

Medical Products Agency
Box 26
SE-751 03 Uppsala
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CC: Affected Competent Authorities, Notified body and affected MCC country
representatives worldwide

Your reference
N/A

Our reference
EVU-160619

Solna, 2016-05-25

**Information about a Field Safety Corrective Action regarding SW 8.00.00 of
SERVO-i and SERVO-s ventilator system**

Dear Sirs and Madams,

Maquet Critical Care AB has initiated a Field Safety Corrective Action concerning the
SERVO-i and SERVO-s ventilator system software version 8.00.00

This Field Safety Notice is issued because in the affected SERVO-i and SERVO-s
ventilators with software version 8.00.00 there is a risk that SERVO-i and SERVO-s
deliver a wrong Pressure above PEEP for the Infant patient category if the ventilation is
started with default settings. The error was found at the manufacturers' site and there
are no reported complaints or injuries.

In order to reduce probability of harm, Maquet Critical Care AB will initiate this Field
Safety Corrective Action to inform that the software version 8.00.00 shall be updated to
software version 8.00.01

This Field Safety Corrective Action will also be sent to all Competent Authorities within
EEA, where the affected SERVO-i and SERVO-s ventilator systems with SW 8.00.00
are installed.

If anything is unclear in this information, please feel free to contact me.

Best Regards,

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