



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. 174.. dated 22/9/22.. Regarding NCMDR Field Safety Corrective Action of Alinity hq Analyzer, Alinity hs Slide Maker Stainer Module from (mfr: Abbott).

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



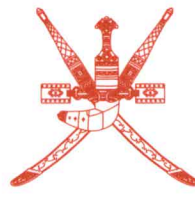
**PADC**  
المديرية العامة للصيدلة والرقابة الدوائية  
Directorate General of Pharmaceutical  
Affairs & Drug Control



ص.ب: ٣٩٣ مسقط - الرمز البريدي: ١٠٠ - هاتف: ٢٢٣٥٧١١١ - فاكس: ٢٢٣٥٨٤٨٩

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Circular No. 174 / 2022

25-02-1444 H

22-09-2022

بنقدم بثقة  
Moving Forward  
with Confidence



**Field Safety Corrective Action of Alinity hq Analyzer, Alinity hs Slide Maker Stainer Module from Abbott.**

Source	NCMDR- National Center for Medical Devices Reporting- SFDA <a href="https://ncmdr.sfda.gov.sa/Secure/CA/CAViewRecall.aspx?caid=4&amp;rid=17272">https://ncmdr.sfda.gov.sa/Secure/CA/CAViewRecall.aspx?caid=4&amp;rid=17272</a>
Product	Alinity hq Analyzer, Alinity hs Slide Maker Stainer Module.
Description	IVD.
Manufacturer	Abbott Vascular.
Local agent	Waleed Pharmacy & Stores LLC.
The affected products	List Number: Alinity hq Analyzer: 09P68-01 Alinity hs Slide Maker Stainer Module: 09P69-01 Refer to " Attachment 1" in the attached FSN Serial Number and UDI
Reason	The Alinity h-series System Control Center (SCC) Application Software Version 4.3 (and below) and the Local User Interface (LUI) Embedded Analyzer Engine (EAE) contain a cybersecurity certificate that expired on 08SEP2022. Whenever the software checks for the cybersecurity certificate expiration date and it detects that it has expired, the SCC and/or LUI becomes nonfunctional. This renders the Alinity h-series unable to process samples.
Action	1. Contact the local agent for remedial action.
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: <a href="mailto:Med-device@moh.gov.om">Med-device@moh.gov.om</a>

Dr. Mohammed Hamdan Al Rubaie  
Director General

