URGENT: MEDICAL DEVICE RECALL

AirLife Infant Heated Wire Circuits (AH165, and AH265)

IMMEDIATE ACTION REQUIRED

1st NOTIFICATION

Date: April 11, 2025

<Consignee Name>
<Address>

Dear Valued Customer/Distributor,

Purpose of the letter:

The purpose of this letter is to advise you that AirLife (legal manufacturer Vyaire) is voluntarily recalling select lots of Infant Heated Wire Circuits (AH165 and AH265). We have identified you as a customer who has received the affected lots.

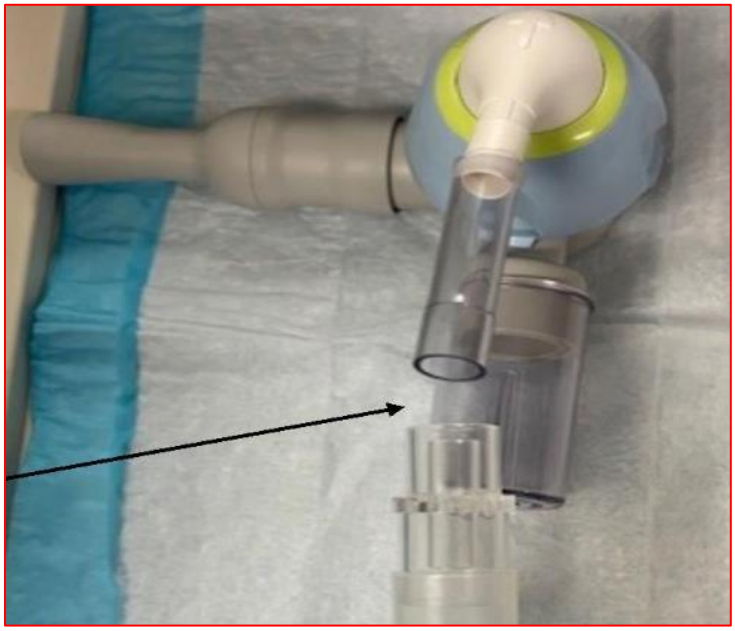
To date, there have been no deaths or injuries reported related to this problem. There was one complaint reported.

Description of the problem:

AirLife Infant Heated Wire Circuits are intended for neonatal and infant patients in professional healthcare environments, functioning as a conduit for respiratory gas between the patient and a ventilator. The adapters depicted in **Image A,** which are included in the accessory bag of the affected product, are used in certain circuit setups to connect to the inspiratory and/or expiratory ventilator ports. These adaptors are made of two components that may unintentionally disconnect either during setup or while in use after reaching operating temperature, potentially interrupting ventilation as depicted in **Image B**. AirLife has received a single complaint related to this issue.

Image A *Adaptors provided in the accessory bag of the AirLife Infant Heated Wire Circuit*

Image B *Disconnection of the adaptor accessory*



The problem occurs when customers utilize the accessory adapters shown in **Image A** from AH165 and AH265 circuit kits to adapt to 11.5 mm inspiratory/expiratory ports of a ventilator (e.g. Drager VN500).

The table below provides the reference number and lot numbers of the recalled products:

Product Description	REF Number	Lot Numbers		UDI Information
AirLife™ Infant Heated Wire Circuit dual-limb, dual-heat, high-flow circuit (>4 L/min)	AH165	0004240347 0004240348 0004252021 0004253194 0004253470 0004255176 0004260100	0004262183 0004262987 0004263371 0004292077 0004300092 0004301668	AirLife Label Each: 10889483595862 Case: 30889483595866 Vyaire Label Each: 10190752145139 Case: 50190752145137
AirLife™ Infant Heated Wire Circuit Kit Dual-limb, Dual-heat, high-flow circuit (>4 L/min) Contains AH165 Circuit, AH290 Chamber	AH265	0004247924 0004247925 0004252940 0004252941 0004256292 0004256293 0004256294 0004256295	0004272325 0004272868 0004278978 0004279156 0004280036 0004285304 0004288036 0004289514	AirLife Label Each: 10889483595909 Case: 30889483595903 Vyaire Label: Each: 10190752145160 Case: 50190752145168

Health risk:

When a neonatal breathing circuit becomes disconnected from the ventilator, it may cause leaks, insufficient pressure and/or volume delivery, which presents critical risks to the vulnerable nature of neonates. Neonates, especially preterm or critically ill infants, may be highly dependent on mechanical ventilation and require adequate oxygenation and ventilation. Any disconnection in the breathing circuit and interruption in ventilation can result in life-threatening consequences, including hypoxia, hypercapnia, organ failure and death if the situation is not identified and addressed promptly by health care personnel.

Customer immediate actions:

1. Review the list of affected products above. Please examine your inventory for the mentioned lot(s). No other lots are affected.
2. Quarantine all affected product in inventory.
3. In-use product:
    a. For affected product in use that is utilizing the adaptor connection shown in **Image A**, immediately, stop/cease use of the product.
    b. For affected product in use that is NOT utilizing the adaptor connection shown in **Image A**, the ventilator circuit may continue to be utilized.

I. Perform frequent checks on ventilator settings, tubing, and connections to ensure they are firmly tight, secure, and functioning properly.

II. Ensure all alarms for pressure, flow, and disconnection are activated, and monitor the patient's respiratory parameters closely.

III. Backup ventilation and/or manual resuscitation devices should be available at the bedside for emergent situations.

IV. Physiological monitoring utilizing oxygen saturation (Sp02), heart rate, and respiratory rate monitors should be used to alert clinicians to an adverse event in a patient.

V. Test circuit prior to use by occluding the patient connection port and pressure test the circuit to ensure that there are no leaks.

4. Please complete and return the attached Response Form via e-mail to **productquality@myairlife.com** as soon as possible. This will enable us to document the amount of product you have on hand for return and/or destruction. It will also allow us to document your receipt of this letter.

5. In addition, if you have further distributed this product, please identify your customers/consignees, and notify them of this product removal. Your notification may be enhanced by including a copy of this removal notification letter.

6. Once you return and/or confirm destruction of the affected product(s), a new replacement product will be sent to you. If you need replacement products to be sent to you urgently, please call AirLife directly on +44 (0)800 058 4870 and we will make every effort to accommodate your needs.

7. Please make sure that all affected personnel in your organization are informed of this removal notice.

AirLife apologizes for any inconvenience this causes. Your satisfaction with AirLife products and with our response to this situation is very important to us. If you have any questions regarding this field action, please call AirLife at +44 (0)800 058 4870, or e-mail at **productquality@myairlife.com.**

Attachments:

A. AirLife Infant Heated Wire Circuits Field Removal/Return Response Form
B. Certificate of Destruction form

Should you have any questions, feel free to reach out to your local AirLife Territory Manager, Customer Service at +44 (0)800 058 4870 or **productquality@myairlife.com.**

The Competent Authority in your country has been notified of this recall.

Thank you for your attention and cooperation.

Rob Yamashita
AirLife - VP of Regulatory Affairs

Immediate Action Requested

Attachment A: AirLife Infant Heated Wire Circuits Field Removal / Return Response Form

REF NUMBER	LOT NUMBER	QTY RECEIVED	QTY TO BE RETURNED	QTY TO BE DESTROYED

Please check ALL appropriate boxes.

- ☐ I have read and understand the removal instructions provided in the letter sent April 11, 2025.
- ☐ I have checked my inventory.
  - ☐ I do not have any affected products.
  - ☐ I am returning the affected product.
  - ☐ I have destroyed and disposed of the affected product. (Complete and return Attachment B)
- ☐ I have further distributed the affected device and have notified the receiving facility by (**specify date & method of notification**): _____

Have any adverse events been reported to you regarding the affected product? ☐ Yes ☐ No

If yes, please explain: _____

_____

Contact Name: _____

Title: _____

Facility Name: _____

Address: _____

City/State/Zip Code: _____

Telephone Number: _____Email: _____

PLEASE SEND COMPLETED RESPONSE FORM(S) TO:

E-MAIL TO: **productquality@myairlife.com**

Received Letter from Distributor/Non-AirLife Center? ☐ Yes ☐ No

If yes, please add name of distributor/non-AirLife Center: _____

Immediate Action Requested

Attachment B – Certificate of Destruction Form

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

Name of Consignee/Company: _____

I have read and understand the recall instructions provided in the letter April 11, 2025.

Yes, _____No _____

Complete the following and send completed form with completed Attachment A form.

Product disposition:

Product catalog number: _____

Lot number: _____ QTY Destroyed: _____

Lot number: _____ QTY Destroyed: _____

Lot number: _____ QTY Destroyed: _____

Lot number: _____ QTY Destroyed: _____

Destroyed by Signature: _____ Date: _____

Print Name: _____

Witnessed by Signature: _____ Date: _____

Print Name: _____