Sultanate of Oman
Ministry of Health
Directorate General of Pharmaceutical Affairs
and Drug Control
MUSCAT

سلطنة عمان
وزارة الصحة
المديرية العامة للصيدلة
والرقابة الدوائية
مسقط

To:
THE DIRECTOR GENERAL OF HEALTH SERVICES IN ALL GOVERNORATES
Commanding Officer, Armed Forces Hospital (Al Khoudh & Salalah)
Director General of Engineering Affairs, MOH
Director General of Royal Hospital
Director General of Khoula Hospital
Director General of Medical Supplies (MOH)
Director General of Pvt. Health Est. Affairs (to kindly arrange distribution to all Pvt. Hospitals)
Hospital Director (Al Nahda Hospital)
Hospital Director (Al Massara Hospital)
The Head of Medical Services in SQU Hospital
The Head of Medical Services in Royal Oman Police
The Head of Medical Services in Ministry of Defence
The Head of Medical Services in The Diwan
The Head of Medical Services in The Sultan's Special Force
The Head of Medical Services in Internal Security Services
The Head of Medical Services in Petroleum Development of Oman
The Head of Medical Services in LNG Oman
ALL PRIVATE PHARMACIES & DRUG STORES

After Compliments,

Please find attached our Circular No.....194..... dated 21/10/20 Regarding SFDA Recall of Neonatal and pediatric ventilator from (mfr: Acutronic Medical Systems AG).

Copy to:

- **Director, Office of H.E. The Undersecretary for Health Affairs**
- **Director of Medical Device Control, DGPA&DC**
- **Director of Pharmacovigilance & Drug Information Dept, DGPA&DC**
- **Director of Drug Control Department, DGPA&DC**
- **Director of Pharmaceutical Licensing Department, DGPA&DC**
- **Director of Central Quality Control Lab., DGPA&DC**
- **Supdt. of Central Drug Information**

ص . ب: ٣٩٣ مسقط - الرمز البريدي: ١٠٠ - هاتف: ٢٢٣٥٧١١١ - فاكس٢٢٣٥٨٤٨٩ البريد الإلكتروني : dg-padc@moh.gov.om
P.O. Box : 393 Muscat, Postal Code: 100, Tel: 22357111 - Fax: 22358489 - E-mail : dg-padc@moh.gov.om

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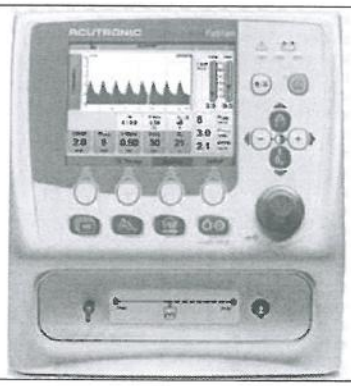
Circular No. 194 / 2020

04 -2-1442 H

21 -10-2020

Recall of Neonatal and pediatric ventilator from Acutronic Medical Systems AG.

Source	SFDA-Saudi& Drug Authority.
Product	Neonatal and pediatric ventilator.
Manufacturer	Acutronic Medical Systems AG.
The affected products	Attached
Reason	Specific Software versions can experience a malfunction associated with over-delivery of peak-inspiratory pressure with delayed or absent alarm during use of the Volume Guarantee (VG) function. This malfunction is associated with the breath-to-breath algorithm and causes a temporary elevation of peak-inspiratory pressure (PIP) above the set Pmax for no longer than 80ms that potentially leads to an increased risk of lung injury, hypoxia, barotrauma, and changes to intrathoracic pressure.
Action	1. Discontinue use of, and/ or do not activate and use the optional Volume Guarantee function with the affected fabian HFO and +nCPAP evolution devices, until the Software update addressing the Volume Guarantee malfunction is installed. 2. Contact the local agent for remedial action.
Product image	
comments	Healthcare professionals are encouraged to report any defect or adverse events Suspected to be associated with the above device or any other medical device to Department of Medical Device Control contact E-mail: Med-device@moh.gov.om

Dr. Mohammed Hamdan Al Rubaie

DIRECTOR GENERAL

SULTANATE OF OMAN - MINISTRY OF HEALTH DIRECTORATE GENERAL OF PHARMACEUTICAL AFFAIRS & DRUG CONTROL

dg-padc@moh.gov.om : البريد الإلكتروني ٢٢٣٥٨٤٨٩ فاكس: ٢٢٣٥٧١١١ هاتف: ١٠٠ - الرمز البريدي: ٣٩٣ مسقط - ص . ب:
P.O. Box : 393 Muscat, Postal Code: 100, Tel: 22357111 - Fax: 22358489 - E-mail : dg-padc@moh.gov.om

المملكة العربية السعودية
الهيئة العامة للغذاء والدواء

Kingdom of Saudi Arabia
Saudi Food & Drug Authority

Medical Device Sector
Surveillance & Biometrics Executive Department

قطاع الأجهزة والمنتجات الطبية
الإدارة التنفيذية للرقابة والقياسات الحيوية

Safety Communication رسالة سلامة

Software Malfunction associated with Over-delivery of peak-inspiratory pressure

Device/ Product Description:	Neonatal and pediatric ventilator		
Affected product:	Device	REF. No.	Software Version(s)
	Fabian HFO	111001 111001.01 112001 113001	5.0x (with VG function) 5.1.x (with VG function)
	Fabian +nCPAP evolution	122001	
Manufacturer:	Acutronic Medical Systems AG		
Problem:	Specific Software versions can experience a malfunction associated with over-delivery of peak-inspiratory pressure with delayed or absent alarm during use of the Volume Guarantee (VG) function. This malfunction is associated with the breath-to-breath algorithm and causes a temporary elevation of peak-inspiratory pressure (PIP) above the set Pmax for no longer than 80ms that potentially leads to an increased risk of lung injury, hypoxia, barotrauma, and changes to intrathoracic pressure.		
Recommendation/Actions:	1. Review this notice and ensure that all affected personnel within your organization are aware of the contents. 2. All users of the fabian HFO and fabian +nCPAP evolution ventilators shall read and take into consideration the immediate mitigative actions below: ***Discontinue use of, and/ or do not activate and use the optional Volume Guarantee function with the affected fabian HFO and +nCPAP evolution devices, until the Software update addressing the Volume Guarantee malfunction is installed.*** *This malfunction does not affect the general use of the ventilators and only impacts the use of the Volume Guarantee function. Other functions of the ventilators are not affected. The ventilators may*		

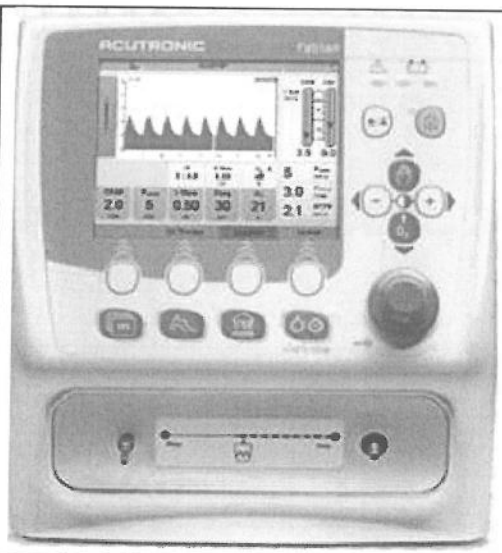
continue to be used for all ventilation modes of therapy, without using the Volume Guarantee function.
For infants with severe lung disease, alternative forms of lung protective ventilation may be considered.

The ongoing "Corrective action" related to the software version 5.1.0 is a mandatory software update to correct identified issues affecting previous software versions. Any devices that have not yet been updated to software version 5.1.0 must still be updated with the "Corrective Action" software. However, the VG function on these updated devices must not be used.

3. Contact the Authorized Representative for required assistance.

For more information, please check the "FSCA"

If you think you had a problem with your device or a device your patient uses, please report the problem to SFDA through:
NCMDR
Vigilance system
19999 unified call center

Devices/Products photo:		
Authorized Representative Details	AR name:	Bio Standards
	Assigned Contact Person:	Ahmed Al Shareef
	Mobile/Phone:	0502923399
	Email:	info@bio-standards.com