

To our customers and users of the:

- **Standalone Infinity® M540 patient monitor**

Notification

The standalone Infinity M540 patient monitor is no longer indicated for use in ambulance settings.

March 2020

Dear Madam or Sir,

Please be advised that as of January 2017, Dräger has removed its claim that the M540 patient monitor can be used in the EMS environment.

This action was taken upon an adoption of a standard IEC 60601-1-12, *Requirements for Emergency Medical Equipment*. This standard classifies equipment intended for use in ambulance environment as Class B (residential facilities) with regards to radiated emissions. The M540 Patient Monitor was designed to meet the requirements of standard EN1789:2007: A2 2014, *Medical Vehicles and their Equipment*, which classifies the patient monitor as Class A (Commercial/hospital facilities) with regards to the radiated emissions. The hardware of our patient monitor is by a small margin not meeting the reduced limits for radiated emissions specified by the IEC 60601-1-12 standard. Therefore, upon the adoption of the standard, Dräger removed the claim from the applicable manuals and ceased to market the product for use in EMS environment.

High radiated emissions may affect performance of other devices utilized in the proximity of the equipment. To date, Dräger has not received any reports that the M540 patient monitor affected other devices when used in the EMS environment.

The patient monitors utilized by your facility were placed in use prior to the release of the IEC 60601-1-12 standard and met the regulatory requirements for radiated emission effective at the time of manufacture.

The radiated emissions are unrelated to the software version of the product and your products may be safely updated to any currently released version.

Please distribute this notification to all potential users and administrators within your facility.

We regret any inconvenience this may cause. If you have any further questions, please contact your local Dräger representative.

Thank you for your continued support.

Sincerely,



Lloyd Stern

Vice President of Product Management
Dräger Patient Monitoring Systems