

CUSTOMER NOTIFICATION

URGENT: CLASS I MEDICAL DEVICE RECALL UPDATE

Voluntary Recall of all lots of BC+201, 45X Liquid Bicarbonate Jugs

Issued by: Nipro Medical Corporation (NMC)

Date: 29May2025

Dear Valued Partner,

Nipro Medical Corporation (NMC) is initiating a **voluntary recall of all lots in commercial distribution** of our **MedicalLyte™ Liquid Bicarbonate Concentrate** (BC+201, 45X) used in dialysis treatment, due to fungal and bacterial contaminants.

This action is being taken with the knowledge of the **U.S. Food and Drug Administration (FDA)** and reflects our commitment to the highest standards of **quality and transparency** — values that guide both our daily work and our long-term promise to care.

SCOPE OF THE RECALL

- **All lots of our MedicalLyte™ Liquid Bicarbonate Concentrate currently in commercial distribution** (see Product Recall Response Form, pages 6-7)
- The device shelf life is 2 years from the date of manufacture; therefore, the scope of the recall is determined to start with lots produced starting in May 2023.
- 185 lots were manufactured since May of 2023.

REASON FOR RECALL

We have received 41 complaints across 18 lots concerning defects in some product jugs with two (2) serious adverse events reported, and three (3) adverse events reported. Samples were sent to a third-party laboratory for analysis, where bacterial and fungal particles were identified.

POTENTIAL HAZARDS ASSOCIATED WITH THE PRODUCT

- Use of recalled products may cause or contribute to immediate health consequences such as **infections, treatment disruptions, risk of sepsis, and possible death.**
- Potential long-range health consequences may be chronic infections which may cause or contribute to organ damage and a weakened immune system.
- The hemodialysis machine will need to be disinfected if the contaminated product is used, following the dialysis machine manufacturer's recommendations, as per standard operating procedure in dialysis facilities.

REQUIRED ACTIONS

Do not use any MedicalLyte™ Liquid Bicarbonate Concentrate (BC+201, 45X)

We kindly ask that you:

1. **Stop dispensing and distributing product and quarantine all lots.**
2. **Isolate identified devices in possession.**
3. **Complete the enclosed Business Reply Card (BRC) and Packing Slip** with a physical count
4. **Return the BRC** — even if you do not have any product to return
5. **Once ready to return the product, please contact Sedgwick at 1-877-546-0126** to arrange return to the below listed facility:

Sedgwick Brand Protection
Attn: Event 4621
2670 Executive Dr., Suite A
Indianapolis, IN 46241

6. **Direct consignees:** This recall is being carried out to the user level. Notifications of this recall are being sent to all direct accounts of Nipro Medical Corp. If the affected lots were further distributed, please forward this notification and report the consignees to 1-877-546-0126.

Credit will be issued at the price in effect at the time of purchase.

OUR COMMITMENT

At Nipro, we believe in standing by our responsibility — not just to the products we provide, but to the people whose lives depend on them. As one of only two U.S. manufacturers of this essential product, we take our role seriously. Dialysis patients are — and will always be — at the heart of everything we do.

We are fully committed to reinforcing trust in our products, and to maintaining continuity of supply during this process. We are working closely with stakeholders to ensure a reliable and transparent recall implementation.

We thank you for your continued collaboration and the trust you have in Nipro.

As always, we remain committed to being a **transparent and reliable partner**, supporting you with the **quality and care your teams — and patients — deserve.**

Warm regards,

Joe Dawson

President, North America Division

URGENT: MEDICAL DEVICE RECALL



Thursday, May 29, 2025 : Event 4621

PRODUCT	<p>Product: MedicalLyte™ Liquid Bicarbonate Concentrate (BC+201) UDI (Bottle): 00817411022824 Strength: 45X-Proportioning Package Size: 1 Gallon (3.78L) bottle, 4 bottles per case. Lot Numbers: See Product Recall Response Form, pages 6-7 Manufactured By: Nipro Renal Solutions USA Corp</p>
REASON	<p>Nipro Renal Solutions USA Corp. is conducting a recall to the wholesale level of all lots in commercial distribution of MedicalLyte™ Liquid Bicarbonate Concentrate. These lots are being recalled due to the presence of fungal and bacterial contaminants.</p>
ACTION	<ol style="list-style-type: none"> 1. Stop dispensing and distributing product and quarantine all lots. 2. Identify and cease immediate use of all devices from the affected lots (See attached list on pages 6-7). 3. Isolate identified devices in possession. 4. Complete the enclosed Business Reply Card (BRC) and Packing Slip with a physical count 5. Return the BRC — even if you do not have any product to return 6. Once ready to return product, please contact Sedgwick at 1-877-546-0126 to arrange return of the product to the facility: <div style="text-align: center; margin-top: 10px;"> <p>Sedgwick Brand Protection Attn: Event 4621 2670 Executive Dr., Suite A Indianapolis, IN 46241</p> </div> 7. Direct consignees: This recall is being carried out to the user level. Notifications of this recall are being sent to all direct accounts of Nipro Medical Corp. If the affected lots were further distributed, please forward this notification and report the consignees to 1-877-546-0126. <p style="margin-top: 20px;">Credit will be issued at the price in effect at the time of purchase.</p>
OTHER INFORMATION	<p>This recall is being carried out to the user level. Notifications of this recall are being sent to all direct accounts of Nipro Medical Corp. Accounts that further distribute this product to the user facility, please notify your accounts. For medical questions contact Nipro Customer Service Center at +1 908-393-7030. For shipping assistance or questions about the recall process please contact Sedgwick at 1-877-546-0126.</p> <p>Patient Monitoring: Hemodialysis patients are closely monitored during treatment, enabling early detection of adverse reactions such as fever, chills, or hypotension. Prompt intervention can mitigate severe outcomes.</p> <p>Medical Intervention: In the event of exposure, early administration of antibiotics and supportive care can effectively manage infections, reducing the risk of long-term complications.</p> <p>Credit will be issued to the wholesaler at the wholesale price in effect at the time of purchase.</p> <p>This recall is being conducted with the knowledge of the Food and Drug Administration. We appreciate your immediate attention and cooperation and sincerely regret any inconvenience caused by this action.</p>

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URGENT: MEDICAL DEVICE RECALL



We are asking for your immediate assistance to complete the following:

1. Warehouse/Distribution Center Product:

- a. Please review your inventory and communicate to your warehouse(s) to place the affected cases of product on hold.
- b. Please contact Sedgwick to coordinate the pickup and removal of product from your facility. If arranging pickup of product, freight will be prepaid by Sedgwick. Alternatively, you may arrange shipment of the product directly to Sedgwick at the following address:

Sedgwick Brand Protection
Attn: Event 4621
2670 Executive Dr., Suite A
Indianapolis, IN 46241

Dock hours are 8 AM – 4:30 PM Monday – Friday. If delivery costs are incurred, please bill the cost of freight back to Sedgwick, INC.

2. User Facility Product:

- a. Please review your inventory and communicate to your location(s) to place the affected product on hold.
- b. If you have a process to return the product to reclamation, your accounts may return the affected product to your reclamation center for processing. All Product must be forwarded to Sedgwick for proper accounting and reporting purposes.
- c. Please contact Sedgwick at 1-877-546-0126 to assist at the facility level to sort, document and remove all affected products for destruction. Please advise your accounts to direct any consumer inquiries to the consumer hot line at 1-877-546-0126 or to Nipro4621@sedgwick.com. Please follow your standard process for consumer returns. Customers may contact us at any time for more information.



Product Recall Response Form

Date: _____

To: Nipro Medical Corp (c/o Sedgwick)
(see bottom of form for e-mail and fax instructions)

From: Customer Name: _____

Mailing Address: _____

Contact Name: _____

Tel. Number: _____

Re: **Recall of ALL lots of MedicaLyte™ Liquid Bicarbonate Concentrate-45X Proportioning Product**

Please check all that apply:

We are a: ☐ Wholesaler/distributor ☐ Retailer ☐ Other (please specify): _____

☐ We have read and understand the recall instructions provided in **MedicaLyte™ Liquid Bicarbonate Concentrate-45X Proportioning Recall Notice** for the Recalled Products.

☐ We have none of the Recalled Products in stock.

☐ We have indicated below the quantity of the Recalled Products in stock that we placed on hold for return
(see attached list on 6-7)

For those customers that have further shipped any of the Recalled Products:

☐ We have notified our consignees to advise them about this recall and included a copy of the Recall Notice.

**Product
Return:**
(choose one)

☐ We will be using our DC/reclamation center to consolidate Recalled Products. Our reclaim center will contact Sedgwick at 1-877-546-0126 to coordinate return of consolidated Recalled Products.

☐ We do not have a reclamation center. We will contact Sedgwick at 1-877-546-0126 to coordinate the pickup and removal of Recalled Product from our facilities or arrange shipment of the product directly to Sedgwick at the following address:
Sedgwick, Attn: Event 4621
2670 Executive Dr., Suite A
Indianapolis, IN 46241

Dock hours are 8 AM – 4:30 PM Monday – Friday.

Comments (if any):

PLEASE EMAIL OR FAX COMPLETED PRODUCTS RECALL RESPONSE FORM TO:
Sedgwick – Email – Nipro4621@sedgwick.com ; Fax 877-496-5036; Questions – 1-877-546-0126



Product Recall Response Form

Lot #	QTY on hand
1. N3E001	
2. N3E003	
3. N3E006	
4. N3E007	
5. N3E009	
6. N3E010	
7. N3E011	
8. N3F001	
9. N3F004	
10. N3F007	
11. N3F008	
12. N3F010	
13. N3F015	
14. N3F021	
15. N3F023	
16. N3G002	
17. N3G012	
18. N3G014	
19. N3G018	
20. N3G020	
21. N3G022	
22. N3H001	
23. N3H003	
24. N3H006	
25. N3H007	
26. N3H010	
27. N3H013	
28. N3H015	
29. N3H017	
30. N3H019	
31. N3J003	
32. N3J005	
33. N3K002	
34. N3K006	
35. N3K007	

Lot #	QTY on hand
36. N3K013	
37. N3K018	
38. N3K021	
39. N3L001	
40. N3L004	
41. N3L007	
42. N3M002	
43. N3M005	
44. N3M007	
45. N3M009	
46. N3M012	
47. N4A001	
48. N4A004	
49. N4A006	
50. N4A011	
51. N4A019	
52. N4B003	
53. N4B013	
54. N4B018	
55. N4B021	
56. N4C001	
57. N4C004	
58. N4C007	
59. N4C015	
60. N4C017	
61. N4C019	
62. N4D002	
63. N4D005	
64. N4D008	
65. N4D011	
66. N4D013	
67. N4D018	
68. N4E019	
69. N4E021	
70. N4E023	

Lot #	QTY on hand
71. N4E024	
72. N4E026	
73. N4E034	
74. N4E035	
75. N4E038	
76. N4E040	
77. N4E041	
78. N4F003	
79. N4F005	
80. N4F010	
81. N4F011	
82. N4F015	
83. N4F017	
84. N4F018	
85. N4F026	
86. N4G013	
87. N4F032	
88. N4F033	
89. N4G001	
90. N4G003	
91. N4G014	
92. N4G015	
93. N4G025	
94. N4G026	
95. N4G028	
96. N4J001	
97. N4J002	
98. N4J013	
99. N4J015	
100. N4J017	
101. N4J019	
102. N4J020	
103. N4J021	
104. N4J024	
105. N4J025	

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Product Recall Response Form

Lot #	QTY on hand
106. N4J026	
107. N4J027	
108. N4J028	
109. N4J029	
110. N4J032	
111. N4J033	
112. N4K001	
113. N4K002	
114. N4K004	
115. N4K005	
116. N4K007	
117. N4K008	
118. N4K010	
119. N4K026	
120. N4K028	
121. N4K031	
122. N4K033	
123. N4K034	
124. N4K036	
125. N4K037	
126. N4K038	
127. N4K040	
128. N4K041	
129. N4K043	
130. N4L002	
131. N4L005	
132. N4L007	

Lot #	QTY on hand
133. N4L008	
134. N4L010	
135. N4L012	
136. N4L013	
137. N4L018	
138. N4L019	
139. N4L023	
140. N4L024	
141. N4L027	
142. N4L029	
143. N4L032	
144. N4L033	
145. N4L035	
146. N4M003	
147. N4M004	
148. N4M006	
149. N4M009	
150. N4M012	
151. N4M013	
152. N4M015	
153. N4M018	
154. N4M019	
155. N4M021	
156. N4M023	
157. N4M028	
158. N4M030	
159. N4M031	

Lot #	QTY on hand
160. N4M033	
161. N4M036	
162. N4M037	
163. N5A008	
164. N5A011	
165. N5A012	
166. N5A014	
167. N5A017	
168. N5A018	
169. N5A026	
170. N5A029	
171. N5A031	
172. N5A032	
173. N5A037	
174. N5A038	
175. N5A039	
176. N5A054	
177. N5A047	
178. N5A048	
179. N5A050	
180. N5A051	
181. N5B002	
182. N5B005	
183. N5B006	
184. N5B009	
185. N5B020	

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