

EVIDENCE TO SUPPORT CLEARUM™ HS DIALYZER EFFICACY AND SAFETY USABILITY



EFFICACY AND SAFETY

STUDY RATIONALE AND OBJECTIVES

The aim of the study was to evaluate the efficacy and risk of hypoalbuminemia of the Clearum™ HS dialyzer compared with previously evaluated hemodialysis (HD), expanded hemodialysis (HDx), and postdilution hemodiafiltration (HDF) treatments.

STUDY DESIGN AND METHODS

Each patient underwent seven dialysis sessions using the below dialyzers. The order of the different treatment sessions was randomly assigned.

Blood and dialysis fluid samples for analyses were taken from each patient in the same dialysis session of the week.

Dialyzers assessed:

MEDTRONIC	FRESENIUS	BAXTER
Phylther™ 17 SD	FX80 Cordiax in HD	Theranova 400 in HDx
Phylther™ 17 G	FX80 Cordiax in Post HDF	
Clearum™ HS 17 in HD		
Clearum™ HS 17 in Post HDF		

Global Removal Score (GRS), Reduction Ratio (RR), and Albumin Dialysate Loss (Albumin) assessed the following toxins:

Small Toxins	<ul style="list-style-type: none">• Urea (60 Da)• Creatinine (113 Da)
Medium Toxins	<ul style="list-style-type: none">● β_2 - microglobulin (11,800 Da)● Myoglobin (17,200 Da)● Prolactin (23,000 Da)
Large Toxins	<ul style="list-style-type: none">● α_1 - microglobulin (33,000 Da)● α_1 - acid glycoprotein (41,000 Da)● Albumin in serum (66,000 Da)

KEY MESSAGE

The new Clearum™ HS dialyzer has significant performance and tolerance in HD and HDF. Its adequate permeability has been proven with its maximal performance in HDF, which could represent an upgrade versus its predecessor polyphenylene dialyzer.

STUDY TYPE

Independent, prospective, single-center study was carried out on 15 patients.

PARAMETERS ASSESSED

- Reduction ratio (RR) %
- Global removal score (GRS) %
- Albumin dialysate loss (Albumin) mg

REFERENCE

Maduell F, Broseta JJ, Guillen MA, et al. Efficacy and Safety of the Clearum Dialyzer. *Artif Organs*. 2021;45(10):1195-1201.

STUDY RESULTS

REDUCTION RATIO (RR) %

Clearum™ HS HDF compared to HDx and HDF dialyzers

		Clearum™ HS Dialyzer-17	FX80 Cordiax	Phylther™ 17 SD	Theranova 400
Reduction Ratio (%)		HDF	HDF	HDx	HDx
Small Toxins	• Urea (60 Da)	84,0 ± 3,8 ^a	83,6 ± 4,8	80,0 ± 5,1	83,6 ± 5,1 ^c
	• Creatinine (113 Da)	78,3 ± 5,1 ^{b,d}	78,0 ± 5,9 ^b	73,4 ± 5,4	77,6 ± 5,4 ^{c,e}
Medium Toxins	• β ₂ -microglobulin (11,818 Da)	85,2 ± 4,1 ^{a,f}	85,1 ± 3,9 ^a	75,6 ± 4,1	81,7 ± 4,9 ^a
	• Myoglobin (17,200 Da)	75,8 ± 7,7 ^{a,g}	77,6 ± 6,9 ^{a,g,h}	68,6 ± 6,8 ⁱ	70,4 ± 7,0 ⁱ
	• Prolactin (23,000 Da)	73,8 ± 9,0 ^{c,i}	75,3 ± 8,5 ^{a,h}	65,7 ± 9,3 ⁱ	70,4 ± 6,5 ⁱ
Large Toxins	• α ₁ -microglobulin (33,000 Da)	23,7 ± 10,5 ^j	26,4 ± 12,3 ^{c,j}	24,0 ± 12,2 ^j	22,1 ± 7,6 ^j
	• α ₁ -acid glycoprotein (41,000 Da)	10,5 ± 6,7	18,2 ± 11,4 ^{h,j}	11,0 ± 8,8 ⁱ	15,6 ± 7,9 ^{c,k}
	• Albumin (66,000 Da)	8,3 ± 6,2	8,5 ± 7,6	7,2 ± 6,6	10,0 ± 7,1

- Similar reduction ratios for small toxins (urea and creatinine), β₂M removal and larger toxin removal
- No significant difference for β₂M RR and larger toxin removal
- Low albumin reduction ratios

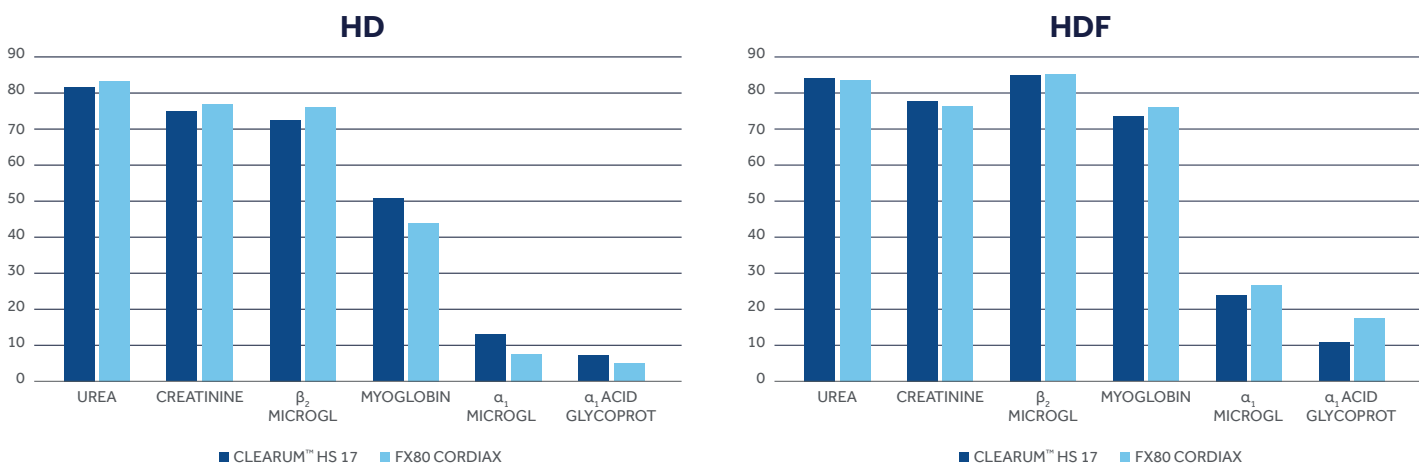
Clearum™ HS HD compared to other HDx and HD dialyzers

		Clearum™ HS Dialyzer-17	FX80 Cordiax	Phylther™ 17 SD	Theranova 400
Reduction Ratio (%)		HD	HD	HDx	HDx
Small Toxins	• Urea (60 Da)	81,3 ± 4,2	81,9 ± 3,5	80,0 ± 5,1	83,6 ± 5,1 ^c
	• Creatinine (113 Da)	74,8 ± 4,7	77,0 ± 7,8	73,4 ± 5,4	77,6 ± 5,4 ^{c,e}
Medium Toxins	• β ₂ -microglobulin (11,818 Da)	72,8 ± 7,7	77,2 ± 3,5	75,6 ± 4,1	81,7 ± 4,9 ^a
	• Myoglobin (17,200 Da)	54,2 ± 7,9 ⁱ	43,7 ± 5,5	68,6 ± 6,8 ⁱ	70,4 ± 7,0 ⁱ
	• Prolactin (23,000 Da)	50,4 ± 9,4	44,7 ± 8,8 ^h	65,7 ± 9,3 ⁱ	70,4 ± 6,5 ^e
Large Toxins	• α ₁ -microglobulin (33,000 Da)	12,2 ± 9,5 ^j	6,6 ± 11,4	24,0 ± 12,2 ^j	22,1 ± 7,6 ^j
	• α ₁ -acid glycoprotein (41,000 Da)	6,8 ± 6,8 ⁱ	4,7 ± 8,6	11,0 ± 8,8 ⁱ	15,6 ± 7,9 ^{c,k}
	• Albumin (66,000 Da)	7,6 ± 5,3	7,1 ± 6,8	7,2 ± 6,6	10,0 ± 7,1

- Similar reduction ratios for small toxins (urea and creatinine)
- No significant differences between FX80, Phylther™ 17 SD in HDx and Clearum™ HS 17 in HD for β₂M RR
- Higher RR for larger molecules with HDx compared to HD
- Low albumin reduction ratios

^ap < .001 vs. FX80- HD, Clearum- HD & Phylther SD- HD. ^bp < .001 vs. Phylther SD- HD. ^cp < .01 vs. Phylther SD- HD. ^dp < .001 vs. Clearum- HD. ^ep < .05 vs. Clearum- HD. ^fp < .05 vs. Theranova. ^gp < .01 vs. Theranova. ^hp < .05 vs. Phylther G- HDF. ⁱp < .001 vs. FX80- HD & Clearum- HD. ^jp < .001 vs. FX80- HD. ^kp < .01 vs. FX80- HD. ^lp < .05 vs. FX80- HD.

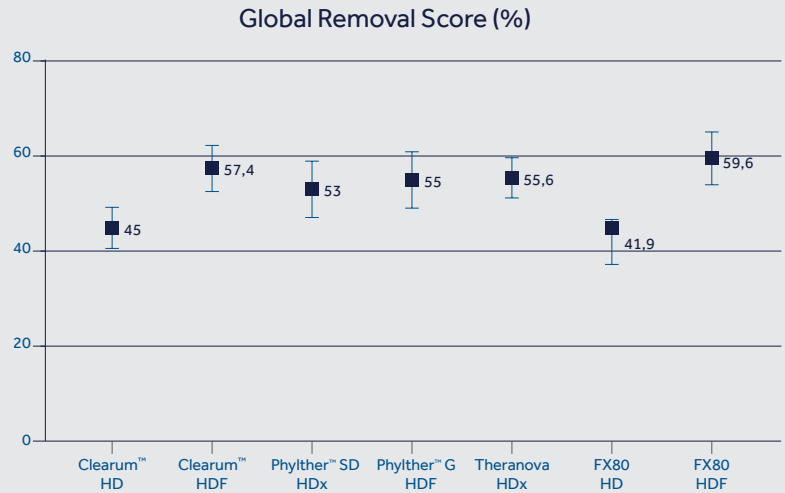
The Clearum™ HS dialyzer in HDF obtained similar results to FX80 Cordiax in HDF and BHD, was slightly superior to Phylther™ 17 G in HDF, and was statistically superior to both dialyzers in HDx.



STUDY RESULTS

GLOBAL REMOVAL SCORE (GRS) %

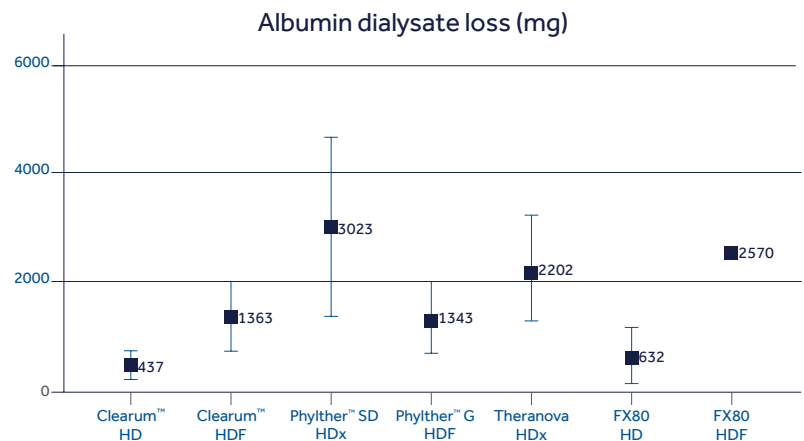
- Comparison of dialysis techniques revealed no differences between small molecules
- HDx and HDF were significantly higher than HD with medium and large molecular weights
- The Clearum™ HS dialyzer in HDF obtained similar results to FX80 Cordiax in HDF, and was slightly superior to Phylther™ 17 G in HDF



ALBUMIN DIALYSATE LOSS (ALBUMIN) MG

The Clearum™ HS dialyzer showed proven safety, with a low RR of albumin in blood, and with dialysate albumin loss less than 0,5 g in HD and less than 1,5 g in post dilution HDF.

Albumin losses with the Clearum™ HS dialyzer was among the lowest, both in HD and HDF treatments.



CONCLUSIONS

- The Clearum™ HS dialyzer in HDF obtained similar results to FX80 Cordiax in HDF, was slightly superior to Phylther™ 17 G in HDF, and was statistically superior to both dialyzers in HDx
- GRS values obtained with the Clearum™ HS dialyzer were among the highest in both HDF and HD
- Albumin losses with the Clearum™ HS dialyzer were among the lowest in both HD and HDF treatments
- The new Clearum™ HS dialyzer has significant performance and tolerance in HD and HDF. Its adequate permeability has been proven with its maximal performance in HDF, which could represent an upgrade versus its predecessor polyethersulfone dialyzer

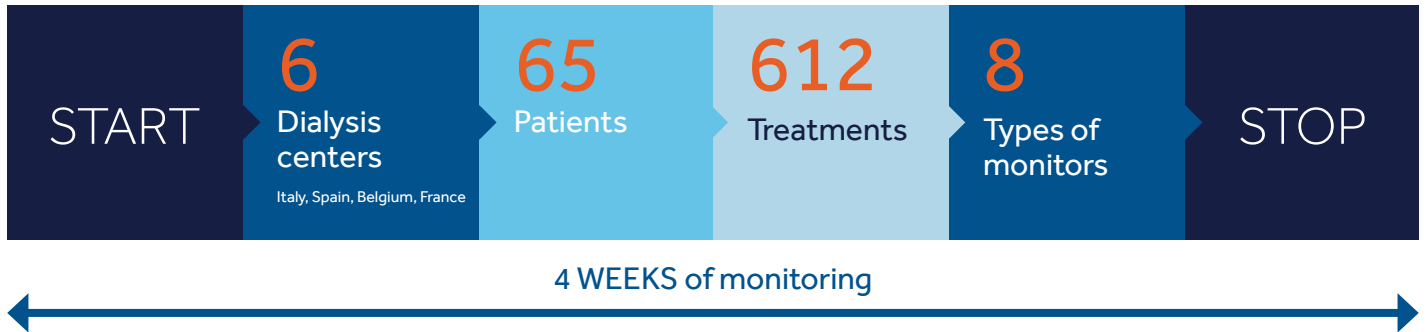
THE RESULTS OF THIS WORK SHOW HOW THE NEW GENERATION POLYETHERSULFONE (PES) DIALYZERS, CLEARUM™ HS DIALYZER, HAVE EXCELLENT BEHAVIOR AND TOLERANCE IN HD AND HDF



USABILITY

Results from Limited Controlled Distribution (LCD) evaluating blood rest, packaging, priming, and handling through two user experience questionnaires, rating the dialyzer at the end of each treatment.

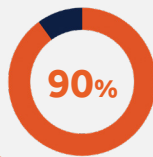
STUDY DESIGN



STUDY RESULTS

PRIMING

Users showed a strong acceptance level (about 90%) of Clearum™ HS dialyzers in priming procedures.



Fresenius – 5008 **96.6%** Nikkiso – DBB EXA **99.4%**

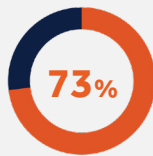
PACKAGING

The 100% of the users interviewed showed good acceptance of the primary and the secondary packaging.



BLOOD REST

Users showed a good acceptance level (>70%) of Clearum™ HS dialyzers in the blood rest procedures using Medtronic Machines.



HANDLING

Users showed good acceptance considering Clearum™ HS dialyzers overall easy to connect not only to Medtronic bloodlines but also with the competitor ones.



Rating scale questionnaire #1:

Excellent – Acceptable – Poor – Very Bad

STRONG ACCEPTANCE

Rating scale questionnaire #2:

Excellent – Acceptable – Poor – Very Bad

GOOD ACCEPTANCE

CUSTOMER FEEDBACK

"I like that I can do both HD and HDF with the same dialyzer."

Hospital in Italy

"The priming of Clearum™ is much easier (better) compared to Phylther™."

Hospital in Belgium

"It looks like EvoDial, is Clearum™ also heparinated? Because it performs so well like it is."

Hospital in Italy

"The dialyzer is perfectly preserved and fixed in the boxes to be transported."

Hospital in Spain

THE MEMBRANE THAT MATTERS

Clearum™ HS dialyzer



The Clearum™ high flux steam sterilized (HS) dialyzer is a standard hemodialysis dialyzer with a biocompatible, high-flux membrane that provides adequate balance between diffusion and convection in both HD, HF and HDF.

1. SAFETY

The Steam Sterilization process¹⁻⁴ and BPA free materials and process⁵ support biocompatibility. BPA may be associated with cardiovascular diseases⁶, is a highly protein-bound-uremic toxin, and is difficult to remove during hemodialysis⁷

2. PERFORMANCE

The Clearum™ HS dialyzer delivers proven dialyzer performance to ensure effective blood purification, without compromising critical protein loss⁸⁻¹⁰

3. USABILITY

The Clearum™ HS dialyzer demonstrated strong or good acceptance of priming, blood rest, packaging, and handling with Medtronic and other machines on the market¹¹

4. ENVIRONMENT

Polypropylene material reduces the carbon footprint by 60%¹², 95% of the water and solvent can be recovered and recycled¹³, and the Steam Sterilization process avoids releasing negative ozone material¹⁴, altogether reducing the negative impact on the environment

ORDERING INFORMATION

CODE	NAME	DESCRIPTION	QUANTITY
IBP4370	Clearum™ HS 13	1,3 m ² High-Flux Dialyzer Sterilized by Moist Heat	21 per box
IBP4371	Clearum™ HS 15	1,5 m ² High-Flux Dialyzer Sterilized by Moist Heat	21 per box
IBP4372	Clearum™ HS 17	1,7 m ² High-Flux Dialyzer Sterilized by Moist Heat	21 per box
IBP4373	Clearum™ HS 20	2,0 m ² High-Flux Dialyzer Sterilized by Moist Heat	18 per box
IBP4374	Clearum™ HS 22	2,2 m ² High-Flux Dialyzer Sterilized by Moist Heat	18 per box

References:

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13. Efficiency of recovery for solvent and water in CLEARUM GmbH, (Sept 2nd-2019)
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