

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 Paul J. Toth, DSN 343-7445)

CLASS I RECALLS: None.

CLASS II RECALLS:

6515 NS

MDC 17429, 14360, 14361
PRODUCT

Ventilators, Intensive Care

Venturi Ventilators With CRT Monitor Part Number 1248.

Recall #Z-1038-9.

Serial numbers: 970129-970194 (not inclusive).

CODE

MANUFACTURER

MICROVITECH, United Kingdom (manufacturer of CRT).

RECALLED BY

Cardiopulmonary Corporation, Milford, Connecticut, by overnight mail on June 14, 1999. Firm-initiated recall ongoing.

DISTRIBUTION

Russia, United Kingdom, Italy.

QUANTITY

43 units were distributed.

REASON

CRT monitor does not meet the mean-time-between-failure (MTBF) specification. The failure may result in the CRT not displaying the monitored patient data.

None Present

Action Taken _____

6515 NS

MDC 14361, 14360, 17429
PRODUCT

Ventilators, Intensive Care

Venturi Ventilator with Hard Drive Part Number 230012.

Recall #Z-1039-9.

Serial numbers: 970129-980258 (not inclusive).

CODE

MANUFACTURER

Cardiopulmonary Corporation, Milford, Connecticut (ventilator); Segate, San Jose, California (hard drive).

RECALLED BY

Cardiopulmonary Corporation, Milford, Connecticut, by letter between June 14-15, 1999. Firm-initiated field correction ongoing.

DISTRIBUTION

Alabama, Connecticut, Florida, North Carolina, Italy, Russia, United Kingdom.

QUANTITY

59 units were distributed.

REASON

User interface software will not load when unit is first powered on.

None Present

Action Taken _____

6515 NS

MDC 16968
PRODUCT

Data Analysis Systems, Ultrasound Obstetried

Doctors Review System, OBLink software releases prior to 9.0.

Recall #Z-1056-9.

CODE

MANUFACTURER

All units.

RECALLED BY

Digisonics, Inc., Houston, Texas.

Manufacturer, by telephone, fax, and letter on March 29, 1999.

Firm-initiated field correction ongoing.

DISTRIBUTION

Nationwide.

QUANTITY

39 units were distributed.

REASON

Y2K software error may produce an incorrect estimated delivery date (EDD).

None Present
 Action Taken _____

6525 NS
MDC 15944
PRODUCT

Cameras, Gamma
GE Millennium MPR/MPS Single Detector Nuclear Medicine System
(Emission Computed Tomography System), Model 2151300.
Recall #Z-1068-9.

CODE
MANUFACTURER
RECALLED BY

All units.
General Electric Medical System, Waukesha, Wisconsin.
Manufacturer, by safety notice dated June 10, 1998.
Firm-initiated field correction ongoing.

DISTRIBUTION
QUANTITY
REASON

Nationwide and international.
167 units were distributed.
An unintended detector tilt motion can occur when the operator
selects the table up/down motion.

None Present
 Action Taken _____

6530 NS
MDC 16982
PRODUCT

Hot Dry Air/Fluidized Medium Units
Henley Healthcare Fluidotherapy Unit, air-fluidized beds
employing dry heat that is intended to treat local pain, range of
motion and blood flow insufficiency in the body extremities:
a) Henley Healthcare Fluidotherapy, Model 110D;
b) Henley Healthcare Fluidotherapy, Model 110DE,
Recall #Z-1054/1055-9.

CODE
MANUFACTURER
RECALLED BY

a) Serial Numbers 2-00001 - 2-00369
b) Serial Numbers 2-00001 - 2-00006.
Henley Healthcare, Inc., Sugarland, Texas.
Manufacturer, by letter dated January 15, 1998. Firm-initiated
recall ongoing.

DISTRIBUTION
QUANTITY
REASON

Nationwide and international.
a) 369 units; b) 6 units were distributed.
Excessively long metal bolts securing metal legs to the wooden
base of the device protruded too far into the housing, contacting
the electrical connection to the heater after collapsing a metal
heater schroud, causing 13 amps of electrical current to be
delivered to the metal legs.

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 **02 Sep 99** 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
PRODUCT **6505 Nonstandard**
 Trihexyphenidyl Hydrochloride Tablets, 5 mg, in 100 tablet blister strips of 10 tablets, Rx oral antispasmodic tablet used as an adjunct in the treatment of all forms of parkinsonism. NDC 51079-124-20. Recall #D-278-9.
CODE Lot #8V938.
MANUFACTURER Lederle Pharmaceutical, Division of American Cyanamid, Pearl River, New York.
RECALLED BY UDL Laboratories, Inc., Rockford, Illinois (repacker), by letter dated June 14, 1999. Firm-initiated recall ongoing.
DISTRIBUTION Nationwide.
QUANTITY 3,624 unit cartons were distributed; firm estimated that 25 percent of the product remained on market at time of recall initiation.
REASON Mislabeling - Some blister strips are held in shelf unit cartons (100's) labeled as Allopurinol Tablets, 300 mg. The blister strips are correctly labeled.
 None Present
 Action Taken _____

NSN
PRODUCT **6515 Nonstandard**
 Bubble Suction Tubing, Catalog #116740. Recall #Z-685-9.
CODE Lot #41AJCM16 EXP 2004-01.
MANUFACTURER ConMed Corporation, El Paso, Texas.
RECALLED BY Manufacturer, by fax on February 19, 1999, and by letter dated February 22, 1999. Firm-initiated recall ongoing.
DISTRIBUTION Florida and North Carolina.
QUANTITY 12 cases (50 units per case) were distributed.
REASON Non-Sterility.
 None Present
 Action Taken _____

NSN
PRODUCT **6515 Nonstandard**
 Bone-Dri Femoral Surgical Wick, used to control and wick fluids from the femoral canal during surgery.
CODE Recall #Z-1069-9
 Catalog Numbers: 6209-1-205 (package of 5 units)
 6209-1-201 (single unit)
 Sterility Lot Codes: 9902144, 9902145, 9902146, 9902147, 9902203, 9902204, 9902501, 9902542, 9902543, 9902544, 9902545, 9902744, 9902747, 9902748, 9902845, 9902846, 9902847, 9902848, 9902849, 9902852.
MANUFACTURER Howmedica Osteonics Corporation, San Jose, California.
RECALLED BY Manufacturer, by letter dated February 17, 1999, followed by telephone. Firm-initiated recall ongoing.

DISTRIBUTION Nationwide.
QUANTITY 178 units were distributed.
REASON The sterility of the device has been compromised due to a lack of adequate sterilization.
 None Present
 Action Taken _____

NSN
PRODUCT **6515 Nonstandard**
CVIS Insight Imaging Catheter for intraluminal coronary interventional procedures; 2.6French/30 MHz and 2.6French/40 MHz, Model C3020 and C3005, indicated for ultrasound examination of the coronary intravascular pathology only. Intravascular ultrasound is indicated in-patients who are candidates for transluminal coronary interventional procedures.
Recall #Z-1051/1052-9.
CODE UPN/Material #H749C30200, Catalog #C3020, Lots: All Lots
UPN/Material #H749C30050, Catalog #C3005, Lots: All Lots.
MANUFACTURER Boston Scientific Corporation, San Jose, California.
RECALLED BY Manufacturer, by letter on June 15, 1999. Firm-initiated recall ongoing.
DISTRIBUTION Nationwide and international.
QUANTITY 44,841 units were distributed.
REASON The product may separate from the proximal segment.
 None Present
 Action Taken _____

NSN
PRODUCT **6515 Nonstandard**
Quest Myocardial Protection System (MPS), a sterile, single-use, prescription device:
a) Model No. 5001101; b) Model No. 5001101 NE;
c) Model No. 5001102. Recall #Z-1061/1063-9.
CODE a) Lot No. 9306.05K; b) Lot No. 9373.08K;
c) Lot Nos. 9267.08J, 290.03K, 9340.01L, 9357.03L, 9394-03L, 9403.04L, 404.07L, 9405.09L, 9415.03M, 9434.05M.
MANUFACTURER Quest Medical, Inc., (QMI), an Atrion company, Allen, Texas.
RECALLED BY Manufacturer, by telephone on May 6, 1999, followed by letter. Firm-initiated recall ongoing.
DISTRIBUTION Nationwide.
QUANTITY 3,430 units were distributed.
REASON The delivery sets may develop a leak in the main pump cassette during use.
 None Present
 Action Taken _____

NSN
PRODUCT **6530 Nonstandard**
Midmark 73018 Attachment Accessories for the Midmark Magnum General Table, hydraulic, sold as kits and are designed for use in the support of patients during orthopedic surgery procedures. Recall #Z-1053-9.
CODE Serial Numbers: TFY1010 through TFY1025.
MANUFACTURER Midmark Corporation, Versailles, Ohio.
RECALLED BY Manufacturer, by telephone on June 14-15, 1999, and by letter mailed on June 24, 1999. Firm-initiated recall ongoing.
DISTRIBUTION New Jersey, Florida, Michigan, Louisiana, Minnesota, Texas, Missouri, District of Columbia.

QUANTITY 14 units.
REASON Defects of table accessories cause unintended motion during orthopedic surgery.
[] None Present
[] Action Taken _____

NSN 6550 Nonstandard
PRODUCT QTEST(R) STREP, an IVD kit for P.O.C. testing to detect Group A streptococcus, using a sample throat swab, Catalog 494776 - 40 tests/kit; 494780 - 80 tests/kit. Recall #Z-1058-9.
CODE SERIAL NOS. 5648, 5663, 5664, 5673, 5665.
MANUFACTURER Becton Dickinson Microbiology Systems, Cockeysville, Marland.
RECALLED BY Manufacturer, by letter on June 10, 1999, and by letter on June 22, 1999. Firm-initiated recall ongoing.
DISTRIBUTION Nationwide.
QUANTITY 1,044 kits were distributed.
REASON The Vol-pak pouch sealer failed to provide an adequate seal, and the Quali-pak leak tester failed to detect the inadequate seal.
[] None Present
[] Action Taken _____

NSN 6550 Nonstandard
PRODUCT Directigen 1-2-3 group A strep test device listing 702228, an IVD kit used by hospitals for detection of Group A streptococcus using a sample of throat swabs or bacterial colonies.
Recall #Z-1059-9.
CODE CATALOG # 852540, Serial Nos. 5638, 5662, 5670.
MANUFACTURER Becton Dickinson Microbiology Systems, Cockeysville, Maryland.
RECALLED BY Manufacturer, by letter on June 10, 1999, and by letters beginning June 22, 1999. Firm-initiated recall ongoing.
DISTRIBUTION Washington state, Tennessee, Florida, Georgia, Connecticut, Utah, Kentucky, New Jersey, Pennsylvania, Indiana, Alaska, Illinois, Minnesota, Arkansas, California, Virginia, District of Columbia.
QUANTITY 1,230 kits were distributed.
REASON The VolPak pouch sealer failed to provide an adequate seal, and the QualiPak leak tester failed to detect the inadequate seal. An inadequate seal may lead to false negative results.
[] None Present
[] Action Taken _____

CLASS III RECALLS:

NSN 6505 Nonstandard
PRODUCT Calcionate Syrup, in 16 fluid ounce (pint) bottles, OTC calcium supplement. Recall #D-281-9.
CODE Lot #802921. EXP 7/00.
MANUFACTURER Hi-Tech Pharmacal Company, Inc., Amityville, New York.
RECALLED BY MANUFACTURER, by letter dated June 14, 1999. Firm-initiated recall ongoing.
DISTRIBUTION Georgia.
QUANTITY 3,564 units were distributed.
REASON Presence of white precipitate and cloudiness; calcium is precipitating out of formulation.
[] None Present
[] Action Taken _____

NSN **6515 Nonstandard**
PRODUCT Connecting screw and compression screw for titanium solid humeral nails, Part Numbers: 358.54 and 358.61.
Recall #Z-1066/1067-9.
CODE Part Number 358.54, Lot Numbers: A4FL336, A4GA308, A4GC384, A4GC813, A4HB049, A4HB716, A4HD872, and A4HD873; Part Number 358.61, Lot numbers: A4GA932, A4GA933, A4GC425, A4GD662, A4GE889, and A4GK100.
MANUFACTURER Synthes (USA), West Chester, Pennsylvania.
RECALLED BY Synthes USA, Paoli, Pennsylvania, by letter sent on June 16, 1999, followed by telephone or visit. Firm-initiated recall ongoing.
DISTRIBUTION Nationwide and Canada.
QUANTITY 339 units were distributed.
REASON Product drawing contained an interference issue which created a potential for the connecting screw not to fit into or bind within the insertion handle.
 None Present
 Action Taken _____

NSN **6515 Nonstandard**
PRODUCT Bivona Fome-Cuf Pediatric Tracheostomy Tube with Stomaseal, Catalog No. 85P045. Recall #Z-1084-9.
CODE Lot No. 842260 EXP 03/2004.
MANUFACTURER Bivona Medical Tech., Division of UroQuest Med. Corporation, Gary, Indiana.
RECALLED BY Manufacturer, by letter sent on June 15, 1999. Firm-initiated recall ongoing.
DISTRIBUTION Arizona, Florida, Michigan, New Hampshire, Texas, Virginia, Australia.
QUANTITY 21 units were distributed.
REASON The tube's outer shaft diameter printed on the neckflange of the tube differed from that on the label.
 None Present
 Action Taken _____

NSN **6525 Nonstandard**
PRODUCT Kodak Digital Science Medical Film EIR-11 Laser Imaging Film, intended for secondary imaging of radiographs, packed 150 sheets per box. Recall #Z-1057-9
CODE Lot/Serial Nos. 4597-0128-003-11/-12/-13/-14/-15.
MANUFACTURER Eastman Kodak Company, Health Imaging Division, Rochester, New York.
RECALLED BY Manufacturer, by telephone on April 26 and 27, 1999. Firm-initiated recall ongoing.
DISTRIBUTION Arizona, Kansas, North Carolina, Nebraska, Ohio, Pennsylvania.
QUANTITY 32 cases (450 sheets per case) were distributed.
REASON The film was exposed to light during the rewind process, and has an elevated background fog. The normal level of fog has a Dmin of 0.18, while the identified product has a Dmin of 0.30.
 None Present
 Action Taken _____

NSN **6550 Nonstandard**

PRODUCT ARCHITECT Estradiol Reagent Kit, list 6C22-20 - 4 x 100 tests and list 6C22-25 - 1 x 100 tests; an in-vitro diagnostic Chemiluminescent Microparticle Immunoassay (CMIA) for the quantitative determination of estradiol in human serum and plasma. Recall #Z-1060-9.

CODE List 6C22-20, lot 49994M100 and List 6C22-25, lot 49994M101.

MANUFACTURER Abbott Laboratories, Abbott Park, Illinois.

RECALLED BY Manufacturer, by letter dated June 29, 1999. Firm-initiated recall ongoing.

DISTRIBUTION Nationwide and international.

QUANTITY 245 400-test kits and 68 100-test kits were distributed.

REASON The Architect Estradiol Reagents may show under-recovery of
 None Present
 Action Taken _____
