

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-P, Capt D. Troy Molnar, DSN 343-4083)**

CLASS I RECALLS: None.

CLASS II RECALLS:

6515 NS
MDC 13209
PRODUCT (Pumps Enteral Feeding)
a) Elan Pharma EP80 Enteral Feeding Pump; b) O'Brien/KMI KM80 Feeding Pumps, used for the controlled administration of enteral feeding formulas. Recall #Z-149/150-9.

CODE All serial numbers.
MANUFACTURER Elan Pharma, Inc., Smithfield, Rhode Island.
RECALLED BY Nutrition Medical, Inc., Minneapolis, Minnesota, by "Customer Safety Notification" dated October 8, 1998. Firm-initiated recall ongoing.

DISTRIBUTION Nationwide.
QUANTITY 1,170 pumps were distributed.
REASON The devices can produce a "free flow" situation where the patient may receive an unintended large volume of feeding solution at a rapid rate.

None Present
 Action Taken _____

6515 NS
MDC 13215
PRODUCT (Infusion Pump)
McGaw Stratus Ambulatory Infusion Pump Model 550 w/Software Version 2.32.00/2.42.01. Recall #Z-189-9.

CODE Serial Numbers P63181, P63182, P64119, P64126, P64114, P64125, P63115, P64123, P64106, P63193, P63188, P64130, P64111, P64129, P64101, P63186, P64110, P64122, P64109, P63210, P63190, P64108, P61131, P63187, P63185, P63184, P63179, AND P61145.

MANUFACTURER Alphamed, Inc., Norcross, Georgia.
RECALLED BY Manufacturer. Pumps were destroyed from 6/97 to 12/97. Firm-initiated field correction ongoing.

DISTRIBUTION Texas.
QUANTITY 28 pumps were distributed and all but one had been returned at time of recall initiation.
REASON A software malfunction could cause the infusion to under infuse in the Circadian, PCA, or Epidural modes.

None Present
 Action Taken _____

6530 NS
MDC 10134
PRODUCT (Anesthesia Unit)
Narkomed MRI Anesthesia Machine/Core-M NAD Omicron Monitor, used to administer anesthesia. Recall #Z-220-9.

CODE AU

MANUFACTURER Core-M Precision Instruments, West Newton, Massachusetts.

RECALLED BY North American Drager, Telford, Pennsylvania, by letter on October 7, 1998.
Firm-initiated recall ongoing.

DISTRIBUTION Nationwide and Puerto Rico.

QUANTITY 29 Anesthesia machines were distributed.

REASON If a Core-M/NAD Omicron Monitor is not warmed up properly prior to calibration, the value store for calibration may be invalid.

None Present
 Action Taken _____

6525NS
MDC 11757
PRODUCT (X-Ray Rad/Fluoro Units, Fixed)
Image Intensified Fluoroscopic X-ray System. Recall #Z-221-9.

CODE All serial numbers.

MANUFACTURER General Electric Medical System, Waukesha, Wisconsin.

RECALLED BY Manufacturer, by field modification instruction #10686 on November 2, 1998.
Firm-initiated field correction ongoing.

DISTRIBUTION Nationwide and international.

QUANTITY 130 units were distributed.

REASON The image intensifier of the device can move down toward the table without operator control of this movement.

None Present
 Action Taken _____

6525 NS
MDC 16544
PRODUCT (X-ray Tables)
FX R&F X-Ray Tables: a) Model 46-262751G2; b) Model 46-262751G3; c) 46-262751G4. Recall #Z-222/224-9.

CODE Tables manufactured 12/90 to 11/91 are affected. The month and year of manufacture are stated on the identification plates attached to each table.

MANUFACTURER General Electric Medical System, Waukesha, Wisconsin.

RECALLED BY Manufacturer, by a field modification instruction (FMI #10692) issued on November 11, 1998. Firm-initiated field corrections ongoing.

DISTRIBUTION Nationwide and international.

QUANTITY 304 units were distributed.

REASON The X-Ray tables can fall. There have been five reported incidents of the problem. The problem has been attributed to breakage of an angulation drive chain.

None Present
 Action Taken _____

6640 NS
MDC 16817
PRODUCT (Software Program)
CODE Blood Bank Software Versions 4.3, 5.0, 5.1, 5.2 and 5.22. Recall #B-221-9.
MANUFACTURER Software versions 4.3, 5.0, 5.1, 5.2 and 5.22.
RECALLED BY Sunquest Information Systems, Inc., Tucson, Arizona.
Manufacturer, by fax on September 23, 1998. Firm-initiated field correction ongoing.
DISTRIBUTION Nationwide and international.
QUANTITY 449 consignees received software.
REASON Computer software contains programing errors which could potentially result in the release of unsuitable blood products.

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 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 **05 March 99** 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	Oxygen, USP, Rx, compressed, in aluminum E size high pressure cylinders. Recall #D-031-9.
CODE	The product is labeled under lot number "8202" and transfilled into cylinders that have the following bar codes: 009501, 011796, 012021, 012436, 012711, 014450, 018366, 020073, 020169, 020235, 024281, 024776, 024943, 038376, 038863, 038876, 039018, 039398, 041374, 043517, 044114, 047659, 047848, 047853, 047915, 048325, 050083, 050090, 051270 and 051754.
MANUFACTURER RECALLED BY DISTRIBUTION QUANTITY	Tech Air, A Division of Dempsey Enterprises Inc., White Plains, New York. Manufacturer, by telephone on October 23, 1998. Firm-initiated recall ongoing. New York. 30 cylinders were distributed; firm estimated that 7 cylinders remained in commerce at time of recall initiation.
REASON	Current good manufacturing practice deviations; including but not limited to failure to maintain production records documenting finished product testing for strength and purity and use of industrial grade oxygen for medical product transfilling.

None Present
 Action Taken _____

NSN	6505 Nonstandard
PRODUCT	Oxygen, USP, Rx, compressed in various high pressure cylinders, for medical use. Recall #D-033-9.
CODE	Lot numbers 1320 through 1510.

MANUFACTURER
RECALLED BY Helget Gas Products, Inc., North Kansas City, Missouri.
Helget Gas Products, Inc., Omaha, Nebraska, by telephone on November 10, 1998,
followed by visit and letter on November 11 & 12, 1998. Firm-initiated recall
ongoing.

DISTRIBUTION
QUANTITY Missouri and Kansas.
Approximately 7,856 cylinders were distributed.

REASON Possibility of oil/foreign substance(s) contamination.

None Present
 Action Taken _____

NSN 6505 Nonstandard
PRODUCT Dosage instruction/promotional literature for Liquid Cantron Electrolyte
Formula, OTC, in 8 ounce and 32 ounce bottles. Recall #D-032-9.

CODE All product codes.
MANUFACTURER Medical Research Products, Miami, Florida.
RECALLED BY Manufacturer, by letter sent during the week of November 16, 1998.
Firm-initiated recall ongoing.

DISTRIBUTION Nationwide and international.
QUANTITY Undetermined. Promotional literature will be field destroyed not physical
product.

REASON Misbranding - Literature/dosage instructions make unapproved medical claims for
product.

None Present
 Action Taken _____

NSN 6505 Nonstandard
PRODUCT Phenylpropanolamine Hydrochloride 75 mg/Chlorpheniramine Maleate
8 mg. extended release capsules packaged in bottles of 10, 20,
and 30 count capsules, OTC under the following brand names:
a) AMERICAN FARE brand Cold Capsules Made for Kmart Corporation,
Troy, Michigan 48084. NDC 0113-0482-52;
b) AMERICAN FARE brand 12 Hour Cold Capsules Made for Kmart
Corporation, Troy, Michigan 48084. NDC 49738-482-60;
c) ARBOR brand Cold Caps Distributed by Arbor Drugs, Inc., Troy,
Michigan 48084. NDC 50165-482-60;
d) CVS cold capsules Distributed by CVS, Woonsocket, RI 02895.
[Label bears no NDC#];
e) equate brand cold capsules Distributed by Perrigo Co.,
Allegan, MI 49010 [Label bears no NDC#];
f) FOOD LION brand Cold Capsules Distributed by Food Lion Stores,
Inc., Salisbury, NC 28144 NDC 55316-008-51;
g) health PRIDE brand Cold Capsules Distributed by Compass Foods,
Montvale, NJ 07645. [label bears no NDC#];
h) H-E-B PHARMACY brand Cold Caps Distributed by H-E-B, San
Antonio, TX 78204;
i) Marquee brand Maximum Strength Severe Cold & Flu Cold Caps
Distributed by Fleming Companies, Inc., Oklahoma City, OK 73216.
NDC 11205-501-73;
j) The Medicine Shoppe brand Cold Capsules Distributed by
Medicine Shoppe International, Inc., St. Louis, Missouri 63132.

NDC 49614-482-52;
 k) Meijer brand Cold Caps Dist. by Meijer, Inc., Grand Rapids, MI 49544. NDC 41250-482-52;
 l) RITE AID brand Cold Caps Distributed by Rite Aid Corporation, Harrisburg, PA 17105. [label bears no NDC#];
 m) SAFEWAY brand Cold Capsules Distributed by Safeway, Inc., P.O. Box 99, Pleasanton, CA 94566-0009. NDC #21130-482-52;
 n) Shurfine brand Cold Caps Distributed by Shurfine International, Inc., Northlake, IL 60164-1889. [label bears no NDC#];
 o) ValueRite brand Cold Caps Distributed by McKesson Corp., One Pst Street, San Francisco, CA 94104. NDC #49348-027-47;
 p) VONS brand Cold Capsules Distributed by Vons, P.O. Box 99, Pleasanton, CA 94566-0009. NDC # 58828-482-52;
 q) Walgreens brand Cold Capsules Distributed by Walgreen Co., Deerfield, IL 60015-4681. NDC # 0363-0482-65;
 r) Wegmans brand Cold Capsules Distributed by Wegmans Food Markets, Inc., Rochester, NY 14692. [label bears no NDC#];
 s) Woolworth brand Cold Capsules Marketed by Woolworth Co., New York, NY 10279. NDC # 12443-482-52. Recall #D-034-9.

CODE Schwarz Lot 1460012. Finished product lots 7HA113, 7HA133, 7HA134, 7HA165 AND 7HA270. Expiration date of all lots is 10/98. Lot 7HA113 was packaged in bottles of 10's. Lots 7HA133, 7HA165 and 7HA270 were packaged in bottles of 20's. Lot 7HA134 was packaged in bottles of 30's.

MANUFACTURER Schwarz.Pharma Manufacturing Inc., Seymour, Indiana, by telephone on June 16,1998 , and leter dated June 28, 1998.

RECALLED BY Perrigo Company, Allegan, Michigan (repacker/distributor).

DISTRIBUTION Nationwide.

QUANTITY approximately 117, 276 Bottles were distributed.

REASON Uniformity of dosage failure Chlorpheniramine Maleate-Superpotent

None Present
 Action Taken _____

NSN 6505 Nonstandard
 PRODUCT a) Red Blood Cells; b) Cryoprecipitated AHF; c) Platelets, Pheresis; d) Recovered Plasma. Recall #B-206/209-9.

CODE Unit numbers: a) 36251-5700, 36253-5120; b) 36251-5700; c) 36252-6738; d) 36251-5700.

MANUFACTURER United Blood Services, Ventura, California.

RECALLED BY Blood Systems, Inc., Scottsdale, Arizona, by telephone on October 7, 1998, and by letter dated October 22, 1998. Firm-initiated recall ongoing.

DISTRIBUTION California and Switzerland.

QUANTITY a) 2 units; b-c) 1 unit of each component was distributed.

REASON Blood products were collected from donors whose donor history screening was incomplete.

None Present
 Action Taken _____

NSN 6505 Nonstandard
 PRODUCT Immune Globulin Intravenous (Human), Venoglobulin-S 5% 5 grams in 100 mL

CODE vial. Recall #B-251-9.
 MANUFACTURER Lot GL8504A.
 RECALLED BY Alpha Therapeutic Corporation, Los Angeles, California.
 DISTRIBUTION Manufacturer, by fax dated October 23, 1998, followed by telephone, and by
 letter dated October 24, 1998. Firm-initiated recall ongoing.
 QUANTITY Alabama, Connecticut, Florida, Georgia, Massachusetts, Maryland, Maine,
 Missouri, New Jersey, New York, Rhode Island, Tennessee, Hong Kong.
 REASON 4,259 vials were distributed; firm estimated that less than 200 vials remained
 on market at time of recall initiation.
 REASON Vials may be cracked or broken as a result of damage to shipping cartons.

None Present
 Action Taken _____

NSN 6515 Nonstandard
 PRODUCT Custom surgical trays used in surgical procedures. Recall #Z-064/089-9.
 CODE AMC General Minor 101805, 109399, 100921
 AMC Lap Chole, PDS 101256, 103276, 109398, 200040,
 AMC Shoulder, PDS 100514
 Arthroscopy Pack 104461
 Basin Kit 107458, 101641
 Basin Set 100154, 100155, 105030
 Cardiac Custom Pack 103021
 Cardiovascular Pack 117405
 Cataract Tray 113070, 109045, 112771, 113070,
 102415, 117854, 114344, 116160,
 116164, 119730, 119731, 124255
 Craniotomy Custom Pack 103014
 C-Section Pack 104854
 C-Section Custom Pack 103048
 C-Section Tray 107219, 101100, 102336, 109122,
 106254, 116818, 117254, 119449,
 121073
 Delivery Drape Basin 111810, 102409, 108297, 115438
 Doctors C-section Pack 121996, 123307, 113705, 114517,
 110287, 116057, 118962
 Lap/Pelviscopy Pack 117305, 117404, 117897
 Major Custom Pack 103014
 Minor Custom Pack 108732, 110026, 100926, 103401,
 108732, 104707
 Minor Eye Pack 120895, 124396
 Minor Eye Tray 116099
 Open Heart Tray 107591, 108362
 Open Heart Tray Haley-Veteran 101464, 101476
 Ophthalmic Pack 121640, 125215
 Plastic Tray 119046, 115685, 122057
 Shoulder Arthroscopy Pack 102963
 Transphenoedal Pack 108427, 104494
 MANUFACTURER MedSurg Industries, Herndon, Virginia.
 RECALLED BY Manufacturer, by letter dated June 19, 1998. Firm-initiated recall ongoing.
 DISTRIBUTION Nationwide.
 QUANTITY 1,800 cases were distributed.
 REASON The foam strips used to secure suture needles were detaching from the needle
 counter box.

None Present
 Action Taken _____

NSN 6520 Nonstandare
PRODUCT Sterile devices and non-sterile device packs/kits. Recall #Z-156-9.
CODE Goretex Gown Packs - Nos. 1001 - 1018;
Liquid Resistant Gown Pack - Nos. 2001 - 2019;
Towel Packs - Nos. 3001 - 3032;
Wrappers/Drapes/Sheets - Nos. 4001 - 4031;
Custom Packs - 5001 - 5011.
MANUFACTURER Associated Hospital Services, Inc., New Orleans, Louisiana.
RECALLED BY Manufacturer, by visit beginning November 3, 1998. Firm-initiated recall ongoing.
DISTRIBUTION Louisiana and Mississippi.
QUANTITY 1,349 packs/kits were distributed.
REASON Lack of sterility validation and inadequate good manufacturing practices.

None Present
 Action Taken _____

NSN 6540 Nonstandard
PRODUCT Miochol E Intraocular Solution 1:100 with electrolyte diluent (Acetylcholine Chloride), in 20 mg/2mL vials, used to obtain miosis of the iris in seconds after delivery of the lens in cataract surgery, in penetrating keratoplasty, iridectomy and other anterior segment surgery where rapid miosis may be required. NDC #58768-773-52. Recall #D-023-9.
CODE Lot #V2333 EXP 4/99.
MANUFACTURER OMJ Pharmaceuticals, San German, Puerto Rico (manufacturer of the finished drug product and an approved testing facility).
RECALLED BY CIBA Ophthalmics (CVO), Duluth, Georgia, by letter dated September 23, 1998, followed by telephone. Firm-initiated recall ongoing.
DISTRIBUTION Nationwide.
QUANTITY Undetermined.
REASON Low pH.

None Present
 Action Taken _____

CLASS III RECALLS:

NSN 6550 Nonstandard
PRODUCT Accu-Dx Recurrent Bladder Cancer Test, used in the screening of bladder cancer in conjunction with the scope method. Recall #Z-009-9.
CODE Lot No. 800081 (single unit), 7167 (box unit/10 units/box) Lot No. 800182 (single unit), 7190 and 8318 (box unit/10 units/box).
MANUFACTURER Organon Teknika, Dublin, Ireland.
RECALLED BY Intercel Corporation, Rockville, Maryland (importer/developer), by, letter dated August 5, 1998. Firm-initiated recall ongoing.

DISTRIBUTION
QUANTITY
REASON

California.
11,083 units were distributed.
Routine stability testing at the six month station revealed the product is
losing stability.

None Present
 Action Taken _____
