Appendix F. MAUDE and Medical Device Recall Reports

Table F1. Reports on Magnetic Resonance Scanners From the FDA MAUDE Database

Report Number	Event Date	Event Type	Manufacturer	Date Received	Product Code	Brand Name	Device Problem	Patient Problem	Event Text
3003768277-2021-10020	2021/04/27	Injury	PHILIPS ELECTRONICS NEDERLAND B.V.	2021/05/26	LNH	INGENIA 1.5T	Adverse Event Without Identified Device or Use Problem	Tinnitus	Philips received a report that a patient allegedly suffered of Tinnitus after an examination on an ingenia 1.5t mr system.
3003768277-2021-10018	2020/12/04	Injury	PHILIPS ELECTRONICS NEDERLAND B.V.	2021/05/21	LNH	INGENIA 3.0T	Improper or Incorrect Procedure or Method	Appropriate Clinical Signs, Symptoms, Conditions Term / Code Not Available	Philips received a report from a customer stating that a patient's leg was attracted in the magnet bore during an examination because of its metal implants. this resulted in the need for refixation of the patient's leg implant. manufacturer narrative: to prevent future incidents, we strongly advise to review the local procedure related to the (unauthorized) access to the controlled access area. also, the mr staff must read and familiarize themselves with the safety chapter of the instruction forUse. other hospital staff that needs access to the mr examination room must also be mr safety trained. ifu r5 section magnet safety - access to controlled access area. warning: do not bring objects made of iron or other magnetic materials into the controlled access area. these objects will be attracted by the magnet and may lead to serious or fatal injury of

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									the patient or operating personnel and may cause system malfunctions. object examples: scissors, pocket knives, lighters, keys, coins, etc. mobile phones and pagers. vacuum cleaners, floor polishers, etc. magnetic wheel chair, magnetic trolley, iron stretchers, etc. mr unsafe fire extinguishers. life supporting, vital sign monitoring, or emergency equipment such objects will be attracted by the magnet and may lead to serious or fatal injury of the patient or operating personnel and may cause system malfunctions.¿ a safety presentation is available on dvd, which explains the rf and other mri related safety issues: (b)(4), mr safety instructions. clearUser error.
3010949642-2021-00006	2021/03/29	Injury	GE HEALTHCARE (TIANJIN) COMPANY LIMITED	2021/05/18	LNH	SIGNA VOYAGER	Use of Device Problem; Improper or Incorrect Procedure or Method	Radiation Burn; Burn(s); Erythema; Blister	it was reported that a patient, who was having a left shoulder exam and passed mr screening, sustained a 4-5cm deep red burn with blister on her arm. the blister was opened by a doctor and wound treatment was provided to aid the healing process. the patient's arms were on her chest and ge recommended pads were not provided to prevent bore or skin to skin contact or looping. manufacturer narrative: unique identifier: (b)(4). there are no additional device identification numbers. ge healthcare's investigation is ongoing. a follow up report will be submitted

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									once the investigation has been completed.
3010949642-2021-00004	2021/04/12	Injury	GE HEALTHCARE (TIANJIN) COMPANY LIMITED	2021/05/11	LNH	SIGNA EXPLORER	Electromagnetic Interference	Laceration(s)	it was reported that during a system upgrade, the ge field engineer was changing the cable pit lid and brought one ferrous lid into the magnet room. while attempting to remove the lid from the scan room, it became attracted to the magnet, lacerating his finger in the process. the laceration required two stitches. additionally, his fingernail was pierced to drain the blood. manufacturer narrative: unique identifier: (b)(4). there are no additional device identification numbers. ge healthcare's investigation is ongoing. a follow up report will be submitted once the investigation has been completed.
3010949642-2021-00005	2021/02/12	Injury	GE HEALTHCARE (TIANJIN) COMPANY LIMITED	2021/05/11	LNH	SIGNA VOYAGER	Adverse Event Without Identified Device orUse Problem	Tinnitus	it was reported by a customer that a patient with a pre-existing hearing condition underwent an mr examination of the brain. the patient requested toUse his own earplugs for the exam, but the technologist also placed the music headphones on the patient. the patient did not complain of noise during the study. approximately a month and a half after the examination, the patient reported that hisTinnitus had worsened. since that time, the customer reported that the patient's condition was improving but at this time, we have not received

Report Number	Event Date	Event Type	Manufacturer	Date Received	Product Code	Brand Name	Device Problem	Patient Problem	Event Text
									information that his condition improved to his pre-mri state. manufacturer narrative: unique identifier: (b)(4). there are no additional device identification numbers. ge healthcare's investigation is ongoing. a follow up report will be submitted once the investigation has been completed. device evaluation anticipated, but not yet begun.
11705943	2021/03/19	Malfunction	GENERAL ELECTRIC COMPANY	2021/04/22	LNK	SIGNA ARTIST	Computer Software Problem;Improper or Incorrect Procedure or Method	Appropriate Clinical Signs, Symptoms, Conditions Term / Code Not Available	this is one of two recent events where right and left (laterality) were reversed on the coronal mri images performed on a ge. the neurosurgeon has been in contact with radiology/imaging leadership about these laterality issues. the cause is evidently related to technologist's error in inputting data after a recent ge software upgrade, but the software allows this to happen with patient orientation changes unknown to the technologist performing the study. this type of error obviously has significant risk of wrong sided surgery if the error is not caught. even when the error is caught, there remains significant exposure for a patient error later because these images are included in the patient's electronic medical record and could be viewed by a surgeon in the future, who is unaware that this laterality issue impacted the views that she/he is seeing. manufacturer response for

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									ge 26 & 28.o platform, (brand not provided) (per site reporter): ge is aware. our mr imaging leaders have been in communication with our physician and technologist staff in regard to this issue across all our campuses and have asked that a gadolinium marker be placed on the left temple for all brain mri cases. our mr imaging leaders are currently reviewing marker placement with staff and will be auditing all brain mri cases to ensure compliance. in addition, we have been in communication with ge on a software patch. the current timeline ¿per ge¿ for completion is december 2021. this timeline is unacceptable to the mri leadership team (this is a huge safety concern). discussions as it relates to this issue are ongoing as we look for a permanent solution from ge.
2183553-2021-00005		Injury	GE MEDICAL SYSTEMS, LLC	2021/04/12	LNH	SIGNA ARCHITECT	Use of Device Problem;Improper or Incorrect Procedure or Method	Total Hearing Loss	it was reported that a patient complained of hearing loss after their mri. the patient was scanned during the week of (b)(6) 2021, for a cervical spine exam with contrast. when the pre-contrast was finished, the mr tech entered the room to give the contrast and the patient informed the tech that the ear plug from the right side and fallen out. the tech told the patient that it was okay and the exam was completed without re-inserting the right side plug. the

Report Number	Event Date	Event Type	Manufacturer	Date Received	Product Code	Brand Name	Device Problem	Patient Problem	Event Text
									patient was seen by an ent consultant and a hearing test confirmed that the patient had complete hearing loss on the right side. the patient is currently still under treatment. manufacturer narrative: incident date is not known. (b)(4). there are no additional device identification numbers. ge healthcare's investigation is ongoing. a follow up report will be submitted once the investigation has been completed. device evaluation anticipated, but not yet begun.
3010949642-2021-00002	2020/12/28	Injury	GE HEALTHCARE (TIANJIN) COMPANY LIMITED	2021/04/02	LNH	SIGNA EXPLORER	Use of Device Problem; Insufficient Information	Unspecified Infection; Necrosis; Superficial (First Degree) Burn; Partial thickness (Second Degree) Burn; Full thickness (Third Degree) Burn	it was reported that following an mr examination, a patient developed a superficial burn around the navel. at the time of the scan, there was no redness, however when the patient complained of the burning, the tech moved the patient's clasped hands away from their abdomen. the customer indicated that some padding wasUsed, however no padding wasUsed to prevent the hands from clasping each other or the clasped hands from resting directly on the patient's abdomen. the patient did not require any medical attention for the initial burn. it was later reported that the patient, who passed the mr screening and was wearing mr compatible clothing, sustained a 20x10cm partial thickness burn and a 5x5cm full thickness burn on her abdomen that

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									required surgical excision of the necrotic tissue to heal. plastic surgery was completed on day six post scan. at the time, there were early signs of infection to the burn wound and the patient was hospitalized for a week. manufacturer narrative: there are no additional device identification numbers. ge healthcare's investigation is ongoing. a follow up report will be submitted once the investigation has been completed.
2183553-2021-00003	2020/12/16	Injury	GE MEDICAL SYSTEMS, LLC	2021/03/03	LNH	SIGNA PIONEER	Use of Device Problem	Full thickness (Third Degree) Burn	the customer reported that a patient underwent an mri of the spine, knee and pelvis. at the end of the exam, the patient mentioned to the technologist that their arm felt hot. the technologist examined the patient's arm and at the time, did not observe any areas of redness. the patient was then seen by their physician who stated that the patient had a burn which could have been received from the mri system. the customer was notified approximately three weeks after the event that the patient sustained a deep full-thickness burn to the back of the arm. the area of concern was a deep wound treated by packing the area with gauze and solugel. the burn/wound has been improving. the wound has scarred over and is currently about one inch wide. the patient has extensive "older" tattoos. pads had been placed between the

Report Number	Event Date	Event Type	Manufacturer	Date Received	Product Code	Brand Name	Device Problem	Patient Problem	Event Text
									patient's legs, however pads were not provided against the sides of the bore or between the hand/arm and leg, per ge recommendation. manufacturer narrative: unique identifier: (b)(4). there are no additional device identification numbers. the investigation by ge healthcare (gehc) has been completed. the mr system was operating within specifications and all safety mitigating devices, including the redundant rf power monitors, were functional when checked by the gehc field engineer. the root cause of the injury was determined to be inadequate patient padding for the mri procedure with a secondary root cause of inadequate patient screening. the operator documentation describes theAppropriate safety measures for padding patients for mr exams. in addition, section a conductive material heating states: before scanning, warn patients with permanent eyeliner or other metallic ink tattoos about the risk of skin irritation and instruct them to get prompt medical attention if they experience severe discomfort following an mr exam. the mr operator has the final responsibility for theUse and placement of non-conductive mr compatible padding and preparation of the patient, prior

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									to starting the mr exam procedure. no further actions are planned by gehc.
2183553-2021-00004	2020/12/23	Injury	GE MEDICAL SYSTEMS, LLC	2021/03/03	LNH	GE 1.5T SIGNA HDX MR SYSTEM	Adverse Event Without Identified Device orUse Problem	Bone Fracture(s); Multiple Fractures	it was reported by a customer that a patient sustained fractures of multiple ribs following a mr breast examination. the injury consisted of fractures of the right anterior lateral 4th, 5th, 7th and 8th ribs and at the chondro-cartilage junction of the 4th, 5th, 6th, 7th and 8th ribs with a subacute element of interval healing. the customer denies any traumatic incident that occurred during the mr examination. manufacturer narrative: there are no additional device identification numbers. ge healthcare's investigation is ongoing. a follow up report will be submitted once the investigation has been completed. device evaluation anticipated, but not yet begun.
3003768277-2021-00022	2021/02/05	Injury	PHILIPS ELECTRONICS NEDERLAND B.V.	2021/03/01	LNH	INGENIA 1.5T	Improper or Incorrect Procedure or Method	Partial thickness (Second Degree) Burn	Philips received a report on a heating incident on an ingenia 1.5t mr system
3002808157-2021-65066	2020/12/17	Injury	SIEMENS HEALTHCARE GMBH - MR	2021/02/16	LNH	MAGNETOM SKYRA	Excessive Heating	Unspecified Tissue Injury	it was reported to siemens that a patient suffered a burn on the left shin (approximately 15 cm x 7 cm in diameter) following examination on the magnetom skyra. it was reported that the patient had undergone a wrist scan for surgery that was completed without incident and the patient was discharged. the patient

Report Number	Event Date	Event Type	Manufacturer	Date Received	Product Code	Brand Name	Device Problem	Patient Problem	Event Text
									returned from wrist surgery and reported that their leg was burned during the mr scan. no further information regarding the type of treatment was provided. siemens has requested additional information in order to conduct an investigation of the reported event. manufacturer narrative: siemens is conducting a thorough investigation of the reported events. as this event is under investigation, a root cause has not yet been determined. a supplement report will be filed upon completion of the investigation.
11301046	2021/01/11	Malfunction	GENERAL ELECTRIC COMPANY	2021/02/09	LNK	SIGNA ARTIST	Image Orientation Incorrect	No Clinical Signs, Symptoms or Conditions	last month, the neurosurgery quality assurance surgeon alerted the mri department to a right/left laterality reversal on the mri images performed for the patient listed in this medsun report. it was caught because a known tumor was presenting on the opposite side in comparison to prior mri exams performed at an outside community hospital. an investigation into the cause showed the particular system software platform the patient was imaged on has the location of the patient orientation selection button extremely close to the save series button. this is different in comparison to two other ge mri platforms at the main campus. the only notification to the technologist of this happening would be a slight change in a small animation on the

Report Number	Event Date	Event Type	Manufacturer	Date Received	Product Code	Brand Name	Device Problem	Patient Problem	Event Text
									scanner console which is easily overlooked. we believe the minor change in the position of the patient orientation button is the root cause for the mislabeled images. that radiologist that dictated the exam was paged and has entered an addendum to the report regarding the right/left reversal. the following was initiated by radiologist member of the mri qa team: to prevent future mislabeled exams: made all the staff (managers and technical staff) aware of the issue. urgent email with slides. called each ge scanner and spoke with the scanning technologists. scheduled/had an emergency meeting with the vendor this afternoon. sent screen shots to the vender as well. we are also inquiring about generating a report for a specific dicom tag to see if there are other mislabeled cases which have not been identified. ge representatives were alerted to this last month (soon after the event occurred). last month, the neurosurgery quality assurance surgeon alerted the mri department to a right/left laterality reversal on the mri images performed for the patient listed in this medsun report. it was caught because a known tumor was presenting on the opposite side in comparison to prior mri exams performed at an outside community

Report Number	Event Date	Event Type	Manufacturer	Date Received	Product Code	Brand Name	Device Problem	Patient Problem	Event Text
									hospital. an investigation into the cause showed the particular system software platform the patient was imaged on has the location of the patient orientation selection button extremely close to the save series button. this is different in comparison to two other ge mri platforms at the main campus. the only notification to the technologist of this happening would be a slight change in a small animation on the scanner console which is easily overlooked. we believe the minor change in the position of the patient orientation button is the root cause for the mislabeled images. that radiologist that dictated the exam was paged and has entered an addendum to the report regarding the right/left reversal. the following was initiated by radiologist member of the mri qa team: to prevent future mislabeled exams: made all the staff (managers and technical staff) aware of the issue. urgent email with slides. called each ge scanner and spoke with the scanning technologists. scheduled/had an emergency meeting with the vendor this afternoon. sent screen shots to the vender as well. we are also inquiring about generating a report for a specific dicom tag to see if there are other mislabeled cases which have not been identified. ge

Report Number	Event Date	Event Type	Manufacturer	Date Received	Product Code	Brand Name	Device Problem	Patient Problem	Event Text
									representatives were alerted to this last month (soon after the event occurred).
3003768277-2021-00012	2020/10/14	Injury	PHILIPS ELECTRONICS NEDERLAND B.V.	2021/02/01	LNH	INGENIA AMBITION X	No ApparentAdverse Event	Hearing Impairment	Philips received a report that a patient allegedly suffered hyperacusis andTinnitus in both ears after undergoing a spine examination on an ingenia ambition x mr system.
2183553-2021-00002	2020/11/26	Injury	GE MEDICAL SYSTEMS, LLC	2021/01/27	LNH	SIGNA PIONEER	Use of Device Problem; Device-Device Incompatibility	Partial thickness (Second Degree) Burn;Appropriate Clinical Signs, Symptoms, Conditions Term / Code Not Available	it was reported that after an mri of the thoracic spine, a female patient presented with a 2nd degree partial thickness burn on her breast. the patient was padded properly but the robe that the patient was wearing may have had conductive material in the seam causing this issue. the patient underwent burn therapy which included a skin graft. manufacturer narrative: (b)(4). there are no additional device identification numbers. ge healthcare's investigation is ongoing. a follow up report will be submitted once the investigation has been completed. device evaluation anticipated, but not yet begun.
3010949642-2021-00001		Injury	GE HEALTHCARE (TIANJIN) COMPANY LIMITED	2021/01/20	LNH	SIGNA ARTIST	Adverse Event Without Identified Device orUse Problem	Hearing Impairment ;Tinnitus	it was reported that the customer was notified by their ear, nose, and throat (ent) department that a patient was being treated forTinnitus. the patient believes that it was due to the mri she underwent in november for her shoulder. the patient was provided ear plugs, and at the time of the exam, did not complain of any hearing issues. the patient reported

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									that the ringing in her ears was noticed the following day. the patient is undergoing treatment however, persistentTinnitus remains. manufacturer narrative: incident date is not known. (b)(4). there are no additional device identification numbers. ge healthcare's investigation is ongoing. a follow up report will be submitted once the investigation has been completed. device evaluation anticipated, but not yet begun.
MW5098897	2021/01/09	Injury	PHILIPS NORTH AMERICA LLC	2021/01/20	LNH	INGENIA MRI SCANNER	Collapse; Detachment of Device or Device Component	Fall	a patient was being moved from the mri trolley back to a stretcher when the table top came off the trolley and collapsed to the floor. the patient was assisted off the table to the floor and was fortunately not injured. fda safety report id # (b)(4).
3003768277-2021-00005	2020/12/15	Injury	PHILIPS ELECTRONICS NEDERLAND B.V.	2021/01/11	LNH	INGENIA	Improper or Incorrect Procedure or Method	Laceration(s)	it was reported that a patient was positioned on the table top on the mri flex track by 2 operators. then the patient and the flex track and table top were positioned above the base of the mri bed. after this the mri bed was raised up. during this upward movement of the bed the patient left her hand hanging between the flex track and the base of the mri bed. this was not noticed by the operators, as a result a finger got pinched and part of it was cut off. it was stated by the operators that they were watching the patient from either side of the mri bed but

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									that they had not noticed the exact position of the patients hand due to the patient being covered by sheets.
3003768277-2021-00004	2020/12/15	Injury	PHILIPS ELECTRONICS NEDERLAND B.V.	2021/01/08	LNH	INGENIA 1.5T	Improper or Incorrect Procedure or Method;Adverse Event Without Identified Device orUse Problem	Partial thickness (Second Degree) Burn	Philips received a report on a heating incident on ingenia 1.5t mr system
3003768277-2020-01039	2020/12/02	Injury	PHILIPS ELECTRONICS NEDERLAND B.V.	2020/12/18	LNH	INGENIA 3.0T	Improper or Incorrect Procedure or Method	Partial thickness (Second Degree) Burn	Philips received a report on a heating incident on an ingenia 1.5t mr system .
3002808157-2020-58550	2020/11/21	Injury	SIEMENS HEALTHCARE GMBH- MR	2020/12/18	LNH	MAGNETOM AERA	Excessive Heating	Unspecified Tissue Injury	it was reported to siemens that anAdverse event occurred following examination on the magnetom aera system. it was reported that a male patient suffered second degree burns (approximately 15mm in diameter) to both inner thighs. the patient received medical treatment by the medical team. no further information regarding the type of treatment was provided. siemens has requested additional information in order to conduct an investigation of the reported event. manufacturer narrative: siemens is conducting a thorough investigation of the reported events. as this event is

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									under investigation, a root cause has not yet been determined. a supplement report will be filed upon completion of the investigation.
3003768277-2020-01037	2019/12/15	Injury	PHILIPS ELECTRONICS NEDERLAND B.V.	2020/12/17	LNH	INGENIA 1.5T	Adverse Event Without Identified Device orUse Problem; No ApparentAdverse Event	Hearing Impairment ; Partial Hearing Loss	Philips received a report that a patient allegedly suffered a permanent hearing loss/Tinnitus after an examination on an ingenia 1.5t mr system.
2183553-2020-00017	2020/11/12	Injury	GE MEDICAL SYSTEMS, LLC	2020/12/03	LNH	SIGNA ARCHITECT	Melted;Use of Device Problem	Partial thickness (Second Degree) Burn	it was reported that a patient undergoing an mri of the spine using the gems flex coil alerted the technologist that the pillow was burning. the patient was able to be brought out of the scanner quickly without any injury. when the technologist flicked the pillow off the table, a small piece of rubber from the casing covering the pillow landed on his face causing a second-degree burn to a high-risk area. the ge healthcare field engineer found that the cable coil adapter had crossed the medium flex coil cable and melted the two together. the mr scanner was inspected and found to be working per specification. manufacturer narrative: (b)(4). there are no additional device identification numbers. ge

Report Number	Event Date	Event Type	Manufacturer	Date Received	Product Code	Brand Name	Device Problem	Patient Problem	Event Text
									healthcare's investigation is ongoing. a follow up report will be submitted once the investigation has been completed. device evaluation anticipated, but not yet begun.
3003768277-2020-01033	2020/10/26	Injury	PHILIPS ELECTRONICS NEDERLAND B.V.	2020/12/03	LNH	INGENIA 1.5T	Improper or Incorrect Procedure or Method	Partial thickness (Second Degree) Burn	Philips received a report on a heating incident on an ingenia 1.5t mr system. patient suffered a large 2nd degree burn to the right buttock/hip.
3002808157-2020-55327	2020/03/01	Injury	SIEMENS HEALTHCARE GMBH- MR	2020/11/13	LNH	MAGNETOM AERA	Adverse Event Without Identified Device orUse Problem	Tinnitus	it was reported to siemens that anAdverse event occurred following examination on the magnetom aera system. theUser reported that a patient is suffering fromTinnitus problems after an mr examination 8 months ago. according to the information provided, the patient had earplugs during the scan. no further information was provided in regards to the state of health of the patient involved. siemens has requested additional information in order to conduct an investigation of the reported event. manufacturer narrative: siemens is conducting a thorough investigation of the reported events. as this event is under investigation, a root cause has not yet been determined. a supplement report will be filed upon completion of the investigation.
2183553-2020-00016	2020/10/18	Injury	GE MEDICAL SYSTEMS, LLC	2020/11/12	LNH	GE 3.0T SIGNA HDX MR SYSTEM	Use of Device Problem; Device	Bone Fracture(s); Skin Irritation;	it was reported that a staff member brought a ferrous oxygen tank into the scan room that became attracted to the magnet. when moving toward

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							Unsafe toUse in Environment; Device-Device Incompatibility	Multiple Fractures	the magnet, the tank struck a staff member on the right side of their mid section, scratching the palm of their hand and breaking two ribs, for which she was admitted to the hospital for treatment. the patient was not injured due to this issue. the ge field engineer ramped ramped down the magnet and removed the oxygen tank from the room. manufacturer narrative: age: 25-30 years old. weight: 50-55kg. unique identifier: udi not required. there are no additional device identification numbers. ge healthcare's investigation is ongoing. a follow up report will be submitted once the investigation has been completed.
3002808157-2020-49136	2020/09/24	Malfunction	SIEMENS HEALTHCARE GMBH- MR	2020/10/22	LNH	MAGNETOM SOLA	No ApparentAdverse Event	No Clinical Signs, Symptoms or Conditions	it was reported to siemens that a malfunction occurred while operating the magnetom sola system. during a cardiac study, theUser reported that the system hung up, and the study had to be repeated. it is not known if additional contrast was administered. at this time, we are unaware of any impact to the state of health of the patient involved. siemens has requested additional information in order to conduct an investigation of the reported event. manufacturer narrative: siemens is conducting a thorough investigation of the reported events. as this event is under investigation, a root cause has not yet been determined. a

Report Number	Event Date	Event Type	Manufacturer	Date Received	Product Code	Brand Name	Device Problem	Patient Problem	Event Text
									supplement report will be filed upon completion of the investigation.
3003768277-2020-01007	2020/09/11	Injury	PHILIPS ELECTRONICS NEDERLAND B.V.	2020/10/05	LNH	INGENIA	Improper or Incorrect Procedure or Method	Bone Fracture(s)	Philips received a report on an attraction incident on an ingenia 1.5t mr system. a fire extinguisher was brought into the examination room, attracted to the magnet, injuring aUser.
2183553-2020-00015		Injury	GE MEDICAL SYSTEMS, LLC	2020/09/21	LNH	GE SIGNA EXCITE 3.0T MR SYSTEM	Adverse Event Without Identified Device orUse Problem	Hearing Impairment ; Hearing Loss	the customer informed ge healthcare that a patient reported hearing loss after a brain mri. the patient was seen by their physician who confirmed the hearing loss and has prescribed cortisone treatment. the patient was provided ear plugs for hearing protection. manufacturer narrative: incident date is not known. there are no additional device identification numbers. ge healthcare's investigation is ongoing. a follow up report will be submitted once the investigation has been completed. device evaluation anticipated, but not yet begun.
MW5096789	2020/07/30	Injury	SIEMENS AG / SIEMENS HEALTHCARE GMBH	2020/09/21	LNH	SIEMENS MAGNETOM	Overheating of Device	Burn, Thermal	patient sustained burn to posterior medial distal thigh, measuring app 2 x 2 cm during mri of right lower extremity. patient reported that he felt warm to technologist after the scan, then reported redness and "bumps" on his leg while driving home. upon questioning, patient admitted that he felt burning during the scan, but did not alert the technologist at the time. (b)(6) healthcare followed its standard mri

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									screening and imaging protocols; patient sustained burn despite allAppropriate action. no risks or contributing factors identified by institutional review. event promptly reported to siemens. patient referred to wound care and plastic surgeon.
3003768277-2020-01006	2020/08/27	Injury	PHILIPS ELECTRONICS NEDERLAND B.V.	2020/09/08	LNH	INGENIA 3.0T	Improper or Incorrect Procedure or Method	Skull Fracture	Philips received a report on an attraction incident on an ingenia 3.0t mr system.
MW5096293	2020/08/14	Injury	SIEMENS AG/SIEMENS HEALTHCARE GMBH	2020/08/26	LNH	SIEMENS MRI	Adverse Event Without Identified Device orUse Problem	Burn, Thermal	pt. received skin contact burns on left distal thumb and left upper outer thigh after post triple study mri under anesthesia. the pts. thumb and thigh were touching during mri. fda safety report id # (b)(4).
3002808157-2020-40244	2020/07/27	Injury	SIEMENS HEALTHCARE GMBH- MR	2020/08/21	LNH	MAGNETOM AERA	Use of Device Problem	Patient Problem/Medical Problem; Partial thickness (Second Degree) Burn	it was reported to siemens that anAdverse event occurred while operating the magnetom aera system. theUser reported that a female patient suffered second degree burns on both thighs following examination. the patient presented with redness and blisters approximately 3 cm in diameter. the patient was provided with medical care. no further information regarding the type of treatment was provided. manufacturer narrative: siemens has completed an investigation of the reported event. the root cause was determined to be aUser error. the root cause for the 2nd degree burn is a skin to skin

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									contact and therefore aUser error. to prevent possible burns, a warning notice is implemented in the magnetom family - operator manual - mr-system - syngo mr e11* (p.19-21), which contains the necessary preventive measures. it is requested that direct skin contact must be avoided by using an at least 5 mm thick cushion between the legs. the system is equipped with a squeeze ball and an intercom for the patient to alert the operator in the event of experiencing discomfort. it is theUser's responsibility to follow the instructions given in the operator manual regarding correct patient positioning and monitoring in order to avoid such incidents in the future.
3002808157-2020-38130	2018/12/13	Injury	SIEMENS HEALTHCARE GMBH	2020/08/06	LNH	MAGNETOM AERA	Use of Device Problem; Human-Device Interface Problem; Inadequate User Interface	Patient Problem/Medical Problem	according to the information provided to siemens healthineers by the hospital, a patient was injured during a scan involving siemens healthineers magnetom aera device. manufacturer narrative: siemens healthineers has requested but hasn't received any additional details from the hospital.
2183553-2020-00013	2020/06/17	Injury	GE MEDICAL SYSTEMS, LLC	2020/08/05	LNH	GE 1.5T SIGNA HDX MR SYSTEM	Use of Device Problem; Unintended Movement	Pain; Skin Irritation; Ulcer; Pressure Sores	it was reported that a patient underwent bilateral shoulder exams. the patient was padded between the bore and arms, however due to involuntary movement, the pads may have shifted. the patient complained of elbow pain and was reported to

Report Number	Event Date	Event Type	Manufacturer	Date Received	Product Code	Brand Name	Device Problem	Patient Problem	Event Text
									present with redness on the skin of the left elbow. the patient was seen by plastic surgery who diagnosed the area on the elbow as pressure ulcer versus an rf burn. treatment was provided by plastic surgery for the pressure ulcers. information provided by the customer states the patient was in the scanner for two hours. manufacturer narrative: unique identifier: udi not required. there are no additional device identification numbers at this time, requested but not yet received. ge healthcare's investigation is ongoing. a follow up report will be submitted once the investigation has been completed. device evaluation anticipated, but not yet begun.
2183553-2020-00011	2015/02/23	Injury	GE MEDICAL SYSTEMS, LLC	2020/07/29	LNH	GE 1.5T SIGNA HDX MR SYSTEM	Improper or Incorrect Procedure or Method	Burn, Thermal	it was reported that there was a dark red burn measuring 10mm in diameter on each calf of a patient that had an mri exam. the patient underwent debridement of his wounds. there was inadequate padding placed between the patient's calves to prevent body loops or between the patient and the magnet bore. manufacturer narrative: patient identifier could not be obtained due to country privacy laws. the initial reporter is located outside the u.s., and initial reporter information is not provided due to country privacy laws. the ge healthcare investigation indicates that the incident appears to

Report Number	Event Date	Event Type	Manufacturer	Date Received	Product Code	Brand Name	Device Problem	Patient Problem	Event Text
									be the result of calf to calf contact due to lack of padding. there was inadequate padding placed between the patient's calves to prevent body loops or between the patient and the magnet bore. the available information did not indicate there were any system related issues that may have contributed to the incident. there is no evidence that the mr system malfunctioned. the system is designed to comply with iec 60601-2-33, including the requirements intended to minimize the likelihood of patient warming. the mr safety guide provides warming and safety instructions regarding patient warming. no further actions are planned at this time. note: this initial report (2183553-2015-00010) is being submitted today as it was submitted in error as a f/u report in 2015 which should have been submitted as initial.
2183553-2020-00009	2020/06/10	Injury	GE MEDICAL SYSTEMS, LLC	2020/07/28	LNH	GE 3.0T SIGNA HDX MR SYSTEM	Adverse Event Without Identified Device orUse Problem	Burn(s); Swelling	it was reported that during their mr exam, a patient developed a burn and blister on the right calf area. the patient made the technologist aware and the exam was stopped immediately and the area was rinsed with cool tap water for 30 minutes, disinfected and bandaged. two days later when changing the dressing on the calf area, a burn and blister were also noted on the patient's heel. both areas are being treated with multiple

Report Number	Event Date	Event Type	Manufacturer	Date Received	Product Code	Brand Name	Device Problem	Patient Problem	Event Text
									dressing changes over time as they heal and in every dressing change, cleaning the wound and removing dead skin tissue. the customer stated that all ge recommended rf padding wasUsed for the exam. manufacturer narrative: unique identifier: udi not required. there are no additional device identification numbers. ge healthcare's investigation is ongoing. a follow up report will be submitted once the investigation has been completed. device evaluation anticipated, but not yet begun.
3002808157-2020-38264	2020/07/14	Malfunction	SIEMENS HEALTHCARE GMBH	2020/07/24	LNH	MAGNETOM AERA	Poor Quality Image;Use of Device Problem	Breast Cancer; Patient Problem/Medical Problem	it was reported to siemens that the magnetom aera system does not produce good quality images. a relapse of a breast tumor was not captured during an mri exam using the 4-channel breast coil. the patient had to undergo a surgery. the reported incident occurred in (b)(6). manufacturer narrative: siemens is conducting a thorough investigation of the reported incident. a supplemental report will be submitted if additional information becomes available. internal id # (b)(4).
3003768277-2020-01005	2020/07/13	Malfunction	PHILIPS ELECTRONICS NEDERLAND B.V.	2020/07/23	LNH	INGENIA 3.0T	No ApparentAdverse Event	No Known Impact Or Consequence To Patient	magnet quench after a fire in the vicinity of the examination room.
3003768277-2020-01004	2020/07/03	Malfunction	PHILIPS ELECTRONICS	2020/07/08	LNH	INGENIA 1.5T	No ApparentA	No Patient Involvement	Philips received a report on a fire in the hospital which damaged the mr system.

Report Number	Event Date	Event Type	Manufacturer	Date Received	Product Code	Brand Name	Device Problem	Patient Problem	Event Text
			NEDERLAND B.V.				dverse Event		
3002808157-2020-36316	2020/06/11	Malfunction	SIEMENS HEALTHCARE GMBH	2020/07/07	LNH	MAGNETOM SOLA	Use of Device Problem	Bone Fracture(s); Patient Problem/Medical Problem	siemens was notified about an incident that occurred on the magnetom sola system. patient was positioned headfirst on the table and completed her cervical and thoracic spine studies. as the patient was being removed from the bore of the mri machine, the patient screamed. the patient informed the technologist that her shoulder hurt. the patient was then placed in the wheelchair and left the facility. later the patient had follow-up x-rays that showed she had an impacted humerus fracture. siemens was not provided details of the aftercare of the patient once she left the medical facility. manufacturer narrative: siemens is conducting a thorough investigation of the reported events. as this event is under investigation, a final root cause has not yet been determined. a supplement report will be filed upon completion of the investigation. internal id # (b)(4).
3002808157-2020-27964	2020/04/21	Injury	SIEMENS HEALTHCARE GMBH- MR	2020/05/19	LNH	MAGNETOM SKYRA	Use of Device Problem	Burn(s); Injury; Full thickness (Third Degree) Burn	it was reported to siemens that anAdverse event occurred following examination on the magnetom skyra system. a sedated patient suffered a 3rd degree burn to the lateral left elbow approximately 10 cm x 6 cm in diameter during a shoulder scan. the patient was positioned with arms at the side and slightly raised from the

Report Number	Event Date	Event Type	Manufacturer	Date Received	Product Code	Brand Name	Device Problem	Patient Problem	Event Text
									table with a towel to facilitate better positioning of iv tubing. additionally, longitudinal pads wereUsed for positioning as well as a pillow case on the left side, a knee cushion, and a strap and sandbag to hold the body 18 coil across the upper chest area. the injury was observed immediately after examination by the technologist and physician. at this time, treatment is ongoing. siemens has requested additional information in order to conduct an investigation of the reported event. manufacturer narrative: siemens is conducting a thorough investigation of the reported events. as this event is under investigation, a root cause has not yet been determined. a supplement report will be filed upon completion of the investigation.
2183553-2020-00007	2020/02/14	Injury	GE MEDICAL SYSTEMS, LLC	2020/05/01	LNH	SIGNA ARCHITECT	Use of Device Problem;Adverse Event Without Identified Device orUse Problem	Burn(s); Full thickness (Third Degree) Burn	it was reported that six weeks after an abdominal exam, a patient went to a clinic stating that she had experienced a left elbow/forearm burn during her exam. the burn was diagnosed as third degree and was treated by excisional debridement. manufacturer narrative: unique identifier: (b)(4). there are no additional device identification numbers. ge healthcare's investigation is ongoing. a follow up report will be submitted once the investigation has been completed.

Report Number	Event Date	Event Type	Manufacturer	Date Received	Product Code	Brand Name	Device Problem	Patient Problem	Event Text
									device evaluation anticipated, but not yet begun.
3002808157-2020-25977	2020/03/31	Injury	SIEMENS HEALTHCARE GMBH- MR	2020/04/08	LNH	MAGNETOM AERA	Use of Device Problem	Tissue Damage; Injury	it was reported to siemens that anAdverse event occurred while operating the magnetom aera system. it was reported that a ferromagnetic chair was attracted to the magnet resulting in an injury to the operators hand. the injury necessitated surgical intervention including a skin graft. there is no report of impact to the state of health of any patient involved. manufacturer narrative: siemens has completed an investigation of the reported event. the root cause was determined to be the introduction of ferromagnetic pieces into the mr examination room and therefore aUser error. due to the strong magnetic field, particular safety measures have to be adhered to in order to prevent injuries. therefore, the corresponding magnetom operator manual and the magnetom system owner manual provide clear instructions and warnings regarding both magnetic field hazards and training of personnel with regards to mr safety. the responsibility to instruct personnel and patients who have access to the mr examination room about magnetic field hazards lies with the customer. the manuals state that only equipment specified or recommended forUse in the

Report Number	Event Date	Event Type	Manufacturer	Date Received	Product Code	Brand Name	Device Problem	Patient Problem	Event Text
									controlled area (mr examination room) shall beUsed. the introduction of ferromagnetic objects into the magnetic field is contrary to the statements given in the operating instructions.
2183553-2020-00006	2016/04/10	Injury	GE MEDICAL SYSTEMS, LLC	2020/03/31	LNH	GE 1.5T SIGNA HDX MR SYSTEM	Adverse Event Without Identified Device orUse Problem	Bone Fracture(s)	ge healthcare recently became aware that a patient who underwent an mri breast exam in 2016 sustained a displaced rib fracture. manufacturer narrative: there are no additional device identification numbers. the investigation by ge healthcare (gehc) has been completed. the mr scanner appeared to be functioning according to specification and the breast coil was fully functional. the ge 1.5t hd breast array is designed to accommodate best female anatomy and padding is provided to relieve any pressure points, which would distribute the patient's weight over entire anterior surface of the chest. based on the information provided, there is no apparent root cause of the injury. the scanner and breast coil were working as expected and the technologist demonstrated good clinical care of the patient from preparation of the scan to attentiveness during the exam. no further actions are planned by gehc.
MW5093952	2020/02/05	Injury	PHILIPS MEDICAL SYSTEMS	2020/03/27	LNH	INGENIA ELITION X	Thermal Decomposition of Device;	No Known Impact Or Consequen	mri burnout; on february 5th, the mri scanner supplied byPhilipshealthcare / medical systems, (b)(4) has burnt. the fire / smoke started from

Report Number	Event Date	Event Type	Manufacturer	Date Received	Product Code	Brand Name	Device Problem	Patient Problem	Event Text
			NEDERLAND B. V.				Fire; Smoking	ce To Patient	magnet. there was a smoke during patient scan and scan was stopped and askedPhilipsengineer to visit to check the problem. during engineer testing the phantom scans smoke emitted from magnet and complete mri was burnt. fortunately, there was not pt during this time. fda safety report id# (b)(4).
3003768277-2020-01003	2020/01/30	Injury	PHILIPS ELECTRONICS LTD.	2020/03/17	LNH	INGENIA 1.5T	Improper or Incorrect Procedure or Method;Adverse Event Without Identified Device orUse Problem	Full thickness (Third Degree) Burn	the patient heating form was send today to customer. actually the event date is unknown, waiting information from customer. translation of the attached email: good morning, (b)(6), thank you for the confirmation of the software version without any connection, (b)(6) alerted me to the occurrence of two very close cases of burns on the left side of the patient, in the normal direction. 1st case of proven burns on the breast, obese patient, push button (shirt) in contact with the mri hood and the breast. mri in progress it has taken steps to isolate the patient's skin with the mri hood. no antenna elements (flexible antenna) are in contact with the patient. i am asking for your opinion. can we rule out the hypothesis of heating at the level of a gradient coil? of another component? do you have any internal probes? a monitoring of the temperature or power consumption of a component located at this location? how could we prove the

Report Number	Event Date	Event Type	Manufacturer	Date Received	Product Code	Brand Name	Device Problem	Patient Problem	Event Text
									absence/presence of internal heating on mri? your elements should allow us to make the right hypotheses. thank you for your input, (b)(6).
2183553-2020-00005	2019/11/28	Injury	GE MEDICAL SYSTEMS, LLC	2020/03/12	LNH	GE 1.5T SIGNA HDX MR SYSTEM	Adverse Event Without Identified Device orUse Problem	Bone Fracture(s)	it was reported to ge healthcare that a patient undergoing a breast mri exam sustained a non-displaced rib fracture. the patient was positioned normally upon the breast coil as instructed by the mri technologist and there were no reports of compression on the sides or top of the magnet during movement into the system. the patient made no complaint at the time of exam, and only reported the injury after having been evaluated by her physician which included imaging, confirming the rib fracture. manufacturer narrative: unique identifier: udi not required. there are no additional device identification numbers. ge healthcare's investigation is ongoing. a follow up report will be submitted once the investigation has been completed.
3002808157-2020-09293	2019/11/12	Injury	SIEMENS HEALTHCARE GMBH- MR	2020/02/28	LNH	MAGNETOM SKYRA	Use of Device Problem	Undesired Nerve Stimulation ; Patient Problem/Medical Problem	it was reported to siemens that anAdverse event occurred while operating the magnetom skyra system. an implanted vns (vagus nerve stimulation) device heated up during the mri scan and caused a burning/glowing experience for the patient in the left thoracic area. the patient pressed the squeeze ball during or after the third

Report Number	Event Date	Event Type	Manufacturer	Date Received	Product Code	Brand Name	Device Problem	Patient Problem	Event Text
									measurement. no injuries were visible on the skin. after aborting the mri scan, the patient was immediately transferred to the emergency department for examination. the palpation around the implant was painful and the patient suffered swallowing problems. the patients lab and ecg were normal. the patient went home later that day with pain medication. the patient is now scheduled for surgical removal of the vns implant and lead. manufacturer narrative: siemens has completed an investigation of the reported event. the root cause was determined to be aUser error. the system is equipped with a squeeze ball and an intercom for the patient to alert the operator in the event of experiencing discomfort. with these existing safety features, a death or serious injury is unlikely. there is a clear warning in the magnetom family operator manual - mr system syngo mr e11. in general, an mr examination is contraindicated for patients with electronic or electronically conductive implants or metals, especially those containing ferromagnetic foreign matter. certain implantable medical devices have been cleared, approved and/or licensed by the competent governmental authorities and/or

Report Number	Event Date	Event Type	Manufacturer	Date Received	Product Code	Brand Name	Device Problem	Patient Problem	Event Text
									labeled by the device manufacturer as "mr conditional". it is the responsibility of the device manufacturer to declare an implantable medical device as mr conditional ifAppropriate and to define the conditions (constraints) for safe mr scanning. the mr operator must be aware of any such conditions for mr scanning. it is the obligation of the mr operator to assure that these conditions are strictly adhered to. to obtain these specific conditions the mr operator may refer to the labeling of the implantable medical device or contact the device manufacturer. siemens mr does not assume responsibility or liability for the operation of the mr system with any implantable medical device.
3003768277-2020-01000	2020/02/05	Malfunction	PHILIPS ELECTRONICS NEDERLAND B.V.	2020/02/19	LNH	INGENIA ELITION X	Fire	No Known Impact Or Consequence To Patient	Philips received a report on a fire incident with the magnet of an ingenia elition x mr system.
3002808157-2020-15121	2020/01/10	Injury	SIEMENS HEALTHCARE GMBH- MR	2020/02/04	LNH	MAGNETOM SOLA	Use of Device Problem	Radiation Overdose; Patient Problem/Medical Problem	it was reported to siemens that anAdverse event occurred following examination on the magnetom sola system. it was reported that two patients received incorrect xray radiotherapy treatment due to misdiagnosis (positioning ball artifacts appears exactly the same as metastasis in the brain region image). at this time, we are unaware of any

Report Number	Event Date	Event Type	Manufacturer	Date Received	Product Code	Brand Name	Device Problem	Patient Problem	Event Text
									impact to the state of health of the patients involved. siemens has requested additional information in order to conduct an investigation of the reported event. manufacturer narrative: at the moment, we still assume a connection with the markers and not a malfunction. when using parallel imaging techniques the high signal from a marker close to a coil element cannot fully be resolved and ghosts may occur shifted by half of the fov in the accelerated encoding direction. in this situation, when using for example caipirinha sequences with a sliceshiftfactor and acceleration in 2 directions (slice and phase encoding direction), the folding artifacts may occur whose position is shifted by half of the field of view in 2 directions. this can be very difficult to identify since the appear not on the same slice in the original acquired, main orientation, and the artifact can easily be confused with a lesion. siemens is conducting a thorough investigation of the reported events. as this event is under investigation, a final root cause has not yet been determined. a supplement report will be filed upon completion of the investigation.
2183553-2020-00003	2019/09/18	Injury	GE MEDICAL SYSTEMS, LLC	2020/01/28	LNH	GE 1.5T SIGNA HDX MR SYSTEM	Use of Device Problem;Adverse Event	Acoustic Trauma;Tinnitus	it was reported via medwatch report # mw5091794, that following an mr exam of the shoulder, a patient complained of an acoustic injury. the

Report Number	Event Date	Event Type	Manufacturer	Date Received	Product Code	Brand Name	Device Problem	Patient Problem	Event Text
							Without Identified Device orUse Problem		patient was evaluated by an ent physician three weeks after the mr exam and was diagnosed withTinnitus and hyperacusis. the patient was prescribed oral steroids which did not resolve the acoustic injury. the patient was provided the alert bulb during the exam, however, the patient never utilized the alert or informed the technologist of any acoustic discomfort or concerns throughout the duration of the exam. the patient was provided headphones with an nrr of 30 which meets ge healthcare's requirements for hearing protection, but the patient stated that they were loose fitting and did not completely cover both ears. manufacturer narrative: ge healthcare's investigation is ongoing. a follow up report will be submitted once the investigation has been completed. device evaluation anticipated, but not yet begun.
3002808157-2020-15561	2018/11/20	Injury	SIEMENS HEALTHCARE GMBH- MR	2020/01/20	LNH	MAGNETOM AERA	Use of Device Problem	Injury; Sensitivity of Teeth; Patient Problem/Medical Problem	it was reported to siemens that anAdverse event occurred while operating the magnetom aera system. a patient reported directly to the health canada authority that during an mri examination of his knee he felt severe and unexpected pain in his knee. the patient clenched his teeth to tolerate the pain and while doing so he broke a tooth. the broken tooth required dental surgery. the customer was unaware

Report Number	Event Date	Event Type	Manufacturer	Date Received	Product Code	Brand Name	Device Problem	Patient Problem	Event Text
									of any issue at the time of the event. siemens has requested additional information in order to conduct an investigation of the reported event. manufacturer narrative: additionally, the patient stated: "i do not believe the mri was the root cause of my severe pain and broken tooth. the condition in my knee pre-existed and was aggravated by the mri. in my case, there was no reason to believe i would encounter this pain during the mri procedure (e.g. no metal in the knee etc.} and the mri created a condition for negative orAdverse consequences." siemens is conducting a thorough investigation of the reported events. as this event is under investigation, a root cause has not yet been determined. a supplement report will be filed upon completion of the investigation.
2183553-2020-00001	2019/12/22	Injury	GE MEDICAL SYSTEMS, LLC	2020/01/15	LNH	SIGNA PIONEER	Electromagnetic Interference;Improper or Incorrect Procedure or Method	Laceration(s); Injury	it was reported that subcontractors were working to improve the shielding to the magnet scan room and were carrying a sheet of steel into the magnet room when it was attracted to the magnet. two workers were seriously injured. worker a sustained a laceration to his neck and was taken to surgery to close up the wound. he is recovering. the customer (b)(6) provided an updated status pending the completion of their investigation. this record will document the injuries for worker a.

Report Number	Event Date	Event Type	Manufacturer	Date Received	Product Code	Brand Name	Device Problem	Patient Problem	Event Text
									(2183553-2020-00002 will document the injuries for worker b). manufacturer narrative: the investigation by ge healthcare has been completed. the incident occurred due to a lack of controlled access to the scan room by the gehc pmi (project manager of install) & failure of the subcontractors to follow verbal and written safety warnings in regards to ferrous material risks. the pmi was confirmed to have received theAppropriate mr safety training and the ferrous object warning signs were present at the site. the mr service safety manual and installation manual clearly define the risks associated with entering the scan room with ferrous materials when the magnet is at field. manufacturer narrative: age at the time of event: (b)(6). unique identifier: (b)(4). there are no additional device identification numbers. ge healthcare's investigation is ongoing. a follow up report will be submitted once the investigation has been completed. device evaluation anticipated, but not yet begun.
2183553-2020-00002	2019/12/22	Injury	GE MEDICAL SYSTEMS, LLC	2020/01/15	LNH	SIGNA PIONEER	Electromagnetic Interference;Improper or Incorrect	Cardiac Arrest; Cardiopulmonary Arrest; Cervical	it was reported that subcontractors were working to improve the shielding to the magnet scan room and were carrying a sheet of steel into the magnet room when it was attracted to the magnet. two workers

Report Number	Event Date	Event Type	Manufacturer	Date Received	Product Code	Brand Name	Device Problem	Patient Problem	Event Text
							Procedure or Method	Changes; Injury	were seriously injured. worker b had a cardiopulmonary arrest immediately after the accident. he was resuscitated with a defibrillator. no visible trauma was noticed at the time of the event, however it was discovered some time later that he had a cervical spine injury which required surgery. the patient was unconscious for some time, however the customer has confirmed that he has regained consciousness. the customer hasn't provided an updated status pending the completion of their investigation. this record will document the injuries for worker b. (2183553-2020-00001 will document the injuries for worker a.) manufacturer narrative: age at the time of event: 60s. (b)(4). there are no additional device identification numbers. ge healthcare's investigation is ongoing. a follow up report will be submitted once the investigation has been completed. device evaluation anticipated, but not yet begun.
3002808157-2019-06931	2019/10/25	Injury	SIEMENS HEALTHCARE GMBH- MR	2019/12/19	LNH	MAGNETOM AERA	Use of Device Problem	Burn(s); Injury	it was reported to siemens that anAdverse event occurred following examination on the magnetom aera system. after examination, a patient suffered from an intense redness on the left side of the abdomen from the arm to the hip which included two large blisters. no information regarding the size or degree of the

Report Number	Event Date	Event Type	Manufacturer	Date Received	Product Code	Brand Name	Device Problem	Patient Problem	Event Text
									blisters has been provided. additionally, no information regarding any medical intervention or healing complications has been provided. siemens has requested additional information in order to conduct an investigation of the reported event. manufacturer narrative: siemens is conducting a thorough investigation of the reported events. as this event is under investigation, a root cause has not yet been determined. a supplement report will be filed upon completion of the investigation.
3003768277-2019-00102	2019/11/13	Injury	PHILIPS HEALTHCARE	2019/12/16	LNH	INGENIA AMBITION X	Adverse Event Without Identified Device orUse Problem	Skin Irritation; Skin Inflammation	Philips received a report from a customer related to a patient heating incident (blistering on the right elbow) with a flex coil on an ingenia ambition x mr system. manufacturer narrative: the investigation is still ongoing for this event. when the investigation is completed a follow-up will sent to the fda.
9383176	2019/09/10	Malfunction	SIEMENS HEALTHCARE GMBH	2019/11/27	LNH	MAGNETOM SKYRA FIT	Mechanical Problem	No Information	equipment ceased to acquire pictures during exam. the software version for our mri is ve 11c. patient was scheduled for mri breast biopsy. patient was thoroughly screened and consented for the procedure. iv was started per routine protocol for contrast administration. patient was positioned for the procedure. however, the mri machine failed to scan and obtain any images. due to the machine failure, the procedure was aborted. dr. explained the

Report Number	Event Date	Event Type	Manufacturer	Date Received	Product Code	Brand Name	Device Problem	Patient Problem	Event Text
									situation to the patient and she was very understanding. patient will be rescheduled as soon as the issue is resolved.
2183553-2019-00028	2019/10/23	Injury	GE MEDICAL SYSTEMS, LLC	2019/11/21	LNH	1.5T SIGNA HDXT	Electromagnetic Interference;Improper or Incorrect Procedure or Method	Injury; Loss of consciousness; Tooth Fracture	it was reported by the news media in (b)(6) and confirmed by the customer that a male technologist entered the mr scan room of a mobile mri unit wearing a weight vest normallyUsed for exercise. the technologist was attracted to the magnet. the technologist is said to have sustained serious injuries to the head/neck area, lost two teeth and was immediately admitted to the hospital's intensive care unit. it was reported that the patient inside the scanner at the time of the event did not sustain any injuries. the patient heard the technologist scream and saw his hand at the edge of the magnet bore. realizing that something was wrong, the patient crawled out of the other end of the magnet and was able to exit the mobile van through the service door. the patient alerted two security guards who responded and cut the weight vest off of the technologist, freeing him from the magnet. both security guards sustained minor injuries. it appears that no damage was caused to the mr system. it was reported that the system was ramped down so that police could conduct an investigation. manufacturer narrative:

Report Number	Event Date	Event Type	Manufacturer	Date Received	Product Code	Brand Name	Device Problem	Patient Problem	Event Text
									unique identifier: udi not required. no additional device identification numbers have been received. information requested but not yet received. ge healthcare's investigation is ongoing. a follow up report will be submitted once the investigation has been completed. device evaluation anticipated, but not yet begun.
3003768277-2019-00086	2019/10/18	Injury	PHILIPS HEALTHCARE	2019/11/08	LNH	INGENIA 3.0T	Overheating of Device	No Known Impact Or Consequence To Patient	Philips received a report on a heating incident with an ingenia 3.0t mr system. manufacturer narrative: based on the provided information and test performed on site there is no indication of a malfunction of the mr system or coilUsed that contributed to the event. the observed blister can be explained by skin to skin contact between the thumb of the patient and the forehead. it was stated by the customer that during the scan the patient moved his thumb to his forehead and created self-inflicted rf loop. contributing factor in this case: 7 scans with high sar values (> 2 w/kg) were consecutively executed, allowing no cool down time for the patient.
2183553-2019-00027	2019/10/10	Injury	GE MEDICAL SYSTEMS, LLC	2019/11/07	LNH	SIGNA PIONEER	Use of Device Problem;Improper or Incorrect	Radiation Burn; Burn(s); Tissue Damage; Full	it was reported that during a mri exam, a patient sustained a burn to the left thumb which had a non mri safe pulse oximeter attached/placed. the patient's burn injury resulted in amputation of the thumb.

Report Number	Event Date	Event Type	Manufacturer	Date Received	Product Code	Brand Name	Device Problem	Patient Problem	Event Text
							Procedure or Method	thickness (Third Degree) Burn	manufacturer narrative: the investigation by ge healthcare (gehc) has been completed. a gehc field engineer completed system testing and verified that the mri scanner was operating normally and within performance specifications. the root cause was determined to be operator error related to theUse of a non-mr safe conductive pulse oximeter during the patient mri scan. the gehc operator manual states that patients are to be thoroughly screened for the presence of any metallic devices or objects.Users should consult the device manufacturer's instructions and safety guidelines. further, the operator manual for the oximax n-65 and nellcor oximax pulse oximeter states, disconnect the oximax n-65 and nellcor oximax sensor from the patient throughout magnetic resonance imaging (mri) scanning. induced current could potentially cause burns. no further actions are planned by gehc. manufacturer narrative: unique identifier: (b)(4). there are no additional device identification numbers. ge healthcare's investigation is ongoing. a follow up report will be submitted once the investigation has been completed. device evaluation anticipated, but not yet begun.

Report Number	Event Date	Event Type	Manufacturer	Date Received	Product Code	Brand Name	Device Problem	Patient Problem	Event Text
2183553-2019-00026	2019/01/28	Injury	GE MEDICAL SYSTEMS, LLC	2019/10/30	LNH	GE 1.5T SIGNA HDX MR SYSTEM	Adverse Event Without Identified Device orUse Problem	Bone Fracture(s)	it was reported that a patient sustained a non-displaced rib fracture during positioning for a mri exam. the patient never entered the mr system/bore, and the issue occurred during patient setup and positioning upon the breast coil and table under the patient's own movement/control and own weight. the patient's exact weight was not provided and only reported by the customer as found in the medical chart as obese. the patient also was reported to have a pre-existing condition of osteoporosis, and history of chemotherapy. manufacturer narrative: the investigation by ge healthcare (gehc) has been completed. both the ge mr 1.5t hdx scanner and ge liberty 9000 breast coil were evaluated and found to be operating within specifications with no issues or defects identified. based on the available information, there is no apparent root cause of the patient injury. there is no evidence that the gehc 1.5t hdx scanner or gehc liberty 9000 breast coil caused the injury. theUser indicated using good clinical practices of preparing, positioning, and monitoring of the patient for mr exam. no further actions are planned by gehc.
MW5090531	2019/10/16	Injury	PHILIPS MEDICAL	2019/10/21	LNH	INGENIA 3.0T	Adverse Event	Alteration In Body	exam: mri rt shoulder arthrogram. after the exam was 3/4 of the way

Report Number	Event Date	Event Type	Manufacturer	Date Received	Product Code	Brand Name	Device Problem	Patient Problem	Event Text
			SYSTEMS NEDERLAND B.V.				Without Identified Device orUse Problem	Temperature	completed, a final sequence was required to visualize inside the joint space of the shoulder, aber view. the pt was positioned with his right arm partially extended above his head and rested on a pillow, and also stabilized with a sand bag. the right arm rested solely on the pillow as the pt was guided in for this last sequence. after the 3 min scan was completed, and the pt exited the scanner, he mentioned feeling hot after he rested his hand on his forehead. pt also mentioned later that after he removed his hand from touching his forehead, the heating sensation stopped. the pt was later seen by a nurse and a radiologist who assessed him. the pt was later discharged with instructions. fda safety report id# (b)(4).
3003768277-2019-00082	2019/08/04	Injury	PHILIPS HEALTHCARE	2019/10/17	LNH	INGENIA 1.5T	Adverse Event Without Identified Device orUse Problem	Full thickness (Third Degree) Burn	Philips received a report on a 3rd degree heating incident with an ingenia 1.5t mr system. manufacturer narrative: based on the provided information and test performed on site there is no indication of a malfunction of the mr system or coilUsed that contributed to the event. based on the information provided by the hospital it was concluded that the injury that is shown on the photographic evidence is not a burn that was the result of the mr examination but a pressure ulcer related to the underlying

Report Number	Event Date	Event Type	Manufacturer	Date Received	Product Code	Brand Name	Device Problem	Patient Problem	Event Text
									condition of the patient. it was stated by the hospital staff that the injury was not noticed until 5 days after the examination even though the patient was examined every day in between by doctors and other physicians. the summary in the patient file also mentions: 'impression : pressure ulcer. manufacturer narrative: the investigation is still ongoing for this event. when the investigation is completed a follow-up will sent to the fda.
3003768277-2019-00081	2019/10/10	Injury	PHILIPS HEALTHCARE	2019/10/16	LNH	INGENIA ELITION X	Patient-Device Incompatibility	Laceration(s)	Philips received a report that a non-compatible mr wheelchair was brought in the examination room. the wheelchair was attracted to the magnet, and the attending nurse got a cut at the eyebrow, requiring stitches. manufacturer narrative: based on the provided information there is no indication of a malfunction of the mri system. this event is considered aUse error.
3002808157-2019-01184	2019/10/01	Injury	SIEMENS HEALTHCARE GMBH	2019/10/15	LNH	MAGNETOM AERA	Use of Device Problem	Brain Injury; Patient Problem/Medical Problem	it was reported to siemens that anAdverse event occurred while operating the magnetom aera system. theUser reported that a ferromagnetic sand bag was attracted to the magnet while positioning a patient. the sand bag was located inside the patients diaper and was not seen by the technician during the patients preparation. the ferrous sand bag was pulled into the magnet hitting

Report Number	Event Date	Event Type	Manufacturer	Date Received	Product Code	Brand Name	Device Problem	Patient Problem	Event Text
									the patients jaw and lifting the head coils anterior section. it was reported that the patient survived but may have suffered a brain injury. manufacturer narrative: the investigation concludes that the cause of this event was the introduction of ferromagnetic pieces into the mr examination room and therefore aUser error. due to the strong magnetic field, particular safety measures have to be adhered to in order to prevent injuries. the corresponding magnetom operator manual and the magnetom system owner manual provide clear instructions and warnings regarding both magnetic field hazards and training of personnel with regards to mr safety. the responsibility to instruct personnel and patients who have access to the mr examination room about magnetic field hazards lies with the customer. the manuals state that only equipment specified or recommended forUse in the controlled area (mr examination room) shall beUsed. the introduction of ferromagnetic objects into the magnetic field is contrary to the statements given in the operating instructions. furthermore, special warning signs are posted at the entrance of the controlled access area (magnet room). no further actions are to be taken as there is no

Report Number	Event Date	Event Type	Manufacturer	Date Received	Product Code	Brand Name	Device Problem	Patient Problem	Event Text
									negative awareness in regards to the quality and performance of the mr system.
2183553-2019-00025	2019/09/12	Injury	GE MEDICAL SYSTEMS, LLC	2019/10/14	LNH	GE 3.0T SIGNA INFINITY TWINSPEED WITH EXCITE MR SYSTEM	Defective Device;Adverse Event Without Identified Device orUse Problem	Hearing Loss	it was reported that following an mri of the spine, a patient reported that the machine was too loud. the patient was later seen by a physician who confirmed hearing loss. manufacturer narrative: there are no additional device identification numbers. unique identifier: udi not required. ge healthcare's investigation is ongoing. a follow up report will be submitted once the investigation has been completed. device evaluation anticipated, but not yet begun
3002808157-2019-99876	2019/08/21	Injury	SIEMENS HEALTHCARE GMBH	2019/10/14	LNH	MAGNETOM SKYRA	Use of Device Problem	Tinnitus; Patient Problem/Medical Problem	it was reported to siemens that anAdverse event occurred following examination on the magnetom skyra system. it was reported that a patient developedTinnitus after the mr examination. the customer stated that the patient had been wearing earplugs and headphones. if the ear plugs recommended in theUser manual wereUsed during examination, the patient'sTinnitus is most likely not connected to the noise development of the mr system. the patient's current health status and if theTinnitus still persists is unknown at this time. siemens has requested additional information in order to conduct an investigation of the reported event. manufacturer

Report Number	Event Date	Event Type	Manufacturer	Date Received	Product Code	Brand Name	Device Problem	Patient Problem	Event Text
									narrative: siemens is conducting a thorough investigation of the reported events. as this event is under investigation, a root cause has not yet been determined. a supplement report will be filed upon completion of the investigation.
9613445-2019-00007		Malfunction	GE HANGWEI MEDICAL SYSTEMS CO., LTD.	2019/10/09	LNH	GE 0.35T SIGNA OVATION WITH EXCITE MR SYSTEM	Image Orientation Incorrect; Connection Problem; Misassembled During Installation	No Consequences Or Impact To Patient	it was reported that the laterality (right and left) of the mr images was incorrect. ge healthcare (gehc) service identified that during prior system servicing/troubleshooting, the gradient cables of the x axis had been swapped and not returned to their correct positions. gehc service placed the gradient cables to their correct positions. no injury or misdiagnosis was reported due to this issue. manufacturer narrative: there was no patient involvement. incident date is not known. there are no additional device identification numbers. unique identifier udi_not_required. ge healthcare's investigation is ongoing. a follow up report will be submitted once the investigation has been completed. device evaluation anticipated, but not yet begun.
3003768277-2019-00073	2019/09/14	Injury	PHILIPS HEALTHCARE	2019/09/24	LNH	INGENIA 3.0T	Adverse Event Without Identified Device orUse Problem	Bone Fracture(s)	Philips received a report from a customer, that during an mr examination the patient sustained a broken finger. manufacturer narrative: the investigation is still ongoing for this event. when the

Report Number	Event Date	Event Type	Manufacturer	Date Received	Product Code	Brand Name	Device Problem	Patient Problem	Event Text
									investigation is completed a follow-up will sent to the fda.
3010949642-2019-00002	2019/06/03	Injury	GE HEALTHCARE (TIANJIN) COMPANY LIMITED	2019/09/17	LNH	SIGNA EXPLORER	Use of Device Problem;Adverse Event Without Identified Device orUse Problem	Burn(s); Partial thickness (Second Degree) Burn	it was reported throughUser facility medwatch mw5088815 that a patient had a left shoulder mri and sustained a second degree burn to the right forearm. additional information obtained noted that initially, the affected area looked like a sunburn but the burn progressed and the patient received wound care and eventually had surgery to excise the area. the patient was not padded and was touching the bore. manufacturer narrative: (b)(4). there are no additional device identification numbers. (b)(6). ge healthcare's investigation is ongoing. a follow up report will be submitted once the investigation has been completed. device evaluation anticipated, but not yet begun.
MW5089812	2019/06/06	NA	GE HEALTHCARE MANUFACTURING LLC	2019/09/16	LNH	GE 1.5 TESLA SIGNA EXCITE	Protective Measures Problem	No Consequences Or Impact To Patient	mri safety incident. pt was properly screened with form and verbally prior to entering mri scan room for mri rt shoulder. once localizer was obtained a metallic foreign body was noted on anterior rt shoulder superficially. technologist informed mrso immediately. mrso directed technologist to check pt's gown and coil to make sure nothing metallic was on them. tech confirmed and removed headphones per mrso. tech scanned localizer again and artifact was still present. radiologist was

Report Number	Event Date	Event Type	Manufacturer	Date Received	Product Code	Brand Name	Device Problem	Patient Problem	Event Text
									called and looked at localizer images. the radiologist was informed pt had previous mri cervical at same facility prior to the test with no issues. radiologist found ct chest from another facility and stated the foreign body was too small and superficial to be worrisome and gave authority to continue the exam. pt did not experience any issues. fda safety report id # (b)(4).
2183553-2019-00023	2019/07/25	Injury	GE MEDICAL SYSTEMS, LLC	2019/09/11	LNH	GE 1.5T SIGNA HDX MR SYSTEM	Adverse Event Without Identified Device orUse Problem	Hearing Loss	it was reported that two weeks following an mr enterography exam, a patient reported hearing loss. audiology reports appear to confirm a diagnosis of a new hearing deficit. it is not known if any medical treatment was required. the patient was provided mr safe headphones. manufacturer narrative: unique identifier: udi not required. there are no additional device identification numbers. ge healthcare's investigation is ongoing. a follow up report will be submitted once the investigation has been completed. device evaluation anticipated, but not yet begun.
2183553-2019-00022	2019/08/03	Injury	GE MEDICAL SYSTEMS, LLC	2019/09/10	LNH	GE 1.5T SIGNA HDX MR SYSTEM	Use of Device Problem;Adverse Event Without Identified Device	Burn(s); Partial thickness (Second Degree) Burn	it was reported that a patient undergoing an mri exam of the knee sustained a burn with blisters to the left ankle. the burn was reported to have worsened and was treated by surgical debridement at a different hospital. manufacturer narrative: there are no device identification

Report Number	Event Date	Event Type	Manufacturer	Date Received	Product Code	Brand Name	Device Problem	Patient Problem	Event Text
							orUse Problem		numbers known at this time. ge healthcare's investigation is ongoing. a follow up report will be submitted once the investigation has been completed. device evaluation anticipated, but not yet begun.
2183553-2019-00021	2019/06/03	Injury	GE MEDICAL SYSTEMS, LLC	2019/09/05	LNH	SIGNA PIONEER	Use of Device Problem;Adverse Event Without Identified Device orUse Problem	Hearing Impairment ;Tinnitus	it was reported that a patient sustained an increase/change to a pre-existing condition ofTinnitus after an mri exam. the patient was provided a music headset without additional earplugs. one month after the exam, the patient reported a change in hisTinnitus, including sound and severity. the patient was seen by a physician and received medical treatment of acupuncture and medication. the patient's condition slightly recovered but has not returned to baseline which is indicative of incremental permanent loss of function. manufacturer narrative: (b)(4). ge healthcare's investigation is ongoing. a follow up report will be submitted once the investigation has been completed. device evaluation anticipated, but not yet begun.
3003768277-2019-00069		Injury	PHILIPS HEALTHCARE	2019/08/30	LNH	INGENIA 1.5T	Overheating of Device	Partial thickness (Second Degree) Burn	Philips received a report from a customer related to a patient heating incident with an anterior coil on an ingenia 1.5t mr system. after the examination, reddening was observed on the inner thighs. later the patient reported a burn on the shoulder and that blisters developed

Report Number	Event Date	Event Type	Manufacturer	Date Received	Product Code	Brand Name	Device Problem	Patient Problem	Event Text
									on the thighs. manufacturer narrative: the investigation is still ongoing for this event. when the investigation is completed a follow-up will sent to the fda .
2183553-2019-00019	2019/08/02	Injury	GE MEDICAL SYSTEMS, LLC	2019/08/29	LNH	3.0T SIGNA HDXT SIGNA VIBRANT	Improper or Incorrect Procedure or Method	Laceration(s)	it was reported that an mr technologist allowed a patient to enter the scan room with a ferrous walker. the technologist did not evaluate the walker for potentially ferrous material prior to entering the room, but intended to leave the walker a safe distance from the mr system. in the process of entering the room, the walker was attracted to the magnet and temporarily pinned the mr technologist's right hand between the walker and the magnet. the technologist was able to forcefully pull her hand out and leave the room with the patient. the technologist was evaluated in the emergency department and required two stitches for a laceration to the right hand. manufacturer narrative: the investigation by ge healthcare has been completed and concluded that the incident occurred due to inattentive behavior of the mr technologist who allowed a patient to bring a ferrous walker into the scan room. the mr operator manual states that it is vital to have supervised and controlled access within the mr environment to keep it safe from ferromagnetic objects. the

Report Number	Event Date	Event Type	Manufacturer	Date Received	Product Code	Brand Name	Device Problem	Patient Problem	Event Text
									mr technologist was magnet safety trained, security zone signs were posted, and the site has a copy of the mr safety manual. the fe was able to safely remove the walker from the magnet. no further actions are planned at this time.
2183553-2019-00020	2019/08/03	Injury	GE MEDICAL SYSTEMS, LLC	2019/08/29	LNH	SIGNA ARCHITECT	Adverse Event Without Identified Device orUse Problem	Burn(s); Full thickness (Third Degree) Burn	it was reported that following an mr exam of the left shoulder, it was discovered that the patient had a round, 2-3 inch burn on the lateral aspect of their right upper arm. the burn was evaluated at the site and diagnosed as a full thickness burn which resulted in a surgical procedure requiring debridement and a skin graft. manufacturer narrative: unique identifier: (b)(4). there are no additional device identification numbers. ge healthcare's investigation is ongoing. a follow up report will be submitted once the investigation has been completed. device evaluation anticipated, but not yet begun.
2183553-2019-00016	2019/01/11	Injury	GE MEDICAL SYSTEMS, LLC	2019/08/21	LNH	3.0T SIGNA HDXT	Use of Device Problem;Adverse Event Without Identified Device orUse Problem	Hearing Impairment ; Hearing Loss	it was reported that a patient who underwent an mri complained of hearing impairment after the exam. the patient was provided hearing protection (head phones) for the exam. the patient was seen by a physician who confirmed hearing loss. treatment was provided, however the actual treatment is unknown. manufacturer narrative: unique identifier: udi not required.

Report Number	Event Date	Event Type	Manufacturer	Date Received	Product Code	Brand Name	Device Problem	Patient Problem	Event Text
									there are no additional device identification numbers. ge healthcare's investigation is ongoing. a follow up report will be submitted once the investigation has been completed. device evaluation anticipated, but not yet begun.
2183553-2019-00017	2019/07/26	Injury	GE MEDICAL SYSTEMS, LLC	2019/08/21	LNH	3.0T SIGNA HDXT	Use of Device Problem;Adverse Event Without Identified Device orUse Problem	Hearing Impairment ;Tinnitus	it was reported that a patient complained of ringing in the ears after an mri of the head. the patient was provided hearing protection (head phones) during the exam and when brought out of the scanner, informed the technologist about the ringing in the ears. the patient was seen by his physician who confirmed non-resolvingTinnitus. manufacturer narrative: unique identifier: udi not required. there are no additional device identification numbers. ge healthcare's investigation is ongoing. a follow up report will be submitted once the investigation has been completed. device evaluation anticipated, but not yet begun.
2183553-2019-00018		Injury	GE MEDICAL SYSTEMS, LLC	2019/08/21	LNH	3.0T SIGNA HDXT	Use of Device Problem;Adverse Event Without Identified Device orUse Problem	Hearing Impairment ;Tinnitus	it was reported that a patient who underwent an mri of the brain reported ringing in one of their ears after their scan. the patient was provided head phones for hearing protection. the patient was seen by a physician who confirmed non-resolvingTinnitus. manufacturer narrative: age ate time of event: 50-60 years old. date of event: (b)(6) 2018. unique identifier: udi not

Report Number	Event Date	Event Type	Manufacturer	Date Received	Product Code	Brand Name	Device Problem	Patient Problem	Event Text
									required. there are no additional device identification numbers. ge healthcare's investigation is ongoing. a follow up report will be submitted once the investigation has been completed. device evaluation anticipated, but not yet begun.
2183553-2019-00015	2019/06/07	Injury	GE MEDICAL SYSTEMS, LLC	2019/08/06	LNH	SIGNA ARCHITECT	Use of Device Problem;Adverse Event Without Identified Device orUse Problem	Burn(s); Burn, Thermal; Burn, Thermal; Partial thickness (Second Degree) Burn; Full thickness (Third Degree) Burn	it was reported that a patient undergoing an mri of the right shoulder sustained a burn with blisters to the left arm. the patient was not padded to prevent contact to the sides of the magnet bore or to prevent skin to skin contact. it was reported that the patient will receive skin grafting for treatment of the injury. manufacturer narrative: unique identifier: udi not required. there are no additional device identification numbers. ge healthcare's investigation is ongoing. a follow up report will be submitted once the investigation has been completed. device evaluation anticipated, but not yet begun
MW5088815	2019/06/03	Injury	GE MEDICAL SYSTEMS, LLC	2019/08/05	LNH	GE MRI	Insufficient Information	Partial thickness (Second Degree) Burn	patient had left shoulder mri. patient sustained second degree burn to the right forearm.
3003768277-2019-00060	2019/07/19	Injury	PHILIPS HEALTHCARE	2019/07/29	LNH	INGENIA 1.5T	Temperature Problem	Burn, Thermal; Partial thickness (Second	Philips received a report from a customer related to a heating incident with the posterior coil on an ingenia 1.5t system. a patient received a 3 centimeter blister on both the buttock and thumb.

Report Number	Event Date	Event Type	Manufacturer	Date Received	Product Code	Brand Name	Device Problem	Patient Problem	Event Text
								Degree) Burn	manufacturer narrative: based on the provided information and tests performed on site, there is no indication of a malfunction of the mri system or coilUsed that contributed to the injury. the blistering on both thumb and buttocks is explained by the direct contact between the patient¿s thumb and buttock. no other contributing factors were identified.
2183553-2019-00014	2019/06/10	Injury	GE MEDICAL SYSTEMS, LLC	2019/07/11	LNH	GE 3.0T SIGNA INFINITY TWINSPEED WITH EXCITE MR SYSTEM	Adverse Event Without Identified Device orUse Problem	Hearing Loss;Tinnitus	it was reported to ge healthcare that a patient undergoing an mri was scanned for a total of 29 minutes using dba rating 33 earplugs and foam pads alongside his head. the patient completed the scan but when the earplugs were removed, he reported having ringing in his ears and some hearing loss. he was seen by an ent who confirmed hearing loss andTinnitus. patient is scheduled for a follow up appointment with the ent, but told the customer that the symptoms have improved. manufacturer narrative: unique identifier: udi not required. there are no additional device identification numbers. ge healthcare's investigation is ongoing. a follow up report will be submitted once the investigation has been completed. device evaluation anticipated, but not yet begun.

Report Number	Event Date	Event Type	Manufacturer	Date Received	Product Code	Brand Name	Device Problem	Patient Problem	Event Text
2183553-2019-00013	2019/06/12	Malfunction	GE MEDICAL SYSTEMS, LLC	2019/07/10	LNH	SIGNA INFINITY MR SYSTEM WITH EXCITE TECHNOLOGY	Break; Fire; Smoking; Arcing	No Consequences Or Impact To Patient	it was reported that after an exam was completed, an mr technologist entered the magnet room and noticed a smell of smoke. the technologist removed the patient from the room and re-entered to see the glow of a flame underneath the rear covers of the mr system. the technologistUsed a non-ferrous extinguisher to put out the flame. the initial investigation found the heating occurred in an area of pinched and damaged cables under the scanner bridge. the patient was unaware of the issue, and no injury occurred. manufacturer narrative: there was no patient involvement. unique identifier: udi not required. there are no additional device identification numbers. ge healthcare's investigation is ongoing. a follow up report will be submitted once the investigation has been completed. device evaluation anticipated, but not yet begun.
MW5087941	2019/06/23	Injury	PHILIPS MEDICAL SYSTEMS	2019/07/08	LNH	PHILIPS MRI SCANNER	Adverse Event Without Identified Device orUse Problem	Pain	patient arrived for an mri exam with an mr-conditional advanced bionics hires ultra-cochlear implant that is approved at 3 tesla after the internal magnet is surgically removed from the patient. the internal magnet however was not removed because the patient was inadvertently cleared and brought into the mri scan room using information from the advanced bionics hires ultra 3d cochlear

Report Number	Event Date	Event Type	Manufacturer	Date Received	Product Code	Brand Name	Device Problem	Patient Problem	Event Text
									implant which is approved at 3 tesla with the internal magnet still in place. after bringing the patient into the mri scan room and placing her on the scanner table the patient immediately expressed to the technologist that she was experiencing a pinching sensation and pain at the implant sight. the patient was slowly brought out of the scan room to our waiting area and then to the er where she was seen. a ct scan was performed to check for anatomical and implant integrity, and implant placement which were found to be normal. the patient subsequently went to audiology for device and haring testing where it was determined the device continued to work accordingly with stable hearing in the patient. fda safety report id # (b)(4).
3002808157-2019-85551	2019/06/04	Injury	SIEMENS HEALTHCARE GMBH	2019/07/05	LNH	MAGNETOM AERA	Use of Device Problem	Burn(s); Patient Problem/Medical Problem; Partial thickness (Second Degree) Burn	it was reported to siemens that anAdverse event occurred following examination on the magnetom aera system. a patient felt heat on the inner side of her legs during hip exam. patient pressed the intercom button to inform the tech, however, the tech did not respond. according to the patient, she developed blisters in between her legs after the exam. despite several requests for additional information, no information was provided to siemens regarding the size and severity of the

Report Number	Event Date	Event Type	Manufacturer	Date Received	Product Code	Brand Name	Device Problem	Patient Problem	Event Text
									blister or area of redness. additionally, no information was provided regarding any medical intervention necessary or healing complications. manufacturer narrative: siemens is conducting a thorough investigation of the reported events. as this event is under investigation, a root cause has not yet been determined. a supplement report will be filed upon completion of the investigation.
3002808157-2019-85539	2019/06/11	Injury	SIEMENS HEALTHCARE GMBH	2019/07/05	LNH	MAGNETOM AERA	Use of Device Problem	Burn(s); Patient Problem/Medical Problem; Partial thickness (Second Degree) Burn	it was reported to siemens that anAdverse event occurred following examination on the magnetom aera system. two 2 separate patients had a mri hip study and claimed burns on their thighs following the examination. despite several requests for additional information, no information was provided to siemens regarding the size and severity of the blisters or area of redness. additionally, no information was provided regarding any medical intervention necessary or healing complications. manufacturer narrative: siemens is conducting a thorough investigation of the reported events. as this event is under investigation, a root cause has not yet been determined. a

Report Number	Event Date	Event Type	Manufacturer	Date Received	Product Code	Brand Name	Device Problem	Patient Problem	Event Text
									supplement report will be filed upon completion of the investigation.
3003768277-2019-00052	2019/05/27	Injury	PHILIPS HEALTHCARE	2019/06/26	LNH	INGENIA 1.5T	Temperature Problem	Injury	Philips received a report from a customer related to a patient heating incident with an anterior coil on an ingenia 1.5t mr system. manufacturer narrative: the investigation is ongoing. when the investigation is completed a follow up will be sent to the fda.
3002808157-2019-80178	2019/05/01	Injury	SIEMENS HEALTHCARE GMBH	2019/06/24	LNH	MAGNETOM SOLA	Use of Device Problem	Burn(s); Injury; Partial thickness (Second Degree) Burn	it was reported to siemens that anAdverse event occurred following examination on the magnetom sola system. a (b)(6) year old male patient with metal hip implants suffered several small blisters and an area of redness bilaterally above the knees on the inner thighs approximately twenty minutes after examination. after several sequences, the patient alerted the operator that he felt heating in the scanning area of the hips. the examination was continued and completed. the patient applied a topical burn cream as treatment as no major medical intervention was necessary. however, the patient is reporting that the wound is still active, experiencing deep burns and continued erythematous to the affected area. siemens has requested additional information in order to conduct an investigation of the reported event. manufacturer narrative: siemens is conducting a thorough investigation of the

Report Number	Event Date	Event Type	Manufacturer	Date Received	Product Code	Brand Name	Device Problem	Patient Problem	Event Text
									reported events. as this event is under investigation, a root cause has not yet been determined. a supplement report will be filed upon completion of the investigation.
2183553-2019-00012	2019/05/28	Injury	GE MEDICAL SYSTEMS, LLC	2019/06/20	LNH	3.0T SIGNA HDX MR SYSTEM	Device-Device Incompatibility;Adverse Event Without Identified Device orUse Problem	Abrasion; Bone Fracture(s); Pain	it was reported that a ge healthcare field engineer (fe) was servicing an mr system and brought a ferrous table motor into the scan room. while still in the field engineer's left hand, the motor was attracted to the magnet and impacted the rear of the system. the field engineer injured his hand and was diagnosed with a minor fracture to the left radial styloid in his wrist and an abrasion to his left thumb. the fe received a plaster cast as well as oral pain killers and antibiotics as treatment for the injury. manufacturer narrative: unique identifier: udi not required there are no additional device identification numbers. ge healthcare's investigation is ongoing. a follow up report will be submitted once the investigation has been completed. device evaluation anticipated, but not yet begun.
3002808157-2019-82853	2019/05/20	Injury	SIEMENS HEALTHCARE GMBH	2019/06/10	LNH	MAGNETOM SKYRA	Use of Device Problem	Injury; Fracture, Arm	it was reported to siemens that anAdverse event occurred while operating the magnetom skyra system. a patient with paralysis in the arm was examined. when pulling the table out from the magnet, the patient's left elbow became stuck. the table continued to be pulled from

Report Number	Event Date	Event Type	Manufacturer	Date Received	Product Code	Brand Name	Device Problem	Patient Problem	Event Text
									the magnet and the patient's left elbow hit the surface of the head coil cover resulting in a dislocation and fracture to the shoulder. no further information regarding medical intervention was provided by the hospital. manufacturer narrative: the system has been checked by a siemens service engineer and found to be operating within specification. furthermore, the siemens service engineer advised the operator to move the table while checking the patient's condition and recommended using the stop button in an emergency.
2183553-2019-00011	2019/04/22	Injury	GE MEDICAL SYSTEMS, LLC	2019/05/30	LNH	SIGNA ARCHITECT	Unexpected Therapeutic Results;Use of Device Problem	Burn(s); Skin Discoloration; Numbness; Skin Inflammation	it was reported that a male patient was having an mri of the lumbar spine under anesthesia. due to the patient's size, ge recommended pads were notUsed. the patient presented with an area of redness the size of a baseball on his left forearm with the inner core appearing dark brown. the patient complained of numbness in his hand and fingers. he was seen by the hospital's wound care team and debridement of the wound was necessary. the patient continues to have dressing changes. manufacturer narrative: (b)(4). there are no additional device identification numbers. ge healthcare's investigation is ongoing. a follow up report will be submitted once the investigation has been completed.

Report Number	Event Date	Event Type	Manufacturer	Date Received	Product Code	Brand Name	Device Problem	Patient Problem	Event Text
									device evaluation anticipated, but not yet begun.
3002808157-2019-77792	2019/04/10	Injury	SIEMENS HEALTHCARE GMBH	2019/05/23	LNH	MAGNETOM PRISMA	Use of Device Problem	Burn(s); Injury	it was reported to siemens that anAdverse event occurred following an examination on the magnetom prisma system. the customer reported that the peru unit was extremely hot to the touch after 1.5 hours of scanning a patient. the patient suffered blisters on the upper left side of the arm. at this time, the size and severity of the blisters are unknown and it was not reported if medical treatment was necessary. siemens has requested additional information in order to conduct an investigation of the reported event. manufacturer narrative: siemens is conducting a thorough investigation of the reported events. as this event is under investigation, a root cause has not yet been determined. a supplement report will be filed upon completion of the investigation.
3003768277-2019-00042	2019/02/15	Injury	PHILIPS HEALTHCARE	2019/05/21	LNH	INGENIA 1.5T	Adverse Event Without Identified Device orUse Problem	Partial thickness (Second Degree) Burn	Philips received a report from a customer related to a patient heating incident with an ingenia1.5t mr system. a patient was scanned for an mri examination. after the examination a blister was observed on the patient's abdomen. manufacturer narrative: the investigation is ongoing on this event. when the investigation is completed a follow up will be sent to the fda.

Report Number	Event Date	Event Type	Manufacturer	Date Received	Product Code	Brand Name	Device Problem	Patient Problem	Event Text
2183553-2019-00008	2019/04/11	Injury	GE MEDICAL SYSTEMS, LLC	2019/05/09	LNH	SIGNA ARCHITECT	Use of Device Problem	Burn(s)	it was reported that a patient sustained a burn injury to the scalp during an intra-operative mri procedure utilizing a medtronic axiem non-invasive patient tracker (nipt). the burn injury occurred at a point of contact directly between the nipt tracker and the patient's scalp. the patient was assessed at the site and diagnosed with a 2cm by 2cm superficial burn on the scalp that was treated with silvadene. the customer reported this to be a superficial burn; however, ge healthcare has conservatively assessed this as a serious injury due to several factors including the appearance and anatomical location of the patient's burn. manufacturer narrative: unique identifier: (b)(4). suspect medical device: there are no additional device identification numbers. device evaluated by mfr: the investigation by ge healthcare (gehc) has been completed. a gehc field engineer completed system testing and verified that the mri scanner was operating normally and within performance specifications. the root cause was determined to be operator error related to theUse of a 3rd party medtronic axiem non-invasive patient tracker (nipt) during the patient mri scan. per discussion with theUser, the medtronic mr conditions forUse were not strictly followed

Report Number	Event Date	Event Type	Manufacturer	Date Received	Product Code	Brand Name	Device Problem	Patient Problem	Event Text
									during this procedure, resulting in an rf burn to the patient. per our gehc operator manual, theUser must ensure the safeUse of mr conditional devices during patient scans.Users should consult the device manufacturer's instructions and safety guidelines. no further actions are planned by gehc. medtronic has been notified of the patient event involving their product.
2183553-2019-00009	2019/03/06	Injury	GE MEDICAL SYSTEMS, LLC	2019/05/09	LNH	3.0T SIGNA HDXT	Adverse Event Without Identified Device orUse Problem	Hearing Loss;Tinnitus	it was reported via maude report # mw5084711 that a patient was provided a music headset prior to a right knee scan. during the exam, the patientUsed the alert ball and stated that the scanner was too loud. at that time, the customer provided the patient with ear plugs in combination with the previously provided headphones. following the scan, the patient reported new ringing and decreased hearing in her right ear. on 18 april 2019, the patient stated that she underwent a hearing test on (b)(6) 2019. the results of the test showed a new hearing deficit in the right ear when compared to a previous hearing test from (b)(6) 2018. to date, her hearing has not improved and she has been prescribed hearing aids. manufacturer narrative: unique identifier: udi not required. there are no additional device identification numbers. ge healthcare's

Report Number	Event Date	Event Type	Manufacturer	Date Received	Product Code	Brand Name	Device Problem	Patient Problem	Event Text
									investigation is ongoing. a follow up report will be submitted once the investigation has been completed. device evaluation anticipated, but not yet begun.
2183553-2019-00006	2019/02/26	Injury	GE MEDICAL SYSTEMS, LLC	2019/04/29	LNH	GE 1.5T SIGNA HDX MR SYSTEM	Adverse Event Without Identified Device orUse Problem; Insufficient Information	Burn(s); Full thickness (Third Degree) Burn	it was reported that a patient undergoing an mri of the right shoulder sustained a small, approximately 2.5cm burn to the right forearm just distal to the elbow. the burn was initially diagnosed as 2nd degree, however it was reported that the burn progressed to a 3rd degree burn that wound care provided intervention of debridement. manufacturer narrative: the investigation by ge healthcare (gehc) has been completed. the mr system was operating within specifications and all safety mitigating devices, including the redundant rf power monitors, were functional when checked by the ge healthcare field engineer. this incident appears to be the result of coupling with high power radiofrequency (rf) energy. the customer indicated that the patient was properly padded and positioned for the exam. in addition, the exam sar levels were within limits. the information reviewed did not indicate there was any system malfunction that may have contributed to the incident. no further actions are planned by gehc.

Report Number	Event Date	Event Type	Manufacturer	Date Received	Product Code	Brand Name	Device Problem	Patient Problem	Event Text
									manufacturer narrative: udi not required. there are no additional device identification numbers. ge healthcare's investigation is ongoing. a follow up report will be submitted once the investigation has been completed. device evaluation anticipated, but not yet begun.
MW5086253	2019/04/01	Injury	GENERAL ELECTRIC CO.	2019/04/29	LNH	GENERAL ELECTRIC 1.5T MRI SCANNER	Adverse Event Without Identified Device orUse Problem	Burn, Thermal	four days following an mri lumbar scan, pt called to state she had been burned by scanner. fda safety report id # (b)(4).
3003768277-2019-00034	2019/04/18	Injury	PHILIPS HEALTHCARE	2019/04/29	LNH	INGENIA 3.0T	Electromagnetic Interference	Bone Fracture(s)	assistant doctor moved a magnetic aspirator into rf room. this aspirator was attracted to the mr system. the anesthetist's leg was between the aspirator and the mr system, which resulted in a broken leg. manufacturer narrative: based on the provided information there is no indication of a malfunction of the mri system. this event is considered to be aUse error. device evaluated by mfr: known inherent risk of an mr system.
2183553-2019-00005	2018/10/23	Injury	GE MEDICAL SYSTEMS, LLC	2019/04/24	LNH	GE SIGNA EXCITE 1.5T MR SYSTEM	Electromagnetic Interference;Improper or Incorrect Procedure or Method	Excessive Tear Production; Injury	it was initially reported that the customer's service personnel brought a ferrous object into the magnet room. the force of the object being attracted to the magnet pulled the individual's arm. the individual sought medical evaluation, however no serious injury had been confirmed and there was no medical

Report Number	Event Date	Event Type	Manufacturer	Date Received	Product Code	Brand Name	Device Problem	Patient Problem	Event Text
									intervention reported. the individual did not provide any further information regarding this event despite multiple attempts by ge healthcare. on 1 april 2019, additional information was received that the individual underwent surgery on (b)(6) 2019 for a partial tear of the left distal biceps tendon and cubital tunnel syndrome. manufacturer narrative: unique identifier: udi not required. there are no additional device identification numbers. ge healthcare's investigation is ongoing. a follow up report will be submitted once the investigation has been completed. device evaluation anticipated, but not yet begun.
2183553-2019-00004	2019/03/27	Injury	GE MEDICAL SYSTEMS, LLC	2019/04/23	LNH	3.0T SIGNA HDXT	Electromagnetic Interference;Use of Device Problem	Laceration(s)	it was reported that a non-ge healthcare contractor entered the scan room with two ferrous 25cm x 15cm metal sheets. upon entering the room, the metal sheets were attracted to the magnet and pulled out of the contractor's hand. in the process, the contractor suffered a laceration to his finger which required sutures, finger splints, analgesics and antibiotics. the metal sheets were safely removed without the need to ramp down the magnet. manufacturer narrative: ge healthcare's investigation is ongoing. a follow up report will be submitted once the investigation has been

Report Number	Event Date	Event Type	Manufacturer	Date Received	Product Code	Brand Name	Device Problem	Patient Problem	Event Text
									completed. device evaluation anticipated, but not yet begun.
3002808157-2017-00879	2014/08/26	Injury	SIEMENS HEALTHCARE GMBH	2019/04/23	LNH	MAGNETOM SKYRA	Use of Device Problem	Burn(s); Patient Problem/Medical Problem; Lead(s), Burn(s) From	siemens became aware of anAdverse event involving a siemens magnetom skyra system through an article published in the journal of radiology and imaging. an unusual case of a third degree skin burn was reported using mri electrocardiographic leads. the electrodes are labeled mr conditional by the manufacturer, however, the electrodes are not a siemens approved product. the vendor of the electrodes was informed by theUser when the incident occurred, however, siemens was not informed of the incident as no malfunction of the siemens system was observed. the patient was treated with aquagel and a foam bandage. manufacturer narrative: the electrodesUsed are labeled mr conditional by the manufacturer; however, theUse of the electrodes is not approved by siemens (unilect tm 4841p electrodes, unomedical ltd. (b)(4)). (b)(6).
3002808157-2017-00880	2014/10/02	Injury	SIEMENS HEALTHCARE GMBH	2019/04/23	LNH	MAGNETOM SKYRA	Use of Device Problem	Burn(s); Patient Problem/Medical Problem; Lead(s), Burn(s) From	siemens became aware of anAdverse event involving a siemens magnetom skyra system through an article published in the journal of radiology and imaging. an unusual case of a third degree skin burn was reported using mri electrocardiographic leads. the

Report Number	Event Date	Event Type	Manufacturer	Date Received	Product Code	Brand Name	Device Problem	Patient Problem	Event Text
									electrodes are labeled mr conditional by the manufacturer, however, the electrodes are not a siemens approved product. the vendor of the electrodes was informed by theUser when the incident occurred, however, siemens was not informed of the incident as no malfunction of the siemens system was observed. the patient did not require any medical treatment. manufacturer narrative: the electrodesUsed are labeled mr conditional by the manufacturer, however, theUse of the electrodes is not approved by siemens. (unilecttm 4841p electrodes, unomedical ltd. (b)(4)). this event occurred in (b)(6).
3002808157-2017-01214	2017/02/15	Injury	SIEMENS HEALTHCARE GMBH	2019/04/23	LNH	MAGNETOM AERA	Use of Device Problem	Burn(s); Patient Problem/Medical Problem	it was reported to siemens that a patient suffered an injury after examination on the magnetom aera system. at the time of the exam, the patient complained of heating during scanning. an area of redness was observed on the right hand and hip following the exam. at a later time, the patient provided a picture of a second degree burn approximately one inch in diameter to the top of the hand. additional information has been requested, however, no further details regarding the patients injury have been provided at this time. manufacturer narrative: siemens is conducting a thorough investigation of the reported events. as this event

Report Number	Event Date	Event Type	Manufacturer	Date Received	Product Code	Brand Name	Device Problem	Patient Problem	Event Text
									is under investigation, a root cause has not yet been determined. a supplement report will be filed upon completion of the investigation. this event occurred in (b)(6). resubmission of initial report as per fda due to report code error.
3003768277-2019-00031	2019/03/31	Injury	PHILIPS HEALTHCARE	2019/04/16	LNH	INGENIA 1.5T	Temperature Problem	Swelling	Philips received a report about a heating incident with the nvc head coil on an ingenia 1.5t. after the examination a blister was observed on the patient's left upper arm. manufacturer narrative: based on the provided information, there is no indication of a malfunction of the mri system or coilUsed that contributed to the injury. the blister that was observed on the left upper arm of the patient is consistent with heating injuries caused by close proximity to the bore wall. it was stated that the patient was not touching the bore wall and that arm boards wereUsed to prevent contact with the bore wall but considering the size of the patient it is concluded that the patient's upper left arm must have been very close or touching the bore wall. the arm boards mentioned are designed to keep the patient's fingers away from the edge of the table and are normally positioned near the hands, not near the upper arms. contributing factors in this case are: the temperature of the examination room was too high. the patient was

Report Number	Event Date	Event Type	Manufacturer	Date Received	Product Code	Brand Name	Device Problem	Patient Problem	Event Text
									obese. the thermoregulation of obese patients is known to be impaired. the risk of rf energy-related injuries is higher in patients with impaired thermoregulation.
3002808157-2019-75720	2019/03/27	Injury	SIEMENS HEALTHCARE GMBH	2019/04/16	LNH	MAGNETOM SKYRA	Use of Device Problem	Burn(s); Injury	it was reported to siemens that anAdverse event occurred following examination on the magnetom skyra system. it was stated in the complaint form that a patient suffered a blister and area of redness on the chest. the area of redness was in the shape of a stripe of unknown dimension. it was stated that the area of redness was considered to be due to a groove in the cushion which was attached to the coil, the long examination time and pressure on the patients skin. despite several requests for additional information, no information was provided to siemens regarding the size and severity of the blister or area of redness. additionally, no information was provided regarding any medical intervention necessary or healing complications. manufacturer narrative: despite several requests for additional information, no information was provided to siemens regarding the size and severity of the blister or area of redness. additionally, no information was provided regarding any medical intervention necessary or healing complications. the manufacturer is

Report Number	Event Date	Event Type	Manufacturer	Date Received	Product Code	Brand Name	Device Problem	Patient Problem	Event Text
									not considering further actions resulting from this event as no systematic error has been recognized.
3002808157-2018-48422	2018/08/06	Injury	SIEMENS HEALTHCARE GMBH	2019/04/05	LNH	MAGNETOM SKYRA	Use of Device Problem	Burn(s); Injury	it was reported to siemens that anAdverse event occurred during examination of a (b)(6) child on the magnetom skyra system. the infant was intubated with a lens tube. one day after the examination a physician performed an endoscopy and found burns inside the trachea/esophagus of the infant. at this time siemens is unaware of any further impact to the state of health of the patient involved. no further information was provided by the hospital. the reported event occurred in (b)(6). manufacturer narrative: (b)(6). it is assumed that the issue was caused by aUser error. a supplemental report will submitted if additional information becomes available. customer's address: (b)(6). resubmission of initial report due to report code error.
3002808157-2019-61179	2018/12/11	Injury	SIEMENS HEALTHCARE GMBH	2019/04/04	LNH	MAGNETOM SKYRA	Use of Device Problem	Patient Problem/Medical Problem; Partial thickness (Second Degree) Burn	it was reported to siemens that anAdverse event occurred followingUse of the magnetom skyra system. theUser reported that a patient suffered a second degree burn on the back during a pelvic exam in the area in which a coil wasUsed. the extent of the burn or medical treatment provided is not known at this time. siemens has

Report Number	Event Date	Event Type	Manufacturer	Date Received	Product Code	Brand Name	Device Problem	Patient Problem	Event Text
									requested additional information in order to conduct an investigation. manufacturer narrative: (b)(4). siemens is conducting a thorough investigation of the reported events. as this event is under investigation, a root cause has not yet been determined. a supplement report will be filed upon completion of the investigation. (b)(6).
3002808157-2019-63811	2018/10/22	Injury	SIEMENS HEALTHCARE GMBH	2019/04/04	LNH	MAGNETOM VIDA	Use of Device Problem	Hearing Impairment; Patient Problem/Medical Problem	it was reported to siemens that anAdverse event occurred following servicing of the magnetom vida system. a siemens service engineer reported a loud noise while performing service on the mr system which resulted inTinnitus in both ears. the engineer was evaluated by a medical professional and treated with anti-inflammatory medication. the engineer continues to experienceTinnitus and it is not clear whether theTinnitus is permanent at this time. siemens is continuing to evaluate this reported incident. manufacturer narrative: (b)(4). siemens is conducting a thorough investigation of the reported events. as this event is under investigation, a root cause has not yet been determined. a supplement report will be filed upon completion of the investigation. (b)(6).
3002808157-2019-62660	2018/12/18	Injury	SIEMENS HEALTHCARE GMBH	2019/04/04	LNH	MAGNETOM VIDA	Use of Device Problem	Burn, Thermal; Patient	it was reported to siemens that anAdverse event occurred while operating the magnetom vida

Report Number	Event Date	Event Type	Manufacturer	Date Received	Product Code	Brand Name	Device Problem	Patient Problem	Event Text
								Problem/Medical Problem	system. theUser reported that a patient complained about heating during a breast examination. an area of redness was detected after the examination which subsided before the patient was released. the following day the patient contacted theUser and reported a blister. the severity of the injury and what medical treatment was provided, if any, is not known at this time. siemens has requested additional information in order to conduct an investigation. manufacturer narrative: (b)(4). siemens is conducting a thorough investigation of the reported events. as this event is under investigation, a root cause has not yet been determined. a supplement report will be filed upon completion of the investigation.
3002808157-2018-52514	2018/10/11	Injury	SIEMENS HEALTHCARE GMBH	2019/04/04	LNH	MAGNETOM AERA	Use of Device Problem	Injury; Partial thickness (Second Degree) Burn	it was reported to siemens that anAdverse event occurred following examination on the magnetom area system. a male patient was positioned head first with arms over the head for examination with a body 18 coil. following the examination, the patient suffered a second degree burn on each inner thigh. there were two areas of redness on each inner thigh approximately 4 inches x 6 inches and in the middle of each red area, a blister approximately 1 inch x 1 inch. the patient was examined by the technologist and a cold compress

Report Number	Event Date	Event Type	Manufacturer	Date Received	Product Code	Brand Name	Device Problem	Patient Problem	Event Text
									was applied. at this time, it is not known if further medical treatment was provided. it is also not known if positional padding wasUsed during the examination. manufacturer narrative: (b)(4). siemens is conducting a thorough investigation of the reported events. as this event is under investigation, a root cause has not yet been determined. a supplement report will be filed upon completion of the investigation. (b)(6).
3002808157-2018-56184	2018/11/06	Injury	SIEMENS HEALTHCARE GMBH	2019/04/04	LNH	MAGNETOM AERA	Use of Device Problem	Bone Fracture(s); Patient Problem/Medical Problem	an obese patient was positioned with the left and right arms along the body with a head coil. it is assumed that the positioning of the patient was head first supine, however, no clear statement regarding the patient positioning could be identified. after the examination was completed, the patient table was moved out of the magnet system. the patients right arm was pinched between the table and the magnet bore during table movements. the patient suffered a compression fracture causing a humeral head fracture on the upper arm. due to body paralysis of the right half of the patient's body, the squeeze ball was placed in the left hand, however, the patient did not press the squeeze ball and alert the operator at the time of the injury. the patient was provided medical treatment immediately and the

Report Number	Event Date	Event Type	Manufacturer	Date Received	Product Code	Brand Name	Device Problem	Patient Problem	Event Text
									fracture is healing without the need for surgery. manufacturer narrative: (b)(4). siemens is conducting a thorough investigation of the reported events. as this event is under investigation, a root cause has not yet been determined. a supplement report will be filed upon completion of the investigation.
3002808157-2019-70442	2018/12/27	Injury	SIEMENS HEALTHCARE GMBH	2019/04/04	LNH	MAGNETOM SOLA	Use of Device Problem	Hearing Impairment; Patient Problem/Medical Problem	it was reported to siemens that anAdverse event occurred while operating the magnetom sola system. a patient with a cochlear implant reported pain during examination. the procedure was continued and completed without delay. it was later reported that the patient underwent surgery in order to replace the cochlear implant. at this time, there is no clear indication that the patients injury was caused by the system. siemens has requested additional information in order to conduct an investigation of the reported event. manufacturer narrative: (b)(4). siemens is conducting a thorough investigation of the reported events. as this event is under investigation, a root cause has not yet been determined. a supplement report will be filed upon completion of the investigation. (b)(6).
3002808157-2018-57132	2018/11/12	Injury	SIEMENS HEALTHCARE GMBH	2019/04/01	LNH	MAGNETOM AERA	Use of Device Problem	Injury; Partial thickness (Second	it was reported to siemens that anAdverse event occurred following examination on the magnetom aera system. it was reported that a patient

Report Number	Event Date	Event Type	Manufacturer	Date Received	Product Code	Brand Name	Device Problem	Patient Problem	Event Text
								Degree) Burn	suffered a second degree burn on the thorax and redness on the face. the dimension of the burn and the extent of medical treatment, if any, is unknown at this time. siemens has requested additional information in order to conduct an investigation, however, no information has yet been provided. manufacturer narrative: (b)(4). siemens has requested additional information in order to conduct an investigation. at this time, no further information has been provided. in the event that additional information becomes available, a supplement report will be filed upon completion of an investigation. (b)(6). **submission resubmitted due to webtrader error/failure**.
1056069-2019-00001		Malfunction	CARMA SALUD, S.L.	2019/03/28	MOS	KFA, GEHC, SIGNA 1.5T 4CH PA	Thermal Decomposition of Device	No Known Impact Or Consequence To Patient	knee coil came into service as a normal routine repair with no indications of heating or patient involvement. during the repair process, invivo technician discovered the housing of the coil was warped (from heating) in an area that would be in constant contact with the patient. manufacturer narrative: a coil was returned to invivo service & repair for normal repair under rma (b)(4). coil was returned for low signal. there was no indication from the customer/endUser that would indicate a patient was involved, nor any heating incidents. upon

Report Number	Event Date	Event Type	Manufacturer	Date Received	Product Code	Brand Name	Device Problem	Patient Problem	Event Text
									inspection of coil during repair it was noticed that there was an overcurrent condition. the coil was scrapped determined to be beyond economical repair. the site will receive a supply stock in it's replacement. repair tech indicates that the current state of the coil failed the bench test on all transmit channels. this failure would flag the system to abort scanning if the site was using under clinicalUse. the coil was delivered to have an engineering evaluation review. after investigation and determination it was noted that from the location and the type of overcurrent conditions, was from transmitting into the coil from the body coil with in the magnet. this information is provided with all coil in theUser manual. the cause of the customer complaint as described above is most likely attributed to aUse error. manufacturer narrative: the investigation is still ongoing for this event. when the investigation is complete a follow-up report will be sent to the fda.
3002808157-2019-74993	2019/03/22	Injury	SIEMENS HEALTHCARE GMBH	2019/03/26	LNH	MAGNETOM SKYRA	Use of Device Problem; Human-Device Interface Problem	Abrasion; Injury; Patient Problem/Medical Problem	it was reported to siemens that anAdverse event occurred while operating the magnetom skyra system. while the operator was positioning the patient for a head examination, an oxygen cylinder was brought into the magnet room. the oxygen cylinder was attracted to the

Report Number	Event Date	Event Type	Manufacturer	Date Received	Product Code	Brand Name	Device Problem	Patient Problem	Event Text
									magnet resulting in an injury to the patient. the patient suffered a large skin abrasion to the back. an x-ray was performed and no further injuries were found. the health status of the patient is unknown at this time. siemens has requested additional information in order to conduct an investigation of the reported event. manufacturer narrative: (b)(4). siemens is conducting a thorough investigation of the reported events. as this event is under investigation, a root cause has not yet been determined. a supplement report will be filed upon completion of the investigation. this event occurred in (b)(6).
3002808157-2019-67427	2019/01/29	Injury	SIEMENS HEALTHCARE GMBH	2019/03/26	LNH	MAGNETOM AERA	Use of Device Problem	Electric Shock; Patient Problem/Medical Problem	it was reported to siemens that anAdverse event occurred while servicing the magnetom aera system. on (b)(6) 2019, siemens received information that an mr operator (not a siemens service engineer) suffered an electrical shock during service on a siemens mr system. the operator was on the top of the electrical cabinet and tried to bypass the ups unit. in order to do the bypassing, the operator switched off the ups unit, but not the mr system itself. the operator unplugged the ups unit cable from the epc of the mr and touched the pins on the opened plug on the epc with his elbow resulting in an electrical shock. the operator was

Report Number	Event Date	Event Type	Manufacturer	Date Received	Product Code	Brand Name	Device Problem	Patient Problem	Event Text
									checked by medical staff following the incident. we are unaware of the current health status of the operator. siemens has requested additional information in order to conduct an investigation of the reported event. manufacturer narrative: (b)(4). siemens is conducting a thorough investigation of the reported events. as this event is under investigation, a root cause has not yet been determined. a supplement report will be filed upon completion of the investigation. (b)(6).
3002808157-2019-69222	2018/05/07	Injury	SIEMENS HEALTHCARE GMBH	2019/03/26	LNH	MAGNETOM AERA	Use of Device Problem	Hearing Loss; Patient Problem/Medical Problem	it was reported to siemens that anAdverse event occurred following examination on the magnetom aera system. it was reported that a patient suffered hearing loss during a one hour spine examination. no further details of the event were provided. additionally, no clear information regarding the current health status of the patient has been provided at this time. siemens has requested additional information in order to conduct an investigation of the reported event. manufacturer narrative: (b)(4). siemens is conducting a thorough investigation of the reported events. as this event is under investigation, a root cause has not yet been determined. a supplement report will be filed upon completion of the investigation. (b)(6).

Report Number	Event Date	Event Type	Manufacturer	Date Received	Product Code	Brand Name	Device Problem	Patient Problem	Event Text
2183553-2019-00002	2019/02/18	Injury	GE MEDICAL SYSTEMS, LLC	2019/03/19	LNH	SIGNA ARCHITECT	Thermal Decomposition of Device;Use of Device Problem	Burn(s); Burn, Thermal	it was reported that following an intra-operative mri procedure involving a brain tumor surgery, the patient had a burn injury to the left scalp which was in direct contact with a medtronic nipt (non-invasive patient tracker) for the duration of the mri scan. the medtronic tracker had visible thermal damage, and the burn injury occurred directly underneath the point of contact between the tracker and the scalp. the patient was diagnosed with a 2.5cm by 1.8cm full thickness burn. the patient was treated with first aid and bandage changes every other day. the patient was referred to plastic surgery, but subsequently cancelled that appointment. manufacturer narrative: the investigation by ge healthcare (gehc) has been completed. a gehc field engineer completed system testing and verified that the mri scanner was operating normally and within performance specifications. the root cause was determined to be operator error related to theUse of a 3rd party medtronic axiem non-invasive patient tracker (nipt) during the patient mri scan. per discussion with theUser, the medtronic mr conditions forUse were not strictly followed during this procedure, resulting in an rf burn to the patient. per our gehc operator manual, theUser must

Report Number	Event Date	Event Type	Manufacturer	Date Received	Product Code	Brand Name	Device Problem	Patient Problem	Event Text
									ensure the safeUse of mr conditional devices during patient scans.Users should consult the device manufacturers instructions and safety guidelines. no further actions are planned by gehc. medtronic has been notified of the patient event involving their product. manufacturer narrative: unique identifier: (b)(4). there are no additional device identification numbers. ge healthcare's investigation is ongoing. a follow up report will be submitted once the investigation has been completed. device evaluation anticipated, but not yet begun.
3003768277-2019-00017	2019/02/28	Injury	PHILIPS HEALTHCARE	2019/03/04	LNH	INGENIA 1.5T	Adverse Event Without Identified Device orUse Problem	Head Injury	Philips received a report on an attraction of a tape cutter to an mr system. the attraction of the tape cutter caused a head injury of 15 centimeter to the patient, which required sutures. manufacturer narrative: this event was due to not following mri safety standards by bringing a magnetic tape cutter into the mr examination room. it is known that magnetic materials should not be brought into the examination room. the safety directions as presented in the instruction forUse already contain warnings on this matter.
3003768277-2019-00018	2019/02/04	Injury	PHILIPS HEALTHCARE	2019/03/01	LNH	INGENIA 3.0T	Adverse Event Without Identified	Swelling	Philips received a report that a patient sustained a blister on the right shoulder and elbow that came open and needed medical

Report Number	Event Date	Event Type	Manufacturer	Date Received	Product Code	Brand Name	Device Problem	Patient Problem	Event Text
							Device orUse Problem		intervention. manufacturer narrative: the investigation is still ongoing on this event. when the investigation is completed, a follow-up will sent to the fda.
MW5083850	2019/02/05	Injury	SIEMENS MEDICAL SOLUTIONS USA, INC.	2019/02/07	LNH	SIEMENS	Adverse Event Without Identified Device orUse Problem	Erythema; Burn, Thermal	patient was in the mri machine, felt some burning on his l thigh. he alerted the mri tech who immediately aborted the test. the patient already has cellulitis on that leg, so it is difficult to tell if there is more redness in the area, as it was already red before this occurrence. the patient has gained 40lbs of fluid recently. all safety measures were in place for the patient to be in the mri machine. the mri was immediately taken out of service after the incident and the rep was called to check functionality. after being checked, it was determined it was workingAppropriate ly and could be placed back into service.
3003768277-2019-00007	2019/01/19	Injury	PHILIPS HEALTHCARE	2019/02/05	LNH	INGENIA 3.0T	Temperature Problem	Erythema; Swelling	Philips received a report from a customer related to a patient heating incident with an ingenia 3.0t mr system. a patient was scanned for an mri examination. after the examination reddening and a blister was observed on the patient's buttocks. manufacturer narrative: based on the provided information and test performed on site on the system there is no indication of a malfunction of the mr system or coilUsed. although this could not be

Report Number	Event Date	Event Type	Manufacturer	Date Received	Product Code	Brand Name	Device Problem	Patient Problem	Event Text
									confirmed, the shape and place of the skin reddening and blistering is consistent with foreign material present in the patient's underwear. further contributing factors observed are: total of 8 scans were performed on high sar; total administered sed of 4.9 kj/kg exceeded the recommended maximum of 3.5 kj/kg; the temperature of the examination room was too high; patient ventilation was at a low level; the patient was covered with a sheet or blanket.
3003768277-2019-00004	2018/12/31	Injury	PHILIPS HEALTHCARE	2019/01/30	LNH	INGENIA 1.5T	Adverse Event Without Identified Device orUse Problem	Swelling	Philips received a report from a customer related to a patient heating incident with an ingenia 1.5t mr system. a patient was scanned for an mri examination. after the examination a blister was observed on the patient's left arm. manufacturer narrative: based on the provided information, there is no indication of a malfunction of the mri system or coilUsed that contributed to the injury. the injury is consistent with injuries caused by close proximity to the bore wall. initially only a sheet/pillow case wasUsed to avoid body-to-bore wall contact. after the patient reported heating, additional padding wasUsed. the additional padding prevented the injury to progress in size and severity. further contributing factors identified: 6 scans administered on

Report Number	Event Date	Event Type	Manufacturer	Date Received	Product Code	Brand Name	Device Problem	Patient Problem	Event Text
									high sar. total sed of 8.2 kj/kg. the patient had diabetes. the patient was obese. both diabetes and obesity impair the thermoregulation of patients. the risk of rf energy-related injuries is higher in patients with impaired thermoregulatory capacity.
3010949642-2019-00001	2018/08/03	Injury	GE HEALTHCARE (TIANJIN) COMPANY LIMITED	2019/01/15	LNH	SIGNA EXPLORER	Improper or Incorrect Procedure or Method;Adverse Event Without Identified Device orUse Problem	Laceration(s)	it was reported after a breast examination, when the patient tried to get up from the cradle by placing her hand on a patient strap, the patient received a 5cm laceration on the palm of the left hand from the edge of the accessory strap. the laceration was sutured. the ge field engineer (fe) confirmed that there was no problem on the mr patient table. manufacturer narrative: unique identifier: (b)(4). there are no additional device identification numbers. ge healthcare's investigation is ongoing. a follow up report will be submitted once the investigation has been completed. device evaluation anticipated, but not yet begun.
MW5082403		Injury	PHILIPS MEDICAL SYSTEMS MR FINLAND	2018/12/20	LNH	PHILIPS HEALTHCARE SCANNING SYSTEM	Dent in Material	Pain	a veteran pt was allowed to enter the bore unwanded for metal. this person had a knife with iron or nickel content in their pocket. the knife was attracted to the static magnetic field in the bore of the scanner, and flew out of the pocket impacting the bore. this item's impact caused pain to the pt and physical dent in the bore of the mri scanner. thisPhilipsmri ((b)(4))

Report Number	Event Date	Event Type	Manufacturer	Date Received	Product Code	Brand Name	Device Problem	Patient Problem	Event Text
									is owned and operated by contract ((b)(4)) between healthcare provider is healthcare ((b)(6)) and the us federal government (b)(6). dates ofUse: (b)(6) 2018.
3003768277-2018-00097	2018/12/10	Injury	PHILIPS HEALTHCARE	2018/12/19	LNH	INGENIA 1.5T	Adverse Event Without Identified Device orUse Problem	Hearing Impairment	Philips received a report from a customer related to a patient who complained of a hearing problem after an mr examination on an ingenia 1.5t system. manufacturer narrative: the investigation is still ongoing on this event. when the investigation is completed a follow-up will be sent to the fda.
8145982	2018/11/12	Malfunction	PHILIPS MEDICAL SYSTEMS, INC.	2018/12/10	LNH	PHILIPS	Appropriate Term/Code Not Available	No Known Impact Or Consequence To Patient	the device quenched without any identifiable cause, which took it out of service for a period of weeks. per manufacturer response to the hospital, the device is being repaired (unsure of the cause).
3003768277-2018-00089	2018/11/22	Injury	PHILIPS HEALTHCARE	2018/12/03	LNH	INGENIA 3.0T	Device Fell	Eye Injury	Philips received a report from a customer related to an incident during an mr examination. a mirror that wasUsed on a coil during this examination fell and hit the patient's right eye. manufacturer narrative: the investigation is still ongoing on this event. when the investigation is completed, a follow-up will sent to the fda.
3002808157-2018-35487	2018/06/16	Injury	SIEMENS HEALTHCARE GMBH	2018/11/29	LNH	MAGNETOM SKYRA	Use of Device Problem	Injury	anAdverse event with the magnetom skyra system was reported to siemens. a linen cart was brought into the examination room. the cart was pulled in by the magnet injuring a patient and a technologist

Report Number	Event Date	Event Type	Manufacturer	Date Received	Product Code	Brand Name	Device Problem	Patient Problem	Event Text
									present in the room. the incident resulted in an orbital fracture to the patient, which required surgery. current health status of the patient is unknown. manufacturer narrative: (b)(4). siemens is conducting a thorough investigation of the reported events. as this event is under investigation, a root cause has not yet been determined. a supplement report will be filed upon completion of the investigation.
3003768277-2018-00087	2018/10/05	Injury	PHILIPS HEALTHCARE	2018/11/26	LNH	INGENIA 1.5T	Temperature Problem	Rash	Philips received a customer report indicating that a heating incident occurred during an mr examination on an ingenia 1.5t cx system. the patient sustained blisters of 3 to 4 centimeter on the inside and outside of the thighs. manufacturer narrative: based on the provided information and tests performed on site, there is no indication of a malfunction of the mri system or coilUsed that contributed to the injury. the injury is consistent with injuries caused by contact. an rf loop was formed between the patient¿s hands and hips, as well as between the inner thighs. the high examination room temperature and the low ventilation setting are also considered a contributing factor.
3002808157-2018-44521	2018/08/08	Injury	SIEMENS HEALTHCARE GMBH	2018/11/20	LNH	MAGNETOM SKYRA	Use of Device Problem	Burn(s); Injury	it was reported to siemens that anAdverse event occurred following examination on the magnetom skyra system. a male patient was

Report Number	Event Date	Event Type	Manufacturer	Date Received	Product Code	Brand Name	Device Problem	Patient Problem	Event Text
									positioned head first, supine with arms extended over his head for a right elbow scan. due to the patients size, the patient was positioned slightly oblique and the left side of the patient's body was touching the magnet bore. the patient gown was separating the bare skin from the bore, however, no other padding or blankets wereUsed for patient positioning. the exam was completed without incident and no areas of redness were observed. several days later the patient contacted the hospital via email to report a blister and scab to the left waist/ buttock area. the hospital offered consultation and medical treatment, however, the patient declined treatment and stated the blister had already begun healing. there is no further report of impact to the state of health of the patient involved. manufacturer narrative: (b)(4). following the reported event, the system was evaluated and found to be operating within specification and no malfunction or device failure was identified. the direct contact of the tissue with the bore wall can result in high-frequency current loops which are capable of causing local burns. to prevent these possible burns a warning notice is implemented in the magnetom family operator manual - mr system syngo mr e11 page 20. it

Report Number	Event Date	Event Type	Manufacturer	Date Received	Product Code	Brand Name	Device Problem	Patient Problem	Event Text
									is recommended that direct skin contact be avoided by using at least a 5 mm thick cushion between the skin and the bore wall and to follow the instructions given in the operator manual regarding correct patient positioning in order to avoid such incidents in the future. (b)(6).
2183553-2018-00017	2018/10/11	Injury	GE MEDICAL SYSTEMS, LLC	2018/11/14	OUO	SIGNA PET/MR	Adverse Event Without Identified Device orUse Problem	Hearing Loss	it was reported that a patient underwent an mri of the internal auditory canals (iacs) to evaluate a pre-existing condition of left sided vestibular schwannoma and left side hearing loss. the patient was providedAppropriate earplugs by the customer for the exam. the patient returned to the radiology department after the mri exam had been completed to report hearing loss in the right ear. the patient was evaluated by the site's audiology department where new hearing loss in the right ear was confirmed and medication was provided for treatment. the patient's condition is confirmed to have fully resolved to prior baseline. manufacturer narrative: the investigation by ge healthcare has been completed. the acoustic performance test was performed on the system and concluded that the testing meets the iec 60601-2-33 requirements and the osha levels are within the specification for this system configuration. the incident appears to

Report Number	Event Date	Event Type	Manufacturer	Date Received	Product Code	Brand Name	Device Problem	Patient Problem	Event Text
									be the result of human medical condition(s). the patient was provided specified hearing protection; however, a patient's medical conditions may cause sensitivity to acoustic levels that occur during normal clinical scanning. no system issue was found. no corrections are required as the system was operating within specification. manufacturer narrative: common device name: tomographic imager combining emission computed tomography with nuclear magnetic resonance. unique identifier: (b)(4). there are no additional device identification numbers. ge healthcare's investigation is ongoing. a follow up report will be submitted once the investigation has been completed. device evaluation anticipated, but not yet begun.
2183553-2018-00013	2018/09/02	Injury	GE MEDICAL SYSTEMS, LLC	2018/10/25	LNH	SIGNA 3.0T MR750 SYSTEM	Adverse Event Without Identified Device orUse Problem	Hearing Loss;Tinnitus	it was reported that a patient with a pre-existing condition ofTinnitus underwent an mri of the internal auditory canals (iacs) on (b)(6) 2018. the patient was providedAppropriate earplugs by the customer and was scanned for a total of 40 minutes after the mri exam, the patient complained of increasedTinnitus and other hearing issues. on (b)(6) 2018, the patient was reported to have had a hearing test which identified high frequency hearing loss and abnormal

Report Number	Event Date	Event Type	Manufacturer	Date Received	Product Code	Brand Name	Device Problem	Patient Problem	Event Text
									movement of the left eardrum. manufacturer narrative: the investigation by ge healthcare has been completed. the acoustic performance test was performed on the system and concluded that the testing met osha regulations and was within the specification for this system configuration. the incident appears to be the result of human medical condition(s). the patient was provided specified hearing protection, however a patient's medical conditions may cause sensitivity to acoustic levels that occur during normal clinical scanning. no system issue was found. no corrections are required as the system was operating within specification. manufacturer narrative: ge healthcare's investigation is ongoing. a follow up report will be submitted once the investigation has been completed. device evaluation anticipated, but not yet begun.
2183553-2018-00012	2018/09/20	Injury	GE MEDICAL SYSTEMS, LLC	2018/10/19	LNH	3.0T SIGNA HDXT SIGNA VIBRANT	Entrapment of Device;Use of Device Problem	Laceration(s)	it was reported that a gehc field engineer (fe) was replacing the driver module on a gehc mr system. as part of the installation, the module which is on a track/rail system, is required to be manually pushed into place. while pushing the module into place, the fe's ring finger (4th digit) became caught in the track/rail resulting in a small laceration at the tip of the finger. the fe sought medical

Report Number	Event Date	Event Type	Manufacturer	Date Received	Product Code	Brand Name	Device Problem	Patient Problem	Event Text
									attention at the customer's emergency room and received three sutures for the laceration. the fe was reported to have been wearing protective gloves when the injury occurred. manufacturer narrative: there are no additional device identification numbers. udi not required. ge healthcare's investigation is ongoing. a follow up report will be submitted once the investigation has been completed. device evaluation anticipated, but not yet begun.
3002808157-2018-41145	2018/04/17	Injury	SIEMENS HEALTHCARE GMBH	2018/10/16	LNH	MAGNETOM AERA	Use of Device Problem	Bone Fracture(s); Injury; Fracture, Arm	it was reported to siemens that anAdverse event occurred while operating the magnetom aera system. a (b)(6) year old male patient was positioned head first supine with arms to the right and left of the body for a head examination. the patient was not sedated nor fixed with restraints. at the completion of the examination, the patient was moved out of the patient bore when the patients upper left arm was caught on the cover of the magnet bore. the operator next to the table immediately pushed the emergency stop button. the patients injury was evaluated and it was determined that the patient suffered a fracture to the left arm. the patient underwent surgery in which osteosynthesis with intramedullary nails were placed. additional information regarding the

Report Number	Event Date	Event Type	Manufacturer	Date Received	Product Code	Brand Name	Device Problem	Patient Problem	Event Text
									current state of health of the patient was requested, however, it was not provided due to european privacy policy. manufacturer narrative: (b)(4). following the reported event, the system was evaluated and the system was found to be operating within specification and no malfunction or device failure was identified. the reported injury is attributed to patient positioning during table movements and not a device failure. the magnetom aera, operator manual provides instruction to carefully monitor the patient during table movements. this event occurred in (b)(6). resubmission of initial report due to report code error.
2183553-2018-00011	2018/09/07	Injury	GE MEDICAL SYSTEMS, LLC	2018/10/12	LNH	GE SIGNA EXCITE 1.5T MR SYSTEM	Use of Device Problem	Burn(s)	it was reported that a patient sustained a 13cm x 7cm second degree burn on the right outer thigh/buttock after an mr of the brain and cervical spine. the patient was not padded per ge recommendations. the patient was treated by a wound care clinic and will require a skin graft procedure for the burn. manufacturer narrative: there are no additional device identification numbers. ge healthcare's investigation has been completed. the mr scanner was operating within specifications and determined to be operating normally when checked by the ge healthcare

Report Number	Event Date	Event Type	Manufacturer	Date Received	Product Code	Brand Name	Device Problem	Patient Problem	Event Text
									field engineer. the root cause of the injury was determined to be inadequate patient padding for the mri procedure. the operator documentation describes theAppropriate safety measures for padding patients for mr exams. the mr operator has the final responsibility for theUse and placement of non-conductive mr compatible padding, and preparation of the patient, prior to starting the mr exam procedure.
3003768277-2018-00074	2018/08/29	Injury	PHILIPS HEALTHCARE	2018/09/26	LNH	INGENIA 1.5T	Adverse Event Without Identified Device orUse Problem	Hearing Loss	Philips received a report indicating that a patient suffered hearing loss after an mr examination. manufacturer narrative: the investigation is still ongoing on this event. when the investigation is completed, a follow-up will be sent to the fda.
MW5079897	2018/08/02	NA	GE MEDICAL SYSTEMS, LLC	2018/09/18	LNH	GE SIGNA	Temperature Problem	Burn, Thermal; Partial thickness (Second Degree) Burn	pt was having an mri of rt shoulder and stated the machine burned her on the left arm. there was no blister that day but she says it came up the following day.
MW5079574	2018/08/13	Injury	PHILIPS MEDICAL SYSTEMS	2018/09/04	LNH	PHILIPS SYSTEM NUCLEAR MAGNETIC RESONANCE	Adverse Event Without Identified Device orUse Problem	Burn, Thermal; Partial thickness (Second Degree) Burn	pt underwent mris of thoracic and lumbar spine while under anesthesia. sustained second degree burn to left upper arm.

Report Number	Event Date	Event Type	Manufacturer	Date Received	Product Code	Brand Name	Device Problem	Patient Problem	Event Text
2183553-2018-00010	2018/07/23	Injury	GE MEDICAL SYSTEMS, LLC	2018/08/29	LNH	GE 3.0T SIGNA INFINITY TWINSPEED WITH EXCITE MR SYSTEM	Use of Device Problem; Patient-Device Incompatibility;Appropriate Term/Code Not Available	Bone Fracture(s); Pain	it was reported that a large, female patient complained of soreness of the ribs following an mri breast exam. the patient has a history of multiple rib injuries which have been reported to occur from simply bending over. the patient did report a new, anterior rib injury after the mri. the customer had ge healthcare applications review patient positioning and it was found that the site had removed coil pads when scanning to accommodate the patient's size. manufacturer narrative: the investigation by ge healthcare has been completed. based on the available information, the root cause is due to aUse error. the technologist removed the breast coil pads to accommodate the patient's size. customer did not follow ge operator manual procedures. manufacturer narrative: there are no additional device identification numbers. ge healthcare's investigation is ongoing. a follow up report will be submitted once the investigation has been completed. device evaluation anticipated, but not yet begun.
3003768277-2018-00065	2018/08/08	Injury	PHILIPS HEALTHCARE	2018/08/24	LNH	INGENIA 3.0T	Insufficient Information	Partial thickness (Second Degree) Burn	Philips received a report from a customer related to a patient heating incident with an ingenia 3.0t mr system. a patient was scanned for an mri examination. after the examination a blister (4cm) developed on the patient's left

Report Number	Event Date	Event Type	Manufacturer	Date Received	Product Code	Brand Name	Device Problem	Patient Problem	Event Text
									hip/buttock. manufacturer narrative: the investigation is still ongoing on this event. when the investigation is completed a follow-up will sent to the fda.
3003768277-2018-00060	2018/07/24	Injury	PHILIPS HEALTHCARE	2018/08/21	LNH	INGENIA 1.5T	Adverse Event Without Identified Device orUse Problem	Hearing Loss	Philips received a report from a hospital representative stating that a patient sustained hearing loss after an mr examination on the ingenia 1.5t system. manufacturer narrative: the investigation is still ongoing on this event. when the investigation is completed a follow-up will be sent to the fda.
3003768277-2018-00061	2018/08/13	Injury	PHILIPS HEALTHCARE	2018/08/21	LNH	INGENIA 1.5T	Adverse Event Without Identified Device orUse Problem	Skin Irritation	Philips received a report from a customer that a patient sustained a 4 centimeter long blister on the left upper arm after a thoracic and lumbar spine examination on the ingenia 1.5t mr system. manufacturer narrative: based on the provided information and tests performed on site, there is no indication of a malfunction of the mri system or coilUsed that contributed to the injury. it was concluded that the injury occurred due to body to bore wall contact. contributing factors identified in this case are: total administered specific energy dose. the patient was obese and anesthetized. manufacturer narrative: the investigation is still ongoing on this event. when the investigation is completed a follow-up will be sent to the fda.

Report Number	Event Date	Event Type	Manufacturer	Date Received	Product Code	Brand Name	Device Problem	Patient Problem	Event Text
3003768277-2018-00058	2018/08/02	Injury	PHILIPS HEALTHCARE	2018/08/15	LNH	INGENIA 1.5TS	Adverse Event Without Identified Device orUse Problem	Swelling	Philips received a report about a heating incident on an ingenia 1.5t cx a female patient was examined in superman position for an examination of the wrist. shortly after the examination a small blister was observed on the nose of the patient. manufacturer narrative: the investigation is still ongoing on this event. when the investigation is completed, a follow-up will be sent to the fda.
2183553-2018-00009	2018/05/18	Malfunction	GE MEDICAL SYSTEMS, LLC	2018/07/20	LNH	SIGNA ARTIST	Installation-Related Problem; Unintended Movement	No Patient Involvement	it was reported that after servicing a newly replaced magnet, the helium in the magnet vessel expelled into the customer¿s unfinished quench vent releasing helium into the customer¿s equipment room. servicing was performed prior to customer turn over, not during customerUse. no injuries occurred as a result of this incident. at this time, it is conservatively believed that if this malfunction were to recur, it would be likely to result in a serious injury. manufacturer narrative: ge healthcares (gehc) investigation has been completed. it was found that service was being performed on a de-energized magnet during site construction and installation of the mr system. the gehc field engineer (fe) was working on the helium coldhead and was following theAppropriate process and safety measures associated with this type of

Report Number	Event Date	Event Type	Manufacturer	Date Received	Product Code	Brand Name	Device Problem	Patient Problem	Event Text
									service. during the service, there was a release of helium, which is inherently unique to magnets. since the magnet was not ramped up, no quench occurred. there was no malfunction and no injury occurred. manufacturer narrative: (b)(4). there are no additional device identification numbers. ge healthcare's investigation is ongoing. a follow up report will be submitted once the investigation has been completed. device evaluation anticipated, but not yet begun.
3003768277-2018-00051	2018/06/26	Injury	PHILIPS HEALTHCARE	2018/07/18	LNH	INGENIA 1.5T	Appropriate Term/Code Not Available	Bone Fracture(s)	Philips received a report from a customer about an attraction of a hospital stretcher to the mr system. this resulted in a fracture in the hand of the nurse. manufacturer narrative: this event was due to not following mri safety standards by bringing a stretcher with magnetic material into the mr examination room. it is known that magnetic materials should not be brought into the examination room. the safety directions as presented in the instruction forUse already contain warnings on this matter.
3003768277-2018-00049	2018/04/14	Injury	PHILIPS HEALTHCARE	2018/07/09	LNH	INGENIA 1.5T	Insufficient Information	Erythema; Partial thickness (Second Degree) Burn	Philips received a report from a customer related to a patient heating incident with an ingenia 1.5t mr system. a patient was scanned for an mri examination. the patient reported two months after the examination to have sustained reddening on the

Report Number	Event Date	Event Type	Manufacturer	Date Received	Product Code	Brand Name	Device Problem	Patient Problem	Event Text
									right side of the abdomen with a circumference of approximately 40 cm, with three blisters. manufacturer narrative: the investigation is ongoing on this event. when the investigation is completed a follow-up will be sent to the fda.
3003768277-2018-00043	2018/05/26	Injury	PHILIPS HEALTHCARE	2018/06/19	LNH	INGENIA 3.0T	Adverse Event Without Identified Device orUse Problem	Erythema; Swelling	Philips received a report about a heating incident on an ingenia 3t. a male patient was scanned with the 8 channel ds shoulder coil and a few days after the examination, he reported skin reddening with a few blisters on his shoulder to the hospital. manufacturer narrative: the investigation is still ongoing on this event. when the investigation is completed, a follow-up will be sent to the fda.
3003768277-2018-00044	2018/05/18	Injury	PHILIPS HEALTHCARE	2018/06/18	LNH	INGENIA 1.5T	Insufficient Information	Partial thickness (Second Degree) Burn	Philips received a report from a customer stating that a patient sustained a large blister on the left upper arm after being examined with the posterior coil. manufacturer narrative: based on the provided information and tests performed on site, there is no indication of a malfunction of the mri system or coilUsed that contributed to the injury. the injury is consistent with injuries caused by close proximity of the skin to the bore wall. the patient was obese and it was stated that the patient¿s arms were close to the bore covers. although padding wasUsed to ensure distance between the patient

Report Number	Event Date	Event Type	Manufacturer	Date Received	Product Code	Brand Name	Device Problem	Patient Problem	Event Text
									and bore covers it was also indicated that these pads might have shifted during the examination. further contributing factors encountered: the long examination time. the total administered specific energy dose. the patient was under general anesthesia, general anesthesia can impair the thermoregulatory capability of the patient. because of this, the patient was unable to sense heating and to alert the operator. it was stated that the patient had microscopic pieces of metallic materials in the body, location of these pieces is unknown. the patient was obese, obesity can impair the thermoregulatory capability of the patient.
3003768277-2018-00041	2018/05/05	Injury	PHILIPS HEALTHCARE	2018/06/11	LNH	INGENIA 1.5T	Adverse Event Without Identified Device orUse Problem	Burn, Thermal; Partial thickness (Second Degree) Burn	Philips received a report from a customer related to a patient heating incident with an ingenia 1.5t mr system. a patient was scanned for an mri examination. after the examination 2nd to 3rd degree blistering (size 8x10 cm) was reported. manufacturer narrative: based on the provided information and test performed on site there is no indication of a malfunction of the mr system or coilUsed that contributed to the event. the injury on the patient¿s right arm is consistent with heating injuries caused by skin-to-bore contact. it was stated that the patient was

Report Number	Event Date	Event Type	Manufacturer	Date Received	Product Code	Brand Name	Device Problem	Patient Problem	Event Text
									touching the bore and no padding wasUsed to prevent body-to-bore contact. contributing factors in this case identified are: the patient was obese. the thermoregulation of obese patients is known to be impaired. the risk of rf energy-related injuries is higher in patients with impaired thermoregulation. the patient had diabetes, which indicates an impaired thermoregulation. manufacturer narrative: the investigation is ongoing on this event. when the investigation is completed a follow-up will sent to the fda.
2183553-2018-00008		Injury	GE MEDICAL SYSTEMS, LLC	2018/06/06	LNH	SIGNA ARCHITECT	Adverse Event Without Identified Device orUse Problem	Chest Pain; Bone Fracture(s)	it was reported that a patient stated she had severe pain in her chest following a breast mri. the patient's physician ordered a chest x-ray that indicated a rib fracture. the patient was able to complete the exam. manufacturer narrative: the investigation by ge healthcare has been completed. based on the available information, there is no apparent root cause of the patient injury. there is no evidence that the signa architect scanner or sentinelle breast coil contributed to the injury. the technologist showed good clinical care in preparation and imaging of the patient. manufacturer narrative: unique identifier: (b)(4). there are no additional device identification numbers. ge

Report Number	Event Date	Event Type	Manufacturer	Date Received	Product Code	Brand Name	Device Problem	Patient Problem	Event Text
									healthcare's investigation is ongoing. a follow up report will be submitted once the investigation has been completed. = device evaluation anticipated, but not yet begun.
3003768277-2018-00038	2018/04/30	Injury	PHILIPS HEALTHCARE	2018/05/25	LNH	INGENIA 3.0T	Improper or Incorrect Procedure or Method	Bone Fracture(s)	Philips received a report from a customer. a patient sustained a fracture in his hand, because of an attraction incident involved with a non mr compatible pump. the pump hit the patient's hand and caused a fracture. manufacturer narrative: updated date of event (b)(6) 2018. manufacturer narrative: this event was due to not following mri safety standards by bringing a pump with magnetic material into the mr examination room. it is known that magnetic materials should not be brought into the examination room. the safety directions as presented in the instruction forUse already contain warnings on this matter.
3010949642-2018-00003	2018/04/20	Injury	GE HEALTHCARE (TIANJIN) COMPANY LIMITED	2018/05/18	LNH	SIGNA VOYAGER	Use of Device Problem	Burn(s)	it was reported that a patient sustained a two inch partial thickness burn to the posterior right shoulder during an mr examination of the left shoulder. padding was placed at the patient's sides, but the customer stated that the pads fell down on the patient because the patient wasn't up against them. the patient was not padded to prevent body loops. the patient was initially treated with (b)(6) cream but is waiting for an appointment with a wound care

Report Number	Event Date	Event Type	Manufacturer	Date Received	Product Code	Brand Name	Device Problem	Patient Problem	Event Text
									specialist and will undergo a debridement according to the patient's wife who is a nurse. manufacturer narrative: unique identifier = (b)(4). there are no additional device identification numbers. ge healthcare¿s investigation has been completed. the mr scanner and surface coil were operating within specifications and all patient and system safety related subsystems were determined to be operating normally when checked by the ge healthcare field engineer. the root cause of the injury was determined to be inadequate patient padding for the mri procedure. the operator documentation describes theAppropriate safety measures for padding patients for mr exams. the mr operator has the final responsibility for theUse and placement of non-conductive mr compatible padding, and preparation of the patient, prior to starting the mr exam process.
3003768277-2018-00035	2018/05/02	Injury	PHILIPS HEALTHCARE	2018/05/08	LNH	INGENIA 1.5T	Electromagnetic Compatibility Problem	Head Injury	Philips received a report that a person was injured. a 'patient walker' was attracted to the magnet and hit the technician. the technician was hit by the walker on the forehead and the injury required stitches. manufacturer narrative: this event was due to not following mri safety standards by bringing a walker with magnetic material into the mr

Report Number	Event Date	Event Type	Manufacturer	Date Received	Product Code	Brand Name	Device Problem	Patient Problem	Event Text
									examination room. it is known that magnetic materials should not be brought into the examination room. the safety directions as presented in the instruction forUse already contain warnings on this matter.
3003768277-2018-00034	2018/04/24	Injury	PHILIPS HEALTHCARE	2018/05/07	LNH	INGENIA 3.0T	Entrapment of Device	Bone Fracture(s)	Philips received a report from a customer related to a pinching incident. a patient was transferred to the mri table using an mr flex trak trolley. when the table was moved upwards, the patient's hand got caught between the patient table and top board of the flex trak. as a result of this the fingertip of the fourth finger of the patient's left hand fractured. manufacturer narrative: filled in usage of device. manufacturer narrative: based on the provided information and investigation performed no malfunction of the mr device was observed that contributed to the injury. this is considered to be an unfortunate incident. the patient was paralyzed on the left side of his body, as a result of a stroke. when the patient table was raised, the fourth finger of the patient's left hand was pinched between the patient table and top board of the flex trak. this resulted in a fracture of the fingertip. during handling and movement of the patient the operator should always check the patient's hands and make sure there are no cable or

Report Number	Event Date	Event Type	Manufacturer	Date Received	Product Code	Brand Name	Device Problem	Patient Problem	Event Text
									extremities positioned such that they can be caught. in this case no arm guides wereUsed to position the patient.
3002808157-2018-26550	2018/04/17	Injury	SIEMENS HEALTHCARE GMBH	2018/05/04	LNH	MAGNETOM SKYRA	Insufficient Information	Bone Fracture(s); Injury	it was reported to siemens that anAdverse event occurred while operating the magnetom skyra system. during a patient procedure, metal bags were brought into the examination room and were attracted to the magnet. as a result, the patient suffered a leg fracture. the patient required surgery to repair the leg fracture. manufacturer narrative: (b)(4). siemens has assessed the complained event and concluded that the cause of this event was the introduction of ferromagnetic pieces into the mr examination room and therefore aUser error. due to the strong magnetic field, particular safety measures have to be adhered to in order to prevent injuries. therefore, the magnetom skyra operator manual and the magnetom system owner manual provides clear instructions and warnings regarding both magnetic field hazards and training of personnel with regards to mr safety. however, the responsibility to instruct personnel and patients who have access to the mr examination room about magnetic field hazards lies with the customer. the manuals state that only equipment specified

Report Number	Event Date	Event Type	Manufacturer	Date Received	Product Code	Brand Name	Device Problem	Patient Problem	Event Text
									or recommended forUse in the controlled area (mr examination room) shall beUsed. the introduction of magnetizable objects into the magnetic field is contrary to the statements given in the operating instructions. furthermore, special warning signs are posted at the entrance of the controlled access area (magnet room). (b)(6).
3003768277-2018-00029	2018/04/12	Injury	PHILIPS HEALTHCARE	2018/05/02	LNH	INGENIA 1.5T	Overheating of Device	Full thickness (Third Degree) Burn	Philips received a report from a customer related to a patient heating incident with an ingenia 1.5t mr system. a patient was scanned for an mri examination. shortly after the examination a 3rd degree blister developed on the patient's left upper arm. manufacturer narrative: based on the provided information there is no indication of a malfunction of the mr system or coilUsed. the blistering is caused by body-to-bore wall contact. no padding wasUsed to avoid body-to-bore contact. the following contributing factors were identified: the patient was obese, which may impair the thermoregulation. one scan on high sar was administered. the total administered specific energy dose of 3.1 kj/kg. the examination room temperature was higher than specified in the instructions forUse.
3003768277-2018-00030	2018/03/15	Injury	PHILIPS HEALTHCARE	2018/04/25	LNH	INGENIA 3.0T	Adverse Event Without	Swelling	Philips received a report from a customer that a female patient sustained a blister of approximately

Report Number	Event Date	Event Type	Manufacturer	Date Received	Product Code	Brand Name	Device Problem	Patient Problem	Event Text
							Identified Device orUse Problem		4x8 cm on the left hip. just before the patient had had a lumbar examination on an ingenia 3.0t. manufacturer narrative: based on the provided information and tests performed on site, there is no indication of a malfunction of the mri system or coilUsed that contributed to the injury. it is concluded that the injury sustained by the patient was caused by contact between the patient¿s hip and the bore covers. factors which contributed and made the injury progress to a large burn: the thermoregulation of obese patients and patients who are hypertensive is often impaired. the risk of rf energy-related injuries is higher in patients with impaired thermoregulation. the patient wore polypropylene clothing which may hinder the heat dissipation. no padding wasUsed to avoid body-to-bore contact. no padding wasUsed to avoid skin-to-skin contact. the ventilation was on level 3. level 5 is recommended for high sar scans, it support the cool down mechanism.
3010949642-2018-00002	2018/03/17	Injury	GE HEALTHCARE (TIANJIN) COMPANY LIMITED	2018/04/24	LNH	1.5T SIGNA VOYAGER	Adverse Event Without Identified Device orUse Problem	Suture Abrasion	it was reported that an mr technologist brought an iv pole into the scan room. the tech thought it was an mr compatible iv pole however, it was ferrous and when brought into the room, it became attracted to the magnet. the tech tried to remove the iv pole which

Report Number	Event Date	Event Type	Manufacturer	Date Received	Product Code	Brand Name	Device Problem	Patient Problem	Event Text
									resulted in an injury to the right hand. the tech was seen in the emergency room where the tech received 16 stitches to two fingers. manufacturer narrative: (b)(4). there are no additional device identification numbers. ge healthcare performed an investigation. the incident occurred due to inattentive personnel. the technologist was magnet safety trained, magnet safety signs are posted and the site has a copy of the mr safety manual. the ge healthcare field engineer was able to safely remove the iv pole from the magnet. no further actions are planned at this time.
2183553-2018-00006	2018/02/13	Injury	GE MEDICAL SYSTEMS, LLC	2018/04/10	LNH	GE 1.5T SIGNA HDX MR SYSTEM	Use of Device Problem	Partial thickness (Second Degree) Burn	it was reported that a patient sustained a partial thickness burn to the chest after it was determined that non-mr compatible electrodes were left on the patient during a lumbar scan. the patient received wound care treatment to the burn which has since healed.User facility medwatch # (b)(4). manufacturer narrative: there are no additional device identification numbers. unique identifier = no udi required. ge healthcare's investigation has been completed. all data was reviewed and system testing verified that the scanner was operating normally and within performance specifications. the root cause was determined to be inadequate patient screening due to

Report Number	Event Date	Event Type	Manufacturer	Date Received	Product Code	Brand Name	Device Problem	Patient Problem	Event Text
									ecg electrodes being left on the inpatient when brought from the ward to the mri scanner. the customer completed the patient warming questionnaire which advises them to review the rf warming section in the safety chapter of the operator manual. rf heating can be caused by theUse of non mr-compatible ecg electrodes.
MW5076292	2018/03/28	Injury	GE	2018/04/03	LNH	GE SIGNA EXCITE 1.5 T MAGNET	Electromagnetic Interference	No Code Available	patient arrived for mri cervical spine. she has medtronic mr conditional (whole body) scs in cervical and thoracic spines, lp shunt, and medtronic pain pump, our facility has scanned patient mr cervical ((b)(6) 2017) before with all documented implants except new implant medtronic synchromed pain pump and had no issues. mrso ((b)(6)) consulted dr. (b)(6) (radiologist) prior to appt and he deemed it safe to scan patient with new implanted pain pump following mr conditional scs medtronic protocol. patient set both scs to mr mode (copies were made confirming mr mode and scanned in pt's emr) in front of mrso. patient was placed on receive only spine coil and was instructed to squeeze "call' ball if she experienced any abnormal sensations including heating. technologist ((b)(6)) talked to patient before and after each scan and test was completed with no complaints during exam. patient's scs conditions

Report Number	Event Date	Event Type	Manufacturer	Date Received	Product Code	Brand Name	Device Problem	Patient Problem	Event Text
									were met: 1.5 t ge closed mri using receive only coil, did not exceed 30 minutes total scan time for exam and did not exceed 1.6 w/kg sar per scan sequence (manual states not to exceed 2.0 w/kg sar per scan sequence). after the exam the patient approached mr tech/ mrso ((b)(6)) stating she did feel an abnormal sensation described as "electrical pulse" between the two scs generations located in rt and lt buttocks and then heating into middle of low back. patient stated it last just a couple of minutes during the 3rd to last scan (this would have been during the lower ax t2 sequence). tech / mrso asked the patient why she didn't squeeze the ball as instructed and she stated she didn't want to stop the test because she wanted to find out what was causing all hf her neck pain. mrso and radiologist discussed possible reasons for this: rf is distributed in that area during mr cervical but sar was not exceeded; possible stimulation now that there is a pain pump lead in same area as scs leads possibly looping around each other? per radiologist this patient should not undergo further mri's unless benefits outweigh risks. scs and pain pump physician (dr. (b)(6)) was made aware of incident and patient went to doctor to have lp shunt and pain

Report Number	Event Date	Event Type	Manufacturer	Date Received	Product Code	Brand Name	Device Problem	Patient Problem	Event Text
									pump reprogrammed. ordering physician was made aware of incident as well and other order mri's were cancelled at this time.
2183553-2018-00005	2018/03/02	Malfunction	GE MEDICAL SYSTEMS, LLC	2018/03/27	LNH	SIGNA INFINITY MR SYSTEM WITH EXCITE TECHNOLOGY	Display or Visual Feedback Problem; Image Orientation Incorrect	No Consequences Or Impact To Patient	it was reported to ge healthcare that axial t1 images of a brain mri exam demonstrated a right to left image flip, resulting in incorrectly displayed anatomy. the patient had a known left side brain tumor, which made the issue detectable to theUser. no injury or misdiagnosis occurred due to this issue. an investigation has been initiated. manufacturer narrative: ge healthcare's investigation has determined that the incident occurred due to the latest on-site software version not being reinstalled after service activities were performed that required software to be reloaded. under specific conditions, this software configuration resulted in an image flip left/right. ge healthcare is initiating an action in the field as reported to the fda under correction number 2183553-06/13/18-001-c on june 13, 2018. manufacturer narrative: corrected data: ge healthcare's investigation has determined that the incident occurred due to the latest on-site software version not being reinstalled after service activities were performed that required software to be reloaded. under

Report Number	Event Date	Event Type	Manufacturer	Date Received	Product Code	Brand Name	Device Problem	Patient Problem	Event Text
									specific conditions, this software configuration resulted in an image flip left/right. ge healthcare is initiating an action in the field as reported to the fda under correction number 2183553-06/13/18-003-c on june 13, 2018. correction/removal report number: 2183553-06/13/18-003-c manufacturer narrative: patient information has been requested but not yet received. there are no additional device identification numbers. ge healthcare's investigation is ongoing. a follow up report will be submitted once the investigation has been completed. device evaluation anticipated, but not yet begun.
3002808157-2018-18062	2018/02/16	Injury	SIEMENS HEALTHCARE GMBH	2018/03/19	LNH	MAGNETOM SKYRA	Insufficient Information	Burn(s); Injury; Partial thickness (Second Degree) Burn	it was reported to siemens that anAdverse event occurred while operating the magnetom skyra system. during examination of the abdomen, med rad anesthesia equipment wasUsed for cardiac monitoring while the patient was sedated. the electrodes and ecg monitoring cables were placed directly on the patients skin without any protection. following the examination, the patient reported pain in the abdominal area and the physician observed a second degree burn to the area. at this time, it is not known what medical treatment was provided. manufacturer narrative: (b)(4). siemens is conducting a

Report Number	Event Date	Event Type	Manufacturer	Date Received	Product Code	Brand Name	Device Problem	Patient Problem	Event Text
									thorough investigation of the reported events. as this event is under investigation, a root cause has not yet been determined. a supplement report will be filed upon completion of the investigation. (b)(6).
3003768277-2018-00021	2018/01/19	Injury	PHILIPS HEALTHCARE	2018/03/14	LNH	INGENIA 1.5T	Insufficient Information	Full thickness (Third Degree) Burn	Philips received a report from a customer related to a patient heating incident on a ingenia 1.5t system. the patient sustained a third degree burn on the outside of her right upper leg. manufacturer narrative: based on the provided information and tests performed on site, there is no indication of a malfunction of the mri system or coilUsed that contributed to the injury. the provided information was insufficient to determine a clear cause for the event. factors which contributed: the thermoregulation of obese patients is known to be impaired. the risk of rf energy-related injuries is higher in patients with impaired thermoregulation. the total administered specific energy dose of 3.3 kj/kg exceeded the recommended limit of 2.0 kj/kg for patients with impaired thermoregulation. manufacturer narrative: the investigation is still ongoing on this event. when the investigation is completed a follow-up will be sent to the fda.

Report Number	Event Date	Event Type	Manufacturer	Date Received	Product Code	Brand Name	Device Problem	Patient Problem	Event Text
3003768277-2018-00018	2018/01/11	Injury	PHILIPS HEALTHCARE	2018/03/07	LNH	INGENIA 1.5T	Adverse Event Without Identified Device orUse Problem	Full thickness (Third Degree) Burn	Philips received a report from a customer related to a patient heating incident with an ingenia 1.5t mr system. a patient was scanned for an mri examination. sometime after the examination 3rd degree blisters developed on both the patient's hips and thumbs. manufacturer narrative: response to fda request mdr#3003768277-2018-00018, (b)(4) manufacturer narrative: based on the provided information there is no indication of a malfunction of the mr system or coilsUsed. the blistering is caused by skin-to-skin contact. no padding wasUsed to avoid skin-to-skin contact between the patient's hands and thighs. it was reported that the patient tucked his hands under his buttocks during the examination. as contributing factors for the observed injuries were observed: - two scans just above high sar were administered. - the patient was sweaty, which facilitates an rf loop. - the examination room temperature was higher as specified in the instructions forUse.
3002808157-2018-17848	2018/02/16	Injury	SIEMENS HEALTHCARE GMBH	2018/03/06	LNH	MAGNETOM PRISMA FIT	Insufficient Information	Laceration(s); Injury; Suture Abrasion	it was reported to siemens that anAdverse event occurred while operating the magnetom prisma fit system. while setting up for an experiment, a high intensity focused ultrasound matching box was placed on the exam room floor. when a student was picking up the device to

Report Number	Event Date	Event Type	Manufacturer	Date Received	Product Code	Brand Name	Device Problem	Patient Problem	Event Text
									place it on a cart, the device was brought too close to the magnet. the hifu matching box was drawn to the front of the mr system resulting in an injury to the students hand. the severity of the injury is not known, however, it was reported the student received a cut on the lower thumb joint which required stitches and a bruised finger. additional details have been requested from the site and have not yet been provided. there was no patient involved in this event and we are unaware of any other impact to the state of health of any persons involved. manufacturer narrative: (b)(4). siemens is conducting a thorough investigation of the reported events. as this event is under investigation, a root cause has not yet been determined. a supplement report will be filed upon completion of the investigation.
7295652	2015/06/16	Malfunction	SIEMENS MEDICAL SOLUTIONS USA, INC.	2018/02/26	LNH	MAGNETOM AERA	Improper or Incorrect Procedure or Method	Radiation Exposure, Unintended	pediatric patient arrived for scheduled mri, patient was sedated by anesthesia, placed on imaging table supine feet first into scanner. patient's legs were not long enough for only one knee to be in theAppropriate position in the coil. both knees fit in the knee coil so the knee coil wasUsed instead of the flex coil. exam was started, scanning technologist requested confirmation of patient position with fellow technologist. fellow technologist

Report Number	Event Date	Event Type	Manufacturer	Date Received	Product Code	Brand Name	Device Problem	Patient Problem	Event Text
									asked scanning technologist if patient position was registered feet first and supine, and to confirm the correct knee. she confirmed position registration and left knee. after the scan, it was brought to the imaging technologist's attention that the incorrect knee was imaged. upon learning this they realized that the patient had been registered in the scanner as head first supine not feet first supine. this flips the left and right sides on the monitor. subsequently the patient had to return for a second scan with anesthesia. manufacturer response for siemens mri aera 1.5 tesla, aera (per site reporter). the event was informally communicated to the manufacturer during a conference call about a similar event; manufacturer requested we formally submit the information about this event.
2183553-2018-00003	2017/12/21	Injury	GE MEDICAL SYSTEMS, LLC	2018/02/20	LNH	GE 1.5T SIGNA HDX MR SYSTEM	Use of Device Problem; Insufficient Information	Burn(s); Necrosis; Full thickness (Third Degree) Burn	it was reported that a patient sustained a burn to the right elbow during her mr examination of the left shoulder. the patient was padded to prevent contact with the magnet bore, however the technologist indicated that when she removed the patient from the bore, she could see that the pad had shifted during the exam allowing the patient's elbow to be in contact with the bore. the burn was described as a 4 cm full

Report Number	Event Date	Event Type	Manufacturer	Date Received	Product Code	Brand Name	Device Problem	Patient Problem	Event Text
									thickness burn to the right elbow. the patient was examined by the radiology nurse in the department and then sent to the emergency department where she was given silvadene cream for the burn and referred to wound care. during treatment by wound care, tissue in the area of the burn became necrotic and the patient will now be scheduled for debridement of the wound. manufacturer narrative: ge healthcare's investigation has been completed. the mr scanner was operating within specifications and determined to be operating normally when checked by the ge healthcare field engineer. the root cause of the injury was determined to be inadequate patient padding for the mri procedure. the operator documentation describes theAppropriate safety measures for padding patients for the mr exams. the mr operator has the final responsibility for theUse and placement of non-conductive mr compatible padding, and preparation of the patient, prior to starting the mr exam procedure. manufacturer narrative: there are no additional device identification numbers. ge healthcare's investigation is ongoing. a follow up report will be submitted once the investigation has been

Report Number	Event Date	Event Type	Manufacturer	Date Received	Product Code	Brand Name	Device Problem	Patient Problem	Event Text
									completed. device evaluation anticipated, but not yet begun.
3010949642-2018-00001	2018/01/22	Malfunction	GE HEALTHCARE (TIANJIN) COMPANY LIMITED	2018/02/20	LNH	SIGNA EXPLORER	Fire; Device Emits Odor; Overheating of Device	No Consequences Or Impact To Patient; No Patient Involvement	it was reported that after a patient was removed from the mr suite following a scan, the technologist noticed a burning smell in the scan room. a ge field service engineer (fse) was on site and investigated. the power to the scanner was removed. flames were noticed in the back of the room and put out with a non-magnetic fire extinguisher. no patient or healthcare person was involved and no injury occurred. manufacturer narrative: ge healthcare's internal investigation concluded the most probable cause of the event was a high voltage cable, damaged during installation, exposing bare conductors. located under the floor in a trough of cabling, it is speculated these conductors arced during normalUse while also being immersed in an atypical leaking conductive fluid. this event has been shown to be an isolated incident. no systemic failure was identified. the mr system has been repaired, tested, and turned back over to the customer. manufacturer narrative: there was no patient involvement. (b)(4). there are no additional device identification numbers. ge healthcare's investigation is ongoing. a follow up report will be submitted once the investigation has been

Report Number	Event Date	Event Type	Manufacturer	Date Received	Product Code	Brand Name	Device Problem	Patient Problem	Event Text
									completed. device evaluation anticipated, but not yet begun.
2183553-2018-00001	2018/01/14	Injury	GE MEDICAL SYSTEMS, LLC	2018/02/19	LNH	3.0T SIGNA HDXT SIGNA VIBRANT	Improper or Incorrect Procedure or Method; Compatibility Problem;Adverse Event Without Identified Device orUse Problem	Laceration(s); Suture Abrasion	it was reported that an mr technologist brought a patient into the room on a ferrous wheelchair. while the patient was seated on the wheelchair, it became attracted to the magnet. the patient's face contacted the side of the magnet causing a laceration of the lip. the patient was removed from the magnet room and evaluated at a local hospital. after evaluation, the patient was treated with stitches in the lip. the ge field engineer was able to safely remove the wheelchair from the magnet. manufacturer narrative: ge healthcare performed an investigation. the incident occurred due to lack of controlled access by the mr technologist. the mr operator manual states it is vital to have supervised and controlled access within the mr environment to keep it safe from ferromagnetic objects. the technologist was magnet safety trained, security zone signs were posted and the site has a copy of the mr safety manual. the fe was able to safely remove the wheelchair from the magnet. no further actions are planned at this time. manufacturer narrative: ge healthcare's investigation is ongoing. a follow up report will be submitted once the investigation has been completed.

Report Number	Event Date	Event Type	Manufacturer	Date Received	Product Code	Brand Name	Device Problem	Patient Problem	Event Text
3003768277-2018-00009	2018/01/05	Injury	PHILIPS HEALTHCARE	2018/02/06	LNH	INGENIA 1.5T	Adverse Event Without Identified Device orUse Problem	Fall; Bone Fracture(s); Head Injury	Philips received a report from a customer related to a patient who fell off the patient support. the patient broke two ribs, a bone in his wrist and had a fracture in his head. manufacturer narrative: no malfunction of the mr system was reported. a patient, with alzheimer's disease, suddenly crawled out of the bore during a head examination, lost his balance and fell off the patient support.
MW5074431	2017/12/19	NA	GE	2018/01/04	LNH	1.5T GE SIGNA EXCITE MRI	Signal Artifact/Noise	Foreign Body In Patient	pt arrived for mri lumbar, filled out screening form and was verbally screened by technologist. pt was changed into a gown. during localizer a large artifact was seen by technologist. technologist had mrso review images and was instructed to check pt's underwear and gown for any metallic objects. no metallic objects found. pt was removed from scanner and given new gown to put on and removed underwear. pt was also questioned again about any injury with metal to that region or surgery which pt denied. attempted localizer again, but still same artifact. mrso contacted radiologist who agreed pt should not undergo study until confirmed what was causing artifact. contacted ordering physician to have pt cleared by x-ray pelvis. xray pelvis completed same day and revealed multiple screws in bowel that had been ingested. per

Report Number	Event Date	Event Type	Manufacturer	Date Received	Product Code	Brand Name	Device Problem	Patient Problem	Event Text
									radiologist unsafe to scan until confirmed screws have passed.
3003768277-2018-00001	2017/12/07	Injury	PHILIPS HEALTHCARE	2018/01/01	LNH	INGENIA 1.5T	Insufficient Information	Radiation Burn	Philips received a report from a customer stating that a patient sustained a blister of 4 inches along the left upper arm after being scanned with the knee coil. manufacturer narrative: based on the provided information and test performed on site there is no indication of a malfunction of the mr system or coilUsed. the patient injury on the left upper arm is consistent with injuries caused by a close proximity or direct contact with the bore wall. no padding wasUsed. although the arm rests wereUsed to keep the arms close to the body, this did not prevent that the left upper arm was potentially in contact with the bore wall during the mr examination. furthermore the following factors were observed that may have contributed to the severity of the injury: the patient was sedated / anesthetized and thus unable to alert the operator. this also indicates an impaired thermo-regulation. the patient was elderly. the patient was covered by a sheet or blanket which hinder the heat dissipation. manufacturer narrative: the investigation is still ongoing on this event. when the investigation is completed a follow-up will be sent to the fda.

Report Number	Event Date	Event Type	Manufacturer	Date Received	Product Code	Brand Name	Device Problem	Patient Problem	Event Text
3002808157-2017-10156	2017/12/15	Injury	SIEMENS HEALTHCARE GMBH	2017/12/21	LNH	MAGNETOM AERA	Insufficient Information	Laceration(s); Injury	it was reported to siemens that anAdverse event occurred while operating the magnetom aera system. it was stated that when bringing a patient into the room, the customer brought in a magnetic drip stick which was attracted to the magnet. while attempting to remove the drip stick, the technician was pinned between the drip stick and the magnet. the technician suffered a laceration to the right index finger requiring 10 sutures. manufacturer narrative: (b)(4). siemens has assessed the complained event and concluded that the cause of this event was the introduction of ferromagnetic pieces into the mr examination room and therefore aUser error. due to the strong magnetic field, particular safety measures have to be adhered to in order to prevent injuries. therefore, the magnetom aera operator manual section 2 and the magnetom system owner manual section 1 provides clear instructions and warnings regarding both magnetic field hazards and training of personnel with regards to mr safety. however, the responsibility to instruct personnel and patients who have access to the mr examination room about magnetic field hazards lies with the customer. the manuals state that only equipment specified or

Report Number	Event Date	Event Type	Manufacturer	Date Received	Product Code	Brand Name	Device Problem	Patient Problem	Event Text
									recommended forUse in the controlled area (mr examination room) shall beUsed. the introduction of magnetizable objects into the magnetic field is contrary to the statements given in the operating instructions. furthermore, special warning signs are posted at the entrance of the controlled access area (magnet room). this event occurred in (b)(6).
3002808157-2017-07938	2017/11/27	Injury	SIEMENS HEALTHCARE GMBH	2017/12/20	LNH	MAGNETOM SKYRA	Insufficient Information	Injury; Partial thickness (Second Degree) Burn	it was reported to siemens that anAdverse event occurred after examination on the magnetom skyra system. after an mri spine examination, a patient suffered a 2nd degree burn and a superficial area of erythema to the skin on her right lateral pannus (4 cm x 10 cm) and right lateral proximal thigh (2 cm x 10 cm). medical treatment was administered by a dermatologist. we are unaware of any further impact to the state of health of the patient involved. manufacturer narrative: (b)(4). the system was checked by a siemens service engineer and found to be operating within specification. as this event is under investigation, a root cause has not yet been determined. a supplement report will be filed upon completion of the investigation.
2183553-2017-00027	2017/11/10	Injury	GE MEDICAL SYSTEMS, LLC	2017/11/30	LNH	GE 1.5T SIGNA	Electromagnetic Interferenc	Injury; Suture Abrasion;	it was reported that a 3rd party contractor brought a box of tools into the scan room during servicing.

Report Number	Event Date	Event Type	Manufacturer	Date Received	Product Code	Brand Name	Device Problem	Patient Problem	Event Text
						HDX MR SYSTEM	e;Adverse Event Without Identified Device orUse Problem	No Code Available	the contractor had been trained on mr safety, however did not check to see if the tools were mri safe. the box had ferrous tools which became attracted to the magnet. when this occurred, the contractor received an injury to the right hand. the right middle finger was fractured and received sutures, the index finger received a suture and the thumb sustained only a flesh wound. manufacturer narrative: the investigation by ge healthcare (gehc) has been completed. the incident occurred due to inattentive behavior of the contractor by not checking the contents of the tool box prior to taking it into the magnet room. the contractor was mr safety trained and should not have brought the box of tools into the magnet room without first checking if they were mr compatible. ferrous object warning signs were present at the site. no additional actions are required by gehc. (b)(4). manufacturer narrative: patient information could not be provided due to country privacy laws. there are no additional device identification numbers. the initial reporter is located outside the u.s., and therefore this information is not provided due to country privacy laws. ge healthcare's investigation is ongoing. a follow up report will be submitted once the investigation has

Report Number	Event Date	Event Type	Manufacturer	Date Received	Product Code	Brand Name	Device Problem	Patient Problem	Event Text
									been completed. device evaluation anticipated, but not yet begun.
3002808157-2017-03138	2017/09/29	Injury	SIEMENS HEALTHCARE GMBH	2017/11/21	LNH	MAGNETOM AERA	Insufficient Information	No Known Impact Or Consequence To Patient	it was reported to siemens that a patient was told by her urologist that she received "radiation" burns on her bladder. the patient had a routine mri of the pelvis using a body coil on the magnetom aera system. the facility where the exam occurred informed the patient that mris do not emit radiation. when the patient spoke to her urologist again, the urologist then redacted his statement that she had "radiation burns." we are unaware of any further impact to the state of health of the patient involved. manufacturer narrative: exemption number (b)(4). (b)(4) is submitting the report on behalf of siemens healthcare (b)(4) (manufacturer). the system will be checked by a siemens service engineer. siemens is conducting a thorough investigation of the reported event. as this event is under investigation, a root cause has not yet been determined. a supplement report will be filed upon completion of the investigation.
3003768277-2017-00095	2017/04/24	Injury	PHILIPS HEALTHCARE	2017/11/16	LNH	INGENIA 3.0T	Adverse Event Without Identified Device orUse Problem	Tinnitus	Philips received a report from a customer related to a patient who complained of aTinnitus after an mr examination on an ungenial 3t mr system. the patient was positioned feet first supine and was scanned for a prostate examination. manufacturer narrative: the investigation is still

Report Number	Event Date	Event Type	Manufacturer	Date Received	Product Code	Brand Name	Device Problem	Patient Problem	Event Text
									ongoing on this event. when the investigation is completed a follow-up will be sent to the fda.
3002808157-2017-02162	2016/11/04	Injury	SIEMENS HEALTHCARE GMBH	2017/11/02	LNH	MAGNETOM SKYRA	Insufficient Information	Misdiagnosis	it was reported to siemens that anAdverse event occurred following examination on the magnetom skyra system. during patient registration, the mr technologist accidentally entered "prone" rather than "supine" as the patients position. as a result, the incorrect leg was diagnosed and metastasis in the patients right leg was not discovered. the issue was detected several weeks later during a peer review of the images. a rescan of the patients correct leg was conducted and diagnosed accordingly. at this time there is no indication that a system failure or malfunction has occurred and this event is considered to be aUser error. manufacturer narrative: (b)(4). siemens is conducting a thorough investigation of the reported events. as this event is under investigation, a root cause has not yet been determined. a supplement report will be filed upon completion of the investigation.
3002808157-2017-99993	2017/10/09	Injury	SIEMENS HEALTHCARE GMBH	2017/10/25	LNH	MAGNETOM SKYRA	Insufficient Information	Burn(s); Injury; Partial thickness (Second Degree) Burn	it was reported to siemens that a sedated patient suffered anAdverse event following examination on the magnetom skyra system. following a pelvis and lumbar spine study, the patient presented with an oval area of redness, approximately 4 inches

Report Number	Event Date	Event Type	Manufacturer	Date Received	Product Code	Brand Name	Device Problem	Patient Problem	Event Text
									long and 2 inches wide, to the right forearm. cushions were placed between the patients arms and the magnet bore during examination. the patient was held overnight in the hospital for observation. the next day, the patient developed a blister in the second degree. it is not known what medical treatment was administered at this time. additionally, we are unaware of any further impact to the state of health of the patient involved. manufacturer narrative: (b)(4). siemens is conducting a thorough investigation of the reported events. as this event is under investigation, a root cause has not yet been determined. a supplement report will be filed upon completion of the investigation.
3003768277-2017-00088	2017/09/22	Injury	PHILIPS HEALTHCARE	2017/10/16	LNH	INGENIA 1.5T	Insufficient Information	Injury	Philips received a report from a customer related to a finger pinching incident with an ingenia 1.5t mr system. a patient was planned to be examined for a head examination (cerebrum). the patient had her hands clamped around the table top edges while moving the table top into the bore. during this movement the left ring finger was pinched which resulted into a torn tendon in the left hand which required medical intervention. manufacturer narrative: based on the provided information and investigation performed no malfunction of the mr device was

Report Number	Event Date	Event Type	Manufacturer	Date Received	Product Code	Brand Name	Device Problem	Patient Problem	Event Text
									observed that contributed to the injury. the patient's fingers were pinched between the tabletop and the covers of the ingenia system during horizontal movement into the bore. during movement the operator should always check the patient's hands and make sure there are no cables or extremities positioned such that they can be caught. in this case no arm supports wereUsed. with the current design and theAppropriate application of the arm supports and operator attention, thePhilipsmri scanner does not pose a significant risk to theUser or the patients.
3004977335-2017-96315	2017/09/12	Injury	SIEMENS HEALTHCARE GMBH	2017/10/12	LNH	MAGNETOM PRISMA FIT	Adverse Event Without Identified Device orUse Problem	Injury; Full thickness (Third Degree) Burn	it was reported to siemens that while being scanned on the magnetom prisma fit unit patient suffered a 3rd degree burn on his right thigh and hand area. the patient sought medical treatment. details of the medical treatment are unknown. manufacturer narrative: siemens has completed an investigation of the reported event. it was reported to siemens that while being scanned on the magnetom prisma fit unit, a patient suffered a 2nd degree burn on his right thigh and hand area. the patient sought medical treatment, however, details of the medical treatment are unknown. our experts analyzed the images generated during the patients' examination. the complete examination of the

Report Number	Event Date	Event Type	Manufacturer	Date Received	Product Code	Brand Name	Device Problem	Patient Problem	Event Text
									patient's lumbar spine lasted 41.4 min with an active scanning time of 35 min. no abnormality was found which would indicate a system malfunction. with the fourth measurement the first level (fl) operating mode wasUsed. the sar values were within the limits defined by the mr safety standard (iec (b)(4)), i.e. the maximum applied sar was 54% of the first level mode limit. the applied rf in this case should not represent a risk under normal circumstances and scan conditions. furthermore, the patient absorbed 60.1 wmin/kg which is clearly below the limit of 240 wmin/kg defined in the mr safety standard (iec (b)(4)) but is a comparatively high energy dose in relation to the clinicalUse. the system was checked by the cse and found to be operating within specification. no hardware or software problem was found which would explain the reported burns of the patient. the location of the second degree burn on the patient's right thigh and hand area is a typical indication of an rf current loop (skin to skin contact between hand and thigh) as described in the magnetom family operator manual - mr system syngo mr e11 (pages 20-21). it is recommended to always follow the instructions given in the operator manual, regarding correct patient

Report Number	Event Date	Event Type	Manufacturer	Date Received	Product Code	Brand Name	Device Problem	Patient Problem	Event Text
									positioning in order to avoid such incidents in the future. manufacturer narrative: (b)(4). the system was checked by a siemens service engineer and the unit was found to be within specifications. siemens is conducting a thorough investigation of the reported event. a supplemental report will submitted if additional information becomes available. this report was submitted october 12, 2017.
3003768277-2017-00082	2017/09/06	Injury	PHILIPS HEALTHCARE	2017/10/05	LNH	INGENIA 1.5T	Adverse Event Without Identified Device orUse Problem	Partial thickness (Second Degree) Burn; Full thickness (Third Degree) Burn	Philips received a report from a customer related to a patient heating incident with an ingenia 1.5t mr system. a patient was scanned for a mri examination of the foot. after the examination second to third degree injuries were observed on the patient calf and heel. manufacturer narrative: based on the provided information and test performed on site there is no indication of a malfunction of the mr system or coilUsed. no definite cause for the injuries on the patients calf and heel could be determined. the following contributing factors for the injuries were observed: the patient was anesthetized. the thermoregulation of anesthetized patients is impacted. the patient was covered by a sheet or blanket made by a synthetic fiber. synthetic fiber is often hindering the heat dissipation as it traps body heat. the plastic and the sandbags may have hindered the

Report Number	Event Date	Event Type	Manufacturer	Date Received	Product Code	Brand Name	Device Problem	Patient Problem	Event Text
									heat dissipation. the patient was dressed in his own clothing which was dry and made of unknown material (underwear and socks). e.g. anti-bacterial socks which often contain silver nano fibers. such socks are not safe toUse in an mri system (material of the socks could not be confirmed) . manufacturer narrative: the investigation is still ongoing on this event. when the investigation is completed a follow-up will be sent to the fda.
2183553-2017-00022	2011/06/13	Injury	GE MEDICAL SYSTEMS, LLC	2017/10/03	LNH	GE 3.0T SIGNA HDX MR SYSTEM	Adverse Event Without Identified Device orUse Problem; Insufficient Information	Hearing Loss	it was reported in a legal document that a patient sustained permanent hearing loss in both ears following a mr procedure. the patient claims to have undergone surgery and other treatment to mitigate the effects of the hearing loss. the patient was provided hearing protection for the mr procedure. manufacturer narrative: ge healthcare¿s (gehc) investigation has been completed. the 3.0t hdxt system limits acoustic noise when hearing protection isUsed. the system operator is responsible for providing the hearing protection. the patient was provided hearing protection for this mr procedure. based on a review of service and complaint records, it was concluded that there¿s no evidence of system malfunction that can lead to high acoustic noise. mr products are designed and released for sale in

Report Number	Event Date	Event Type	Manufacturer	Date Received	Product Code	Brand Name	Device Problem	Patient Problem	Event Text
									compliance with iec acoustic requirements. gehc¿s responsibility is to meet the iec standard while the customer needs toUse the product in a safe and clinically acceptable manner. no systemic issue was found. no corrections are required as the system was operating within specification. manufacturer narrative: there are no additional device identification numbers. no additional reporter information is known; information received via a legal document. ge healthcare's investigation is ongoing. a follow up report will be submitted once the investigation has been completed. device evaluation anticipated, but not yet begun.
2183553-2017-00020	2017/08/26	Injury	GE MEDICAL SYSTEMS, LLC	2017/09/15	LNH	1.5T SIGNA HDXT	Device Operates Differently Than Expected;Adverse Event Without Identified Device orUse Problem	Hemorrhage/Bleeding; Laceration(s); Injury	it was reported that while lowering the table, a patient who had just completed a lumbar spine mri exam, grazed their head on the cradle hook. due to the amount of bleeding from the scalp injury, the patient was sent to urgent care where a staple was placed to stop the bleeding. manufacturer narrative: ge healthcare¿s (gehc) investigation has been completed. the root cause of the injury wasUser error. the mr technologist failed to recognize and remove accessory pads that became wedged within an opening underneath the table, thereby blocking the table sensor. this

Report Number	Event Date	Event Type	Manufacturer	Date Received	Product Code	Brand Name	Device Problem	Patient Problem	Event Text
									resulted in the lpca not retracting properly, exposing the lpca hook. in addition, the ctl coil, which was intact and working, was positioned improperly as it was too close to the lpca and not secured to the table. the gehc field engineer instructed the customer to not store the pads under the table and about the proper placement of the ctl coil on the table. the system was checked for cradle movement and table operation and found to have been operating normally. manufacturer narrative: there are no additional device identification numbers. ge healthcare's investigation is ongoing. a follow up report will be submitted once the investigation has been completed. device evaluation anticipated, but not yet begun.
1219930-2017-07097	2017/08/17	Malfunction	COVIDIEN LP LLC NORTH HAVEN	2017/09/15	GDW	SIGNA	Device Displays Incorrect Message; Difficult to Open or Close	No Known Impact Or Consequence To Patient	according to the reporter: for the third firing for gastrointestinal stromal tumor resection in a laparoscopic partial gastrectomy procedure, they checked the jaws opening/closing, however the green buttons of handle were not illuminated. they tried to re-check the jaws opening/closing, however could not open the jaws. then removed the cartridge from adapter with the manual adapter tool. replaced by an ultra handle, the procedure was completed. after the surgery, they tried the powered

Report Number	Event Date	Event Type	Manufacturer	Date Received	Product Code	Brand Name	Device Problem	Patient Problem	Event Text
									approach, however the display screen showed power handle error indicator. then removed the handle from shell, and inserted handle to charger, however the display screen showed power handle error indicator again. the event occurred inUse for patient. the procedure was completed with another device. the status of the patient: no problem. manufacturer narrative: this event has been reassessed and found to be a non-mdr reportable complaint. if information is provided in the future, a supplemental report will be issued.
1219930-2017-07060	2017/08/02	Injury	COVIDIEN LP LLC NORTH HAVEN	2017/09/14	GDW	SIGNA	Entrapment of Device; Difficult to Open or Close; Human-Device Interface Problem	Tissue Damage; No Code Available	according to the reporter, during a left upper lobectomy procedure, first stapler fired correctly several times and was reloaded several times. it later locked on lung tissue and would not open. a second stapler wasUsed to free the first stapler. it fired in tissue and was able to open, however the scrub could not open the jaws to reload so a third stapler was opened. surgical intervention was required to cut around the stuck reload to be able to remove from the lung tissue. there was tissue loss and tissue damage. manufacturer narrative: evaluation summary: post market vigilance (pmv) led an evaluation of the device. visual inspection found that the reload was received engaged with the i instrument. visual evaluation of the reload noted that it

Report Number	Event Date	Event Type	Manufacturer	Date Received	Product Code	Brand Name	Device Problem	Patient Problem	Event Text
									was fully fired with the jaws clamped. flush staple pushers relative to the staple cartridge were observed on the cartridge surface. further evaluation also noted the knife bar laminates within the reload were bent. this variation does not interfere with normal function when applied according to the instructions forUse.Use on over indicated tissue thickness resulted in damage to the knife bar assembly. the laminate variation was considered to be a secondary condition. records from each manufacturing lot are thoroughly reviewed to ensure that products are released meeting all quality release specifications at the time of manufacture. replication of the flush pushers may occur under the following conditions. application over tissue that is beyond the recommended thickness range. application with an obstacle incorporated in the jaws. in any of these circumstances, it will become increasingly difficult to actuate the firing handle and the instrument return knobs will be difficult to retract. in addition, staples may not form properly and tissue may not be fully transected. should new information become available, the file will be re-opened and the investigation summary amended asAppropriate . . if information is

Report Number	Event Date	Event Type	Manufacturer	Date Received	Product Code	Brand Name	Device Problem	Patient Problem	Event Text
									provided in the future, a supplemental report will be issued. manufacturer narrative: a good faith effort will be made to obtain the applicable information relevant to the report. if information is provided in the future, a supplemental report will be issued.
2183553-2017-00019	2017/08/01	Injury	GE MEDICAL SYSTEMS, LLC	2017/09/14	LNH	1.5T SIGNA HDXT	Device Slipped;Use of Device Problem;Adverse Event Without Identified Device orUse Problem	Tinnitus	it was reported that following a mr exam of the pelvis, the patient experienced symptoms ofTinnitus. the patient stated that they were evaluated by a physician and diagnosed withTinnitus. the patient underwent five days of steroid treatments. however, the treatment did not improve or resolve the condition. the customer stated that ear plugs were provided, but that they had partially slid out of the patient's ears during the exam. manufacturer narrative: ge healthcare¿s investigation has been completed. the 1.5t hdxt system limits acoustic noise when hearing protection isUsed. the system operator is responsible for providing the hearing protection and proper usage guidance. in this case, hearing protection was provided but partially slid out of the patient's ears during the exam. the system acoustic testing concluded that the scanner meets iec & osha levels and is within the specification for this system configuration. no systemic issue was

Report Number	Event Date	Event Type	Manufacturer	Date Received	Product Code	Brand Name	Device Problem	Patient Problem	Event Text
									found. no corrections are required as the system was operating within specification. the root cause of the injury appears to be inadequate hearing protection. manufacturer narrative: patient information could not be provided due to country privacy laws. there are no additional device identification numbers. (b)(6). ge healthcare's investigation is ongoing. a follow up report will be submitted once the investigation has been completed. device evaluation anticipated, but not yet begun.
MW5072156	2017/09/11	Injury	GE	2017/09/14	LNH	GE	Adverse Event Without Identified Device orUse Problem	Burning Sensation; Partial thickness (Second Degree) Burn	pt was scanned for a wrist mri post arthrogram. pt was positioned in the superman position with contralateral arm not touching the arm that was being scanned. pt had a pad between head and arm. during the exam the pt moved the contralateral hand under the elbow region of the affected side. this caused contact and a loop. scanning technologist was not aware of this. pt stated that he felt heat/burning sensation during the last sequence of exam and had a reddened area on knuckles and elbow. pt left and about 20 min later called and reported blistering where it was red. pt came back to the clinic and was evaluated by a radiologist and also sent to an urgent care for treatment.

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3002808157-2017-94154	2017/08/20	Injury	SIEMENS HEALTHCARE GMBH, MR QT	2017/09/11	LNH	MAGNETOM SKYRA	No ApparentAdverse Event	Laceration(s); Injury	it was reported to siemens that a hospital worker was injured when accessing the exam room of the magnetom skyra. the worker brought an aluminium ladder into the scan room, not knowing that there were also ferromagnetic joints, resulting in the ladder being drawn towards the magnet. the worker became trapped between the ladder and the magnet, but was able to free himself without the magnet being ramped down. the employee suffered a small laceration over the right eye which required stitches and an undisclosed injury to the left arm that did not require treatment. no further information regarding follow up medical treatment was provided. manufacturer narrative: (b)(4). siemens conducted an investigation into the reported event and concluded that the cause of the event was the introduction of ferromagnetic pieces into the mr examination room and aUser error. due to the strong magnetic field, particular safety measures have to be adhered to in order to prevent injuries. therefore, the magnetom skyra system operator manual section 2 and the magnetom system owner manual section 1 provide clear instructions and warnings regarding both magnetic field hazards and training of personnel with regards to

Report Number	Event Date	Event Type	Manufacturer	Date Received	Product Code	Brand Name	Device Problem	Patient Problem	Event Text
									mr safety. the responsibility to instruct personnel and patients who have access to the mr examination room about magnetic field hazards lies with the customer. the manuals state that only equipment specified or recommended forUse in the controlled area (mr examination room) shall beUsed. the introduction of magnetic objects into the magnetic field is contrary to the statements given in the operating instructions. furthermore special warning signs are posted at the entrance of the controlled access area (magnet room). this event occurred in (b)(6).
3003768277-2017-00075	2017/08/02	Injury	PHILIPS HEALTHCARE	2017/08/23	LNH	INGENIA 3.0T	Mechanical Problem	Bruise/Contusion; Laceration(s)	Philips received a report that a service engineer from the hospital got injured during a service action. the shim filter was attracted to the magnet when the service engineer tried to remove it from the examination room. the engineer sustained a severe cut on one of his fingers, that required stitches, a cut in his thumb and bruising on his stomach. manufacturer narrative: the injuries sustained by the engineer were caused due to the service instructions not being followed. it is mentioned in the service documentation of the high order shimming (hos) that the shim filter is magnetic and the part contains a warning sticker as well.

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2183553-2017-00017	2017/07/24	Injury	GE MEDICAL SYSTEMS, LLC	2017/08/22	LNH	GE 1.5T SIGNA HDX MR SYSTEM	Use of Device Problem;Adverse Event Without Identified Device orUse Problem	Burn(s); Unspecified Infection; Superficial (First Degree) Burn; Partial thickness (Second Degree) Burn; Full thickness (Third Degree) Burn	it was reported that an inpatient underwent an mr of the lumbar spine with sedation. the patient complained to the staff of feeling warm during the exam, but did not complain of any burning sensation. following the scan, the patient's nurse discovered two burns on the patient, a first degree burn near the clavicle area and a 2nd-3rd degree burn on the anterior ribs. the burns occurred at the locations where ecg patches were attached to the patient's skin and were the approximate size of the ecg patches. the ecg patches were not attached to any wires for monitoring. the patient has been undergoing daily dressing changes as an outpatient for the 2nd-3rd degree burn. during the following week, the burn appeared to become infected and additional wound care was recommended. manufacturer narrative: ge healthcare¿s investigation has been completed. the system was operating normally and within performance specifications. based on the information supplied, the root cause of this incident appears to be inadequate patient screening due to the ecg electrode being left on the patient when moved from an inpatient ward to the mri scanner. manufacturer narrative: there are no additional device identification

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									numbers. ge healthcare's investigation is ongoing. a follow up report will be submitted once the investigation has been completed. device evaluation anticipated, but not yet begun.
2183553-2017-00015	2017/06/26	Injury	GE MEDICAL SYSTEMS, LLC	2017/08/11	LNH	1.5T SIGNA HDXT	Adverse Event Without Identified Device orUse Problem	Hearing Loss	it was reported that a patient underwent an mr of the spine on (b)(6) 2017. the patient later contacted the mr department on (b)(6) 2017 and informed them that they visited a laryngologist because of hearing impairment in the left ear. the patient said that their hearing was improved but still not the same as prior to the mr exam. the patient has not presented or sent any confirmation of hearing loss that has been diagnosed by a physician. the patient did not provide information on whether any treatment was received. the customer confirmed that hearing protection had been utilized during the exam. manufacturer narrative: ge healthcare¿s investigation has been completed. the 1.5t hdxt system limits acoustic noise when hearing protection isUsed. the system operator is responsible for providing the hearing protection and in this case, hearing protection was provided. the system acoustic testing concluded that the scanner meets iec & osha levels and is within the specification for this system

Report Number	Event Date	Event Type	Manufacturer	Date Received	Product Code	Brand Name	Device Problem	Patient Problem	Event Text
									configuration. no systemic issue was found. no corrections are required as the system was operating within specification. manufacturer narrative: patient information could not be provided due to country privacy laws. there are no additional device identification numbers. the initial reporter is located outside the u.s., and therefore this information is not provided due to country privacy laws. ge healthcare's investigation is ongoing. a follow up report will be submitted once the investigation has been completed. device evaluation anticipated, but not yet begun.
6770337	2017/07/08	Malfunction	PHILIPS MEDICAL SYSTEM	2017/08/07	LNH	INGENIA 1.5T	Adverse Event Without Identified Device orUse Problem	Burn, Thermal	during mri exam of thigh and leg, patient received a suspected thermal burn to right thigh. ice packs were placed with improvement. later felt warm again and exam was terminated. upon inspection the patient had a few spots to the inner thigh that was red and splotchy.
MW5071394	2017/07/07	Injury	GE HEALTHCARE	2017/08/03	MOS	GE SIGNA HD XT	Adverse Event Without Identified Device orUse Problem	Partial thickness (Second Degree) Burn	mri of the right shoulder. patient returned to the facility the following day with second degree burns to the anterior and posterior aspect of the right shoulder. the patient was imaged with a patient gown and no direct contact with the shoulder coil occurred. patient was seen in the er and released with no further issues.
2183553-2017-00014	2017/05/26	Injury	GE MEDICAL SYSTEMS, LLC	2017/07/25	LNH	SIGNA INFINITY MR	Use of Device Problem;Im	Burn(s); Full thickness	while a ge field engineer was on site for servicing, the customer reported that a patient undergoing a mri of the

Report Number	Event Date	Event Type	Manufacturer	Date Received	Product Code	Brand Name	Device Problem	Patient Problem	Event Text
						SYSTEM WITH EXCITE TECHNOLOGY	proper or Incorrect Procedure or Method	(Third Degree) Burn	right pelvis/hip sustained a third degree burn to the right forearm. the patient was positioned for the exam with their arms at their sides. no padding was utilized to prevent skin contact to the sides of the magnet bore or to prevent skin to skin contact. initially, the customer determined the patient's burn to be superficial and pink in color, which then progressed to a third degree burn. the patient was treated surgically with debridement of a third degree burn of the right forearm to vital tissue. manufacturer narrative: ge healthcare¿s investigation has been completed. the mr scanner was operating within specifications and all patient and system safety related subsystems were determined to be operating normally when checked by the ge healthcare field engineer. the root cause of the injury was determined to be inadequate patient padding for the mri procedure. the operator documentation describes theAppropriate safety measures for padding patients for mr exams. the mr operator has the final responsibility for theUse and placement of non-conductive mr compatible padding, and preparation of the patient, prior to starting the mr exam process. manufacturer narrative: ge healthcare's investigation is ongoing. a follow up

Report Number	Event Date	Event Type	Manufacturer	Date Received	Product Code	Brand Name	Device Problem	Patient Problem	Event Text
									report will be submitted once the investigation has been completed. device evaluation anticipated, but not yet begun.
3003768277-2017-00066	2017/05/24	Injury	PHILIPS HEALTHCARE	2017/07/24	LNH	ACHIEVA XR 1.5T/3.0 T	Adverse Event Without Identified Device orUse Problem	Partial thickness (Second Degree) Burn	Philips received a report from a customer. a patient was examined on an ingenia 3.0t mr system using the torso xl coil. a day after the examination, the patient went to the family doctor, which reported a large blister to the hospital. manufacturer narrative: based on the provided information and tests performed on site, there is no indication of a malfunction of the mri system or coilUsed that contributed to the injury. as the provided information was insufficient to determine the cause of the injury, further information was requested. regretfully, after several requests no further information was provided. the heating sensation the patient experienced can be explained by the combination of administered whole body specific energy dose and administered high sar scans. furthermore, it was stated that the examination room temperature was 27 degrees celsius, which can contribute to the event. manufacturer narrative: the investigation is still ongoing on this event. when the investigation is completed a follow up report will be sent to the fda.

Report Number	Event Date	Event Type	Manufacturer	Date Received	Product Code	Brand Name	Device Problem	Patient Problem	Event Text
2183553-2017-00012	2017/06/13	Malfunction	GE MEDICAL SYSTEMS, LLC	2017/07/13	LNH	SIGNA 3.0T MR750 SYSTEM	Fire; Overheating of Device; Smoking; Arcing	No Consequences Or Impact To Patient; No Known Impact Or Consequence To Patient	it was reported that while scanning a patient, the mr scanner stopped. the technologist went into the mr scan room and smelled and noticed smoke. the patient was removed from the room. the technologist then noticed an orange glow coming from a gap between the doors of the magnet room closet. it was determined that the gradient cables were arcing in the closet causing a small flame. the fire alarm was pulled. the technologist put out the flame with an extinguisher before the fire department arrived. no injuries were reported. the ge field engineer replaced all gradient cables and the filter panel assembly. the system passed all gradient diagnostic tests, system performance tests and test scans. the system was turned back over to the customer forUse. received sus voluntary event report #mw5070499. manufacturer narrative: the investigation by ge healthcare has been completed. based upon the analysis, installation workmanship is the singular root cause of this incident. the lack of proper mechanical retention due toImproper crimping, coupled with a reduced cross-sectional area caused by cut strands, prevented a hermetic seal from being formed. the resistivity of the cable connections continued to increase over 5 years to

Report Number	Event Date	Event Type	Manufacturer	Date Received	Product Code	Brand Name	Device Problem	Patient Problem	Event Text
									the point where enough voltage potential was created to allow an electrical arc to form. the small flame that occurred at the gradient filter box was contained to only the plastic safety cover and damage was isolated to the enclosed area of the penetration panel. toxicology of the burnt acrylic plastic electrical safety cover and fire-retardant pvc gradient cable insulation material indicate that no toxic chemicals were released during the time of combustion. this incident has been assessed as a minor hazard. if this event were to recur, it is not likely to lead to a serious injury. manufacturer narrative: there is no additional patient information. there are no additional device identification numbers. ge healthcare's investigation is ongoing. a follow up report will be submitted once the investigation has been completed. device evaluation anticipated, but not yet begun.
3002808157-2017-85502	2017/06/23	Injury	SIEMENS HEALTHCARE GMBH	2017/06/30	LNH	MAGNETOM SKYRA	Adverse Event Without Identified Device orUse Problem	Patient Problem/Medical Problem	it was reported that during an mri scan on the magnetom skyra system the patient coded. the patient had to be defibrillated on the scanner bed. the cause of the patient's cardiac arrest is unknown. manufacturer narrative: exemption number (b)(4) is submitting the report on behalf of siemens (b)(4) (manufacturer). additional information about the

Report Number	Event Date	Event Type	Manufacturer	Date Received	Product Code	Brand Name	Device Problem	Patient Problem	Event Text
									patient health status was requested, however, it has not yet been provided. the system was checked by siemens local service and found to be within specifications. this report was submitted (b)(6) 2017.
3002808157-2017-82924	2017/06/01	Injury	SIEMENS HEALTHCARE GMBH	2017/06/28	LNH	MAGNETOM AERA	Adverse Event Without Identified Device orUse Problem	Patient Problem/Medical Problem	it was reported that a patient did not receive ear plugs at the beginning of the exam on the magnetom aera system. the patient squeezed the ball after 2-3 sequences and the tech went in to give the patient ear plugs. the customer provided information that the patient claimed to haveTinnitus due to this incident. manufacturer narrative: siemens has completed an investigation of the reported event. additional information for investigation was requested, however, not supplied. there is no additional information available regarding the severity of the injury or if medical treatment was necessary. the patient did not receive ear plugs at the beginning of the examination. the patient interrupted the examination by using the squeeze ball after 2 or 3 sequences and was then provided ear plugs. generally, the magnetom aera can produce acoustic noise levels higher than 99db(a) this is the maximum noise level at the patient's ear defined in the mr safety standard iec 60601-2-33. for safety reasons,Appropriate hearing

Report Number	Event Date	Event Type	Manufacturer	Date Received	Product Code	Brand Name	Device Problem	Patient Problem	Event Text
									protection needs to be provided to the patient. the magnetom operator manual and the magnetom system owner manual provide instructions and warnings regarding noise levels and the respective hearing protection required (section "hearing protection data"). the headphones provided by siemens mr are not classified as hearing protectors. their primaryUse is to provide a channel of communication between the mr operator and the patient. the headphones may beUsed to provide additional noise attenuation for increased patient comfort. suitable hearing protectors are ear plugs with a noise attenuation coefficient equal or greater than the required hearing protection. the required level of hearing protection can be found in the system owner manual of each mr system. it is recommended to always follow the safety warnings and instructions in the system owner manual and the operator manual. manufacturer narrative: (b)(4). the customer was informed that according to the safety manual hearing protection is required and it should lower noise to at least 99 db.
3002808157-2017-83941	2017/06/06	Injury	SIEMENS HEALTHCARE GMBH	2017/06/19	LNH	MAGNETOM AERA	Insufficient Information	Injury; Partial thickness (Second	it was reported to siemens that a patient suffered an injury during examination on the magnetom aera system. the patient suffered a second degree burn on the right buttock as

Report Number	Event Date	Event Type	Manufacturer	Date Received	Product Code	Brand Name	Device Problem	Patient Problem	Event Text
								Degree) Burn	well as the right thumb during a lumbar examination. a blister was observed, approximately 3 cm in diameter, and a topical cream was applied. we are unaware of any further impact to the state of health of the patient involved. manufacturer narrative: (b)(4). the system was checked by a siemens service engineer and found to be operating within specification. siemens is conducting a thorough investigation of the reported events. as this event is under investigation, a root cause has not yet been determined. a supplement report will be filed upon completion of the investigation.
2183553-2017-00011	2017/05/22	Injury	GE MEDICAL SYSTEMS, LLC	2017/06/16	LNH	GE 3.0T SIGNA INFINITY TWINSPEED WITH EXCITE MR SYSTEM	Electromagnetic Interference;Adverse Event Without Identified Device orUse Problem	Bone Fracture(s); Injury	it was reported that a patient from the emergency room (er) was brought to the mr department for an mri of the cervical, thoracic and lumbar spine. the patient was accompanied by the er nurse who also brought along a portable cart with laptop for charting. while the patient was being brought out of the scanner for medication, the er nurse moved the cart too close to the door where it became attracted to the magnet. the cart struck the technologist who experienced soreness only. the cart then went into the bore where it struck the patient below the breast and then in the chin. the patient sustained multiple cuts and three (3) broken

Report Number	Event Date	Event Type	Manufacturer	Date Received	Product Code	Brand Name	Device Problem	Patient Problem	Event Text
									ribs. manufacturer narrative: ge healthcare¿s investigation has been completed. based on the information received, the root cause of the incident appears to be lack of controlled access which allowed the ferrous cart to be brought into the scan room. the operator manual has warnings about ferromagnetic objects brought into the scan room. the operator manual with integrated safety section defines the need for the customer to keep the magnet room door closed, never to hold the door open for others. only essential people are allowed within the magnet room. the site has been corrected as the ferrous object has been removed from the magnet. manufacturer narrative: there are no additional device identification numbers. ge healthcare¿s investigation in ongoing. a follow up report will be submitted once the investigation has been completed. device evaluation anticipated, but not yet begun.
3002808157-2017-02880	2017/05/15	Injury	SIEMENS HEALTHCARE GMBH, MR QT	2017/06/12	LNH	MAGNETOM AERA	Insufficient Information	Injury; Partial thickness (Second Degree) Burn	it was reported to siemens that a patient suffered an injury following examination on the magnetom aera system. during a right knee study, the patient complained of pain in the heels before and after the examination. the patient was positioned feet first supine and the legs were not crossed. the operator

Report Number	Event Date	Event Type	Manufacturer	Date Received	Product Code	Brand Name	Device Problem	Patient Problem	Event Text
									did not observe any areas of redness on the heels following the examination. following the examination, the patients family reported second and third degree burns to the heels which required skin transplantation. no further information regarding the state of health of the patient involved was provided. manufacturer narrative: exemption number (b)(4). (b)(4) is submitting the report on behalf of siemens (b)(4), erlangen (manufacturer). the system was checked by a siemens service engineer and found to be operating within specification. no cause for the patients injury could be determined as no element was in contact with the heels. this event occurred in (b)(6).
2183553-2017-00010	2017/05/11	Injury	GE MEDICAL SYSTEMS, LLC	2017/06/08	LNH	GE 1.5T SIGNA® HDX MR SYSTEM	Use of Device Problem; Insufficient Information	Burn(s); Full thickness (Third Degree) Burn	it was reported that a patient sustained a burn, described as a full thickness burn with blister, above her right elbow. the size of the burn was not provided and to date, no treatment information. the patient was padded to prevent contact with the bore wall but the pad may have not been replaced or may have moved when the patient was re-positioned for the second exam of a double study. no pads wereUsed to prevent body loops. the system was tested and passed per ge healthcare specifications. in a sus voluntary

Report Number	Event Date	Event Type	Manufacturer	Date Received	Product Code	Brand Name	Device Problem	Patient Problem	Event Text
									event report, # mw5069793, received from the fda on 07 jun 2017, the customer stated that it is believed that the patient had a prior infection and had gotten some saline as well as possibly other medications on the sheet near her arm and this could have contributed to the burn. manufacturer narrative: ge healthcare¿s (gehc) investigation has been completed. based on the information received, this incident appears to be the result of incorrectUse of padding by the mr staff technologist. the technologist acknowledged that the patient warming was because the pad moved during the scan. the technologist should have checked the padding to ensure it was still in place for the lumbar and pelvis exams. the operator documentation describes theAppropriate safety measures for padding patients for mr exams. in cases where adequate padding is compromised or not possible due to patient size, it is the operator¿s decision to conduct the mr exam, and their responsibility to monitor and maintain communication with the patient during the entire exam process. no systemic issues were identified and the system appears to have been operating within specifications, and functioning normally. all patient and system

Report Number	Event Date	Event Type	Manufacturer	Date Received	Product Code	Brand Name	Device Problem	Patient Problem	Event Text
									safety related subsystems appear to have been operating normally when checked by the gehc field engineer. manufacturer narrative: there are no additional device identification numbers. ge healthcare's investigation is ongoing. a follow up report will be submitted once the investigation has been completed. device evaluation anticipated, but not yet begun.
3002808157-2017-03018	2017/05/20	Injury	SIEMENS HEALTHCARE GMBH, MR QT	2017/06/01	LNH	MAGNETOM AERA	Use of Device Problem; Device Handling Problem	Bone Fracture(s)	it was reported to siemens that anAdverse event occurred while operating the magnetom aera system. the system operator engaged the emergency stop button when a metal trolley was brought into the magnet room and was attracted to the magnet. the operators hand was fractured when the metal trolley was drawn to the magnet. there is no report of patient involvement. manufacturer narrative: (b)(4). siemens has completed an investigation of the reported event. the cause of this event was the introduction of ferromagnetic pieces into the mr examination room and therefore, aUser error. due to the strong magnetic field, safety measures have to be adhered to in order to prevent injuries. therefore, the magnetom aera system operator manual section 2 and the magnetom system owner manual section 1 provide clear instructions and

Report Number	Event Date	Event Type	Manufacturer	Date Received	Product Code	Brand Name	Device Problem	Patient Problem	Event Text
									warnings regarding both magnetic field hazards and training of personnel with regards to mr safety. the responsibility to instruct personnel and patients who have access to the mr examination room about magnetic field hazards lies with the customer. the manuals state that only equipment specified or recommended forUse in the controlled area (mr examination room) shall beUsed. the introduction of magnetizable objects into the magnetic field is contrary to the statements given in the operating instructions. furthermore, special warning signs are posted at the entrance of the controlled access area (magnet room). this event occurred in (b)(6): (b)(6).
3002808157-2017-02136	2017/03/24	Injury	SIEMENS HEALTHCARE GMBH	2017/05/23	LNH	MAGNETOM SKYRA	Insufficient Information	Burn(s); Injury; Partial thickness (Second Degree) Burn	it was reported to siemens that a patient suffered an injury following examination on the magnetom skyra system. a sedated patient underwent four different studies. after examination, two second degree blisters were observed on the patients abdomen, approximately 5cm and 3cm in diameter. the patient was treated with a chamomile compress and antibiotic spray by a nurse. manufacturer narrative: (b)(4). the system was checked by a siemens service engineer and found to be operating within specification. the complete examination of the

Report Number	Event Date	Event Type	Manufacturer	Date Received	Product Code	Brand Name	Device Problem	Patient Problem	Event Text
									patient's shoulder, c-spine, t- spine and hip lasted 140 min with an active scan time of 65 min. no abnormality was found which would indicate a system malfunction. the complete measurement was performed in the normal operating mode. the sar values were within the limits defined by the mr safety standard (iec 60601-2-33), i.e. the maximum applied sar was 99% of the normal mode limit. the applied rf in this case should not represent a risk under normal circumstances and scan conditions. furthermore, the patient absorbed 69.7 wmin/kg which is below the limit of 240 wmin/kg defined in the mr safety standard (iec 60601-2-33). it was determined the rf burn was caused by the presence of clips at the patient's thorax. in general, an mr examination is contraindicated for patients with electronic or electronically conductive implants or metals, especially those containing ferromagnetic foreign matter. this is explained in the magnetom aera, skyra operator manual - mr system syngo mr e11, pages 22. (b)(6).
3002808157-2017-02136	2017/03/24	Injury	SIEMENS HEALTHCARE GMBH	2017/05/23	LNH	MAGNETOM SKYRA	Insufficient Information	Burn(s); Injury; Partial thickness (Second	it was reported to siemens that a patient suffered an injury following examination on the magnetom skyra system. a sedated patient underwent four different studies. after examination, two second degree

Report Number	Event Date	Event Type	Manufacturer	Date Received	Product Code	Brand Name	Device Problem	Patient Problem	Event Text
								Degree) Burn	blisters were observed on the patients abdomen, approximately 5cm and 3cm in diameter. the patient was treated with a chamomile compress and antibiotic spray by a nurse. manufacturer narrative: (b)(4). the system was checked by a siemens service engineer and found to be operating within specification. the complete examination of the patient's shoulder, c-spine, t- spine and hip lasted 140 min with an active scan time of 65 min. no abnormality was found which would indicate a system malfunction. the complete measurement was performed in the normal operating mode. the sar values were within the limits defined by the mr safety standard (iec 60601-2-33), i.e. the maximum applied sar was 99% of the normal mode limit. the applied rf in this case should not represent a risk under normal circumstances and scan conditions. furthermore, the patient absorbed 69.7 wmin/kg which is below the limit of 240 wmin/kg defined in the mr safety standard (iec 60601-2-33). it was determined the rf burn was caused by the presence of clips at the patient's thorax. in general, an mr examination is contraindicated for patients with electronic or electronically conductive implants or metals, especially those containing

Report Number	Event Date	Event Type	Manufacturer	Date Received	Product Code	Brand Name	Device Problem	Patient Problem	Event Text
									ferromagnetic foreign matter. this is explained in the magnetom aera, skyra operator manual - mr system syngo mr e11, pages 22. (b)(6).
2183553-2017-00006	2016/01/20	Injury	GE MEDICAL SYSTEMS, LLC	2017/04/27	OUO	SIGNA PET/MR	Adverse Event Without Identified Device orUse Problem; Insufficient Information	Hearing Loss	it was initially reported that a patient, who was wearing ear plugs, complained of not being able to hear after a mri exam. the patient was sent to the site's nursing station for care, however no details were provided that the patient required or received medical treatment. the site followed up the following day and the patient said that it had improved but not fully. the customer later confirmed that the patient had mild sensorineural hearing loss at 2 khz in the right ear. baseline hearing was not known. manufacturer narrative: the investigation by ge healthcare has been completed. acoustic measurements were performed on the pet/mr system and based on the testing completed, it was concluded that the pet/mr system met the (b)(4) requirements and osha levels. the system was operating within the regulatory limits. system logs were reviewed and no unusual errors that may have indicated gradient subsystem failures or other contributing factors to potential high acoustic noise were identified. the likely primary root cause of this event is a patient medical condition that caused sensitivity to acoustic

Report Number	Event Date	Event Type	Manufacturer	Date Received	Product Code	Brand Name	Device Problem	Patient Problem	Event Text
									levels. no systemic product issue was identified. however, due to the additional engineering investigation that was performed, the customer¿s gradient coil was replaced. manufacturer narrative: there are no additional device identification numbers. tomographic imager combining emission computed tomography with nuclear magnetic resonance ge healthcare's investigation is ongoing. a follow up report will be submitted once the investigation has been completed. device evaluation anticipated, but not yet begun.
2183553-2017-00003	2017/03/05	Injury	GE MEDICAL SYSTEMS, LLC	2017/04/11	LNH	SIGNA 1.5 ECHO	Use of Device Problem;Adverse Event Without Identified Device orUse Problem	Burn(s); Erythema; Discomfort; Full thickness (Third Degree) Burn	it was reported that a patient sustained a 3rd degree burn during a mri scan of the left shoulder. the patient was positioned without padding to prevent patient contact to the magnet bore sides or to prevent body loops. the patient did not report any issues during the exam but upon exiting the system, reported a localized area of three inches of redness and discomfort, one inch above the elbow on the left upper arm. the patient was provided a cool wet towel and was discharged from the facility. the patient contacted the site two days later to report that medical attention was sought at an outside emergency room. the patient stated she sustained a 3rd degree burn. the patient has not provided

Report Number	Event Date	Event Type	Manufacturer	Date Received	Product Code	Brand Name	Device Problem	Patient Problem	Event Text
									any additional information to the customer regarding the burn injury or any details of medical treatment for the injury. manufacturer narrative: ge healthcare¿s investigation has been completed. based on the information provided, this incident appears to be the result of inattentive behavior by the mr staff technologist. the technologist was inexperienced in theUse ofAppropriate padding for shoulder exams and in this event, the patient was positioned for the shoulder exam without proper padding. the customer acknowledges properUse and recommendations for patient padding which were not adhered to in this case. no systemic issues were identified in the available information. all patient and system safety related subsystems appear to have been operating normally when checked by the ge healthcare field engineer. no additional actions are required. based on the information reviewed, the root cause of the injury appears to be an inexperienced technologist that did not allow for adequate padding for the shoulder exam. manufacturer narrative: unique identifier: udi_not_required. there are no additional device identification numbers. ge healthcare's investigation is ongoing. a follow up report will be submitted once the investigation has been completed.

Report Number	Event Date	Event Type	Manufacturer	Date Received	Product Code	Brand Name	Device Problem	Patient Problem	Event Text
									device evaluation anticipated, but not yet begun.
2240869-2017-73867	2017/03/09	Injury	SIEMENS HEALTHCARE, MAGNETIC RESONANCE	2017/04/06	LNH	MAGNETOM SKYRA	Device Operates Differently Than Expected	Partial thickness (Second Degree) Burn	it was reported to siemens that two patients suffered an injury following examination on the magnetom skyra system. a female patient suffered a second degree burn to her abdominal area. the patient was treated with first aid. it was also reported that a male patient suffered a second degree burn to his shoulder area. the patient was treated with first aid. we are unaware of any further impact to the state of health of the patients involved. manufacturer narrative: siemens has completed an investigation of the reported event. the system was checked by the cse and found to be operating within specification. siemens has analyzed the images generated during the patients' examinations (part 1 and 2). no hardware or software problem was found which would explain the reported heating sensation of the patients and no abnormalities were found which would indicate a system malfunction. part 1: the complete examination of the patient's pelvis lasted 17 min with an active scanning time of 12.7 min. the complete measurement was performed in the normal operating mode. the sar values were within the limits defined by the mr safety standard (iec 60601-2-33), i.e. the maximum

Report Number	Event Date	Event Type	Manufacturer	Date Received	Product Code	Brand Name	Device Problem	Patient Problem	Event Text
									applied sar was 99% of the normal mode limit. furthermore, the patient absorbed 24.1 wmin/kg which is clearly below the limit of 240 wmin/kg defined in the mr safety standard (iec 60601-2-33). the applied rf should not represent a risk under normal circumstances and scan conditions. the intensity of the rf burn and the fact that the patient pressed the squeeze ball several times during her examination, indicate that external circumstances caused the rf burns. it was stated that the patient did wear her own clothes during the examination. most likely the patient was wearing a non mr compatible t-shirt (inclusion of an electrically conducting yarn) during the examination. part 2: the complete examination of the right shoulder lasted 13.3 min with an active scanning time of 10.5 min. the complete measurement was performed in the normal operating mode. the sar values were within the limits defined by the mr safety standard (iec 60601-2-33), i.e. the maximum applied sar was 56% of the normal mode limit. furthermore, the patient absorbed 7.3 wmin/kg which is clearly below the limit of 240 wmin/kg defined in the mr safety standard (iec 60601-2-33). the applied rf should not represent a risk under normal circumstances and scan

Report Number	Event Date	Event Type	Manufacturer	Date Received	Product Code	Brand Name	Device Problem	Patient Problem	Event Text
									conditions. the applied rf load was relatively low which would indicate that external circumstances caused the rf burns. it was reported that the patient was also wearing their own clothing. most likely the patient was wearing non mr compatible clothing (inclusion of an electrically material) during the examination. it is requested in the magnetom aera, skyra operator manual - mr system syngo mr e11, pages 24, that the patient removes all clothing including electrically conducting material, for example, bras, metallic appliqués or woven metallic yarns. manufacturer narrative: following the reported incidents, a siemens service engineer checked the system and it was found to be operating within specifications. siemens is conducting a thorough investigation of the reported events. as these events are under investigation, a root cause has not yet been determined. a supplement report will be filed upon completion of the investigation. this event occurred in (b)(6).
2240869-2017-73867	2017/03/09	Injury	SIEMENS HEALTHCARE, MAGNETIC RESONANCE	2017/04/06	LNH	MAGNETOM SKYRA	Device Operates Differently Than Expected	Partial thickness (Second Degree) Burn	it was reported to siemens that two patients suffered an injury following examination on the magnetom skyra system. a female patient suffered a second degree burn to her abdominal area. the patient was treated with first aid. it was also reported that a male patient suffered a second

Report Number	Event Date	Event Type	Manufacturer	Date Received	Product Code	Brand Name	Device Problem	Patient Problem	Event Text
									degree burn to his shoulder area. the patient was treated with first aid. we are unaware of any further impact to the state of health of the patients involved. manufacturer narrative: siemens has completed an investigation of the reported event. the system was checked by the cse and found to be operating within specification. siemens has analyzed the images generated during the patients' examinations (part 1 and 2). no hardware or software problem was found which would explain the reported heating sensation of the patients and no abnormalities were found which would indicate a system malfunction. part 1: the complete examination of the patient's pelvis lasted 17 min with an active scanning time of 12.7 min. the complete measurement was performed in the normal operating mode. the sar values were within the limits defined by the mr safety standard (iec 60601-2-33), i.e. the maximum applied sar was 99% of the normal mode limit. furthermore, the patient absorbed 24.1 wmin/kg which is clearly below the limit of 240 wmin/kg defined in the mr safety standard (iec 60601-2-33). the applied rf should not represent a risk under normal circumstances and scan conditions. the intensity of the rf burn and the fact that the patient

Report Number	Event Date	Event Type	Manufacturer	Date Received	Product Code	Brand Name	Device Problem	Patient Problem	Event Text
									pressed the squeeze ball several times during her examination, indicate that external circumstances caused the rf burns. it was stated that the patient did wear her own clothes during the examination. most likely the patient was wearing a non mr compatible t-shirt (inclusion of an electrically conducting yarn) during the examination. part 2: the complete examination of the right shoulder lasted 13.3 min with an active scanning time of 10.5 min. the complete measurement was performed in the normal operating mode. the sar values were within the limits defined by the mr safety standard (iec 60601-2-33), i.e. the maximum applied sar was 56% of the normal mode limit. furthermore, the patient absorbed 7.3 wmin/kg which is clearly below the limit of 240 wmin/kg defined in the mr safety standard (iec 60601-2-33). the applied rf should not represent a risk under normal circumstances and scan conditions. the applied rf load was relatively low which would indicate that external circumstances caused the rf burns. it was reported that the patient was also wearing their own clothing. most likely the patient was wearing non mr compatible clothing (inclusion of an electrically material) during the examination. it is requested in the magnetom aera,

Report Number	Event Date	Event Type	Manufacturer	Date Received	Product Code	Brand Name	Device Problem	Patient Problem	Event Text
									skyra operator manual - mr system syngo mr e11, pages 24, that the patient removes all clothing including electrically conducting material, for example, bras, metallic appliqués or woven metallic yarns. manufacturer narrative: following the reported incidents, a siemens service engineer checked the system and it was found to be operating within specifications. siemens is conducting a thorough investigation of the reported events. as these events are under investigation, a root cause has not yet been determined. a supplement report will be filed upon completion of the investigation. this event occurred in (b)(6).
2240869-2017-64568	2016/10/19	Injury	SIEMENS HEALTHCARE, MAGNETIC RESONANCE	2017/02/23	LNH	MAGNETOM AERA	Insufficient Information	Burn(s); Injury	it was reported to siemens that a patient suffered an injury following an examination on the magnetom aera system. the patient underwent a scan of the elbow lasting 107.7 minutes with an active scanning time of 95 minutes. the patient was placed in the magnet bore asymmetrically in order to bring the elbow iso centre with the patients left flank in direct contact with the bore wall. immediately following the exam, a blister approximately 4 inches in diameter was noticed on the patients side. the patient was referred to a wound specialist. manufacturer narrative: the complete examination of the patients elbow lasted 107.7

Report Number	Event Date	Event Type	Manufacturer	Date Received	Product Code	Brand Name	Device Problem	Patient Problem	Event Text
									min with an active scanning time of 95 min. no abnormality was found which would indicate a system malfunction. the complete measurement was performed in the normal operating mode. the sar values were within the limits defined by the mr safety standard (iec 60601-2-33), i.e. the maximum applied sar was 99% of the normal mode limit. the applied rf in this case should not represent a risk under normal circumstances and scan conditions. furthermore, the patient absorbed 162.6 w min/kg which is below the limit of 240 w min/kg defined in the mr safety standard (iec 60601-2-33). the system was checked by a siemens service engineer and found to be within specification. no hardware or software problem was found. the contact with the bore wall in combination with the extreme long duration of the examination with notable rf intensity is the root cause for this incident. direct contact of the tissue with the bore wall can result in high-frequency current loops which are capable of causing local burns. to prevent these possible burns a warning notice is implemented in the magnetom aera operator manual - mr system syngo mr e11 page 20/21, which contains the necessary preventive measures.

Report Number	Event Date	Event Type	Manufacturer	Date Received	Product Code	Brand Name	Device Problem	Patient Problem	Event Text
3003768277-2017-00011		Malfunction	PHILIPS HEALTHCARE	2017/02/08	LNH	INGENIA 3.0T	Premature Activation; Device Operates Differently Than Expected	No Consequences Or Impact To Patient	Philips received a report from a customer related to a magnet quench with an ingenia 3.0t mr system. the magnet quench occurred when the mr system was not inUse. the helium gas was expanded within the mr examination room instead of being vented through the specially installed ventilation path. there was no one within the examination room during the quench. no persons were harmed.Philips received a report from a customer related to a magnet quench with an ingenia 3.0t mr system. the magnet quench occurred when the mr system was not inUse. the helium gas was partially expanded within the mr examination room instead of being vented completely through the specially installed ventilation path. there was no one within the examination room during the quench. no persons were harmed. manufacturer narrative: the investigation is still ongoing on this event. when the investigation is completed, a follow-up will sent to the fda. manufacturer narrative: the cause of the quench itself was determined to be spontaneous and conditions found at site are known to contribute to an increased probability of magnet quenching. the partially ruptured burst disc created a higher peak pressure in the magnet than normal which caused the helium fill

Report Number	Event Date	Event Type	Manufacturer	Date Received	Product Code	Brand Name	Device Problem	Patient Problem	Event Text
									port cap to pop out into the ceiling. this resulted that the helium leaked thru the open fill port cap and partially filled the mr examination room. based on further investigation, it was determined that the event that occurred is unlikely to result in any serious injury or death. correction: the helium gas was partially expanded within the mr examination room not completely.
2240869-2017-06196	2016/10/21	Injury	SIEMENS HEALTHCARE GMBH	2017/01/26	LNH	MAGNETOM AERA	Adverse Event Without Identified Device orUse Problem	Swelling	it was reported to siemens that a patient suffered an injury during examination on the magnetom aera system. the patient reported a blister < 30 mm in diameter on one hand and a thigh after examination. a dressing was applied by a nurse and no further medical treatment was required. manufacturer narrative: the system was checked by a siemens service engineer and found to be within specification and no hardware or software problem was found. the locations of the burn on the patient's hand and hip are typical indications of an rf current loop as described in the magnetom family operator manual - mr system syngo mr d13e (pages 16 - 17). additionally, instructions are given in the operator manual regarding correct patient positioning in order to avoid such incidents. this event occurred in brazil: (b)(6).

Report Number	Event Date	Event Type	Manufacturer	Date Received	Product Code	Brand Name	Device Problem	Patient Problem	Event Text
2183553-2017-00001	2016/11/16	Injury	GE MEDICAL SYSTEMS, LLC	2017/01/09	OUO	SIGNA PETMR	Adverse Event Without Identified Device orUse Problem	Hearing Loss; Pain	it was reported that a patient undergoing a petmr exam complained of right ear pain and hearing loss. the hearing loss was later confirmed by a physician. manufacturer narrative: the investigation by ge healthcare has been completed. the signa pet/mr system limits acoustic noise, when hearing protection isUsed. the system operator is responsible for providing the hearing protection. in this case, hearing protection was provided and placed by the patient. the system acoustic level was tested to meet local regulations. no systemic issue was found. no corrections are required as the system was operating within specification. manufacturer narrative: ge healthcare¿s investigation in ongoing. a follow up report will be submitted once the investigation has been completed. device evaluation anticipated, but not yet begun.
3003768277-2016-00123	2016/06/12	Injury	PHILIPS HEALTHCARE	2016/12/27	LNH	INGENIA 1.5T	Adverse Event Without Identified Device orUse Problem	Full thickness (Third Degree) Burn	Philips received a report from a hospital concerning a 3rd degree burn on the left hand. the patient was scanned for a pelvic examination with theUse of the anterior coil together with multiple monitoring devices. manufacturer narrative: based on the provided information and tests performed on site, there is no indication of a malfunction of the mri system or coilUsed that

Report Number	Event Date	Event Type	Manufacturer	Date Received	Product Code	Brand Name	Device Problem	Patient Problem	Event Text
									contributed to the injury. although it is stated that no objects were close to the affected area, contact between part of the peripherals to monitor the patient and the fingers is the most likely cause for the burns. the movement of the table may have altered the positioning and led to a loop. a contributing factor was that the patient was anesthetized. manufacturer narrative: the investigation is still ongoing on this event. when the investigation is completed a follow-up will sent to the fda.
2240869-2016-58567	2016/09/07	Injury	SIEMENS HEALTHCARE GMBH	2016/12/20	LNH	MAGNETOM AERA	Adverse Event Without Identified Device orUse Problem	Burn, Thermal	it was reported to siemens that a male patient underwent an mri exam on the magnetom aera system. following the exam, the patient reported two blisters on the chest at the site of the adhesive cardiac monitor lead pads. the patient was treated with a topical anesthetic ointment. there is no further report of impact to the state of health of the patient involved. manufacturer narrative: the system was evaluated by a siemens service engineer and all relevant data was found to be operating within specifications. no abnormality or technical defects were found which would contribute to the described injuries. the cardiac monitor lead padsUsed during the procedure are not a siemens accessory and have not been tested

Report Number	Event Date	Event Type	Manufacturer	Date Received	Product Code	Brand Name	Device Problem	Patient Problem	Event Text
									forElectromagnetic compatibility. additionally, theUser manual clearly outlines "use only proven mr-safe or mr-conditional accessories, parts subject to wear and tear, and disposable articles with the mr system."
2240869-2016-06061	2016/10/20	Injury	SIEMENS HEALTHCARE GMBH	2016/12/19	LNH	MAGNETOM SKYRA	Improper or Incorrect Procedure or Method	Abdominal Pain; Abrasion; Injury	it was reported to siemens that a nurse suffered an injury while operating the magnetom skyra system. a nurse entered the magnet room with a ferromagnetic oxygen bottle which was immediately attracted to the magnet. the nurse sustained an abrasion to her right thumb as well as pressure pain to the abdomen. the nurse was transferred and evaluated in the clinic, however, no further information concerning the injury or medical treatment was provided. manufacturer narrative: siemens has completed an investigation of the reported event. the cause of this event was the introduction of ferromagnetic pieces into the mr examination room and therefore, aUser error. due to the strong magnetic field, particular safety measures have to be adhered to in order to prevent injuries. the magnetom skyra system manual section and the magnetom system owner manual section provide clear instructions and warnings regarding both magnetic field hazards and training of personnel with regards to

Report Number	Event Date	Event Type	Manufacturer	Date Received	Product Code	Brand Name	Device Problem	Patient Problem	Event Text
									mr safety. special warning signs are posted at the entrance of the controlled access area (magnet room). the responsibility to instruct personnel and patients who have access to the mr examination room about magnetic field hazards lies with the customer. the manuals state that only equipment specified or recommended forUse in the controlled area (mr examination room) shall beUsed. the introduction of magnetizable objects into the magnetic field is contrary to the statements given in the operating instructions. this event occurred in (b)(6).
3003768277-2016-00116	2016/11/07	Injury	PHILIPS HEALTHCARE	2016/12/12	LNH	INGENIA 1.5T	Adverse Event Without Identified Device orUse Problem	Necrosis	Philips received a report from a customer related to a patient heating incident with an ingenia 1.5t mr system. a female patient was positioned head first supine and scanned for a spine examination. more then 1 hour after the examination necrosis of the skin (3rd degree) with a size of 5cm was observed on the outside of the right upper thigh / hip. manufacturer narrative: based on the provided information and test performed on site there is no indication of a malfunction of the mr system or coilsUsed. it is concluded that the injury on the patient right upper thigh/hip was caused by a combination of factors: no padding

Report Number	Event Date	Event Type	Manufacturer	Date Received	Product Code	Brand Name	Device Problem	Patient Problem	Event Text
									wasUsed between the magnet bore wall and patient. this resulted into direct contact with the bore wall close to the affected area. the patient was obese which may indicate a hampered thermo regulation. a wrong patient weight was entered; the fact that the patient weight is not filled correctly leads to incorrect (higher) sar values.
3003768277-2016-00115	2016/10/11	Injury	PHILIPS HEALTHCARE	2016/12/06	LNH	INGENIA 1.5T	Overheating of Device	Burn(s); Skin Inflammation	Philips received a report from a customer related to a heating incident with the quadrature body coil (qbc) on an ingenia 1.5t. the patient was positioned head first supine (tilted) and scanned for a lumbar spine examination. skin reddening and blistering with a size of 3cm on the backside of the patient's left arm was observed shortly after the examination. manufacturer narrative: based on the provided information and test performed on site the system was operating according to specifications, there is no indication of a malfunction of the mr system or coilsUsed. . the combination of patient physical status (anesthetized obese patient) and scanning in contravention of instructions for safe operation, as provided in the ifu and during training (no padding between the patient and the bore, no patient ventilation), contributed to the initiation and severity of the injury.

Report Number	Event Date	Event Type	Manufacturer	Date Received	Product Code	Brand Name	Device Problem	Patient Problem	Event Text
									manufacturer narrative: the investigation is still ongoing on this event. when the investigation is completed a follow-up will sent to the fda.
3003768277-2016-00117	2016/11/24	Injury	PHILIPS HEALTHCARE	2016/12/06	LNH	INGENIA 1.5T	Adverse Event Without Identified Device orUse Problem	Bone Fracture(s); Physical Entrapment	Philips received a report from a customer related to a finger pinching with an ingenia 1.5t mr system. when the patient support was moving out of the mr bore, the patient took hold of the table top in order to sit up, before the table finished moving. consequently the patient's finger got caught between the table top and table support. the patient's finger nail got loose and the patient sustained a fracture in the tip of the finger. manufacturer narrative: based on the provided information and investigation performed no malfunction of the mr device was observed that contributed to the injury. it was recognized by the customer that in this case the issue was caused by the patient wanting to move up from the tabletop, when the table was still moving out of the bore. during movement the operator should always check the patient's hands and make sure there are no cables or extremities positioned such that they can be caught. manufacturer narrative: when the investigation is completed, a follow-up report will be sent.

Report Number	Event Date	Event Type	Manufacturer	Date Received	Product Code	Brand Name	Device Problem	Patient Problem	Event Text
2240869-2016-57916	2016/10/06	Injury	SIEMENS HEALTHCARE GMBH	2016/11/30	LNH	MAGNETOM SKYRA	Inadequate User Interface	Partial thickness (Second Degree) Burn	it was reported to siemens that a patient suffered an injury while being examined on the magnetom skyra system. the customer reported that a narcotized patient suffered a second degree burn approximately 8 centimeters in diameter on the right side of the body. the patient was advised to look for a hospital for follow up treatment. manufacturer narrative: the system was evaluated by a siemens service engineer and was found to be operating within specification. this event occurred in (b)(6).
6053563	2016/06/17	Malfunction	GE MEDICAL SYSTEMS, LLC	2016/10/25	LNH	SIGNA HDX	Noise, Audible	Dyspnea	patient brought down from room to perform mri of the abdomen (mrcp). on the requisition sheet the patient's weight was stated as (b)(6) lbs; the weight limit of the mr scanner is 330 lbs, so the patient was placed on the mri exam table. we began positioning the patient for the procedure when the table began to make a grinding noise and stopped. we tried to move the table once more to get the patient near to the centering point when the table, again, made a grinding noise and stopped. we brought the patient out, who stated that she was "too tight and can't breathe." we got the patient out of the mri room and onto her bed. biomed was paged and informed of the situation and will begin repair on the mr scanner.

Report Number	Event Date	Event Type	Manufacturer	Date Received	Product Code	Brand Name	Device Problem	Patient Problem	Event Text
6002554	2015/11/17	Malfunction	GE MEDICAL SYSTEMS, LLC	2016/10/06	LNH	GE 3.0T SIGNA INFINITY TWINSPEED WITH EXCITE MR SYSTEM	Insufficient Information	Burning Sensation	the patient was placed in the scanner with non-thermal conducting mri pads in between arms and torso on both sides, as well as, pads between the patient's arms and the scanner with a strap around him to hold everything in place and was placed in scanner for approximately 8-10 minutes. patient was pulled out of scanner complaining that his arms were really hot. patient has tattoos covering large portions of arms-mri was terminated immediately.
3003768277-2016-00083	2016/08/29	Injury	PHILIPS HEALTHCARE	2016/09/15	LNH	INGENIA 1.5T	Adverse Event Without Identified Device orUse Problem	Burn(s)	Philips received a report from a customer related to a patient's injury (reddening of the skin with a 3 cm blister) on the lower leg of the patient. the patient was scanned with the ds head coil on an ingenia 1.5t system. manufacturer narrative: based on the provided information and test performed on site, there is no indication of a malfunction of the mri system or coilUsed. no definite cause for the injury on the patient left leg could be determined. the spo2 sensor was close to the affected area but is not likely to have caused the injury. the sensor is mr safe and the monitoring device with the same accessories wasUsed before and after the incident in a similar set up without problems. the patient was covered by a blanket which may have contributed to the incident. the development of the

Report Number	Event Date	Event Type	Manufacturer	Date Received	Product Code	Brand Name	Device Problem	Patient Problem	Event Text
									blister was not observed as the area was covered with the blanket. also, the blanket is made of polyester. polyester is an insulator and therefore hinders the heat dissipation. the blanket does not contain conductive materials. manufacturer narrative: the investigation is still ongoing on this event. when the investigation is completed a follow-up will sent to the fda. (b)(4).
MW5064333	2016/08/18	Malfunction	PHILLIPS	2016/08/23	LNH	PHILLIPS	Device Operates Differently Than Expected	No Consequences Or Impact To Patient	patient was sedated. mri machine was unable to scan due to technical issues. patient was rescheduled. no injury occurred.
2183553-2016-00017	2016/07/19	Injury	GE MEDICAL SYSTEMS, LLC	2016/08/15	LNH	GE SIGNA EXCITE 1.5T MR SYSTEM	Use of Device Problem; Insufficient Information	Laceration(s); Injury	it was reported that while a field engineer (fe) was removing the hard drive, one of tabs broke into his hand. he reached in to remove the hard drive and sliced his thumb along the metal guide rail. the fe went to urgent care where four stitches were required. manufacturer narrative: the investigation by ge healthcare has been completed. this incident occurred due to accessible sharp edges while servicing the host pc. it was concluded that the primary root cause of the incident was due toImproper maintenance by the field engineer by reaching into the pc once the green restraining tab was broken. manufacturer narrative: there are no additional device

Report Number	Event Date	Event Type	Manufacturer	Date Received	Product Code	Brand Name	Device Problem	Patient Problem	Event Text
									identification numbers at this time. ge healthcare's investigation is ongoing. a follow up report will be submitted once the investigation has been completed.
2183553-2016-00014	2012/06/05	Injury	GE MEDICAL SYSTEMS, LLC	2016/07/22	LNH	1.5T SIGNA HDX MR SYSTEM	Adverse Event Without Identified Device orUse Problem; Insufficient Information	Hearing Loss; Concussion	a notice was received alleging that a patient's head was compressed while being placed into the mr scanner bore. it was also reported that the patient was seen in the emergency department and diagnosed as having a brain concussion. the patient also claims to have suffered hearing loss however this has not been confirmed by a physician. manufacturer narrative: theUser facility was contacted on july 11, 13, 15, 19 and 25, 2016, in an effort to obtain device information. no device information was received. the investigation by ge healthcare has been completed. there are two ge mr systems at theUser facility. it is unknown which system was involved in the alleged incident. as per service records, preventative maintenance was current for both systems. the plaintiff alleges that once placed in the mr, the tube appeared to taper and plaintiff was wedged and compressed in the bore. the system has a cylindrical patient bore, open at both ends, with in-bore lighting and ventilation system. the bore does not taper. investigation is inconclusive given insufficiency of information.

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									manufacturer narrative: note that this report is due to a legal notice that contained the complaint that ge healthcare became aware of on 6/23/2016. patient weight and age are not available at the time of mdr filing. the device identification number is not available at the time of mdr filling. the initial reporter name and occupation are not available at the time of mdr filing. report source other: legal notice. the date of device manufacture is not available at the time of mdr filing. ge healthcare's investigation into the reported occurrence is still ongoing. a follow-up report will be issued when the investigation has been completed. device evaluation anticipated, but not yet begun.
2183553-2016-00013	2016/05/31	Injury	GE MEDICAL SYSTEMS, LLC	2016/06/23	LNH	SIGNA EXCITE 1.5T	Improper or Incorrect Procedure or Method; Device Dislodged or Dislocated	Eye Injury	it is reported that a 3rd party vendor employee involved with upgrading an mri system walked into the magnet room with two ferrous utility knives. the magnetic field captured one knife due toImproper proximity to the bore. when the employee attempted to recover the first knife, the second knife dislodged from his belt and impacted his eye. the injured employee was taken to the customer's emergency department. the employee required further medical care/intervention which included emergency surgery. the

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									injured employee has been able to distinguish light in his injured eye. the early prognosis is that the employee may be able to regain vision in the eye but it is uncertain to what capacity. manufacturer narrative: the primary root cause of the incident per the investigation is inattentive behavior by a third party vendor. the site has been corrected as the ferrous object has been removed from the magnet. magnet safety signs were present and caution tape was on the floor during the upgrade. in addition, the injured third party vendor had mr safety training and had previously been involved in multiple installations and upgrades. 3rd party mechanical installer vendors, contracted by ge healthcare, are given theAppropriate mr installation/upgrade documentation so they can generate their own mr safety and training material. the third party vendor had been supplied theAppropriate information for the 1.5t signa echospeed plus hd excite system. manufacturer narrative: date of birth is currently unavailable. weight is currently unavailable. report source is a 3rd party contractor. ge healthcare's investigation is ongoing. a follow-up report will be submitted once the investigation has been completed.

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3003768277-2016-00059	2016/05/21	Injury	PHILIPS HEALTHCARE	2016/06/15	LNH	INGENIA 3.0T	Adverse Event Without Identified Device orUse Problem	Laceration(s)	Philips received a report that during a service action, coldhead maintenance, a third party engineer sustained a serious injury on the right side of the middle finger which needed three stitches. the cold head motor was attracted by the magnet causing the injury. manufacturer narrative: the engineer sustained the injury because the instructions as present in the service instructions were not followed. it is mentioned in the coldhead service manual for 4k mri magnet systems that the coldhead motor is magnetic and that this motor must be removed with theUse of a special coldhead removal tool when the magnet is energized. this tool was notUsed. (b)(4).
9612283-2016-00003	2016/05/13	Injury	GE HEALTHCARE JAPAN CORPORATION	2016/06/09	LNH	SIGNA PIONEER	Improper or Incorrect Procedure or Method; No ApparentAdverse Event	Laceration(s); Suture Abrasion	during planned maintenance to replace the facility plumbing unit (fpu) sensor, a ge healthcare field engineer (fe) received a 1-2 cm laceration to the dorsal side of their left hand which required 4 stitches. the hand struck a bracket while attempting to pull out the pin holding the sensor. the fe was not wearing gloves when removing the pin. manufacturer narrative: the investigation by ge healthcare has been completed and concluded that the field engineer (fe) was injured during facility plumbing unit (fpu) sensor replacement in the integrated cooling cabinet (icc). the fe didn't

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									wear gloves during replacement and didn't slide out the fpu to the position where the sensor was accessible because the customer had placed items in front of the icc. in this position, it was difficult to gain access wearing gloves due to the narrow space. fe inserted his left hand up to his wrist without a glove to remove the sensor resulting in the injury. it was concluded that there were no issues with the service manual replacement procedure, icc design or actual parts of the site. the root cause of the injury was a result of not following service manual replacement procedures. proper actions that should have been taken to prevent injury were discussed with the fe. manufacturer narrative: ge healthcare's investigation is ongoing. a follow-up report will be submitted once the investigation has been completed.? patient information could not be provided due to country privacy laws. the initial reporter is located outside the u.s., and therefore this information is not provided due to country privacy laws. ge healthcare's investigation is ongoing. a follow-up report will be submitted once the investigation has been completed.? patient information could not be provided due to country privacy laws. the initial reporter is located outside the

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									u.s., and therefore this information is not provided due to country privacy laws.
5690719	2016/05/12	Malfunction	GE MEDICAL SYSTEMS LLC	2016/06/01	MOS	GE SIGNA MRI SCANNER	Image Resolution Poor	No Information	scan commenced at 11:55 with anesthesia; at approximately 12:30 scanner images were not clear/readable - coil changed. patient rescanned, images unable to be collected. several attempts were made to collect images and the engineers were called, but scanner failed. at 14:38 scan aborted. scan commenced at 11:55 with anesthesia; at approximately 12:30 scanner images were not clear/readable - coil changed. patient rescanned, images unable to be collected. several attempts were made to collect images and the engineers were called, but scanner failed. at 14:38 scan aborted.
9612283-2016-00002	2016/03/11	Injury	GE HEALTHCARE JAPAN CORPORATION	2016/06/01	LNH	SIGNA PIONEER	Adverse Event Without Identified Device orUse Problem;Appropriate Term/Code Not Available	Hearing Loss	the customer reported that a patient underwent a gad brain scan. the patient was given earbuds for music. after the scan was completed the patient complained of hearing loss. a physician confirmed that the patient sustained a bilateral sensorineural hearing loss. manufacturer narrative: ge healthcare's investigation confirmed that the pioneer ((b)(4)) system limits acoustic noise when hearing protection isUsed. the system operator is responsible for providing the hearing protection. in this case, hearing protection was

Report Number	Event Date	Event Type	Manufacturer	Date Received	Product Code	Brand Name	Device Problem	Patient Problem	Event Text
									provided and placed by the patient. the system acoustic level was tested to meet local regulations. this gradient was removed and replaced with a new gradient based on customer satisfaction concerns. manufacturer narrative: ge healthcare's investigation is ongoing. a follow-up report will be submitted once the investigation has been completed.
2183553-2016-00011	2016/04/26	Injury	GE MEDICAL SYSTEMS, LLC	2016/05/31	LNH	GE 1.5T SIGNA HDX MR SYSTEM	Fracture;Appropriate Term/Code Not Available	Bone Fracture(s); Pain	during an examination, a patient with dementia was positioned on the table and secured with the wide table strap in place to assure that the patient did not fall. the patient crawled out of the magnet bore and off of the table without the technologist noticing. the patient complained of pain in their left foot so x-rays were taken but no abnormalities were found. several days later the patient continued to complain of pain, so more x-rays were taken and a fracture was detected. manufacturer narrative: ge healthcare's investigation found this complaint to be the result of inadequate patient monitoring for a patient where reliable communication cannot be maintained. it was recommended the customer review the section of the hdxt operation manual that concerns the need to closely monitor high risk patients. a ge healthcare service

Report Number	Event Date	Event Type	Manufacturer	Date Received	Product Code	Brand Name	Device Problem	Patient Problem	Event Text
									representative confirmed the customer understood it is their responsibility to carefully monitor high risk patients. manufacturer narrative: patient information could not be provided due to country privacy laws. the initial reporter is located outside the u.s., and therefore this information is not provided due to country privacy laws. ge healthcare's investigation is ongoing. a follow up-report will be submitted once the investigation has been completed.
2240869-2016-02717	2016/05/05	Injury	SIEMENS HEALTHCARE GMBH	2016/05/27	LNH	MAGNETOM PRISMA	Improper or Incorrect Procedure or Method;Appropriate Term/Code Not Available	Hemorrhage/Bleeding	it was reported to siemens that while scanning a pediatric patient on the magnetom prisma, the childs parent brought a ferrous metal chair into the scan room. the chair was drawn to the magnet and collided with the childs head. the child was evaluated by the attending physician and did not suffer any bone fractures, however, the child did have moderate bleeding from the nose. siemens is unaware of any follow up medical treatment. the mr suite has two entrances, both of which are labeled with warning signs regarding the introduction of magnetic materials to the examination room. manufacturer narrative: the device was evaluated and was found to be operating within specification. the system operators manual clearly warns of the

Report Number	Event Date	Event Type	Manufacturer	Date Received	Product Code	Brand Name	Device Problem	Patient Problem	Event Text
									introduction of ferrous objects to the examination room. this event occurred in (b)(6): (b)(6).
2240869-2016-42199	2015/05/27	Injury	SIEMENS HEALTHCARE GMBH	2016/05/19	LNH	MAGNETOM AERA	Adverse Event Without Identified Device orUse Problem	Partial thickness (Second Degree) Burn; Full thickness (Third Degree) Burn	it was reported to siemens that a male patient underwent an mri c spine, t spine, and l spine on the magnetom aera system for a thoracic spine fracture. the patient experienced 2nd and 3rd degree burns at the site of the adhesive cardiac monitor lead pads. the lead pads were described as large, red, cloverleaf patterned. the patient was treated with silvadene ointment. manufacturer narrative: the system was evaluated by a siemens service engineer and all relevant data was found to be operating within specifications. no abnormality or technical defects were found which would contribute to the described injuries. the cardiac monitor lead padsUsed during the procedure are not a siemens accessory and have not been tested forElectromagnetic compatibility. additionally, theUser manual clearly outlines "use only proven mr-safe or mr-conditional accessories, parts subject to wear and tear, and disposable articles with the mr system."
5629959	2016/03/25	Malfunction	SIEMENS MEDICAL SYSTEMS	2016/05/04	LNH	MAGNETOM AERA	Adverse Event Without Identified Device	Burn(s); Pain; Weakness	a female patient was admitted with complaints of back pain, bilateral leg weakness with radiating pain in both lower extremities. the patient underwent mri. mri l-spine, mri brain,

Report Number	Event Date	Event Type	Manufacturer	Date Received	Product Code	Brand Name	Device Problem	Patient Problem	Event Text
							orUse Problem		mri c-spine and mri t-spine. the patient experienced a left chest wall burn underneath the site of a blue meditrace cardiac electrode patch. the patient was treated with silvadene and calcium alginate. an earlier burn on a patient was noted in the same mri magnet, therefore it was decided to have siemens manufacturer come out and inspect the machine. siemens has completed their inspection.
2240869-2016-38502	2016/03/25	Injury	SIEMENS HEALTHCARE GMBH	2016/04/20	LNH	MAGNETOM	Insufficient Information	Full thickness (Third Degree) Burn	it was reported to siemens that a patient suffered a third degree burn during an mr examination the patient was positioned head first supine with arms at their side. the patient had an ekg pad on the skin at the location of the wound left on from the er. the wound was reported as approximately 1 inch in circumference at the upper left chest wall. the injury was assessed by the wound care specialist and topical cream was applied. manufacturer narrative: the system was evaluated by a siemens service engineer and all relevant data was found to be operating within specifications. no abnormality or technical defects were found which would contribute to the described injury.
MW5061807	2016/03/28	Injury	GENERAL ELECTRIC	2016/04/18	LNH	SIGNA HDXT 1.5T MRI	Adverse Event Without Identified	Burn(s)	one week after this patient's lumbar spine mri exam, the patient notified the mri facility via website email that he sustained what appeared to be

Report Number	Event Date	Event Type	Manufacturer	Date Received	Product Code	Brand Name	Device Problem	Patient Problem	Event Text
						SCANNER	Device orUse Problem		burns at the base of his right thumb and at the lateral aspect of his right hip/buttock. he reported he noted redness on his thumb after his scan while changing into his clothing and that the redness appeared to become more intense and sore after he had left the imaging facility. the following morning he noticed a small blister on the lateral aspect of his right thumb as well as a blister on his right lateral hip/buttock area. the patient reported the blisters popped the following day and he self-treated with otc antibiotic ointment. upon notification on (b)(6) 2016 the mri facility referred the patient to his primary care physician for evaluation. the mri dept medical director notified the patient's doctor who examined the patient on (b)(6) 2016. the patient's doctor reported healing areas of what appeared to be thermal burns measuring approximately 4mm at the base of the thumb, and approximately 1.5 cm x 0.5 cm on the lateral right hip/buttock. the patient incidentally reported a prior history of a surgically implanted metal pin in his right thumb and was concerned about internal damage to the pin. upon questioning the patient stated he was wearing two facility-provided gowns during his mri scan and he did not feel he had skin to skin contact during his scan. the

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									performing technologist recalls padding the patient between his arms and the bore of the scanner, but states she did not provide padding between his arms and torso. the mri dept safety officer and mri medical director conclude this injury was most likely caused by skin to skin contact and/or inadequate insulation/padding between the patient's arms and torso resulting in an electrically conductive large caliber body loop. (thumb touching the side of his hip/buttock). remedial mri safety education was subsequently provided for all mri technologists at the imaging facility. the attending radiologist followed up with a phone call to the patient on (b)(6) 2016 who reported continued healing but remained concerned about the integrity of his metal pin. he was advised to see a plastic surgeon for soft tissue assessment. the patient reported complete healing to his pcp on (b)(6) 2016 but requested a referral to his orthopedic surgeon to be certain there was no permanent damage to thumb. the patient has an appointment scheduled to see his orthopedic doctor next month. add'l info received from reporter on 04/27/2016: this report is a correction to a previously filed report. (pt id: (b)(6), filed on (b)(6)

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									2016 by (b)(6), health professional, regarding a serious injury involving theUse of a ge mri scanner, sigma hdxt 1.5t.) this report is intended to correct a specific items: the correct mri scanner serial number, the correct unique identifier (udi) for that device, and the correct pt weight.
2183553-2016-00009	2016/02/08	Injury	GE MEDICAL SYSTEMS, LLC	2016/04/01	LNH	1.5T SIGNA HDX MR SYSTEM	Insufficient Information ; Noise, Audible	Hearing Impairment ; Hearing Loss;Tinnitus	a patient undergoing an mri exam reported hearing loss immediately after the exam. upon follow up with the patient a few days after the exam the patient reported the hearing loss to be resolving without medical intervention. manufacturer narrative: ge healthcare performed a checkout of the equipment and a review of the logs. there is no indication of any failure. the patient was properly equipped with hearing protection. the system acoustic level was tested and meets local regulations. the patient¿s hearing loss was confirmed by an ent physician and treated with steroids. it is reported the patient¿s hearing loss remains after steroid treatment, indicating this to be a permanent hearing loss. no further actions are planned at this time. manufacturer narrative: ge healthcare's investigation is ongoing. a follow up-report will be submitted once the investigation has been completed. patient identifier could not be obtained after multiple attempts. attempts were made as

Report Number	Event Date	Event Type	Manufacturer	Date Received	Product Code	Brand Name	Device Problem	Patient Problem	Event Text
									follows: on (b)(6) 2016 phone call; on (b)(6) 2016 phone call; on (b)(6) 2016 phone call.
2183553-2016-00010	2016/01/28	Injury	GE MEDICAL SYSTEMS, LLC	2016/04/01	LNH	1.5T SIGNA HDX MR SYSTEM	Device Operates Differently Than Expected; Noise, Audible	Hearing Impairment ; Hearing Loss	a patient that underwent an mri procedure reported hearing loss. the patient has been evaluated and treated by an ent physician, and the patient has a reported 10% hearing loss/deficit which has not improved. manufacturer narrative: ge healthcare performed a checkout of the equipment and a review of the logs. there is no indication of any failure. the patient was properly equipped with hearing protection. the system acoustic level was tested and meets local regulations. no further actions are planned at this time. manufacturer narrative: ge healthcare's investigation is ongoing. a follow up-report will be submitted once the investigation has been completed. patient identifier could not be obtained after multiple attempts. attempts were made as follows: 03/04/2016 phone call; 03/10/2016 phone call; 03/25/2016 phone call.
2183553-2016-00006	2016/02/16	Malfunction	GE MEDICAL SYSTEMS, LLC	2016/03/17	LNH	SIGNA 3.0T MR750 SYSTEM	Fire; Electrical Shorting	No Patient Involvement; No Information	smoke and fire was detected in magnet room after an exam. patient had left the magnet room before smoke was detected. the emergency ramp-down unit was activated and magnet was subsequently quenched.

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									firefighter services were called and powder extinguishing agents were applied. manufacturer narrative: the investigation by ge healthcare has concluded that there was an internal short at the y0 interconnect lead of the gradient coil subsystem. this joint is constructed by overlapping copper bars, single bolt, solder and then supported by epoxy. the short y0 interconnect lead failed due to fatigue at the minimum cross sectional area, induced due to a solder joint failure. this area was severely damaged by the event and additional root causes could not be determined at this location. this event has been shown to be an isolated incident. this investigation closed with site corrections only. manufacturer narrative: no report of patient involvement. the initial reporter is located outside the u.s., and therefore this information is not provided due to country privacy laws. ge healthcare's investigation is ongoing. a follow up-report will be submitted once the investigation has been completed.
3003768277-2016-00027	2016/02/21	Injury	PHILIPS HEALTHCARE	2016/03/17	LNH	INGENIA 1.5T	Insufficient Information	Rash	a customer reported toPhilipsthat a male patient sustained reddening of the skin on the left elbow which developed into a blister with a size of approx. 3 inches. the patient was positioned head first supine and scanned for an mr angio of the neck.

Report Number	Event Date	Event Type	Manufacturer	Date Received	Product Code	Brand Name	Device Problem	Patient Problem	Event Text
									manufacturer narrative: based on the provided information and tests performed on site there is no indication of a malfunction of the mr system or coilsUsed. it is concluded that the injury on the patients elbow was caused by the too close proximity of the bore wall. no padding wasUsed to prevent direct contact with the bore wall. the following factors were identified that may have contributed to the injury the patient sustained. three (3) consecutive scans on high sar were administered. the patient was covered by a sheet/blanket that may hamper heat dissipation. the patient was obese which may indicate a restricted thermo-regulation (b)(4). manufacturer narrative: the investigation is still ongoing on this event. when the investigation is completed a follow-up will sent to the fda. (b)(4).
3010949642-2016-00001	2016/02/10	Injury	GE HEALTHCARE (TIANJIN) COMPANY LIMITED	2016/03/11	LNH	SIGNA EXPLORER	Break; Detachment Of Device Component	Injury	during the upgrade of the device, two field engineers were loosening the three-leg jig when a piece of the jig handle broke off and hit one of the field engineer's face causing an injury. manufacturer narrative: manufacturer narrative: ge healthcare performed a checkout of the device and found the screw ("m16") stud and screw holes of the three-leg jig tool had a thread galling issue making it difficult to rotate the

Report Number	Event Date	Event Type	Manufacturer	Date Received	Product Code	Brand Name	Device Problem	Patient Problem	Event Text
									handle. the field engineers applied a large force to the handle which caused two other screws ("m4") on the handle to break. the m16 screw stock has been checked and no issues were found. it was confirmed that other units shipped to the field do not have the issue. service procedures includes proper instructions for using the tool. no further actions are planned at this time. manufacturer narrative: patient information could not be provided due to country privacy laws. (b)(4). the device was not being operated at the time of this incident. the initial reporter is located outside the u.s., and therefore this information is not provided due to country privacy laws. ge healthcare's investigation is ongoing. a follow-up report will be submitted once the investigation has been completed.
2240869-2016-31335	2016/01/22	Injury	SIEMENS HEALTHCARE GMBH	2016/02/23	LNH	MAGNETOM AERA	Insufficient Information	Swelling	it was reported to siemens that a patient was scanned on the magnetom aera system while under anesthesia for approximately 5.5 hours. after the scan, the patient reported blisters on both thighs in the groin area of approximately 4cm and 2cm in diameter at the location in which a urine bag had been placed. a skin barrier dressing was applied. manufacturer narrative: the system was evaluated by a siemens service engineer and found to be operating

Report Number	Event Date	Event Type	Manufacturer	Date Received	Product Code	Brand Name	Device Problem	Patient Problem	Event Text
									within specifications. the systemUser manual contains detailed information of the physiological reactions to rf exposure and ways to avoid them.
3003768277-2016-00016	2016/01/20	Injury	PHILIPS HEALTHCARE	2016/02/10	LNH	INGENIA 1.5T	Human Factors Issue	Burn(s)	Philips received a report that a patient experienced a heating sensation and a blister of 4 cm was observed on the outside of the left lower back. the patient was positioned feet first supine, oblique, off center and scanned for a right wrist mr examination using the sense small extremity 8 coil. manufacturer narrative: based on the provided information and tests performed on site there is no indication of a malfunction of the mr system or coilUsed. it is concluded that the injury on the left lower back is caused by the close proximity of the body to the bore wall. no padding wasUsed between the patient and the bore wall and it was stated that the patient was in direct contact with the bore wall close to the affected area. further contributing factors identified were: -total specific energy dose (sed) of 4.0kj/kg. (b)(4).
3003768277-2016-00012	2016/01/03	Injury	PHILIPS HEALTHCARE	2016/02/02	LNH	INGENIA 1.5T	Adverse Event Without Identified Device orUse Problem	Bone Fracture(s); Physical Entrapment	a claustrophobic patient was scanned for lumbar spine examination. when the patient was moved out of the bore after the exam the patient immediately sat up and took hold of the table. his finger got stuck between the table top and the trolley docking block resulting in

Report Number	Event Date	Event Type	Manufacturer	Date Received	Product Code	Brand Name	Device Problem	Patient Problem	Event Text
									a broken finger. manufacturer narrative: the event is considered aUser error. after the patient was moved out of the bore the patient immediately sat up, before the patient table came to a halt. while sitting up the patient grabbed hold of the table top, which allowed his finger to become stuck between the tabletop and the trolley docking block located at the site of the table top carrier. within the instructions for Use there are warnings associated to movement of the patient. during movement the operator should always check the patient's hands and make sure there are no cables or extremities positioned such that they can be caught. (b)(4).
5387511	2015/10/10	Malfunction	GE MEDICAL SYSTEMS, LLC	2016/01/25	LNH	SIGNA HDX	Device Displays Incorrect Message; Device Operates Differently Than Expected	No Code Available	mri machine was giving a diagnostic error and wouldn't scan while patient was under anesthesia.
2183553-2016-00003	2013/12/11	Injury	GE MEDICAL SYSTEMS, LLC	2016/01/13	LNH	1.5T SIGNA HDX	Improper or Incorrect Procedure or Method; Adverse Event Without Identified	Bone Fracture(s); Injury	the customer reported that, in (b)(6) 2015, a patient underwent an mri of the breast. during the exam the patient alerted the technologists by squeezing the alert bulb and reported to the nurse assisting her that she was feeling pressure on her chest. the patient stated she would try to

Report Number	Event Date	Event Type	Manufacturer	Date Received	Product Code	Brand Name	Device Problem	Patient Problem	Event Text
							Device or Use Problem		continue the exam, and the patient remained on the coil. during the next series the patient alerted the technologists by squeezing the alert bulb, and the exam was terminated at that time. it was reported the patient sustained a broken bone. manufacturer narrative: corrected data: the incident date was initially reported as (b)(6) 2015. the investigation found that the incident occurred on (b)(6) 2013. additional manufacturer narrative: ge healthcare's investigation found that the scanner and breast coil were working as expected and the technologist demonstrated good clinical care of the patient from preparation of the scan to attentiveness during the exam. the patient had an expander, which likely was a breast tissue expander Used post total mastectomy to expand the skin and other tissue prior to plastic surgery or cosmetic silicone implant. it is unknown if patient¿s pre-existing medical conditions increased the risk of fracture. given the available information it is unclear what the root cause was; however there is no evidence that the scanner contributed to the injury. no further actions are planned at this time. manufacturer narrative: ge healthcare's investigation is ongoing. a follow up report will be submitted

Report Number	Event Date	Event Type	Manufacturer	Date Received	Product Code	Brand Name	Device Problem	Patient Problem	Event Text
									once the investigation has been completed. patient information is not provided due to country privacy laws. incident occurred in (b)(6) 2015. the initial reporter is located outside the u.s., and therefore this information is not provided due to country privacy laws. device evaluation anticipated, but not yet begun.
3003768277-2016-00006	2015/12/17	Injury	PHILIPS HEALTHCARE	2016/01/12	LNH	INGENIA 3.0T	Human Factors Issue	Bone Fracture(s); Laceration(s)	Philips received a report that a 3rd party service engineer got injured while trying to install a 3rd party fmri filter panel in the examination room enclosure. the filter panel plate was attracted to the magnet. the engineer sustained a broken left thumb and 5 sutures were required in the left hand. manufacturer narrative: this event occurred because mri safety standards were not followed bringing the filter panel plate to close to the magnet. it is stated in the instructions forUse that no magnetic materials should be brought into the examination room. the safety directions in the instruction forUse contain warnings on this matter. (b)(4).