



بمقدم بثقة
Moving Forward
with Confidence



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 204 dated 14/11/2022 Regarding NCMDR
FSCA of ED-FLOW, Automated Endoscope Reprocessor (AER) from (mfr: Getinge Lancer).

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



PADC
المديرية العامة للصيدلة والرقابة الدوائية
Directorate General of Pharmaceutical
Affairs & Drug Control



ص.ب: ٣٩٣ مسقط - الرمز البريدي: ١٠٠ - هاتف: ٢٢٣٥٧٨٨ - فاكس: ٢٢٣٥٨٤٨٩

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Circular No. 204 / 2022

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14 -11-2022

Field Safety Corrective Action of ED-FLOW, Automated Endoscope Reprocessor (AER) from Getinge

Lancer

Source	NCMDR- National Center for Medical Devices Reporting- SFDA https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=17318
Product	ED-FLOW, Automated Endoscope Reprocessor (AER).
Description	Automated Endoscope Reprocessor Wasaher disinfectant for flexible endoscopes.
Manufacturer	Getinge Lancer.
Local agent	Waleed Pharmacy & Stores LLC.
The affected products	Getinge ED-FLOW AER and ED-FLOW SD AER Affected Serial Nos.: All ED-FLOW AER-models manufactured since start 2010 until 2022-08-24.
Reason	The washer disinfectant ED-FLOW AER range potentially exhibit behavior due to a system error whereby, during the disinfection process, program parameter value or data block values for the endoscope tag have been overwritten with the value "0" instead of the correct values.
Action	1. Getinge has released a Field action upgrade kit (hardware and software) to correct the issue of corrupt endoscope tags. The device is still safe to use but pay extra attention to view the information on the HMI when loading an endoscope for a new process. 2. Contact the local agent for remedial action.
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 Department of Medical Device Control through the E-mail: Med-device@moh.gov.om

Dr. Mohammed Hamdan Al Rubaie
Director General