OPERATOR'S MANUAL FOR NIKKICART

Renal Care Dialysis Solutions SA de CV.

INTENDED USE

The NikkiCart cartridge is indicated for use in patients undergoing extracorporeal bicarbonate hemodialysis for acute renal failure, chronic renal failure, or acute intoxication with dialyzable substances. The NikkiCart cartridge is intended to be used as one component in the preparation of dialysate according to a physician's prescription in a 3-stream proportioning machine on all Nikkiso Hemodialysis systems equipped with a compatible bicarbonate cartridge holder assembly.

Additional performance testing and analysis of risk have been completed that demonstrate that this device can be safely used on non-Nikkiso brand Hemodialysis systems with compatible bicarbonate cartridge holder assemblies that meet the fit specifications of the NikkiCart cartridge*. Use on machines with bicarbonate cartridge holder assemblies outside of the fit specifications have not been verified and is therefore not recommended.

CAUTIONS

- The information in this manual must be carefully read and understood before using the product.
- The operation of the specially adapted dialysis machine is restricted to persons who are trained in dialysis and who a completely familiar with the operating instructions stated in the operator's manual of the corresponding dialysis machine and in this NikkiCart Operator manual.

WARNINGS

- The concentrate in the NikkiCart cartridge must be used within 24 hours after being primed. Bacterial growth may occur when using bicarbonate concentrate.
- Test the conductivity and approximate pH of the dialysate with an independent device before beginning treatment. Use of a dialysate with incorrect conductivity or pH can cause serious injury or death.
- For use only on hemodialysis systems equipped with a compatible bicarbonate cartridge holder assembly that meet the fit specifications of the NikkiCart cartridge*.
- DO NOT use the NikkiCart product if any damage is found or suspected.
- DO NOT use any other type of acid concentrate than the type specified under Specification.
- DO NOT refill the NikkiCart cartridge.
- DO NOT perform any unauthorized modifications or alterations to the NikkiCart product or to the dialysis machine as this may result in a malfunction or have other serious consequences on the safe operation of the dialysis treatment.

SPECIFICATION

Contents

The NikkiCart cartridge contains dry sodium bicarbonate powder in compliance with Ph. Eur. And USP.

Capacity

At a machine normal setting of 137 mEq/L sodium and 37 mEq/L sodium bicarbonate, up to 32.19 liters of dialysis fluid can be produced per 100 grams of bicarbonate powder when the sodium bicarbonate concentrate, and water are mixed together with a 45X acid concentrate as specified below.

Requirements on the acid concentrate

To be used with acid concentrate 45x in a 1:44 ratios to obtain the final dialysis fluid composition.

As an example, A 45X in a ratio 1:44 concentrate is used. When mixed to 1:44, this will yield (mEq/L):

Sodium	100.00
Potassium	2.0
Calcium	2.50
Magnesium	1.00
Chloride	105.50
Acetate	4.0

Together with the sodium bicarbonate concentrate from the NikkiCart cartridge the final dialysis fluid will have a sodium concentration of 137 mEq/L and a sodium bicarbonate concentration of 33 mEq/L at a normal machine setting.

Requirements for water

Only hemodialysis grade feed water as defined by ANSI/AAMI/ISO 23500-3: 2019 Preparation and quality management of fluids for haemodialysis and related therapies – Part 3: Water for haemodialysisand related therapies, shall be used to dilute the bicarbonate powder and the saturated bicarbonate concentrate to make the dialysis fluid.

System Requirements

The NikkiCart cartridge is intended to be used as one component in the preparation of dialysate according to a physician's prescription in a 3-stream proportioning machine on Hemodialysis systems equipped with a compatible bicarbonate cartridge holder assembly*.

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*Compatible with dialysis systems that contain a bicarbonate cartridge holder assembly that will accommodate a cartridge of the following dimensions:
Total cartridge height 235.50 +/- 0.50 mm; Cartridge body nipple height 10.00 +/- 0.20 mm; Cartridge body nipple diameter 10.00 +/- 0.20 mm @ 4.5 mm; Cartridge cap nipple height 10.00 +/- 0.20 mm; and Cartridge cap nipple diameter 10.00 +/- 0.20 mm @ 4.5 mm.

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Run Times

Format 720 g	NikkiCart Bicarbonate Powder Cartridge Sodium Bicarbonate mEq/L																		Ratio 1:44
Dialysate Flow mL/min.	28	29	30	31	32	33	34	35	36	37	38	39	40	41	42	44	45	46	Estimated Running time hh:mm
300	14:52	14:22	13:53	13:26	13:01	12:37	12:15	11:54	11:34	11:15	10:57	10:41	10:25	10:09	09:55	09:28	09:15	09:03	
400	11:09	10:46	10:25	10:04	09:45	09:28	09:11	08:55	08:40	08:26	08:13	08:00	07:48	07:37	07:26	07:06	06:56	06:47	
500	08:55	08:37	08:20	08:03	07:48	07:34	07:21	07:08	06:56	06:45	06:34	06:24	06:15	06:05	05:57	05:40	05:33	05:26	
600	07:26	07:11	06:56	06:43	06:30	06:18	06:07	05:57	05:47	05:37	05:28	05:20	05:12	05:04	04:57	04:44	04:37	04:31	
700	06:22	06:09	05:57	05:45	05:34	05:24	05:15	05:06	04:57	04:49	04:41	04:34	04:27	04:21	04:15	04:03	03:58	03:52	
800	05:34	05:23	05:12	05:02	04:52	04:44	04:35	04:27	04:20	04:13	04:06	04:00	03:54	03:48	03:43	03:33	03:28	03:23	

Running Times are estimates and may vary per dialysis unit policy and procedure.

Format 900 g	NikkiCart Bicarbonate Powder Cartridge Sodium Bicarbonate mEq/L																		Ratio 1:44
Dialysate Flow mL/min.	28	29	30	31	32	33	34	35	36	37	38	39	40	41	42	44	45	46	Estimated Running time hh:mm
300	19:07	18:28	17:51	17:16	16:44	16:14	15:45	15:18	14:52	14:28	14:05	13:44	13:23	13:03	12:45	12:10	11:54	11:38	
400	14:20	13:51	13:23	12:57	12:33	12:10	11:49	11:28	11:09	10:51	10:34	10:18	10:02	09:47	09:33	09:07	08:55	08:44	
500	11:28	11:05	10:42	10:22	10:02	09:44	09:27	09:11	08:55	08:41	08:27	08:14	08:02	07:50	07:39	07:18	07:08	06:59	
600	09:33	09:14	08:55	08:38	08:22	08:07	07:52	07:39	07:26	07:14	07:02	06:52	06:41	06:31	06:22	06:05	05:57	05:49	
700	08:11	07:55	07:39	07:24	07:10	06:57	06:45	06:33	06:22	06:12	06:02	05:53	05:44	05:35	05:27	05:13	05:06	04:59	
800	07:10	06:55	06:41	06:28	06:16	06:05	05:54	05:44	05:34	05:25	05:17	05:09	05:01	04:53	04:46	04:33	04:27	04:22	

Running Times are estimates and may vary per dialysis unit policy and procedure.

ADVERSE REACTIONS

Some undesirable effects related to dialysis can occur, for instance hypotension, nausea, vomiting, cramps, and headaches.

WARRANTY AND LIMITATIONS OF LIABILITY

a) The manufacturer warrants that the NikkiCart product has been manufactured in accordance with its specifications and in compliance with Good Manufacturing Practices, other applicable industry standards and regulatory requirements. If provided with the lot number of the defective product, the manufacturer will, by replacement, remedy manufacturing defects in the product becoming apparent within the stated expiration period.

b) The warranty under paragraph a) above is in lieu of, and to the exclusion of, any other warranty, whether written or oral, expressed, or implied, statutory, or otherwise, and there are no warranties of merchantability or other warranties, which extended beyond those described in paragraph a) above. The remedy set out above for manufacturing defects is the sole remedy available to any person due to defects in the product and the manufacturer shall not be liable for any consequential or incidental loss, damage, injury, or expense arising directly or indirectly from the use of the product. Whether as a result of any defect therein or otherwise.

c) The manufacturer shall not be liable for any misuse, improper handling, non-compliance with warnings and instructions, damage arising from events after the manufacturer's release of the product, failure, or omission to inspect the product before use in order to ensure that the product is in proper condition, or any warranty given by independent distributors or dealers.

d) The product is manufactured at RENAL CARE DIALYSIS SOLUTIONS, S.A. de C.V.

DESCRIPTION

The NikkiCart is a single use polypropylene (PP) cartridge containing dry sodium bicarbonate powder, which enables on-line preparation of saturated Sodium Bicarbonate solution that, in conjunction with a 45X acid concentrate solution and dialysis water, creates a bicarbonate-base dialysis fluid that meets the Association for the Advancement of Medical Instrumentation (AAMI) guidelines.
When the NikkiCart® is attached to a hemodialysis system with a compatible bicarbonate cartridge holder assembly*, water is drawn by the dialysis machine through the cartridge, producing a saturated solution of sodium bicarbonate. The dialysis machine mixes the saturated sodium bicarbonate solution with water and the 45X acid concentrate to produce a bicarbonate-based dialysis fluid. The acid concentrate must have a dilution ratio of 1:44 also known as 45X to be used with the NikkiCart Sodium Bicarbonate powder cartridge.

*Compatible with dialysis systems that contain a bicarbonate cartridge holder assembly that will accommodate a cartridge of the following dimensions:
Total cartridge height 235.50 +/- 0.50 mm; Cartridge body nipple height 10.00 +/- 0.20 mm; Cartridge body nipple diameter 10.00 +/- 0.20 mm @ 4.5 mm; Cartridge cap nipple height 10.00 +/- 0.20 mm; and Cartridge cap nipple diameter 10.00 +/- 0.20 mm @ 4.5 mm.

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INDICATIONS

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Additional performance testing and analysis of risk have been completed that demonstrate that this device can be safely used on non-Nikkiso brand Hemodialysis systems with compatible bicarbonate cartridge holder assemblies that meet the fit specifications of the NikkiCart cartridge*. Use on machines with bicarbonate cartridge holder assemblies outside of the fit specifications have not been verified and is therefore not recommended.

CONTRADICTIONS

There are no absolute contradictions for bicarbonate dialysis. The NikkiCart product must be used only on the direction of a physician who has evaluated all the pertinent features of the product in relation to the individual patient.

INSTRUCTIONS FOR USE AND INSTALLATION

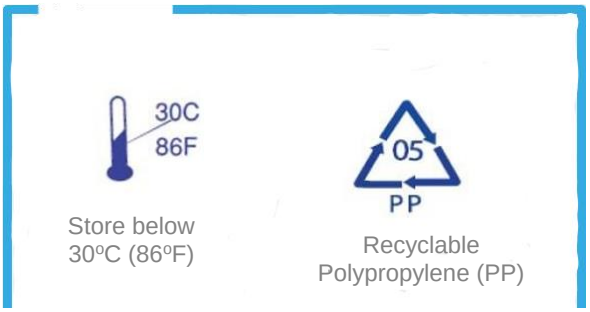
Refer to the operator's manual of the applicable Nikkiso dialysis machine when using a Nikkiso Hemodialysis system.
If your non-Nikkiso brand hemodialysis dialysis system is equipped with a compatible bicarbonate cartridge holder, refer to the operator manual of the corresponding dialysis machine or follow the policies and procedures established by your dialysis facility.
For best performance gently shake the NikkiCart cartridge to release any caking of the powder so it is free flowing before use.

STORAGE AND SHELF LIFE

Storage
Store below +30° C (86° F)

Shelf life
See the expiry date stated on the product label.

SYMBOLS



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