Optiflux[®] Dialyzers

Trusted in More Treatments Than Any Other Brand

The Physician's Choice -

The #1 Prescribed Dialyzer Brand in the U.S.

Optiflux[®] dialyzers continue to be the leading dialyzer brand in the United States, with more prescriptions filled than all other dialyzer manufacturers combined. Optiflux dialyzers are the time-tested choice for over twenty years for nephrologists seeking high performance, biocompatible dialyzers with consistent small and middle molecule clearance.

Featuring improved convenience to use in the arterial upright or inverted position[†]



Product Code	Optiflux F160NRe 0500316E	Optiflux F180NRe 0500318E	Optiflux F200NRe 0500320E	Optiflux F250NRe 0500325E		
Surface Area (m²)	1.5	1.7	1.9	2.5		
Prime Volume (mL)	87	102	113	142		
Kuf (in vitro bovine, Hct 32%)	61	76	74	111		
KoA Urea (at QB300/ QD500 mL/min.)	1167	1321	1415	1714		
Middle Molecule Performance* (mL/min)	74	87	83	113		
Membrane Wall Thickness (microns)	35	35	35	30		
Inner Diameter (microns)	185	185	185	185		
Membrane	Advanced Fresenius Polysulfone®					
Potting Compound	Polyurethane					
Housing	Polycarbonate					
Sterilization	Electron Beam					

Dialyzer Clearances	Urea	Creatinine	Phosphate	Vitamin B12
Qb (mL/min)	300 400 400 400 500 600	300 400 400 400 500 600	300 400 400 400 500 600	300 400 400 400 500 600
Qd (mL/min)	500 500 600 800 800 800	500 500 600 800 800 800	500 500 600 800 800 800	500 500 600 800 800 800
Optiflux F160NRe	271 317 332 349 394 423	242 274 288 302 331 350	241 279 290 304 340 369	153 162 167 173 180 183
Optiflux F180NRe	277 328 344 360 412 449	253 290 304 320 355 379	253 297 307 321 362 396	169 181 189 195 207 212
Optiflux F200NRe	280 333 348 365 420 465	259 298 311 328 366 399	254 298 309 324 366 398	177 189 195 203 215 231
Optiflux F250NRe	287 349 366 381 446 496	273 321 338 357 404 439	274 328 341 356 409 452	205 226 235 248 264 276

Clearance data is in vitro with UFR = 0 mL/min. Data on file.

* Lysozyme (MW 14,300) used as a surrogate for middle molecule clearance.

In vivo performance may differ. Sodium used as a marker for urea. † Applies to only the Optiflux high-flux electron beam series.

Optiflux[®] Dialyzers Setting the Standard in Membrane Technology

BIOCOMPATIBILITY

- $\,$ $\,$ Unique asymmetric, dense fiber wall architecture adsorbs endotoxins reducing exposure of the patient to bacterial toxins 1,2,3
- Low activation of inflammatory factors like TNF-alpha and cytokines⁴
- Efficiently clears β-2 microglobulin and Cystatin C^{1,4}
- · Microcrimping creates uniform waves in the fiber. This allows:
 - High packing density
 - · Improved clearance efficiency (KoA Urea) in most models
 - Minimizes dialysate channeling 5,6

REDUCED SALINE PRIME

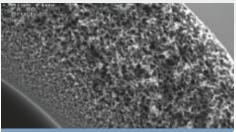
- Up to 40% reduction in saline fill requirement [‡]
- · Potential to use one bag of saline per treatment

IMPROVED CONVENIENCE

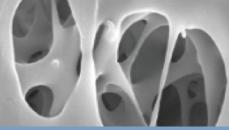
• Flexibility for use during the treatment in the traditional arterial upright or inverted position

EXPERIENCE, EXPERTISE, AND UNPARALLELED LEADERSHIP

- Most experienced manufacturer of the synthetic membrane dialyzer
 Over twenty years of high-flux, synthetic dialyzer manufacturing experience
- Over 400 million treatments performed with the Optiflux dialyzers ⁷
- Unsurpassed quality
 - Consistently low complaint rate ⁸
 - Historically less than 9.0 reportable incidents per million dialyzers ⁹
- Unequalled Capacity
 - World's largest dialyzer production facility (Ogden, UT) ¹⁰
- Order Fill Rate 98.2%
- Fully-integrated HD system-machines, dialyzers, bloodlines, concentrates and modules specifically tested and designed to work together



Unique Dense Fiber Wall Architecture



Rigorous Barrier for Endotoxins



Fresenius Renal Technologies, a division of Fresenius Medical Care North America 920 Winter Street, Waltham, MA 0245 I 800-662-1237 | www.fmcna-dialyzers.com

300 mL saline for initial fill of dialyzer and bloodlines for priming of Optiflux high flux electron beam sterilized dialyzers vs. 500 mL saline for Optiflux ethylene oxide sterilized dialyzers

REFERENCES

- 1. Michael Henrie, Cheryl Ford, Eric Stroup and Chih-Hu Ho (2011). Dialysis Membrane Manipulation for Endotoxin Removal, Progress in Hemodialysis From Emergent Biotechnology to Clinical Practice, Prof. Angelo Carpi (Ed.), ISBN: 978-953-307-377-4, InTech.
- 2. Weber, Viktoria et al. *Pyrogen Transfer across High and Low Flux Hemodialysis Membrane.* Artificial Organs 28, no. 2 (February 2004): 210-17.
- 3. Henrie, Michael et al. *In Vitro Assessment of Dialysis Membrane as an Endotoxin Transfer Barrier: Geometry, Morphology, and Permeability." Artificial Organs 32, no. 9 (September 2008): 1-10.
- 4. Hoffmann, Ute et al. "Induction of Cytokines and Adhesion Molecules in Stable Hemodialysis Patients: Is There an Effect of Membrane Material?" American Journal of Nephrology 23, no. 6 (November/December 2003): 442-47.
- 5. Leypoldt, John K et al. *Hollow Fiber Shape Alters Solute Clearances in High Flux Hemodialyzers." ASAIO Journal 49, no. 1 (January/February 2003): 81-87.
- 6. Ronco, Claudio et al. "Flow Distribution Analysis by Helical Scanning in Polysulfone Hemodialyzers: Effects of Fiber Structure and Design on Flow Patterns and Solute Clearances." Hemodialysis International 10, no. 4 (October 2006): 380-88.
- 7. FMCNA Results: Data as of March 2016
- 8. 2015 FMCNA Results
- 9. Source FDA Maude site: (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfmaude/search.cfm) 2010-2015, Data as of 4/12/2016. Past results are not an indicator of future performance
- 10. As of April 2016
- 11. FMCNA Results as of March 2016

Indications for Use: Optiflux FI60NRe, FI80NRe, F200NRe and F250NRe dialyzers are intended for patients with acute or chronic renal failure when conservative therapy is judged to be inadequate.

Caution: Federal (US) law restricts these devices to sale by or on order of a physician.

Note: Read the Instructions for Use for safe and proper use of these devices. For a complete description of hazards, contraindications, side effects and precautions, see full package labeling at www. fmcna.com.

Note: The applicability of a dialyzer for a particular treatment is the responsibility of the physician. In rare cases, thrombocytopenia or hypersensivity reactions including anaphylactic or anaphylactoid reactions to the dialyzer, or other elements in the extracorporeal circuit may occur during hemodialysis.

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