Baxter
Theranova
DIALYZER

# Theranova 400

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).[1] 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 rates.[3]
- Superior removal of large middle molecules compared to HD and HDF modalities[3]
- Limited albumin removal of between 1 and 4 grams per session[3]
- 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 material[8]

## 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

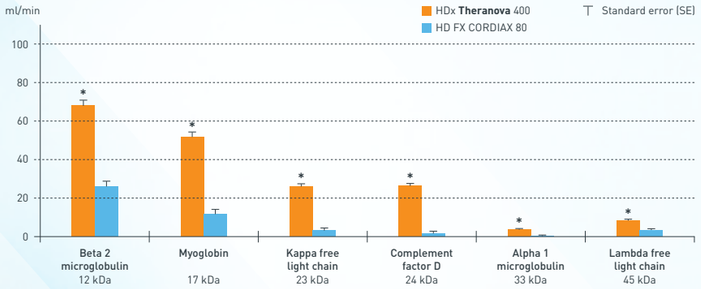
‡ Based on data presented in a congress abstract – see reference for details.
‡‡ Based on data presented in a congress abstract – see reference for details. Restless leg syndrome was only one of several secondary endpoints.

# CLINICAL PERFORMANCE[3]

## OVERALL CLEARANCE HDx vs. HD

HDx with **Theranova** 400 dialyzer
HD with latest generation high-flux dialyzer
$Q_B$ = 300 ml/min – Treatment Time = 4 h (Mean) – n = 19

* p<0.001 vs high-flux HD

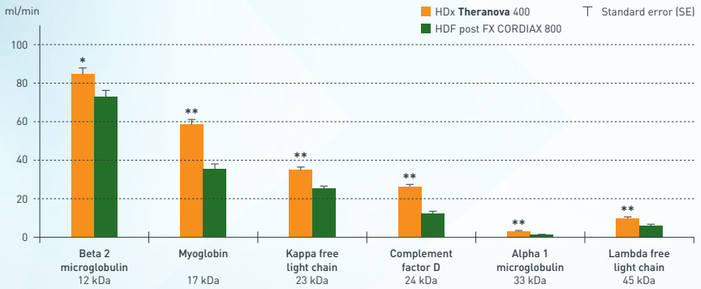



Modified after Kirsch AH, et al. *Performance of hemodialysis with novel medium cut-off dialyzers.* Nephrol Dial Transpl 2017; 32(1):165-72.

## OVERALL CLEARANCE HDx vs. HDF

HDx with **Theranova** 400 dialyzer
HDF with latest generation high-flux dialyzer for HDF
$Q_B$ = 400 ml/min – Treatment Time = 4.4 h – Vconv = 24L (Mean) – n = 20

* p<0.01 vs HDF
** p<0.001 vs HDF

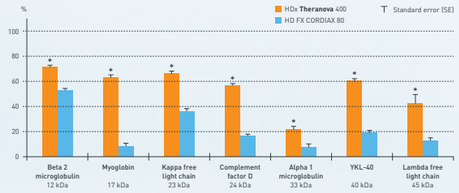



Modified after Kirsch AH, et al. *Performance of hemodialysis with novel medium cut-off dialyzers.* Nephrol Dial Transpl 2017; 32(1):165-72.

## REDUCTION RATIO HDx vs. HD

HDx with **Theranova** 400 dialyzer
HD with latest generation high-flux dialyzer
$Q_B$ = 300 ml/min – Treatment Time = 4 h (Mean) – n = 19

* p<0.001 vs high-flux HD

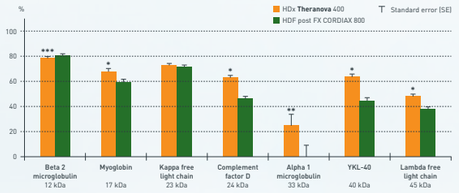



Modified after Kirsch AH, et al. *Performance of hemodialysis with novel medium cut-off dialyzers.* Nephrol Dial Transpl 2017; 32(1):165-72.

## REDUCTION RATIO HDx vs. HDF

HDx with **Theranova** 400 dialyzer
HDF with latest generation high-flux dialyzer for HDF
$Q_B$ = 400 ml/min – Treatment Time = 4.4 h – Vconv = 24L (Mean) – n = 20

* p<0.001 vs HDF
** p<0.01 vs HDF
*** p<0.05 vs HDF

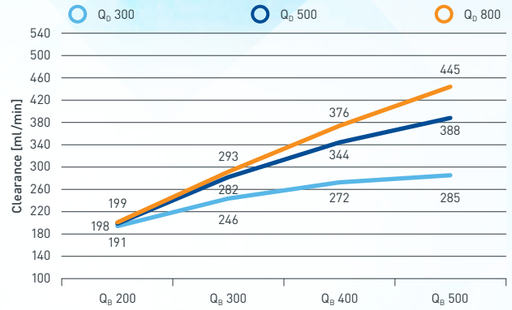



Modified after Kirsch AH, et al. *Performance of hemodialysis with novel medium cut-off dialyzers.* Nephrol Dial Transpl 2017; 32(1):165-72.

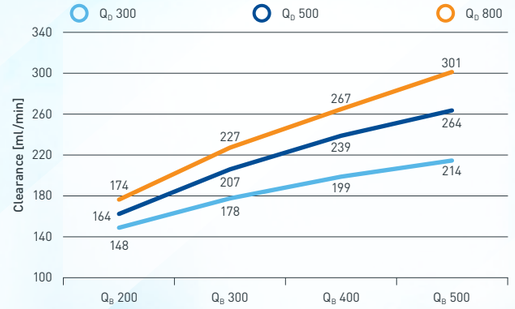
# IN VITRO CLEARANCES

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

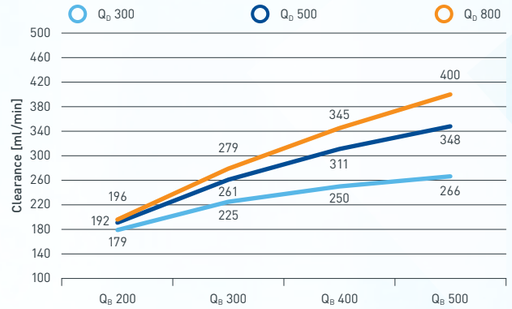
## UREA
60 Da



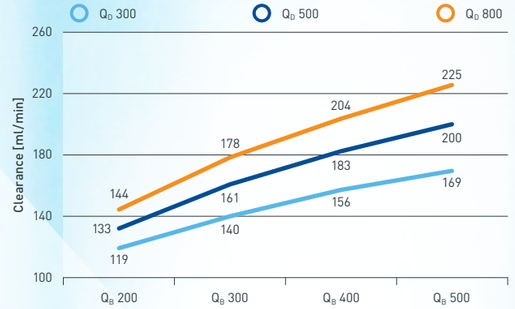

## VITAMIN B12
1.4 kDa



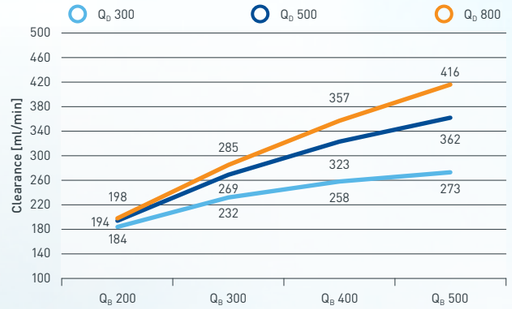

## PHOSPHATE
95 Da



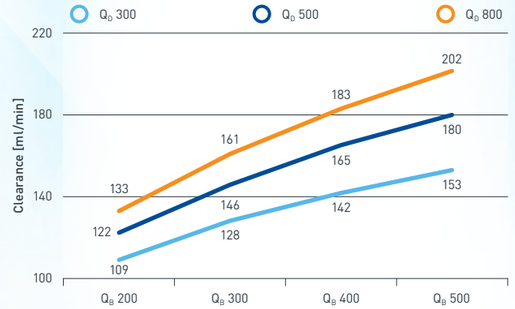

## INULIN
5.2 kDa



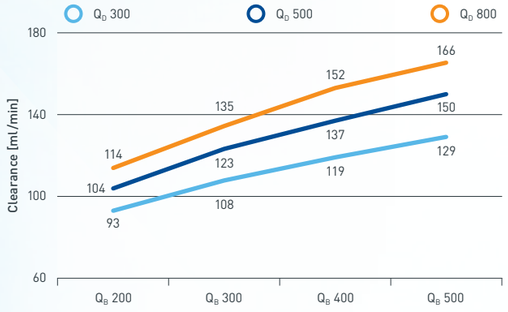

## CREATININE
113 Da




## CYTOCHROME C
12 kDa




## MYOGLOBIN
17 kDa



# **THERANOVA 400** SPECIFICATIONS

| MATERIALS | **THERANOVA** 400 |
|---|---|
| Membrane | Medium Cut Off<br>Polyarylethersulfone and Polyvinylpyrrolidone blend<br>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 |
| KoA urea* | 1482 |
| Blood Compartment volume (mL) | 91 |
| Minimum recommended priming volume (mL) | 300 |
| Maximum TMP (mmHg) | 600 |
| Recommended $Q_B$ (mL/min) | 200-600 |
| Storage conditions | <30°C (or <86°F) |
| Units per box | 24 |
| Gross/net weight (g) | 229/170 |

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

| SIEVING COEFFICIENTS* | |
|---|---|
| Vitamin B12 (1,4 kDa) | 1.0 |
| Inulin (5,2 kDa) | 1.0 |
| $\beta_2$-microglobulin (11,8 kDa) | 1.0 |
| Myoglobin (17 kDa) | 0.9 |
| Albumin (66,4 kDa) | 0.008 |

| CLEARANCES IN VITRO (mL/min)* | **THERANOVA** 400 |
|---|---|
| **Urea (60 Da)** ($Q_B$-$Q_D$, mL/min) | |
| 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 |
| **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 |

* 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.)

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


1. Ronco C, et al. *The rise of Expanded Hemodialysis*. Blood Purif 2017; 44:I-VIII.
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, Glorieux G, Eloot 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.
9. 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.
10. 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.
11. 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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