

# Technical Data; B3 Series Filtrizer

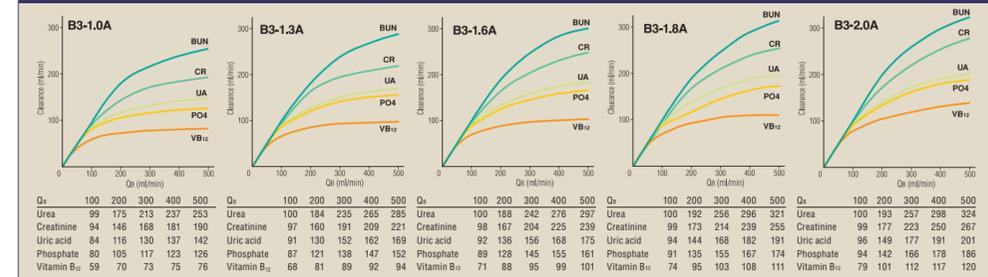
Type		B3-1.0A	B3-1.3A	B3-1.6A	B3-1.8A	B3-2.0A	
<b>Housing</b>	Material	Polystyrene					
	Length (mm)	283					
	Diameter (mm)	36	41	45	45	53	
	Weight (filled) (g)	350	420	520	520	660	
	Blood volume (mL)	61	76	95	105	118	
<b>Fibers</b>	Filled fluid	Sterile water					
	Material	Polymethylmethacrylate (PMMA)					
	Quantity	8,400	10,900	13,300	14,700	16,500	
	Inside diameter (μm)	200					
	Membrane thickness (μm)	20					
	Effective surface area (m <sup>2</sup> )	1.0	1.3	1.6	1.8	2.0	
<b>Potting</b>	Material	Polyurethane					
	Sterilization	Gamma-ray irradiation					
<b>Clearance in vitro (mL/min)*</b>	Urea	designed	175	184	188	192	193
		not less than	157	168	173	176	177
	Creatinine	designed	146	160	167	173	177
	Uric acid	designed	116	130	136	144	149
	Phosphate	designed	105	121	128	135	142
	Vitamin B <sub>12</sub>	designed	70	81	88	95	101
	<b>UFR in vitro (mL/hr, at 13.3kPa (100mmHg))**</b>		700	880	870	990	1,100

\* Clearance are data with aqueous solution.  
 Q<sub>b</sub>: 200 ±4mL/min, Q<sub>d</sub>: 500 ±10mL/min, TMP: 13.3k ±1.3Pa (100 ±10mmHg)  
 Temp.: 37 ±1°C

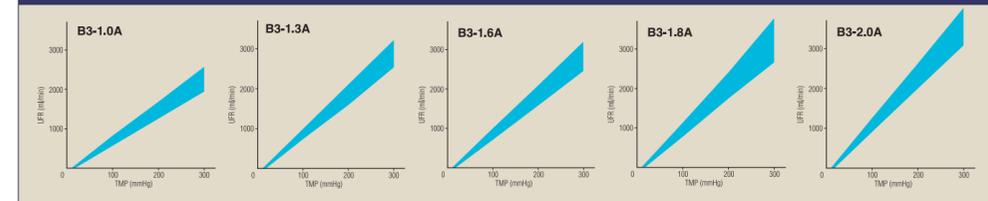
Allowable ranges:  
 Blood volume: ±13%  
 Designed clearance: Urea upper limit: +6%, Urea lower limit: see above, Creat: ±6%, Others: ±13%  
 UFR in vitro: ±15%

\*\* UFR is typical data with bovine blood. (Ht 30 ±3%, TP 6 ±0.5g/dL)  
 Q<sub>b</sub>: 200 ±4mL/min, TMP: 13.3 ±1.3kPa (100 ±10mmHg), Temp.: 37 ±1°C

## Clearance



## UFR \*\*



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CE 0123

EC REP

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Printed in Japan 1009G

**TORAY**

# FILTRYZER® B3 SERIES

Hollow Fiber Dialyzer



PMMA for better quality of life

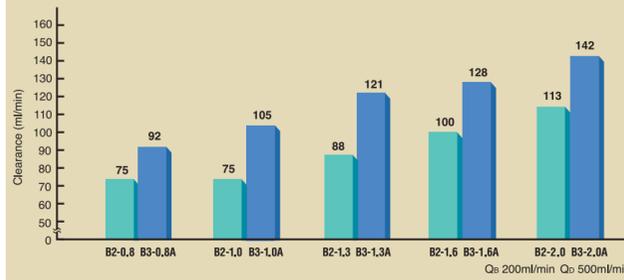


**The PMMA membrane offers excellent clinical benefits to renal failure patients.**

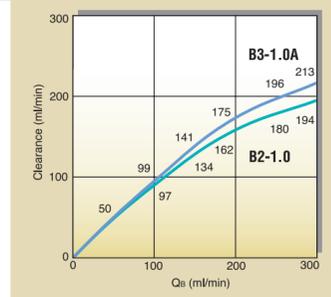
## Filterzyer B3 Series for Higher Clearance in Small and Middle Molecular Weight Substances and Phosphate

The Filterzyer B3 series gives improved performance for the removal of small and middle molecular weight substances, and efficiently removes a wide variety of uremic toxins from such small molecular weight substances as BUN and creatinine to middle molecular weight substances. In particular, it more efficiently removes phosphate than our conventional low-flux dialyzers.

Comparison of Phosphate Clearance between B2 series and B3 series



Comparison of BUN Clearance between B2-1.0 and B3-1.0A



## B3 Series for Moderate Dialysis

For Pediatric Dialysis  
B3-0.8A

For High Efficiency Dialysis  
B3-2.0A

For Conventional Dialysis  
B3-1.0A, B3-1.3A  
B3-1.6A

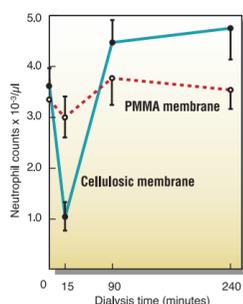
It allows for gentler dialysis treatment, especially for pediatric, elderly patients or those at an earlier stage of hemodialysis, with its moderate ultrafiltration rates.

**B3-0.8A is recommended for pediatric dialysis.**

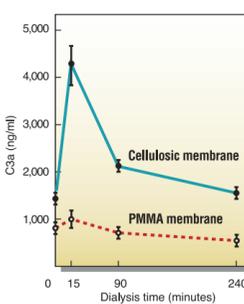
## Biocompatibility

Polymethylmethacrylate (PMMA) membrane does not promote generation of the complement fractions which results in less reduction in the neutrophil counts, and does little damage to platelets<sup>2)</sup> during dialysis, due to its superior biocompatibility.

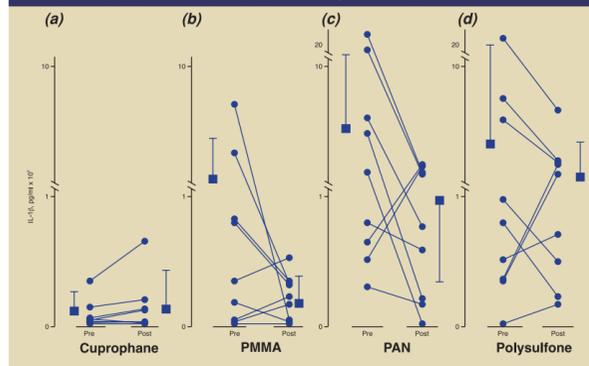
Change in Neutrophil Counts during Dialysis<sup>1)</sup>



Change in C3a during Dialysis<sup>1)</sup>



Pre- and Post-dialytic Levels of IL-1 $\beta$  in Patients Undergoing Hemodialysis with Cuprophane (a), and Hemodiafiltration with Polymethyl-methacrylate (PMMA) (b), AN-69 (PAN) (c) and Polysulfone (d)



According to the interleukin hypothesis, hypotension and fever are caused mainly by IL-1, during hemodialysis.<sup>3)</sup>

Increasing IL-1 produces  $\beta_2$ -MG, which may lead to dialysis-related amyloidosis.<sup>4)</sup>

PMMA membrane decreases production of IL-1 $\beta$  and tumor necrosis factor (TNF- $\alpha$ ).<sup>5)</sup>

## Use of PMMA Membranes Improves Outcome and Recovery from Acute Renal Failure (ARF)

Patients with ARF dialyzed with PMMA membrane have a lower mortality rate and a higher recovery rate compared to patients with similar degree of illness dialyzed with cellulosic membrane<sup>6)</sup>.

	CUPROPHANE	PMMA	TOTAL
Number of Patients	22	18	40
Number of Deaths	16	7	23
Mortality Rate	73%	39%	58%
Mean Number of HD Treatments	11	11	11
Mean Number of Hospital Days	42	45	43
ARF Recovery Rate	27%	67%	45%
Mean Number of HD Days to Recovery	27	15	19

### REFERENCES:

- 1) From Hakim RM, et al. Biocompatibility of dialysis membranes: Effects of chronic complement activation. *Kidney International* 1984; 26: 194-200.
- 2) Akizawa T, Nishizawa H, Koshikawa S. Plasma  $\beta$ -thromboglobulin levels in chronic renal failure patients. *Int. Soc. Art Organs* 1981; 5: 54-58.
- 3) Henderson LW, Koch KM, Dinarello CA, et al. Hemodialysis hypotension: The interleukin hypothesis. *Blood Purif.* 1983; 1: 3-8.
- 4) Kitaoka T, Akizawa T. *Kidney and Dialysis* 1986; 21: 495-499.
- 5) Tetta C, Camussi G, Turello E, et al. Production of Cytokines in Hemodialysis. *Blood Purif.* 1990; 8: 337-346.
- 6) From Hakim RM, Wingard RL, Lawrence P, et al. Use of biocompatibility membranes (BCM) improves outcome and recovery from acute renal failure (ARF). *JASN* 1992; 3: 367 (Abstract).

### INSTRUCTIONS:

Filterzyer B3 series is a medical device intended for hemodialysis (HD), but not designed for hemodiafiltration (HDF) and hemofiltration (HF). This device must be used by or at the direction of a physician. Patients with bleeding tendencies or coagulation disorders must be carefully evaluated by the physician. When adverse reaction are observed, the patients must be promptly treated under the direction of the physician. For some reactions, manipulation of blood flow rate, ultrafiltration rate, and electrolytic balance can be applied. The "Instructions for Use" should be read thoroughly prior to the use of this medical device. Filterzyer is manufactured in accordance with "Approval Standard of Artificial

Kidney" by the Ministry of Health, Labour and Welfare of Japanese Government. Each unit is carefully tested, sterilized and packaged prior to shipment. Toray cannot assume any responsibility for damage that may occur during transport or due to mishandling. Filterzyer is filled with sterile water. Before starting dialysis, rinse it out with one liter or more of physiological saline solution. Filterzyer is designed for single use only. Since Filterzyer B3 series has high ultrafiltration rates, it is necessary to use a dialysis machine equipped with a volumetric ultrafiltration rate controller.

