

Voluntary Medical Device Field Correction Notice

Aachen, 26. Feb. 2010

ABIOMED AB 5000 Console

Dear Valued Customer,


This letter is to notify you that ABIOMED is conducting a voluntary field correction on our AB 5000 Console. ABIOMED has received reports that the AB 5000 Console may lose power unexpectedly due to a rare component failure and thus may stop pumping without an audible alarm.

An internal failure investigation was conducted and determined that a diode defect was the root cause for the loss of power to the system and alarms. Abiomed has developed a corrective action and will add additional power failure alarm hardware to the AB 5000 Console to ensure an independent alarm is activated in case system power failed or is lost.

Our records indicate that your AB 5000 Console(s) is potentially affected and therefore subject to this correction. An ABIOMED Field Service Engineer will be contacting you (or may have already contacted you) to schedule a time to visit your facility to correct the affected console(s). Until you can confirm that your console(s) has been corrected by ABIOMED Field Service, we recommend the following actions if you encounter this failure mode:

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

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 notified the appropriate regulatory authorities. If you have any questions, please contact me at (+49 (0)241 8860-) or our Technical Field Service (+49 (0)241 8860-216).

Sincerely,


Director QA Europe
ABIOMED Europe GmbH**Management Board:**Dr. Thorsten Sieß
Dirk Michels**Commercial Register No.:**

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