

WHITewater



quality in purity

Dialysis water requirements

1.1 Dialysis water verification and monitoring

The quality of the dialysis water, as specified in 1.2 and 2.2 shall be verified upon installation of a water treatment system. Monitoring of the dialysis water quality shall be carried out thereafter.

1.2 Microbiological requirements

Total viable microbial counts in dialysis water shall be less than 100 CFU/ml or lower if required by national legislation or regulations. An action level shall be set based on knowledge of the microbial dynamics of the system. Typically, the action level will be 50% of the maximum allowable level.

Endotoxin content in dialysis water shall be less than 0.25 EU/ml or lower if required by national legislation or regulations. An action level shall be set, typically at 50% of the maximum allowable level.

Note: See Clause A1 for a history of these requirements.

1.3 Chemical contaminants

Dialysis water shall not contain chemicals at concentrations in excess of those listed in Tables 1 and 2, or as required by national legislation or regulations.

Note See A.2 for explanation of values supplied.

Where the dialysis water is used for the reprocessing of haemodialyzers, (cleaning, testing and mixing of disinfectants) the user is cautioned that the dialysis water shall meet the requirements of this International Standard. The dialysis water should be measured at the input to the dialyzer reprocessing equipment.

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Table 1 – Maximum allowable levels of toxic chemicals and dialysis fluid electrolytes in dialysis water ^a

Contaminant	Maximum concentration mg/l ^b
Contaminants with documented toxicity in haemodialysis	
Aluminum	0.01
Total Chlorine	0.1
Copper	0.1
Fluoride	0.2
Lead	0.005
Nitrate (as N)	2
Sulfate	100
Zinc	0.1
Electrolytes normally included in dialysis fluid	
Calcium	2 (0.05 mmol/l)
Magnesium	4 (0.15 mmol/l)
Potassium	8 (0.2 mmol/l)
Sodium	70 (3.0 mmol/l)
^a The physician has the ultimate responsibility for ensuring the quality of water used for dialysis	
^b Unless otherwise noted	

Table 2 – Maximum allowable levels of trace elements in dialysis water

Contaminants	Maximum concentration mg/l
Antimony	0.006
Arsenic	0.005
Barium	0.1
Beryllium	0.0004
Cadmium	0.001
Chromium	0.014
Mercury	0.0002
Selenium	0.09
Silver	0.005
Thallium	0.002