

Rev 1: 12<sup>st</sup> December 2023

FSN Ref: FSN-01-2023

  
FSCA Ref: FSCA-01-2023

Date: 18:Dec:2023

## **Urgent Field Safety Notice**

### **Bugzi**

**For attention of:** All persons connected with the use, supply, and maintenance of Bugzi powered wheelchairs.

#### **Contact detail**

##### **MERU**

Email: Bugzi@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)

### Bugzi

Dear User, parent, carer,

We would like to inform you about a Field Safety notice (FSN) affecting occupant safety on all Bugzi units. Bugzi is a small, green powered wheelchair (fig. 1), which is intended for use by children typically between the ages of 2-7 years. Bugzi is an indoor powered wheelchair which is intended for use in the home and school environments to facilitate mobility.

Bugzis within the following serial number range are potentially affected:

Serial numbers E30001 to E30294 inclusive.

The serial number of the Bugzi is shown on the small round plate located on the rear of the Bugzi, to the left of the battery unit, as shown in fig. 2.



Figure 1: Bugzi - Childrens powered wheelchair



Figure 2: Serial number plate

### **Actions To Be Taken by the User**

Our records have shown that you have a Bugzi. 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.
- **Stop using Bugzi** – the combinations of technical and safety related issues mean that it is safest to stop using Bugzi. Please disconnect the battery and take it off charge.
- Help facilitate MERU to inspect and modify Bugzi.

MERU will contact you shortly to discuss the completion of the acknowledgement form and discuss the immediate next steps.

## Reason For Field Safety Corrective Action

MERU has identified a series of areas where Bugzi and Bugzi accessories do not conform to the relevant standards. Information regarding this process can be seen in the background section.

**Active Design MiniCAPS seating** – The chest harness (fig. 3.) and grey mesh (shown in fig. 4.) might not meet the current safety standards for flame resistance. All seats have this harness, however only some seats supplied with the Bugzi will have the grey mesh.



Figure 3: MiniCAPS Harness



Figure 4: MiniCAPS grey sports mesh

**Battery unit** – Components of the battery unit might not meet current safety standards for flame resistance, water resistance, colour coding and labelling.



Figure 5: Battery Unit OMNI 1



Figure 6: Battery Unit OMNI 2

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



Figure 7: Moozi

**Charger** – The chargers do not meet the requirements for water resistance.



Figure 8: Numax Charger Black 2/4amp



Figure 9: Numax Charger Red 2/4amp

**Fuse** – Current fuse amp rating allows for the use of more higher amperage chargers, which can degrade the batteries.



Figure 10: Battery Unit fuse holder (top black circle)

## Potential Risks To Health

To help understand the language we are using. A patient would be the person in the Bugzi. The user would be the adult, carer, healthcare facility worker.

Overall, these result in a potential patient risk ranging from no clinical relevance up to serious injury or risk to life. As well as a potential user risk ranging from no clinical relevance up to serious injury. .

**Active Design MiniCAPS seats** – If the harness or grey seat cover is exposed to a source of ignition, there is a possibility that the harness or seat cover may ignite, causing burns to the user/patient and others. This presents the potential risk to the user and others of serious injury or risk to life. Potential patient risk ranging up to serious injury or risk to life, and a potential user risk ranging up to serious injury.

**Battery unit** – If the battery unit is exposed to a source of ignition, there is a possibility that the protective component may ignite. This could cause burns to the user/patient and others. This presents a potential risk to the user and others of serious injury or risk to life. potential patient risk ranging up to serious injury or risk to life, and a potential user risk ranging up to serious injury.

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

**Charger** - If the charger comes into contact with water, there is a possibility that it may not operate correctly. potential user risk ranging up to serious injury.

**Fuse** - If a charger other than the one supplied with the Bugzi is used to charge the batteries, this may result in the incorrect level of power being supplied to the batteries. If the level of power is greater than that which is intended, this may result in the batteries becoming deformed and/or overheating. The rating of the fuse in the Bugzi is too low to prevent this situation occurring. There is a potential risk of minor burns to anyone who comes into contact with the batteries in this circumstance. potential patient risk ranging up to serious injury or risk to life, and a potential user risk ranging up to serious injury.

## Probability Of Problem Arising

### Active Design MiniCAPS seat

The non-compliance with current flammability standards was identified during laboratory testing. We are unaware of any in-field incidences of ignition of the harness or grey mesh cover and are therefore unable to accurately estimate the probability of risk associated with this occurrence.

### Battery Unit

The non-compliance with current flammability and water-resistant standards was identified during laboratory testing. We are unaware of any in-field incidences of ignition of the battery unit and are therefore unable to accurately estimate the probability of risk associated with this occurrence.

### Moozi

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.

### Charger

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

### Fuse

We are aware of 1 incidence where an 8 Amp charger, instead of the 2 or 4 Amp chargers supplied with the Bugzi, was used in a care setting to charge the batteries over a period of months. This resulted in an incident where the batteries deformed and overheated. No harm was reported as a result of this incident. We estimate that the probability of a similar incident occurring in an environment of use where other wheelchair chargers are available is likely to be probable.

## Background

Bugzi 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 issues and produce a plan for corrective action so that we can be confident that any future Bugzis we upgrade or produce will meet the latest safety standards.

**Active Design MiniCAPS seats** – We submitted 2 different samples from different batches of the MiniCAPS seat for testing. The grey mesh on one of the samples failed the flammability test. The harness on both samples failed the flammability test. We have notified Active Design Ltd, the manufacturer of these seats, of these results. As Active Design are unable to supply information about which seat batches are affected, we have taken the decision to issue this FSN for all Bugzi units.

**Fuse** – During our investigation of the incident where the Bugzi batteries overheated we identified that the fuse rating was too high to prevent a similar situation occurring if a charger with a rating higher than 4Amps was used to charge the batteries. This affects all Bugzi units.

## **Corrective Actions To Be Taken By MERU**

We will arrange for collection of all Bugzi battery units, and Active Design seat harnesses from your home or care/education facility. We will replace the affected parts on the battery unit. We will replace the harness with a similar product that meets the required flammability standard.

If you identify that the Active Design seat covers on your MiniCAPS seat feature the grey mesh material, we ask that you remove the affected covers and return them to us at the same time as the harness and battery unit.

We will update our quality management system to reflect these actions.

Unfortunately, we are unable to confirm when we will be able to return the replacement parts to you. If you would prefer to return the whole Bugzi unit to us, please indicate this on the attached form.

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

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*Gary Thomas*

Gary Thomas  
Director of Commercial

## Field Safety Corrective Action Acknowledgement Form

### Bugzi

<b>1. Field Safety Notice (FSN) information</b>	
FSN Reference number*	FSN-01-2023
FSN Date*	18th December 2023
Product/ Device name*	Bugzi
Serial Number (s)	1 2 3 4 5 6

<b>2. Customer Details</b>	
Healthcare Organisation Name	
Address*	
Department/Unit	
Shipping address if different to above	
Contact Name*	
Title or Function	
Telephone number*	
Email*	

<b>3. Customer action undertaken</b>		
<input type="checkbox"/>	I confirm receipt of the Field Safety Notice and that I read and understood its content.	Customer to complete or enter N/A
<input type="checkbox"/>	I performed all actions requested by the FSN.	Customer to complete or enter N/A
<input type="checkbox"/>	The information and required actions have been brought to the attention of all relevant users and executed.	Customer to complete or enter N/A

<input type="checkbox"/>	I will return affected devices and <b>want it returned after the corrective actions</b> - enter Serial Number (s) of devices to returned, and collection address.	Serial Number (s):  Collection address: (if different from above)
<input type="checkbox"/>	I will return affected devices and <b>do not want it back after the corrective actions</b> - enter Serial Number (s) of devices to returned, and collection address.	Serial Number (s):  Collection address: (if different from above)
<input type="checkbox"/>	I <b>own</b> affected devices and have destroyed affected devices – enter Serial Number (s) of devices destroyed and date complete.	Serial Number (s):  Date:
<input type="checkbox"/>	Other Action (Define):	Customer to complete or enter N/A
<input type="checkbox"/>	I do not have any affected devices.	Customer to complete or enter N/A
<input type="checkbox"/>	I have a query please contact me .	Customer to enter contact details if different from above and brief description of query
Print Name*		Customer print name here
Signature*		Customer sign here
Date*		

<b>4. Return acknowledgement to sender</b>	
Email	Bugzi@meru.org.uk
Customer Helpline	+44 (0) 1372 725 203
Postal Address	Metcalfe Avenue Carshalton SM5 4AW
Web Portal	<a href="http://www.merushop.org.uk/BugziFSNDec2023">www.merushop.org.uk/BugziFSNDec2023</a>
Deadline for returning the customer reply form*	22/01/2024