White Paper – Monitoring Dialysis Water Treatment Quality

Introduction

Water treatment systems used in dialysis are a critical factor in the overall care received by dialysis patients; they also provide one of the greatest hazards to the patients if they are not functioning properly.
Monitoring of water treatment systems has been an identified area of concern, and an opportunity for quality improvement worldwide.
Facilities and clinics rely on their water treatment systems, and these systems must be superior in order to provide the best water possible. The incoming water, the distribution piping that carries the purified water, and a reliable back-up system all must be designed and maintained in order to meet the stringent demands of the AAMI water standards.
Water purification system combines media filtration, reverse osmosis (RO), and ultra-filtration.

Since the chlorine levels in this application are very low (< 0.1 ppm), accuracy, resolution and response time are very important. HG-702 Blue I analyzer is able to provides high resolution, high accuracy and faster response time to changes in chlorine levels. Due to the pre-measurement automated self calibration for each reading the analyzer can adjust to changes in the process and increase system reliability. Likewise, the Blue I analyzer is able to provide measurements for both free chlorine and total chlorine measurements in a single system improving the management of the process.

Dialysis Water Treatment

Typical System Components:

- Mixing Valve - blends incoming hot and cold water for reliable temperature production
- Booster Pump - designed to provide consistent and adequate water pressure to the RO machine
- Sediment, Softeners and Carbon absorption Filters
- Reverse Osmosis (RO) - designed for medical applications
- Optional Storage Tank - provides continuous loop operation & allows for reduced pretreatment & RO size
- Exchangeable Pyrogen Filtration units - designed to remove bacteria and endotoxins
- Deionization (DI) Interface - used for improving quality or for stand-by operation

Dialysis water treatment system components detailed explanation (See figure 1):
Temperature Mixing Valve:
A temperature mixing valve mixes the cold and hot incoming water feed to approximately 77degree F. Advantage - A reverse osmosis membrane is most efficient with a 77 degree F water feed. Disadvantage - Loss of cold or hot water supply pressure will cause the mixing valve to shut off its outlet and consequently shut down the dialysis water purification system.

Backflow Prevention (RPD):
Backflow prevention is incorporated to insure the integrity of a potable water system. In the event a treated water system reverses flow, the backflow preventer will divert the treated water to drain insuring the integrity of the potable water feed. Backflow prevention should be installed to meet state and local requirements.
Carbon Filtration:
Carbon filtration is used to remove chlorine, chloramines, and low molecular weight organics through the process of adsorption. Adsorption is the process by which vapor, dissolved material or very small particle adheres to the surface of a solid. Carbon filtration capacity is commonly sized for the empty bed contact time (EBCT) required for removing chlorine and chloramines from the supply water.
AAMI standard for EBCT is 6 minutes for chlorine and 10 minutes for chloramines removal.
AAMI recommends a test for free and total chlorine is conducted prior to every patient shift.
Water Softener:
Water softening, with the use of ion exchange, removes positively charged ions (calcium, magnesium, and heavy metals) from the incoming water supply. The positively charged ions are replaced with sodium ions. The main function of a water softener in a dialysis water purification system is to protect and extend the life of the reverse osmosis membranes.
Reverse Osmosis:
A reverse osmosis unit used for dialysis should be equipped with the following:
· 5-micron pre-filtration
· Pressure readings
· Flow readings
· Temperature monitor
· Conductivity water quality monitor equipped with visual and audible alarms
Storage Tank:
A storage tank should be made of an inert material and opaque in color. It is of a sealed-top/coned-bottom design. The tank has a hydrophobic vent filter to control airborne bacteria from entering the tank.
Deionization:
Deionization is normally utilized in a dialysis water purification system for the following reasons:
- provides the best quality water for dialysis
- Emergency bypass in the event of RO failure
- Bacteria control when cation and anion resins are separated
- Polish the reverse osmosis water
- Polish the distribution loop return water before it goes out to the dialysis stations

Minimum 1 megaohm-cm water
Installed in a worker-polisher configuration (carbon filtration)
Temperature compensated resistivity monitor located at the output of the final deionizer
Ultraviolet Disinfection:
UV disinfection is utilized in a dialysis water purification system for bacteria control.
Final Filtration:
Final Filtration of 0.05-micron or smaller is recommended for bacteria and endotoxin control. The final filter or ultra-filter should be the last component the purified water passes through before going out to the dialysis stations.
System Sanitization:
Sanitization should be based on bacteria testing and a preventative maintenance schedule.
Dialysis sanitization chemicals are chlorine and Renalin.

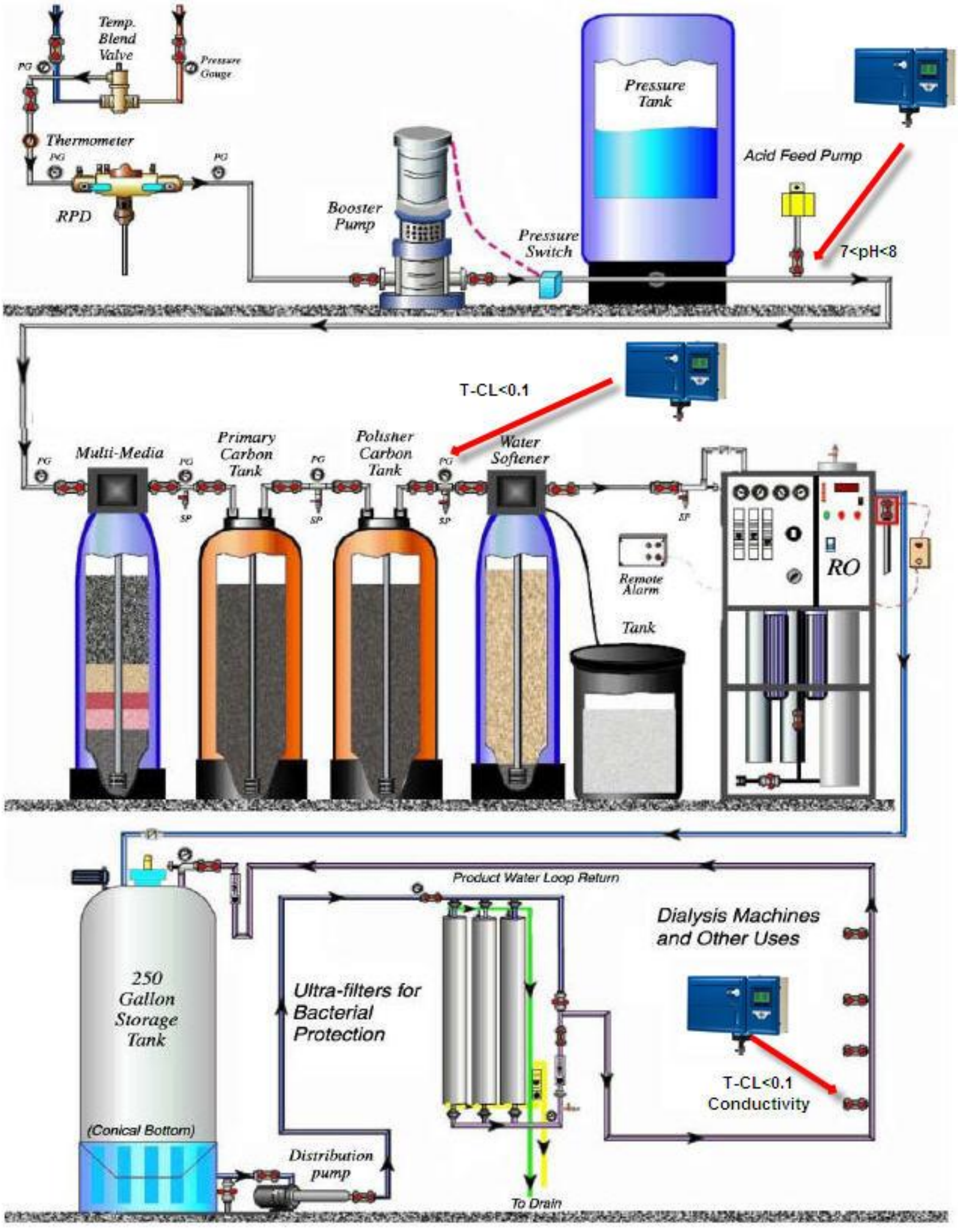

Figure 1: Dialysis water treatment system schematics

Application Overview

Acid Feed Pump:
Though this is not needed in all water treatment systems, adding an acidic solution to the raw water is indicated in areas where the pH of incoming feed water is high. Some municipalities add a base such as sodium hydroxide into the water system to increase the pH of the water. This minimizes leaching of metals from the pipes. Carbon filtration and Reverse Osmosis devices will not work as effectively at a pH of >8.5. In these municipalities, adding an inorganic acid to lower the feed water pH may be required for the proper functioning of water treatment system. Organic acids are discouraged because they encourage bacterial growth. To assure that the acid is fed in at the appropriate rate, pH must be monitored from a sample port just downstream from the acid feed pump. This monitoring should be performed with a pH meter or pH strip that is designed for the level anticipated.
The expected range for pH should be between 7.0 and 8.0. Some important points to consider:

1. Place the acid feed system before the multi-media since the lower pH can cause aluminum to precipitate.
2. Online monitoring of pH is required with both audible and visual alarms in place
3. An independent test of pH is required daily

Note: Sometimes as an alternative pretreatment, weak acid cation tanks are used to lower pH by adding hydrogen ions.

Carbon Tanks:
One of the most critical tasks regarding patient safety in the day of a dialysis technician is checking the water treatment system for chlorine and chloramines. Chlorine and its combined form, chloramines, are high-level oxidative chemicals. They are added to municipal water systems to kill bacteria—but they also destroy red blood cells. For this reason they must be removed from water to be used for dialysis.
Unfortunately the R/O system is not very effective at removing chlorine and chloramines. In fact, many membranes are destroyed by them. Chlorine is removed from the incoming water by running it through tanks filled with Granulated Activated Charcoal (GAC, or carbon), which absorbs it.
Carbon tanks are part of the pre-treatment section of a water treatment system and normally are arranged where water will flow first through one tank and then directly into another. This is called a “series” configuration. The first tank in the series (Primary Carbon Tank) is referred to as the “worker” tank and second is called the “polisher.”
Knowing the flow arrangement of the carbon tanks will help understand how and where to test them. The amount of carbon in the tanks must be adequate to allow the chlorine to be absorbed in the amount of time the water is flowing through it.

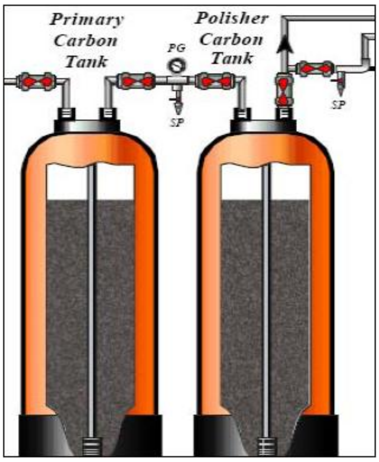

Figure 2: Carbon Tanks

The water must be exposed to the carbon for 5 minutes in each tank, for a total of 10 minutes for both the worker and polisher. This residence time is known as Empty Bed Contact Time, or EBCT. It is calculated using the formula EBCT=V/Q, where V= the Volume of Carbon (in cubic feet) and Q= the water flow rate, in cubic feet per minute. To calculate the volume of carbon needed, use the formula V= (Q * EBCT) / 7.48 (this is the number of gallons in one cubic foot of water).

For example, if the flow rate is 10 Gallons per Minute (GPM), and the needed EBCT is 5 minutes, the calculation would be:

V = (Q * EBCT) / 7.48
V = (10 * 5) / 7.48
V = 6.69

A 6.69 cubic foot carbon tank is needed for each working and polishing tank.
To calculate the EBCT from a known carbon tank volume and flow rate (assume a 6 cubic foot tank and a 12 GPM flow rate), the calculation would be:

EBCT = V/Q
EBCT = 6 / (12/7.48)
EBCT = 6 / 1.6
EBCT = 3.75 minutes per 6 cubic foot tank

The objective of the chlorine/chloramines testing is to verify that chlorine has been removed from the water entering the RO. The sample should be taken at the point where the water leaves the first tank (worker) and before entering the second (polisher). If the results show any chlorine leaving the first tank, a second sample should be taken immediately after the water leaves the second tank.
If there is chlorine leaving the second tank, dialysis should be discontinued in the facility.
If there is no breakthrough, the chlorine level should continue to be monitored after the second tank on an hourly basis until the primary tank is replaced. This is because there is no redundant protection anymore.
It is very important that the water system be in full operation for *at least 15 to 20 minutes* before taking the first test. If a sample is taken as soon as the system starts up, the testing will be of water that has been sitting in the tank overnight, and it will not give a representative sample of the carbon tank's capability at normal flow rates.
There are various ways to test water for chlorine/chloramines but the most widely used are colorimeters.
AAMI limits for chlorine is 0.5 PPM, and for chloramines is 0.1 PPM. There is no method to test directly for chloramines, to that one must perform two separate tests: one for Total Chlorine, and one for Free Chlorine. The chloramines level is the difference between the two tests.
Example:

The measurement of Total Chlorine is 1.2 PPM
The measurement of Free Chlorine is 0.8 PPM
1.2 - 0.8 = 0.4 PPM
Therefore the Chloramines level is 0.4 PPM

It is acceptable, according to the AAMI, to just test for total chlorine so long as the test is of appropriate sensitivity and the result *does not exceed* 0.1 PPM. The rationale being if there is a zero reading for total chlorine then there is no chloramines present.

Feed Water:
A chemical analysis of the feed water should be performed periodically in order to be aware of the chemical composition, and assure that the water treatment system is designed to be able to reduce those contaminants to levels identified by AAMI.
The feed water analysis should be taken from the water before it enters any part of the water treatment system. It can be taken from a sink near the water treatment room so long as it has not been treated in any way.
If the back-up water plan is to use softened, de-chlorinated water, or DI water in the event of an RO failure, one must also test this water. Testing should be performed for pH, endotoxin and bacteria on water from this back up plan as well.
The samples should be sent to a qualified lab that has the capability of analyzing them by the correct methodology and to the levels specified by AAMI. It is strongly suggested that the feed water be analyzed at least four times a year so that any seasonal variations, which are often present, will be known. There are no standards for contaminant levels in feed water. The results of the feed water

analysis can be used to predict product water contamination by simply multiplying the individual results by the RO's percent rejection.
A trend analysis should be performed to show trends over time.

Product Water:
An indirect method must be employed to continuously monitor the chemical quality of the water. This is achieved by monitoring conductivity in RO systems and resistivity in DI systems. In an RO system, conductivity is generally measured before (input) and after (output) the water passes through the RO membrane. Conductivity indicates the level of Total Dissolved Solids (TDS) in the water in terms of Parts per Million (PPM).
By using the "percent rejection" formula {1-(output conductivity / input conductivity)}* 100, one can determine the percentage of a given solute that is removed by the RO membrane. The conductivity monitor should be temperature compensated to give a consistent conductivity reading.
Example:

Input conductivity is 100 PPM, and Output conductivity is 8 PPM.
Enter into the formula: {1-(8/100)}*100
Equals (1-0.08)*100
Equals 0.92*100
Therefore, there is a 92% rejection of total dissolved solids.

Note: Conductivity of raw and RO water is actually measured in Micro Siemens.
This measurement is equivalent to PPM, and is usually stated as PPM on the RO water quality monitor.
In a Deionization System, water quality is monitored differently. Because the water from a DI is more pure than RO water, the conductivity is too low to monitor accurately. For this reason, we monitor resistance to the flow of electricity, which is the inverse of conductivity. Percent rejection is not monitored, just the final product water. The acceptable limit of resistivity is greater than 1 mega ohm/cm resistance. It is very important to understand the monitor on the particular DI system, as they can be variable.

Blue-I Solution:

Technology:

Multi-parameter analyzer based on DPD colorimetric method

Objective:

- Measurement of free and/or total chlorine with high resolution (0.01ppm) and accuracy
- Meet ANSI/AAMI standard requirements for Hemodialysis systems
- Identify zero level chlorine with high accuracy and repeatability
  - Suited for chlorine measurements in post carbon filter (GAC) water
  - Suited for chlorine measurements in pre RO water

Technology Description:

The method of determining chlorine employed in our analyzer relies on a color indicator, usually N, N-diethyl-p-phenylene-diamine, denoted in its short and known term 'DPD'. In the presence of chlorine, DPD reacts rapidly to form a red color, the intensity of which is an indicator of chlorine concentration. When the absorbance is low it means that the chlorine concentration is low. Though the photochemical reaction is pH sensitive, DPD/chlorine system typically appears in a red color, measured at about 515 nm. At a near neutral pH, the primary oxidation product is a semi-quinoid cationic compound known as a Wurster dye. The DPD Wurster dye color has been measured photo-metrically at wavelengths ranging from 490 to 555 nm.

The analyzer comprise of a novel spectrophotometric measuring cell, useful for automated reagent mixing and for hands free physical cleansing. The measuring cell is characterized by that whereat fluids and/or reagents are filling the measuring tube; they are effectively mixed by to obtain a homogenized solution. In this way, a tedious necessity of manually cleansing routine is thus avoided. A detector is used, which has means to measure the emission of the solution and datermin the chlorine concentarion with high accurecy and repeatability.

Figure 3: Analyzer schematics

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Technology benefits

- Maintenance advantages
    - Very low reagents consumption (~0.03mL/sample)
    - Self calibration and true zero with every measurement without any need for initial calibration
    - Automatic self cleaning photocell by a build in piston in each unit (patent pending)
- Performances advantages
    - Measurement range: 0-10 ppm
    - Measurement interval: 2 to 10 minutes
    - Measurement accuracy (+/- 5%)
- System benefits
    - Six independent relays for equipment control
    - Having means to measure additional parameters such as pH, Redox, conductivity, turbidity and temperature.

Summary

Online automated monitoring of chlorine is essential and critical for dialysis water treatment applications as it helps keeping the dialysis patients safe. In virtually every instance in which patients have come to harm from water treatment systems in dialysis, there has been a lapse in effective monitoring.

Water treatment systems and dialysis machines need to be disinfected periodically. Chemicals such as bleach (chlorine) are commonly used for this purpose. It is necessary to continuously monitor the chemicals concentrations. After the disinfection procedure is complete and the system is rinsed, monitoring absence of chemicals in the system is of most importance.

Since the chlorine levels in this application are very low (< 0.1 ppm), accuracy, resolution and response time are very important. HG-702 Blue I analyzer is able to provides high resolution, high accuracy and faster response time to changes in chlorine levels. Due to the pre-measurement automated self calibration for each reading the analyzer can adjust to changes in the process and increase system reliability. Likewise, the Blue I analyzer is able to provide measurements for both free chlorine and total chlorine measurements in a single system improving the management of the process.

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