09 Mar 2026 (Version 02)
Ref: CAPA-100

Urgent Field Safety Notice Update

APL Valve FSN – risk of patient harm as a result of APL valve sticking across affected breathing systems and PEP therapy devices.

This is an update to the Field Safety Notice – Ref CAPA-100 originally issued on 9 March 2026. As a precautionary measure the FSN has been extended to include other devices which contain the APL valve – Paediatric Ayres T Piece, Adult Coaxial Systems and PEP therapy devices. If you don't purchase any of the new codes added – see table on page 4 and have already actioned the original FSN no further action is required.

Type of Action:	To communicate an identified risk of patient harm associated with rare instances of APL valve sticking during opening or closing.
Devices:	Resuscitation Sets (Mapleson Systems) Paediatric Ayres T-Piece Systems (Resuscitation Set) Adult Coaxial Breathing Systems Positive Expiratory Pressure (PEP) Therapy Devices
Manufacturer:	Armstrong Medical Limited, Wattstown Business Park, Newbridge Road, Coleraine, BT52 1BS, Northern Ireland.
Date of Issue:	09 March 2026
For Attention of:	Healthcare professionals working in anaesthesia, critical care, resuscitation, and post-operative recovery areas of hospitals and all others to whom potentially affected devices have been transferred, including distributors.
Scope of Action:	**Manufacturing product code Field Safety Notice.**
Keywords:	Resuscitation Sets, APL Valve, Mapleson Systems, Ayres T-Piece, Coaxial Breathing Systems, PEP Therapy Devices.

Summary
Armstrong Medical Limited is issuing this Field Safety Notice (FSN) to inform users of an identified issue associated with the APL valve used in certain devices, which may, in rare cases, cause the valve to stick during adjustment or operation.

- For breathing system devices, the issue may affect pressure regulation during ventilation.
- For PEP therapy devices, the issue may affect the generation of controlled expiratory resistance and therapeutic pressure during airway clearance therapy.

During routine post-market surveillance, Armstrong Medical received four (4) customer complaints from healthcare facilities describing performance issues involving the APL valve during clinical use. These reports indicated that, despite adjustment of the valve, elevated

airway pressures were observed due to the valve not opening as expected. In one reported case, this resulted in a transient adverse patient event, which resolved following removal of the device from use.

Following internal investigation and testing of returned products, Armstrong Medical determined that the issue is linked to a manufacturing-related defect affecting components of the APL valve assembly, which may lead to mechanical sticking. As a result, a Field Safety Corrective Action is being implemented to mitigate potential risk to patients.

Armstrong Medical records indicate that devices listed in Table 1 were shipped to your facility. Please review the information below and take the required actions.

Issue Description
A manufacturing-related issue affecting components of the APL valve has been identified, which may, in rare cases, cause the valve to stick during adjustment or operation, resulting in incomplete pressure relief.

In PEP therapy devices, malfunction of the valve may lead to inconsistent expiratory resistance, resulting in either excessive resistance (causing higher-than-intended pressure) or insufficient resistance (reducing therapeutic pressure), both of which can compromise the effectiveness of airway clearance therapy.

Risk to Health
Use of affected devices incorporating the APL valve may, in rare cases, result in partial or complete sticking of the valve during opening or closing. This failure mode can lead to incomplete pressure relief during use of the device, with the potential for sustained elevated airway pressures being delivered to the patient.

For PEP therapy devices, which rely on controlled expiratory resistance, valve malfunction can lead to either excessive resistance, resulting in higher-than-intended expiratory pressures, increased patient effort, discomfort, and potential respiratory strain, or insufficient resistance, leading to reduced therapeutic pressure and diminished effectiveness of airway clearance therapy.

The immediate health risk associated with this issue includes acute pressure-related physiological effects such as excessive positive end-expiratory pressure (PEEP), hypotension, and respiratory compromise. One (1) confirmed case of transient patient harm has been reported, which resolved promptly following removal of the device from use, with no permanent injury or fatalities identified.

Actions Armstrong is taking
Armstrong Medical is implementing a Field Safety Corrective Action to advise users of the information that must be followed within the IFU relating to pre-use checks for the affected product codes. Corrective actions are underway to address the identified manufacturing-related issue and to further strengthen component controls and inspection processes.

Actions for the User

Notify all relevant departments, users, and any organisations to whom affected product may have been supplied.

Armstrong Medical Limited advises that the device may continue to be used provided that the Instructions on page 2 of the Instructions for Use (IFU), repeated below, are followed.

In the event of repeated failure to pass the test(s), immediately discontinue use, and report the issue to Armstrong Medical.

Resuscitation set with APL valve

Instruction For Use (IFU), page 2:

1. **Connect fresh gas tubing to gas supply source (oxygen flowmeter outlet or anaesthesia common gas outlet) and to other system equipment, if required, ensuring that connections are secure and that unused ports are sealed.**
2. **Prior to clinical use, occlude the patient connection with a cap or gloved thumb or forefinger. With fresh gas flow set at 10L/min and the APL valve cap rotated to the fully-closed position, observe that the reservoir bag inflates and distends for 3 (three) seconds. Then, rotate the APL valve cap anti-clockwise and observe that the reservoir bag collapses.**
3. **Verify flow patency alternately through the APL valve exhaust port and the patient connection.**
4. **Verify that separate inspiratory and expiratory gas paths are present and functioning.**
5. **Perform other pre-use function test(s) as required for use on connected equipment.**
6. **If the product does not pass these tests, verify correct set-up and re-test.**
7. **In the event of repeated failure to pass the test(s), replace the system and/or contact a technician.**
8. **When the product passes the test(s) connect to patient and commence therapy.**
9. **Summary IFU for the APL valve is:**
    a. **Rotate valve cap clockwise to apply increasing system pressure.**
    b. **Rotate valve cap anti-clockwise to decrease system pressure and to facilitate spontaneously breathing patients.**
    c. **Consider anaesthetic gas scavenging via the valve exhaust port.**
10. **If a gas sampling line is connected, ensure that this is securely connected and monitored in use for occlusion by condensed water or by tube kinking.**
11. **Monitor performance of the system in use to ensure adequate and safe ventilation therapy.**

Mapleson D Modification (Coaxial Bain System)

Instruction For Use (IFU), page 2:

1. **Assemble to anaesthesia machine (and to other system equipment, if required), ensuring that connections are secure and that unused ports are sealed.**
2. **If a gas sampling line is connected, ensure that this is securely connected and monitored in use for occlusion by condensed water or by tube kinking.**
3. **If an Adjustable Pressure Limiting (APL) valve is included with this circuit, use of the assembly is restricted to anaesthesia or anaesthesia reanimation only. For information on correct use of the APL valve and gas scavenging from the APL valve, please refer to specific IFU. Summary IFU for the APL valve is:**
    a. **Rotate valve cap clockwise to apply increasing system pressure.**
    b. **Rotate valve cap anti-clockwise to decrease system pressure and to facilitate spontaneously breathing patients.**
    c. **Consider anaesthetic gas scavenging via the valve exhaust port.**
4. **Verify flow patency and verify that separate inspiratory and expiratory gas paths are present and functioning.**
5. **Perform other pre-use function test(s) as required for use on connected equipment.**
6. **If the circuit does not pass these tests, verify correct set-up and re-test.**
7. **In the event of repeated failure to pass the test(s), replace the system and/or contact a technician.**
8. **When the system passes the test(s), enable therapy and connect to patient.**
9. **Monitor performance of the system in use to ensure adequate and safe therapy.**

10. To avoid retention of CO_2, the following settings are recommended:
    a. Spontaneous breathing: set the APL valve to 'OPEN'. Adjust the total fresh gas flow to >120mL/Kg body weight per minute.
    b. Controlled ventilation: set the APL valve to partially-closed. Adjust the total fresh gas flow to >70mL/Kg body weight per minute.

Combi-Flex Universal F Breathing System (Coaxial)

Instruction For Use (IFU), page 2:

1. Assemble to anaesthesia machine or ventilator (and to other system equipment, if required), ensuring that connections are secure and that unused ports are sealed.
2. If a gas sampling line is connected, ensure that this is securely connected and monitored in use for occlusion by condensed water or by tube kinking.
3. Verify that separate inspiratory and expiratory gas paths are present and functioning.
4. Verify flow patency and test for leakage/compliance.
5. Perform other pre-use function test(s) as required for use on connected equipment.
6. If the circuit does not pass these tests, verify correct set-up and re-test.
7. In the event of repeated failure to pass the test(s), replace the system and/or contact a technician.
8. When the system passes the test(s), enable ventilation and connect to patient.
9. Monitor performance of the system in use to ensure adequate and safe ventilation therapy.

PEP Therapy

Instruction For Use (IFU), page 2:

1. Patient to follow these steps:
    a. Adjust the expiratory valve cap to a position between 1 and 4 (and moderate as necessary thereafter).
    b. Put the mouthpiece in your mouth and seal your lips around it.
    c. Make a normal inhalation and then exhale slowly but firmly against the resistance. Try to breathe all the way out to the end of your breath. Exhalation should last 6 seconds. You should be able to hear a hissing sound as the air comes out of the valve.
    d. Repeat for 10 breaths if possible. You may need to cough before you reach 10th breath. If so, take the device out of your mouth and cough to clear any loosened secretions.
    e. Rest for 30 seconds.
    f. Cough and clear any phlegm that has been loosened and rest again.
    g. Repeat the above cycle at least 3 times or as often as is necessary to clear the chest.

Table 1. Affected Devices

Product Codes and Lot Numbers Affected			
AMBS1604-001	AMBS1604-062	AMBS1608-022	AMCA1904
AMBS1604-013	AMBS1604-063	AMBS1608-023	AMCA1904-1
AMBS1604-027	AMBS1604-064	AMBS1608-026	AMCX4405-002
AMBS1604-029	AMBS1604-3	AMBSJN1608-3-8	AMCX4604-001
AMBS1604-031	AMBS1604-5-2	AMBSJN1608-3-9	AMCX4605
AMBS1604-035	AMBS1604-5-2-02	AMBSJN160839001	AMCX4606-6-001
AMBS1604-036	AMBS1608	AMBSJN1609-3-002	AMCXN4605
AMBS1604-043	AMBS1608-003	AMBSN1604	AMCXN4605-6
AMBS1604-044	AMBS1608-005	AMBSN1604-002	AMPT1001
AMBS1604-045	AMBS1608-007	AMBSN1604-3	AMPT1001-002
AMBS1604-049	AMBS1608-008	AMBSN1604-5	AMPT1001-003

AMBS1604-051	AMBS1608-012	AMBSN1604-5-2	AMPT1003
AMBS1604-054	AMBS1608-013	AMBSN1604-5-2-01	AMUF1940-013
AMBS1604-055	AMBS1608-014	AMBSN1608	
AMBS1604-057	AMBS1608-016	AMCA1903-1	

Codes highlighted in yellow are the newly added codes.

Armstrong Medical Limited confirms that this Field Safety Notice has been submitted to the UK Competent Authority, the Medicines and Healthcare Products Regulatory Agency (MHRA), and has also been communicated to all relevant Competent Authorities in jurisdictions where the device has been placed on the market.

If you are in any way unsure if you hold product which is impacted, please contact the customer service team and we will be able to check and advise accordingly.

We are committed to patient safety and appreciate your prompt attention to this matter. If you have any questions regarding this communication, please contact your Armstrong representative by telephone at +44 (0)28 7035 6029 and request the Sales Department.

Field Safety Notice Response Form

FSN Reference: CAPA-100 Date: 09 Mar 2026 (Version 02)

Hospital or Delivery Location Name: _____

Hospital or Delivery Location Address: _____

_____

_____

Please complete the information below and return to respiratory.regulatoryaffairs@eakinhealthcare.com. Alternatively, you may contact Armstrong Medical by telephone at +44 (0)28 7035 6029 and request the Sales Department.

Please also tick one of the following options:

☐ We confirm that we have received this FSN and have distributed it to relevant individuals or departments within our organisation.

☐ We confirm that we have received this FSN and will continue using the device in accordance with the Instructions for Use (IFU), including the specified pre-use checks, as detailed in this Field Safety Notice.

☐ **Armstrong Medical Distributors Only:** We confirm that we have received this FSN and have distributed it to all customers that have been supplied with the products listed in Table 1.

Form Completed by:

Name: _____

Department or Position: _____

E-mail Address: _____

Date: _____