Rev 2: February 2020

FSN Ref: FSN1

FSCA Ref: Qaelum - F04 CAPA 20230718 - 18JUL2023

Date: 2023.09.26

Field Safety Notice
DOSE: Patient radiation dose monitoring software

For Attention of*:Please distribute this voluntary Field Safety Notice to preferably all DOSE users of your organization, but at least to those DOSE users with a role that gives access to the functionality of “Compliance Management”.

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

Field Safety Notice (FSN)

DOSE: Patient radiation dose monitoring software

Potential hazard in specific situation related to renaming of study groups.

1. Information on Affected Devices*	
1.	1. Device Type(s)*
	DOSE patient radiation dose monitoring software is the medical software for monitoring and analysis of all types of clinical images for the received dose information, which stores them in a separate database for further future retrieval and makes it possible to have an overview of this data on a patient level and to compare the intended doses per study of the different X-ray devices.
1.	2. Commercial name(s)*
	DOSE: Patient radiation dose monitoring software
1.	3. Unique Device Identifier(s) (UDI-DI)
	Not applicable
1.	4. Primary clinical purpose of device(s)*
	DOSE is intended to extract, analyze and monitor patient radiation dose of the individual patient who undergo X-ray examinations. The intended users are the medical professionals in radiology departments or diagnostic imaging facilities. Its use is independent of any patient disease or condition, frequency of imaging, patient characteristics, or the imaged anatomy. Nevertheless, it can assist the user to evaluate the dose levels and the potential improvement points for the examinations performed on the individual patient and thus to improve diagnosis and fit a better treatment. Additionally, it helps the user to manage all the patient radiation related data that are available in the imaging department in a faster and more efficient way.
1.	5. Device Model/Catalogue/part number(s)*
	GTIN 05430003132012
1.	6. Software version
	Current and previous version of DOSE (v23, v21.2)
1.	7. Affected serial or lot number range
	Not applicable
1.	8. Associated devices
	Not applicable

2. Reason for Field Safety Corrective Action (FSCA)*	
2.	1. Description of the product problem*
	Missing notifications by loss of study group mappings and caused by changing the name of a study group via the study group “Import” UI.
2.	2. Hazard giving rise to the FSCA*
	We concluded that when DOSE is running on the “Locale” set as (German, Germany), the validation process of the text values, to be imported, does not provide the information concerning the foreseen possible hazardous situation related to the Study Group “Name” change, loss of their mapping and therefore result in missing notifications.
2.	3. Probability of problem arising
	Unlikely chance for occurrence. Important to note here is that only a very limited subgroup of DOSE users has access to the functionality of “Compliance Management” and therefore

	can have access to the Study Group “Import” UI function in particular. Moreover, changing the “Name” value of a Study Group is seen as a rare and exceptional action performed in the DOSE software. The "Locale" variable is set at the installation phase by Qaelum. (German, Germany) is only set for German based installations.
2.	4. Predicted risk to patient/users
	Risk index= low (based on Medium Severity of harm * Unlikely probability of occurrence)
2.	5. Further information to help characterise the problem
	/
2.	6. Background on Issue
	Following 1 initial suspected serious incident report on DOSE received from a user in Germany, concerning missing notifications by loss of study group mappings and caused by changing the name of a study group via the study group “Import” UI. Observed dose values higher than the a priori defined dose limits (e.g. Dose Reference Levels or the German StrlSchV limits) return notifications to the DOSE user. These limits are linked to Study Groups with a certain “Name”. By default, the Study Group settings are managed by the vendor through the vendor access role functionality of "Super Administrator”. If the end-user wants to be able to modify Study Groups themselves, then the access role functionality of “Compliance Management” can be assigned to adequately trained end-user(s). When an end-user has the access functionality of “Compliance Management”, changes to Study groups can be made using the foreseen “Edit” mode within the Overview of Study Groups in Settings. The “Edit” mode works correctly as designed and without potential hazard. Next to the “Edit” mode, there is also the “Import” mode for Study Groups. This mode is designed with a purpose to import new Study Groups. Because the “Import” mode also visualizes the existing Study Groups and their values as text, the end-user can also modify values of existing Study Groups rather than only import new Study Groups. In case the Study Group parameter “Name” is modified, a foreseen hazardous situation can occur as a side-effect. It is intended by DOSE that, by changing the “Name” of a Study Group in the “Import” UI, that that Study Group is considered as obsolete and therefore will be deleted. Subsequently, DOSE should also remove the mapping for that specific Study group. The renamed (newly named) Study Group is considered as a completely new Study Group that, as a result, also requires new mappings to be set up. The user may here mistakenly expect that the mappings are transferred from the old to the newly named study group, however this is not the case as mentioned during DOSE training and as highlighted in the UI. However, after comprehensive testing on our inhouse DOSE installations, we further identified that the end user, on a DOSE installation set up with Locale (German, Germany), is not made sufficiently aware that existing Study Group and their mapping to parameters (Study Description, Protocol Name, Acquisition Protocol, …) will be removed when renaming Study Group(s) via the “Import” UI, and thus it is also required from this user that he/she needs to reconfigure the affected Study Group mappings to guarantee that notifications will be generated. We concluded that when DOSE is running on the “Locale” set as (German, Germany), the validation process of the text values, to be imported, does not provide the information concerning the foreseen possible hazardous situation related to the Study Group “Name” change, loss of their mapping and therefore result in missing notifications. Important to note here is that only a very limited subgroup of DOSE users has access to the functionality of “Compliance Management” and therefore can have access to the Study Group “Import” UI function in particular. Moreover, changing the “Name” value of a Study

	Group is seen as a rare and exceptional action performed in the DOSE software. The "Locale" variable is set at the installation phase by Qaelum. (German, Germany) is only set for German based installations.
2.	7. Other information relevant to FSCA
	As Qaelum puts quality and the safety of the patients to the highest priority, the "Import" UI will be adjusted in the next scheduled version of DOSE to avoid occurrences of this event. In the meantime we focus actions, for the current affected versions, towards detailed clarifications via advice/instructions.

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

Further details on identified actions:
Advice to the user:

An alternative to using the "Import" UI to make changes to Study Groups is to use the "Edit" UI instead. Please note that this option is only available for CUSTOMIZED study groups. To change a LEGAL study group name, we recommend that you contact Qaelum. The "Edit" UI will make the requested changes while also keeping all mappings intact as here the Add/Edit/Delete options are clearly separated.
"Name" changes to Study Groups of the type LEGAL, are strongly advised not to be done via the "Import" UI for safety purposes.
In case you do want to make modifications to the study group "Name" please afterwards also reassign the study group mappings to the devices that were using the study group(s) of which the names have been modified as the mappings of these study groups will have been removed. You should also assign new limits to the updated study group "Name".

In case you want to "rename" a study group via the "import" UI without having to re-apply the device mappings, we advise you to contact Qaelum or one of our Partners to support.
"Name" changes to Study Groups of the type CUSTOMIZED can be done via the Edit button on "Settings > Study Groups > Overview > Edit".
In case you suspect your DOSE system to be affected because one of your end-users may have renamed Study Groups from within the "Import" UI of the Study Groups Settings and thereby possibly lost study group mappings and missing notifications for these study groups, please contact Qaelum or one of our Partners to request further investigation.

Clarification in User Manual:

Qaelum added the above clarification to the User Manual of DOSE (version 23-rev2, version 21.2-rev2) so to avoid future occurrences of this event. The updated user manual

	is also made publicly available at the Qaelum website: https://qaelum.com/solutions/dose#user-manual.	
3.	2. By when should the action be completed?	Action from distributor: we would kindly ask you the acknowledge of the receipt of this Field Safety Notice and take the requested actions. Action from user: we would kindly ask you to acknowledge the receipt of this Field Safety Notice. Please sign and send back the attached Confirmation of Receipt within four weeks after the receipt of this Field Safety Notice. In case you suspect your DOSE system to be affected: contact your DOSE supplier.
3.	3. Particular considerations for: Choose an item. Is follow-up of patients or review of patients' previous results recommended? Choose an item. Provide further details of patient-level follow-up if required or a justification why none is required.	
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 ☐ Software upgrade ☐ Other ☐ On-site device modification/inspection ☒ IFU or labelling change ☐ None
3.	6. By when should the action be completed?	Action from manufacturer: user manuals already updated and made available.
3.	7. Is the FSN required to be communicated to the patient /lay user?	N/A
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:	
	Not applicable	
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:	
	Not applicable	
4.	6. Anticipated timescale for follow-up FSN	N/A
4.	7. Manufacturer information (For contact details of local representative refer to page 1 of this FSN)	
	a. Company Name	Qaelum NV
	Address	Kolonel Begaultlaan 1B 3012 Leuven (Wilsele) Belgium
	b. Website address	www.qaelum.com
4.	8. The Competent (Regulatory) Authority of your country has been informed about this communication to customers. *	
4.	9. List of attachments/appendices:	For customer: Qaelum - FSN1 customer reply_en - 23AUG2023 ; For distributor: Qaelum - FSN1 distributor reply_en - 23AUG2023
4.	10. Name/Signature	[redacted], CEO Qaelum NV

	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.