**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. Indeed, many of them are linked to the development of inflammation, cardiovascular disease, and other co-morbidities in dialysis patients. 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.

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.

**HDF PERFORMANCE AND BEYOND, AS SIMPLE AS HD**
- 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 and with standard dialysis fluid quality

**SIEVING PROFILE CLOSER TO THE NATURAL KIDNEY**
An innovative membrane and dialyzer design that combines:
- 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

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

* Do not use THERANOVA dialyzers in HDF or HF mode
COMPONENTS | MATERIALS
--- | ---
Membrane | Polyethersulfone / Polyvinylpyrrolidone (PAES / PVP – BPA-free)
Potting | 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* | 56 +/- 3
MWCO (cut-off) [kDa] | 9.4 +/- 0.2
Effective Membrane Area [m²] | 1.7
Fiber Dimension
– Inner diameter [µm] | 180
– Wall thickness [µm] | 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
Minimum Requirements | Standard Dialysis Fluid Quality
ISO 11663:2014 or ANSI/AAMI KD62 standard

IN-VITRO CLEARANCES (at UF = 0 ml/min)

<table>
<thead>
<tr>
<th>Substance</th>
<th>Qb / Qd</th>
<th>ml/min</th>
</tr>
</thead>
<tbody>
<tr>
<td>Urea (60 Da)</td>
<td>200/500</td>
<td>198</td>
</tr>
<tr>
<td></td>
<td>300/500</td>
<td>282</td>
</tr>
<tr>
<td></td>
<td>400/500</td>
<td>344</td>
</tr>
<tr>
<td></td>
<td>400/800</td>
<td>376</td>
</tr>
<tr>
<td></td>
<td>500/800</td>
<td>445</td>
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<tr>
<td>Phosphate (95 Da)</td>
<td>200/500</td>
<td>192</td>
</tr>
<tr>
<td></td>
<td>300/500</td>
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<td></td>
<td>500/800</td>
<td>400</td>
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<tr>
<td></td>
<td>600/800</td>
<td>478</td>
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<tr>
<td>Creatinine (113 Da)</td>
<td>200/500</td>
<td>194</td>
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<tr>
<td></td>
<td>300/500</td>
<td>269</td>
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<td>400/500</td>
<td>338</td>
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<tr>
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<td>400/800</td>
<td>357</td>
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<td>416</td>
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<tr>
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<td>600/800</td>
<td>488</td>
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<tr>
<td>Vitamin B12 (1.4 Da)</td>
<td>200/500</td>
<td>164</td>
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<tr>
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<td>300/500</td>
<td>207</td>
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<td>239</td>
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<tr>
<td></td>
<td>400/800</td>
<td>267</td>
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<tr>
<td></td>
<td>500/800</td>
<td>301</td>
</tr>
</tbody>
</table>

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

Sievng 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


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

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


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