

Dräger Medical GmbH, 23542 Lübeck

**To our customers and users
of the Infinity® Acute Care System (IACS) Monitoring Solution
using DualHemo Mcable for invasive blood pressure measurement**

November 2012

Important Safety Notice!

**Infinity® Acute Care System (IACS) with DualHemo Mcable:
Possible wrong invasive blood pressure measurements values**

Dear Madam/Sir,

Within our product surveillance activities we were informed about four cases in which the displayed value for the invasive blood pressure measurement of the IACS was lower than the actual patient values were. In one of the cases the user started an incorrect patient therapy because of the indicated too low pressure. No patient injury has been reported in relation to these four complaints.

Investigations on this topic have shown that liquid ingress in the cable connection of the DualHemo Mcable may cause inaccurate measurements. Further investigation revealed that this can happen if the DualHemo MCable is used in a non-vertically position or vertically but top down instead of top up, or if it is simple laid down on the floor or on the patient bed and is not adequately positioned.

The Instructions for Use of the IACS does identify that the DualHemo MCable should be positioned in a vertical orientation, however, it does not describe what is meant by the term vertical. Vertical is intended to mean that the DualHemo should be hung on a pole with the two MCables pointed toward the floor. The DualHemo contains an integrated clip on the single cable that is intended to facilitate proper placement and orientation of the DualHemo Pod.

Attached to this Safety Notice is an amendment for your Instructions for Use describing the correct handling of the DualHemo MCable supported by graphics.

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Please add this amendment to your Instructions for Use, inform your users about this safety notice and inform them about this recommended preventive action.

Further we would like to remind you about the disinfecting and cleaning description given in the current Instructions for Use of the IACS/M540:

- Do not spray cleaning agents on the M540 or the peripheral devices.
- Do not immerse the MCables in water, organic solvents, or cleaning solutions.
- Make sure that no liquid enters the MCables.

We apologize for any inconvenience this action may cause and appreciate your patience and cooperation.

If you have any further questions, please contact your local Dräger representative

With kind regards,

Marita Klafke
President,
SBF Monitoring, Systems & IT

Amendment