Rev 1: September 2018

FSN Ref: FSN001813 FSCA Ref: FSCA001813

Date: 16:03:2023

Urgent Field Safety Notice

SANGO ADVANCED, SANGO SLIMLINE, SANGO (X)XL

For Attention of*:All Dealers and Importers

Contact details of local representative (name, e-mail, telephone, address etc.)*
DIETZ Power BV, Vlamovenweg 12, 5708JV Helmond, T +31 492 792 196, info@dietz-power.com

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Combination of tilt and biomechanical backrest 45º

1. Information on Affected Devices*	
1.	1. Device Type(s)*
	All wheelchairs fitted with a combination of an adjustable tilt and biomechanical backrest 45º
1.	2. Commercial name(s)
	SANGO advanced, SANGO slimline
1.	3. Unique Device Identifier(s) (UDI-DI)
	See Appendix 2
1.	4. Primary clinical purpose of device(s)*
	Electric powered wheelchair for use by persons with impaired mobility
1.	5. Device Model/Catalogue/part number(s)*
	SANGO advanced, SANGO slimline
1.	6. Software version
	NA
1.	7. Affected serial or lot number range
	See Appendix 3
1.	8. Associated devices
	6000483 biomechanical backrest 45º

2 Reason for Field Safety Corrective Action (FSCA)*	
2.	1. Description of the product problem*
	When all adjustment functions of the wheelchair are used in extreme positions, it may be possible for the Sango wheelchair to start tipping.
2.	2. Hazard giving rise to the FSCA*
	Tipping of the wheelchair not only results in an unpleasant feeling for the user but can, in rare cases, lead to the user slipping out of the Sango. Wheelchairs with a combination of a 45 degrees biomechnical backrest and tilt adjustment module are most susceptible to this issue. If the user does follow up on the instructions given in this FSN there is no residual risk.
2.	3. Probability of problem arising
	Occasional, in case of improper use or >0,01-0,1%
2.	4. Predicted risk to patient/users
	In case of users that are already in bad health, sliding out of the wheelchair can possibly lead to (permanent) injury.
2.	5. Further information to help characterise the problem
	Users that are in good condition will most likely have only have minor injury
2.	6. Background on Issue
	While testing extreme positions of a Sango wheelchair fitted with an electrical biomechanical 45 degrees backrest in combination with a tilt adjustment module, a Dietz employee has slid out of the chair. The employee has only minor injuries.
2	7. Other information relevant to FSCA

.	NA

	3. Type of Action to mitigate the risk*	
3.	**1. Action To Be Taken by the User***	
	☐ Identify Device ☐ Quarantine Device ☐ Return Device ☐ Destroy Device ☐ On-site device modification/inspection ☐ Follow patient management recommendations ☒ Take note of amendment/reinforcement of Instructions For Use (IFU) ☐ Other ☐ None Provide further details of the action(s) identified.	
3.	2. By when should the action be completed?	NA
3.	3. Particular considerations for: Choose an item. Is follow-up of patients or review of patients' previous results recommended? No In case of injury due to slipping out of the chair this will be directly noticed. The chance of a patient developing injuries on long term is very low.	
3.	4. Is customer Reply Required? * (If yes, form attached specifying deadline for return)	Yes
3.	**5. Action Being Taken by the Manufacturer** ☐ Product Removal ☐ On-site device modification/inspection ☐ Software upgrade ☒ IFU or labelling change ☐ Other ☐ None Provide further details of the action(s) identified.	
3	6. By when should the action be completed?	31/03/23
3.	7. Is the FSN required to be communicated to the patient /lay user?	Yes
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?	
	Yes Appended to this FSN	

	4. General Information*	
4.	1. FSN Type*	New
4.	2. For updated FSN, reference number and date of previous FSN	Provide reference and date of previous FSN if relevant
4.	**3.** For Updated FSN, key new information as follows:	
	Summarise any key difference in devices affected and/or action to be taken.	
4.	4. Further advice or information already expected in follow-up FSN? *	No
4	5. If follow-up FSN expected, what is the further advice expected to relate to:	
	Eg patient management, device modifications etc	
4	6. Anticipated timescale for follow-up FSN	For provision of updated advice.
4.	7. Manufacturer information (For contact details of local representative refer to page 1 of this FSN)	
	a. Company Name	**DIETZ Power**
	b. Address	**Vlamovenweg 12, 5708JV, Helmond**
	c. Website address	**https://dietz-power.com/**
4.	8. The Competent (Regulatory) Authority of your country has been informed about this communication to customers. *	
4.	9. List of attachments/appendices:	**Appendix 1 User Communication Appendix 2 List of UDI-DI**
4.	**10. Name/Signature**	

	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..*

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