

AAMI ANALYSIS

An AAMI (Association for the Advancement of Medical Instrumentation) Analysis along with other tests, are performed on the feed water, pre-sale, in order to aid in the design, sizing, and pre-treatment considerations of the RO system. AAMI guidelines (see AAMI Water Quality Standards, this section) were established using 10% of EPA (Environmental Protection Agency) safe drinking water standards as the criteria, and are also based on contaminant levels that are benign to patients. Thus, if the source water is within EPA safe drinking water standards and the RO membrane operates at around 95% ± rejection performance for listed AAMI contaminants, then it can be estimated that AAMI standards will be more than met. To validate this, the product water is analyzed post-installation. Thereafter, it is mandatory that an AAMI product water analysis be performed once a year, preferably more often with seasonal changes.

Mar Cor Purification will provide, upon request, laboratory water analysis of the source water with equipment purchase. Samples will be tested for contaminants listed in the *American National Standard for Hemodialysis Systems*, published by AAMI, with the exception of chlorine and chloramine, that must be tested on-site.

The P/N is ME70001. The cost of the source water analysis **may** be absorbed as 'pre-sale activity' for central systems or quantities of portables with prior approval. A post-installation product water AAMI Analysis is included in the price of the sale and is used to validate the proper functioning of the RO system at initial start-up.

Mar Cor will provide water sampling kits to the customer for collection and shipping of water samples for testing. Each kit consists of one sample bottle, a laboratory request form, shipping package, labels, and complete instructions. Tests other than AAMI Standard are necessary to fully evaluate the source water. Additional tests will be recommended on a case-by-case basis and may include iron, silica, chloride, bicarbonate, alkalinity, or others as required.

The laboratory results, along with any other previous water analyses that may be available or water quality reports from municipal water suppliers, will be evaluated to determine the pre-treatment modes (multi-media, carbon filtration, softening, dealkalization) and size necessary to provide AAMI Standard quality water to the hemodialysis unit and maximize the performance of the overall system.

It is the responsibility of the Salesperson to inform Mar Cor of the impending sale so that we can contact the customer and consequently send, if necessary, a water analysis kit to a responsible person in the dialysis facility. A Facility Survey (see Facility Survey, this section) is also sent to the centers that are purchasing large RO systems.

Details of the analysis include a pass/fail assessment of each listed contaminant (relative to the AAMI Standard limit) as well as 'pH' and 'Total Hardness' measurements. The dialysis unit Medical Director and other responsible personnel will be notified of the results and recommendations as well as the Salesperson.

ON-SITE TESTS:

1. Chlorine and Chloramine:

Because chlorine and chloramine in the water sample will dissipate over a short period of time, chlorine and chloramine levels must be measured on-site and consequently will **not** be reported on the AAMI Analysis lab results.

Chlorine and chloramine tests are obtained to appropriately size the carbon tanks. Even if chlorine or chloramines are not present in the water source, it is a regulation that all RO systems are equipped with carbon filtration (refer to Equipment section, # 10 Carbon Tanks).

Most dialysis providers will already have a means of testing chlorine and chloramine levels, but if they do not, chlorine test kits are available from the Hach Company (Cat. No. 2231-01 or 14542-00) by calling 1-800-227-4224.

2. Hardness:

Water hardness is a limiting factor in the application of reverse osmosis as it can create scale or mineral deposits on the membrane surface. Over time, scale can build up and cause degradation of the product water quality and flow rate. The tendency of a given water source to cause scaling is a function of the hardness of the water that is directly related to its calcium [CaCO₃] and magnesium carbonate [MgCO₃] content and pH value.

The "Pre-Treatment Graph" in this section shows the 'scaling curve', defining the relationship between hardness and pH. The more alkaline the water source, the higher the tendency for scale to develop. A water source whose pH and hardness intersect in the shaded area is at definite risk of scale formation. A customer whose water source comes close to the line would benefit from either a softener or a pH reduction such as a dealkalizer (refer to Equipment section, #8 Softener).

Hardness and pH can be performed on-site with simple test strips. A Langelier Saturation Index (LSI) can also be calculated to evaluate the propensity of the feed water to form calcium and magnesium carbonate deposits (see heading "Langelier Saturation Index", on page 4, for details).

"Zero-Soft" (no hardness) water is, of course, the most desirable feed water for any RO system. Softening of the feed water is a very effective method of removing calcium and magnesium ions from the water stream before it enters the RO. Large central RO systems routinely incorporate water softening as a part of pre-treatment because water supplies can change on a seasonal, or even daily, basis. Hardness and pH can vary with changes in the municipal water supplier's raw water sources, so softening is both standard practice and good insurance against scaling in large central RO systems.

However, for small portable systems, there may sometimes be a fine line between *needing* a softener and maintaining *portability*. Every component added to a portable system increases the weight of that system, so we will generally recommend the minimum necessary to meet AAMI standards. In some parts of the country; however,

the source water has both very high hardness and high pH. This will necessitate the use of both a softener and a dealkalizer to reduce pH and increase the operational life of the membrane (refer to Hardness Map, this section).

"Borderline" situations, in that the scaling potential falls just inside the shaded area of the curve (see Pre-Treatment Graph), allow other options for the portable RO customer. The customer may decide to use softening pre-treatment with its attendant time, materials (salt), added weight, and capital expense considerations; or, the customer may elect to perform a weekly cleaning procedure to remove precipitate (scale) before it becomes too thick and solid to remove. We recommend a cleaner called **BIOSAN™** for this procedure. Not only does it remove the mineral scale, it also decreases the organic biofilm that develops in all water systems (refer to BIOSAN™ information in the Mar Cor Purification Literature section).

3. Silt Density Index:

Many source waters, in spite of their apparent clarity, may carry a large amount of suspended particulate matter that can adversely affect RO membrane systems. Silt Density Index (SDI) measurements are not performed routinely, but may sometimes be required to determine the water's propensity for fouling and plugging the membranes due to suspended matter.

An SDI is obtained by running the source water through a test apparatus containing a microporous membrane filter (0.45 Micron) at a standard pressure (30 PSI), and then, at 5-minute intervals, monitoring the time required to collect a 100ml sample. As the membrane filter loads up with particulate matter, the time required to obtain each 100ml sample will increase. The data are then converted into a single number, the 'index', by that relative fouling tendency may be gauged. The higher the index number, the higher the fouling potential of the water. Most RO membrane manufacturers recommend that feed water Silt Density Index not exceed 5.0.

Adequate filtration is required to reduce the silt content of the feed water to acceptable levels. Multi-media filters will accomplish this and are most often a part of large central systems, providing the first stage of filtration, and followed by cartridge-type particulate filters in various Micron ratings. Mar Cor Purification can provide semi-automatic, backwashable, multi-media filters for the portable RO units, but there is rarely a need for filtration beyond the disposable 5 Micron cartridge-type filters supplied with these systems.

Over the life of a membrane, a certain amount of fouling will occur even with adequate filtration. Regular cleanings with a silt/organic type (high pH) cleaner followed by de-scalant treatment (low pH), as recommended in the operator's manual, will remove most foulants and keep the system functioning normally.

OTHER TESTS:

The following tests are performed on a case-by-case basis and are not routinely performed with every system purchased.

1. Langelier Saturation Index:

The Langelier Saturation Index (LSI) is a method of predicting whether or not carbonate deposits will form under given circumstances on the RO membrane. The formula for computing the pH of saturation is defined as the point at which CaCO_3 (calcium carbonate) neither precipitates nor dissolves. High source water pH promotes scaling and lower water pH prevents the formation of scale.

The pH of saturation is derived from the total dissolved solids, calcium concentration, total alkalinity, pH, and temperature of the reject stream. Since pH, alkalinity and temperature change rapidly, they must be tested ON-SITE. Once the pH of saturation is determined, the LSI can be calculated.

If the pH of the reject stream is higher than that of the pH of saturation, the higher the chance for the system to form scale and the LSI will come out as a positive number. If the pH of the reject stream is lower than that of the pH of saturation, the less likely the system is to form scale and the LSI will be a negative number.

It is useful to calculate the LSI in order to determine the maximum recovery and rejection rates that can be achieved in a system before carbonate deposits will seriously diminish water quality and recovery.

2. **Iron:**

Iron is present in source water in two forms, soluble and insoluble. Insoluble iron is fine particulates or colloidal matter and its effects can be measured by the Silt Density Index. Soluble or dissolved iron can form scale on the RO membrane similar to calcium and is measured by lab analysis, but is not included on the AAMI Analysis.

Iron collected on the membrane not only fouls the membrane but also reacts strongly with Renalin-type disinfectants. Therefore, the membrane needs to be cleaned of its iron content on a routine basis and before Renalin-type disinfectants are introduced into the system.

A water softener is the method of choice for removing dissolved iron from the supply water. A softener can remove the dissolved iron in levels up to 5 PPM as long as the ratio of dissolved iron in PPM and total hardness in Grains Per Gallon does not exceed 1:10.

A non-recommended, rare practice is the use of a component that contains manganese greensand resin. Manganese greensand will also aid in the removal of dissolved iron from the feed stream, but it has to be regenerated with a highly toxic chemical known as potassium permanganate that is highly staining and may be hazardous to patients.

3. **Silica:**

Silica (SiO_2) in the presence of calcium or aluminum can become very insoluble and form a colloidal scale on the RO membrane. In alkaline solution, the solubility of silica is greater than in neutral or acidic solutions, where it becomes more insoluble. Silica can be measured on-site with a Hach test kit or through lab analysis.

Ultrafiltration or RO is the method of choice for removing silica in dialysis applications. Other means add chemical permeators to remove silica and these can be caustic to the dialysis patient.

If silica is discovered to be high in the source water, the RO membranes need to be cleaned more often. Also, the recovery rate of the system can be decreased in order to compensate for the high silica level and help delay scaling of the RO membrane.

4. **Bicarbonate:**

The pH of a solution can be altered by the presence of bicarbonate in the feed water; the higher the bicarbonate level, the more alkaline the solution may become. As stated previously, in the presence of an alkaline pH, calcium and magnesium will form carbonate scale deposits on the membrane surface. Bicarbonate is expressed as HCO_3 and measured as CO_2 on lab analysis.

If bicarbonate is found to be high in the source water in conjunction with a very alkaline pH, a dealkalizer may be added to the pre-treatment line. A dealkalizer contains resin that will reduce the anions (negatively charged ions) in the water in exchange for chloride, thus reducing the pH. Similar to a softener (a softener removes cations that are positively charged ions), it is regenerated with sodium chloride.

Acid feed systems, with a metering pump that continually injects acid into the stream, have been used to reduce pH in the feed water. However, the pH of the feed water can change daily, and these systems have to be manually adjusted and monitored continuously, that leaves a margin for error.

5. **Chloride:**

Chloride has no adverse effects on RO membranes. It is listed on the Facility Survey only for reasons of projecting membrane performance (see Membrane Performance Projection, this section), because the Desal membrane performance computer program requires this value.