MEDIUM CUT-OFF MEMBRANE

Baxter

Gambro theranova

PERFORMANCE OF HDF, AS SIMPLE AS HD

Thanks to its unique permeability and selectivity properties[1], the Gambro Theranova dialyzer provides HDF performance from a standard HD treatment[2]

IN REGULAR HD MODE, THERANOVA EFFECTIVELY TARGETS MIDDLE MOLECULES, IN AN EQUIVALENT WAY TO HIGH-VOLUME HDF[2]

- Similar removal to high volume post-dilution HDF up to the lower end of the middle molecule spectrum
- Greater removal possible of larger middle molecules (> 25 kDa)

THE THERANOVA DIALYZER PROVIDES THE OPPORTUNITY FOR AN EXPANDED HD THERAPY

- Significant intradialytic reduction in plasma levels for solutes up to the size of 45 kDa – also at Qb 300 ml/min[2]
- Greater clearance and greater per cent reduction in comparison to a conventional high-flux dialyzer in HD[2]

ENHANCED SELECTIVITY TO LIMIT THE LOSS OF ALBUMIN

- Medium cut-off membrane enhances selectivity, in order to limit the loss of Albumin and is an effective barrier to endotoxins and bacterial by-products[3]
- Albumin removal (1-4g/session, 3g in average) is within the range of published data on albumin removal in HDF[2]

TYPICAL PATIENT PROFILE: **PATIENTS REQUIRING HIGHER CLEARANCES OF MIDDLE MOLECULES**

Making possible personal.

The Gambro **Theranova** Dialyzer

COMPONENTS	MATERIALS	
Membrane	Polyarylethersulfone / Polyvinylpyrrolidone	PAES / PVP – BPA-free
Potting	Polyurethane	PUR
Housing, Header	Polycarbonate	PC
Gasket	Silicon rubber	SIR
Protection Cap	Polypropylene	PP

MEMBRANE	
Membrane design	Asymmetric wall, 3-layer finger structure Medium Cut-Off, narrow pore size distribution
Effective Membrane Area [m^2]	1.7
Fiber Dimension	
– Inner diameter [µm] – Wall thickness [µm]	180 35
Sterilizing Agent	Steam
Sterile Barrier	Medical Grade Paper

BLOOD COMPARTMENT	
Blood Compartment Volume [ml]	91
Residual Blood Volume [ml]	<1

LIMITS FOR USE	
Maximum TMP [mmHg]	600
Operating blood flow range [ml/min]	200-600
Operating dialysate flow range [ml/min]	300-800

STORAGE CONDITIONS	
Storage conditions	<30 °C; <86 °F

INDICATIONS FOR USE	
Indications For Use	Hemodialysis only Not for Hemodiafiltration, Hemofiltration, Isolated UF

DIALYSIS FLUID QUALITY REQUIREMENTS[2]	
Minimum requirements[2]	Standard Dialysis Fluid Quality ISO 11663:2014 standard

PERFORMANCES*	
UF-coefficient** [ml/(h-mmHg)]	48
Pressure Drop – Blood Compartment [mmHg]	
Qb=200	≤90
Qb=300	≤130
Qb=400	≤170
Qb=500	≤210
Qb=600	≤250
Pressure Drop – Dialysate Compartment [mmHg]	
Qd=300	≤20
Qd=500	≤30
Qd=800	≤50

IN-VITRO CLEARANCES (at UF = 0 ml/min)

	Qb / Qd	ml/min
Urea (60 Da)	200/500	198
	300/500	282
	400/500	344
	400/800	376
	500/800	445
Phosphate (95 Da)	200/500	192
	300/500	261
	400/500	311
	400/800	345
	500/800	400
Creatinine (113 Da)	200/500	194
	300/500	269
	400/500	323
	400/800	357
	500/800	416
Vitamin B12 (1.4 kDa)	200/500	164
	300/500	207
	400/500	239
	400/800	267
	500/800	301

	Qb / Qd	ml/min
Inulin (5.2 kDa)	200/500	133
	300/500	161
	400/500	183
	400/800	204
	500/800	225
Cytochrome C (12 kDa)	200/500	122
	300/500	146
	400/500	165
	400/800	183
	500/800	202
Myoglobin (17 kDa)	200/500	104
	300/500	123
	400/500	137
	400/800	152
	500/800	166

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, amended by Directive 2007/47/EC)

* According to ISO 8637:
Measured with bovine blood, Hct 32%, Pct 60g/l, 37°C, UF = 120 ml/min

** According to ISO 8637:
UF-coefficient: measured with bovine blood, Hct 32%, Pct 60g/l, 37°C
Pressure drop blood: measured with bovine blood, Hct 32%, Pct 60g/l, 37°C, UF = 0 ml/min. Pressure drop dialysate: measured with dialysate

1. Boschetti-de-Fierro A, et al. MCO membranes: Enhanced Selectivity in High-Flux Class. Abstract accepted at the 52nd EDTA-ERA congress. London (United Kingdom). 2015. [Abstract FP478]
2. MCO-PERCOM (HD and HDF): Kirsch A et al. ERA-EDTA 2016 Abstract SP416 and Krieter D et al. ERA-EDTA 2016 Abstract MP464
3. Hulko M, et al. Dialysis membrane pore size does not determine LPS retention. Abstract accepted at the 52nd EDTA-ERA congress. London (United Kingdom). 2015. [Abstract FP516]

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