EXPANDED HD (HDx)

Baxter

theranova 400

HDx THERAPY ENABLED BY THERANOVA

The new HDx therapy (expanded HD) is the next evolution in hemodialysis, as it effectively targets the removal of large middle molecules.[1] Indeed, many of them are linked to the development of inflammation, cardiovascular disease, and other co-morbidities in dialysis patients.[2] Not only can HDx therapy provide HDF performance and beyond in the removal of conventional middle and large middle molecules, it does so using regular HD workflow and infrastructure.[3]

The HDx therapy is enabled by the THERANOVA* dialyzer featuring an innovative membrane that combines a higher permeability than regular high-flux dialyzers with effective selectivity for large proteins.[4,5]

HDF PERFORMANCE AND BEYOND, AS SIMPLE AS HD[3]

- Markedly greater clearances and intradialytic reduction ratios for middle molecules than regular HD – at ordinary blood flow rates
- Equivalent removal of small and conventional middle molecules to high-volume HDF – Greater removal possible for large middle molecules
- Albumin removal limited to between 1 and 4 grams
- Compatible with any HD monitor[6,7] and with standard dialysis fluid quality[8]

SIEVING PROFILE CLOSER TO THE NATURAL KIDNEY

An innovative membrane and dialyzer design that combines[4,5]:

- High permeability to middle molecules
- Effective selectivity by size exclusion
- Augmented internal filtration
- Similar retention of endotoxins as other dialysis membranes of the same material[6]

TYPICAL PATIENT PROFILE: **PATIENTS BELIEVED TO BENEFIT FROM GREATER REMOVAL OF LARGER UREMIC TOXINS**

*** Do not use THERANOVA dialyzers in HDF or HF mode**

Making possible personal.

The theranova 400 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
Before blood exposure[4] MWCO (cut-off) [kDa] MWRO (rentation onset) [kDa]	 56 +/-3 9.4 +/- 0.2
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

DIALYSIS FLUID QUALITY REQUIREMENTS[3,4]	
Minimum Requirements	Standard Dialysis Fluid Quality ISO 11663:2014 or ANSI/AAMI RD62 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
Sieving Coefficients* (%)	
Inulin (5,2 kDa)	100
β-2-microglobulin (11,8 kDa)	100
Myoglobin (17 kDa)	90
Albumin (66,4 kDa)	0,8

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

* 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. Sieving coefficients: measured with human plasma, Qb = 300 mL/min, UF = 60 mL/min

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

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 0086

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2. Hutchison CA, et al. The Rationale for Expanded Hemodialysis Therapy (HDx). Contrib Nephrol 2017; 191:142-52
3. Kirsch AH, et al. Performance of hemodialysis with novel medium cut-off dialyzers. Nephrol Dial Transpl 2017; 32(1):165-72
4. Boschetti-de-Fierro A, et al. MCO membranes: Enhanced Selectivity in High-Flux Class. Scientific Reports 2015; 5:18448
5. Zweigart C, et al. Medium cut-off membranes - closer to the natural kidney removal function. Int J Artif Organs 2017; 40(7):328-334
6. Baxter. Data on file. Theranova Limited Controlled Distribution Report 2016
7. Baxter. Theranova 400/500 Instructions For Use. N50 648 rev 003, 2017-05-29
8. Schepers E, 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

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