The Ministry of Health New Requirements for Dialysis Centers at Hospitals

Riad Farah
Medical Engineering Manager
Saint George Hospital
University Medical Center

Introduction

The Ministry of Public Health MOH issued a decree number 1/1690, dated 30 Sep 2014, requesting Hospitals to change their water treatment systems, to become Ultrapure, with specific maximum allowable measurements: TDS <10ppm, Microbial count <0.1CFU/mL and Endotoxin <0.03 EU/mL. This is important for patient safety and offers better Dialysis treatment quality. The Ultrapure Dialysis Fluid UPDF in Hemofiltration mode relies on 4 basic principles to assure its performance: advanced ultrapure water system, use of Pyrogen filters, proper Hemodialysis equipment, implementation of strict hygienic rules and most importantly regular microbiological monitoring. We shall shed some light on the MOH decision by briefing out Kidney Dialysis technology, and equally important, clarifying what are the water purity requirements.

Definitions

Haemodialysis (or Kidney Dialysis) achieves the extracorporeal removal of waste from the blood; such as creatinine, urea and free water. This is a life-saving procedure when the kidneys are in state of renal failure. Treated water is used as a raw material that is mixed with a powdered Dialysate to create a highly concentrated solution in the Dialysis process. The Dialysate runs counter current flow past the patient's blood in a hollow fiber membrane, whereby osmosis occurs, and removes contaminants from the blood stream.

Hemofiltration is used to treat acute kidney injury (AKI), and may be of benefit in multiple organ dysfunction syndrome or sepsis. It is achieved by movement of solutes across a semi-permeable membrane, but without using a dialysate. Hemofiltration requires higher level of water purity and advanced technology in the equipment to be able to choose between Low Flux filters or Hi Flux Filters, and to be able to install an Endo-Toxin Filter.

The Ultrapure Dialysis Fluid (UPDF) is a highly purified dialysis fluid, used in the concept of Renal Replacement Therapy (RRT), to clear out uremic toxins, correct anemia, metabolic bone disease and associated metabolic disorders. It requires Hemofiltration mode, blood volume and temperature control, use of high flux filter, and an ultrapure water treatment station.

The concept design of an Ultrapure water treatment station covers: Pretreatment system (softener, activated carbon, microfiltration), Online Double RO system (parallel or series), Online Heating system, Distribution loop system and Drain system for the Hemodialysis machines. All of these parts shall be explained shortly. Ultrapure Water imposes an additional cost associated with the periodic changes of the pyrogen filters on the dialysis machines.

Standards

The Association for the Advancement of Medical Instrumentation AAMI has developed minimum standards for the purity of water used in Haemodialysis. AAMI is the standard reference in the United States of America. It states that, hospitals offering Hemodialysis and Hemofiltration treatments must test regularly the following minimum water parameters: TDS, EndoToxin units, total viable Microbial counts, and preferably the following contaminants: Arsenic, Barium, Cadmium, total chlorine, Chromium, Copper, Fluoride, Lead, Mercury, Selenium, Silver, and Zinc. The Contaminants found in water could be Chemical impurities, Biological impurities, and Particulate contaminants.

Accordingly, water requirements for hospitals offering HemoDialysis are: TDS < 60ppm, EndoToxin < 0.25EU/mL and Total viable Microbial counts < 100cfu/mL.

Water requirements for hospitals offering HemoDiaFiltration treatments are: TDS < 10ppm with Hi Flux Filters, EndoToxin units < 0.03EU/mL with Hi Flux Filter, Total viable Microbial counts < 0.1cfu/mL, Aluminium <0.01, Arsenic <0.005, Barium < 0.1, Cadmium <0.001, Total chlorine <0.1, Chromium <0.014, Copper < 0.1, Fluoride < 0.2, Lead < 0.005, Mercury < 0.0002, Selenium < 0.09, Silver < 0.005, Zinc < 0.1.

The AAMI/ISO 13959 standard defines precisely the cultivation Microbiological Testing Procedure or Technique.

Water Treatment Systems

The principle components for water purifying technology are: Sediment, Softening, Activated Carbon, Reverse Osmosis RO, De-Ionization, Ultra-Violet and Heat/chemical disinfection.

The Sand, Sediment or Multimedia Filtration is capable of removing solid contaminants down to a size of 7 to 10 µm from the incoming source water supply.

The Water Softening system works on exchanging Calcium and Magnesium ions with Sodium ions using a cation exchange resin. It is typically used as pretreatment to a reverse osmosis system to reduce scaling on reverse osmosis membranes. It must be properly sized for both Flow Rate and Hardness removal Capacity (Figure1).

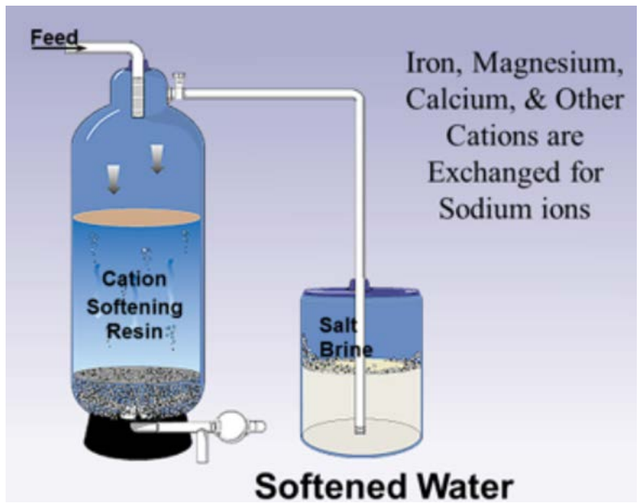

Figure1.The water softening system.

The granular activated carbon filters are generally employed to remove chlorine and chloramines prior to a reverse osmosis or deionized water system, however they are very effective at absorbing dissolved organics.

The Reverse Osmosis RO is the common method which is used to purify water for Haemodialysis. It is capable of removing more than 90% of the impurities and produce sufficiently pure water for dialysis. For better water quality, hospitals must have double Reverse Osmosis R/O water treatment system, and a continuous microbiological testing and monitoring. Reverse Osmosis RO occurs when hydraulic pressure is applied to water containing a concentration of dissolved inorganics against a semi permeable membrane. Pure water is driven through the semi permeable membrane and a more concentrated solution is rejected.

Deionization (DI) is an effective method of improving the chemical quality attributes of water by removing cations and anions, and removing dissolved inorganics with a high level of efficiency. The ion exchange resins consist of cation and anion resins. Because free endotoxin is negatively charged, there is some removal of endotoxin achieved by the anionic resin.

The Ultraviolet Disinfection system relies on Ultraviolet light of 254nm wavelength, which can be used for bacterial reduction, removal of ozone, removal of chlorine and Total Organic Carbon TOC reduction. To sterilize properly, this system relies on the proper contact time without which, the Ultraviolet light will not have enough time to destroy the DNA of micro-organisms. On the other hand, it generates endotoxins.

Heat Disinfection is regulated and standardized in AAMI/ISO 13959:2009 and AAMI/ISO 13958:2009. Water treatment systems can be sanitized using either thermal or chemical means. On-line Thermal approaches to system sanitization include periodic or continuously circulating hot water and the use of steam. Temperatures of at least 80 are most commonly used for this purpose, but continuously recirculating water of at least 65 has also been used effectively in insulated stainless steel distribution systems. These techniques are limited to systems that are compatible with the higher temperatures needed to achieve sanitization. Although thermal methods control biofilm development, but they are not effective in removing established biofilms. In such cases, a combination of routine thermal and

periodic supplementation with chemical sanitization is more effective. The frequency of sanitization should be according to the results of system microbial monitoring, without exceeding alert levels.

Endotoxins are lipopolysaccharides found in and shed from the cell envelope that is external to the cell wall of Gram-negative bacteria. Gram-negative bacteria that form biofilms can become a source of endotoxins in pure waters. Storage tanks may be included in water distribution systems to optimize processing equipment capacity. Storage also allows for routine maintenance within the pretreatment train while maintaining continuous supply. Proper design, materials like stainless steel, and operation considerations are needed to prevent or minimize the development of biofilm. On-line RO systems do not have storage tanks, and offer cleaner water quality, but offer limitations on the operation capacity of the system, and make the maintenance more difficult. The distribution loop and drainage system must be studied as well to compliment the proper design of the whole water treatment system.

Equipment Technology

The Hemodialysis equipment must have a relatively advanced technology to offer several types of dialysis procedures, for the doctors to choose the best procedure suitable for each patient medical case: Single Needle technology (which is more suitable for patients with special catheter lumen conditions), Biofeedback (which controls and monitors the patient blood pressure by changing the ultrafiltration rate) (blood volume and Temperature control), direct quantification, use of high flux filter, KT/V measurements (which is essential for Urea clearance calculation), and Hemofiltration mode.

References

AAMI adopted ISO Standards in 2012. The AAMI Standardsare:

- *RD 61: 2000 Concentrates for Hemodialysis*
- *RD 51: 2003 Hemodialysis Systems*
- *RD 52 : 2004 Dialysate for Hemodialysis*
- *RD 62 : 2006 Water Treatment Equipment for Hemodialysis Applications*
- *ANSI/AAMI/ISO 23500:2011, Guidance for the preparation and quality management of fluids for hemodialysis and related therapies*
- *ANSI/AAMI/ISO 11663:2009, Quality of dialysis fluid for hemodialysis and related therapies*
- *ANSI/AAMI/ISO 13958:2009, Concentrates for hemodialysis and related therapies*
- *ANSI/AAMI/ISO 13959:2009, Water for hemodialysis and related therapies*
- *ANSI/AAMI/ISO 26722:2009, Water treatment equipment for hemodialysis applications and related therapies*
- *ANSI/AAMI/ISO 8637:2010, Cardiovascular implants and extracorporeal systems — Hemodialyzers, hemodiafilters, hemofilters and hemoconcentrators*
- *ANSI/AAMI/ISO 8638:2010, Cardiovascular implants and extracorporeal systems — Extracorporeal blood circuit for hemodialyzers, hemodiafilters and hemofilters*
- *ANSI/AAMI/ISO 60601-2-16:2012, Medical electrical equipment - Part 2-16: Particular requirements for basic safety and essential performance of hemodialysis, hemodiafiltration and hemofiltration equipment*
- *U.S. PHARMACOPEIA USP2*