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DATE: **April 15th, 2022**
FSCA Ref: **FARS-006**

Urgent Field Safety Notice (FSN)
ook snow ALL

For Attention of:
Clinical Managers, Biomedical Managers, and Maintenance Managers.

Contact details of local representative
[redacted]

Urgent Field Safety Notice (FSN)
ook snow ALL
Risk of Collision due to Uninterrupted Motion of the Motorized Wheel System

	1. **Information on Affected Devices***
1.	1. Device Type(s)*
	Powered medical bed with a powered drive system (the “Motorized Wheel System”) bearing the option number OL2000200WG. 
1.	2. Commercial name(s)
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1.	3. Unique Device Identifier(s) (UDI-DI)
	N/A
1.	4. Primary clinical purpose of device(s)*
	The medical bed model 200-0000 is intended for medical purposes as a patient bed for rest/sleep as well as for alleviation of, or compensation for, an injury, a handicap or the patient condition.
	5. Device Model/Catalogue/part number(s)*

1.	200-0000
1.	6. Software version
	N/A
1.	7. Affected serial or lot number range
	20004202; 20004203; 20004479; 20004480; 20004718; 20004719; 20004720; 20004721
1.	8. Associated devices
	N/A

	2 Reason for Field Safety Corrective Action (FSCA)*
2.	1. Description of the product problem*
	There is a potential hazard of uninterrupted motion of the Motorized Wheel System due to the possible failure of a component in the electrical system of the Product. If this happens, the Motorized Wheel System may fail to decrease speed and stop when the trigger is released.
2.	2. Hazard giving rise to the FSCA*
	A failure could potentially result in the Product colliding with a physical object while transporting an in-bed patient or potentially result in an impact with a nearby person. No related injury was reported. Hypothetical situations could result in adverse consequences.
2.	3. Probability of problem arising
	A risk assessment has concluded that the probability of occurrence is “remote”.
2.	4. Predicted risk to patient/users
	A failure could potentially result in the Product colliding with a physical object while transporting an in-bed patient or potentially result in an impact with a nearby person. No related injury was reported. Hypothetical situations could result in adverse consequences.
2.	5. Further information to help characterise the problem
	The units of Product manufactured between July 5th, 2021, and February 17th, 2022, inclusively, bearing the option number OL2000200WG, were assembled with a Motorized Wheel System option and are the subject of this recall by way of onsite correction. The manufacturing date and serial number of each unit is found on the manufacturer’s label located at the external head end of the device.
2.	6. Background on Issue
	No related injury was reported.
2.	7. Other information relevant to FSCA
	N/A

	3. Type of Action to mitigate the risk*

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3.	1. **Action To Be Taken by the User*** ☒ Identify Device ☐ Quarantine Device ☐ Return Device ☐ Destroy Device ☒ On-site device modification/inspection ☐ Follow patient management recommendations ☐ Take note of amendment/reinforcement of Instructions For Use (IFU) ☒ Other ☐ None OTHER: Temporarily avoid using the Motorized Wheel System functionality of the Product. All other functionalities of the Product can be safely used, including for patient support and patient transfers.A representative of [redacted] will contact your site to coordinate the software correction. The corrective measure will take approximately 15 minutes per unit to perform. The bed can remain in the patient room during such time.	
3.	2. By when should the action be completed?	June 10, 2022
3.	3. Is follow-up of patients or review of patients' previous results recommended? No, not applicable.	
3.	4. Is customer Reply Required? *	Yes
3.	5. **Action Being Taken by the Manufacturer** ☐ Product Removal ☒ On-site device modification/inspection ☒ Software upgrade ☐ IFU or labelling change ☐ Other ☐ None Update package to be send by the Manufacturer to the Distributor. Appointment will be taken for onsite modification. The corrective measure will take approximately 15 minutes per unit to perform. The bed can remain in the patient room during such time.	

3	6. By when should the action be completed?	June 10, 2022
3.	7. Is the FSN required to be communicated to the patient /lay user?	No.

	4. General Information*	
4.	1. FSN Type*	New
4.	2. Further advice or information already expected in follow-up FSN? *	No
4.	3. Manufacturer information (For contact details of local representative refer to [redacted]SN)	
	a. Company Name	Umano Medical Inc.
	b. Address	230 boulevard Nilus-Leclerc, L'Islet (QC) G0R 2C0 CANADA
	c. Website address	www.umanomedical.com
4.	4. The Competent (Regulatory) Authority of your country has been informed about this communication to customers. * YES.	
4.	5. List of attachments/appendices:	**Customer Reply Form, Distributor Reply Form**
4.	6. Name/Signature	**Benoit Leclerc** 

	Transmission of this Field Safety Notice
	This notice needs to be passed on all those who need to be aware within your organisation or to any organisation where the potentially affected devices have been transferred. (As appropriate)

	Please transfer this notice to other organisations on which this action has an impact. (As appropriate) Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action. Please report all device-related incidents to the manufacturer, distributor or local representative, and the national Competent Authority if appropriate, as this provides important feedback.*

Note: Fields indicated by * are considered necessary for all FSNs. Others are optional.

[redacted]