North Texas Chapter of NANT
16th Annual Symposium

Hemodialysis Water Treatment
Today's Technology and Trends

Burke A. West, P.E., CWS-MWS

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Presentation Will Cover

- Short history of hemodialysis water treatment
- Today's traditional hemodialysis water treatment
- Latest Trends and Future

History of Hemodialysis Water Treatment

- Short history of hemodialysis water treatment
- Today's traditional hemodialysis water treatment
- Latest Trends and Future

History of Hemodialysis Water Treatment

- When was dialysis discovered?
  - 1854 by Thomas Graham who worked at Glasgow University in Scotland and proposed, together with Dr. Richard Bright (who was working on renal disease), that this would form the basis of a treatment for renal failure

History of Hemodialysis Water Treatment

- When was the first human dialysis performed?
  - 1924 by Haas at the University of Giessen in Germany

History of Hemodialysis Water Treatment

- Hemodialysis as we know it today:
  - Was basically developed by the mid-1960s
  - Is available today every developed country in the world (except China) as part of their national health care program.

History of Hemodialysis Water Treatment

- Water treatment has always been part of hemodialysis
  - First water used was municipal water. There was no standard for this water.
  - The hemodialysis water treatment systems evolved over time. Ingrid Ledebo of Gambro R&D has commented, "The required equipment was empirically developed and consisted of sedimentation filters, carbon filters and softeners. In the mid-1970s the toxic effect of aluminum accumulation was discovered and led to the introduction of reverse osmosis (RO) modules."

History of Hemodialysis Water Treatment

- Reverse osmosis (RO) machines were in the early stages of development. The best machines could reject over 90% of the metal salts. As such, AAMI chose as its water quality standard that RO machines must have a minimum rejection rate of 90%. Modern machines have between 98% and 99% rejection. But the AAMI standard got fixed in time at 90%.
- The first hemodialysis water treatment systems were based upon industrial water treatment technology. This typically included a multimedia filter, a softener, a back-washable carbon filter, and a sediment filter before the RO machine. The product water from the RO machine was then put into a storage tank and used as needed in the industrial process.

History of Hemodialysis Water Treatment

- This original technology of over 50 years ago got institutionalized into hemodialysis water treatment mentality and impeded the development of water treatment systems until recently.
  - One of the reasons is that since 1976 the FDA has required that new medical device equipment get a 510 (k) clearance before selling the unit in the United States. However, pre-1976 systems were grandfathered into the 510 (k) system. Thus the easiest way for a water treatment equipment manufacturer to get a 510 (k) clearance was to copy a water treatment system in existence before 1976.

History of Hemodialysis Water Treatment

- Another reason is that the hemodialysis water treatment suppliers almost always came from the industrial water treatment industry and felt more comfortable supplying industrial equipment systems. Few companies specialized in medical water systems.
- A third reason was that the larger hemodialysis chains made some of their own specifications for the water treatment system. Unfortunately although the intensions were good, they were ill advised when putting together the specifications.

History of Hemodialysis Water Treatment

- I call the period between the 1960s and the new millennium the dark ages for hemodialysis water treatment systems.
  - There were many suppliers that should not have been in the market.
  - No-one questioned the technology.
  - And, little evolution occurred during those years.
- However, the biggest change during this time was the maturing of the market along with the hemodialysis provider market.
  - The number of water treatment suppliers dropped by a couple of magnitudes
  - Today there are only a few major hemodialysis water treatment companies providing much better equipment to a much small number of hemodialysis providers.

History of Hemodialysis Water Treatment

- Short history of hemodialysis water treatment
- Today's traditional hemodialysis water treatment
- Latest Trends and Future

Traditional Hemodialysis Water Treatment System

- AAMI RD62 is the standard currently used today for hemodialysis water treatment systems. It includes the AAMI Water Profile specifies that water used for hemodialysis has a total viable microbial count of less than 200 CFU/mL and an endotoxin concentration of less than 2 EU/mL.

Traditional Hemodialysis Water Treatment System

Contaminants with documented toxicity in hemodialysis	Maximum Concentration (mg/L)b)
Aluminum	0.010
Chloramines	0.100
Free Chlorine	0.500
Copper	0.100
Fluoride	0.200
Led	0.005
Nitrate (as N)	2.000
Sulfate	100.0
Zinc	0.100
Calcium	2 (0.1 mEq/L)
Magnesium	4 (0.3 mEq/L)
Potassium	8 (0.2 mEq/L)
Sodium	70 (3.0 mEq/L)

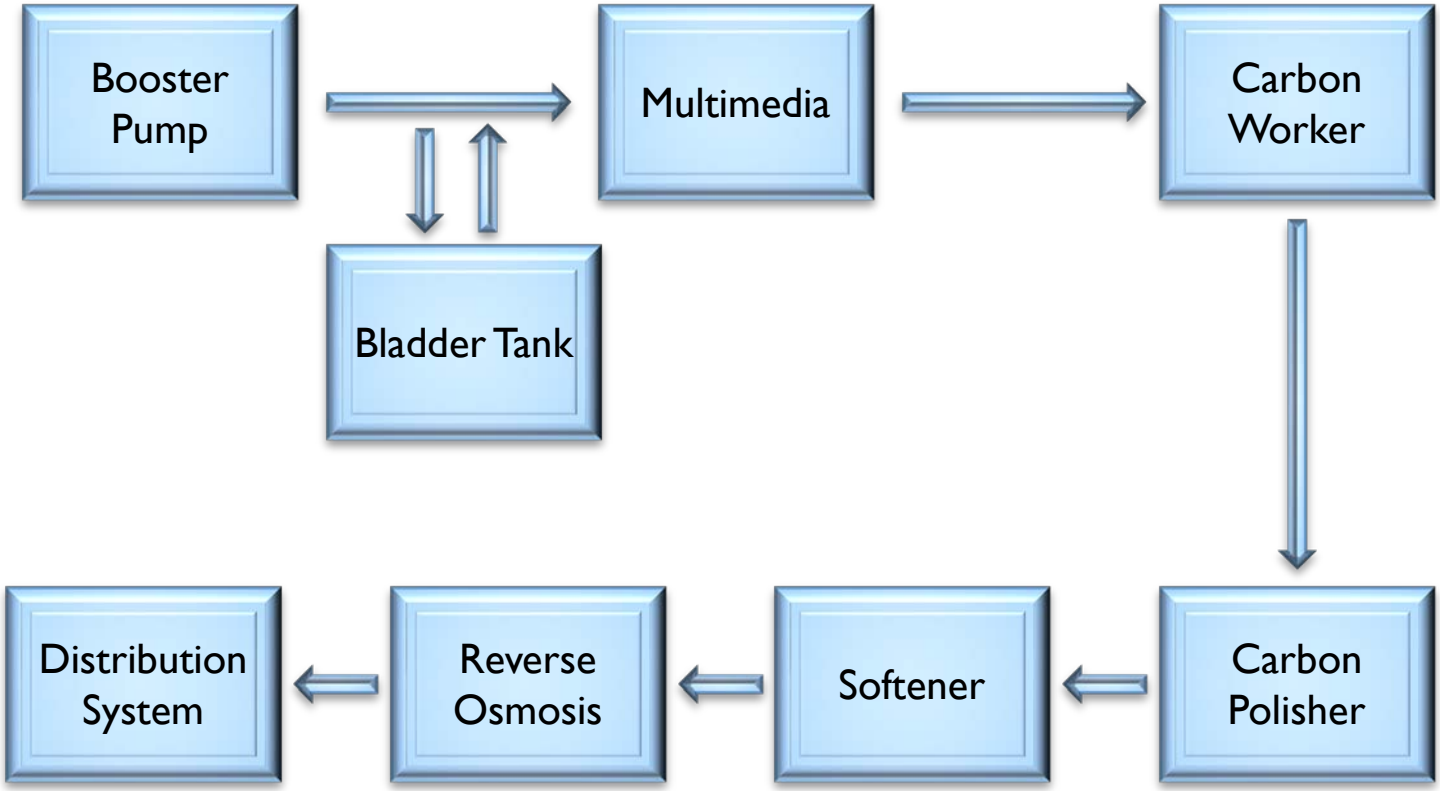
Traditional Hemodialysis Water Treatment System

Contaminants with documented toxicity in hemodialysis	Maximum Concentration (mg/L)b)
Antimony	0.006
Arsenic	0.005
Barium	0.100
Beryllium	0.0004
Cadmium	0.001
Chromium	0.014
Mercury	0.0002
Selenium	0.090
Silver	0.005

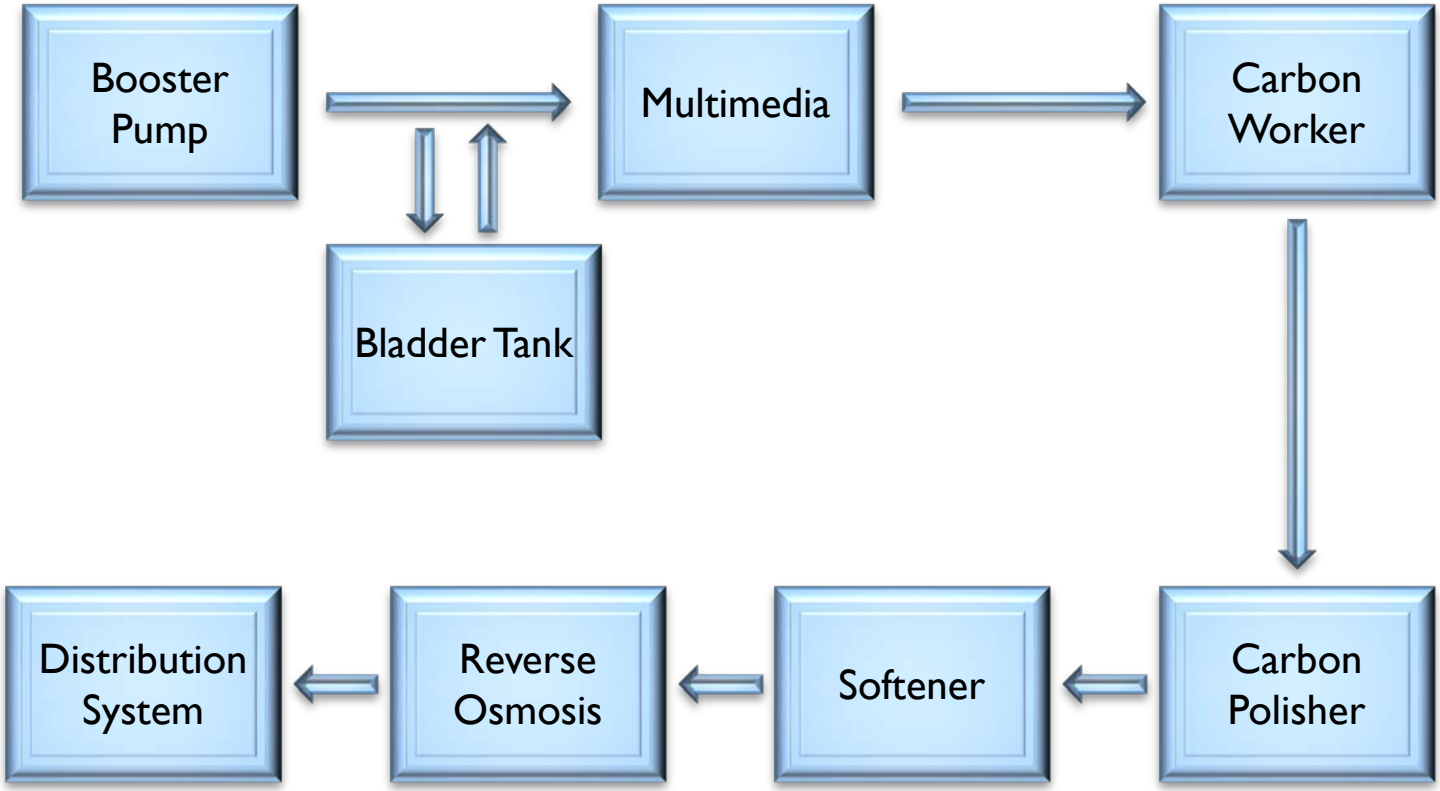
Traditional Hemodialysis Water Treatment System

- AAMI/ISO13959 (which replaced RD62) defines the minimum water treatment system as:
  - two carbon tanks with a minimum empty bed contact time (EBCT) of 10 minutes
  - an RO machine with a minimum 90% recovery, a conductivity monitor and a divert in the product water stream
  - deionization (DI) media followed by a divert and an ultrafilter may be substituted for RO machines.

Traditional Hemodialysis Water Treatment System



Traditional Hemodialysis Water Treatment System



Traditional Hemodialysis Water Treatment System

Picture of Booster pump

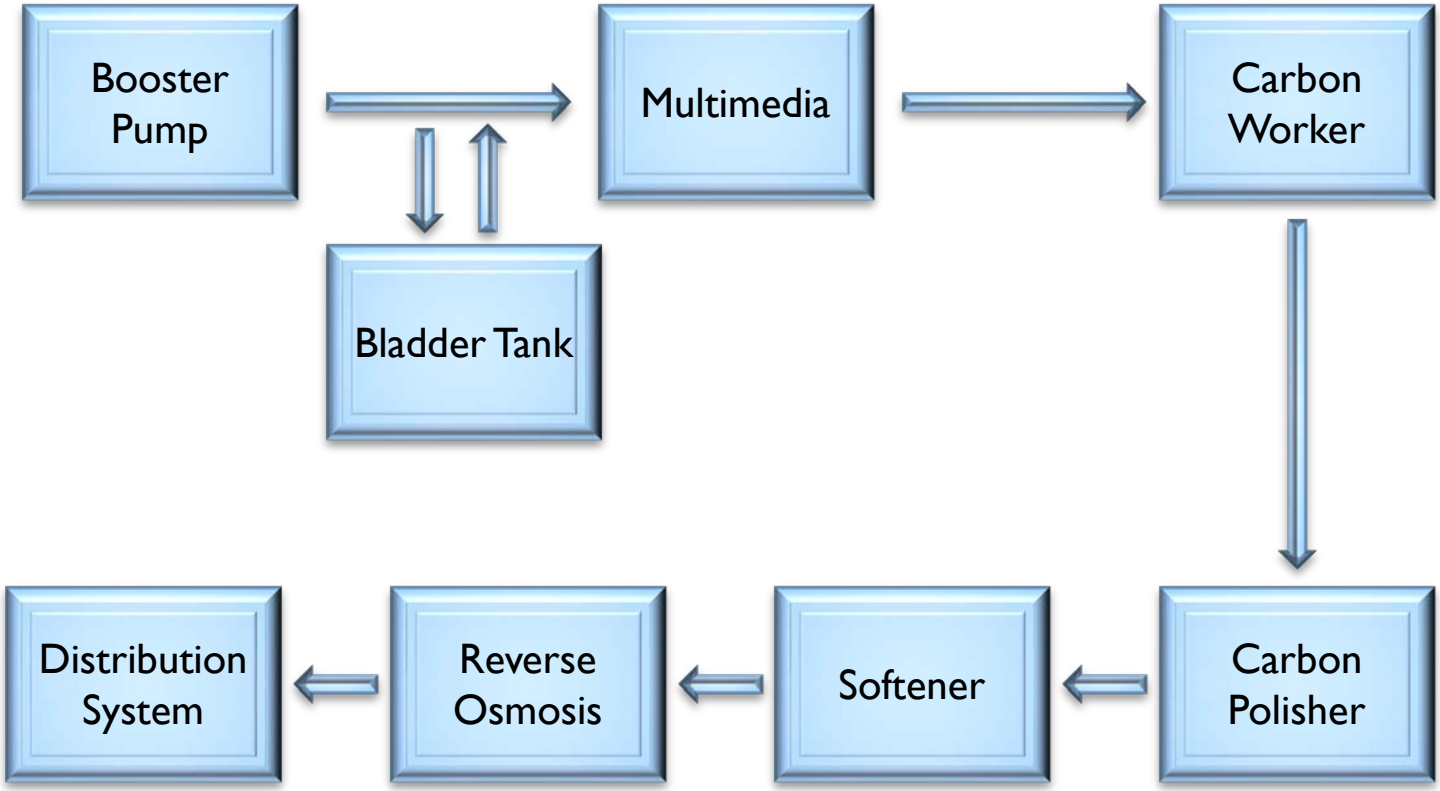
Traditional Hemodialysis Water Treatment System

- Booster Pump
  - The booster pump is an essential part of the hemodialysis water treatment system.
  - After the backflow preventers, the pressure of the municipal water is typically around 40 psi and when drawing 20 gpm to 25 gpm for backwashing bed filters drops significantly.
  - Traditionally a booster pump was used in conjunction with a pressure switch which would turn on the booster pump when the pressure dropped below the set point and turn off once the pressure reached the upper set point.

Traditional Hemodialysis Water Treatment System

- Bladder tanks were used and engineered to allow one minute of service water once the booster pump turned off (to prolong the life of the pump).
- If a flow switch was used instead of the pressure switch, the pump will turn on when there is a flow and turn off when there is no flow.
- Unfortunately, few of the water treatment companies knew how to properly specify the required sizing of the booster pump which has resulted in many poorly engineered pretreatment systems.

Traditional Hemodialysis Water Treatment System



Traditional Hemodialysis Water Treatment System

Multimedia Filter

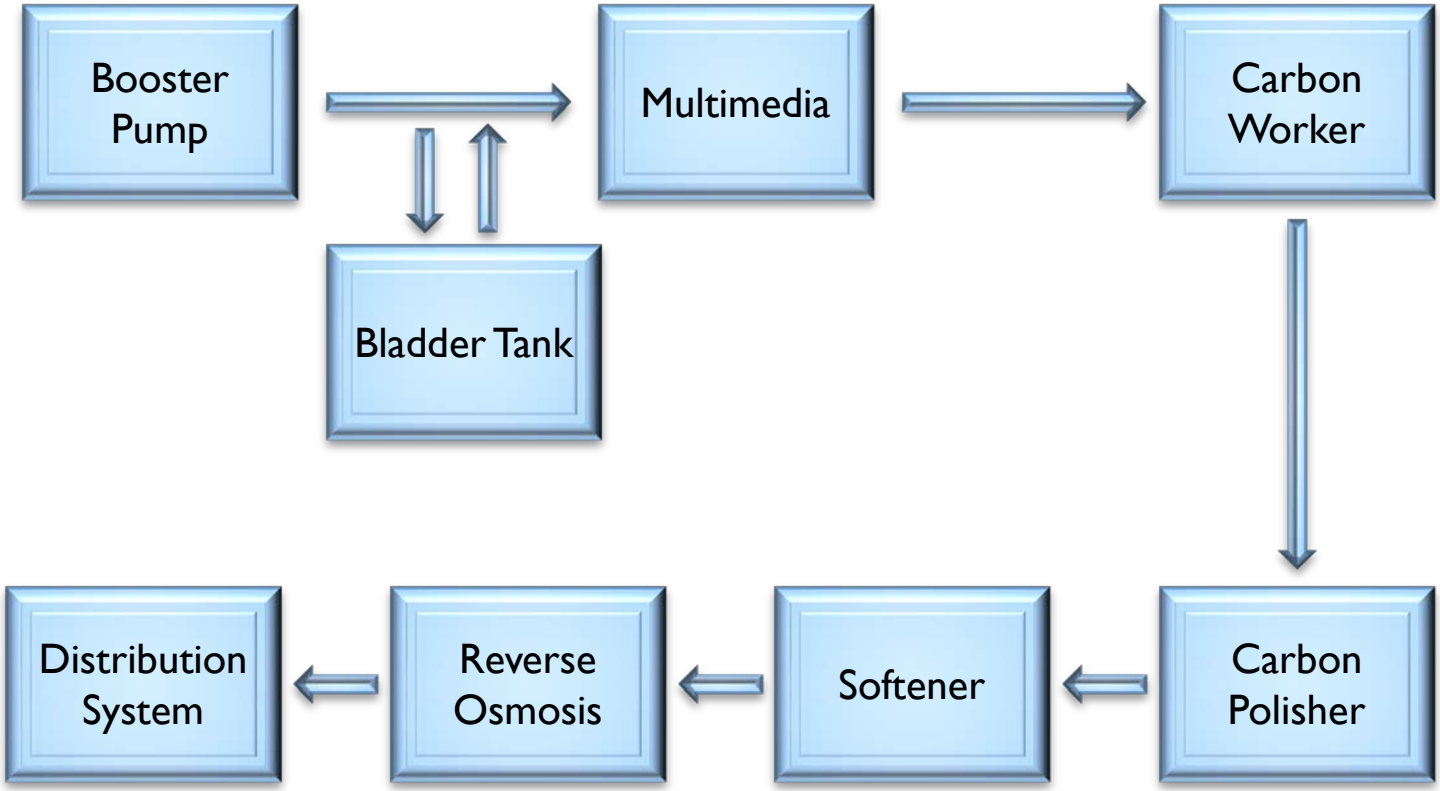
Traditional Hemodialysis Water Treatment System

- Multimedia Filter
  - Misused – should only be backwashed when delta pressure >10psi
  - Filters down to only 20µm to 40µm
  - Wastes 1,000 gallons per backwash (daily or bi-daily typically)
  - Does not protect carbon filters

Traditional Hemodialysis Water Treatment System

- Multimedia filters in hemodialysis are a crime against nature. If backwashed daily to ensure that they are ineffective, they waste 365,000 gallons a year. At $2.50 per thousand gallons for water and sewer charges, the cost is $912.5 per year.

Traditional Hemodialysis Water Treatment System



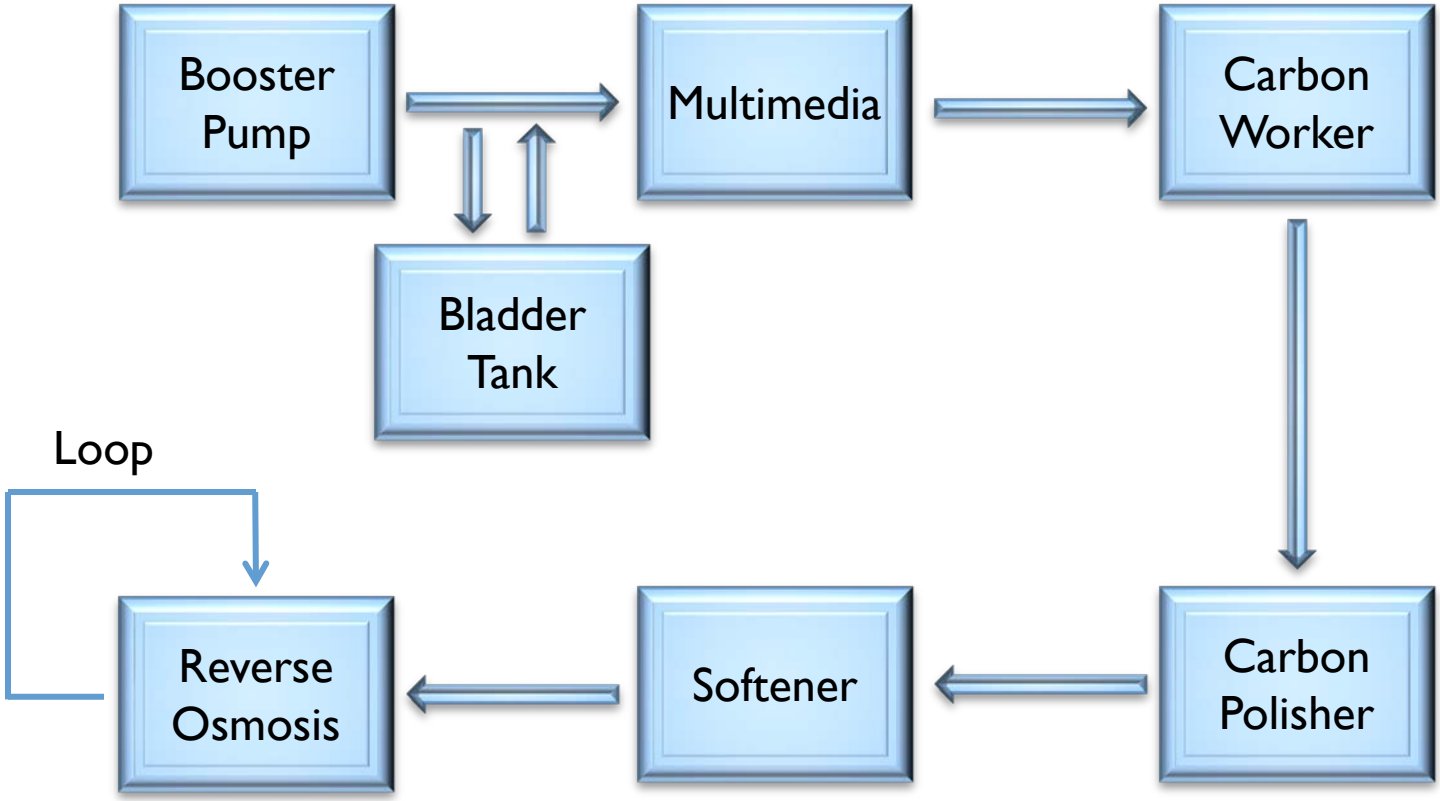
Traditional Hemodialysis Water Treatment System

Carbon Filter

Traditional Hemodialysis Water Treatment System

- Back-washable carbon tanks
  - Misused – should only be backwashed when delta-pressure increases >10psi
  - GAC is very effective at removing small particle-sized sediment. Backwashing used to remove sediment from supply water
  - Backwashing carbon produces carbon fines that contribute to RO membrane fouling
  - Backwashing introduces raw dirty city water to the bottom of the carbon tank.
  - Causes false positive chlorine breakthrough readings when city periodically uses free chlorine

Traditional Hemodialysis Water Treatment System



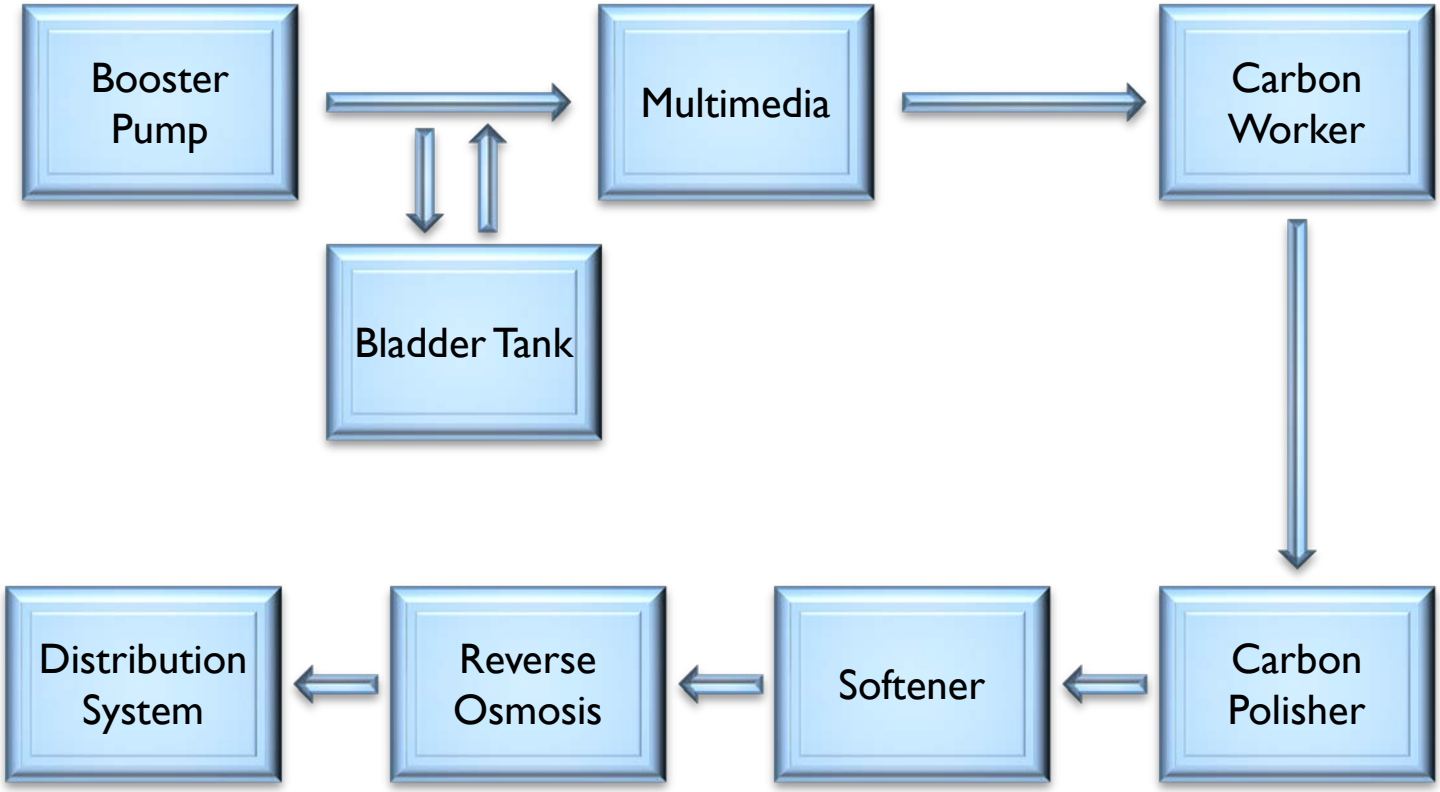
Traditional Hemodialysis Water Treatment System

softener

Traditional Hemodialysis Water Treatment System

- Softener
  - A relic from last millennium industrial water treatment systems
  - Probably fewer than 10% of the systems in the USA need softeners
  - Modern technology does not need softeners for most hemodialysis systems
  - Wastes salt and contaminates the environment
  - For hemodialysis, it is a crime against nature

Traditional Hemodialysis Water Treatment System



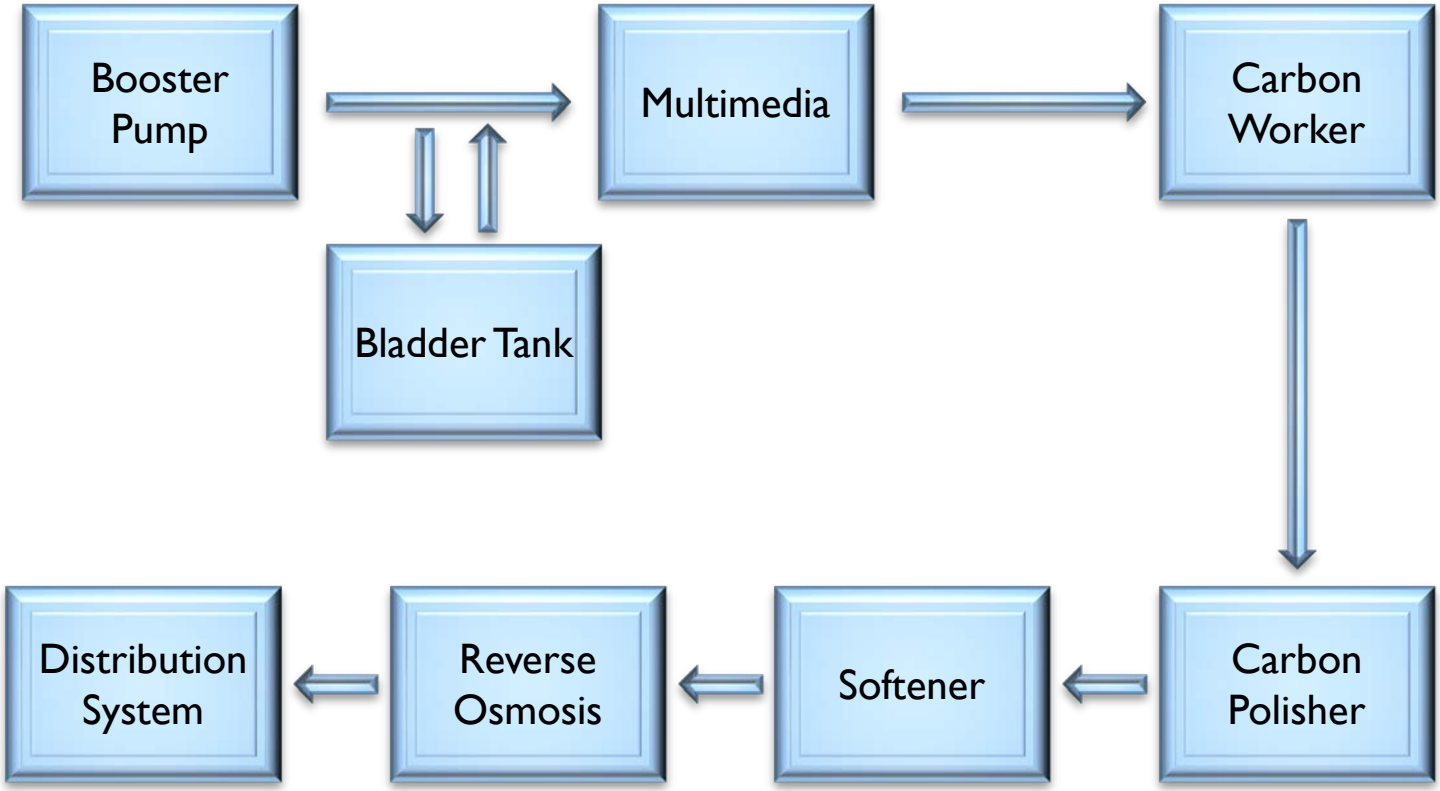
Traditional Hemodialysis Water Treatment System

Reverse Osmosis (RO)

Traditional Hemodialysis Water Treatment System

- Reverse Osmosis (RO)
  - The traditional hemodialysis RO was either an industrial RO machine or based upon an industrial RO machine.
  - Biological growth issues were not a concern or a high priority when the machines were designed.

Traditional Hemodialysis Water Treatment System

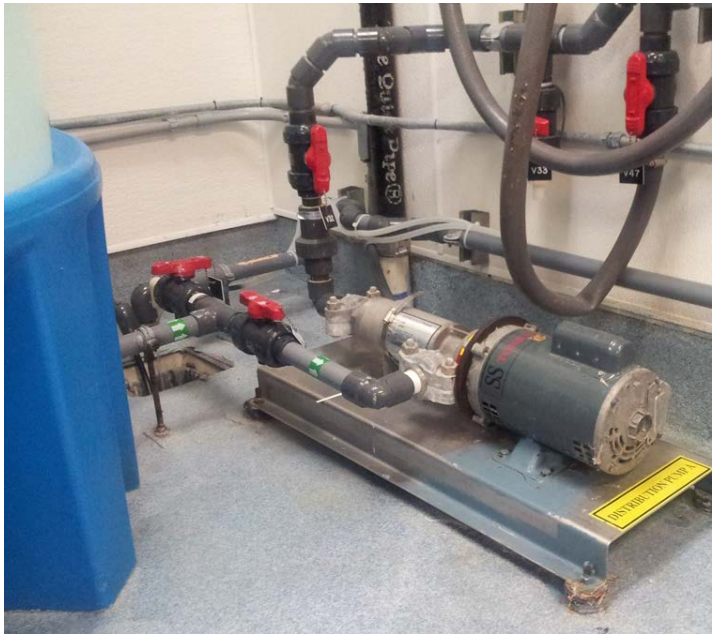


Traditional Hemodialysis Water Treatment System

Storage Tank

Traditional Hemodialysis Water Treatment System

Re-pressurizing Pump



Traditional Hemodialysis Water Treatment System

Ultrafilter

Traditional Hemodialysis Water Treatment System

- Water Delivery System
  - Storage Tanks typically were those offered in the market which were difficult to hermetically seal and were typically not optimally engineered.
  - Re-pressurizing pumps provided the flow of water through the patient loop but flows varied considerably based upon how many hemodialysis machines were in use.
  - If UF filters were used, they typically used three or four 4” x 40” membranes housed in a rack.

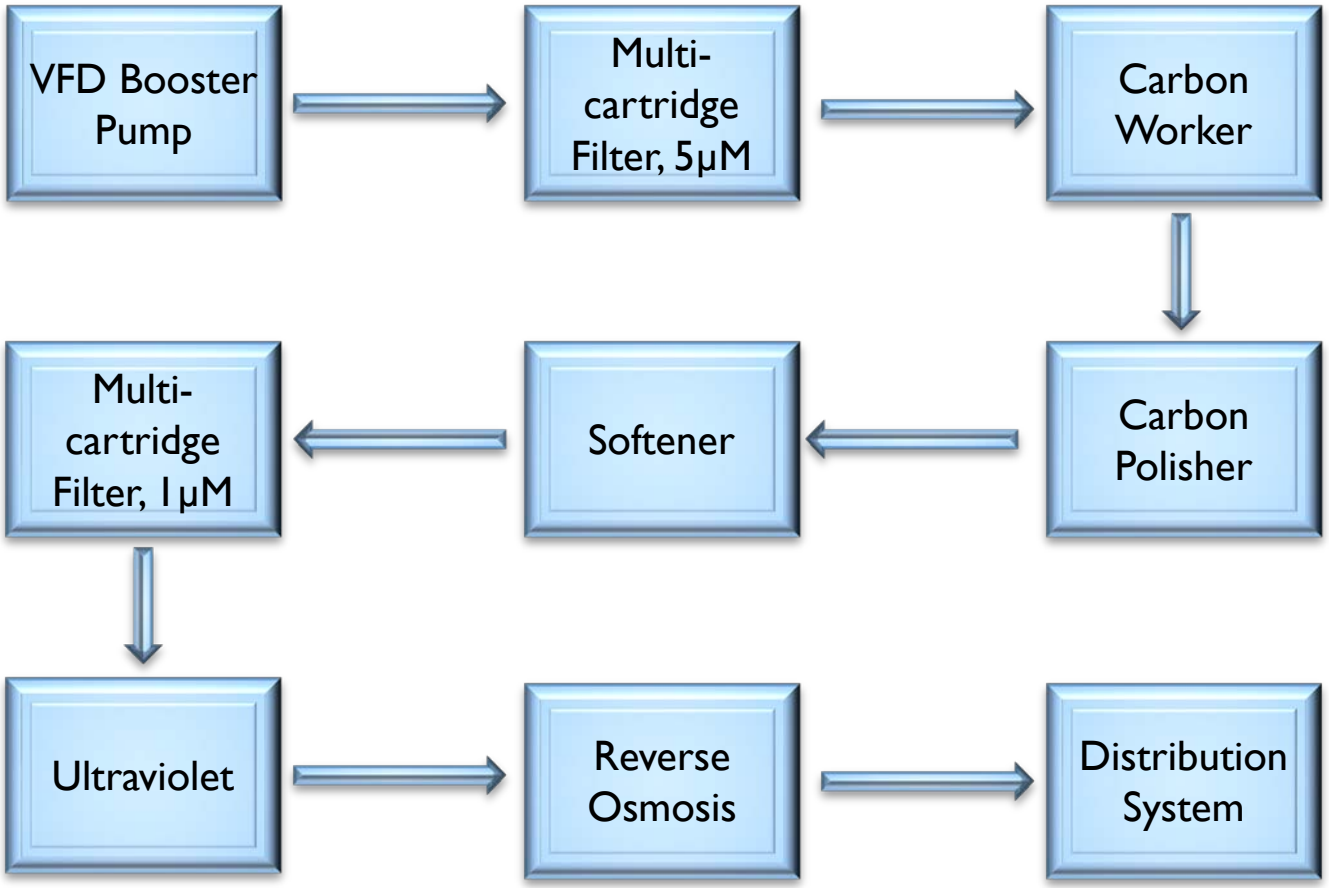
Traditional Hemodialysis Water Treatment System

- Schedule 80 PVC pipe and fittings were used to transport water through the patient loop.
- It was difficult to stop or maintain microbiological growth. Once bacteria colonies form, chemical cleaning just kills the surface of the colony and contains it at the best.

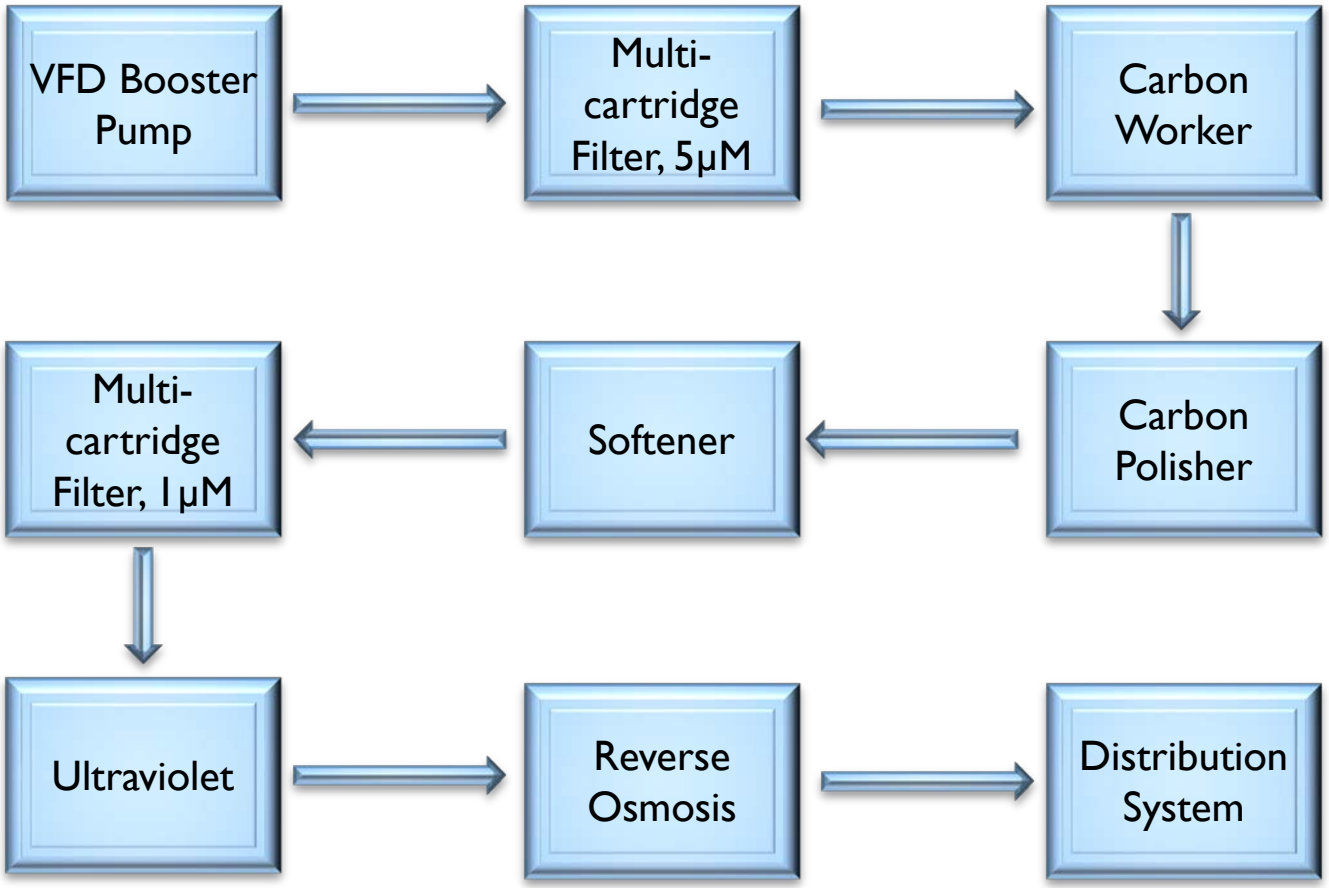
History of Hemodialysis Water Treatment

- Short history of hemodialysis water treatment
- Today's traditional hemodialysis water treatment
- Latest Trends and Future

Latest Trends and Future



Latest Trends and Future



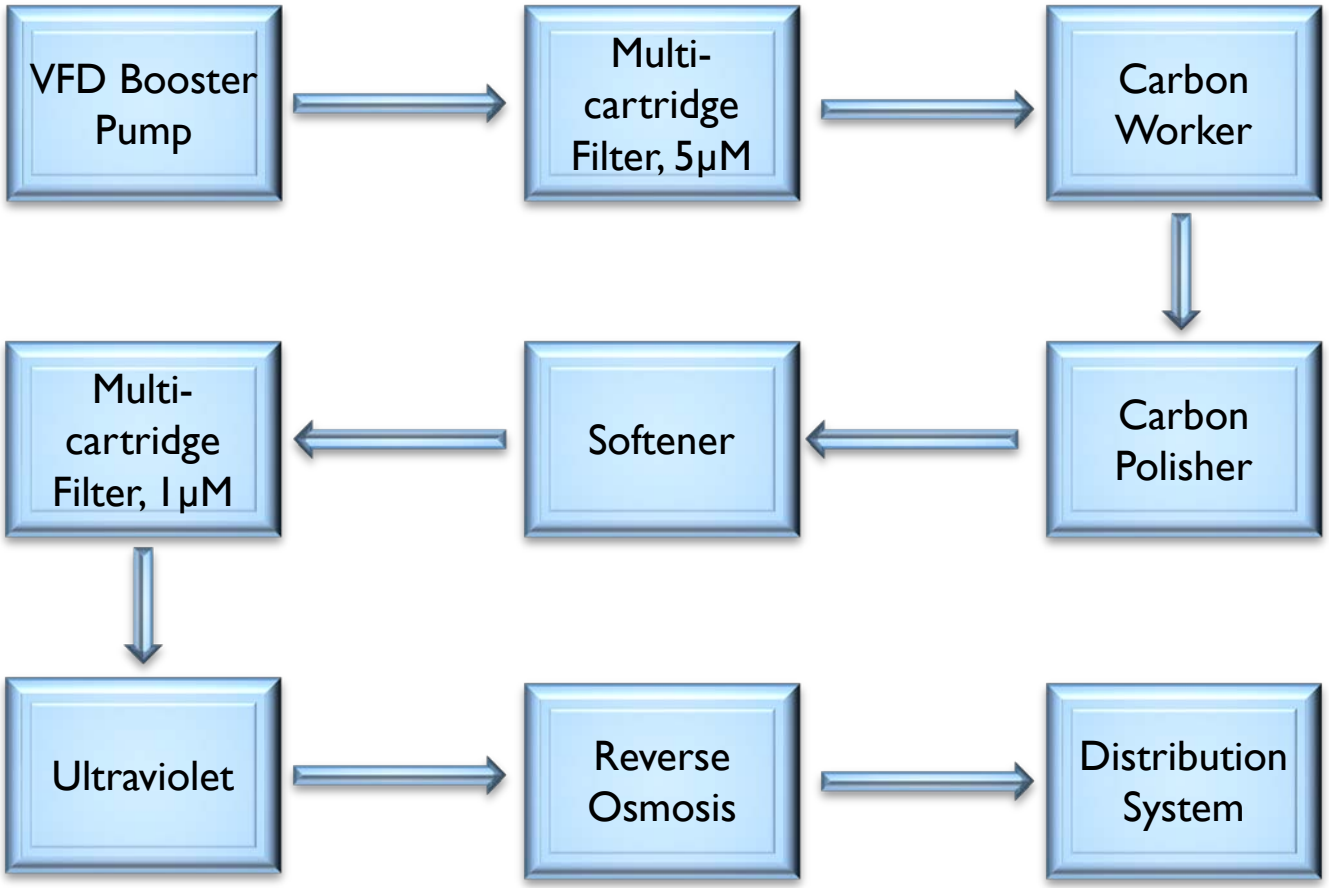
Latest Trends and Future

VFD Booster Pump

Latest Trends and Future

- VFD Booster Pump
  - These pumps provide constant pressure to a preset value.
  - When properly engineered into the water treatment system are very efficient often paying for themselves in a short period of time through energy savings.
  - Further benefits are that they ramp up and ramp down flow such that there are no hydraulic shocks caused by the turning on or off of a traditional pump and they have a small footprint.

Latest Trends and Future



Latest Trends and Future

Multi-cartridge Filter

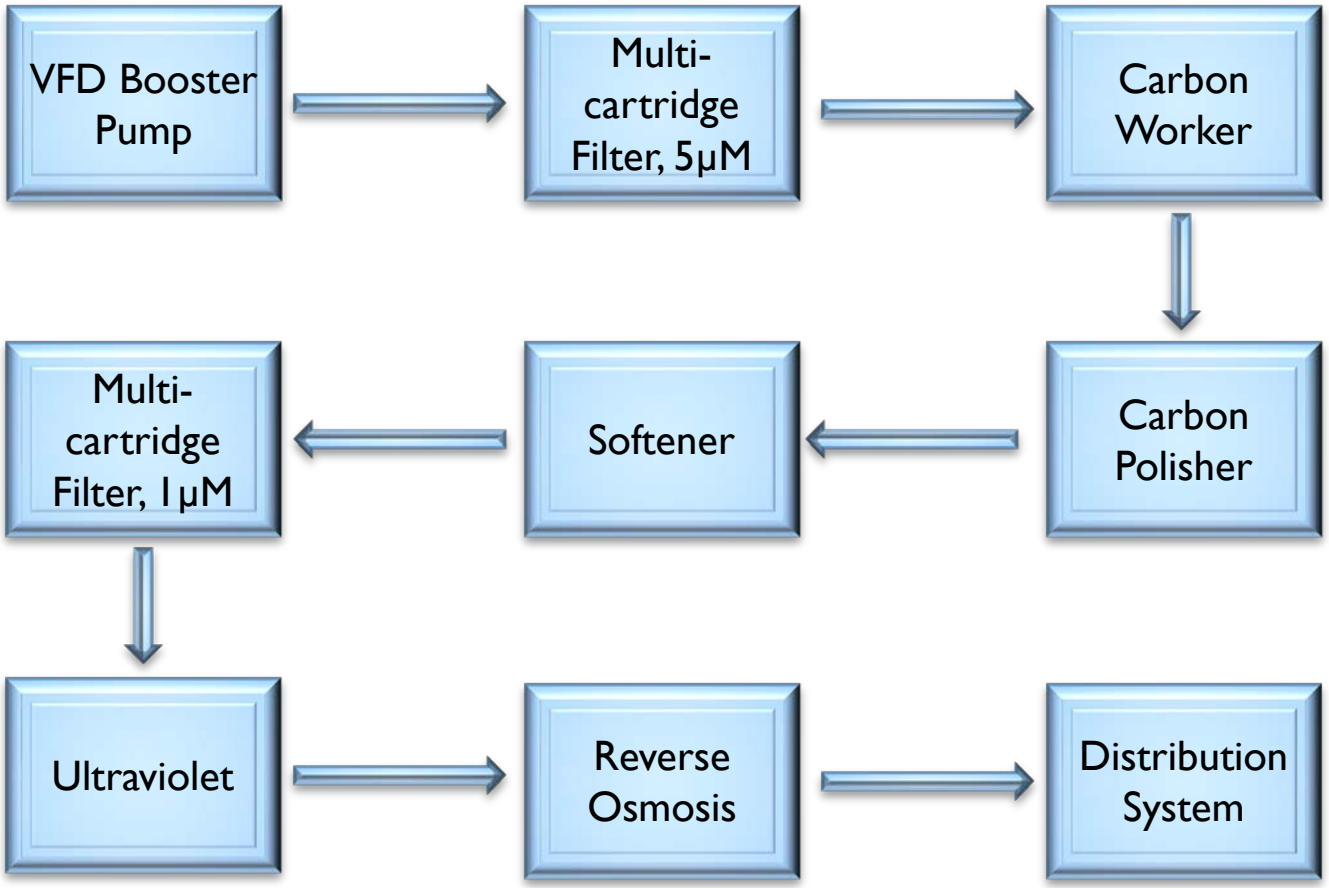
Latest Trends and Future

- Multi-cartridge filter housing
  - Multi-cartridge filter housings with 5-µm or 1-µm depth filter cartridges provide effective filtering to protect the media in the carbon tanks.
  - Cartridges should only be changed once the delta pressure exceeds 10 psi over the initial delta pressure.
  - Cartridges form a cake that filters to the submicron range.

Latest Trends and Future

Cartridge Filter Showing Cake

Latest Trends and Future



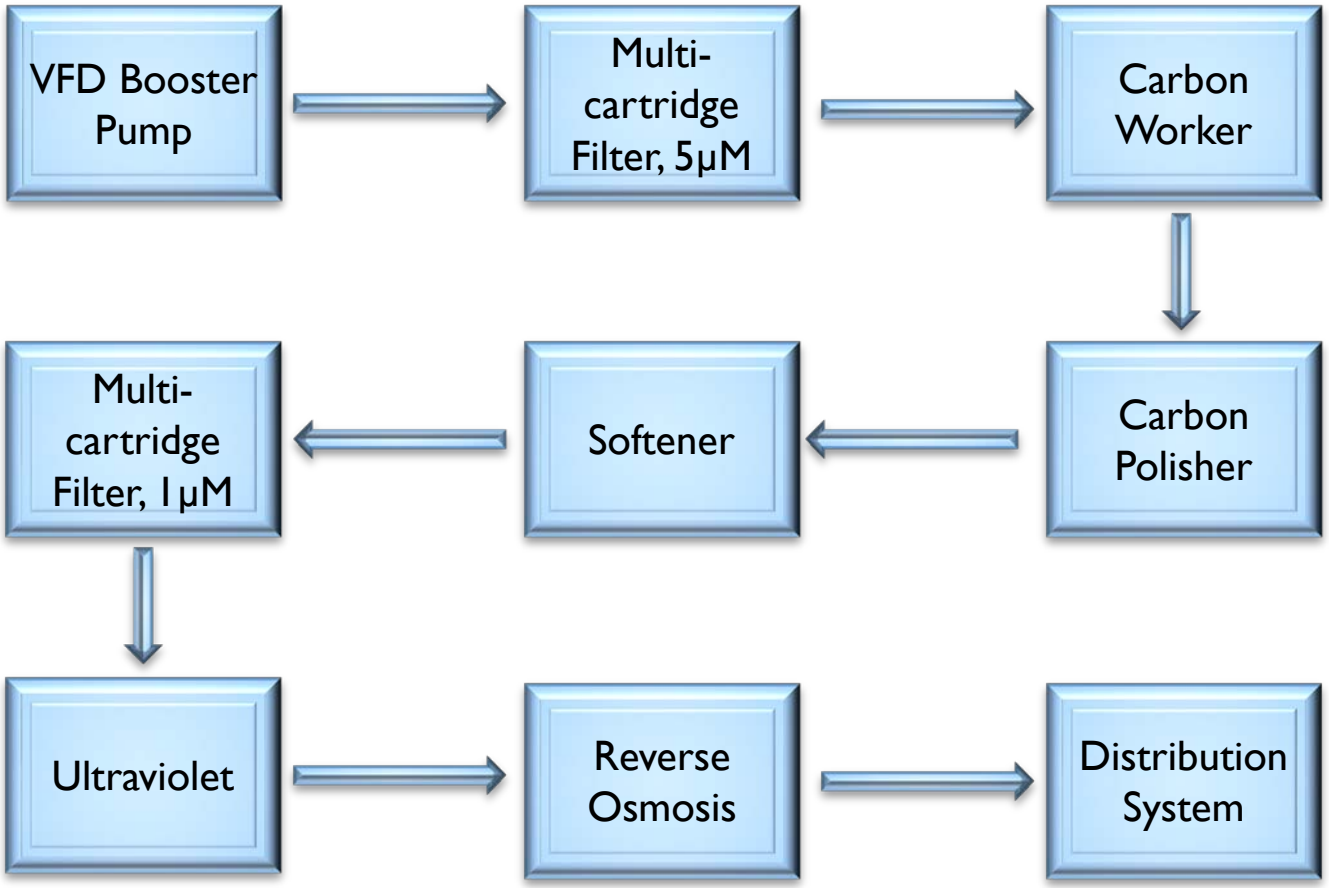
Latest Trends and Future

- Back-washable carbon tanks
  - Carbon bed filters were originally back-washed daily as it was thought that that operation would keep the beds "fresh".
  - However, now it is becoming more recognized that backwashing the media is creating many problems for little benefit. Backwashing the bed causes carbon fines that contribute to the biomass on the RO membranes and causes false positive chlorine breakthrough when the city switches to free chlorine.

Latest Trends and Future

- With proper sediment pre-filtration (multi-cartridge filter) carbon tanks should only be backwashed when the delta pressure exceeds 10 psi.
- Up to 1,000 gallons per day for two carbon filters can be saved per day by not backwashing the carbon tanks. The annual cost savings can be $912.50.

Latest Trends and Future



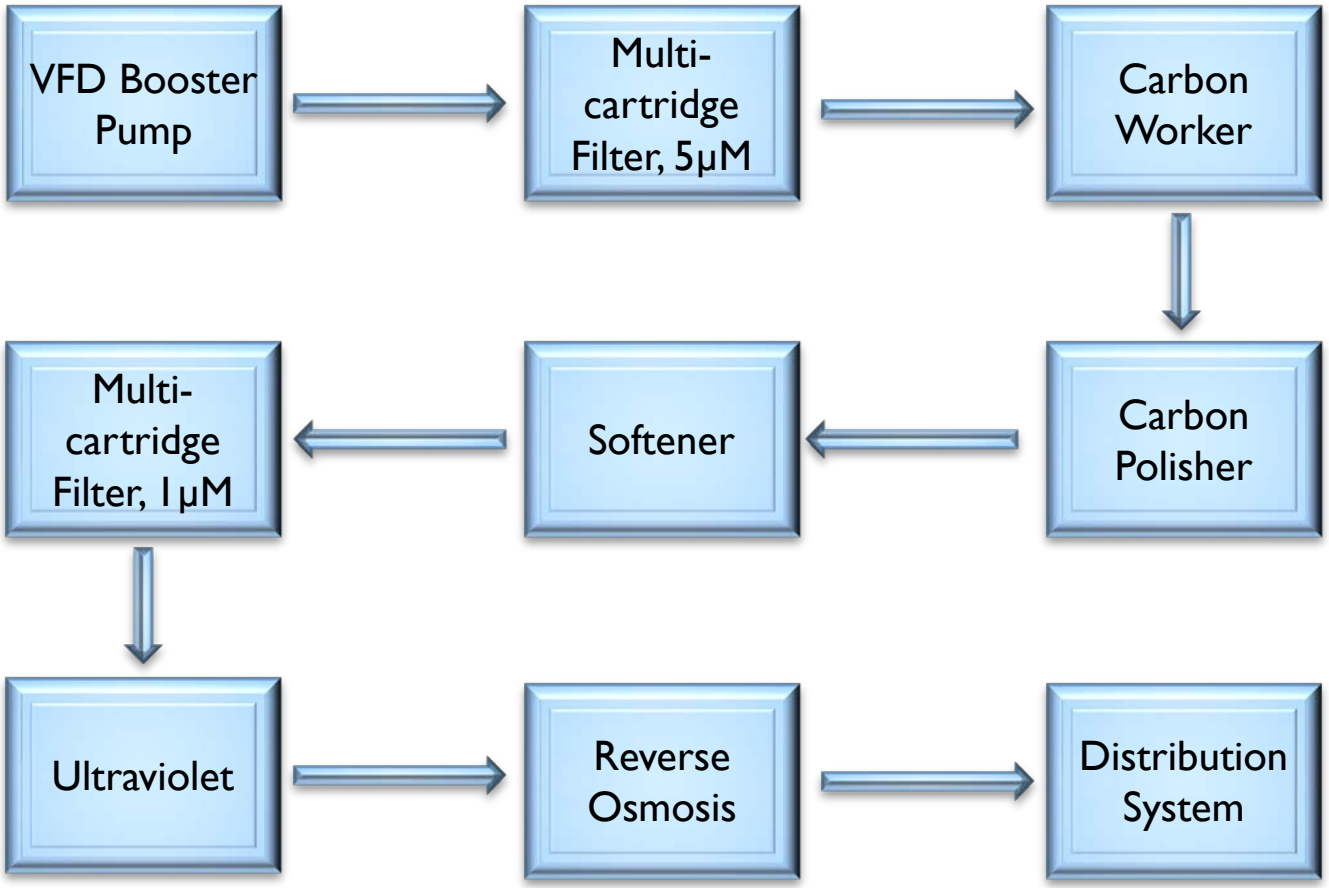
Latest Trends and Future

- Softener Usage
  - Softeners should only be used if shown that they are necessary.
  - Twin-alternating softeners use the full capacity of the softener saving both salt and water.
  - Bed tanks with anti-scaling media (not magnets) should be considered if scale protect appears to be a concern. These devices are inexpensive and do not use salt.
  - Unnecessary use of softeners for hemodialysis water should also be considered a crime against nature. Used when not needed wastes both water and salt.

Latest Trends and Future

Anti-scalant device

Latest Trends and Future



Latest Trends and Future

Multi-cartridge sediment filter/UV Sterilization

Latest Trends and Future

- RO Membrane Fouling Reduction
  - Research has been done that shows that membranes in RO machines that follow carbon filters have an enormous microbiological life on their surface that fouls the membranes. When the carbon tanks were removed the microbiological life died. The carbon fines from the carbon filter were feeding the abundant life on the membranes.
  - Much research has been put into understanding and controlling scaling in the water treatment industry particularly with respect to boilers and cooling towers.

Latest Trends and Future

- Two types of scaling have been identified border (surface) scaling and scale caused by global precipitation.
- Border scaling occurs when the saturation index point is exceeded for a compound due to temperature. Thus boiler water must not contain carbonates and bicarbonates.
- Global precipitation occurs when the concentration of a compound in a solution reaches its saturation index point and spontaneously produces colloidal sized solids that come out of the solution. (precipitate) This is what happens when de-watering the pre-treatment water solution through an RO machine

Latest Trends and Future

- Membrane scale was originally thought to be a border phenomenon caused by the concentration of the compounds exceeding their saturation point on the surface of the membrane. Research has proved that almost all membrane fouling is caused by microorganism fouling that captures the global precipitation and is the glue to forming and keeping the scale in place.

Latest Trends and Future

- Multi-cartridge sediment filter/UV Sterilization Unit
  - Membrane fouling has been significantly reduced by reducing the carbon fines that reach the RO membranes.
  - This is done by:

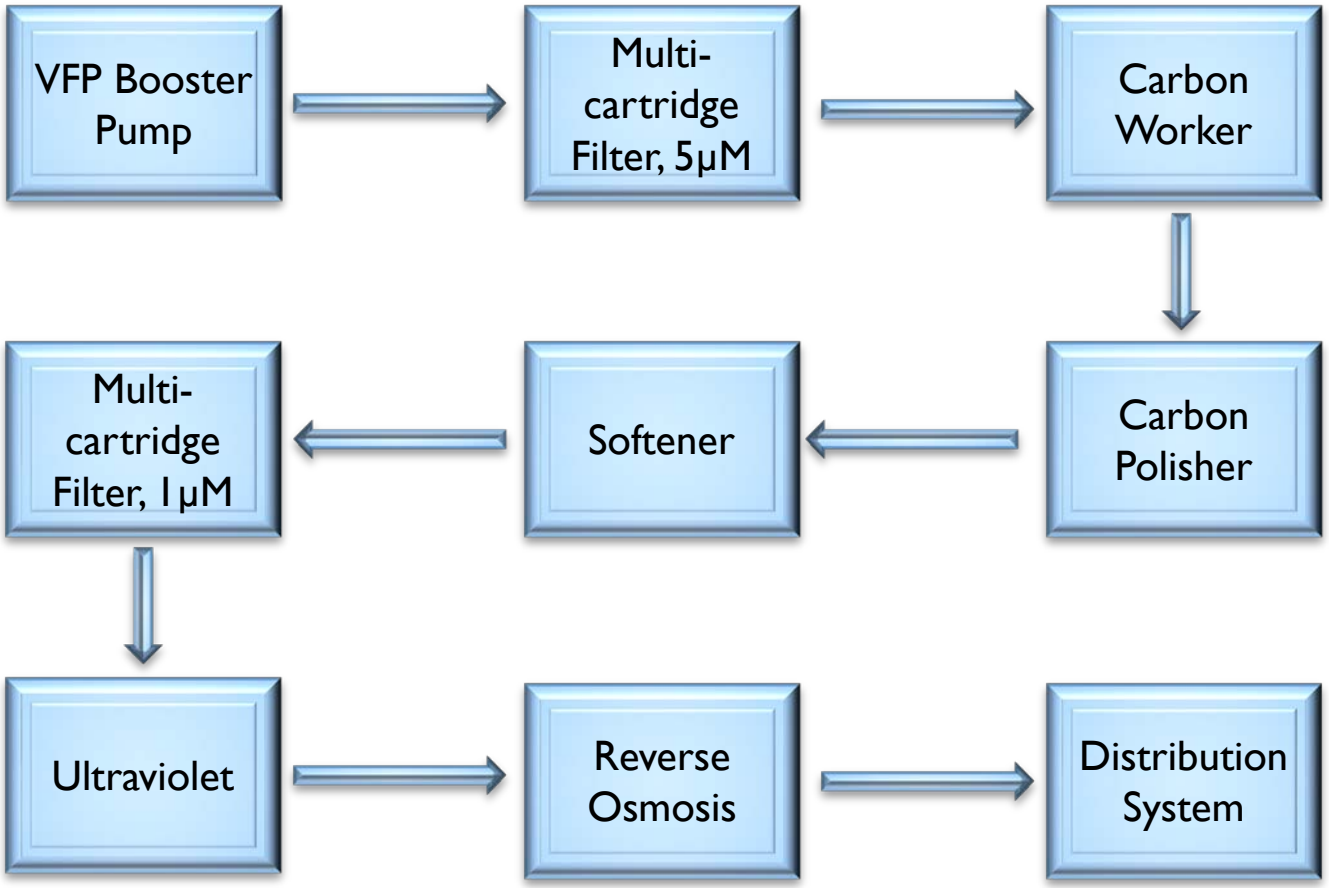
Latest Trends and Future

1. Providing a properly-engineered, multi-cartridge housing with 1-µm depth cartridge filters.
   - It is critical that the cartridges in the multi-cartridge housing are only replaced after the delta pressure across the housing increases by at least 10 psi.
   - The longer the cartridges remain in the housing the better. Research has shown that as the filters start to filter the water, a cake builds up and that the 1-µm nominal initial filtering actually drops to the sub-micro range once the cake is in place.
   - The worst thing that you can do is replace the cartridges before necessary.

Latest Trends and Future

2. An UV sterilization unit is used after the multi-cartridge sediment filter to prevent any bacteria from forming colonies on the membranes.
3. Replace the RO pre-filter cartridges with 0.35-µm pleated cartridges. These filters in the RO cartridge housings will help protect the RO membranes as the multi-cartridge filter is building up the cake.

Latest Trends and Future



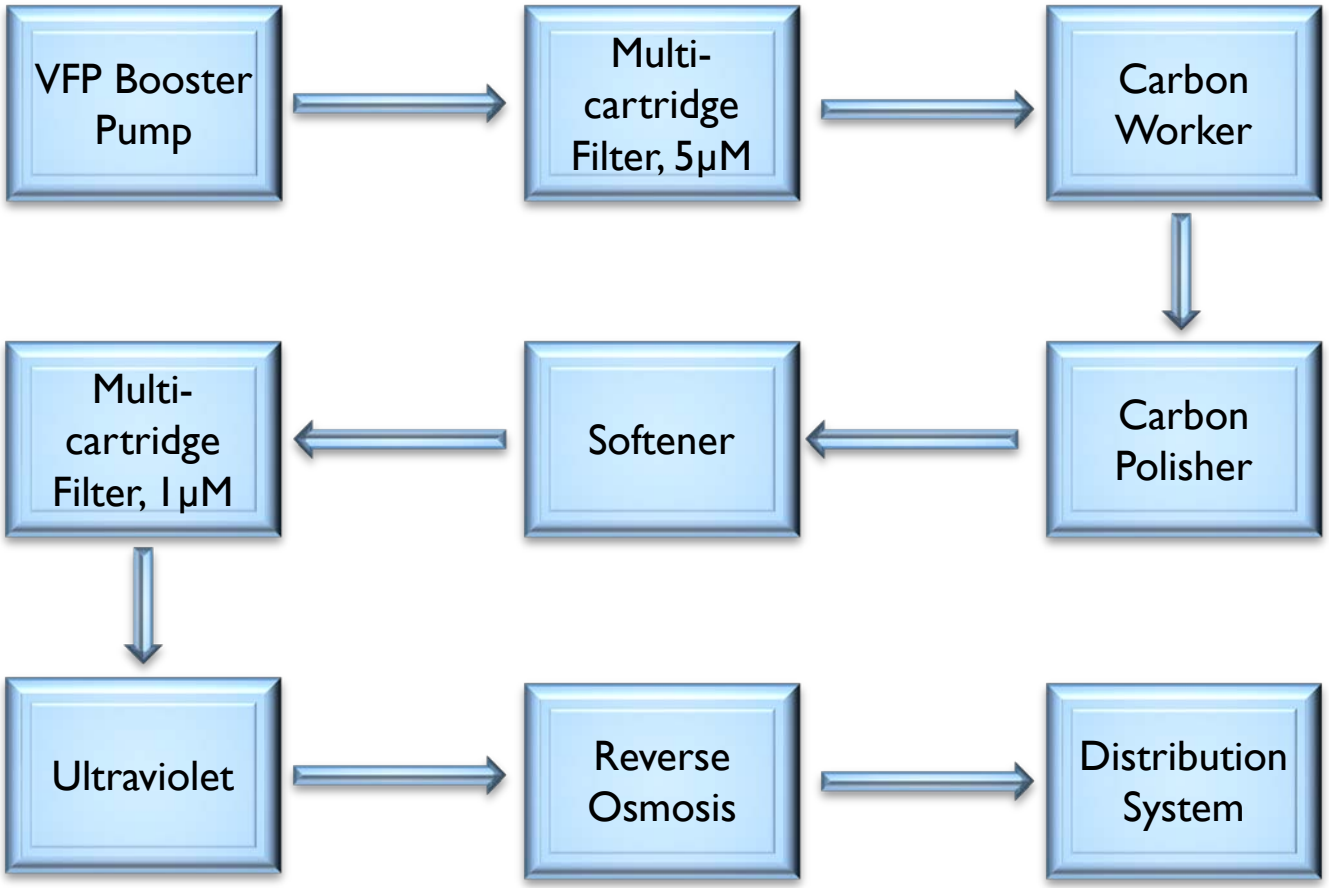
Latest Trends and Future

Reverse Osmosis (RO)

Latest Trends and Future

- Reverse Osmosis (RO)
  - Current RO systems are significantly improved over those of the last millennium. The Gambro CWP is the most advanced RO machine today and is the standard by which other RO manufacturers are designing their RO machines today.

Latest Trends and Future



Latest Trends and Future

- Product Water Delivery System (Distribution System)
  - Storage Tank
  - VFD re-pressurizing pump
  - Ultrafilter
  - Patient Loop - PEX, Teflon or high-purity plastic

Latest Trends and Future

Storage Tank

Latest Trends and Future

- Storage Tank
  - Storage tank designed specifically for applications such as hemodialysis water treatment.
  - Hermetically sealed cap
  - Cone-bottomed
  - 250 gallons (smaller to increase water turnover).
  - Level sensors on outside of tank
  - Ball sprayers on inlet and return flows to keep the top of the tank fresh

Latest Trends and Future

Re-pressurizing Pump

Latest Trends and Future

- VFD Pump
  - VFD pumps provide a constant pressure regardless of the number of hemodialysis machines are in service.
  - It maintained the desired pressure at the variable flow rate.

Latest Trends and Future

Ultrafilter

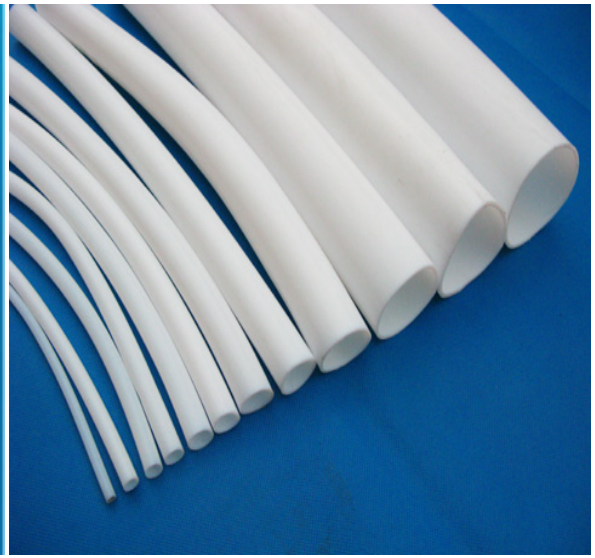
Latest Trends and Future

- Patient Loop UF Filter
  - All patient loops incorporate a UF filter at the beginning of the loop.
  - Much progress has been made in UF filters in the area of flow capacity and chemical and heat resistance.
  - Current UF filters use 2.5” x 20” diameter 0.01-µm cartridge filters

Latest Trends and Future

Patient Loop Tubing

Teflon Tubing



PEX Tubing

Latest Trends and Future

- Patient Loop
  - Either non-heat disinfected or heat disinfected
    - Heat disinfection of the loop has proved to be very effective in maintaining bacteria free patient loops. Heat disinfected loops currently use PEX tubing.
    - For non-heat disinfected loops, Teflon tubing has significantly reduced biological growth.

Latest Trends and Future

- Speed of Progress
  - The hemodialysis industry and the water treatment suppliers are making much more progress this millennium.
  - The RO machines are developing much faster and patient loops are being upgraded at an accelerated rate.
  - However, the pretreatment section of the hemodialysis water treatment systems has lagged behind.
  - As the hemodialysis industry learns more about water technology, progress in this area also will start to pick up speed.

Latest Trends and Future

- A snap-shot of the future
  - Future systems will be completely integrated water treatment systems with remote monitoring of such parameters as flows, pressures, temperatures and chlorine.
  - The future is exciting with patient health and safety greatly improved.