

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-P, Capt Paul J. Toth, DSN 343-7445)

CLASS I RECALLS: None

CLASS II RECALLS:

**6515 NS
MDC 12636
PRODUCT**

Monitor Systems, Physiologic

SpO2 Extension Cables (Part Number 33 68 433 E53OU AND 33 75 834 E53OU) used with Siemens Patient Monitors: SC7000, SC8000, SC9000XL, and SC6002XL AND MIXED MONITORS-SC9000 or SC5000/6000 with SC7000, SC8000, SC900X, OR SC6002XL. Cables are connected to spO2 sensors and to either multimed or neomed pods are then connected to monitors. Recall #Z-937-0.
CODE Siemens SpO2 Extension Cables (part numbers: 3368433E53OU-1 meter and 3375834e53OU- 2 meters) used with Siemens Infinity Patient Monitor Systems: SC9000XL, SC7000, SC8000, AND SC6002XL and mixed monitors SC9000 OR SC5000/6000 WITH SC7000, SC8000, SC900X, OR SC6002XL.
MANUFACTURER Siemens Medical Systems, Inc., Danvers, Massachusetts.
RECALLED BY Manufacturer, by letter on May 26, 2000. Firm-initiated recall ongoing.
DISTRIBUTION Nationwide.
QUANTITY Undetermined.
REASON Older versions of the SpO2 Extension Cables may result in high SpO2 readings.

None Present
 Action Taken _____

**6630 NS
MDC 10588
PRODUCT**

Carbon Dioxide Analyzers

Hewlett Packard (HP) M1465A Airway Adapter, accessory to carbon dioxide gas analyzer, intended to provide a breath-through gas sample cell for making CO2 concentration measurements as part of the HP CO2 monitoring systems for patients weighing more than 10 kg. Recall #Z-921-0.
CODE HP lots with first four digits less than 4016.
MANUFACTURER Hewlett-Packard Company, Andover, Massachusetts.
RECALLED BY Agilent Technologies, Inc., Andover, Massachusetts, by letter dated June 2, 2000. Firm-initiated recall ongoing.
DISTRIBUTION Nationwide, Asia pacific, Canada, Latin America and Europe.
QUANTITY 70,000 units were distributed.
REASON Airway adapter out of dimensional specification which may result in air leak.

None Present
 Action Taken _____

MEDICAL DEVICE SAFETY ALERT:

6640 NS
MDC 16557
PRODUCT

Blood Cell Processors

COBE BCT brand Trima Automated Blood Component Collection System, a transportable automated system that separates whole blood from a donor into its major components. Safety Alert #N-017-0.

CODE
MANUFACTURER
RECALLED BY

Catalog #91700-000, All serial numbers.
GAMBRO BCT, Inc., Lakewood, Colorado.

DISTRIBUTION

Manufacturer, by letter on August 4, 2000, and by letter. Firm-initiated recall ongoing.

Nationwide, Argentina, Australia, Austria, Belgium, Brazil, Canada, Chili, Dominican Republic, Egypt, France, Germany, Ireland, Israel, Italy, Japan, Korea, Netherlands, Norway, Poland, Portugal, Saudi Arabia, Scotland, South Africa, Spain, Sweden, Switzerland, Turkey, United Kingdom and Uruguay.

QUANTITY
REASON

450 units.

Failure to follow instructions could cause air embolism.

None Present

Action Taken _____

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 material 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 **15 DEC 00** for disposition instructions. They should include nomenclature; lot number; manufacturer; quantity suspended; strength size; requisition; and DSCP 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	Platelets, Pheresis. Recall #B-1105-0.
CODE	Unit #53LT65902.
MANUFACTURER	American Red Cross Blood Services, Baltimore, Maryland.
RECALLED BY	Manufacturer, by letters April 18, 2000, and July 14, 2000. Firm-initiated recall ongoing.
DISTRIBUTION	Maryland.
QUANTITY	1 unit was distributed.
REASON	Blood product was collected from a donor who reported travel to an area designated as endemic for malaria.

None Present
 Action Taken _____

NSN	6505 Nonstandard
PRODUCT	a) Red Blood Cells; b) Platelets; c) Plasma; d) Source Leukocytes. Recall #B-1112/1115-0.
CODE	Unit Numbers: a) 53GN98918, 53T30027; b) 53GN98918; c) 53GN98918, 53T30027; d) 53T30027.
MANUFACTURER	American Red Cross Blood Services, Baltimore, Maryland.
RECALLED BY	Manufacturer, by letters February 15, 2000 and March 22, 2000. Firm-initiated recall ongoing.
DISTRIBUTION	Maryland and New Jersey.

QUANTITY a) 2 units; b) 1 unit; c) 2 units; d) 1 unit was distributed.
REASON Blood products were collected from a donor with a history of having tested positive for Hepatitis C.

None Present
 Action Taken _____

NSN 6505 Nonstandard
PRODUCT Sodium Bicarbonate Injection, USP, 8.4% (84 mg/mL), for IV use only, in 50 mL single dose vial, Rx for correction of metabolic acidosis and other conditions requiring systemic alkalization. NDC #63323-006-50. Recall #D-448-0.

CODE Lot #190365 EXP 11/00.
MANUFACTURER American Pharmaceutical Partners, Inc., Melrose Park, Illinois.
RECALLED BY MANUFACTURER, by letter dated July 26, 2000. Firm-initiated recall ongoing.

DISTRIBUTION Nationwide.
QUANTITY 37,500 vials were distributed; firm estimated that little if any remains on the market.

REASON Lack of assurance of sterility (particle counts exceeding action level).

None Present
 Action Taken _____

NSN 6505 Nonstandard
PRODUCT Synercid(r) I.V. (Quinupristin and Dalfopristin for injection), 500 mg, in 10 mg single dose vial, lyophilized, Rx indicated for the treatment of patients with serious or life-threatening infections associated with vancomycin-resistant Enterococcus faecium (VREF) bacteremia. NDC #0075-9051-10. Recall #D-450-0.

CODE 9G1439 9G1471 9H1854 9J2122 0A1297
9G1440 9G1438 9H1855 9L2562 0A1316
9G1470 9G1441 9H1853 0A1298 0A1419.

MANUFACTURER Catalytica Pharmaceuticals, Inc., Greenville, North Carolina.
RECALLED BY Aventis Pharmaceuticals, Inc., Kansas City, Missouri, by letter dated July 20, 2000. Firm-initiated recall ongoing.

DISTRIBUTION Nationwide, Spain, Canada.
QUANTITY 582,130 vials were distributed.

REASON Lack of assurance of sterility (seal integrity).

None Present
 Action Taken _____

NSN 6505 Nonstandard
PRODUCT SangCya(tm) Oral Solution (Cyclosporine Oral Solution, USP Modified), 100 mg/mL, Rx indicated for the prophylaxis of organ rejection in kidney, liver, and heart allogeneic

transplants; for severe active, rheumatoid arthritis where treatment with methotrexate is not adequate; and for the treatment of adult nonimmunocompromised patients with severe, recalcitrant, plaque psoriasis who have failed to respond to at least one systemic therapy. NDC #62053-359-05. Recall #D-451-0.

CODE

LOT # EXP DATE
2MG69M----- 06/01/99
1NC30P----- 01/01/00
1NG00M----- 04/01/00
1NE00N----- 03/01/00
2MH05N----- 05/01/00
2MH06M----- 07/01/00
2MH06MA----- 01/01/01
2MH07M----- 08/01/00
2MH07MA----- 02/01/01
2MH04N----- 05/01/00
2MH52M----- 08/01/00
2MH52MA----- 02/01/01
2MH53M----- 08/01/00
2MR63N----- 02/01/01
2MR64N----- 02/01/01
2ND22M----- 04/01/01
2ND22MA----- 10/01/01
2NE50M----- 04/01/01.

MANUFACTURER
RECALLED BY

Eli Lilly and Company, Indianapolis, Indiana.
SangStat Medical Corporation, Fremont, California, by fax on July 10, 2000, by mail on July 10 and 11, 2000, by press release on July 10, 2000, followed by telephone and fax. Firm-initiated recall ongoing.

DISTRIBUTION
QUANTITY
REASON

Nationwide, United Kingdom, Germany, Hong Kong, Israel.
15,418 bottles were distributed.
Bioequivalence - Product is not bioequivalent when taken with apple juice.

None Present
 Action Taken _____

NSN
PRODUCT

6505 Nonstandard
Butyl-P-Aminobenzoate Injection, (Butamben (2.5% (25 mg/mL), in Methocel E-4, 1%, 10 mL amber vials, Rx compounded parenteral drug. Recall #D-452-0.

CODE
MANUFACTURER
RECALLED BY
DISTRIBUTION
QUANTITY
REASON

0400060, 0400052, 0500130.
Medical Center Pharmacy, Fort Worth, Texas.
Manufacturer, by letter July 5, 2000. Firm-initiated recall ongoing.
Texas.
17 bottles were distributed.
Misbranding - Product on withdrawn list for compounding.

None Present
 Action Taken _____

NSN
UPDATE

6505 Nonstandard
Neomycin and Polymyxin B Sulfates Solution for Irrigation, USP, USP, 1 mL, ampul (Steris Laboratories, Inc., Phoenix, Arizona), Recall #D-124-0, which appeared in the December 15, 1999 Enforcement Report, has been extended to include lot #97K040.

None Present
 Action Taken _____

NSN
PRODUCT
CODE
MANUFACTURER
RECALLED BY
DISTRIBUTION
QUANTITY
REASON

6515 Nonstandard
IGT 135mm Wireless Probe, (a pointer), an accessory to Carl Zeiss' image guided surgery system. Recall #Z-907-0.
Part #:146210, Serial Numbers: 403092, 397894, 397933, 398039.
Image Guided Technologies, Inc., Boulder, Colorado.
Carl Zeiss, Inc., Thornwood, New York, by letter on May 15 and 31, 2000.
Firm-initiated field correction ongoing.
Louisiana, Iowa, Canada.
4 units were distributed
Trajectory deviation of wireless probe. The line of sight trajectory for this pointer follows the angle of the bayonet, while the tracking system trajectory follows the line from the LED's to the tip of the bayonet in a straight line

None Present
 Action Taken _____

NSN
PRODUCT
CODE
MANUFACTURER
RECALLED BY
DISTRIBUTION
QUANTITY
REASON

6515 Nonstandard
1524, Tumisensor, all sizes, used for the diagnosis and treatment of erectile dysfunction. Recall #Z-922-0.
All units distributed after May 9, 2000.
Life-Tech Intl., Inc., Stafford, Texas.
Manufacturer, by letter on June 28, 2000. Firm-initiated recall ongoing.
Utah and Minnesota.
24 units were distributed.
Product does not comply with performance standard: Electrode Lead Wires/Patient Cables, in that the connections are exposed.

None Present
 Action Taken _____

NSN
PRODUCT

6515 Nonstandard
Insyte AutoGuard IV Catheter, intravascular catheter to be inserted into the patient's vascular system for short term use to sample blood, monitor blood pressure, or administer fluids intravenously: Catalog No's. 381412, 381423, 381433, 381434, 381437, 381444, 381447, 381454, 381457, 381512, 381523, 381533, 381534, 381544 . Recall #Z-923/936-0.

CODE Insyte AutoGuard IV Catheter, Cat. No. 381412: Lots 909170, 910152, 910171, 911151, 911164, 912160 381423: Lots 909166, 909169, 909171, 909172, 909180, 909181 910153, 910158, 910163, 910170, 910172, 910175, 910180, 910186, 11157, 911161, 911163, 912165, 911166, 911173, 911177, 912153, 912155, 912158, 912161, 912174, 912180, 912183, 001152, 001157, 001163, 001171. 381433: 909173, 910151, 910154, 911158, 912151, 912167. 381434: 907176, 907177, 908166, 908175, 908176, 909152, 909165, 910157, 910173, 910177, 910182, 911153, 911154, 911169, 911172, 911182, 911185, 912156, 912164, 912166, 912171, 912173, 912176, 912182, 001151, 001158, 001170.381437: 911176 381444: 909178, 910155, 910162, 910164, 910174, 910176, 910179, 911156, 911159, 911165, 911178, 911180, 912152, 912159, 912162, 912169, 912177, 001153, 001159, 001164, 001172. 381447: 910169, 912172 381454: 910156 381457: 910167 381512: 910166, 910178, 911168, 911175, 912168. 381523: 908177, 910161, 910183, 911179, 912154, 912185, 001162. 381533: 910181, 911152, 912157.381534: 908172, 909179, 910165, 911155, 911170, 912179, 001160.381544: 910184, 911171, 912175.

MANUFACTURER Becton Dickinson Infusion Therapy Systems, Inc., Sandy, Utah.
RECALLED BY Manufacturer, by mail and visit on February 23-24, 2000. Firm-initiated recall ongoing.

DISTRIBUTION California, Delaware, Florida, Illinois, Indiana, Massachusetts, Michigan, Missouri, North Carolina, South Dakota, Tennessee, Texas, Washington state, West Virginia, Australia, Brazil, Canada, France, Italy, Japan, Mexico, Spain, United Kingdom.

QUANTITY 9,511,350 units were distributed.
REASON Localized skin irritation and infection at catheter insertion site.

None Present
 Action Taken _____

NSN 6515 Nonstandard
PRODUCT Strykeflow Suction Irrigator II, Model/Part #250-070-500, Intended for use in laparoscopic general surgery, laparoscopic gynecological surgery and nasal surgery. Recall #Z-939-0. Serial Numbers: 00065832 and 0065812.

CODE Stryker Puerto Rico, Arroyo, Puerto Rico.
MANUFACTURER Stryker Endoscopy, Santa Clara, California, by
RECALLED BY Letter and telephone on June 28, 2000. Firm-initiated recall ongoing.

DISTRIBUTION Nationwide.
QUANTITY 1,452 units were distributed.
REASON Loss of sterility is possible.

None Present
 Action Taken _____

NSN 6515 Nonstandard
PRODUCT Sandhill Scientific Schuster Anorectal Manometry Probe: a) Schuster Anorectal Probe (Adult); b), Schuster Anorectal Probe (Pediatric). Recall #Z-940/941-0.

CODE a) Catalog # A86-4050; b) Catalog # A86-5050.
MANUFACTURER Sandhill Scientific, Inc., Highlands Ranch, Colorado.

RECALLED BY Manufacturer, by telephone beginning June 26, 2000. Firm-initiated recall ongoing.
DISTRIBUTION California, Colorado, Georgia, Iowa, Indiana, Maryland, New Mexico, Oklahoma, Oregon, Pennsylvania, Tennessee, Texas, Washington state, Switzerland.
QUANTITY 481 units were distributed.
REASON Labeling for internal and external balloons was reversed.

None Present
 Action Taken _____

NSN 6550 Nonstandard
PRODUCT Troponin I Immunoassay, used in the quantitative determination of cardiac Troponin I in serum or heparinized plasma and as an aid in the diagnosis of acute myocardial infarction using the ACS:180 and ADVIA Centaur Automated Chemiluminescence System: ACS: 180 SYSTEMS AND ADVIA CENTAUR TROPONIN I Part # 110631 ACS:180 Troponin I 50T KitPart # 110632 ACS:180 Troponin I 300 KitPart # 116993 Advia Centaur Troponin I 100T KitPart # 116994 Advia Centaur Troponin I 500 T Kit. Recall #Z-886/889-0.

CODE All lots.
MANUFACTURER Bayer Corporation, Medfield, Massachusetts.
RECALLED BY Manufacturer, by notification titled "Advia Centaur and ACS:180 Troponin I (CTN)..." Publication No. TN00397-40 on May 17, 2000. Firm-initiated field correction ongoing.

DISTRIBUTION Nationwide, Switzerland, Sweden, the Netherlands, Australia, England, France, Belgium, Korea, Hong Kong, Canada, Greece, New Zealand, Italy, Africa, Poland, Germany.

QUANTITY Undetermined.
REASON Revised instruction for use due to false positive results.

None Present
 Action Taken _____

NSN 7030 Nonstandard
PRODUCT a) Precision Link Blood Glucose Data Management System Software Version 2.0 and 2.1; b) Precision Link Plus Data Management Software Version 1.0. The program extracts test results from glucose monitors and converts these results into charts, graphs, and reports. It provides information to monitor diet, exercise, and medication. Recall #Z-913/914-0.

CODE a) Software Versions 2.0 and 2.1; b) Software Version 1.0.
MANUFACTURER Abbott Laboratories, Inc., Bedford, Massachusetts.
RECALLED BY Medisense, Inc., Bedford, Massachusetts, by letter on March 13, 2000. Firm-initiated field correction ongoing.

DISTRIBUTION Nationwide.

QUANTITY
REASON

a) 16,179 units; b) 1,113 units were distributed.
Glucose values greater than 600mg/dl are downloaded incorrectly.

None Present
 Action Taken _____

CLASS III RECALLS:

NSN
PRODUCT

6505 Nonstandard
Etoposide Injection, USP, 20 mg/mL, (100mg/mL), 5 mL multiple dose vial, Rx
used in the management of refractory testicular tumors and small cell lung cancer,
and must be diluted before I.V. infusion. NDC #63323-104-05.
Recall #D-449-0.

CODE
MANUFACTURER
RECALLED BY
DISTRIBUTION
QUANTITY
REASON

Lot #100006 EXP 01/02.
American Pharmaceutical Partners, Inc., Melrose Park, Illinois.
Manufacturer, by letter dated July 27, 2000. Firm-initiated recall ongoing.
Nationwide.
12,021 vials were distributed.
Misbranding - Some vial cartons are missing printed text.

None Present
 Action Taken _____
