

Healthcare Solutions

Pure water guide for better Healthcare

Contents

\angle	
Renal	10
Renal Water Systems	12
Our Technologies and Systems	13
Recommended testing	14

4

At Your Service 20 Service You Can Trust 22

First Class Project Management 24 and Services



Sterile Services and Endoscopy Decontamination of endoscopes 4

6

8



Clinical	16
Water Purity	18
Water Purification Technologies	19

Our Commitment 26 to the future

Recognised Healthcare Pure Water Experts

Veolia Water Technologies (Veolia) is the market leader in the provision of packaged pure water solutions and services for Healthcare applications. Our experience in Healthcare spans over 80 years, during which we have constantly strived to meet our customers' priorities: reliability, innovation, functionality, and patient and staff safety, with an unfailing commitment to provide exceptional service and value for money.



Our services

Our services range from water treatment system design, project management, installation and validation to 24/7 service support and digital services. Our AQUAVISTA Digital Services have been designed to support our customers to fully comply with regulations and to guarantee system uptime. Ensuring that patient care can be delivered whenever it is required.

In an ever increasing regulatory environment our services ensure:

- System design
- Project management
- Plant design
- Installation and validation
- Testing and service support

Pure water guide for better healthcare. Think Veolia

Recognised Healthcare Pure Water Experts

Our skills and experience enable us to deliver solutions that:

> Protect specialist areas or equipment



Reduce operating cost and cancelled patient orocedures



Improve patient care



Guarantee uninterrupted service



Safeguard the safety and comfort of patients, visitors and staff

Pure water guide for better healthcare. Think Veolia

Sterile Services and Endoscopy



Cleaning and sterilising reusable medical devices and equipment is now highly regulated by industry guidelines and international standards as concern grows over infection control in hospitals and the spread of MRSA, hepatitis, CJD and other resistant pathogens.

There are two key elements – the protection of people (patients and staff) and the protection of equipment - to be considered in the sterilisation of reusable medical equipment:

Patient and staff protection

Patient and staff protection (avoidance of crosscontamination). There is a risk that transmission of pathogenic organisms could take place during routine surgery, therefore to prevent contamination, healthcare professionals must ensure that their instruments and endoscopes are always perfectly clean, disinfected and ready for use. The thorough cleaning of instruments is necessary to ensure that adherent infectious agents are removed together with the organic matter that protects them, to enable better contact between the disinfectant and any remaining infectious agents on the surfaces of the instrument or medical device.

Protecting equipment

Protecting equipment Inorganic contaminants such as rust, hard water deposits (scale) and residues from cleaners can, over time, damage the surface of the medical instrument and create a habitat that facilitates bacterial growth. Also, heat and some disinfectants (alcohols and aldehydes) are tissue fixatives and may cause moving parts of a device

to stiffen if the surfaces are not thoroughly cleaned before sterilisation/disinfection. Additional economic benefits can be demonstrated where the use of improved water quality reduces the volumes of chemical cleaners.

Typical water quality requirements include:

- Bacteria Total Viable Count of less than 10 CFU/100ml
- Endotoxin levels of less than 0.25 EU/ml
- Conductivity of less than 30µS/cm
- Rinsewater systems should be regularly disinfected and validated to ensure they continue to meet the water specification
- Water samples should be routinely taken to demonstrate compliance

Decontamination of Endoscopes

Most surgical instruments are disinfected using a process of cleaning, thermal disinfection and sterilisation; however, endoscopes and several other instruments are thermally labile.

Endoscopes and other instruments are unable to tolerate temperatures of 60°C or above, they cannot, therefore, be thermally disinfected and sterilised. Instead, endoscopes are cleaned and sterilised using a chemical disinfection procedure and then rinsed in purified water (Final rinse water) to remove all traces of the disinfectant. After decontamination, the equipment must be handled carefully to minimise any risk of recontamination.

The water quality required for final rinse is set out in the Health Technical Memorandums HTM 0101 (Sterile Services), HTM 0106 (Endoscopy) and the European EN15883 Part 1-4. These standards specify the use of water which has a microbial specification of <1CFU/100ml (HTM) or <10CFU/100ml (EN15883) (tested on at least two samples) and if the medical device comes into contact with the bloodstream or other normally sterile areas of the body, then the standard requires that the final rinse water is controlled and monitored within the limits specified by national regulations (for example HTM 0106 in the UK or perhaps United States Pharmacopeia 'Water for Injection' in some other countries). For many countries this requires an endotoxin specification of <0.25 EU/ml.

To achieve these stringent standards a water purification system that uses an RO with recirculated UV and on-line endotoxin filtration is recommended. However, overall the most important aspect of the requirements is the need to use a water purification system that maintains biopurity through simple and easy sanitisation.

Due to the complex design of endoscopes and the importance of cleaning them, the use of (AERs) Automated Endoscope Reprocessors are at the forefront for ensuring the highest standards of reliability and flexibility.

To achieve these standards and to meet the HTM and European standards for final rinse water quality, a reliable source of final rinse water is required which continually meets the HTM + EN standards.

We work closely with the AERs, washer and steriliser manufacturers, it is one of our key objectives to design, manufacture, install, maintain and operate water treatment systems specifically for decontamination, which meets our customers' commercial, quality and reliability requirements, as well as maintaining statuary and regulatory requirements.

Whether in Endoscopy or Sterile services, we ensure that the quality of water consistently meets or surpasses the HTM and EN regulations. Our commitment to quality and final rinse water is to guarantee consistent final rinse water to <10cfu/100ml + <0.25 EU/ml.

We are dedicated in helping our customers; with our expertise, we can deliver the best solution including: design and install, removing risk, streamlining operational efficiencies, becoming energy efficient and reducing your carbon footprint – all of which goes towards every decontamination department's success.



+ Importance of water

- High purity water is used after a decontamination cleaning process for rinsing surgical instruments
- Microbiologically pure water is used after a chemical disinfection process for rinsing endoscopes
- Microbiologically and chemically pure water is used to produce steam for instrument sterilisation processes

+ Our value to you

- Guaranteed HTM guality water
- Reduction of instrument cross infection to protect staff and patients
- Extensive technical and operational expertise to ensure long term compliance through use of latest pure water technologies

+ Our solutions

- \cdot Complete service and validation support services to ensure optimum system performance and reliability
- · Extensive range of standard and bespoke products available to meet your requirements, including expert design solutions

- Integrated chemical and heat disinfection programmes to ensure consistent, validated microbiological performance

Renal



Veolia specialises in supplying innovative process solutions for dialysis and we understand the issues and key challenges dialysis facilities face in delivering a high quality, reliable and cost-effective service for their patients.

Our experience and expertise enable us to offer innovative and proven solutions to help you at every stage of the project; from initial consultation and system specification to installation and ongoing service and support. Furthermore we have a track record for delivering projects on time and on budget. We have the capability to provide you with total water purification and central concentrate systems to support dialysis treatments.

Our water treatment systems cover all aspects from pre-treatment, reverse osmosis, ultrafiltration and hot sanitisation systems, right up to the supply connection on the dialysis machines. We can advise you on the best combination of equipment for your needs, whether it is a standalone single patient unit, a small ringmain for a satellite station, or a larger system for a hospital. As you would expect, our equipment is designed to be simple and intuitive to use. What's more, because it is so compact and quiet in operation, it can be situated close to the renal ward for easy accessibility.



Renal Water Systems

We set the standard in dialysis water treatment and are one of the only companies producing ultrapure permeate by combining reverse osmosis and a thermally sanitised ultrafiltration membrane, with integrated heat-disinfection of the ring-main to the dialysis machines.

Reverse osmosis represents the best water purification technology for dialysis, and we have a wide range of reverse osmosis systems that incorporate a host of technologically advanced features that ensure patient safety and reliability over many years' service.

Water of the appropriate quality used in the preparation of dialysis fluid is an essential requirement of haemodialysis and related therapies. International standards have been

developed to promote the installation of fit for purpose water treatment systems for haemodialysis and to safeguard the routine production of dialysis water suitable for use for haemodialysis and haemodiafiltration. Quality requirements for the water and concentrates used to prepare dialysis fluid, and for dialysis fluid, are provided in a series of standards issued by the British Standards Institute.

Standards	BS EN ISO 13959: 2015 Water for haemodialysis and related therapies	BS EN ISO 11663: 2015 Quality of dialysis fluid for haemodialysis and related therapies
BS EN ISO 13958: 2015 Concentrates for haemodialysis and related therapies	BS EN ISO 26722: 2015 Water treatment equipment for haemodialysis and related therapies	BS EN ISO 23500: 2015 Guidance for the preparation and quality management of fluids for haemodialysis and related therapies.

Our Technologies and Systems

The need for high quality water treatment facilities for haemodialysis is highlighted in the recent WHO guidelines on water safety in buildings.

Water treatment facilities installed in all new and refurbished satellite and main renal unit HD facilities should be integrated within the specification that is required for a modern haemodialysis unit which has been outlined in the National Service Framework for Renal Services.¹

Documented in detail in Health Building Notes 07-01 and 07-02 for satellite and main renal units respectively, published by the Department of Health.²

There has been need for guidelines on the detailed specification of water treatment systems as well as the building of haemodialysis units so that the dialysis water is fit for purpose for modern haemodialysis therapies (haemodiafiltration and high flux haemodialysis).^{3,4}

Better protecting patients and their dialysis equipment

- (f) Operators who are trained in the use of the water treatment for dialysis and the facility on the whole should be assigned, and training should be delivered by the manufacturer or their UK distributor.
- Ideally a renal technologist should also be the person responsible for policies for monitoring and recording of the quality of dialysis water and dialysis fluid are in place and being followed however an appropriately trained member of the renal team can also perform these duties. A process should also be in place if this person is absent from work.
- It is recommended that new build renal units should have a direct feed (drinking / potable) water supply separate from that of the hospital water supply. If water treatment systems use a hospital water supply there should be awareness of the potential risks that may arise from the introduction of chemicals into the hospital water supply by hospital engineering staff.
- All new water treatment facilities should be capable of producing water with microbial and endotoxin concentrations of < 0.1CFU/mL and < 0.03EU/mL, respectively, and have a robust sanitisation strategy in place.
- + All chemical and microbiological test results and remedial actions in respect of feed water and dialysis water, should be recorded, kept up to date and stored in a safe location.

Recommended Testing

Contaminant	Frequency of testing
Total chlorine	At least weekly
Total viable counts	At least monthly
Endotoxin	At least monthly
Chemical contaminants other than chlorine	At least every 3 months

It is recommended that water treatment systems for haemodialysis are CE marked medical devices as defined by the Medical Devices Directive and, due to the intermittent nature of equipment use, a point of use endotoxin filter should be used in order to provide a safety barrier. Guidance for healthcare and social services organisations, MHRA, April 2015 has produced guidance on managing medical devices.

At the planning stage, the following should also be considered:

- Dialysis water capacity during sanitisation
- Dialysis water capacity during the winter months
- 🕀 Use of RO reject water
- 🕀 Sanitisation of the system
- Compliance with BS EN ISO 13958; 2015: Concentrates for haemodialysis and related therapies
- Central concentrate delivery system
- Connectors for non dialysis water outlets within the dialysis area
- Contingency plans in the event of system failure or malfunction.

Haemodialysis patients are directly exposed to large volumes of dialysis fluid, with the dialyser membrane being the only barrier against transfer of hazardous contaminants from the dialysis fluid to the patient. To minimise this hazard, BS EN ISO 13958; 2015: Concentrates for haemodialysis and related therapies and BS ISO 13959; 2015: Water for haemodialysis and related therapies, set out the quality requirements for the water and concentrates used to prepare dialysis fluid.^{1,2}

However, dialysis fluid could contain unacceptable levels of contaminants even though it is prepared from water and concentrates meeting the requirements of the above standards. Furthermore, the dialysis fluid might be used as the starting material for the online preparation of fluids intended for infusion into the patient, for example, in therapies such as online haemodiafiltration.

For these reasons, BS EN ISO 11663:2015: Quality of dialysis fluid for haemodialysis and related therapies outlines the acceptable limits for microbiological contaminants of the dialysis fluid. BS EN ISO 11663:2015: Quality of dialysis fluid for haemodialysis and related therapies defines three levels of quality of dialysis fluid: standard dialysis fluid, ultrapure dialysis fluid, and online prepared substitution fluid.³



+ Standard dialysis

Standard dialysis fluid shall contain a total viable microbial count of less than 100 CFU/ml and an endotoxin concentration of less than 0.25 EU/ml. The action level for the total viable microbial count in dialysis fluid should be 50 CFU/ml. If microbial counts exceeding the action levels are observed in the dialysis fluid, corrective measures, such as disinfection and retesting, should be taken promptly to reduce the levels.

+ Ultrapure dialysis

Ultrapure dialysis fluid shall contain a total viable microbial count of less than 0.1 CFU/ml and an endotoxin concentration less than 0.03 EU/ml. As for standard dialysis fluid, if the limits are exceeded corrective measures should be taken to reduce the levels to an acceptable range. The production of ultrapure dialysis fluid necessitates the treatment of standard dialysis fluid using point of use filtration. The filters used for this, must be used and operated in accordance with manufacturers instructions for use.

+ Microbiological

Microbiological requirements for online prepared substitution fluid for convective therapies, such as haemodiafiltration and haemofiltration, may be produced online by a process of ultrafiltration with bacteria and endotoxin retentive filters. Compliance of online produced fluid with the requirements of BS EN ISO 11663; 2015: Quality of dialysis fluid for haemodialysis and related therapies cannot be demonstrated with traditional test procedures. For this reason, compliance with BS EN ISO 11663:2015: Quality of dialysis fluid for haemodialysis and related therapies shall be ensured by proper operation of a validated system, verified according to the manufacturer's instructions on installation, and confirmed by a regular monitoring and maintenance schedule.

In summary the need for high quality water for dialysis is critical to positive patient outcomes. The relationship between the supplier and customer is key to ensuring all standards are met and adhered to.

 * 1,2 and 3 as per WHO guidelines in water safety in buildings

Clinical



Clinical grade water is essential in a clinical laboratory and the trend is certainly towards higher purity requirements to meet the range of analyses carried out. Poor water quality not only affects the tests themselves directly but also impacts on all aspects of analyser operation. Good water purification design, especially providing recirculation through the key purification technologies, is the key to effective and long-term bacterial control, which is the most challenging aspect of water purification. This approach, combined with duplex operation and good support will provide the water needed.



Water Purity

Water purity has always been important in clinical diagnostics but on-going developments in the approach to clinical testing and in the sophistication and range of tests available have made water purity even more critical. The key requirements for water for clinical analysers are:



Traditionally, analyser feed water systems were mainly for chemistry-based analysers that used principally colorimetric and ion selective electrode technologies. The overall trend towards less invasive technologies has led to smaller blood and other samples and their use for a wider range of tests.

The Clinical Laboratory Reagent Water (CLRW) resistivity specification of >10 $M\Omega$ -cm restricts the concentrations of ionic impurities to ppb levels or less and, in effect, requires the elimination of carbon dioxide. This is adequate for most clinical work including general chemical, electrolyte, lipid and protein assays, enzymology, enzyme immunoassay, toxicology and therapeutic drug monitoring and, more recent, molecular biological techniques. When trace elements need to be determined, the water resistivity needs to be much higher – at $18.2 \text{ M}\Omega$ -cm. Bacterial contamination has serious effects on all aspects of analyser operation. The key is achieving consistently low levels. For example, problems can arise in immunoassay due to fluorescein released from bacteria (e.g. pseudomonas aureuginosa) giving high blanks and out-of-range standards during calibration and false positives with samples.

Clinical and Laboratory Standards Institute (CLSI) emphasises the need for rigorous trending of water system parameters to ensure that water purity is achieved and maintained. Water must be validated as fit for purpose and water purification system validation is strongly recommended.

Water Purification Technologies

In the first stage of pre-treatment particles in the feed-water are removed by filtration and disinfection residues, such as chlorine and chloramines, are reacted with activated carbon.

Reverse Osmosis (RO) is now the established method of removing the great majority of impurities. It is a membrane technique in which over 95% of ions are rejected along with virtually all particulates, colloids, bacteria and organic molecules with higher mass. However, it produces clinical grade water relatively slowly and its product water (permeate) is usually stored in a reservoir.

To meet CLRW or better the water needs to be purified further, usually by exposure to germicidal UV light and micro-filtration to maintain very low levels of bacterial contamination and passage through beds of ion-exchange resins which reduce ionic contamination to extremely low levels.

As well as needing pure water to feed analysers there are a variety of other requirements for clinical grade water in the clinical laboratory. The general applications can be more than adequately met by CLRW and can be provided by the analyse feed systems. Special requirements, such as for trace elemental analysis or nucleic-acid-based assays, may be met with specific water purification systems. Molecular diagnostics requires type I nuclease-free water suitable for gene sequencing. To avoid interferences, this must be kept free from calcium, magnesium, organics, endotoxin and bacterial nucleases using further purification technologies, such as multiple ionexchange, dual wavelength photo-oxidation and ultrafiltration. Chromatographic techniques, for example, LCMS-MS, GC-MS and HPLC in toxicology, require type I water with the lowest possible levels of organic contamination, best achieved by optimal system design with high purity components and dual wavelength photo-oxidation. ICP-MS and ultra-trace IC require water that is virtually free of elemental and ionic impurities, needing a high purity water system with multistage removal of ions using the highest efficiency and purity ion-exchange resins.

Clinical grade water is clearly essential in a clinical laboratory and the trend is certainly towards higher purity requirements to meet the range of analyses carried out. Less pure water impacts on all aspects of analyser operation. Good water purification design, especially providing recirculation through the key purification technologies, is the key to effective and long-term bacterial control, which is the most challenging aspect of water purification. This approach, combined with duplex operation and good support can provide the water needed.

At Your Service

Pure water guide for better healthcare. Think Veolia



Failure to maintain and service your water treatment systems could lead to plant failure or shut down. The consequence of which may lead to department closures and/ or patient lists cancelled. Our service offerings are tailored to meet our customer's changing needs. We work with our customer's to develop a service solution that suits their business needs, no matter the size or scope of the sites.



"Aquavista digital connectivity is embedded by design in our standard equipment. Ensuring easy connectivity to our wide range of digital services"



Many of the products are designed, assembled and tested in the UK and we hold an extensive parts and consumables inventory at our central distribution facility in Stoke-on-Trent to ensure minimised system downtime and the associated risk of cancelled procedures.

Service You Can Trust

We invest in a field based service team enabling nation-wide access to service engineers 24 hours a day via a dedicated call centre. Our customers obtain the security and confidence that we can provide fast and consistent support to meet your individual needs wherever you are.

Service support

- + Access to a nation-wide dedicated team of service engineers ensures continued compliance and support
- + System maintenance, calibration and validation is carried out as part of ISO9001:2015 quality system
- + Range of flexible service programmes provide guaranteed service levels in hospitals to ensure instruments are available for the operating theatre when they are needed. Our service solutions are tailored to your individual healthcare requirements.
- Each Healthcare service engineer carries their own stock of parts and receives appropriate and regular factory training to carry out system maintenance, calibration, revalidation and hardware/software enhancements as part of our ISO9001:2015 quality system

- We retain the capability and flexibility to provide you with a response to meet your specific needs -*4, 8, 12 & 24 hour response times
- + Customer training is delivered during commissioning and further training/refresher training can be organised.
- + Further support is provided with raw water and processed water testing



AQUAVISTA[™] Digital Services

Intelligent water management - AQUAVISTA offers a wide and flexible range of digital solutions that respond to your challenges. From operators to management, AQUAVISTA provides your plant personnel with system insights that:

- Improve system performance and uptime
- Lower operational costs
- Deliver ongoing system compliance

AQUAVISTA is suitable for new or existing systems - Veolia or non Veolia. Once connected, AQUAVISTA will free up time and budget, giving you more time to devote on delivering 24/7 patient care.



customer satisfaction and innovative pure water solutions.



• Maintaining investment in our people and expertise to provide long term



First Class Project Management and Service

Whether you require a completely new installation, refurbishment or modification of an existing system, we can help you find the most efficient, safe and cost-effective solution.

Our Partnership approach is simple. We have a long and strong history of working with scientists, architects, consultants and equipment suppliers throughout a project, to ensure customers' specific pure water requirements are met.

We can advise on the best technologies, materials and components for any application. Our experienced Project Team is familiar with the challenges associated with all project sizes and specifications, with a proven track record in large projects where delivery within timescale and budget are essential.

We work hard to meet our customers' expectations for performance, quality and regulatory compliance, regardless of laboratory size.

Our value to you

- Long-term reliable performance
- Patient safety and comfort
- + Advice on design, equipment combination and installation
- + Avoidance of cancelled dialysis sessions minimising time, cost and inconvenience
- Unrivalled service support for continued operations



Our experienced team of engineering consultants and project managers will advise you on the best technology for your needs and project manage every step of the process including design, installation, calibration, commissioning and training, for a successful handover.

Our solutions

- Palidated systems guarantee water purity for concentrate production
- Bespoke system designs meet all standards and specifications from all types of feedwater supplies
- Systems are designed to ensure supply and production of microbiologically pure water to maintain patient safety during treatment
- Integrated heat cleaning cycles ensure maintenance of hygienic pathways
- E Secure system design along with skilled technical support provides total peace of mind

Our Commitment to the future



Veolia consistently provides the world of Healthcare with reliable, high quality water for decontamination systems, renal and clinical pathology.

Rethink Water





Veolia Water Technologies

Windsor Court, Kingsmead Business Park, High Wycombe, Buckinghamshire, HP111JU

Tel. +44 (0)1628 897260

Email. sales.watertech@veolia.com Website.www.veoliawatertechnologies.co.uk