

Field Safety Notice

Ref. CAPA 200012574

Dear Valued Customer,

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

The IH 6-18 probe power monitoring settings have been found to be not appropriate under specific operating conditions when connected to the devices listed below. 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

MyLab Seven
MyLab Six Crystaline
MyLab Six
MyLab Alpha
MyLab Gamma

MyLabClass C
MyLab Eight
MyLab60
MyLab65
MyLab70
MyLab75
MyLab70 X Vision
MyLab70 XV-L

2. DESCRIPTION OF THE PROBLEM

The probe power monitoring settings may not be effective when the B-TEI mode is activated 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 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 to use the probe IH 6-18 in B-TEI mode or any combined mode including B-TEI in Pediatric, Neonatal and Intraoperative clinical applications.

For all the other applications, you are requested to monitor the possible temperature rise at the surface of the probe head and immediately stop scanning if the patient notices 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 any longer than is 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,

A handwritten signature in blue ink, appearing to read 'M. Polignano'.

Massimo Polignano
Head of Quality Assurance