FSN Ref: FSN-2023-01 FSCA Ref: FSCA-2023-01

Date: 12-SEP-2023

Urgent Field Safety Notice
Sapphire™ Multi-Therapy
Rev 16.10.1 only

Dear Valued Customers: Directors of Nursing, Pharmacy, Biomedical Engineering, Risk Management

The purpose of this letter is to advise you that Eitan Medical LTD is voluntarily issuing this urgent Field Safety Notice relating to Sapphire infusion pumps with Software Revision 16.10.1 which may fail to detect air in line.

No other Sapphire pump software versions are affected. This Field Safety Notice provides a information on the potential risk to patients and the recommended actions to be taken by users with the affected pumps.

This issue will be corrected via a software update which will be made available soon.

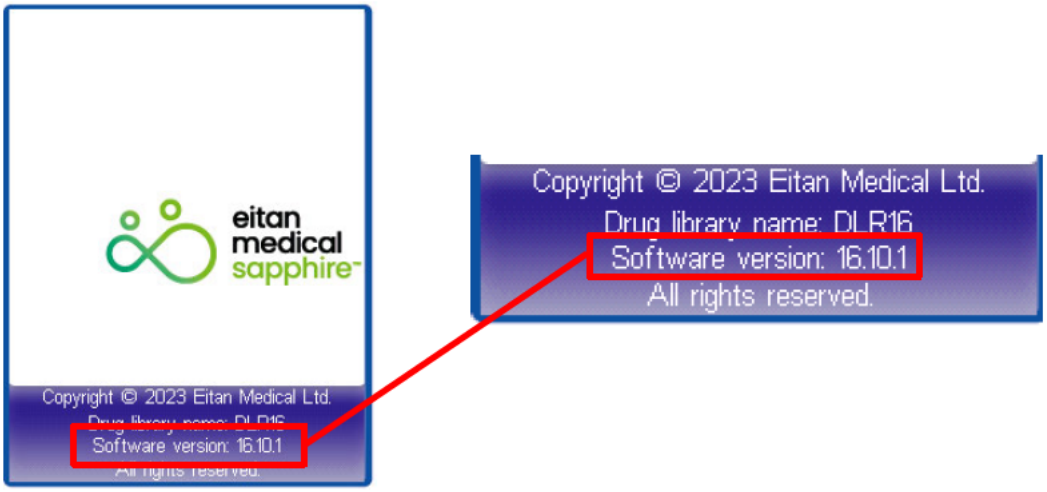
1. Information on Affected Devices (Germany)

1.1. Device Types, Commercial Name and Identification Information:

Unique Device Identifier(s) (UDI-DI): 7290109150001WP			
Commercial name(s)	**Device part numbers**	**GTIN numbers**	**Software version**
Sapphire™ Multi-Therapy	15031-000-0012	7290109150802	16.10.1

1.2. How to identify whether you have Software Revision 16.10 pumps:

Turn the pump on and read the software identification at the bottom part of the "power on" screen (first screen after the pump turns on):



1.3. Primary clinical purpose of the device:

Intended Purpose: The Sapphire infusion pump is intended for controlled infusions.

1.4. Contact details of local distributor:

Name	Email	Telephone	Address
[redacted]	[redacted]	[redacted]	[redacted]

2. Reason for Field Safety Corrective Action (FSCA)

2.1. Description of the product problem

The Affected Pumps may fail to identify air in line when both of the following conditions are met:

a. The pump is operating on battery power (not connected to a power supply)
b. Treatments are water-like solutions (TPN and other opaque solutions are not affected)

2.2. Potential risk to patients

Lack of air in line detection may lead to air embolism.

No patient injuries or deaths have been reported to Eitan Medical as a result of this issue.

3. Action to be taken by Users to mitigate the risk

a. **Inform.** Inform the users and healthcare professionals in your organization and provide them with a copy of this notification so they can implement one of the following preventive actions.
b. **Preventive actions.** Until the Affected Pumps in your facility have been updated with new software, users are advised to only operate the affected devices as follows:
    i. Connect to continuous AC power during treatment (i.e., connect to a power supply) **and/or**;
    ii. Use with air eliminating filters sets:
        - Available Eitan Medical sets with filters: AP206, AP210, AP237, AP 204, or;
        - Connect a 3rd party air eliminating filter set extension to the end of the Sapphire set

    Alternatively, use Sapphire Revision 15.00 installed pump.
c. **Complete form.** Complete and return the Customer Response (Acknowledgement and Receipt Form) as directed at the end of this notice.

4. Action Being Taken by the Manufacturer

The software is being corrected. Eitan Medical will provide information on the availability of the update soon.

4.1. Contact information for questions:

Contact your distributer (see section 1.4 above) or Eitan Medical team:

Eitan Medical Contact	Contact Information	Areas of Support
Global Complaint Management	complaints@eitanmedical.com	To report adverse events or product complaints
Customer Service and Technical Assistance	support@eitanmedical.com +972-73-2388826 or +972-73-2388870	Additional information or technical assistance

5. Manufacturer information

Company Name	Eitan Medical Ltd.
Address	29 Yad Haruzim St. Netanya 4250529 ISRAEL
EU Single Registration No:	IL-MF-000011869
Website address	www.eitanmedical.com

The relevant Competent Authority is being notified of the distribution of this Field Safety Notice.

Eitan Medical is committed to patient safety. Thank you for your prompt support on this important matter.

[redacted]

[redacted]

[redacted]

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MEDICAL DEVICE FIELD SAFETY NOTICE RETURN RESPONSE

Acknowledgement and Receipt Form

Response is Required

E-mail the completed form to: compliance@eitanmedical.com

Customer Information:

Business Name

_____

Address/City/State/Zip

_____

Contact Name/Phone/E-mail Address

_____

Completed by: Printed Name/Signature/Date

_____

- I have read and understand the Field Safety Notice instructions provided in the SEP 2023 letter.

  Yes □ No □

  If NO, state reason: _____

Return Response Box:

Please provide any additional information, if applicable.

Signature of Receipt _____

Name/Title	
Telephone	
Email address	