

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: 2240869-2009-00031	Mfr Name: SIEMENS MEDICAL SOLUTIONS USA, INC.	10-Sep-2009
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Event Date (B3): 17-Aug-2009	Event Report Type: INJURY	Adverse Event (B1): Y	Problem (B1): N
Report Date (B4): 20-Aug-2009	Event Outcome (B2): REQUIRED INTERVENTION		
Report Date (F8):	Reporter Occupation (E3): NA - NOT APPLICABLE	Event Location (F12):	
Date Mfr Rec'd (G4):	Device Operator: HEALTH PROFESSIONAL	Report Source (G3): FOREIGN, COMPANY REPRESENTATIVE	

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

Device Age (F9):

Manufacture Date (H4):

Expiration Date:

Single Use (H5): N

Device Usage (H8): *

Event Description (B5):

Mfr 17-SEP-2009: IT WAS REPORTED THAT DURING AN MRI SCAN, A FERROMAGNETIC FLAT SCREEN MONITOR WAS MOVED BY HOSPITAL STAFF, AND WAS SUBSEQUENTLY PULLED TOWARD THE MAGNET. THE MRI ROOM IS USED FOR RESEARCH PURPOSES. WHILE SCANNING A VOLUNTEER, THE MONIROT WAS ATTRACTED INTO THE SYSTEM, AND STRUCK THE VOLUNTEER CAUSING SERIOUS FACIAL INJURIES. THE VOLUNTEER'S INJURIES REQUIRED AN OPERATION. THIS INCIDENT WAS CAUSED BY A FERROMAGNETIC OBJECT PRESENT IN THE CONTROLLED AREA, AND WAS NOT RELATED TO PRODUCT FAILURE. THIS EVENT OCCURRED IN A FOREIGN COUNTRY.

Concomitant Medical Products:

Mfr Name: SIEMENS AG

Address: HENKESTRASSE 127
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):

17-SEP-2009: .

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DEVICE INFORMATION:

Brand: MAGNETOM TRIO A TIM SYSTEM

Device Type: SYSTEM, NUCLEAR, MAG. RESONANCE IMAGING

Device Type: 10018221

Catalog: NA

Serial: (*confidential*)

Lot: NA

Other ID:

Reprocessed & Reused: N