URGENT MEDICAL DEVICE CORRECTION

May 22, 2026

Dear Home Care Patient:

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 an oxygen level drop in the patient and ineffective nebulization, which may affect the delivery of the prescribed treatment. The issue has been associated with improper locking of the nebulizer cup after adding medication during user setup.

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	

Hazard Involved

If the nebulizer cup is damaged or not properly engaged during assembly, the issue could lead to medication leakage and ineffective delivery of therapy. If less medication than intended reaches the lungs, the device may still work, but the patient may not receive the full benefit of the treatment, making it less effective. 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 instructions provided in this letter. If leakage is observed during therapy, please discontinue use of that nebulizer and replace the patient circuit. If leakage persists or you are unsure whether to continue therapy, contact your healthcare provider or care team for guidance.

2. Nebulizer cups with patient circuits are routinely replaced as part of normal therapy usage. Additional patient circuits will 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.

Further Information and Support

For clinical assistance with your **Volara** therapy, please contact Baxter's Clinical Support team at 800-397-9071.

For general questions regarding this communication, please contact Baxter's Home Care Customer Service team at 800-426-4224, option 3 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.

Sincerely,

Brian Ray
Senior Director, Quality
Baxter Healthcare Corporation

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

Baxter

VOLARA System Single Patient Circuit

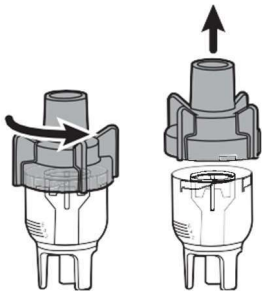
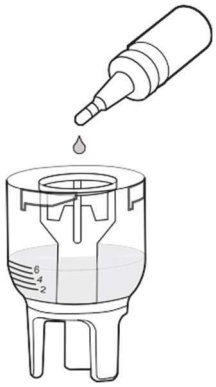
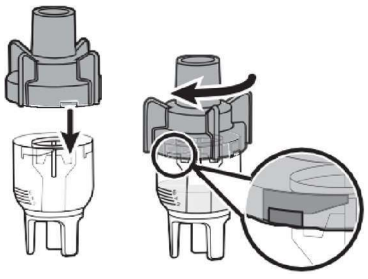
FR Système **Volara** - Circuit pour patient unique pour traitement par oscillation et expansion pulmonaire

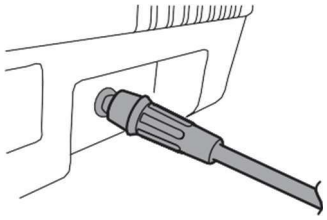
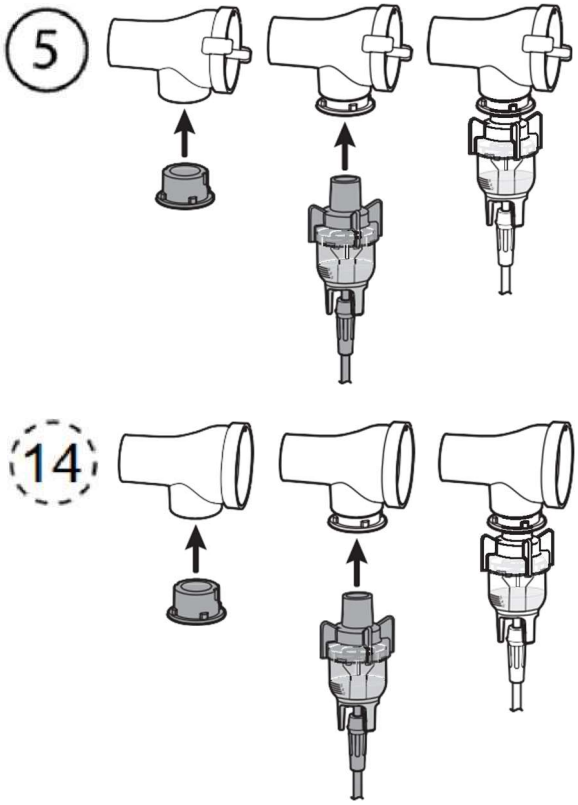
WARNING / AVERTISSEMENT

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