Rev 1: January 2025

FSN Ref: FSN 76-17173
FSCA Ref: FSCA 76-17173 MHRA Ref: 2025/012/011/601/066

Date 12 Jan 2026

Field Safety Notice
Mangar Archimedes Bath Lift

For Attention of: Users, health care professionals & care givers

Contact details of local representative (name, e-mail, telephone, address etc.)
Sarah Geddes Quality & Regulatory Manager Sarah.geddes@winncare.uk 01544 267 674 Presteigne Industrial Estate, Powys, Wales LD8 2UF

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Field Safety Notice (FSN)
Device Commercial Name
Mangar Archimedes Bath Lift

	1. Information on Affected Devices
1.	1. Device Type
	 Mangar Archimedes bath lift is a lightweight actuator driven bath lift
1.	2. Commercial name(s)
	Mangar Archimedes Bath Lift
1.	3. Primary clinical purpose of device
	The Archimedes is intended solely for use as a bathing aid to assist a person to lower themselves into and out of a bath. The Archimedes is not intended for any other use and should never be used outside of a bath. When properly maintained, the Archimedes will give many years of trouble-free service.
1.	4. Device Model/Catalogue/part numbers
	LAA3702A, LAA3703A

	2. Reason for Field Safety Corrective Action (FSCA)
2.	1. Description of the product problem
	The Mangar Archimedes is a lightweight battery powered actuator driven bath lift. Following a complaint report of a user being stuck in the bath, it has come to our attention that there is a rare possibility that a lone user of the device may incur serious injuries if they get stuck for an excessive amount of time. The risk of the device being unable to raise the user out of the bath may occur due to poor device battery maintenance. The device battery capacity can be affected by use and storage conditions, the device is designed for constant use and if left uncharged for periods of time can affect battery performance. The battery is not replaceable, when the battery fails to retain charge indicated by a frequent red light on the battery indicator the hand control should be replaced. It is not possible to identify a time period for exactly when the hand control will reach the end of its usable life as this will differ with how each device is used and maintained.

2.	2. Hazard giving rise to the FSCA
	Use of the hand control once its battery has deteriorated significantly. Deterioration of the hand control battery may occur from poor storage & battery care or maintenance, excessive usage and ageing. Deterioration can be seen by the device inability to accept and retain charge. There is a low residual risk of using the device that is required to be brought to the attention of users: the FSCA has been raised to remind users of the need to replace the hand control, indicated by the batteries failure to accept or retain charge (frequently showing red on the battery state indicator), and warn users that assistance should always be on hand either within ear shot or by an accessible communication device whilst the Archimedes is in use. The Device IFU has been updated to include the following warning: The independence that the bath lift provides does not negate the need to ensure that adequate assistance is on hand in case it is required. A telephone or other means of communication should be taken into the bathroom when bathing without assistance. As with all mechanical and electrical devices, unforeseen breakdowns can occur and so whilst in the unlikely event that there is a malfunction of the bath lift, a method of summoning adequate assistance must be available.

	3. Type of Action to mitigate the risk*
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 Provide further details of the action(s) identified. Action to be taken by the user: We would like to remind users of the need to replace the hand control, indicated by the batteries failure to accept or retain charge, -frequently showing red on the battery state indicator. We recommend checking your hand control and contacting our customer service team if a replacement is needed. We also like to take this opportunity to reinforce the information with in the IFU. With regards to the battery maintenance. The device is designed for constant use and if left uncharged for periods of time can affect battery performance. Action to be taken by the distributor: Request that devices in stock should be issued with the updated IFU provided by Winncare. Additionally, it is available on our website. Our updated IFU: MI0173 Issue 21 Archimedes - User Instructions is available to download here: https://www.winncare.uk/products/mangar-archimedes-bath-lift/

3.	2. Is customer Reply Required?	Yes
3.	**3. Action Being Taken by the Manufacturer** ☐ Product Removal ☐ On-site device modification/inspection ☐ Software upgrade ☒ IFU or labelling change ☐ Other ☐ None Provide further details of the action(s) identified.	
3	4. By when should the action be completed?	As soon as possible
3.	5. Is the FSN required to be communicated to the patient /lay user?	Yes
3	6. If yes, has manufacturer provided additional information suitable for the patient/lay user in a patient/lay or non-professional user information letter/sheet?	
	Yes Appended to this FSN	

	4. General Information*	
4.	1. FSN Type	New
4.	2. Further advice or information already expected in follow-up FSN?	No
4	3. Anticipated timescale for follow-up FSN	For provision of updated advice.
4.	4. The Regulatory Authority of your country has been informed about this communication to customers.	

	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.

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Customer Reply Form

1. Field Safety Notice (FSN) information	
FSN Reference number*	FSCA 76-17173
FSN Date*	12 Jan 2026
Product/ Device name*	Mangar Archimedes bath lift
Batch/Serial Number (s)	1 2 3

2. Customer Details	
Account Number	
Healthcare Organisation Name*	
Organisation Address*	
Contact Name*	
Title or Function	
Telephone number*	
Email*	

3. Customer action undertaken on behalf of Healthcare Organisation		
☐	I confirm receipt of the Field Safety Notice and that I read and understood its content.	
☐	I performed all actions requested by the FSN.	
☐	The information and required actions have been brought to the attention of all relevant users and executed.	
☐	I do not have any affected devices.	*Customer to complete or enter N/A*
☐	I have a query please contact me (e.g. need for replacement of the product).	*Customer to enter contact details if different from above and brief description of query*
Print Name*		
Signature*		
Date*		

4. Return acknowledgement to sender	
Email	Sarah.geddes@winncare.uk
Customer Helpline	01544 267 674
Deadline for returning the customer reply form*	31 Jan 2026

It is important that your organisation takes the actions detailed in the FSN and confirms that you have received the FSN.

Your organisation's reply is the evidence we need to monitor the progress of the corrective actions.