

TECHNICAL DATA SHEET

Acidflex™ liquid hemodialysis acid concentrate with glucose in cubitainer



Figure 1.

PRODUCT DESCRIPTION

The Acidflex™ solution is medical device and is used on machines for blood purification by extracorporeal circulation. The solution is used for the preparation of hemodialysis (HD) dialysate. In currently available HD systems, dialysate is prepared using fixed ratio proportioning systems, utilizing a volume of “acid” concentrate, “base” concentrate and dialysis-quality water to prepare the final dialysate. The operating principle is a combination of all electrolytes present in the concentrated solution for hemodialysis. The compound is used after dilution and the addition of sodium bicarbonate solution. This dialysate is then used within the dialyzer for blood purification.

The device enables elimination of urea and other nitrogenous waste for extra-renal purification and the correction of hydroelectrolytic and plasma acid-base imbalances.

The concentrated acid solution for hemodialysis is packaged in 1000 liter, single-piece, high density polyethylene (HDPE) cubitainers (Figure 1).

CODES AVAILABLE

CFN	Model	Description	CND	GMDN
BS390L1000E	ACIDFLEX™ 390 cubitainer 1000 L	Concentrated acid solution in 1000 L cubitainer	F040101	35849
BS431L006	ACIDFLEX™ 431 cubitainer 1000 L	Concentrated acid solution in 1000 L cubitainer	F040101	35849
BS497L007	ACIDFLEX™ 497 cubitainer 1000 L	Concentrated acid solution in 1000 L cubitainer	F040101	35849
BS531L005	ACIDFLEX™ 531 cubitainer 1000 L	Concentrated acid solution in 1000 L cubitainer	F040101	35849
BS547L005	ACIDFLEX™ 547 cubitainer 1000 L	Concentrated acid solution in 1000 L cubitainer	F040101	35849
BS597L1000E	ACIDFLEX™ 597 cubitainer 1000 L	Concentrated acid solution in 1000 L cubitainer	F040101	35849
BS660L002	ACIDFLEX™ 660 cubitainer 1000 L	Concentrated acid solution in 1000 L cubitainer	F040101	35849
BS660L1000E	ACIDFLEX™ 660 cubitainer 1000 L	Concentrated acid solution in 1000 L cubitainer	F040101	35849
BS661L002	ACIDFLEX™ 661 cubitainer 1000 L	Concentrated acid solution in 1000 L cubitainer	F040101	35849
BS662L002	ACIDFLEX™ 662 cubitainer 1000 L	Concentrated acid solution in 1000 L cubitainer	F040101	35849

STERILIZATION METHOD AND VALIDITY

Non-sterile and non-pyrogenic solution

Shelf life: 18 months

TECHNICAL CHARACTERISTICS

The technical characteristics of Acidflex™ in cubitainer are reported below.

Components	Materials
Cubitainer	High density polyethylene (HDPE)
Valve	Polypropylene (PP)
Vent	Plastic material
Solution	See table “Solution composition”

Technical characteristics							
Model	Dimension (mm)	Useful volume (L)	Real volume (L)	Retention volume (L)	Unloaded weight (Kg)	Maximum loaded weight (Kg)	Load stacking
T1004 (1000 mL)	1150 × 1150 × 1690	1000	1100	0	153	2053	1/1

Solution composition										
Model	Volume (L)	Dilution	Na ⁺ (mmol/L)	K ⁺ (mmol/L)	Ca ⁺⁺ (mmol/L)	Mg ⁺⁺ (mmol/L)	Cl ⁻ (mmol/L)	H ⁺ (mmol/L)	CH ₃ COO ⁻ (mmol/L)	C ₆ H ₁₂ O ₆ (g/L)
ACIDFLEX™ 390	1000	1:45	103.00	1.50	1.25	0.50	108.00	3.00	3.00	1.00
ACIDFLEX™ 431	1000	1:35	103.00	2.00	1.75	0.50	109.50	3.00	3.00	1.00
ACIDFLEX™ 497	1000	1:35	103.00	3.00	1.50	0.50	110.00	3.00	3.00	1.00
ACIDFLEX™ 531	1000	1:35	103.00	2.50	1.50	0.50	109.50	3.00	3.00	1.00
ACIDFLEX™ 547	1000	1:35	103.00	2.00	1.50	0.50	109.00	3.00	3.00	1.00
ACIDFLEX™ 597	1000	1:45	103.00	2.00	1.25	0.50	108.50	3.00	3.00	1.00
ACIDFLEX™ 660	1000	1:45	103.00	2.00	1.50	0.50	109.00	3.00	3.00	1.00
ACIDFLEX™ 660	1000	1:45	103.00	2.00	1.50	0.50	109.00	3.00	3.00	1.00
ACIDFLEX™ 661	1000	1:45	103.00	2.00	1.75	0.50	109.50	3.00	3.00	1.00
ACIDFLEX™ 662	1000	1:45	103.00	3.00	1.50	0.50	110.00	3.00	3.00	1.00

STORAGE AND DISPOSAL CONDITIONS

Storage conditions: store at temperatures between +4 and +25 degrees Celsius.

Disposal: remove from the place of dialysis immediately after use, any unused portion of solution should be discarded. Disposal must be carried out in accordance with the regulations in force.

BIOCOMPATIBILITY

Biocompatibility tests of the Acidflex™ solution have been performed according to applicable ISO 10993-1 standard series.