

## 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

User Facility Report No:

Mfr Name: PHILIPS MEDICAL SYSTEMS

19-May-2009

Event Date (B3): 13-May-2009

Event Report Type: \*

Adverse Event (B1): Problem (B1): N

Report Date (B4): 19-May-2009

Event Outcome (B2):

Report Date (F8): 19-May-2009

Reporter Occupation (E3): 500 - RISK MANAGER

Event Location (F12): HOSPITAL

Date Mfr Rec'd (G4):

Device Operator: HEALTH PROFESSIONAL

Report Source (G3):

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

Device Age (F9):

Manufacture Date (H4):

Expiration Date:

Single Use (H5):

Device Usage (H8):

## Event Description (B5):

User 27-MAY-2009: IV NURSE ENTERED MRI SUITE AND BROUGHT HER METAL IV CART HALFWAY IN DOORWAY OF MRI SUITE. THE FORCE OF THE MRI MAGNET CAUSED THE IV CART TO LIFT UP AND IT FLEW THROUGH THE AIR, ON TO THE MRI MACHINE. PATIENT WAS LYING OUTSIDE OF THE MRI, ON THE MRI TABLE AT THE TIME. THE CART DID NOT HIT HIM. ANOTHER NURSE WAS ON RIGHT SIDE OF PATIENT AND WAS LOOKING FOR VENOUS ACCESS IN HIS RIGHT ARM AT THE TIME OF THE INCIDENT. SHE WAS NOT INJURED. NO INJURY FOR ANY INDIVIDUAL - LOTS OF POTENTIAL FOR INJURY!

THE IV NURSE HAD BEEN CALLED TO ACCESS THE PATIENT LOCATED IN MRI. SHE DID NOT REALIZE THE POWER OF THE MRI MAGNET ESPECIALLY WHEN THE PATIENT WAS NOT IN THE MRI. SHE INTENDED TO LEAVE THE CART AT THE DOOR, BUT SHOULD NOT HAVE ENTERED THE ROOM.

THIS IS BEING REPORTED NOT BECAUSE OF A DEVICE MALFUNCTION BUT AS AN ALERT OF AN INCIDENT REGARDING AN MRI AND NEED FOR BETTER VIGILANCE AND PERHAPS EDUCATION REGARDING THE FACT THAT MRI MAGNETS ARE ALWAYS ON AND THE NEED FOR BETTER SAFETY.

## Concomitant Medical Products:

NOT APPLICABLE

Mfr Name: PHILIPS MEDICAL SYSTEMS

Address: 3000 MINUTEMAN RD  
ANDOVER, MA 01810  
UNITED STATES

## Device Available for Evaluation:

Device Evaluated by Manufacturer (H3): No Answer

## Remedial Action (H7):

Correction/Removal No (H9):

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**Additional Mfr Narrative (H10 & H11):**

27-MAY-2009:

**DEVICE INFORMATION:****Brand:** PHILIPS ACHIEVA**Device Type:** MRI, 1.5T**Device Type:** \***Catalog:** \***Serial:** (\*confidential\*)**Lot:** \***Other ID:** \***Reprocessed & Reused:** N/A