

## Urgent: Medical Device Correction Customer Safety Advisory Notice

**Re.:** MOSAIQ™ Oncology Information System

Attention: Radiation Oncology Department

Dear MOSAIQ customer,

This letter is intended to inform you about a potential safety risk with your MOSAIQ Oncology Information System that has been identified by the manufacturer ELEKTA IMPAC Software.

**For details about the issue please refer to the attached Safety Notice from ELEKTA IMPAC Software (Document ID: LINMSQ0001).**

Since you have purchased your MOSAIQ system from SIEMENS, please disregard all references to ELEKTA IMPAC Support and contact SIEMENS Healthcare if you require any assistance or have questions related to MOSAIQ.

What will Siemens do to address this issue?

Your site will be contacted by Siemens service to schedule the application of a patch or upgrade within the same MOSAIQ version that resolves this issue. This will happen once the resolution has been provided by Elekta.

Please include this Safety Advisory Notice including the Safety Notice from ELEKTA IMPAC Software in your product related documentation, where it should remain until further notice. If you have any questions, please contact your responsible SIEMENS Service Engineer or Application Specialist.

**In the interests of safety, we ask that you perform the proposed interim mitigations and inform all affected personnel immediately.**

We regret any inconvenience that this may cause, and we thank you in advance for your understanding.

Sincerely,

signed   
General Manager, Radiation Oncology

signed   
Vice-President, QM, Radiation Oncology

This document is valid without original signature

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Healthcare Sector  
Radiation Oncology

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T6-010.680.02.01.02



## **IMPORTANT SAFETY NOTICE**

MOSAIQ v1.60V1 to v2.30.01: Customizing or Changing Numeric Regional Settings May Result in Mistreatment

IMPAC Medical Systems, Inc. has discovered an issue that may cause MOSAIQ to fail to recognize the designated decimal separator as valid, resulting in misinterpretation and/or incorrect display of fractional numeric data, or to correctly interpret date values under very particular conditions.

### **Versions 1.60V1 to 2.20.03**

The cause of the issue is a defect in MOSAIQ's design to support Microsoft Operating System regional settings, specifically its ability to properly handle customized regional settings. Customized regional settings is defined as any modification to the standard, predefined Microsoft delivered regional settings. This customization can take place in one of three ways:

- Manually selecting the Customize button to modify the regional settings on a given workstation
- Pushing out a Windows group policy object with customized regional settings
- Using the MOSAIQ feature *Force all Workstations to use these Numeric Symbols*

### **Versions 2.20.04 to 2.30.01**

If Regional Settings are switched while MOSAIQ is running, there is also a potential for misinterpretation and/or incorrect display of fractional numeric data and date values.

### **Clinical Impact**

There is a potential for mistreatment resulting in serious adverse health consequences if systemic misinterpretation of fractional numeric data is undetected by the user; however, the probability of such a critical mistreatment is remote, if users heed all treatment delivery warning messages and verify treatment parameters prior to overriding any such warnings. The mistreatment would result from MOSAIQ ignoring the decimal symbol for fractional numeric values (integers are not affected), and thus errantly converting a fractional value to an integer value, and refactoring the value by ten (10) or more. Incorrect meterset (Monitor Units or time) and/or incorrect geometric positions could be used for treatment. In the case of meterset (MU and time), the likelihood of the user being able to use the incorrect values for treatment without having been warned of a fractional dose mismatch is very remote (this likelihood is dependent on the distribution of field dose contribution). For geometric parameters, MOSAIQ would not allow treatment when values are out of range for the given treatment machine.

#### **Hazard: Meterset = Monitor Units (MU)**

If there is a zero to the right of the decimal, the MU will not be affected and will retain its integrity, e.g. 55,0 remains as 55,0. There is no factoring error. If there is a non-zero numeric character to the right of the decimal with resolution *deci*, the MU will be saved with a factoring error of 10. Integers are not affected.

#### **Hazard: Meterset = Seconds or Minutes**

If there is a non-zero numeric character to the right of the decimal with resolution *centi*, the time will be saved with a factoring error of 100. If there is non-zero numeric character to the right of the decimal with resolution *mili*, the time will be saved with a factoring error of 1000. Integers are not affected.

For Cobalt treatments that are manual recording only, the user could be misled by a time that has been errantly factored, but a resultant mistreatment would require the user to manually set that time on the machine.

#### **Hazard: Geometric Parameters**

Geometric parameters used for treatment could be affected by the misinterpretation of the decimal symbol. Gantry and collimator angle could be set incorrectly (e.g. 15,5 degrees can be misinterpreted as 155 degrees), and jaw and MLC positions could be set incorrectly (e.g. 1,5cm could be set to 15 cm).



**Interim Mitigations**

Perform the following steps in order:

1. Go to *File | System Utilities | Department Setup | International* tab, and **uncheck** or leave **unchecked** the *Force all Workstations to use these Numeric Symbols* feature. [Note: This setting applies to the entire database, so it only needs to be **unchecked** once to apply the change across all Departments in the same database.]
2. Review the Microsoft Operating System regional settings on all MOSAIQ workstations that are set for English (United States). Verify that the decimal symbol is a dot ('.'), if you want to retain the English (United States) setting, or change the language/locale to something other than English (United States) if desired.



*Elekta strongly warns you that Regional Settings must **never** be switched while MOSAIQ is running. Always close MOSAIQ prior to modifying Regional Settings.*

**Final Resolution**

Product resolutions for this issue are being developed and will be available soon. MOSAIQ will continue to allow users to use customized regional settings, but will disallow non-standard decimal or digit grouping symbols. The *Force all Workstations to use these Numeric Symbols* feature will be removed. Additionally, MOSAIQ will detect when changes are made to Regional Settings while it is operating and display a warning to users.

Your site shall be contacted by Elekta Support to schedule the application of a patch or an upgrade within the same MOSAIQ version that resolves this issue. The patch/upgrade is mandatory. This patch/upgrade can be quickly applied and does **not** entail an upgrade to a new version of MOSAIQ, new hardware, or network modifications.

For questions, concerns, and requests for upgrade, email [support@impac.com](mailto:support@impac.com) or call:

United States	1-800-488-4672	Netherlands	00 800 4672 2222
Australia	1-800-420692	New Zealand	0800-449224
Austria	0800 005 003	Portugal	8008-60282
Belgium	0800-71560	Singapore	800-1204294
France	0800-901281	Spain	900-991937
Germany	0800-664-4968	Sweden	020-79-3490
Hong Kong	800-901702	Switzerland	0800-561563
Ireland	1-800-570033	Taiwan	00801-13-7789
Israel	1-80-9214848	United Kingdom	00-800-4672-2222
Italy	800-787669		
General European (toll charged)	44 1293 654320		

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Please distribute this notice to any and all users of IMPAC software at your organization who are potentially affected by this issue. The applicable regulatory agencies have been notified of this corrective field action.

### Confirmation of Receipt

<b>Product</b>	MOSAIQ
<b>Subject</b>	MOSAIQ v1.60V1 to v2.30.01: Customizing or Changing Numeric Regional Settings May Result in Mistreatment
<b>Reference</b>	CAR0231

**Please sign and date this form and return it in one of the three ways indicated below**

I acknowledge receipt and understanding of this notice.	
Site Name	_____
Recipient's Name	_____
Recipient's Title	_____
Signature	_____
Date	_____



NORTH AMERICA and ASIA

Fax to: **702-992-5002**  
/ **ATTN: Elekta OIS Support**

Scan and email to : [support@impac.com](mailto:support@impac.com)  
/ **ATTN: Elekta OIS Support**

Mail to (requires postage) :  
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**Henderson, NV**  
**USA**

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