

May 04, 2026

## FIELD SAFETY NOTICE

### Hamilton Medical device IntelliCuff

**Reference #: FSCA-2026-05-02****Field Safety Corrective Action**

Type: On-site device repair

**For Attention of:** Hamilton Medical subsidiaries and distribution partners and their service engineers.**Information  
on Affected  
Devices:**

Device name	Product number	UDI-DI	Serial number
IntelliCuff	951001 (*Standalone only)	07630002800839	Smaller than 19732

\*IntelliCuff devices integrated into HAMILTON-C6 are not in the scope of this FSCA.

The IntelliCuff device is intended to continuously measure and automatically maintain the user-set cuff pressure of an endotracheal tube (ETT) or tracheostomy tube (TT) during mechanical ventilation.



Dear Subsidiaries and Distribution Partners,

This Field Safety Notice (FSN) provides information on Hamilton Medical IntelliCuff devices.

**A. Reason for Field Safety Corrective Action (FSCA)**

During Post Market Surveillance activities, Hamilton Medical AG became aware of an issue with the IntelliCuff (Standalone) devices. Affected IntelliCuff devices may alarm with “Cuff system leakage”, the motor pumps continuously and does not maintain the cuff pressure set by the user.

<b>Description of the product problem:</b>	<p>During handling of the device (applying excessive force when connecting the cuff pressure tube or accidental drop), the cuff connector may crack. In some cases, such crack may lead to a leakage which may result in a reduction or loss of the cuff pressure (also referred to as cuff system leakage).</p> <p>Cracks on the connector may be found externally or internally, depending on their location. Internal cracks are detectable only when the IntelliCuff housing is opened by trained and certified service technicians.</p>
<b>Problem effect:</b>	<p>Due to the crack induced leakage, the cuff pressure cannot be maintained as intended. In the event of a leakage, the device would continuously attempt to pump the connected cuff to reach the set point and thus compensate for the leak. If the leakage reaches a certain level, the device will trigger a visual and audible “Cuff system leakage” alarm.</p>
<b>Patient risks:</b>	<p>If the leakage remains undetected during use, there is potential for oxygen desaturation or aspiration pneumonia for the patient. However, within complaint data of almost 10 years (2016-2026), no serious injuries or deaths have been reported in relation to leaking cuff. As stated, such a device issue would trigger an alarm and hence, any personal involved are informed and may react properly.</p>
<b>Required user actions if problem occurs:</b>	<p>In case of “Cuff system leakage” alarm, the user is requested to perform the following steps:</p> <ol style="list-style-type: none"><li>1. Check applied pressure settings, cuff pressure tube, ET tubing, and all connections.</li><li>2. If leakage persists, make sure the cuff is blocked properly (manually) and the patient does not aspirate. Switch off the IntelliCuff.</li><li>3. Once patient safety is ensured, the device must be taken out of service. The IntelliCuff must be serviced by trained and certified personnel before being returned to use.</li></ol>

For further information, refer to Chapter 7 (Alarms and troubleshooting) of the IntelliCuff Instructions for use (PN 624741/07).

## **B. Type of Action to mitigate the risk**

With this FSCA Hamilton Medical AG is implementing replacement of the cuff connector. The improved cuff connectors will be provided to trained and certified service technicians by Hamilton Medical AG free of charge.

All affected devices in the field are to be addressed by replacing the cuff connector. This replacement is mandatory and must be performed by trained and certified service technicians only.

No quarantine or removal of devices from use has been deemed necessary. Devices may remain in operation until the corrective action is performed, provided that no crack or leakage is present and the information provided above is considered and complied with. If a crack or leakage is identified, the device must not be used and should be taken out of service till the repair.

In the interim, users are instructed to avoid applying excessive force when connecting the cuff pressure tube and to ensure that the device is not dropped, as this may damage the cuff connector.

**C. Required Actions to be taken by subsidiaries and distribution partners**

1. Identify and document all affected IntelliCuff devices and corresponding end users in your territory.
2. Review all documentation (IntelliCuff Instructions for use – PN 624741/07, IntelliCuff Service Manual PN 10181712/00) related to this field action.
3. Translate the FSN for end users to your local language, if applicable. Do not modify the content.
4. Notify your national Competent Authority, if applicable and if Hamilton Medical AG has not already submitted the notification. Notification must be completed no later than **10 calendar days (May 14, 2026)** after receipt of this FSN.

Important: If reporting is not required as per local regulations, please inform us about it via email.

5. Contact [fieldactions.med.global@hamilton-medical.com](mailto:fieldactions.med.global@hamilton-medical.com) in case of any questions regarding reportability.
6. Send proof of notification to the national Competent Authority to [fieldactions.med.global@hamilton-medical.com](mailto:fieldactions.med.global@hamilton-medical.com).
7. Inform all affected end users or sub-distributors and provide them with the end user FSN.
8. Cuff connectors of devices still in use in your market must be replaced. Once you identify the number of devices that need to be repaired, you can order needed amount of cuff connectors (PN 10182793) free of charge through regular order processing.

Please use the following reference in your order: *“FSCA-2026-05-02 IntelliCuff connectors FOC”*.

9. Coordinate appointments for the required exchange of cuff connectors with affected end users.
10. Collect all customer reply forms and retain them according to your quality system.
11. If an end user does not respond, send at least three documented follow-up attempts. After three attempts with no response, document internally and close the case.
12. Fill in, sign and return to [fieldactions.med.global@hamilton-medical.com](mailto:fieldactions.med.global@hamilton-medical.com) distributor reply form confirming that all affected end users were notified. This must be completed no later than **45 calendar days (June 18, 2026)** after receipt of this FSN.
13. Ensure for all affected devices the cuff connector has been exchanged **by May 04, 2027**. To exchange cuff connector, follow IntelliCuff Service Manual (PN 10181712/00, section 8.6).
14. Return filled and signed list of affected devices and confirm the exchange of cuff connectors as instructed.
15. Report any device incident via ETQ or the applicable Hamilton Medical complaint handling tool.

**Manufacturer:**

Hamilton Medical AG  
Via Crusch 8  
7402 Bonaduz  
Switzerland

**Contact:**

Hamilton Medical AG  
Vigilance Team  
Via Crusch 8  
7402 Bonaduz  
Switzerland

Tel. +41 58 610 10 20

E-Mail:

[fieldactions.med.global@hamilton-medical.com](mailto:fieldactions.med.global@hamilton-medical.com)

**Please keep this FSN in your data records.**

Important notice:

The local distribution partner or subsidiary of Hamilton Medical AG remains the first point of contact for the management of technical interventions.

We appreciate your support in this matter and sincerely regret any inconvenience you may experience because of the issue described above.

Sincerely,

Vigilance Team  
Hamilton Medical AG  
*(document without signature)*

### Distributor Reply Form

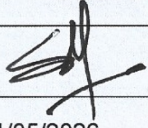

Please fill in points 2. and 3., sign and return this Distributor Reply Form to [fieldactions.med.global@hamilton-medical.com](mailto:fieldactions.med.global@hamilton-medical.com) by June 18, 2026.

1. Field Safety Notice (FSN) information	
FSN Reference number	FSCA-2026-04-02
FSN Date	May 04, 2026
Device name	IntelliCuff
Serial Number	Smaller than 19732

Please fill in

2. Distributor Details	
Company Name	STAR MEDIK SDN BHD
Address	43, JALAN TIARA SENTRAL 2, NILAI UTAMA ENTERPRISE PARK, 71800 NILAI, NEGERI SEMBILAN
Country	MALAYSIA
Contact Name	SYAFIQ ZULQARNAIN BIN ZAINUDIN
Title or Function	HEAD OF CORPORATE DEVELOPMENT (MEDICAL)
Telephone number	+6011-2804 3787
Email	zulqarnain.starmedik@gmail.com

Please fill in and sign

3. Distributor (tick all that apply and indicate numbers)		
<input checked="" type="checkbox"/>	I confirm the receipt, the reading and understanding of the FSN.	
<input type="checkbox"/>	I have informed the identified end users of this FSN.	Number of identified end users: _____
Choose one	<input type="checkbox"/>	I have received confirmation of reply from all identified end users.
	<input type="checkbox"/>	I have not received confirmation of reply from all identified end users, but I made and documented minimum three follow-up attempts.
		Number of end users that replied: _____
Print Name	SYAFIQ ZULQARNAIN BIN ZAINUDIN	
Signature	 	
Date	11/05/2026	

It is important that your organisation takes the actions detailed in the FSN and confirms that you have received the FSN.

Your organisation's reply is the evidence we need to monitor the progress of the corrective action.