FSN Ref: 1269554 FSCA Ref: 1269554

Date: 19.05.2020

Urgent Field Safety Notice
Device Commercial Name

For Attention of: Caregivers and residents in extended care facilities who are using the Abena Nova with MediSens.

Contact details of local representative
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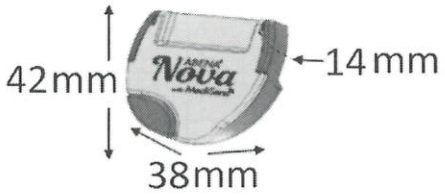
Urgent Field Safety Notice (FSN)
Device Commercial Name
Risk addressed by FSN

1. Information on Affected Devices	
1.	1. Device Type
	The Abena Nova with MediSens Clip (Clip), is an essential part of the Abena Nova with MediSens Wearable Platform. It is a battery powered electronic device that attaches to a Abena Nova incontinence product and remotely notifies the caregiver when a Abena Nova incontinence product is wet, the Clip collects and transmits incontinence data wirelessly to the caregiver. The height of the clip is 42 mm, the width is 38 mm and the thickness is 14 mm. 
1.	2. Commercial name
	Abena Nova with MediSens Clip (Clip)
1.	3. Unique Device Identifier(s) (UDI-DI)
	n/a
1.	4. Primary clinical purpose of device
	Clip – The Bluetooth Clip is attached to the outside front of the diaper. The Clip collect and transmit incontinence data to the Relay.
1.	5. Device Model/Catalogue/part number
	We have experienced inconsistency of the quality of a production batch of 200 clips. *The device was still safe to use by the customer, no incidents was reported due to the manufacturing fault*
1.	6. Software version
	n/a
1.	7. Affected serial or lot number range
	A4001 - A4201
1.	8. Associated devices
	n/a

2 Reason for Field Safety Corrective Action (FSCA)	
2.	1. Description of the product problem
	We have experienced irregularities with the closing function of a clip. Hence, the clip was not tightening appropriately around the tab of the incontinence product. The manufacturer had used a wrong Printed Circuit Board (PCB), hence the PCB was thinner and therefore the closing function did not work as intended.
2.	2. Hazard giving rise to the FSCA

	Choking Hazard *The device was still safe to use by the customer, no incidents was reported due to the manufacturing fault. However, there is an increased hazard for people with in oral fixation to put the clip in the mouth, if it detaches too easy from the incontinence tab.*
2.	3. Probability of problem arising
	n/a *All clips accounted for.*
2.	4. Predicted risk to patient/users
	The Clip is safe to use. *Persons with an oral fixation should not use the Clip.*
2.	5. Further information to help characterise the problem
	n/a
2.	6. Background on Issue
	In October 2019, Abena was informed by a customer, that the customer was experiencing irregularities with the closing function of a Abena Nova with MediSens Clip (Clip). Hence, the clip was not tightening appropriately around the tab of the incontinence product.
2.	7. Other information relevant to FSCA
	Consequently, we have introduced an improved quality control of the Clips. *We are testing the closing function of 100% of the clips.*

	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. All clips was identified and returned to Abena, by December 2019.	
3.	2. By when should the action be completed?	Done *All clips in the concerning batch has been accounted for.*
3.	3. Particular considerations for: No considerations, except already mentioned. Is follow-up of patients or review of patients' previous results recommended? No follow-up needed. .	
3.	4. Is customer Reply Required? (If yes, form attached specifying deadline for return)	No *All clips was identified and returned to Abena by December 2019.*

3.	**5. Action Being Taken by the Manufacturer** ☐ Product Removal ☐ On-site device modification/inspection ☐ Software upgrade ☐ IFU or labelling change ☒ Other ☐ None • Improved quality control of Clips.	
3	6. By when should the action be completed?	All actions are fully implemented.
3.	7. Is the FSN required to be communicated to the patient /lay user?	No *All clips are accounted for.*
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 Not appended to this FSN	

	4. General Information	
4.	1. FSN Type	New
4.	2. For updated FSN, reference number and date of previous FSN	n/a
4.	**3.** For Updated FSN, key new information as follows:	
	n/a	
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:	
	No further follow-up is expected.	
4	6. Anticipated timescale for follow-up FSN	No further follow-up is expected.
4.	7. Manufacturer information (For contact details of local representative refer to page 1 of this FSN)	
	a. Company Name	Abena A/S
	b. Address	Egelund 35, 6200 Aabenraa, Denmark
	c. Website address	http://www.abenanova.com/
4.	8. The Competent (Regulatory) Authority of your country has been informed about this communication to customers. The Competent (Regulatory) Authority in Denmark and the Netherlands has been informed.	
4.	9. List of attachments/appendices:	
4.	10. Name/Signature	[redacted]

	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.