POLYAMIX MEMBRANE

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Gambro polyflux h

DESIGNED FOR EFFECTIVE HIGH FLUX, HEMODIAFILTRATION AND HEMOFILTRATION TREATMENTS (HFHD, HDF, HF)[1,2]

The Gambro POLYFLUX H dialyzer has an established heritage of use in convective treatments, facilitating the achievement of target convective volume and providing effective clearance of middle molecules such as $ß_2$microglobulin ($ß_2$m).[3-6] The exclusive asymmetric three-layer POLYAMIX membrane has been designed to facilitate transport of fluid and solutes across the membrane, help to prevent the loss of essential proteins such as albumin, and promote biocompatibility.[7,8]

CONSISTENT MOLECULAR CLEARANCE AND RETENTION

- Effective removal of middle molecules such as $ß_2$m and minimal loss of essential proteins throughout dialysis[7,9-11]
- POLYAMIX membrane is designed for endotoxin retention[2,12-13]

VERSATILE MEMBRANE DESIGN

- Proprietary membrane approved for use in hemodiafiltration, hemofiltration and high flux hemodialysis therapies[1]
- 3-layer membrane structure designed to provide high transport rates[2]
- Membrane microstructure promotes biocompatibility[2,14]
- Designed to help minimize the risk of clotting[2]

DESIGNED FOR THE PATIENT

- Steam sterilized, which eliminates exposing patients to potential EtO residuals and helps to reduce the risk of possible cytotoxic effects due to gamma irradiation[2,15,16]
- Removable patient label available to streamline documentation and help avoid charting errors

TYPICAL PATIENT PROFILE:
HEMODIAFILTRATION (HDF) PATIENTS

Gambro POLYFLUX H Dialyzer

PERFORMANCES IN VITRO

Measured according to ISO 8637

CLEARANCE IN VITRO (ml/min) ± 10%	POLYFLUX 140H				POLYFLUX 170H				POLYFLUX 210H			
	200	300	400	500	200	300	400	500	200	300	400	500
Hemodialysis UF=0 ml/min, Q_D=500 ml/min, Q_B (ml/min)												
Urea	193	262	309	–	196	270	321	–	–	281	339	378
Creatinine	181	232	266	–	186	243	281	–	–	259	303	334
Phosphate	174	220	250	–	180	232	266	–	–	249	289	317
Vitamin B_{12}	128	149	163	–	137	162	178	–	–	183	203	218
Inulin	91	102	109	–	100	113	121	–	–	131	143	151
Hemodiafiltration UF=60 ml/min, Q_D=500 ml/min, Q_B (ml/min)												
Urea	198	277	332	–	199	283	343	–	–	290	359	406
Creatinine	191	252	292	–	194	262	306	–	–	274	327	363
Phosphate	187	242	277	–	191	252	292	–	–	266	314	347
Vitamin B_{12}	152	177	193	–	159	189	208	–	–	208	232	249
Inulin	120	133	141	–	128	143	153	–	–	161	174	183

SPECIFICATIONS

KoA for urea*	**998**	**1153**	**1452**
Ultra filtration** (ml/min) ± 10%, measured at Q_B=300 ml/min and TMP=300 mmHg	113	127	144
UF-coefficient** (ml/h·mmHg)	60	70	85
Priming volume (ml)	94	115	125
Fluid volume for priming (ml)	≥500		
Residual blood volume (ml)	<1	<1	~1
Maximum TMP (mmHg)	600		
Recommended Q_B (ml/min)	200-400	250-500	300-500
Sieving coefficient* **			
Vitamin B_{12}	1.0		
Inulin	1.0		
β_2-microglobulin	0.7		
Albumin	<0.01		
Membrane			
Surface area (m^2)	1.4	1.7	2.1
Fiber dimensions			
Wall thickness (µm)	50		
Inner diameter (µm)	215		

COMPONENTS	MATERIALS	STERILIZATION AGENT	STERILE BARRIER	QUANTITY PER CASE
Membrane	POLYAMIX****	Steam	Medical grade paper	24
Potting material	Polyurethane (PUR)			
Housing, caps	Polycarbonate (PC)			
Protective caps	Polypropylene (PP)			
O-ring	Silicon rubber (SIR)			

* Calculated at QB=300 ml/min, QD=500 ml/min and UF=0.

** Measured with bovine blood, hematocrit of (32 ± 3) %, protein content of (60 ± 5) g/l at 37 °C.

*** Typical values measured with Polyflux 170H dialyzer, with bovine plasma, a protein content of (60 ± 5) g/l at 37 °C. Sieving coefficient determined at a filtration rate of 0.70x10^{-4} cm/s and a wall shear rate of 461 s^{-1}.

**** Polyarylethersulfone, Polyvinylpyrrolidone, Polyamide blend.

For further information and operating instructions, please refer to the operator's manual and the Instructions for Use of the product.

CE 0086 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 concerning medical devices.

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