

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

To our customers and users of the:

- Dual Hemo MCable pod used with the Infinity Acute Care System (IACS) Monitoring Solution.

Important Safety Notice!

Potential incorrect measurement of invasive blood pressure due to possible liquid ingress. The device may not perform to the claimed IPX4 rating.

September 2017

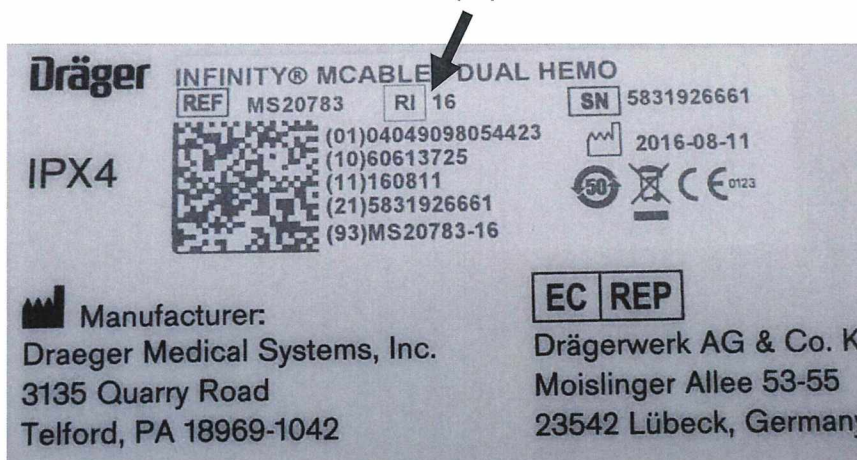
Dear Madam or Sir:

Dräger has determined through internal testing that Dual Hemo MCable Pods with Revision Index (RI) 15 and 16, which are used with the Dräger Infinity Acute Care System, may permit liquid ingress inconsistent with their IPX4 rating, which could potentially result in an incorrect measured value of invasive blood pressure. Dräger has not received any complaints and is not aware of any negative patient consequences arising from this issue. Revisions prior to RI 15, with proper orientation will still maintain its designated IPX1 rating and are not within the scope of this safety notice. In addition, revisions labelled RI 17 and greater are not affected by this notice because these revisions continue to meet the IPX4 standard.

Based on our information, your facility is using at least one Dual Hemo MCable Pod that is affected by this notice.

Please check your Dual Hemo MCable Pods to identify whether they have the affected Revision Indexes (RI) 15 or 16.

The Revision Index is located on the rear side of the Dual Hemo MCable Pod. An example of where to find the Revision Index (RI) is shown below.



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

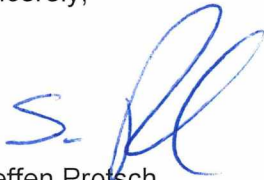
If you have affected Dual Hemo MCable Pods please contact us with the attached Reply & Order card to receive a sleeve that can be applied to protect against liquid ingress. See attachment for required upright orientation of the Dual Hemo MCable Pod and installation instructions for the sleeve.

Please distribute this Safety Information to all potential users within your facility.

We regret any inconvenience this may cause. We consider it a necessary preventive measure to increase patient and user safety.

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

Sincerely,



Steffen Protsch

Draeger Medical Systems, Inc.

2 Attachments:

- Reply and Order Card, 1 Page
- Dual Hemo MCable Pod Upright orientation and sleeve installation instructions, 1 Page