

Polyflux 2H/6H

DESIGNED FOR:

HFHD [High flux]

OTHER APPLICABLE THERAPIES:

CONVECTIVE [HDF-HF]

MEMBRANE:

POLYAMIX [PAES/PVP, PA, BPA-free]

The **Polyflux** 2H/6H dialyzer is intended to be used for the treatment of chronic or acute renal failure by hemodialysis, hemodiafiltration and hemofiltration. In consideration of extracorporeal blood volume, blood flow and body weight, the **Polyflux** 2H/6H dialyzer can be used for low weight patients.

SPECIALIZED FOR LOW BODY WEIGHT PATIENTS

The **Polyflux** 2H/6H dialyzer series enables high flux dialysis compatibility and performance to low body weight patients, typically children.^{1,2,3}

FOCUSED ON LOW BLOOD COMPARTMENT VOLUME

- The **Polyamix** membrane has been integrated into a more compact housing design, aiming at supporting effective high flux performance for this specific patient population^{2,3}
- Blood compartment volume reduced down to 17 ml and 52 ml respectively for **Polyflux** 2H/6H
- Small dialyzer compartments also help promote simple and easy priming²

WITH BIOCOMPATIBILITY IN MIND

The **Polyflux** 2H/6H dialyzers are compatible with conventional high-flux hemodialysis, as well as convective therapies (HDF or HF mode).

- The 3-layer-membrane structure has been designed to optimize the combination of high diffusive and convective transport rates⁴, while acting as a safety barrier to endotoxins⁵
- The **Polyflux** 2H/6H dialyzers are steam sterilized inside-out to promote biocompatibility, avoiding exposure to chemicals such as ethylene oxide and manufacturing residues⁶



Polyflux 2H/6H Specifications

MATERIALS	POLYFLUX 2H	POLYFLUX 6H
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)*	15	33
KoA urea*	146	461
Blood Compartment volume (mL)	17	52
Minimum recommended priming volume (mL)	500	1000
Maximum TMP (mmHg)	600	
Recommended Q _B (mL/min)	20-100	50-300 (HDF, HF: 50-200)
Storage conditions	<30°C (or <86°F)	
Units per box	24	
Gross/net weight (g)	98/75	152/140

MEMBRANE		
Effective Membrane Area (m ²)	0.2	0.6
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 EN 1283/ISO 8637:
 - UF-Coefficient: measured with bovine blood, Hct 32%, Pct 60g/L, 37°C
 - KoA for urea: calculated at UF = 0 mL/min, at Q_B = 60 mL/min and Q_D = 300 mL/min for P2H, at Q_B = 200 mL/min and Q_D = 500 mL/min for P6H
 - 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=20 mL/min (2H) or UF=30 mL/min (6H), ±10%

CLEARANCES IN VITRO (mL/min)*	2H	6H	2H	6H
	HEMODIALYSIS MODE (HD)		HEMODIAFILTRATION MODE (HDF/HF)	
Urea (60 Da) (Q_B-Q_D, mL/min)				
20/30	16			
60/30	24			
100/30	26			
60/300	53			
100/300	72		79	
50/500		50		
100/500	76	97		99
150/500		136		141
200/500		167		174
Creatinine (113 Da)				
20/30	14			
60/30	22			
100/30	24			
60/300	44			
100/300	55		64	
50/500		49		
100/500	59	89		94
150/500		116		125
200/500		136		147
Phosphates (142 Da)				
20/30	15			
60/30	23			
100/30	25			
60/300	48			
100/300	62		70	
50/500		50		
100/500	65	93		96
150/500		124		131
200/500		146		156
Vitamin B12 (1.4 kDa)				
20/30	10			
60/30	15			
100/30	18			
60/300	27			
100/300	32		43	
50/500		45		
100/500	35	68		79
150/500		81		94
200/500		90		104
Inulin (5.2 kDa)				
20/30	7			
60/30	10			
100/30	11			
60/300	19			
100/300	21		33	
100/500	23			65
150/500				74
200/500				79

1. Ronco C, et al. *Evolution of synthetic membranes for blood purification: the case of the Polyflux family*. Nephrol Dial Transplant 2003;18(Suppl 7):vii10-20.
2. Goldstein SL, et al. *Polyflux® 6H dialyzer: a new option for small children requiring dialysis* Int J Artif Organs 2007; 30:321-324.
3. Cochat P, et al. *Pediatric Dialysis, Chapter 19. Maintenance hemodialysis during infancy*. 2012. Kluwer Academic Publishers, Dordrecht, pp 35-46.
4. Krieter DH, et al. *A new synthetic dialyzer with advanced permselectivity for enhanced low-molecular weight protein removal*. Artif Organs 2008; 32:547-554.
5. Ertl T, et al. *Barrier function of low and high flux synthetic membranes for endotoxins in contaminated dialysis fluid*. Blood Purif 2003; 21:358.
6. D'Ambrosio FP, et al. *Ethylene oxide allergy in dialysis patients*. Nephrol Dial 1997;12:1461-1463.

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

