

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 16333**

PRODUCT

**Dosimeters**

Model 35040 Keithley Therapy Dosimeter, intended use for calibration of dosimetry of therapeutic radiation treatment machine for high energy accelerators, cobalt 60, and brachytherapy equipment. Recall #Z-1261-9.

CODE

Serial Numbers: 69450-69469; 80276-80295; 82666-82685; 81909-81928; 86087-86106; 86597-86616; and 88276-88295.

MANUFACTURER

Inovision Radiation Measurements, Cleveland, Ohio.

RECALLED BY

Manufacturer, by letters on July 8, 1999, and September 10, 1999. Firm-initiated field correction ongoing.

DISTRIBUTION

Nationwide and international.

QUANTITY

89 units.

REASON

An incorrect fuse was installed on units causing power failures from blown fuse.

None Present

Action Taken \_\_\_\_\_

**6515 NS**

**MDC 16333**

PRODUCT

**Dosimeters**

The Tracker Display Model #35360A is sold with the Detector Model #35300A and marketed together as the Keithley Model #90100 Tracker System, a radiation measurement system intended for use in quality assurance programs for high energy accelerators, and cobalt 60 machines. Recall #Z-1262-9.

CODE

Serial Numbers: 83728-83747; 84582-84601; 85682-85701; and 87309-87328.

MANUFACTURER

Inovision Radiation Measurements, Cleveland, Ohio.

RECALLED BY

Manufacturer, by letters on July 8, 1999, and September 10, 1999. Firm-initiated field correction ongoing.

DISTRIBUTION

Nationwide and international.

QUANTITY

40 units.

REASON

An incorrect fuse was installed on units causing power failures from blown fuse.

None Present

Action Taken \_\_\_\_\_

**6525 NS**  
**MDC 11757, 11758**  
PRODUCT  
CODE  
MANUFACTURER  
RECALLED BY

DISTRIBUTION  
QUANTITY  
REASON

**X-Ray Rad/Fluoro Units, Fixed/Mobile**

Visualizer 2000 Diagnostic X-Ray System. Recall #Z-1242-9.  
Model XV 903 C, Serial Numbers 848001 through 848062.  
VF-Works, Inc., Palm Harbor, Florida.  
Manufacturer. FDA approved the firm's corrective action plan on  
September 27, 1999. Firm-initiated field correction ongoing.  
Nationwide.  
62 units.  
All units are in noncompliance with 21 CFR 1020.32(b)(2) because  
the collimator was not properly designed to provide necessary x-  
ray field limitation. In addition, 25 of the units manufactured  
on or before July 29, 1997, are also in noncompliance with 21 CFR  
1020.32(h) because they were not equipped with a five-minute  
cumulative timer.

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

**6525 NS**  
**MDC 13269**  
PRODUCT  
CODE  
MANUFACTURER  
RECALLED BY

DISTRIBUTION  
QUANTITY  
REASON

**X-Ray Rad Units, Dental**

Aztech 70 X-Ray System, intended for use in dental radiography.  
Recall #Z-1254-9.  
Model Number: Aztech 70 Dental System.  
Villa Sistemi Medicali S.p.A.  
The Aztech Group, Inc., Boulder, Colorado. FDA approved the  
firm's corrective action plan on September 27, 1999. Firm-  
initiated field correction ongoing.  
Nationwide.  
19 units were distributed.  
The diagnostic x-ray devices were found defective under 21 CFR  
1003.11. The defect occurs as a result of incomplete equipment  
specifications on equipment manufactured before September 1,  
1999.

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

**6530 NS**  
**MDC MMPA, M0001, M0001,**  
**16437**

PRODUCT  
CODE  
MANUFACTURER  
RECALLED BY

DISTRIBUTION  
QUANTITY

**Wheelchairs, (General)**

The Kid Kart 19-Inch Lap Belts, a component of mechanical chair  
with casters. Recall #Z-1239-9.  
Part#: 9332100001, Model #s: EZ1, EZ2, EZB1, EZB2, EX1, EX2,  
EXB1, EXB2, SPICA, MT, MTB, AT, ATB, T-RACER.  
Sunrise Mobility Products Division, Kid Kart Operations,  
Belgrade, Montana.  
Sunrise Medical, HHG, Mobility Products Division, Fresno,  
California, by letters dated August 17, 1999. Firm-initiated  
recall ongoing.  
Nationwide and international.  
68 units were distributed.

REASON

The lap belts were assembled incorrectly.

None Present

Action Taken \_\_\_\_\_

\_\_\_\_\_

**MEDICAL DEVICE SAFETY ALERT**

**6530 NS**

**MDC 12283**

PRODUCT

**Lights, Ultraviolet**

Olympic Mini Bili-Lite, Model 70 and 71.

Safety Alert #N-010/011-9.

CODE

Catalog Numbers: 51470 and 51471.

MANUFACTURER

Burton Medical Products, Chatsworth, California.

ALERTED BY

Olympic Medical Corporation, Seattle, Washington, by fax during the week of September 7, 1999.

DISTRIBUTION

Nationwide and international.

QUANTITY

314 units were distributed.

REASON

Interior casting in Bili-Lites may fracture causing light to fall.

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 **10 December 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	<b>6505 Nonstandard</b>
PRODUCT	TUSSIONEX Pennkinetic (hydrocodone polistirex), extended- release suspension (Hydrocodone polistirex equivalent to 10 mg hydrocodone bitartrate and Chlorpheniramine polistirex equivalent to 8 mg chlorpheniramine maleate), in 473 mL bottle, Rx medication for relief of cough and upper respiratory symptoms associated with allergy or a cold.
CODE	NDC #53014-548-67. Recall #D-423-9. 90299, EXP 04/01 90300, EXP 04/01 90301, EXP 04/01 90302, EXP 04/01 90303, EXP 04/01 90309, EXP 05/01 90310, EXP 05/01.
MANUFACTURER RECALLED BY	Medeva Pharmaceuticals, Inc., Rochester, New York. Manufacturer, by letter dated August 6, 1999. Firm-initiated recall ongoing.
DISTRIBUTION QUANTITY	Nationwide. Lot 90299: 7,491 units were distributed between 5/17/99 and 5/19/99. Lot 90300: 7,622 units were distributed between 5/18/99 and 5/28/99. Lot 90301: 7,702 units were distributed between 5/28/99 and 6/10/99. Lot 90302: 7,714 units were distributed between 5/24/99 and 6/15/99. Lot 90303: 3,166 units were distributed on 6/15/99

Lot 90309: 7,446 units were distributed between 5/25/99 and 6/10/99.

Lot 90310: 7,637 units were distributed between 6/10/99 and 6/30/99.

REASON

Microbial contamination (acetobacter SPP).

None Present

Action Taken \_\_\_\_\_

NSN  
PRODUCT

**6505 Nonstandard**

V.A.D. Access Kit/Dressing Change Tray, a sterile single use tray containing the equipment needed, including heparin lock flush, to change the dressing on a vascular access device.

Recall #Z-1253-9.

CODE  
MANUFACTURER  
RECALLED BY

Catalog #DC-680, Lot 906014, EXP 06/01.

MEDIKMARK, Inc., Buffalo Grove, Illinois.

Manufacturer, by telephone on August 4, 1999, followed by letter on August 9, 1999. Firm-initiated recall ongoing.

DISTRIBUTION  
QUANTITY  
REASON

Illinois, New York, Texas, Arizona.

360 trays.

Tray may contain 1000 u/ml heparin instead of 100 u/ml heparin.

None Present

Action Taken \_\_\_\_\_

NSN  
PRODUCT

**6505 Nonstandard**

PRE-PENÆ Skin Test Antigen, (benzylpenicilloyl polylysine injection, USP), in single dose ampuls (5 per carton), Rx used in assessing a patient's allergy status to penicillin.

NDC #0091-1640-05. Recall #D-424-9.

Lot #33911, 33912, 33913 EXP 10/99.

CODE  
MANUFACTURER  
RECALLED BY

Hollister-Stier Laboratories LLC, Spokane, Washington.

Manufacturer, by letters sent on September 3 and 8, 1999. Firm-initiated recall ongoing.

DISTRIBUTION  
QUANTITY

Nationwide and international.

500 units of lot 33911, 4,716 units of lot 33912 and 200 units of lot 33913 were distributed.

REASON

Subpotency (30 month stability testing).

None Present

Action Taken \_\_\_\_\_

NSN  
PRODUCT

**6510 Nonstandard**

Codman Surgical Patties (size 1/2 x 1/2 inch), sterile, indicated use is protection of tissue, including brain and other tissues of the central nervous system, during surgery.

Recall #Z-1260-9.

CODE  
MANUFACTURER

Product Code: 80-1400, Lot #CR528.

Codman - A Johnson & Johnson Company, Norton, Massachusetts.

RECALLED BY Codman - A Johnson & Johnson Company, Raynham, Massachusetts, by letters on August 20, 1999, and August 23, 1999. Firm-initiated recall ongoing.

DISTRIBUTION Nationwide and international.

QUANTITY 67,200 patties were distributed.

REASON Surgical Patties incorrectly assembled without a radiopaque marker and string.

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

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**NSN**  
**PRODUCT** **6515 Nonstandard**  
Gammamed 12i and 12it High Dose Rate Afterloader Sources, used for HDR afterloader radiation therapy, radionuclide brachytherapy source. Recall #Z-1255/1256-9.

**CODE** 6455-6464 (source).

**MANUFACTURER** MDS Nordion/Theratronics International, Ltd., Kanata, Ontario, Canada.

**RECALLED BY** Manufacturer, by letter August 12, 1999. Firm-initiated recall ongoing.

**DISTRIBUTION** Nationwide and Canada.

**QUANTITY** 36 units were distributed.

**REASON** Use of substandard Ir-192 sealed sources may lead to overexposure of the patient to radiation with the potential for a significant overdose.

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

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**CLASS III RECALLS:**

**NSN**  
**UPDATE** **6505 Nonstandard**  
Recall #D-262/263-9, Hygroton Tablets (clorthalidone, USP), 50 mg, manufactured by Rhone Poulenc Rorer, Manati, Puerto Rico, in 100 tablet bottles, which appeared in the June 23, 1999 Enforcement Report has been extended to include lot numbers: MN2564 and MN2882 EXP 9/30/99.

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

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**NSN**  
**PRODUCT** **6515 Nonstandard**  
Omni-Jug Disposable Suction Canister, 15000 cc, for collection, transport, and disposal of large amounts of irrigation fluid generated during surgical procedures:  
a) Omni-Jug Disposable Suction Canister, Model #5036-00;  
b) Omni-Jug Disposable Suction Canister, Model #5036-01.  
Recall #Z-1243/1244-9.

CODE O-rings are not coded; Canister lids are stamped with run dates of 7/5/99 to 7/26/99.

MANUFACTURER Maryland Plastics, Inc., Federalsburg, Maryland.

RECALLED BY Waterstone Medical, Inc., Falls Church, Virginia, by letter on July 29, 1999, followed by visit. Firm-initiated recall ongoing.

DISTRIBUTION Nationwide.

QUANTITY 8,000 units.

REASON The O-ring component of the suction canister may fail to properly seal, which may not allow proper vacuum seal.

[ ] None Present  
 [ ] Action Taken \_\_\_\_\_  
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NSN **6515 Nonstandard**

PRODUCT Latex and Non-Latex Operating Room and Area Shoe Covers; Non Latex Gripper Shoe Covers and Boot Covers, packaged in cases of 50, 100, 150, 200 and 300 covers each, under the American Health & Safety Sure-Tread label:

a) NON23758 - Gripper Shoe Covers, Non-Conductive, Universal Size

NON24758 - Gripper Shoe Covers, Non-Conductive, Universal Size

NON24759 - Gripper Shoe Covers, Non-Conductive, X-Large

b) NON24752 - Gripper Sport Shoe Covers, Sport Shoe Size

NON24852 - Gripper Sport Shoe Covers, SMS Material, Sport Shoe Size

c) NON24758R - Gripper Reverse Shoe Covers, Universal Size, Reverse Seam, Blue

NON24759R - Gripper Reverse Shoe Covers, X-Large, Reverse Seam, Blue

d) NON24758L - Gripper II Spunbond Shoe Covers, White

e) NON27144 - Boot Cover Impervious Knee High No Latex

NON27144XL - Boot Cover Impervious Knee High No Latex

f) NON27752 - Shoe Cover w/Non Latex Grid Sport Size,

NON27758R - Shoe Cover W/Non Latex Grid Reverse Blue,

NON27759R - Shoe Cover W/Non Latex Grid X-Large Reverse,

NON27852 - Shoe Cover W/Non Latex Grid Sport Size SMS

g) NON27758 - Shoe Cover Gripper Non-Skid Blue No Latex,

NON27759 - Shoe Cover Gripper Blue X-Large No Latex,

h) AHS1151009 - American Health & Safety Sure Tread Disposable Shoe Covers, Stretch Size 5-12.

Recall #Z-1245/1252-9.

CODE All lots ending with JC followed by a numeral of the part numbers/reorder numbers listed above.

MANUFACTURER Hangzhou Jinchen Knitting & Textiles Co., Ltd., Hangzhou, China.

RECALLED BY Medline Industries, Inc., Mundelein, Illinois, by letter dated August 27, 1999. Firm-initiated recall ongoing.

DISTRIBUTION Nationwide.

QUANTITY  
REASON

39,266 cases.  
Some of the shoe covers have the gripper pattern made of a water-soluble substance, and may smear or may be more prone to slippage if exposed to water.

None Present  
 Action Taken \_\_\_\_\_  
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**6515 NS**  
PRODUCT

**Nonstandard**  
Port-A-CATH Implantable Access System, designed to permit repeated access to the vascular system for the parenteral delivery of medications, nutritional solutions, and other fluids and for the sampling of venous blood.

CODE  
MANUFACTURERS  
RECALLED BY

Recall #Z-1259-9.  
Catalog Number: 21-4023-22, Lot Number: 66161.  
ims Deltec, Inc., St. Paul, Minnesota.  
Manufacturer, by letter dated August 30, 1999. Firm-initiated recall ongoing.

DISTRIBUTION  
QUANTITY  
REASON

Europe.  
122 units were distributed.  
Product equipped with an incorrect size catheter introducer component. The recalled lot contain size 6 French introducers rather than the specified size 8.5 French introducers.

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