19 Dec 2025 Version 01
Ref: CF-1573

Urgent Field Safety Notice

BiPAP Tubing – risk of patient harm as a result of the tubing separating from the purple cuff connector.

Type of Action:	To communicate an identified risk of patient harm as a result of the tubing separating from the purple cuff connector.
Devices:	Anaesthetic Circuit, AquaVENT® CPAP System, Ventilator Circuit for Non-invasive Ventilation
Manufacturer:	Armstrong Medical Limited, Wattstown Business Park, Newbridge Road, Coleraine, BT52 1BS, Northern Ireland
Date of Issue:	19 Dec 2025
For Attention of:	Healthcare professionals working in anaesthesia and critical care areas of hospitals and all others to whom potentially affected devices have been transferred, including distributors.
Scope of Action:	**All product codes listed below with expiry after 19 Dec 2020.**
Keywords:	Anaesthetic Circuit, AquaVENT® CPAP System, Ventilator Circuit for Non-invasive Ventilation

Summary
Armstrong Medical Limited is issuing an update to the Instructions for Use (IFU) for Anaesthetic Circuits, AquaVENT® CPAP Systems and Ventilator Circuits for Non-invasive Ventilation devices.

This IFU update follows receipt of seven (7) reports from customers stating that there have been tears occurring between the tubing and the purple cuff connector when disconnecting to replace the filter, resulting in a delay to treatment and/or the need to replace the entire circuit. You are receiving this FSN because Armstrong records indicate that these devices were shipped to your facility.

All devices identified in Table 1 below should continue to be used in line with this FSN.

Issue Description
Our investigation of the customer reports did not identify any anomaly or non-conformance with the product as all devices were manufactured to the specifications set. The existing IFU requires an update to prevent reasonable forseeable misuse when handling the device.

Risk to Health
Pulling on the tubing may lead to inadvertent tubing separation from the purple cuff connector. Replacement of the circuit may result in delays in treatment and will require intervention by Healthcare Professional. These situations present a potential risk of

respiratory distress, hypoxia, and/or low oxygen saturation as the Healthcare Provider swaps out the breathing circuit.

Actions Armstrong is taking

January 2026, Armstrong is issuing an update to the Instructions for Use (IFU) for the devices listed on Table 1, to include the following:

1. Do not disconnect the circuit by pulling on the tubing. Always disconnect by holding the purple cuff connector and pulling the breathing filter gently.
2. When connecting a breathing filter do not push excessively in to the purple cuff connector. Push to the point of resistance and ensure the breathing filter can be easily attached and detached from the breathing circuit/tubing during setup before proceeding.

Actions for the User

Users are requested to review the list of potentially affected devices in Table 1 and take the following immediate actions with circuits in use:

1. Check all circuits currently in use to ensure there are no signs of tubing separation from the purple cuff connector.
2. When changing the breathing filter, hold the purple cuff connector securely whilst gently pulling on the filter to remove. Do not pull on the tubing.
3. When adding a new filter, push the filter into position gently until reaching the point of resistance. Do not push the purple cuff connector excessively onto the breathing filter.
4. Pass and post this notice for all who need to be aware within your organisation or to any organisation where the potentially affected product has been transferred or distributed.

Table 1. Affected Devices

Product Codes Affected			
AMAC1401-001	AMVC1792-070	AMVC1792-137	AMVC1792-168
AMAC1784-039	AMVC1792-078	AMVC1792-138	AMVC1792-177
AMCPUK01209	AMVC1792-092	AMVC1792-142	AMVC1792-178
AMCPUK01265	AMVC1792-126	AMVC1792-143	AMVC1792-234
AMVC1790-006	AMVC1792-127	AMVC1792-155	AMVC1871-136
AMVC1792-013	AMVC1792-128	AMVC1792-156	AMVC1871-157

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: CF-1573 Date: 19 Dec 2025

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.

☐ **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: _____