Culligan®

MEDICAL DIVISION

WATER TREATMENT IN THE HAEMODIALYSIS AND MEDICAL MARKETS

HAEMODIALYSIS MARKET

The **quality of water** used in haemodialysis systems is critically important, not only are haemodialysis patients extremely vulnerable to contaminants in the water due to their inability to renally excrete any contaminants taken up from the distillate, they are also exposed to extremely large volumes of water. The estimated water intake of a healthy infividual is 2 litres per day or 14 litre per week. By comparison, a haemodialysis patient may be exposed to 350 to 500 litres of water per week.

As one of the first water treatment companies to provide water treatment systems for haemodialysis Culligan know how important it is to provide reliable and above all safe water for patients undergoing life saving haemodialysis.

Culligan has over 30 years of experience of treating water used for haemodialysis ensuring the safe removal of physico-chemical and microbiological contaminants.

Culligan was the first company to introduce the Bi-Osmosis (double-pass in series) treatment concept, now widely accepted as the industry standard in best in class haemodialysis water treatment.
With R&D facilities in Chicago, USA and manufacturing facilities in America, Italy and Dubai, Culligan rigorously controls all stages of the manufacturing chain. This control helps to ensure your patients receive safe, reliable and pure water at all times.

The complete Culligan water treatment system for haemodialysis is certified MEDICAL DEVICE according to UNI EN ISO 13485NORMS, Notified Body No. CE 0434.

R.O.^{2}® MD

For flows of up to 3600 l/h of product water for haemodialysis treatment.

Introducting our most technologically advanced haemodialysis water treatment system, the **Culligan R.O.^{2} Bi-Osmosis**.

Designed to be as **easy to use and intuitive** as possible all of the **CULLIGAN R.O.^{2} BI-OSMOSIS** units come fitted with a "**touch screen**" interface. All key parameters are clearly displayed in flow diagram or graphical form for quick view interpretation allowing key parameters, such as the Reverse Osmosis **water quality** (used for the haemodialysis process) or the **operating pressure**, to be constantly displayed. Other parameters are selectable by the user so it is possible, for example, to display the **real-time consumption of product water** during operation.

Automatic **fail safe** control systems ensure that in the unlikely event of a problem with one of the Reverse Osmosis systems the other will continue to run providing high quality safe water at all times.

As well as safety and reliability the **Culligan R.O.^{2}** haemodialysis water treatment system has been designed to minimize water consumption and be as energy efficient as possible, helping you to save money and be environmentally friendly at the same time.

System Certified as Class II b
Medical Device, Notified Body No. CE 0434

SDS MD

The **SDS MD** (Single Dialysis System) is a state of the art water treatment system, intended for dialysis in the home, emergency services, dialysis in acute cases and for transplant patients.
The **SDS MD** can deliver up to 80 l/h water production. Compact and elegant, the equipment is on wheels for easier mobility.
The S**DS MD** consists basically of a Reverse Osmosis water treatment system, with a compound filter pre-treatment section providing filtration and dechlorination.
The main feature of this equipment is its extreme user-friendliness, thanks to a touch-control electronic panel governing all functions.

The **SDS MD** is equipped with:

- initial and final flushing device
- automatic disinfection
- audio and visual alarms
- continuous monitoring of the treated water quality
- main water circuit components in stainless steel
- touch-control keypad at 24 Volts
- digital conductivity meter for quality check.

The **SDS MD** is complete with break-tank and all devices necessary to bring it into line with the strictest international standards.

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MFP 4-44 MD

This equipment is the result of Culligan's several decades of experience in the haemodialysis sector. Its exceptional **operating simplicity, strength and flexibility** allow it to be adapted for the most widely varying installations.
All the electrical components of **MFP 4-44** are included in an electric control panel, and the construction materials, particularly those in contact with water, are resistant to corrosion and do not shed.
The **noiseless** three-phase **motor** (IP 54) meets the toughest **safety requirements**.
The **MFP 4-44** is prefitted for **easy connection** to an external module sanitisation system.

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WATER TREATMENT

Sanitisation

Reverse Osmosis plants and the distribution loops require sanitisation to prevent the proliferation of microorganisms (bacteria, algae, fungi, etc.) and to guarantee the pure water supply to the point of use. Culligan offers a range of automatic and semi-automatic solutions to allow this operation to take place with the maximum effectiveness and safety:

- **chemical sanitisation** - using sanitising solutions based on Peracetic Acid, aldehydes or other specific products. Can be performed on all types of distribution circuits;
- **thermal sanitisation** - ith steam or superheated water. It is possible with circuits in PVDF HP BCF or in AISI 316 L stainless steel or in PEX, and also with osmotic membranes for suitable equipment.

Culligan sanitisation process and components are part of Medical Device certification, Notified Body No. CE 0434.

Distribution systems

A well designed, correctly constructed distribution system is essential for maintaining the water quality characteristics. Greatest care must be taken to **avoid formation of dead zones** where the water may stagnate and allow bacteria to proliferate. High water flow rate must be kept in the entire circuit to **avoid deposit formation**.
It is also advisable - and in many countries compulsory - to provide a flow break system which **eliminates even the most remote risk that water** used for medical purposes **may return to the urban mains**.

Culligan designs and constructs systems for water distribution to kidney machines in various materials, in accordance to engineering and economic decisions and the chosen sanitisation technique.

PVDF HP BCF

Inert and absolutely shedding-proof, this is certainly the most innovative material. It is assembled by poly-welding, a technique which does not add any other material. It can be sanitised chemically or by heat, using superheated water or steam (temperatures up to 140 °C).

AISI 316 L stainless steel

Can be sanitised chemically or by heat, using superheated water or steam. The automatic welds are made in an inert gas atmosphere, while manual welds (limited to those strictly necessary) are of orbital T.I.G. type.

PEX

Can be sanitised chemically or by heat, using superheated water at 95 °C; it is easy to install. The feeding valves are in AISI 316 L stainless steel.

Non toxic u-PVC

This is the most widely used material, because of its low cost and because it is easy to use. It is assembled and glued using solvents. Can only be sanitised chemically.

Even the fixed distribution systems are certified as Medical Device accessories, Class IIb by Notified Body No. CE 0434.

Dual Box

Hospital conditions often make a system design which **cuts the time and space required for installation** a necessity. The **Culligan DUAL BOX** is the simple, logical answer to this problem: two different satin-finish steel boxes house the pre-treatment and Bi-Osmosis systems, completely preassembled and with all hydraulic and electrical connections already made. This means the equipment is immediately operational, from the moment of delivery; the user has only to make the inlet, outlet and water drain connections and connect the system to the electrical mains. The box housing the Bi-Osmosis equipment also contains an electrical panel with PLC for complete control of the system. The boxes have locks to prevent tampering by unauthorised staff.

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HOT WATER DISINFECTION

The system produces water at 95 °C for the sanitization of the distribution loop and/or the osmotic membranes of suitable process. It includes one control panel, the automatic valves for draining and filling, stainless steel heater and temperature control. Fully assembled in a cabinet, interfaced with the PLC general control panel.

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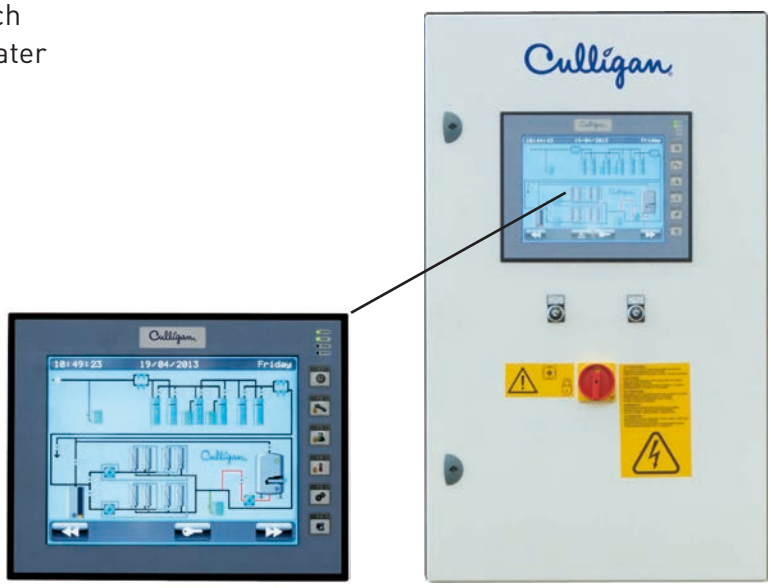
PLC GENERAL CONTROL PANEL

A Culligan exclusive dedicated PLC, 12.1" touch screen, controls all functions related to the water treatment plant, including night recirculation, hot water (or steam) sanitisation, chemical sanitisation and all safety devices.
Alarm transmission to remote unit.



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ARTIFICIAL KIDNEY DRAIN

The artificial kidney drain, designed to prevent any flow back between piping drain and artificial kidney, is in stainless steel with internal siphon. It is complete with fast connection and check valve.

Water quality and dialysate guide line

MICROBIOLOGICAL CONTROLS

Test	Raw water		Treated water		Regular dialysate		Ultrapure dialysate	
	Reference value	Frequency	Reference value	Frequency	Reference value	Frequency	Reference value	Frequency
UFC/mL Bacteria at 22 °C	<100	every 6 months	<100	monthly	<100	every 4 months in each display	<0.1	every 2 months in each display where online treatments are effected
Molds and Yeasts /mL	-	-	<10	every 6 months	<10		0	
Endotoxins UI/mL	-	-	<0.25	monthly	<0.25		<0.03	

Note: these data refer to Italian Pharmacopoeia

CHEMICAL CONTAMINANTS

Category		Parameter	Measure unit	Monitoring place and maximum acceptable level	
				Raw water (yearly frequency) Max level	Dilution water (every 6 months) Max level
1) Natural source	*Inorganic:*	Calcium	mg/L		2
		Chloride	mg/L	250	50
		Hydrogen ions	Unità pH	6.5 ÷ 9.5	4.4 ÷ 7.5
		Fluoride	mg/L	1.5	0.2
		Magnesium	mg/L		2
		Potassium	mg/L		2
		Sodium	mg/L	200	50
		Sulphate	mg/L	250	50
2) Anthropogenic	*Inorganic:*	Mercury	mg/L	0.001	0.001
		Lead	mg/L	0.01 (0.025 up to 25/12/2013)	0.1
		Nitrates (as NO_3)	mg/L	50	2
		Ammonium	mg/L	0.5	0.2
	Organic:	Total organo-alogenated compounds	µg/L	30	30
3) Products used for potabilisation	*Inorganic:*	Aluminium	mg/L	0.2	0.01
		Total Chlorine	mg/L	0.2	0.1
4) Byproducts for potabilisation treatment	*Inorganic:*	Zinc	mg/L		0.1
	Organic:	Total THM	µg/L	30	30

Note: these data refer to Italian Pharmacopoeia

Place your medical water treatment needs in the hands of a global leader.

Culligan®

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MEDICAL DEVICE QUALITY SYSTEM CERTIFIED ACCORDING TO UNI EN ISO 13485

Culligan Guarantee – Any manufacturing defects and corrosion are covered by the Culligan guarantee's norms.

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