

Rueil-malmaison December 03, 2019,

NOTICE

Reminder of field safety corrective action (Valencia, January 31, 2018)

TO THE ATTENTION OF OPERATORS AND USERS OF WINNMOTION 150 AND 175 HOISTS.

Subject : Pre-operational inspection of the condition of arm's central suspension point

WINNMOTION 175 : From serial No. 170355 and batch No. 001 ; Ref. L0900, L090001, L090033, L0900-UK

WINNMOTION 150 : From serial No. 170380 and batch No. 001 ; Ref. 120102040, 120102040

Please note that **good operating condition** of the hoist **should be verified before making it available** to the users.

Four cases were reported during the period 2017 to 2019, where the hoist's lifting arm came off the central suspension point, situated at the top end of the lifting column, causing the patient/resident to fall, without incurring serious medical consequences. The incident was due to an **incorrectly positioned pin**.

We have since focused our attention on our assembly process, quality control, user information and training, ensuring due attention is given to this issue.

We recommend to all our operators and users the equipment manufactured since June 17, 2016, to **inspect the central suspension point before use**, as well as to carry out periodic inspections, at least once every year (refer to ISO 10535, APPENDIX B) as set out in the section entitled "ANNUAL INSPECTION OF HOISTS", situated on pages 19 to 24 of the operating manual.

We thank you for your trust in our products and ask you to undertake all necessary measures to control the risks associated with the use of this medical device.

The ANSM [French National Agency for Medicines and Health Products Safety] has been notified of the content of the present notice.

Please contact Pascal TURCOT, export manager, for any information +(33)6 15 46 92 76

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Advice : read the instructions provided with the medical device. Available in digital version on our website www.winnocare.fr