Rev 1: May 18, 2020
FSN Ref: LUN200518 FSCA Ref: pCAR0012

Date: 05/18/2020

Urgent Field Safety Notice
Device Commercial Name

For Attention of*: …

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

Mevion Medical Systems, Inc.

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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(s)*
	MEVION S250i Proton Beam Radiation Therapy System
1.	2. Commercial name(s)
	MEVION S250i Proton Beam Radiation Therapy System
1.	3. Unique Device Identifier(s) (UDI-DI)
	DI: (01)00864366000124, PI: (11)181219
1.	4. Primary clinical purpose of device(s)*
	Proton Beam Radiation Therapy Device
1.	5. Device Model/Catalogue/part number(s)*
	MEVION S250i
1.	6. Software version
	2.2.0
1.	7. Affected serial or lot number range
	Only single device, identified with above UDI
1.	8. Associated devices
	No other associated device affected by this Field Safety Notice.

2 Reason for Field Safety Corrective Action (FSCA)*	
2.	1. Description of the product problem*
	Verity allows multiple imaging modalities for 2D and 3D corrections to be sent to the Couch to align a patient. The default is to capture and use 6 degrees of correction either from a pair of 2D orthogonal images or from a CT image set. A single planar image can be used and only 3 degrees of correction will be determined and shown to the user as check marks next the axes used. When another image is acquired, or the Couch is moved the 6 check marks should all reset to be on. A software error causes the check mark boxes to not reset occasionally when a single planar image is followed by a CBCT scan. The sporadic nature of this occurrence is hard to predict and may be related to the workflow as practiced by dual users. If the user does not notice the check marks are missing, it is possible to complete a Couch move to an unintended location and treat a patient.
2.	2. Hazard giving rise to the FSCA*
	The greatest hazard is to a patient. The treatment location although wrong, tends to be close to the correct location even when only 2 degrees of translation and 1 degree of rotation are applied. In the worst case a geometric misadministration could occur.
2.	3. Probability of problem arising
	The sporadic nature of these occurrences allows for a trained user to ignore the state of the check box indicators most of the time. The magnitude of the location errors is typically too small to be noticed by the user. This leads to an occasional probability of a small misaligning a patient. The chance of the misalignment contributing to a significant overdose of a structure is remote.

2.	4. Predicted risk to patient/users
	Potential harm is associated with the delivery of unintended dose to normal or critical non-target tissue. The amount of unintended dose to non-target tissue could in some foreseeable case of standard fractionation be as high as 2 Gy. Harm from a single exposure of 2 Gy to normal tissue could range from short-term effects in most tissue below its dose limit peripheral to a treatment field to serious injury in the rare case that a critical tissue is nearby and exceeds its dose limit for permanent injury. The severity would be Marginal for the short-term effects and Critical for the permanent injury. We do not consider the reduced dose to target tissue as causing harm since in standard fractionation a single fraction contributes no more than 5% (1 of ≥ 20) of the total dose, which is within the practice guidelines established by ICRU.
2.	5. Further information to help characterise the problem
	The issue was discovered incidentally by a site physicist looking at records of corrections for a new protocol that relied on single planar imaging. Retrospective examinations showed occurrences on 15 patients at least once during treatment and in 2 case more than once on a patient. Dosimetric evaluation of all instances showed no dose errors in excess of 5%.
2.	6. Background on Issue
	Software engineering was able to reproduce the error on a simulator and located a coding error that likely facilitated this problem. The error will be corrected and a version released that will always reset the Check Boxes to the default condition before subsequent images can be acquired.
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	
3.	2. By when should the action be completed?	Not Applicable
3.	3. Particular considerations for: Choose an item. Is follow-up of patients or review of patients' previous results recommended? No Customer is aware of treatment status of all patients and can follow, if/as per medical judgment.	
3.	4. Is customer Reply Required? * Customer and Mevion shall amicably arrange for software upgrade, which will resolve any foreseeable risk of harm.	No
3.	5. Action Being Taken by the Manufacturer ☐ Product Removal ☐ On-site device modification/inspection ☒ Software upgrade ☐ IFU or labelling change ☐ Other ☐ None Mevion to perform the following corrective actions: • Mevion is sending this User Notice to direct all customers using a protocol with single planar imaging followed by CT imaging to always look at the check boxes before applying Couch corrections. Should the check boxes not agree with the intended moves, they can back up one step and resend the corrections with the correct boxes checked. • Mevion is releasing Verity Version 2.2.7.1, which corrects the defect and will always reset the checkboxes to the all checked state.	

3.	6. By when should the action be completed?	Mevion and Customer shall arrange an amicable upgrade date, per Customer availability and urgency.
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:	
	N/A	
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	**Mevion Medical Systems, Inc.**
	b. Address	**300 Foster Street, Littleton, MA 01460**
	c. Website address	**www.mevion.com**
4.	8. The Competent (Regulatory) Authority of your country has been informed about this communication to customers. *	
4.	9. List of attachments/appendices:	**Attached: None**
4.	10. Name/Signature	**Ping Hu** **VP General Counsel**

	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..*