

URGENT - Voluntary Medical Device Field Correction Notice

Aachen, 11. Mai 2009

AB Portable™ Circulatory Support System

Dear Valued Customer,

This letter is to notify you that ABIOMED, Inc. is conducting a voluntary field correction on our AB Portable Driver. ABIOMED has identified that the Emergency System Operation (ESO) mode may not provide adequate patient support under a specific operating condition. The Driver permanently surveils correct functioning and automatically enables the ESO mode taking over operation of the Driver if the microprocessor unit that controls pumping malfunctions.

The change into ESO mode is performed by the following actions:

- Activates an audible alarm.
- Turns ON the LEDs: Battery Status, the Wrench Status, AC status LED
- Turns OFF the user interface display.

An internal failure investigation was conducted and it was determined that high or low ambient operating temperatures may adversely affect patient support while the AB Portable Driver is in ESO. This is only an issue in ESO mode: Normal console operation under the microprocessor unit's control is NOT affected. Our records indicate that your AB Portable Driver(s) is(are) affected and is(are) subject to this voluntary removal.

You may continue to support patients with the AB Portable Driver during this process. This failure did NOT occur during patient support, and has not been reported by clinical sites.

An ABIOMED Field Service Engineer will be contacting you (or may have already contacted you) to arrange for a temporary exchange of the affected Driver(s) and swap out with a corrected Driver(s). Until you can confirm that your Driver(s) has(have) been corrected by ABIOMED Field Service, we recommend the following actions if the Driver enters ESO:

1. Switch the patient to hand pump support
2. Switch patient to backup Driver
3. Inform ABIOMED Technical Field Service

In case you delivered the affected product to third parties, please hand over a copy of this information or inform the contact person mentioned below.

Management Board:

Dr. Thorsten Sieß

Dirk Michels

Commercial Register No.:

Amtsgericht Aachen HRB 13059

VAT ID No.:

DE 813 647 191

Bank Account:

Sparkasse Aachen BLZ 390 500 00, Kto.: 47 866 322

IBAN: DE 153 905 000 000 47 866 322

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We regret any inconvenience this action may cause and we appreciate your understanding as we strive to ensure the highest quality and customer satisfaction.

This is a voluntary correction and ABIOMED will be notifying the appropriate regulatory authorities. If you have any questions, please contact me at (+49 (0)241 8860-226) or our Technical Field Service (+49 (0)241 8860-216).

Sincerely,

Max Eisen
Director QA Europe

ABIOMED Europe GmbH

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