URGENT MEDICAL DEVICE CORRECTION

May 21, 2026

Dear Healthcare Provider:

Baxter Healthcare Corporation is issuing an urgent medical device correction for **Volara** system patient circuits due to reports of air and medication leakage from the nebulizer cup during therapy. The leakage can lead to patient desaturation and ineffective nebulization, impacting the delivery of prescribed therapy. The issue has been associated with improper locking of the nebulizer after medication is added to the cup.

Affected Products

Product Code	Product Description	UDI Number	Lot Number
M08085	VOLARA P.CIRCUIT KIT, HC	00887761985018	All lot numbers distributed starting on 4/28/2025
M08270	VOLARA P.CIRCUIT 5KIT	10887761985015	
M08473	VOLARA P.CIRCUIT KIT AC	00887761981492	
M08474	VOLARA P.CIRCUIT 5KIT AC	10887761981499	

Hazard Involved

If the nebulizer cup is damaged or is not properly engaged during assembly, this issue could lead to medication leakage and ineffective delivery of therapy. If less medication than intended reaches the lungs, the mechanical benefits may still occur; however, the pharmacologic benefit may be reduced or lost. This may lead to serious or critical adverse health consequences such as increased airway inflammation and mucus retention (which may lead to infection), prolonged coughing, worsening shortness of breath, and/or reduced oxygenation. Baxter has received one report of a serious injury related to this issue

Actions to be Taken by Customers

1. Before each use, carefully inspect the nebulizer cup for damage and ensure it is fully and securely locked during assembly, following the enclosed instructions. If leakage is observed during therapy, discontinue the use of that nebulizer and replace the patient circuit.

2. Nebulizer cups with patient circuits are routinely replaced as part of normal therapy usage. Additional patient circuits can be provided through standard distribution.

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 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 Accenture LLP on behalf of Baxter to confirm your receipt of this notification.

4. If you purchased this product from a distributor or wholesaler, 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 notify your customers of this urgent medical device correction in accordance with your customary procedures and check the associated box on the customer portal. Please continue distributing this communication to all new customers until the IFU updates are complete. Baxter will advise when the new IFU is released.

Further Information and Support

For general questions regarding this communication, please contact Baxter's Acute Care Customer Service team at 800-426-4224, option 2 between the hours of 8:00 a.m. - 5:00 p.m. CST.

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 Baxter Product Surveillance at the Baxter product feedback portal at https://productfeedback.baxter.com, or emailing Baxter at corporate_product_complaints_round_lake@baxter.com

- Reporting to the FDA MedWatch Serious Injury Reporting Program:

- **Online:** By completing and submitting the report at 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

Enclosures:
VOLARA System Single Patient Circuit
Baxter Customer Reply Instruction Sheet
Baxter Home Patient Letter

Baxter

VOLARA System Single Patient Circuit

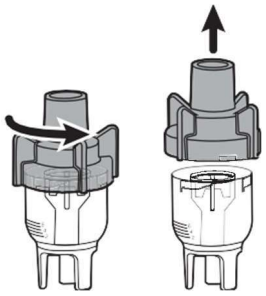
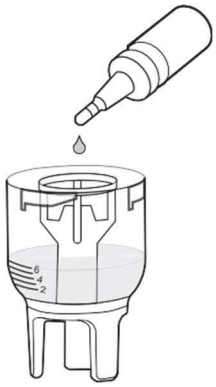
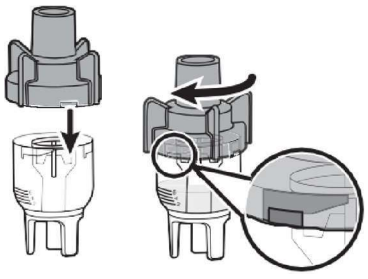
FR Système **Volara** - Circuit pour patient unique pour traitement par oscillation et expansion pulmonaire

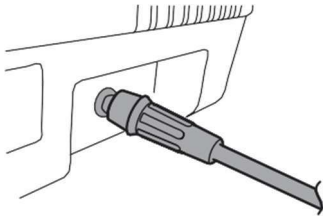
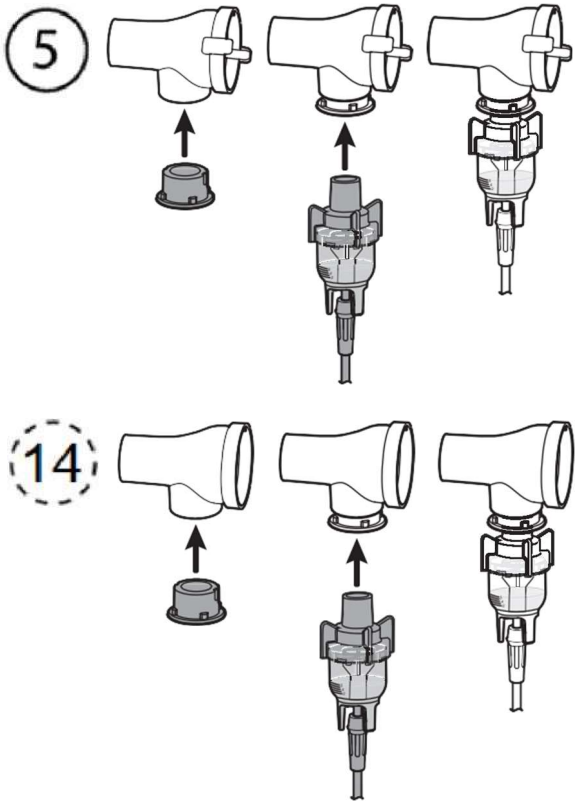
WARNING / AVERTISSEMENT

EN **WARNING—**If leakage is observed during use, stop the therapy. Inspect all components to ensure they are correctly assembled and free from damage. If leakage persists, discontinue use and replace the patient circuit. Continued leakage may result in reduced or ineffective therapy delivery.

FR **AVERTISSEMENT—**Si une fuite est observée pendant l'utilisation, arrêtez le traitement. Inspectez tous les composants afin de vous assurer qu'ils sont correctement assemblés et exempts de dommages. Si la fuite persiste, cessez l'utilisation et remplacez le circuit patient. La persistance d'une fuite peut entraîner une administration réduite ou inefficace du traitement.

Assemble the Nebulizer Kit and Add Medication

1	**EN** Remove the lid from the nebulizer cup. **FR** Retirez le couvercle du godet du nébuliseur.	
2	**EN** Fill the nebulizer cup with prescribed medication or saline. **FR** Remplissez le godet du nébuliseur avec le médicament prescrit ou une solution saline.	
3	**EN** Replace the lid and turn clockwise until the nebulizer cup locks. Do not over-tighten. **FR** Replacez le couvercle et tournez-le dans le sens des aiguilles d'une montre jusqu'à ce que le godet du nébuliseur se verrouille. Ne serrez pas excessivement.	

4	**EN** Attach tubing to the control unit's nebulizer port. **FR** Raccordez le tube au port du nébuliseur de l'unité de commande.	
5	**EN** Attach the other end of tubing to the base of the nebu-lizer cup. **FR** Fixez l'autre extrémité du tube à la base du godet du nébuliseur.	
6	**EN** Connect the nebulizer adapter to the breathing adapter (either part 5 or part 14), and then connect the nebulizer adapter to the lid of the nebulizer cup. **FR** Raccordez l'adaptateur du nébuliseur à l'adaptateur respiratoire (pièce?5 ou pièce 14), puis raccordez l'adapta-teur du nébuliseur au couvercle du godet du nébuliseur.	

Revision date: 2026-05

Baxter

Hillrom Services PTE Ltd 1 Yishun Avenue 7 Singapore 768923 baxter.com