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

سلطنـة عُمــان
وزارة الـصـحـة
الـمـديـريـة الـعـامـة لـلـصـيـدلـة
والـرقـابـة الـدوائـيـة
مـسـقـط

بـتـقـدم بـثـقـة
Moving Forward
with Confidence

رؤية عُمـان
2040

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...**55**....... dated **23/3/22** Regarding GHC FSCA of
CARESCAPE Central Station (CSCS) V2.0 from (mrf: 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**

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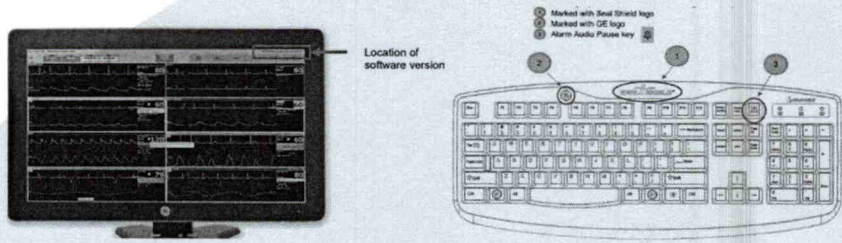المديرية العامة للصيدلة والرقابة الدوائية
Directorate General of Pharmaceutical
Affairs & Drug Control

ISO
9001:2015
CERTIFIED
QUALITY MANAGEMENT SYSTEMS

ص.ب: ٣٩٣ مسقط – الرمز البريدي: ١٠٠ – هاتف: ٢٢٣٥٧١١١ – فاكس: ٢٢٣٥٨٤٨٩
P.O. Box: 393 Muscat - Postal Code : 100 - Tel: 22357111 - Fax: 22358489
dgpa_dc   Email: dg-padc@moh.gov.om

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

سلطنة عُمان
وزارة الصحة
المديرية العامة للصيدلة
والرقابة الدوائية
مسقط

Circular No. 55 / 2022

20 -08-1443 H

23 -03-2022

Moving Forward
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رؤية عُمان
2040

Field Safety Corrective Action of CARESCAPE Central Station (CSCS) V2.0 from GE Healthcare.

Source	GHC- Gulf Health Council.
Product	CARESCAPE Central Station (CSCS) V2.0.
Manufacturer	GE Healthcare.
Local Agent	Muscat Pharmacy & Stores LLC.
The affected products	SKN17400026SA / SNF18150007SA / SNF18150012SA / SNF18150014SA/ SNF18150015SA / SNF18150017SA / SNF18150018SA / SNF18150019SA / SNF18150020SA / SNF18150021SA / SNF18150022SA / SNF18150028SA / SNF18150029SA / SNF18150030SA / SNF18150031SA / SNF18150032SA / SNF18150037SA / SNF18150038SA / SNF18150039SA / SNF18150040SA / SNF18150041SA / SNF18150042SA / SNF18150043SA / SNF18150044SA SNF18150045SA / SNF18150051SA / SNF18150052SA / SNF18150053SA / SNF18150054SA / SNF18150055SA.
Reason	If the CARESCAPE Central Station (CSCS) V2.0 is used with an unapproved keyboard that contains a mute key, and if the mute key is pressed, the audio will be muted resulting in loss of audible alarms. This issue can result in a delay in noticing a change in patient condition. Visual alarms are not impacted.
Action	1. Ensure all staff continues to be aware of the serious risks if an unapproved keyboard is used with the CSCS V2.0 and all users who interact with CSCS V2.0 are fully aware of, understand, and always follow these instructions. 2. You can continue to use the CARESCAPE Central Station V2.0 with the GE-approved keyboard that is shipped with every CARESCAPE Central Station. 3. These characteristics can be placed in slightly different locations depending on the keyboard model:1) Marked with Seal Shield logo, 2) Marked with GE logo ,3) Alarm Audio Pause key. 4. Contact the local agent for remedial action.
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

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

ISO
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CERTIFIED

ص.ب: 393 مسقط – الرمز البريدي: 100 – هاتف: 22357111 – فاكس: 22358489
P.O. Box: 393 Muscat - Postal Code : 100 - Tel: 22357111 - Fax: 22358489
dgpa_dc   Email: dg-padc@moh.gov.om

<Date of Letter Deployment>

To: Director of Biomedical / Clinical Engineering
        Chief of Nursing
        Health Care Administrator / Risk Manager

RE: **CARESCAPE Central Station (CSCS) V2.0 – Use of unapproved keyboards can mute audio.**

This document contains important information for your product. Please ensure all potential users in your facility are made aware of this safety notification and the recommended actions. Please retain this document for your records.

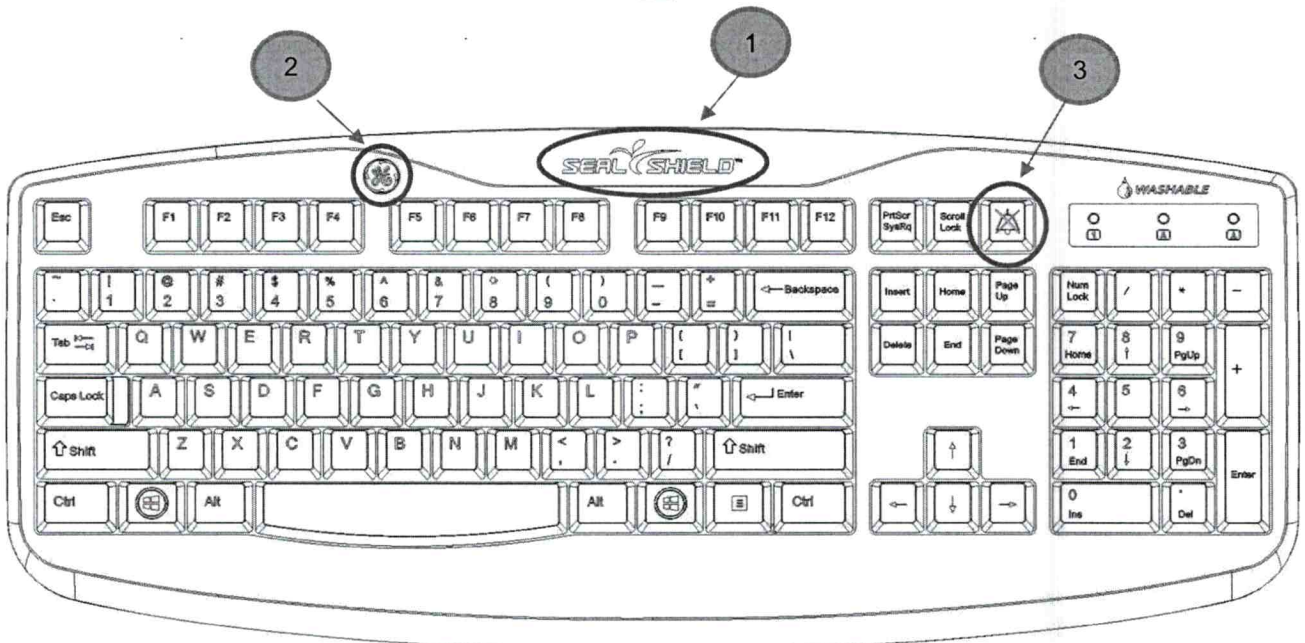|	
Safety Issue	If the CARESCAPE Central Station (CSCS) V2.0 is used with an unapproved keyboard that contains a mute key, and if the mute key is pressed, the audio will be muted resulting in loss of audible alarms. This issue can result in a delay in noticing a change in patient condition. Visual alarms are not impacted.
Actions to be taken by Customer / User	**It is important to ensure that your staff continues to be aware of the serious risks if an unapproved keyboard is used with the CSCS V2.0.** Ensure all users who interact with CSCS V2.0 are fully aware of, understand, and always follow these instructions: You can continue to use the CARESCAPE Central Station V2.0 with **the GE-approved keyboard** that is shipped with every CARESCAPE Central Station. The approved GE keyboard can be identified by the following characteristics. These characteristics can be placed in slightly different locations depending on the keyboard model: ① Marked with Seal Shield logo ② Marked with GE logo ③ Alarm Audio Pause key

If you are not using a GE-approved keyboard with the CSCS V2.0, follow the below instructions:

1) Ensure the **CSCS V2.0 is NOT muted** before moving to the next step. This can be confirmed by listening for active audio alarms or if the CSCS V2.0 is currently silent then perform the following steps to initiate an audio test.
   a. From the Single Viewer menu, select **Monitor Setup > Alarm Setup**
   b. Select **Alarm Help > Low (Advisory) Alarm**
   c. Check that the audio alarm sounds through the speakers
   d. If a sound cannot be heard, press the mute key to unmute the CSCS V2.0 and repeat steps a-d
2) **Replace any unapproved keyboard with a GE-approved keyboard.**
3) If the unapproved keyboard cannot be replaced immediately:
   a. **Ensure the mute key is not pressed** as it will silence all audible alarms.
   b. **Post these instructions at each CSCS V2.0.** See Appendix A for a copy of these instructions. Users can make as many copies of Appendix A as necessary.

If needed, please contact your GE Healthcare representative for additional copies of Appendix A and to order an approved keyboard to use with the CSCS V2.0 (see Appendix B with orderable part numbers).

Although the planned software solution provided by this field action will prevent unintended muting of the audible alarms from unapproved keyboards, it is required to use a GE-approved keyboard qualified for use in clinical settings with any CSCS V2.0 to avoid any other unintended system behavior.

Additionally, please complete and return the attached response form.

Affected Product Details

CARESCAPE Central Station units with software version V2.0.x. This includes software versions 2.0.0, 2.0.1, 2.0.2, and 2.0.3.

Please see the table below to identify the affected products. Identification numbers are located on the product label affixed to the back of the Central Station for an integrated unit, and on the back of the CPU for a desktop unit. Serial numbers are also viewable in the upper right corner of the screen. Identify the affected product code by locating the 13-digit GE Healthcare serial number.

Model Identifier:

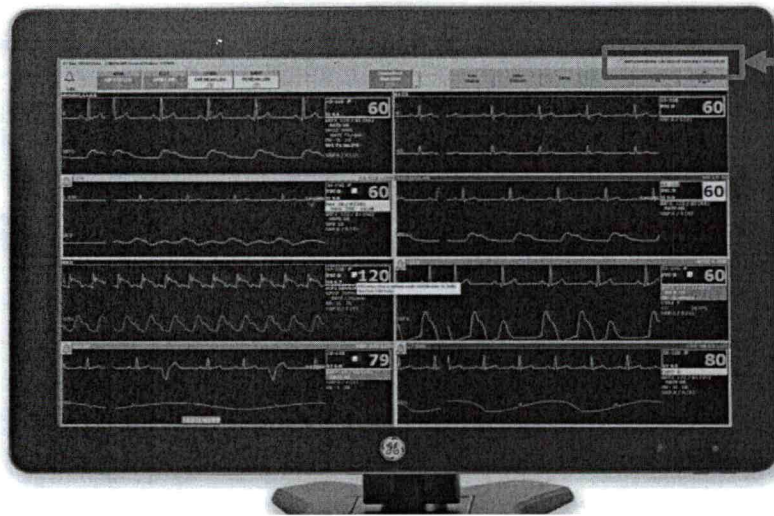| ITEM	PRODUCT CODE	REF #	GTIN
CSCS V2 MAI700 Integrated	SKN	2082278-001	00840682109666
CSCS V2 MAS700 Desktop	SNF	2082279-001	00840682109604

Serial Number: 13-Digit
XXX XX XX XXXX XX
Three-digit product code identifier

Software Media and FRU part numbers:

Part Number	Description
2082326-001	CSCS v2 Re-Image Kit
2082326-002	Service Orderable CSCS V2.0.2 Software Reimage Kit
2104019-001	Commercial CSCS v2.0.2 Software Update Kit
2104019-002	CSCSV2 RE-IMAGE KIT; Service FRU kit
R-FMI36121-001	FMI KIT CSCS (v2.0.1 software)
R-FMI36124-001	FMI KIT CSCS (v2.0.3 software)

Units identified with a SKN or SNF serial number product code have the software version listed in the upper right corner of the display:

Location of software version

Software Versions 2.0.x (requires updating)	SKNxxxxxxxxxx CA:7.0.x. OS:4.0.x. SV:2.0.x or SNFxxxxxxxxxx CA:7.0.x. OS:4.0.x. SV:2.0.x

Note: Software version 2.1.x is not affected and does not require an update.

Intended Use:
The intended use of the CARESCAPE Central Station is to provide clinicians with adult, pediatric, and neonatal patient data within a hospital or clinical environment. The CARESCAPE Central Station is intended to collect, display, and print information from a network, including patient demographics, physiological parameters and waveforms, alarm annunciation and/or other non-medical information from monitors and telemetry systems. Additionally, CARESCAPE Central Station supports the ability to access patient information collected from the CARESCAPE network and stored on a network server.

Product Correction

GE Healthcare will update all affected products at no cost to you. A GE Healthcare representative will contact you to arrange for the update.

After the CARESCAPE Central Station software is updated, discontinue usage of any CARESCAPE Central Station software V2.0.0, V2.0.1, V2.0.2, or V2.0.3 and destroy any software media containing those versions. This includes any software upgrade kits as well.

Contact Information

If you have any questions or concerns regarding this notification, please contact GE Healthcare Service or your local Service Representative.
8004292222 SaudiArabiaServiceCenter@ge.com

Please be assured that maintaining a high level of safety and quality is our highest priority. If you have any questions, please contact us immediately per the contact information above.

Sincerely,

Laila Gurney
Chief Quality & Regulatory Officer

Jeff Hersh, PhD MD
Chief Medical Officer

Appendix A: POST near CSCS V2.0 units that do not have GE-approved Keyboards

If you are not using a GE-approved keyboard with the CSCS V2.0, follow the below instructions:

1) Ensure the **CSCS V2.0 is <u>NOT</u> muted** before moving to the next step. This can be confirmed by listening for active audio alarms or if the CSCS V2.0 is currently silent then perform the following steps to initiate an audio test.
    a. From the Single Viewer menu, select *Monitor Setup > Alarm Setup*
    b. Select *Alarm Help > Low (Advisory) Alarm*
    c. Check that the audio alarm sounds through the speakers
    d. If a sound cannot be heard, press the mute key to unmute the CSCS V2.0 and repeat steps a-d
2) **Replace any unapproved keyboard with a GE-approved keyboard.**
3) If the unapproved keyboard cannot be replaced immediately:
    a. **Ensure the mute key is not pressed as it will silence all audible alarms.**
    b. **Post these instructions at each CSCS V2.0.** Users can make as many copies of Appendix A as necessary. If additional copies are needed, please contact your GE Healthcare representative.

Once audible alarms are present, DO NOT PRESS THE MUTE KEY