

A Dräger and Siemens Company

Date: October 16, 2009

To all customers and users of Trident NMT and/or PiCCO SmartPods

## **Important Safety Notice!**

Omega or Omega S package which may include SC7000/SC8000/SC9000XL, Kappa, Delta/Delta XL (Delta Family) and Infinity Explorer, in combination with the Trident NMT and/or PiCCO SmartPod

Dear Madam/Sir:

As part of our world wide post-market surveillance activities, we learned about events involving the use of the above mentioned product combinations.

The reported events involve the rebooting (resetting) of the Delta Family Monitors when used in conjunction with Infinity Explorer and the Trident NMT and/or PiCCO SmartPods. The reboots could occur intermittently or in some cases multiple times depending on the monitor's system configuration. Our investigation determined that the rebooting is due to intensive processing of signal information and messaging with the Trident NMT and/or PiCCO SmartPod parameters, which causes a rise in the CPU usage. In the case of high CPU loading the safety mechanism built into the monitor is to reboot. Monitoring data is unavailable during rebooting. This issue only affects the Delta Family monitors with software version VF6 or higher when used in conjunction with Infinity Explorer and the Trident NMT and/or PiCCO SmartPods.

We are currently working on a software solution that will reduce the processing load by better managing/optimizing the messaging traffic from the Pods to the monitor. When the solution is available it will need to be installed on your Delta Family monitors.

Our records indicate that Trident NMT and/or PiCCO SmartPods were shipped to your facility. When the software solution is available, a DrägerService Representative will contact you to schedule a time to install the software in the Delta Family monitors that are used in combination with Infinity Explorer and the Trident NMT and/or PiCCO SmartPods. The software will be provided free of charge.

Until the software solution is implemented, your Trident NMT and/or PiCCO SmartPods may continue to be used in conjunction with the above mentioned product combinations. We suggest that you take the following precautionary measures:

- Inform all users within your organization of the potential issues with the monitoring combinations listed above.
- If you observe sluggishness in use of menus with Trident NMT and/or PiCCO SmartPods or multiple rebooting, disconnect the pods. Manually restarting the monitor may be necessary to resume proper operation.

The corresponding competent authority has been informed about this action.

Dräger is committed to customer satisfaction. We apologize for any inconvenience this action may cause and appreciate your patience and cooperation.

If you should have any guestions or comments, please contact your local Dräger Representative.

Draeger Medical Systems, Inc