



FSN Ref: M18022

FSCA Ref: M18022

Date: 23 October 2019

Urgent Field Safety Notice
Apollo, Apollo DRF, Apollo EZ, Apollo EZ DRF

For Attention of: Dealers and Users with Apollo, Apollo DRF, Apollo EZ, Apollo EZ DRF

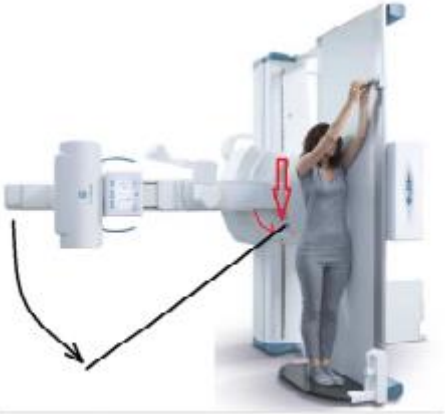
Contact details of local representative (name, e-mail, telephone, address etc.)*
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This could be a distributor or local branch of the manufacturer. To be added at the appropriate stage in the different local languages
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Urgent Field Safety Notice (FSN)
Apollo, Apollo DRF, Apollo EZ, Apollo EZ DRF
Angulation chain issue

1. Information on Affected Devices*	
1.	1. Device Type(s)* Remote controlled table
1.	2. Commercial name(s) Apollo, Apollo DRF, Apollo EZ, Apollo EZ DRF
1.	3. Unique Device Identifier(s) (UDI-DI) N/A
1.	4. Primary clinical purpose of device(s)* Medical purpose is the diagnosis, visualization and documentation of various human diseases or injuries. The system permit the following Clinical applications: Routine X-ray examinations and special examinations on patients in the standing, seated or lying positions. This includes standard radiography and standard fluoroscopy procedures: Lung fluoroscopy, Barium studies of the upper and lower gastro intestinal tract, Other examinations of the digestive tract, Urinary studies (IVP, Cystourethrography), Myelography, Arthrography, Hysterosalpingography, Phlebography, Examinations of the gall-bladder / ERCP, Pediatric examinations, Tomography, X-ray examinations of the skeleton (including skull, ribs, spine, pelvis, upper extremities, lower extremities, etc.), X-ray examinations of the lung, X-ray examinations of soft tissue such as abdomen, Stitching examinations (optional - mostly for lower limbs and spine).
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

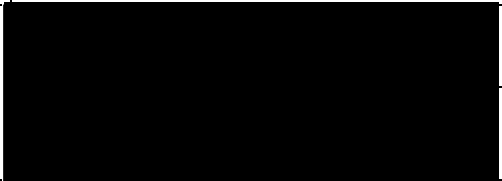
2 Reason for Field Safety Corrective Action (FSCA)*	
2.	1. Description of the product problem* It was found that the angulation chain is very close to the design limit for metal fatigue and, under severe workload conditions might fail before the expected lifetime of 10 years. Therefore, the Ifu and the Service Manual need to be amended to prescribe the replacement of the angulation chain after 8 years of service life of the unit.
2.	2. Hazard giving rise to the FSCA* In case of failure of the chain, the column falls and stops hitting the shoulders of the DRF carrier / SFD as shown in the following picture, so the column does not come in contact with the tabletop since the distance between the tabletop and the collimator, in this condition, is about 0.5 m:

	 <p>Generally, the patient lays on the tabletop and the operator is away from the table, or in the front side.</p> <p>In case this advice is followed, the residual risk is lowered to the initially estimated level, with likelihood lowered to “Improbable” level.</p>
2.	<p>3. Probability of problem arising</p>
	<p>The likelihood is considered Remote (only under severe workload conditions)</p>
2.	<p>4. Predicted risk to patient/users</p>
	<p>The identified hazard is: Mechanical hazard (collision, squeezing) due to the column fall due to a broken chain due to fatigue. The risk has severity “serious” and probability “remote”</p>
2.	<p>5. Further information to help characterise the problem</p>
	<p>Only one case happened, without involvement of patient or operator</p>
2.	<p>6. Background on Issue</p>
	<p>Following information received from field, it was found that the number of tilting cycles for some units used in high-workload environments had to be increased with respect to the initial specifications. After laboratory testing of the current angulation chain, it was found that it is very close to the design limit for metal fatigue and, under severe workload conditions might fail before the expected lifetime of 10 years</p>
2.	<p>7. Other information relevant to FSCA</p>
	<p>N/A</p>

	<p>3. Type of Action to mitigate the risk*</p>	
3.	<p>1. Action To Be Taken by the User*</p> <p>Take note of amendment/reinforcement of Instructions For Use (IFU) and Service Manual, attached to this FSN</p> <p>Replace the attached pages in the User Manual and in the Service Manual, prescribing the periodic replacement of the angulation chain. Fill the table present in the addendum; In the cell “Next replacement date” write the date adding 8 years to the replacement date</p>	
3.	<p>2. By when should the action be completed?</p>	<p>as soon as possible</p>



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 taken	
3.	4. Is customer Reply Required? * (If yes, form attached specifying deadline for return)	Yes
3.	5. Action Being Taken by the Manufacturer An ECO has been implemented in order to adopt a new type of angulation chain, whose design limit for metal fatigue exceeds the expected lifetime of 10 years. Instructions For Use (IFU) and Service Manual have been updated to prescribe the replacement of the angulation chain after 10 years of service life of the unit.	
3	6. By when should the action be completed?	The action is already completed: first unit with new type of chain and updated IfU and Service Manual is the unit with s/n 19102065 manufactured on October 2019
3.	7. Is the FSN required to be communicated to the patient /lay user?	No

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
4.	8. The Competent (Regulatory) Authority of your country has been informed about this communication to customers. *	
4.	9. List of attachments/appendices:	1. IfU and Service Manual addendum 2. Distributor and User reply form 3. List of Affected Units
4.	10. Name/Signature	



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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.</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>



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Attachment 1

IfU and Service Manual Addendum



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Addendum to
Apollo / Apollo EZ / Apollo
DRF / Apollo EZ DRF
User's Manual

The User's Manual provided with your equipment does not include all the Maintenance information for the device.

Please insert the following pages at the beginning of chapter Maintenance of your User's Manual.

All other specifications are unchanged with respect to the ones provided in your Manual.

User Manual Addendum

The expected service life for Apollo angulation chain is 8 years.

Contact your service organization in order to plan the intervention once the unit is close to reach the next replacement date given in the table below.

At replacement, FSE will fill the column “Next replacement date” adding 8 years to the replacement date in both User and Service Manual

Angulation chain replacement date (dd – mm – yyyy)	Reason of the replacement corrective maintenance / planned maintenance	next replacement date mm/yyyy	Executed by Organization (FSE Name)	Date / Signature

Betriebsanleitung Nachtrag

Die erwartete Lebensdauer für die Apollo Angulationskette beträgt 8 Jahre.

Wenden Sie sich an Ihre Serviceorganisation, um den Eingriff zu planen, sobald der in der folgenden Tabelle angegebene nächste Austauschdatum für Ihr Gerät näher rückt.

Beim Austausch wird der FSE in der Spalte “Nächster Austauschtermin” in der Betriebsanleitung und im Servicehandbuch 8 Jahre zum Austauschdatum hinzufügen.

Austauschdatum Angulationskette (tt – mm – jjjj)	Austauschgrund korrektive Wartung/ planmäßige Wartung	nächster Austauschtermin mm/jjjj	Ausgeführt durch die Organisation (Name des FSE)	Datum / Unterschrift

Apéndice del manual de usuario

La vida útil prevista de la cadena de angulación del Apollo es de 8 años. Contacte con su empresa de mantenimiento para planificar la intervención cuando la unidad se aproxime a la próxima fecha de sustitución indicada en la tabla siguiente. Con ocasión de la sustitución, el FSE rellenará la columna «Próxima fecha de sustitución» añadiendo 8 años a la fecha de sustitución en el manual del usuario y en el manual de mantenimiento

Fecha de sustitución de la cadena de angulación (dd – mm – aaaa)	Motivo de la sustitución mantenimiento correctivo / mantenimiento programado	próxima fecha de sustitución mm/aaaa	Realizado por la empresa (nombre del FSE)	Fecha / Firma

Addendum al manuale d'Uso

La vita utile prevista per la catena di angolazione del telecomando Apollo è di 8 anni. Contatta il Servizio Tecnico locale per pianificare l'intervento quando la macchina è prossima al raggiungimento della data di sostituzione successiva indicata nella seguente tabella.

A sostituzione avvenuta, il FSE compilerà la colonna «Prossima data di sostituzione» sia nel manuale d'Uso che di Service aggiungendo 8 anni all'ultima data di sostituzione

Data di sostituzione catena angolazione (dd – mm – aaaa)	Motivo della sostituzione manutenzione correttiva/ manutenzione programmata	Prossima data di sostituzione mm/aaaa	Eseguito dal Centro Assistenza (nome del FSE)	Data / Firma

Addenda au manuel d'utilisation

La durée de vie prévue de la chaîne d'inclinaison Apollo est de 8 ans.
 Contactez votre entreprise d'entretien afin de planifier l'intervention lorsque l'unité est près d'atteindre la prochaine date de remplacement indiquée dans le tableau ci-dessous.
 Lors du remplacement, le FSE remplira la colonne « Prochaine date de remplacement » en ajoutant 8 ans à la date de remplacement dans le manuel d'utilisation et de service

Date de remplacement de la chaîne d'inclinaison (jj- mm - aaaa)	Motif du remplacement entretien correctif / entretien programmé	prochaine date de remplacement mm/aaaa	Exécuté par Entreprise (nom FSE)	Date / Signature

Addendum van gebruikershandleiding

De verwachte levensduur van de ketting voor hoekinstelling van Apollo is 8 jaar.
 Neem contact op met uw serviceorganisatie om de werkzaamheid te organiseren zodra de unit de datum voor de volgende vervanging, die in de onderstaande tabel staat, nadert.
 Tijdens de vervanging vult de FSE de kolom "Datum volgende vervanging" in en voegt 8 jaar toe aan de datum voor vervanging zowel in de gebruikershandleiding als in de onderhoudshandleiding

Datum vervanging ketting voor hoekinstelling (dd - mm - jjjj)	Reden van vervanging correctief onderhoud / gepland onderhoud	datum volgende vervanging mm/jjjj	Uitgevoerd door de organisatie (naam van FSE)	Datum / Handtekening

Anexo ao manual do usuário

A vida útil prevista da corrente de angulação Apollo é de 8 anos.

Entre em contato com o seu fornecedor para planificar a substituição quando a próxima data de substituição, indicada na tabela abaixo, estiver perto de ser alcançada.

Durante a substituição, o FSE deverá preencher a coluna “Próxima data de substituição”, acrescentando 8 anos à data de substituição no manual de serviço e no manual do usuário

Data de substituição da corrente de angulação (dd - mm - aaaa)	Motivo da substituição manutenção de correção / manutenção programada	próxima substituição data mm/aaaa	Realizada pela organização (nome do FSE)	Data / Assinatura

Дополнение к руководству по эксплуатации

Расчетный срок эксплуатации поворотной цепи Apollo составляет 8 лет.

Свяжитесь с сервисным центром для плановой замены, когда срок эксплуатации узла будет заканчиваться (см. далее таблицу с датами замены).

При замене специалист по техобслуживанию (FSE) заполнит столбец "Дата следующей замены", добавив 8 лет к текущей дате в "Руководстве пользователя" и "Руководстве по техническому обслуживанию"

Дата замены поворотной цепи (дд - мм - гггг)	Причина замены ремонтное обслуживание / плановое техобслуживание	следующая дата замены, мм / гггг	Выполнено организацией (имя FSE)	Дата / подпись

Анекă ла мануалул де утилizare

Durata de exploatare preconizată pentru lanțul de transmisie este de 8 ani.
 Contactați furnizorul de service local pentru a planifica intervenția odată ce produsul se apropie de următoarea dată de înlocuire specificată în tabelul de mai jos.
 Cu ocazia înlocuirii, FSE va completa coloana Următoarea dată de înlocuire adăugând 8 ani la data de înlocuire atât în manualul de utilizare cât și în cel de service

Data de înlocuire a lanțului de transmisie (zz – ll – aaaa)	Motivul înlocuirii întreținere corectivă / întreținere programată	următoarea dată de înlocuire ll/aaaa	Executată de societatea (numele FSE)	Data / Semnătura

Допълнение към Ръководството за Потребителя

Очакваният експлоатационен живот на ъгловата верига Apollo е 8 години.
 Обърнете се към сервизното обслужване, за да планирате следващата смяна, когато устройството наближи датата, посочена в таблицата по-долу.
 След смяната, FSE трябва да попълни колоната “Дата за следваща смяна”, като добави 8 години към датата, както в Ръководството за Потребителя, така и в Ръководството за обслужване

Дата за смяна на ъгловата верига (дд – мм – гггг)	Причина за смяната коригираща поддръжка / планирана поддръжка	следваща дата за смяна мм/гггг	Изпълнена от Организация (Име FSE)	Дата / Подпис



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Addendum to
Apollo / Apollo EZ / Apollo
DRF / Apollo EZ DRF
Service Manuals

The Service Manual provided with your equipment does not include all the Maintenance information for the device.

Please insert the following pages at the beginning of chapter “Maintenance and Cleaning” of your Service Manual.

All other specifications are unchanged with respect to the ones provided in your Manual.



Service Manual Addendum

9.2 Parts to be replaced periodically

The expected lifetime of Apollo angulation chain is 8 years. After the operation time of 8 years, the following part must be replaced:

Code	Description	Replace after	Installation date
6690702200	Angulation chain	Every 8 years	

At replacement, FSE have to fill the column “Next replacement date” adding 8 years to the replacement date in both User and Service Manual

Angulation chain replacement date (dd – mm – yyyy)	Reason of the replacement corrective maintenance / planned maintenance	next replacement date mm/yyyy	Executed by Organization (FSE Name)	Date / Signature



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Attachment 2

Distributor and User reply forms



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Distributor/Importer Reply Form

1. Field Safety Notice (FSN) information	
FSN Reference number*	M18022
FSN Date*	23 October 2019
Product/ Device name*	Apollo, Apollo DRF, Apollo EZ, Apollo EZ DRF
Product Code(s)	
Batch/Serial Number (s)	

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

3. Return acknowledgement to Sender	
Email	p.casagrande@villasm.com ; vsmservice@villasm.com
Postal Address	Villa Sistemi Medicali S.p.A. via delle Azalee 3, 20090 Buccinasco (MI), ITALY to the attention of Paolo Casagrande Santin
Deadline for returning the Distributor/Importer reply form*	31 December 2019



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"/>	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*	M18022
FSN Date*	23 October 2019
Product/ Device name*	Apollo, Apollo DRF, Apollo EZ, Apollo EZ DRF
Product Code(s)	
Batch/Serial Number (s)	

2. Customer Details	
Account Number	
Healthcare Organisation Name*	
Organisation Address*	
Department/Unit	
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"/>	Other Action (Define):	
<input type="checkbox"/>	I do not have any affected devices.	Customer to complete or enter N/A



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<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*		

1. Return acknowledgement to sender	
Email	p.casagrande@villasm.com ; vsmervice@villasm.com
Postal Address	Villa Sistemi Medicali S.p.A. via delle Azalee 3, 20090 Buccinasco (MI), ITALY to the attention of Paolo Casagrande Santin
Fax	+39 02 48859 303; +39 02 48859 222
Deadline for returning the customer reply form*	31 December 2019

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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Attachment 3

Affected units (sorted by serial number)



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part number	serial number
9784200813	07120452
9784120013	07120455
9784220813	08010462
9784100231	08020473
9784220813	08040483
9784120113	08040484
9784120113	08040485
9784120013	08040486
9784120113	08050487
9784120113	08050488
9784120113	08050489
9784220813	08050490
9784120113	08060494
9784120113	08060495
9784120113	08060496
9784120113	08060497
9784120113	08060498
9784220813	08070499
9784120113	08070500
9784120231	08070501
9784220813	08070503
9784120113	08070508
9784120013	08070510
9784120013	08090525
9784220831	08090531
9784110013	08100538
9784120013	08100540
9784120013	09010565
9784220813	09010569
9784120013	09010571
9784229813	09020572
9784229813	09020573
9784229813	09020574
9784229813	09020575
9784229813	09020576
9784229813	09020577
9784120013	09040586
9784120113	09050588
9784229813	09060591
9784220813	09060594
9784120013	09070595
9784120113	09070597
9784220813	09070598
9784220813	09070599

part number	serial number
9784219813	09070601
9784220831	09090591
9784120013	09090606
9784120013	09090610
9784120013	09090611
9784120013	09090612
9784120013	09090613
9784120013	09090614
9784120013	09090615
9784120013	09090616
9784120013	09090617
9784120013	09100618
9784120113	09100619
9784120013	09100620
9784120013	09100621
9784120013	09100627
9784120013	09100629
9784120013	09100630
9784120013	09100631
9784229813	09110632
9784229813	09110633
9784219813	09110634
9784239813	09110635
9784120013	09110637
9784120013	09110638
9784120113	09110639
9784120113	09110640
9784120113	09110642
9784120113	09110643
9784120113	09110644
9784120113	09110645
9784229813	09120654
9784229813	09120655
9784120013	09120659
9784120013	10010661
9784109113	10010669
9784129113	10020672
9784129113	10030675
9784129113	10030676
9784129113	10030677
9784220831	10040680
9784220813	10050683
9784229813	10060696
9784229813	10060702



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part number	serial number
9784100113	10080726
9784170013	10080728
9784129113	10080729
9784252813	10090748
9784153013	10100756
9784229813	10100761
9784229813	10110769
9784120113	10120782
9784120213	10120783
9784220813	10120785
9784220813	10120786
9784142013	11010789
9784120013	11010791
9784129213	11010793
9784220831	11020798
9784152013	11020800
9784219813	11020802
9784142013	11020804
9784229813	11030807
9784120413	11030809
9784100013	11040816
9784152013	11040817
9784152013	11040821
9784119213	11040822
9784270813	11050827
9784120013	11050828
9784220813	11050829
9784220813	11050830
9784153013	11060832
9784143013	11060835
9784129113	11060839
9784152013	11070840
9784170013	11070843
9784220813	11070851
9784153013	11090863
9784239813	11090868
9784120131	11100873
9784120013	11100874
9784120113	11100883
9784120113	11100885
9784229813	11110897
9784120113	11110899
9784229813	11110905
9784229813	11110906
9784229813	11110907

part number	serial number
9784229813	11110908
9784120113	11120912
9784229813	11120917
9784242813	11120921
9784142013	11120922
9784142013	11120923
9784142013	11120924
9784142013	11120925
9784270813	11120927
9784170013	11120928
9784100013	12010948
9784120113	12010969
9784120113	12010970
9784239813	12010972
9784239813	12010973
9784279813	12020980
9784229813	12020987
9784270813	12020988
9784270813	12030991
9784120013	12031000
9784279813	12041001
9784279813	12041002
9784120113	12041005
9784279813	12051007
9784219813	12061015
9784252813	12061016
9784252813	12061022
9784120113	12071027
9784120113	12071028
9784120113	12071030
9784120113	12071037
9784120113	12071038
9784120113	12081041
9784120113	12081042
9784120113	12081043
9784120113	12081048
9784229813	12081049
9784152013	12091053
9784120113	12091057
9784120113	12091058
9784120113	12091059
9784120113	12091060
9784220813	12091061
9784220813	12091062
9784220813	12091063



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part number	serial number
9784220813	12091064
9784239813	12091065
9784120113	12091066
9784120113	12091067
9784120113	12091068
9784239813	12101078
9784120113	12101079
9784120113	12101080
9784120113	12101081
9784120013	12101082
9784120113	12101091
9784120113	12101092
9784120113	12101093
9784120113	12101094
9784120113	12101095
9784220813	12101096
9784120113	12101097
9784279813	12101098
9784219813	12101103
9784120113	12101109
9784220813	12101110
9784220813	12101111
9784220813	12101112
9784120113	12101113
9784152013	12111128
9784120113	12111129
9784120113	12111130
9784120113	12111134
9784120113	12111135
9784239813	12111140
9784120113	12111141
9784120113	12111142
9784120113	12111143
9784120113	12111144
9784120113	12111145
9784120113	12111146
9784120113	12111147
9784120113	12111148
9784120113	12111149
9784220813	12121158
9784220813	12121162
9784220813	12121165
9784220813	12121166
9784200813	12121176
9784120113	13011190

part number	serial number
9784152013	13011194
9784220813	13011199
9784220813	13011202
9784229813	13021206
9784229813	13021207
9784120113	13021208
9784252813	13041223
9784280813	13041224
9784142013	13061232
9784220813	13061234
9784142013	13071238
9784129113	13071244
9784152036	13101261
9784229813	13101270
9784229813	13111271
9784229813	13111272
9784120113	13111276
9784270813	13121284
9784142013	13121285
9784252813	14011290
9784153013	14011292
9784220813	14011293
9784279813	14021300
9784139213	14021303
9784279813	14041315
9784229813	14051336
9784154113	14061338
9784239813	14071348
9784120113	14071349
9784252813	14071351
9784220813	14081360
9784142013	14091361
9784279813	14091364
9784279813	14091365
9784252813	14101377
9784255813	14101378
9784239813	14101379
9784239813	14111385
9784209813	14111387
9784242813	14111388
9784255813	14111393
9784220813	14111398
9784152013	14111399
9784142013	14121401
9784142013	14121402



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part number	serial number
9784155013	14121404
9784220813	14121405
9784279813	15011412
9784270813	15011414
9784252813	15011415
9784220813	15011417
9784239813	15011420
9784279813	15021428
9784252813	15031434
9784130013	15031436
9784130131	15041446
9784279813	15041447
9784220831	15051450
9784142013	15051458
9784229813	15071465
9784229813	15071470
9784252813	15071472
9784285813	15091476
9784153013	15091481
9784270813	15101485
9784255813	15101494
9784252813	15111492
9784255813	15111493
9784252813	15111495
9784252813	15111496
9784229813	16011506
9784279813	16011508
9784279813	16021513
9784142013	16031519
9784229813	16041529
9784152013	16041536
9784229813	16051542
9784270813	16051543
9784279813	16061545
9784252813	16061550
9784270813	16071555
9784252813	16081560
9784170013	16081561
9784252813	16091565
9784242813	16101571
9784252813	16101572
9784252813	16111581
9784229813	16111584
9784220813	16111588
9784229813	16121589

part number	serial number
9784142013	16121590
9784142013	16121594
9784220831	17011602
9784220813	17021615
9784229813	17021616
9784229813	17031630
9784142013	17041633
9784152013	17041635
9784220831	17041639
9784229813	17041643
9784152013	17041645
9784239813	17051651
9784152013	17061666
9784252813	17061675
9784270813	17071681
9784229813	17071682
9784279813	17081695
9784279813	17081697
9784270813	17091705
9784242813	17091708
9784155013	17091712
9784279813	17101721
9784229813	17101731
9784239813	17101737
9784152013	17111742
9784220813	17111744
9784220813	17111746
9784170013	17111768
9784220813	17121778
9784155013	18011792
9784129113	18011798
9784279813	18021805
9784G95313	18031819
9784120013	18031820
9784G75313	18031821
9784279813	18031823
9784K45313	18031824
9784242813	18031825
9784G95313	18031826
9784NB2213	18041827
9784G75313	18041828
9784G95313	18051837
9784142013	18061847
9784G95313	18061849
9784G75313	18071850



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part number	serial number
9784139013	18071852
9784G75313	18071856
9784G95313	18081867
9784142013	18091871
9784252813	18091879
9784G95313	18101894
9784K55313	18101900
9784G95313	18101901
9784152013	18101902
9784142013	18111908
9784G95313	18111909
9784G95313	18111914
9784NB2213	18111915
9784NB2213	18111916
9784NB2213	18121917
9784J90213	18121919
9784G95313	19011927
9784142013	19021937
9784G95313	19021939
9784G75313	19021941
9784G95313	19031945
9784142013	19031948
9784G75313	19041960
9784G95313	19041966
9784NA0013	19041967
9784G95313	19051975
9784G95313	19051977
9784NB0213	19051978
9784G95313	19062003
9784229813	19052013
9784K55313	19072019
9784K45313	19072022
9784K45313	19072025
9784NB0013	19082032
9784G95313	19082033
9784K55313	19092042
9784G95313	19092051
9784K55313	19102063



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Date: 23 October 2019

Urgent Field Safety Notice
Clinodigit EVO

For Attention of: Dealers and Users with Cinodigit EVO

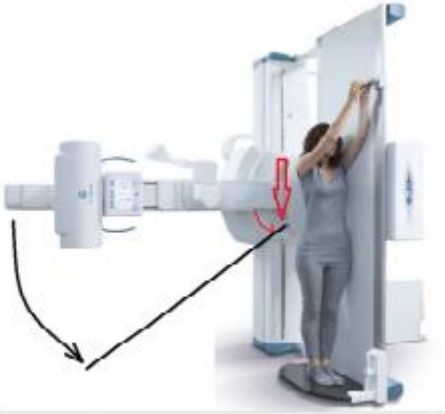
Contact details of local representative (name, e-mail, telephone, address etc.)*
This could be a distributor or local branch of the manufacturer. To be added at the appropriate stage in the different local languages



Urgent Field Safety Notice (FSN)
Clinodigit EVO
Angulation chain issue

1. Information on Affected Devices*	
1.	1. Device Type(s)* Remote controlled table
1.	2. Commercial name(s) Clinodigit EVO
1.	3. Unique Device Identifier(s) (UDI-DI) N/A
1.	4. Primary clinical purpose of device(s)* Medical purpose is the diagnosis, visualization and documentation of various human diseases or injuries. The system permit the following Clinical applications: Routine X-ray examinations and special examinations on patients in the standing, seated or lying positions. This includes standard radiography and standard fluoroscopy procedures: Lung fluoroscopy, Barium studies of the upper and lower gastro intestinal tract, Other examinations of the digestive tract, Urinary studies (IVP, Cystourethrography), Myelography, Arthrography, Hysterosalpingography, Phlebography, Examinations of the gall-bladder / ERCP, Pediatric examinations, Tomography, X-ray examinations of the skeleton (including skull, ribs, spine, pelvis, upper extremities, lower extremities, etc.), X-ray examinations of the lung, X-ray examinations of soft tissue such as abdomen, Stitching examinations (optional - mostly for lower limbs and spine).
1.	5. Device Model/Catalogue/part number(s)* 9784520013
1.	6. Software version not relevant
1.	7. Affected serial or lot number range 15101490, 15111497, 16011509
1.	8. Associated devices N/A

2 Reason for Field Safety Corrective Action (FSCA)*	
2.	1. Description of the product problem* It was found that the angulation chain is very close to the design limit for metal fatigue and, under severe workload conditions might fail before the expected lifetime of 10 years. Therefore, the Ifu and the Service Manual need to be amended to prescribe the replacement of the angulation chain after 8 years of service life of the unit.
2.	2. Hazard giving rise to the FSCA* In case of failure of the chain, the column falls and stops hitting the shoulders of the DRF carrier / SFD as shown in the following picture, so the column does not come in contact with the tabletop since the distance between the tabletop and the collimator, in this condition, is about 0.5 m:

	 <p>Generally, the patient lays on the tabletop and the operator is away from the table, or in the front side.</p> <p>In case this advice is followed, the residual risk is lowered to the initially estimated level, with likelihood lowered to “Improbable” level.</p>
2.	<p>3. Probability of problem arising</p>
	<p>The likelihood is considered Remote (only under severe workload conditions)</p>
2.	<p>4. Predicted risk to patient/users</p>
	<p>The identified hazard is: Mechanical hazard (collision, squeezing) due to the column fall due to a broken chain due to fatigue. The risk has severity “serious” and probability “remote”</p>
2.	<p>5. Further information to help characterise the problem</p>
	<p>Only one case happened, without involvement of patient or operator</p>
2.	<p>6. Background on Issue</p>
	<p>Following information received from field, it was found that the number of tilting cycles for some units used in high-workload environments had to be increased with respect to the initial specifications. After laboratory testing of the current angulation chain, it was found that it is very close to the design limit for metal fatigue and, under severe workload conditions might fail before the expected lifetime of 10 years</p>
2.	<p>7. Other information relevant to FSCA</p>
	<p>N/A</p>

	<p>3. Type of Action to mitigate the risk*</p>	
3.	<p>1. Action To Be Taken by the User*</p> <p>Take note of amendment/reinforcement of Instructions For Use (IFU) and Service Manual, attached to this FSN.</p> <p>Replace the attached pages in the User Manual and in the Service Manual, prescribing the periodic replacement of the angulation chain. Fill the table present in the addendum; In the cell “Next replacement date” write the date adding 8 years to the replacement date</p>	
3.	<p>2. By when should the action be completed?</p>	<p>as soon as possible</p>



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 taken	
3.	4. Is customer Reply Required? * (If yes, form attached specifying deadline for return)	Yes
3.	5. Action Being Taken by the Manufacturer An ECO has been implemented in order to adopt a new type of angulation chain, whose design limit for metal fatigue exceeds the expected lifetime of 10 years. Instructions For Use (IFU) and Service Manual have been updated to prescribe the replacement of the angulation chain after 10 years of service life of the unit.	
3	6. By when should the action be completed?	The action is already completed: first unit with new type of chain and updated IfU and Service Manual is the unit with s/n 19102065 manufactured on October 2019
3.	7. Is the FSN required to be communicated to the patient /lay user?	No

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
4.	8. The Competent (Regulatory) Authority of your country has been informed about this communication to customers. *	
4.	9. List of attachments/appendices:	1. IfU and Service Manual addendum 2. Distributor and User reply form
4.	10. Name/Signature	



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	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.</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>



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Attachment 1

IfU and Service Manual Addendum



FSN Ref: M18022

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Addendum to

Clinodigit EVO

User's Manual

The User's Manual provided with your equipment does not include all the Maintenance information for the device.

Please insert the following pages at the beginning of chapter Maintenance of your User's Manual.

All other specifications are unchanged with respect to the ones provided in your Manual.

User Manual Addendum

The expected service life for Clinodigit EVO angulation chain is 8 years.

Contact your service organization in order to plan the intervention once the unit is close to reach the next replacement date given in the table below.

At replacement, FSE will fill the column “Next replacement date” adding 8 years to the replacement date in both User and Service Manual

Angulation chain replacement date (dd – mm – yyyy)	Reason of the replacement corrective maintenance / planned maintenance	next replacement date mm/yyyy	Executed by Organization (FSE Name)	Date / Signature

Betriebsanleitung Nachtrag

Die erwartete Lebensdauer für die Clinodigit EVO Angulationskette beträgt 8 Jahre.

Wenden Sie sich an Ihre Serviceorganisation, um den Eingriff zu planen, sobald der in der folgenden Tabelle angegebene nächste Austauschdatum für Ihr Gerät näher rückt.

Beim Austausch wird der FSE in der Spalte “Nächster Austauschtermin” in der Betriebsanleitung und im Servicehandbuch 8 Jahre zum Austauschdatum hinzufügen.

Austauschdatum Angulationskette (tt – mm – jjjj)	Austauschgrund korrektive Wartung/ planmäßige Wartung	nächster Austauschtermin mm/jjjj	Ausgeführt durch die Organisation (Name des FSE)	Datum / Unterschrift

Apéndice del manual de usuario

La vida útil prevista de la cadena de angulación del Clinodigit EVO es de 8 años. Contacte con su empresa de mantenimiento para planificar la intervención cuando la unidad se aproxime a la próxima fecha de sustitución indicada en la tabla siguiente. Con ocasión de la sustitución, el FSE rellenará la columna «Próxima fecha de sustitución» añadiendo 8 años a la fecha de sustitución en el manual del usuario y en el manual de mantenimiento

Fecha de sustitución de la cadena de angulación (dd – mm – aaaa)	Motivo de la sustitución mantenimiento correctivo / mantenimiento programado	próxima fecha de sustitución mm/aaaa	Realizado por la empresa (nombre del FSE)	Fecha / Firma

Addendum al manuale d'Uso

La vita utile prevista per la catena di angolazione del telecomando Clinodigit EVO è di 8 anni.

Contatta il Servizio Tecnico locale per pianificare l'intervento quando la macchina è prossima al raggiungimento della data di sostituzione successiva indicata nella seguente tabella.

A sostituzione avvenuta, il FSE compilerà la colonna «Prossima data di sostituzione» sia nel manuale d'Uso che di Service aggiungendo 8 anni all'ultima data di sostituzione

Data di sostituzione catena angolazione (dd – mm – aaaa)	Motivo della sostituzione manutenzione correttiva/ manutenzione programmata	Prossima data di sostituzione mm/aaaa	Eseguito dal Centro Assistenza (nome del FSE)	Data / Firma

Addenda au manuel d'utilisation

La durée de vie prévue de la chaîne d'inclinaison Clinodigit EVO est de 8 ans.
 Contactez votre entreprise d'entretien afin de planifier l'intervention lorsque l'unité est près d'atteindre la prochaine date de remplacement indiquée dans le tableau ci-dessous.
 Lors du remplacement, le FSE remplira la colonne « Prochaine date de remplacement » en ajoutant 8 ans à la date de remplacement dans le manuel d'utilisation et de service

Date de remplacement de la chaîne d'inclinaison (jj- mm - aaaa)	Motif du remplacement entretien correctif / entretien programmé	prochaine date de remplacement mm/aaaa	Exécuté par Entreprise (nom FSE)	Date / Signature

Addendum van gebruikershandleiding

De verwachte levensduur van de ketting voor hoekinstelling van Clinodigit EVO is 8 jaar.
 Neem contact op met uw serviceorganisatie om de werkzaamheid te organiseren zodra de unit de datum voor de volgende vervanging, die in de onderstaande tabel staat, nadert.
 Tijdens de vervanging vult de FSE de kolom "Datum volgende vervanging" in en voegt 8 jaar toe aan de datum voor vervanging zowel in de gebruikershandleiding als in de onderhoudshandleiding

Datum vervanging ketting voor hoekinstelling (dd - mm - jjjj)	Reden van vervanging correctief onderhoud / gepland onderhoud	datum volgende vervanging mm/jjjj	Uitgevoerd door de organisatie (naam van FSE)	Datum / Handtekening

Anexo ao manual do usuário

A vida útil prevista da corrente de angulação Clinodigit EVO é de 8 anos.

Entre em contato com o seu fornecedor para planificar a substituição quando a próxima data de substituição, indicada na tabela abaixo, estiver perto de ser alcançada.

Durante a substituição, o FSE deverá preencher a coluna “Próxima data de substituição”, acrescentando 8 anos à data de substituição no manual de serviço e no manual do usuário

Data de substituição da corrente de angulação (dd - mm - aaaa)	Motivo da substituição manutenção de correção / manutenção programada	próxima substituição data mm/aaaa	Realizada pela organização (nome do FSE)	Data / Assinatura

Дополнение к руководству по эксплуатации

Расчетный срок эксплуатации поворотной цепи Clinodigit EVO составляет 8 лет.

Свяжитесь с сервисным центром для плановой замены, когда срок эксплуатации узла будет заканчиваться (см. далее таблицу с датами замены).

При замене специалист по техобслуживанию (FSE) заполнит столбец "Дата следующей замены", добавив 8 лет к текущей дате в "Руководстве пользователя" и "Руководстве по техническому обслуживанию"

Дата замены поворотной цепи (дд - мм - гггг)	Причина замены ремонтное обслуживание / плановое техобслуживание	следующая дата замены, мм / гггг	Выполнено организацией (имя FSE)	Дата / подпись

Анекă ла мануалул де утилizare

Дурата де експлоатаре прекоизатă пентру ланџул де трансмисие есте де 8 ани.

Контактаџи фуърнизорул де сервисе локал пентру а планифика интервенџия одаџă це продусул се апропие де урмăтоареа датă де ѓнлоцире специфичатă ѓн табелул де май жоу.

Су оцазия ѓнлоцирии, FSE ва коплета колоана Урмăтоареа датă де ѓнлоцире адăугăнд 8 ани ла дата де ѓнлоцире атџт ѓн мануалул де утилizare кџт џи ѓн цел де сервисе

Дата де ѓнлоцире а ланџулу де трансмисие (zz – ll – aaaa)	Мотивул ѓнлоцирии ѓнтреџинере корективă / ѓнтреџинере програматă	урмăтоареа датă де ѓнлоцире ll/aaaa	Екзекуатă де societatea (numele FSE)	Дата / Semnătura

Допълнение кџм Рџководството за Потребителя

Очакванияџт експлоатационен живот на џгловата верига Clinodigit EVO години.

Обърнете се кџм сервисното обслужване, за да планирате следваџтата смяна, когато устройството наблџжи датата, посочена в таблицата по-долу.

След смяната, FSE трябва да попълни колоната “Дата за следваџта смяна”, като добави 8 години кџм датата, кџкто в Рџководството за Потребителя, така и в Рџководството за обслужване

Дата за смяна на џгловата верига (дд – мм – гггг)	Причина за смяната коригираџа поддрџжа / планирана поддрџжа	следваџта дата за смяна мм/гггг	Изпълнена от Организация (Име FSE)	Дата / Подпис



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Addendum to

Clinodigit EVO

Service Manuals

The Service Manual provided with your equipment does not include all the Maintenance information for the device.

Please insert the following pages at the beginning of chapter “Maintenance and Cleaning” of your Service Manual.

All other specifications are unchanged with respect to the ones provided in your Manual.



Service Manual Addendum

9.2 Parts to be replaced periodically

The expected lifetime of Clinodigit EVO angulation chain is 8 years. After the operation time of 8 years, the following part must be replaced:

Code	Description	Replace after	Installation date
6690702200	Angulation chain	Every 8 years	

At replacement, FSE have to fill the column “Next replacement date” adding 8 years to the replacement date in both User and Service Manual

Angulation chain replacement date (dd - mm - yyyy)	Reason of the replacement corrective maintenance / planned maintenance	next replacement date mm/yyyy	Executed by Organization (FSE Name)	Date / Signature



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Attachment 2

Distributor and User reply forms



FSN Ref: M18022

FSCA Ref: M18022

Distributor/Importer Reply Form

1. Field Safety Notice (FSN) information	
FSN Reference number*	M18022
FSN Date*	23 October 2019
Product/ Device name*	Clinodigit EVO
Product Code(s)	
Batch/Serial Number (s)	

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

3. Return acknowledgement to Sender	
Email	p.casagrande@villasm.com ; vsmservice@villasm.com
Postal Address	Villa Sistemi Medicali S.p.A. via delle Azalee 3, 20090 Buccinasco (MI), ITALY to the attention of Paolo Casagrande Santin
Deadline for returning the Distributor/Importer reply form*	31 December 2019



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"/>	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*	M18022
FSN Date*	23 October 2019
Product/ Device name*	Clinodigit EVO
Product Code(s)	
Batch/Serial Number (s)	

2. Customer Details	
Account Number	
Healthcare Organisation Name*	
Organisation Address*	
Department/Unit	
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"/>	Other Action (Define):	
<input type="checkbox"/>	I do not have any affected devices.	Customer to complete or enter N/A



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<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	p.casagrande@villasm.com ; vsmervice@villasm.com
Postal Address	Villa Sistemi Medicali S.p.A. via delle Azalee 3, 20090 Buccinasco (MI), ITALY to the attention of Paolo Casagrande Santin
Fax	+39 02 48859 303; +39 02 48859 222
Deadline for returning the customer reply form*	31 December 2019

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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Date: 23 October 2019

Urgent Field Safety Notice
Juno DRF

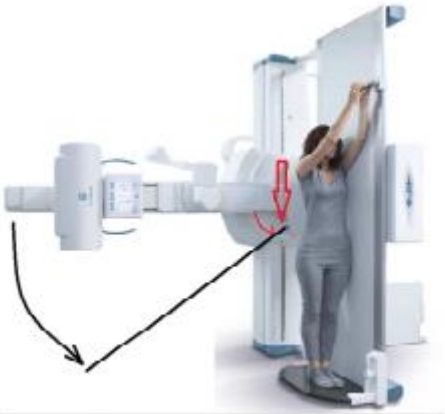
For Attention of: Dealers and Users with Juno DRF

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

Urgent Field Safety Notice (FSN)
Juno DRF
Angulation chain issue

1. Information on Affected Devices*	
1.	1. Device Type(s)* Remote controlled table
1.	2. Commercial name(s) Juno DRF
1.	3. Unique Device Identifier(s) (UDI-DI) N/A
1.	4. Primary clinical purpose of device(s)* Medical purpose is the diagnosis, visualization and documentation of various human diseases or injuries. The system permit the following Clinical applications: Routine X-ray examinations and special examinations on patients in the standing, seated or lying positions. This includes standard radiography and standard fluoroscopy procedures: Lung fluoroscopy, Barium studies of the upper and lower gastro intestinal tract, Other examinations of the digestive tract, Urinary studies (IVP, Cystourethrography), Myelography, Arthrography, Hysterosalpingography, Phlebography, Examinations of the gall-bladder / ERCP, Pediatric examinations, Tomography, X-ray examinations of the skeleton (including skull, ribs, spine, pelvis, upper extremities, lower extremities, etc.), X-ray examinations of the lung, X-ray examinations of soft tissue such as abdomen, Stitching examinations (optional - mostly for lower limbs and spine).
1.	5. Device Model/Catalogue/part number(s)* 709020 (Villa Sistemi Medicali part numbers: 9784729816 and 9784729831)
1.	6. Software version not relevant
1.	7. Affected serial or lot number range all serial numbers
1.	8. Associated devices N/A

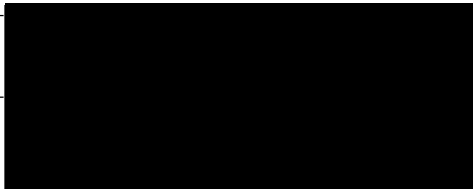
2 Reason for Field Safety Corrective Action (FSCA)*	
2.	1. Description of the product problem* It was found that the angulation chain is very close to the design limit for metal fatigue and, under severe workload conditions might fail before the expected lifetime of 10 years. Therefore, the Ifu and the Service Manual need to be amended to prescribe the replacement of the angulation chain after 8 years of service life of the unit.
2.	2. Hazard giving rise to the FSCA* In case of failure of the chain, the column falls and stops hitting the shoulders of the DRF carrier / SFD as shown in the following picture, so the column does not come in contact with the tabletop since the distance between the tabletop and the collimator, in this condition, is about 0.5 m:

	 <p>Generally, the patient lays on the tabletop and the operator is away from the table, or in the front side.</p> <p>In case this advice is followed, the residual risk is lowered to the initially estimated level, with likelihood lowered to “Improbable” level.</p>
2.	<p>3. Probability of problem arising</p>
	<p>The likelihood is considered Remote (only under severe workload conditions)</p>
2.	<p>4. Predicted risk to patient/users</p>
	<p>The identified hazard is: Mechanical hazard (collision, squeezing) due to the column fall due to a broken chain due to fatigue. The risk has severity “serious” and probability “remote”</p>
2.	<p>5. Further information to help characterise the problem</p>
	<p>Only one case happened, without involvement of patient or operator</p>
2.	<p>6. Background on Issue</p>
	<p>Following information received from field, it was found that the number of tilting cycles for some units used in high-workload environments had to be increased with respect to the initial specifications. After laboratory testing of the current angulation chain, it was found that it is very close to the design limit for metal fatigue and, under severe workload conditions might fail before the expected lifetime of 10 years</p>
2.	<p>7. Other information relevant to FSCA</p>
	<p>N/A</p>

	<p>3. Type of Action to mitigate the risk*</p>	
3.	<p>1. Action To Be Taken by the User*</p> <p>Take note of amendment/reinforcement of Instructions For Use (IFU) and Service Manual, attached to this FSN</p> <p>Replace the attached pages in the User Manual and in the Service Manual, prescribing the periodic replacement of the angulation chain. Fill the table present in the addendum; In the cell “Next replacement date” write the date adding 8 years to the replacement date</p>	
3.	<p>2. By when should the action be completed?</p>	<p>as soon as possible</p>



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 taken	
3.	4. Is customer Reply Required? * (If yes, form attached specifying deadline for return)	Yes
3.	5. Action Being Taken by the Manufacturer None The product is no more manufactured, so only field action is applicable	
3	6. By when should the action be completed?	N.A.
3.	7. Is the FSN required to be communicated to the patient /lay user?	No

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
4.	8. The Competent (Regulatory) Authority of your country has been informed about this communication to customers. *	
4.	9. List of attachments/appendices:	1. IfU and Service Manual addendum
4.	10. Name/Signature	



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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.</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>



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Attachment 1

IfU and Service Manual Addendum



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FSCA Ref: M18022

Addendum to Juno DRF User's Manual

The User's Manual provided with your equipment does not include all the Maintenance information for the device.
Please insert the following pages at the beginning of chapter 11 of your User's Manual.
All other specifications are unchanged with respect to the ones provided in your Manual.



User Manual Addendum

The expected service life for Juno DRF angulation chain is 8 years.

Contact your service organization in order to plan the intervention once the unit is close to reach the next replacement date given in the table below.

At replacement, FSE will fill the column “Next replacement date” adding 8 years to the replacement date in both User and Service Manual

Angulation chain replacement date (dd – mm – yyyy)	Reason of the replacement FCO/corrective maintenance / planned maintenance	next replacement date mm/yyyy	Executed by Organization (FSE Name)	Date / Signature
	FCO70900046			

Betriebsanleitung Nachtrag

Die erwartete Lebensdauer für die Juno DRF Angulationskette beträgt 8 Jahre.

Wenden Sie sich an Ihre Serviceorganisation, um den Eingriff zu planen, sobald der in der folgenden Tabelle angegebene nächste Austauschdatum für Ihr Gerät näher rückt.

Beim Austausch wird der FSE in der Spalte “Nächster Austauschtermin” in der Betriebsanleitung und im Servicehandbuch 8 Jahre zum Austauschdatum hinzufügen.

Austauschdatum Angulationskette (tt – mm – jjjj)	Austauschgrund FCO/ korrektive Wartung/ planmäßige Wartung	nächster Austauschtermin mm/jjjj	Ausgeführt durch die Organisation (Name des FSE)	Datum / Unterschrift
	FCO70900046			

Apéndice del manual de usuario

La vida útil prevista de la cadena de angulación del Juno DRF es de 8 años. Contacte con su empresa de mantenimiento para planificar la intervención cuando la unidad se aproxime a la próxima fecha de sustitución indicada en la tabla siguiente. Con ocasión de la sustitución, el FSE rellenará la columna «Próxima fecha de sustitución» añadiendo 8 años a la fecha de sustitución en el manual del usuario y en el manual de mantenimiento

Fecha de sustitución de la cadena de angulación (dd – mm – aaaa)	Motivo de la sustitución FCO / mantenimiento correctivo / mantenimiento programado	próxima fecha de sustitución mm/aaaa	Realizado por la empresa (nombre del FSE)	Fecha / Firma
	FCO70900046			

Addendum al manuale d'Uso

La vita utile prevista per la catena di angolazione del Juno DRF è di 8 anni. Contatta il Servizio Tecnico locale per pianificare l'intervento quando la macchina è prossima al raggiungimento della data di sostituzione successiva indicata nella seguente tabella.

A sostituzione avvenuta, il FSE compilerà la colonna «Prossima data di sostituzione» sia nel manuale d'Uso che di Service aggiungendo 8 anni all'ultima data di sostituzione

Data di sostituzione catena angolazione (dd – mm – aaaa)	Motivo della sostituzione FCO / manutenzione correttiva/ manutenzione programmata	Prossima data di sostituzione mm/aaaa	Eseguito dal Centro Assistenza (nome del FSE)	Data / Firma
	FCO70900046			

Addenda au manuel d'utilisation

La durée de vie prévue de la chaîne d'inclinaison Juno DRF est de 8 ans.

Contactez votre entreprise d'entretien afin de planifier l'intervention lorsque l'unité est près d'atteindre la prochaine date de remplacement indiquée dans le tableau ci-dessous.

Lors du remplacement, le FSE remplira la colonne « Prochaine date de remplacement » en ajoutant 8 ans à la date de remplacement dans le manuel d'utilisation et de service

Date de remplacement de la chaîne d'inclinaison (jj- mm - aaaa)	Motif du remplacement FCO/ entretien correctif / entretien programmé	prochaine date de remplacement mm/aaaa	Exécuté par Entreprise (nom FSE)	Date / Signature
	FCO70900046			

Addendum van gebruikershandleiding

De verwachte levensduur van de ketting voor hoekinstelling van Juno DRF is 8 jaar.

Neem contact op met uw serviceorganisatie om de werkzaamheid te organiseren zodra de unit de datum voor de volgende vervanging, die in de onderstaande tabel staat, nadert.

Tijdens de vervanging vult de FSE de kolom "Datum volgende vervanging" in en voegt 8 jaar toe aan de datum voor vervanging zowel in de gebruikershandleiding als in de onderhoudshandleiding

Datum vervanging ketting voor hoekinstelling (dd - mm - jjjj)	Reden van vervanging FCO/correctief onderhoud / gepland onderhoud	datum volgende vervanging mm/jjjj	Uitgevoerd door de organisatie (naam van FSE)	Datum / Handtekening
	FCO70900046			

Anexo ao manual do usuário

A vida útil prevista da corrente de angulação Juno DRF é de 8 anos.

Entre em contato com o seu fornecedor para planificar a substituição quando a próxima data de substituição, indicada na tabela abaixo, estiver perto de ser alcançada.

Durante a substituição, o FSE deverá preencher a coluna “Próxima data de substituição”, acrescentando 8 anos à data de substituição no manual de serviço e no manual do usuário

Data de substituição da corrente de angulação (dd - mm - aaaa)	Motivo da substituição FCO / manutenção de correção / manutenção programada	próxima substituição data mm/aaaa	Realizada pela organização (nome do FSE)	Data / Assinatura
	FCO70900046			

Дополнение к руководству по эксплуатации

Расчетный срок эксплуатации поворотной цепи Juno DRF составляет 8 лет.

Свяжитесь с сервисным центром для плановой замены, когда срок эксплуатации узла будет заканчиваться (см. далее таблицу с датами замены).

При замене специалист по техобслуживанию (FSE) заполнит столбец "Дата следующей замены", добавив 8 лет к текущей дате в "Руководстве пользователя" и "Руководстве по техническому обслуживанию"

Дата замены поворотной цепи (дд - мм - гггг)	Причина замены FCO / ремонтное обслуживание / плановое техобслуживание	следующая дата замены, мм / гггг	Выполнено организацией (имя FSE)	Дата / подпись
	FCO70900046			

Anexă la manualul de utilizare

Durata de exploatare preconizată pentru lanțul de transmisie este de 8 ani.

Contactați furnizorul de service local pentru a planifica intervenția odată ce produsul se apropie de următoarea dată de înlocuire specificată în tabelul de mai jos.

Cu ocazia înlocuirii, FSE va completa coloana Următoarea dată de înlocuire adăugând 8 ani la data de înlocuire atât în manualul de utilizare cât și în cel de service

Data de înlocuire a lanțului de transmisie (zz - ll - aaaa)	Motivul înlocuirii FCO/întreținere corectivă / întreținere programată	următoarea dată de înlocuire ll/aaaa	Executată de societatea (numele FSE)	Data / Semnătura
	FCO70900046			

Допълнение към Ръководството за Потребителя

Очакваният експлоатационен живот на ъгловата верига Juno DRF е 8 години.

Обърнете се към сервизното обслужване, за да планирате следващата смяна, когато устройството наближи датата, посочена в таблицата по-долу.

След смяната, FSE трябва да попълни колоната “Дата за следваща смяна”, като добави 8 години към датата, както в Ръководството за Потребителя, така и в Ръководството за обслужване

Дата за смяна на ъгловата верига (дд - мм - гггг)	Причина за смяната FCO / коригираща поддръжка / планирана поддръжка	следваща дата за смяна мм/гггг	Изпълнена от Организация (Име FSE)	Дата / Подпис
	FCO70900046			



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FSCA Ref: M18022

Addendum to Juno DRF Service Manual

The Service Manual provided with your equipment does not include all the Maintenance information for the device.

Please insert the following pages at the beginning of chapter 22 of your Service Manual. All other specifications are unchanged with respect to the ones provided in your Manual.



Service Manual Addendum

9.2 Parts to be replaced periodically

The expected lifetime of Juno DRF angulation chain is 8 years. After the operation time of 8 years, the following part must be replaced:

Code	Description	Replace after	Installation date
4512-134-49941	Angulation chain	Every 8 years	

At replacement, FSE have to fill the column “Next replacement date” adding 8 years to the replacement date in both User and Service Manual

Angulation chain replacement date (dd – mm – yyyy)	Reason of the replacement FCO/corrective maintenance / planned maintenance	next replacement date mm/yyyy	Executed by Organization (FSE Name)	Date / Signature
	FCO70900046			



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Attachment 2

Distributor and User reply forms



FSN Ref: M18022

FSCA Ref: M18022

Distributor/Importer Reply Form

1. Field Safety Notice (FSN) information	
FSN Reference number*	M18022
FSN Date*	23 October 2019
Product/ Device name*	Juno DRF
Product Code(s)	
Batch/Serial Number (s)	

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

3. Return acknowledgement to Sender	
Email	p.casagrande@villasm.com ; vsmservice@villasm.com
Postal Address	Villa Sistemi Medicali S.p.A. via delle Azalee 3, 20090 Buccinasco (MI), ITALY to the attention of Paolo Casagrande Santin
Deadline for returning the Distributor/Importer reply form*	31 December 2019



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"/>	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.



FSN Ref: M18022

FSCA Ref: M18022

Customer Reply Form

1. Field Safety Notice (FSN) information	
FSN Reference number*	M18022
FSN Date*	23 October 2019
Product/ Device name*	Juno DRF
Product Code(s)	
Batch/Serial Number (s)	

2. Customer Details	
Account Number	
Healthcare Organisation Name*	
Organisation Address*	
Department/Unit	
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"/>	Other Action (Define):	
<input type="checkbox"/>	I do not have any affected devices.	Customer to complete or enter N/A



FSN Ref: M18022

FSCA Ref: M18022

<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	p.casagrande@villasm.com ; vsmervice@villasm.com
Postal Address	Villa Sistemi Medicali S.p.A. via delle Azalee 3, 20090 Buccinasco (MI), ITALY to the attention of Paolo Casagrande Santin
Fax	+39 02 48859 303; +39 02 48859 222
Deadline for returning the customer reply form*	31 December 2019

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.