

theranova

LIMITED CONTROLLED DISTRIBUTION (LCD), 2016

Selected dialysis centres (private centers and public clinics) were chosen post-approval to share their first experiences using THERANOVA in clinical settings. A questionnaire was used to collect usability of data regarding various aspects of the product design. In total, 1,364 questionnaires were collected. The quantitative evaluation of the questionnaire focused on priming outcome (elimination of air from dialyzer) and rinseback outcome (clarity of dialyzer).

- Feedback based on over 5,000 treatments to > 240 patients in 18 clinics
- Confirmed high level of satisfaction and promising potential usage¹

	# of Clinics	# of Treatment	Key Takeaways
	6	1,978	<ul style="list-style-type: none"> • Usability of THERANOVA was as expected and can be rated as equivalent to other Baxter Gambro dialyzers (Revaclear) • Compatibility verified on a wide range of competitive HD monitors*
	5	2,692	
	7	521	
Total	18	5,191	

Evaluation**				Key Takeaways
Priming (all protocols)	84%	12%	4%	<ul style="list-style-type: none"> • Priming: great feedback on all monitors, especially when best practice guidelines are carefully followed² • Rinseback quality is often recognized as a potential product strength • THERANOVA can provide a treatment quality equivalent to high-volume on-line HDF
Priming (PS = 100 mL/min, PV > 500 mL)***	93%	7%	0%	
Rinseback (PS = 100 mL/min, PV > 500 mL)***	76%	20%	4%	

* HD monitors compatibility verified for: Gambro Artis Physio, Gambro AK 200 S / ULTRA S, Fresenius 4008, Fresenius 5008, Fresenius Genius, Nikkiso DDB 05, B.Braun Dialog

** Questionnaires: n= 1364

*** PS = Pump Speed (mL/min), PV = Priming Volume (mL)

1. Baxter. Data on file. Theranova Limited Controlled Distribution Report 2016
2. LCD and Risk Analysis reports

Additional comments were provided about the potential of the HDx therapy enabled by THERANOVA:

“Same removal as in HDF for middle molecules by a simpler therapy.”

– Clinic in Compiègne, France

“HDF treatments are perceived as more complicated and time consuming than HD treatments for nursing staff. Switching to THERANOVA is therefore seen as a great advantage.”

– Clinic in Eckemförde, Germany

“THERANOVA should be able to offer patients the same removal in HD as in HDF, which can’t be done in smaller units. As a private center, we have several self-care units and THERANOVA can allow us to provide the same quality of treatment in any unit.”

– Clinic in Bordeaux, France



Indications for use: THERANOVA dialyzers are indicated for treatment of chronic and acute renal failure by Hemodialysis.

Do not use THERANOVA dialyzers for HDF or HF due to the higher permeability of larger molecular weight proteins such as albumin.

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

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ELUMP/MG209/16-0018