

# Clearum™ HS series high flux dialyzers

## Product description

The Clearum™ HS series high flux hollow-fiber steam sterilized dialyzers are single use devices indicated for extracorporeal dialysis treatments. The series consists of different sized dialyzers that are manufactured using the same materials, methods and overall design. Each model of the family is designed with standard connection, as per ISO 8637-1, which ensures proper interface with bloodlines and external circulation circuits. The dialyzers have nominal filtering areas that range from 1.3 to 2.2 m<sup>2</sup>.

The dialysis fluid is forced to circulate in countercurrent on the outside of the fiber bundle through the dialysate inlet and outlet connectors, i.e. the dialysate compartment. Blood flows from the inlet to the outlet of the blood compartment into the hollow fibers where the particulate exchange with the dialysis fluid takes place. The exchange process between the blood and the dialysate is governed by diffusion or by ultrafiltration and convection, individually or in combination between them. A typical circuit diagram is shown in figure 1.

During dialysis treatment, the blood aspirated from the uremic patient flows through the extracorporeal circuit and enters the hollow-fiber bundle to remove the highly concentrated toxic substances. This re-establishes the electrolyte balance and removes some of the excess plasma water.

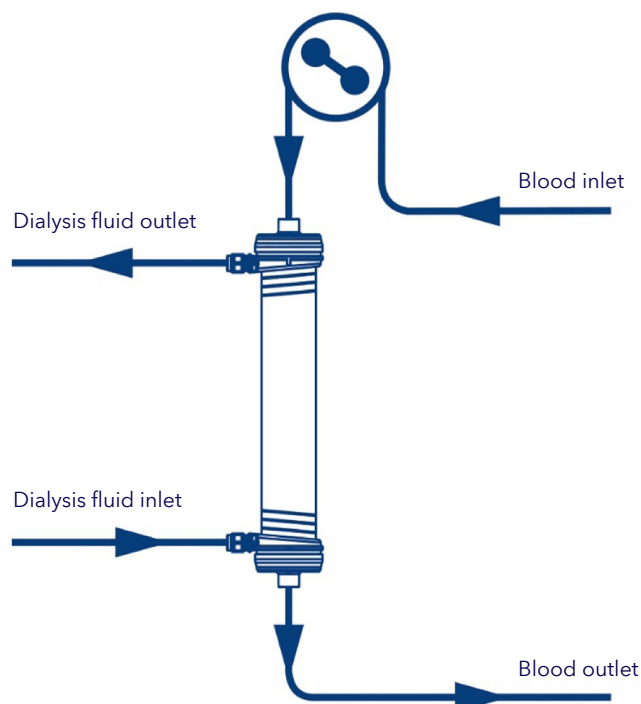


Figure 1

## Intended use

The Clearum™ HS dialyzer family is intended to be used to perform extracorporeal dialysis treatments, such as hemodialysis (HD), hemofiltration (HF) and hemodiafiltration (HDF).

## Codes available

Code	Name	Description	CND	GMDN	EMDN
IBP4370	CLEARUM™ HS 13	1.3 m <sup>2</sup> High Flux Dialyzer, steam sterilized	F01060303	44601, 47072	F010603
IBP4371	CLEARUM™ HS 15	1.5 m <sup>2</sup> High Flux Dialyzer, steam sterilized	F01060303	44601, 47072	F010603
IBP4372	CLEARUM™ HS 17	1.7 m <sup>2</sup> High Flux Dialyzer, steam sterilized	F01060303	44601, 47072	F010603
IBP4373	CLEARUM™ HS 20	2.0 m <sup>2</sup> High Flux Dialyzer, steam sterilized	F01060303	44601, 47072	F010603
IBP4374	CLEARUM™ HS 22	2.2 m <sup>2</sup> High Flux Dialyzer, steam sterilized	F01060303	44601, 47072	F010603

## Sterilization method and validity

The device is steam sterilized, delivered sterile, non-pyrogenic and labeled for single use

Sterilizing agent: steam sterilized

Shelf life: 3 years

Do not resterilize

## Technical characteristics

The technical characteristics of the Clearum™ HS dialyzers are reported below:

Components	Materials
Membrane	Polyethersulfone (PES) / Polyvinylpyrrolidone (PVP)
Housing	Polypropylene (PP)
Header	Polypropylene (PP)
Protective caps	Polypropylene (PP)
Potting	Polyurethane (PU)
O-ring	Silicone

Model	Effective surface area (m <sup>2</sup> )	Fiber wall thickness (μm)	Fiber internal diameter (μm)	Blood compartment priming volume (ml)	Blood compartment pressure drop <sup>1</sup> (mmHg)	Dialysis fluid compartment pressure drop <sup>2</sup> (mmHg)	Total length <sup>3</sup> (mm)	External diameter <sup>3</sup> (mm)	Weight <sup>4</sup> (g)	Max blood flow rate (ml/min)	Max trans-membrane pressure - TMP (mmHg)
HS 13	1.3	40	200	84	< 90	< 20	306	55	194	500	600
HS 15	1.5	40	200	95	< 75	< 20	306	55	205	500	600
HS 17	1.7	40	200	105	< 75	< 20	306	55	225	500	600
HS 20	2.0	40	200	120	< 90	< 25	366	55	253	500	600
HS 22	2.2	40	200	126	< 80	< 25	366	55	265	500	600

<sup>1</sup> Bovine blood: Hct= 32±3%, protein = 60±5 g/l, Q<sub>B</sub> = 300 ml/min

<sup>2</sup> Dialysis fluid: NaCl = 0.9%, Q<sub>D</sub> = 500 ml/min

<sup>3</sup> Outer body characteristics

<sup>4</sup> Approximate finished product weight

Model	KoA (ml/min)															
	Urea				Creatinine				Phosphates				Vitamin B12			
Q <sub>B</sub> (ml/min)	200	300	400	500	200	300	400	500	200	300	400	500	200	300	400	500
HS 13	774	770	756	764	534	552	554	567	453	463	466	476	220	227	233	241
HS 15	1055	1014	1008	1013	684	709	713	721	585	593	596	609	273	281	288	294
HS 17	1128	1049	1042	1050	704	738	749	770	599	631	637	654	286	304	313	320
HS 20	1221	1150	1181	1207	802	851	870	912	684	738	749	783	342	366	386	406
HS 22	1354	1246	1254	1267	904	919	935	969	774	792	810	837	392	409	426	450

Calculated at Q<sub>D</sub> = 500 ml/min; Q<sub>i</sub> = 10 ml/min

## Performance

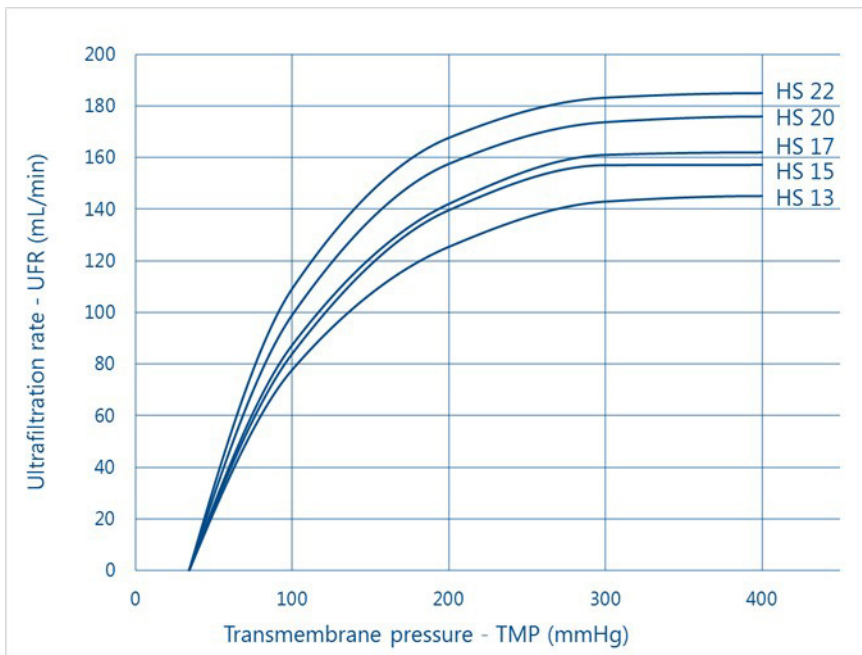
The measurements in the charts below are taken in accordance with EN ISO 8637-1. The values indicated are to be considered approximate and may vary due to measurement methods, inherent variations of the membrane, manufacturing and storage conditions. During the treatment, performance on the individual patient may vary due to variable clinical parameters of the patient.

Model	In vitro clearance <sup>5</sup>				UF coefficient <sup>6</sup>
	Urea (ml/min)	Creatinine (ml/min)	Phosphates (ml/min)	Vitamin B12 (ml/min)	Kuf (ml/h*mmHg)
HS 13	246	220	205	141	42
HS 15	264	240	226	160	48
HS 17	266	243	231	167	55
HS 20	271	253	243	184	64
HS 22	275	258	248	194	70

<sup>5</sup> In vitro clearance: Q<sub>B</sub> = 300 ml/min, Q<sub>F</sub> = 10 ml/min, Q<sub>D</sub> = 500 ml/min

<sup>6</sup> Ultrafiltration coefficient: Q<sub>B</sub> = 300 ml/min, bovine blood Hct= 32±3%, protein = 60±5 g/l

## Ultrafiltration rate<sup>7</sup>



<sup>7</sup> Ultrafiltration rate:  $Q_b = 300$  ml/min, bovine blood Hct=  $32 \pm 3\%$ , protein =  $60 \pm 5$  g/l

Sieving coefficient	
Markers	Mean values <sup>8</sup>
Inulin	1
Myoglobin	0.70
Albumin	0.004
$\beta$ 2-Microglobulin	0.90

<sup>8</sup> Experimental values according to IFU

## Packaging

Model	Primary packaging - Pouch	
	Material	Pouch weight (g)
HS 13 HS 15 HS 17	OPA (BX)/PP shatterless Medical grade paper 65 g/m <sup>2</sup>	8
HS 20 HS 22	OPA (BX)/PP shatterless Medical grade paper 65 g/m <sup>2</sup>	11

Model	Secondary packaging - Box					
	Box	Cardboard insert	Internal division	Soft PE layer	Weight <sup>9</sup> (kg)	Pcs/ Box
HS 13 HS 15 HS 17	Tobacco colored rippled cardboard 4 mm - KLK/333/C - C Flute. Dimensions: 41 x 37 x 27 cm	Rippled cardboard 4 mm - KLK/333/C - C Flute	Rippled cardboard 4 mm - KLK/333/C - C Flute (soft)	CELL-AIRE 2.0 mm N -sealed air (low-density polyethylene foam)	< 6	21
HS 20 HS 22	Tobacco colored rippled cardboard 4 mm - KLK/333/C - C Flute Dimensions: 41 x 37 x 27 cm	Rippled cardboard 4 mm - KLK/333/C - C Flute	Rippled cardboard 4 mm - KLK/333/C - C Flute (soft)	CELL-AIRE 2.0 mm N -sealed air (low-density polyethylene foam)	< 6	18

<sup>9</sup> Max box weight filled with products

## Storage and disposal conditions

Storage conditions: the expiration date refers to the product in undamaged packaging and stored at temperatures between 0°C and 30°C, avoiding direct exposure to the sun and vibrations.

Disposal: after its use, the device and all the connected components must be disposed of in accordance with the guidelines or procedures in force in the hospital/clinic for dangerous hospital medical waste.

## Biocompatibility

Biocompatibility tests of the Clearum™ HS dialyzers have been performed according to ISO 10993-1 and related applicable standard series.

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