NIKKISO Europe GmbH
Desbrocksriede 1
30855 Langenhagen
Germany

Field Safety Corrective Action (Update)

Affected product:	**Hemofiltration Device AQUARIUS**
REF:	**GE-F096-00 and GE-F097-00**
Affected devices:	**All Regular Platform 6 devices**
FSCA:	**Baxter FCA #2009-019-RN**
Type of FSCA:	**Software Upgrade**

2013-01-15

Update regarding the on-going Field Safety Corrective Action (FSCA) for AQUARIUS device GE-F096-00 and GE-F097-00: Risk of Hypovolemia or Hypervolemia by Repeatedly Overriding the Balance Alarm

Dear Sir or Madam,

Edwards Lifesciences (previous legal manufacturer of AQUARIUS devices in the market) initiated a FSCA to address the issue related to the potential risk of fluid overload or fluid loss caused by repetitive clearing of the balance alarm without solving the balance alarm cause. Field Safety Notices were sent to customers warning them about the potential danger for repetitive clearing of the balance alarm without solving the balance alarm cause.

NIKKISO Europe (current legal manufacturer of AQUARIUS devices) has now completed a software solution to prevent the repeated overriding of the balance alarm without resolving the root cause by implementing Total Fluid Loss (TFL) management in software 6.02. All validation testing was done with the new AQUASPIKE 2 manifold, manufactured by Haemotronic S.p.A., Italy.

The TFL management in software version 6.02 works as follows:

1. The software memorizes the direction and the value of the fluid imbalance.
2. After clearing the balance alarm only the filtrate or substitution pump (depending on the direction of imbalance) will operate to compensate for the fluid imbalance.
3. If the root cause (clamp on tubing or any other occlusion) has been removed, the filtrate or substitution pump will automatically compensate for the imbalance and then normal operation of the AQUARIUS system will continue.
4. If the root cause has not been removed, a new balance alarm will occur.
5. If the user clears the balance alarm 5 times without solving its cause, the treatment will be terminated. In this case a new treatment has to be started with new disposables.

The implementation of the TFL management will increase the patient safety and improve the user's attention to resolve the root cause of any balance alarm.

The changes in the software are not limited to the improvement of the balance alarm handling only. Additional changes also include enhanced functionalities (listed in the addendum of this FSCA). Therefore, the new software is supported by a revised Instructions For Use (IFU) that requires the attention of the user.

Baxter Healthcare (exclusive distributor for the AQUARIUS devices) will implement the new software by a FSCA to the affected devices globally. Therefore the Baxter technical service team will contact customers to schedule the

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onsite modification and calibration based on availability of hospital staff as well as devices. The global timeline is 17 months, however, the FCA will be executed as rapidly as possible, and in some countries it will be completed in less than 17 months. Until devices are upgraded with the new 6.02 software, please continue to follow the instructions provided in the Field Safety Notice issued by Edwards Lifesciences on 2009-10-23.

This FSCA does not pertain to the AQUARIUS devices with citrate option GE-F095-00.

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

Best Regards
NIKKISO Europe GmbH
Desbrocksriede 1
D-30855 Langenhagen, Germany

[redacted]
Director Quality & Regulatory Affairs

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Director Research and Development

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Addendum for Field Safety Corrective Action (Update)
Baxter FCA #2009-019-RN

Main enhanced functionalities of software version 6.02.07 versus version 6.01

1. Total Fluid Loss (TFL) Management.
2. Heater cool down management after STOP of the substitution pumps.
3. The Renal Dose is displayed during CVVH, CVVHD and CVVHDF. For this display the Aquarius provides the possibility of programming the patient weight.
4. If a heparin syringe is installed and the heparin rate is programmed to zero the user is notified with a message: "Syringe pump off".If an alarm is displayed, the using of the help button leads directly to the error help screen.
5. Treatment pumps stop when Automatic Degassing Unit (ADU) is alarming. Treatment pumps re-start after the ADU alarm is resolved.
6. The ADU detects and alarms if the pressure port is not correctly connected.
7. During Recirculation mode the Blood Leak Detector (BLD) control is off.
8. The BLD disables the 'next' function during the operation mode 'priming completed' if the blood leak chamber is not correctly filled.
9. Selected screen pages close after 5 minutes last key press and lead back to the main menu page.
10. A detected red alarm will lead back to the main menu.
11. "No Bag" alarm implemented for filtration scale
12. After 80 hours blood pump run time (Priming and Recirculation time included) the device generates an alarm to notify that the treatment stops and the patient must be disconnected.
13. Heparin pump programming steps are 0.5ml/h.
14. Lower alarm limit of the return sensor did change from 10mmHg to 20mmHg.

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Field Safety Corrective Action (Update 2)

Affected product:	**Hemofiltration Device AQUARIUS**
REF:	**GE-F095-00**
Affected devices:	**All Citrate Platform 6 devices**
FSCA:	**Baxter FCA #2009-019-RN**
Type of FSCA:	**Software Upgrade**

2014-01-07

Update regarding the on-going Field Safety Corrective Action (FSCA) for AQUARIUS device GE-F095-00: Risk of Hypovolemia or Hypervolemia by Repeatedly Overriding the Balance Alarm

Dear Sir or Madam,

Edwards Lifesciences (previous legal manufacturer of AQUARIUS devices in the market) initiated a FSCA to address the issue related to the potential risk of fluid overload or fluid loss caused by repetitive clearing of the balance alarm without solving the balance alarm cause. Field Safety Notices were sent to customers warning them about the potential danger for repetitive clearing of the balance alarm without solving the balance alarm cause.

NIKKISO Europe (current legal manufacturer of AQUARIUS devices) has now completed a software solution to prevent the repeated overriding of the balance alarm without resolving the root cause by implementing Total Fluid Loss (TFL) management in software 6.02. All validation testing was done with the new AQUASPIKE 2 manifold, AQUALINE RCA, manufactured by Haemotronic S.p.A., Italy.

The TFL management in software version 6.02 works as follows:

1. The software memorizes the direction and the value of the fluid imbalance.
2. After clearing the balance alarm only the filtrate or substitution pump (depending on the direction of imbalance) will operate to compensate for the fluid imbalance.
3. If the root cause (clamp on tubing or any other occlusion) has been removed, the filtrate or substitution pump will automatically compensate for the imbalance and then normal operation of the AQUARIUS system will continue.
4. If the root cause has not been removed, a new balance alarm will occur.
5. If the user clears the balance alarm 5 times without solving its cause, the treatment will be terminated. In this case a new treatment has to be started with new disposables.

The implementation of the TFL management will increase the patient safety and improve the user's attention to resolve the root cause of any balance alarm.

The changes in the software are not limited to the improvement of the balance alarm handling only. Additional changes also include enhanced functionalities (listed in the addendum of this FSCA). Therefore, the new software is supported by a revised Instructions For Use (IFU) that requires the attention of the user.

Baxter Healthcare (exclusive distributor for the AQUARIUS devices) will implement the new software by a FSCA to the affected devices globally. Therefore the Baxter technical service team will contact customers to schedule the

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onsite modification and calibration based on availability of hospital staff as well as devices. The global timeline is 12 months, however, the FCA will be executed as rapidly as possible, and in some countries it will be completed in less than 12 months. Until devices are upgraded with the new 6.02 software, please continue to follow the instructions provided in the Field Safety Notice issued by Edwards Lifesciences on 2009-10-23.

This FSCA (update 2) only pertain to the AQUARIUS devices with citrate option GE-F095-00. The ongoing FCA for GE-F096-00 and GE-F097-00 is not affected by this up-date.

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

Best Regards
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Addendum for Field Safety Corrective Action (Update)
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Main enhanced functionalities of software version 6.02.07 versus version 6.01

1. Total Fluid Loss (TFL) Management.
2. Heater cool down management after STOP of the substitution pumps.
3. The Renal Dose is displayed during CVVH, CVVHD and CVVHDF. For this display the Aquarius provides the possibility of programming the patient weight.
4. If a heparin syringe is installed and the heparin rate is programmed to zero the user is notified with a message: “Syringe pump off”.If an alarm is displayed, the using of the help button leads directly to the error help screen.
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