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. 55 **dated** 03/03/20 **Regarding Safety Alerts of Anesthesia Systems of (Mfr: GE Healthcare)**

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 - فاكس: ٢٢٣٥٨٤٨٩ 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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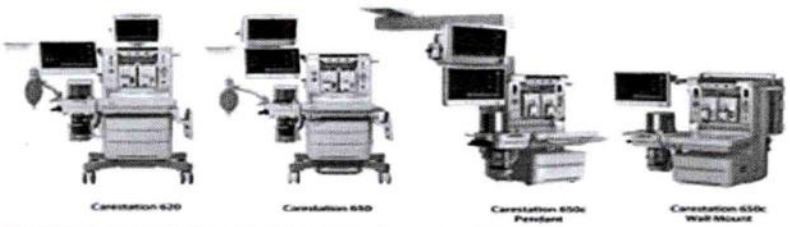
Circular No. 55 / 2020

08 -07-1441 H

03 -03-2020

Ref: 36/2020

Safety Alerts of Anesthesia Systems (Carestation 620/650/650c (A1 & A2)) from GE Healthcare

Source of Recall	Gulf Health Council
Product	Anesthesia Systems (Carestation 620/650/650c (A1 & A2))
Manufacturer	GE Healthcare
Local Agent	Muscat Pharmacy & Store L.L.C
The affected products	**Affected Devices - WU Manufactured** Year (YY) / Fiscal Week (FW) / Manufacture Site (SA) 2018 / 34 to 52 / WA 2019 / 01 to 24 / WA **Affected Devices - MA Manufactured** Year (YY) / Fiscal Week (FW) / Manufacture Site (SA) 2018 / 34 to 52 / MA 2019 / 01 to 30 / MA
Reason for Recall	The Manufacturer has become aware that there is a potential for a loose cable connection inside specific manufactured anaesthesia devices. This would cause a loss of mechanical ventilation and the system will provide high priority audio and visual alarms. Loss of mechanical ventilation could lead to hypoxia if the clinician does not intervene
Action	1. Kindly check your stock, contact your local agent for remedial action 2. . If you observe the message – "Ventilate Manually!" change from mechanical to manual ventilation. At any time, the clinician may use a self-inflating bag to ventilate the patient and/or switch to another anaesthesia device. 3. Perform the planned maintenance (PM) every 12- months at a minimum per the User's Reference Manual, which includes inspection of the cable connection.
Product image	
comments	Healthcare professionals are encouraged to report any adverse events Suspected to be associated with the above device or any other medical Device to Director of Medical Device Control contact E-mail dg-padc@moh.gov.om

NHP

Directorate General of Pharmaceutical Affairs & Drug Control
Sultanate of Oman

Dr. Mohammed Hamdan Al Rubaie

DIRECTOR GENERAL

dg-padc@moh.gov.om : البريد الإلكتروني ٢٢٣٥٨٤٨٩ - فاكس: ٢٢٣٥٧١١١ - هاتف: ١٠٠ - الرمز البريدي: ٣٩٣ مسقط - ص . ب:

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