



**To: California Building Standards Commission  
2525 Natomas Park Drive, Suite 130  
Sacramento, CA -95833**

**Attn: Dave Walls. Executive Director**

**Sub: Comment on Annual Code Adoption Cycle**

**Re: To allow PEX as an approved material for Dialysis Water feed lines per CPC 613.1**

This letter is a request to include PEX piping as an approved material for the Dialysis water feed lines per CPC Section 613.1.

1. **SUPPORTING DOCUMENTATION**

The following documents provide technical and scientific justification for the inclusion of PEX as a suitable material for Dialysis Water feed lines.

a) **AAMI RD52: 2004 SECTION 5.3.3 WATER DISTRIBUTION SYSTEMS**

Table 2 describes the compatibility of common disinfectants with common piping materials used in dialysis water distribution system. PEX is one of the piping materials stated under that table and it shows that it can be disinfected using hot water. Patients are less likely to be exposed to chemicals because of heat sanitation and hence safer and healthier to patients.

b) **LETTER FROM DAVITA DIALYSIS DIVISIONAL BIOMEDICAL SUPERVISOR**

This letter explains in detail about the capability of PEX piping to be disinfected using heat rather than chemical sanitization, which can be ultimately safer for patients.

c) **E-MAIL FROM LEAD MICROBIOLOGIST, CENTERS FOR DISEASE CONTROL & PREVENTION**

This e-mail reiterates that the hot water disinfection method used in PEX systems par better than the chemical sanitation used in PVC. There is also pertaining information regarding the 510K notification for Gambro's CWP 100-WRO H which basically uses PEX piping material for its water distribution loops.

## 2. SUMMARY

In summary, the documentation / evidence suggests that PEX, as a piping material for the Dialysis Water feed lines has the capability to be hot water sanitized rather than being chemically sanitized. This system of disinfecting the pipes is safer for the dialysis patients as they are less likely to be exposed to chemicals.

This issue has been previously brought to this Commission's attention during public comment period of the Draft Environmental Impact Report pertaining to the use of PEX by Gambro (dated May 15, 2008) and Stanford University Medical Center (dated May 21, 2008). We request that the Commission amend the CPC 613.1 to include PEX as an approved material for Dialysis Water feed lines. Please contact us with any questions or concerns.

Thank you,

A handwritten signature in blue ink, appearing to be 'D.P.K.', written in a cursive style.

Donald P. Kinyon A.I.A  
Stephen E. Harriman A.I.A & Associates  
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should be changed on a regular schedule according to the manufacturer's instructions. A means shall be provided to effectively disinfect any storage tank installed in a water distribution system. Internal spray mechanisms can facilitate effective disinfection and rinsing of a storage tank.

**5.3.3 Water distribution systems**

Two types of water distribution systems are used: direct feed systems and indirect feed systems. In a direct feed system, water flows directly from the last stage of the purification cascade to the points of use. In an indirect feed system, water flows from the end of the purification cascade to a storage tank. From there, it is distributed to the points of use. In general, direct feed systems offer the least favorable environment for bacterial proliferation. However, with a direct feed system the purification cascade must be sized to provide sufficient water to meet the peak demand, and the system must have sufficient pressure at the end of the purification cascade to distribute the water to the points of use. Those two requirements often preclude the use of a direct feed system. Whichever type of system is used, water distribution systems should be configured as a continuous loop and designed to minimize bacterial proliferation and biofilm formation (see clause 7). A centrifugal pump made of inert materials is necessary to distribute the purified water and aid in effective disinfection. A multistage centrifugal pump is preferred for this purpose.

Product water distribution systems shall be constructed of materials that do not contribute chemicals, such as aluminum, copper, lead, and zinc, or bacterial contaminants to the purified water. The choice of materials used for a water distribution system will also depend on the proposed method of disinfection. Table 2 provides some guidance on the compatibility of different materials and disinfection agents. Whatever material is used, care should be taken to select a product with properties that provide the least favorable environment for bacterial proliferation, such as smooth internal surfaces.

**Table 2—Compatibility of common disinfectants with piping materials used in water distribution systems**

Material	Bleach	Peracetic acid	Formaldehyde	Hot water	Ozone
PVC	X	X	X		
CPVC	X	X	X		X
PVDF	X	X	X	X	X
PEX	X	X	X	X	
SS		X	X	X	X
PP	X	X	X	X	
PE	X	X	X		
ABS		X			
PTFE	X	X	X	X	X
Glass	X	X	X	X	X

PVC = polyvinylchloride, CPVC = chlorinated polyvinylchloride, PVDF = polyvinylidene fluoride, PEX = cross-linked polyethylene, SS = stainless steel, PP = polypropylene, PE = polyethylene, ABS = acrylonitrile butadiene styrene, PTFE = polytetrafluoroethylene.

NOTE—Table 2 is not intended as an exhaustive compilation of all possible compatible combinations of piping material and disinfectant. Users should verify compatibility between a given germicide and the materials of a piping system with the supplier of that piping system before using the germicide. Considerations of compatibility should include any joint materials and pipe fittings, as well as the actual piping material. The concentration of germicide and the duration and frequency of exposure also should be taken into account.

**5.3.4 Bacterial control devices**

**5.3.4.1 Ultraviolet irradiators**

NOTE—Requirements for ultraviolet (UV) irradiators intended for use in hemodialysis applications can be found in subclause 4.3.13 of normative reference 2.3. The recommendations provided in this clause concern UV irradiators used specifically for bacterial



## MEMORANDUM

TO: Whom it may concern

FROM: Michael Macias, DaVita Divisional Biomedical Supervisor

DATE: October 12, 2009

RE: Use of PEX in Dialysis Applications

PEX is a "newer" material since developed for use in dialysis since the original materials were considered for use in the late 1970's. PEX is used World Wide including almost all states in our country for use in dialysis. PEX has been approved for use in some municipalities in California based on approval by local building departments. PEX, unlike PVC, can be heat sanitized which is considered not only more efficient than chemical sanitizations, but safer for patients since patients would be less likely to be exposed to chemicals used in the sanitization process.

PVC, when used in a dialysis application, is subject to harboring microorganisms in the glued joints where the piping material is joined. In a typical dialysis loop, it would be typical to have a hundred or more glue joints. Unlike PVC, PEX is tubing that does not require "glued joints" to install, thus the opportunity for harboring microorganisms is greatly reduced making PEX safer for the dialysis application.

PEX tubing has a significantly smoother pipe surface in comparison to PVC. The smoothness of the PEX tubing makes it more difficult for microorganisms to attach to the interior surfaces which can cause a serious condition known as "biofilm." Biofilms are difficult to remove, even with chemicals, once established.

PEX is used in the dialysis product water loop. The loop is the piping that carries the purified water from the Reverse Osmosis (RO) machine to each dialysis machine in the facility. Piping for pre water treatment is typically a combination of copper and/or PVC.

While both Glass and Stainless Steel are currently accepted materials in addition to PVC, each has significant drawbacks. Glass is considered too fragile for this application and as such has never been used by any provider in this country that I am aware of. Stainless Steel is good for both chemical and heat sanitization, but is very cost prohibitive. As such, I am not aware of any kidney facilities in this country that have used either Glass or Stainless Steel for a dialysis distribution loop. Again, typically distribution loops for use in dialysis in this country are almost exclusively PVC schedule 80 or PEX.

**Letter from:**

**Matthew J. Arduino, M.S., Dr.P.H.**  
**Lead Microbiologist**  
**Clinical and Environmental Microbiology Branch**  
**Division of Healthcare Quality Promotion**  
**National Center for Preparedness, Detection, and Control of Infectious Diseases**  
**Centers for Disease Control and Prevention**  
**1600 Clifton Road, C16**  
**Atlanta, GA 30333**

**The letter was received via e-mail on 12-21-07**

**The letter from Mr. Arduino supports the use of Pex for use in heat disinfection based units and medical devices for dialysis use and also clarifies that the Pex used after the back flow prevention device is out of OSHPD's jurisdiction.**

Mr. Vezirian

Water treatment systems that utilize hot water pasteurization for sanitization purposes (some chemicals will still have to be used but not on a frequent basis) are the next generation of systems that are catching on through out the US. The benefits of these systems are they involve an integrated hot water loop disinfection with dialysis machines which if designed could be fully automated, end-to-end heat. The PEX tubing is a medical-grade PEX tubing that will accommodate hot water disinfection  $\geq 80^{\circ}\text{C}$  to prevent bacteria biofilm buildup. The use of these systems also reduces chemical exposure to the distribution loop (glues, solvents, disinfectants, etc.). So that the process can be potentially completely automated capable of performing nightly sanitization as we begin to move in the direction of ultrapure dialysis fluids.

These systems have a longer track record in Europe (where they were first introduced).

I personally, support the use of hot water systems because they do not require these tend to be more proactive; facilities using chemicals tend to sanitize systems less frequently so that one may end of chasing a problem (costly use of chemicals) in an attempt to bring the water back to with in standards. The PVC pipe that has been used for years was the cheapest inert material facilities would go for but life expectancy of these types of systems tend to be about 10 years or less due to bacterial buildup of biofilm on the walls of the pipes. Other plumbing materials that are used in ultrapure water systems 316L Stainless, PVDF, etc tend to be higher priced materials.

PVC schedule 80 is not really compatible with hot water disinfection. Dr. Nathan Levine and Rob Levine (Chief Tech) Renal Research Institute (NY) had attempted this back in the '90s. The system because of expansion and contraction would develop cracked pipes.

**What the plumbing and code people need to realize is that once water from municipal supply passes the back flow prevention device at the front of a water treatment system it is no longer plumbing it is a medical device regulated by the US FDA as such the PEX used in these systems can be considered medical grade (they do not contribute to contamination of the purified water. There is an on going war between the dialysis community and those responsible for the plumbing code since publication of the UPC in 2000.**

I also looked at the October 2007 announcement for Adoption of Statewide Regulations Allowing the Use of PEX Tubing.

A number of manufacturer's have 510K Approved hot water disinfect systems:

**Gambro's CWP            510K K974899**

Gambro's WRO 300 H    510K K042797

Mar Cor 4400HX Hot Water Disinfection Reverse Osmosis System (BioLab Equipment) 510K K030348

Dialysis Services (Inc) DIALYSIS SERVICES WATER TREATMENT & DISTRIBUTION    510K K043344

#### REFERENCES:

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[Matthew J. Arduino, M.S., Dr.P.H.](#)

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**GAMBRO WATER SYSTEMS-USA**

**Title:** Water system schematic, CWP Large (Laminated Poster Size Schematic of complete Water System)

**Document Number:** WTSCHCWP01 **REVISION:** D **CO#** 07090

These documents are the property of GAMBRO WATER SYSTEMS-USA and shall not be reproduced, copied or used to manufacture or sell apparatus without written permission.

**APPLICABILITY:** This document specifies the printing instructions for the part number listed below.

**Bill of Reference**

Item Number	Qty	U/M	Vendor	Part Number	Item Description
1	1	copy	Gambro Print Shop or other printing / copying service	WTSCHCWP01	Complete Water System Schematic for Single CWP and Single plus Supplemental CWP systems.

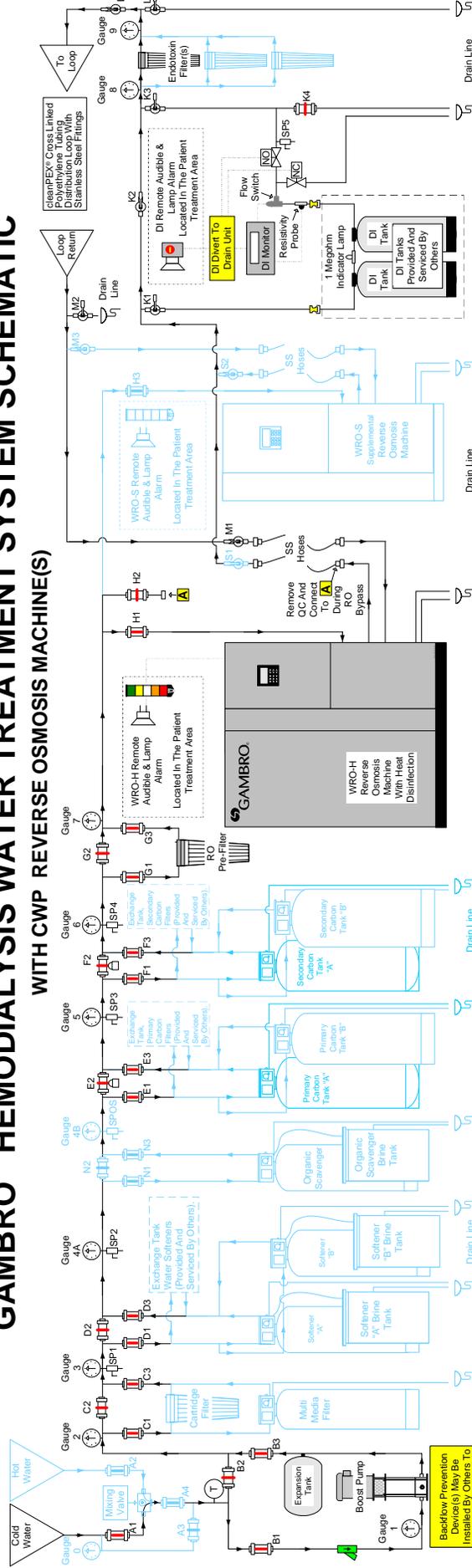
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- Document will be printed using a full color printing or plotting process on white paper.
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- The finished size of the laminated document shall not exceed 27" x 18"
- Artwork stored by GWS-USA
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Rev	Description	Date Created	Originator	CO#
A	Original Release	01/09/2006	Mark Richers	06003
B	Corrected title block	01/20/06	Dave Fisher	06009
C	Address and Gambro logo color change	07/12/07	Barry Land	07071
D	Remove arc and circle color specification from print spec.	08/22/07	Rob Williams	07090

# GAMBRO® HEMODIALYSIS WATER TREATMENT SYSTEM SCHEMATIC

## WITH CWP REVERSE OSMOSIS MACHINES(S)



**Note: Items Shown In BLUE Are Provided And Installed Based On Clinic Specific Information. Refer To The Clinic Specific Equipment Listing To Determine Which Components Are Included In Your System.**

VALVE TAG	DESCRIPTION	PROVIDED	MAINTAINED	OTHER
A1	COLD WATER INLET	N.O.	G1	RO PRE-FILTER INLET
A2	HOT WATER INLET	N.O.	G2	RO PRE-FILTER BYPASS
A3	MIXING VALVE BYPASS	N.C.	G3	RO PRE-FILTER OUTLET
A4	MIXING VALVE OUTLET	N.O.	H1	RO INLET, CWP WRO H
B1	BOOST PUMP INLET	N.O.	H2	RO BYPASS
B2	BOOST PUMP BYPASS	N.C.	H3	RO INLET, CWP WRO S
B3	BOOST PUMP OUTLET	N.O.	K1	DI INLET
C1	SEDIMENT FILTRATION INLET	N.C.	K2	DI BYPASS
C2	SEDIMENT FILTRATION BYPASS	N.O.	K3	DI OUTLET
C3	SEDIMENT FILTRATION OUTLET	N.O.	L1	DI FLUSH TO DRAIN
D1	WATER SOFTENER INLET	N.O.	L1	ENDOTOXIN FILTER OUTLET
D2	WATER SOFTENER BYPASS	N.C.	L2	ENDOTOXIN FILTER FLUSH
D3	WATER SOFTENER OUTLET	N.O.	M1	LOOP RETURN, CWP WRO H
E1	PRIMARY CARBON INLET	N.O.	M2	LOOP RETURN, CWP WRO S
E2	PRIMARY CARBON BYPASS	N.C. & S	M3	ORGANIC SCAVENGER INLET
E3	PRIMARY CARBON OUTLET	N.O.	N1	ORGANIC SCAVENGER BYPASS
F1	SECONDARY CARBON INLET	N.C. & S	N2	ORGANIC SCAVENGER OUTLET
F2	SECONDARY CARBON BYPASS	N.C. & S	S1	RO OUTLET, CWP WRO H
F3	SECONDARY CARBON OUTLET	N.O.	S2	RO OUTLET, CWP WRO S

N.O. = NORMALLY OPEN VALVE  
 N.C. = NORMALLY CLOSED VALVE  
 N.C. & S. = NORMALLY CLOSED & SECURED VALVE  
 WRO H = MAIN CWP REVERSE OSMOSIS MACHINE (MASTER)  
 WRO S = SUPPLEMENTAL CWP REVERSE OSMOSIS UNIT

GAUGE & SAMPLE PORT	DESCRIPTION
T	THERMOMETER FOR INLET TO WATER SYSTEM
G0	COLD WATER INLET
G1	BOOST PUMP INLET
G2	BOOST PUMP OUTLET/SEDIMENT FILTRATION INLET
G3	SEDIMENT FILTRATION OUTLET/WATER SOFTENER INLET
G4	WATER SOFTENER OUTLET/SCAVENGER TANK INLET OR PRIMARY CARBON INLET
G4B	SCAVENGER TANK OUTLET/PRIMARY CARBON INLET
G5	PRIMARY CARBON OUTLET/SECONDARY CARBON INLET
G6	SECONDARY CARBON OUTLET/RO PRE-FILTER INLET
G7	RO PRE-FILTER OUTLET/RO PRE-FILTER INLET
G8	ENDOTOXIN FILTER INLET
G9	ENDOTOXIN FILTER OUTLET (LOOP FEED PRESSURE)
SP1	POST SEDIMENT FILTRATION SAMPLE PORT
SP2	HARDNESS SAMPLE PORT
SP3	PRIMARY CHLORINE SAMPLE PORT
SP4	SECONDARY CHLORINE SAMPLE PORT
SP5	POST DI SAMPLE PORT
SP OS	POST ORGANIC SCAVENGER SAMPLE PORT

LEGEND	DESCRIPTION
(T)	NORMALLY CLOSED PVC BALL VALVE
(B)	NORMALLY OPEN PVC BALL VALVE
(C)	NORMALLY CLOSED PVC BALL VALVE (SECURED CLOSED WITH TOLON TIE)
(V)	CHECK VALVE
(1)	THERMOMETER
(P)	PRESSURE GAUGE
(S)	SAMPLE PORT
(O)	NORMALLY OPEN SS BALL VALVE
(OC)	NORMALLY CLOSED SS BALL VALVE
(OE)	NORMALLY OPEN ELECTRIC VALVE
(OC)	NORMALLY CLOSED ELECTRIC VALVE
(D)	PROCESS AND/OR OTHER DRAIN
(C)	SS QUICK CONNECT COUPLING
(P)	PLASTIC QUICK CONNECT COUPLING
(W)	WATER PIPE W/ FLOW DIRECTION
(E)	ELECTRICAL
(S)	SITE SPECIFIC EQUIPMENT

This water system has been manufactured as a medical device. Any alteration to this water system, its components, and/or this schematic may be an adulteration of this medical device.  
**CAUTION:** When used as a medical device, Federal law restricts this device to sale by, or on the order of, a physician.

**INDICATIONS FOR USE:** The Gambro Water Treatment System is intended to be used by hemodialysis clinics for the purification of water to be used for the dilution of dialysate concentrate and in the reprocessing of dialyzers.  
**WARNING:** Prior to bypassing, deactivating, or maintaining any component, the **Operation and Maintenance Manual** should be reviewed for applicable cautions and warnings.

Gambro Systems, Inc.  
 Colorado, U.S.A.  
 1-800-525-2623



Document Number: WTSCH001  
 Revision: D  
 Effective Date: 08/29/2007  
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SEP 23 1998

## 510K(k) SUMMARY

**SUBMITTER:** Gambro Healthcare  
1185 Oak Street  
Lakewood, CO 80215  
(303) 231-4436

**DATE PREPARED:** Friday, December 26, 1997

**DEVICE NAME:** Gambro Central Water Treatment System  
CWP 100 – WRO H

**CLASSIFICATION NAMES:** Water Purification System for Hemodialysis

**PREDICATE DEVICE:** Osmonics Osmo 23 G Series Reverse Osmosis  
Machines

**Device Description:****General Description**

The Gambro Central Water Treatment System CWP 100 – WRO H is designed to produce water of adequate quality for hemodialysis, both chemically and microbiologically with an adequate flow, provided that the feed water complies with the existing standards for drinking water and has been properly pre-treated. The WRO or the base unit of the CWP system, operates under the principle of reverse osmosis (RO) which is the preferred method for the purification of water for hemodialysis. This system removes at least 95% of the total dissolved salts (based on conductivity measurements) and more than 99% of the bacteria and endotoxins from the inlet water. The WRO H also include a heat disinfection unit for disinfection of the distribution system which utilizes hot water to minimize any form of microbial growth and biofilm formation. With this system, dialysis machines can be included in this heat disinfection cycle, provided that they have heat disinfection capability. This procedure is called *integrated heat disinfection*.

In order to ensure that the microbiological quality will be maintained, this system has:

- an automated disinfection procedure to keep the membrane surfaces clean and to minimize bacterial growth;
- a hygienic design with smooth surfaces and a minimum of stagnant zones;
- automatic flushing programs at preset intervals when the system is not in use

In addition, the WRO H has been designed to reduce water consumption by automatically regulating the pump speed to the actual demand of pure water.

After pretreatment (i.e. sediment filter, water softener, charcoal filter, etc.) the water enters an inlet tank (please refer to position 4 on the following diagram) via a solenoid

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valve (1). The inlet water tank (4) has a float valve (5) and an air gap to help isolate the flowpath from the municipal water system. The main pump (33) then creates a pressure of up to 20 bar that is required for the reverse osmosis process.

Pure water from the WRO unit is distributed directly to the distribution system in the hemodialysis unit via solenoid valves (48), (103), and (105). Excess pure water that has not been used in the hemodialysis unit is recirculated back to the inlet water tank (4) via solenoid valve (106).

In order to reduce water consumption, the speed of the pump is automatically adjusted so that the return flow of water is kept constant. Part of the reject water is recirculated back to the sucking side of the main pump via valve (71) to help minimize water consumption and to maintain a high flow velocity over the membrane surface. The rest of the reject water is, however, continuously sent to the drain via a needle valve (41).

The WRO unit utilizes a proportioning pump (45) and solution container (46) to proportion disinfectant during the disinfection cycle. The proportioning pump is disconnected from the flow path during normal operation.

The pure water line has a solenoid valve (36) for automatic flushing to drain at the start up, in conductivity alarm situations, every two hours, when the unit is in stand-by mode and at rinse during disinfection. The pure water line also has a solenoid valve arrangement to isolate the system from the distribution system during disinfection. The WRO unit has an overflow valve (64) on the pure water side to control pressure and to relieve pressure peaks.

### **Conductivity Monitoring**

The conductivity of the inlet water and pure water are continuously monitored by two conductivity cells (32) and (35), and are presented on the display on the operator's panel.

### **Flow Monitoring**

The following flow rates are monitored

<b>Flow</b>	<b>Sensor Position</b>	<b>Designation</b>
<b>Inlet Water</b>	<b>3</b>	<b>F1</b>
<b>Reject From the RO Unit</b>	<b>42</b>	<b>F2</b>
<b>Return Pure Water from the Clinic</b>	<b>51</b>	<b>F4</b>

These flow rates are used to calculate the following:

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- **Actual pure water consumption,**  
( $F5=F1-F2$ )
- **Outlet pure water flow,**  
( $F6=F1-F2+F4$ )

All flow rates are presented on the operator's panel on request.

### **Heat Disinfection Unit**

The heat disinfection unit consists of a tank (90) made of stainless steel and an electrical heater (91). The heater maintains the temperature of the pure water in the tank at either 60 °C (Low) or 90 °C (High). Heat disinfection of the pure water distribution system is initiated by the operator at the end of the dialysis day / session. A circulation pump (96) circulates hot water in the loop until the process is interrupted either manually by the operator, or at a preset time prior to the start of the next dialysis day / session. During the disinfection period, integrated heat disinfection with the dialysis machines can also be performed if the dialysis machines have a heat disinfection capability. The tank automatically refills with pure water from the WRO unit during the next operation. Heating of the water from 60 °C (Low) to 90 °C (High) takes approximately 2.5 hours if no circulation the loop takes place. During circulation periods the required time is longer because of heat losses and varies depending on the length and design of the system.

### **Heating Capacity**

The heat disinfection unit is capable of maintaining 85 °C in a well insulated piping system with a maximum length of 150 meters.

**Predicate Devices:**

The Gambro Central Water Treatment System CWP 100 – WRO H is substantially equivalent to other water purification systems for hemodialysis in commercial distribution in the United States to include the Osmonics Osmo 23 G Series Reverse Osmosis Machines (FDA Document Control Number K931595 B. Both systems utilized reverse osmosis for purification of water to be used for hemodialysis. Both systems utilize a polyamide, thin film composite, spiral wound membrane for reverse osmosis. Both systems are intended to be used for water purification for hemodialysis. Both systems utilize substantially equivalent water contact materials for pumps, tubing, and other fittings, etc. Both systems utilize software for control and alarm systems. Both systems come in a number of sizes to accommodate varying product water output requirements. Both systems can utilize chemical disinfection using peracetic acid disinfection products. The Gambro water purification system has the additional advantage of having an integrated heat disinfection capability for both the reverse osmosis system and the distribution system.

We therefore consider the Gambro Central Water Treatment System CWP 100 – WRO H to be substantially equivalent to the Osmonics Osmo 23 G Series Reverse Osmos Machines. The following table provides the necessary information on the predicate device to which this system is substantially equivalent.

**PREDICATE DEVICE**

<b>DEVICE NAMES</b>	<b>Osmonics Osmo 23 G Series Reverse Osmosis Machines</b>
<b>INTENDED USE</b>	<b>Water Purification System for Hemodialysis</b>
<b>510K NUMBER</b>	<b>K 931595B</b>
<b>APPROVAL DATE</b>	<b>1993</b>

**Intended Use:**

*The Gambro Central Water Treatment System CWP 100 – WRO H is designed to produce water of adequate quality for hemodialysis, both chemically and microbiologically with an adequate flow, provided that the feed water complies with the existing standards for drinking water and has been properly pre-treated.*

This indication statement is essentially the same as the indication statement for the predicate device.

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**Technological Characteristics:**

Comparing the proposed device to the predicate device, some similarities and differences are noted in the design employed to accomplish the same intended use. Both systems utilized reverse osmosis for purification of water to be used for hemodialysis. Both systems utilize a polyamide, thin film composite, spiral wound membrane for reverse osmosis. Both systems are intended to be used for water purification for hemodialysis. Both systems utilize substantially equivalent water contact materials for pumps, tubing, and other fittings, etc. Both systems utilize software for control and alarm systems. Both systems come in a number of sizes to accommodate varying product water output requirements. Both systems can utilize chemical disinfection using peracetic acid disinfection products. The Gambro water purification system has the additional advantage of having an integrated heat disinfection capability for both the reverse osmosis system and the distribution system.

**Summary of Non-Clinical Tests:**

In vitro performance testing was performed on the Gambro Central Water Treatment Systems to establish normal operating performance to include flow rates, rejection of dissolved salts, organic materials, bacteria, and pyrogen. Additional testing was performed to evaluate the safety of the materials having water contact at various temperatures. The results of these tests confirmed that the proposed device is substantially equivalent to the proposed device for these parameters.

**Clinical Test Results:**

Clinical testing was not performed

**Conclusions:**

Testing performed on the Gambro Central Water Treatment System CWP 100 WRO H indicates that they are safe, effective, and perform as well as the predicate device, when used in accordance with the instructions for use.

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Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850Jeffrey R. Shideman, Ph.D.  
GAMBRO Healthcare  
1185 Oak Street  
Lakewood, CO 80215-4498Re: K974899  
GAMBRO Reverse Osmosis System  
CWP 100-WRO-H  
Dated: July 7, 1998  
Received: July 13, 1998  
Regulatory Class: II  
21 CFR 876.5665/Procode: 78 FIP

Dear Dr. Shideman:

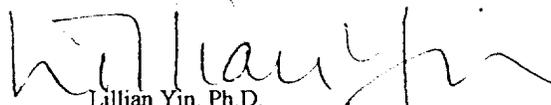
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address "<http://www.fda.gov/cdrh/dsma/dsmamain.html>".

Sincerely yours,

Lillian Yin, Ph.D.  
Director, Division of Reproductive,  
Abdominal, Ear, Nose and Throat  
and Radiological Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

**Intended Use:**

*The Gambro Central Water Treatment System CWP 100 – WRO H is designed to produce water of adequate quality for hemodialysis, both chemically and microbiologically with an adequate flow, provided that the feed water complies with the existing standards for drinking water and has been properly pre-treated.*



(Division Sign-Off)  
Division of Reproductive, Abdominal, ENT,  
and Radiological Devices

510(k) Number K974899/S2

Prescription Use  \_\_\_\_\_  
(Per 21 CFR 801.109)