

Date: 2022:03:30

**Field Safety Notice**  
**Euroflex**

For Attention of\*: All customers of the Euroflex 24V

Contact details of local representative (name, e-mail, telephone, address etc.)*
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<b>SWEDEN</b>

**Field Safety Notice (FSN)**  
**Euroflex**  
**Short Circuit 24V**

<b>1. Information on Affected Devices*</b>	
1.	<b>1. Device Type(s)*</b> Work chair with 24V electronics.
1.	<b>2. Commercial name(s)*</b> Euroflex
1.	<b>3. Unique Device Identifier(s) (UDI-DI)</b> 7332216000025S
1.	<b>4. Primary clinical purpose of device(s)*</b> Work chair with electric functions used to lift/tilt the user.
1.	<b>5. Device Model/Catalogue/part number(s)*</b> Euroflex 24V
1.	<b>6. Software version</b>
1.	<b>7. Affected serial or lot number range</b> All 24V electronics.
1.	<b>8. Associated devices</b>

<b>2. Reason for Field Safety Corrective Action (FSCA)*</b>	
2.	<b>1. Description of the product problem*</b> 24V electrics are missing a fuse.
2.	<b>2. Hazard giving rise to the FSCA*</b> Without a fuse there is a risk for a short circuit to occur.
2.	<b>3. Probability of problem arising</b>
2.	<b>4. Predicted risk to patient/users</b> In worst case scenario a fire could occur in the electronics.
2.	<b>5. Further information to help characterise the problem</b>
2.	<b>6. Background on Issue</b> A user had a work chair stop working. Technician on site could tell that there had been a short circuit in the electronic box. All 24V will have to be upgraded with a fuse adapter. Future work chairs will have a built-in fuse.
2.	<b>7. Other information relevant to FSCA</b>

<b>3. Type of Action to mitigate the risk*</b>		
3.	<b>1. Action To Be Taken by the User*</b>  <input type="checkbox"/> Identify Device <input type="checkbox"/> Quarantine Device <input type="checkbox"/> Return Device <input type="checkbox"/> Destroy Device  <input checked="" type="checkbox"/> On-site device modification / inspection  <input type="checkbox"/> Follow patient management recommendations  <input type="checkbox"/> Take note of amendment / reinforcement of Instructions For Use (IFU)  <input type="checkbox"/> Other <input type="checkbox"/> None  Please see document "103584 Upgrade Instruction & Alternatives"	
3.	2. By when should the action be completed?	2022-12-31
3.	3. Particular considerations for:  Is follow-up of patients or review of patients' previous results recommended? No	
3.	4. Is customer Reply Required? * (If yes, form attached specifying deadline for return)	Yes
3.	<b>5. Action Being Taken by the Manufacturer*</b>  <input type="checkbox"/> Product Removal <input checked="" type="checkbox"/> On-site device modification/inspection <input type="checkbox"/> Software upgrade <input type="checkbox"/> IFU or labelling change <input type="checkbox"/> Other <input type="checkbox"/> None  Please see document "103584 Upgrade Instruction & Alternatives"	
3.	6. By when should the action be completed?	2022-12-31
3.	7. Is the FSN required to be communicated to the patient /lay user?	No
3.	8. If yes, has manufacturer provided additional information suitable for the patient/lay user in a patient/lay or non-professional user information letter/sheet?  No	

<b>4. General Information*</b>		
4.	1. FSN Type*	New
4.	2. For updated FSN, reference number and date of previous FSN	
4.	3. For Updated FSN, key new information as follows:	
4.	4. Further advice or information already expected in follow-up FSN? *	Not planned yet
4.	5. If follow-up FSN expected, what is the further advice expected to relate to:	
4.	6. Anticipated timescale for follow-up FSN	
4.	7. Manufacturer information (For contact details of local representative refer to page 1 of this FSN)	
	a. Company Name	Eurovema Mobility AB
	b. Address	Baldersvägen 38, SE-33235, Gislaved, SWEDEN
	c. Website address	www.eurovema.com
4.	8. The Competent (Regulatory) Authority of your country has been informed about this communication to customers. * Yes	
4.	9. List of attachments/appendices:	"FSCA Euroflex 24V ENG", "103584 Upgrade instruction & Alternatives" and "103584 Confirmation Letter ENG"
4.	10. Name/Signature	xxx

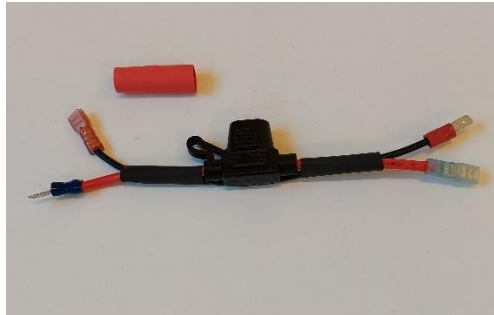
<b>Transmission of this Field Safety Notice</b>	
	<p>This notice needs to be passed on all those who need to be aware within your organisation or to any organisation where the potentially affected devices have been transferred. (As appropriate)</p> <p>Please transfer this notice to other organisations on which this action has an impact. (As appropriate)</p> <p>Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.</p> <p>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.*</p>

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

## Acknowledgment of receipt – Euroflex 24V

I hereby confirm as owner / responsible user of the above product that I have received the Field Safety Notice with reference

FSCA \_\_\_\_\_ dated \_\_\_\_\_



I have read and understood the instructions in this Field Safety Notice? Yes  No

We choose alternative: 1  2  3

Name: \_\_\_\_\_

Title: \_\_\_\_\_

Institution / section: \_\_\_\_\_

Address: \_\_\_\_\_

Postal address: \_\_\_\_\_

Telephone: \_\_\_\_\_

Email: \_\_\_\_\_

Return to Eurovema no later than the 15<sup>th</sup> of April 2022.

If you have any questions, please contact us by email: [Demir.Masinovic@eurovema.se](mailto:Demir.Masinovic@eurovema.se)

Eurovema Mobility AB  
Baldersvägen 38  
SE-332 35 Gislaved  
Sverige

# Update of 24V electronics for Euroflex



Information to all customers regarding a necessary field safety corrective action to  
Euroflex 24V electronics

## Update to Euroflex 24V electronics

It is necessary to install a fuse adapter on all 24V work chairs. Eurovema will send out fuse adapters to affected customers during the period of April-May 2022.

Please see Appendix 1 for instructions on how to mount the fuse adapter.

### Alternative approaches:

- 1) Eurovema delivers fuse adapters and serial numbers to Euroflex distributors. Technician at the distributor installs the fuse adapter.
- 2) Customer installs fuse adapter.
  - a. In this case, the Distributor sends both the contact information and serial number to Eurovema, who in turn will then send the fuse adapter directly to the customer with information how to install the fuse adapter.
- 3) If none of these options is of convenience for you, please contact us to find a solution that will benefit you.

**Please let us know that you have received the information by filling out the “103584 Confirmation Letter ENG” form with which approach you prefer.**

How to install the fuse adapter 10A on work chairs with 24V electronics.

- 1) The heat-shrink tubing must be mounted and crimped over the cable lugs on the **plus cable**.
- 2) **B+** (red cable) to **battery +** (red cable)
- 3) **B-** (black cable) to **battery -** (black cable)
- 4) Attach the wiring so that it cannot get caught.

