# Polyflux L

DESIGNED FOR:
**LFHD** (Low flux)

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

## THE PROVEN BALANCE OF QUALITY AND PERFORMANCE IN LOW-FLUX

The **Polyflux** L dialyser series is specialized for low-flux haemodialysis treatments, featuring a distinctive membrane acting as an effective barrier to potential fluid contaminants,[1] while still delivering high performance.[2] **Polyflux** L dialysers are a good choice for proven biocompatible yet effective low-flux therapies, designed with safety in mind.


## DESIGNED TO PROMOTE BIOCOMPATIBILITY[2]

The **Polyflux** L dialysers are designed to deliver high-quality low-flux haemodialysis treatments.

> Since 1988, over 300 million **Polyflux** dialysers have been used globally[3]
> The **Polyflux** L dialysers are designed to prevent endotoxins from crossing the dialyser membrane[1,2]
> The **Polyflux** L dialysers 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 dialysers 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 phosphates[6]
> A clinical case series study suggests the **Polyflux** L dialysers may reduce the signs and symptoms of haemodialysis-associated eosinophilia[7]

The images are for illustration purposes only and may differ from the actual product.

# **POLYFLUX L** Specifications

| MATERIALS | **POLYFLUX** 14 L | **POLYFLUX** 17 L | **POLYFLUX** 21 L |
|---|---|---|---|
| Membrane | | **Polyamix**<br>Polyarylethersulfone, Polyvinylpyrrolidone and Polyamide blend<br>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 (mL/min)* | 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 ($m^2$) | 1.4 | 1.7 | 2.1 |
| Fiber inner diameter (µm) | | 215 | |
| Fiber wall thickness (µm) | | 50 | |

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

** At the end of the manufacturing process, the dialyser is sterilized with steam.
Steam enters the closed sterile packaging, reaching the inside and outside of the device.

| 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 | 353 |
| 500/700 | | 380 | 403 |
| **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 |
| **Phosphate** (142 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 | 292 |
| **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 |


1. 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.
2. 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. Vantive. Data on file. *Dialysers Sales Report.* 2018.
4. Golli-Bennour EE, et al. *Cytotoxic effects exerted by polyarylsulfone dialyser membranes depend on different sterilization processes.* Int Urol Nephrol. 2011; 43:483-490.
5. D'Ambrosio FP, et al. *Ethylene oxide allergy in dialysis patients.* Nephrol Dial 1997;12:1461-1463.
6. 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.


**The capillary dialyser/filter is intended for use in haemodialysis 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


MANUFACTURER
Gambro Dialysatoren GmbH
Holger-Crafoord-Strasse 26
72379 Hechingen
Germany





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