

ALARM SET POINT FOR REVERSE OSMOSIS (RO) MACHINES

An RO system used for hemodialysis applications is designed to deliver product water quality that meets ANSI/AAMI/ISO standards. Monitoring of the RO product water is based on conductivity and/or Total Dissolved Solids (TDS). Whenever that limit is exceeded, an alarm will sound, indicating the water quality is above an acceptable limit. Another limit indicator, such as percent rejection, is beneficial but should not be considered an absolute measurement.

So, what is the appropriate limit? The best answer is “it depends.” Changes in feed water quality, water temperature, and/or normal operation of membranes over time will result in changes in product water quality in the form of increased product water conductivity or TDS. Current, AAMI standards agree and as a result have not established a maximum TDS or high conductivity alarm limit for product water.

All RO machines designated for use for hemodialysis come with either a factory preset limit setting on product (i.e., permeate) water conductivity or the limit is established and set during the initial system installation. The settings established per machine are system specific and should be complied with for safe and effective operation.

RO Machine Models	Water Quality Alarm Setting	Set at Factory*	Set at Time of Installation
23G	30 µS/cm	✓	
4400M	30 µS/cm	✓	
700 Series	2 X's initial TDS		✓
CWP	30 µS/cm	✓	
Millenium HX	2 X's initial TDS		✓
WRO 300 & 300H	30 µS/cm	✓	
BioPure HX2	30 µS/cm	✓	
EON	2 X's initial TDS		✓

* Factory preset limits can be adjusted by a qualified representative during installation based on local conditions.

If an alarm set point is reached, an investigation should be conducted to determine the cause. Investigation categories for increased conductivity or TDS should include, but are not limited to:

- Feed water quality changes.
- Pretreatment operation.
- RO operation and settings.
- Ineffectual or infrequent cleaning and disinfection practices.
- Membrane(s) nearing end of life expectancy.
- Water testing results.

The investigation may indicate that the change is due to normal or acceptable operational conditions (feed water changes/membrane conditions), or an issue has been found and corrected. Since the RO alarm setting is adjustable, an adjustment can be made as long as the

RO is still producing water that meets or exceeds the AAMI limits for dialysis water, and the adjustment of the RO alarm setting has been reviewed and approved by the Medical Director.

Keep in mind that percent rejection is used as a performance indicator, but should not be used as the end-all monitoring parameter. Under normal water treatment conditions, an alert or action level is typically set at 85-90%. Furthermore, since the conductivity and/or TDS value does not always indicate the suitability of water for dialysis, the quality of water should be verified by regular AAMI water analyzes to demonstrate compliance with AAMI standards for water used in dialysis.