

Dräger Medical Systems, Inc., Andover, MA 01810 USA

**To our customers and users
of the Infinity® Delta Family which includes Delta, Delta XL and Kappa with
software VF10.0**

Important Safety Notice!

**Infinity® Delta Family which includes Delta, Delta XL and Kappa with SW VF10.0
Various middle and high priority alarms will not go off in combination with
Scio, Scio Four Scio Four Oxi plus, Scio Four Oxi, Scio Four plus**

March 2017

Dear Madam or Sir,

Within our product surveillance activities we were informed about a case in which a Dräger Infinity® Delta monitor running VF10.0 software did not generate a set low O₂ alarm although the O₂ level that was measured by the Dräger Scio gas measurement module was below the adjusted alarm limit. No patient consequences occurred. Our analyses revealed a failure within the VF10.0 software. Earlier software versions are not affected.

Based on the information we have, you are using at least one Infinity® Delta Family monitor, with this software in your facility.

If Delta Family monitors that are running VF10.0 software are combined with a Scio module the following alarms will not be generated (# represents the set alarm limit): iO₂ > #, iO₂ < #, i[agent] > #, i[agent] < #, Inspired MAC High, etN₂O > 82%.

Although the alarms are not generated, the parameter readings are not affected and will be displayed properly.

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If you have Scio modules in your facility do not combine them with Delta Family monitors running VF10.0 software unless you can ensure adequate patient surveillance! A downgrade to software VF9.1 is required as a short term measure. If you have Scio modules, please contact us with the attached Reply & Order card. Your sales and service representative will contact you and carry out the downgrade to VF9.1 free of charge.

Please distribute this Safety Information to all potential users of Infinity® Delta Family monitors with VF10.0 software within your facility.

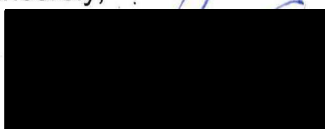
If you don't have any Scio modules no immediate action is required.

Dräger is developing a new software version VF10.1 to fix this issue. Once the VF10.1 software is released, your Dräger sales and service representative will contact you and carry out the update to VF10.1 on your Delta Family monitors that are running VF10.0 software free of charge. Delta Family monitors that were downgraded as a result of this effort can also be upgraded to VF10.1 software.

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

Sincerely,



Steffen Protsch

Draeger Medical Systems, Inc.

Attachment:

- Reply & Order card, 1 page