Field Safety Notice

Commercial name of the affected product

Praezis Plus 3

FSCA-identifier (e.g. date): 20130419_PP_FSN

Type of action (e.g. chapter 4 definition of a FSCA):

1. advice given by manufacturer regarding the use of the device
2. release of updated software product

Date : **April 26th, 2013**

Attention :

Details on affected devices :

List of affected devices and abbreviations used:

PP 3.1 – Praezis Plus version 3.1 a 3.1 SP1 – all builds
Note: The information which version is used is available from the menu "Help → About".

Description of the problem :

Based on the phone call received on April 16th 2013 from inomed Medizintechnik GmbH, following observations were reported and consequential investigation was performed.

Observation

In the reported case, the patient data consisted of CT stereotactic image series and MR series.
Then a stereotactic transformation on the CT series was defined.
Afterwards the automatic registration of CT series to one of the MR series was invoked.
The re-slicing process of involved CT series started and before completion, the software crashed.

Analysis

The software product Praezis Plus is used for stereotactic target point planning based on series of digital images in the standard DICOM format obtained from imaging modalities (e.g. CT, MRI). The image series contains multiple single images. Every single image has a coordinate referenced to the table of the image modality. During the software procedure of Stereotactic Registration, the original images are aligned to the stereotactic frame and the software recalculates fitting the position to the stereotactic device.

The reported problem was reviewed and identified that in case of existing original image slice with the position -1.000, the software recalculates the new value of that particular slice in a wrong way thus shifting the calculated stereotactic slice position by 1 mm to the position corresponding to the slice with image position equal to 0.000. Thus, in such case of both slices occurred in that particular image series, both slices will obtain the same stereotactic position. Afterwards image series is treated as an inconsistent image series and thus will not be accepted for further automatic registration.

The software attempts to solve this problem by recalculation (re-slice function), but during this process the software crashes down. Unsaved planning data are lost at that moment. The reason is that the DICOM slice position equal to -1.000 is interpreted internally in a wrong way when the stereotactic registration is calculated.

Result:

1. The problem disables automatic registration with stereotactic series and may lead to the system crash if the stereotactic series contains slice with the original DICOM slice position equal to -1.000 and another slice with the original DICOM position equal to 0.000.
2. The problem can influence the stereotactic target calculation and can cause an additional error of 1 mm in case the target point or entry point is defined exactly at the slice with original DICOM slice position equal to -1.000.

Usually, the slices with negative positions are located below the target or even below the ring, so they do not influence the target calculation therefore the problem above occurs rarely.

Corrective actions:

1. User notification:

This notice will be forwarded to the appropriate end-users and distributors of the software product.
Advises on action to be taken by the user are described in this notice hereinafter.

2. Software changes designed:

Software codes of the functions returning the coordinate values should be reviewed and fixed.
The hybrid system based partly on the ACR-NEMA position localization tags and partly on the DICOM coordinates tags should be unified, with preference given to the DICOM coordinates.
The Volume Cube SW module should check consistency of the data received and should report the understandable description of the status in case of failure, as a hint to the user and support.

3. Release of software with bug-fix

The manufacturer provides a bug-fix to solve this problem and release the updated software.
The release date is scheduled in the end of May 2013.

4. Update of software

The distributor will provide the released software with a bug-fix to end-user customers.
After providing of the released software, users should take care to update their system.

Any possible risk to patients associated with previous use of affected devices

Planning on the stereotactic image series with negative DICOM slice positions (if all the preconditions are met as described above and the slice interferes to the target or trajectory position) may lead to a target displacement of +1 mm, that may harm patient and cause health injury, if not taken in account by the user. The automatic registration can be impossible with such a series.

Advise on action to be taken by the user

1. Always perform the image acquisition of the stereotactic image series in a way that only positive DICOM slice positions are acquired (e.g. the first slice at the ring level is set to ZERO and the other slices show positive increments)
2. In case you obtain image series with negative DICOM slice positions anyway, assure that no slice has DICOM slice positions equal to -1.000.
3. In case any slice has DICOM slice positions equal to -1.000 perform re-slicing of the intended stereotactic series immediately after it is imported (choose preset to maintain original series parameters). Continue planning on the re-sliced image series, and avoid any activity with the original image series.

Transmission of this Field Safety Notice:

This notice needs to be passed on all those who need to be aware within your organization or to any organization where the potentially affected devices have been transferred.

Please transfer this notice to other organizations on which this action has an impact.

Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.

Closing paragraph:

- inomed is informed about and should be aware of the possible risks and limitations in use.
- inomed should inform the customers using PP3 about possible risks and limitations in use.
- TATRAMED as the manufacturer will fix the bug to solve the problem and release the service pack.
- inomed will distribute the released software service pack to the customers using PP3.

We regret any inconvenience related to this and thank you in advance for your cooperation. If you need further information, please contact our representatives or reference persons.

Contact reference person :
Name / organization, address, contact details

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The under sign confirms that this Field Safety Notice has been forwarded to the appropriate Competent Authority (National Institute for Drugs and Medical Devices).

Signature: 

[redacted]quality manager
TATRAMED, spol. s r.o.