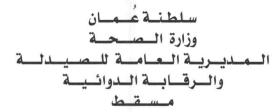
## Sultanate of Oman Ministry of Health Directorate General of Pharmaceutical Affairs and Drug Control Muscat







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.. 5.2..... dated 23.13.122 Regarding NCMDR FSCA of Auralis pump from (mrf: ArjoHuntleigh.).

## 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





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



سلطنة عُهمان وزارة الصحة المديرية العامة للصيدلة والرقابة الدوائية مسقط

Circular No. 52/2022 Forward

20 -08-1443 H

23 -03-2022

## Field Safety Corrective Action of Auralis pump from ArjoHuntleigh.

-		
	Source	NCMDR-National Center for Medical Device Regulator <a href="https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&amp;rid=16075">https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&amp;rid=16075</a>
	Product	Auralis pump.
	Description	Alternating-pressure bed mattress overlay system (pump).
	Manufacturer	ArjoHuntleigh.
	Local Agent	MUSCAT PHARMACY & STORES L.L.C.
	The affected products	Model Numbers: 636001 7237 Auralis pumps manufactured between July and December 2021
	Reason	Premature wear of compressor.
	Action	<ol> <li>Arjo will schedule a service visit to perform the upgrade.</li> <li>If any pump failure occurs before your pump is fixed, please contact your local representative.</li> <li>Contact the local agent for remedial action.</li> </ol>
7	Product Picture	
	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 contact E-mail:  Med-device@moh.gov.om

Dr. Mohammed Hamdan Al Rubaie

DIRECTOR GENERAL



