

Field Safety Notice

Response is Required – Ref. CAPA 200034498

1. DESCRIPTION OF THE PROBLEM

Esaote received notice by the manufacturer XP Power of a reliability issue of the AC/DC adapter (power supply) component of the portable ultrasound systems listed below that may result in the connector heating up, generating smoke and melting. This condition is caused by the mechanical stress of the connection between the AC/DC power adapter and the mains cable over the time of use.

Harm related to this problem includes electrical shock that could lead to **Serious injury and/or death**. According to our verification the probability of occurrence is very low. No shock hazard has been reported.

The risk of personal injury is greatest when disconnecting the power cord from the AC/DC Adapter while the power cord is plugged into the wall outlet. By always disconnecting the power cord from the wall outlet, as instructed in the system user manual, the operator eliminates the possibility of harm in this situation. Therefore, using the ultrasound system as specified in the system user manual does not pose any safety risk.

2. AFFECTED DEVICES

XP Power AC/DC Adapters in the range of Serial Numbers listed below

Part Number	Description	XP Power Model	Serial Number
151004300	POWER SUPPLY for 7400	AHM180PS19-XE0338	Below K17510001
151004301	POWER SUPPLY for 7400	AHM180PS19-XE1057	Below K17350001

The affected XP Power AC/DC Adapters are used with the Ultrasound systems listed below

Name	Code	Name	Code	Name	Code
MyLabAlpha	101740000	MyLabGamma	101741000	MyLabDelta	100743000
MyLabAlphaVET	101740001	MyLabGammaVET	101741001	MyLabDeltaVET	100743001
MyLabOmega	101740004	MyLabSigma	101741004		
MyLabOmegaVET	101740005	MyLabSigmaVET	101741005		
MyLab XPro30	101740007	MyLabSigma elite	101741007		

3. ACTION TO BE TAKEN BY THE USERS

Using the ultrasound system as specified in the system user manual does not pose any safety risk. As instructed in the system user manual, never disconnect the power cord from the AC/DC Adapter when the power cord is plugged into the wall outlet.

The customer and any system user are requested to:

- Verify the mains cable has not been changed since purchasing the system. If the cable is not the original supplied by Esaote, contact your local Esaote service representative for assistance.
- In case you see unexpected alert messages on the screen reporting that the system is out of power and not plugged in when in fact the mains cable and AC/DC power adapter are connected, you are requested to refrain the use of the system and contact your local Esaote service representative for assistance
- If you observe smoke coming from the system or the AC/DC Power adapter, immediately unplug the mains power cord from the wall outlet, removing power to the system. If the ultrasound system continues to operate via batteries, power down the system. You are requested to refrain from using the ultrasound system and to contact your local Esaote service representative for assistance.
- **Never disconnect the power cable from the AC/DC adapter when the power cord is plugged into the wall outlet.** As recommended in the User Manual of the system, in “Getting Started” chapter 3 and chapter 5 “to insulate the system from the mains always disconnect the cable from the power outlet”.
- With the system “off” and completely unplugged from the wall outlet, you can remove the mains power cord from the AC/DC adapter to inspect the cable and outlet on the AC/DC adapter for any damage, such as melting of the corner of the mains power cord where it plugs into the AC/DC adapter. If you see damage or suspect the mains power cord or AC/DC adapter are possibly damaged, you are requested to refrain the use of the system and contact your local Esaote service representative for further instructions.
- **Do not use the AC/DC power adapter if damage is observed or suspected.**

In addition to these actions, please also:

- Distribute this Urgent Medical Device Correction Notification to all appropriate personnel in your organization and forward to all users of the systems. If you no longer are in possession of your system, please inform Esaote of the new owner or status of the system.
- Complete & return the acknowledgement form

Esaote will be providing replacement AC/DC adapters to all customers with affected devices (listed in Section 2). Your local Esaote service representative will contact you regarding arrangements for the replacement.

4. CONTACT INFORMATION

You are requested to contact your Esaote local representative should you have any question or concern regarding this Notification.

We sincerely regret any inconvenience this issue may cause in your daily operations. We trust you understand that Esaote’s first concern is the safety of the users and the patients and maintaining a high level of quality of our products.

Massimo Polignano
Chief Quality Officer