

# TECHNICAL DATA SHEET

## Acidflex liquid hemodialysis acid concentrate with glucose in bag

### PRODUCT DESCRIPTION

The Acidflex solution is a single-use medical device and is used on dialysis equipment for blood purification by extracorporeal circulation. The solution is used for the preparation of dialysis. In currently available hemodialysis systems, dialysate is prepared using fixed ratio proportioning systems that mix volumes of "acid" concentrate, "base" concentrate, and dialysis-quality water. The Acidflex solution is a combination of electrolytes that is used, after dilution with the addition of sodium bicarbonate solution, to create the dialysis fluid. This dialysate is then used within the dialyzer for blood purification.

In this way, the solution enables elimination of urea and other nitrogenous waste from patient blood, during extracorporeal blood purification, as well as the correction of hydroelectrolytic and plasma acid-base imbalances.

The Acidflex solution is packaged in 3.8 or 5.5 liter bags (Figure 1).



Figure 1. Acidflex bags

## CODES AVAILABLE

CFN	Model	Description	CND	GMDN
BS409L055/T	ACIDFLEX bag 409 5.5 L	Concentrated acid solution in 5.5 L bag	F040101	35849
BS431L055/T	ACIDFLEX bag 431 5.5 L	Concentrated acid solution in 5.5 L bag	F040101	35849
BS473L055/T	ACIDFLEX bag 473 5.5 L	Concentrated acid solution in 5.5 L bag	F040101	35849
BS477L055/T	ACIDFLEX bag 477 5.5 L	Concentrated acid solution in 5.5 L bag	F040101	35849
BS493L055/T	ACIDFLEX bag 493 5.5 L	Concentrated acid solution in 5.5 L bag	F040101	35849
BS497L055/T	ACIDFLEX bag 497 5.5 L	Concentrated acid solution in 5.5 L bag	F040101	35849
BS547L055/T	ACIDFLEX bag 547 5.5 L	Concentrated acid solution in 5.5 L bag	F040101	35849
BS549L055/T	ACIDFLEX bag 549 5.5 L	Concentrated acid solution in 5.5 L bag	F040101	35849
BS559L055/T	ACIDFLEX bag 559 5.5 L	Concentrated acid solution in 5.5 L bag	F040101	35849
BS606L055/T	ACIDFLEX bag 606 5.5 L	Concentrated acid solution in 5.5 L bag	F040101	35849
BS649L055/T	ACIDFLEX bag 649 5.5 L	Concentrated acid solution in 5.5 L bag	F040101	35849
BS597L055/T	ACIDFLEX bag 597 5.5 L	Concentrated acid solution in 5.5 L bag	F040101	35849
BS660L055/T	ACIDFLEX bag 660 5.5 L	Concentrated acid solution in 5.5 L bag	F040101	35849
BS661L055/T	ACIDFLEX bag 661 5.5 L	Concentrated acid solution in 5.5 L bag	F040101	35849
BS662L055/T	ACIDFLEX bag 662 5.5 L	Concentrated acid solution in 5.5 L bag	F040101	35849
BS669L055/T	ACIDFLEX bag 669 5.5 L	Concentrated acid solution in 5.5 L bag	F040101	35849
BS597L038/T	ACIDFLEX bag 597 3.8 L	Concentrated acid solution in 3.8 L bag	F040101	35849
BS660L038/T	ACIDFLEX bag 660 3.8 L	Concentrated acid solution in 3.8 L bag	F040101	35849
BS661L038/T	ACIDFLEX bag 661 3.8 L	Concentrated acid solution in 3.8 L bag	F040101	35849
BS662L038/T	ACIDFLEX bag 662 3.8 L	Concentrated acid solution in 3.8 L bag	F040101	35849
BS664L038/T	ACIDFLEX bag 664 3.8 L	Concentrated acid solution in 3.8 L bag	F040101	35849
BS665L038/T	ACIDFLEX bag 665 3.8 L	Concentrated acid solution in 3.8 L bag	F040101	35849
BS667L038/T	ACIDFLEX bag 667 3.8 L	Concentrated acid solution in 3.8 L bag	F040101	35849
BS668L038/T	ACIDFLEX bag 668 3.8 L	Concentrated acid solution in 3.8 L bag	F040101	35849
BS669L038/T	ACIDFLEX bag 669 3.8 L	Concentrated acid solution in 3.8 L bag	F040101	35849

## STERILIZATION METHOD AND VALIDITY

Non-sterile and non-pyrogenic solution.

Shelf life: 18 months

## TECHNICAL CHARACTERISTICS

The technical characteristics of Acidflex solution in bag are reported below.

Components	Materials
Bag	Polyvinyl chloride (PVC) with TOTM plasticizer
Tube	Polyvinyl chloride (PVC) with TOTM plasticizer
Clamp	Polypropylene (PP)
Male Luer Block Connector	Low Density Polyethylene (LDPE)
Solution <sup>1</sup>	Sodium chloride (NaCl) Potassium chloride (KCl) Calcium chloride dihydrate (CaCl <sub>2</sub> ·2H <sub>2</sub> O) Magnesium chloride hexahydrate (MgCl <sub>2</sub> ·6H <sub>2</sub> O) Dextrose monohydrate C <sub>6</sub> H <sub>12</sub> O <sub>6</sub> ·H <sub>2</sub> O Acetic acid (CH <sub>3</sub> COOH) Purified water (H <sub>2</sub> O)

<sup>1</sup> See table "Solution composition" for electrolyte concentration

Solution composition										
Model	Volume (L)	Dilution	Na <sup>+</sup> (mmol/L)	K <sup>+</sup> (mmol/L)	Ca <sup>++</sup> (mmol/L)	Mg <sup>++</sup> (mmol/L)	Cl <sup>-</sup> (mmol/L)	H <sup>+</sup> (mmol/L)	CH <sub>3</sub> COO <sup>-</sup> (mmol/L)	C <sub>6</sub> H <sub>12</sub> O <sub>6</sub> (g/L)
ACIDFLEX bag 409 5.5 L	5.5	1:35	103.00	3.00	1.75	0.50	110.50	3.00	3.00	1.00
ACIDFLEX bag 431 5.5 L	5.5	1:35	103.00	2.00	1.75	0.50	109.50	3.00	3.00	1.00
ACIDFLEX bag 473 5.5 L	5.5	1:35	103.00	1.50	1.25	0.50	108.00	3.00	3.00	1.00
ACIDFLEX bag 477 5.5 L	5.5	1:35	103.00	3.00	1.60	0.50	110.20	3.00	3.00	1.00
ACIDFLEX bag 493 5.5 L	5.5	1:35	103.00	1.50	1.50	0.50	108.50	3.00	3.00	1.00
ACIDFLEX bag 497 5.5 L	5.5	1:35	103.00	3.00	1.50	0.50	110.00	3.00	3.00	1.00
ACIDFLEX bag 547 5.5 L	5.5	1:35	103.00	2.00	1.50	0.50	109.00	3.00	3.00	1.00
ACIDFLEX bag 549 5.5 L	5.5	1:35	103.00	2.00	1.25	0.50	108.50	3.00	3.00	1.00
ACIDFLEX bag 559 5.5 L	5.5	1:35	103.00	2.00	1.60	0.50	109.20	3.00	3.00	1.00
ACIDFLEX bag 606 5.5 L	5.5	1:35	103.00	3.00	1.25	0.50	109.50	3.00	3.00	1.00
ACIDFLEX bag 649 5.5 L	5.5	1:35	103.00	1.00	1.60	0.50	108.20	3.00	3.00	1.00
ACIDFLEX bag 597 5.5 L	5.5	1:45	103.00	2.00	1.25	0.50	108.50	3.00	3.00	1.00
ACIDFLEX bag 660 5.5 L	5.5	1:45	103.00	2.00	1.50	0.50	109.00	3.00	3.00	1.00
ACIDFLEX bag 661 5.5 L	5.5	1:45	103.00	2.00	1.75	0.50	109.50	3.00	3.00	1.00
ACIDFLEX bag 662 5.5 L	5.5	1:45	103.00	3.00	1.50	0.50	110.00	3.00	3.00	1.00
ACIDFLEX bag 669 5.5 L	5.5	1:45	103.00	3.00	1.25	0.50	109.50	3.00	3.00	1.00
ACIDFLEX bag 597 3.8 L	3.8	1:45	103.00	2.00	1.25	0.50	108.50	3.00	3.00	1.00
ACIDFLEX bag 660 3.8 L	3.8	1:45	103.00	2.00	1.50	0.50	109.00	3.00	3.00	1.00
ACIDFLEX bag 661 3.8 L	3.8	1:45	103.00	2.00	1.75	0.50	109.50	3.00	3.00	1.00
ACIDFLEX bag 662 3.8 L	3.8	1:45	103.00	3.00	1.50	0.50	110.00	3.00	3.00	1.00
ACIDFLEX bag 664 3.8 L	3.8	1:45	103.00	3.00	1.75	0.50	110.50	3.00	3.00	1.00
ACIDFLEX bag 665 3.8 L	3.8	1:45	103.00	2.00	1.60	0.50	109.20	3.00	3.00	1.00
ACIDFLEX bag 667 3.8 L	3.8	1:45	103.00	1.00	1.50	0.50	108.00	3.00	3.00	1.00
ACIDFLEX bag 668 3.8 L	3.8	1:45	103.00	4.00	1.50	0.50	111.00	3.00	3.00	1.00
ACIDFLEX bag 669 3.8 L	3.8	1:45	103.00	3.00	1.25	0.50	109.50	3.00	3.00	1.00

## PACKAGING

Model	Primary packaging – Protective film	
	Material	Protective film weight (g)
ACIDFLEX bag	Overwrapping film in Low Density Polyethylene (LDPE)	27.44

Model	Secondary packaging – Box		
	Box	Weight <sup>2</sup> (kg)	Pcs/Box
ACIDLFEX 3.8 L bag	American Cardboard Box Dimensions: 36.2 x 23.6 x 21.4 cm	12.3	3
ACIDFLEX 5.5 L bag	American Cardboard Box Dimensions: 36.2 x 23.6 x 21.4 cm	11.8	2

<sup>2</sup>Max box weight filled with products

## STORAGE AND DISPOSAL CONDITIONS

Storage conditions: store at temperatures between +4 and +30 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 on the Acidflex solution have been performed according to applicable ISO 10993-1 standard series.