



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

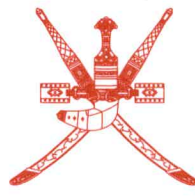
After Compliments,

Please find attached our Circular No...173 dated 22/9/2018 Regarding GHC FSCA of Connector Box CB01 for Imaging Module IM 910 from (mfr: Haag-Streit 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





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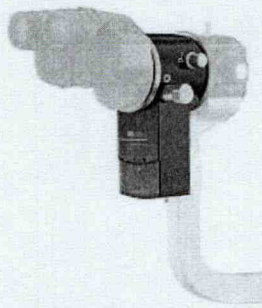
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ببمودة بثقة
Moving Forward
with Confidence



Field Safety Corrective Action of Connector Box CB01 for Imaging Module IM 910 from Haag-Streit AG.

Source	GHC-Gulf Health Council.
Product	Connector Box CB01 for Imaging Module IM 910.
Manufacturer	Haag-Streit AG.
Local agent	Advanced Medical Instruments CO. (AMICO).
The affected products	Reference No.1023640 Affected Serial Nos. 73-79, 100-122, 124, 125, 128-136,138-164, 172.
Reason	The distance between the Connector Box's ethernet-port and internal electronic components is insufficient to provide adequate electrical insulation to the medical device in case of the presence of high voltages on ethernet installations. In its current state, the device does not conform to company requirements.
Action	<ol style="list-style-type: none">1. Disconnect all connected devices from the ethernet network now. Please do not connect any devices without sufficient voltage protection.2. A safety kit, consisting of a network isolator which is tested for compliance with the stipulations set out in EN 60601- 1:2006/A1:2013, a supplement to the Instructions for Use, as well as a warning label to be affixed to affected devices, will be provided to all users of affected devices. This safety kit will be dispatched to you by your distributor or by Haag-Streit directly.3. 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

