Myrian® Safety note

Montpellier, 29th nov. 2022

Dear users,

We contact you to declare a potential patient hazard in our Myrian® software.

Safety issue:

By default, Myrian® hides series of types scout, dose report and other documents to make the workspace clearer and only display series that are made to be visualized by our users.

Today, if a serie contains keywords such as « Scout », « Localizer », « Surview », « LOC », « CAL », « Topogramme », « Dose Report » or « Rapport dose », in the « SeriesDescription (0008,103E) » field, it will automatically be hidden from our interface, considered as an optional serie.
We have noticed that, depending on manufacturers and application engineers, the DICOM field « SeriesDescription » could include words that contain « LOC » or « CAL » even though they are series meant to be interpreted by the user (e.g. if a series contain the words « CliniCAL» or « BLOCK » in its SeriesDescription field, it will be automatically hidden).

These hidden series may lead to a delayed diagnosis from the practitioner and therefore a delayed patient care.

Concerned Myrian® version:

- Myrian® 2.8
- Myrian® 2.9

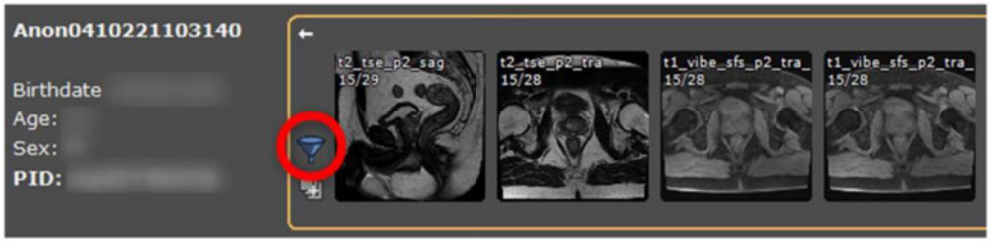
Immediate action:

For Myrian® distributors:
Intrasense requests that all distributors share this safety note to their final users in order to bring awareness on this safety action and ensure implementation of temporary actions until their version upgrade.

Distributors are also requested to acknowledge receipt of this safety note by filling the form in ANNEX A.

For Myrian® users:
DICOM standard is permissive with this field, so modality manufacturers can use it as they wish.

We recommend you to be careful by clicking on the icon hereunder to make sure you do not miss any hidden series that could be useful for your diagnosis:



All users are also requested to acknowledge receipt of this safety note by filling the form in ANNEX B.

Corrective action:

Our investigation performed on Myrian® has identified the root cause of this issue. Therefore, a maintenance version of Myrian® has been developed (maintenance version Myrian® 2.9.12) and will be made available for all users of versions concerned by this safety note.

We apologize for any inconvenience, and we thank you for your understanding.

Transmission of this safety note:

This letter needs to be passed on all those who need to be aware within your organization, or to any organization where the concerned products have been transferred.

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

This letter was already sent to the French Health Authority (ANSM) as well as to the other concerned competent authorities.

Thank you for your understanding.
Kind regards,

Signature

30/11/2022

[redacted]

ANNEX A – Distributor/importer reply form

1. Field Safety Notice (FSN) information	
FSN Reference number	2022-01 – Safety notice
Product/ Device name	Myrian
Version	☐2.8 ☐2.9 ☐Other, specify :
Licence number	

2. Distributor/Importer Details	
Company Name	
Account Number	
Address	
Contact Name	
Title or Function	
Telephone number	
Email	

3. Return acknowledgement to Sender	
Email	regulatory@intrasense.fr
Postal Address	1231 Avenue du Mondial 98 34000 Montpellier (FRANCE)
Deadline for returning the Distributor/Importer reply form	14/12/2022

	4. Distributors/Importers (Tick all that apply)	5. Comment
☐	I confirm the receipt, the reading and understanding of the safety notice	
☐	I have identified customers that received or may have received this device	
☐	I have attached customer list including their contact details to enable the record of the safety case	
☐	I have informed the identified customers of this safety notice	Date of communication:
☐	I have received confirmation of reply from all identified customers	
☐	Neither I nor any of my customers are concerned by this safety note	

By filling this form, your organization takes the actions detailed in this safety notice and confirms that you have received the safety notice.

Your organization's reply is the evidence we need to monitor the progress of the corrective actions.

Name	
Date	
Signature	

ANNEX B – Customer/end user reply form

1. Field Safety Notice (FSN) information	
FSN Reference number	2022-01
Product/ Device name	Myrian
Version	☐2.8 ☐2.9 ☐Other, specify :
Licence number	

2. Customer Details	
Account Number	
Healthcare organisation name	
Address	
Department/unit	
Contact Name	
Title or Function	
Telephone number	
Email	

3. Return acknowledgement to Sender	
Email	regulatory@intrasense.fr
Postal Address	1231 Avenue du Mondial 98 34000 Montpellier (FRANCE)
Deadline for returning the customer/end user reply form	14/12/2022

	4. Customer action undertaken on behalf or healthcare organisation (Tick all that apply)	5. Comment
☐	I confirm the receipt, the reading and understanding of the Field Safety Notice.	
☐	I performed all actions requested by the safety notice.	
☐	The information and required actions have been brought to the attention of all relevant users and executed.	
☐	I am not concerned by this safety note.	
☐	Other action, specify:	
☐	I have a query please contact me.	

By filling this form, your organization takes the actions detailed in this safety notice and confirms that you have received the safety notice.

Your organization's reply is the evidence we need to monitor the progress of the corrective actions.

Name	
Date	
Signature	