

Sultanate of Oman

Ministry of Health

Directorate General of Pharmaceutical Affairs
and Drug Control

MUSCAT



سِلاطِنَا عُومَانِ
وَزَارَةُ الصِّحَّةِ
المديرية العامة للصحة
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...180... dated 29/1/12 Regarding NCMDR Field Safety Notice of Revolution Apex CT Systems from (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

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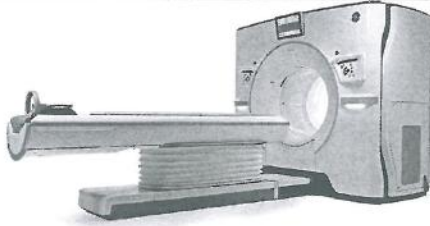
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Circular No. 180/2020

11 -02-1442 H

29 -09-2020

Field Safety Notice of Revolution Apex CT Systems from GE Healthcare.

Source	NCMDR - National Centre Medical Device Reporting- SFDA. https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=15363
Product	Revolution Apex CT Systems.
Description	X-Ray System, Diagnostic, Computed Tomography, Full-body.
Manufacturer	GE Healthcare.
Local Agent	Waleed Pharmacy & Stores L.L.C.
The affected products	The following CT systems are potentially affected: Revolution Apex Revolution CT with Apex edition
Reason	The Revolution Apex CT system could experience a potential smudge artifact that could be suspect for pathology in some images due to incorrect settings.
Action	1. GE Healthcare will inspect and, if required, correct all affected products. 2. Contact 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 an E-mail: Med-device@moh.gov.om

Dr. Mohammed Hamdan Al Rubaie

DIRECTOR GENERAL



**Medical Devices Sector**

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NCMDR

National Center for Medical Devices Reporting

المركز الوطني لبلاغات الأجهزة والمنتجات الطبية

NCMDR Recall**Reference Number:** mdprc 033 09 20 000[Back](#)**Date submitted:** 9/27/2020

Manufacturer:	GE Healthcare
Device Type:	Revolution Apex CT Systems
Description:	X-Ray System, Diagnostic, Computed Tomography, Full-body
Medical Device Identifier:	The following CT systems are potentially affected: Revolution Apex Revolution CT with Apex edition
Reason of Field Safety Corrective Action:	The Revolution Apex CT system could experience a potential smudge artifact that could be suspect for pathology in some images due to incorrect settings.
Remedy Action:	GE Healthcare will inspect and, if required, correct all affected products.
Athorized Representative/Importer/Distributor:	GE Healthcare
Report Source:	NCMDR
Source Ref. Number:	EAA5DB7766347
SFDA Comments:	SFDA urges all hospitals that have devices subjected to this FSCA to contact the company.
Attachments:	 GE Healthcare.pdf

[View History](#)

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