

CUSTOMER INFORMATION
Addendum to the current Operator's Manuals AK 200 S / AK 200 ULTRA S
FA-2014-006

Month day, year

Dear valued customer,

Gambro would like to ask you to pay attention to the enclosed Addendum to the Operator's Manuals for the AK 200 S and AK 200 ULTRA S rev. 11.xx and earlier.

AFFECTED DEVICES:

AK 200 S / AK 200 ULTRA S

DESCRIPTION OF THE ISSUE:

Gambro has received some complaints related to the technical error FCN 1.39 011, which will stop all the pumps and close the venous clamp. One section in the Operator's Manuals for the AK 200 S and the AK 200 ULTRA S instructs the user to contact technical service and to restart the blood pump to return the extracorporeal blood to the patient. Restarting the blood pump is however not possible, since the venous clamp is closed and the consequence will be a blood loss for the patient.

ACTION TO BE TAKEN:

Please include a copy of this addendum with all AK 200 S and AK 200 ULTRA S Operator's Manuals.

The information in this Addendum will be incorporated into the Operator's Manuals for the AK 200 S and the AK 200 ULTRA S during the next revision.

Please share this Addendum with all users.

Should you have any questions or concerns, please do not hesitate to contact your local Gambro representative.

Sincerely,

Add local contact information