FIELD SAFETY NOTICE

Prismaflex® control unit enabled with PrismaLung™ therapy option

FSCA: FA_LUND 003-2014 (FA-2014-007)

Air in the extracorporeal circuit

Dear Valued Customer,

October, 2014

Gambro has become aware of a problem during priming of the extracorporeal circuit of the Prismaflex® system when used in combination with the PrismaLung™ therapy option.

AFFECTED DEVICES:

Prismaflex® control unit (SW 7.11) used together with the PrismaLung™ Kit disposable (all lot numbers).

DESCRIPTION OF THE ISSUE:

The issue is limited to use of the Prismaflex® system in combination with the PrismaLung™ therapy option. During the final phase of priming air may be released into the circuit through the PrismaLung device™ and can then accumulate in the patient return line prior to patient connection. The accumulated air may be located downstream of the Air Detector in the Prismaflex® control unit.

In case the operator is unable to detect air downstream of the Air Detector an air embolism event may occur. The presence of air may not be easily detectable in all situations.

ADVICE:

Customers are **advised not to use the PrismaLung™ therapy option** until further notice.

CORRECTIVE ACTIONS:

Customers will be notified on the details of the corrective action which is expected to be performed latest by November, 2014.

TRANSMISSION OF THIS FIELD SAFETY NOTICE:

Please share this notice with all interested and affected users at your facility. Please maintain awareness on this notice. Should you have any questions or concerns, please do not hesitate to contact your local Gambro representative.

A copy of this Field Safety Notice has been sent to the German authority BfArM and the French authority ANSM.

Sincerely,

[redacted]

Manager CEM Lund