



Rev 1: September 2018  
FSN Ref: M21031-1

FSCA Ref: M21031-1

Date: 3 November 2021

## **Urgent Field Safety Notice** **Column iC**

For Attention of\*:Dealers and Users with Column iC

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


**Urgent Field Safety Notice (FSN)**  
**Column iC**  
**Risk addressed by FSN**

<b>1. Information on Affected Devices*</b>	
1	1. Device Type(s)*
.	Floor Mounted Tubestand
1	2. Commercial name(s)
.	Column iC
1	3. Unique Device Identifier(s) (UDI-DI)
.	N/A
1	4. Primary clinical purpose of device(s)*
.	The medical purpose of Column iC 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

<b>2 Reason for Field Safety Corrective Action (FSCA)*</b>	
2	1. Description of the product problem*
.	It has been found that some support pins for the X-ray tube mounted on the Column iC produced in the period April 2014 - 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" and probability "Improbable".
2	5. Further information to help characterise the problem
.	1. Only one case of broken welding happened on installed units without involvement of patient or operator. 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
.	Checking parts collected from warehouse, we found some parts with the weld throat size of 2mm instead of 4mm.

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

3. Type of Action to mitigate the risk*	
3.	<b>1. Action To Be Taken by the User*</b> <div style="display: flex; justify-content: space-between; margin-top: 10px;"> <input checked="" type="checkbox"/> Identify Device           <input type="checkbox"/> Quarantine Device           <input type="checkbox"/> Return Device           <input type="checkbox"/> Destroy Device         </div> <div style="margin-top: 10px;"> <input type="checkbox"/> On-site device modification/inspection  <input type="checkbox"/> Follow patient management recommendations  <input type="checkbox"/> Take note of amendment/reinforcement of Instructions For Use (IFU)  <input checked="" type="checkbox"/> Other <input type="checkbox"/> None         </div> <p>Request the Service Engineer to perform the actions described in the Service Note NIM004-2021e.</p>
3.	<b>2.</b> By when should the action be completed? <span style="float: right;">as soon as possible</span>
3.	<b>3.</b> Particular considerations for: <span style="float: right;">Diagnostic Imaging device</span>  Is follow-up of patients or review of patients' previous results recommended? No The issue has no impact on the images already taken
3.	<b>4. Is customer Reply Required? *</b> <span style="float: right;">Yes</span> (If yes, form attached specifying deadline for return)
3.	<b>5. Action Being Taken by the Manufacturer</b> <div style="display: flex; justify-content: space-between; margin-top: 10px;"> <input type="checkbox"/> Product Removal           <input checked="" type="checkbox"/> On-site device modification/inspection         </div> <div style="margin-top: 10px;"> <input type="checkbox"/> Software upgrade           <input type="checkbox"/> IFU or labelling change         </div> <div style="margin-top: 10px;"> <input type="checkbox"/> Other           <input type="checkbox"/> None         </div> <p>Action will be performed by Distributor / Importer according the Service Note NIM004-2021</p>
3	<b>6.</b> By when should the action be completed? <span style="float: right;">within 31 May 2022</span>
3.	<b>7.</b> Is the FSN required to be communicated to the patient /lay user? <span style="float: right;">No</span>
3	<b>8.</b> If yes, has manufacturer provided additional information suitable for the patient/lay user in a patient/lay or non-professional user information letter/sheet? <div style="display: flex; justify-content: space-between; margin-top: 5px;"> <span>Choose an item.</span> <span>Choose an item.</span> </div>

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: <b>N/A</b>	
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: <b>N/A</b>	
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	<b>Villa Sistemi Medicali S.p.A.</b>
	b. Address	<b>via delle Azalee 3 - 20090 Buccinasco (MI) - ITALY</b>
	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 NIM004-2021 2. Distributor and User reply form 3. List of Affected Units
4.	10. Name/Signature	<b>Paolo Casagrande Santin</b> <b>Quality Assurance Manager</b> 

Transmission of this Field Safety Notice	
	<p>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)</p> <p>Please transfer this notice to other organisations on which this action has an impact. (As appropriate)</p> <p>Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.</p> <p>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..*</p>

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



FSN Ref: M21031-1

FSCA Ref: M21031-1

## **Attachment 1**

### **Service Note NIM04-2021**

## Service Note

N. NIM004-2021

*Date:* November 3, 2021

*Subject:* Pin soldering verification

*To:* Villa dealers with Moviplan iC systems including Column iC

*Equipment:* Column iC

### DESCRIPTION

With this Note, we inform you that the some tube support shaft mounted on Columns iC manufactured between April 2014 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).

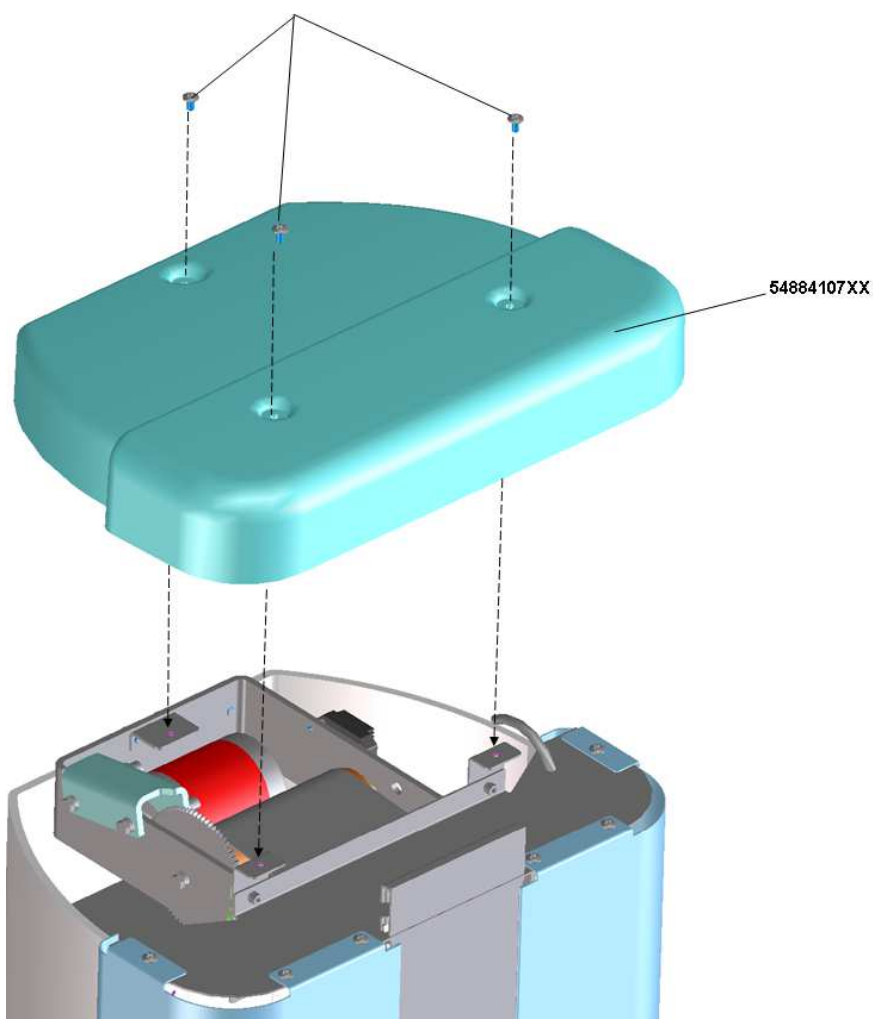


In case it is necessary the replacement, the spare part code is:

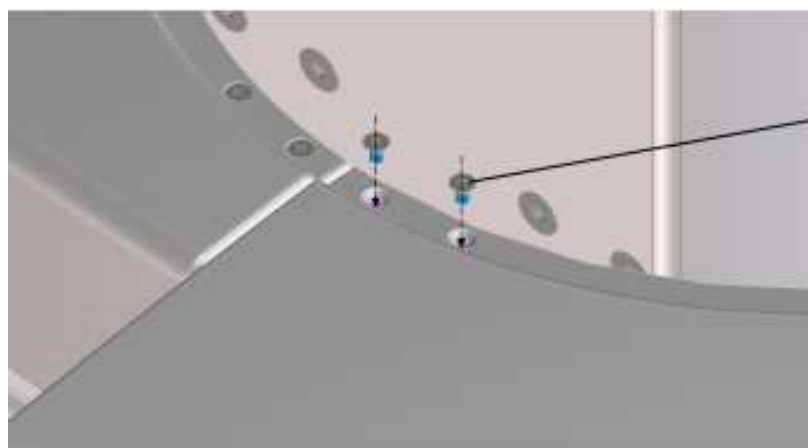
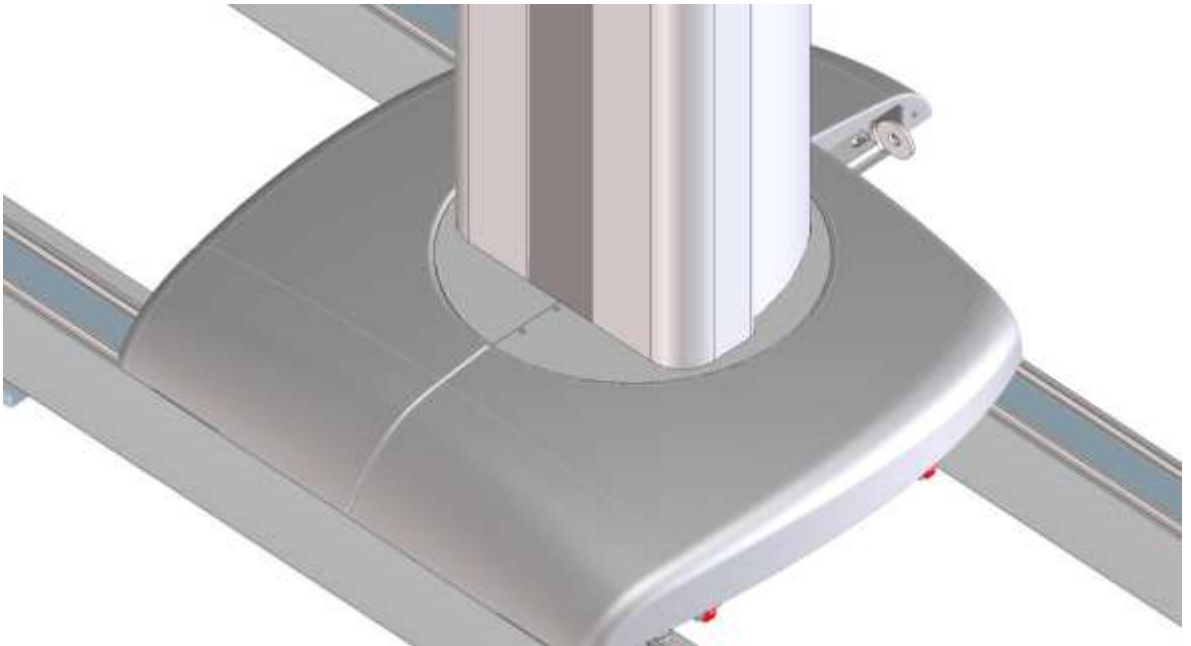
- code 5288701200 pin for Column iC:

## *Replacement procedure*

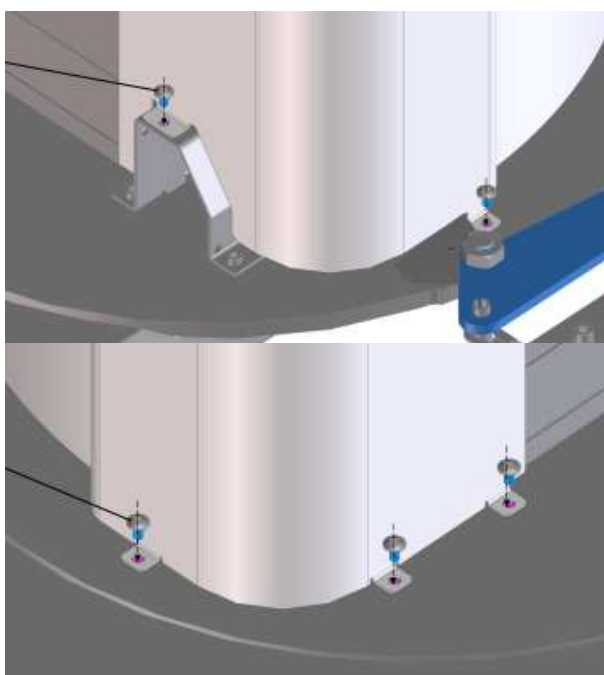
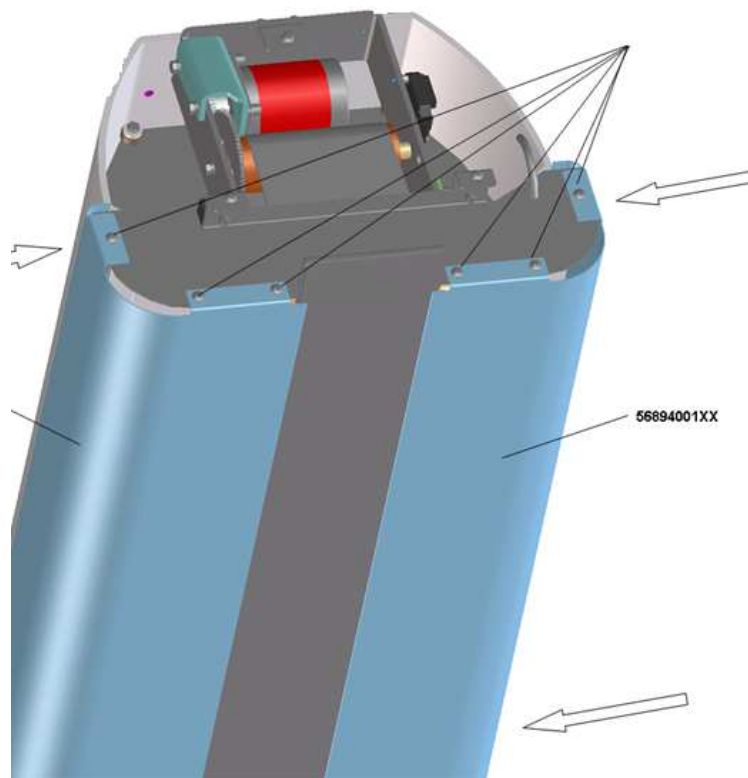
Remove plastic upper cover of the Column iC,



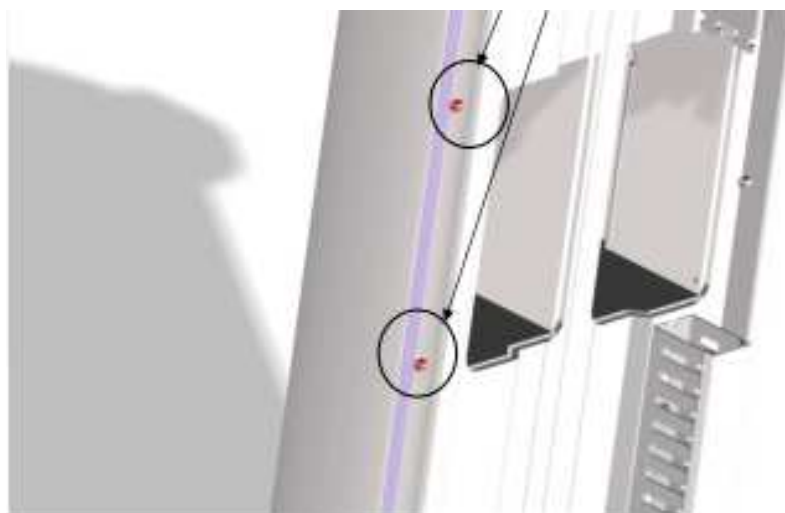
Remove the base covers



Remove lateral covers

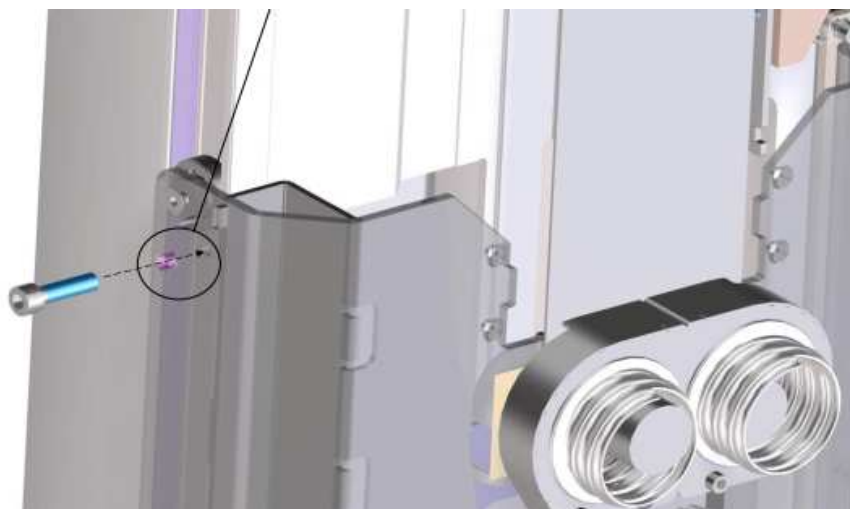


Move the upper part of the counterweight box, depending on the models, the fixing could be front with the two M6 screws in the appropriate holes or lateral with two M5 screws.

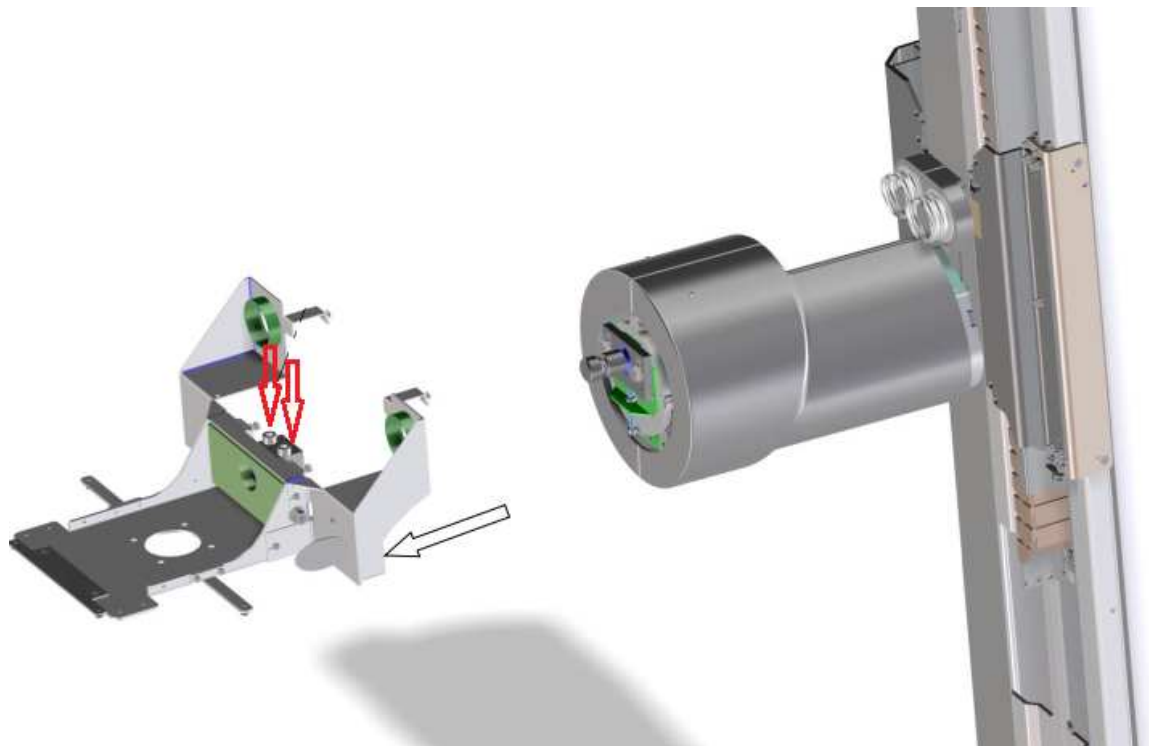


Old systems had fixing screws in front side

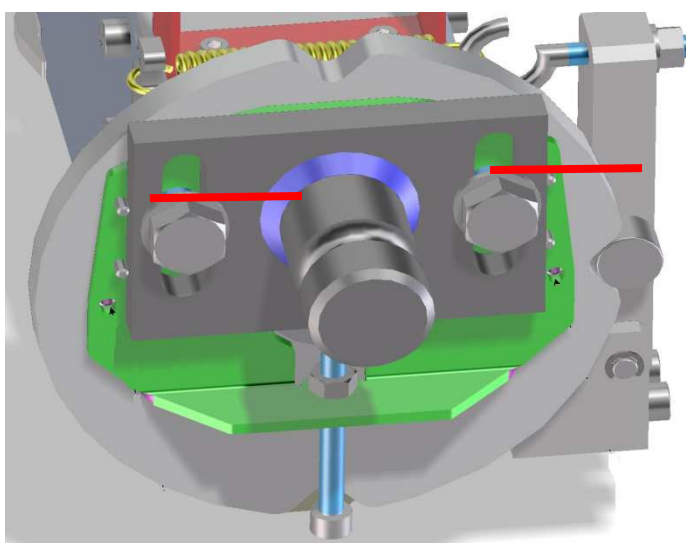




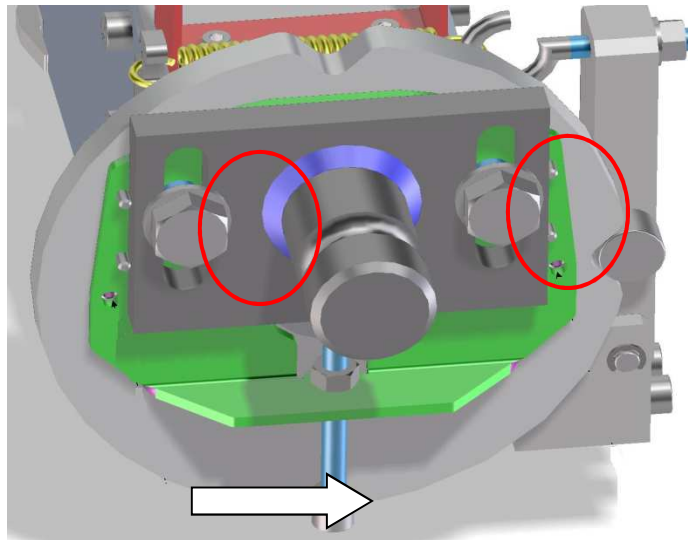
Remove the two screws fixing tube group  
And pull out the tube group



Take note of the pin actual position in order to put the new one in the same position



Loosen the lower screw and remove the rounded screws in order to remove the tube support pin



Replace the pin and mount the new one in the same position then tighten the positioning screw.

Mount the tube group and using air bubble, compare the tube rotation with arm position, then tighten the screws

Remove safety screws and before mounting the column lateral covers, check the alignment of x-ray beam on image receptor

*C. Bena*

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



FSN Ref: M21031-1

FSCA Ref: M21031-1

## **Attachment 2**

### **Distributor and User reply forms**



Rev 1: July 2018

FSN Ref: M21031-1

FSCA Ref: M21031-1

## Distributor/Importer Reply Form

1. Field Safety Notice (FSN) information	
FSN Reference number*	M21031-2
FSN Date*	3 November 2021
Product/ Device name*	Column iC
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	<a href="mailto:p.casagrande@villasm.com">p.casagrande@villasm.com</a> ; <a href="mailto:vsmervice@villasm.com">vsmervice@villasm.com</a>
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)		
<input type="checkbox"/>	*I confirm the receipt, the reading and understanding of the Field Safety Notice.	Distributor/Importer to complete or enter N/A
<input type="checkbox"/>	I have checked my stock and quarantined inventory	Distributor/Importer to enter quantity and date
<input type="checkbox"/>	I have identified customers that received or may have received this device	
<input type="checkbox"/>	I have attached customer list	
<input type="checkbox"/>	I have informed the identified customers of this FSN	Date of communication:
<input type="checkbox"/>	I have received confirmation of reply from all identified customers	
<input type="checkbox"/>	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)
<input type="checkbox"/>	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)
<input type="checkbox"/>	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.



Rev 1: July 2018

FSN Ref: M21031-1

FSCA Ref: M21031-1

## Customer Reply Form

### 1. Field Safety Notice (FSN) information

FSN Reference number*	M21031-2
FSN Date*	3 November 2021
Product/ Device name*	Column iC
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

<input type="checkbox"/>	I confirm receipt of the Field Safety Notice and that I read and understood its content.	Customer to complete or enter N/A		
<input type="checkbox"/>	I performed all actions requested by the FSN.	Customer to complete or enter N/A		
<input type="checkbox"/>	The information and required actions have been brought to the attention of all relevant users and executed.	Customer to complete or enter N/A		
<input type="checkbox"/>	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:	

<input type="checkbox"/>	I have destroyed affected devices – enter number destroyed and date complete.	Qty:	Lot/Serial Number:
		Qty	Lot/Serial Number:
		N/A	Comments:
<input type="checkbox"/>	No affected devices are available for return/ destruction	Customer to complete or enter N/A	
<input type="checkbox"/>	Other Action (Define):		
<input type="checkbox"/>	I do not have any affected devices.	Customer to complete or enter N/A	
<input type="checkbox"/>	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	<a href="mailto:p.casagrande@villasmi.com">p.casagrande@villasmi.com</a> ; <a href="mailto:vsmservice@villasmi.com">vsmservice@villasmi.com</a>
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	serial number
9788153200	15050007
9788030100	15050008
9788030100	15060009
9788153200	15070010
9788211100	15100016
9788030100	15110017
9788153200	16070018
9788030100	16070019
9788030100	16120031
9788153200	17040035
9788030100	17060036
9788153200	17070037
9788153200	17100040
9788030100	17120044
9788153200	18010047
9788153200	18040049
9788133200	18060054
9788030100	18120068
9788030100	18120069

part number	serial number
9788030100	19010070
9788193200	19050073
9788193200	19050074
9788031100	19070080
9788133200	19090081
9788153200	20020094
9788153200	20070115
9788153200	20100125
9788153200	20100126
9788153200	20110130
9788153200	20110131
9788153200	20110132
9788153200	20110133
9788030100	20120134
9788030100	21010136
9788030100	21020138
9788153200	21020139
9788153200	21030140
9788153200	21030141