

EN SYNTHETIC HEMODIALYZER

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.

<u>Clinical Benefits:</u> 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 absormal symptom
- If the patient exhibits any abnormal symptoms such as discomfort, pruritus, urticaria, peripheral and facial edema, respiratory arrest, facial flush, erythema, asthmatic reaction, hypotension, 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:
- (1)have a history of hypotension with therapy, (2)have inflammatory reaction, allergic reaction, hypersensitivity, or increase in the immunity by infections,
- (3)take hypotensive drugs such as inhibitor of angiotensin converting enzyme and calcium antagonist,
- (4) 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 physicial'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
- Administration of Repairin Systemic or regionalized heparinization may need to be administered based on instructions from the attending physician.

Caution in us

- 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»

- (1) Take the dialyzer out of the package and set it to the holder so that the venous side is directed upward. (Fig. 1)
- (2)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).
- (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.
- (4)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

- (1)Fully prime the arterial and venous lines and the dialyzer with physiological saline by operating the blood pump; then stop the pump operation.
- (2)Clamp the arterial line near the dialyzer and the distal end of the venous line with clamps.
- (3)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.)
- (4)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.
- (1)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.
- (2)Confirm that no air bubbles remain in venous header or venous blood line.
- (3)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.
- (4)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.
- (5)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

- (1)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.)
- (2)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.
- (3)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
- (1)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.
- (2) Unclamp the arterial line and run physiological saline to rinse out the blood from the arterial and venous lines and the dialyzer.
- (3)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.



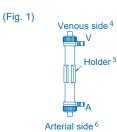
This device must be used on dialysis machines with an ultrafiltration controller or an accurate balancing system.¹

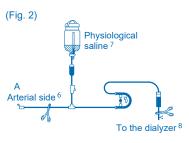


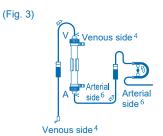
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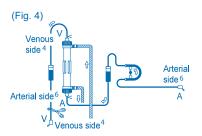


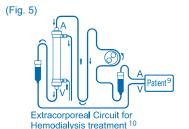
NON-Bisphenol-A³











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PERFORMANCE DATA

Clearance ²	arance² ELISIO™-H						ELISIO"-M					_ ELISIO™-L					
(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 10 Qf 75	263 272 286	270 278 294	275 285 298	280 288 300	284 291 300	200/500 300/500 400/500	194 257 299	195 264 309	196 272 319	197 275 325	198 281 335	192 251 290	194 261 301	195 267 314	196 273 322	197 277 332
Creatinine 4	Qf 0 Qf 10 Qf 75	240 250 269	252 259 279	259 268 287	268 273 290	269 275 294	200/500 300/500 400/500	186 237 267	189 243 277	194 252 290	195 257 302	197 263 308	182 227 252	187 236 265	191 246 280	194 252 289	195 260 302
Phosphate ⁵	Qf 0 Qf 10 Qf 75	224 230 253	233 241 262	245 254 271	251 258 277	256 265 281	200/500 300/500 400/500	163 198 219	170 210 231	177 223 247	181 232 256	185 239 269	153 182 204	161 194 216	167 205 230	171 214 244	176 221 254
Vitamin B ₁₂ ⁶	Qf 0 Qf 10 Qf 75	161 165 196	173 180 213	185 190 225	195 200 234	198 206 243	200/500 300/500 400/500	108 121 125	118 134 141	128 144 151	130 148 162	138 160 171	92 107 110	101 117 124	109 124 135	115 135 143	121 143 154
Inulin ⁷	Qf 0 Qf 10 Qf 75	97 102 131	109 112 141	117 121 152	127 132 159	138 145 173	200/500 300/500 400/500	=	=	=	=	=	=	=	=	=	=
Myoglobin 8	Qf 0 Qf 10 Qf 75	78 80	89 90	96 98	101 107	103 111 —	200/500 300/500 400/500		_ _ _	=	=			_ _ _	=	=	
KUF (mL/hr/n	nmHg)	64	67	74	76	82		18	20	22	24	28	14	16	18	20	22
KoA Urea (m	L/min)	1010	1145	1265	1415	1569		812	916	1045	1103	1239	801	888	1010	1083	1239
Specification	ons ⁹			ELISIO" -	н			ELISIO"-M ELISIO			ELISIO"=	L					

13M

1.3

82

15M

1.5

93

Specifications *			:LISIO"=	н		
	13H	15H	17H	19H	21H	
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	

EN

ı	In-Vitro Test Condition	ons 19 (E	N ISO 8637-1)	
	Clearance: Qb 300mL			
	KUF: Bovine Blood 20	(Hct 32 ±	2%, Protein 21 60g/L	, 37°C), Qb 300mL/mi
	KoA: Qb 300mL/min, Q	d 500mL	/min, Qf 0mL/min	
	Sieving Coefficient 22 *			
	Vitamin B ₁₂	0,989	Membrane 24	POLYNEPHRON
	Inulin	0,94		Polyethersulfone 28
	β2-microglobulin	1,00	Housing ²⁵	Polypropylene 29
ı	Marine and a factor	0.04	Detting a commercial 26	Dalaman Harman 30

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

Albumin 23 0,0017 Sterilization 27

245	259	271	281	290	245	259	271	281		
200	200	200	200	200	200	200	200	200		
40	40	40	40	40	40	40	40	40		
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		
56/27	54/25	53/27	52/24	50/22	56/26	53/24	50/30	49/29		
		ions ¹⁹ (EN L/min. Qf 10				Test Condit				
KUF: Bov		(Hct 32±2%,		Clearance: Qd 500mL/min, Qf 10mL/min KUF: Bovine Blood 20 (Hct 32±2%, Protein 21) Oh 300ml/min						

21M

2.1

131

13L

1,3

81

1,5

91

ı	Clearance . Qu 300min, Qr 10min
	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
ı	Membrana 24 BOLVNEDHDON™

17M

1,7

108

19M

1.9

116

Membrane 24	POLYNEPHRON™
	Polyethersulfone 28
Housing 25	Polypropylene 29
Potting compound ²⁶	Polyurethane 30
Sterilization 27	Gamma Ray 31

O 8637-1)

Protein 21 60g/L, 37°C),

17L

1,7

19L

1.9

281

21L 2,1

127

290

200

40

500

200/500

47/22

KoA: Qb 300mL/min, Qd 500mL/min, Qf 0mL/min

Membrane 24 POLYNEPHRON™ Polyethersulfone 28 Housing ²⁵ Polypropylene 29 Potting compound ²⁶ Polyurethane ³⁰ Gamma Ray 31

Recommended connectors for blood ports
Recommended connectors for dialysate ports
Recommended connectors for dialysate ports
Acc. to EN ISO 8637-1
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Acc. to Further information may be obtained on request.

Gamma Ray 31

CN4-CE-ELHMLMDR-01

DE DEUTSCH	ER FRANÇAIS	ES ESPAÑOL	IT ITALIANO	NL NEDERLANDS	PT PORTUGUÉS	EL EANHNIKA	SV SVENSKA	DA DANSK	NO NORSK	FI SUOM	RU РУССКИЙ	PL POLSK	RO LIMBA ROMANA
 Diese Vorrichtung muss auf Dielesemaschinen nit einem Ulasiftrationzeger oder einen genasen Ausglochssystem verwendet verden. 		Este dispositivo debe utilicarse en máquimas de dal als equipadas con un control ador de sitrafilmación o con un sistema preciso de equilibrio.	preciso sistems di bianciamento.	Oit appealant most op dielpsemachines worden gebruikt met een uitstelle productie of een neuwkoorig belanceringsspräeers.	O dispositivo deve ser utilizado em nitrojunte de dialgas equi pedas com um controlador de situal fração ou um sistema de equillorio preciso.	choopperment acollicies	dalysmaskiner Brandda med disabbeingskerbeil eller eit roppsert arksetningssystem.	Denne prordning skal anvencies pli classy expounts med ubstitutions controller eller et nejugligt belance ingspyelen:	Dette utstyret må brukes på disparmaskiner med en utsøftjorrende kontrollentet, eller et mysktig balansosystem.		Данное устройство греднамичено для использования в давтельки аппаратах с начеровтором утиграфитиградии или точной системой балансировах	To urzadzenie może być sżywane wylącze ie w maczynach do dlaże wyposażonych w koetolor ukrafilmoji bie w precyzjity system bilasowania.	
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ва Български	d hérodalyse CS ČEŠTNA	de herodolius TR TURKÇE	HR HRVATSK	SR CPRCKU	de Herostellas HU MAGYAR	eLoredapors LT LIETUVIU	berodaljobeharding	SK SLOVENČINA	SL SLOVENŠČINA	BT EEST KEEL	UK YKPAÏHCEKA	KK KA3AKUA	herocidati العرسة AR
 Това устройство требва да се моналова с мациен за дистина с во-гропер за уктройствация или точно была мородова о основни. 		Du anur, altrafficilens tentroloro le tal·lide ye de dilippio ve dengeli bir sistem speriode kullant hallatir.	Ovej urudej more bili korillen na uredejma zo djel zu o kontrolon utrafisocije I procurim austavom ravnoteže,	Овој уриђај мора да се осрасти на опъратина за дирскиу с контролом утпрафиттрације или прецизнам сестимом се осрочавање равнотеке,	Est az eszkizet dzaszteta szabályozós vagy pomos kiegyerátő rezászent dokatió kiesztálkokon kell tessznári,	Sį įrenginį rekte resudot au dializte apartosis au skraftirasimo regulatasiumi arta tiraliu balansavimo statemu.	So lertid citical terrantici uz dialitare apprilita ar viscolitatojna kontra lertici vai proctica listervana siastersu.	Toto zastadovin reast byť použítí na dokycečných prismjech s ukrallycečným regulátovom alebo pesaným vysovnásocím sodárnom.	Ta pripomoček je treba uposabljaš na diažneh oparably z regulatorjem ubrofitoroje ali netančnim sistemom stanytems.	Seeder kijds kosutskis uitselijterikse konsolien viit titose tasskaalskussaskideeriga dialütatmasinatal	Цей прастрій празначенні для векроктичні в діві іння опараток з нонтропером унипрафітатриції або з точною окслетов битин-рушник.	Бул курытвым утытросутлеу контрожней немосе-кого-беланству культа биральны куритрирымен колтам изом	يجب استخدام لجهزة القديل الكوان الطوودة ولقام تحكم بالتصالية الفاطة أو يتكام موازدة دقيق
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CH REP

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

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