

MAQUET

Safety Alert Letter

2006-11-20

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Please forward this to all users and biomedical staff concerned

Subject: Overheating during cleaning cycle due to low water level

Products affected: Jostra HCU30 Type1, with Article number 93 90 01

Dear Jostra HCU30 users

It has come to our knowledge that, the HCU30, during cleaning, has been overheated due to low water level in the system. The result has been that smoke has come from the HCU30 due to high temperature. This has happened when users have run the cleaning program with too low water level in the system.

This behavior of overheating will be avoided if you always ensure that the water level in the water tank is sufficient during the cleaning cycle and/or daily usage. Please refer to your User's Manual for HCU30.

The water level shall always be 1 cm above the cooling spirals during any kind of operation with the machine.

We apologize for any inconveniences this has caused you. If you have questions or require additional information regarding the content of this letter, please contact your local MAQUET representative.

Sincerely,



Vice President, Quality Management



Product Manager, Perfusion systems

Maquet Critical Care AB
SE-171 95 Solna, Sweden
www.maquet.com/criticalcare

MAQUET

To Fax NO.: Int. Int + 46 8 730 78 38

Att. MCC-Q

Maquet Critical Care AB
SE-171 95 Solna, Sweden.

Confirmation of completion

Safety Alert Letter 2006-11-20

Product Name: Jostra HCU30 Type1, Article number 93 90 01

Subject: Overheating during cleaning cycle due to low water level

We herewith confirm that all customers concerned have received this Safety Alert Letter.

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Country

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Name of Med Country Manager

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Date

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Signature