

Emergency Response Safety Kit Recall: AirLife Removes Certain Broselow Pediatric Emergency Rainbow Tapes and Broselow ALS Organizers

The affected products and recommendations for what to do with the devices below have not changed.

This recall ([/medical-devices/medical-device-recalls-and-early-alerts/what-medical-device-recall](#)) ***involves removing certain devices from where they are used or sold.*** The FDA has identified this recall as the most serious type. This device may cause serious injury or death if you continue to use it.

Affected Product



Feedback

The FDA is aware that AirLife has issued a letter to affected customers recommending certain Broselow Rainbow Tapes and Broselow ALS Organizers be removed from where they are used or sold. Affected devices:

Product Description	REF Number	Lot Numbers	Unique Device Identifier
Broselow Pediatric Emergency Rainbow Tape	7700REA	Rev. 3 All Lots	Each- 10889483588970 (https://accessgudid.nlm.nih.gov/devices/10889483588970) Case- 30889483588974 (https://accessgudid.nlm.nih.gov/devices/10889483588970)
Broselow Pediatric Emergency Rainbow Tape	7700RE	Rev. 3 All Lots	Each- 10889483588963 (https://accessgudid.nlm.nih.gov/devices/10889483588963) Case- 30889483588967 (https://accessgudid.nlm.nih.gov/devices/10889483588963)

Broselow, ALS Organizer, Full	7730ALS	Rev. 3 All Lots	Each- 10889483589151 (https://accessgudid.nlm.nih.gov/devices/10889483589151)
Broselow, ALS Organizer, Full	7730IALS	Rev. 3 All Lots	Each- 10889483589205 (https://accessgudid.nlm.nih.gov/devices/10889483589205) Case- 30889483589209 (https://accessgudid.nlm.nih.gov/devices/10889483589205)



Broselow Rainbow Tape version with incorrect information is identified with the AirLife brand, 2025 Edition, and 36-23446 Rev 3 Print Version.

What to Do

Immediately identify, cease use, and discard affected product.

On December 15, AirLife sent all affected customers a letter recommending the following actions:

- Stop using the affected tapes.
- Identify and segregate affected product
 - Examine your inventory and clinical areas for affected Broselow Rainbow Tapes.
 - Remove all affected tapes from clinical service
 - Segregate or quarantine the affected tapes to prevent further use

- Follow disposition instructions
 - Follow the instructions provided in the accompanying communication regarding discarding/destruction of the affected tapes.
 - Do not redistribute or place any affected tapes back into service.
- Notify your internal users
- Ensure that all clinicians and healthcare professionals within your organization who may use the Broselow Rainbow Tape are informed of this recall/field removal and understand that the affected Rev 3 tapes must not be used.
- Notify downstream customers (if applicable)
 - If you have further distributed the affected tapes, please identify your customers/consignees and notify them of this recall/field removal promptly.
 - Your notification may be enhanced by including a copy of this letter.
 - If you have impacted product on hand, do not ship it; instead, hold it for discarding/destruction as instructed.

Check this web page for updates. The FDA is currently reviewing information about this potentially high-risk device issue and will keep the public informed as significant new information becomes available.

Reason for Recall

AirLife stated that the affected product version contains three medication-related errors:

- Vecuronium
 - In the Calculation Basis “Red to Head” reference section, the dosage is shown as 0.1 mg/mL (concentration) instead of the correct 0.1 mg/kg (weight-based dose).
 - This medication is a neuromuscular blocking agent used to produce paralysis during intubation or mechanical ventilation. The incorrect dosing information can lead to confusion and potential delays as clinicians interpret or convert the dosing information in an emergency. Because the tape is used in time-sensitive critical care environments, such delays or confusion can contribute to serious patient harm, including hypoxia, failed or delayed intubation, or other life-threatening complications.
- Flumazenil

- In the Calculation Basis “Red to Head” section, the dosage is shown as 0.1 mg/kg instead of the correct 0.01 mg/kg.
- The color-coded sections of the tape list the correct Flumazenil dose, but the reference table is incorrect and represents a 10-fold overdose.
- This medication is used primarily to reverse the effects of benzodiazepines, including in pediatric patients. Potential consequences of an elevated Flumazenil dose include seizures, withdrawal symptoms, re-sedation, cardiac arrhythmias, agitation or anxiety, nausea, vomiting, dizziness, sweating, and blurred vision.
- Ketamine (IV/IO for pain/analgesia)
 - The tape lists IV/IO ketamine for pain/analgesia as 1 mg/kg, whereas the appropriate pediatric analgesic (sub-dissociative) dose is 0.1 mg/kg.
 - This represents a 10-fold overdose and may result in a dissociative sedation dose being administered when only analgesia was intended.
 - Potential clinical consequences of administering 1 mg/kg IV/IO ketamine for analgesia include dissociative sedation, respiratory depression or apnea, loss of airway reflexes, potential airway collapse, laryngospasm, increased secretions with risk of aspiration, hypertension and tachycardia, emergence agitation, prolonged recovery time, and need for assisted ventilation or advanced airway management.

The clinical consequences for incorrect medication doses based on the printed information may be serious or life-threatening.

As of November 14, AirLife has not reported any serious injuries or deaths associated with this issue.

Device Use

The Broselow Rainbow Tape is a color-coded length-based tape used in pediatric emergencies. A child’s height corresponds to a color zone and weight range. Each color zone provides pre-calculated medication doses, equipment sizes, and other emergency information to reduce the time needed for dose and equipment calculations in time-critical situations.

Contact Information

Customers in the U.S. with adverse reactions, quality problems, or questions about this issue should contact AirLife at productquality@myairlife.com (<mailto:productquality@myairlife.com>) or 1-800-433-2797.

Additional FDA Resources

- [FDA Enforcement Report \(https://www.accessdata.fda.gov/scripts/ires/index.cfm?Event=98208\)](https://www.accessdata.fda.gov/scripts/ires/index.cfm?Event=98208)
- [CDRH Medical Device Recall Database \(https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRES/res.cfm?start_search=1&event_id=98208\)](https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRES/res.cfm?start_search=1&event_id=98208)

Unique Device Identifier (UDI)

The unique device identifier (UDI) helps identify individual medical devices sold in the United States from distribution to use. The UDI allows for more accurate reporting, reviewing, and analyzing of adverse event reports so that devices can be identified more quickly, and as a result, problems potentially resolved more quickly.

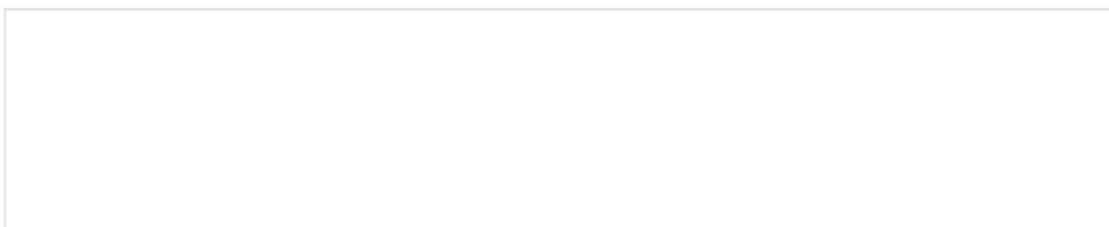
- [How do I recognize a UDI on a label? \(/medical-devices/unique-device-identification-system-udi-system/udi-basics\)](/medical-devices/unique-device-identification-system-udi-system/udi-basics)
- [AccessGUDID database - Identify Your Medical Device \(https://accessgudid.nlm.nih.gov/\)](https://accessgudid.nlm.nih.gov/)
- [Benefits of a UDI System \(/medical-devices/unique-device-identification-system-udi-system/benefits-udi-system\)](/medical-devices/unique-device-identification-system-udi-system/benefits-udi-system)

How do I report a problem?

Health care professionals and consumers may [report adverse reactions or quality problems \(https://www.accessdata.fda.gov/scripts/medwatch/index.cfm?action=reporting_home\)](https://www.accessdata.fda.gov/scripts/medwatch/index.cfm?action=reporting_home) they experienced using these devices to MedWatch: The FDA Safety Information and Adverse Event Reporting Program.

Timeline of Communication Updates

Date	Actions
02/11/2026	The FDA updated this communication to inform the public that this issue has been classified as a Class I Recall.
01/16/2026	The FDA issued an Early Alert communication to notify the public of a potentially high-risk device issue.



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