Rev 1: September 2018
FSN Ref: M21031-2 FSCA Ref: M21031-2

Date: 3 November 2021

Urgent Field Safety Notice
Moviplan 800

For Attention of*:Dealers and Users with Moviplan 800

Contact details of local representative (name, e-mail, telephone, address etc.)*
This could be a distributor or local branch of the manufacturer. To be added at the appropriate stage in the different local languages

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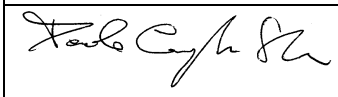
Urgent Field Safety Notice (FSN)
Moviplan 800
Risk addressed by FSN

1. Information on Affected Devices*	
1.	1. Device Type(s)*
	Radiografic unit
1.	2. Commercial name(s)
	Moviplan 800
1.	3. Unique Device Identifier(s) (UDI-DI)
	N/A
1.	4. Primary clinical purpose of device(s)*
	The medical purpose of Moviplan 800 is diagnostic radiology
1.	5. Device Model/Catalogue/part number(s)*
	see attachment 3
1.	6. Software version
	not relevant
1.	7. Affected serial or lot number range
	see attachment 3
1.	8. Associated devices
	N/A

2 Reason for Field Safety Corrective Action (FSCA)*	
2.	1. Description of the product problem*
	It has been found that some support pins for the X-ray tube mounted on the Moviplan 800 column produced in the period April 2020 - March 2021 could have a non compliant welding due to the dimension of the welding throat.
2.	2. Hazard giving rise to the FSCA*
	In the worst case, the welding could break and the x-ray tube + collimator could fall eventually hitting the patient or the operator.
2.	3. Probability of problem arising
	The probability that the x-ray tube + collimator group falls due to breakage of welding is considered “Occasional”
2.	4. Predicted risk to patient/users
	The identified hazard to patient/user is: Mechanical hazard (collision, squeezing) due to the x-ray tube+ collimator group fall due to a broken welding. The risk has severity “Serious”.
2.	5. Further information to help characterise the problem
	1. No case of broken welding happened on Moviplan 800 installed units. 2. Before the pin completely detaches from the plate where it is welded, it begins to rotate inside the plate and this causes loss of x-ray beam centering that is easily detectable by the operator.
2.	6. Background on Issue
	When checking parts collected from warehouse, we found some parts with the weld throat size of 2mm instead of 4mm. We identified a production period of the shaft when the parts could be affected by the non conformity, so the field action is addressed to the units manufactured with shafts manufactured in that period.

	As corrective action, all the non compliant parts in stock have been reworked to make a compliant welding. As preventive action, the Incoming Inspection sampling level on the shaft welding has been increased to 100%.
2.	7. Other information relevant to FSCA
	N/A

	3. Type of Action to mitigate the risk*	
3.	**1. Action To Be Taken by the User***	
	☒ Identify Device ☐ Quarantine Device ☐ Return Device ☐ Destroy Device ☐ On-site device modification/inspection ☐ Follow patient management recommendations ☐ Take note of amendment/reinforcement of Instructions For Use (IFU) ☒ Other ☐ None Request the Service Engineer to perform the actions described in the Service Note NIM003-2021.	
3.	2. By when should the action be completed?	as soon as possible
3.	3. Particular considerations for: Diagnostic Imaging device Is follow-up of patients or review of patients' previous results recommended? No The issue has no impact on the images already taken	
3.	4. Is customer Reply Required? * (If yes, form attached specifying deadline for return)	Yes
3.	**5. Action Being Taken by the Manufacturer** ☐ Product Removal ☒ On-site device modification/inspection ☐ Software upgrade ☐ IFU or labelling change ☐ Other ☐ None Action will be performed by Distributor / Importer according the Service Note NIM003-2021	
3	6. By when should the action be completed?	within 31 May 2022
3.	7. Is the FSN required to be communicated to the patient /lay user?	No
3	8. If yes, has manufacturer provided additional information suitable for the patient/lay user in a patient/lay or non-professional user information letter/sheet?	
	Choose an item. Choose an item.	

	4. General Information*	
4.	1. FSN Type*	New
4.	2. For updated FSN, reference number and date of previous FSN	N/A
4.	3. For Updated FSN, key new information as follows:	
	N/A	
4.	4. Further advice or information already expected in follow-up FSN? *	No
4	5. If follow-up FSN expected, what is the further advice expected to relate to:	
	N/A	
4	6. Anticipated timescale for follow-up FSN	N/A
4.	7. Manufacturer information (For contact details of local representative refer to page 1 of this FSN)	
	a. Company Name	**Villa Sistemi Medicali S.p.A.**
	b. Address	**via delle Azalee 3 - 20090 Buccinasco (MI) - ITALY**
	c. Website address	Only necessary if not evident on letter-head.
4.	8. The Competent (Regulatory) Authority of your country has been informed about this communication to customers. *	
4.	9. List of attachments/appendices:	1. Service Note NIM003-2021 2. Distributor and User reply form 3. List of Affected Units
4.	10. Name/Signature	**Paolo Casagrande Santin** **Quality Assurance Manager**
		

	Transmission of this Field Safety Notice
	This notice needs to be passed on all those who need to be aware within your organisation or to any organisation where the potentially affected devices have been transferred. (As appropriate) Please transfer this notice to other organisations on which this action has an impact. (As appropriate) Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action. Please report all device-related incidents to the manufacturer, distributor or local representative, and the national Competent Authority if appropriate, as this provides important feedback..*

Note: Fields indicated by * are considered necessary for all FSNs. Others are optional.

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Attachment 1

Service Note NIM03-2021

FSN Ref: M21031-2 FSCA Ref: M21031-2

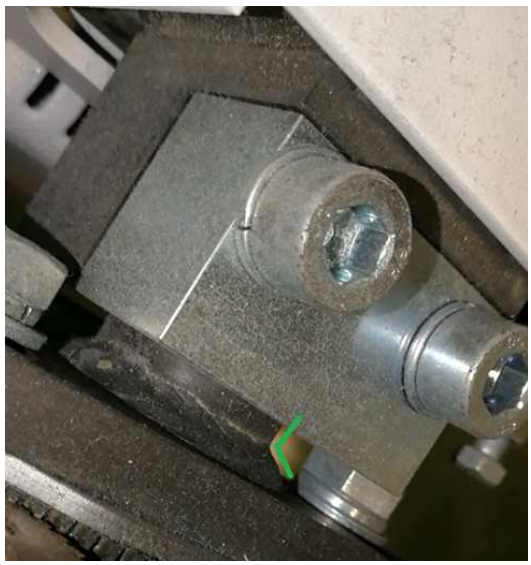
Service Note

N.	NIM003-2021
Date:	*November 3, 2021*
Subject:	*Pin soldering verification*
To:	*Villa dealers*
Equipment:	Moviplan 800

DESCRIZIONE
DESCRIPTION

With this Note, we inform you that the some tube support shaft mounted on Moviplan 800 columns manufactured between April 2020 and March 2021 could have a non compliant welding due to the dimension of the welding throat.
In case you find this type of welding, it is required the tube support replacement.

Just for reference, here following the type of verification to be done in field on installed units, where it is visible, without dismounting x-ray tube, the difference between correct welding, that should have the weld throat size of about 4mm, and non compliant welding



In green you can see the correct weld throat size

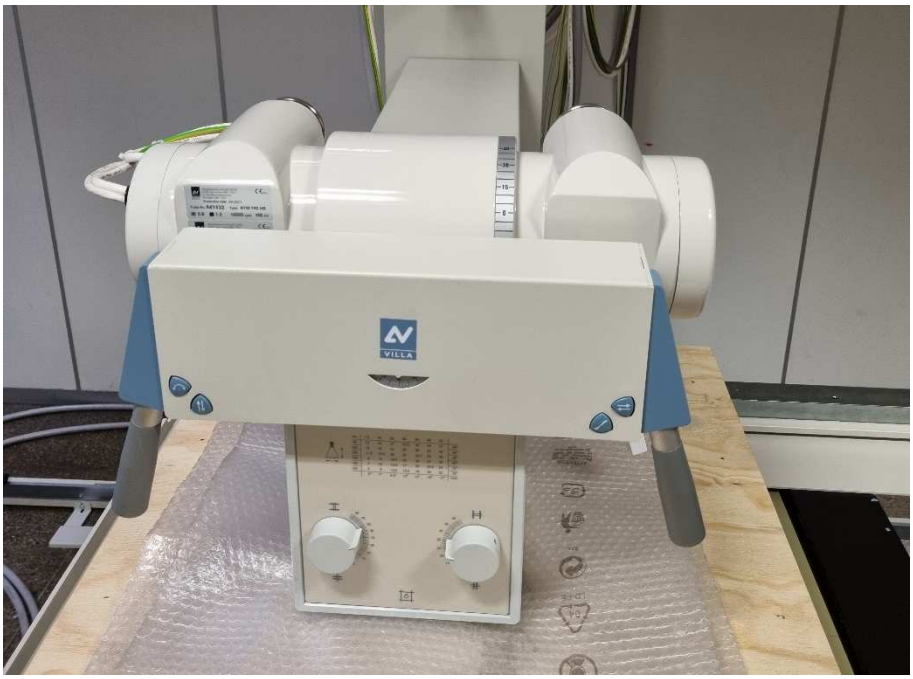
For better understanding, here following the differences between a correct welding (green arrow) and a non compliant welding (red arrow).

In case it is necessary the replacement, the spare part code is:

6174791100 Tube support for Moviplan 800 column

Replacement procedure

Position the column close to the table top centre in order to put on the tube group.
Protect table top surface in order to avoid scratches



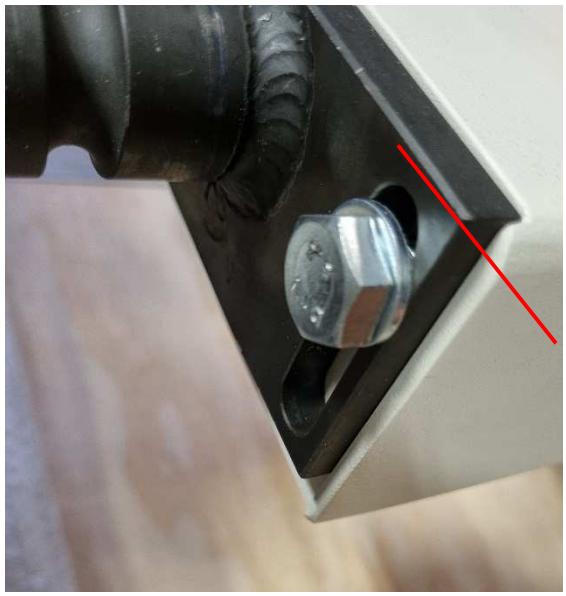
Move bumpers in both sides against the column frame to avoid longitudinal movement of the column during replacement

Position the collimator in touch with table top and fix cursor using a locker plier and moving end run bumpers against cursor

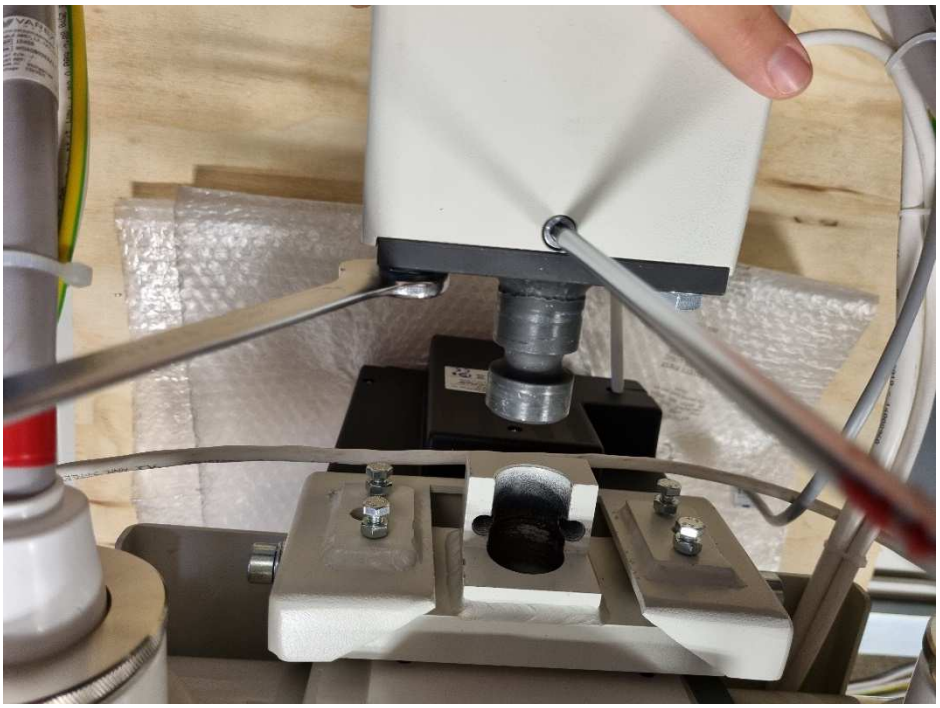
Remove the upper block screws

Pull out the tube group and leave it on the table top

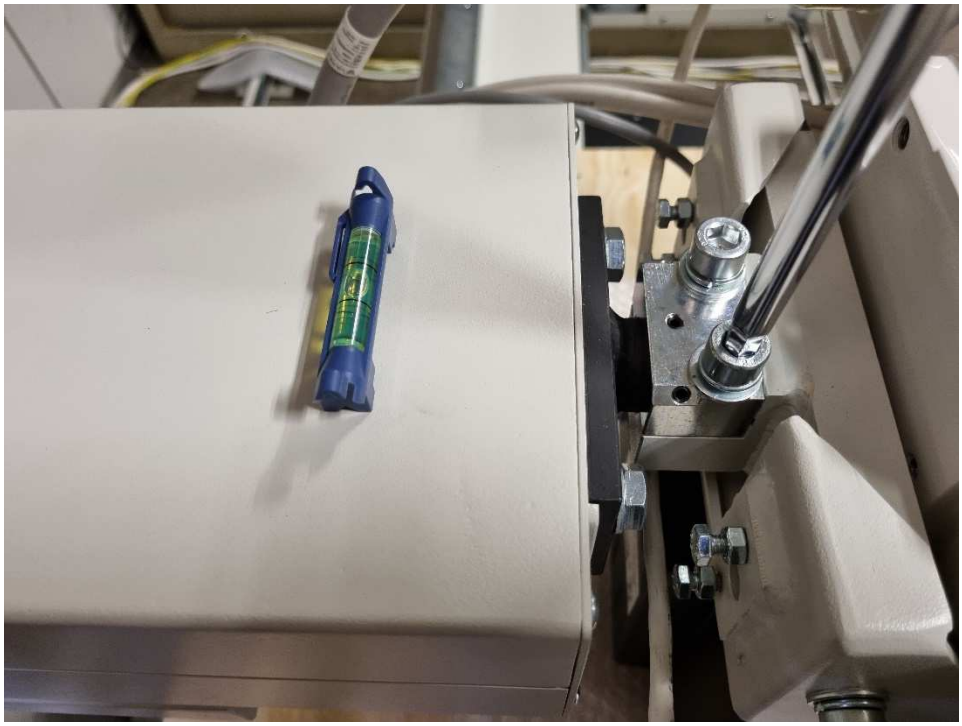
Take a reference of the actual pin position



Remove the three fixing screws before the lateral ones, then the middle one



After pin replacement, mount the tube group, and verify if tune and column are at the same level using an air bubble. Fix the screws. Before fixing the grub screws, verify x-ray beam alignment



Release locking plier and reposition the end run bumpers on column and rails

Once verified the centering, fix the grub screws.

Technical Services Department
Villa Sistemi Medicali
Via Delle Azalee, 3 - 20090 Buccinasco- Milan - ITALY
phone: +39 02 48859288; fax: +39 02 48859222
e-mail : service_support@villasm.com

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Attachment 2

Distributor and User reply forms

Distributor/Importer Reply Form

1. Field Safety Notice (FSN) information	
FSN Reference number*	M21031-2
FSN Date*	3 November 2021
Product/ Device name*	Moviplan 800
Product Code(s)	1 2 3
Batch/Serial Number (s)	1 2 3

2. Distributor/Importer Details	
Company Name*	
Account Number	
Address*	
Shipping address if different to above	
Contact Name*	
Title or Function	
Telephone number*	
Email*	

3. Return acknowledgement to Sender	
Email	p.casagrande@villasm.com; vsmservice@villasm.com
Distributor/Importer Helpline	
Postal Address	Villa Sistemi Medicali S.p.A. via delle Azalee 3, 20090 Buccinasco (MI), ITALY to the attention of Paolo Casagrande Santin
Web Portal	
Deadline for returning the Distributor/Importer reply form*	31 May 2022

4. Distributors/Importers (Tick all that apply)		
☐	*I confirm the receipt, the reading and understanding of the Field Safety Notice.	Distributor/Importer to complete or enter N/A
☐	I have checked my stock and quarantined inventory	Distributor/Importer to enter quantity and date
☐	I have identified customers that received or may have received this device	
☐	I have attached customer list	
☐	I have informed the identified customers of this FSN	Date of communication:
☐	I have received confirmation of reply from all identified customers	
☐	I have returned affected devices - enter number of devices returned and date complete.	Add quantity, Lot/Serial Number/Date Returned (same information as requested by the Customer Reply form
☐	I have destroyed affected devices – enter number destroyed and date complete.	Add quantity, Lot/Serial Number/Date Returned (same information as requested by the Customer Reply form
☐	Neither I nor any of my customers has any affected devices in inventory	
Print Name*		Distributor/Importer print name here
Signature*		Distributor/Importer sign Here
Date *		

Mandatory fields are marked with *

It is important that your organisation takes the actions detailed in the FSN and confirms that you have received the FSN.

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

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Customer Reply Form

1. Field Safety Notice (FSN) information	
FSN Reference number*	M21031-2
FSN Date*	3 November 2021
Product/ Device name*	Moviplan 800
Product Code(s)	
Batch/Serial Number (s)	

2. Customer Details	
Account Number	
Healthcare Organisation Name*	
Organisation Address*	
Department/Unit	
Shipping address if different to above	
Contact Name*	
Title or Function	
Telephone number*	
Email*	

3. Customer action undertaken on behalf of Healthcare Organisation				
☐	I confirm receipt of the Field Safety Notice and that I read and understood its content.	Customer to complete or enter N/A		
☐	I performed all actions requested by the FSN.	Customer to complete or enter N/A		
☐	The information and required actions have been brought to the attention of all relevant users and executed.	Customer to complete or enter N/A		
☐	I have returned affected devices - enter number of devices returned and date complete.	Qty:	Lot/Serial Number:	Date Returned (DD/MM/YY):
		Qty:	Lot/Serial Number:	Date Returned(DD/MM/YY):
		N/A	Comments:	

☐	I have destroyed affected devices – enter number destroyed and date complete.	Qty:	Lot/Serial Number:
		Qty	Lot/Serial Number:
		N/A	Comments:
☐	No affected devices are available for return/ destruction	Customer to complete or enter N/A	
☐	Other Action (Define):		
☐	I do not have any affected devices.	Customer to complete or enter N/A	
☐	I have a query please contact me (e.g. need for replacement of the product).	Customer to enter contact details if different from above and brief description of query	
Print Name*		Customer print name here	
Signature*		Customer sign here	
Date*			

4. Return acknowledgement to sender	
Email	p.casagrande@villasm.com; vsmservice@villasm.com
Customer Helpline	Pre-filled by manufacturer/sender/requester
Postal Address	Villa Sistemi Medicali S.p.A. via delle Azalee 3, 20090 Buccinasco (MI), ITALY to the attention of Paolo Casagrande Santin
Web Portal	Pre-filled by manufacturer/sender/requester
Fax	+39 02 48859 303; +39 02 48859 222
Deadline for returning the customer reply form*	31 May 2022

Mandatory fields are marked with *

It is important that your organisation takes the actions detailed in the FSN and confirms that you have received the FSN.

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

Attachment 3

Affected units (sorted by serial number)

part number	device	serial number
9771100503	MOVIPLAN 800 TA	20034236
9771100503	MOVIPLAN 800 TA	20044237
9771100503	MOVIPLAN 800 TA	20064240
9771100503	MOVIPLAN 800 TA	20074241
9771100503	MOVIPLAN 800 TA	20094248
9771100603	MOVIPLAN 800 TF	20094249
9771100503	MOVIPLAN 800 TA	20114302
9771100503	MOVIPLAN 800 TA	20124303
9771100603	MOVIPLAN 800 TF	20124304
9771101103	MOVIPLAN 800 TA	20124306
9771100903	MOVIPLAN 800 TF	21014307
9771101103	MOVIPLAN 800 TA	21024321
9771101103	MOVIPLAN 800 TA	21034342