

Rev 1: 4th June 2024

FSN Ref: FSN-01-2024


FSCA Ref: FSCA-01-2024

Date: 4:June:2024

Urgent Field Safety Notice

Moozi

For attention of: All persons connected with the use, supply, and maintenance of Moozi Switched Joystick.

Please distribute this notice to all relevant persons connected with the use, supply, and maintenance of Moozi Switched Joystick.

Contact details

MERU

Email: info@meru.org.uk
Telephone: +44 (0) 1372 725 203
Address: Metcalfe Avenue Carshalton SM5 4AW
Web: <https://www.merushop.org/>
Availability: Monday - Friday

Urgent Field Safety Notice (FSN)

Moozi

Dear User, parent, carer,

We would like to inform you about a Field Safety notice (FSN) affecting Moozi units. Moozi is a switched joystick (fig. 1.), which is intended for use on indoor powered wheelchair or other switch activated equipment. The top cover maybe blue, green, red, or black. There will be further identification stickers on the underside of the Device. With a MERU logo and a serial number starting with the letter 'P'.

This FSN applies to all Moozi units, although not every Moozi unit may be impacted.



Figure 1: Moozi

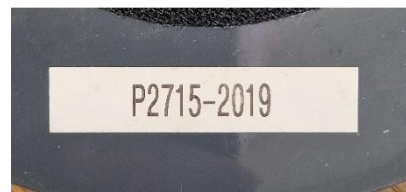


Figure 2: Serial number stickers

Actions To Be Taken by the User

Our records have shown that you have a Moozi. We kindly ask you to initiate the following activities with priority.

- Please review this Field Safety Notice in its entirety and ensure that all persons connected with the use of the above-mentioned product in your home or organization and other concerned persons are informed about this Field Safety Notice.
- **Read the updated user guide before further use.**
- Optional - If you would like a physical manual, please fill in the form attached.

User Guide - <https://www.merushop.org/PDF/UG-002-2024-B-Moozi>

Reason For Field Safety Corrective Action

Moozi – Components might not sufficiently meet the requirements for water resistance.

Potential Risks To Health

Moozi - potential patient risk ranging up to serious injury or risk to life.

Probability Of Problem Arising

The non-compliance with current water-resistant standard was identified during laboratory testing. We are unaware of any in-field incidences of effects from water damage and are therefore unable to accurately estimate the probability of risk associated with this occurrence.

Background

Moozi has been tested by TÜV SÜD, an accredited testing laboratory, to EN 12184:2022 which is the current safety standard for electrically powered wheelchairs, scooters, and their chargers. This testing has helped us to identify the aforementioned issue and produce a plan for corrective action.

Corrective Actions To Be Taken By MERU

We have updated the Moozi user guide to reflect best practices in case you get your moozi wet. There is a link available below and an extract from the guide.

User Guide - <https://www.merushop.org/PDF/UG-002-2024-B-Moozi>

Warning!

Do not use expose Moozi to water, rain, drinks, or other liquids. Doing so can cause uncontrolled movement.

In the event of exposure to a liquid. Switch off your device immediately and disconnect the Moozi.

Dry Moozi as thoroughly as possible with a towel. Leave Moozi in a dry space, such as an airing cupboard or similar for several days. This will allow unseen moisture to evaporate. Perform a function test before continued use.

Function Test

To be performed by an adult without a user in or near the powered wheelchair or switch activated device.

- Connect the Moozi to the device and turn on the system.
- Observe any error message that might be on the screen.
- Test on the moozi forward, backwards, left and right.
- Test on the moozi diagonally top left, top right, bottom left, bottom right.

If there are any issues, please contact MERU.



This notice needs to be shared with all those who need to be aware within your organisation or to any organisation where the potentially affected devices have been transferred.

Please transfer this notice to other organisations on which this action has an impact. (As appropriate).

Please maintain awareness of 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.

The Competent Authority MHRA has received a copy of this safety information.

We believe in improving people's health through everything we do. Patient and user safety is our highest priority. Kindly accept our apologies for any inconveniences caused and thank you in advance for your cooperation to resolve this matter quickly.

Signature

Gary Thomas

Gary Thomas
Director of Commercial

Optional
Field Safety Corrective Action Form
Moozi

1. Field Safety Notice (FSN) information					
FSN number	<i>FSN-01-2024</i>	FSN Date	<i>4th June 2024</i>	Device name	<i>Moozi</i>

2. Customer Details	
Healthcare Organisation Name	
Address*	
Department/Unit	
Contact Name*	
Title or Function	
Telephone number*	
Email*	

3. Customer action undertaken			
<input type="checkbox"/>	I would like physical manual	Quantity:	
		address: (if different from above)	
<input type="checkbox"/>	Other Action (Define):	Customer to complete or enter N/A	
<input type="checkbox"/>	I have a query please contact me.	Customer to enter brief description of query	
Print Name*	Customer print name here	Date*	
Signature*	Customer sign here		

4. Return acknowledgement to sender	
Email	info@meru.org.uk
Customer Helpline	+44 (0) 1372 725 203
Postal Address	Metcalfe Avenue Carshalton SM5 4AW