

# 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, while helping control the loss of essential proteins such as albumin, 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 globally4
- · Composed of the Polyamix membrane, which is BPA-free, the Polyflux H dialyzers may limit the risk of clotting events1
- 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  $(\beta_2 m)^{8,9}$



# Polyflux H Specifications

MATERIALS	POLYFLUX 140 H	POLYFLUX 170 H	POLYFLUX 210 H	
Membrane				
	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	125	
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			

- \* According to EN 1283/ISO 8637:
- UF-Coefficient: measured with bovine blood, Hct 32%, Pct 60g/L, 37°C
- 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,  $\pm 10\%$
- 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.
- Maduell F, et al. High-efficiency postdilution online hemodiafiltration reduces all-cause mortality in hemodialysis patients. J Am Soc Nephrol. 2013;24:487-497
- Potier J et al. Are all dialyzers compatible with the convective volumes suggested for postdilution online hemodiafiltration? Int J Artif Org 2016;39:460-70.
- 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.
- 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.
- 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.

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

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

196

270

321

180

232

266

186

243

281

137

162

178

100

113

121

199

283

343

191

252

292

194

262

306

159

189

208

128

143

153

281

339

378

249

289

317

259

303

334

183

203

218

131

143

151

290

359

406

266

314

347

274

327

363

208

232

249

161

174

183

193

262

309

174

220

250

181

232

266

128

1/19

163

91

102

109

198

277

332

187

242

277

191

252

292

152

177

193

120

133

141

HEMODIALYSIS MODE (HD) Urea (60 Da) (Q<sub>B</sub>-Q<sub>D</sub>, mL/min)

200/500

300/500

400/500

500/500

300/500

400/500

500/500

200/500

300/500

400/500

500/500

200/500

300/500

400/500

500/500

300/500

400/500

500/500

200/500

300/500

400/500

500/500

300/500

400/500

500/500

200/500

300/500

400/500

500/500

200/500

300/500

400/500

500/500

200/500

300/500

400/500

500/500

Inulin (5.2 kDa)

Creatinine (113 Da) 200/500

Phosphates (142 Da)

Vitamin B12 (1.4 kDa)

Inulin (5.2 kDa) 200/500

HEMODIAFILTRATION MODE (HDF/HF) Urea (60 Da) (Q<sub>B</sub>-Q<sub>D</sub>, mL/min)

Creatinine (113 Da) 200/500

Phosphates (142 Da)

Vitamin B12 (1.4 kDa)