MEDIUM CUT-OFF MEMBRANE

Baxter

theranova 400

HDx THERAPY, ENABLED BY THE THERANOVA DIALYZER

The THERANOVA dialyzer, featuring an innovative membrane, effectively targets large middle molecules not efficiently removed by currently available dialysis treatments. It provides the opportunity for an expanded hemodialysis therapy, HDx, providing HDF performance and beyond in the removal of middle and larger middle molecules, using regular HD infrastructure.

HDF PERFORMANCE AND BEYOND, AS SIMPLE AS HD

- Markedly greater clearances and intradialytic reduction ratios than regular HD – at ordinary blood flow rates[1]
- Equivalent removal of small and conventional middle molecules to high-volume HDF – Greater removal possible for larger middle molecules[2]
- Albumin removal limited to between 1 and 4 grams[1,2]
- Compatible with any HD monitor[3] and with standard-quality dialysis fluid quality[4,5]

ACHIEVED THROUGH MEMBRANE INNOVATION

- Higher permeability[6,7]
- Enhanced selectivity by size exclusion[6,7]
- A step closer to the natural kidney[6,7]

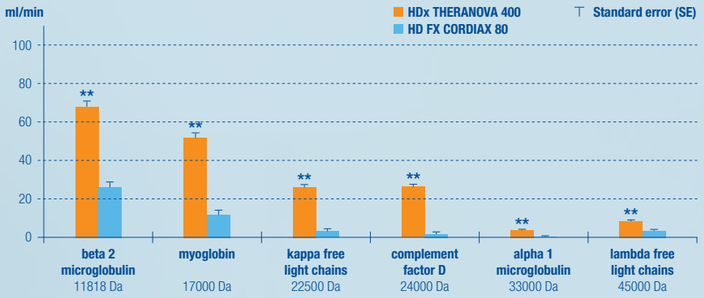
TYPICAL PATIENT PROFILE: **PATIENTS REQUIRING HIGHER CLEARANCES OF LARGER UREMIC TOXINS, WITHOUT ACCESS TO HDF**

Making possible personal.

CLINICAL PERFORMANCE[1,2]

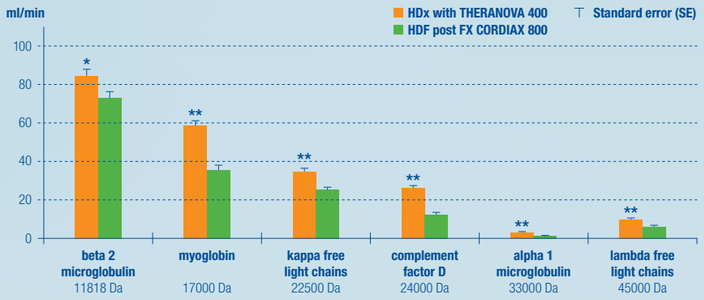
OVERALL CLEARANCE HDx VS. HD[1]

HDx with THERANOVA 400 dialyzer HD with latest generation high-flux dialyzer ** p<0.001 vs high-flux HD
Qb = 300 ml/min – Treatment Time = 4 h (Mean) – n = 19



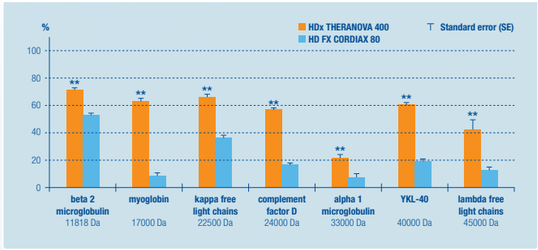
OVERALL CLEARANCE HDx VS. HDF[2]

HDx with THERANOVA 400 dialyzer HDF with latest generation high-flux dialyzer for HDF * p<0.01 vs HDF
Qb = 400 ml/min – Treatment Time = 4.4 h – Vconv = 24L (Mean) – n = 20 ** p<0.001 vs HDF



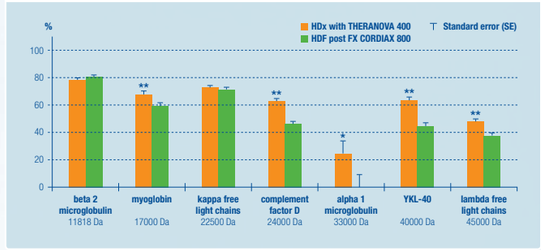
REDUCTION RATIO HDx VS. HD[1]

HDx with THERANOVA 400 dialyzer HD with latest generation high-flux dialyzer ** p<0.001 vs high-flux HD
Qb = 300 ml/min – Treatment Time = 4 h (Mean) – n = 19



REDUCTION RATIO HDx VS. HDF[2]

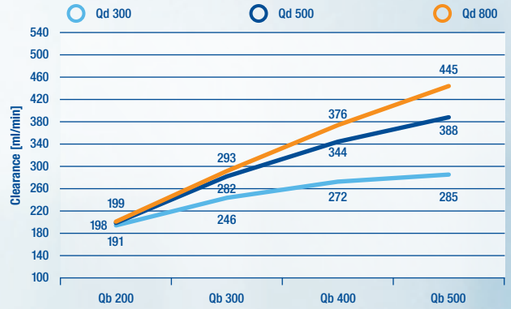
HDx with THERANOVA 400 dialyzer HDF with latest generation high-flux dialyzer for HDF * p<0.01 vs HDF
Qb = 400 ml/min – Treatment Time = 4.4 h – Vconv = 24L (Mean) – n = 20 ** p<0.001 vs HDF



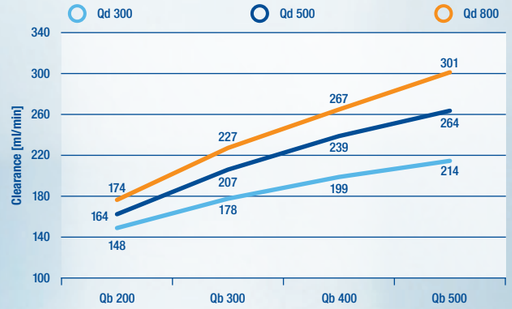
IN VITRO CLEARANCES

In vitro clearances are indicated in (ml/min) ± 10%

UREA
60 Da

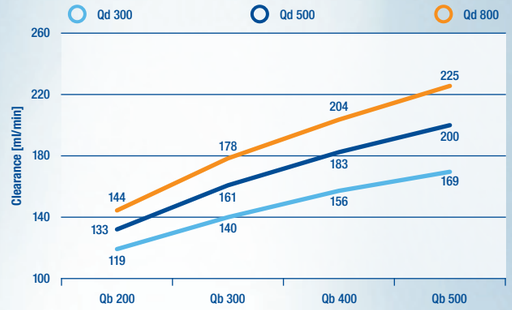


VITAMIN B12
1.4 kDa

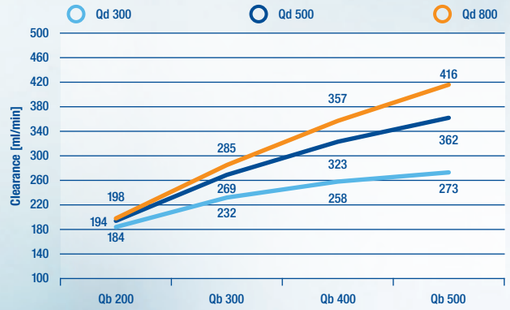


PHOSPHATE
95 Da

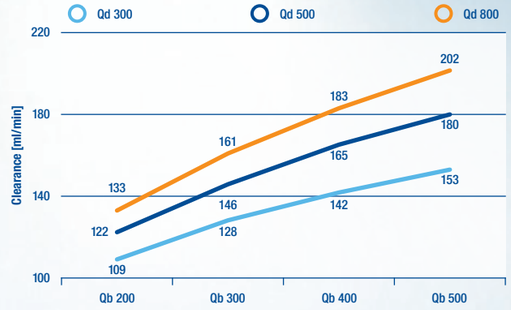
INULIN
5.2 kDa



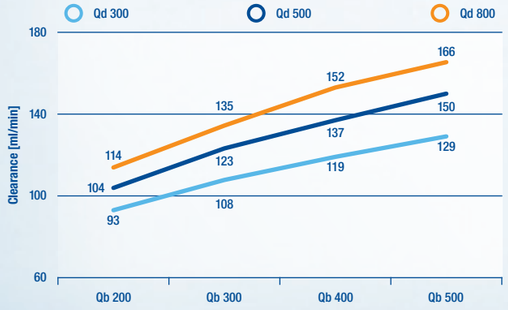
CREATININE
113 Da



CYTOCHROME C
12 kDa



MYOGLOBIN
17 kDa



The theranova 400 Dialyzer

INDICATIONS FOR USE	
Indications For Use	**THERANOVA dialyzers are indicated for treatment of chronic and acute renal failure by hemodialysis. Do not use for hemodia-filtration, hemofiltration due to higher permeability of larger molecular weight proteins such as albumin**

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 For the safe and proper use of device, please refer the Instructions for Use
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[4,5]	
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

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

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

* 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. Kirsch A, et al. *Large Middle Molecule Removal During Hemodialysis Using A Novel Medium Cutoff Dialyzer.* ERA-EDTA 2016, Abstract SP416
2. Krieter D, et al. *Clinical Performance of Medium Cutoff Hemodialysis versus High-Flux Hemodialysis and High-Volume Hemodiafiltration.* ERA-EDTA 2016, Abstract MP464
3. Baxter. Data on file. *Theranova Limited Controlled Distribution Report 2016*
4. Baxter. Theranova 400/500 Instructions For Use. N50 648
5. Hulko M, et al. *Dialysis membrane pore size does not determine LPS retention.* ERA-EDTA 2015, Abstract FP516
6. Boschetti-de-Fierro A, et al. *MCO membranes: Enhanced Selectivity in High-Flux Class.* Scientific Reports (2015); 5: 18448
7. Krause B, et al. *Highly selective membranes for blood purification.* Euromembrane Congress 2015, Abstract E139

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