

**MAUDE EVENT REPORT (FOI)**

**SORTED BY DATE OF EVENT**



This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Date Received

**MFR Report No:** 2240869-2009-00027 **Mfr Name:** SIEMENS MEDICAL SOLUTIONS USA, INC. 20-Aug-2009

<b>Event Date (B3):</b> 15-Jul-2009	<b>Event Report Type:</b> INJURY	<b>Adverse Event (B1):</b> Y	<b>Problem (B1):</b> N
<b>Report Date (B4):</b> 10-Aug-2009	<b>Event Outcome (B2):</b> REQUIRED INTERVENTION		
<b>Report Date (F8):</b>	<b>Reporter Occupation (E3):</b> NA - NOT APPLICABLE	<b>Event Location (F12):</b>	
<b>Date Mfr Rec'd (G4):</b>	<b>Device Operator:</b> HEALTH PROFESSIONAL	<b>Report Source (G3):</b> FOREIGN, COMPANY REPRESENTATIVE	

**Product Code:** (RA)-SYSTEM, NUCLEAR MAGNETIC RESONANCE IMAGING (LNH)

<b>Device Age (F9):</b>	<b>Manufacture Date (H4):</b>
<b>Expiration Date:</b>	<b>Single Use (H5):</b> N
	<b>Device Usage (H8):</b> *

**Event Description (B5):**

Mfr 27-AUG-2009: IT WAS REPORTED THAT A CONSULTING SIEMENS TRAINING SPECIALIST WAS INADVERTENTLY PUSHED INTO THE MR MAGNET BY AN UNMANNED CART THAT UNEXPECTEDLY BEGAN TO ROLL. THE INCIDENT OCCURRED FOLLOWING COMPLETION OF THE EQUIPMENT INSTALLATION OF THE MR, BUT PRIOR TO EQUIPMENT TURNOVER TO THE CUSTOMER AND PRIOR TO PT USE. THE CONSULTING SIEMENS TRAINING SPECIALIST ALLEGEDLY BECAME TRAPPED BETWEEN THE CART AND THE MAGNET, AND SUBSEQUENTLY RECEIVED MULTIPLE FRACTURES TO THE FACE, AS WELL AS BRAIN TRAUMA. SURGICAL INTERVENTION WAS REQUIRED TO REPAIR THE FRACTURES. THIS EVENT OCCURRED IN ANOTHER COUNTRY.

**Concomitant Medical Products:**

**Mfr Name:** SIEMENS AG  
**Address:** 127 HENKESTRASSE  
 ERLANGEN,  
 GERMANY

**Device Available for Evaluation:** Y  
**Device Evaluated by Manufacturer (H3):** Yes

**Remedial Action (H7):**  
**Correction/Removal No (H9):**  
**Additional Mfr Narrative (H10 & H11):**  
 27-AUG-2009: .

**SORTED BY DATE OF EVENT**

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

**DEVICE INFORMATION:**

**Brand:** MAGNATOM ESPREE

**Device Type:** SYSTEM, NUCLEAR MAG. RESONANCE IMAGING

**Device Type:** 100118165

**Catalog:** NA

**Serial:** (\*confidential\*)

**Lot:** NA

**Other ID:**

**Reprocessed & Reused:** N