

Dräger Medical GmbH, 23542 Lübeck

**To our customers and users
of the Infinity® Acute Care System (IACS) Monitoring Solution
with software versions VG1, VG1.2 and VG1.3**

October 2011

Important Safety Notice!

- **Possible wrong drug dosage calculation recommendation**
- **Possible misalignment of ECG and ART waveforms on Infinity Central Station**

Dear Madam/Sir,

During product training on the Infinity® Acute Care System (IACS), Monitoring System it was discovered that the weight-based drug dosage calculation may deliver incorrect recommendation values. The failure occurs if the patient's body weight is not entered via the admin- / demographics screen, but entered via the drug dosage application screen. In such a case, the patient's weight will be increased by the factor ten, resulting in wrong drug dosage recommendation if the dosage value is used in relation to the body weight. The failure occurs only when entering more than one drug and will apply to the second and all further drug entries until the patient is discharged. This will result in a drug dose that is ten times higher since the flow rate recommended from the weight-based calculation will be ten times higher than intended.

Even if the failure becomes obvious for the user and the weight is corrected in the drug dosage application screen, the displayed drug dosage will not be adjusted based on the corrected weight.

The described behavior will not occur if the patient's weight is correctly entered via the admin- / demographics screen. We therefore strictly recommend when using the drug calculation application to enter the patient's weight in the admin- / demographics screen on the medical cockpit.

Once the patient's weight is added to this field, all drug calculations will automatically populate with the correct weight.

Dräger Medical GmbH
Moislinger Allee 53-55
23558 Lübeck, Deutschland
Postanschrift:
23542 Lübeck, Deutschland
Tel. +49 451 882-0
Fax +49 451 882-2080
info@draeger.com
www.draeger.com
UID-Nr. DE813745277

Bankverbindungen:
Commerzbank AG, Lübeck
Konto-Nr. 014 679 500
BLZ 230 400 22
IBAN DE95 2304 0022 0014 6795 00
SWIFT-Code COBADEFF230

Sparkasse zu Lübeck
Konto-Nr. 1 071 117
BLZ 230 501 01
IBAN DE15 2305 0101 0001 0711 17
SWIFT-Code NOLADE21SPL

Sitz der Gesellschaft: Lübeck
Handelsregister:
Amtsgericht Lübeck HRB 4358 HL

Vorsitzender des Aufsichtsrats:
Stefan Dräger
Geschäftsführer:
Dr. Christian Hauer

Additionally to the issue mentioned above, Dräger has been informed about cases in one hospital in Germany where a misalignment of ECG and ART waveforms delivered from an Infinity® Acute Care System (IACS) Monitoring Solution has been observed on Infinity Central Station. The time discrepancy between the curves observed was in the range of 5-10 seconds. In one case this situation reportedly contributed to a misdiagnosis resulting in a delay in treatment. In this instance a high priority alarm was issued at the bedside and the central station. The alarm was silenced at the central station and the patient was not checked personally.

Investigations on this topic have shown that a misalignment may occur on the network waveform data only. The Local display of waveforms at the bedside is not affected and will appear aligned on the IACS displays (M540 display and Cockpit display). The parameter and alarm information neither at the Infinity Central Station nor at the bedside displays is impacted.

The Instructions for Use of the Infinity CentralStation state: “For primary monitoring and diagnosis of bed- side patients, use the bedside monitor. Use the Infinity CentralStation only for remote assessment of a patient’s status”. Therefore we ask you to follow these instructions and recommend that you do not consider the waveforms on Infinity Central Station for primary diagnosis purposes. In case of a high priority alarm situation, “Check the patient and treat if necessary” as stated in the Instructions for Use of the Infinity® Acute Care System (IACS) Monitoring Solution.

If the misalignment issue is observed, it could be cleared by undocking and redocking of the M540 or by changing the order of waveforms displayed on the Cockpit screen (or any other change to the auto display screen layout).

Please inform your staff members and any users about this safety notice and inform them about the recommended preventive action stated in this Safety Notice.

A software update will be available soon to fix these issues. You will be contacted by a DrägerService representative to update your Infinity® Acute Care System (IACS) Monitoring System.

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



President,
SBF Monitoring, Systems & IT