

Field Safety Notice

July 23, 2018

Ref. CAPA 200015362

Dear Valued Customer,

Esaote has recently become aware of a potential safety issue as described below.

The power monitoring settings for the probes listed below have been found to be not appropriate under specific operating conditions when connected to the ultrasound system identified in the table. This issue may result in overheating of the probe head.

To-date, no patient injury has been reported with regards to this issue.

1. AFFECTED DEVICES: probe in combination with ultrasound system model as specified below

Probe model	Ultrasound system model	Operating conditions
IOT332	MyLab Alpha, MyLab Seven, MyLab Six Crystalline	CFM, PW, Duplex, Triplex
IOT342	MyLab Alpha, MyLab Seven, MyLab Six Crystalline	CFM, PW, Duplex, Triplex
P2 5-13	MyLab Alpha, MyLab Seven, MyLab Six Crystalline	B, CFM, PW, Duplex, Triplex
TLC 3-13	MyLab Alpha, MyLab Seven, MyLab Six Crystalline, MyLab Six, MyLab Gamma	CFM, PW, Duplex, Triplex
TRT33	MyLab Seven	CFM, PW, Duplex, Triplex
IL 4-13	MyLab Six, MyLab Gamma	CFM
LP 4-13	MyLab Six, MyLab Gamma	CFM

2. DESCRIPTION OF THE PROBLEM

The probe power monitoring settings may not be effective in specific operating conditions so that the surface of the probe head may overheat in around one minute of continuous operations. The patient may experience discomfort, reddening of epidermis and/or mild pain.

3. CORRECTIVE ACTIONS:

At no cost for the Customer, Esaote will provide and install a corrective software update as required for each affected unit.

4. ADVICE ON ACTION TO BE TAKEN BY THE USERS

Until the Customer receives the corrective software update, Customer is requested to refrain from use of the probes in the operating conditions specified in the table above under section 1.

For all the other operating conditions, Customer is requested to monitor the possible temperature rise at the surface of the probe head and immediately stop scanning if the patient reports any discomfort.

As a general safety rule, it is recommended to use the probe in default settings, to keep the examination time as short as is necessary to produce a useful diagnostic result and not to hold the probe in a fixed position for no longer than strictly necessary.

You are requested to distribute this Field Safety Notice to all appropriate personnel in your organization and forward to all users of the systems, including others to whom you may have transferred the systems, in which case you are requested to provide information to Esaote regarding the new owner.

5. CONTACT INFORMATION

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

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

Sincerely,



Massimo Polignano
Head of Quality Assurance