Urgent Medical Device Recall

May 30, 2024

Dear Healthcare Provider or Distributor:

Problem Description

Baxter is issuing an Urgent Medical Device Recall for multiple lots of the **Volara** system single-patient use circuit due to customer reports of the handset plug disconnecting from the nebulizer port on the blue ventilator adapter (See Figure 1 below). When using the **Volara** system in-line with a ventilator and without a nebulizer connected to the blue ventilator adapter, the handset plug is required to ensure proper operation and ventilator gas flow.

Figure 1: Blue ventilator adapter with a disconnected handset plug

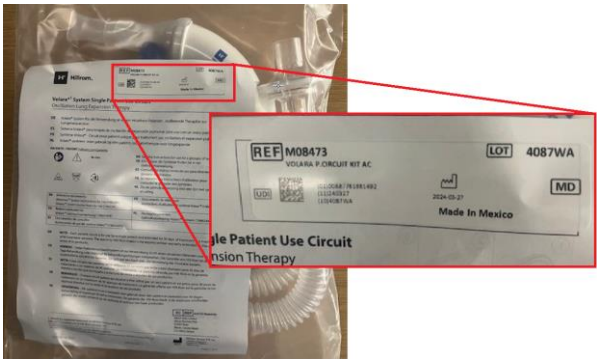

Figure 2: For identification purposes only - Location of Product Code and Lot Number

The affected product was distributed between 8/26/2022 and 12/30/2023 in the United States.

Affected Product

Product Code	Product Description	DI Number	Lot Number
M08473	**VOLARA** PATIENT CIRCUIT AC	00887761981492	See Attachment A
M08474	**VOLARA** PATIENT CIRCUIT 5KIT AC	00887761981499	

Hazard Involved

If the handset plug disconnects and this is unrecognized prior to or during therapy, it may lead to an interruption or delay of care which may result in reduced oxygenation due to the ventilator leaking gas flow from the nebulizer port on the blue ventilator adapter. This may be detected by hearing noise coming from the port and/or visual inspection of the nebulizer port. To date, there have been no reports of adverse events associated with this issue.

Actions to be taken by Customers

1. Immediately locate, isolate, and cease all use of the affected lot numbers. The product code and lot number can be found in the upper right-hand corner of the package insert in unopened circuits (See Figure 2 above). For product code M08474, the product code and lot number can also be found on the shipping box label.
2. Arrange for return and replacement of your impacted product by contacting the Baxter Advanced Respiratory, Acute Care Customer Service team, at 800-426-4224, option 2, between the hours of 8:00 am and 5:00 pm Central Time, Monday through Friday.

3. **If you received this communication directly from Baxter, please acknowledge receipt of this notification by responding on our customer portal at https://BaxterFieldActionCustomerPortal.onprocess.com, even if you do not have any remaining inventory.** Log in to the portal using the account number listed in the enclosed reply form instruction sheet. Acknowledging receipt of this notification will prevent you from receiving repeat notices. If you do not complete the acknowledgement, you will receive a phone call from OnProcess Technology on behalf of Baxter to confirm your receipt of this notification.
4. If you purchased this product from a distributor or wholesaler, please contact your supplier to arrange for return of the affected product. Please note that responding on the Baxter customer portal is not applicable. If a response is requested by your distributor or wholesaler, please respond to the supplier according to their instructions.
5. If you distributed this product to other facilities or departments within your institution, please forward a copy of this communication to them.
6. If you are a dealer, wholesaler, distributor/reseller, or original equipment manufacturer (OEM) that distributed any affected product to other facilities, please conduct a consumer-level recall of the affected product that you distributed to customers and **check the associated box on the customer portal.**

Further information and support For general questions regarding this communication, please contact Baxter Advanced Respiratory, Acute Care Customer Service team, at 800-426-4224, option 2, between the hours of 8:00 am and 5:00 pm Central Time, Monday through Friday.

The United States Food and Drug Administration (FDA) has been notified of this action. Any product quality complaints or adverse events experienced with the use of these products may be reported using one of the following options:

- Contacting the Baxter Advanced Respiratory, Acute Care Customer Service team, at 800-426-4224, option 2, between the hours of 8:00 am and 5:00 pm Central Time, Monday through Friday.
- Reporting to the FDA MedWatch Serious Injury Reporting Program:
  - **Online:** By completing and submitting the report online at: https://www.accessdata.fda.gov/scripts/medwatch/
  - **Regular mail or fax:** Download the form from www.fda.gov/MedWatch/getforms.htm or call 800-332-1088 to request a reporting form, then complete and mail it to the address on the pre-addressed form, or submit by fax to 800-332-0178

We apologize for any inconvenience this may cause you and your staff.

Sincerely,

Brian Ray
Senior Director, Quality
Baxter Healthcare Corporation

Enclosure: Attachment A
Baxter Reply Form Instruction Sheet