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IMPORTANT NOTICE

Notice No : A301

Date : 30th July 2007

Regional Settings for Use with MOSAIQ

To our MOSAIQ customers,

We bring to your attention important information regarding the operation of your equipment. We advise all Users of the equipment to follow any instructions or recommendations covered in this Notice.

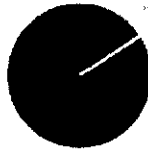This document should be filed in the Important Notice section of the appropriate User Manual.

IMPAC has recognized and resolved a potential numerical data display, recording, and calculation issue affecting our continental European and Quebecois customers that use IMPAC's Oncology software.

If the Microsoft Window Operating System decimal separator is set to a comma (',') as opposed to a dot ('.'), decimal or fractional data within MOSAIQ may display and/or record incorrectly, and therefore those applications may potentially miscalculate equations based on that errant data.
Specifically, dose information may be recorded incorrectly if the decimal separator standard is not set to a dot ('.'). Although it is essential for you to be made fully aware of this issue, we would like to stress that this fault in the system has not been observed in any way to affect the actual dose delivered, only the dose recorded in the Treatment Chart.

In IMPAC's Oncology software, the actual treatments are delivered using the Monitor Unit values in the database, which can be stored as integers and therefore are not subject to potential misinterpretation (if MU values are stored as integers*). In order to track the actual dose delivered, the software uses a dose coefficient, which is calculated automatically by dividing the planned dose by the Monitor Units required to deliver this dose (both of which are usually imported from the Treatment Planning System). This dose coefficient can be seen in each individual Treatment Field Definition window. Following treatment, IMPAC's Oncology software will then multiply the Monitor Units delivered by the dose coefficient to calculate the final, delivered dose to be recorded in the Treatment Chart. As the dose coefficient is stored as a decimal or fractional value, it is therefore at this stage that the figures are subject to potential misinterpretation by the application running on any workstation using a comma (',') as the decimal separator setting.

Such a miscalculation is immediately apparent in the system following treatment, with Radiotherapists receiving a clear warning of a potential Dose Mismatch and the Treatment Chart displaying in red for that session. IMPAC's Oncology software also has dose tracking warnings in place, which inform the operator – prior to any subsequent treatment – of the potential overdosing of patients, providing that the user has activated the 'Dose Tracking Check' on the Clinical (RO) tab of the Department Setup window. Overdosing of a patient would require the operator to have the appropriate system rights, choose to ignore the overdosing warnings, and enter a password in order to override the system and proceed with the treatment.

This error, should it occur, is easily fixed by an immediate correction of the dose coefficient as displayed in the Historic Treatment for each affected Field.

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Additionally, if the user is utilizing IMPAC's Treatment Calendar functionality, as taught in IMPAC product training and highly recommended, the Treatment Calendar will automatically verify the dose of all fields scheduled for treatment in any given session to ensure that there is no misinterpretation (underdose or overdose) of the dose as set in the Radiation Prescription. Any potential errors in planned dose will be immediately highlighted in the electronic chart for the user to clearly see and act upon.

* Monitor Units can be input and stored as fractional values, depending on the linac in use at a given site and the machine configuration of that linac. In such cases, MU would be subject to the fractional value misinterpretation explained above. There is thus a potential for mistreatment in this scenario based on the errant MU.

In order to ensure that all numerical data is displayed, recorded, and calculated correctly, IMPAC requires the following setting for all MOSAIQ versions prior to 1.20P2: the decimal separator standard must be set to dot ('.') as opposed to a comma (','). Go to the Microsoft Operating System Regional and Language Options in the Control Panel. Click the Customize button under the Regional Settings tab to display the Customize Regional settings dialog box. Set the Decimal symbol to dot ('.'), click Apply, and then OK. This setting must be configured for all user profiles on each workstation.

In MOSAIQ version 1.20P2 and all subsequent MOSAIQ versions, the application will automatically check to ensure that the decimal separator standard is set to a dot ('.'); if it is not, the application will prompt the user to change the decimal separator standard to the supported setting. If the user refuses to allow MOSAIQ to change the decimal separator setting to dot ('.'), the user will be forced to exit from the software and cannot proceed with the use of the application.

IMPAC recognizes that such a fix, although it fully mitigates any potential health & safety risk, may pose an inconvenience to your facility due to the forced change in workstation settings, which may affect other programs running on these systems. IMPAC encourages you to upgrade your software to a version containing this fix; however, there will be a less invasive upgrade solution available in the near future, whereby the application automatically converts all commas entered by a user in a numerical field to dots regardless of the decimal separator setting, and interprets the fractional value correctly. Should you prefer to wait until this fix is released and proceed without upgrading at this time, please attest to your refusal by affixing your signature to the statement on the next page.

Sincerely,

███████

Technical Manager - Europe & AFLAMEI

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On behalf of and with full signature authority for _____ , I hereby refuse IMPAC's offer of an upgrade containing the interim fix (incorporated into MOSAIQ v1.20P2 and beyond) for the decimal separator setting issue and acknowledge the potential safety risk inherent to operating the software without that fix.

Signed,

_____   _____
Signature   Date

_____
Printed Name

Note: For return information, please see page 2 of the FCO.