Rev. 0: July 2023

FSN Ref : TNEM/DCA06//FSN FSCA Ref : TNEM/DCA06/FSCA

Date: 20/07/2023

Urgent field safety notice
Easymoov6 enteral feeding pump

For the attention of*: Person responsible of Medical Devices safety/vigilance biomedical manager, quality manager -Passed on to all user department and users.

Contact details of local representative (name, e-mail, telephone, address, etc.) *.
Local distributor

Urgent Field Safety Notice (FSN)
Device brand name
Risk addressed by FSN

<table>
<tr><td></td><td colspan="2">1. Information on the devices concerned*.</td></tr>
<tr><td rowspan="2">1</td><td colspan="2">1. Type(s) of device(s)*</td></tr>
<tr><td colspan="2">Enteral feeding pump</td></tr>
<tr><td rowspan="2">1</td><td colspan="2">2. Trade name(s)</td></tr>
<tr><td colspan="2">Easymoov6</td></tr>
<tr><td rowspan="2">1</td><td colspan="2">3. Unique device identifier(s) (UDI-DI)</td></tr>
<tr><td colspan="2">
<table>
<tr><th>Reference</th><th>UDI-ID</th></tr>
<tr><td>0VEPM6</td><td>03660812096560</td></tr>
<tr><td>0VEPM6A06</td><td>03660812096669</td></tr>
<tr><td>0VEPM6C02</td><td>03660812096577</td></tr>
<tr><td>0VEPM6C06</td><td>03660812096614</td></tr>
<tr><td>0VEPM6C10</td><td>03660812099028</td></tr>
<tr><td>0VEPM6C11</td><td>03660812144360</td></tr>
<tr><td>0VEPM6D02</td><td>03660812106160</td></tr>
<tr><td>0VEPM6G02</td><td>03660812096553</td></tr>
</table>
</td></tr>
<tr><td rowspan="2">1</td><td colspan="2">4. Primary clinical purpose of the device(s)*.</td></tr>
<tr><td colspan="2">Enteral feeding</td></tr>
<tr><td rowspan="2">1</td><td colspan="2">5. Device model/catalog/parts number(s)*.</td></tr>
<tr><td colspan="2">See reference 1.3</td></tr>
<tr><td rowspan="2">1</td><td colspan="2">6. Software version</td></tr>
<tr><td colspan="2">All software versions</td></tr>
<tr><td rowspan="2">1</td><td colspan="2">7. Range of serial or batch numbers concerned</td></tr>
<tr><td colspan="2">All serial numbers</td></tr>
<tr><td rowspan="2">1</td><td colspan="2">8. Associated devices</td></tr>
<tr><td colspan="2">N/A</td></tr>
</table>

2 **Reason for safety corrective action in the field (FSCA)***	
2	1. Product problem description
	a. Medwin was informed, the detection system fails to detect downstream occlusion with the use of some feeding solutions (See list in appendix 1) b. Medwin was informed of an incident during home enteral feeding. The user didn't place the silicone of the enteral feeding set around the pump's rotor, resulting in a significant overflow.
2	2. Risks behind the FSCA
	a. Risk of not detecting a downstream occlusion. b. Risk of overflow and free flow.
2	3. Probability of a problem occurring
	a. The problem may occur when using a low opacity feeding solution. b. This is the first report of this problem, it may occur if the user is not fully trained.
2	4. Foreseeable risk for patients/users
	a. Lack of nutrition / Delay in the nutrition. b. Overfeeding, digestive disorders.
2	5. Additional information to help characterize the problem
	N/A
2	6. Context of the question
	a) The sensitivity of the sensor used to detect downstream occlusions is not adapted to some feeding solutions, and it is necessary to adjust a software parameter in order to increase this sensitivity and ensure correct detection.
2	7. Other FSCA information
	N/A

3.	**3. Type of action to mitigate risk*.**	
3.	**1. Measures to be taken by the user*.** a. ☒ Identify the device ☐ Quarantine the device ☐ Return device ☐ Destroy device ☐ Modify/inspect device on site ☐ Follow recommendations for patient management ☐ Take note of modification/strengthening of instructions for use (IFU) ☒ Other ☐ None • Check if some feeding solutions listed in appendix 1 are used by the users, • Identify the pumps which have difficulties to detect downstream occlusions, • Contact the local Vygon representative to organize for the identified pumps the update of the software on site or in manufacturer's workshop. b. ☐ Identify device ☐ Quarantine device ☐ Return device ☐ Destroy device ☐ Modify/inspect device on site ☒ Follow recommendations for patient management ☐ Take note of modification/strengthening of instructions for use (IFU) ☒ Other ☐ None It's advised to remind users, especially lay users, of the correct way to install the enteral feeding set on the enteral feeding pump. A reminder of the rules and instructions for use is presented in the appendix 2.	
3.	When must the action be completed?	As soon as possible
3.	3. Special considerations for : N/A. Is patient follow-up or review of previous patient results recommended? N/A.	
3.	4. Does the customer have to reply? * (If yes, form attached specifying deadline for return)	Yes
3.	**5. Measures taken by the manufacturer** a. ☐ Removal of product ☐ Modification/inspection of device on site ☒ Software update ☐ Modification of IFU or labeling ☐ Other ☐ None The update can be done in 2 ways: - Vygon experts in active medical devices can update pumps directly on user sites. - Pumps can be returned to MEDWIN for after-sales service after that MEDWIN sent loan pumps to ensure continuity of care. b. ☐ Removal of product ☐ Modification/inspection of device on site ☐ Software update ☐ Modification of IFU or labeling ☑ Other ☐ None Adding a plastic part on the pump cover to create an occlusion if the enteral feeding set is not well placed.	
3	6. When must the action be completed?	a. As soon as possible b. 15/12/2023

3.	7. Should the FSN be communicated to the patient/end user ?	Yes
3	8. If yes, has the manufacturer provided additional information tailored to the patient/user in a letter/information sheet for the patient/bed user or lay user?	
.	See appendix 2	

4. General information		
4.	1. FSN Type*	New
4.	2. For the updated FSN, the reference number and date of the previous FSN.	N/A
4.	3. For the updated FSN, enter the new information as follows:	
	N/A	
4.	4. Other advice or information already expected as part of the FSN follow-up? *	Not yet scheduled
4	5. If a follow-up FSN is planned, what should the additional advice cover?	
	N/A	
4	6. Timeframe for FSN follow-up	N/A
4.	7. Manufacturer information (for contact details of local representative, see page 1 of this memo)	
	a. Company name	MEDWIN France
	b. Address	9, Allée de la Vigne Grande 34600 Les Aires
	c. Website address	www.vygon.com
4.	8. The competent (regulatory) authority in your country has been informed of this communication to customers. *	
4.	9. List of attachments/appendices:	Appendix 1: List of feeding solutions Appendix 2: User mail
4.	10. Name/Signature	Jérémy Imbert, Quality Manager
	Transmission of this safety notice to the field	
	This notice must be sent to all persons who need to be informed within your organization or to any organization to which potentially affected equipment has been transferred. (if applicable) Please forward this notice to other organizations on which this action has an impact. (if applicable) We ask you to remain attentive to this notice and the resulting action for an appropriate period of time to ensure the effectiveness of the corrective action. Please report all incidents relating to the device to the manufacturer, distributor or local representative, as well as to the relevant national authority where applicable, as this provides important feedback.*.	

Note: Fields marked with an asterisk (*) are considered necessary for all FSNs. Other fields are optional.

APPENDIX 1

Update: 17/07/2023

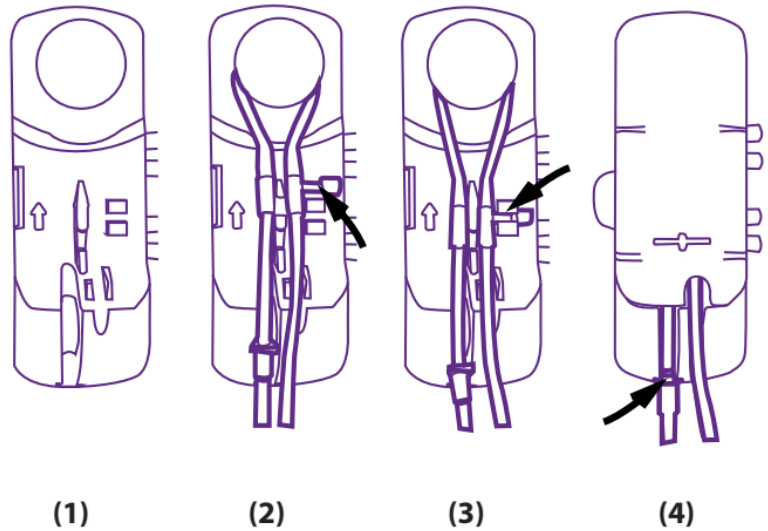
Manufacturer	Feeding solution reference
/	SELF MADE PREPARATIONS
FRESENIUS	FRESUBIN ENERGY
FRESENIUS	FRESUBIN HP ENERGY
NUTRICIA	NUTRIMAX ENERGY 1,5Kcal
NUTRICIA	NUTRIMAX ENERGY MULTIFIBRE 1,5kcal
NUTRICIA	NUTRISON PROTEINE PLUS
NUTRICIA	NUTRISON ENERGY 1,5kcal
NESTLE	ISOSOURCE JUNIOR
NESTLE	ISOSOURCE ENERGY FIBRE
NESTLE	SONDALIS HP 2kcal
NESTLE	PEPTAMEN
NESTLE	PEPTAMEN HN
NESTLE	PEPTAMEN NEUTRAL HF

APPENDIX 2

Reminder of how setting the enteral feeding sets on the Easymoov6 enteral feeding pumps

The setting of the enteral feeding set must be made following these steps:

- Connecting the set to the feeding solution bag.
- After checking the integrity of the packaging, remove the set from the bag.
- Connect the set to the feeding solution bag and hang the bag.
- Install the set on the pump and purge in accordance with the table below from the instructions for use:

(1) Open Easymoov6 pump cover.	
(2) Place the silicone loop around the rotor and make sure the cassette is in the right direction.	
(3) Push the cassette in the middle of the pins with your thumb and make sure the cassette is well postioned between the two black pins. Guide both tubes down, in line with their respective slots.	
(4) Close the pump cover, then place the adapter into the designated slot.	
Remove the protective cap from the tubing.	
Launch automatic priming (see section 3.5).	
Connect the tubing to the patient enteral feeding tube and program the pump.	

Please note that it is better:

- Not to connect the set to the probe before purging,
- To check that the silicone tube is correctly positioned around the rotor:

COMPLIANT

NON COMPLIANT