

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: 2240869-2009-00002	Mfr Name: SIEMENS MEDICAL SOLUTIONS USA, INC.	15-Jan-2009
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Event Date (B3): 12-Jan-2009	Event Report Type: INJURY	Adverse Event (B1): Y	Problem (B1): N
Report Date (B4): 13-Jan-2009	Event Outcome (B2): OTHER SERIOUS (IMPORTANT MEDICAL EVENTS)		
Report Date (F8):	Reporter Occupation (E3): NA - NOT APPLICABLE	Event Location (F12):	
Date Mfr Rec'd (G4): 13-Jan-2009	Device Operator: HEALTH PROFESSIONAL	Report Source (G3): USER FACILITY	

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 23-JAN-2009: SITE BROUGHT PATIENT INTO SCAN ROOM ON A FERROMAGNETIC GURNEY. THE PATIENT WAS THROWN INTO THE MAGNET WITH THE GURNEY. THE TECHNICIAN IMMEDIATELY QUENCHED THE MAGNET IN ORDER TO RELEASE THE PATIENT AS WELL AS THE GURNEY FROM THE MAGNET. THE PATIENT SUSTAINED FRACTURES TO THE FOOT, ANKLE AND LEG.

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):

23-JAN-2009: SIEMENS SERVICE ENGINEER EVALUATED THE EQUIPMENT ON JANUARY 13, 2009. THE EQUIPMENT WAS OPERATING ACCORDING TO SPECIFICATIONS. THE ENGINEER REPAIRED THE BROKEN COVERS ON THE FRONT OF THE MAGNET AND THE SYSTEM WAS RETURNED TO SERVICE.

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DEVICE INFORMATION:

Brand: MAGNETOM VERIO

Device Type: SYSTEM, NUC. MAGNETIC RESONANCE IMAGING

Device Type: 10276755

Catalog:

Serial: (*confidential*)

Lot:

Other ID:

Reprocessed & Reused: N