

Eurovema AB  
Baldersvägen 38  
S-332 35 GISLAVED  
Sweden

**URGENT FIELD SAFETY NOTICE**

**REFERENCE EUR/FSN/2010**



ITO by Alvema

**POTENTIAL FRAME FAILURES - FRAME TO BE REPLACED,  
ALVEMA ITO PUSHCHAIR**

The ITO is a pushchair designed for children with moderate disabilities that do not require a large degree of postural support. The ITO can be identified by labels on either side of the seat unit at the pivot points. Further information can be found on the Eurovema website – [www.eurovema.se](http://www.eurovema.se)

**Description of problem:**

The rear vertical support tubes that the wheels are attached to have a weak point at the brake attachment pivot point. Frequent use of the foot-brake over an extended period of time causes an elongation of the holes drilled in the vertical tubes. This causes the vertical tubes to fracture and in some instances snap at the brake attachment point (below the transport fixing brackets). We have also had 2 instances of the front frame holding the castor assembly snapping at the castor wheel connection point.

**Action to be taken:**

We recommend that you stop using the ITO for vehicle transportation purposes with immediate effect. Eurovema, the manufacturer, will replace all units that have the potential to fail. New ITOs with reinforced frames will be available from the end of March 2010. Please contact Rehabilitation Manufacturing Services on 01634 578881 information relating to the chair replacement programme.

Please note that you can also contact Rainbow Mobility on 0151 353 1234 for information relating to this matter.

**Details of affected devices:**

ITO small with serial number within 104769 – 105306 with brake as shown in picture below

ITO large with serial number within 104009 – 106786 with brake as shown in picture Below.

Serial numbers can be found underneath the seat base plate.



**Transmission of this Field Safety Notice:**

This notice should be passed onto anyone within your organisation who needs to be aware and to any other organisation/institution where the potentially affected buggy may have been transferred. This information needs to be passed onto the buggy user and anybody involved with the care of the buggy user, including family members and healthcare professionals. To ensure this information is passed on effectively, please complete the attached response form and return it to RMS Limited, Medway House, 277 Gillingham Road, Gillingham, Kent ME7 4QZ – [sales@rms-kent.co.uk](mailto:sales@rms-kent.co.uk)

This FSN will be made available on the following websites MHRA website [www.mhra.gov.uk](http://www.mhra.gov.uk)

Eurovema website – [www.eurovema.se](http://www.eurovema.se)

Rainbow Mobility website - [www.rainbowmobility.com](http://www.rainbowmobility.com) and RMS Limited website – [www.inedawheelchair.co.uk](http://www.inedawheelchair.co.uk)

The undersigned confirms that this information has been passed on to the appropriate regulatory agencies.

Brian Young, Managing Director, Rainbow Mobility.



Medway House,  
277 Gillingham Road, Gillingham, Kent, ME7 4QX  
Tel: 01634 578881 Fax: 01634 581456  
Email: [sales@rms-kent.co.uk](mailto:sales@rms-kent.co.uk) Website: [www.ineedawheelchair.co.uk](http://www.ineedawheelchair.co.uk)

March 2010

«Title»  
«Company»  
«Address1»  
«Address2»  
«Address3»  
«Address4» «PostalCode»

Dear Sir/Madam

**ITO Buggy Field Safety Notice (FSN)**

We have been informed by Eurovema about a frame modification to the ITO buggy. This design change gives increased frame strength and improved reliability.

Eurovema, the manufacturer of the ITO buggy, and RMS the supplier, need to supply complete buggy frames free of charge as part of the FSN issued by the MHRA, a copy of which is enclosed. Please acknowledge receipt of the FSN by returning the enclosed form to RMS.

Our records show that we have provided you with ITO buggy serial number \_\_\_\_\_ but we are unsure whether it is still in use by you. At the time of supply, we were informed of the client name \_\_\_\_\_. If the buggy is still in use, please contact us by telephone or email and we will arrange to send the replacement unit to your Approved Repairer for exchange; we will need the name and address of your Approved Repairer. If the ITO buggy is no longer in use in your district, would you kindly let us know whether the buggy has been scrapped or the client has moved away from your district so that our records can be updated.

I look forward to hearing from you.

Yours faithfully

A handwritten signature in black ink, appearing to read 'Alan Wombell', written in a cursive style.

**ALAN WOMBELL**  
**Director**

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Medway House,  
277 Gillingham Road, Gillingham, Kent, ME7 4QX  
Tel: 01634 578881 Fax: 01634 581456  
Email: [sales@rms-kent.co.uk](mailto:sales@rms-kent.co.uk) Website: [www.ineedawheelchair.co.uk](http://www.ineedawheelchair.co.uk)

**FSN Receipt Form**

**Urgent Field Safety Notice**

**Re: Eurovema ITO buggy potential frame failure information update**

Date: March 2010

Dear Customer

To ensure you have received this Field Safety Notice (FSN) attached, we request that you sign this form and fax it back to Rehabilitation Manufacturing Services Ltd on 01634 581456.

Confirmation of receipt:

Organisation:.....

WCS representative .....

Position .....

Telephone .....

Date .....

ITO serial number .....