

Field Safety Notice

December 22, 2017

Ref. CAPA 200009905

Dear Valued Customer,

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

Probes default settings in ElaXto mode (Elastosonography application) are found to be not appropriate for certain probes as listed below in Section 2 resulting in overheating of the probe head.

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

1. AFFECTED DEVICES

Ultrasound systems listed below with software versions 12.10 to 13.60 and ElaXto mode enabled (Elastosonography application).

REF 1016200XX	REF 1016250XX
MyLabTwice	MyLabClass C
MyLabClass C Advanced	MyLab Eight
MyLabEight eXP	
REF 9806100XXX	REF 9806150XXX
MyLab70 XVG	MyLab60
MyLab70 XVG-L	MyLab65
MyLab90	MyLab70
	MyLab75
	MyLab70 X Vision
	MyLab70 XV-L

QElaXto mode (Shear Wave Elastosonography application) is not affected by the issue.

2. DESCRIPTION OF THE PROBLEM

In Elaxto mode (Elastosonography application) the default settings can be inadequate for the following probes:

BL433	C 1-8	CA541	EC1123
EC123	IH 6-18	IOT332	IOT342
L 4-15	LA332E	LA435	LA523
LA533	SI2C41	SL2325	TRT33

Under default settings in Elaxto Mode, the surface of the probe head may overheat within approximately 1 (one) minute.

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 for each affected unit.

3. ADVICE ACTION TO BE TAKEN BY THE USERS

Until the Customer receives the corrective software update, Customer is requested to refrain to use the Elaxto mode (Elastosonography application) in the following clinical applications where the patient is unconscious or sedated: Intraoperative and Neurosurgery.

Please note that ElaXto mode is not indicated for Neonatal or Pediatric use.

You are also requested to check the temperature at the surface of the probe head in Elaxto mode before the use.

In the case where the User experiences overheating as described above, you are requested to refrain the use of the system in Elaxto mode.

You are requested to distribute this Customer Safety Notification 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.

4. Contact information

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

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