URGENT: MEDICAL DEVICE RECALL

BROSELOW RAINBOW TAPE
(7700REA and AE-4800)

IMMEDIATE ACTION REQUIRED

1st NOTIFICATION

Date: May 20, 2025

<Customer Name>
<Address>

Dear Distributor/Customer,

Purpose of the letter:

The purpose of this letter is to advise you that AirLife is voluntarily recalling a specific print revision of the AirLife branded Broselow Rainbow Tape. Impacted products are distributed as 7700REA by AirLife and as AE-4800 by Armstrong Medical Industries. We have identified you as a customer of Armstrong who has received the affected products.

Description of the problem:

The impacted AirLife branded Broselow Rainbow Tape is distributed in product codes 7700REA and AE-4800. The "AirLife brand, 2025 Edition, and 36-23446 Rev 2 Print Version" Broselow Rainbow Tape have been manufactured with incorrect information on the tape. See **Image A** for the identification of the impacted Broselow Rainbow Tape.

Prior versions of the Broselow Rainbow Tape are not impacted. AirLife has received three complaints related to this issue, but there were no serious injuries or death reported.

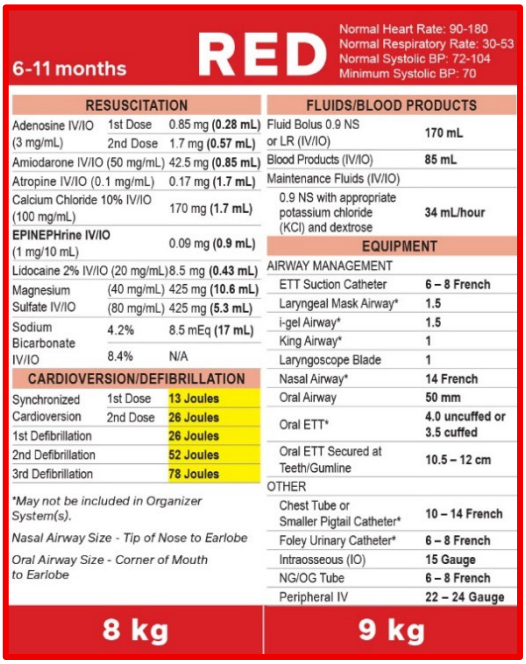
The table below provides the reference number and lot numbers or other identification of the recalled products:

Product Description	REF Number	Lot Numbers	UDI Information
Broselow Pediatric Emergency Rainbow Tape (distribution by AirLife)	7700REA	0004316661	EA: 10889483588970 CS: 30889483588974
Armstrong Labeled Broselow Pediatric Emergency Rainbow Tape (pack of 5 ea) (distribution by Armstrong)	AE-4800	N/A – Identify impacted product utilizing the "AirLife brand, 2025 Edition, and 36-23446 Rev 2 Print Version" identification on the Broselow Tape as identified in **Image A**.	N/A

Image A. *Broselow Rainbow Tape version with incorrect information is identified with the AirLife brand, 2025 Edition, and 36-23446 Rev 2 Print Version*

The incorrect information on the "AirLife brand, 2025 Edition, and 36-23446 Rev 2 Print Version" of the Broselow Rainbow Tape includes:

- Incorrect Information: The values for the Red zone (6-11 months, 8/9kg) in the Cardioversion/Defibrillation section contain the incorrect Joules. These reference values are a new addition to the tape per this revision of the tape. See **Image B** where the incorrect information is highlighted.



6-11 months **RED**

Normal Heart Rate: 90-180
Normal Respiratory Rate: 30-53
Normal Systolic BP: 72-104
Minimum Systolic BP: 70

RESUSCITATION		
Adenosine IV/IO (3 mg/mL)	1st Dose	0.85 mg **(0.28 mL)**
	2nd Dose	1.7 mg **(0.57 mL)**
Amiodarone IV/IO (50 mg/mL)		42.5 mg **(0.85 mL)**
Atropine IV/IO (0.1 mg/mL)		0.17 mg **(1.7 mL)**
Calcium Chloride 10% IV/IO (100 mg/mL)		170 mg **(1.7 mL)**
EPINEPHrine IV/IO (1 mg/10 mL)		0.09 mg **(0.9 mL)**
Lidocaine 2% IV/IO (20 mg/mL)		8.5 mg **(0.43 mL)**
Magnesium Sulfate IV/IO	(40 mg/mL)	425 mg **(10.6 mL)**
	(80 mg/mL)	425 mg **(5.3 mL)**
Sodium Bicarbonate IV/IO	4.2%	8.5 mEq **(17 mL)**
	8.4%	N/A

CARDIOVERSION/DEFIBRILLATION		
Synchronized Cardioversion	1st Dose	**13 Joules**
	2nd Dose	**26 Joules**
1st Defibrillation		**26 Joules**
2nd Defibrillation		**52 Joules**
3rd Defibrillation		**78 Joules**

**May not be included in Organizer System(s).*

Nasal Airway Size - Tip of Nose to Earlobe

Oral Airway Size - Corner of Mouth to Earlobe

FLUIDS/BLOOD PRODUCTS	
Fluid Bolus 0.9 NS or LR (IV/IO)	**170 mL**
Blood Products (IV/IO)	**85 mL**
Maintenance Fluids (IV/IO)	
0.9 NS with appropriate potassium chloride (KCl) and dextrose	**34 mL/hour**

EQUIPMENT	
AIRWAY MANAGEMENT	
ETT Suction Catheter	**6 – 8 French**
Laryngeal Mask Airway*	**1.5**
i-gel Airway*	**1.5**
King Airway*	**1**
Laryngoscope Blade	**1**
Nasal Airway*	**14 French**
Oral Airway	**50 mm**
Oral ETT*	**4.0 uncuffed or 3.5 cuffed**
Oral ETT Secured at Teeth/Gumline	**10.5 – 12 cm**
OTHER	
Chest Tube or Smaller Pigtail Catheter*	**10 – 14 French**
Foley Urinary Catheter*	**6 – 8 French**
Intraosseous (IO)	**15 Gauge**
NG/OG Tube	**6 – 8 French**
Peripheral IV	**22 – 24 Gauge**

8 kg | **9 kg**

Image B. *Information highlighted in yellow is the* ***incorrect*** *information in "AirLife brand, 2025 Edition, and 36-23446 Rev 2 Print Version" of the Broselow Rainbow Tape.*

The correct Cardioversion/Defibrillation information for a 6–11-month patient (8/9 kg) in the Red zone of the Broselow Rainbow Tape is as below:

- Synchronized Cardioversion 1st Dose should be 9 Joules
- Synchronized Cardioversion 2nd Dose should be 18 Joules
- 1st defibrillation should be 18 Joules
- 2nd defibrillation should be 36 Joules
- 3rd defibrillation should be 54 Joules

- Incorrect Information: The information for sodium bicarbonate in the Orange zone of the tape (7-9 years, 24-28 kg) is incorrect. See **Image C** where the incorrect information is highlighted. The correct sodium bicarbonate concentration for the Orange zone (7-9 years, 24-28 kg) should be 27 mEq (27 mL).

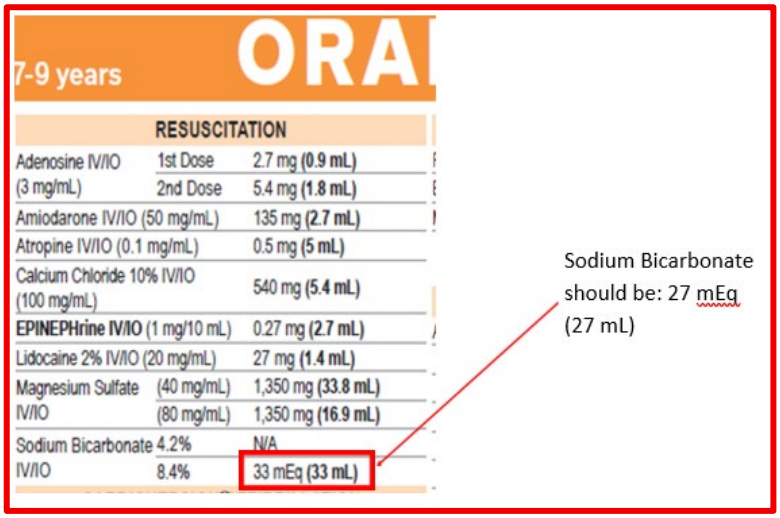


Image C. *Information circled in Red is the* ***incorrec****t information in "AirLife brand, 2025 Edition, and 36-23446 Rev 2 Print Version" of the Broselow Rainbow Tape.*

- Incorrect Information: The information for sodium bicarbonate concentration in the Grey zone of the tape (<3months, 3-5 kg) is incorrect. See **Image D** where the incorrect information is highlighted. The correct sodium bicarbonate concentration for the Grey zone (<3months, 3-5 kg) should be 8.4%.

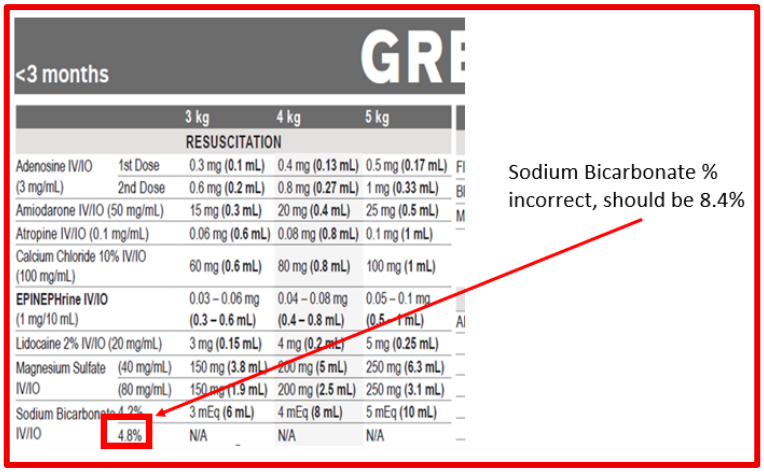


Image D. *Information circled in Red is the incorrect information in "AirLife brand, 2025 Edition, and 36-23446 Rev 2 Print Version" of the Broselow Rainbow Tape.*

Health risk:

The Broselow Rainbow Tape is a color-coded length-based tape measure that was created by emergency medicine physician James Broselow and emergency medicine physician Robert Luten. A specific child's height, measured on the tape, corresponds to a color zone and a weight range. This color zone provides pre-calculated information for medication dosages, equipment sizes, and other relevant emergency procedures. It reduces the time needed to calculate dosages and equipment sizes in a critical emergency.

The incorrect information in the Red zone of the tape (6-11 months, 8/9 kg) is related to the cardioversion/defibrillation section having the incorrect joules. The incorrect joules that are printed in the Red zone are the same as the ones printed in the Yellow zone. Although according to the AHA (American Heart Association) guidelines what is currently printed in the Broselow Rainbow Tape in the Red zone falls within the parameters of the guidelines for an 8/9kg patient, they are not the recommended starting joules for this patient size. Using the correct joule level is crucial for effective cardioversion and defibrillation while minimizing the risk of harm to the patient. Shocking an 8/9 kg patient with an excessive dose of joules may cause significant harm, including burns, heart damage, and potential cardiac arrest.

The incorrect information in the Orange zone of the tape (7-9 years, 24-28 kg) is related to the incorrect sodium bicarbonate concentration. The incorrect concentration listed may lead to overdosing the patient and may cause metabolic alkalosis, electrolyte imbalances, tissue damage, and potentially worsen respiratory status.

The incorrect information in the Grey zone of the tape (<3months, 3-5 kg) is related to the incorrect sodium bicarbonate concentration. The incorrect concentration listed may lead to underdosing the patient and may cause reduced myocardial contractility, decreased response to vasopressors, and increased risk of dysrhythmia.

Customer immediate actions:

a. Review the list of affected products and how to identify affected products. Please examine your inventory for the affected product version “AirLife brand, 2025 Edition, and 36-23446 Rev 2 Print Version” as shown in **Image A**. Product was distributed starting March 2025. No other product versions are affected.

b. Quarantine all affected product in inventory.

c. In-use product or product that has been removed from the outer bulk labeling (e.g. included on a Broselow Color-code Cart):

    a. For affected product in use that is utilizing the affected product version “AirLife brand, 2025 Edition, and 36-23446 Rev 2 Print Version” as shown in **Image A**, immediately stop/cease use of the product.

d. Please complete and return the attached Response Form(s) 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 destruction. It will also allow us to document your receipt of this letter.

e. 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. If support is required to notify your customers/consignees, provide the list to AirLife email to **productquality@myairlife.com**.

f. Once you confirm destruction of the affected product(s) utilizing the attached Response Form, 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 1-800-433-2797 and we will make every effort to accommodate your needs.

g. 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 **1-800-433-2797**, or e-mail at **productquality@myairlife.com.**

The adverse reactions or quality problems experienced with the use of these products should 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 or Fax**: Download form www.fda.gov/MedWatch/getforms.htm or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form or submit by fax to 1-800-FDA-0178.

Attachments:

A. Broselow Rainbow Tape Field Removal 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 1.800.433.2797 or **productquality@myairlife.com.**

Thank you for your attention and cooperation.

Rob Yamashita
AirLife - VP of Regulatory Affairs

Immediate Action Requested

Attachment A: Broselow Rainbow Tape Field Removal Response Form

REF NUMBER	LOT NUMBER	QTY RECEIVED (Eaches)	QTY TO BE DESTROYED (Eaches)

Please check ALL appropriate boxes.

☐ I have read and understand the removal instructions provided in the letter sent May 20, 2025.

☐ I have checked my inventory.

- ☐ I do not have any affected products.
- ☐ I have destroyed and disposed of the affected product. (Complete and return Attachment B)

☐ I have further distributed the affected device and have attached the ship history list including customer name, ship date, address, and quantity (**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**

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 May 20, 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: _____