URGENT: MEDICAL DEVICE RECALL NOTICE BROSELOW RAINBOW TAPE (7700REA, 7700RE, 7730ALS, 7730IALS) IMMEDIATE ACTION REQUIRED

1st NOTIFICATION

Date: December 15, 2025

Dear Distributor/Customer,

Purpose of the letter:

The purpose of this voluntary Medical Device Recall Notice is to inform you of multiple content discrepancies on the AirLife Broselow Rainbow Tape (2025 Edition, 36-23446 Rev 3) and to provide instructions for examining inventory to identify affected product, cease use, and discard such product.

Impacted products are distributed as part of 7700REA, 7700RE, 7730ALS, and 7730IALS by AirLife. We have identified you as a customer who has received the affected products.

Description of the problem:

AirLife has identified three medication-related errors in the content printed on the affected product version (Image B shows these errors on the product):

1. **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).
2. **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.

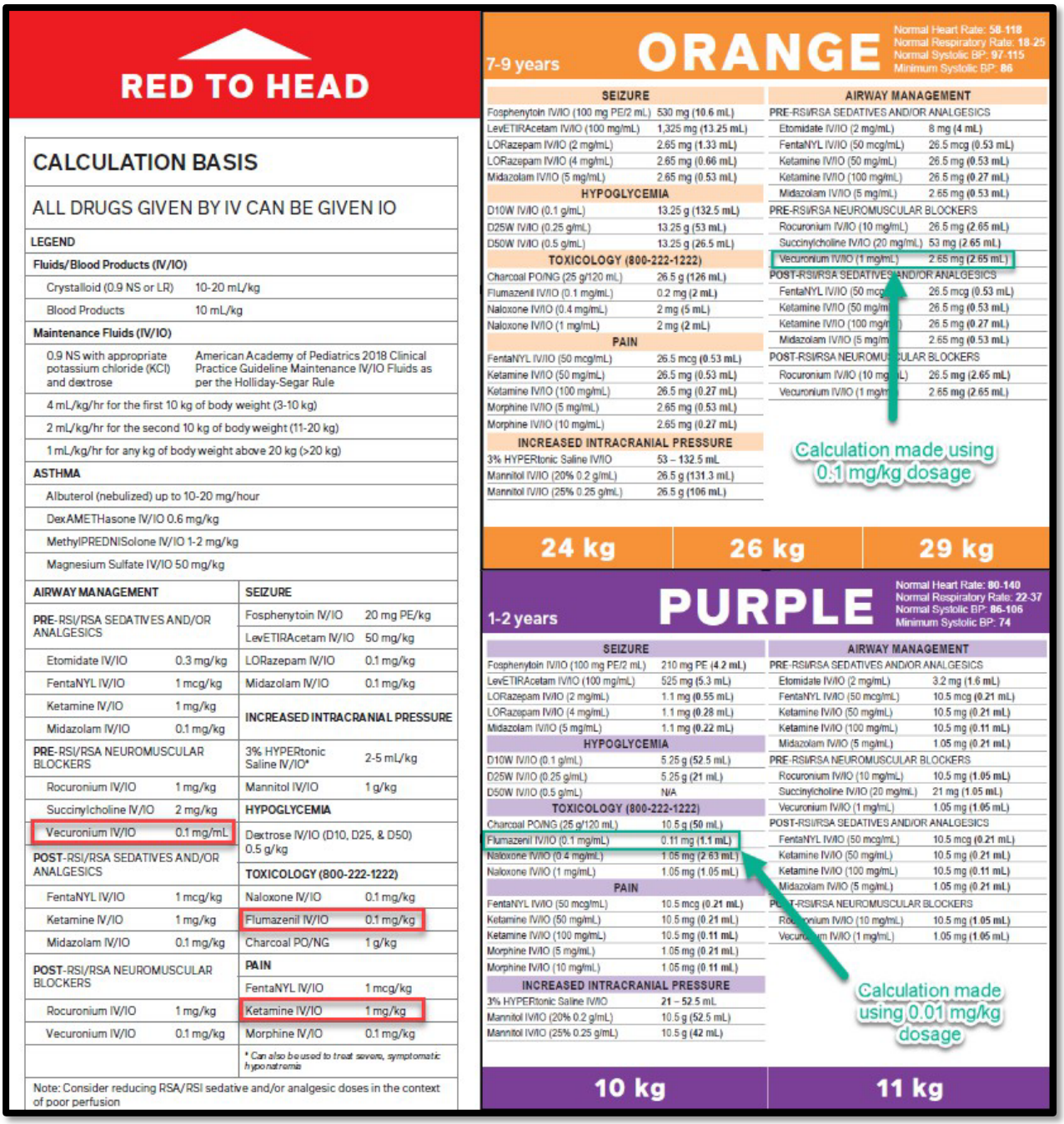
3. **Ketamine (IV/IO for pain/analgesia)**
    - The tape lists IV/IO ketamine for pain/analgesia as 1 mg/kg, whereas the appropriate pediatric analgesic (sub-dissociative) dose is 0.1 mg/kg.
    - This represents a 10-fold overdose and may result in a dissociative sedation dose being administered when only analgesia was intended.

These issues are present on the **AirLife brand, 2025 Edition, 36-23446 Rev 3 Print Version** of the Broselow Rainbow Tape (see Image C for identification of the specific version).

Prior versions of the Broselow Rainbow Tape are not impacted by the incorrect Flumazenil or Ketamine doses. The "AirLife brand, 2025 Edition, 36-23446 Rev 2 Print Version" is impacted by the incorrect Vecuronium dosage and is already under recall per FSCA-2025-0005 (initiated May 2025).

AirLife has received complaints related to these issues; however, **no patient injuries or adverse events have been reported to date**.

Image A. *Photo of the Broselow Rainbow Tape.*



RED TO HEAD

CALCULATION BASIS

ALL DRUGS GIVEN BY IV CAN BE GIVEN IO

LEGEND

Fluids/Blood Products (IV/IO)	
Crystalloid (0.9 NS or LR)	10-20 mL/kg
Blood Products	10 mL/kg
Maintenance Fluids (IV/IO)	
0.9 NS with appropriate potassium chloride (KCl) and dextrose	American Academy of Pediatrics 2018 Clinical Practice Guideline Maintenance IV/IO Fluids as per the Holliday-Segar Rule
4 mL/kg/hr for the first 10 kg of body weight (3-10 kg)	
2 mL/kg/hr for the second 10 kg of body weight (11-20 kg)	
1 mL/kg/hr for any kg of body weight above 20 kg (>20 kg)	
ASTHMA	
Albuterol (nebulized) up to 10-20 mg/hour	
DexAMETHasone IV/IO 0.6 mg/kg	
MethylPREDNISolone IV/IO 1-2 mg/kg	
Magnesium Sulfate IV/IO 50 mg/kg	

AIRWAY MANAGEMENT		SEIZURE	
PRE-RSI/RSA SEDATIVES AND/OR ANALGESICS		Fosphenytoin IV/IO	20 mg PE/kg
		LevETIRAcetam IV/IO	50 mg/kg
Etomidate IV/IO	0.3 mg/kg	LORazepam IV/IO	0.1 mg/kg
FentaNYL IV/IO	1 mcg/kg	Midazolam IV/IO	0.1 mg/kg
Ketamine IV/IO	1 mg/kg	**INCREASED INTRACRANIAL PRESSURE**	
Midazolam IV/IO	0.1 mg/kg		
PRE-RSI/RSA NEUROMUSCULAR BLOCKERS		3% HYPERtonic Saline IV/IO*	2-5 mL/kg
Rocuronium IV/IO	1 mg/kg	Mannitol IV/IO	1 g/kg
Succinylcholine IV/IO	2 mg/kg	**HYPOGLYCEMIA**	
Vecuronium IV/IO	0.1 mg/mL	Dextrose IV/IO (D10, D25, & D50)	0.5 g/kg
POST-RSI/RSA SEDATIVES AND/OR ANALGESICS		**TOXICOLOGY (800-222-1222)**	
FentaNYL IV/IO	1 mcg/kg	Naloxone IV/IO	0.1 mg/kg
Ketamine IV/IO	1 mg/kg	Flumazenil IV/IO	0.1 mg/kg
Midazolam IV/IO	0.1 mg/kg	Charcoal PO/NG	1 g/kg
POST-RSI/RSA NEUROMUSCULAR BLOCKERS		**PAIN**	
		FentaNYL IV/IO	1 mcg/kg
Rocuronium IV/IO	1 mg/kg	Ketamine IV/IO	1 mg/kg
Vecuronium IV/IO	0.1 mg/kg	Morphine IV/IO	0.1 mg/kg
		* Can also be used to treat severe, symptomatic hyponatremia	

Note: Consider reducing RSA/RSI sedative and/or analgesic doses in the context of poor perfusion

7-9 years ORANGE

Normal Heart Rate: 58-118
Normal Respiratory Rate: 18-25
Normal Systolic BP: 97-115
Minimum Systolic BP: 86

SEIZURE	
Fosphenytoin IV/IO (100 mg PE/2 mL)	530 mg (10.6 mL)
LevETIRAcetam IV/IO (100 mg/mL)	1,325 mg (13.25 mL)
LORazepam IV/IO (2 mg/mL)	2.65 mg (1.33 mL)
LORazepam IV/IO (4 mg/mL)	2.65 mg (0.66 mL)
Midazolam IV/IO (5 mg/mL)	2.65 mg (0.53 mL)
HYPOGLYCEMIA	
D10W IV/IO (0.1 g/mL)	13.25 g (132.5 mL)
D25W IV/IO (0.25 g/mL)	13.25 g (53 mL)
D50W IV/IO (0.5 g/mL)	13.25 g (26.5 mL)
TOXICOLOGY (800-222-1222)	
Charcoal PO/NG (25 g/120 mL)	26.5 g (126 mL)
Flumazenil IV/IO (0.1 mg/mL)	0.2 mg (2 mL)
Naloxone IV/IO (0.4 mg/mL)	2 mg (5 mL)
Naloxone IV/IO (1 mg/mL)	2 mg (2 mL)
PAIN	
FentaNYL IV/IO (50 mcg/mL)	26.5 mcg (0.53 mL)
Ketamine IV/IO (50 mg/mL)	26.5 mg (0.53 mL)
Ketamine IV/IO (100 mg/mL)	26.5 mg (0.27 mL)
Morphine IV/IO (5 mg/mL)	2.65 mg (0.53 mL)
Morphine IV/IO (10 mg/mL)	2.65 mg (0.27 mL)
INCREASED INTRACRANIAL PRESSURE	
3% HYPERtonic Saline IV/IO	53 – 132.5 mL
Mannitol IV/IO (20% 0.2 g/mL)	26.5 g (131.3 mL)
Mannitol IV/IO (25% 0.25 g/mL)	26.5 g (106 mL)

AIRWAY MANAGEMENT	
PRE-RSI/RSA SEDATIVES AND/OR ANALGESICS	
Etomidate IV/IO (2 mg/mL)	8 mg (4 mL)
FentaNYL IV/IO (50 mcg/mL)	26.5 mcg (0.53 mL)
Ketamine IV/IO (50 mg/mL)	26.5 mg (0.53 mL)
Ketamine IV/IO (100 mg/mL)	26.5 mg (0.27 mL)
Midazolam IV/IO (5 mg/mL)	2.65 mg (0.53 mL)
PRE-RSI/RSA NEUROMUSCULAR BLOCKERS	
Rocuronium IV/IO (10 mg/mL)	26.5 mg (2.65 mL)
Succinylcholine IV/IO (20 mg/mL)	53 mg (2.65 mL)
Vecuronium IV/IO (1 mg/mL)	2.65 mg (2.65 mL)
POST-RSI/RSA SEDATIVES AND/OR ANALGESICS	
FentaNYL IV/IO (50 mcg/mL)	26.5 mcg (0.53 mL)
Ketamine IV/IO (50 mg/mL)	26.5 mg (0.53 mL)
Ketamine IV/IO (100 mg/mL)	26.5 mg (0.27 mL)
Midazolam IV/IO (5 mg/mL)	2.65 mg (0.53 mL)
POST-RSI/RSA NEUROMUSCULAR BLOCKERS	
Rocuronium IV/IO (10 mg/mL)	26.5 mg (2.65 mL)
Vecuronium IV/IO (1 mg/mL)	2.65 mg (2.65 mL)

Calculation made using 0.1 mg/kg dosage

24 kg	26 kg	29 kg

1-2 years PURPLE

Normal Heart Rate: 80-140
Normal Respiratory Rate: 22-37
Normal Systolic BP: 86-106
Minimum Systolic BP: 74

SEIZURE	
Fosphenytoin IV/IO (100 mg PE/2 mL)	210 mg PE (4.2 mL)
LevETIRAcetam IV/IO (100 mg/mL)	525 mg (5.3 mL)
LORazepam IV/IO (2 mg/mL)	1.1 mg (0.55 mL)
LORazepam IV/IO (4 mg/mL)	1.1 mg (0.28 mL)
Midazolam IV/IO (5 mg/mL)	1.1 mg (0.22 mL)
HYPOGLYCEMIA	
D10W IV/IO (0.1 g/mL)	5.25 g (52.5 mL)
D25W IV/IO (0.25 g/mL)	5.25 g (21 mL)
D50W IV/IO (0.5 g/mL)	N/A
TOXICOLOGY (800-222-1222)	
Charcoal PO/NG (25 g/120 mL)	10.5 g (50 mL)
Flumazenil IV/IO (0.1 mg/mL)	0.11 mg (1.1 mL)
Naloxone IV/IO (0.4 mg/mL)	1.05 mg (2.63 mL)
Naloxone IV/IO (1 mg/mL)	1.05 mg (1.05 mL)
PAIN	
FentaNYL IV/IO (50 mcg/mL)	10.5 mcg (0.21 mL)
Ketamine IV/IO (50 mg/mL)	10.5 mg (0.21 mL)
Ketamine IV/IO (100 mg/mL)	10.5 mg (0.11 mL)
Morphine IV/IO (5 mg/mL)	1.05 mg (0.21 mL)
Morphine IV/IO (10 mg/mL)	1.05 mg (0.11 mL)
INCREASED INTRACRANIAL PRESSURE	
3% HYPERtonic Saline IV/IO	21 – 52.5 mL
Mannitol IV/IO (20% 0.2 g/mL)	10.5 g (52.5 mL)
Mannitol IV/IO (25% 0.25 g/mL)	10.5 g (42 mL)

AIRWAY MANAGEMENT	
PRE-RSI/RSA SEDATIVES AND/OR ANALGESICS	
Etomidate IV/IO (2 mg/mL)	3.2 mg (1.6 mL)
FentaNYL IV/IO (50 mcg/mL)	10.5 mcg (0.21 mL)
Ketamine IV/IO (50 mg/mL)	10.5 mg (0.21 mL)
Ketamine IV/IO (100 mg/mL)	10.5 mg (0.11 mL)
Midazolam IV/IO (5 mg/mL)	1.05 mg (0.21 mL)
PRE-RSI/RSA NEUROMUSCULAR BLOCKERS	
Rocuronium IV/IO (10 mg/mL)	10.5 mg (1.05 mL)
Succinylcholine IV/IO (20 mg/mL)	21 mg (1.05 mL)
Vecuronium IV/IO (1 mg/mL)	1.05 mg (1.05 mL)
POST-RSI/RSA SEDATIVES AND/OR ANALGESICS	
FentaNYL IV/IO (50 mcg/mL)	10.5 mcg (0.21 mL)
Ketamine IV/IO (50 mg/mL)	10.5 mg (0.21 mL)
Ketamine IV/IO (100 mg/mL)	10.5 mg (0.11 mL)
Midazolam IV/IO (5 mg/mL)	1.05 mg (0.21 mL)
POST-RSI/RSA NEUROMUSCULAR BLOCKERS	
Rocuronium IV/IO (10 mg/mL)	10.5 mg (1.05 mL)
Vecuronium IV/IO (1 mg/mL)	1.05 mg (1.05 mL)

Calculation made using 0.01 mg/kg dosage

10 kg	11 kg

Image B. *The impacted Broselow Rainbow Tape lists an incorrect Vecuronium dose of 0.1 mg/mL instead of the correct 0.1 mg/kg dose, an incorrect Flumazenil dose of 0.1 mg/kg instead of the correct 0.01 mg/kg dose, and an incorrect Ketamine dose for pain of 1 mg/kg instead of the correct 0.1 mg/kg in the Calculation Basis section circled above in red. The dose calculations on each color-coded section are correct and circled above in green.*

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

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

Product Description	REF Number	Lot Numbers	UDI Information
Broselow Pediatric Emergency Rainbow Tape (distribution by AirLife)	7700REA		
Broselow Pediatric Emergency Rainbow Tape (distribution by AirLife)	7700RE		
Broselow, AIs Organizer, Full (distribution by AirLife)	7730ALS		
Broselow, AIs Organizer, Full (distribution by AirLife)	7730IALS		

Health risk:

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.

Flumazenil

Flumazenil is used primarily to reverse the effects of benzodiazepines, including in pediatric patients. In the Calculation Basis section of the affected Rev 3 tape, the Flumazenil dose is incorrectly listed as 0.1 mg/kg instead of the correct 0.01 mg/kg (10-fold overdose). Potential consequences of an elevated Flumazenil dose include:

- Seizures
- Withdrawal symptoms (in benzodiazepine-dependent patients)
- Re-sedation
- Cardiac arrhythmias
- Agitation and anxiety
- Nausea, vomiting, dizziness, headache
- Sweating and blurred vision

These events can be serious and, in some cases, life-threatening.

Vecuronium

Vecuronium is a neuromuscular blocking agent used to produce paralysis during intubation or mechanical ventilation. It is dosed on a weight (mg/kg) basis, not by fixed mg/mL concentration.

In the Calculation Basis section of the affected Rev 3 tape, the dosage is incorrectly expressed as 0.1 mg/mL rather than 0.1 mg/kg. This 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.

Ketamine (IV/IO for pain/analgesia)

The affected tape lists IV/IO ketamine for pain/analgesia as 1 mg/kg, instead of the appropriate pediatric analgesic (sub-dissociative) dose of 0.1 mg/kg (10-fold overdose). A 1 mg/kg IV dose is

consistent with dissociative sedation rather than analgesia.

Potential clinical consequences of administering 1 mg/kg IV/IO ketamine for analgesia include:

- Dissociative sedation
- Respiratory depression or apnea
- Loss of airway reflexes and potential airway compromise
- Laryngospasm
- Increased secretions, with risk of aspiration
- Hypertension and tachycardia
- Emergence agitation
- Prolonged recovery time
- Need for assisted ventilation or advanced airway management

These events can be serious and, in some cases, life threatening.

Due to the potential for serious harm associated with these three medication-related errors, AirLife is initiating an immediate voluntary recall and field removal of all affected units.

Customer immediate actions:

Please take the following actions immediately:

1. **Stop using the affected tapes**
    - Immediately discontinue use of all AirLife Broselow Rainbow Tapes identified as 2025 Edition, 36-23446 Rev 3 Print Version.
2. **Identify and segregate affected product**
    - Examine your inventory and clinical areas for affected Broselow Rainbow Tapes (see Image B for identifying characteristics).
    - Remove all affected tapes from clinical service.
    - Segregate or quarantine the affected tapes to prevent further use.
3. **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.
4. **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.

5. **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.
6. **Complete and return the Response Form (Attachment A)**
    - Please complete and return the attached Response Form via e-mail to **productquality@myairlife.com** as soon as possible. Please complete and return Attachment B if you have affected product for discarding/destruction. This allows us to document your receipt of this recall notice and the status of affected product at your facility.

Please ensure that all relevant personnel in your organization are informed of this Urgent Medical Device Recall Notice.

Contact information, replacement product, and adverse event reporting:

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 Medical Device Recall Notice, please call AirLife at **1-800-433-2797**, or e-mail at **productquality@myairlife.com.**

There is currently no available replacement product. A revised Broselow Rainbow Tape with corrected information is expected to be available for purchase starting Q2 2026. AirLife will send a notice to customers when such product is available.

Any 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 Safety Notice 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 Recall 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 December XX, 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.

☐ I have notified the receiving facility by (specify date & method of notification):

☐ I need support communicating with my customer/consignees. I have attached the ship history list including customer name, ship date, address, and quantity

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**