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

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 270 **dated** 21/12/23 **Regarding NCMDR Field Safety Corrective Action of Valleylab™ FT10 FT Series Energy Platform from (mfr: Covidien llc).**

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

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

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Circular No. 270/ 2023

08 -05-1445 H

21 -12-2023

Field Safety Corrective Action of Valleylab™ FT10 FT Series Energy Platform from Covidien llc.

Source	NCMDR - National Center Medical Device Reporting- SFDA. https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=19799
Product	Valleylab™ FT10 FT Series Energy Platform.
Description	General-purpose Electrosurgical Diathermy System Generator.
Manufacturer	Covidien llc.
Local agent	Al Zahrawi Medical Supplies LLC.
The affected products	Model: VLFT10GEN Serial Number: All Serial Numbers running software versions 4.0.1, 4.0.2 and 4.0.3
Reason	The Valleylab™ FT10 Energy Platform running software versions 4.0.1, 4.0.2 and 4.0.3 may erroneously indicate that the LigaSure™ device was used previously upon insertion of a new (unused). When this occurs, the energy platform will display error "E420 Usage Limit" or error "E416 Unknown Instrument," and the LigaSure™ device would not be allowed to be used.
Action	1. Update ValleylabTM FT10 Energy Platform to software version 4.0.4 as described in the attachment to eliminate the above issue. 2. Until the software is updated, the Valleylab™ FT10 Energy Platform and LigaSure™ devices can continue to be used as instructed in the User Guide and per your facility protocols. However, please note that the error messages precluding use of LigaSure™ devices may be encountered until software version 4.0.4 is installed. 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

PADC
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P.O. Box: 393 Muscat - Postal Code: 100 - Tel: 22357111 - Fax: 22358489
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Medtronic

Urgent Field Safety Notice

Valleylab™ FT10 FT Series Energy Platform Model # VLFT10GEN

Software update

November 2023

Medtronic Reference: FA1383

Dear Health Care Providers:

The purpose of this letter is to inform you of an update of the software running on the Valleylab™ FT10 Energy Platform to version 4.0.4. This software update serves as a correction applicable to all Valleylab™ FT10 Energy Platforms running software versions 4.0.1, 4.0.2, and 4.0.3. The software update is available through the Medtronic Valleylab™ Exchange (VLEx) and through your Medtronic sales or service representatives. Note that software version 4.0.4 is available for update to all Valleylab™ FT10 Energy Platforms, regardless of current software version.

Issue Description:

As a part of the investigation into this issue, it was noted that upon insertion of a new (unused) LigaSure™ device, the Valleylab™ FT10 Energy Platform running software versions 4.0.1, 4.0.2 and 4.0.3 may erroneously indicate that the LigaSure™ device was used previously. When this occurs, the energy platform will display error "E420 Usage Limit" or error "E416 Unknown Instrument," and the LigaSure™ device would not be allowed to be used. Through 07-November-2023, there have been 138 complaints for this issue. Upgrading the Valleylab™ FT10 Energy Platform to the newly released software version 4.0.4 will eliminate this issue.

Potential Health Hazard:

No patient harm has been reported in relation to this issue. The anticipated patient harm is delay of treatment. There is no impact on patients who have previously undergone a procedure using the energy platform. These patients should continue to be monitored per your practice's normal follow-up procedures.

Product Scope:

Product Name	Model Number	Serial Number
Valleylab™ FT10 FT Series Energy Platform	VLFT10GEN	All Serial Numbers running software versions 4.0.1, 4.0.2 and 4.0.3.

Actions to be taken:

- Immediately notify all personnel in all care environments in which the Valleylab™ FT10 Energy Platform is used about this notice.
- Update Valleylab™ FT10 Energy Platform to software version 4.0.4 to eliminate this issue.
    - For customers already familiar with the software update process through VLEx, software may be directly updated.
    - For customers not familiar with the software update process through VLEx, your Medtronic representative will assist in updating your Valleylab™ FT10 Energy Platform to software version 4.0.4. Your Medtronic representatives will schedule servicing to update the software within the coming weeks.
- Until the software is updated, the Valleylab™ FT10 Energy Platform and LigaSure™ devices can continue to be used as instructed in the User Guide and per your facility protocols. However, please note that the error messages precluding use of LigaSure™ devices may be encountered until software version 4.0.4 is installed.
- Complete the attached Customer Acknowledgement Form and return it as directed to confirm your receipt and understanding of this information.

Additional Information:

Medtronic has notified the Competent Authority of your country of this action.

Medtronic regrets any inconvenience this may cause. We are committed to patient safety and appreciate your prompt attention to this matter. If you have any questions regarding this communication, please contact your Medtronic Representative.

Sincerely,

Mohamad Seifeddine

Sr.Operating Unit Manager Surgical Innovations

Medtronic

FA1383 Customer Acknowledgement Form - Response is required

Valleylab FT10 Energy Platform SW update

Please complete this Form in its entirety.

Date: _____

Name of Person Completing this Form: _____

Title: _____

Direct Phone #: _____

Email: _____

Account Name: _____

Account Number: _____

Account Address: _____

City: _____ Zip Code: _____

Country: _____

☐ I have read and understand the instructions provided and acknowledge receipt of the **notification** regarding the use of the **Valleylab FT10 Energy Platform** by signing below. I also agree to further distribute and communicate this important information within my facility and to anyone whom I have further distributed **Valleylab FT10 Energy Platform** as required.

☐ I confirm that the Valleylab FT10 Energy Platform(s) at my facility have been update to software version 4.0.4. Please populate in below table the software updates that have been completed at your facility.

System Serial Number	Software Version updated to 4.0.4
	☐ YES ☐ NO, Rationale:
	☐ YES ☐ NO, Rationale:
	☐ YES ☐ NO, Rationale:

_____ _____ _____

Name: (print) Signature: Date:

If you have any questions regarding this notification, please contact your Medtronic sales representative.

PLEASE EMAIL OR FAX THIS ACKNOWLEDGEMENT TO:

nahar.s.alsurayi@medtronic.com