

URGENT – Field Safety Notice

Philips EPIQ & Affiniti Ultrasound Systems Patient Data Error

Dear Distributor,

Philips is initiating an action related to Philips EPIQ and Affiniti Patient Data

The attached Field Safety Notice is intended to inform customers about:

- the problem is and under what circumstances it can occur
- the actions that should be taken by a customer or user to prevent risks for patients, and
- the actions planned by Philips to correct the problem.

It is imperative that all affected end users of EPIQ & Affiniti Ultrasound Systems receive the attached Field Safety Notice. Because Philips sells these products through distributors, including your organization, we may not have the information necessary to contact all end users. Therefore, please send the Field Safety Notice provided to each customer to whom you have distributed one of the affected devices. A description of the affected device can be found in the Field Safety Notice.

Thank you for your cooperation.

Sincerely,

Ron Nolte
Head of Quality & Regulatory
Ultrasound

Enclosed:

FSN79500532