



FSN Ref: M18022

FSCA Ref: M18022

Date: 23 October 2019

**Urgent Field Safety Notice**  
**Clinodigit EVO**

**For Attention of:** Dealers and Users with Cinodigit EVO

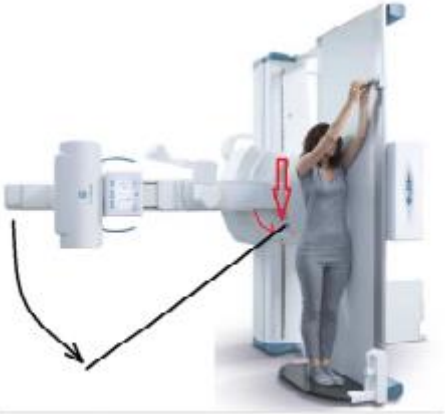
Contact details of local representative (name, e-mail, telephone, address etc.)*
This could be a distributor or local branch of the manufacturer. To be added at the appropriate stage in the different local languages



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

<b>1. Information on Affected Devices*</b>	
1.	1. <b>Device Type(s)*</b> Remote controlled table
1.	2. <b>Commercial name(s)</b> Clinodigit EVO
1.	3. <b>Unique Device Identifier(s) (UDI-DI)</b> N/A
1.	4. <b>Primary clinical purpose of device(s)*</b> 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. <b>Device Model/Catalogue/part number(s)*</b> 9784520013
1.	6. <b>Software version</b> not relevant
1.	7. <b>Affected serial or lot number range</b> 15101490, 15111497, 16011509
1.	8. <b>Associated devices</b> N/A


<b>2 Reason for Field Safety Corrective Action (FSCA)*</b>	
2.	1. <b>Description of the product problem*</b> 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. <b>Hazard giving rise to the FSCA*</b> 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><b>3. Probability of problem arising</b></p>
	<p>The likelihood is considered Remote (only under severe workload conditions)</p>
2.	<p><b>4. Predicted risk to patient/users</b></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><b>5. Further information to help characterise the problem</b></p>
	<p>Only one case happened, without involvement of patient or operator</p>
2.	<p><b>6. Background on Issue</b></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><b>7. Other information relevant to FSCA</b></p>
	<p>N/A</p>

	<p><b>3. Type of Action to mitigate the risk*</b></p>	
3.	<p><b>1. Action To Be Taken by the User*</b></p>	
	<p>Take note of amendment/reinforcement of Instructions For Use (IFU) and Service Manual, attached to this FSN. 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><b>2. By when should the action be completed?</b></p>	<p>as soon as possible</p>



3.	<b>3.</b> 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.	<b>4.</b> Is customer Reply Required? * (If yes, form attached specifying deadline for return)	Yes
3.	<b>5. Action Being Taken by the Manufacturer</b> 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	<b>6.</b> 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.	<b>7.</b> Is the FSN required to be communicated to the patient /lay user?	No

<b>4. General Information*</b>		
4.	<b>1. FSN Type*</b>	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.	<b>4. Further advice or information already expected in follow-up FSN? *</b>	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.	<b>7. Manufacturer information</b> (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>
4.	<b>8. The Competent (Regulatory) Authority of your country has been informed about this communication to customers. *</b>	
4.	9. List of attachments/appendices:	1. IfU and Service Manual addendum 2. Distributor and User reply form
4.	10. Name/Signature	<b>Paolo Casagrande Santin</b> <b>Quality Assurance Manager</b> 



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	<b>Transmission of this Field Safety Notice</b>
	<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**

# **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

## 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 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 Clinodigit EVO 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**

# **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**





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## Distributor/Importer Reply Form

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

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

<b>3. Return acknowledgement to Sender</b>	
Email	<a href="mailto:p.casagrande@villasm.com">p.casagrande@villasm.com</a> ; <a href="mailto:vsmservice@villasm.com">vsmservice@villasm.com</a>
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



<b>4. Distributors/Importers (Tick all that apply)</b>		
<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*		

<b>4. Return acknowledgement to sender</b>	
Email	<a href="mailto:p.casagrande@villasm.com">p.casagrande@villasm.com</a> ; <a href="mailto:vsmervice@villasm.com">vsmervice@villasm.com</a>
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.