Appendix A – Customer notification

Eitan Medical LTD

September 11, 2023

URGENT: MEDICAL DEVICE RECALL

Sapphire Infusion Pumps:

Models: Multi-Therapy, Epidural and SapphirePlus

Software version: Revision 16.10 (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 recalling Sapphire infusion pumps with Software Revision 16.10.x[18] which may fail to detect air in line.

No other Sapphire pump software versions are affected. This recall notice provides a detailed description of the potential risk 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.

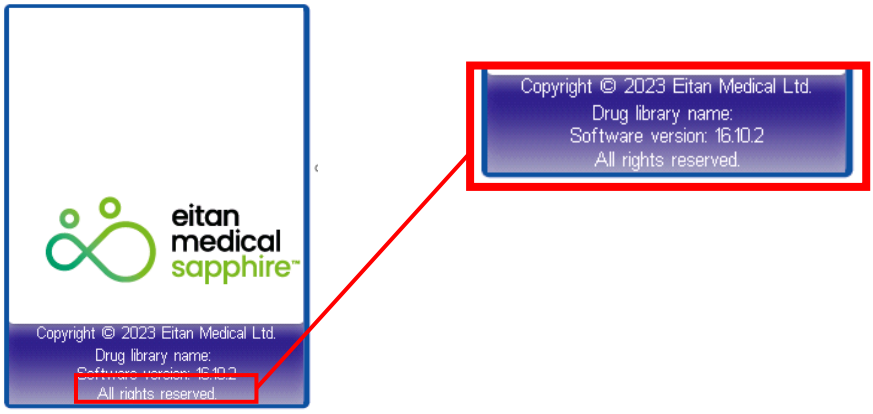
Affected Pumps:

- **Model:**
  - Sapphire Multi-Therapy (REF 15031-000-0028; GTIN 7290109150109),
  - Sapphire Epidural (REF 15032-000-0027; GTIN 7290109150147),
  - SapphirePlus (REF 15038-000-0001; GTIN 7290109150161),
- **Software version**: Revision 16.10 only

("**Affected Pumps**")

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):

[18] Can be 16.10.1 or 16.10.2



The issue (Reason for the Voluntary Recall):

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

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

Risk to Health:

Improper air in line detection may lead to air embolism.

No patient injuries or deaths have been reported from use of Software Revision 16.10 pumps.

Actions to be taken by the Customer:

b. **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 actions in this notice.

c. **Preventive actions.** Until the Affected Pumps in your facility have been updated with new software, users are advised to only operate the effected 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: AP206-01, AP240-01, AP 214-01, AP 204-01, AP223-01, or;
- Connect a 3rd party air eliminating filter set extension to the end of the Sapphire set

Alternatively, use software version - Rev15.10.

d. **Complete form.** Complete and return the Customer Response (Acknowledgement and Receipt Form) as directed at the end of this notice.

Type of Action taken by the Company:

The software is being corrected. Eitan Medical will provide an update of its availability.

Contact information for questions

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	customerservice@eitanmedical.com 1-877-541-9944	Additional information or technical assistance

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

Sincerely,

Guy Mlechkovich
Vice President of Regulatory Affairs

MEDICAL DEVICE RECALL RETURN RESPONSE

Acknowledgement and Receipt Form

Response is Required

E-mail the completed form to: compliance@eitanmedical.com, **or**
Fax to +1-724-259-8490

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 recall instructions provided in the SEP 2023 letter.

  Yes □ No □

  If NO, state reason: _____

Any adverse events or quality problems experienced with the use of these products may be reported using one or more of the following options:

- Call Eitan Medical Customer Service at 877-541-9944 between the hours of 7:00 am and 4:00 pm Pacific Standard Time, Monday through Friday.
- Email Eitan Medical at: complaints@eitanmedical.com.
- Reporting to the FDA MedWatch Serious Injury Reporting Program:
  - Online: By completing and submitting the report online at: https://www.accessdata.fda.gov/scripts/medwatch/
  - Regular mail or Fax: Download the form from www.fda.gov/MedWatch/getforms.htm or call 800-332-1088 to request a reporting form, then complete and mail it to the address on the pre-addressed form or submit by fax to 800-332-0178.

Return Response Box:

Please provide any additional information, if applicable.

Distributors:

I have checked my stock and have quarantined inventory consisting of affected devices until a new software version is available and all quarantined devices are updated.

Please provide a separately attached a list of the Affected Pumps in your possession:

_____

Signature of Receipt _____

Name/Title	
Telephone	
Email address	