

# Polyflux H

DESIGNED FOR: **CONVECTIVE** (HDF-HF) | **HFHD** (High flux)

OTHER APPLICABLE THERAPIES:

MEMBRANE: **POLYAMIX** (PAES/PVP/PA, BPA-free)

#### FOR EFFECTIVE CONVECTIVE THERAPIES

The **Polyflux** H dialyzer series deliver proven biocompatibility<sup>1</sup> with consistent performance. The **Polyflux** H dialyzers effectively support the delivery of high-volume convective therapies,<sup>2</sup> while helping control the loss of essential proteins such as albumin<sup>3</sup>, particularly challenging at high flows and TMPs.

#### DESIGNED TO PROMOTE BIOCOMPATIBILITY<sup>1</sup>

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

- Since 1988, over 300 million Polyflux dialyzers have been used globally<sup>4</sup>
- Composed of the Polyamix membrane, which is BPA-free, the **Polyflux** H dialyzers may limit the risk of clotting events<sup>1</sup>
- The Polyflux H dialyzers are steam sterilized inside-out, designed to promote biocompatibility, avoiding the risks associated with the exposure to chemicals such as ethylene oxide and manufacturing residues<sup>5,6</sup>

### WITH HIGH CONVECTIVE VOLUMES IN MIND

The Polyflux H dialyzers 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 molecules<sup>1</sup>
- The 3-layer-membrane structure has been designed to optimize the combination of high diffusive and convective transport rates, while acting as a barrier to endotoxins<sup>7</sup>
- Facilitates obtention of high convective flow rate, and provides effective clearance of conventional middle molecules such as  $\beta_2$ -microglobulin ( $\beta_2$ m)<sup>8,9</sup>

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## 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)				
Sterilization	Steam (inside-out)				
Sterile barrier	Medical Grade Paper				
SPECIFICATIONS					
UF-Coefficient (mL/(h*mmHg))*	60	70	85		
KoA urea*	998	1153	1452		
Blood Compartment volume (mL)	94	115	141		
Minimum recommended priming volume (mL)		500			
Maximum TMP (mmHg)		600			
Recommended Q <sub>B</sub> (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 (m²)	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 <sub>2</sub> -microglobulin (11,8 kDa)**	0.82				
Myoglobin (17 kDa)**		0.37			
Albumin (66,4 kDa)**		0.0022			

- KoA urea: calculated at Q<sub>B</sub>=300 mL/min, Q<sub>D</sub>=500mL/min, UF=0 mL/min

- Sieving coefficients: measured with bovine (or human\*\*) plasma, Q<sub>B</sub>=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%

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- 4 Baxter. Data on file. Dialyzers Sales Report. 2018.
- 5. Golli-Bennour EE, et al. Cytotoxic effects exerted by polyarylsulfone dialyser membranes depend on different sterilization processes. Int Urol Nephrol. 2011; 43:483-490.
- 6. 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.
- 8. 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.
- 9. 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.

The capillary dialyzer/filter is intended for use in hemodialysis, hemodiafiltration and hemofiltration 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

**CE** 2797

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HEMODIALYSIS MODE (HD)			
<b>Urea (60 Da)</b> (Q <sub>B</sub> -Q <sub>D</sub> , 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
HEMODIAFILTRATION MODE (HDF)			
<b>Urea (60 Da)</b> (Q <sub>B</sub> -Q <sub>D</sub> , 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)	107		
200/500	187	050	2//
300/500	242	252	266
400/500	277	292	314
500/500			347
VITAMIN B12 (1.4 kDa)			
200/500	150		
21.0.17.051.0.1	152	100	200
300/500	152 177	189	208
400/500 500/500	152 177 193	189 208	208 232 249
400/500 500/500	152 177 193	189 208	208 232 249
300/500 400/500 500/500 Inulin (6.2 kDa) 200/500	152 177 193	189 208	208 232 249
300/500 400/500 500/500 Inulin (6.2 kDa) 200/500	152 177 193 120	189 208	208 232 249
300/500 400/500 500/500 Inulin (6.2 kDa) 200/500 300/500 400/500	152 177 193 120 133	189 208 143	208 232 249 161
300/500 400/500 500/500 Inulin (6.2 kDa) 200/500 300/500 400/500 500/500	152 177 193 120 133 141	189 208 143 153	208 232 249 161 174 183

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