

URGENT RECALL NOTICE

2K8008BR & 2K8010BR - Pediatric & Infant Resuscitation devices - BROSELOW
8030673-4/27/17-002-R

April-27-2017

Dear Customer:

The purpose of this letter is to inform you of a voluntary Recall initiated by Vyairé Medical (a company comprised of the Respiratory Solutions businesses previously a part of CareFusion/BD) due to a potential patient safety risk associated with the 2K8008BR and 2K8010BR, *AirLife®* Pediatric and Infant resuscitators.

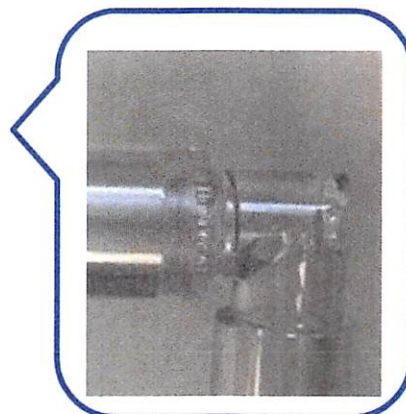
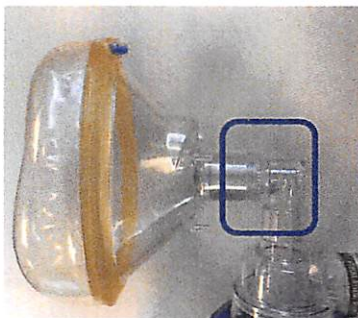
Products affected by this voluntary Recall have been purchased through your distributor, *Armstrong Medical*. Your facility has been identified by Armstrong Medical as potentially having received affected product.

PRODUCT DESCRIPTION/ PROBLEM STATEMENT:

The 2K8008BR and 2K8010BR are manual resuscitation devices that are used to provide positive pressure ventilation to infant and pediatric patients who require assisted ventilation. These devices come fully assembled and ready to use with a cushioned mask. A key feature of the manual resuscitation device(s) includes removal of the mask component.

Various lots of the 2K8008BR and 2K8010BR manual resuscitation devices have been identified as having the potential to exhibit a sticking condition which may result in a difficult to/ unable to disconnect condition of the mask from the elbow of the resuscitator. Reference Illustration A

Illustration A:



POTENTIAL RISK:



The potential patient safety risk associated with the sticking condition and the difficult to/ unable to disconnect malfunction may result in a delay in or inability to provide ventilation to the patient after placement of an advanced airway (tracheal or tracheostomy tube).

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AFFECTED PRODUCT:

The affected 2K8008BR and 2K8010BR Pediatric and Infant Manual Resuscitation devices exist within five (5) various configurations for use within the BROSELOW Pediatric Safety System Reference **Table 1**.

Table 1

2K8008BR	RESUS, PED W/3 MASKS, 40" TBG, P/O
2K8010BR	RESUS, INF W/MASK, 40" TBG,P/O
7730ALS	Broselow Hinkle Kit 
7730IALS*	
7730POCH	Replacement Kit for outer shell 

*The 7730ALS and 7730IALS are the same configuration. Part Number 7730IALS is the internationally distributed Part Number.

This notification applies to a total of twenty-five (25) lots of the five (5) Part Numbers, 2K8008BR, 2K8010BR, 7730ALS, 7730IALS and 7730POCH. The twenty-five (25) lots have been identified as containing the affected Pediatric and Infant Resuscitation devices.

Reference **Appendix 1** for the affected Part Numbers and lot information.

***Refer to FAQ's (Appendix 2), Q. 6 for identification of lot information for the various configurations.**

The remainder of the components kitted within the 7730ALS, 7730IALS and 7730POCH are **NOT** affected by this voluntary Recall.

ACTION TO BE TAKEN BY THE CUSTOMER:

- Inspect current inventory on-hand. A 100% physical inventory of your BROSELOW systems (7730ALS/7730IALS & 7730POCH) should immediately be performed to identify and remove the affected 2K8008BR and 2K8010BR pediatric and infant resuscitators.
- Complete the **Customer Response Form (Appendix 3)** by providing all accurate and complete information *as required* and return to GMB-GLB-VSFieldActions@CareFusion.com

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75 N. Fairway Dr.
Vernon Hills, IL 60061

VyairéMedical.com

- Destroy all affected 2K8008BR and 2K8010BR resuscitators in-stock in accordance with your facility's destruction protocol.
- If you wish to obtain replacement for the AirLife Pediatric and Infant resuscitators that have been destroyed in accordance with this voluntary Recall, contact your distributor, *Armstrong Medical*, direct at (800)323.4220 X129.

*Please have your **original PO** number available when calling to expedite the replacement process.

For any additional questions and support concerning this voluntary Recall, please contact Kristina Scheppa, *Customer Advocacy Analyst*, at (224)706.6829 or Kristina.Scheppa@CareFusion.com

We appreciate your **prompt return** of the enclosed **Customer Response Form** to expedite the correction process and acknowledge receipt of this notification.

We recognize the inconvenience this issue may cause your facility and thank you for your support in this important matter.

Sincerely,

Kristina Scheppa
Clinical Customer Advocacy Analyst
Vyairé Medical

Enclosures: Affected Part Numbers & lots (Appendix 1)
FAQ'S (Appendix 2)
Customer Response Form (Appendix 3)

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Appendix 1

Distributor (Armstrong Medical) Part Number	Manufacturer Part Number (Vyair Medical)	Product Description	Lot Number(s)	Lot Number on 2K8008BR Resuscitator (Packaged in BROSELOW Kits 7730ALS/ 7730IALS & 7730POCH)	Lot number on 2K8010BR Resuscitator (Packaged in BROSELOW Kits 7730ALS/ 7730IALS & 7730POCH)
AE 4709(S)	2K8008BR	RESUS, PED W/3 MASKS, 40" TBG, P/O	0000890354 0000890352 0000940373 0000979974 0000994500	N/A	N/A
AE 4708(S)	2K8010BR	RESUS, INF W/MASK, 40" TBG,P/O	0000890355 0000890357 0000890358 0000940369 0000994501	N/A	N/A
AE-4700	7730ALS	Broselow Hinkle Kit	0000993426 0000994766 0000996685 0001011762 0001011763 0001017478 0001026192 0001026868 0001028306 0001031760 0001032932 0001048406	0000994500	0000994501
N/A	7730IALS	Broselow Hinkle Kit	000996572 0001011800	0000994500	0000994501
AE-4703 *PBL-PC-9A	7730POCH	Replacement Kit for outer shell	0000993427	0000994500	0000994501

*The PBL-PC-9A distributor Part Number contains the 7730POCH, Replacement Kit for outer shell



Appendix 2

2K8008BR & 2K8010BR - Pediatric & Infant Resuscitation devices – BROSELOW

Corrective Action FAQ's

Core Messages

- Vyairé Medical has identified a potential patient safety risk associated with the sticking condition of the mask component of the resuscitation device which may result in a difficult to/ unable to disconnect condition between the mask and elbow component of the 2K8008BR & 2K8010BR AirLife® manual resuscitators.
- The affected 2K8008BR and 2K8010BR Pediatric and Infant Manual Resuscitation devices impact a total of twenty-five (25) lots of five (5) Part Numbers, 2K8008BR, 2K8010BR, 7730ALS, 7730IALS & 7730POCH.
- Inspect current inventory on-hand. A 100% physical inventory of your BROSELOW systems (7730ALS/7730IALS & 7730POCH) should immediately be performed to identify and remove the affected 2K8008BR and 2K8010BR pediatric and infant resuscitators.
- Vyairé Medical appreciates your prompt return of the enclosed **Customer Response Form** to expedite the correction process and acknowledge receipt of this notification.

Customer FAQ

1. Why is Vyairé Medical initiating this voluntary Recall?

Vyairé Medical is committed to ensuring patient safety and maintaining the highest level of regulatory compliance with the FDA and other Agency's around the globe. As part of this commitment, Vyairé Medical has issued this voluntary Recall involving removal of all 2K8008BR and 2K8010BR AirLife Pediatric and Infant resuscitators belonging to the Part and lot numbers identified in **Appendix 1** due to the identified potential patient safety risk.

2. How does this failure manifest?

The sticking of the mask component may be difficult to detach/unable to be detached from the elbow of the resuscitator. This malfunction may be identified when trying to remove the mask component to provide ongoing ventilation to a patient after placement of an advanced airway.

3. Have any patient injuries been reported?

Vyairé Medical has received one (1) report of serious injury involving "desaturation" due to the inability to detach condition.

4. When will replacement of the AirLife Pediatric and Infant Resuscitators be available?

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Corrective actions have been implemented to address the sticking condition. Please work with your distributor, *Armstrong Medical*, to receive available replacement product. Contact *Armstrong Medical* at (800)323.4220 X129.

5. Are all units affected by this voluntary Recall?

All units, of the twenty-five (25) lots of Part Numbers 2K8008BR, 2K8010BR, 7730ALS, 7730IALS and 7730POCH are affected by this voluntary Recall.

The remainder of the components kitted within the 7730ALS, 7730IALS and 7730POCH are **NOT** affected by this voluntary Recall.

6. Where is the lot information located on Part Numbers 2K8008BR, 2K8010BR, 7730ALS, 7730IALS and 7730POCH?

*See label Illustration(s) below

- Illustration A: 2K8008BR product label with illustration of Part and lot Number
- Illustration B: 2K8010BR product label with illustration of Part and lot Number
- Illustration C: Label insert located inside cover/lid of 7730ALS/7730IALS
- Illustration D: Armstrong Medical carton label for 7730ALS or 7730POCH with Distributor Part Number

Illustration A:

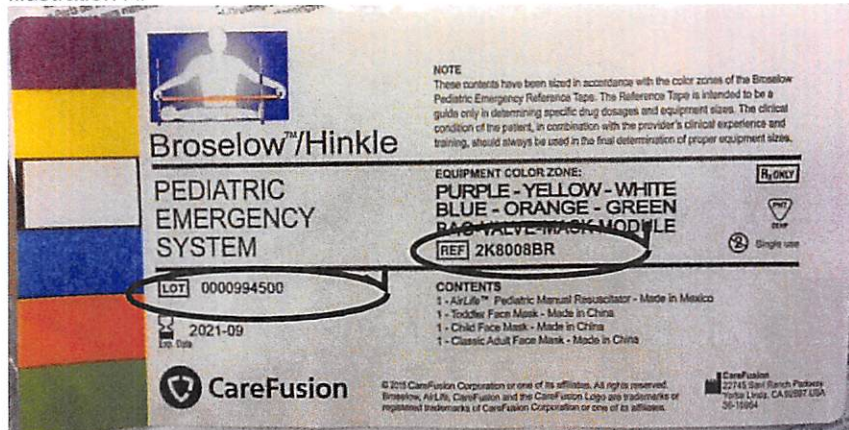
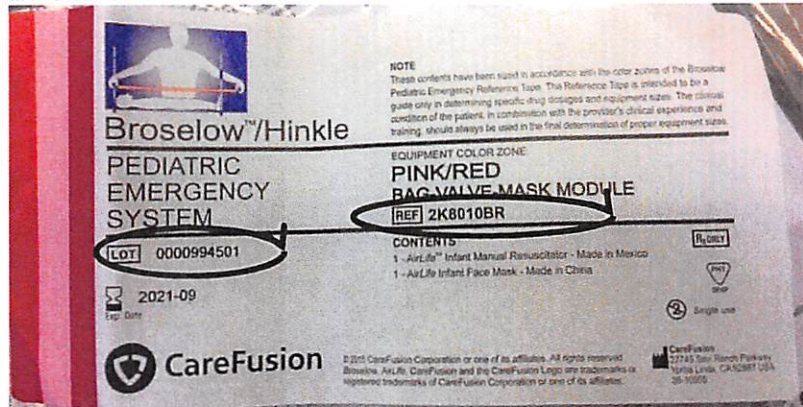


Illustration B:



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Illustration C:

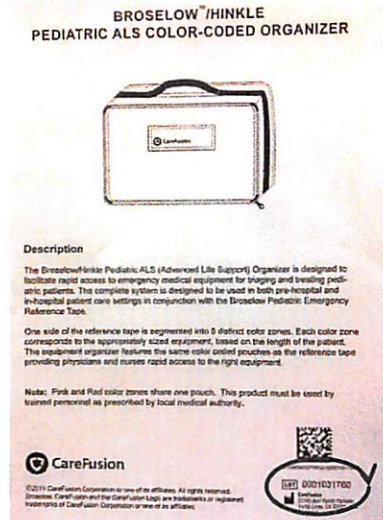


Illustration D:



*The BROSELOW Convenience Kits contain the individually packaged 2K8008BR & 2K8010BR resuscitators that can be identified by Illustration A & Illustration B

7. Has Vyairé Medical notified the FDA?

Yes. Vyairé Medical has notified the FDA of this voluntary Recall. Vyairé Medical is initiating this voluntary Recall in strict accordance with FDA regulations (specifically, 21 CFR Part 7).

8. May customers continue to use the 2K8008BR & 2K8010BR resuscitators(s)?

No. It is important that our distributors and healthcare facilities take prompt action and follow their facility's procedures for destruction of affected product. Attention to this recall is mandated by FDA regulations (specifically, 21 CFR Part 7).

The remainder of the components kitted within the 7730ALS, 7730IALS and 7730POCH are **NOT** affected by this voluntary Recall.

9. If my facility does not allow destruction of affected product who should I contact for instructions on where to send affected product?

For instructions on where to send product affected by this voluntary Recall please contact Vyairé Medical's *Customer Advocacy Analyst, Kristina Scheppa*, via email at Kristina.Scheppa@CareFusion.com or by phone (224)706.6829.

10. Who do I contact if I have additional questions concerning this voluntary Recall?

If you are a **Healthcare Facility/ End-User Customer** and have questions concerning **replacement** of affected product please contact your distributor, *Armstrong Medical* at (800)323.4220 X129

For all other questions or for additional support regarding this voluntary Recall please contact Vyairé Medical's *Customer Advocacy Analyst, Kristina Scheppa*, via email at Kristina.Scheppa@CareFusion.com or by phone (224)706.6829.

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11. What should customers do if an adverse event occurs following use of any of the affected products?

Any adverse reactions experienced with the use of this product, and/or quality problems should be reported to Vyairé Medical and may be done by email to GMB-RS-DISP-Complaint-Intake@CareFusion.com or by calling (800)323.9088 (Option #3, followed by Option #1).

Any adverse reactions experienced with the use of this product, and/or quality problems may also be reported to the FDA through FDA's MedWatch Program by:

Web: MedWatch website at www.fda.gov/medwatch
Phone: 1 800-FDA-1088 (1 800-332-1088)
Mail: MedWatch, HF-2, FDA, 5600 Fishers Lane, Rockville, MD 20852-9787

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Appendix 3

FIELD SAFETY NOTICE-CUSTOMER RESPONSE FORM

**2K8008BR & 2K8010BR - Pediatric & Infant Resuscitation devices - BROSELOW -
8030673-4/27/17-002-R)**

Acknowledgment and Verification Form – Immediate Attention Required

8030673-4/27/17-002-R

Affected Product Table:

Part Number	Part Number Description	Quantity in stock (in units/eaches)	Purchase Order (P.O.) #
2K8008BR	RESUS, PED W/3 MASKS, 40" TBG, P/O		
2K8010BR	RESUS, INF W/MASK, 40" TBG,P/O		
7730ALS/ 7730IALS	Broselow Hinkle Kit		
7730POCH	Replacement Kit for outer shell		

Indicate by checking box if you are requesting replacement for quantity in stock per above, that has been destroyed in accordance with this voluntary Field Safety Corrective action.

Name of Healthcare Facility/Distributor	
Address of Healthcare Facility/ Distributor	
Email address	
Telephone number	
Name of person completing form (Please Print)	

By signature completion of this form, I certify the following:

- ✓ I have read and understand the contents of this Field Safety Notice and confirm that I understand all instructions noted within the notification.
- ✓ I have performed a **100% physical inventory inspection** and I have accurately reported the quantity in stock above.
- ✓ I certify that I have destroyed all affected product indicated, if any, as indicated as in inventory at the time of receipt of this notification.
- ✓ Applicable to **distributors Only**: I certify that I have further notified my end user customers (indicate by checking method below).

Mail E-mail Phone Other _____

Signature of person completing form	
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Please return this form to: GMB-GLB-VSFieldActions@CareFusion.com or FAX to (312)949.0972

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