

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: 3003768277-2009-0029	Mfr Name: PHILIPS MEDICAL SYSTEMS NEDERLAND B.V.	21-Apr-2009
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Event Date (B3): 04-Apr-2009	Event Report Type: OTHER	Adverse Event (B1): Y Problem (B1): N
Report Date (B4): 04-Apr-2009	Event Outcome (B2): OTHER SERIOUS (IMPORTANT MEDICAL EVENTS)	
Report Date (F8): 04-Apr-2009	Reporter Occupation (E3): OTHER	Event Location (F12): HOSPITAL
Date Mfr Rec'd (G4): 08-Apr-2009	Device Operator: HEALTH PROFESSIONAL	Report Source (G3): HEALTH PROFESSIONAL

Product Code: (RA)-SYSTEM, NUCLEAR MAGNETIC RESONANCE IMAGING (LNH)	Manufacture Date (H4): 01-Oct-2002	
Device Age (F9): 6 YR 0 DAYS (6 YR)	Single Use (H5): N	
Expiration Date:	Device Usage (H8): R	

Event Description (B5):

Mfr 06-MAY-2009: THIS REPORT IS BEING FILED UPON NOTIFICATION FROM OUR MR MANUFACTURER IN ANOTHER COUNTRY, TO SUBMIT THIS ADVERSE EVENT. PROBLEM: A SMALL METAL TABLE, USUALLY USED AT THE PT'S BED, WAS ROLLED INTO THE MR EXAMINATION ROOM WHILE A PT WAS ON THE PT SUPPORT. THIS HOSPITAL TABLE WAS DRAWN INTO THE MAGNET. THE PT WAS INJURED AND THE MAGNET COVERS WERE DAMAGED. THE MAGNET HAD TO BE RAMPED DOWN IN ORDER TO REMOVE THE METAL TABLE. THE ONLY PT INFORMATION THE HOSP WOULD CONVEY WAS THE PT INCURRED FACIAL LACERATIONS AND RECEIVED MEDICAL TREATMENT.

Concomitant Medical Products:

NA

Mfr Name: PHILIPS MEDICAL SYSTEMS

Address: VEENPLUIS 4-6
PO BOX 10.000
BEST,
NETHERLANDS

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

Remedial Action (H7):**Correction/Removal No (H9):**

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Additional Mfr Narrative (H10 & H11):

06-MAY-2009: (CONCLUSIONS): IT IS A KNOWN ISSUE THAT NO MAGNETIC MATERIALS SHOULD BE BROUGHT INTO THE EXAMINATION ROOM. THE INSTRUCTIONS FOR USE ALREADY CONTAIN EXTENSIVE WARNING RELATED TO THIS ISSUE. NO CORRECTIVE ACTION IS NEEDED ON THIS MATTER. NOTE: THE INDICATED IMPORTER HAS RECEIVED FDA EXEMPTION NUMBER TO SUBMIT ONE FDA FORM 3500A TO SATISFY BOTH THE IMPORTER AND MANUFACTURER FOR THE SAME EVENT.

DEVICE INFORMATION:

Brand: INTERA 1.5T

Device Type: LNH (MAGNETIC RESONANCE DIAGNOSTIC DEVICE)

Device Type: 781106

Catalog: NA

Serial: (*confidential*)

Lot: NA

Other ID:

Reprocessed & Reused: N