URGENT: Customer Notification Letter

AirLife™ Manual Resuscitator

December 5, 2023

Vyaire Medical, Inc.
26125 N. Riverwoods Blvd.
Mettawa, IL 60045

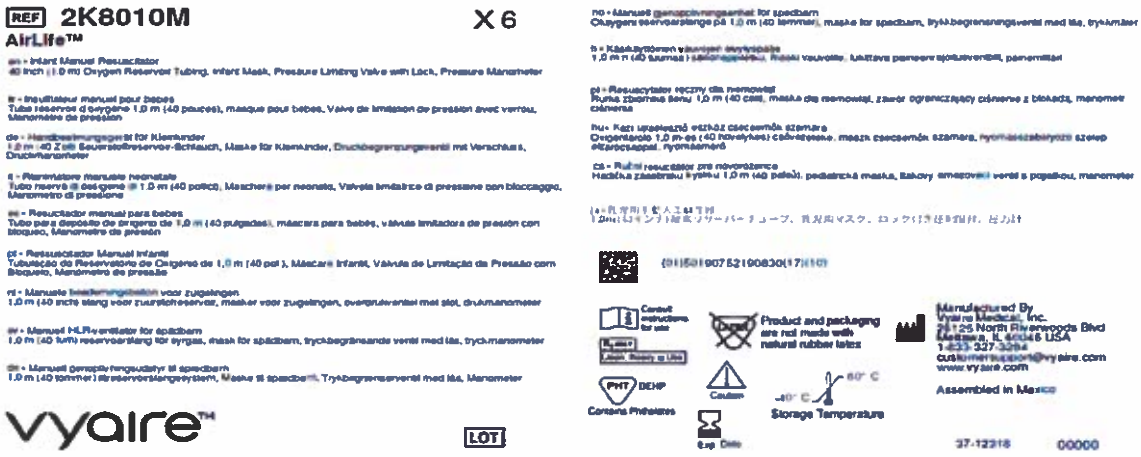
Dear Valued Customer/Distributor:

The purpose of this letter is to inform you to discard or destroy any Vyaire Medical, Inc. AirLife™ Manual Resuscitation Bags manufactured in 2017 or earlier. Reference **Attachment A** for the list of product SKUs to discard or destroy.

Vyaire has received thirty-seven (37) customer reports relating to product issues, including two deaths and two serious injuries. It has been identified that the affected product issues are due to faulty mold/tooling producing out of specification components. This device failure may result in improper ventilation or no ventilation that may result in hypoventilation or hypoxia, and potentially may lead to death. The mold/tooling used to produce the affected component was replaced in 2017. While the products involved in the reported complaints were produced prior to 2017 with the original tools, Vyaire believes that these products may still be in use. Therefore, Vyaire requesting all products labeled with a manufacturing date before 2017 and those without a manufacturing date to be discarded or destroyed.

The mold/tooling used to produce the affected component was replaced in 2017. There have been zero (0) reported complaints with products manufactured since the mold tooling was implemented in 2017.**Vyaire Medical, Inc. is advising customers/distributors to discard or destroy product(s) that have a manufacturing date of 2017 or earlier, as well as products that do not contain an expiry date on the label (example provided below).**

Example Label with Expiration Date



Actions to be taken by customers:

Please examine your inventory for the affected product and isolate pending destruction. **Please DO NOT RETURN the product to Vyaire Medical, Inc.** When destroying affected product(s) please follow your facility's disposal protocol/procedure. If hospital policy does not allow destruction, please contact productquality@myairlife.com. Following destruction, please complete the attached Certificate of Destruction Form (**Attachment B**) and return it to productquality@myairlife.com. NOTE: customers that no longer have product will also need to fill out and return Attachment B to acknowledge that you have read and understand the recall instructions provided in the December 5, 2023, letter.

If you distributed this product to other facilities, departments, or mobile units within your institution, please forward a copy of this communication to them.

Actions to be taken by distributors:

Please examine your inventory for the affected product and destroy following your facility's disposal protocol. If you distributed any affected product to other facilities, please distribute this notification to customers and request they follow the instructions under the Actions to be taken by customers section above.

This customer notification letter is being conducted with the knowledge of the United States Food and Drug Administration (FDA) in accordance with FDA regulations. Any complaints and/or adverse events experienced with the use of this product must be reported promptly to Customer Service at productquality@myairlife.com. Adverse reactions or quality problems experienced with this product may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax.

- Complete and submit the report online: www.fda.gov/medwatch/report.htm.
- Regular Mail: Download form from www.fda.gov/medwatch/getforms.htm or call 1-800-322-1088 to request a reporting form, then complete and return to the address on the pre-addressed form
- Fax: 1-800-FDA-0178

Vyaire Medical, Inc. appreciates your immediate attention to this **Medical Device Recall**. We recognize the inconvenience this issue may cause your facility and thank you for your support in this important matter. If you have any questions related to this notification, please contact Tiffany Flores, *Clinical Risk Coordinator*, at TFlores@myairlife.com.

Sincerely,

Erin Salbilla Sr. Director, Quality Systems

Enclosures:
Attachment A – Affected Product Codes and Description
Attachment B – Certificate of Destruction Form

Attachment A – Affected Products manufactured in 2017 or before to discard or destroy:

Product Codes	Product Description
2K8000	AirLife™ Adult Manual Resuscitator, Oxygen Reservoir Bag, without Mask
2K8001	AirLife™ Adult Manual Resuscitator, 40" (1.0m) Oxygen Reservoir Tubing, without Mask
2K8004F	AirLife™ Adult Manual Resuscitator, Oxygen Reservoir Bag, Expiratory Filter
2K8004C2	AirLife™ Adult Manual Resuscitator, Oxygen Reservoir Bag, Adult Mask, CO2 Detector
2K8005	AirLife™ Adult Manual Resuscitator, 40" (1.0m) Oxygen Reservoir Tubing, Adult Mask
2K8005F	AirLife™ Adult Manual Resuscitator, 40" (1.0m) Oxygen Reservoir Tubing, Adult Mask, Expiratory Filter
2K8005C2	AirLife™ Adult Manual Resuscitator, 40" (1.0 m) Oxygen Reservoir Tubing, Adult Mask, CO2 Detector
2K8017	AirLife™ Adult Manual Resuscitator, Variable Volume Oxygen Reservoir Tubing, Adult Mask
2K8004	AirLife™ Adult Manual Resuscitator, 40" (1.0m) Oxygen Reservoir Tubing, Adult Mask

Attachment B – Certificate of Destruction Form

Certificate of Destruction Form

I have read and understand the recall instructions provided in the December 5, 2023, letter.
Yes ____ No_____

Required when product disposition designation is **Discard/Destroy**

Complete the following and maintain with other project related documents.

Product disposition given per: *Identify project by name or reference number*

Product catalog number

Lot number Quantity destroyed

Lot number Quantity destroyed

Lot number Quantity destroyed

Lot number Quantity destroyed

Destroyed by Signature: _____ Date: _____

Print Name: _____

Witnessed by Signature: _____ Date: _____

Print Name: _____

After filling out this form, please return to productquality@myairlife.com.