



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. 104..... dated 24/15/22 Regarding GHC FSCA of MUSE™ NX R1 systems with Web Edit option from ( mrf: GE Healthcare USA.).

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





Circular No. 104 / 2022

بالتقدم  
Moving Forward  
with Confidence

رؤية عمان  
2040  
Oman Vision

23 -10-1443 H

24 -05-2022

**Field Safety Corrective Action of MUSE™ NX R1 systems with Web Edit option from GE Healthcare USA.**

Source	GHC- Gulf Health Council.
Product	MUSE™ NX R1 systems with Web Edit option.
Manufacturer	GE Healthcare USA.
Local Agent	Muscat Pharmacy & Stores LLC.
The affected products	R1 SP2, R1 SP3, R1 SP4
Reason	This FSN due to Edits to measurements and diagnosis statements can be lost after a test is signed in the MUSE NX web client. There are two scenarios where edits can be lost after a test is signed. Edits can be lost in the unlikely event a memory error occurs during the following sequence: 1. A test is opened from the Work List. 2. While editing in the Report Editor screen, the QT and/or Vent. rate (Ventricular rate) values are modified. (Changes to other 12SL measurements will not cause this issue to occur.) 3. The user clicks Sign. OR 1. While editing in the Report Editor screen, the user adds or modifies a statement. The acronym drop-down box appears as the user begins typing. 2. The user clicks Sign without selecting a statement from the drop-down list. This issue could result in a potentially delayed or inappropriate treatment
Action	1. Contact local agent for more information about IFU and software correction.
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: <a href="mailto:Med-device@moh.gov.om">Med-device@moh.gov.om</a>

Dr. Mohammed Hamdan AlRubaie  
DIRECTOR GENERAL

