

Instructions for Use

Indications: Hemodialysis or Hemodiafiltration with ELISIO-H (or -K) is indicated for patients having acute or chronic renal failure when dialysis is prescribed by the physician. Hemodialysis with ELISIO-M and -L is indicated for patients having acute or chronic renal failure when dialysis is prescribed by the physician.

Contraindications: Do not re-use. Patients indicating allergic reactions to polyethersulfone membranes should not be dialyzed with this product.

Clinical Benefits: Dialysis treatment can be performed by connecting the device to a dialysis machine, a blood line, and an AVF needle, and waste and unnecessary water is removed from the blood to support the life of renal failure patients.

Warning

- Use this product according to instructions of a physician who is well familiar with the patient's condition.
- Follow these instructions and those of the dialysis machine supplier.
- Do not use for any other purposes than dialysis.
- If any abnormalities such as foam generation or mixture, blood leakage, blood coagulation and hemolysis occurred during the use of this product, take appropriate measures according to a physician's instructions.
- In case drugs including an anticoagulant are administered before or during use of this product, follow a physician's instructions about the administration and dose and the administration time of the drugs.
- Do not re-use this product since this is a single-use product.
- The foreseeable risks in association with re-use of the product are:
 - Infection by contamination,
 - Deterioration of solute removal performance and ultrafiltration performance,
 - Exposure of patients and/or technicians to residual medicinal agents such as disinfectant used for product re-use, and/or adverse effects of residual medicinal agents on them, and
 - Damage of hollow fiber and/or leakage.
- Do not expose this product to chemical solvents, such as bleach and alcohols. Residual disinfectant in this product may cause adverse patient reactions.
- If the patient exhibits any abnormal symptoms such as discomfort, pruritus, urticaria, peripheral and facial edema, respiratory arrest, facial flush, erythema, asthmatic reaction, hypertension, hypotension and/or cardiac arrhythmia during the use of this product, take appropriate measures according to a physician's instructions.
- Commonly seen side effects (hypotension, hypertension, headache and nausea which are sometimes with hypovolemia or hypervolemia) can be minimized by careful management of the patient fluid and electrolyte balance, as well as the dialysis condition (blood flow rate and ultrafiltration rate).
- During dialysis, constantly monitor the patients who ;
 - have a history of hypotension with therapy,
 - have inflammatory reaction, allergic reaction, hypersensitivity, or increase in the immunity by infections,
 - take hypotensive drugs such as inhibitor of angiotensin converting enzyme and calcium antagonist,
 - use this product for the first time.
- To avoid abnormal symptoms and syndromes during therapy, the blood flow, dialysate flow, filtration flow, substitute flow, and de-watering rate should be set according to the patient's condition and attending physician's instructions.

Caution: Caution should be employed against excessive water removal. Use of accurate UF control system is required. Do not use on non-de-aerated dialysis fluid delivery systems. Confirm that the dialysate does not contain pyrogens in order to prevent transfer of pyrogens from dialysate to blood.

Any incidents shall be reported to the manufacturer and the competent authority of your State.

Caution before use

- Do not use if package is damaged.
- Do not use the device if the protective end caps are not in place.
- Unpack immediately before use.
- Avoid air mix-in and contamination during rinsing / priming operations.
- Start dialysis immediately after rinsing / priming operations.
- Rinsing / priming should be carried out under the following conditions according to this "Instructions for Use":
 - Blood side : Rinsing and priming with physiological saline at a flow rate of 200 mL/min (not less than 500 mL).
 - Dialysate side : Verify conductivity and temperature, and rinse with dialysate at a flow rate of 500 mL/min for about 3 minutes.
- Check the integrity of the blood line and dialyzer.
- Administration of Heparin
 - Systemic or regionalized heparinization may need to be administered based on instructions from the attending physician.

Caution in use

- Continuously monitor the pressure in the blood line and check for blood leakage during dialysis.
- Carefully avoid contamination during blood sampling and blood reinfusion.
- Set TMP alarm (max. 500 mmHg).
- Avoid air during blood reinfusion to minimize the risk of air embolisms.
- Do not apply excessive pressure to the blood line, the dialyzer and their connections.

Caution after use

- Single use only. Dispose of the dialyzer immediately after use.
- Dispose of the used blood lines and dialyzer by any means suitable for avoiding contamination.
- Dispose of the device in an approved biohazard container as per facility protocol.

Caution for storage

- If the device is exposed to abnormal conditions (for example, high temperature and humidity) or if it is unintentionally opened before use, do not use the device.
- Handle carefully in low temperature environments.

Instructions for Use

I. Rinsing / priming

Follow instructions on the machine's operator manual.

«In case of priming with a physiological saline bag»

- Take the dialyzer out of the package and set it to the holder so that the venous side is directed upward. (Fig. 1)
- Connect the arterial and venous dialyzer connector to dialyzer. Connect the arterial patient line to physiological saline bag (Fig. 2). Start arterial blood pump at a flow rate of 200 mL/min (not less than 500 mL) (Fig. 3).
- Stop the blood pump; rotate the dialyzer for 180 degree. Put the dialysate connectors to the dialyzer (dialysate inlet at the venous blood side, dialysate outlet at the arterial blood side) (Fig. 4). Make sure of degassing the dialysate part of the dialyzer. Start running through dialysate at a flow rate of about 500 mL/min.
- Restart the blood pump. Make sure that the blood compartment is free of air-bubbles and filled with physiological saline. The preparations for dialysis is complete (Fig. 5).

«In case of online priming»

Follow instructions on the machine's operator manual.

[Leakage test] In case of physiological saline priming

It is recommended to perform the following operations before connecting the dialysate lines to the dialyzer.

- Fully prime the arterial and venous lines and the dialyzer with physiological saline by operating the blood pump ; then stop the pump operation.
- Clamp the arterial line near the dialyzer and the distal end of the venous line with clamps.
- Place the clamped distal end about 1 m below the dialyzer and remove the clamps. (This results in application of a negative pressure of approximately 70 mmHg to the blood compartment of the dialyzer.)
- Examine whether or not continuous bubble formation is observed in the venous header to check for leakage from the dialyzer, if observed, replace the dialyzer with a new one.

II. Start of dialysis

Follow instructions on the machine's operator manual.

- Prepare the blood access site and connect to the arterial line. Remove the clamps from the arterial and venous lines. While running dialysate at a flow rate of approximately 500 mL/min, operate the blood pump at a flow rate of approximately 50 mL/min.
- Confirm that no air bubbles remain in venous header or venous blood line.
- Fully prime the arterial and venous lines including the dialyzer with blood by operating the blood pump, and then stop the pump operation. Clamp the distal end of the venous line with clamps.
- Prepare the blood return site and connect to the venous line. After confirming that there are no bubbles in the line, remove the clamps from the line. After checking that there are no clamps on the lines and no line folding, operate the blood pump at a low flow rate. Check the integrity of the connections.
- After confirming that there are no bubbles in the arterial and venous headers, turn the dialyzer 180° to allow removal of bubbles from dialysate. If bubbles are detected in the venous header before the turning, run blood at a prescribed flow rate for 5 to 10 minutes with the venous side kept upward.

III. Operations during dialysis

- If stopping the blood pump is required during dialysis due to insufficient blood flow, lower the dialysate pressure to approximately 0 mmHg. (This is to avoid blood coagulation due to dehydration.)
- Set the UF rate carefully to avoid excessive water removal according to the patients' needs. Reduce the blood flow rate if disequilibrium syndrome is suspected.
- If blood leakage is suspected, judge by testing dialysate sampled from the dialysate outlet port of the dialyzer using occult blood reaction test paper. If a leakage is detected, reduce the UF rate to minimum rate according to the institutional protocol, stop the dialysate supply and blood reinfusion, then replace the dialyzer with a new one.

IV. Dialysis termination and blood reinfusion

- Stop the blood pump, clamp the arterial line and remove the line from the arterial blood access site ; then connect the line to the physiological saline vial for blood reinfusion.
- Unclamp the arterial line and run physiological saline to rinse out the blood from the arterial and venous lines and the dialyzer.
- After the blood reinfusion, discard the arterial and venous lines and the dialyzer. Do not reuse them.

Performance and Specification

The performance of the hemodialyzer varies with types.

Refer to respective catalogues and performance data sheets.

Connection with other devices

The device contacts and is connected with the blood line at the header and the dialysis machine through the coupler port of the housing.

Guarantee

- Non-pyrogenic, sterile fluid path that has been sterilized using irradiation.
- This dialyzer is manufactured under strict quality control and the quality is assured. If the dialyzer is defective (broken package, damaged dialyzer), it shall be replaced with a new one at our cost upon return of the broken package or damaged dialyzer. We will not be responsible, however, for the injury of a patient or any person or the damage to any object that is attributed to transport, storage and operation in your institution.
- If a patient or any person is injured or any object is damaged by use of our dialyzer, we will not be responsible for the injury or damage unless we are clearly identified as being at fault.
- If a patient or any person is injured or any object is damaged by reuse of our dialyzer, we will not be responsible for the injury or damage of any nature.
- We will not be responsible for any injury or damage caused by use of our dialyzer after the expiry date mentioned on the label or packaging.

This device must be used on dialysis machines with an ultrafiltration controller or an accurate balancing system.¹

UF Control

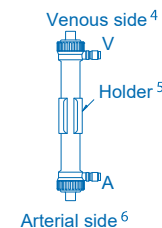
Not made with DEHP

Not made with BPA

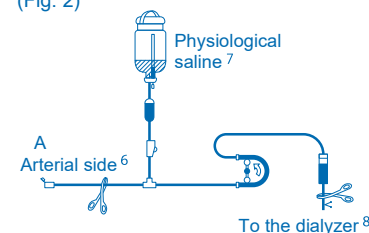
NON-Bis(2-ethylhexyl) phthalate²

NON-Bisphenol-A³

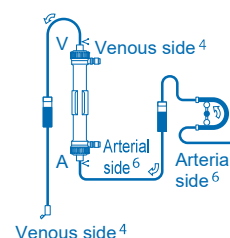
(Fig. 1)



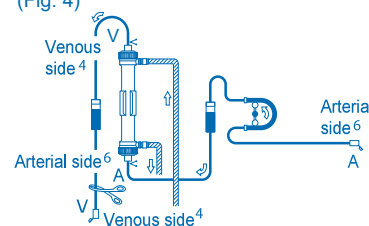
(Fig. 2)



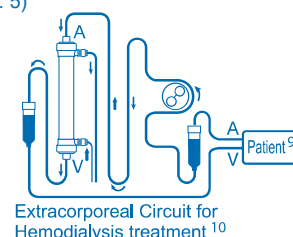
(Fig. 3)



(Fig. 4)



(Fig. 5)



Extracorporeal Circuit for Hemodialysis treatment¹⁰

PERFORMANCE DATA¹

DE DEUTSCH	FR FRANÇAIS	ES ESPAÑOL	IT ITALIANO	NL NEDERLANDS
1 Clearwater ²	CONNETTE DE PERFORMANCE	CONNETTE DE PERFORMANCE	CONNETTE DE PERFORMANCE	CONNETTE DE PERFORMANCE
2 Clearwater ²	CONNETTE DE PERFORMANCE	CONNETTE DE PERFORMANCE	CONNETTE DE PERFORMANCE	CONNETTE DE PERFORMANCE
3 Clearwater ²	CONNETTE DE PERFORMANCE	CONNETTE DE PERFORMANCE	CONNETTE DE PERFORMANCE	CONNETTE DE PERFORMANCE
4 Clearwater ²	CONNETTE DE PERFORMANCE	CONNETTE DE PERFORMANCE	CONNETTE DE PERFORMANCE	CONNETTE DE PERFORMANCE
5 Clearwater ²	CONNETTE DE PERFORMANCE	CONNETTE DE PERFORMANCE	CONNETTE DE PERFORMANCE	CONNETTE DE PERFORMANCE
6 Clearwater ²	CONNETTE DE PERFORMANCE	CONNETTE DE PERFORMANCE	CONNETTE DE PERFORMANCE	CONNETTE DE PERFORMANCE
7 Clearwater ²	CONNETTE DE PERFORMANCE	CONNETTE DE PERFORMANCE	CONNETTE DE PERFORMANCE	CONNETTE DE PERFORMANCE
8 Clearwater ²	CONNETTE DE PERFORMANCE	CONNETTE DE PERFORMANCE	CONNETTE DE PERFORMANCE	CONNETTE DE PERFORMANCE
9 Clearwater ²	CONNETTE DE PERFORMANCE	CONNETTE DE PERFORMANCE	CONNETTE DE PERFORMANCE	CONNETTE DE PERFORMANCE
10 Clearwater ²	CONNETTE DE PERFORMANCE	CONNETTE DE PERFORMANCE	CONNETTE DE PERFORMANCE	CONNETTE DE PERFORMANCE
11 Clearwater ²	CONNETTE DE PERFORMANCE	CONNETTE DE PERFORMANCE	CONNETTE DE PERFORMANCE	CONNETTE DE PERFORMANCE
12 Clearwater ²	CONNETTE DE PERFORMANCE	CONNETTE DE PERFORMANCE	CONNETTE DE PERFORMANCE	CONNETTE DE PERFORMANCE
13 Clearwater ²	CONNETTE DE PERFORMANCE	CONNETTE DE PERFORMANCE	CONNETTE DE PERFORMANCE	CONNETTE DE PERFORMANCE
14 Clearwater ²	CONNETTE DE PERFORMANCE	CONNETTE DE PERFORMANCE	CONNETTE DE PERFORMANCE	CONNETTE DE PERFORMANCE
15 Clearwater ²	CONNETTE DE PERFORMANCE	CONNETTE DE PERFORMANCE	CONNETTE DE PERFORMANCE	CONNETTE DE PERFORMANCE
16 Clearwater ²	CONNETTE DE PERFORMANCE	CONNETTE DE PERFORMANCE	CONNETTE DE PERFORMANCE	CONNETTE DE PERFORMANCE
17 Clearwater ²	CONNETTE DE PERFORMANCE	CONNETTE DE PERFORMANCE	CONNETTE DE PERFORMANCE	CONNETTE DE PERFORMANCE
18 Clearwater ²	CONNETTE DE PERFORMANCE	CONNETTE DE PERFORMANCE	CONNETTE DE PERFORMANCE	CONNETTE DE PERFORMANCE
19 Clearwater ²	CONNETTE DE PERFORMANCE	CONNETTE DE PERFORMANCE	CONNETTE DE PERFORMANCE	CONNETTE DE PERFORMANCE
20 Clearwater ²	CONNETTE DE PERFORMANCE	CONNETTE DE PERFORMANCE	CONNETTE DE PERFORMANCE	CONNETTE DE PERFORMANCE
21 Clearwater ²	CONNETTE DE PERFORMANCE	CONNETTE DE PERFORMANCE	CONNETTE DE PERFORMANCE	CONNETTE DE PERFORMANCE
22 Clearwater ²	CONNETTE DE PERFORMANCE	CONNETTE DE PERFORMANCE	CONNETTE DE PERFORMANCE	CONNETTE DE PERFORMANCE
23 Clearwater ²	CONNETTE DE PERFORMANCE	CONNETTE DE PERFORMANCE	CONNETTE DE PERFORMANCE	CONNETTE DE PERFORMANCE
24 Clearwater ²	CONNETTE DE PERFORMANCE	CONNETTE DE PERFORMANCE	CONNETTE DE PERFORMANCE	CONNETTE DE PERFORMANCE
25 Clearwater ²	CONNETTE DE PERFORMANCE	CONNETTE DE PERFORMANCE	CONNETTE DE PERFORMANCE	CONNETTE DE PERFORMANCE
26 Clearwater ²	CONNETTE DE PERFORMANCE	CONNETTE DE PERFORMANCE	CONNETTE DE PERFORMANCE	CONNETTE DE PERFORMANCE
27 Clearwater ²	CONNETTE DE PERFORMANCE	CONNETTE DE PERFORMANCE	CONNETTE DE PERFORMANCE	CONNETTE DE PERFORMANCE
28 Clearwater ²	CONNETTE DE PERFORMANCE	CONNETTE DE PERFORMANCE	CONNETTE DE PERFORMANCE	CONNETTE DE PERFORMANCE
29 Clearwater ²	CONNETTE DE PERFORMANCE	CONNETTE DE PERFORMANCE	CONNETTE DE PERFORMANCE	CONNETTE DE PERFORMANCE
30 Clearwater ²	CONNETTE DE PERFORMANCE	CONNETTE DE PERFORMANCE	CONNETTE DE PERFORMANCE	CONNETTE DE PERFORMANCE
31 Clearwater ²	CONNETTE DE PERFORMANCE	CONNETTE DE PERFORMANCE	CONNETTE DE PERFORMANCE	CONNETTE DE PERFORMANCE
32 Clearwater ²	CONNETTE DE PERFORMANCE	CONNETTE DE PERFORMANCE	CONNETTE DE PERFORMANCE	CONNETTE DE PERFORMANCE
33 Clearwater ²	CONNETTE DE PERFORMANCE	CONNETTE DE PERFORMANCE	CONNETTE DE PERFORMANCE	CONNETTE DE PERFORMANCE
34 Clearwater ²	CONNETTE DE PERFORMANCE	CONNETTE DE PERFORMANCE	CONNETTE DE PERFORMANCE	CONNETTE DE PERFORMANCE
35 Clearwater ²	CONNETTE DE PERFORMANCE	CONNETTE DE PERFORMANCE	CONNETTE DE PERFORMANCE	CONNETTE DE PERFORMANCE
36 Clearwater ²	CONNETTE DE PERFORMANCE	CONNETTE DE PERFORMANCE	CONNETTE DE PERFORMANCE	CONNETTE DE PERFORMANCE
37 Clearwater ²	CONNETTE DE PERFORMANCE	CONNETTE DE PERFORMANCE	CONNETTE DE PERFORMANCE	CONNETTE DE PERFORMANCE
38 Clearwater ²	CONNETTE DE PERFORMANCE	CONNETTE DE PERFORMANCE	CONNETTE DE PERFORMANCE	CONNETTE DE PERFORMANCE
39 Clearwater ²	CONNETTE DE PERFORMANCE	CONNETTE DE PERFORMANCE	CONNETTE DE PERFORMANCE	CONNETTE DE PERFORMANCE
40 Clearwater ²	CONNETTE DE PERFORMANCE	CONNETTE DE PERFORMANCE	CONNETTE DE PERFORMANCE	CONNETTE DE PERFORMANCE
41 Clearwater ²	CONNETTE DE PERFORMANCE	CONNETTE DE PERFORMANCE	CONNETTE DE PERFORMANCE	CONNETTE DE PERFORMANCE
42 Clearwater ²	CONNETTE DE PERFORMANCE	CONNETTE DE PERFORMANCE	CONNETTE DE PERFORMANCE	CONNETTE DE PERFORMANCE
43 Clearwater ²	CONNETTE DE PERFORMANCE	CONNETTE DE PERFORMANCE	CONNETTE DE PERFORMANCE	CONNETTE DE PERFORMANCE
44 Clearwater ²	CONNETTE DE PERFORMANCE	CONNETTE DE PERFORMANCE	CONNETTE DE PERFORMANCE	CONNETTE DE PERFORMANCE
45 Clearwater ²	CONNETTE DE PERFORMANCE	CONNETTE DE PERFORMANCE	CONNETTE DE PERFORMANCE	CONNETTE DE PERFORMANCE
46 Clearwater ²	CONNETTE DE PERFORMANCE	CONNETTE DE PERFORMANCE	CONNETTE DE PERFORMANCE	CONNETTE DE PERFORMANCE
47 Clearwater ²	CONNETTE DE PERFORMANCE	CONNETTE DE PERFORMANCE	CONNETTE DE PERFORMANCE	CONNETTE DE PERFORMANCE
48 Clearwater ²	CONNETTE DE PERFORMANCE	CONNETTE DE PERFORMANCE	CONNETTE DE PERFORMANCE	CONNETTE DE PERFORMANCE
49 Clearwater ²	CONNETTE DE PERFORMANCE	CONNETTE DE PERFORMANCE	CONNETTE DE PERFORMANCE	CONNETTE DE PERFORMANCE
50 Clearwater ²	CONNETTE DE PERFORMANCE	CONNETTE DE PERFORMANCE	CONNETTE DE PERFORMANCE	CONNETTE DE PERFORMANCE
51 Clearwater ²	CONNETTE DE PERFORMANCE	CONNETTE DE PERFORMANCE	CONNETTE DE PERFORMANCE	CONNETTE DE PERFORMANCE
52 Clearwater ²	CONNETTE DE PERFORMANCE	CONNETTE DE PERFORMANCE	CONNETTE DE PERFORMANCE	CONNETTE DE PERFORMANCE
53 Clearwater ²	CONNETTE DE PERFORMANCE	CONNETTE DE PERFORMANCE	CONNETTE DE PERFORMANCE	CONNETTE DE PERFORMANCE
54 Clearwater ²	CONNETTE DE PERFORMANCE	CONNETTE DE PERFORMANCE	CONNETTE DE PERFORMANCE	CONNETTE DE PERFORMANCE
55 Clearwater ²	CONNETTE DE PERFORMANCE	CONNETTE DE PERFORMANCE	CONNETTE DE PERFORMANCE	CONNETTE DE PERFORMANCE
56 Clearwater ²	CONNETTE DE PERFORMANCE	CONNETTE DE PERFORMANCE	CONNETTE DE PERFORMANCE	CONNETTE DE PERFORMANCE
57 Clearwater ²	CONNETTE DE PERFORMANCE	CONNETTE DE PERFORMANCE	CONNETTE DE PERFORMANCE	CONNETTE DE PERFORMANCE
58 Clearwater ²	CONNETTE DE PERFORMANCE	CONNETTE DE PERFORMANCE	CONNETTE DE PERFORMANCE	CONNETTE DE PERFORMANCE
59 Clearwater ²	CONNETTE DE PERFORMANCE	CONNETTE DE PERFORMANCE	CONNETTE DE PERFORMANCE	CONNETTE DE PERFORMANCE
60 Clearwater ²	CONNETTE DE PERFORMANCE	CONNETTE DE PERFORMANCE	CONNETTE DE PERFORMANCE	CONNETTE DE PERFORMANCE
61 Clearwater ²	CONNETTE DE PERFORMANCE	CONNETTE DE PERFORMANCE	CONNETTE DE PERFORMANCE	CONNETTE DE PERFORMANCE
62 Clearwater ²	CONNETTE DE PERFORMANCE	CONNETTE DE PERFORMANCE	CONNETTE DE PERFORMANCE	CONNETTE DE PERFORMANCE
63 Clearwater ²	CONNETTE DE PERFORMANCE	CONNETTE DE PERFORMANCE	CONNETTE DE PERFORMANCE	CONNETTE DE PERFORMANCE
64 Clearwater ²	CONNETTE DE PERFORMANCE	CONNETTE DE PERFORMANCE	CONNETTE DE PERFORMANCE	CONNETTE DE PERFORMANCE
65 Clearwater ²	CONNETTE DE PERFORMANCE	CONNETTE DE PERFORMANCE	CONNETTE DE PERFORMANCE	CONNETTE DE PERFORMANCE
66 Clearwater ²	CONNETTE DE PERFORMANCE	CONNETTE DE PERFORMANCE	CONNETTE DE PERFORMANCE	CONNETTE DE PERFORMANCE
67 Clearwater ²	CONNETTE DE PERFORMANCE	CONNETTE DE PERFORMANCE	CONNETTE DE PERFORMANCE	CONNETTE DE PERFORMANCE
68 Clearwater ²	CONNETTE DE PERFORMANCE	CONNETTE DE PERFORMANCE	CONNETTE DE PERFORMANCE	CONNETTE DE PERFORMANCE
69 Clearwater ²	CONNETTE DE PERFORMANCE	CONNETTE DE PERFORMANCE	CONNETTE DE PERFORMANCE	CONNETTE DE PERFORMANCE
70 Clearwater ²	CONNETTE DE PERFORMANCE	CONNETTE DE PERFORMANCE	CONNETTE DE PERFORMANCE	CONNETTE DE PERFORMANCE
71 Clearwater ²	CONNETTE DE PERFORMANCE	CONNETTE DE PERFORMANCE	CONNETTE DE PERFORMANCE	CONNETTE DE PERFORMANCE
72 Clearwater ²	CONNETTE DE PERFORMANCE	CONNETTE DE PERFORMANCE	CONNETTE DE PERFORMANCE	CONNETTE DE PERFORMANCE
73 Clearwater ²	CONNETTE DE PERFORMANCE	CONNETTE DE PERFORMANCE	CONNETTE DE PERFORMANCE	CONNETTE DE PERFORMANCE
74 Clearwater ²	CONNETTE DE PERFORMANCE	CONNETTE DE PERFORMANCE	CONNETTE DE PERFORMANCE	CONNETTE DE PERFORMANCE
75 Clearwater ²	CONNETTE DE PERFORMANCE	CONNETTE DE PERFORMANCE	CONNETTE DE PERFORMANCE	CONNETTE DE PERFORMANCE
76 Clearwater ²	CONNETTE DE PERFORMANCE	CONNETTE DE PERFORMANCE	CONNETTE DE PERFORMANCE	CONNETTE DE PERFORMANCE
77 Clearwater ²	CONNETTE DE PERFORMANCE	CONNETTE DE PERFORMANCE	CONNETTE DE PERFORMANCE	CONNETTE DE PERFORMANCE
78 Clearwater ²	CONNETTE DE PERFORMANCE	CONNETTE DE PERFORMANCE	CONNETTE DE PERFORMANCE	CONNETTE DE PERFORMANCE
79 Clearwater ²	CONNETTE DE PERFORMANCE	CONNETTE DE PERFORMANCE	CONNETTE DE PERFORMANCE	CONNETTE DE PERFORMANCE
80 Clearwater ²	CONNETTE DE PERFORMANCE	CONNETTE DE PERFORMANCE	CONNETTE DE PERFORMANCE	CONNETTE DE PERFORMANCE
81 Clearwater ²	CONNETTE DE PERFORMANCE	CONNETTE DE PERFORMANCE	CONNETTE DE PERFORMANCE	CONNETTE DE PERFORMANCE
82 Clearwater ²	CONNETTE DE PERFORMANCE	CONNETTE DE PERFORMANCE	CONNETTE DE PERFORMANCE	CONNETTE DE PERFORMANCE
83 Clearwater ²	CONNETTE DE PERFORMANCE	CONNETTE DE PERFORMANCE	CONNETTE DE PERFORMANCE	CONNETTE DE PERFORMANCE
84 Clearwater ²	CONNETTE DE PERFORMANCE	CONNETTE DE PERFORMANCE	CONNETTE DE PERFORMANCE	CONNETTE DE PERFORMANCE
85 Clearwater ²	CONNETTE DE PERFORMANCE	CONNETTE DE PERFORMANCE	CONNETTE DE PERFORMANCE	CONNETTE DE PERFORMANCE
86 Clearwater ²	CONNETTE DE PERFORMANCE	CONNETTE DE PERFORMANCE	CONNETTE DE PERFORMANCE	CONNETTE DE PERFORMANCE
87 Clearwater ²	CONNETTE DE PERFORMANCE	CONNETTE DE PERFORMANCE	CONNETTE DE PERFORMANCE	CONNETTE DE PERFORMANCE
88 Clearwater ²	CONNETTE DE PERFORMANCE	CONNETTE DE PERFORMANCE	CONNETTE DE PERFORMANCE	CONNETTE DE PERFORMANCE
89 Clearwater ²	CONNETTE DE PERFORMANCE	CONNETTE DE PERFORMANCE	CONNETTE DE PERFORMANCE	CONNETTE DE PERFORMANCE
90 Clearwater ²	CONNETTE DE PERFORMANCE	CONNETTE DE PERFORMANCE	CONNETTE DE PERFORMANCE	CONNETTE DE PERFORMANCE
91 Clearwater ²	CONNETTE DE PERFORMANCE	CONNETTE DE PERFORMANCE	CONNETTE DE PERFORMANCE	CONNETTE DE PERFORMANCE
92 Clearwater ²	CONNETTE DE PERFORMANCE	CONNETTE DE PERFORMANCE	CONNETTE DE PERFORMANCE	CONNETTE DE PERFORMANCE
93 Clearwater ²	CONNETTE DE PERFORMANCE	CONNETTE DE PERFORMANCE	CONNETTE DE PERFORMANCE	CONNETTE DE PERFORMANCE
94 Clearwater ²	CONNETTE DE PERFORMANCE	CONNETTE DE PERFORMANCE	CONNETTE DE PERFORMANCE	CONNETTE DE PERFORMANCE
95 Clearwater ²	CONNETTE DE PERFORMANCE	CONNETTE DE PERFORMANCE	CONNETTE DE PERFORMANCE	CONNETTE DE PERFORMANCE
96 Clearwater ²	CONNETTE DE PERFORMANCE	CONNETTE DE PERFORMANCE	CONNETTE DE PERFORMANCE	CONNETTE DE PERFORMANCE
97 Clearwater ²	CONNETTE DE PERFORMANCE	CONNETTE DE PERFORMANCE	CONNETTE DE PERFORMANCE	CONNETTE DE PERFORMANCE
98 Clearwater ²	CONNETTE DE PERFORMANCE	CONNETTE DE PERFORMANCE	CONNETTE DE PERFORMANCE	CONNETTE DE PERFORMANCE
99 Clearwater ²	CONNETTE DE PERFORMANCE	CONNETTE DE PERFORMANCE	CONNETTE DE PERFORMANCE	CONNETTE DE PERFORMANCE
100 Clearwater ²	CONNETTE DE PERFORMANCE	CONNETTE DE PERFORMANCE	CONNETTE DE PERFORMANCE	CONNETTE DE PERFORMANCE

EN	Clearance ² (mL/min)	Qf (mL/min)	13H	15H	17H	19H	21H	Qb/Qd (mL/min)	13M	15M	17M	19M	21M	13L	15L	17L	19L	21L
Urea ³	Qf 0	Qf 0	263	270	275	280	284	200/500	194	195	196	197	198	192	194	195	196	197
	Qf 10	Qf 10	272	278	285	288	291	300/500	257	264	272	275	281	251	261	267	273	277
	Qf 75	Qf 75	286	294	298	300	300	400/500	299	309	319	325	335	290	301	314	322	332
Creatinine ⁴	Qf 0	Qf 0	240	252	259	268	269	200/500	186	189	194	195	197	182	187	191	194	195
	Qf 10	Qf 10	250	259	268	273	275	300/500	237	243	252	257	263	227	236	246	252	260
	Qf 75	Qf 75	269	279	287	290	294	400/500	287	277	290	302	308	252	265	280	289	302
Phosphate ⁵	Qf 0	Qf 0	224	233	245	251	256	200/500	163	170	177	181	185	153	161	167	171	176
	Qf 10	Qf 10	230	241	254	258	265	300/500	198	210	223	232	239	182	194	205	214	221
	Qf 75	Qf 75	253	262	271	277	281	400/500	219	231	247	256	269	204	216	230	244	254
Vitamin B12 ⁶	Qf 0	Qf 0	161	173	185	195	198	200/500	108	118	128	130	138	92	101	109	115	121
	Qf 10	Qf 10	165	180	190	200	206	300/500	121	134	144	148	160	107	117	124	135	143
	Qf 75	Qf 75	196	213	225	234	243	400/500	125	141	151	162	171	110	124	135	143	154
Inulin ⁷	Qf 0	Qf 0	97	109	117	127	138	200/500	—	—	—	—	—	—	—	—	—	—
	Qf 10	Qf 10	102	112	121	132	145	300/500	—	—	—	—	—	—	—	—	—	—
	Qf 75	Qf 75	131	141	152	159	173	400/500	—	—	—	—	—	—	—	—	—	—
Myoglobin ⁸	Qf 0	Qf 0	78	89	96	101	103	200/500	—	—	—	—	—	—	—	—	—	—
	Qf 10	Qf 10	80	90	98	107	111	300/500	—	—	—	—	—	—	—	—	—	—
	Qf 75	Qf 75	—	—	—	—	—	400/500	—	—	—	—	—	—	—	—	—	—
KUF (mL/hr/mmHg)			64	67	74	76	82		18	20	22	24	28	14	16	18	20	22
KoA Urea (mL/min)			1010	1145	1265	1415	1569		812	916	1045	1103	1239	801	888	1010	1083	1239

Specifications ⁹	ELISIO [®] -H
Effective Surface Area ¹⁰ (m ²)	1,3 1,5 1,7 1,9 2,1
Priming Volume ¹¹ (mL)	85 96 107 117 129
Effective Length ¹² (mm)	245 259 271 281 290
Inner Diameter ¹³ (µm)	200 200 200 200 200
Membrane Thickness ¹⁴ (µm)	40 40 40 40 40
Maximum TMP ¹⁵ (mmHg)	500 500 500 500 500
Pressure Qb/Qd (mL/min)	200/500 200/500 200/500 200/500 200/500
Drops ¹⁶ Blood ¹⁷ /Dialysate ¹⁸ (mmHg)	54/32 52/29 51/31 51/28 49/26

In-Vitro Test Conditions ¹⁹ (EN ISO 8637-1)
Clearance : Qb 300mL/min, Qd 500mL/min
KUF : Bovine Blood ²⁰ (Hct 32±2%, Protein ²¹ 60g/L, 37°C), Qb 300mL/min
KoA : Qb 300mL/min, Qd 500mL/min, Qf 0mL/min
Sieving Coefficient ^{22*}
Vitamin B12 0.989 Membrane ²⁴ POLYNEPHRON [™]
Inulin 0.94 Polyethersulfone ²⁸
β2-microglobulin 1.00 Housing ²⁵ Polypropylene ²⁹
Myoglobin 0.61 Potting compound ²⁶ Polyurethane ³⁰
Albumin ²³ 0.0017 Sterilization ²⁷ Gamma Ray ³¹

* Typical values measured with ELISIO-15H, with bovine plasma, protein 60g/L, at 37°C

Recommended connectors for blood ports Acc.to EN ISO 8637-1
Recommended connectors for dialysate ports Acc.to EN ISO 8637-1

Note: Operation of the dialyzer under clinical conditions may produce values different from those illustrated because of the variables involved in the clinical dialysis procedure, in the POLYNEPHRON Polyethersulfone membrane, and in the manufacture of the device. Therefore, the values given are for approximate only. See in-vitro test conditions for explanatory materials relating to the test conditions from which the data were derived. Further information may be obtained on request.

ELISIO [®] -M	ELISIO [®] -L
13M 15M 17M 19M 21M	13L 15L 17L 19L 21L
1,3 1,5 1,7 1,9 2,1	1,3 1,5 1,7 1,9 2,1
82 93 108 116 131	81 91 104 114 127
245 259 271 281 290	245 259 271 281 290
200 200 200 200 200	200 200 200 200 200
40 40 40 40 40	40 40 40 40 40
500 500 500 500 500	500 500 500 500 500
200/500 200/500 200/500 200/500 200/500	200/500 200/500 200/500 200/500 200/500
56/27 54/25 53/27 52/24 50/22	56/26 53/24 50/30 49/29 47/22

In-Vitro Test Conditions ¹⁹ (EN ISO 8637-1)	In-Vitro Test Conditions ¹⁹ (EN ISO 8637-1)
Clearance : Qd 500mL/min, Qf 10mL/min	Clearance : Qd 500mL/min, Qf 10mL/min
KUF : Bovine Blood ²⁰ (Hct 32±2%, Protein ²¹ 60g/L, 37°C), Qb 300mL/min	KUF : Bovine Blood ²⁰ (Hct 32±2%, Protein ²¹ 60g/L, 37°C), Qb 300mL/min
KoA : Qb 300mL/min, Qd 500mL/min, Qf 0mL/min	KoA : Qb 300mL/min, Qd 500mL/min, Qf 0mL/min
Membrane ²⁴ POLYNEPHRON [™]	Membrane ²⁴ POLYNEPHRON [™]
Polyethersulfone ²⁸	Polyethersulfone ²⁸
Polypropylene ²⁹	Polypropylene ²⁹
Polyurethane ³⁰	Polyurethane ³⁰
Gamma Ray ³¹	Gamma Ray ³¹

NIPRO CORPORATION
3-26, Senriokashimachi, Settsu, Osaka, 566-8510, Japan

CE REP
NIPRO MEDICAL EUROPE
Bokhuisstraat 42, 2800 Mechelen, BELGIUM

CE 0123
CN4-CE-ELHMLMDR-01

CH REP
Theramid AG Therapie- und Medizintechnik
Sagihof 7, 6043 Adligenswil, Switzerland

[Manufacturing facility]
NIPRO MEDICAL (HEFEI) CO., LTD.
No.350, Yungu Road, Economic & Technology Development Zone, Hefei City, Anhui Province, 230601, P.R.China

[Sponsor in Australia]
NIPRO AUSTRALIA PTY LTD
Suite 2.02, Level 2, 657 Pacific Highway, St Leonards, NSW 2065, AUSTRALIA