

To whom it may concern

Heilbronn, 31. Jan 2021

Field Action: "FSN20-03"

Dear valued customer,

Medos AG has sold a Trolley with a potential risk to the stability of the trolley due to the lack of securing of axis of rolls and due to that the roller-wheel might become loose, in case the axis becomes loose unnoticed. The trolleys in question are produced between 2009 and 2011.

1. Information on Affected Devices*	
a) Device Type(s)*	Trolley M
b) Commercial name(s)	DELTASTREAM® Systemwagen III MDC
c) Unique Device Identifier(s) (UDI-DI)	N/A
d) Device Model/Catalogue/part number(s)*	MEDP100321
e) Software version	N/A
f) Affected serial or lot number range	SYSMDC-001 - SYSMDC-003 SWIIIMDC002 - SWIIIMDC004 SWIIIMDC006 - SWIIIMDC020 0001 0003 0007 Prototyp1
g) Associated devices	Within context of the FSCA: All



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2. Reason for Field Safety Corrective Action (FSCA)*

a) Description of the product problem*
A possible risk to the stability of the trolley due to the lack of securing of the axis of rolls, in case the axis becomes loose unnoticed. Under these circumstances the wheel might become loose.
b) Hazard giving rise to the FSCA*
N/A
c) Probability of problem arising
Yes, if the axis of rollers are not properly secured unnoticed.
d) Predicted risk to patient/users
Risk for patient is given, if the stability of the trolley is not given.
e) Further information to help characterize the problem
See Picture below
f) Background on issue
Please identify if your Trolley is affected or not
g) Other information relevant to FSCA
N/A



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3. Type of Action to mitigate the risk*	
<p>a) Action To Be Taken by the User*</p> <p> <input checked="" type="checkbox"/> Identify Device <input checked="" type="checkbox"/> Quarantine Device <input type="checkbox"/> Return Device <input type="checkbox"/> Destroy Device </p> <p> <input type="checkbox"/> On-site device modification/inspection </p> <p> <input type="checkbox"/> Follow patient management recommendations </p> <p> <input type="checkbox"/> Take note of amendment/reinforcement of Instructions For Use (IFU) </p> <p> <input checked="" type="checkbox"/> Other <input type="checkbox"/> None </p> <p>Identify if a Trolley of the affected Trolleys is still in use. The Trolley can be identified by the uni-colored grey wheel-housing. If the trolley is still in use, please quarantine the device and please contact Xenios AG for the further procedure of exchanging the Trolley.</p>	
b) Actions to be completed by:	6 months
c) Is customer reply required? * (If yes, form attached specifying deadline for return)	Yes
d) Deadline (if needed)	
<p>e) Action Being Taken by the Manufacturer</p> <p> <input checked="" type="checkbox"/> Product Removal <input type="checkbox"/> On-site device modification/inspection </p> <p> <input type="checkbox"/> Software upgrade <input type="checkbox"/> IFU or labelling change </p> <p> <input type="checkbox"/> Other <input type="checkbox"/> None </p>	
f) Until when should the action be completed?	6 months
g) Is the FSN required to be communicated to the patient or user?	Yes
<p>h) If yes, has manufacturer provided additional information suitable for the patient or user in a patient or non-professional user information letter?</p> <p>No Not appended to this FSN</p>	



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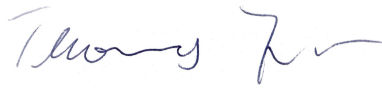
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4. General Information*	
a) FSN Type	New
b) For updated FSN, reference number and date of previous FSN	N/A
c) For Updated FSN, key new information as follows:	
N/A	
d) Further advice or information already expected in follow-up FSN? *	No
e) If follow-up FSN expected, what is the further advice expected to relate to:	
N/A	
f) Anticipated timescale for follow-up FSN	None
g) Manufacturer information (For contact details of local representative refer to page 1 of this FSN)	
• Company Name	See letter-head
• Address	See letter-head
• Website address	See letter-head
h) List of attachments/appendices:	none
i) Name/Signature	Thomas-Helge Junesch, Safety Officer
	
j) FSN Type	New
k) For updated FSN, reference number and date of previous FSN	N/A



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Transmission of this Field Safety Notice

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)

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

Please maintain awareness on 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.*



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Customer Reply Form for Field Action: "FSN20-03"

1. Field Safety Notice (FSN) information	
FSN Reference number*	FSN20-03
FSN Date*	Jan 2021
Product/ Device name*	DELTASTREAM® Systemwagen III MDC
Product Code(s)	
Batch/Serial Number (s)	

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

3. Customer action undertaken on behalf of Healthcare Organisation				
<input type="checkbox"/>	I confirm receipt of the Field Safety Notice and that I read and understood its content. I need new rolls.	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 have returned affected devices - enter number of devices returned and date complete.	Qty:	Lot/Serial Number:	Returned (DD/MM/YY):
		Qty:	Lot/Serial Number:	Returned(DD/MM/YY):
		Comments:		
<input type="checkbox"/>	I have destroyed affected devices – enter number destroyed and date complete.	Qty:	Lot/Serial Number:	
		Qty:	Lot/Serial Number:	
		Comments:		
<input type="checkbox"/>	No affected devices are available for return/ destruction	Customer to complete or enter N/A		
<input type="checkbox"/>	Other Action (Define):			



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<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 (e.g. need for replacement of the product).	Customer to enter contact details if different from above and brief description of query
Print Name*:		
Signature*:		
Date*		

4. Return acknowledgement to sender	
Email	fsn@xenios-ag.com
Deadline for returning the customer reply form*	2 weeks

Mandatory fields are marked with *

It is important that your organisation takes the actions detailed in the FSN and confirms that you have received the FSN.

Your organisation's reply is the evidence we need to monitor the progress of the corrective actions.



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