

Polyflux H

DESIGNED FOR:

CONVECTIVE (HDF-HF)

OTHER APPLICABLE THERAPIES:

HFHD (High flux)

MEMBRANE:

POLYAMIX (PAES/PVP/PA, BPA-free)

FOR EFFECTIVE CONVECTIVE THERAPIES

The **Polyflux** H dialyser series deliver proven biocompatibility¹ with consistent performance. The **Polyflux** H dialysers effectively support the delivery of high-volume convective therapies,² while helping control the loss of essential proteins such as albumin,³ particularly challenging at high flows and TMPs.

DESIGNED TO PROMOTE BIOCOMPATIBILITY¹

The **Polyflux** H dialysers deliver convective treatments (HDF or HF mode), as well regular high-flux haemodialysis.

- > Since 1988, over 300 million **Polyflux** dialysers have been used globally⁴
- > Composed of the **Polyamix** membrane, which is BPA-free, the **Polyflux** H dialysers may limit the risk of clotting events¹
- > The **Polyflux** H dialysers are steam sterilised inside-out**, designed to promote biocompatibility, avoiding the risks associated with the exposure to chemicals such as ethylene oxide and manufacturing residues^{5,6}

WITH HIGH CONVECTIVE VOLUMES IN MIND

The **Polyflux** H dialysers are aimed at delivering stable and high performing convective treatments, supporting a consistent reach of high volumes of substitution fluid.

- > Narrow pore size distribution is responsible for a carefully controlled albumin selectivity, combined with an effective permeability to small and conventional middle molecules¹
- > The 3-layer-membrane structure has been designed to optimise the combination of high diffusive and convective transport rates, while acting as a barrier to endotoxins⁷
- > Facilitates obtention of high convective flow rate, and provides effective clearance of conventional middle molecules such as β_2 -microglobulin (β_2m)^{8,9}



POLYFLUX H Specifications

MATERIALS	POLYFLUX 140 H	POLYFLUX 170 H	POLYFLUX 210 H
Membrane	Polyamix Polyarylethersulfone, Polyvinylpyrrolidone and Polyamide blend BPA-free		
Potting	Polyurethane (PUR)		
Housing	Polycarbonate (PC)		
Gaskets	Silicone rubber (SIR)		
Protection caps	Polypropylene (PP)		
Sterilisation	Steam (inside-out**)		
Sterile barrier	Medical Grade Paper		

SPECIFICATIONS

UF-Coefficient (mL/(h*mmHg))*	60	70	85
KoA urea (mL/min)*	998	1153	1452
Blood Compartment volume (mL)	94	115	141
Minimum recommended priming volume (mL)	500		
Maximum TMP (mmHg)	600		
Recommended Q _B (mL/min)	200-400	250-500	300-500
Storage conditions	<30°C (or <86°F)		
Units per box	24		
Gross/net weight (g)	274/245	304/275	317/300

MEMBRANE

Effective Membrane Area (m ²)	1.4	1.7	2.1
Fiber inner diameter (µm)	215		
Fiber wall thickness (µm)	50		

SIEVING COEFFICIENTS*

Vitamin B12 (1,4 kDa)	1.0		
Inulin (5,2 kDa)	1.0		
β ₂ -microglobulin (11,8 kDa)**	0.82		
Myoglobin (17 kDa)**	0.37		
Albumin (66,4 kDa)**	0.0022		

* According to ISO 8637-1

> UF-Coefficient: measured with bovine blood, Hct 32%, Pct 60g/L, 37°C

> KoA urea: calculated at Q_B=300 mL/min, Q_D=500mL/min, UF=0 mL/min

> Sieving coefficients: measured with bovine (or human**) plasma, Q_B=300 mL/min, UF=60 mL/min

> Clearances In-Vitro: measured at UF=0 mL/min, ±10%

HDF/HF mode: measured at UF=60 mL/min, ±10%

** At the end of the manufacturing process, the dialyser is sterilised with steam.

Steam enters the closed sterile packaging, reaching the inside and outside of the device.

- Ronco C, et al. *Evolution of synthetic membranes for blood purification: the case of the Polyflux family*. Nephrol Dial Transplant 2003;18(Suppl 7):viii10-20.
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- Vantive. Data on file. *Dialyzers Sales Report*. 2018.
- Golli-Bennour EE, et al. *Cytotoxic effects exerted by polyarylsulfone dialyser membranes depend on different sterilization processes*. Int Urol Nephrol. 2011; 43:483-490.
- D'Ambrosio FP, et al. *Ethylene oxide allergy in dialysis patients*. Nephrol Dial 1997;12:1461-1463.
- Schepers E, Glorieux G, Eloot S, et al. *Assessment of the association between increasing membrane pore size and endotoxin permeability using a novel experimental dialysis simulation set-up*. BMC Nephrology. 2018; 19:1.

The capillary dialyser/filter is intended for use in haemodialysis, hemodiafiltration and haemofiltration for the treatment of chronic or acute renal failure.

The products meet the applicable provisions of Annex I (Essential Requirements) and Annex II (Full quality assurance system of the Council Directive 93/42/EEC of 14 June 1993, amended by Directive 2007/47/EC).

For safe and proper use of the device, please refer to the Instructions for Use



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CLEARANCES IN VITRO (mL/min)* POLYFLUX 140 H POLYFLUX 170 H POLYFLUX 210 H

CLEARANCES IN VITRO (mL/min)*	POLYFLUX 140 H	POLYFLUX 170 H	POLYFLUX 210 H
HAEMODIALYSIS MODE (HD)			
Urea (60 Da) (Q_B/Q_D, mL/min)			
200/500	193		
300/500	262	270	281
400/500	309	321	339
500/500			378
Creatinine (113 Da)			
200/500	181		
300/500	232	243	259
400/500	266	281	303
500/500			334
Phosphate (142 Da)			
200/500	174		
300/500	220	232	249
400/500	250	266	289
500/500			317
Vitamin B12 (1.4 kDa)			
200/500	128		
300/500	149	162	183
400/500	163	178	203
500/500			218
Inulin (6.2 kDa)			
200/500	91		
300/500	102	113	131
400/500	109	121	143
500/500			151
HAEMODIAFILTRATION MODE (HDF)			
Urea (60 Da) (Q_B/Q_D, mL/min)			
200/500	198		
300/500	277	283	290
400/500	332	343	359
500/500			406
Creatinine (113 Da)			
200/500	191		
300/500	252	262	274
400/500	292	306	327
500/500			363
Phosphate (142 Da)			
200/500	187		
300/500	242	252	266
400/500	277	292	314
500/500			347
Vitamin B12 (1.4 kDa)			
200/500	152		
300/500	177	189	208
400/500	193	208	232
500/500			249
Inulin (6.2 kDa)			
200/500	120		
300/500	133	143	161
400/500	141	153	174
500/500			183

- Panichi V, et al. *Divert to ULTRA: differences in infused volumes and clearance in two on-line hemodiafiltration treatments*. Int J Artif Org 2012; 35 (6):435-443.
- Meert N, et al. *Effective removal of protein-bound uraemic solutes by different convective strategies: a prospective trial*. Nephrol Dial Transplant 2009; 24:562-570.

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