

theranova⁵⁰⁰

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 middle and larger 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 HD³

- 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 larger middle molecules
- Albumin removal limited to between 1 and 4 grams
- Compatible with any HD monitor^{6,7} and with standard dialysis fluid quality⁸

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 material⁶



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

* Do not use THERANOVA dialyzers in HDF or HF mode



The theranova⁵⁰⁰ 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 exposure⁴	
MWCO (cut-off) [kDa]	56 +/- 3
MWRO (rentation onset) [kDa]	9.4 +/- 0.2
Effective Membrane Area [m ²]	2.0
Fiber Dimension	
– Inner diameter [µm]	180
– Wall thickness [µm]	35
Sterilizing Agent	STEAM
Sterile Barrier	Medical Grade Paper

BLOOD COMPARTMENT	
Blood Compartment Volume [ml]	105
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)]	59

Pressure Drop – Blood Compartment [mmHg]	
Qb=200	≤80
Qb=300	≤120
Qb=400	≤160
Qb=500	≤200
Qb=600	≤240

Pressure Drop – Dialysate Compartment [mmHg]	
Qd=300	≤15
Qd=500	≤25
Qd=800	≤40

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	199
	300/500	285
	400/500	351
	400/800	381
	500/800	454
Phosphate (95 Da)	200/500	194
	300/500	267
	400/500	320
	400/800	354
	500/800	413
Creatinine (113 Da)	200/500	196
	300/500	274
	400/500	331
	400/800	365
	500/800	428
Vitamin B12 (1.4 kDa)	200/500	169
	300/500	215
	400/500	249
	400/800	280
	500/800	317

	Qb / Qd	ml/min
Inulin (5.2 kDa)	200/500	139
	300/500	170
	400/500	193
	400/800	216
	500/800	241
Cytochrome C (12 kDa)	200/500	128
	300/500	155
	400/500	175
	400/800	196
	500/800	217
Myoglobin (17 kDa)	200/500	110
	300/500	130
	400/500	147
	400/800	163
	500/800	180

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)

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