Omda

FSN Ref: DEVIATION-432 FSCA Ref:XXXXXXX

Date: 01-09-2024

Urgent Field Safety Notice
Omda ProSang Electronic Health Declaration functionality (EHD)

For Attention of*:Mainly customers using Electronic Health Declaration (EHD) in ProSang 9.8 but also to inform customers using 9.7 and 9.9 and lastly all ProSang users utilizing the Electronic Health Declaration (EHD) functionality.

Contact details of local representative (name, e-mail, telephone, address etc.)*
Omda AB, Telegrafgatan 4, 169 72, Solna, +47 976 19 830, compliance@omda.com

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Urgent Field Safety Notice (FSN)
Omda ProSang 9.7 to 9.9
Risk of missing questions in Electronic Health Declaration (EHD) when adding new donation site

1. **Information on Affected Devices***	
1.	1. Device Type(s)*
	Omda ProSangs donor module for Electronic Health Declaration (EHD)
1.	2. Commercial name(s)
	Omda ProSang
1.	3. Unique Device Identifier(s) (UDI-DI)
	ProSang 9.8: 09005723972550
1.	4. Primary clinical purpose of device(s)*
	This FSN is for sections handling donor management and especially the tasks of creating new donation sites, and maintaining the Electronic Health Declaration (EHD) in ProSang routine G958.
1.	5. Device Model/Catalogue/part number(s)*
	Version 9.7 to 9.9.2
1.	6. Software version
	Version 9.7 to 9.9.2
1.	7. Affected serial or lot number range
	N/A
1.	8. Associated devices
	N/A

2 **Reason for Field Safety Corrective Action (FSCA)***	
2.	1. Description of the product problem*
	Electronic Health Declaration (EHD) filtering of questions on e.g donor type, age, sex etc. has been an option since the beginning (more than 15 years ago ProSang version 2008.7) The configuration of the EHD is made and maintained by the customer in a well designed and user friendly user interface. From ProSang version 9.7 (9/2-2022 in PS-10785) a further filtering function was added to the EHD functionality which made it possible to filter questions based on donation site. If customer is not using the filtering on donation sites: When adding a new donation site in ProSang 9.7 the new donation site is by default included in all questions of the EHD. We recently learned that in ProSang 9.8 the behaviour was the opposite which by default excludes a new donation site from all questions of the EHD. In ProSang 9.9 a big job on EHD functionality was done due to introduction of the possibility to maintain both original and foreign language on the EHD. This reverted the implementation in ProSang 9.8 and from ProSang 9.9 the functionality when adding new donation sites in ProSang by default, the donation site is included in the EHD. If customer is using the donation site filtering function, the customer is aware of controlling the G958 configuration after creation of a new donation site. In that case questions that is excluded on one donation site will also be excluded on new donation sites.
	2. Hazard giving rise to the FSCA*

2.	EHD could be approved without donors answering all questions, which could potentially seriously harm patients receiving the donated products.
2.	3. Probability of problem arising
	The incident will occur at a customer site running ProSang 9.8 and utilizing the EHD functionality and having created a new donation site without walking through every question in the questionnaire administration routine G958 and saved the questionnaire after the adding of a new donation site. However the standard behaviour of G958 when a new questionnaire is added in ProSang 9.8 is to exclude the donation site on all questions which will render the donation site useless until an administrator has revised and saved a new version of the questionnaire template. Meaning no single questions will be excluded by default.
2.	4. Predicted risk to patient/users
	Versions 9.8 is considered to have probability 2 and severity 3, hence the anticipated risk was 2x3=6. ProSang 9.7 and 9.9 hence the anticipated risk is considered to be 1x3=3.
2.	5. Further information to help characterise the problem
	N/A
2.	6. Background on Issue
	In ProSang 9.8 a customer observed donors not answering all the questions in the EHD which they expected. This happened at a rather newly added donation site. This lead to an investigation by Omda in all releases since the donation site filter functionality was added, and uncovered a different behaviour in ProSang 9.8 which mislead the customer.
2.	7. Other information relevant to FSCA
	N/A

	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?	Omda advises all customers using the EHD functionality to carefully inspect all main and follow up questions are filtered as expected. Especially customers using ProSang 9.7 and higher should show great care when adding a new donation site and thoroughly review the questionnaire administration filters of G958 for every question, with special focus on the newly added donation site, and save a new version of the questionnaire.

3.	3. Particular considerations for: Choose an item. Is follow-up of patients or review of patients' previous results recommended? No There has been no reporting of faulty conclusions on answer reports due to this problem	
3.	4. Is customer Reply Required? * (If yes, form attached specifying deadline for return)	Yes Reply to the email with this information by 16 of September 2024.
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?	Omda will in the next patch version (9.9.3) add a heads up in the relevant section of the user manual, and also a clear warning in the screen where donation sites are created.
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?	
	Choose an item. Choose an item.	

	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:	
4	6. Anticipated timescale for follow-up FSN	Not yet planned
4.	7. Manufacturer information (For contact details of local representative refer to page 1 of this FSN)	
	a. Company Name	**Omda AB**
	b. Address	**Telegrafgatan 4, 169 72 Solna, Sweden**
	c. Website address	**www.Omda.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:	
4.	10. Name/Signature	**Daniel Wiman** **Business Area Manager**

	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.