

To whom it may concern

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- Perfusor- and Infusomat Space with Prime Function

Dear Ladies and Gentlemen,

today we would like to take the opportunity to inform you about an unexpected behaviour of Perfusor Space, Infusomat Space and Infusomat Space P infusion pumps (software C and D) which might cause some inconvenience during the infusion therapy.

The above mentioned pumps are equipped with a so called Prime function in order to prime the line before the infusion is started. This is a special feature which is initially disabled at the production site and can only be enabled via a special service software upon customer request. In the case that the prime function is enabled the following behaviour might occur:

- While priming the infusion line the pumps are working at the highest occlusion pressure level in order to prevent faulty pressure alarms. After the prime process is finished the occlusion pressure does not automatically fall back to the manual pressure setting but remains at the maximum (level 9) although the display of the pump indicates a lower pressure level. Compared to lower pressure settings this would lead to a longer alarm reaction time in case of a downstream occlusion.

In order to restore the individual pressure setting the pressure menu has to be entered and the pressure level has to be confirmed with the OK-key. Alternatively the device can be switched off and on again. The pump then works again at the manually adjusted level.

We would like to point out that the described flaw is not safety relevant and the maximum specified occlusion pressure levels of the pumps will never be exceeded so that the requirements of the IEC 60601-2-24 are still met.

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Alarm reaction times in case of a system occlusion do not only depend on the set pressure level but also on the infusion rate and the compliance of the total infusion system.

Therefore it is mandatory to use an adequate vital monitoring while infusing life-saving drugs with low half-life times. The user is very likely to be informed faster by the monitoring of the vital signs than by the pressure sensor of a pump.

In the meantime B. Braun has solved the problem with the new software version "E". Pumps with Software C and D can furthermore be used but we would like to recommend to switch off the Prime function or not to handle this feature during operation.

For further information please contact your local B. Braun service partner.

Kind Regards,

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