09 Mar 2026 (Version 01)
Ref: CAPA-100

Urgent Field Safety Notice

APL Valve FSN – risk of patient harm as a result of APL valve sticking during opening or closing.

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 Set with APL Valve (Mapleson Systems)
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 Set with APL Valve (Mapleson Systems), Mapleson C.

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 Resuscitation Sets. In rare cases, the APL valve may stick during opening or closing, which can result in incomplete pressure relief.

During routine post-market surveillance, Armstrong Medical received two (2) 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.

Risk to Health
Use of affected resuscitation sets 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 manual ventilation, with the potential for sustained elevated airway pressures being delivered to the patient.

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) are followed.

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.**

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

Table 1. Affected Devices

Product Codes and Lot Numbers Affected			
AMAC1614	AMBS1604-047	AMBSN1604	AMCX4606-6-001
AMAC1614-001	AMBS1604-048	AMBSN1604-002	AMCX4606-8
AMAC1614-002	AMBS1604-049	AMBSN1604-005	AMCX4607
AMAC1614-6	AMBS1604-050	AMBSN1604-3-5-6	AMCX4607-6
AMAC1616-6	AMBS1604-051	AMBSN1604-5	AMCX4612
AMAC4705	AMBS1604-053	AMBSN1604-5-1	AMCX4615
AMAC4705-001	AMBS1604-054	AMBSN1604-5-2	AMCX4617
AMAC4707-6	AMBS1604-055	AMBSN1604-5-2-01	AMCX4617-001
AMACN1614	AMBS1604-056	AMBSN1604-5-5	AMCX4617-002
AMBS1604	AMBS1604-057	AMBSN1604-5-6	AMCXN4605
AMBS1604-002	AMBS1604-062	AMBSN1608-3	AMCXN4605-002
AMBS1604-003	AMBS1604-3	AMBSN1608-6-2	AMCXN4605-6
AMBS1604-007	AMBS1604-3-5-6	AMBSN1608-8	AMCXN4606
AMBS1604-027	AMBS1604-5-2	AMBSN1608-8-001	AMCXN4606-2
AMBS1604-028	AMBS1604-5-2-02	AMBSN1608-8-2	AMCXN4606-6
AMBS1604-029	AMBS1604-5-3	AMBSN1608-9	AMCXN4607
AMBS1604-031	AMBS1608	AMCA1903-1	AMCXN4608
AMBS1604-033	AMBS1608-003	AMCAI1903-1	AMCXN4617
AMBS1604-034	AMBS1608-007	AMCX4405-002	AMUF1900-004
AMBS1604-035	AMBS1608-010	AMCX4604-001	AMUF1901
AMBS1604-036	AMBS1608-012	AMCX4605	AMUF1902
AMBS1604-037	AMBS1608-013	AMCX4605-003	AMUF1910-010
AMBS1604-038	AMBS1608-016	AMCX4605-007	AMUF1910-040
AMBS1604-039	AMBS1608-021	AMCX4605-008	AMUF1911
AMBS1604-042	AMBS1608-022	AMCX4605-6	AMUF1913-002
AMBS1604-044	AMBS1608-023	AMCX4606	AMUF1940-013
AMBS1604-045	AMBS1608-8	AMCX4606-002	AMUF1950
AMBS1604-046	AMBS1608-9	AMCX4606-6	AMVC1828-007

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.

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 01)

Hospital or Delivery Location Name: _____

Hospital or Delivery Location Address: _____

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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: _____