

Polyflux L

DESIGNED FOR:

MEMBRANE:

LFHD [Low flux]

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

THE PROVEN BALANCE OF QUALITY AND PERFORMANCE IN LOW-FLUX

The Polyflux L dialyzer series is specialized for low-flux hemodialysis treatments, featuring a distinctive membrane acting as an effective barrier to potential fluid contaminants, while still delivering high performance? Polyflux L dialyzers are a good choice for proven biocompatible yet effective low-flux therapies, designed with safety in mind.

DESIGNED TO PROMOTE BIOCOMPATIBILITY²

The **Polyflux** L dialyzers are designed to deliver high-quality low-flux hemodialysis treatments.

- Since 1988, over 300 million Polyflux dialyzers have been used globally³
- The Polyflux L dialyzers are designed to prevent endotoxins from crossing the dialyzer membrane^{1,2}
- The Polyflux L dialyzers are steam sterilized inside-out, to promote biocompatibility, avoiding exposure to chemicals such as ethylene oxide and manufacturing residues^{4,5}

WITH HIGH PERFORMANCE IN MIND

The **Polyflux** L dialyzers feature an exclusive 3-layered membrane structure, designed to support a stable high performance over time.

- Effective clearance of standard dialysis markers, such as urea or phosphates⁶
- A clinical case series study suggests the Polyflux L dialyzers may reduce the signs and symptoms of hemodialysis-associated eosinophilia⁷



Polyflux L Specifications

MATERIALS	POLYFLUX 14 L	POLYFLUX 17 L	POLYFLUX 21 L	
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))*	10	12.5	15	
KoA urea*	851	1026	1268	
Blood Compartment volume (mL)	81	104	123	
Minimum recommended priming volume (mL)	500			
Maximum TMP (mmHg)	600			
Recommended Q _B (mL/min)	200-400	200-500	300-500	
Storage conditions	<30°C (or <86°F)			
Units per box	24			
Gross/net weight (g)	254/225	274/245	294/265	
MEMBRANE				
Effective Membrane Area (m²)	1.4	1.7	2.1	
Fiber inner diameter (µm)	215			
Fiber wall thickness (µm)	50			

^{*} According to EN 1283/ISO 8637:

CLEARANCES IN VITRO [mL/min]*	POLYFLUX 14 L	POLYFLUX 17 L	POLYFLUX 21 L
Urea (60 Da) (Q _B -Q _D , mL/min)			
200/500	190	194	
300/500	252	264	275
400/500	293	310	328
500/500		342	364
200/700	194	197	
300/700	267	276	285
400/700	319	336	343
500/700		380	403
Phosphate (95 Da)			
200/500	152	163	
300/500	183	200	218
400/500	203	224	247
500/500		240	267
200/700	160	170	
300/700	197	213	231
400/700	221	242	266
500/700		264	272
Creatinine (113 Da)			
200/500	171	179	
300/500	214	230	246
400/500	241	262	283
500/500		284	310
200/700	178	185	
300/700	229	244	258
400/700	264	284	306
500/700		313	341
Vitamin B12 (1.4 kDa)			
200/500	90	101	
300/500	100	114	131
400/500	106	122	142
500/500		128	149
200/700	96	107	
300/700	107	121	138
400/700	114	130	150
500/700		137	159

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 **C**€ 0086

MANUFACTURER Gambro Dialysatoren GmbH Holger-Crafoord-Strasse 26 72379 Hechingen Germany Baxter Healthcare Corporation One Baxter Parkway Deerfield, IL 60015 USA 1-800-422-9837

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

[–] KoA urea: calculated at $\rm Q_B{=}300~mL/min$, $\rm Q_D{=}500mL/min$, UF=0 mL/min

[–] Clearances In-Vitro: measured at UF=0 mL/min, $\pm 10\,\%$

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.

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.

^{3.} Baxter. 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.
 Krause B, et al. Polymeric Membranes for Medical Applications. Chemie Ingenieur Technik. 2003; 75:1725-1732.

^{7.} Tielemans C, et al. Clinical assessment of Performance and Blood Compatibility Profile of a New Synthetic Low Flux Hemodialyzer. Blood Purif. 2002; 20:214-215.