

Theranova

DESIGNED FOR:

HDx

MEMBRANE:

MCO [PAES/PVP, BPA-free]

HDx THERAPY ENABLED BY THERANOVA*

HDx therapy (expanded HD) is the next evolution in hemodialysis, as it targets the efficient removal of large middle molecules (25 kDa to < 60 kDa)! Indeed, many of them are linked to the development of inflammation, cardiovascular disease, and other co-morbidities in dialysis patients.² With HDx therapy, **Theranova** provides superior removal of large middle molecules compared with HD and HDF modalities and it does so using regular HD workflow and infrastructure.³

HDx therapy is enabled by the **Theranova** dialyzer series, which features an innovative membrane design that combines a permeability higher than that of regular high-flux dialyzers with effective selectivity for large proteins.^{4,5}

PROVIDE EXPANDED HD, RETAIN HD SIMPLICITY

- Markedly greater clearances and intradialytic reduction ratios for middle molecules than regular HD – at ordinary blood flow rates³
- Superior removal of large middle molecules compared to HD and HDF modalities³
- Limited albumin removal of between 1 and 4 grams per session³
- Compatible with any HD monitor^{6,7} and with standard dialysis

WITH BAXTER'S LATEST DIALYZER INNOVATION, COMING CLOSER TO THE NATURAL KIDNEY^{4,5}

- High permeability to large middle molecules
- Effective selectivity by size exclusion
- Augmented internal filtration
- Similar retention of endotoxins to other dialysis membranes of the same material⁸

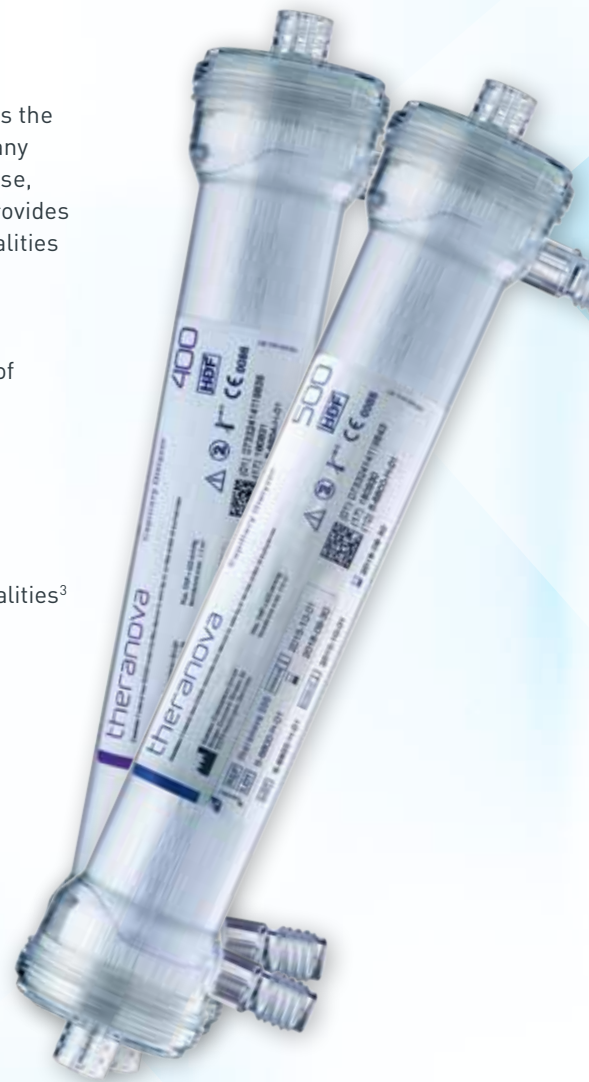
CLINICAL EFFICIENCY AND PATIENT-REPORTED OUTCOMES

- Pre-dialysis levels of beta 2 microglobulin and kappa and lambda free light chains were reduced after 3 and 6 months with HDx therapy using the **Theranova** dialyzer in a multi-centric observational study of 41 HD patients^{9,†}
- Restless Leg Syndrome criteria are reduced approximately 50% after 6 months for prevalent HD patients in a large observational study by Baxter.^{11,‡} A smaller before-after study found no difference in patient-reported symptom burden.^{10,‡‡}

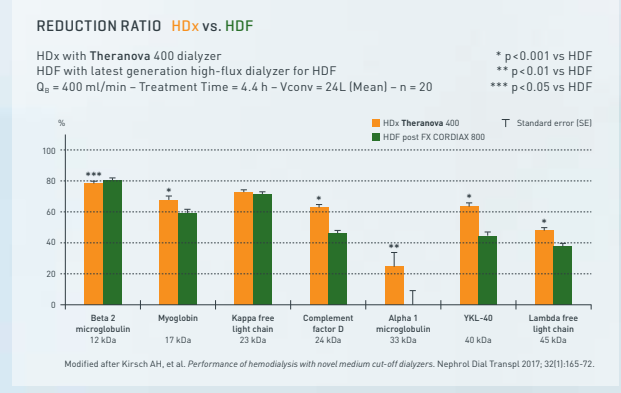
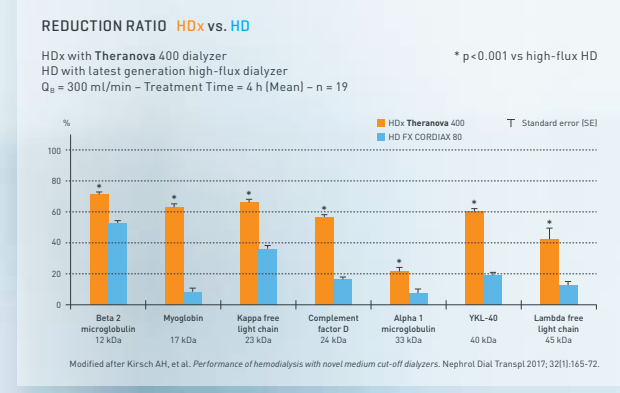
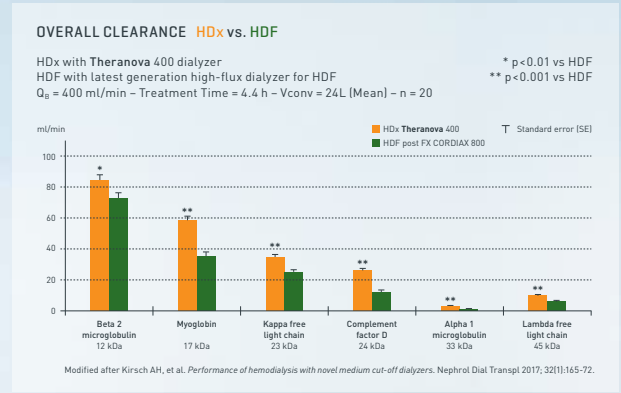
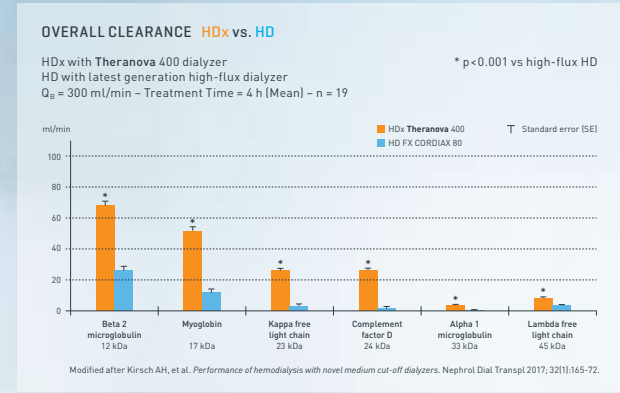
*** Do not use Theranova dialyzers in HDF or HF mode**

† Based on data presented in a congress abstract – see reference for details.

‡‡ Based on data presented in a congress abstract – see reference for details. Restless leg syndrome was only one of several secondary endpoints.



CLINICAL PERFORMANCE³



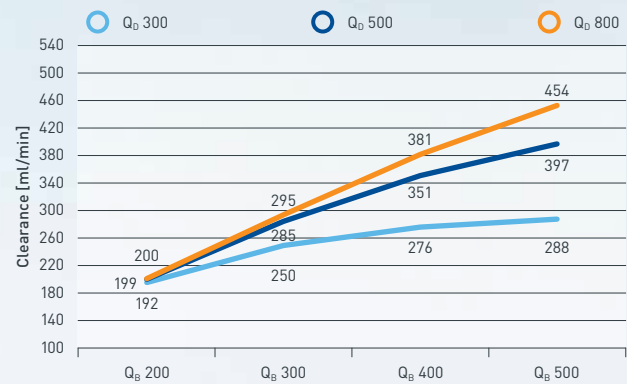
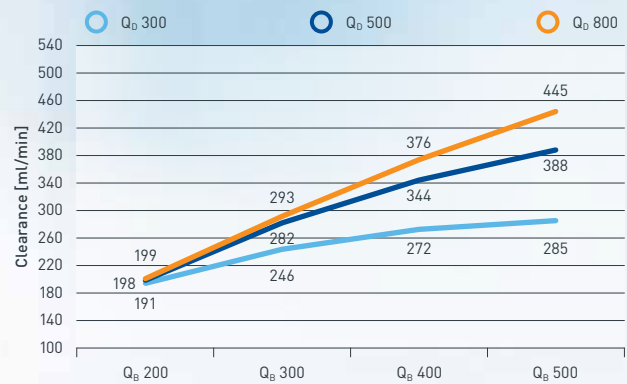
IN VITRO CLEARANCES

In vitro clearances are indicated in [ml/min] ± 10%

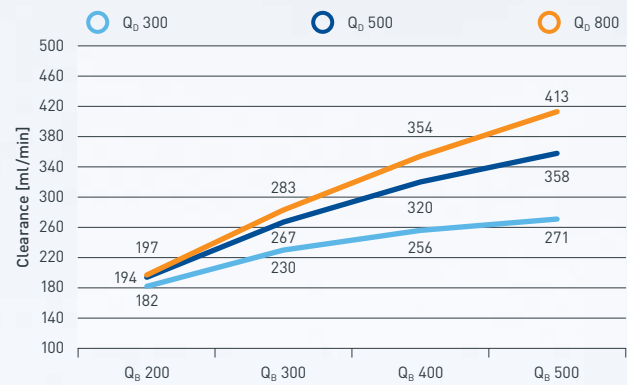
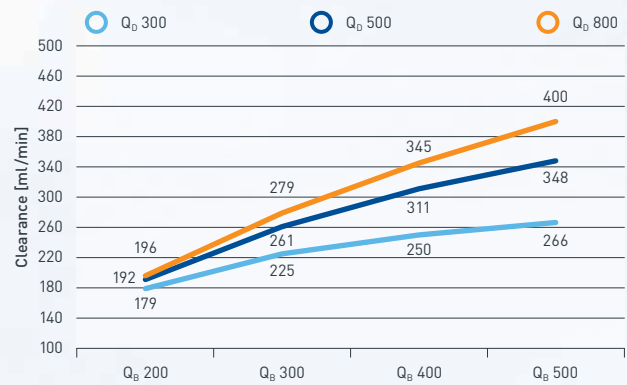
THERANOVA 400

THERANOVA 500

UREA
60 Da



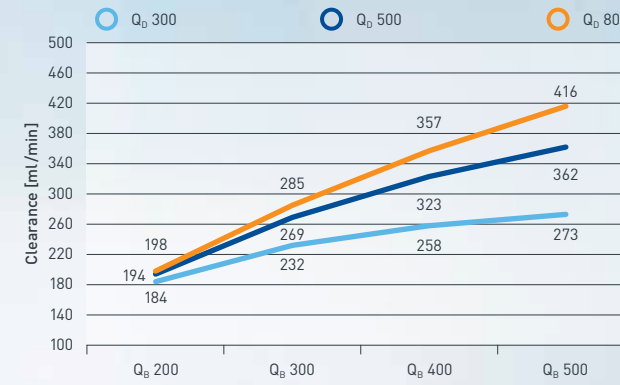
PHOSPHATE
95 Da



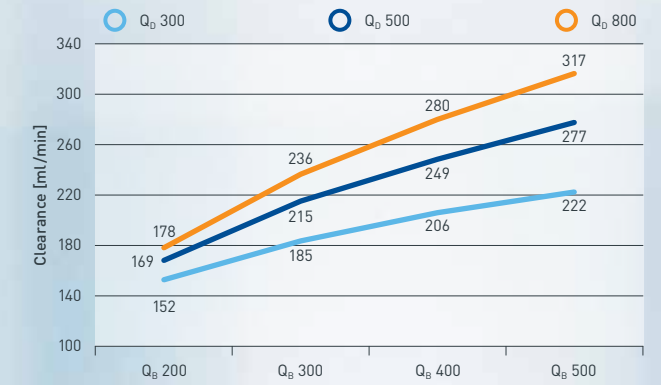
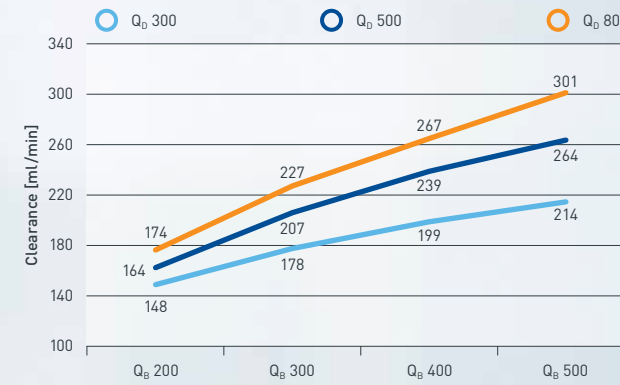
THERANOVA 400

THERANOVA 500

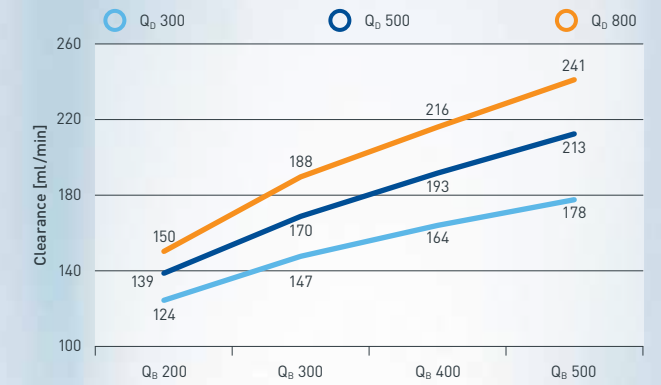
CREATININE
113 Da



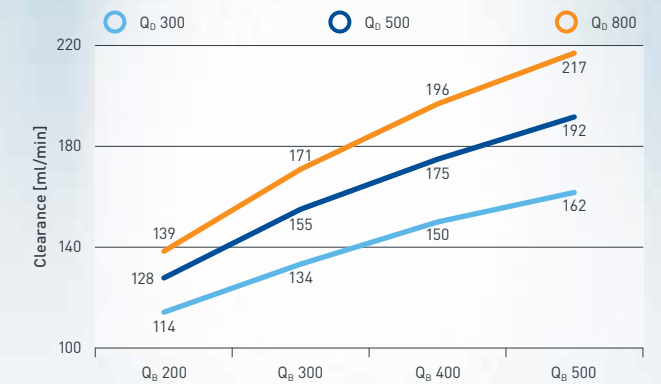
VITAMIN B12
1.4 kDa



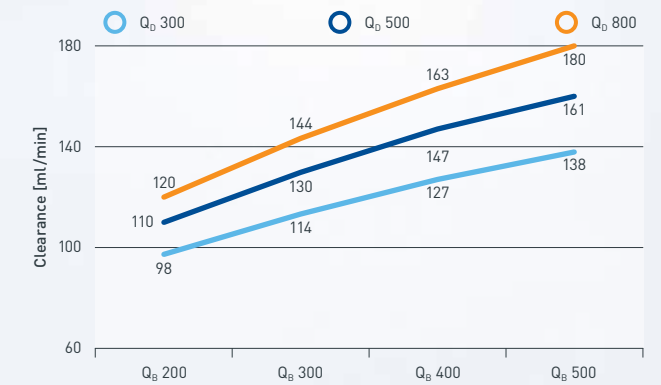
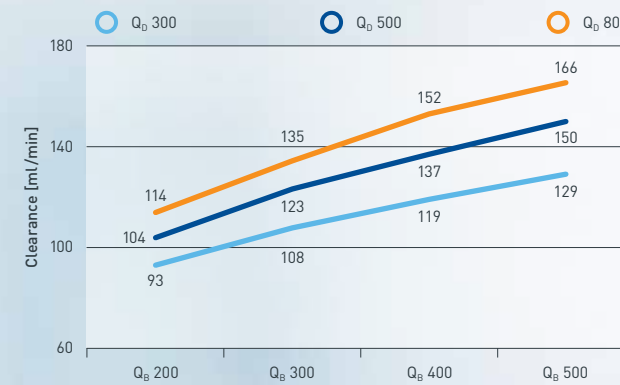
INULIN
5.2 kDa



CYTOCHROME C
12 kDa



MYOGLOBIN
17 kDa



THERANOVA SPECIFICATIONS

MATERIALS	THERANOVA 400	THERANOVA 500
Membrane	Medium Cut Off Polyarylethersulfone and Polyvinylpyrrolidone blend BPA-free	
Potting	Polyurethane (PUR)	
Housing	Polycarbonate (PC)	
Gaskets	Silicone rubber (SIR)	
Protection caps	Polypropylene (PP)	
Sterilization	Steam (inside-out)	
Sterile barrier	Tyvek	

SPECIFICATIONS		
UF-Coefficient (mL/(h*mmHg))*	48	59
KoA urea*	1482	1630
Blood Compartment volume (mL)	91	105
Minimum recommended priming volume (mL)	300	
Maximum TMP (mmHg)	600	
Recommended Q _B (mL/min)	200-600	250-600
Storage conditions	<30°C (or <86°F)	
Units per box	24	
Gross/net weight (g)	229/170	246/190

MEMBRANE		
Effective Membrane Area (m ²)	1.7	2.0
Fiber inner diameter (μm)	180	
Fiber wall thickness (μm)	35	
Sieving profile – before blood exposure ⁴		
MWCO [cut-off] [kDa]	56 +/- 3	
MWRO [retention onset] [kDa]	9.4 +/- 0.2	

SIEVING COEFFICIENTS*		
Vitamin B12 (1,4 kDa)	1.0	
Inulin (5,2 kDa)	1.0	
β ₂ -microglobulin (11,8 kDa)	1.0	
Myoglobin (17 kDa)	0.9	
Albumin (66,4 kDa)	0.008	

* According to EN 1283/ISO 8637:
 – 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
 – Sieving coefficients: measured with human plasma, Q_B=300 mL/min, UF=60 mL/min
 – Clearances In-Vitro: measured at UF=0 mL/min, ±10% [±20% Cyt. C, ±30% Myo.]

CLEARANCES IN VITRO (mL/min)*	THERANOVA 400	THERANOVA 500
Urea (60 Da) (Q_B-Q_D, mL/min)		
200/500	198	199
300/500	282	285
400/500	344	351
400/800	376	381
500/800	445	454
Phosphate (95 Da)		
200/500	192	194
300/500	261	267
400/500	311	320
400/800	345	354
500/800	400	413
Creatinine (113 Da)		
200/500	194	196
300/500	269	274
400/500	323	331
400/800	357	365
500/800	416	428
Vitamin B12 (1.4 kDa)		
200/500	164	169
300/500	207	215
400/500	239	249
400/800	267	280
500/800	301	317
Inulin (5.2 kDa)		
200/500	133	139
300/500	161	170
400/500	183	193
400/800	204	216
500/800	225	241
Cytochrome C (12 kDa)		
200/500	122	128
300/500	146	155
400/500	165	175
400/800	183	196
500/800	202	217
Myoglobin (17 kDa)		
200/500	104	110
300/500	123	130
400/500	137	147
400/800	152	163
500/800	166	180

For safe and proper use of the device, please refer to the Instructions for Use

- Ronco C, et al. *The rise of Expanded Hemodialysis*. Blood Purif 2017; 44:1-VIII.
- Hutchison CA, et al. *The Rationale for Expanded Hemodialysis Therapy (HDx)*. Contrib Nephrol 2017; 191:142-52.
- Kirsch AH, et al. *Performance of hemodialysis with novel medium cut-off dialyzers*. Nephrol Dial Transpl 2017; 32(1):165-72.
- Boschetti-de-Fierro A, et al. *MCO membranes: Enhanced Selectivity in High-Flux Class*. Scientific Reports 2015; 5:18448.
- Zweigart C, et al. *Medium cut-off membranes – closer to the natural kidney removal function*. Int J Artif Organs 2017; 40(7):328-334.
- Baxter. Data on file. *Theranova Limited Controlled Distribution Report*. 2016.
- Baxter. *Theranova 400/500 Instructions For Use*. N50 648 rev 003, 2017-05-29.
- Schepers E, Glorieux G, Eloit 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.
- Cantaluppi V, et al. *Removal of large-middle molecules on expanded hemodialysis (HDx): a multicentric observational study of 6 months follow-up*. ASN 2018 Kidney Week Abstract TH-PO357.
- Krishnasamy R, et al. *Trial evaluating mid cut-off value membrane clearance of albumin and light chains in hemodialysis patients (REMOVAL-HD): a safety and efficacy study*. ASN 2018 Kidney Week Abstract TH-PO353.
- Sanabria M, et al. *Quality of life reported by patients with expanded hemodialysis by the Theranova dialyzer in RTS Colombia*. ASN 2018 Kidney Week Abstract TH-PO296.

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)

CE 0086

Baxter

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