Rev 1: October 5th, 2020
FSN Ref: LUN201005 FSCA Ref: pCAR0014

Date: 10/22/2020

Urgent Field Safety Notice
Device Commercial Name

For Attention of*: Mirko Unipan

Contact details of local representative(s) (name, e-mail, telephone, address etc.)*
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Mevion Medical Systems, Inc.

Rev 1: October 5th, 2020
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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
	2.5.3.2
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*
	Upon initiation of a treatment beam, the Treatment Console (TC) screen unexpectedly terminated the beam and blanked out the current field delivery information. The MU Counter on the top right of the TC screen continued to increment up, and the Beam Control Box continued to emit beeping sounds consistent with beam delivery. No DICOM record for that beam was created or sent to the OIS, and the records accessible to the users showed no delivery of dose to that field. This left the therapist and physicist uncertain as to how much beam was delivered. Had the users decided to deliver the same beam again the patient could be over treated. The Hardwired Monitor Unit Counter (HMUC) located in the system cabinet accurately captured the dose delivered but was not recorded before a subsequent user action cleared that counter.
2.	2. Hazard giving rise to the FSCA*
	The greatest hazard is to a patient. Treatment can be delivered with the blank screen; in the worst case the patient could be over treated.
2.	3. Probability of problem arising
	It is unlikely a trained user would ignore the blank screen and resume with therapy causing an overtreatment. The chance of the therapist over treating is remote.

2.	4. Predicted risk to patient/users
	Potential harm is associated with the delivery of unintended excess dosage to the patient. This defect causes the detail information about an active beam being delivered to disappear from the screen and the history of delivery of that beam to not be captured in the beam sequence. A therapists uncertainty if a beam was delivered and unaware of the hard-wired backup systems that always displays dose delivered could in some remote scenario lead a therapist to incorrectly deliver the beam a second time. The severity of delivering one beam within one fraction twice could result in over treatment of that fraction. This would be corrected on subsequent fractions unless it was the last session of a treatment. This could cause temporary conditions such as erythema or other inflammatory reactions.
2.	5. Further information to help characterise the problem
	N/A
2.	6. Background on Issue
	The software team has analyzed the logs and extracted the actual delivery values for the field. Salesforce has been updated with these numbers so that the site can record and replan as necessary. The root cause of this issue appears to stem from the MCC and TC state machines becoming out of sync, with the field becoming unloaded on the TC side within the small window between the beam on handshake verification completing and the actual transition into the beam on state.
2.	7. Other information relevant to FSCA
	N/A

<table>
<tr><th></th><th colspan="2">3. Type of Action to mitigate the risk*</th></tr>
<tr><td>3.</td><td colspan="2">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

The User should actively monitor the TC screen during beam delivery. In the event the TC screen beam information appears blank during “Beam On”, the user should:
• Immediately suspend treatment by selecting “Beam Off” on the Beam Control Box.
• Record the MU counts displayed on the HMUC before any other action is taken.
• Consult physics to make manual adjustments of the plan.
• Notify Field Service to retrieve machine records of the partial beam delivery.
• Resumption of treatment requires Setup workflow to be repeated.</td></tr>
<tr><td>3.</td><td>2. By when should the action be completed?</td><td>60 days</td></tr>
<tr><td>3.</td><td colspan="2">3. Particular considerations for: N/A 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.</td></tr>
<tr><td>3.</td><td>4. Is customer Reply Required? *

Confirm receipt of user notification.</td><td>Yes</td></tr>
<tr><td>3.</td><td colspan="2">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 prompt user attention should this rare instance occur.</td></tr>
</table>

3.	6. By when should the action be completed?	20 days
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	**.....** **.....**

	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..*