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Xstrahl.com

Urgent Field Safety Notice
Xstrahl Concerto 2.x User Interface Software
Ref: TN019
Advice on Use

26th April 2021

Attention: Radiotherapy Personnel, Risk Managers

Dear Customer,

Xstrahl Limited is issuing this Field Safety Notice to advise of an added caution in the use of Concerto 2.x User Interface Software. Our records show you have purchased an Xstrahl system that uses Concerto 2.x User Interface Software.

Description:

A software problem within Concerto 2.0 and above has been identified.

If a saved treatment plan with 2 beams is edited prior to approval, then Beam 2 is not updated with the changed parameters upon selecting save.

This may lead to error messages during the treatment of the plan and possible mistreatment.

This only occurs if 2 opposing beams are defined for a treatment plan and a saved treatment plan is edited prior to approval.

As a precautionary measure, Xstrahl Limited are issuing the following advice until a software update has been implemented and released.

Cont./

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Impact:

This issue may affect treatment plans from January 2018 onwards, from the date of implementation of Concerto 2.0 and above with your Xstrahl Limited radiotherapy system.

If a saved treatment plan with 2 opposing beams (Beam 1 and Beam 2) is edited prior to or during the treatment plan approval, changes to any of the following parameters are **NOT** applied to Beam 2:

- Filter
- Applicator
- Irradiation Duration (monitor unit or unit in time)

Scenario 1 Change in Filter and/or Applicator

- A plan with 2 opposing beams is created and saved with the parameters of:
 - Filter **9**, Applicator **A** and **21** MU.
- The approver when reviewing the plan edits the following values for the field:
 - Filter **5**, Applicator **C** and **21** MU.
- When the edits are saved, the parameters for Beam 1 are updated but the values for Beam 2 are not as follows:
 - Field 1: Filter **5**, Applicator **C** and **21** MU
 - Field 2: Filter **9**, Applicator **A** and **21** MU

It is not possible to identify this issue prior to initiating Beam 2.

When attempting to deliver the plan in this scenario:

For Xstrahl 80, 100, 200 and 300 systems, on initiating Beam 2, a “Filter Encoding Error” or an “Applicator Encoding Error” is displayed.

On 150 systems a “Filter Encoding Error” is displayed.

These error codes will prevent a treatment occurring.

CAUTION:

The Filter, Applicator or Irradiation Duration (Monitor Units or Time) must be the same for each beam. DO NOT attempt to clear these error codes by physically changing the Filter or Applicator. This may result in a mistreatment.

See **Action to be Taken** below on the procedure to clear these codes.

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Scenario 2 Change in Irradiation Duration

- A plan with 2 opposing beams is created and saved with the parameters of:
 - Filter **9**, Applicator **A** and **69** MU.
- The approver when reviewing the plan edits the following values for the field:
 - Filter **9**, Applicator **A** and **42** MU.
- When the edits are saved, the parameters for Beam 1 are updated but the values for Beam 2 are not as follows:
 - Field 1: Filter **9**, Applicator **A** and **42** MU
 - Field 2: Filter **9**, Applicator **A** and **69** MU

It is possible to identify this issue prior to treatment by verifying that the set values of Irradiation Duration in the Treatment Plan screen are the same:

The screenshot shows the 'Treatment Plan [ID1245 X Rays]' interface. At the top, 'Treatment Field Setup' includes 'Filter 1', 'Current 10 mA', 'Voltage 40 kV', 'HVL 1 mm ALUMINIUM', 'Applicator A', 'FSD 20 cm', 'Shape CIRCULAR', and 'Size 3 cm dia.'. To the right, 'Prescribed Dose (MU)' shows 'MU per fraction and target volume: 84', 'No of fractions: 5', 'Total MU: 420', and 'Fractionation:'. Below this, 'Current Fraction: 1 / 5 - (Session Beam 1: 1 - Session Beam 2: 1)' is displayed. The main area shows two beams: 'Beam 1' with 'Description left' and 'MU per fraction: 42 MU' (circled in green), and 'Beam 2' with 'Description right' and 'MU per fraction: 69 MU' (circled in red). Both beams have '50% dose' and 'START SESSION' buttons. At the bottom, navigation buttons include '<< Treatment Site Setup', 'Treatment Field Setup >>', 'Save', 'Close', 'Back to patient list', 'Approve', and 'Terminate treatments'.

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If this issue is not identified prior to initiating Beam 2 no error will be triggered on initiating Beam 2. The 2nd field will be treated with a different "Irradiation Duration" (Monitor Units or Time).

See **Action to be Taken** below on the procedure to mitigate this risk.

Action to be Taken - Concerto 2.x 2 Beam Plans Only:

1. If at the approval stage, a 2 beam plan is identified as requiring amendment, terminate the plan and create a new plan correctly defining the parameters.
2. If at any stage of treatment, a difference in set parameters between Beam 1 and Beam 2 is identified, either through filter or applicator encoding errors or differences in set Irradiation Duration (Monitor Units or Time) do not continue with the treatment.
 - Terminate the plan and create a new plan correctly defining the parameters if no fractions/partial fractions have been administered.
 - Terminate the plan and proceed as in 5 below if any fractions/partial fractions have been administered.
3. Follow your own local rules and radiotherapy professional guidelines and standards for safe radiotherapy and in particular:
 - Verification of set values of Irradiation Duration in the Treatment Plan Screen PRIOR to commencing each treatment.
 - Conduct routine checks of each treatment report and the daily report, specifically checking the SET VALUES of all parameters for Beam 1 and Beam 2 against the PLAN VALUES.
4. Conduct a review of 2 beam treatment plans from January 2018 or the date of implementation of Concerto 2.x with your Xstrahl Limited radiotherapy system, whichever is the latter.

Xstrahl Ltd can provide assistance to you in identifying this information from the radiotherapy system database should you require this. Please contact our Xstrahl Customer Support at helpdesk@xstrahl.com for this.

Please Note. This assistance may require remote access by our team to your system database. In general terms, such access may be prohibited by local regulatory or organisational data protection requirements however, in many cases access to this information is permitted in these circumstances. Again, we can assist you in determining this.

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5. In the case of a plan where any of the parameters are different between Beam 1 and Beam 2 and where one or more fractions have already been delivered, review the actual dose delivered against the prescription and take appropriate action for any clinically significant under or overdose.
6. Please advise Xstrahl Limited of any identified clinically significant under or overdose.

Please complete the attached Medical Device Field Safety Notice Response Form and return it no later than 30 days of the date of this letter to quality@xstrahl.com

Further Information:

Please distribute this information immediately to any staff within your organisation who need to be aware.

Xstrahl Limited has informed the appropriate Regulatory Agencies of this field safety corrective action.

When available, the final corrective action will be to update Concerto v2.x. The above actions should be observed until this update is installed. You will be notified when the software update is available.

Contact:

If you have any questions concerning the information in this Field Safety Notice, please contact Xstrahl Customer Support at helpdesk@xstrahl.com

We appreciate your immediate attention to this matter and apologise for any inconvenience this may have caused.

Yours Sincerely,

A handwritten signature in blue ink, appearing to read 'Tracey'.

Tracey Dimon BEng MSc.H.Dip | Technical Support Director

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26th April 2021

Ref: TN019

Medical Device Field Safety Notice Response Form

Xstrahl Concerto 2.x User Interface Software

I confirm receipt of the Field Safety Notice Ref: TN019 for Xstrahl Concerto 2.x User Interface Software and have read and understood the actions outlined in this notice.

Please provide details of any clinically significant under or overdose associated with this issue identified from your records.

Please Tick (✓)	
	No clinically significant under or overdose events have been identified from our records
	Clinically significant under or overdose events have been identified from our records

In the event of clinically significant under or overdose events having been identified from your records, a representative of Xstrahl Limited will contact you for further details.

Name:		Position:	
Sign:		Date:	
Organisation:		Email:	
System Serial Number:			

PLEASE RETURN COMPLETED AND SIGNED FORM TO EMAIL: quality@Xstrahl.com

It is important that your organisation takes action as detailed in this notice and also replies without delay by using this response form. Your reply is evidence, which Xstrahl Limited and Regulatory Agencies need to monitor the progress of Field Safety Corrective Actions. Without your reply Xstrahl Limited cannot verify the effectiveness or completeness of this Field Safety Corrective Action.

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