

Medical Device/Equipment ALERT

Ref. MDEA(NI)2005/82
 Issued: 18 November 2005

Update of MDEA(NI)2004/34



**NORTHERN
 IRELAND
 ADVERSE
 INCIDENT
 CENTRE**

For:	IMMEDIATE ACTION	✓
	ACTION	
&:	UPDATE	✓
	INFORMATION REQUEST	

	Section
Medical Device/Equipment: AUTOMATED ENDOSCOPE REPROCESSORS: RISK OF FAILURE TO DECONTAMINATE AUXILIARY CHANNELS	▶ ①
Problem: Decontamination of narrow auxiliary channels in flexible endoscopes may be compromised by blockages within the AER (automated endoscope reprocessor).	▶ ②
Action by: <ul style="list-style-type: none"> • Chief Executives – Boards and Trusts, • Estates Managers • Decontamination Leads • Staff who reprocess endoscopes <ul style="list-style-type: none"> • Staff with responsibility for the training of other staff in the use of reprocessing equipment • Infection Control Team • Risk Management Team 	▶ ③
Action: All makes and models of AER used for processing flexible endoscopes should be inspected to ensure that correct fluid flow rates are being achieved and pressure alarm functions, if fitted, are functioning within specification. This MDEA is an update of the guidance outlined in MDEA(NI)2004/34.	▶ ④
Distributed by NIAIC to: Chief Executive of each HSS Board Chief Executive of each HSS Trust Chief Executive of each Agency NIAIC Liaison Officers For onward distribution see Section 5 Private Clinics	▶ ⑤
Contacts NIAIC contact for technical aspects	▶ ⑥
Feedback Requirements to NIAIC None Required	▶ ⑦

This Alert is on our web site: <http://www.dhsspsni.gov.uk/niaic>

1. DEVICE/EQUIPMENT:

Automated Endoscope Reprocessors: Risk of failure to decontaminate auxiliary channels of flexible endoscopes

2. PROBLEM:

An incident has been reported in Scotland in which the auxiliary channel in a flexible endoscope was found to be blocked during a procedure. The endoscope was removed from the patient and, when flushed through, discoloured fluid was emitted from the distal end.

The AER used to reprocess all the endoscopes in the department was an AFOS ICU2 Mk2 and had been in use for about 10 years. It is a 2-basin, 4-scope unit with 4 sets of 3-way fluid ports. It does not comply with the requirements of HTM 2030. Each set of ports includes a low flow port for irrigation of the endoscope auxiliary channel if appropriate.

The hospital staff in conjunction with the manufacturer's service engineer examined the operation of the AER and found that:

- 7 of the 12 pressure sensors did not function and 5 of those 7 sensors were subsequently bench tested and found to operate at too high a pressure,
- no fluid flow existed from 3 out of the 4 auxiliary (low flow) ports and the 4th port appeared to have reduced flow,
- plastic and silicone tubing within the AER contained deposits and in the case of the small bore (1.6 mm) silicone tubing the bore was substantially restricted or blocked along the entire length and, crucially, between the pumps and the pressure sensors,
- small pieces of unidentified debris were recovered from the fluid ports, possibly deposits ejected from the tubing.

The AER had been serviced regularly but the only tubing to be replaced was the silicone tubing within the peristaltic pumps. It is likely that the remainder of the tubing was original to the AER. The causes of the tubing and pressure alarm problems are as yet unknown and investigation is ongoing.

MDEA(NI)2004/34: Flexible Endoscopes, gave advice on endoscope decontamination and difficulties in achieving adequate decontamination of, for example, elevator wire channels or auxiliary irrigation channels. This notice supplements MDEA(NI)2004/34. The MHRA have produced a Poster "Top ten tips on Endoscope Decontamination" a copy of which can be found on our website at

<http://www.dhsspsni.gov.uk/niaic/guidance.asp>

3. ACTION BY:

- Chief Executives – Boards and Trusts,
- Estates Managers
- Decontamination Leads
- Staff who reprocess endoscopes
- Staff with responsibility for the training of other staff in the use of reprocessing equipment
- Infection Control Team
- Risk Management Team

4. ACTION:

All makes and models of AER used for processing flexible endoscopes should be inspected to ensure that correct fluid flow rates are being achieved and pressure alarm functions, if fitted, are functioning within specification in accordance with the following action:

- Machines without flow monitoring on all channels should be examined as soon as possible to confirm correct fluid flow rates as well as pressure alarm functions. Where possible, and depending on the type of machine, users should measure the flow from each port to ensure that it is adequate. Particularly attention should be given to any auxiliary ports as the flow rate may be very low even when working correctly, and correct flow may be difficult to determine visually. Personal exposure to hazardous chemicals should, of course, be avoided.
- Where possible, and again depending on the type of machine, users should carry out an alarm test by temporarily occluding each fluid port in turn while the machine is running, to confirm that the alarm activates.
- Lack of adequate fluid flow or failure of any alarm to function correctly should result in the machine

being withdrawn from service until the fault is identified and repaired.

- It is recommended that fluid flow and pressure alarm tests be repeated at least weekly until further notice, unless it can be demonstrated that the machine and its alarm systems will fail to safety, i.e. loss of flow, loss of fluid pressure or failure of a critical component will always result in an alarm or cycle abort.
- All makes and models of AERs (including AFOS) which do not have fail safe flow rate monitoring and alarms should have a full service carried out as soon as possible. The service should include testing and, if necessary, recalibration of pressure sensors as well as examination of all internal tubing and fluid carrying components to ensure their patency and freedom from deposits, restrictions and debris of any kind. Correct fluid flow rates should be confirmed by direct measurement. If any problems are found or suspected with pressure sensors or tubing, they should be replaced. Any problems identified should be reported to NIAIC.
- The condition of connectors used to connect the endoscope to the AER ports should be examined regularly to ensure they are in good condition, paying particular attention to sealing O-rings. Any deterioration could cause leaks which may affect the operation of alarms, especially those on auxiliary channels.
- For AERs with pressure/flow alarms, Y-pieces should not be used in connectors to attach 2 separate endoscope channels to one port, as a blockage in one channel might not result in an alarm.

5. ONWARD DISTRIBUTION TO:

Please bring this notice to the attention of all who need to know or be aware of it. This will include distribution to:

- Risk Managers
- Health & Safety Officers/Advisors
- Clinical Governance Leads
- Decontamination Leads
- Infection Control Doctors
- Infection Control Nurses
- Estates Managers
- Medical Directors
- Nursing Directors
- Medical & Nursing Staff
- Endoscopy Suite Managers
- Gastroenterologists
- CSSD Managers
- Surgeons
- Urologists
- Nurse Endoscopists
- Intensive Care Units
- Day Procedure Units
- Theatres
- Outpatient Departments
- Physicians
- Supplies Staff
- Directors of Public Health
- Consultants in Communicable Disease Control
- Independent Health Care Providers – Private Clinics through HSSRIA

6. CONTACTS:

Technical Enquires to NIAIC should quote reference number MDEA(NI)2005/82 and be addressed to:

Northern Ireland Adverse Incident Centre (NIAIC)
Health Estates
Estate Policy Directorate
Stoney Road
Dundonald
Belfast BT16 1US

Tel: 028 9052 3868

Fax: 028 9052 3900

Email: NIAIC@dhsspsni.gov.uk

For Advice and Guidance on Decontamination Processes:

John Singh (Authorised Person(Sterilizers))
Health Estates
Estate Policy Directorate
Stoney Road
Dundonald
Belfast
BT16 1US

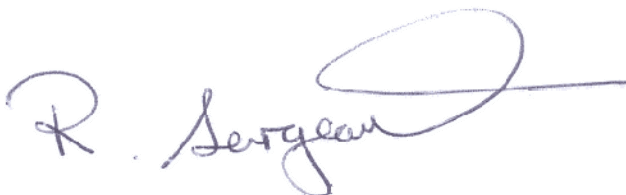
Tel: 028 9052 3802

Fax: 028 9052 3900

Email: john.singh@dhssps.gov.uk

7. FEEDBACK:

None Required

A handwritten signature in blue ink that reads "R. Sergeant". The signature is fluid and cursive, with a large loop at the end of the last name.

Robert Sergeant
NIAIC Operational Manager

HOW TO REPORT ADVERSE INCIDENTS

Adverse Incidents relating to medical devices, non-medical equipment, plant and buildings should be reported to NIAIC as soon as possible. Advice on how to report is given in MDEA(NI)2004/01. If you are in doubt about how to report incidents, please speak to your liaison officer or contact NIAIC using the telephone number provided. Adverse Incident reporting forms and an on-line reporting facility are available on the NIAIC website at www.dhsspsni.gov.uk/niaic

Heath Estates is an Executive Agency of the Department of Health, Social Services and Public Safety