Recall Number	Trade Name/Product	Recall Cla	Date Initiated	Date Posted	Recalling Manufacturer	Reason for Recall
Z-2341-2008	LIFEPAK CR Plus	1	08-28-2008	09-18-2008	Physio Control Inc.	This recall is being conducted due to the device being configured with the incorrect software for semi-automatic instead of fully automatic use. When the device is needed for a cardiac arrest emergency the device will require that the user press the shock button instead of automatically delivering a shock as per the normal operation of the fully automatic device. Fully automatic defibrillators h
Z-1238-2007	Exacta-Mix 2400	1	06-27-2007	09-27-2007	Baxa Corporation	A software defect could allow up to 50mL of extra volume being added to a TPN solution.
Z-1091-2007	Colleague 3 3 CX and 3 CXE Volumetric Infusion Pumps	1	08-20-2007	07-18-2007	Baxter Healthcare Corp.	A software anomaly is causing newly upgraded Colleague Triple Channel Infusion Pumps to alarm display an error code (16:310:887:0002) and stop the infusion. This occurs during user programming with all three channels simultaneously infusing fluids. In reported cases the pump stopped infusing and both an audible and a visual alarm notification were activated.
Z-0854-2007	LADAR6000	1	02-21-2007	06-05-2007	Alcon Refractive Horizons Inc.	Observed 'central islands' in patients following custom myopia laser procedures using the LADAR6000 Excimer Laser. (On May 11 2007 Alcon notified consignees that the device software programs for CustomCornea Myopia and CustomCornea Myopia with Astigmatism of the device would be deactivated)
Z-0580-2007	Lifeline AED-Defibtech Sentry	1	02-17-2007	03-08-2007	Defibtech LLC	Device Malfunction-The self-test software may allow a self-test to clear a previously detected low battery condition. If this occurs the operator may be unaware of the low battery and the device may be unable to deliver a defibrillation shock which could result in failure to resuscitate a patient.
Z-0581-2007	RevivaR AED-Defibtech Sentry	1	02-17-2007	03-08-2007	Defibtech LLC	Device Malfunction-The self-test software may allow a self-test to clear a previously detected low battery condition. If this occurs the operator may be unaware of the low battery and the device may be unable to deliver a defibrillation shock which could result in failure to resuscitate a patient.
Z-0841-05	SAMARITAN AED DEFIBRILLATORS	1	02-14-2005	03-23-2005	Heartsine Technologies Inc	The affected Automatic External Defibrillators (AED) announce a fault warning and shut themselves off before a shock can be delivered to the patient. This is reportedly due to slow capacitor charging rates which are interpreted by the AED software as a fault condition.
Z-0218-05	Tosoh	1	04-02-2003	11-30-2004	Tosoh Bioscience Inc.	A software upgrade was released by the firm for its AIA-600 II analyzers in that washing deficiencies caused by the analyzer were corrected.
Z-1334-04	8870 Software Application Card Version AAA 02	1	08-24-2004	09-23-2004	Medtronic Inc Neurological & Spinal Division	With the Model 8870 software application card versions AAA 02 BBB 04 BBC 02 and BBD 01 which is used in conjunction with the Model 8840 N'Vision Clinician Programmer users may have mistakenly entered a periodic bolus interval into the minutes field rather than the hours field resulting in drug overdoses. This issue is limited to programming the SynchroMed and SynchroMed EL pumps.
Z-1021-04	COBAS Gui software interface between the Cobas AMPLICOR instrument and the Tecan clinical workstatio...	1	05-05-2004	07-20-2004	Roche Diagnostics Corp.	The Roche COBAS interface driver for the Tecan software may assign sample results to the wrong patient.
Z-0999-04	Tecan clinical workstation; 10-410 Tecan Genesis 150 back end Roche catalog number 03585352001.	1	05-05-2004	07-20-2004	Roche Diagnostics Corp.	Tecan software has the potential to match the patient with a different patient's test results.
Z-1001-04	Tecan clinical workstation; Tecan Genesis 150/8 front end COBAS Roche catalog number 03600530001.	1	05-05-2004	07-20-2004	Roche Diagnostics Corp.	Tecan software has the potential to match the patient with a different patient's test results.
Z-1000-04	Tecan clinical workstation; 10-415 Tecan Genesis 150 front end Roche catalog number 03585379001.	1	05-05-2004	07-20-2004	Roche Diagnostics Corp.	Tecan software has the potential to match the patient with a different patient's test results.
Z-0007-04	Mysis Laboratory	1	08-12-2003	07-20-2004	Misys Healthcare Systems	Software defect. Clinical Laboratory results failing quality assurance were filed directly to a patient's chart without
Z-1022-04	Tecan Genesis	1	05-03-2004	07-20-2004	Tecan U S Inc	Tecan software has the potential to match the patient with a different patient's test results.
Z-1651-2009	CXR4 Computed Tomography X-Ray System	2	04-14-2009	07-07-2009	Hitachi Medical Systems America Inc	Incorrect scale on image: A software error can occur if two (2) different Field-of-View (FOV) settings are registered in a protocol using Multi-Reconstruction. This could cause the image generated to be displayed with the wrong scale factor rendering anatomical measurements incorrect.
Z-1652-2009	ECLOS Computed Tomography X-Ray System	2	04-14-2009	07-07-2009	Hitachi Medical Systems America Inc	Incorrect scale on image: A software error can occur if two (2) different Field-of-View (FOV) settings are registered in a protocol using Multi-Reconstruction. This could cause the image generated to be displayed with the wrong scale factor rendering anatomical measurements incorrect.
Z-1582-2009	CardiAssist	2	04-09-2009	07-07-2009	Cardiomedics Incorporated	Cuff may underinflate or device may stop working during use. Cardioassist software version 4.3.1 utilized a signal from the plethysmograph that was found not to be sensitive enough due to the shape of the waveform in certain circumstances where there was excessive motion artifact.
Z-1579-2009	GEMINI GXL	2	02-19-2009	07-06-2009	Philips Medical Systems (Cleveland) Inc	A software anomaly in the TumorLoc software for the firm's Brilliance CT scanners was discovered. The same software anomaly was subsequently determined to be present in the firm's GEMINI PET/CT units. The software defect results in a the potential for data to be lost during reconstruction of images in which slices can either be discarded or interleaved based upon their series ID.
Z-1580-2009	GEMINI RAPTOR	2	02-19-2009	07-06-2009	Philips Medical Systems (Cleveland) Inc	A software anomaly in the TumorLoc software for the firm's Brilliance CT scanners was discovered. The same software anomaly was subsequently determined to be present in the firm's GEMINI PET/CT units. The software defect results in a the potential for data to be lost during reconstruction of images in which slices can either be discarded or interleaved based upon their series ID.
Z-1578-2009	PHILIPS PLUS COMPUTED TOMOGRAPHY SYSTEM	2	02-19-2009	07-06-2009	Philips Medical Systems (Cleveland) Inc	A software anomaly in the TumorLoc software for the firm's Brilliance CT scanners was discovered. The same software anomaly was subsequently determined to be present in the firm's GEMINI PET/CT units. The software defect results in a the potential for data to be lost during reconstruction of images in which slices can either be discarded or interleaved based upon their series ID.
Z-1549-2009	GE Centricity PACS software	2	04-03-2009	07-01-2009	GE Healthcare Integrated IT Solutions	There is a potential safety issue associated with the use of GE Centricity PACS software related to configuration of DICOM query retrieval with rejected images.
Z-1582-2009	BRILLIANCE VOLUME	2	12-22-2008	06-29-2009	Philips Medical Systems (Cleveland) Inc	Software anomaly. An artifact may appear in brain scans and brain perfusion studies when using 80kV and a UA UB or UC filter with this CT scanning device.
Z-1436-2009	CareVue Chart	2	05-05-2009	05-27-2009	Philips Healthcare Inc.	Software: A software defect under certain circumstances could lead to the unintended administration of a duplicate dose of a scheduled medication within a single 24 hour period
Z-1401-2009	Panorama Patient Monitoring Network	2	04-10-2009	05-27-2009	Mindray DS USA Inc. dba Datascope Patient Monitoring	Software Anomaly: Software anomaly can occur when the Panorama is attempting to play an audio file either a physiological or technical alarm sound at which time the system software may cause the system to freeze due to an interaction in the alarm system.
Z-1397-2009	Centricity TriWin Laboratory	2	11-17-2008	05-15-2009	GE Healthcare Integrated IT Solutions	A software defect in the Centricity Lab (TriWin) product may incorrectly link patient information to a wrong report. Also when viewing results in Patient Viewer and a coagulation result is higher or lower than the linearity limit then all of the results following the higher or lower result will show the same result as the first flagged result.
Z-1232-2009	CIC PRO CLINICAL INFORMATION CENTER CENTRAL STATION	2	02-27-2009	05-04-2009	GE Medical Systems Information Tecnology	GE Healthcare is aware of potential network time issues associated with the time change aspects of certain CARESCAPE CIC Pro software versions. These issues may impact patient safety.
Z-1002-2009	GE QUASAR NUCLEAR MEDICINE SYSTEM	2	06-02-2008	04-21-2009	GE Medical Systems LLC	GE Healthcare has recently became aware of excessive pressure applied by the collimator pressure sensitive cover of Infinia (Infinia Infinia Hawkeye? Infinia Hawkeye? 4) that may impact patient safety. It was reported at a customer site that the pressure used to activate the Pressure Sensitive Device (PSD) should be lowered and that the body contouring software requires correction to prevent po
Z-1003-2009	GE QUASAR NUCLEAR MEDICINE SYSTEM	2	06-02-2008	04-21-2009	GE Medical Systems LLC	GE Healthcare has recently became aware of excessive pressure applied by the collimator pressure sensitive cover of Infinia (Infinia Infinia Hawkeye? Infinia Hawkeye? 4) that may impact patient safety. It was reported at a customer site that the pressure used to activate the Pressure Sensitive Device (PSD) should be lowered and that the body contouring software requires correction to prevent po
Z-1001-2009	GE QUASAR NUCLEAR MEDICINE SYSTEM	2	06-02-2008	04-21-2009	GE Medical Systems LLC	GE Healthcare has recently became aware of excessive pressure applied by the collimator pressure sensitive cover of Infinia (Infinia Infinia Hawkeye? Infinia Hawkeye? 4) that may impact patient safety. It was reported at a customer site that the pressure used to activate the Pressure Sensitive Device (PSD) should be lowered and that the body contouring software requires correction to prevent po
Z-0988-2009	DELTEC COZMO INSULIN INFUSION PUMP WITH COZMONITOR BLOOD GLUCOSE METER	2	11-20-2008	04-16-2009	Smiths Medical MD Inc.	Smiths Medical has become aware of a display irregularity with the Deltec Cozmo? Insulin Pump Model 1800 and Model 21-1700 containing Model 1800 software. There have been adverse events reported that the amount of Extended Bolus delivered was not accurately displayed by the Pump. The amount of extended Bolus displayed on the Pump Home Screen 2 and in the Bolus Summary Report is less than what w
Z-0989-2009	DELTEC COZMO INSULIN INFUSION PUMP WITH COZMONITOR BLOOD GLUCOSE METER MODELS 21-	2	11-20-2008	04-16-2009	Smiths Medical MD Inc.	Smiths Medical has become aware of a display irregularity with the Deltec Cozmo? Insulin Pump Model 1800 and Model 21-1700 containing Model 1800 software. There have been adverse events reported that the amount of Extended Bolus delivered was not accurately displayed by the Pump. The amount of extended Bolus displayed on the Pump Home Screen 2 and in the Bolus Summary Report is less than what w
Z-1064-2009	CELL-Dyn Ruby Hematology	2	11-17-2008	04-10-2009	Abbott Laboratories	Carryover failures in software revisions 1.0ML and 2.0ML result in elevated PLT background count.
Z-0999-2009	Viasys Healthcare Sonara Transcranial Doppler (TCD) System	2	01-06-2009	04-07-2009	Cardinal Health Inc	Internal testing has identified several several scenarios where unexpected System lockups shutdowns or system errors would render the Sonara unavailable for use until the Sonara can be restarted. These issues can be corrected by installing the Version 6.0 b045 software updating the Audio Driver and updating to XP Service Pack 3. Additionally improper wiring could cause the cooling fan to not op

Z-0998-2009	Viasys Healthcare Sonora Transcranial Doppler (TCD) System	2	01-06-2009	04-07-2009	Cardinal Health Inc	Internal testing has identified several several scenarios where unexpected System lockups shutdowns or system errors would render the Sonara unavailable for use until the Sonara can be restarted. These issues can be corrected by installing the Version 6.0 b045 software updating the Audio Driver and updating to XP Service Pack 3. Additionally improper wiring could cause the cooling fan to not op
Z-1040-2009	QCA and iQCA Software	2	11-06-2008	03-24-2009	Leica Microsystems Inc.	A change in the software to open up the software architecture to include other analytes other than Estrogen Receptor was made without FDA review and approval.
Z-1090-2009	BD PrepStain System	2	09-26-2008	03-19-2009	Bd Diagnostic Systems Tripath	Software Error in the non-gyn program of some devices may cause non-gyn samples to be incorrectly transferred from centrifuge tubes to slides potentially result in mismatched patient results.
Z-0861-2009	Eclipse treatment planning system	2	11-21-0008	02-20-2009	Varian Medical Systems Oncology Systems	Possible incorrect wedge orientation in treatment: Software labeling was issued without warning message relating to preservation of user selected values for Siemens wedge orientation wedge limits and SAD values for Elekta machines and collimator operating limits for Saturne Machines when the software version is upgraded.
Z-0624-2009	O-ARM(R)	2	11-27-2007	02-04-2009	Medtronic Navigation Inc	Navigation accuracy problem: Accuracy may fall outside of specification when used in combination with the Medtronic Synergy Experience StealthStation System Spine Software with the O-Arm Intraoperative Imaging System and tracker.
Z-0853-2009	TheraMap	2	12-09-2008	01-27-2009	iCAD Inc.	Software modules not approved for this indication.
Z-0554-2009	PrecisionPoint	2	12-09-2008	01-27-2009	iCAD Inc.	Software modules not approved for this indication.
Z-0473-2009	Innova 2100IQ	2	01-30-2008	01-21-2009	GE Medical Systems LLC	Software error computer: GE Healthcare has became aware of an issue with Error Management affecting the Innova 2100 3100/3100 IQ & 4100/4100IQ. It was reported that when the foot switch was pressed the live monitor screen was blank and it looked like there were no X-rays being emitted. But the message Acquisition in progress was displayed on the DL monitor even after the foot switch was r
Z-0474-2009	Innova 3100/3100IQ	2	01-30-2008	01-21-2009	GE Medical Systems LLC	Software error computer: GE Healthcare has became aware of an issue with Error Management affecting the Innova 2100 3100/3100 IQ & 4100/4100IQ. It was reported that when the foot switch was pressed the live monitor screen was blank and it looked like there were no X-rays being emitted. But the message Acquisition in progress was displayed on the DL monitor even after the foot switch was r
Z-0475-2009	Innova 4100/4100IQ	2	01-30-2008	01-21-2009	GE Medical Systems LLC	Software error computer: GE Healthcare has became aware of an issue with Error Management affecting the Innova 2100 3100/3100 IQ & 4100/4100IQ. It was reported that when the foot switch was pressed the live monitor screen was blank and it looked like there were no X-rays being emitted. But the message Acquisition in progress was displayed on the DL monitor even after the foot switch was r
Z-0129-2009	Cytomics FC 500 Flow Cytometry System with CXP Software	2	10-11-2007	01-13-2009	Beckman Coulter Inc	Software error: This field action was initiated after Beckman Coulter determined that the CXP software does not refresh the dataset automatically under certain circumstances. The User documentation does not clearly state that the user should refresh the dataset after changes are made.
Z-0870-2009	Centricity Web	2	12-12-2008	01-12-2009	GE Healthcare Integrated IT Solutions	Software error: There are two potential safety situations with Centricity Enterprise Web software – a forced log off may occur while using the Centricity Enterprise Web during an open session and Centricity Enterprise Web does not utilize calibration performed on image measurements in Centricity RA1000 Workstation.
Z-0608-2009	CXR4 Computed Tomography	2	11-05-2008	01-08-2009	Hitachi Medical Systems America Inc	Software error: The device has a software error that can result in a condition where the displayed image orientation does not match the display orientation markers (right-left reversal).
Z-0455-2009	FC 500 with CXP Acquisition Software	2	08-01-2007	01-07-2009	Beckman Coulter Inc	Software error: The recall was initiated after Beckman Coulter identified that the CXP User documentation does not adequately characterize the use of the Live Gate feature.
Z-0320-2009	Somatom Sensation 40 X-Ray System	2	09-03-2008	01-05-2009	Siemens Medical Solutions USA Inc	software error – does not allow protocol to properly synchronize with ECG triggers
Z-0321-2009	Somatom Sensation 64 X-Ray System	2	09-03-2008	01-05-2009	Siemens Medical Solutions USA Inc	software error – does not allow protocol to properly synchronize with ECG triggers
Z-0285-2009	GE Healthcare Solar 8000M System	2	04-02-2008	01-05-2009	GE Healthcare	A software error has been discovered when using Combination Monitoring with Solar 8000M/i – PDM – Telemetry in combo mode. This error has only been noted with this particular configuration and mode of monitoring. It has not been observed in other monitoring applications. The software error will result in a reset of the Solar 8000M/i causing a loss of monitoring for approximately 1-2 minutes a
Z-0522-2009	Philips Diagnostic Ultrasound System	2	08-12-2008	12-31-2008	Philips Medical Systems	The system has a software defect that affects the display of Estimated Fetal Weight (EFW) Growth Percentile result values.
Z-0523-2009	Philips Diagnostic Ultrasound System	2	08-12-2008	12-31-2008	Philips Medical Systems	The system has a software defect that affects the display of Estimated Fetal Weight (EFW) Growth Percentile result values.
Z-0472-2009	GE Centricity Ultra Laboratory System	2	09-22-2008	12-31-2008	GE Healthcare Integrated IT Solutions	Software computer error: The abnormal result flag is not being sent in the HL7 messages on results that are lower than the normal range. For further information please telephone GE Healthcare Integrated IT Solutions at 800-437-1171.
Z-0449-2009	Hologic	2	09-24-2008	12-29-2008	Hologic Inc.	Software error may lead to a high estimate of major fracture probability
Z-0454-2009	Vidiera NsP Nucleic Sample Preparation	2	08-30-2007	12-16-2008	Beckman Coulter Inc	Incorrect results: under certain circumstances when transfer volume is not within the set range the Vidiera NsP software does not report sample exclusion and does not flag the excluded sample in the Run Results report.

Z-0460-2009	GE Centricity PACS RA1000 Workstation	2	09-25-2008	12-13-2008	GE Healthcare Integrated IT Solutions	Software anomalies result in patient safety issues involving patient jacket content intermittently becoming unintentionally out of synchronization with the images being displayed and involving Default Display Protocols (DDPs) which are used to layout images when displaying a study. If the user does not check the Study Date Time of the exam on the image title bar then they may interpret the curr
Z-0456-2009	Centricity Perinatal ((formerly Quantitative Sentinel) System – Alert and Reminder	2	09-25-2008	12-03-2008	GE Healthcare Integrated IT Solutions	Software anomalies in the Alert and Reminder feature could result in a delay of treatment. When attempting to select the last visible alert or reminder choice the next choice on the list below the desired choice is selected and an inconsistent color may be displayed for the same clinical element across a set of work stations.
Z-0195-2009	GSI AUDERA	2	09-16-2008	11-12-2008	Cardinal Health Inc	GSI Audera systems requires a system software update due to issues with the Split-Screen and the Vestibular Evoked Myogenic Potential (VEMP) functions.
Z-0213-2009	Mobile Care Server used in conjunction with Web Viewer Pocket Viewer and Cellular Viewer WT	2	07-16-2008	11-05-2008	GE Healthcare	Issue 1 -Possible failure of CIC Pro audible alarms: Requests for telemetry defaults from Mobile Care Server could cause excessive CIC Pro memory consumption. This excessive memory consumption may lead to potential loss of audio at the CIC or a system reset or reboot. Issue 2 – Mobile Care software/Mobile Viewers don not recognize ApexPro FH Telemetry transmitter: Mobile Care server does not ac
Z-0165-2009	Roche/Hitachi Modular E Module	2	06-24-2008	10-22-2008	Roche Diagnostics Corp.	A software bug may result in pipetting from an incorrect reagent pack and/or assigning calibration curve parameters incorrectly
Z-0164-2009	Varian RV Software	2	06-02-0008	10-22-2008	Varian Medical Systems Oncology Systems	A malfunction within the Varis software might result in a misadministration (underdose). The software does not correctly interpret the number causing field parameters having decimal values to be incorrect.
Z-0088-2009	Envision E700 Low Airloss Therapy	2	06-19-2008	10-07-2008	Hill-Rom Manufacturing Inc.	A defect in the software of the device may not allow the patient bed exam alarm or the patient movement alarm to function correctly.
Z-1751-2008	Siemens syngo Dynamics	2	02-08-2008	09-29-2008	Siemens Medical Solutions USA Inc	Incorrect data: A software bug may result in a transfer of patient demographic data to a different patient's file.
Z-1882-2008	GE Definium 8000	2	03-07-2008	09-25-2008	GE Healthcare	Radiation dose reading greater than actual dose: Error in the generator software on the GE Healthcare Revolution XR/d configured with HP 8200 PC consoles and all Definium 8000 systems may impact patient safety. Occasional generator software errors may cause light X-ray Images with reported mAs readings higher than was actually exposed to the patient using the overhead X-ray tube. The mAs rea
Z-1822-2008	GE Definium 8000	2	03-07-2008	09-25-2008	GE Healthcare	Loss of image data: Software anomaly in the Processing Software on the Definium 8000 system may impact patient safety when using the VolumeRAD advanced application (option). The slice visualization of VolumeRAD exams acquired on the Wallstand receptor will be offset by 17mm. This prevents the visualization of anatomy WITHIN a distance of 17mm from the wallstand patient barrier (receptor cover).
Z-2459-2008	NicoletOne 5.30.2 Software	2	06-13-2008	09-23-2008	Cardinal Health NeuroCare Division	NicoletOne 5.30.2 Software when used with CSeries amplifiers in Fixed Room LTM Configurations with patient room kits. Cardinal Health NeuroCare has confirmed that the 3rd party room relay connected to the A2 wall plate does not always activate if the patient event button connected to the CSeries Amplifier is pressed twice within one second.
Z-1612-2008	Eclipse TPS	2	02-13-2008	09-23-2008	Varian Medical Systems Oncology	A software error causes the wedge accessory calculation to be ignored in the radiotherapy treatment plan.
Z-2329-2008	SoftPath GUI Release Software Versions 3.17 and 4.1	2	02-23-2008	09-22-2008	SCC Soft Computer	Loss of text misrepresented individual tissue diagnosis on the final diagnosis print out from the HIS system software. The specimen heading J was removed and the diagnosis appeared under the specimen heading I as a result the specimen with the heading I had two diagnosis.
Z-2239-2008	ARCHITECT i1000SR System Assay CD ROM WW (excluding US)	2	06-16-2008	09-19-2008	Abbott Laboratories	When running the Automated Dilution Protocol with the assay files CMV IgG or Toxo IgG on the ARCHITECT i1000SR system a software error [9010 (Pipettor Robotics) preventing (Process Path) from operating] is generated and the instrument stops running. No results are generated.
Z-2184-2008	Hologic Discovery Bone	2	06-27-2008	09-17-2008	Hologic Inc.	Software densitometer readings for left hip and lumbar spine under certain conditions may be inaccurate.
Z-2308-2008	Eclipse V. 6.5	2	06-11-2008	09-17-2008	Varian Medical Systems Oncology Systems	Software anomaly in which swapping IDs of planning fields can produce inconsistencies between dose matrix and field parameters.
Z-2185-2008	Hologic QDR4500 Bone Densitometers	2	06-27-2008	09-17-2008	Hologic Inc.	Software densitometer readings for left hip and lumbar spine under certain conditions may be inaccurate.
Z-2188-1991	Hologic Qdsia Bone Densitometers	2	06-27-2008	09-17-2008	Hologic Inc.	Software densitometer readings for left hip and lumbar spine under certain conditions may be inaccurate.
Z-2186-2008	Hologic Delphi Bone Densitometers	2	06-27-2008	09-17-2008	Hologic Inc.	Software densitometer readings for left hip and lumbar spine under certain conditions may be inaccurate.
Z-2187-2008	Hologic Explorer Bone Densitometers	2	06-27-2008	09-17-2008	Hologic Inc.	Software densitometer readings for left hip and lumbar spine under certain conditions may be inaccurate.
Z-2095-2008	Coherence AG Therapist	2	05-15-2008	09-17-2008	Siemens Medical Solutions USA Inc	Software – Under certain circumstances the portal image may be overwritten which may lead to incorrect dosage.
Z-2098-2008	AG Therapist 3rd party V&R	2	05-15-2008	09-17-2008	Siemens Medical Solutions USA Inc	Software – Under certain circumstances the portal image may be overwritten which may lead to incorrect dosage.
Z-2097-2008	PRIMEVIEW 3i System	2	05-15-2008	09-17-2008	Siemens Medical Solutions USA Inc	Software – Under certain circumstances the portal image may be overwritten which may lead to incorrect dosage.
Z-2104-2008	PRIMEVIEW 3i System 2.1	2	05-15-2008	09-17-2008	Siemens Medical Solutions USA Inc	Software – Under certain circumstances the portal image may be overwritten which may lead to incorrect dosage.
Z-2099-2008	Impression Therapist 3rd party V&R	2	05-15-2008	09-17-2008	Siemens Medical Solutions USA Inc	Software – Under certain circumstances the portal image may be overwritten which may lead to incorrect dosage.
Z-2096-2008	Coherence Impression Therapist	2	05-15-2008	09-17-2008	Siemens Medical Solutions USA Inc	Software – Under certain circumstances the portal image may be overwritten which may lead to incorrect dosage.

Z-2103-2008	Coherence Therapist System 2.1	2	05-15-2008	09-17-2008	Siemens Medical Solutions USA Inc	Software - Under certain circumstances the portal image may be overwritten which may lead to incorrect dosage.
Z-2101-2008	Coherence Therapist 2.0	2	05-15-2008	09-17-2008	Siemens Medical Solutions USA Inc	Software - Under certain circumstances the portal image may be overwritten which may lead to incorrect dosage.
Z-2102-2008	PRIMEVIEW 3i System 2.0	2	05-15-2008	09-17-2008	Siemens Medical Solutions USA Inc	Software - Under certain circumstances the portal image may be overwritten which may lead to incorrect dosage.
Z-2100-2008	Syngo Based WS for 3rd party V&R	2	05-15-2008	09-17-2008	Siemens Medical Solutions USA Inc	Software - Under certain circumstances the portal image may be overwritten which may lead to incorrect dosage.
Z-1811-2008	Intuitive Surgical	2	04-18-0008	09-17-2008	Intuitive Surgical Inc.	The product has a software interface problem. When the product is connected to the da Vinci IS2000 System it will not allow the System to recognize the Instrument which makes the IS2000 CPG instrument nonfunctional at all sites. Risks associated are loss of operability of the instrument delay in surgery and loss of dexterity.
Z-2006-2008	Boston Scientific iReview Software	2	05-02-0008	09-17-2008	Boston Scientific Corporation	The firm initiated a recall of a specific iReview Software Ver 1.0 Kit which was released for distribution in a non-validated format.
Z-1804-2008	LIFEPAK) 12 defibrillator/monitor	2	04-16-2008	09-16-2008	Physio Control Inc.	The LIFEPAK 12 defibrillator / monitors with software version 130 have an increase in likelihood for an incorrect Shock Advisory Algorithm (SAS) decision if the Auto Analyze setting in AED mode is On leading to incorrectly render of shock or no shock decision. When Auto Analyze is set to On in AED mode the device initiates the SAS analysis immediately (no waiting period or warning prior to analys
Z-1806-2008	LIFEPAK) 20e defibrillator/monitor	2	04-16-2008	09-16-2008	Physio Control Inc.	The LIFEPAK 20e defibrillator / monitors with software versions 058 have an increase in likelihood for an incorrect Shock Advisory Algorithm (SAS) decision if the Auto Analyze setting in AED mode is On leading to incorrectly render of shock or no shock decision. When Auto Analyze is set to On in AED mode the device initiates the SAS analysis immediately (no waiting period or warning prior to anal
Z-1805-2008	LIFEPAK) 20 defibrillator/monitor	2	04-16-2008	09-16-2008	Physio Control Inc.	The LIFEPAK 20 defibrillator / monitors with software versions 048 052 and 054 have an increase in likelihood for an incorrect Shock Advisory Algorithm (SAS) decision if the Auto Analyze setting in AED mode is On leading to incorrectly render of shock or no shock decision. When Auto Analyze is set to On in AED mode the device initiates the SAS analysis immediately (no waiting period or warning p
Z-2183-2008	GE Centricity AW Suite Software version 2.0 and 2.0.1 with Card IQ Xpress Pro or Plus	2	06-11-2008	09-16-2008	GE Healthcare Integrated IT Solutions	When using any vessel analysis protocol of the AW Suite Card IQ application the software can reload saved tracking objects (Save State) incorrectly and display an incorrect vessel label over the restored images. This failure only occurs when users create a custom label in the vessel analysis protocol and include leading or trailing blank characters (space bar) in the custom label.
Z-2204-2008	da Vinci S Surgical System IS2000	2	06-01-2008	09-16-2008	Intuitive Surgical Inc.	Defective software chip may cause the system to fail and lock up.
Z-2203-2008	740 Series Multiparameter Monitor	2	06-24-2008	09-16-2008	CAS Medical Systems Inc.	Software: Audible alarm may be silenced if changed from the factory setting
Z-2211-2008	GE Signa) Excite 1.5T MR System GE Signa) Excite 3.0T MR	2	10-01-2007	09-16-2008	GE Healthcare	A software issue that may result in misregistration of functional and anatomical images associated with the 3.0T BrainwaveRT fMRI Application on the 3.0T Signa HDx scanner.
Z-2210-2008	GE 1.5T and 3.0T Signa) HDx MR	2	10-01-2007	09-16-2008	GE Healthcare	A software issue that may result in misregistration of functional and anatomical images associated with the 3.0T BrainwaveRT fMRI Application on the 3.0T Signa HDx scanner.
Z-1244-2008	WEB1000	2	05-14-2007	09-11-2008	AGFA Corp.	Java version 1.6x (JAVA 6) is not compatible with AGFA IMPAX Administration/Service Tools. Due to a Software Mismatch data can be lost.
Z-1243-2008	IMPAX	2	05-14-2007	09-11-2008	AGFA Corp.	Java version 1.6x (JAVA 6) is not compatible with AGFA IMPAX Administration/Service Tools. Due to a Software Mismatch data can be lost.
Z-1316-2008	Stryker Digital Capture System Ultra (SDC Ultra)	2	02-15-2008	09-11-2008	Stryker Endoscopy	Patient identification numbers and names may be applied to images from another patient due to a software issue. This failure mode can only occur when the pre-load function of the SDC ultra is used.
Z-2231-2008	ARCHITECT c8000 Clinical Analyzer	2	05-23-2008	09-11-2008	Abbott Laboratories Inc	Software defect can allow tests ordered for one sample to be aspirated from a different sample reporting erroneous results for the affected sample.
Z-2227-2008	Panda) iRes and Giraffe) Infant Warmers	2	05-20-2008	09-11-2008	Datex Ohmeda Inc. dba GE Healthcare	Medical device software may be subject to signal interference of the Hands Free Alarm Silence feature that could impact patient safety.
Z-1826-2008	GE Centricity PACS RA1000 Workstation	2	05-06-2008	09-02-2008	GE Healthcare Integrated IT Solutions	A software anomaly results in incorrect study date and time information being displayed in the report screen and title which may result in a potential patient misdiagnosis.
Z-1776-2008	Q-Logic Controller Software	2	04-11-2008	08-27-2008	Pride Mobility Products Corp	Software - Watch dog timer feature was disabled.
Z-1640-2008	Logix TPN Software Solution	2	03-28-2008	08-24-2008	Baxter Healthcare Corp.	Software anomaly results in inaccurate information being printed out on the Delivery Report even though the compounder performed the compounding correctly.
Z-1695-2008	AMO WaveScan WaveFront System v3.65	2	11-17-2006	08-20-2008	VISX INCORPORATED A SUBSIDIARY OF AMO INC	Firm became aware of a significant overcorrection in one eye of a patient who had received a wavefront-guided LASIK treatment at a facility in Germany. The probability of a recurrence of this error was determined to be extremely remote. To ensure that this type of incident will not happen again a software update was developed.
Z-1769-2008	Siemens	2	10-03-0007	08-20-2008	Siemens Medical Solutions USA Inc	Software, The firm issued an Advisory Letter Update instruction TH030/07/S as a result of a complaint that images viewed in the device may shift which could result in mistreatment. The advisory alerts all its affected customers of the image issue to prevent potential mistreatment.
Z-1925-2008	BD Biosciences FACSDiva Software Versions 4.0.1 to 5.0.2	2	04-05-2007	08-16-2008	BD Biosciences	When data file containing one or no fluorescence parameters is exported the software will automatically apply compensation to this file and all subsequently exported files.
Z-1515-2008	MOSAIQ versions 1.3 and 1.4	2	02-14-2008	08-16-2008	Impac Medical Systems Inc	Software issue may result in change to intended treatment field potentially resulting in mistreatment.
Z-1442-2008	Varian Medical Systems On-Board Imager Versions 1.0.15 and 1.2.05	2	01-03-2008	08-15-2008	Varian Medical Systems Oncology Systems	If used with a third party radiation therapy treatment planning software system mistreatment may occur because of a misalignment.
Z-1529-2008	CytoFLEX S 500 Flow Cytometry System with Data Innovations Instrument	2	08-20-2007	08-08-2008	Beckman Coulter Inc	Labeling provided by two integrated software systems are not clear enough to avoid potential demographic and sample type mismatches under certain conditions.
Z-1459-2008	High-Definition 120 MultiLeaf Collimator	2	01-30-2008	08-02-2008	Varian Medical Systems Oncology Systems	Dose Calculation Error: Software anomaly may result in failure of a MLC leaf to reach planned position potentially resulting in misadministration of dose to a patient.
Z-1138-2008	syngo US Workplace	2	12-06-2007	05-20-2008	Siemens Medical Solutions USA Inc.	Inaccurate results: A software bug may cause inaccurate wall motion abnormality scoring results to be displayed.
Z-0661-2008	ACUSON Sequoia Diagnostic Ultrasound System	2	09-25-2007	04-24-2008	Siemens Medical Solutions USA Inc.	Measurement Error affecting all Sequoia systems using the PAL video standard configuration and have a perspective PC installed: 1) The Sequoia system is operating at a software revision below 8.0. 2) The Sequoia system is configured to PAL video mode (normal for systems running at 240V 50 Hz.). 3) While using any of the Perspective advanced display options listed above an image or clip is t
Z-0575-2008	BioPlex 2200	2	11-13-2007	04-22-2008	Bio-Rad Laboratories Inc	Incorrect values: An error was found in the BioPlex 2200 Software Version 2.0 that results in assignment values being utilized for the BioPlex assay Calibrator Set that may be slightly different from those printed on the Value Assignment Data Sheet. Some values may be identical between the lot assignment combinations with the ANA Screen with MDSS kit.
Z-1349-2008	Agfa IMPAX CardioVascular Suite Results Management	2	02-22-2008	03-31-2008	AGFA Corp.	Reporting Differences: The Outbound Report software produces an Outbound Report (text version) which does not contain all the clinical content elements present in the PDF version of the report also generated on the Nuclear Cardiology Reporting Module.
Z-0571-2008	Ventana Image Analysis System (VIAS)	2	06-26-2007	03-18-2008	Ventana Medical Systems Inc	Incomplete upgrade: The software upgrade from February 1 2007 may not have been
Z-0570-2008	MultiSET	2	09-06-2007	03-04-2008	BD Biosciences	Inaccurate results: Software error results in inaccurate display result statistics. If the user adjusts the lymph gate or attractors in the Lab Report view without using the Manual Gate function (as described in the system manual) the statistic results will not be updated to match the adjusted gate.
Z-0134-2008	Sentry Pro Medication Safety Software	2	08-14-2007	02-26-2008	Smiths Medical MD Inc.	Incorrect dosage possible: A software anomaly in the CADD-Sentry Pro Administrator software (version B) where the values of a weight based protocol go to zero or round up to the next higher hundredths place even if Administrator displayed the values correctly at data entry.
Z-0079-2008	daVinci S Surgical System IS2000	2	03-30-2007	02-21-2008	Intuitive Surgical Inc.	System Lock-Up: Software anomalies could cause product failure during use or on start-up. System transitions to a safe soft-lock state.
Z-0719-2008	ACUSON Aspen Diagnostic Ultrasound System	2	09-18-2007	02-15-2008	Siemens Medical Solutions USA Inc.	Software error: Error affects all Aspen customer systems using the PAL video standard configuration and have a Perspective PC installed. This can lead to a measurement error under this specific condition: On secondary capture images/clips stored from within any Perspective advanced display option (specifically: 3D Surface Rendering 3D MultiPlanar Reconstruction Color Doppler 3D MultiPlanar Reco
Z-0720-2008	VARiS PRT Exchange	2	10-02-2007	02-15-2008	Varian Medical Systems Inc	Incorrect Software Validation: The ARC treatment plans containing a Dose Dynamic MLC for IMRT delivery that will not be recognized properly by the system. Under these circumstances an arc plan can be administered to a patient whereby the gantry will not rotate resulting in delivery to a single location rather than through the gantry arc.
Z-0676-2008	Precedence SPECT/CT System	2	09-28-2007	02-08-2008	Philips Nuclear Medicine	Incorrect Measurement: The firm discovered a software defect in Cardiac and Pulmonary Viewer software application options used in the Precedence CT Sub-System. The defect causes incorrect measurements in derived images which are zoomed and saved in a batch file.
Z-0554-2008	Varian RPM System version 1.7.3	2	09-26-2007	01-29-2008	Varian Medical Systems Inc	Erroneously Resetting: RPM System version 1.7.3 software failure can occur that affects the gated radiotherapy treatment when phase-based gating is used. RPM 1.7 erroneously resets the phase-based gating thresholds to system default during the treatment session if the user accesses the Session options during the treatment session. This can lead to difference between the planned and delivered
Z-0527-2008	RenalSoft	2	11-14-2007	01-26-2008	Baxter Healthcare Renal Div	Pre-Treatment/Post-Treatment Report errors: 1) The Heparin Bolus Value is displayed on Pre and Post Treatment Reports for patients with No Heparin orders (RenalSoft v2.0 Renal Software Suite v.3.0 and v.3.1) and 2) Withheld Medications are incorrectly displayed as Administered on the Pre-Treatment report (RenalSoft v.2.0 only).
Z-0528-2008	RenalSoft	2	11-14-2007	01-26-2008	Baxter Healthcare Renal Div	Pre-Treatment/Post-Treatment Report errors: 1) The Heparin Bolus Value is displayed on Pre and Post Treatment Reports for patients with No Heparin orders (RenalSoft v2.0 Renal Software Suite v.3.0 and v.3.1) and 2) Withheld Medications are incorrectly displayed as Administered on the Pre-Treatment report (RenalSoft v.2.0 only).
Z-0592-2008	Hoana LifeBed	2	11-07-2007	01-24-2008	Hoana Medical	Bed Exit Failure: Failure to recognize Bed Exit when the feature is active due to a software anomaly.

Z-0365-2008	WaveScan WaveFront System	2	05-30-2007	01-23-2008	Visx Inc	Erroneous Treatment Calculations – Two software caused errors; in combination in the WaveScan System Software will result in an erroneous treatment calculation (overcorrection) in patients. (1) Installation of software for a certain brand of computer (Dedicated Computing LLC) can cause a software registry setting for an algorithm that identifies image reflection to be erroneously set in the off
Z-0298-2008	SONOLINE Antares	2	07-10-2007	01-09-2008	Siemens Medical Solutions USA Inc.	Image error: A software problem results in on-screen indications (graphics) that lead the user to believe that the patient's right and left and the transducer orientation are oriented the same. This is not the case and the actual patient's right and left are reversed from the on-screen
Z-0297-2008	ACUSON Antares Ultrasound sytem and premium edition	2	07-10-2007	01-09-2008	Siemens Medical Solutions USA Inc.	Image error: A software problem results in on-screen indications (graphics) that lead the user to believe that the patient's right and left and the transducer orientation are oriented the same. This is not the case and the actual patient's right and left are reversed from the on-screen
Z-0148-2008	Eye Cubed Ultrasound System	2	09-25-2007	12-28-2007	Ellex Inc.	Incorrect IOL calculations: software behavior with Version 3.0 Eye Cubed Ultrasound systems running Biometry A-scan enabled Version 3.0.0 software can cause incorrect IOL
Z-0364-2008	CyberKnife Robotic Radiosurgery System	2	03-21-0007	12-12-2007	Accuray Inc	Software problem – Sagittal oblique or coronal sliced MR Images imported from a non-Accuray manufactured device into the product may result in inverted image orientation.
Z-0269-2008	ECAT ACCEL	2	07-23-2007	11-29-2007	Siemens Medical Solutions USA Inc	Incorrect Decay Correction Results – ECAT System's software versions 7.2.2 and 7.4 calculate the decay correction for emission data incorrectly while performing whole-body studies with all transmissions followed by all emissions.
Z-0270-2008	ECAT ART	2	07-23-2007	11-29-2007	Siemens Medical Solutions USA Inc	Incorrect Decay Correction Results – ECAT System's software versions 7.2.2 and 7.4 calculate the decay correction for emission data incorrectly while performing whole-body studies with all transmissions followed by all emissions.
Z-0272-2008	ECAT EXACT HR 47	2	07-23-2007	11-29-2007	Siemens Medical Solutions USA Inc	Incorrect Decay Correction Results – ECAT System's software versions 7.2.2 and 7.4 calculate the decay correction for emission data incorrectly while performing whole-body studies with all transmissions followed by all emissions.
Z-0271-2008	ECAT EXACT 47	2	07-23-2007	11-29-2007	Siemens Medical Solutions USA Inc	Incorrect Decay Correction Results – ECAT System's software versions 7.2.2 and 7.4 calculate the decay correction for emission data incorrectly while performing whole-body studies with all transmissions followed by all emissions.
Z-0273-2008	ECAT EXACT HR+	2	07-23-2007	11-29-2007	Siemens Medical Solutions USA Inc	Incorrect Data Results – ECAT System's software versions 7.2.2 and 7.4 may calculate the decay correction for emission data incorrectly while performing whole-body studies with all transmissions followed by all emissions.
Z-0265-2008	GE Healthcare Advantage Workstations	2	09-10-2007	11-28-2007	GE Healthcare	Aortic Length over-estimated. Incorrect measurements when using the Aorta analysis protocol or customized protocols. Until a new software version is installed the aorta analysis protocol or the customized protocols for an aneurysm should NOT BE
Z-0293-2008	Digital Radiography System with Flat Panel	2	10-01-2007	11-27-2007	Toshiba American Med Sys Inc	System Lock-up: When performing DAS One Shot the system may lockup due to a software timing error.
Z-0294-2008	Medtronic O-arm Imaging System	2	10-17-2007	11-27-2007	Medtronic Navigation Inc	Reversed Instrument Position : a defect in the software version 3.0 causes an error in the position of surgical instruments and relative motion are reversed 180° on the StealthStation image. (If the StealthStation is not used or if the patient orientation is prone or supine the problem does not occur)
Z-0257-2008	ACCELERATOR APS System	2	10-10-2007	11-24-2007	Abbott Laboratories Inc	Sample problems; Five issues identified related to software utilized by the ACCELERATOR APS System Input/Output Module to include: Under three specific conditions the post-aspiration radio-frequency identification (RF ID) read of the tube carrier is not performed and the APS work cell may not appropriately generate Sample Presentation/Sample Queue errors with APS software version 1.1.1 or earlie
Z-0180-2008	VoxelQ Workstation Imaging Workstation	2	03-01-2007	11-21-2007	Philips Medical Systems (Cleveland) Inc	Incorrect simulation and/or beam placement: An anomaly has been identified with the Philips VoxelQ workstation utilizing AcQPlan software version 4.2 4.2.1 4.9 4.9.1 4.9.2 4.9.3 5.0 5.0.1 5.0.2 or 5.0.3 when computing absolute patient marking coordinates with data containing reconstruction offsets from the Mx800 the Mx8001DT and the Brilliance 6 10 16 16P and Big Bore CT systems. Whe
Z-0146-2008	ARCHITECT cSystem	2	09-05-2007	11-07-2007	Abbott Laboratories Inc	Incorrect Sample/Test Identification: Due to a software timing defect with certain versions of ARCHITECT cSystem Software test results may be incorrectly associated to a Sample Identification during specific sample-processing conditions of the Robotic Sample Handler.
Z-0147-2008	ARCHITECT cSystem	2	09-05-2007	11-07-2007	Abbott Laboratories Inc	Incorrect Sample/Test Identification: Due to a software timing defect with certain versions of ARCHITECT cSystem Software test results may be incorrectly associated to a Sample Identification during specific sample-processing conditions of the Robotic Sample Handler.
Z-0121-2008	Brilliance CT Big Bore	2	09-27-2007	11-07-2007	Philips Medical Systems (Cleveland) Inc	The maximum intensity projection (MIP) images produced from respiratory gated images by the Tumor Localization (Tumor LOC) software application on Brilliance Big Bore CT scanners will be labeled incorrectly for certain patient orientations and view conventions when saved for later viewing
Z-0040-2008	Interstim for Urinary Control	2	06-25-2007	10-12-2007	Medtronic Neuromodulation	Software issue may cause false low battery alert to be displayed when interrogating an Interstim Implantable Neurostimulator (Model 3023) with an N'Vision Clinician Programmer (Model 8840) or with an Inter Stim iCon Patient
Z-0037-2008	Interstim for Urinary Control	2	06-25-2007	10-11-2007	Medtronic Neuromodulation	A software issue may cause a lower than expected battery capacity estimate when evaluating an InterStim II Implantable Neurostimulator (model 3058) with an N'Vision Clinician Programmer(Model 8840) before implant
Z-1244-2007	daVinci Surgical System Model IS1200 A4.3 SW level	2	05-03-0007	03-26-2007	Intuitive Surgical Inc.	Under certain circumstances the product's software may crash and require a manual override or restart before functioning again. In addition there is an unrelated addendum to the User Manual to clarify an icon not described in the previous User

Z-1212-2007	Fully-Integrated Radiation Therapy Planning	2	08-21-2007	09-25-2007	Philips Nuclear Medicine Inc.	Incorrect Absolute Marking Coordinates when used with PQ-Series scanners due to a software malfunction
Z-1201-2007	ABL80 FLEX	2	06-04-2007	08-29-2007	Sendx Medical Inc	The ABL80 FLEX software version 1.10 contains errors in the derived parameter calculation for cBase(Box) and cBase(Ecfox). These incorrect calculations result in a mild to moderate lowering of the base excess value the severity depending on the concentration of hemoglobin and the oxygen saturation in the sample. Elevated hemoglobin concentrations have the greatest impact on this calculation err
Z-1171-2007	CELL-DYN 1700 Hematology Analyzer	2	05-16-2007	08-18-2007	Abbott Laboratories	Abnormal results may not be flagged appropriately because of a software anomaly. (Flags for the Hemoglobin (HGB) MCH and MCHC parameters when the upper assay paramter limit has been exceeded)
Z-1170-2007	CELL-DYN 1700 Hematology Analyzer	2	05-16-2007	08-18-2007	Abbott Laboratories	Abnormal results may not be flagged appropriately because of a software anomaly. (Flags for the Hemoglobin (HGB) MCH and MCHC parameters when the upper assay paramter limit has been exceeded)
Z-1167-2007	VITROS? 5 1 FS Chemistry System	2	05-17-2007	08-16-2007	Ortho-Clinical Diagnostics	Software design. The firm received a customer complaint regarding a qualitative positive THC (Cannabinoids) result obtained from a THC quality control fluid that was known to be negative when using VITROS? Chemistry Products THC Reagent. A second customer complaint was received a month later. OCD's investigation concluded that under specific circumstances incorrect qualitative results for Cannabi
Z-1154-2007	ISOLOC	2	12-30-2004	08-08-2007	Northwest Medical Physics Equipment Inc	When ISOLOC version 6.0 software was used in the Anatomic Landmark mode the couch moves display in the Couch Translator window was incorrect.
Z-1146-2007	ISOLOC	2	04-07-2006	08-08-2007	Northwest Medical Physics Equipment Inc	This correction was for several software bugs which caused image format problems; incorrect ruler display; software crashes; failure to update pixel spacing; display of unattainable treatment table positions; failure to update gantry angles; wrong shifts for two of three axes of treatment table movement.
Z-1145-2007	Image guided radiation treatment software.	2	01-02-2006	08-08-2007	Northwest Medical Physics Equipment Inc	Isoloc version 6.5 and 4.5 software issued a false warning message regarding Gantry angles when set to Anatomic Landmark setting.
Z-1106-2007	Amplilink	2	05-21-2007	08-02-2007	Roche Molecular Systems Inc.	For select COBAS AMPLICOR Tests run on the COBAS AMPLICOR Analyzer in conjunction with AMPLILINK software a discrepancy has been identified between the onboard working reagent stability information reported by AMPLILINK Software (versions 1.1 1.3 1.4 and 2.41) and the stability information provided in the test kit package inserts/method manual.
Z-1107-2007	Amplilink	2	05-21-2007	08-02-2007	Roche Molecular Systems Inc.	For select COBAS AMPLICOR Tests run on the COBAS AMPLICOR Analyzer in conjunction with AMPLILINK software a discrepancy has been identified between the onboard working reagent stability information reported by AMPLILINK Software (versions 1.1 1.3 1.4 and 2.41) and the stability information provided in the test kit package inserts/method manual.
Z-1044-2007	GE Healthcare Innova 3100/ 3100 IQ	2	03-26-2007	07-10-2007	General Electric Med Systems LLC	Caution on the non-detection of small invasive objects devices which project out from the skin surfaces (e.g. biopsy or other needles) while using the Innova Sense software option designed for patient contouring. Usage of Innova Sense patient contouring for such devices could potentially lead to patient
Z-1043-2007	GE Healthcare Innova 2100 IQ	2	03-26-2007	07-10-2007	General Electric Med Systems LLC	Caution on the non-detection of small invasive objects devices which project out from the skin surfaces (e.g. biopsy or other needles) while using the Innova Sense software option designed for patient contouring. Usage of Innova Sense patient contouring for such devices could potentially lead to patient
Z-1000-2007	Viatron T-Series Dual Chamber pacemakers	2	02-05-2007	07-07-2007	Medtronic Inc. Cardiac Rhythm Managment	Pacing rate; Software anomaly affecting Viatron dual chamber C-series and T-series pacemakers related to automatic retrograde conduction testing can inhibit the device from pacing if the patient's intrinsic rate falls below the programmed lower
Z-0999-2007	Viatron C-Series dual chamber Rate Responsive Pacemakers	2	02-05-2007	07-07-2007	Medtronic Inc. Cardiac Rhythm Managment	Pacing rate; Software anomaly affecting Viatron dual chamber C-series and T-series pacemakers related to automatic retrograde conduction testing can inhibit the device from pacing if the patient's intrinsic rate falls below the programmed lower rate.
Z-0966-2007	Invacare Storm TDX Power Wheelchair	2	03-19-2007	07-04-2007	Invacare Corporation	Software error may permit the chair to recline too far.
Z-1010-2007	BrainLAB Target Positioner for Leksell Headring	2	06-05-2007	07-03-2007	Brainlab AG	Target Alignment Error : A mechanical component/software incompatibility caused by a specific combination of the BrainLAB Target Positioner version 40700-3A for Leksell headrings and BrainLAB planning software resulted in a 1.25 mm shift in target area alignment during radiosurgery treatment.
Z-0978-2007	LINAC aka FastPlan Treatment Planning Sysytem	2	03-09-2007	06-28-2007	Varian Medical Systems Inc	A software anomaly in a medical device used for patient treatment could result in accidental or unintended exposure radiation exposure. The tilt rotation compensation algorithm does not adequately compensate for the tilt rotation.
Z-0953-2007	ARCHITECT c16000	2	04-30-2007	06-19-2007	Abbott Laboratories Inc	One or more of four software issues : 1) calculation error for Architect cSystem assays using the Spline math model. 2) The system configuration option Run controls onboard reagents by Kit does not function correctly for assays requiring a standard sample dilution. 3) Infrequent data may be missing from automatically or manually printed reports generated on the Architect system. 4) Clinical Chem
Z-0952-2007	ARCHITECT c8000	2	04-30-2007	06-19-2007	Abbott Laboratories Inc	One or more of four software issues : 1) calculation error for Architect cSystem assays using the Spline math model. 2) The system configuration option Run controls onboard reagents by Kit does not function correctly for assays requiring a standard sample dilution. 3) Infrequent data may be missing from automatically or manually printed reports generated on the Architect system. 4) Clinical Chem

Z-0950-2007		ARCHITECT i2000		2	04-30-2007	06-19-2007	Abbott Laboratories Inc	One or more of four software issues : 1) calculation error for Architect cSystem assays using the Spline math model. 2) The system configuration option Run controls onboard reagents by Kit does not function correctly for assays requiring a standard sample dilution. 3) Infrequent data may be missing from automatically or manually printed reports generated on the Architect system. 4) Clinical Chem
Z-0951-2007		ARCHITECT i2000sr		2	04-30-2007	06-19-2007	Abbott Laboratories Inc	One or more of four software issues : 1) calculation error for Architect cSystem assays using the Spline math model. 2) The system configuration option Run controls onboard reagents by Kit does not function correctly for assays requiring a standard sample dilution. 3) Infrequent data may be missing from automatically or manually printed reports generated on the Architect system. 4) Clinical Chem
Z-0925-2007		LIFEPAK 20 Defibrillator/monitor		2	04-27-2007	06-09-2007	Medtronic Emergency Response Systems Inc.	White Screen Lock up: LifePak 20 defibrillators with software version 46 or version 52 may experience an intermittent timing issue during the power on sequence. This may lock up the device resulting in the monitor screen going white and may cause a potential delay or prevention of shock treatment.
Z-0891-2007		CIC Pro System		2	01-24-2007	06-06-2007	General Electric Medical Systems Information Technology	Alarm and Reboot problems: Two separate issues could occur with the CIC Pro system when used with Telemetry. Each issue occurs in software version v4.1 only: A) the system may experience a loss of audible alarms when operating system memory resources reach 170MB and/or B) the system may intentionally or unexpectedly reboot.
Z-0905-2007		FramelessArray software		2	03-14-2007	06-06-2007	Varian Medical Systems Oncology Systems	Localization error: with planning data transferred to the Optical Guidance Platform via DICOM RT; The software incorrectly computes the center of the CT volume resulting in a potential axial error ranging from 0.3 mm to 1.5 mm affecting both Fractionated and Stereotactic Radiosurgery (SRS) Treatments
Z-0870-2007		GE Healthcare Innova 3100/ 3100 IQ		2	03-26-2007	06-05-2007	General Electric Med Systems LLC	Measurement errors during the computation of vessel diameters while using the Stenosis Analysis software (also known as Quantitative Coronary Analysis function-QCA) using the auto-calibration function on Innova Digital (located in control room) or in-room InnovaCentral/Touch-Screen
Z-0869-2007		GE Healthcare Innova 4100/4100 IQ		2	03-26-2007	06-05-2007	General Electric Med Systems LLC	Measurement errors during the computation of vessel diameters while using the Stenosis Analysis software (also known as Quantitative Coronary Analysis function-QCA) using the auto-calibration function on Innova Digital (located in control room) or in-room InnovaCentral/Touch-Screen
Z-0871-2007		GE Healthcare Innova 2100 IQ		2	03-26-2007	06-05-2007	General Electric Med Systems LLC	Measurement errors during the computation of vessel diameters while using the Stenosis Analysis software (also known as Quantitative Coronary Analysis function-QCA) using the auto-calibration function on Innova Digital (located in control room) or in-room InnovaCentral/Touch-Screen
Z-0709-2007		Precision Link Software		2	12-18-2006	05-23-2007	Abbott Diabetes Care Inc.	If the time and date are not set correctly on both the user's meter and computer there is the potential for incorrect times and dates to be assigned to the results in the Precision Link Software.
Z-0815-2007		EXCITE		2	06-01-2006	05-18-2007	GE Medical Systems LLC	To provide the 3.0T MRI systems users with the 8-channel brain coil the proper coil weighting software. The proper coil weighting factors for the eight-channel brain coil were not included in the software.
Z-0766-2007		Medfusion 3500		2	02-03-2007	04-26-2007	Smiths Medical MD Inc.	Software anomaly that causes the pump to experience a sudden and unexpected failure. This anomaly occurs during the pump's startup sequence when the pump's Preventative Maintenance Alarm goes off preventing the pump from completing its power up routine. Lock-up occurs and the pump
Z-0705-2007		ABL800 Series analyzer with FLEXQ module		2	01-16-2007	04-05-2007	Radiometer America Inc	In some situations pre-registered patient data is not reset when leaving the pre-registration mode in the software. This occurs when a Safe Pico blood sampler associated with a specific patient is pre-registered in the analyzer by scanning a barcode.
Z-0704-2007		InstaTrak 3500 Plus system		2	01-26-2005	03-30-2007	GE OEC Medical SystemsInc	Tracking inaccuracy of 5-10 mm may result when the shunt guide accessory is used with version 5.1 software.
Z-0671-2007		LIFEPAK		2	03-02-2007	03-29-2007	Medtronic Emergency Response Systems Inc.	LIFEPAK CR Plus defibrillators with software version 1.16 or lower may miscalculate the HLC battery capacity and result in the CHARGE-PAK battery charger icon/indicator to display and falsely indicate battery needs replacement.
Z-0652-2007		syngo Dynamics		2	01-31-2007	03-28-2007	Siemens Medical Solutions USA Inc	The cardiac calculation feature may incorrectly calculate a derived V max value (reported out lower than it should be) and certain values imported into worksheets and reports may be incorrect due to a software defect.
Z-0397-2007		Portrait/		2	10-02-2006	02-01-2007	Rhytec Inc.	Inadequate Directions for Use: Software Upgrade to set maximum energy level at 2.5 Hz
Z-0381-2007		Terumo APS 1		2	11-08-2006	02-01-2007	Terumo Cardiovascular Systems Corp	Following installation of software version 1.30 in October 2006 the firm confirmed a complaint that the new software caused a discrepancy in the pump speed calculation and caused the pump to stop during clinical use and a "connect motor" message to be displayed.
Z-0373-2007		GE Centricity PACS RA1000 Workstation		2	01-12-2007	01-25-2007	GE Healthcare Integrated IT Solutions	The Centricity PACS RA1000 Workstation Software may manifest certain mammography image display problems only if the images were acquired through GE Senographe versions 2000D DS or Essential.
Z-0314-2007		Terumo APS 1		2	05-01-2004	12-27-2006	Terumo Cardiovascular Systems Corp	The gas system may fail calibration prior to use due to incorrect gas system flowmeter software.
Z-0315-2007		Terumo APS 1		2	05-01-2004	12-27-2006	Terumo Cardiovascular Systems Corp	The gas system may fail calibration prior to use due to incorrect gas system flowmeter software.
Z-0296-2007		APS III		2	10-06-2006	12-19-2006	St Jude Medical CRMD	St. Jude Medical has identified a low-frequency anomaly in the software used in the APS III Model 3500/3510 and Merlin PCS Model 3650 programmers that can lead to incorrect reporting of battery voltage expected battery longevity and Elective Replacement Indicator (ERI) status.
Z-0298-2007		Identity		2	10-06-2006	12-19-2006	St Jude Medical CRMD	St. Jude Medical has identified a low-frequency anomaly in the software used in the APS III Model 3500/3510 and Merlin PCS Model 3650 programmers that can lead to incorrect reporting of battery voltage expected battery longevity and Elective Replacement Indicator (ERI) status.
Z-0297-2007		Merlin PCS Programmer		2	10-06-2006	12-19-2006	St Jude Medical CRMD	St. Jude Medical has identified a low-frequency anomaly in the software used in the APS III Model 3500/3510 and Merlin PCS Model 3650 programmers that can lead to incorrect reporting of battery voltage expected battery longevity and Elective Replacement Indicator (ERI) status.
Z-0223-2007		Roche Modular Drive		2	11-03-2006	11-29-2006	Data Innovations Inc.	Software of modular driver may incorrectly report patient results as Quality Control Results
Z-0224-2007		Roche Cobas driver		2	11-03-2006	11-29-2006	Data Innovations Inc	Software of modular driver may incorrectly report patient results as Quality Control Results
Z-0197-2007		Cytomics Flow Cytometry System		2	07-26-2006	11-21-2006	Beckman Coulter Inc	Mis-identification-If a panel or protocol is added to an existing worklist but the tube location is not specified the CXP Acquisition software will run the last specified tube through the remaining protocols and will generate results and printouts of these runs leading to a Mis-Identification condition.
Z-1516-06		ADVIA Centaur CP System		2	08-04-2006	09-23-2006	Bayer Healthcare LLC (Diagnostics Division)	Under a specific configuration of software, the system can associate a test result and sample identification (SID) with an incorrect patient name when the Patient Demographics feature is used and the Patient Identification (PID) field is left
Z-1502-06		LIFEPAK		2	08-30-2006	09-13-2006	Medtronic Emergency Response Systems Inc.	Devices with v38 system software do not display a "LOW BATTERY: CONNECT TO AC POWER" message when the monitor is on backup (DC) battery power and may shut down without warning.
Z-1398-06		GammaMed software		2	05-01-2006	08-10-2006	Varian Medical Systems	Software control program for a medical device used in radiation treatment may cause practitioners to incorrectly administer the treatment plan to cancer patients. There is a hazard when entering the treatment plans manually that the user neglects to change the default step size and/or the origin or accidentally enters incorrect parameters.
Z-1399-06		GammaMed software		2	05-01-2006	08-10-2006	Varian Medical Systems	Software control program for a medical device used in radiation treatment may cause practitioners to incorrectly administer the treatment plan to cancer patients. There is a hazard when entering the treatment plans manually that the user neglects to change the default step size and/or the origin or accidentally enters incorrect parameters.
Z-1375-06		VARiS Version 6.6		2	09-20-2005	08-05-2006	Varian Medical Systems Oncology Systems	A software anomaly may occur which can lead to patient treatment with the wrong field. The anomaly is reported only to occur when this software version (6.6.5022) is used with Elekta or Siemens linear accelerators.
Z-1310-06		VIGILANCE MONITOR		2	06-21-2006	08-02-2006	Edwards Lifesciences Llc	Edwards Lifesciences Vigilance monitors with software release 5.3 or earlier may improperly cause the monitor to deliver power to the Continuous Cardiac Output (CCO) catheter without alerting the user to this situation. This can result in overheating and thermal damage to the CCO catheter and serious patient injury.
Z-1317-06		Blood Gas and Co-Ox Electrolyte & Metabolyte Analyzers		2	06-17-2005	08-02-2006	Radiometer America Inc	Software defect. pO2 and pCO2 sample test results run on the firm's ABL700/800 Series Blood Gas Analyzers are not being properly flagged during the sample calibration phase.
Z-1318-06		Blood Gas and Co-Ox Electrolyte & Metabolyte Analyzer.		2	06-17-2005	08-02-2006	Radiometer America Inc	Software defect. pO2 and pCO2 sample test results run on the firm's ABL700/800 Series Blood Gas Analyzers are not being properly flagged during the sample calibration phase.
Z-1305-06		TriActiv ProGuard Embolic Protection System		2	04-06-2006	07-28-2006	Kensey Nash Corp	Alarm activation-A priming issue involving the flow control unit due to a software problem has caused false postive Extraction Line Block (ELB) alarming. Use of this product may result in a health hazard resulting from early termination of the flush and extraction procedure after stenting.
Z-1262-06		Radiance STAT Analyzer Management System		2	03-02-2005	07-27-2006	Radiometer America Inc	Software anomaly. Data generated by blood gas equipment did not correlate with data shown in the Radiance Data Management System.
Z-1270-06		GammaWin		2	05-01-2006	07-27-2006	Varian Medical Systems	Medical device software for brachytherapy may cause erroneous data to be recorded and affect patient radiation treatments. Erroneous data may be listed on the treatment history report and the default step size may lead to a misadministration if treatment data is entered manually.
Z-1269-06		GammaWin		2	05-01-2006	07-27-2006	Varian Medical Systems	Medical device software for brachytherapy may cause erroneous data to be recorded and affect patient radiation treatments. Erroneous data may be listed on the treatment history report and the default step size may lead to a misadministration if treatment data is entered manually.
Z-1268-06		GammaWin		2	05-01-2006	07-27-2006	Varian Medical Systems	Medical device software for brachytherapy may cause erroneous data to be recorded and affect patient radiation treatments. Erroneous data may be listed on the treatment history report and the default step size may lead to a misadministration if treatment data is entered manually.
Z-1161-06		OBSERVA		2	03-28-2006	06-22-2006	bioMerieux Inc	Software problem with scanner inter-character delay which may result in false positive or false negative results after incorrect scanning of bottle ID's.
Z-1147-06		LADARVision Excimer Laser System.		2	08-01-2005	06-21-2006	Alcon Laboratories Inc.	Alcon has identified a software error associated with the use of the Measuring Mode (ruler tool) on the LADARVision4000 Excimer Laser Systems. Use of this feature after alignment of the horizontal reference line will negate compensation for cyclotorsion on CustomCornea procedures possibly adversely affecting clinical outcomes.
Z-1105-06		MRP-7000 AIRIS magnetic resonance imaging devices		2	03-17-2006	06-10-2006	Hitachi Medical Systems America Inc	Software anomaly. A software defect in the referenced systems can cause a slice indicator (reference line) to be mis-positioned on the cross-reference image when it is magnified. This image error could result in a possible patient mis-diagnosis.
Z-1104-06		AIRIS II Altaire Magnetic Resonance Imaging Devices		2	04-28-2006	06-10-2006	Hitachi Medical Systems America Inc	Software anomaly-A software defect can cause the slice line indicator to become mis-positioned during Multi-Planar Reconstructions (MPR) with the potential for patient mis-diagnosis.
Z-1079-06		CXR-4CT (including Scepter P3 PET/CT)		2	02-21-2006	06-03-2006	Hitachi Medical Systems America Inc	The device has a software anomaly which causes blank images to be created during Multiplanar Reconstruction processing or results in an inherent filming error in which a reference scale is improperly sized.

Z-1078-06	Hitachi CXR-4 CT (including SceptreP3 PET/CT)	2	02-21-2006	06-03-2006	Hitachi Medical Systems America Inc	The device has a software anomaly which affects the system's ability to create Multiplanar Reconstructions (MPR). Some images from the resulting series do not display correctly or display at all when MPR was run on them.
Z-0910-06	Altair Airis Elite AIRIS II MRI System	2	02-21-2006	05-31-2006	Hitachi Medical Systems America Inc	The device has a software anomaly which causes the operating system to 'lock up' and data to become corrupted during service procedures.
Z-0869-06	Extended Brilliance Workspace Imaging Workstation	2	08-02-2004	05-19-2006	Philips Medical Systems (Cleveland) Inc	Due to a software deficiency that occurs in the combine mode a patients image can be filmed over a different patients image.
Z-0854-06	Image Processing System	2	10-08-2004	05-09-2006	General Electric Med Systems LLC	Display in fused mode viewer allows 2 studies (PET/CT) registered in the same spatial domain to be viewed simultaneously. These 2 images should be visually aligned to a precision of less than 1/2 PET Voxel. A problem associated with this version of software may introduce a shift of up to 1.5 PET Voxels which can be as much as 8 mm with certain zoom
Z-0832-06	RenalSoft v.1.1	2	03-29-2006	05-03-2006	Baxter Healthcare Renal Div	Software Error: There are software discrepancies that may increase the possibility of a medication error if the dialysis clinic software is used to track record or coordinate the administration of medications.
Z-0833-06	Renal Software Suite v.3.1	2	03-29-2006	05-03-2006	Baxter Healthcare Renal Div	Software Error: There are software discrepancies that may increase the possibility of a medication error if the dialysis clinic software is used to track record or coordinate the administration of medications.
Z-0831-06	RenalSoft Observational Study v.2.0	2	03-29-2006	05-03-2006	Baxter Healthcare Renal Div	Software Error: There are software discrepancies that may increase the possibility of a medication error if the dialysis clinic software is used to track record or coordinate the administration of medications.
Z-0821-06	CALM perinatal monitoring system	2	01-11-2005	04-27-2006	LMS Medical Systems Ltd	A deficiency in the software code can in certain circumstances cause data for the wrong patient to be displayed in the Tracing Review screen when a user is acknowledging an Alert.
Z-0809-06	AXIOM Artis Angiographic X-Ray System	2	03-10-2006	04-26-2006	Siemens Medical Solutions USA Inc	The recalling firm became aware of a potential problem when imaging patients on their stomach on the AXIOM Artis X-ray Systems running software versions VB11K and VB22G. In some instances the orientation labels could be incorrect.
Z-0797-06	SOMATOM Sensation CT Systems	2	03-17-2006	04-26-2006	Siemens Medical Solutions USA Inc	The customer is aware of a potential problem that could affect scan results and require patient exam to be repeated when using the customized ECG-gated scan protocols in the CT2006A and CT2006G software of their SOMATOM Sensation
Z-0757-06	Digital mammography system.	2	03-27-2006	04-11-2006	Fischer Imaging Corporation	Software upgrade to preclude lost images during mammography procedure.
Z-0713-06	SonoCalc IMT 3.0	2	10-26-2005	04-06-2006	Sonosite Inc.	When SonoCalc IMT 3.0 software is used with the SonoSite 180Plus ultrasound system the software miscalculates the intima-media-thickness a measurement of risk for cardiovascular or cerebrovascular events. Underestimates percentage of stenosis false negative result
Z-0682-06	RapidLab1200 System	2	01-20-2006	03-29-2006	Bayer Healthcare LLC (Diagnostics Division)	When stored data is recalled from memory the results do not agree with the original results. Software anomaly: a calculation error occurs when using the correlation adjustment feature on the RapidLab 1200 Systems with software versions 1.0 1.01 or 1.02. The correlation feature applies user-defined slope and offset parameters each time stored test results are recalled to the display.
Z-0684-06	RapidLab1200 System	2	01-20-2006	03-29-2006	Bayer Healthcare LLC (Diagnostics Division)	When stored data is recalled from memory the results do not agree with the original results. Software anomaly: a calculation error occurs when using the correlation adjustment feature on the RapidLab 1200 Systems with software versions 1.0 1.01 or 1.02. The correlation feature applies user-defined slope and offset parameters each time stored test results are recalled to the display.
Z-0683-06	RapidLab1200 System	2	01-20-2006	03-29-2006	Bayer Healthcare LLC (Diagnostics Division)	When stored data is recalled from memory the results do not agree with the original results. Software anomaly: a calculation error occurs when using the correlation adjustment feature on the RapidLab 1200 Systems with software versions 1.0 1.01 or 1.02. The correlation feature applies user-defined slope and offset parameters each time stored test results are recalled to the display.
Z-0685-06	RapidLab1200 System	2	01-20-2006	03-29-2006	Bayer Healthcare LLC (Diagnostics Division)	When stored data is recalled from memory the results do not agree with the original results. Software anomaly: a calculation error occurs when using the correlation adjustment feature on the RapidLab 1200 Systems with software versions 1.0 1.01 or 1.02. The correlation feature applies user-defined slope and offset parameters each time stored test results are recalled to the display.
Z-0557-06	The ETI-Mumps IgG Enzyme Immunoassay Test Kit is sold with assay software version 1.0, that is desig...	2	08-08-2005	02-23-2006	Diasorin Inc.	Potential for false negative results.
Z-0529-06	Lumenis	2	04-08-2005	02-16-2006	Lumenis Inc.	Software anomaly recorded incorrect filter in patient database and this may lead to patient skin burns.
Z-0520-06	RotoProne Therapy System	2	01-24-2005	02-14-2006	Kinetic Concepts Inc	To correct software issues in software versions 1.3 and 1.5 and to upgrade hatch latch handles to a more ergonomic design.
Z-0423-06	Accu-Chek Aviva	2	11-09-2005	01-24-2006	Roche Diagnostics Corp.	Incorrect patient blood glucose test results may be reported due to a software problem.
Z-0424-06	Accu-Chek Aviva	2	11-09-2005	01-24-2006	Roche Diagnostics Corp.	Incorrect patient blood glucose test results may be reported due to a software problem.
Z-0418-06	Accu-Chek Aviva	2	11-09-2005	01-24-2006	Roche Diagnostics Corp.	Incorrect patient blood glucose test results may be reported due to a software problem.
Z-0419-06	Accu-Chek Aviva	2	11-09-2005	01-24-2006	Roche Diagnostics Corp.	Incorrect patient blood glucose test results may be reported due to a software problem.
Z-0421-06	Accu-Chek Aviva	2	11-09-2005	01-24-2006	Roche Diagnostics Corp.	Incorrect patient blood glucose test results may be reported due to a software problem.

Z-0426-06	Accu-Chek Aviva	2	11-09-2005	01-24-2006	Roche Diagnostics Corp.	Incorrect patient blood glucose test results may be reported due to a software problem.
Z-0417-06	Accu-Chek Aviva	2	11-09-2005	01-24-2006	Roche Diagnostics Corp.	Incorrect patient blood glucose test results may be reported due to a software problem.
Z-0420-06	Accu-Chek Aviva	2	11-09-2005	01-24-2006	Roche Diagnostics Corp.	Incorrect patient blood glucose test results may be reported due to a software problem.
Z-0422-06	Accu-Chek Aviva	2	11-09-2005	01-24-2006	Roche Diagnostics Corp.	Incorrect patient blood glucose test results may be reported due to a software problem.
Z-0425-06	Accu-Chek Aviva	2	11-09-2005	01-24-2006	Roche Diagnostics Corp.	Incorrect patient blood glucose test results may be reported due to a software problem.
Z-0437-06	Panorama Patient Monitoring Network Cardiac Arrhythmia	2	12-07-2005	01-24-2006	Datascope Corp	Software anomaly that affects the Panorama Telepack where if communications are lost during standby certain alarms which appear set could be actually off.
Z-0378-06	Instrumentation Laboratory	2	12-16-2005	01-11-2006	Instrumentation Laboratory Co.	Software error may report higher results for glucose and lactate
Z-0380-06	Cytomics FC500 with CXP Software	2	11-23-2005	01-11-2006	Beckman Coulter Inc	Under certain conditions an incorrect Tube ID (Barcode) can be displayed and printed on the Runtime Panel Report in CXP Cytometer Software Version 2.0
Z-0364-05	LANTIS software	2	01-06-2005	01-07-2006	Siemens Medical Solutions USA Inc	When using the Creatine Clearance dose calculations a software bug will allow the algorithm to assume a patients age to be in years when it is entered in months. This miscalculation may result in patients less than two years old to be seriously overdosed with radiation.
Z-0358-06	System Nuclear Magnetic Resonance Imaging	2	12-09-2005	01-06-2006	Philips Medical Systems North America Co. Phillips	The Gyroscan NT MRI system has a computer software problem which results in images from one patient being placed into another patient's image record.
Z-0324-06	Digital Radiography System Model DFP8000D	2	11-10-2005	12-23-2005	Toshiba American Med Sys Inc	To correct a software problem that caused the LV images which were acquired for 15 seconds at the end of the examination to be lost.
Z-0325-06	Digital Radiography System Model DFP-8000D/FPD	2	11-10-2005	12-23-2005	Toshiba American Med Sys Inc	To correct a software problem that caused the LV images which were acquired for 15 seconds at the end of the examination to be lost.
Z-0298-06	Pentra 80 and Pentra 80XL Hematology Analyzers	2	04-08-2004	12-23-2005	ABX Diagnostics Inc	Software defect instrument may erroneously give a result of '0' or '---'.
Z-0175-06	EKOS Lysus Infusion System	2	01-18-2005	11-23-2005	Ekos Corp	Potential for a faulty thermal channel offset to be reported to the software causing faulty lower temperature values to be reported which allow a power increase.
Z-0153-06	Accura System for Blood Filtration	2	08-29-2005	11-16-2005	Baxter Healthcare Renal Div	A software anomaly that occurs when the Reset Totals option is selected during CVVHD therapy with a dialysate flow rate of less than 600 mL/hour or CVVH therapy with a predilution flow rate of less than 600 mL/hour causes balance alarms without an obvious cause.
Z-0132-06	HemoSense	2	09-07-2005	11-15-2005	HemoSense Inc	A software problem that may cause the INRatio meter to incorrectly display 'INR>7.5' test message under a particular use condition.
Z-0088-06	MISYS	2	09-29-2005	10-22-2005	Misys Healthcare Systems	Customer complaint during testing of module prior to production use. Software problem when the user has indicated to enter a coded comment instead of using the defined keyboard then enters 100000 the system willfile the number 100 instead of number 100000.
Z-0010-06	ARCHITECT c8000 System	2	09-14-2005	10-06-2005	Abbott Laboratories Inc	Software deficiency causing potential shift in absorbance readings for test results.
Z-0009-06	Synchron LX Systems Version 4.5Operating Software	2	09-06-2005	10-06-2005	Beckman Coulter Inc	Synchron LX Systems Operating Software Version 4.5/v4.8 CBD (Chemistry Database) introduced an adjustment to the urine Uric Acid database calculation scheme which for some patients depending on the volume of 24 hour urine sample results may be reduced from above the upper limit of the laboratory's reference interval to below the limit.
Z-1594-05	FreeStyle CoPilot	2	09-30-2005	10-01-2005	Abbott Laboratories Medisense Products	Downloadable software obtained from the firm's website displays user data (including but not limited to insulin levels and pump statistics data) in a matter that may be misinterpreted and result in mistreatment of therapy.
Z-1592-05	Baxter 6060E & Sabratek 6060 Epidural Infusion Pumps	2	08-17-2005	09-28-2005	Baxter Healthcare Corp.	Potential overinfusion in the Auto-Ramp mode with software versions 3.00 or higher
Z-1567-05	Panorama Patient Monitoring Network Cardiac Arrhythmia	2	08-19-2005	09-21-2005	Datascope Corp	The software version contains an anomaly which could freeze the unit when the right click button is used on the mouse.
Z-1378-05	SmartCycler	2	07-22-2005	08-17-2005	Cepheid	A problem in the software has the potential to be associated with the incorrect reporting of sample results.
Z-1377-05	Cytomics FC500 MPL with MXP Software versions 1.1 and	2	07-06-2005	08-17-2005	Beckman Coulter Inc	Software anomally. If the laser is shutdown or fluctuates outside of the specification limits the software continues to run and will not indicate a laser failure and could therefore cause erroneous results.
Z-1104-05	Panorama Patient Monitoring Network. Cardiac Arrhythmia Monitor.	2	06-16-2005	08-08-2005	Datascope Corp	Upon the new release of software the firm started receiving reports of unexpected system failures in the database subsystem related to virtual memory pages.
Z-0958-05	90JAK System Computed Tomography X-ray Scanning System	2	03-23-2004	07-06-2005	Philips Medical Systems (Cleveland) Inc	Software anomaly in the DICOM Modality Worklist. When restoring a patient's images from the optical disk images from the wrong patient may be displayed.

Z-0957-05	90JAK System Computed Tomography X-ray Scanning System	2	03-23-2004	07-06-2005	Philips Medical Systems (Cleveland) Inc	Software anomaly in the DICOM Modality Worklist. When restoring a patient's images from the optical disk images from the wrong patient may be displayed.
Z-0938-05	Misys Laboratory with Lab Access Results application for versions 5.3 and later.	2	05-13-2005	06-28-2005	Misys Healthcare Systems	Software anomaly may rarely allow modification of previously reported specimen results.
Z-0923-05	Envisor	2	05-13-2005	06-22-2005	Philips Ultrasound Inc.	A defect in the software allows incorrect measurement results to be entered into the system's built-in report.
Z-0896-05	View Forum 2003 software SW 3.4L1	2	04-29-2005	06-16-2005	Philips Medical Systems North America Co. Phillips	Automated analysis of vascular obstruction tool in software gives unreliable calibration and analysis results when using unprocessed images acquired on the Philips Allura FD10.
Z-0889-05	Hitachi AIRIS II Magnetic Resonance Imaging Device	2	06-30-2005	06-14-2005	Hitachi Medical Systems America Inc	Image reconstruction software problem that could potentially cause multiple patient images to be stored in one patient folder.
Z-0888-05	Hitachi Altaire Magnetic Resonance Imaging Device.	2	06-30-2005	06-14-2005	Hitachi Medical Systems America Inc	Image reconstruction software problem that could potentially cause multiple patient images to be stored in one patient folder.
Z-0890-05	Hitachi AIRIS Elite Magnetic Resonance Imaging Device	2	06-30-2005	06-14-2005	Hitachi Medical Systems America Inc	Image reconstruction software problem that could potentially cause multiple patient images to be stored in one patient folder.
Z-0711-05	Stereotaxic Navigation System	2	01-28-2005	04-16-2005	Medtronic Surgical Navigation Technologies Inc	The Stealth Station Cranial Application Version 4.5 contains a software anomaly which may present a hazard to the patient.
Z-0710-05	KION	2	01-11-2005	04-14-2005	Maquet Inc	Software update so US customers will be updated equally with worldwide customers. Ver. 5.0 will be upgraded to ver 7.0. Quality will improve and enhance functionality.
Z-0397-05	HomeChoice PRO	2	12-23-2004	01-15-2005	Baxter Healthcare Renal Div	A software anomaly may allow concentrated solution to be infused into the patient when the HomeChoice unit is used with Physioneal Clear-Flex PD products.
Z-0394-05	Logix-CM Compounder Software	2	12-20-2004	01-13-2005	Baxter Healthcare Corp.	Logix-CM software version 3.0.4 has not completed its official release process.
Z-0392-05	Logix-CM Compounder Software	2	12-08-2004	12-30-2004	Baxter Healthcare Corp.	A software anomaly in the Logix CM software could result in a drug mixture being compounded without one of the ingredients if two drugs have the same indentifier in Logix and another order entry program being used with the Logix software.
Z-0373-05	StreamLab Analytical Workcell	2	11-12-2004	12-28-2004	Dade Behring Inc.	Software can sample the incorrect specimen from the StreamLAB to the Dimension RxL or RxL Max Systems.
Z-0345-05	Colleague 3 CX Triple Channel Volumetric Infusion Pumps	2	11-04-2004	12-22-2004	Baxter Healthcare Corp.	A software anomaly causes a failure alarm code 12:303 which audibly alarms and stops the function of all channels in use. This causes an interruption in therapy which may result in a risk to the patient.
Z-0344-05	Colleague CX Single Channel Volumetric Infusion Pumps	2	11-04-2004	12-22-2004	Baxter Healthcare Corp.	A software anomaly causes a failure alarm code 12:303 which audibly alarms and stops the function of all channels in use. This causes an interruption in therapy which may result in a risk to the patient.
Z-0342-05	Colleague Single Channel Volumetric Infusion Pumps	2	11-04-2004	12-22-2004	Baxter Healthcare Corp.	A software anomaly causes a failure alarm code 12:303 which audibly alarms and stops the function of all channels in use. This causes an interruption in therapy which may result in a risk to the patient.
Z-0343-05	Colleague 3 Triple Channel Volumetric Infusion Pumps	2	11-04-2004	12-22-2004	Baxter Healthcare Corp.	A software anomaly causes a failure alarm code 12:303 which audibly alarms and stops the function of all channels in use. This causes an interruption in therapy which may result in a risk to the patient.
Z-0341-05	Philips	2	12-15-2004	12-21-2004	Philips Medical Systems	In Software versions below A.02.00 with the sync function enabled and the device switched from manual to AED there may be an unexpected delay in delivery of energy.
Z-0297-05	MagNA Pure	2	11-05-2004	12-08-2004	Roche Diagnostics Corp.	Test results may be adversely affected by software shutting down the cooling blocks in systems with software version 3.09.
Z-0273-05	Magnetic Resonance Imaging Systems under the following names:VisartEx celartExcelart P2Excel...	2	08-24-2004	12-02-2004	Toshiba American Med Sys Inc	Software defect causes patient identification number to be truncated.
Z-0270-05	Magnetic Resonance Imaging Systems under the following names:VisartEx celartExcelart P2Exce...	2	10-06-2004	12-02-2004	Toshiba American Med Sys Inc	Software defect causes images to be rotated 180 degrees.
Z-0265-05	Access Immunoassay Systems Discrete photometric chemistry analyzer	2	11-08-2004	11-30-2004	Beckman Coulter Inc	A rare condition of the Access 2 Immunoassay Systems software versions 2.0 2.1 and 2.2 could present a risk of an erroneous confirmatory result under a specific set of circumstances. The Chlamydia Blocking results may be affected. The instrument will erroneously perform the blocking calculation on the affected test by using the mean of the diluted and neat results.
Z-0360-04	Coherent	2	03-30-2004	11-30-2004	Coherent Inc.	Software problem that may cause unintended emission of laser radiation.
Z-0540-04	Coherent	2	01-19-2004	11-16-2004	Coherent Inc.	Software problem that may cause unintended emission of laser radiation.

Z-0063-05	Pagewriter Touch Cardiograph Software Versions A.01.01 or A.01.02	2	10-13-2004	11-02-2004	Philips Medical Systems	Software can generate printed ECG's that associate incorrect patient data with the waveform
Z-0018-05	Trio Monitor, Cardiac Monitor (including cardiotachometer and rate alarm).	2	09-24-2004	10-13-2004	Datascope Corp	Software anomaly where the variable heart rates may be displayed inaccurately or intermittent 'dashes' may be displayed when the patient's heart rate is derived from ECG.
Z-1446-04	Axiom Sensis Report Workstation	2	05-17-2004	09-14-2004	Siemens Medical Solutions USA Inc	Software issue. Allows for users to enter data in Pre-Cath Holding Area prior to registering the patient in the Cath Lab.
Z-1432-04	Roche/Hitachi 747 - 200 clinical chemistry analyzer; catalog number 04009223680.	2	08-06-2004	09-02-2004	Roche Diagnostics Corp.	A software defect will allow the reporting out of believable but clinically significant erroneous results under certain conditions.
Z-1431-04	Roche/Hitachi Modular Additional D Module DAT clinical chemistry analyzer; catalog number 0442933916.	2	08-06-2004	09-02-2004	Roche Diagnostics Corp.	A software defect will allow the reporting out of believable but clinically significant erroneous results under certain conditions.
Z-1430-04	Roche/Hitachi Modular Analytical D Module DAT clinical chemistry analyzer; catalog number 0442933816.	2	08-06-2004	09-02-2004	Roche Diagnostics Corp.	A software defect will allow the reporting out of believable but clinically significant erroneous results under certain conditions.
Z-1428-04	Roche/Hitachi 747 - 100 clinical chemistry analyzer; catalog number 04009223680.	2	08-06-2004	09-02-2004	Roche Diagnostics Corp.	A software defect will allow the reporting out of believable but clinically significant erroneous results if the analyzer is in operation and a channel has been masked or not requested over a period of time.
Z-1429-04	Roche/Hitachi Modular Analytical D Module clinical chemistry analyzer; catalog number 03739923001.	2	08-06-2004	09-02-2004	Roche Diagnostics Corp.	A software defect will allow the reporting out of believable but clinically significant erroneous results under certain conditions.
Z-1400-04	Magnetom Sonata	2	07-28-2004	08-24-2004	Siemens Medical Solutions USA Inc	An input error can be made with Magnetom MRI software. Software allows users to manually change Transmit Reference Voltage in certain windows.
Z-1399-04	Magnetom Symphony	2	07-28-2004	08-24-2004	Siemens Medical Solutions USA Inc	An input error can be made with Magnetom MRI software. Software allows users to manually change Transmit Reference Voltage in certain windows.
Z-1397-04	Magnetom Harmony	2	07-28-2004	08-24-2004	Siemens Medical Solutions USA Inc	An input error can be made with Magnetom MRI software. Software allows users to manually change Transmit Reference Voltage in certain windows.
Z-1402-04	Magnetom Sonata	2	07-28-2004	08-24-2004	Siemens Medical Solutions USA Inc	An input error can be made with Magnetom MRI software. Software allows users to manually change Transmit Reference Voltage in certain windows.
Z-1396-04	Magnetom Harmony	2	07-28-2004	08-24-2004	Siemens Medical Solutions USA Inc	An input error can be made with Magnetom MRI software. Software allows users to manually change Transmit Reference Voltage in certain windows.
Z-1404-04	Magnetom Trio	2	07-28-2004	08-24-2004	Siemens Medical Solutions USA Inc	An input error can be made with Magnetom MRI software. Software allows users to manually change Transmit Reference Voltage in certain windows.
Z-1403-04	Magnetom Trio	2	07-28-2004	08-24-2004	Siemens Medical Solutions USA Inc	An input error can be made with Magnetom MRI software. Software allows users to manually change Transmit Reference Voltage in certain windows.
Z-1401-04	Magnetom Sonata	2	07-28-2004	08-24-2004	Siemens Medical Solutions USA Inc	An input error can be made with Magnetom MRI software. Software allows users to manually change Transmit Reference Voltage in certain windows.
Z-1395-04	Magnetom Avanto	2	07-28-2004	08-24-2004	Siemens Medical Solutions USA Inc	An input error can be made with Magnetom MRI software. Software allows users to manually change Transmit Reference Voltage in certain windows.
Z-1398-04	Magnetom Symphony	2	07-28-2004	08-24-2004	Siemens Medical Solutions USA Inc	An input error can be made with Magnetom MRI software. Software allows users to manually change Transmit Reference Voltage in certain windows.
Z-1371-04	MagNA Pure	2	08-06-2004	08-17-2004	Roche Diagnostics Corp.	A hardware/software problem will result in low elution volumes and bias sample results for various protocols.
Z-1342-04	PENTRA 120 and PENTRA 120 Retic Hematology Analyzer	2	06-24-2004	08-13-2004	ABX Diagnostics Inc	Power failure having impact on software.
Z-1339-04	Prolieve)	2	07-19-2004	08-11-2004	Celsion Corporation	Software controlling a medical device for patient treatment may malfunction and cause thermal injury to patient.
Z-1314-04	Varian Medical Systems VARiS	2	06-24-2004	08-07-2004	Varian Medical Systems Inc	A malfunction in the software of the VARIS versions 6.2.2 and 6.2.05 which is used to set up radiation therapy devices which will reset parameters to null for future treatments if a patient receives treatment on a non-varian machine and a varian machine and a non-varian field is loaded in the treatment

Z-1235-04	3 Series Full Body Phototherapy Device with Smart Touch Control System Model #LNBH-0048.	2	09-01-2003	07-30-2004	Daavlin Distributing Company	Software errors cause the unit to not deliver the prescribed therapy and do not allow the patient records to be saved.
Z-1233-04	3 Series Full Body Phototherapy Device with Smart Touch Control System Models #PASNBSM-2424.	2	09-01-2003	07-30-2004	Daavlin Distributing Company	Software errors cause the unit to not deliver the prescribed therapy and do not allow the patient records to be saved.
Z-1236-04	3 Series Full Body Phototherapy Device with Smart Touch Control System Model #SNBSM-0048.	2	09-01-2003	07-30-2004	Daavlin Distributing Company	Software errors cause the unit to not deliver the prescribed therapy and do not allow the patient records to be saved.
Z-1234-04	3 Series Full Body Phototherapy Device with Smart Touch Control System Model All Touch Control Sys...	2	09-01-2003	07-30-2004	Daavlin Distributing Company	Software errors cause the unit to not deliver the prescribed therapy and do not allow the patient records to be saved.
Z-1237-04	3 Series Full Body Phototherapy Device with Smart Touch Control System Model #ANBSM-0048.	2	09-01-2003	07-30-2004	Daavlin Distributing Company	Software errors cause the unit to not deliver the prescribed therapy and do not allow the patient records to be saved.
Z-1153-04	Synchron Systems Lipid Calibrator (HDLD)Part 650218	2	10-03-2003	07-23-2004	Beckman Coulter Inc	Incorrect units are printed in labeling but not in software.
Z-0151-04	Misys Laboratory System Versions 5.2 5.23 5.3 up to 5.3.2.	2	07-07-2003	07-20-2004	Misys Healthcare Systems	Software defect causes orders to be lost under certain conditions of use. A typographical error at the Accept/Modify/Reject prompt will cause the order not to be processed by the system.
Z-1012-04	HomeChoice & Yume	2	05-24-2004	07-20-2004	Baxter Healthcare Renal Div	A software defect could result in a patient experiencing an overfill with software versions 8.5 and higher. The possibility of an overfill can occur when the Initial Drain Alarm Volume is set to OFF and a change to the volume is made at the Verify I-DRAIN:XXXXML prompt.
Z-1013-04	HomeChoice PRO & Yume Plus	2	05-24-2004	07-20-2004	Baxter Healthcare Renal Div	A software defect could result in a patient experiencing an overfill with software versions 8.5 and higher. The possibility of an overfill can occur when the Initial Drain Alarm Volume is set to OFF and a change to the volume is made at the Verify I-DRAIN:XXXXML prompt.
Z-1005-04	Hitachi HI VISION 6500	2	05-07-2004	07-20-2004	Hitachi Medical Systems America Inc	Due to a software anomaly various patient images may be intermixed within a single patient folder which may result in mis-diagnosis and delay in treatment.
Z-0987-04	Coulter ACT 5diff Autoloader (AL) Hematology	2	04-20-2004	07-20-2004	Beckman Coulter Inc	Software anomaly causes sample results to be not credible reported as '0' or left blank. The next sample will also be incorrectly reported for the same parameter.
Z-1027-04	DL 2000 Data Manager Software Version 6.2	2	02-14-2004	07-20-2004	Beckman Coulter Inc	Software defect. The type of results affected were replicate type results for a single sample transmitted within the same data stream.
Z-0929-04	Concha IV Plus Heated Humidifier	2	04-20-2004	07-20-2004	Hudson Respiratory Care Inc	Software malfunction. The humidifier did not retain the clinician selected default settings for temperature gradient after the unit had been placed in the "pause" mode.
Z-0904-04	UniCel Dxl 800 Access Immunoassay System P/N 973100.	2	03-29-2004	07-20-2004	Beckman Coulter Inc	Software coding error may cause a fatal error message.
Z-0289-04	Pulsox	2	11-14-2003	07-20-2004	Minolta Corp	Error in the internal software. When a pulse level is high or subject has SPO2 of less than 80% the data shifts.
Z-0290-04	Pulsox	2	11-14-2003	07-20-2004	Minolta Corp	Error in the internal software. When a pulse level is high or subject has SPO2 of less than 80% the data shifts.
Z-1095-04	Magic View	2	04-01-2004	07-20-2004	Siemens Medical Solutions USA Inc	Recalling firm became aware of a potential problem through the submission of a product complaint to the firm reporting the Image Navigator feature in the MagicView 300 VA42A or VA42B software are not being imported accurately to certain CT or MR images.
Z-0903-04	Espirit Ventilator	2	06-01-2001	07-20-2004	Respironics California Inc	Ventilator would spontaneously suspend ventilatory support to patients due to a hardware/software compatibility issue.
Z-1084-04	Millenium MLC Software Suite	2	05-27-2004	07-20-2004	Varian Medical Systems Inc	An anomaly occurs in the software suite (Millennium MLC Workstation v 6.3 and 6.4 Integrated Treat v.6.5) when used in combination with the standard series MLC controller software v 5.0 or 5.1
Z-0902-04	RenalSoft Software System	2	04-12-2004	07-20-2004	Baxter Healthcare Renal Div	There are software anomalies present that may increase the possibility of a medication error if the dialysis clinic software is used to track record or coordinate the administration of medications.
Z-0901-04	Baxter Renal Software Suite for Windows	2	04-12-2004	07-20-2004	Baxter Healthcare Renal Div	There are software anomalies present that may increase the possibility of a medication error if the dialysis clinic software is used to track record or coordinate the administration of medications.
Z-0912-04	Pinnacle3	2	03-03-2004	07-20-2004	ADAC Laboratories	A software defect relating to the motorized wedge functionality when using an Elekta linear accelerator can result in incorrect dose delivery to the patient. Also dose delivery in the wrong location may occur when using a Elekta Leksell headframe.
Z-0913-04	Pinnacle3	2	03-03-2004	07-20-2004	ADAC Laboratories	A software defect relating to the motorized wedge functionality when using an Elekta linear accelerator can result in incorrect dose delivery to the patient. Also dose delivery in the wrong location may occur when using a Elekta Leksell headframe.
Z-0914-04	Pinnacle3	2	03-03-2004	07-20-2004	ADAC Laboratories	A software defect relating to the motorized wedge functionality when using an Elekta linear accelerator can result in incorrect dose delivery to the patient. Also dose delivery in the wrong location may occur when using a Elekta Leksell headframe.
Z-0911-04	Pinnacle3	2	03-03-2004	07-20-2004	ADAC Laboratories	A software defect relating to the motorized wedge functionality when using an Elekta linear accelerator can result in incorrect dose delivery to the patient. Also dose delivery in the wrong location may occur when using a Elekta Leksell headframe.
Z-0736-04	Instrumentation Laboratory	2	03-04-2004	07-20-2004	Instrumentation Laboratory Co.	Software may cause instrument to omit step causing reagent carryover which may effect patient test result.
Z-0737-04	Instrumentation Laboratory	2	03-04-2004	07-20-2004	Instrumentation Laboratory Co.	Software may cause instrument to omit step causing reagent carryover which may effect patient test result.
Z-0357-04	Coherent/	2	11-17-2003	07-20-2004	Coherent Inc Laser Group	Software problem that may cause the instrument to remain on and emitting laser radiation after the interlock has been activated.
Z-0727-04	PatientNet	2	02-27-2004	07-20-2004	General Electric Medical Systems Information Technology	Non-invasive blood pressure readings on central station may not match bedside monitor due to software anomaly.
Z-0636-04	Cytomics MXP Software Version 1.0 Part No. 623688.	2	02-13-2004	07-20-2004	Beckman Coulter Inc	Software anomaly. Sample ID and the Run Date may become fixed within a header on the FlowPAGE printout. All samples subsequently run with results printed using the FlowPAGE print format will have the fixed Sample ID and Run Date rather than the correct Sample ID and Run Date.
Z-0635-04	CXP software Part No. 623560 version 1.0	2	02-13-2004	07-20-2004	Beckman Coulter Inc	Software anomaly. Sample ID and the Run Date may become fixed within a header on the FlowPAGE printout. All samples subsequently run with results printed using the FlowPAGE print format will have the fixed Sample ID and Run Date rather than the correct Sample ID and Run Date.
Z-0637-04	Cytomics RXP Software Version 1.0 Part Numbers:17548 8641848917526 017526117526 2175263...	2	02-13-2004	07-20-2004	Beckman Coulter Inc	Software anomaly. Sample ID and the Run Date may become fixed within a header on the FlowPAGE printout. All samples subsequently run with results printed using the FlowPAGE print format will have the fixed Sample ID and Run Date rather than the correct Sample ID and Run Date.
Z-0582-04	EPROM and Control Software (embedded) version 5.08 for the GammaMed 12i/i Afterloader manufactur...	2	02-06-2004	07-20-2004	Varian Medical Systems	Radiation treatment software could potentially cause a healthcare practitioner to apply incorrect treatment regimen to patients undergoing brachytherapy.
Z-1094-04	Mammography X-ray system.	2	05-21-2004	07-20-2004	Fischer Imaging Corporation	Existing software may allow image data to be truncated in the margin of the breast on processed patient images.
Z-1020-04	Radionics Head and Neck Localilizer (HNL) Version B	2	05-25-2004	07-20-2004	Radionics Inc.	Software may provide inaccurate coordinates and cause mistreatment
Z-0250-04	Solar	2	11-10-2003	12-18-2003	General Electric Medical Systems Information Technology	Software gives inaccurate readings when transferring TRAM module from Solar 9500 to other Solar monitoring systems without discharging TRAM first.
Z-0235-04	Mysis	2	09-25-2003	12-18-2003	Misys Healthcare Systems	Software Defect. When orders are modified before the Roche Cobas Integra query for a specimen the sample ID locks.
Z-0176-03	Vision (tm)	2	10-31-2003	12-03-2003	Varian Brachytherary Virginia	The manufacturer's instructions for using radiation treatment software may cause healthcare practitioner to mistreat the patient.
Z-0094-04	Philips Odyssey FX Workstations	2	09-15-2003	11-06-2003	Philips Medical Systems (Cleveland)	Due to a software anomaly an incorrect patient name may be transmitted with image to Odyssey workstation.
Z-0095-04	Philips Odyssey LX Workstations	2	09-15-2003	11-06-2003	Philips Medical Systems (Cleveland) Inc	Due to a software anomaly an incorrect patient name may be transmitted with image to Odyssey workstation.
Z-0093-04	Philips Odyssey VP	2	09-15-2003	11-06-2003	Philips Medical Systems (Cleveland)	Due to a software anomaly an incorrect patient name may be transmitted with image to Odyssey workstation.
Z-0047-04	Olympus ImageManager Software	2	08-19-2003	10-15-2003	Olympus America Inc.	Software malfunction; potential for simultaneous cross-linking of exam images to another patient's file.
Z-1240-03	Mysis Laboratory	2	07-23-2003	10-15-2003	Misys Healthcare Systems	Software Defect. Data used in the diagnosis and or treatment of a patient's illness are missing from the patient result report.
Z-1217-03	Misys Laboratory System versions 5.2 through 5.3.2 using LabAccess	2	07-22-2003	09-11-2003	Misys Healthcare Systems	Software design deficiency. If the dilution factor is added to the same result twice incorrect specimen values are reported.
Z-1220-03	Mysis Commercial Laboratory	2	07-24-2003	09-11-2003	Misys Healthcare Systems	Software Design Defect. Under certain conditions results are removed.
Z-1092-03	Misys Laboratory System version 5.3	2	07-02-2003	08-07-2003	Misys Healthcare Systems	Patient files become mixed up due to a software defect.

Z-1090-03	Misys Laboratory System versions 5.3 up to 5.3.2 with Anatomic Pathology	2	06-16-2003	06-07-2003	Misys Healthcare Systems	Software anomaly allows patient reports to contain incomplete data used for diagnosis or treatment.
Z-1078-03	Alcon Ladarwave	2	07-21-2003	08-05-2003	Alcon Laboratories Inc.	Software error could under specific circumstances allow the patient's centration images and data to be stored incorrectly.
Z-1044-03	MagNA Pure	2	08-26-2003	07-23-2003	Roche Diagnostics Corp.	A software bug in version 3.0 may result in prolonged mixing time evaporation of elution volume and biased sample results for various protocols.
Z-1029-03	MagicView 1000U version VE40A	2	02-28-2003	07-19-2003	Siemens Medical Solutions USA Inc	software issue
Z-1007-03	Misys Laboratory System versions 5.2	2	06-10-2003	07-15-2003	Misys Healthcare Systems	Software anomally
Z-1001-03	MagNA Pure LC	2	05-27-2003	07-15-2003	Roche Diagnostics Corp.	Potential for false negative patient results with software version 3.0
Z-0984-03	Axiom Aristos X-Ray System	2	04-19-2003	07-08-2003	Siemens Medical Solutions USA Inc	software malfunction. May indicate that the image is flipped when it is not.
Z-0979-03	Axiom Sensis	2	02-28-2003	07-03-2003	Siemens Medical Solutions USA Inc	software problem - erroneous results or system crashes
Z-0975-03	Acuson Cypress Echocardiograph System	2	04-01-2003	07-02-2003	Siemens Medial Solutions USA Inc	software problem - loss of data
Z-0954-03	Evita 4 Continuous Ventilator	2	05-07-2003	06-27-2003	Draeger Medical Inc.	software problems - ventilation mode changes without user input settings change without corresponding display change false auto-set alarm.
Z-0932-03	Fujifilm	2	05-12-2003	06-12-2003	Fujifilm Medical System USA Inc.	Synapse Version 2.2.1 and 2.3.1 Software [Free-Hand Region] may lead to incorrect density calculations during CT scan
Z-0905-03	Infinite Imaging TM Software model Ultra 10PACS System Version	2	03-11-2003	06-05-2003	Canon USA Inc	Imaging archive system software mismatches images and patient names.
Z-0842-03	Somatom	2	10-11-2002	05-16-2003	Siemens Medical Solutions USA Inc	Perfusion CT is displaying a higher gray and color values than normal. A software problem.
Z-0841-03	Leonardo	2	10-11-2002	05-16-2003	Siemens Medical Solutions USA Inc	Perfusion CT is displaying a higher gray and color values than normal. A software problem.
Z-0807-03	Misys Laboratory System version 5.3	2	04-01-2003	05-09-2003	Misys Healthcare Systems	Software anomally One client reported patient tests and results are deleted when duplicate orders are placed.
Z-0804-03	Misys Laboratory System versions 5.23	2	03-27-2003	05-09-2003	Misys Healthcare Systems	Software anomaly.
Z-0798-03	Deltec Cozmo	2	03-14-2003	05-09-2003	Deltec Inc	A software error can result in the delivery of a larger bolus of insulin than anticipated when the pump is programmed in a particular manner.
Z-0788-03	AEROSET	2	02-24-2003	05-01-2003	Abbott Laboratories Inc	Software failure to detect error in reference solution set-up can cause inaccurate results for Sodium Potassium and
Z-0678-03	Misys Laboratory Calculator/Data processing Module for Clinical Use (21 CFR 862.2100)Misys	2	01-17-2003	03-26-2003	Misys Healthcare Systems	Software anomally. Graphical display omits results containing a less than (<) greater than (>) or percent (%) symbol.
Z-0670-03	Misys Laboratory System Version 5.3	2	02-19-2003	03-21-2003	Misys Healthcare Systems	Software anomaly
Z-0647-03	Misys Laboratory	2	10-18-2002	03-13-2003	Sunquest Information Systems	Software anomaly incorrect coding. Some comments were not transfered when coming from the Reference Laboratory Interface.
Z-0633-03	Varian	2	01-31-2003	03-12-2003	Varian Medical Systems Inc	The product has a software problem. This could result in a treatment without a motorized wedge where one had been planned.
Z-0614-03	Misys Laboratory System Versions 5.2 5.23 and 5.3	2	01-31-2003	03-05-2003	Misys Healthcare Systems	Software anomaly. Rejecting the selected Autofiling status may result in the change being accepted rather than rejected.
Z-0626-03	Misys Laboratory System versions 5.2	2	01-31-2003	03-05-2003	Misys Healthcare Systems	Software anomaly. Patient results may be filed in the incorrect patient file
Z-0492-03	Misys Laboratory version 5.3	2	12-20-2002	01-30-2003	Misys Healthcare Systems	Software anomally. English text code does not translate.
Z-0497-03	Misys Laboratory	2	12-06-2002	01-30-2003	Sunquest Information Systems	Software system defect resulting in incomplete patient results information.
Z-0422-03	Misys Laboratory version 5.3	2	11-15-2002	01-11-2003	Sunquest Information Systems	Software development logic defect.
Z-0423-03	Misys Laboratory versions 5.23 and 5.3	2	11-22-2002	01-11-2003	Sunquest Information Systems	Software anomally.
Z-0415-03	COULTER LH 700 Series Hematology Analyzers	2	11-08-2002	01-09-2003	Beckman Coulter Inc	Software vote out logic changed. Erroneous white blood cell counts.
Z-0417-03	COULTER LH 700 Series Hematology Analyzers	2	11-08-2002	01-09-2003	Beckman Coulter Inc	Software.
Z-0416-03	COULTER LH 700 Series Hematology Analyzers	2	11-08-2002	01-09-2003	Beckman Coulter Inc	Software.
Z-0418-03	COULTER LH 700 Series Hematology Analyzers	2	11-08-2002	01-09-2003	Beckman Coulter Inc	Software.
Z-0325-03	Misys Laboratory versions 5.2 5.23 or 5.3 with ADT Interface to CoPathPlus.	2	10-24-2002	12-11-2002	Sunquest Information Systems	Interfacing software systems have inconsistent character recognition characteristics.
Z-0319-03	Misys Laboratory version 5.2 with Results Interface 14	2	10-28-2002	12-05-2002	Sunquest Information Systems	Software coding error caused data formatting error.
Z-0324-03	Misys Laboratory	2	10-18-2002	12-05-2002	Sunquest Information Systems	Software anomally - animal ranges when desired on reports are defaulting to human male ranges.
Z-1172-2009	Lead Integrity Alert	3	11-03-2008	04-08-2009	Medtronic Inc. Cardiac Rhythm Managment	Medtronic has identified an issue related to installation or removal of the Lead Integrity Alert software in EnTrust(R) and EnTrust(R) Escudo defibrillators. In those devices only installation or removal of LIA will inadvertently turn off two audible patient alerts.
Z-2322-2008	iCon Patient Programmer	3	05-12-2008	09-20-2008	Medtronic Neuromodulation	Medtronic is retrieving four (4) patient programmers that were not properly loaded with application software. The application software is needed for a patient programmer to synchronize and bond with a neurostimulation device. Without this functionality a patient programmer is not useable and can not communicate with a neurostimulation device.
Z-2323-2008	Medtronic Patient programmer	3	05-12-2008	09-20-2008	Medtronic Neuromodulation	Medtronic is retrieving four (4) patient programmers that were not properly loaded with application software. The application software is needed for a patient programmer to synchronize and bond with a neurostimulation device. Without this functionality a patient programmer is not useable and can not communicate with a neurostimulation device.
Z-2369-2008	Philips	3	07-22-2008	09-18-2008	Philips Medical Systems	Software: If 'Weight Limits edited' values will return to default values that were deleted
Z-1766-2008	ACUSON Antares 5.0 ultrasound system	3	03-21-2008	09-02-2008	Siemens Medical Solutions USA Inc.	Software issue may result in distorted images and inaccurate measurements which could lead to a misdiagnosis.
Z-1767-2008	Sonoline Antares 5.0 ultrasound system	3	03-21-2008	09-02-2008	Siemens Medical Solutions USA Inc.	Software issue may result in distorted images and inaccurate measurements which could lead to a misdiagnosis.
Z-1309-2008	HOUVA III Phototherapy System with DermaSense Technology	3	02-19-2008	08-28-2008	National Biological Corp	Software allows operator to override low line voltage error warning and store light intensity value.
Z-1571-2008	Diagnostic Ultrasound Unit	3	02-25-2008	07-24-2008	Hitachi Medical Systems America Inc	Miscalculation reading. A software error in the firm's EUB-5500/HI VISION diagnostic scanning system causes a miscalculation of the left ICA/CCA ratio when using the Carotid Calculation package for patient scans.
Z-1546-2008	The Selenia Full Field Digital Mammography System	3	02-28-2008	05-28-2008	Lorad A Hologic Inc.	Marker Misalignment: The new software version contained a magnification factor that shows CAD markers misaligned with the identified indications. The marked area is misaligned up to 2cm from the indication.
Z-1644-2008	EVMS (Enterprise Visual Medical System Software)	3	01-01-2008	05-28-2008	Emageon	Miscalculation: The calculation of the standard uptake value does not include the required calibration factor/decay correction factor. The resulting value is incorrectly calculated which may lead to incorrect interpretation of tissue density. The calculation error exists in both the software and user guide
Z-1317-2008	OneTouch Data Management Software v1.0	3	12-18-2007	04-08-2008	Lifescan Inc	Meter Temporarily Freezes— A software compatibility issue may cause the blood glucose meter to cease operations and freeze temporarily.
Z-0041-2008	PEMView	3	09-01-2007	10-11-2007	Naviscan PET Systems	Naviscan has identified a potential safety issue with all versions of PEM View Software commonly used for analyzing patient images acquired on the PEMFlex product line.
Z-1095-2007	ABL 800 FLEX analyzers	3	11-13-2006	07-24-2007	Radiometer America Inc	Software anomaly. Protein removing program incorporated in the operating software for Versions: V3.823 and V5.24 of the ABL700 and ABL800 Blood Gas Analyzers may allow for protein build up on the electrode membranes of blood gas analyzers. This condition can influence analyzer results. When the protein removal program is run too frequently more than once a week or when running the protein rem
Z-1094-2007	ABL 700 series analyzers	3	11-13-2006	07-24-2007	Radiometer America Inc	Software anomaly. Protein removing program incorporated in the operating software for Versions: V3.823 and V5.24 of the ABL700 and ABL800 Blood Gas Analyzers may allow for protein build up on the electrode membranes of blood gas analyzers. This condition can influence analyzer results. When the protein removal program is run too frequently more than once a week or when running the protein rem
Z-0718-2007	CADD - Prizm	3	01-19-2007	04-05-2007	Smiths Medical MD Inc.	The year of manufacture had been incorrectly entered as 1900 into the pumps software during the manufacture process. As a result the pump may go into an immediate 'Clock battery is Low/Service Immediately' or 'Clock Battery needs service soon' alarm message indicating that the pump requires
Z-0380-2007	NicoletOne monitoring system version 5.20 software	3	08-25-2006	02-15-2007	Nicolet Biomedical Div of Viasys Healthcare	A software anomaly exists in the 5.20.1038 NicoletOne LTM Sleep nEEG vEEG and ICU Monitor systems using the M and/or C series amplifiers. If this anomaly occurs the system will display the data for channel one in all channels on NicoletOne LTM Sleep nEEG vEEG or ICU Monitor systems.

Z-0002-2007	Guidant Zoom Latitude Programming System	3	05-19-2006	10-12-2006	Guidant Corporation	Final software load did not occur prior to shipment of select programmers.
Z-1235-06	KinetDx	3	04-06-2006	07-13-2006	Siemens Medical Solutions USA Inc	The cardiologist's report comments may not be retained by the system due to a software bug.
Z-0900-06	SYNCHRON LX 20 Clinical System	3	03-15-2006	05-25-2006	Beckman Coulter Inc	It was confirmed that the ORDAC (Over Range Detection And Correction) feature (auto & manual) does not perform correctly for the glucose cup chemistry (GLUCm) when sample type of 'Other' is selected w/operating software version 4.5. Results for these samples could be elevated as much as twice the actual value. The ORDAC feature does function properly w/serum plasma urine & CSF.
Z-0902-06	UniCel DxC 600/800 SYNCHRON Clinical Systems	3	03-15-2006	05-25-2006	Beckman Coulter Inc	It was confirmed that the ORDAC (Over Range Detection And Correction) feature (auto & manual) does not perform correctly for the glucose cup chemistry (GLUCm) when sample type of 'Other' is selected w/operating software version 1.0 & 1.2. Results for these samples could be elevated as much as twice the actual value. The ORDAC feature does function properly w/serum plasma urine & CSF.
Z-0901-06	SYNCHRON LX i 725 Clinical Systems	3	03-15-2006	05-25-2006	Beckman Coulter Inc	It was confirmed that the ORDAC (Over Range Detection And Correction) feature (auto & manual) does not perform correctly for the glucose cup chemistry (GLUCm) when sample type of 'Other' is selected w/operating software version 4.5. Results for these samples could be elevated as much as twice the actual value. The ORDAC feature does function properly w/serum plasma urine & CSF.
Z-0905-06	Medtronic Restore Neurostimulator	3	11-22-2005	05-25-2006	Medtronic Inc Neurological & Spinal Division	A limited number of Model 37711 Restore Neurostimulators have an incorrect internal memory parameter that causes the device to indicate it is fully recharged when it may only be 80% to 90% recharged. This anomaly does not affect patient safety. This anomaly can be corrected by reprogramming the Restore Neurostimulator using specific software.
Z-0860-06	ARCHITECT B12 Reagent	3	03-08-2006	05-11-2006	Abbott Laboratories MPG	The 30-day onboard storage information is not included in the barcode labels for these two lots. As a result the ARCHITECT system software is unable to track how long a reagent kit has been stored onboard the ARCHITECT instrument.
Z-0853-06	Affymetrix GeneChip Microarray Instrumentation System consisting of GeneChip 3000Dx scanner with au...	3	04-26-2005	05-06-2006	Affymetrix Inc.	Incorrect software version of instrument controller is not compatible with new configuration. This incorrect configuration may cause the instrument system to fail at start-up or during a run.
Z-0398-06	ARCHITECT c8000 System	3	12-08-2005	01-18-2006	Abbott Laboratories Inc	System software assigns a calibrator default volume of 2.0uL when field is left empty by operator at time assay parameters set. Patient results could be affected if the volume required is not 2.0 uL.
Z-0177-06	Passport 2 with View 12 ECG Analysis Module. It is a transportable multi-parameter physiological	3	09-07-2005	11-23-2005	Datascope Corp	Software anomalies which include shut down while printing invalid diastolic blood pressure display and incomplete and inaccurate interpretation reports of 12-Lead ECG data.
Z-0176-06	Spectrum Patient Monitor Physiological Patient with arrhythmia detection or alarms. Monitor can m...	3	09-07-2005	11-23-2005	Datascope Corp	Software anomalies which include shut down while printing invalid diastolic blood pressure display and incomplete and inaccurate interpretation reports of 12-Lead ECG data.
Z-1371-05	Regius	3	03-30-2005	08-13-2005	Konica Medical Imaging Inc.	One feature of the software on some of the devices which permits assembling three digital images into one image has occasionally had problems aligning the three images exactly.
Z-0807-05	Programming software for Polymedco PolyTitar Immunofluoresc ent Titration System	3	09-24-2004	05-10-2005	Diasorin Inc.	A problem with software for the PolyTiter Immunofluorescent Titration System in that no flags or warnings appear when PolyTiter Calibrator Values are re-entered or changed (including values changed to unacceptable values) after the initial curve has been generated if the 'refresh button' has not been pressed. The graph may appear valid; however erroneous results may occur.
Z-0703-05	DiaSorin Software	3	05-20-2004	04-13-2005	Diasorin Inc.	When software was updated for the Washer program of the Bio Tek Automated Microplate Washer Model ELx50 the software did not automatically clear old versions of the wash program when new ones were added.
Z-0702-05	DiaSorin programming software	3	04-12-2004	04-13-2005	Diasorin Inc.	The software program written for use in the automated microtiter plate reader (Bio-Tek ELx800) for use with the Pro-Trac II Tacrolimus ELISA kit was found to be faulty. Assay software program did not include the Calibrator Zero OD specification (STDO>=1,500) as specified in the product insert.
Z-0266-05	CXP software for Cytomics FC500 Cytometer	3	11-02-2004	11-30-2004	Beckman Coulter Inc	Incorrect sample identification can be displayed and printed on the Runtime Panel Report due to a software defect.
Z-0267-05	DL2000 Data Manager Software Version 6.4.108	3	11-05-2004	11-30-2004	Beckman Coulter Inc	Possibility of reporting an incorrect result occurs due to a software anomaly.
Z-0259-05	CXP Software Version 1.0 and 1.1 (operating software for Cytomics FC500 Cytometer.Part	3	08-02-2004	11-30-2004	Beckman Coulter Inc	Software anomaly.

Z-0061-05	Excalart (tm) VANTAGE P2 & P3 Magnetic Resonance Imaging System	3	09-16-2004	11-02-2004	Toshiba American Med Sys Inc	Scanned images are acquired at a position that is shifted relative to the intended position in the slice direction due to a software anomaly.
Z-1096-04	DataLink 2000 Data Manager	3	11-03-2003	07-28-2004	Beckman Coulter Inc	Software anomaly allows results to be archived prior to validation or to be uploaded to the lab information system.
Z-0993-04	Fuji Flash IIP and CR-IR346CL	3	05-05-2004	07-20-2004	Fujifilm Medical System USA Inc.	Software: Incorrect measurement of objects within a CR image
Z-0937-04	Magnetic Resonance Imaging System Core SoftwareSoftwa re installed in all of the following...	3	05-06-2004	07-20-2004	Toshiba American Med Sys Inc	Software anomaly.
Z-0818-04	ARCHITECT	3	03-19-2004	07-20-2004	Abbott Laboratories Inc	When using a LIS the software system will send up a test result of up to 20 characters although the field is set to display only 15 characters per the RS-232 Manual.
Z-0744-04	Acuson Cypress Echocardiograp hy System	3	02-02-2004	07-20-2004	Siemens Medial Solutions USA Inc	software problem - made does not appear on screen
Z-0546-04	Toshiba	3	01-27-2004	07-20-2004	Toshiba American Med Sys Inc	Software anomally causes image slices to be in incorrect order.
Z-1079-04	CardioMD	3	08-21-2004	07-20-2004	Adac Labs	Software problems may cause the detector head to drift unexpectedly.
Z-0531-04	Medtronic MiniMed Model 7311 Version 5.0B Solutions Pumps and Meters Software.	3	01-28-2004	02-10-2004	Medtronic MiniMed	A minor software anomaly results in an error in the calculation of the average glucose range that appears on one of the reports available in the model 7311 software.
Z-0527-04	GEMSIM Onepass Nuclear Medicine	3	01-16-2004	02-10-2004	GVI Technology Partners	Due to limitations in the operating software the acquired scan may not be processed properly.
Z-0265-04	Medtronic MiniMed Model 731 Version 5.0A Solutions Pumps and Meters	3		12-24-2003	Medtronic MiniMed	Accessory software fails to report certain reports following download of data from 712 pump.
Z-1142-03	AEROSET	3	12-29-2000	08-21-2003	Abbott Laboratories Inc	ICT assays run using a manual dilution will not be calculated correctly by the software.
Z-1146-03	Access Immunoassay System Technical Update 03.1 Part number 387851 Software	3	06-18-2003	08-21-2003	Beckman Coulter Inc	Defective software media distributed with upgrade software may cause installation failure and systems lock.
Z-1138-03	Immulite 2000, Immunoassay system. Software version 2.6 was to be uploaded on systems running 2.5b...	3	06-13-2003	08-20-2003	DPC Cirrus	Version 2.6 software was released however it will not properly handle adjustment slopes.
Z-1126-03	Olympus ImageManager	3	03-05-2003	08-12-2003	Olympus America Inc.	Software defect; potential under certain circumstances to incorrectly identify endoscopy images that have been uploaded & saved to the network system.
Z-1093-03	Misys Laboratory System versions5.3 up to 5.3.2 with LabAccess Results Workstation.	3	06-23-2003	08-07-2003	Misys Healthcare Systems	Software defect.
Z-1088-03	Leonardo Workstations with software version 2022A/B 2003A	3	02-28-2003	08-07-2003	Siemens Medical Solutions USA Inc	software problem
Z-1087-03	MR Systems	3	02-28-2003	08-07-2003	Siemens Medical Solutions USA Inc	software problem
Z-1089-03	Leonardo Workstations	3	02-28-2003	08-07-2003	Siemens Medical Solutions USA Inc	software problem
Z-0865-03	Acuson	3	03-31-2003	05-22-2003	Siemens Medical Solutions USA Inc.	The product has a software condition in that the surface temperature of the transducer may reach above the thermal limit.
Z-0864-03	Acuson	3	03-31-2003	05-22-2003	Siemens Medical Solutions USA Inc.	The product has a software condition in that the surface temperature of the transducer may reach above the thermal limit.
Z-0806-03	Misys Commercial Laboratory Laboratory Information System version 3.4.1	3	03-24-2003	05-09-2003	Misys Healthcare Systems	Software logic error.

Z-0805-03	COULTER PrepPlus and PrepPlus 2 Pipetting and Diluting station for Clinical Use	3	03-28-2003	05-09-2003	Beckman Coulter Inc	Software problem may cause the instrument to skip the probe-wash step before processing different reagents.
Z-0727-03	ICON 9.5 Software	3	02-10-2003	04-16-2003	Siemens Medical Solutions USA Inc.	ICON 9.5 software does not apply flood corrections during whole body SPECT studies with multiple bed positions.
Z-0669-03	LH 700 Series Hematology Analyzers.Part numbers 66056032 6605633 6605645	3	12-27-2002	03-21-2003	Beckman Coulter Inc	Incorrect Hemoglobin result can be reported at software version 2A and higher.
No reported patient injuries or illnesses for the use of this device in conjunction with this device correction.						
The primary use of a Live Gate is for the international removal of unwanted events such as debris. The data outside of the Live Gate will not be stored to the final listmode file this reducing the data set size.						
The softwa						
The software error associated with the excluded sample appears as Liquid was not successfully transferred to well#.....the sample will be excluded from further proce						
A. Split Screen Field Correction:						
GSI Audera units with version 2.6 software may mislabel Auditory Evoked Potential (AEP) waveform responses with respect to the identification of the stimulus ear. When using 2.6 software in split-screen mod						
completed. This software upgrade adds the algorithm (Slidetype) for						
PATHWAY anti-HER-2/neu (4B5) antibody to the VIAS system.						
1. The Positron Emission Mammography Standardized Uptake Value (PEMSUV) and distance measurements for the product mentioned above may be inaccurate if a zoomed image has been opened measurement tools are used and the applet rema						
A software anomaly may occur when performing the ETI-Mumps IgG assay on the ETI-Max 3000 automated platform. The error occurs when running a combined plate on the ETI-Max 3000 with the ETI-Mumps IgG assay as the second assay on a combined plate with ETI-Measles IgG and/or ETI-						
When Quality Assurance failure warnings are missing from a patient's report abnormal results could be used for diagnosis or						
This error may cause the loss of peripheral image information when there is a difference between the dimensions of the image matrix and the display segment.						
This error may cause the loss of peripheral image information when there is a difference between the dimensions of the image matrix and the display segment.						
This error may cause the loss of peripheral image information when there is a difference between the dimensions of the image matrix and the display segment.						

【参考】iPhone は医療機器　　2009/06/30(古川)

FDA が iPhone で動作するソフトウェアを医療機器と認定したことに対して"When is an iPhone a Medical Device？"なる記事が載った FDC reports で発行されたようです。

その部分を抜粋した内容を下記に添付します。

内容的には、「CTG の表示装置が iPhone のアプリとして FDA 認可を受けているが、iPhone 自体は一般装置なので、医療機器ではない。但し、アップルが 医療ソフトを含んだ状態で出荷した場合は iPhone も医療機器となる。」

雑誌名：
"The Silver Sheet"
Medical Device Quality Control Reports
Vol.13,No.4 April 2009

内容：p11 から抜粋

The same applies to Apple's iPhone. San Antonio-based AirStrip Technologies received FDA clearance April 6 to market its AirStrip OB application for use on the iPhone.

Obstetricians can use the AirStrip software to remotely access real-time data for a mother and baby, including heart tracings and contraction patterns.

Further, Johnson & Johnson subsidiary LifeScan has produced a prototype system for the iPhone that aids patients with diabetes management.

However, Apple probably won't need to worry

about meeting FDA regulations.

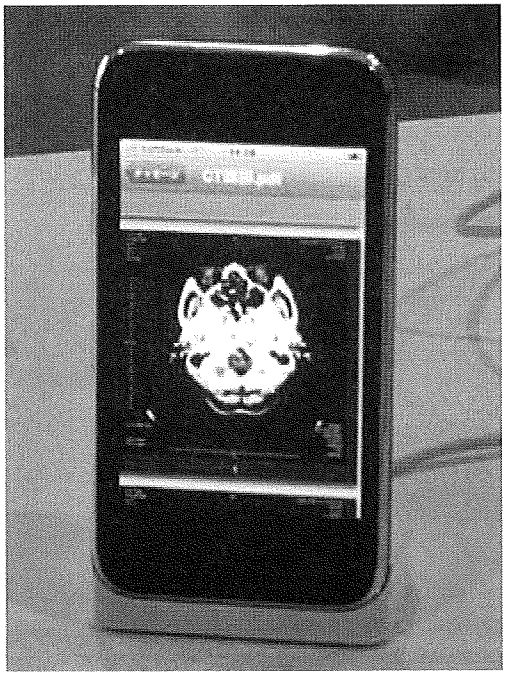
"If an iPhone is sold as a general-purpose mobile phone and a hospital decides to use it for some medical purpose, it would not be a medical device," Eagles says. But if Apple "marketed it for a purpose that met the definition of a medical device, such as a nurse call station, then it would be regulated as a medical device."

ニュース NEWS

記事一覧へ

ソフトバンクテレコム、遠隔医療などでの iPhone の業務事例公開

ソフトバンクテレコムは 2009 年 10 月 14 日、医療・教育分野における iPhone 利用事例を公開した。遠隔での画像診断や在宅医療などでの活用が始まっているという。ソフトバンクテレコムの宮内謙代表取締役副社長兼 COO（最高執行責任者）は「単なるインターネット端末としてではなく、仕事に直結する使い方をする企業や団体が増えている」と分析する。



医療画像を iPhone で閲覧する

医療分野では、放射線を使った医療画像の診断に iPhone を使う共同研究を実施していることを明かした。鹿児島県霧島市にある霧島市立医師会医療センターなど 4 医療機関が、IT 企業ジェイマックシステムを共同で実施している。院内に専門の診断医がいなくても、iPhone に画像を送って遠隔で診断可能にした（写真）。

在宅利用でも使われている。都内で桜新町アーバンクリニックなどを運営する医療法人社団プラ

タナスは、病気などで通院が困難な患者の在宅医療を担当する医師に iPhone を持たせ、情報共有に取り組んでいる。「ノート PC よりもスピーディに情報を共有できる」と桜新町アーバンクリニックの遠矢純一郎氏は話す。

ファイル共有サービス「Dropbox」や「Google カレンダー」を使って患者情報やスケジュールを共有するほか、画像や映像を使った処置支援にも取り組んでいる。「患者に気管カニューレと呼ばれるチューブを挿入する際に、患者によっては斜めに入れたほうがいいなど、注意すべき点がある。それを動画や画像で共有する」(遠矢氏)。

青山学院大学や日本電子専門学校は、教育分野で iPhone を使う。青山学院大学は講義に必要な資料を、学生が持つ iPhone 向けに配信している。同大学は 2009 年 5 月に、iPhone を教員と学生 550 人に配布済みである。資料データの配信システムには、インフォテリアの iPhone 向けデータ配信サービス「Handbook」を採用した。

日本電子専門学校は 2010 年 4 月に「ケータイ・アプリケーション科」を新設し、教育内容の一つとして iPhone 向けアプリケーション開発を取り上げるほか、授業の資料配付や資格検定の教育などにも利用するという。(ITPro)

▲ PAGE TOP

TITLE:ソフトバンクテレコム、遠隔医療などでの iPhone の業務事例公開：日経メディカル オンライン
DATE:2009/12/24 09:25
URL:http://medical.nikkeibp.co.jp/leaf/all/special/it/news/200910/512899.html

企業調査報告　ソフトウエアの規制に関する検討
アンケート実施から分析まで

財団法人　先端医療振興財団
クラスター推進センター　医療機器サポートプラザ
総括・中小企業相談担当　調査役　吉川　典子

1　調査背景

医療機器の研究開発に関する相談業務に従事しているが、ソフトウエアに関する相談を持ち込む相談者の背景を見ていると、企業規模が小さいことが多いことが判明した。こうした企業から、ざっくばらんな意見を聴取したところ、ソフトウエアが単独では、医療機器として扱われていないことについて、賛成意見と反対意見に二分されていた。さらに、業界団体への加盟がないことも多く、なかなか意見を出す機会もないことも判明した。こうしたことから、平成２０年度報告に続き、筆者のいる神戸医療産業都市関連以外の企業にも対象を広げ、調査を行うこととした。

このような背景から、調査対象者の選定については、いわゆる医療機器が関連する学会展示会を中心とはせずに、医療機器やものづくりに関する産業系の展示会に出展しているようなところを対象とした。

別添のとおりのアンケート用紙を送付し、得られたご回答をもとに、扱っているソフトウエアの対象範囲や、製品開発のきっかけ、規制に関する意見を知り、実態を明らかにすることとした。なお、アンケート用紙の作成にあたっては、平成２０年において、神戸医療産業都市エリア内の企業からいただいた自由意見をもとに設計を行った。

（参考）　アンケート送付先の抽出

２段階にて抽出し、
神戸医療産業都市構想関連企業から、取扱企業をピックアップする

1　進出企業リスト
2　地元企業に関するデータブック
3　産学連携コンソーシアム

大規模調査のための資料

4　２００８国際医用画像総合展
5　CADM&CAD
6　日本画像医療システム工業会 JIRA
7　メディカルクリエーションふくしま　出展者資料
8　岐阜大垣地域ロボティッククラスター

合計として１００企業を選択した。

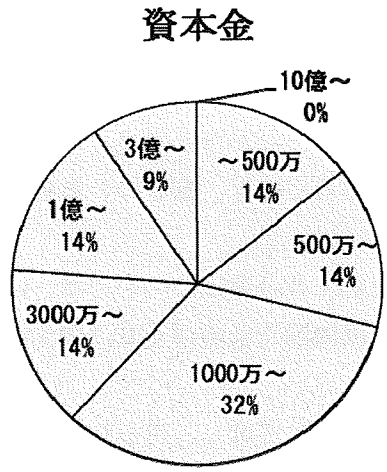
2　アンケート結果のまとめ

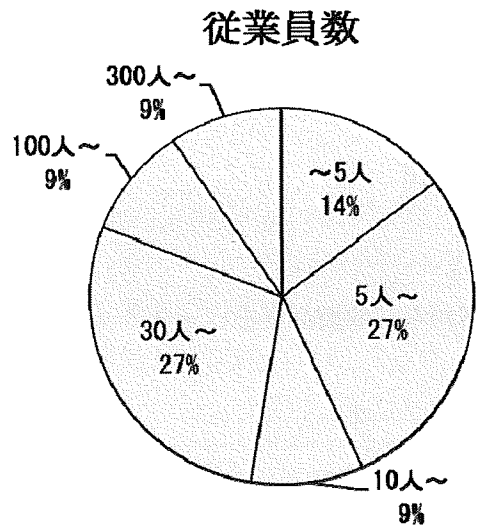
２－１　回答者の像

回答者属性

大学	2
公設研究所	1
医療機関	0
企業	２２

企業サイズについては、下記のような回答が得られた。資本金としてのサイズと、人数としてのサイズである。





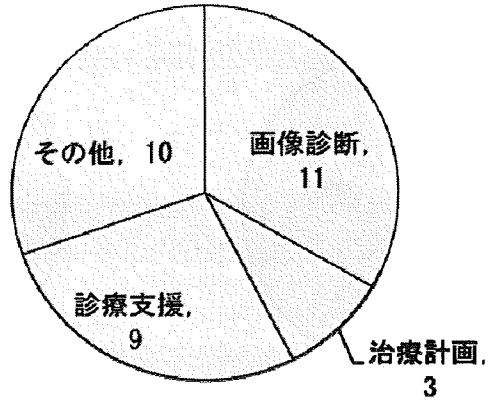
なお、このうち、企業２２社のうち、何らかの業界団体への所属があるところは１１である。ほとんどがＪＩＲＡへの所属である。地元商工会のものもあった。

２－２　取り扱い状況

取り扱う製品について、大きく、画像診断、治療計画、診療支援、その他と分類して、回答を求めた。製品群の選定にあたっては、複数回答を受け入れており、いくつかの該当がある企業もあった。画像診断、診療支援、その他で、ほぼ３分した結果となった。

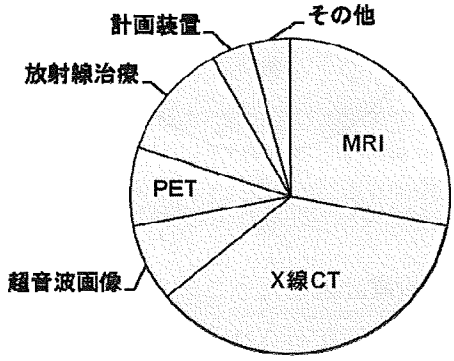
その他としての事例は、データの授受ソフトウエア、座標表示、計測といった基礎的な

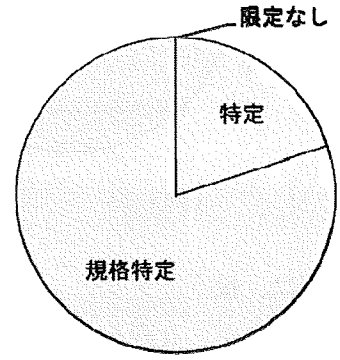
処理のものが中心である。いくらかは、カテゴリーの選定に苦慮した結果、その他を選んだのかもしれない。

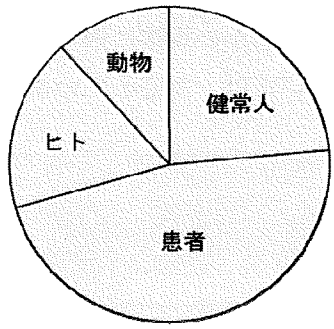


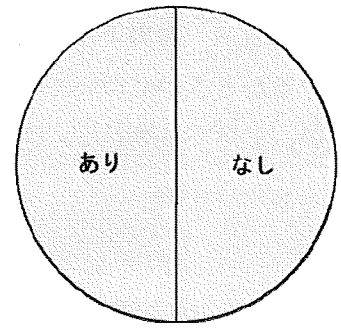
それぞれの製品群別の、扱い状況の結果を示す。

画像診断



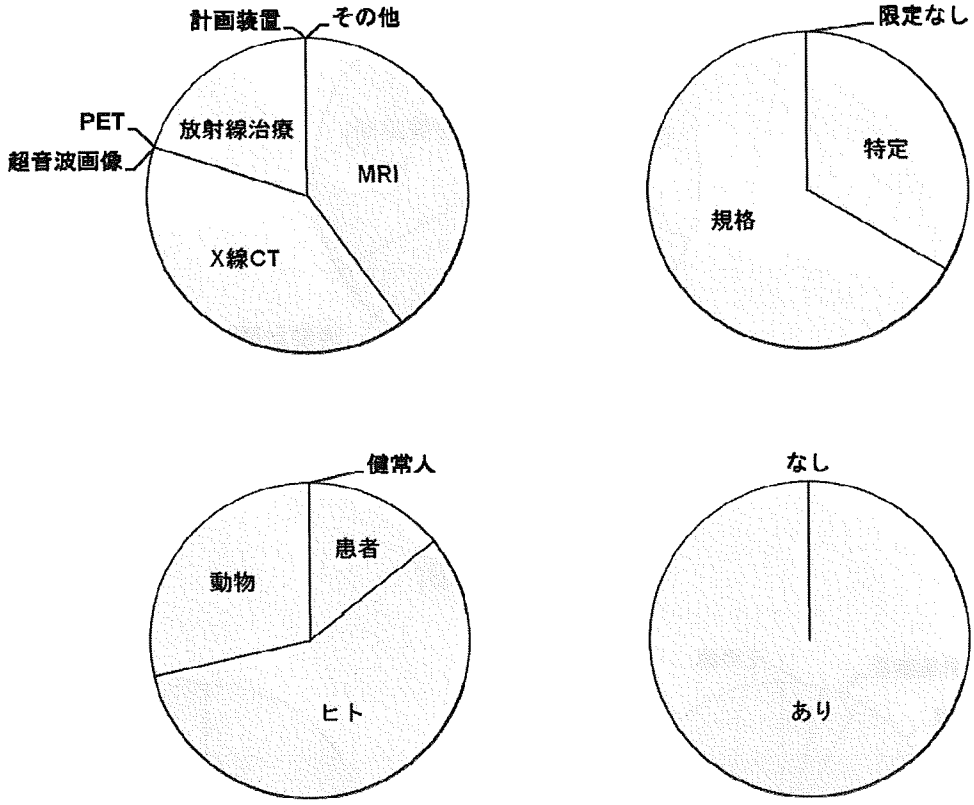






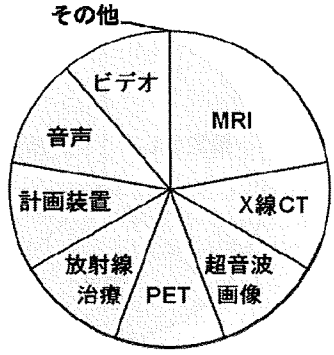
左上の円は、扱うモダリティの種類を回答している。また、左下は、扱うデータの対象を示している。右上は、ハードウエアとの組み合わせの確認のため、適用する機種の特定をしているか、何らかの規格に適合していることを求めているかどうかについての回答である。右下においては、規格の対応を行っているかについてであるが、半数が適合している規格があり、ＤＩＣＯＭであった。

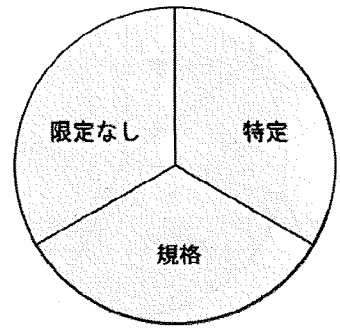
治療計画

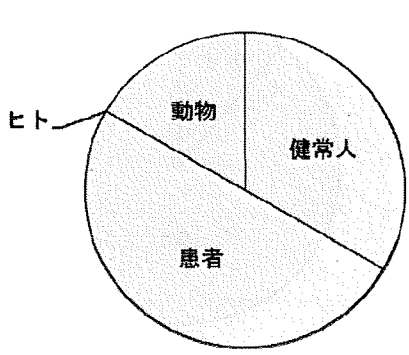


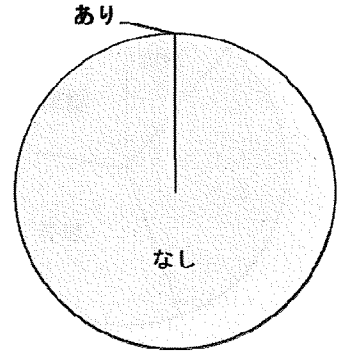
左上の円は、扱うモダリティの種類を回答している。治療計画を行うことから、元となるデータソースが、計画をするに値するかどうかということに左右されるため、ＭＲＩ、Ｘ線ＣＴに集中している。また、左下は、扱うデータの対象を示している。動物分野も対象としている回答が目立つ。右上は、ハードウエアとの組み合わせの確認を行っているかについてであるが、適用する機種の特定をしているか、何らかの規格に適合していることを求めているかどうかについての回答である。右下においては、対応している規格についてであるが、すべてが対応し、ＤＩＣＯＭであった。

診療支援









左上の円は、扱うモダリティの種類を回答している。複数回答を可能としている。診療支援のためのものであり、様々
なデータを基に診療を行うことを反映して、非常に多くの種類の回答があった。また、左下は、扱うデータの対象を示している。右上は、ハードウエアとの組み合わせの確認をしているかにおいて、適用する機種の特定をしているか、何らかの規格に適合していることを求めているかどうかについての回答である。三分されており、診療支援内容によっては、全く限定していないものもあった。右下においては、そのソフトウエアが規格に適合しているかについてであるが、全数が適合させている規格がないという回答であった。