

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. (AFMLO/FOM, Capt David Zemkosky, DSN 343-4028)

CLASS I RECALLS:

6515NS

MDC 12636 Physiological Monitoring Systems

Product: Solar 8000 Bedside Patient Monitor.

Recall #Z-908-7.

Code: Serial #s beginning with B7, C7, D7, E7, All monitors manufactured between February 1, 1997 and July 10, 1997, with s7 or G7.

Manufacturer: Marquette Electronics, Inc., Milwaukee, Wisconsin.

Recalled by: Manufacturer, by letter on August 15, 1997. Firm-initiated field correction ongoing.

Distribution: Nationwide and international..

Quantity: 1,769 units were distributed.

Reason: The speaker of the monitor may fail to audibly alarm due to the inappropriate length of the speaker lead wire.

None Present

Action Taken _____

CLASS II RECALLS: None

CLASS III RECALLS: None

MEDICAL EQUIPMENT SAFETY ALERTS:

6530NS

MDC 16405 Apheresis Units

Product: Autopheresis-C Plasmapheresis System.

Safety Alert #N-028-7.

Code: Model A-200, Model A-201, Model A-401.

Manufacturer: Baxter Healthcare Corporation, Largo, Florida.

Alerted by: Baxter Healthcare Corporation, Deerfield, Illinois, by letter on August 4, 1997.

Distribution: Nationwide.

Quantity: 5,229 instruments were distributed.

Reason: The use of 250 ml anticoagulant containers may result in the potential for donor air embolus when performing plasmapheresis with the Autopheresis-C instrument.

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 14 NOV 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:

NSN 6505 Nonstandard
PRODUCT Prograf Tacrolimus Capsules, 1 mg, in bottles of 100, Rx oral drug indicated for the prophylaxis of organ rejection in patients receiving allogenic liver transplants. Recall #D-276-7.
CODE Lot 1C3062B EXP 4/30/99.
MANUFACTURER Fujisawa Ireland Ltd., Republic of Ireland.
RECALLED BY Fujisawa USA, Inc., Deerfield, Illinois, by letters dated September 3 and 5, 1997. Firm-initiated recall ongoing.
DISTRIBUTION Nationwide.
QUANTITY 6,890 bottles were distributed; firm estimated that 25-30% of product remained on market at time of recall initiation.
REASON Mislabeling -- At least one bottle labeled to contain 1 mg capsules actually contained 5 mg capsules.

[] None Present
[] Action Taken _____



CLASS II RECALLS:

NSN 6505 Nonstandard
PRODUCT Allergenic Extract and Allergenic Treatment Sets. Recall #B-1412-7.
CODE Lot # 648304, 653265, 663176, 666156, 668804, 668925, 668926, 670458, 671334, 678222, 678223, 678224, 678225, 678226, 678227, 678228, 678229, 678230, 678231, 678232, 678233, 678234, 678235, 678236, 678237, 678238, 678239, 678240, 678241, 692263, 693755.
MANUFACTURER ALK Laboratories, Berkeley, California.
RECALLED BY Manufacturer, by letter on August 16 and 27, 1997, followed by telephone. Firm-initiated recall ongoing.
DISTRIBUTION Nationwide.
QUANTITY 31 lots.
REASON Lack of assurance that products met sterility testing requirements prior to release.

[] None Present
[] Action Taken _____

NSN 6515 Nonstandard
PRODUCT Lead Aprons, Collars, and Gonadal Shields. Recall #Z-912/914-7.
CODE Products received from vendor between 5/97 and 7/97. No lot number or catalog number.
MANUFACTURER Burlington Medical, Inc., Newport News, Virginia.
RECALLED BY Manufacturer, by letter on July 15, 1997. Firm-initiated recall complete.
DISTRIBUTION Nationwide.
QUANTITY Undetermined.
REASON The radiation protection devices contain lead contaminated with small amounts of radioactive substances.

[] None Present
[] Action Taken _____

NSN 6515 Nonstandard
PRODUCT Ultra-Flex Adult Anesthesia Breathing Circuits:
1. Product No. 51213F-6154
2. Product No. 5613B-61
3. Product No. 5613F-61
4. Product No. 5613F-80

5. Product No. 5753B-61
 6. Product No. 5753F-10021
 7. Product No. 61453B-8015X
 8. Product No. 6753F-13621
 9. Product No. 8613B-164
 10. Product No. 8613B-84X
 11. Product No. 8613F-13633
 12. Product No. 8613F-164E
 13. Product No. 8613F-61
 14. Product No. 8613F-6121
 15. Product No. 8613F-80
 16. Product No. 8613F-84
 17. Product No. 8613F-8433
 18. Product No. 8752B-84X
 19. Product No. 8753B-61
 20. Product No. 8753F-104
 21. Product No. 8753F-231
 22. Product No. 8753F-248
 23. Product No. 8753F-249
 24. Product No. 8753F-61
 25. Product No. 90337
 26. Product No. 90358
 27. Product No. Q5753F-28B31.
- Recall #Z-915/941-7.

CODE

Lot numbers:

1. 1947E7
2. 0236F7, 1948E7
3. 0237F7, 1337E7
4. 1238F7
5. 0101F7
6. 2296E7
7. 0680F7
8. 2058E7
9. 0586F7, 1341E7
10. 1139E7, 0243F7, 0213E7, 1205F7
11. 0101F7, 2300E7, 1728E7
12. 1342E7
13. 0244F7, 1952E7, 2158E7
14. 0587F7
15. 1037F7, 1343E7, 1953E7
16. 1282F7
17. 1212E7
18. 0504F7
19. 0505F7, 1603E7
20. 2061E7, 0104F7
21. 0105F7
22. 0247F7
23. 2062E7, 0106F7, 1346E7, 0248F7
24. 0250F7, 2041E7
25. 1734E7
26. 2042E7
27. 0002F7.

MANUFACTURER King Systems Corporation, Noblesville,
Indiana.

RECALLED BY Manufacturer, by fax on August 11, 1997.

Firm-initiated recall ongoing.
DISTRIBUTION Nationwide and Singapore.
QUANTITY 328 cases were distributed.
REASON The expandable tube is breaking around the circumference of the tube.

None Present
 Action Taken _____

CLASS III RECALLS:

NSN 6505 Nonstandrd
PRODUCT Gentamicin Sulfate Injection, USP, 40 mg/mL, in 20 ml multiple dose vials, under the following labels: Steris, Rugby, Goldline (Zenith on label).
Recall #D-277-7.
CODE Lot #95K550.
MANUFACTURER Steris Laboratories, Inc., Phoenix, Arizona.
RECALLED BY Manufacturer, by letter on March 31, 1997.
Firm-initiated.
DISTRIBUTION Nationwide.
QUANTITY 19,000 vials were distributed.
REASON White precipitate in product (preservatives).

None Present
 Action Taken _____

SAFETY ALERTS:

PRODUCT Autopheresis-C Plasmapheresis System.
Safety Alert #N-028-7.
CODE Model A-200, Model A-201, Model A-401.
MANUFACTURER Baxter Healthcare Corporation, Largo, Florida.
ALERTED BY Baxter Healthcare Corporation, Deerfield, Illinois, by letter on August 4, 1997.
DISTRIBUTION Nationwide.
QUANTITY 5,229 instruments were distributed.
REASON The use of 250 ml anticoagulant containers may result in the potential for donor air embolus when performing plasmapheresis with the Autopheresis-C instrument.

None Present
 Action Taken _____
