

Update Instructions

MI006/14/S

Customer Advisory Notice: Motor Mounting Plate Update

Safety

Update within	30 days			
Update by	<input type="checkbox"/> Remote	<input checked="" type="checkbox"/> CSE	<input type="checkbox"/> Apps	
Intranet download available	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No		
Remote update	<input type="checkbox"/> Yes	<input checked="" type="checkbox"/> No		
Materials for logistic update required	<input type="checkbox"/> Yes	<input checked="" type="checkbox"/> No		
Materials free of charge	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> No, credit if returned	
Return of parts	<input type="checkbox"/> Yes	<input checked="" type="checkbox"/> No		
Customer application training	<input type="checkbox"/> Yes	<input checked="" type="checkbox"/> No	<input type="checkbox"/> Recommended	
Estimated completion time	.25 Hours(s)	Number of CSE(s): 0		
Application training time	0 Hours(s)			

Remarks: n.a.

Scope

Material number	See Systems/Products Affected
Software version	See Prerequisites
Related to Update Instructions	n.a.

Change reference no.: ECO 600059
 Name: A. Agarwal
 Department: H CX CS MI PS HES

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1. General Information

1.1 Systems/Products Affected

Sub-IVK Description	Sub-IVK Part Number	Serial Number	
		Start	Ending
P15 Symbia T2	10165631	68001	68336, 68401,68402
P15 Symbia T6	10165632	68501	68635
P15 Symbia T16	10165633	69001	69114, 69491
P18 Symbia T2	10611610	75001	75193
P18 Symbia T6	10611611	68701	68801
P18 Symbia T16	10611612	69201	69382
P18 Intevo_2	10415136	89401	89418
P18 Intevo_6	10415137	89901	88913
P18 Intevo_16	10415138	90201	90216

NOTE

This UI applies to all Symbia T series (PNs 10275007, 10275008, 10275009, 10275010) and Symbia Intevo systems (PNs 10764801, 10764802, 10764803 and 10764804) with P15/P18 CT gantry.

1.2 ECO Number(s)

Service ECO - 600059

1.3 Reason for the Update

Distribute Customer Safety Advisory Notice for the Motor Mounting Plate Update (MI005/14/S).

1.4 Prerequisites

One of the following systems with **P15** or **P18** Gantry:

Symbia T (PN 10275007)	Symbia Intevo Excel (PN 10764801)
Symbia T2 (PN 10275008)	Symbia Intevo 2 (PN 10764802)
Symbia T6 (PN 10275009)	Symbia Intevo 6 (PN 10764803)
Symbia T16 (PN 10275010)	Symbia Intevo 16 (PN 10764804)

Check the MED CS Intranet/Extranet for the latest version of this document (For Service -> Product Information -> MI Systems -> Updates -> 2014) or contact your local Siemens office if you don't have access to the Siemens Intranet/Extranet. IVK and Serial numbers affected are listed on MED CS Intranet/Extranet (CS Web Site).

1.5 Special Tools

N.A.

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2. Material Information

2.1 Ordering Information

n.a.

2.2 Content of Update Kit

n.a.

2.3 Return of Parts

n.a.

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3. Update

3.1 Work Steps

3.1.1 Preparation

3.1.1.1 Intranet Download

The required file: "MI006_14_S_customer_advisory_notice.zip" has to be downloaded from the Siemens Healthcare Intranet -> Customer Services.

1. Go to the (CS Intranet start page,
<https://intranet.healthcare.siemens.com/cms/CS/en/>)
2. Follow the path:
For Service -> Product Information -> MI -> SPECT Systems -> Downloads -> Customer Safety Letters
3. Select the year "UIs 2014"
4. Click the left mouse button on the file to be downloaded:
"MI006_14_S_customer_advisory_notice.zip"
5. Save the file on the hard drive D:\...
6. When finished saving, close the window.
7. Check the file with a standard anti-virus program

3.1.2 Work Steps

1. Open the zip file "MI006_14_S_customer_advisory_notice.zip".
2. Select the customer advisory notice in the correct language and unzip the corresponding file.
3. Print out the customer advisory notice.
4. Send the letter to the customer via certified mail and with a proof of delivery. (The reception needs to be acknowledged.)
5. When you have received the proof of delivery report the update. See Final work Steps.

3.1.3 Final Check

n.a.

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3.2 Final Work Steps

1. Fill out, and if needed, make a copy of the attached "Completion Protocol" and file it in the corresponding binder.
2. The update shall be reported by authorized personnel, either via an intranet application or by automated data transfer (only for countries connected via update handling interface).

3.3 Changes to Previous Version

n.a.

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4. Completion Protocol

Customer Advisory Notice: Motor Mounting Plate Update

4.1 Reason for the Update

Distribute Customer Safety Advisory Notice for the Motor Mounting Plate Update (MI005/14/S).

4.2 Protocol

This update has been completed successfully. The customer has been informed of the benefits or improvements resulting from this update.

Customer:

Customer No.: Func. Location:

Material No. Serial number
of the system: of the system:

Notification:

Remark:

Remark:

Country: Site:

Performed By: Telephone:

Date: Signature:

NOTE

After completing the update, make a copy of this page, fill it out and file it in the corresponding System Binder/User Handbook.



Customer Safety Advisory Notice (CAN 006-2014)

**To: Director of the Radiology Department
Director of the Nuclear Medicine Department
Risk Management Officer
Users of Symbia T camera systems
Users of Symbia Intevo camera systems**

Re: Symbia T Series and Symbia Intevo camera system with rubber component on the motor mounting plate

Dear Valued Siemens Customer,

You are receiving this letter because you have been identified as owning a Symbia T Series or Symbia Intevo camera system that may be affected by a hardware problem within the CT gantry.

This letter serves as notification of an upcoming field correction. The field correction is required because we recently detected a rubber isolator with unfavorable aging properties. The function of this rubber isolator, which is situated within the rotate motor mounting assembly, may degrade over time and may impact motor support. We have not received any reports of injury with the Symbia T or Symbia Intevo camera systems as a result of this problem.

When could this problem occur and what is the potential risk?

In rare cases, when unfavourable ageing has occurred, the rubber isolator may break and cause loss of support for the rotate motor. This event does not pose a hazard by itself but could lead to a rupture of the drive belt which in turn could damage the gantry covers and make contact with the patient. While we expect any subsequent injury to be minor, the possibility of a serious injury does exist if the belt makes contact with the patient.

What should you do until the repair is performed?

Based on our investigation, you can continue to use your system while waiting for the field correction to be scheduled and performed. If you are experiencing abnormal noise or vibration, discontinue use immediately and please contact your service engineer.

Your local service engineer will contact you and perform the mounting plate replacement by December 2014. This new mounting plate includes improved rubber components and a backup device to ensure trouble free operation in the future.

Please ensure that this safety advisory is placed in the System Owner's Manual. If you rely on non-Siemens service, please share this letter with your support staff. If you have sold this equipment and it is no longer in your possession, we kindly ask that you forward this safety notice to the new owner of this equipment. Please inform us about the new owner of the equipment.

If you have any questions regarding this important advisory notice, please contact your local Service representative at the contact numbers provided below.

- America: 1-800-888-7436
- Europe, Middle East, and Africa: +49 9131 940 4000
- Asia and Australia: +86 (21) 3811 2121

Sincerely,



Matt Shah
Vice President, Quality, Regulatory, and EHS
Molecular Imaging
CAN006-2014