

# Quality of Water for Dialysis Use: A Trend Toward Heat Disinfection

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## Introduction:

Mains water supply treatment and the end-product distribution of the treated water for safe and effective dialysis use is a basic technology well described and relatively uncomplicated.

Producing water for home and acute dialysis use (permeate) is a hydraulic configuration of pre-treatment components, Reverse Osmosis Unit (RO) and recirculating tubing. The hydraulic configuration can include media vessels, filters, pumps, reverse osmosis membrane elements, together with sensing devices and microprocessor control system.

The quality of the permeate water from any water treatment system is largely determined by site-specific feed supply water characteristics that determine system specifications, selected component parts and installation methodology. Post installation of the water treatment plant requires that a continuous assurance of permeate quality and purity is critical to the safe delivery of haemodialysis therapies. It is dependent upon reverse osmosis membrane element integrity, consistent system monitoring and service maintenance, a programme of regular permeate tubing disinfection ideally to include the reverse osmosis membrane elements, together with appropriate monitoring of the chemical and microbiological quality of the permeate produced.

The microbiological purity of permeate is complex and dependent upon many factors, not least of which is the method and the frequency of the disinfection process

## The importance of permeate water purity during haemodialysis

Patients rely on maintenance dialysis treatments for the removal of excess bodily fluid and wastes and to normalise electrolytic balance. In so doing, the possibility of water (dialysate) borne contaminants back-diffusing to patient blood via the dialyser (artificial kidney) is well documented. It should be noted that water (permeate) comprises >95% of the dialysate mix and that within the dialyser patient blood is separated from the dialysate mix via a semi-permeable membrane only. The membrane is selective with regard to molecular size but is not selective toward water-borne contaminants

Heat pasteurisation is well known in the haemodialysis centre, as many dialysis machines and central water treatment plants use this proven process for routine disinfection. However, it has not, until recently, been available for use in the smaller, single patient, water treatment systems as used in Home and Acute dialysis applications. Heat disinfection will not remove established biofilms. It is, however, a convenient disinfection process that requires little to no rinse time, so it could be used more often, thus not allowing biofilm to form. An occasional chemical disinfection might be necessary. Generally,  $\leq 80\%$  for a 30-minute exposure time will perform a more than adequate disinfection of an RO system and its internal piping system. The temperature and contact time need to be established and validated by the manufacturer of the system. Reaching the correct temperature for the right amount of time is considered a successful disinfection (AAMI, 2004)

## Key Words

Water Treatment, Reverse Osmosis, Pasteurisation, Biofilms, Microbiological

## Discussion:

The ERA-EDTA Best Practice Guidelines for Dialysis Fluid Purity specify that water for the production of dialysis fluid should meet or exceed the requirements of the European Pharmacopoeia. EP Monograph 1167 requires that water used for diluting concentrated haemodialysis solutions should have a total viable aerobic count of <100 cfu/ml and that the concentration of endotoxin should be <0.25 IU/ml. Lower levels for viable organisms and endotoxin in the water and/or dialysis fluid may be specified locally. Where Ultrapure fluid is required, the limits will normally be <0.1 cfu/ml and <0.03 IU/ml

## Quality Assurance or Quality Control?

Quality assurance (QA) applied to production of water for dialysis, means designing and maintaining the entire system for the production and distribution of purified water to a standard that ensures that the water meets or exceeds the requirements of the EP. This will include preventing the proliferation of bacteria. In the context of quality assurance, bacteria levels are monitored for the purpose of audit only.

QA is provided by regular disinfection and is required to prevent bacteria growth on the internal surfaces of the RO membrane and piping system. In most centres this is feasible only with an

automated disinfection procedure that is easy for dialysis unit patients or hospital personnel to use. Heat disinfection is amenable to automation and can be left unattended. It also eliminates the need to handle aggressive chemicals and carries no risk for the patient as all dialysis machines have high temperature alarms

Internal quality control (QC) involves analysing samples to find out if they meet the criteria for acceptability. If a sample fails the QC test, appropriate action is taken. When monitoring water for dialysis, QC measurements showing an increasing trend in counts may be used to adapt the maintenance schedule, for example by initiating a disinfection

These systems are difficult to keep clean because bacterial biofilm can build up in the interval between disinfections, also because the disinfectant cannot penetrate biofilm and destroy bacteria that are deeply embedded. They are also very difficult to monitor effectively because bacteria levels obtained by culturing the viable organisms in a mid-stream sample gives a very limited indication of the number of bacteria in the system

**Conclusion**

Internal QC can be used to keep the measured level of microbiological contamination below the AAMI / EP limits; it relies on the ability of staff /

patients to keep the growth of bacteria under control. Over the lifetime of a system this will inevitably become more difficult.

With the QA approach, there is no build-up of resistant biofilm, so there is no reason why the system should not continue to produce high quality water as long as the maintenance schedule followed is uncomplicated, easy and safe.

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