Urgent Medical Device Recall

May 30, 2024

Dear Patient or Caregiver,

Problem Description

Baxter is issuing an Urgent Medical Device Recall for two 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 <u>without</u> a nebulizer connected to the blue ventilator adapter, the handset plug is required to ensure proper operation and ventilator gas flow.

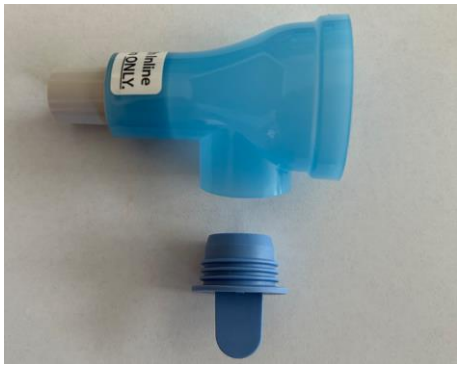

Figure 1: Blue ventilator adapter with a disconnected handset plug

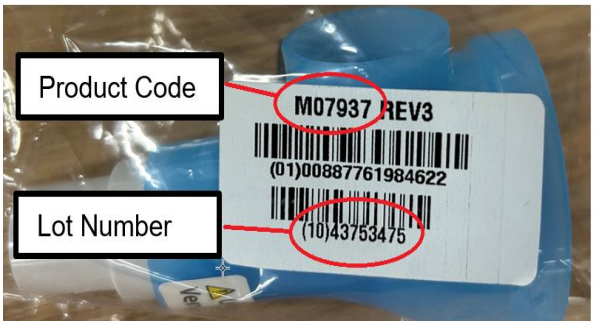

Figure 2: For identification purposes only- Location of product code and lot number

The affected product was distributed between 8/29/2022 and 8/17/2023 in the United States.

Affected Product

Product Code	Product Description	DI Number	Lot Number
M07937	Blue Ventilator Adapter Module	00887761984622	4210495
			4325617

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 and if possible, cease all use of the affected lot numbers. The product code and lot number can be found on the label on the clear packaging of the blue ventilator adapter module (see Figure 2 above).
2. If you do not have other options in stock, in order to not delay therapy, you may continue to use with caution. Visually inspect the nebulizer port prior to therapy and assess for ventilator gas flow leaks for the duration of therapy.
3. If you need general assistance with your **Volara** therapy, please contact the Baxter Advanced Respiratory, Home Care Customer service team at 800-397-9071.
4. Arrange for the return and replacement of your impacted product by contacting the Baxter Advanced Respiratory, Home Care Customer service team, 800-426-4224, option 3, between the hours of 8:00 am and 5:00 pm Central Time, Monday through Friday. Replacement product (a blue ventilator adapter module) will be shipped, and you will be provided with instructions to return your impacted blue ventilator adapter to Baxter.
5. Acknowledge receipt of this letter, even if you do not have remaining product, using one of the two methods detailed on the enclosed Home Patient Reply Form Instruction Sheet. Acknowledging receipt promptly will prevent you from receiving repeat notifications. 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.

Further information and support

For general questions regarding this communication, please contact Baxter Advanced Respiratory, Home Care Customer service team at 800-426-4224, option 3, 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, Home Care Customer service team at 800-426-4224, option 3, 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: Home Patient Reply Form Instruction Sheet