Sultanate of Oman
Ministry of Health
Drug Safety Center
Muscat

سلطنة عُمان
وزارة الصحة
مركز سلامة الدواء
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 91 **dated** 27/6/2024 **Regarding NCMDR Field Safety Notice of DEFIGARD HD-7 from (mfr: Schiller AG).**

Copy to:

- **Director, Office of H.E. The Undersecretary for Health Affairs**
- **Director of Medical Device Control, DSC**
- **Director of Pharmacovigilance & Drug Information Dept, DSC**
- **Director of Drug Control Department, DSC**
- **Director of Pharmaceutical Licensing Department, DSC**
- **Director of Central Quality Control Lab., DSC**
- **Supdt. of Central Drug Information**

DSC
مركز سلامة الدواء
Drug Safety Center

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

Sultanate of Oman
Ministry of Health
Drug Safety Center
Muscat

سلطنة عُمان
وزارة الصحة
مركز سلامة الدواء
مسقط

Circular No. 91 **/ 2024**

20-12-1445 H
27-06-2024

Field Safety Notice of DEFIGARD HD-7 from Schiller AG.

Source	NCMDR - National Center Medical Device Reporting- SFDA. https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=21076
Product	DEFIGARD HD-7.
Description	Medical electronics / Electromedical devices – electrotherapy.
Manufacturer	Schiller AG.
Local agent	Waleed Pharmacy & Stores LLC.
The affected products	All DEFIGARD HD-7 devices.
Reason	Correction of software faults: 1) An automatic self-test time stamp fault (on 01/01/1970) can set off an alarm on the device without there being a technical fault. 2) In rare cases, there are reports that when the device is switched on for manual defibrillation, the defibrillator was in synchronized defibrillation mode instead of in direct mode.
Action	1. Customers/users are to follow the instructions provided by Schiller Medical in the attachment. 2. Schiller Medical is releasing a new software version that corrects these faults. 3. 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: Med-device@moh.gov.om

Dr. Mohammed Hamdan Al Rubaie
Director General

DSC مركز سلامة الدواء Drug Safety Center

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

SCHILLER MEDICAL
4, rue Louis Pasteur
67160 Wissembourg – France

SCHILLER MEDICAL

Safety notice reference: IM0499
May 2024

Safety notice
DEFIGARD HD-7 monitor and defibrillator

For the attention of users of DEFIGARD HD-7 monitors and defibrillators

Local contact
Customer assistance:

1. Device information
1. Type
DEFIGARD HD-7
2. Trade names
DEFIGARD HD-7
3. Main clinical use of device
Monitoring and automated external defibrillation
4. Models concerned by the notice
All DEFIGARD HD-7 devices

2 Reason for safety notice
1. Description of problem
Correction of software faults: 1) An automatic self-test time stamp fault (on 01/01/1970) can set off an alarm on the device without there being a technical fault. 2) In rare cases, there are reports that when the device is switched on for manual defibrillation, the defibrillator was in synchronised defibrillation mode instead of in direct mode.
2. Risk
Could lead to delayed patient treatment.
3. Source of the problem
The faults are software-related.

SCHILLER MEDICAL

SCHILLER MEDICAL
4, rue Louis Pasteur
67160 Wissembourg – France

SCHILLER MEDICAL

3. Action to mitigate the risk

Immediate steps

Until your DEFIGARD HD-7 is updated with the software version 02:

1) If there is a self-test alarm, please verify the dates of the latest self-tests. If you find a self-test dated 01/01/1970, the device memory must be reformatted, after first saving your data. The procedure is described in sections 8.1 Post-intervention and 9.1.1 Device settings menu.

2) After switching on in manual defibrillation mode, check that the defibrillator is in the defibrillation mode appropriate for the procedure to be applied. Change modes if needed.

Corrective action

Schiller Medical is releasing a new software version that corrects these faults.

With this Soft02 version and above, the time stamping of self-tests is made more reliable, and the manual defibrillator always starts in direct defibrillation mode.

Please update your DEFIGARD HD-7 as soon as possible, using the procedure described in paragraph 10.3 of the manual

Additional information: The software also includes another modification: the default energy for internal defibrillation (using defibrillation paddles) has been reduced to 10 Joules. It remains user-modifiable.

Please attach a copy of this safety notice to the instructions for use, and insert one copy in each DEFIGARD HD-7 bag to inform its users.

1.	Response required from the user Please see the modalities in the letter from your distributor	YES

4. General information

4.	1. Type of notice	Initial
	2. additional information expected while monitoring the FSN?	None
	2. The competent (regulatory) authority of your country has been informed of this notice to customers.	
	3. Surname/signature	[redacted] Quality and Regulatory Affairs Director

	Circulation of this safety notice
	This notice is to be passed on to all those who need to be informed within your organisation or any other organisation to which devices that are potentially concerned have been transferred.

SCHILLER MEDICAL