NIPRO

Cellentia™-H

HEMODIALYZER

Approximate Performance Characteristics

Note: Operation of the dialyzer under clinical conditions may procedure values different from those illustrated because of the variables involved in the clinical dialysis procedure, in the cellulose triacetate membrane, and in the manufacture of the device. Therefore, the values given are for approximation only. See in-vitro test conditions for explanatory materials relating to the test conditions from which the data were derived.

Warning: Cellentia-H Dialyzers must be used on dialysis machines equipped with an ultrafiltration controller or an accurate fluid balancing system.

Specifications and In-Vitro Data

		Cellentia-15H	Cellentia-17H	Cellentia-19H	Cellentia-21H
Surface area (m^2)		1.5	1.7	1.9	2.1
CLEARANCE (mL/min)					
Blood (mL/min)		**200 300 400 500**	**200 300 400 500**	**200 300 400 500**	**200 300 400 500**
Dialysate (mL/min)					
Urea	**500**	195 265 315	198 273 326	198 277 337	199 281 344
	800	338 383	353 402	364 417	372 430
Creatinine	**500**	187 246 280	191 258 294	193 266 306	195 273 315
	800	307 335	323 358	336 374	345 390
Vitamin B_{12}	**500**	133 150 163	142 162 177	149 175 190	154 184 203
	800	174 183	190 201	205 218	218 234
Phosphate	**500**	183 224 252	186 234 264	189 242 277	192 250 285
	800	273 301	289 319	303 335	316 350
Ultrafiltration Coefficient (mL/hr/mmHg)		41	45	48	52
Priming volume (mL)		87	98	110	122
Pressure Drop					
Blood (mL/min)		**200 500**	**200 500**	**200 500**	**200 500**
Dialysate (mL/min)		**500 800**	**500 800**	**500 800**	**500 800**
Blood Compartment		65 155	64 152	63 149	62 145
Dialysate Compartment		14 22	15 24	14 22	14 22
Maximum blood flow rates		500	500	500	500
Maximum dialysate flow rates		800	800	800	800
Sieving coefficient data for those substances tested		Urea 1.00 Creatinine 1.00 Albumin <0.01			

Cellentia-H Dialyzer Technical Information

Hollow Fiber	
Membrane Polymer	Cellulose triacetate
Inner Diameter	200 microns
Membrane Thickness	15 microns
Maximum TMP	500 mmHg
Header	Polypropylene
Housing	Polypropylene
Potting Compound	Polyurethane
Sterilization	Gamma Irradiation

In-Vitro Test Conditions

Testing was performed in compliance with the evaluation standard for dialyzer performance called for by ANSI/AAMI ISO 8637.

1. Clearance
   Temperature: 37°C
   Ultrafiltration Rate: 10 mL/min
2. Ultrafiltration Rate
   Test Solution: Bovine Blood
   Hematocrit: 32%
3. Priming Volume (Blood compartment)
   Test Solution: Water
4. Pressure Drop
   50 mmHg transmembrane pressure
5. Maximum Blood flow 500mL/min
   Maximum Dialysate flow 800mL/min
6. Minimum Blood flow 200mL/min
   Minimum Dialysate flow 500mL/min

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Instructions for Use

Be familiar with instructions specified in this instructions for use before use.

Indications
Hemodialysis with Cellentia-H Dialyzer is indicated for patients with acute or chronic renal failure when conservative therapy is judged to be inadequate. It also may be indicated in the treatment of patients intoxicated with poisons or drugs.

Caution:
Federal (USA) law restricts this device to sale by or on order of a physician.

Caution for Storage
Store at 0°C to 40°C (32°F to 104°F), avoiding direct exposure to sunlight and vibrations.

Contraindications
There are no special contraindications for use of this dialyzer for hemodialysis.

WARNING
1. This product is intended for single use only. Reuse or reprocessing of a single use device may lead to contamination and compromised device function or structural integrity. Ineffective removal of residual disinfectant may lead to adverse patient reactions. Do not expose fibers to bleach.
2. Device should not be used beyond the expiration date.
3. Do not use if the package is damaged due to potential sterility break.
4. Keep blood inflow and outflow connectors closed until connecting the dialyzer to the bloodline connectors.
5. The dialysis circuit must remain sterile before connecting the dialyzer.

Adverse Reactions
Adverse reactions may occur due to the complex interaction between blood and the arterial surfaces of the entire extracorporeal circuit. These reactions may also occur due to other factors related to patient's underlying renal disease, comorbid conditions and concomitant treatments or medications. Patients may experience hypersensitivity (allergic) reactions during treatment.
Symptoms and signs have included asthmatic reactions respiratory arrest, pruritus, urticaria, erythema, peripheral and facial edema, hypertension, hypotension, and cardiac arrhythmia. A history of allergic responses, including asthma, is an indication for careful monitoring for such signs or symptoms during treatment.
Other reactions which may occur include drop in platelet hypotension, hypertension, headache and nausea, which may be associated with hypovolemia, can usually be avoided by careful management of the patient's fluid, electrolyte balance, blood flow rate and ultrafiltration rate.

Air Embolism
Air in the extracorporeal circuit during treatment must be avoided. If air gets into the system, the treatment must be discontinued and the blood must not be returned to the patient. If any abnormalities such as foam generation, blood leakage, blood coagulation and hemolysis occurred during the use of this product, take appropriate measures according to a physician's instructions.

Hypersensitivity Reactions
It is recommended that treatment be discontinued in any patient exhibiting signs or symptoms of a hypersensitivity reaction. The blood contained in the extracorporeal circuit at the time of the reaction should not be returned to the patient.

High Permeability Dialyzers
Use of the Cellentia-H Dialyzer under clinical conditions of high transmembrane pressure may result in net ultrafiltration rates that greatly exceed the ultrafiltration requirements of some patients. Under these conditions, the use of sterile reinfusion fluid is mandatory.

Dialysate Fluid
Use of an in-line conductivity monitor is recommended.
To avoid hemolysis, dialysate temperature should never exceed 42°C (107.6°F).

Treatment Procedure
1. Aseptic technique must be employed.
2. All connections should be checked carefully before and during treatment.
3. The inlet (arterial) and outlet (venous) drip chambers must be at manufacturer's recommended full level at all times. Since air may be drawn into the extracorporeal circuit on the negative pressure side of the blood pump, the use of an air detector on the venous line is recommended.
4. To preserve fiber integrity, do not exceed 500 mmHg (66 kPa) transmembrane pressure. Weighing the patient before and after treatment is recommended to verify the extent of ultrafiltration.
5. If the patient is under drug therapy, blood levels must be monitored to assure appropriate therapeutic levels are maintained.

Set Up Procedure
Refer to Warnings and Precautions section for additional statements. Do not use if the package is broken or if the product is damaged.
Do not use if blood port tip protectors are not in place.
Unpack immediately before use.

Initial Assembly
Connect the inlet (arterial) set, outlet (venous) set, monitoring lines, saline administration line, heparin line (if applicable) to the dialysis machine and dialyzer.

Initiation of Treatment
For extracorporeal circuit configuration, refer to Figure 1.

Priming
1. Place the dialyzer in a vertical position. Connect the arterial and venous blood lines to the respective dialyzer blood ports.
2. Attach isotonic saline (0.9%) and prime the dialyzer at a flow rate of 100 mL/min.
3. After the blood compartment has been rinsed with 500 mL of saline, stop the blood pump. Attach the arterial and venous patient connectors. Recirculate the extracorporeal circuit with a minimum of 500 mL of saline, with the blood pump speed set per clinic protocol.
4. Start the blood pump. After the blood compartment has been purged of air, stop the blood pump.
5. Attach the dialysate connectors so that the dialysate fluid inlet line is near the venous blood port.
6. Start the blood pump and the dialysate flow. Prime the dialysate compartment.
7. Ensure the blood compartment is filled with isotonic saline. Stop the blood pump and dialysate flow.
8. Clamp the arterial and venous lines near the patient connector.

Note: When the priming procedure has been completed, and the extracorporeal circuit is free of air, set the ultrafiltration rate as low as possible. Do not allow the dialysate-side pressure to become greater than the blood-side pressure. This will minimize the ultrafiltration of priming solution from the dialyzer between the time when the circuit is primed and treatment is to commence. If for any reason the treatment procedure is not started immediately following the completion of priming, the isotonic saline in the circuit should be replaced with fresh isotonic saline immediately prior to the initiation of treatment.

Treatment Procedure
1. Specific directions should be given by the attending physician.
2. Operation of the dialyzer at a zero net ultrafiltration rate or at extremely low net ultrafiltration rates may cause the dialysate-side pressure to exceed the blood-side pressure in a portion of the dialyzer. Because the likelihood of reverse ultrafiltration of nonsterile dialysate into the blood is increased under these conditions, the ultrafiltration rate must be carefully adjusted as directed by a physician.
3. Carefully observe the outlet (venous) drip chamber as blood enters. If blood appears hemolyzed, clamp the outlet (venous) set and simultaneously shut off the blood pump. Clamp the inlet (arterial) set. If dialysate fluid is used, verify that the dialysate mixture is proportioned correctly and properly formulated, then explore other causes (e.g. dialysate over temperature, improper priming fluids). Purge all incompatible fluid from the dialyzing fluid path. The blood must not be returned to the patient. When cause has been determined and corrected, discard the dialyzer and sets.

Replacement of Dialyzer
1. Connect the arterial access port to the arterial set patient connector.
2. Connect the venous access port to the venous set patient connector.
3. Remove the clamps from the patient's access and the arterial patient connector, then remove the venous patient connector clamp. Coordinate the starting of the blood pump with this action. Start the blood pump.

Treatment Monitoring
If monitoring the post-pump arterial pressure during treatment, a continuing rise in post-pump arterial pressure may indicate an obstruction in the dialyzer or extracorporeal circuit. Although this dialyzer has been tested for mechanical integrity, a rupture or leak leading to blood loss can occur during treatment. Therefore, constant monitoring using a blood leak detector on the dialysate fluid line or ultrafiltration line, and visual inspection of the system, is recommended. If a blood leak occurs, an attempt may be made (at the discretion of the attending physician) to return blood from the extracorporeal system to the patient (see Termination of Treatment). If the decision is made not to return the blood to the patient, clamp the venous set and simultaneously stop the blood pump. Clamp the arterial set. Discard the dialyzer and sets.

Administration of Heparin
Systemic or regionalized heparinization may need to be administered based on instructions from attending physician.

Termination of Treatment
Any air that was trapped inadvertently in the dialyzer during priming and treatment may be dislodged. Carefully monitor the level of the venous drip chamber at all times. Air rinsing of blood at the termination of treatment is not recommended.
1. Set ultrafiltration rate as low as possible. Do not allow the dialysate-side pressure to become greater than the blood side pressure.
2. Stop dialysate flow.
3. Reduce blood pump speed to zero and sequentially clamp venous and arterial sets and arterial access.
4. Separate the arterial set from the arterial access and connect the arterial set to a source of sterile isotonic saline.
5. Open the clamps on the fluid administration set, the arterial set, and the venous set and increase the blood pump setting slowly to 100 mL/min to return the blood to the patient.
6. Rinse isotonic saline through the blood tubing until the fluid in the venous set is as clear as desired.
7. Stop the blood pump and clamp the venous set and the venous access. Separate the venous set from the venous access.
8. Discard dialyzer and all other disposable equipment in accordance with appropriate biohazardous material disposal practices.
9. Provide appropriate care to the patient's vascular access as prescribed by the physician.

WARRANTY CLAUSE

Nipro warrants that Cellentia-H is designed and manufactured in accordance with the written specification for Cellentia-H applicable to the specific model purchased by the user and in compliance with current applicable industry standards, and regulatory requirements.

The warranty above is in lieu of and to the exclusion of any other warranty, whether written or oral, express or implied, statutory or otherwise, and there are no warranties of merchantability, or fitness or other warranties, which extend beyond those described above.

Nipro's sole liability to the purchaser for breach of warranty, and purchaser's sole remedy, shall be to replace Cellentia-H for which a valid claim is presented. Nipro shall not be liable for any consequential or incidental loss, damage, injury, or expense directly or indirectly arising or resulting from the breach of any warranty herein.

Nipro shall not be liable for any damage, loss or injury caused by the reuse of Cellentia-H misuse, improper, handling, noncompliance with warnings and instructions, damage caused by events occurring after the product is released, failure to ensure that the product is in proper condition before use, or any warranty given by independent distributors.

THERE ARE NO ADDITIONAL WARRANTIES, EITHER EXPRESSED ORIMPLIED, ARISING OUT OF THE SALE OF THIS PRODUCT OTHER THAN THOSE CONTAINED HEREIN.

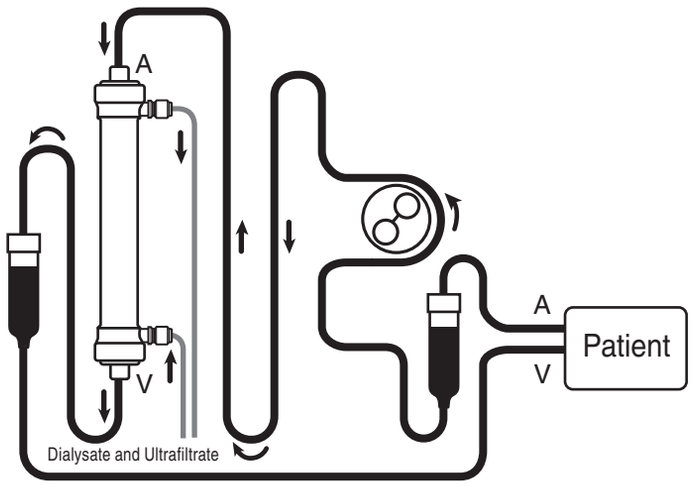

Figure 1 - Extracorporeal Circuit for Hemodialysis Treatment

STERILE R

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