily for the protection of RMDs.

The final steam sterilisation process used in hospitals that employs a maximum temperature of 134°C, is not a depyrogenation process. It is a “validated process used to render a product free from viable microorganisms” [1]. Temperatures greater than 180°C are required to effectively destroy endotoxin [2]. With temperatures below 180°C, depyrogenation may be incomplete - even after extended periods of sterilisation. Therefore, the feed water quality for the generation of steam for the sterilisation process must have a low level of pyrogens/endotoxins and the success of each level of decontamination is critical in achieving the desired quality of sterile products.

When sterilising solid goods such as RMDs in a steam steriliser, the steam in the steriliser chamber condenses on the surfaces of the RMDs/load. This condensation process is necessary to heat the load to the temperature required to provide a moist condition necessary for rapid sterilisation. At the end of the sterilisation process, the condensate is evaporated from the load by reducing the pressure in the steriliser chamber to produce a cooler, dry load [3]. Any bacterial endotoxin present in the steam will be deposited with the condensate and will be concentrated on the surfaces of the load during the process of condensate evaporation/cooling/drying of the chamber.

The monitoring of the sterilisation procedure using biological indicators will not detect bacterial endotoxins on the load and hence can pose a health risk to patients. For this reason, it is critical the bacterial endotoxin level in the feed water, as well as in the steam condensate, be monitored and controlled.

Once endotoxins are introduced to the processes of disinfecting and sterilising, they will not be destroyed by the disinfection or steam sterilisation process and will remain on the surfaces of RMDs. In the presence of a non-compliant level of bacterial endotoxin in the feed water to the steriliser, even a compliant level of endotoxin measured in the steam condensate is an indication that endotoxin contamination of the steam generator or the steriliser has occurred.

With feed water in compliance with bacterial endotoxin levels, a non-compliant level of bacterial endotoxin in the steam condensate is an indication that another form of contamination has occurred. Therefore, both the feed water and the condensate from the steriliser should be monitored for assurance that the steam steriliser and the sterilised goods are safe from bacterial endotoxins. Once bacterial endotoxins are identified, it is difficult to remove them from the steriliser and, is also difficult and impractical to remove them from RMDs after reprocessing.

It is well understood and generally not debated, that the feed water quality and the steam purity within the sterilisers must meet the chemical purity limits as stipulated in AS/NZS 4187:2014 Amdt.2, to achieve the desired quality of sterile products, for the longevity of RMDs, and for the serviceability of the sterilisers. However, if the feed water conductivity to the dedicated steam generators is much less than the stipulated limit of 5µS/cm, the water can be chemically aggressive and can cause irreversible damage to the steam generators, sterilisers, and the sterilised goods.

In essence, the chosen purification process for sterilisation must be designed to not only protect the equipment (i.e. Washer-Disinfectors, Sterilisers, dedicated steam generator, RMDs, etc.) but also protect patients and staff. It must not contribute to the increase/growth of bacteria and endotoxins.

In Australia, the quality of town water is relatively high in chemical impurities. With the sporadic weather patterns experienced at present, the microbiological purity of our water supply can also be a challenge. Therefore, the water used for the final rinse of the disinfection process and the water used for the generation of steam for the sterilisation process must be treated using a water purification method such as Reverse Osmosis (RO) or De-ionisation (DI).

For the final rinse and sterilisation process, RO is the preferred primary process technology due to its adaptation of membrane as a barrier against microorganism and chemical contaminants (both organic and inorganic) in the town water supply. DI is a process that is commonly known to increase the bio-burden on the purification process [4].

For thermolabile endoscopes, AS/NZS 4187:2014 Amdt. 2 does not stipulate a limit on chemical purity for the final rinse. Hence, typical water purification for endoscope reprocessing involves filter cartridges. In areas where water is high in hardness, water softeners which use ion exchange resin are employed. If a water softening process is used as the purification process, it must be emphasised that with water softeners, meeting microbial compliance can be challenging as this process is an ion exchange process which uses resin similar to DI. As per the paper by H. C. Flemming [4], bacteria in resin beds find enough organic material to live on adsorbed matter from the water passing through it as well as substances which may be released from the resin material. They settle on the outer surface of the resin material but are not securely attached. Nevertheless, contaminated ion exchange resin cannot be sanitised by flushing, back flushing, or other rinsing processes. Regeneration removes a part of the microbial population but is not sufficient for sanitation. If DI units can be left standing in the regenerant (i.e. acid or caustic solution) during off-periods, the bactericidal effect can be utilised. Also, a continuous mode of operation prevents bacterial growth to a certain extent. However, recirculation during off-periods acts as a fermentation process and cannot prevent bacterial growth.

The research paper by V. Penna et al. [5] based on a study of a typical water purification system consisting of multimedia filters, water softeners, carbon filters, 5 micron filter, RO, Continuous DI (CDI), storage tank and ringmain with UV lamp and 0.05 micron filter, at a Lifesciences facility, supported the above findings.

Results presented in this paper showed that water samples analysed for the identification of isolated bacteria in each stage of the purification system indicated higher plate count post water softeners, carbon filters and CDI, in comparison to the plate count at the feed to each process. A water sample taken post water softener was 173 cfu/100ml in comparison to 33 cfu/100ml post multimedia filters. Although the water sample taken post carbon filters indicated the highest plate count (i.e. 897 cfu/100ml post carbon filters compared to 507 cfu/100ml in the feed water supply), a significant decrease in plate count was achieved post RO (8 cfu/100ml). Despite this significant reduction in plate count by the RO unit, the CDI installed post RO was found to re-contaminate the purified water. A significant increase in plate count from 8 cfu/100ml post RO to 653 cfu/100ml post CDI was evident.

Depending on the quality of the incoming town water supply at the hospital, at times single pass RO will not meet the chemical contaminant limits stipulated in AS/NZS 4187:2014 Amdt:2. In this instance a secondary purification process such as a second RO unit (where essentially the water is filtered via two sets of RO membranes), Electro De-ionisation (EDI) or DI is required.

When selecting a secondary purification process to meet AS/NZS4187, scientific facts and evidence based practices should be the cornerstone. **It is imperative that the selected processes do not adversely affect the primary goal, which is the control of bacterial endotoxins.**

Moreover, to prevent irreversible damage to the steam generators, the sterilisers, and the sterilised goods, the selected purification process must not produce water that is much purer than 5 µS/cm in conductivity. Subsequent damages caused by corrosion will increase bacterial endotoxin levels on the RMDs and the reprocessing equipment.

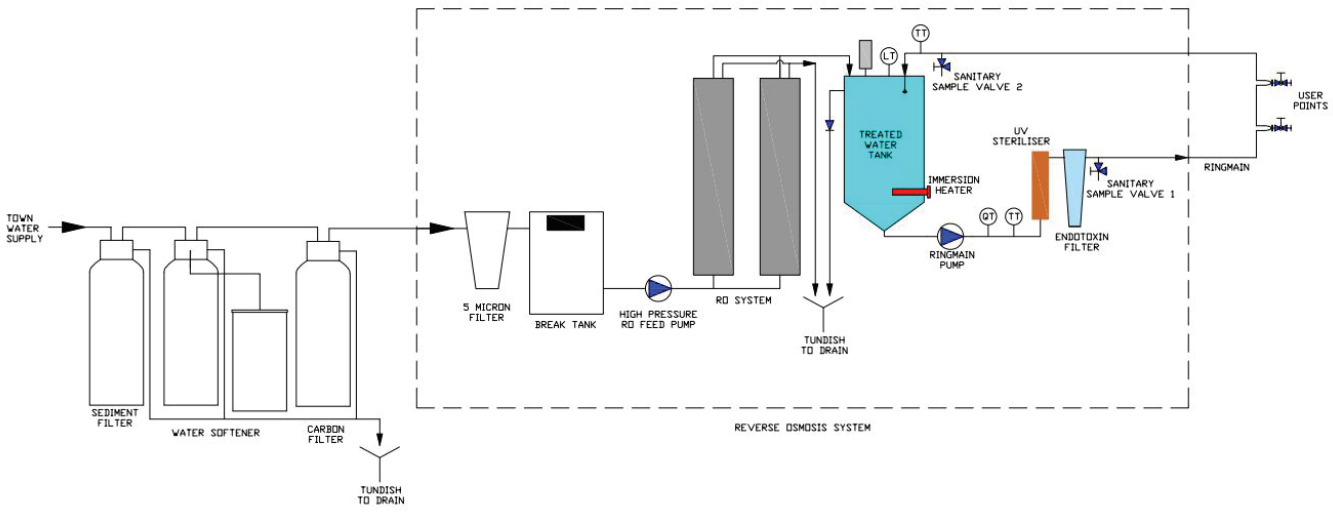
The purification process selected for each hospital must be fit for purpose to gain a higher Return on Investment (ROI). To achieve a high ROI, a “one size fits all” design of purification plant cannot be implemented.

A well designed purification plant that consistently and continuously meets the requirements of AS/NZS 4187:2014 must operate as a continuous flow through system with sanitary designed storage tank and ringmain. The storage tank and the ringmain must incorporate routine automatic disinfection for the proactive control of biofilm and to minimise the generation of endotoxins.

If using thermal disinfection for microbial compliance, the heating unit used to increase the water temperature to greater than 80oC must be of a sanitary design, to prevent dead legs that can contribute towards an increase in biofilm growth, and must incorporate process mechanisms, to avoid external contamination of the purified water by the hospital boiler or the hot water unit.

The best practice would be to use an immersion heating element to reduce external contamination risks and to reduce cost. If in-line heating is implemented, it is imperative that the design avoids the generation of superheat. Superheating not only impedes the disinfection process but can damage water treatment equipment and associated pipework.

A typical water purification plant based on single pass RO to meet the requirements of AS/NZS 4187:2014 is depicted below:



A well-designed system can have 20+ year life cycle and will consume less water and power, making it environmentally sustainable.

Without the implementation of this design as a minimum, the purification plant will fail to meet microbial compliance in less than 3 years, resulting in a poor ROI.

A summary of the major differences between commonly used water purification processes and technologies in meeting AS/NZS 4187:2014 compliance is detailed in the table below. The information in the table is designed to provide questions and answers that are helpful in making unbiased and informative decisions by healthcare professionals in order to achieve better ROI on the purchase of a water purification system.

Choosing a suitable solution based on scientific facts and evidence would allow for future proofing our healthcare system without compromising quality, cost and our environmental footprint.

Questions	Common Water Purification Processes / Technologies						
	Water Softening	**Single Pass RO**	**De-ionisation (DI)**	**Electro De-ionisation (EDI)**	**Two Pass RO**	**RO + EDI**	**RO + DI**
Does the process reduce chemical contaminants from the incoming town water supply?	Yes ☑ It is an ion exchange process similar to DI but only reduces hardness causing elements hence not all chemical contaminants are reduced	Yes ☑ It uses semipermeable membrane(s) to reduce chemical contaminants	Yes ☑ It is an ion exchange process similar to water softener but with both positively and negatively charged ions to reduces chemical contaminants	Yes ☑ The process is similar to DI with electronic regeneration of the ion exchange resin to continuously reduce chemical contaminants	Yes ☑ It uses semipermeable membrane(s) to reduce chemical contaminants	Yes ☑ It uses membrane(s) and EDI to reduce chemical contaminants	Yes ☑ It uses semipermeable membrane(s) and ion exchange process to reduce chemical contaminants
Does the process reduce microbial contaminants (bacteria and endotoxins) from the incoming town water supply?	No ☒ The ion exchange resin will proliferate bacteria due to the bio-physical nature of the resin material. Higher bacteria population in the product water than the feed water supply is common	Yes ☑ As it uses semipermeable membrane(s), it reduces microbial contaminants from the town water supply	No ☒ The ion exchange resin will proliferate bacteria due to the bio-physical nature of the resin beads. Higher bacteria population in the product water than the feed water supply is common	No ☒ The continuous electronic regeneration process minimises microbial growth within the resin. However, it will not reduce microbial contaminants from the town water supply	Yes ☑ As it uses two semipermeable membrane(s), it will reduce microbial contaminants from the town water supply	Yes ☑ As it uses semipermeable RO as a primary process, it will reduce microbial contaminants from the town water supply	No ☒ RO reduces microbial contaminants from the town water supply. However, the resin will proliferate bacteria due to its bio-physical nature. Higher bacteria population in the product water than the feed water supply is common
How often do the main components require replacement?	Resin is automatically regenerated using brine solution when exchange sites are exhausted. Resin life depends on water volume throughput and regeneration frequency	Membrane life is typically 3 to 5 years	Resin is replaced when exchange sites are consumed. Resin life depends on water volume throughput. Not suitable as a primary process unless resin is continuously regenerated using acid and caustic	Not suitable as a primary process as EDI is designed to be a secondary process to RO. EDI cell replacement is typically every 3 years, depending on the performance of the primary process	Membrane life is typically 3 to 5 years	Membrane life is typically 3 to 5 years and EDI cell replacement is typically every 3 years depending on the performance of the RO membranes	Membrane life is typically 3 to 5 years and resin is replaced when all exchange sites are consumed. Resin life depends on the volume of water treated as well as feed water quality

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	Water Softening	**Single Pass RO**	**De-ionisation (DI)**	**Electro De-ionisation (EDI)**	**Two Pass RO**	**RO + EDI**	**RO + DI**
Does the process generate waste?	Yes ☒ As the resin bed is automatically regenerated using brine solution, brine waste is continuously generated	Yes ☒ When operating, continuously typically produces 25 to 50% wastewater, depending on the design	Yes ☒ No wastewater is generated when non-regenerable mixed bed (NRMB) resin is used. However, when NRMB is used, the exhausted resin contributes towards the generation of more environmental waste. This applies if the resin is regenerated and reused or disposed of	Yes ☒ When operating, continuously, it typically produces 1 to 5% wastewater. As it is only used as a secondary purification process, this waste is recycled back into the primary process hence typically no wastewater is generated	Yes ☒ When operating, continuously typically produces 25 to 50% wastewater, depending on the design	Yes ☒ When operating, continuously typically produces 25 to 50% wastewater, depending on the design	Yes ☒ When operating continuously, typically produces 25 to 50% wastewater. When non-regenerable mixed bed resin is used, the exhausted resin contributes towards the generation of more environmental waste. This applies if the resin is regenerated and reused or disposed of
Does it require pre-treatment to remove Chlorine and water hardness?	Yes ☒ Yes. Sediment filters and carbon filters are required if the solid concentration and the chlorine concentration in the incoming town water supply is high	Yes ☒ Yes. RO membranes are Chlorine intolerant hence Chlorine removal is required. It also requires feed water low in water hardness so it requires water softeners	Yes ☒ Yes. Resin beads are Chlorine intolerant hence Chlorine removal is required. Water softener recommended as pre-treatment to prolong the life of the ion exchange resin	Yes ☒ Yes. Resin beads are Chlorine intolerant hence Chlorine removal is required. It also requires feed water low in water hardness so require water softeners. EDI is not suitable as a primary purification process	Yes ☒ Yes. RO membranes are Chlorine intolerant hence Chlorine removal is required. It also requires feed water low in water hardness hence requires water softeners	Yes ☒ Yes. Both RO membranes and EDI cells are Chlorine intolerant hence Chlorine removal and water softener are required	Yes ☒ Yes. Both RO membranes and resin beads are Chlorine intolerant hence Chlorine removal is required. It also requires feed water low in water hardness so requires water softener

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	Water Softening	**Single Pass RO**	**De-ionisation (DI)**	**Electro De-ionisation (EDI)**	**Two Pass RO**	**RO + EDI**	**RO + DI**
How does the process compare in operational cost?	Lowest ☑ Lowest operational cost compared to other purification processes as only brine is required for the continuous operation of the softener	Low ☑ Low operational cost compared to DI, two pass RO and RO+DI	High ☒ High operational cost due to frequent resin replacement/resin regeneration. DI without automatic resin regeneration with acid and caustic is not recommended	High ☒ High operational cost as EDI cells are expensive to purchase. EDI cannot be used as a primary process	Low ☑ Low operational cost compared to other purification processes	High ☒ EDI makes this process a high operational cost compared to other purification processes	High ☒ Frequent replacement of ion exchange resin makes this process high in operational cost compared to two pass RO
How does the process compare in capital purchase cost?	Low ☑ Low compared to RO based processes. However, more expensive than DI using non-regenerable mixed bed resin	Medium ☑ High capital cost solution in comparison to DI	Lowest ☑ Lowest capital cost solution to the other processes if automatic resin regeneration facility is not implemented	Highest ☒ Highest capital cost solution to the other processes however EDI cannot be used as a primary process	High ☒ High capital cost solution in comparison to RO+DI	Highest ☒ Highest capital cost solution in comparison to the other processes mentioned herewith	Medium ☑ Low capital cost in comparison to two pass RO and RO+EDI
Is the process robust, and does it reliably manage variations in the feed water?	Yes ☑ Robust and reliably copes with feed water variations to supply the set/required product water hardness. However, the final water quality depends on the feed water hardness level	Yes ☑ Robust and reliably copes with feed water variations to supply the set/required product water quality	No ☒ Performance and product water quality depends highly on incoming feed water quality. As resin experiences exhaustion, elevated level of contaminants already held by the resin can be released back into the water, resulting in poorer water quality than the incoming feed water	No ☒ Not suitable as a primary purification process as EDI technology is designed to be a secondary process to RO	Yes ☑ Robust and reliably copes with feed water variations to supply the set/required product water quality	Yes ☑ Robust and reliably copes with feed water variations to supply the set/required product water quality	No ☒ Although the RO is robust and reliably copes with feed water variations, DI performance depends on water volume throughput. As resin experiences exhaustion, elevated level of contaminants already held by the resin can be released back into the water, resulting in poorer water quality than the incoming feed water

Questions	Common Water Purification Processes / Technologies						
	Water Softening	**Single Pass RO**	**De-ionisation (DI)**	**Electro-Deionisation (EDI)**	**Two Pass RO**	**RO + EDI**	**RO+DI**
Does the process allow for better control of product water quality to achieve ≤ 5 µS/cm conductivity?	No ☒	Yes ☑	No ☒	No ☒	Yes ☑	No ☒	No ☒
	It is a selective ion exchange process designed to remove water hardness. Hence it will not produce the chemical purity required to meet AS/NZS 4187:2014	Allows better control of the product water quality. ≤ 5 µS/cm conductivity can only be achieved when the incoming water conductivity is relatively low	No control of the product water quality. Newly installed unit will produce highly purified water of much less than 5 µS/cm. As the resin experiences exhaustion, elevated level of chemical contaminants already held by the resin can be released back into the water, hence resulting in poorer water quality than the incoming feed water	Not suitable as a primary purification process as EDI technology is designed to be a secondary process to RO hence reliant on the performance of the RO unit	Allows better control of the product water quality. Product water quality is typically ≤5 µS/cm	Product water quality is typically < 5 µS/cm	Product water quality is typically < 5 µS/cm hence can be extremely aggressive on dedicated steam generators, sterilisers and the sterilised goods. However, as the resin experiences exhaustion, elevated level of chemical contaminants already held by the resin can be released back into the water and low water pH can be experienced, hence it can result in poorer water quality than the incoming feed water
Will the process continuously and consistently meet AS/NZS 4187:2014?	No ☒	Yes ☑	No ☒	No ☒	Yes ☑	Yes ☑	No ☒
	It is a selective ion exchange process only designed to remove water hardness. Hence it will not meet chemical purity required for compliance	Well designed and maintained system will guarantee compliance if the incoming water conductivity is relatively low	Compliance is susceptible to incoming feed water quality and the volume throughput	Not suitable as a primary purification process as EDI technology is designed to be a secondary process to RO hence reliant on the performance of the RO unit	Well designed and maintained system will guarantee AS/NZS 4187:2014 compliance	Well designed and maintained system will guarantee AS/NZS 4187:2014 compliance	Compliance is susceptible to the water volume throughput. As the resin active sites are consumed, elevated level of chemical contaminants already held by the resin can be released back into the water, resulting in poorer water quality than the incoming feed water

Questions	Common Water Purification Processes / Technologies						
	Water Softening	Single Pass RO	De-ionisation (DI)	Electro-Deionisation (EDI)	Two Pass RO	RO + EDI	RO+DI
Does the process offer operational redundancy?	No ☒ Offers no redundancy unless two trains of water softeners are incorporated	No ☒ Offers no redundancy unless two trains of single pass RO are incorporated	No ☒ Offers no redundancy unless two trains of DI are incorporated	No ☒ Not suitable as a primary purification process as EDI technology is designed to be a secondary process to RO	Yes ☑ Offers a form of redundancy as each RO membrane unit can operate individually to reduce contaminants to offer continuity of supply	☑☒ Offers a form of redundancy only if the RO unit is operating. In the event of RO failure, EDI cell will be damaged and hence replacement is required	☑☒ Offers a form of redundancy only if the RO unit is operating. In the event of RO failure, DI resin will experience rapid exhaustion. Once the resin is exhausted, elevated level of chemical contaminants already held by the resin can be released back into the water, resulting in poorer water quality than the incoming feed water. Depending on which ion exchange sites experience exhaustion first, a decrease in water pH can also be experienced

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