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: Healthcare facilities, physicians and end users which have purchased and/or are using Hamilton Medical device IntelliCuff.

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 Sir or Madam,

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.

Hamilton Medical AG
Via Crusch 8, 7402 Bonaduz
Switzerland

☎ +41 58 610 10 20
fieldactions.med.global@hamilton-medical.com
www.hamilton-medical.com

Description of the product problem:	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). Cracks on the connector may be found externally or internally, depending on their location. Internal cracks are detectable only if the IntelliCuff housing is opened by trained and certified service technicians.
Problem effect:	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.
Patient risks:	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 personnel involved are informed and may react properly.
Required user actions if problem occurs:	In case of "Cuff system leakage" alarm, the user is requested to perform the following steps: 1. Check applied pressure settings, cuff pressure tube, ETT tubing, and all connections. 2. If leakage persists, make sure the cuff is blocked properly (manually) and the patient does not aspirate. Switch off the IntelliCuff. 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. 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 the user

- Identify affected devices (consider devices in use, in stock, spare devices etc.) and make them available for exchange of cuff connectors. Cuff connector exchanges will be organized and conducted by the local Hamilton Medical distribution partner or subsidiary who is trained and certified to open the housing of IntelliCuff.
- Continue to use IntelliCuff devices according to their labelling. Mitigate potential risks by following the actions described in point “B. Type of Action to mitigate the risk”.
- Please fill in and sign Customer Reply Form (page 5) and send it to your Hamilton Medical distribution partner or subsidiary. This must be conducted as quickly as possible, but no later than 30 calendar days after receiving the Field Safety Notice.

The Competent Authority of your country has been informed about this communication to user. The local distribution partner or subsidiary, as approved by Hamilton Medical AG to conduct all activities around Hamilton Medical devices, is always the first point of contact in this matter.

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

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.
The local distribution partner or subsidiary of Hamilton Medical AG will contact you as soon as possible. Please prepare a list of the affected IntelliCuff devices.
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)

Transmission of this Field Safety Notice

This notice needs to be passed on to all those who need to be aware within your organization or to any organization where the potentially affected devices have been transferred.
Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.
Please keep this field safety notice with your IntelliCuff Instructions for use.
Please report all device-related incidents to the manufacturer, distributor or local representative, and the national Competent Authority if appropriate, as this provides important feedback.

Customer Reply Form

Please fill in points 2. and 3., sign and return this Customer Reply Form to your Hamilton Medical AG distribution partner or subsidiary no later than 30 calendar days after receiving the Field Safety Notice.

1. Field Safety Notice (FSN) information	
FSN Reference number	FSCA-2026-05-02
FSN Date	May 04, 2026
Device name	IntelliCuff
Serial number	Smaller than 19732

Please fill in

2. Customer Details	
Healthcare Organization Name	
Address	
Country	
Contact Name	
Title or Function	
Telephone number	
Email	

Please fill in and sign

3. Customer action undertaken on behalf of Healthcare Organization (tick all that apply and if applicable indicate quantity)			
☐		I confirm receipt of the FSN and that I read and understood its content.	
☐		The information and required actions have been brought to the attention of all relevant users and executed.	
Choose one	☐	I have identified the following number of affected devices in our organization.	Quantity: _____
	☐	I do not have any affected devices.	

Print Name	
Signature	
Date	

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.