“衛寶” 中央水處理系統

“Gambro” CWP 100 Central Water Treatment System

衛署醫器輸字第 021843 號

型號: WRO 131 ROHH / WRO 132 ROHH
使用前請務必詳閱原廠之使用說明書並遵照指示使用

產品敘述及用途

本產品係作爲透析之搭配器材，其目的係用於藉由逆滲透方式來製造純化水。本產品係用於醫療院所或診所使用。

警告與注意事項

警告
未經許可之修改、維修可能會導致損壞或導致其他有關儀器安全操作上的嚴重後果。

警告
與本產品水路配送管路連接之透析機器必須符合 IEC 60601-2-16 的規範。

注意

- 本系統須由受過儀器操作訓練與詳閱使用說明書之人員使用。
- 安裝及開啓本系統必須經由合格人員操作。
- 本系統附近使用手提電話等通話設備可能會影響機器的效能。
- 須依照原廠的指示維護機器。

前處理需求

進入本產品之水質必須符合規格中”進水”之規範。本產品安裝時必須在評估各個區域的水質及當地需求後，確認進水是否需要進行預處理。

效能及規格

<table>
<tr><td colspan="3" rowspan="2"></td><td colspan="2">規格</td></tr>
<tr><td>型號 131</td><td>型號 132</td></tr>
<tr><td rowspan="10">出水</td><td rowspan="6">最低輸出量</td><td>溫度</td><td></td><td></td></tr>
<tr><td>+5℃</td><td>10</td><td>19</td></tr>
<tr><td>+10℃</td><td>14</td><td>23</td></tr>
<tr><td>+15℃</td><td>16</td><td>26</td></tr>
<tr><td>+20℃</td><td>17</td><td>28</td></tr>
<tr><td></td><td colspan="2">(單位爲 l/min，在出水口壓力爲 200kPa 時)</td></tr>
<tr><td colspan="2" rowspan="4">品質</td><td colspan="2">依照進水品質而有所不同·如果是飲用水且系統有妥善的保養，則可得到下列之排除率</td></tr>
<tr><td colspan="2">總溶解鹽類: ＞95%</td></tr>
<tr><td colspan="2">細菌(CFU)及內毒素(EU): ＞99%</td></tr>
<tr><td colspan="2">水轉換係數最大: 75%</td></tr>
<tr><td rowspan="4">進水</td><td>最低進水量</td><td>l/min</td><td>30</td><td>50</td></tr>
<tr><td>最低進水壓力</td><td>kPa</td><td>100</td><td>250</td></tr>
<tr><td colspan="2"></td><td colspan="2">在沖洗時爲最大流量</td></tr>
<tr><td>最大進水壓力</td><td>kPa</td><td colspan="2">500 (所有型號)</td></tr>
<tr><td colspan="2">溫度</td><td colspan="2">+5℃ 至 +25℃</td></tr>
</table>

	品質		應使用飲用水，一般需要額外的預處理，膜及機器壽命會受到進水品質的影響，建議不要在超出下列範圍下使用 CWP，	
	硬度		＜1dH	
	鐵		＜0.1 mg/l	
	鎂		＜0.1 mg/l	
	氯化物		＜100 mg/l	
	二氧化矽		＜25 mg/l	
	總溶解鹽		＜1500 mg/l	
	氯		＜0.1 mg/l	
	污濁指數(S.D.I.)		＜5	
排水規範	需求量	l/min	30	50
連接	進水		PP union，符合水管 OD25mm	
	加熱桶排水處		PP union，符合水管 OD32mm(耐熱)	
	RORO-單位排水處		PP union，符合水管 OD40mm	
	排水盤		1/2" 母螺紋	
	出水出口及返回口		Wirsbo Q&E OD25mm	
膜	膜材質		modified polyamide，薄膜組成物	
	膜規格		旋轉式纏繞	
	pH 耐受度		2-11	
電源	主要電壓		120/208V，60Hz，三相(5 線)	
			230/400V，50Hz，三相(5 線）	
			240/415V，50Hz，三相(5 線)	
			220/380V，50Hz，三相(5 線)	
			請參照 CWP 單元上標籤	
	功率定額	RO-單元	4.7 kW	
			4.0 kW (120/208V，60Hz)	
		加熱單元	9.0 kW	
	保險絲		16AT + 16AT (slow blow) 380/400/415V	
			40AT + 40AT (slow blow) 208/220V	
			32AT (slow blow) 380/400/415V 如果只有 1 個電源供應	
測量範圍	溫度		0 - 100℃ (±10℃)	
	流速	出水	2-40 l/min (±10%)	
		拒絕水流速	2-40 l/min (±10%)	
		返回流速	2-40 l/min (±10%)	
	導電度	進水	100-1000 μS/cm (±15%)	
		出水	2-200 μS/cm (±15%或±1.5μS/cm 如果＜10μS/cm)	
登入介面	介面		RS 232，9pin 公頭，依據 EIA232C	
	最大輸入電壓		±15VDC	
	高階最小輸出		+5VDC	
	低階最小輸出		-5VDC	
	最大電流		±5mA	

			型號 131	型號 132
尺寸	測量	長 mm	700	700
		寬 mm	2000	2570
		高 mm	1820	1820
			在機器右邊及後方必須保留 500mm 的空間	
加熱桶	體積	公升	460	460
重量	單元	kg	570	750
	單元+包裝	kg	750	1000
	操作	kg	1170	1430

		型號 131	型號 132
環境溫度	運送及儲存	-10℃至+40℃	
	操作	+5℃至+35℃	

製造廠名稱: Gambro Lundia AB
製造廠地址: Box 10101, Magistratsvagen 16, SE-220 10 Lund, Sweden
藥商名稱: 衛寶股份有限公司
藥商地址: 臺北市中山區民生東路 2 段 143 號 11 樓

1 Introduction

1.1 Intended use

The CWP 100, model WRO ROHH (the device), is designed to be used as a dialysis accessory device to obtain purified water by using the reverse osmosis concept. The device can be used in conjunction with dialysis machines provided that the input flow and pressure demands correspond to the output of the device and that they comply with IEC 60601-2-16. The device is designed for hospital or clinic use.

WARNING
This device does not remove chlorine and chloramines. Carbon filtration to remove these substances is therefore required if the total chlorine concentration might exceed 0,1 mg/l (ppm). Severe patient injury may otherwise occur. Ensure by testing, or by other means, that the total chlorine concentration is below 0,1 mg/l (ppm) prior to initiating dialysis treatment.

1.2 General function

The Gambro CWP unit WRO ROHH is a two stage reverse osmosis unit, that has been specifically designed to fulfil the requirements of the dialysis clinic:

- It can be programmed to perform all modes of operation automatically without any operator intervention (automatic operation) or programmed for automatic operation but with manual stop of water production (semi-automatic operation).
- Any of the two stages can be operated separately in case of a technical break-down.
- Hot water can be circulated in the distribution loop and in the reverse osmosis unit at preset time periods during non-dialysis hours to minimize the potential for biofilm build-up in the fluid system. Dialysis machines that are designed for hot water can also be included in this process (Integrated heat).

1.2.1 Pretreatment requirements

The quality of the inlet water to the CWP unit must comply with the specifications in *"Water Supply" on page 41*. The pretreatment requirement will vary from installation to installation depending on the quality of the municipal water and local preferences.

Safety considerations

WARNING
Unauthorized modifications, alterations or repair of the water purification unit CWP 100, model WRO ROHH, may result in malfunctioning or have other serious consequences for the safe operation of the equipment.

WARNING
Dialysis machines that are to be connected to the distribution loop supplied with water from Gambro water purification unit CWP 100, model WRO ROHH, must comply with IEC 60601-2-16.

CAUTION

- The water purification unit CWP 100, model WRO ROHH, may only be operated by persons trained in this equipment and who have studied the instructions in this manual. If the water purification unit CWP 100, model WRO ROHH does not perform as described in this manual, it should not be used until the condition is rectified.
- The installation and start up of water purification unit CWP 100, model WRO ROHH, must be made by authorized personnel.
- The use of mobile telephones or communication equipment in the vicinity of the water purification unit CWP 100, model WRO ROHH could adversely influence the performance of the machine.
- The water purification unit CWP 100, model WRO ROHH, will perform as intended only if it is used and maintained in accordance with Gambro's instructions. Any warranties made by Gambro with respect to the water purification unit CWP 100, model WRO ROHH, are void if the equipment is not used in accordance with the instructions provided. Gambro will not accept responsibility for any damage or injury resulting from improper use or maintenance or unauthorized repair.

6 Technical data

6.1 CWP 100, WRO 131 and 132ROHH

6.1.1 Performance and specifications

			Specifications	
			Model 131	*Model 132*
Product water	Minimum outlet capacity	Temp		
		+ 5 °C	10	19
		+10 °C	14	23
		+15 °C	16	26
		+20 °C	17	28
			(in l/min at a product water outlet pressure of 200 kPa)	
	Quality		Depends on inlet water quality. If potable water is used and the system is properly maintained, the following rejection rates will be obtained: Total dissolved salts: >95 % Bacteria (CFU) & endotoxins (EU): >99% Water conversion factor max. 75%	
Water Supply	Min. input	l/min	30	50
	Min. input pressure	kPa	100	250
			Maximum flow occurs during flushing.	
	Max. input pressure	kPa	500 (all models)	
	Temperature	+5 °C to +25 °C		
	Quality		Potable water should be used. Additional pretreatment is normally necessary. Membrane and machine life expectancy depends on inlet water quality. It is recommended not to operate the CWP unit outside the following limits.	
	Hardness		< 1 °dH	
	Iron		< 0.1 mg/l	
	Manganese		< 0.1 mg/l	
	Chloride		< 100 mg/l	
	Silica		< 25 mg/l	
	Total dissolved salts		< 1500 mg/l	
	Chlorine		< 0.1 mg/l	
	Fouling index (S.D.I.)		< 5	
Drain Requirements	Required capacity	l/min	30	50

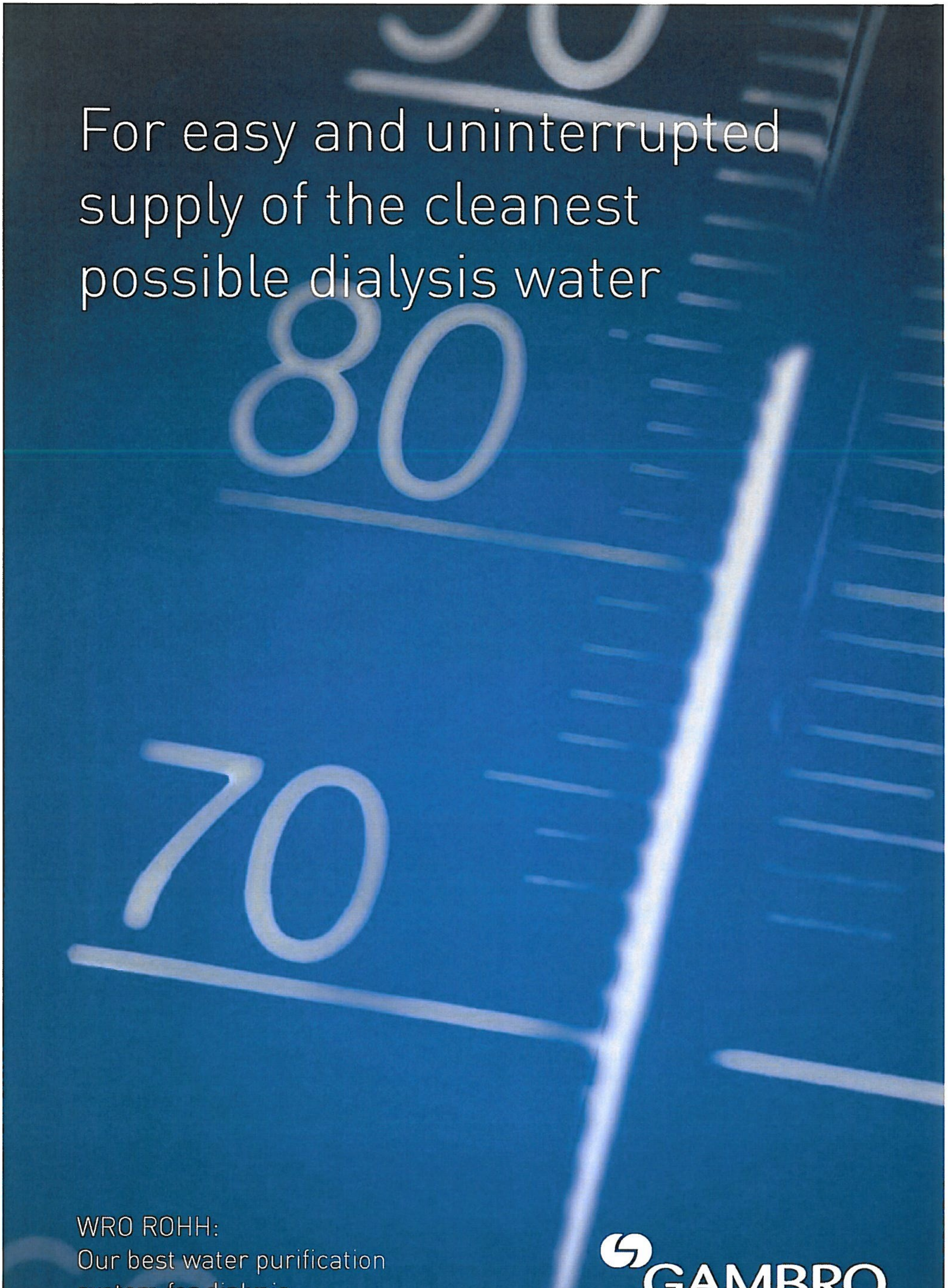
			Specifications	
			Model 131	*Model 132*
Connec-tions	Inlet		PP union, fits to pipe OD 25 mm	
	Drain from heating tank		PP union, fits to pipe OD 32 mm (heat resistant)	
	Drain from RORO-unit		PP union, fits to pipe OD 40 mm	
	Drain from tray		1/2" female thread	
	Product water outlet & return		Wirsbo Q&E OD25 mm	
Mem-branes	Membrane material		modified polyamide, thin film composite	
	Membrane configuration		Spiral wound	
	pH-tolerance		2 - 11	
Power Supply	Mains voltage		120/208 V, 60 Hz, three-phase (five wires) 230/400 V, 50Hz, three-phase (five wires) 240/415 V, 50 Hz, three-phase (five wires) 220/380 V, 50 Hz, three-phase (five wires) Refer to label on the CWP unit for correct information	
	Power rating	RO-unit	4.7 kW	
			4.0 kW (120/208 V, 60 Hz)	
		Heating unit	9.0 kW	
	Fuse		16 AT + 16 AT (slow blow) 380/400/415 V 40 AT + 40 AT (slow blow) 208/220 V 32 AT (slow blow) 380/400/415 V if powered from one supply	
Measur-ing Ranges	Temperature		0 - 100 °C (±10%)	
	Flow	Product water	2 - 40 l/min (±10%)	
		Reject flow	2 - 40 l/min (±10%)	
		Return flow	2 - 40 l/min (±10%)	
	Conductivity	Inlet water	100 - 1000 µS/cm (±15%)	
		Product water	2 – 200 µS/cm (±15% or ±1,5 µS/cm if < 10 µS/cm)	
Logging Interface	Interface		RS 232, 9 pin male According to EIA 232 C	
	Max. input Voltage		±15 VDC	
	High level min. output		+5 VDC	
	Low level min. output		-5 VDC	
	Max. Current		±5 mA	

6.1.2 Physical data

			Model 131	*Model 132*
Dimen-sions	Measures	Depth mm	700	700
		Width mm	2000	2570
		Height mm	1820	1820
			500 mm space is required on on the right-hand side and behind the unit.	
Heating tank	Volume	Liters	460	460
Weight	Unit	kg	570	750
	Unit+packing	kg	750	1000
	Operation	kg	1170	1430

6.1.3 Environmental data

		Model 131	*Model 132*
Ambient temperature	Shipping and stor-age	-10 °C to +40 °C	
	Operation	+5 °C to +35 °C	


For easy and uninterrupted supply of the cleanest possible dialysis water
WRO ROHH:
Our best water purification system for dialysis
GAMBRO®

WRO 132 ROHH unit

Gambro's CWP water purification systems for dialysis

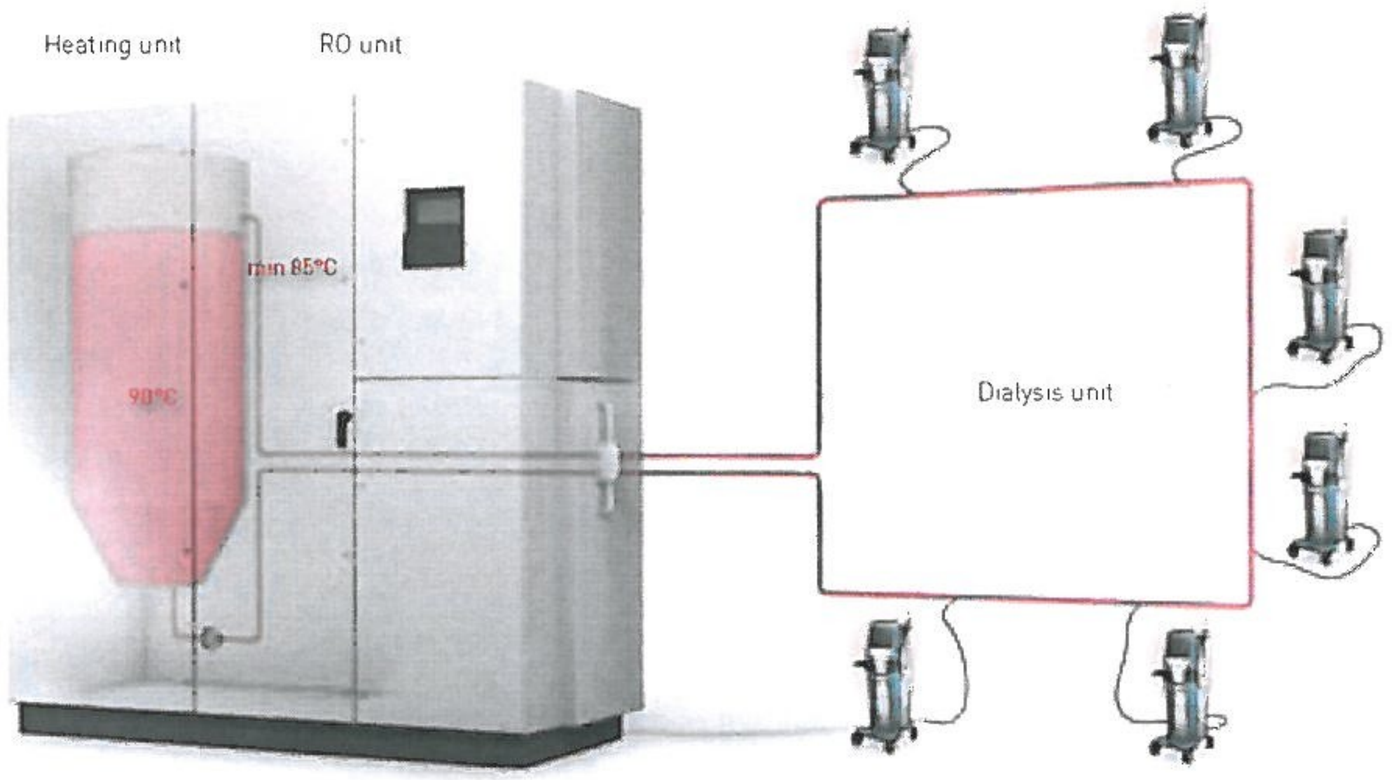
For more than two decades, Gambro's CWP systems have had a worldwide reputation for producing high-quality water for dialysis.

Now, another member has entered the CWP family. The WRO ROHH units offer new, unique features that make water purification for dialysis even more convenient. This fully automated unit has been specially developed to prepare and distribute the cleanest water possible for dialysis with a minimum of operator intervention.

Two-stage bi-osmosis concept

In the WRO ROHH unit, pre-treated, potable water is purified by two-stage reverse osmosis, resulting in superior water quality that surpasses existing dialysis water standards regarding electrolytes and trace elements.

The unit also allows independent operation of any of the two stages, called bi-osmosis. This feature guarantees an uninterrupted supply of single-stage reverse osmosis water at all times.



On-line heat disinfection principle

Quality assurance by preventive disinfection

It is a well-known fact that reverse osmosis membranes remove microbiological contaminants very effectively. In spite of this, bacteria will, over time, proliferate on the surfaces of the pure-water side downstream of the reverse osmosis unit, causing secondary contamination and biofilm formation in the entire fluid system in the clinic. The only way to stop this from occurring and to assure a consistent, high microbiological quality is to perform preventive disinfection frequently on all parts of the system.

Hot water disinfection of the entire pure water system

Gambro has offered the concept of hot water disinfection of the loop for many years. Now, in the WRO ROHH unit, this effective way to keep the system clean has also been implemented for the reverse osmosis unit itself. The internal fluid path, including the membrane elements, is regularly exposed to hot water for the inhibition of microorganisms. This means that there is no risk of patients or staff being exposed to chemicals, and no need for rinsing and testing for residuals after disinfection.

With this new concept, heating can be programmed for the entire water system, including the reverse osmosis unit, loop piping, connection hoses and the dialysis machines themselves. This mode, often referred to as "integrated heat", is possible because of the hot water tank that is included in the unit.

Fully automated operation

The operation of the system can be set according to the needs and desires of the individual clinic, from manual to fully automatic operation of all necessary modes. A five-colored lamp panel, installed in the clinic, gives clear information of the operational status of the WRO ROHH unit. If more detailed information is required, this can easily be accessed from the operator's panel on the machine.

Advantages of the WRO ROHH unit

- Quality assurance by proactive heating of the entire pure water system
- Hot water eliminates need for chemicals
- Can be programmed to perform all daily functions automatically
- Two-stage reverse osmosis, with the possibility to run either stage separately
- Built-in logging system backs up performance data for three days
- The compact design and silent operation allows for installation close to the dialysis clinic
- One easy-to-read panel screen displays all the information you need for programming or monitoring

WRO 131-132 ROHH

Technical data

Product water
Minimum capacity in liters/minute (liters/hour) at a pure water outlet pressure of 200 kPa:

Model	131	132
+ 5°C	10(600)	19(1140)
+10°C	14(840)	23(1380)
+15°C	16(960)	26(1560)
+20°C	17(1020)	28(1680)

Quality
Depends on inlet water quality. If potable water is used and the system is properly maintained, the following rejection rates will be obtained:

Total dissolved salts	>95%
Bacteria reduction (LRV*)	>6
Endotoxin reduction (LRV*)	>3
Water conversion factor:	max. 75%

*LRV = Log Reduction Value

Water supply

Model	131	132
Min. input, l/min (l/h)	30(1800)	50(3000)
Min. input pressure, kPa	100	250
Maximum flow occurs during flushing		

Max. input pressure	500 kPa (all models)
Temperature:	+5°C to +25°C

Quality
Potable water should be used. Additional pretreatment is normally necessary. Membrane and machine life expectancy depends on inlet water quality. It is recommended not to operate the CWP outside the following limits:

Hardness	< 1°dH (1.8°fH)
Iron	< 0.1 mg/l
Manganese	< 0.1 mg/l
Chloride	< 100 mg/l
Silica	< 25 mg/l
Total dissolved salts	< 1500 mg/l
Chlorine	< 0.1 mg/l
Fouling index (S.D.I.)	< 5

Drain requirements
Required capacity in liters/minute (liters/hour):

Model	131	132
	30(1800)	50(3000)

Connections

Inlet	PVC union, fit to pipe OD 25 mm
Drain from heating tank	PP female union, fit to pipe OD 32 mm (heat resistant)
Drain from RORO-unit	PP union, fits to pipe OD 40 mm
Drain from tray	1/2" female thread
Product water outlet & return	WIRSBO Q&E OD 25 mm

Membranes

Membrane material	Modified polyamide, thin film composite
Membrane configuration	Spiral wound
pH-tolerance	2-11

CE 0086 This product is CE-marked in accordance with the requirements in EC Council Directive 93/42/EEC of 14 June 1993 concerning medical devices

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Phone + 46 46 16 90 00
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Power supply

Mains voltage	230/400 V, 50 Hz, three-phase (five wires), other voltages on request
Power rating	RO/RO-unit, 131: 4.0 kW RO/RO-unit, 132: 4.0 kW Heating unit, 131-132: 9.0 kW
Fuse	16 AT + 16 AT (slow blow) or 32 AT (slow blow), if powered from one supply

Measuring ranges

Temperature	0-100 °C (±10%)
Flow	
Inlet water	2-40 l/min (±10%)
Reject flow	2-40 l/min (±10%)
Return flow	2-40 l/min (±10%)
Pure water	2-40 l/min (±10%)
Conductivity	
Inlet water	100-1000 µS/cm (±15%)
Pure water	2-200 µS/cm (±15% or ±1,5 µS/cm if < 10 µS/cm)

Ambient temperature

Shipping and storage	-10°C to +40°C
Operation	+5°C to +35°C

Dimensions

Model	131	132
Depth (mm)	700	700
Width (mm)	2000	2570
Height (mm)	1820	1820

500 mm space is required on the right-hand side and behind the unit.

Effective volume in heating tank (liters)

Model	131	132
	460	460

Weight

Model	131	132
Unit (kg)	570	750
Unit + packing (kg)	750	1000
Operation (kg)	1170	1430

Logging interface

RS 232, 9-pin male
According to EIA 232 C

Max. input voltage	± 15 VDC
High level min. output	+ 5 VDC
Low level min. output	- 5 VDC
Max. current	± 5 mA

Heat treatment of RO/RO-unit

Model	131	132
Cooling water consumption (liters/cycle):	250	450 (+10 °C)
Hot water consumption (liters/cycle):	60	75

Heat loss

Model	131	132
Heat loss max. (W/h):	1000 (-10% at 20 °C)	1000 (-10% at 20 °C)

The information herein may be subject to change without further notice
For further information and operating instructions, please refer to the operator´s manual

GAMBRO®