

**FOOD AND DRUG ADMINISTRATION (FDA)  
RECALLS/ALERT NOTICES**

1. FDA MEDICAL EQUIPMENT RECALLS AND ALERTS. The following recalls are reported in accordance with AFMLL 2-95, page CE-4, and should be treated as directed modifications in accordance with that AFMLL and AFI 41-201, Chapter 2, Section D. If you possess any of these items and have not received recall notification, you should contact the manufacturer for recall instructions. Suspension is only required for Class I items. (FOM, Capt David Zemkosky, DSN 343-4028)

**CLASS I RECALLS: None**

**CLASS II RECALLS:**

6525NS  
MDC 13469  
PRODUCT Scanners, Computed Tomography  
Imatron CT Scanner, a component of the patient table potentiometer assembly (Y-potentiometer): (a) Imatron C100 CT Scanner; (b) Imatron C150 Series Scanners. Recall #Z-298/299-7.

CODE Various model numbers and serial numbers are involved.  
MANUFACTURER Imatron, Inc., South San Francisco, California.  
RECALLED BY Manufacturer, by sending an "Advance Letter" in July 1996, and issuing its own Field Modification Instructions, followed by visit. Firm-initiated field correction ongoing.

DISTRIBUTION Nationwide and international.  
QUANTITY 81 units were distributed.  
REASON The table would go beyond its limits and could not be driven back due to a blown fuse.

None Present  
 Action Taken \_\_\_\_\_  
\_\_\_\_\_

6515NS  
MDC 12602  
PRODUCT Monitors, EEG  
EEG Tend Monitor, Model OEE-7102B, intended for long term EEG monitoring and analysis. Recall #Z-303-7.

CODE Serial numbers: 00003, 00004, 00006-00016, 00020-00023, 00031, 00033-00035, 00038, and 00043.

MANUFACTURER Nihon Kohden Corporation, Shinjuku-Ku, Tokyo, Japan.  
RECALLED BY Nihon Kohden America, Inc., Irvine, California, by letter dated October 16, 1996. Firm-initiated recall ongoing.

DISTRIBUTION Arizona, California, Illinois, Kansas, Louisiana, South Dakota, Texas, Utah.  
QUANTITY 23 units were distributed.  
REASON When the 12V DC power supply conductor is broken, and the main power is turned on, a higher than acceptable current leakage is applied to the monitoring electrodes and a chemical reaction is generated with EEG paste, which can discolor the patient's skin when the electrodes are placed on the patient skin.

None Present  
 Action Taken \_\_\_\_\_  
\_\_\_\_\_

6515NS  
MDC 11218  
PRODUCT Hemodialysis Units  
Cobe Centrysystem HG Dialyzer, used in chronic hemodialysis procedures to remove body wastes and water from the blood: (a) 600 HG Dialyzer; (b) 700 HG Dialyzer. Recall #Z-295/296-7.  
CODE Lot numbers: (a) G07B5291, G07B5292, G07B5293, G07B5294, G08B5292, G09B5291, G09B5293, G09B5294, G10B5291, G10B5292, G10B5293, G11B5291; (b) G10B5311, G10B5312, G10B5313, G11B5311, G11B5313, G01C5311.  
MANUFACTURER Secon GMBH, Dransfeld, Germany.  
RECALLED BY Gambro Healthcare, Lakewood, Colorado, by telephone followed by FedEx on January 31, 1997. Firm-initiated recall ongoing.  
DISTRIBUTION Colorado, District of Columbia, Florida, Illinois, Kentucky, Missouri, New York, Tennessee, Virginia, Washington state, Wisconsin, Canada.  
QUANTITY (a) 11,740 units; (b) 13,980 units were distributed.  
REASON The blood in the dialyzers was leaking from the blood side into the dialysate.

None Present  
 Action Taken \_\_\_\_\_  
\_\_\_\_\_

6515NS  
MDC 13215  
PRODUCT Infusion Pumps  
Medtronic Synchronomed Programmable Pumps: (a) Model #8617-18; (b) 8617L-18. Recall #Z-310/311-7.  
CODE None.  
MANUFACTURER Medtronic, Inc., Neurological Division, Columbia Heights, Minnesota.  
RECALLED BY Manufacturer, by letter on January 31, 1997. Firm-initiated recall ongoing.  
DISTRIBUTION Nationwide.  
QUANTITY 97 pumps were distributed.  
REASON The infusion pump could leak, resulting in corrosion of the components, causing a motor stall condition.

None Present  
 Action Taken \_\_\_\_\_  
\_\_\_\_\_

6515NS  
MDC 12712  
PRODUCT Nebulizers  
Aero-Mist Nebulizer/Compressor System, Reorder #HCS 1200, a disposable home use nebulizer used to atomize liquid medications for inhalation, normally used by asthmatics. Recall #Z-315-7.  
CODE Lot numbers 601 and 604, Serial numbers 13003-22000.  
MANUFACTURER Medel Italiana S.R.L., Polo Di Torriale (PR), Italy.  
RECALLED BY Medline Industries, Inc., Mundelein, Illinois, by letter dated February 18, 1997. Firm- initiated recall ongoing.  
DISTRIBUTION Nationwide and international.  
QUANTITY Approximately 6,100 units were distributed.  
REASON The units may experience a drop in air pressure over time during use, causing difficulty in administering the recommended dosage of medication.

None Present  
 Action Taken \_\_\_\_\_  
\_\_\_\_\_

6515NS  
MDC 15993  
PRODUCT Pacemaker Programmers  
Model 531-30 (software) Rx2000 Program Module, an electronic memory cartridge containing instructions needed by the Model 522-06 Rx2000 graphics programmer to program and obtain data from Intermedics Res-Q Arrhythmia Control, life support devices. Recall #Z-316-7.

CODE All lots. Serial numbers involved range within #1330-1657 and #101680-102337. Manufactured from August 24, 1990 to current.

MANUFACTURER Intermedics, Inc., Angleton, Texas.

RECALLED BY Manufacturer, by letter sent on February 3, 1997. Firm-initiated field correction ongoing.

DISTRIBUTION Nationwide and Lebanon.

QUANTITY 280 units were distributed.

REASON A software condition can cause inappropriate programming of parameter data that can result in undersensing, oversensing, and loss of capture.

None Present  
 Action Taken \_\_\_\_\_  
\_\_\_\_\_

6525NS  
MDC 15944  
PRODUCT Cameras, Gamma  
Toshiba Digital Gamma Cameras, used to perform a wide range of nuclear medicine examinations: (a) Model No. GCA-7100A  
(b) Model No. GCA-7200A  
(c) Model No. GCA-7100A/DI  
(d) Model No. GCA-7200A/DI.

Recall #Z-317/320-7.

CODE All serial numbers.

MANUFACTURER Toshiba Corporation, Tochigi, Japan.

RECALLED BY Toshiba America Medical Systems, Inc., Tustin, California, by letter on November 18, 1996. Firm-initiated field correction ongoing.

DISTRIBUTION Nationwide.

QUANTITY Approximately 76 units are installed.

REASON Allen head bolts located in the rotating assembly drive train section had been sheered off, allowing the single head assembly to rotate freely between 90 to 270 degrees beneath the patient.

None Present  
 Action Taken \_\_\_\_\_  
\_\_\_\_\_

**CLASS III RECALLS:**

6525NS  
MDC 13469  
PRODUCT Scanners, Computed Tomography  
C-150XP CT Scanner Installed with Software Version 12.22. Recall #Z-304-7.

CODE All models with 12.22 version software.

MANUFACTURER Imatron, Inc., South San Francisco, California.

RECALLED BY Manufacturer, by "Software Notice" letter on August 28, 1996. Firm-initiated field correction ongoing.

DISTRIBUTION Nationwide and international.

QUANTITY 30 units were distributed.



REASON The device's software version 12.22 contains an error which prevents it from detecting an unexpected stop in table motion during certain low velocity Continuous Volume Studies (CVS), resulting in unnecessary x-ray radiation exposures to the patient.

None Present  
 Action Taken \_\_\_\_\_  
\_\_\_\_\_

6525NS  
MDC 13469  
PRODUCT Scanners, Computed Tomography  
Software Versions 11.53 and 12.13 installed in computed tomography scanners: (a) Model C-100; (b) Model C-150XP; (c) Model C-150L. Recall #Z-305/307-7.  
CODE Models C100, C150XP, and C150L.  
MANUFACTURER Imatron, Inc., South San Francisco, California.  
RECALLED BY Manufacturer, by sending Software Notice #20 on or about November 16, 1995. Firm-initiated field correction ongoing.  
DISTRIBUTION Nationwide and international.  
QUANTITY 37 units were distributed.  
REASON During reconstruction of images, the Fast Reconstruction System software (FSR) may produce an error condition which the computer may interpret as a warning, causing the computer to display erroneous data for the image.

None Present  
 Action Taken \_\_\_\_\_  
\_\_\_\_\_

6515NS  
MDC 17148  
PRODUCT Oximeters, Pulse  
Nellcor Symphony N-3000 Pulse Oximeter, Model N-3000. Recall #Z-308-7.  
CODE 111 units with suspect printed circuit boards, each with an individual serial number.  
MANUFACTURER Nellcor Puritan Bennett, Inc., Chula Vista, California.  
RECALLED BY Nellcor Puritan Bennett, Inc., Carlsbad, California, by letter on October 23, 1996. Firm-initiated recall ongoing.  
DISTRIBUTION Nationwide and international.  
QUANTITY 111 units were distributed.  
REASON The device may be potentially subject to printed circuit board damage which can result in the monitor reporting SpO2 values slightly outside the normal accuracy range stated in the Operations Manual.

None Present  
 Action Taken \_\_\_\_\_  
\_\_\_\_\_

6515NS  
MDC 17148  
PRODUCT Oximeters, Pulse  
Nellcor-Equipped MicroDigitrapper-S/Oxy-Holter, used in the diagnosis of sleep disorders. Recall #Z-301-7.  
CODE Various serial numbers.  
MANUFACTURER Synectics Medical, Inc., Irving, Texas.  
RECALLED BY Manufacturer, by letter on November 2, 1995. Firm-initiated recall ongoing.  
DISTRIBUTION Nationwide and international.

QUANTITY 103 units were distributed.  
REASON The device experiences loss of pulse-oximetry data from high artifact levels due to a design problem.

None Present  
 Action Taken \_\_\_\_\_

MEDICAL EQUIPMENT SAFETY ALERTS: None

2. DRUG/SUPPLY PRODUCT RECALLS AND MEDICAL INFORMATION. The Food and Drug Administration (FDA) advises that the drug products listed below were recalled by the manufacturers or distributors concerned. The FDA has classified these recalls as follows:

CLASS I: A situation in which there is a reasonable probability that the use of, or exposure to, a violative product will cause serious, adverse health consequences or death.

CLASS II: A situation in which the use of, or exposure to, a violative product may cause temporary or medically reversible adverse health consequences or where the probability of serious adverse health consequences is remote.

CLASS III: A situation in which the use of, or exposure to, a violative product is not likely to cause adverse health consequences.

Most of these items are nonstandard, and the possibility exists that medical activities may have purchased them locally. There is also a possibility that some of these items have NSNs assigned and may have been reported in earlier Q.A. messages. Activities having quantities of these items on hand will immediately suspend the materiel from issue and use. CONUS activities will contact the nearest office of the respective manufacturer or distributor for disposition instructions. OVERSEAS activities will report quantities suspended to AFMLO/FOM-P no later than 16 MAY 97 for disposition instructions. They should include nomenclature; lot number; manufacturer; quantity suspended; strength size; requisition; and DPSC purchase order number, contract number, and stock record account number (SRAN). (FOM-P), Bonnie Phillips, DSN (343-4170)

CLASS I RECALLS: None

CLASS II RECALLS:

NSN 6505 Nonstandard  
PRODUCT Plasma Apheresis Bowl, Model 00625B, with Ultra-Sonic Weld & Sterile Fluid Path, used with Haemonetics Plasma Collection System. Recall #B-432-7.  
CODE Lot numbers T96 (starts with T96001), U96, V96, W96 (ends W96069):  
T96001-T96009; T96012-T96030; T96032-T96038;  
T96040-T96069; T96071; T96073-T96085;  
T96088-T96089; T96092-T96095; T96098-T96099;  
T96102-T96107; T96110; T96112-T96114;  
T96116-T96119; T96121-T96125; T96129-T96131;  
T96134; T96136-T96137; T96141; T96143; T96144;  
T96147-T96149; T96152-T96154; T96158.  
U96015-U96027; U96029-U96037; U96039-U96042;  
U96044-U96045; U96048-U96051; U96053-U96062;

U96064-U96070; U96072-U96078; U96080-U96082;  
 U96084-U96112.  
 V96001-V96007; V96010-V96012; V96014-V96019;  
 V96021-V96022; V96026-V96028; V96031-V96032;  
 V96034-V96035; V96037-V96039; V96041;  
 V96043-V96050; V96052-V96056; V96058-V96062;  
 V96064-V96065; V96067-V96087; V96091-V96092;  
 V96094; V96096-V96098; V96100-V96106;  
 V96108-V96139; V96141-V96145; V96147-V96153;  
 V96155- V96159; V96163.  
 W96001-W96004; W96007-W96008; W96010;  
 W96012-W96013; W96015; W96017-W96022;  
 W96024-W96030; W96032-W96037; W96039-W96042;  
 W96044-W96045; W96047-W96049; W96051-W96058;  
 W96060-W96080; W96085-W96086; W96088-W96089;  
 W96093-W96094; W96097-W96101; W96105-W96106;  
 W96108-W96110; W96113-W96115; W96117; W96120;  
 W96123; W96138; W96146; W96148; W96151;  
 W96154; W96157; W96160; W96161; W96163;  
 W96164.

MANUFACTURER Haemonetics Corporation, Leetsdale,  
 Pennsylvania.  
 RECALLED BY Haemonetics Corporation, Braintree,  
 Massachusetts, by fax on February 20, 1997.  
 Firm-initiated recall ongoing.  
 DISTRIBUTION California, Florida, Georgia, Iowa, Indiana,  
 Massachusetts, New York, Oklahoma,  
 Pennsylvania, South Carolina, Tennessee.  
 QUANTITY 2,073,099 bowls were distributed.  
 REASON Plasma Apheresis Bowls, determined to have an  
 incomplete seal in the ultrasonic weld joint  
 causing the bowl to leak during normal  
 plasmapheresis operations.

None Present  
 Action Taken \_\_\_\_\_  
 \_\_\_\_\_

NSN 6505 Nonstandard  
 PRODUCT BayRab brand, Rabies Immune Globulin (Human).  
 Recall #B-459-7.  
 CODE Lot #618R01A, EXP 21MAR98 (2 ml vials),  
 618R01B, EXP 21MAR98 (10 ml vials).  
 MANUFACTURER Bayer Corporation, Clayton, North Carolina.  
 RECALLED BY Manufacturer, by letter on December 2, 1996.  
 Firm-initiated recall ongoing.  
 DISTRIBUTION Nationwide.  
 QUANTITY Approximately 6,000 doses of single dose vials  
 were distributed.  
 REASON Product was labeled as preservative free but  
 contained low levels of thimerosal.

None Present  
 Action Taken \_\_\_\_\_  
 \_\_\_\_\_

NSN 6505 Nonstandard  
 UPDATE Fluogen (Influenza Virus Vaccine, Trivalent,

Types A & B), an extension of Recall #B-117-7, which appeared in the December 11, 1996 Enforcement Report.

CODE Syringes: Lot #00296P.  
Vials: Lot numbers: 00376P, 00476P, 00596P, 00696P, 01186P, 01286P, 01386P.

MANUFACTURER Warner-Lambert Company, Parke-Davis, Sterile Products Division, Rochester, Michigan.

RECALLED BY The Parke-Davis Division of Warner-Lambert Company, Morris Plains, New Jersey, letter on February 12, 1997. Firm-initiated recall ongoing.

DISTRIBUTION Nationwide.

QUANTITY Approximately 551,000 units were distributed.

REASON Parke-Davis Fluogen showed a decrease in potency of one component of the vaccine after distribution.

None Present  
 Action Taken \_\_\_\_\_

NSN 6505 Nonstandard

PRODUCT Diltiazem Hydrochloride Extended Release Capsules, USP, 60 mg, in bottles of 100, Marketed under the Lemmon label, used for the treatment of hypertension. Recall #D-125-7.

CODE Lots OB 6780 EXP 5/98 and OB 6781 EXP 6/98, distributed between 12/9/96 and 1/28/97.

MANUFACTURER Prographarm Laboratories S.A., France (responsible firm).

RECALLED BY Teva Pharmaceuticals, Sellersville, Pennsylvania, by letter dated January 28, 1997. Firm-initiated recall ongoing.

DISTRIBUTION Nationwide.

QUANTITY 25,000 bottles.

REASON Product fails to meet dissolution specification (lot ob 6781 assays as low as 48% after 12 hours; spec is 55-80%).

None Present  
 Action Taken \_\_\_\_\_

NSN 6505 Nonstandard

PRODUCT Oxygen, USP, Rx in portable aluminum cylinders, sizes B, C, D, and E. Recall #D-124-7.

CODE All codes distributed between November 13, 1996 and January 31, 1997.

MANUFACTURER Mersco Medical, Inc., Sioux Falls, South Dakota.

RECALLED BY Eastern Dakota Health, doing business as Mersco Medical, Inc., Sioux Falls, South Dakota, by visits on or about February 3, 1997. Firm-initiated recall ongoing.

DISTRIBUTION Minnesota, Iowa, South Dakota.

QUANTITY Undetermined. All product distributed from  
11/13/96 to 1/31/97.  
REASON Good manufacturing practice deficiencies.

None Present  
 Action Taken \_\_\_\_\_  
\_\_\_\_\_

NSN 6515 Nonstandard  
PRODUCT SPUR Infant/Child Resuscitator, single use.  
Recall #Z-309-7.

CODE Catalog Nos. (Old Catalog Nos.)  
430013000 (243004000)  
430013001 (243004000001)  
430014000 (2430050NIT)  
430015000 (243001000004)  
430015002 (n/a)  
430017000 (n/a)  
430613000 (243004600)  
430613001 (2430046000001)  
430613002 (243004600002)  
430613003 (n/a)  
430614000 (2430056NIT)  
430614004 (n/a)  
430814000 (243006000NIT)  
431813000 (243014000)  
431813002 (243014000002)  
431814000 (243009800 &243015000NIT)  
431815000 (243014000IT)  
431817000 (n/a)  
Discontinued Catalog Nos.  
430013002 (243004000002)  
430014002 (2430050NIT002)  
430014004 (n/a).

MANUFACTURER Ambu, Inc., Linthicum, Maryland.  
RECALLED BY Manufacturer, by letter dated June 21, 1995.  
Firm-initiated recall ongoing.

DISTRIBUTION Nationwide and Canada.  
QUANTITY 48,315 units were distributed; firm estimates  
none remains on the market.

REASON The patient mask connector can cause  
deformation of the resuscitator connector,  
resulting in inability to connect an  
endotracheal tube for a patient to be  
intubated.

None Present  
 Action Taken \_\_\_\_\_  
\_\_\_\_\_

NSN 6515 Nonstandard  
PRODUCT Angio-Seal Hemostatic Puncture Closure Device,  
8 French, indicated for use in closing and in  
reducing time to hemostasis at the femoral  
arterial puncture site in patients who have  
undergone diagnostic angiography or  
percutaneous transluminal coronary angioplasty  
procedures using an 8F or smaller procedural

sheath: (a) Catalog No. 8888-610089;  
 (b) Catalog No. 1180-580050.  
 Recall #Z-312/313-7.

CODE Lot Numbers: (a) 879905, 880245, 880445,  
 880446, 881486, 881700; (b) 881474, 96I041E,  
 96I201E.

MANUFACTURER Quinton Instrument Company, Bothell,  
 Washington.

RECALLED BY Sherwood Davis & Geck, St. Louis, Missouri, by  
 letter dated January 27, 1997, and by  
 telephone on January 28, 1997. Firm-initiated  
 recall ongoing.

DISTRIBUTION Nationwide and international.  
 QUANTITY Between 9/30/96-1/21/97, 2,090 devices in the  
 U.S. and 2,272 devices internationally were  
 distributed.

REASON During deployment, the devices anchor may  
 become detached from the remainder of the  
 device, remaining within the femoral artery of  
 the patient.

[ ] None Present  
 [ ] Action Taken \_\_\_\_\_

NSN 6515 Nonstandard  
 PRODUCT Kendall Sheridan JETTX Jet  
 Ventilation/Tracheal Tube Exchanger, used as a  
 airway management system. Recall #Z-314-7.

CODE Product #5-24205, Lot #051472.

MANUFACTURER Kendall Healthcare, Argyle, New York.

RECALLED BY Kendall Healthcare Products Company,  
 Mansfield, Massachusetts, by overnight mail on  
 January 31, 1997, and February 3, 1997. Firm-  
 initiated recall ongoing.

DISTRIBUTION Nationwide and international.  
 QUANTITY 470 units were distributed.

REASON The Luer Lock Adapter may be missing,  
 preventing attachment of conventional jet  
 ventilation devices to the tracheal tube  
 exchanger.

[ ] None Present  
 [ ] Action Taken \_\_\_\_\_

NSN 6515 Nonstandard  
 PRODUCT Sensi-Touch Regional Anesthesia Delivery  
 System, Spinal Anesthesia Tray, Catalog #8888-  
 828111, 22 ga plastic hub, diamond point,  
 Marcaine. Recall #Z-297-7.

CODE Lot #801685.

MANUFACTURER Kelsar S.A., Tijuana, B.C., Mexico.

RECALLED BY Sherwood Davis & Geck, St. Louis, Missouri, by  
 letter on January 31, 1997. Firm-initiated  
 recall ongoing.

DISTRIBUTION Michigan, Missouri, Connecticut, Texas, New  
 Jersey, Kentucky, Minnesota, Pennsylvania,



QUANTITY 8,410 bottles were distributed.  
REASON Fails to meet dissolution specification at the  
6-month stability testpoint (assay is 78% of  
label strength; spec is not less than 85%  
after 30 minutes).  
  
[ ] None Present  
[ ] Action Taken \_\_\_\_\_  
\_\_\_\_\_

NSN 6505 Nonstandard  
PRODUCT Mechanical Servants brand Regular Afrin Nasal  
Decongestant 12 Hour Nasal Spray,  
(Oxymetazoline HCl, USP), 0.05% in a 1/10  
fluid ounce spray bottle. Recall #D-127-7.  
CODE Lot #6-CFC-100 EXP 6/98.  
MANUFACTURER Schering-Plough Healthcare Products, Memphis,  
Tennessee.  
RECALLED BY Mechanical Servants, Inc., Chicago, Illinois,  
by letter dated March 3, 1997. Firm-initiated  
recall ongoing.  
DISTRIBUTION Nationwide.  
QUANTITY 14,405 units were distributed; firm estimated  
that 25 percent of product remained on market  
at time of recall initiation.  
REASONS Some outer packages are labeled with an  
incorrect expiration date (the expiration date  
may appear as "10/97" or "6/98"). The bottles  
bear the correct expiration date.  
  
[ ] None Present  
[ ] Action Taken \_\_\_\_\_  
\_\_\_\_\_

NSN 6515 Nonstandard  
 PRODUCT Neurosign Straight Concentric Bipolar Probe with Touch Proof Connectors, Catalog #7033-0919, an accessory to the Neurosign 100 Motor Nerve Monitor. Recall #Z-293-7.  
 CODE Serial numbers: 076, 078, 079, 080, 081, 082, 083, 084, 085, 087.  
 MANUFACTURER The MAGSTIM Company Ltd., United Kingdom.  
 RECALLED BY Smith & Nephew ENT, Smith & Nephew Richards, Inc., Bartlett, Tennessee, by fax on October 16, 1996. Firm-initiated recall complete.  
 DISTRIBUTION Arizona, Kentucky, New York, Texas, Washington state, Wisconsin.  
 QUANTITY 8 units were distributed and are accounted for.  
 REASON The device is subject to possible extrusion of silicone from the end of the probe when the device was autoclaved by the manufacturer.

[ ] None Present  
 [ ] Action Taken \_\_\_\_\_

NSN 6550 Nonstandard  
 PRODUCT Incstar VCA IgG Clin-ELISA Test Kit, Product #4590, an in-vitro diagnostic test kit for detecting antibodies in human serum to Epstein-Barr Viral Capsid Antigen (VCA). Recall #Z-294-7.  
 CODE Lot #395406.  
 MANUFACTURER Incstar Corporation, Stillwater, Minnesota.  
 RECALLED BY Manufacturer, by letter on February 3, 1997. Firm-initiated recall complete.  
 DISTRIBUTION California, New Jersey, New York, international.  
 QUANTITY 131 kits were distributed.  
 REASON Some negative samples may yield a positive assay response.

[ ] None Present  
 [ ] Action Taken \_\_\_\_\_

NSN 6550 Nonstandard  
 PRODUCT Cytomegalovirus IgM ELISA Test Kit, Product #2325250, used for the qualitative determination of IgM antibody to cytomegalovirus in human serum. Recall #Z-302-7.  
 CODE Lot numbers 108 and 109.  
 MANUFACTURER Clark Laboratories, Inc., Jamestown, New York.  
 RECALLED BY Manufacturer, by letter January 23, 1997. Firm-initiated recall ongoing.  
 DISTRIBUTION Nationwide and international.  
 QUANTITY 495 kits were distributed.  
 REASON The absorbance values for controls and specimens are lower than expected.

None Present  
 Action Taken \_\_\_\_\_  
\_\_\_\_\_

MEDICAL DEVICE SAFETY ALERTS:

NSN 6515 Nonstandard  
PRODUCT Sherpa Vector and Sherpa Vector X Coronary Guiding Catheters, designed to provide a pathway through which therapeutic devices are introduced:  
(a) Vector 6F, Catalog numbers PA5xx;  
(b) Vector 7F, Catalog numbers AS7xxx;  
(c) Vector 8F, Catalog numbers AS8xxx;  
(d) Vector X 6F, Catalog numbers S26xxx;  
(e) Vector X 7F, Catalog numbers S27xxx;  
(f) Vector X 8F, Catalog numbers S28xxx.  
Safety Alert #N-007/012-7.  
CODE All lots.  
MANUFACTURER Medtronic Interventional Vascular Inc., Danvers, Massachusetts.  
ALERTED BY Manufacturer, by letter on November 25, 1996.  
DISTRIBUTION Nationwide.  
QUANTITY Approximately 38,796 units were distributed.  
REASON Resistance may be experienced while passing interventional devices through the lumen of the guiding catheter, which may result in the inability to move the interventional device within the lumen of the guiding catheter.

None Present  
 Action Taken \_\_\_\_\_  
\_\_\_\_\_