
Field Safety Notice

Affected product: **AQUARIUS HEMOFILTRATION DEVICE**
REF: **GE-F082-00; GE-F095-00; GE-F096-00; GE-F097-00**
Serial numbers: **Serial No 101 to Serial No 3534**
FSCA: **FCA-NE-05**
Type of FSCA: **Safety Advice / Device Modification**

Wednesday, August 31, 2011

Risk of damage of machine's wheels

Dear Sir or Madam,

We are writing to inform you that Nikkiso Europe is initiating a Field Safety Corrective Action of the Haemofiltration device AQUARIUS. Product models **GE-F082-00; GE-F095-00; GE-F096-00; and GE-F097-00** with serial numbers between 101 and 3534 are affected.

Aquarius Haemofiltration machines used to be manufactured and labeled by Edwards Lifesciences. However Nikkiso Europe GmbH, Germany took over the manufacturer responsibility effective October 1st 2010. Baxter Healthcare is the exclusive distributor and technical service provider for Aquarius Haemofiltration Devices.

The Advisory Notice is being initiated due to risk of damage to the machine's wheels.

Problem description

Nikkiso has received reports of 8 cases of broken / damaged wheels on the AQUARIUS. The damage to the wheels occurred during the moving of the device. The damaged wheel may result in loss of stability of the device. In the worst case, the device can fall over and potentially impact on a person.

Nikkiso's internal investigation and testing has determined that the most probable cause for the damage of machine wheels is movement of the machine over steps, stairs or other uneven surfaces, or movement of the device with locked front wheels. This may result in an unexpected release of the wheel threaded stem from the trolley and may also result in high shear stress on the wheel threaded stem.

The advised actions to be taken are:

**Release the locking tabs of both front wheels before moving the device!
Move the device carefully over steps or uneven surfaces.**

1. To move or transport the Aquarius machine, it is necessary to release the locking tabs on the wheels. The Aquarius machine can then be rotated and freely moved about.
2. To move the Aquarius machine over steps or stairs, the locking tabs must be released. The system should be tilted, lifted and carried by at least three people.
3. Please strictly follow the information given in the instruction for use / operators manual.

Nikkiso has initiated a corrective action performed by the responsible field services engineers who will inspect the wheels of all installed AQUARIUS machines. Appropriate maintenance activities will be performed in accordance with the AQUARIUS technical bulletin 134 at the next regular service event. The technical inspection ensures that the wheels are correctly fixed on the trolley with defined torque and an additional threaded locker which prevents any unexpected release of the wheel threaded stem from the trolley.

Nikkiso Europe GmbH apologizes for any inconvenience this may cause and is available to answer any questions you may have regarding this issue.

In case of further questions or information, please contact the Quality & Regulatory Affairs Department of Nikkiso Europe (+49 511 67 9999 251) or your local Baxter sales organization.

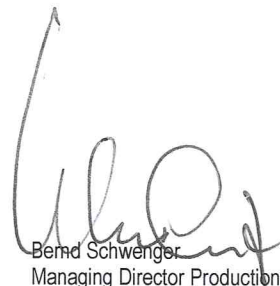
Please provide this Safety Notice to all those who need to be aware of it within your organization.

Please confirm the receipt of this Field Safety Notice by sending the completed "Confirmation of Receipt" form back to Nikkiso.

Best Regards
Nikkiso Europe GmbH



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