

Date: 29 Aug 2019

Urgent Field Safety Notice

TxRx Knee Coil 1.5T and 3T for Use on Siemens MR Systems

For Attention of*: Users of TxRx Knee Coils on Siemens 1.5T and 3T MR Systems



Urgent Field Safety Notice (FSN)
TxRx Knee Coil 1.5T and 3T for Use on Siemens MR Systems
Risk of Image Distortion or Projectile during MR Scan

1. Information on Affected Devices*																									
1	1. Device Type(s)*																								
.	TxRx Knee coils to be used in conjunction with 1.5T and 3T Siemens MR systems for diagnostic imaging of the knee.																								
1	2. Commercial name(s)																								
.	TxRx Knee Coils, see #1.4 below for list of names																								
1	3. Primary clinical purpose of device(s)*																								
.	Diagnostic imaging of the knee																								
1	4. Device Model/Catalogue/part number(s)*																								
.	Add as Appendix if necessary.																								
	<table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th style="width: 30%;">Product Name</th> <th style="width: 30%;">QED Model Number</th> <th style="width: 30%;">Siemens Model Number</th> </tr> </thead> <tbody> <tr> <td>TxRx 15CH Knee Coil 3T</td> <td>Q7000008</td> <td>10185460</td> </tr> <tr> <td>TxRx 15CH Knee Coil 1.5T</td> <td>Q7000016</td> <td>10185453</td> </tr> <tr> <td>TxRx CP Extremity Coil 3T</td> <td>Q7000019</td> <td>10185464</td> </tr> <tr> <td>TxRx 15CH Knee Coil 1.5T</td> <td>Q7000050</td> <td>10606524</td> </tr> <tr> <td>TxRx 15CH Knee Coil 3T</td> <td>Q7000051</td> <td>10606525</td> </tr> <tr> <td>TxRx Knee 15 Coil 1.5T</td> <td>Q7000056</td> <td>10606828</td> </tr> <tr> <td>TxRx Knee 15 Coil 3T</td> <td>Q7000057</td> <td>10606829</td> </tr> </tbody> </table>	Product Name	QED Model Number	Siemens Model Number	TxRx 15CH Knee Coil 3T	Q7000008	10185460	TxRx 15CH Knee Coil 1.5T	Q7000016	10185453	TxRx CP Extremity Coil 3T	Q7000019	10185464	TxRx 15CH Knee Coil 1.5T	Q7000050	10606524	TxRx 15CH Knee Coil 3T	Q7000051	10606525	TxRx Knee 15 Coil 1.5T	Q7000056	10606828	TxRx Knee 15 Coil 3T	Q7000057	10606829
Product Name	QED Model Number	Siemens Model Number																							
TxRx 15CH Knee Coil 3T	Q7000008	10185460																							
TxRx 15CH Knee Coil 1.5T	Q7000016	10185453																							
TxRx CP Extremity Coil 3T	Q7000019	10185464																							
TxRx 15CH Knee Coil 1.5T	Q7000050	10606524																							
TxRx 15CH Knee Coil 3T	Q7000051	10606525																							
TxRx Knee 15 Coil 1.5T	Q7000056	10606828																							
TxRx Knee 15 Coil 3T	Q7000057	10606829																							
1	5. Affected serial number range																								
.	See attached list of potentially affected model and serial numbers																								
1	6. Associated devices																								
.	Siemens 1.5T and 3T MR systems																								

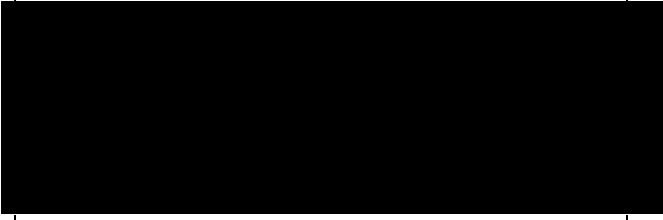
2 Reason for Field Safety Corrective Action (FSCA)*	
2	1. Description of the product problem*
.	Magnetic/ferrous material may be present in the pushbutton of the knee coil frame.
2	2. Hazard giving rise to the FSCA*
.	Use of this product will likely produce readily noticeable image distortion during an MR scan. The risk of the push button becoming unthreaded or separated from the frame assembly was also assessed and found to be remote. No incidents have been reported and the risk of an incident occurring due to the identified issue is negligible.
2	3. Probability of problem arising
.	There is a high probability of image distortion occurring if ferrous material is present in the push button. The image distortion would be obvious to the trained professional using the device. It is highly improbable that the ferrous material could separate from frame assembly and cause harm.
2	4. Predicted risk to patient/users
.	There is negligible risk to patients and users. The risk assessment resulted in a maximum RPN of 5, which is an acceptable risk level per established risk criteria.



2	5. Background on Issue
.	The ferrous material was identified upon incoming inspection of the knee coil frame at the manufacturer site; however, several potentially affected devices had been distributed prior to detection of the issue.

3. Type of Action to mitigate the risk*			
3.	<p>1. Action To Be Taken by the User*</p> <p> <input checked="" type="checkbox"/> Identify Device <input checked="" type="checkbox"/> Quarantine Device <input type="checkbox"/> Return Device <input type="checkbox"/> Destroy Device </p> <p> <input checked="" type="checkbox"/> On-site device modification/inspection </p> <p> <input type="checkbox"/> Follow patient management recommendations </p> <p> <input type="checkbox"/> Take note of amendment/reinforcement of Instructions For Use (IFU) </p> <p> <input type="checkbox"/> Other <input type="checkbox"/> None </p> <p>Immediately examine your inventory for potentially affected product listed in this notice and quarantine any affected product found. Contact your Siemens Healthineers representative. A Siemens Field Service Engineer will inspect the product and, if needed, correct the product on-site or replace the product.</p>		
3.	<table border="1" style="width: 100%;"> <tr> <td style="width: 40%;">2. By when should the action be completed?</td> <td style="text-align: center;">10 September 2019</td> </tr> </table>	2. By when should the action be completed?	10 September 2019
2. By when should the action be completed?	10 September 2019		
3.	<table border="1" style="width: 100%;"> <tr> <td style="width: 70%;">3. Is customer Reply Required? * (If yes, form attached specifying deadline for return)</td> <td style="text-align: center;">No</td> </tr> </table>	3. Is customer Reply Required? * (If yes, form attached specifying deadline for return)	No
3. Is customer Reply Required? * (If yes, form attached specifying deadline for return)	No		
3.	<p>4. Action Being Taken by the Manufacturer</p> <p> <input type="checkbox"/> Product Removal <input checked="" type="checkbox"/> On-site device modification/inspection <input type="checkbox"/> Software upgrade <input type="checkbox"/> IFU or labelling change <input type="checkbox"/> Other <input type="checkbox"/> None </p> <p>Siemens Field Service Representatives will inspect and correct the knee coil frame at the customer site or replace the customer's coil and return the device to Quality Electrodynamics for correction.</p>		
3	<table border="1" style="width: 100%;"> <tr> <td style="width: 40%;">5. By when should the action be completed?</td> <td style="text-align: center;">30 September 2019</td> </tr> </table>	5. By when should the action be completed?	30 September 2019
5. By when should the action be completed?	30 September 2019		
3.	<table border="1" style="width: 100%;"> <tr> <td style="width: 70%;">6. Is the FSN required to be communicated to the patient /lay user?</td> <td style="text-align: center;">No</td> </tr> </table>	6. Is the FSN required to be communicated to the patient /lay user?	No
6. Is the FSN required to be communicated to the patient /lay user?	No		
4. General Information*			
4.	<table border="1" style="width: 100%;"> <tr> <td style="width: 50%;">1. FSN Type*</td> <td style="text-align: center;">New</td> </tr> </table>	1. FSN Type*	New
1. FSN Type*	New		
4.	<table border="1" style="width: 100%;"> <tr> <td style="width: 50%;">2. Further advice or information already expected in follow-up FSN? *</td> <td style="text-align: center;">No</td> </tr> </table>	2. Further advice or information already expected in follow-up FSN? *	No
2. Further advice or information already expected in follow-up FSN? *	No		
4.	<p>3. Manufacturer information (For contact details of local representative refer to page 1 of this FSN)</p> <table border="1" style="width: 100%;"> <tr> <td style="width: 50%;">a. Company Name</td> <td style="text-align: center;">Quality Electrodynamics, LLC</td> </tr> </table>	a. Company Name	Quality Electrodynamics, LLC
a. Company Name	Quality Electrodynamics, LLC		



	b. Address	6655 Beta Drive Suite 100, Mayfield Village, OH 44143 USA
	c. Website address	www.qualityelectrodynamics.com
4.	4. The Competent (Regulatory) Authority of your country has been informed about this communication to customers. *	
4.	5. List of attachments/appendices:	List of affected units
4.	6. Name/Signature	

Transmission of this Field Safety Notice	
	<p>This notice needs to be passed on all those who need to be aware within your organisation or to any organisation where the potentially affected devices have been transferred. (As appropriate)</p> <p>Please transfer this notice to other organisations on which this action has an impact. (As appropriate)</p> <p>Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.</p> <p>Please report all device-related incidents to the manufacturer, distributor or local representative, and the national Competent Authority if appropriate, as this provides important feedback..*</p>

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

