

Background

The ACCUSOL CLEAR-FLEX technology provides a 5L container suitable for CRRT solution by using a peel-sealing technology. This container has two compartments to hold respectively a pH 9.0 concentrate of bicarbonate solution and a pH 2.0 electrolyte concentrate solution. The 5L ACCUSOL CLEAR-FLEX product design has been recently improved. To the first long peel-seal (1) dividing the bag in two chambers to separate the active ingredients, a second short peel-seal (2) isolating the access system from the solution has been added (**Fig.1**). The sequential opening of the two peel-seals has been validated to ensure firstly the opening of the long peel-seal allowing instant mixing of the concentrates to constitute the ACCUSOL solution, and secondly the opening of the short seal allowing infusion of the mixed solution into the patient. In addition, both access system and hanger hole have been changed from an off-centered to a centered position.

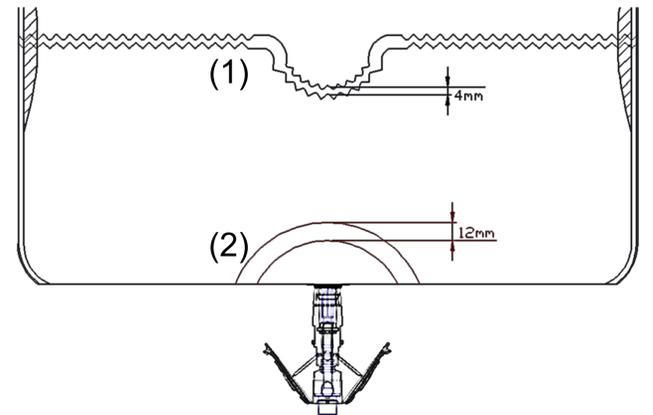


Figure 1: Drawing of the new Accusol 5L bag design

Objectives & Methods

The aim of this study was to assess the compatibility of the improved 5L ACCUSOL CLEAR-FLEX product with the PrismaFlex® system (**Fig.2**).

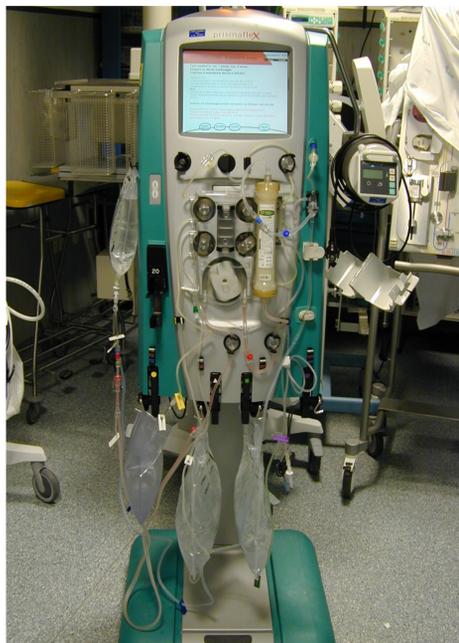


Figure 2: Prismaflex® system

Continuous Veno-Venous Hemofiltration (CVVH) and Continuous Veno-Venous Hemodialysis (CVVHD) therapy simulations have been performed using the therapy parameters presented in **Table 1** and using a saline bag to mimic the patient. For the CVVHD therapy, a total of 20 Accusol bags were used, whilst for the CVVH therapy a total of 40 Accusol bags were used, 20 for pre-dilution and 20 for post-dilution. The middle hook of the Prismaflex® system scales was always used to hang the different Accusol bags (**Fig. 3**).

Table 1: CVVH and CVVHD therapy simulation parameters

Therapy parameters	CVVHD	CVVH
Dialysate flow rate (L/h)	8	-
Pre-pump flow rate (mL/h)	-	700
Post-pump flow rate (mL/h)	-	1800
Blood flow rate (mL/min)	450	200
Ultrafiltration rate (mL/h)	100	100



Figure 3: Positioning of the Accusol 5L bag on the middle hook of the Prismaflex® system scale

For the CVVHD therapy, the maximum dialysate flow rate allowed by the system was used as it represents the worse-case condition for the study, whilst for the CVVH, therapy settings were defined to represent clinically prescribed parameters. During the therapy simulation, the following parameters have been monitored in order to assess the compatibility of the improved Accusol product with the Prismaflex® system:

- ◇ For each bag, “Replacement bag/replacement bag 2 empty” message shall be displayed before the bag is fully empty and air is potentially injected into the circuit;
- ◇ No “Air in blood” alarm shall occur during the therapy simulation;
- ◇ No “Replacement/replacement 2 weight” alarms shall occur during the therapy simulation.

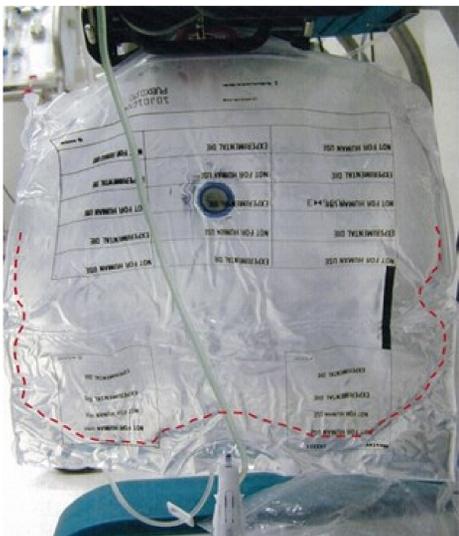


Figure 4: Illustration of the solution level in the bag when the « Replacement bag/replacement bag 2 empty » message is triggered

Results

For all the bags used to perform both CVVH and CVVHD therapy simulations, the top of the access system was still immersed in the solution at each “Replacement bag/replacement bag 2 empty” message, ensuring that no air enters into the system (**Fig. 4**). No “Air in blood” alarm was recorded during the therapy simulations. In addition, all the bags were found to be stable on the Prismaflex® system scales as no balance alarms were triggered during the simulations.

Conclusion

Based on the generated data, we can confirm that the improved 5L ACCUSOL CLEAR-FLEX product is compatible with the Prismaflex® system and can be used in combination with this CRRT device under the conditions prescribed in this study.