



Urgent Field Safety Notice

FSCA-2016-12-27

Safety screws check on Apollo, Apollo DRF, Apollo EZ, Apollo EZ DRF

Buccinasco, December 27th, 2016

To: Dealers and Users with Apollo, Apollo DRF, Apollo EZ, Apollo EZ DRF equipped with flat table top

Details on affected devices:

Apollo, Apollo DRF, Apollo EZ, Apollo EZ DRF equipped with flat table top

Serial numbers: see Annex C

Description of the problem:

Villa Sistemi Medicali became aware that a patient fell from the table because the footrest of the device detached from the table top while the patient was positioned on the table and the table was moving from vertical position.

The analysis showed that the footrest of the device detached from the table top because the safety screws were discarded at installation. The purpose of these screws is to prevent the footrest to completely detach from the table in order to avoid the patient to fall.

Advise on action to be taken by the user:

The field correction focuses on verifying the presence of the safety screws on the table top, and to replace them in case they have been removed for any reason.

The user shall request a service technician to do the check and correction at the latest during the next periodic preventive maintenance visit.

Pending the check and the eventual correction, the user **MUST NOT** use the footrest.

All the examinations performed on the device before the check and the eventual correction remain valid,

The actions requested are described in detail in Annex A

Transmission of this Field Safety Notice:

This notice needs to be passed to all users of Juno DRF and to all those who need to be aware within your organisation or to any organisation where the potentially affected devices have been transferred.



Contact reference person:

For any information and assistance regarding this Field Safety Notice and the implementation of the corrective actions, please contact:

VILLA SISTEMI MEDICALI Technical Service

Tel. +39 02 48859288

Fax +39 02 48859222

E-mail: service_support@villasm.com

Villa Sistemi Medicali confirms that this notice has been notified the appropriate Competent Authorities

Apologizing for any inconvenience you may have experienced, we send you our best regards

A handwritten signature in black ink, appearing to read 'Paolo Casagrande Santin'.

Paolo Casagrande Santin
Quality Assurance Manager
Villa Sistemi Medicali S.p.A.



Annex A: Service Note NIM003-2016e

N.	NIM003-2016e
Data:	9 novembre 2016
<i>Date:</i>	<i>November 9, 2016</i>
Oggetto:	Viti di sicurezza pedana salita paziente
<i>Subject:</i>	<i>Safety screws for foot rest</i>
A:	Distributori con Apollo, Apollo DRF, Apollo EZ, Apollo EZ DRF barella piana
<i>To:</i>	<i>Dealers with flat table top</i> Apollo, Apollo DRF, Apollo EZ, Apollo EZ DRF
Apparecchiatura:	Telecomandato Apollo, Apollo DRF, Apollo EZ, Apollo EZ DRF barella piana
<i>Equipment:</i>	<i>Remote controlled table</i> Apollo, Apollo DRF, Apollo EZ, Apollo EZ DRF with flat table top
Azione richiesta:	Verificare presenza viti di sicurezza sulla barella ed eventualmente ripristinarle. Applicare gli adesivi forniti nel caso di utilizzo del reggispolle p/n 7173151500
<i>Required Action:</i>	<i>Check presence of safety screws on table top and replace them if necessary. Apply stickers in case shoulder rest p/n 7173151500 is used with the system.</i>
Parti incluse in questa FSN	<ul style="list-style-type: none"> - q.tà 4 viti M5x6 - q.tà 4 rondelle elastiche - q.tà 2 adesivi per l'identificazione di lato testa e lato piedi della barella - le presenti istruzioni - addendum al Manuale d'Uso - addendum al Manuale di Servizio
<i>Parts included in this FSN</i>	<ul style="list-style-type: none"> <i>- q.ty 4 screws M5x6</i> <i>- q.ty 4 elastic washers</i> <i>- q.ty 2 stickers for head side and foot side table top identification</i> <i>- this instruction</i> <i>- User Manual addendum</i> <i>- Service Manual addendum</i>

DESCRIZIONE

DESCRIPTION

Sono stati segnalati casi in cui sono state rimosse impropriamente le viti di sicurezza che evitano la fuoriuscita della pedana salita paziente.

It has been noticed that on some units, have been removed the safety screws necessary to avoid the exit of patient foot rest.

Trattandosi di un componente di sicurezza, è **OBBLIGATORIO** effettuare la verifica della presenza delle viti di sicurezza:

*Since this is a safety component, it is **MANDATORY** to verify the presence of the safety screws:*

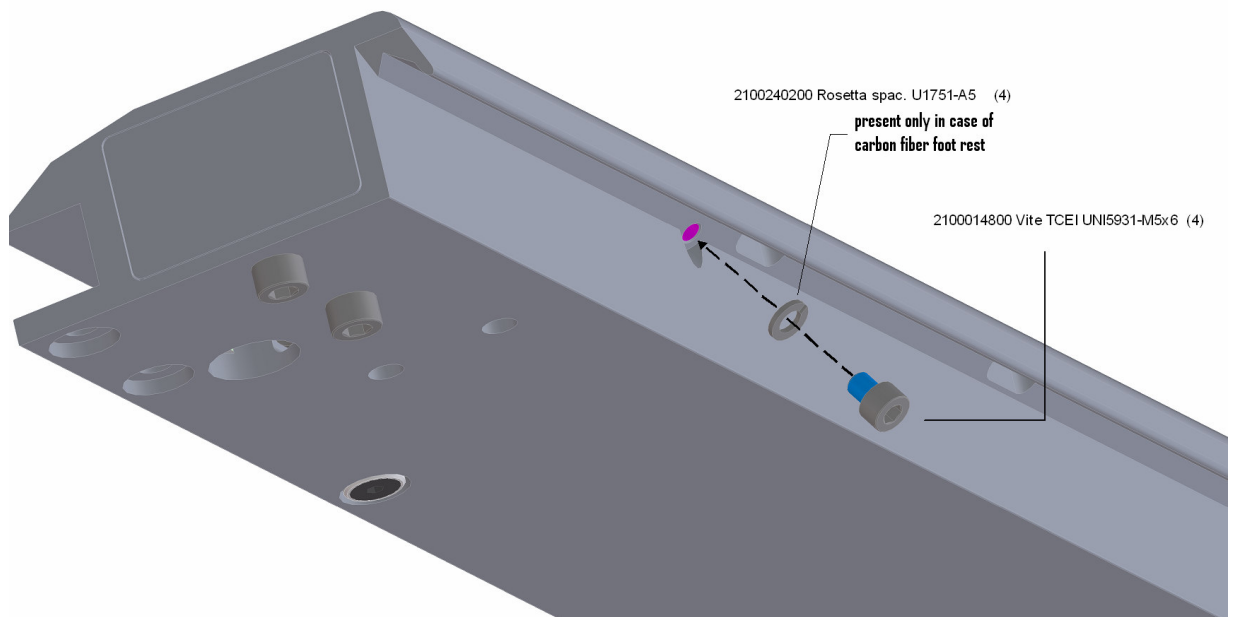
Le viti previste sono 2100014800 M5x6 + ranelle elastiche spaccate 2100240200 (ranelle presenti solo in caso di pedana salita paziente in fibra di carbonio) e devono essere presenti sui bordi barella lato piedi e lato testa, interno e esterno.

The screws are 2100014800 M5x6 + elastic washers 2100240200 (washers present only in case of carbon fiber foot rest) and must be present in head and foot side, internal and external sides.



In caso le viti non siano presenti, inserirle come indicato in figura.
La rondella deve essere utilizzata solo con pedane in fibra di carbonio

*In case the screws are not present, insert them as shown in picture
Washed is used only in case of carbon fiber foot rest*

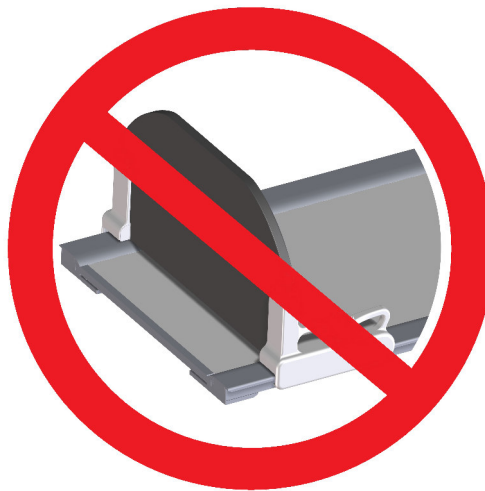


SOLO IN CASO DI UTILIZZO DEL SUPPORTO SPALLE

ONLY IN CASE OF SHOULDER REST SUPPORT

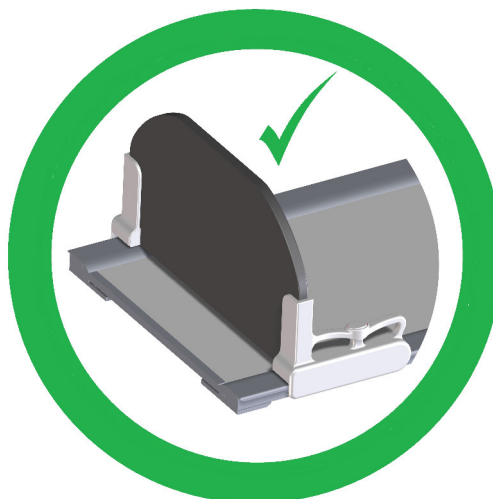
In caso di utilizzo supporto spalle, è necessario rimuovere le viti dalla barella solo dal lato testa paziente. In questo caso applicare sul lato testa il simbolo adesivo indicato

In case of shoulder rest support, it is necessary to remove screws only from head side of table top. In this case, apply on head side the provided symbol



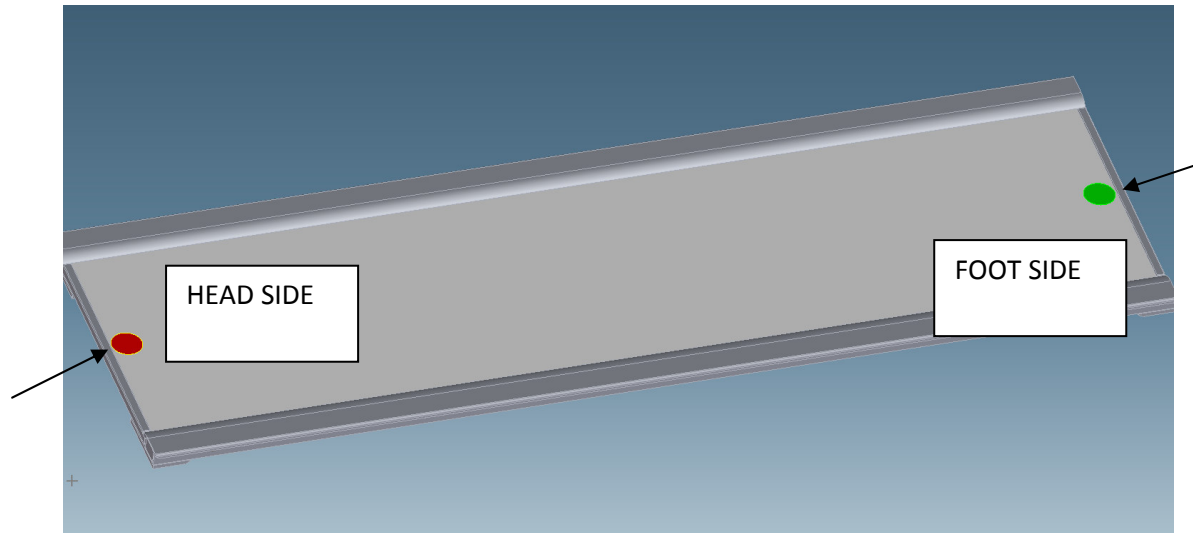
E sul lato piedi il simbolo adesivo

And in foot side the symbol



Applicarli come da figura, in modo che siano contro la traversa metallica della barella.

Apply as for figure, so that adhesives are against the iron plate



Se la barella viene rimossa per esigenze di servizio, accertarsi che venga rimontata nella stessa posizione testa-piedi paziente.

In case of table top removal for service purposes, be sure to mount table top in the same head-foot direction.

Sensibilizzare gli operatori affinché utilizzino correttamente la pedana come descritto sul manuale d'uso, verificando sempre che l'aggancio avvenga in maniera salda facendo oscillare la pedana fino a quando entrambi i lati non sono saldamente ancorati.



ATTENZIONE:

- Verificare che gli accessori siano ben fissati prima di posizionare il paziente per l'esame.
- Per tavoli equipaggiati con barella piana, verificare che la pedana appoggio paziente sia saldamente agganciata al profilo metallico della barella; la posizione è corretta se entrambi i pulsanti di sblocco sono completamente sollevati e non è possibile vedere la linea rossa. Se la condizione non è raggiunta, usando le maniglie, muovere la pedana appoggio paziente senza premere i pulsanti finché non si blocca correttamente (linea rossa non più visibile).

Instruct operators, as mentioned on the user's manual, to verify always that foot rest is well engaged oscillating the foot rest until both sides are well inserted.



WARNING:

- Check that the accessories are securely fastened before positioning the patient for the examination.
- In case of table equipped with flat tabletop, check that the patient footrest is properly engaged and locked to the table top metallic profile; the correct position is reached when both the unlocking buttons are completely out and it is not possible to see the red line on the buttons area.
If the condition is not reached, using the handles, move the footrest without pressing the buttons, until it locks properly (red line on the buttons area no more visible).



After releasing the two pushbuttons, shake the footrest up and down with both hands to ensure it is properly locked.



Service Note

Inserire l'addendum ai manuali nel manuale d'uso e nel manuale di servizio

Insert manual addendums in the user's manual and in the service manual

Inviare a Villa Sistemi Medicali il Modulo di Conferma incluso in questa Service Note come allegato B

Send back to Villa Sistemi Medicali the Confirmation Form included as Annex B

Best regards

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



Annex B: Confirmation Form

Please send the filled form by fax or e-mail to:
Villa Sistemi Medicali S.p.A.
Paolo Casagrande Santin
p.casagrande@villasm.com
fax +39 02 48859 303

NOTE: this Confirmation Form must be sent back to the manufacturer within 10 days from the implementation of the corrective action, that has to be applied as soon as possible, in any case not later the 30 days after receiving this Field Safety Notice.

- I have received the Field Safety Notice from Villa Sistemi Medicali together with the kit for field correction
- I have passed this notice to all those who need to be aware within my organisation or to any organisation where the potentially affected devices have been transferred
- I have implemented on the device the actions described in the Service Note attached as Annex A to this Field Safety Notice
- I have supplemented the IfU and the Technical documentation with the supplied manual addendums
- I have / haven't (*delete the option not applicable*) removed the screws from head side and applied the stickers

Signature: _____

Name: _____

Date: _____

Organization: _____

Address: _____

Device s/n: _____



Annex C: List of affected units

p/n	serial number
9784020513	06050079
9784020513	06060085
9784020013	06070102
9784020013	06080107
9784020113	06090113
9784020513	06100121
9784020513	06100124
9784020213	06100125
9784020513	06120141
9784020213	07010148
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9784020113	07070308
9784020513	07070320
9784020513	07070321
9784020013	07090369
9784020013	07090370
9784020213	07090392
9784020013	07100398
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9784029113	07110443
9784920014	07110444

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9784920414	07120449
9784020013	07120451
9784120013	07120455
9784920014	07120456
9784920014	07120457
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9784120113	08050489
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9784120113	08060494
9784120113	08060495
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9784120113	08060497
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9784220813	08070499
9784120113	08070500

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9784029113	08080512
9784020113	08080514
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9784120013	08090525
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9784020013	08100546
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9784020013	09010563
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9784020013	09010567
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9784220813	09010569
9784020013	09010570
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9784229813	09020572
9784229813	09020573
9784229813	09020574



Service Note

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9784229813	09020577
9784020213	09030578
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9784430813	09030583
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9784120113	09050588
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9784229813	10060696
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Service Note

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9784153013	10100756
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9784052013	11010797

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9784142013	11020804
9784229813	11030807
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Service Note

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9784020113	12030992
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9784120113	12041005



Service Note

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9784020213	12071024
9784020213	12071025
9784020213	12071026
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9784021813	12071034
9784120113	12071037
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9784039113	12071039
9784120113	12081041
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9784020213	12081044
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9784042013	13111273
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9784055013	14051326
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9784055013	14051328
9784042013	14051329
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Service Note

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9784055013	16111582
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