

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 12648
PRODUCT

Physiologic Monitoring System, Cardiac Catheterization

Quinton Q-Cath Hemodynamic Analysis System, a hemodynamic recording system, which acquires, displays, stores and may print out waveform data acquired from a patient undergoing a cardiac catheterization procedure:

- a) Q-Cath; b) Q-Cath II; c) Q Cath II NT; d) Q-Cath DS;
e) Q-Cath Remote Station. Recall #Z-855/859-9.

CODE

Units with version 4.5 software.

MANUFACTURER

Quinton Instrument Company, Bothell, Washington.

RECALLED BY

Manufacturer, by letter on October 1, 1998, followed by visit. Firm-initiated field correction ongoing.

DISTRIBUTION

Nationwide, Canada, The Netherlands, Thailand, New Zealand, Egypt.

QUANTITY

Approximately 81 units were distributed.

REASON

Device has potential to display previous patient's blood pressure

None Present

Action Taken _____

6515 NS

MDC 12282. 12276
PRODUCT

Lights, Surgical, Lights Examination

FlexiMount Ceiling Track Mount System with Trolley, Model #0102180, part of the mounting system designed to connect the Burton Outpatient Plus, Outpatient II, Coolspot and Coolspot lights to the ceiling. Recall #Z-862-9.

CODE

Serial numbers: 940080-940250 and 97253-97313.

MANUFACTURER

Burton Medical Products Corporation, Chatsworth, California.

RECALLED BY

Manufacturer, by letter on April 13, 1999. Firm-initiated recall ongoing.

DISTRIBUTION

Nationwide and Canada.

QUANTITY

122 units were distributed.

REASON

The device has the potential to fall because setscrews used to secure the down-tube on the trolley were omitted from the installation pack.

None Present

Action Taken _____

6515 NS

MDC 11490
PRODUCT

Electrosurgical Units

Pressure Reduction Valve, Part #20132-065, a component of the Argon Plasma Coagulation (APC) Unit. Recall #Z-863-9.

CODE

Serial numbers: M0005001 to M0005050.

MANUFACTURER

ERBE, Tübingen, Germany,

RECALLED BY

ERBE USA, Inc., Marietta, Georgia, by visit and by letters sent on April 5, 1999. Firm-initiated recall ongoing.

DISTRIBUTION

Nationwide and Canada.

QUANTITY

50 units with the affected serial numbers have been distributed.

REASON The valve has the potential to separate from the Argon tank because it does not fit securely in the tank.
 None Present
 Action Taken _____

6515 NS
MDC 17634
PRODUCT

Infusion Pump, Multi-Channel

Colleague 3 Volumetric Infusion Pump (Triple Channel) for continuous or intermittent delivery through clinically acceptable routes of administration such as intravenous, intra-arterial, subcutaneous, epidural or irrigation of fluid spaces applications. Recall #Z-872-9.

CODE
MANUFACTURER
RECALLED BY

Product Code 2M8153, All serial numbers.
Baxter Healthcare PTE. Ltd. Singapore.
Baxter Healthcare Corporation, IV Systems Division, Round Lake, Illinois, by letter April 16, 1999. Firm-initiated field correction ongoing.

DISTRIBUTION
QUANTITY
REASON

Nationwide.
6,992 pumps were distributed.
A software communication error occurs predominately when all three channels are in use, causing an alarm condition (533:320:717:000) that will stop the function of all of the channels in use. The pump will alarm appropriately, alerting the user of the failure state.
 None Present
 Action Taken _____

6515 NS
MDC 13775
PRODUCT

Stimulators, Neuromuscular

a) Minnova Pelvic Floor Stimulation System;
b) InnoSense Pelvic Floor Stimulation and Electromyography System. Both systems use mild electrical stimulation to help control urinary incontinence. Recall #Z-865/866-9.

CODE
MANUFACTURER
RECALLED BY

Various serial numbers.
EMPI, Inc., St. Paul, Minnesota.
Manufacturer, by letter dated March 26, 1999. Firm-initiated recall ongoing.

DISTRIBUTION
QUANTITY
REASON

Nationwide and international.
a) 126 units; b) 73 units were distributed.
Electrical short at a pin connector may change the location of the stimulation to an incorrect location.
 None Present
 Action Taken _____

6515 NS
MDC 11218
PRODUCT

Hemodialysis Units

System 1000 and Tina Single Patient Hemodialysis Delivery System with DPSND and SPSND options that are fitted with a J089700 Arterial Line Clamp. Also there are Spare Part Kits that are under recall because they contain the suspect Arterial Line Clamp, their spare part numbers J08970S and K100DRC. Recall #Z-912/913-9.

CODE

System 1000 and TINA Single Patient Hemodialysis Delivery Systems with DPSND and SPSND Options that are fitted with a J089700 Arterial Line Clamp with the following serial numbers: 11521-11525, 11971-11975, 12106-12131, 51701-51703, 51718-51730, 51760-

51794, 51795-51805, 51809-51810, 51817-51829, 51830-51850, 51865-51869, 51870-51873, 51894-51896, 51901-51904, 51905-51916, 51919-51921 and 51934. is a Spare Part Arterial Clamp part numbers involved are: J08970S. The firm also markets a Spare Parts Kits that contains the recalled Clamp it is labeled with Item # K100DRC.

MANUFACTURER
RECALLED BY

Althin Medical, Inc., Miami Lakes, Florida.
Manufacturer, by letter December 21, 1998. Firm-initiated recall ongoing.

DISTRIBUTION
QUANTITY

Illinois, Georgia, international.
162 machines and 102 spare part kits with the recalled clamp were distributed.

REASON

Damaged, leaking blood lines.
 None Present
 Action Taken _____

6530 NS
MDC 10347
PRODUCT
CODE
MANUFACTURER
RECALLED BY

Beds, Electric
Mobilite Electric Homecare Bed. Recall #Z-915-9.
All beds manufactured prior to June 1993.
Invacare Corporation, Sanford, Florida.
Manufacturer, by letter on February 8, 1999.
Firm-initiated recall ongoing.

DISTRIBUTION
QUANTITY
REASON

Nationwide.
319,714 beds were distributed.
Old style pull ring may cause serious finger injuries.
 None Present
 Action Taken _____

6630 NS
MDC 15551
PRODUCT
CODE
MANUFACTURER
RECALLED BY

Clinical Chemistry Analyzer
All Architect I System Processing Modules with Software Versions 1.0 and 1.01. Recall #Z-910-9.
List #08C89-00-01.
Abbott Laboratories, Irving, Texas.
Manufacturer, by letter and telephone on April 12, 1999. Firm-initiated recall ongoing.

DISTRIBUTION
QUANTITY
REASON

Nationwide and international.
173 units were distributed.
The device may report incorrect results for diluted samples; and/or when used with the Laboratory Information System or Host Information Systems, the system may incorrectly associate test results with patient ID or incorrectly associate control results with patient records.
 None Present
 Action Taken _____

6640 NS
MDC 17740
PRODUCT

Hematology, Analyzer
Bayer ADVIA 120 Hematology System, a quantitative automated hematology analyzer that provides a leukocyte differential count and reticulocyte analysis for in-vitro-diagnostic use in clinical laboratories:
a) ADVIA 120 Hematology System, Catalog No. 453-0024-03;
b) ADVIA 120 Hematology System, Catalog No. 453-0024-04.
Recall #Z-869/870-9.

CODE All serial numbers.
 MANUFACTURER Bayer Diagnostic Manufacturing Ltd., Swords, Co Dublin, Ireland.
 RECALLED BY Bayer Corporation, Elkhart, Indiana, by customer bulletin sent on February 9, 1999. Firm-initiated recall ongoing.
 DISTRIBUTION Nationwide and international.
 QUANTITY Approximately 920 units were distributed.
 REASON The device may give erroneous results because of the valve gasket deterioration in the Baso channel check valve, and the software designed will not flag significant discrepancies in the results between the two methodologies at extremely low counts.
 None Present
 Action Taken _____

6650 NS
MDC 12539
 PRODUCT **Microscopes, Operations**
 NC-1 Floor to Ceiling Mount, an accessory to a microscope used for various surgical procedures. Recall #Z-864-9.
 CODE Identification number is KBC 002, with fabrication (serial) Numbers 10-2044 and lower.
 MANUFACTURER Oberlikon Contraves, A.G., Zurich, Switzerland.
 RECALLED BY Carl Zeiss, Inc., Thornwood, New York, by letter on April 1, 1999. Firm-initiated field correction ongoing.
 DISTRIBUTION Florida, Kentucky, Texas, North Carolina, Illinois, Alabama, Missouri, Ohio, Louisiana, Arizona, Georgia, California, Hawaii, Delaware, Colorado, Utah, Pennsylvania, Arkansas.
 QUANTITY 52 units were distributed.
 REASON The device has the potential to fall during use.
 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 **09 Jul 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 6505 Nonstandard
 PRODUCT Compressed Oxygen USP, Rx in high pressure E and D size

CODE cylinders. Recall #D-208-9.
Lot #31C992.
MANUFACTURER Red Ball Oxygen Company, Inc., Shreveport, Louisiana.
RECALLED BY Manufacturer, by telephone on April 12, 1999. Firm-initiated recall ongoing.
DISTRIBUTION Louisiana and Texas.
QUANTITY 38 cylinders were distributed.
REASON Failure to document the analysis of potency and identity testing.
[] None Present
[] Action Taken _____

NSN 6505 Nonstandard
PRODUCT Platelets, Pheresis. Recall #B-782-9.
CODE Unit #42FR75059 (split unit).
MANUFACTURER American Red Cross Blood Services, Cleveland, Ohio.
RECALLED BY Manufacturer, by letter dated March 16, 1999. Firm-initiated recall ongoing.
DISTRIBUTION Ohio.
QUANTITY 1 unit was distributed.
REASON Blood products were collected from a donor who traveled to an area considered endemic for malaria.
[] None Present
[] Action Taken _____

NSN 6505 Nonstandard
PRODUCT Various Rx drugs:
a) Levsin SL Tablets (Hyoscyamine/SL 0.125 mg), in 20 count units;
b) Ibuprofen Tablets, 800 mg, in 50 count units,
c) Bactrim DS Tablets (Sulfamethoxazole/Trimethoprim DS 800/160), in 20 count units,
d) Cimetadine Tablets, 400 mg in 60 count units
e) Atenolol Tablets, 50 mg in 30 count units,
f) Hydrochlorothiazide Tablets, 25 mg in 30 and 60 count units,
g) Chlorzoxazone Tablets, 500 mg, in 40 count units,
h) Chlopropamide Tablets, 250 mg, in 60 count units,
i) Verapamil Tablets, 120mg, in 60 count units.
Recall #D-221/229-9.
CODE Lot numbers: a) J32893; b) J32895; c) J60891; d) J60893;
e) J60894; f) J60895 and J60896; g) J91893; h) J91894;
i) J51893.
MANUFACTURER Rural Health Services Consortium, Inc., Rogersville, Tennessee.
RECALLED BY Manufacturer, by letter December 14, 1998. Firm-initiated recall ongoing.
DISTRIBUTION Tennessee.
QUANTITY Undetermined.
REASON Possible penicillin and/or cephalosporin cross contamination.
[] None Present
[] Action Taken _____

NSN 6515 Nonstandard
PRODUCT a) 5 Fr Angiographic Catheters Model Nos. SPC-454D, SPC-454E, and SPC-454F; b) 5 Fr Pressure/Volume Catheters; Model Nos. SPC-465A, SPC-550, SSD-795, and SSD-814.
CODE Recall #Z-853/854-9.
All lot numbers.

MANUFACTURER
RECALLED BY Millar Instruments, Houston, Texas.
Manufacturer, by letter on March 19, 1999. Firm-initiated recall ongoing.

DISTRIBUTION
QUANTITY Nationwide, Canada, Japan.
REASON 290 units were distributed.
A coagulated clot was found within the catheter which were made of nylon instead of polyurethane as specified in the firm's 510(k).
 None Present
 Action Taken _____

NSN
PRODUCT 6515 Nonstandard
GEM Implantable Cardioverter Defibrillator:
a) Model No. 7227Cx; b) Model No. 7227.
Recall #Z-860/861-9.

CODE
MANUFACTURER All serial numbers.
Medtronic Med Rel, Inc., Humacao, Puerto Rico; Medtronic, Switzerland Manufacturing Operations, Tolochenaz, Switzerland.

RECALLED BY Medtronic, Inc., Minneapolis, Minnesota, by letter on April 2, 1999. In the recall action, a voltage test is being used to identify defibrillators which have premature battery depletion. Firm-initiated recall ongoing.

DISTRIBUTION
QUANTITY Nationwide and international.
REASON Approximately 5,000 devices were distributed.
A high current drain in some of the defibrillators causes premature battery depletion.
 None Present
 Action Taken _____

NSN
PRODUCT 6515 Nonstandard
8F Zuma Guiding Catheter, designed to provide a pathway through which therapeutic devices are introduced. The guiding catheter is intended to be used in the coronary or peripheral vascular system. Recall #Z-911-9.

CODE
MANUFACTURER All lots.
Medtronic Interventional Vascular, Inc., Danvers, Massachusetts.

RECALLED BY Manufacturer, by letter dated March 31, 1999. Firm-initiated recall ongoing.

DISTRIBUTION
QUANTITY Nationwide.
REASON 6,752 units were distributed.
Instructions for use are inadequate.
 None Present
 Action Taken _____

NSN
PRODUCT 6515 Nonstandard
Coaxial Biopsy System composed of an introducer (coaxial needle) and an 18 gauge biopsy needle for specimen sampling, marketed under the Achieve label, Bauer Medical, Inc., packaged 5 systems per box. Recall #Z-914-9.

CODE
MANUFACTURER Catalog #CA18/15, Lot B07/99D99.
Allegiance Healthcare Corporation, Clearwater, Florida.

RECALLED BY Allegiance Healthcare Corporation, McGaw Park, Illinois, by letter dated April 29, 1999. Firm-initiated recall ongoing.

DISTRIBUTION Florida, New Jersey, Minnesota, Nebraska, Missouri, North Carolina, Louisiana, Texas, Oregon, Illinois, New York, Hawaii, Georgia, California.

QUANTITY 205 units were distributed.
REASON The introducer needle (19 gauge) is too small in diameter for the 18 gauge biopsy needle to insert through it, preventing specimen sampling.
[] None Present
[] Action Taken _____

NSN 6515 Nonstandard
PRODUCT Millipore Vented Millex GS Sterilizing Filter Unit (Sterile and Non-Pyrogenic), intended for sterilizing aqueous solutions, such as antibodies and critical care solutions dispensed with a syringe. Recall #Z-918-9.
CODE Catalog #SLGS V25 5F, Lot #R8EM78710.
MANUFACTURER Millipore, Cork, Ireland
RECALLED BY Millipore Corporation, Bedford, Massachusetts, by letter on May 7, 1998. Firm-initiated recall ongoing.
DISTRIBUTION Nationwide and international.
QUANTITY 113 boxes (50 units per box) were distributed.
REASON Sterile Filter exceeds USP limits for Bacterial Endotoxins.
[] None Present
[] Action Taken _____

NSN 6515 Nonstandard
PRODUCT DMR2 Disposable Manual Resuscitators:
1. Model No. ARXL; 2. Model No. ARML;
3. Model No. ARMLDP; 4. Model No. ARPML;
5. Model No. ARMS; 6. Model No. ARXB;
7. Model No. ARMB; 8. Model No. ARPMB;
9. Model No. ARMBDP; 10. Model No. AVXL;
11. Model No. AVML; 12. Model No. AVPML;
13. Model No. AVMLDP; 14. Model No. AVMS;
15. Model No. AVXB; 16. Model No. AVMB;
17. Model No. AVPMB; 18. Model No. AVMBDP;
19. Model No. CRPML; 20. Model No. CRPMS;
21. Model No. CRPXB; 22. Model No. CRPMB;
23. Model No. CVPML; 24. Model No. CVPMS;
25. Model No. CVPXB; 26. Model No. CVPMB;
27. Model No. CVPMBDP; 28. Model No. IRPML;
29. Model No. IRPXB; 30. Model No. IRPMB;
31. Model No. IVPMS; 32. Model No. IVPXB;
33. Model No. IVPMB; 34. Model No. IVPMBDP.
Recall #Z-874/907-9.
CODE All lots.
MANUFACTURER Nellcor Puritan Bennett de Mexico S.A. de C.V., Tijuana, Mexico.
RECALLED BY Mallinckrodt, Inc., St. Louis, Missouri, by letter on March 30, 1999. Firm-initiated recall ongoing.
DISTRIBUTION Nationwide and international.
QUANTITY Approximately 100,716 units were distributed.
REASON The non-rebreathing valve (NRV) housing assembly may crack resulting in the swivel elbow fitting becoming loose and disengaging from the NRV during use.
[] None Present
[] Action Taken _____

NSN 6540 Nonstandard
PRODUCT Storz Silicone Tire Implant for Retinal Detachment Surgery

CODE a) Catalog No. E5381 721 (287 Style);
 b) Catalog No. E5381 620 (78g Style). Recall #Z-867/868-9.
 Lot numbers: a) MI70870, MI70880, MA83090, MC80850, MC80860,
 MC80870, and MC80880; b) MA81790.
 MANUFACTURER Vesta, Inc., Franklin, Wisconsin.
 RECALLED BY Bausch and Lomb Surgical, Inc., St. Louis, Missouri, by letter
 dated February 24, 1999 and the week of April 19, 1999. Firm-
 initiated recall ongoing.
 DISTRIBUTION Nationwide and international.
 QUANTITY 473 pouches were distributed.
 REASON The package labeling may not correctly identify the size and
 style of the contents.
 None Present
 Action Taken _____

NSN 6540 Nonstandard
 PRODUCT Ocufilecon D 55 Visibility Tinted Contact Lenses .
 Recall #Z-871-9.

CODE Product Names (trade names)Involved In Recall:
 Brand (-)(+): Product Code: Brand: Product Code:
 Aqualens Disp. 55 5133 Proflex 55 2210
 Aqualens Disp. 55 5134 Proflex 55 2222
 Aquatech 55 2225 Prosite 55 2252
 Aquatech 55 2226 Prosite 55 2253
 Clinasoft 55 2202 Sofmed 55 2228
 Clinasoft 55 2214 Softech 55 2248
 Diagnostic 55 2263 Softech 55 2249
 Diagnostics 55 2262 Softique 55 2235
 Hydroflex 55 2264 Softmed 55 2227
 Hydron Biomedics 55 2208 Ultraflex 7/14 55 2201
 Hydron Biomedics 55 2220 Ultraflex 7/14 55 2213
 Hydrovue 55 2246 Veraflex Eyerned 55 5141
 Hydrovue 55 2247 Versaflex 55 2250
 Mediflex 2203 Versaflex 55 2251
 Mediflex 55 2215 Versaflex Eyerned 55 5143
 Optiflex 2209 Optiflex 55 2221
 Optiform 55 2254 Optiform 55 2255
 P Label Disp. 55 2223 Polysoft 55 2256
 Polysoft 55 2257 Private Label 55 2211
 Procon 55 2230 Procon 55 2229.

MANUFACTURER Ocular Sciences, Inc., South San Francisco, California.
 BY Manufacturer, by letter on April 26, 1999. Firm-initiated recall
 ongoing.
 DISTRIBUTION Nationwide and international.
 QUANTITY 1,283,472 lenses were distributed.
 REASON Incomplete seal could compromise product sterility.
 None Present
 Action Taken _____

CLASS III RECALLS:

NSN 6505 Nonstandard
 PRODUCT Tripedia Multidose Injection (Diphtheria and Tetanus Toxoids
 Accellular Pertussis Vaccine Adsorbed), 7.5 ml, in 10 ml vials.
 Recall #B-730-9.
 Lot #0916490.
 CODE
 MANUFACTURER Pasteur Merieux Connaught USA, Swiftwater, Pennsylvania.
 RECALLED BY Manufacturer, by letter sent on January 27, 1999, and by

DISTRIBUTION
QUANTITY
REASON

telephone on January 26, 1999. Firm-initiated recall ongoing.
Nationwide.
45,682 units were distributed.
Diphtheria component of the injectable vaccine was found to be
subpotent at the nine month stability test point.
 None Present
 Action Taken _____

NSN
PRODUCT
CODE
MANUFACTURER
RECALLED BY

6505 Nonstandard
Red Blood Cells. Recall #B-761-9.
Unit #20LC23399.
American Red Cross Blood Services, Boise, Idaho.
Manufacturer, by telephone on May 15, 1998. Firm-initiated
recall ongoing.

DISTRIBUTION
QUANTITY
REASON

Utah.
1 unit was distributed.
Leukodepleted blood product failed the requirement for red cell
recovery.
 None Present
 Action Taken _____

NSN
PRODUCT

6515 Nonstandard
Medline Gripper Sport and Gripper II Latex Free Operating Room
Shoe Covers: a) Catalog No. NON27752;
b) Catalog No. NON27758; c) Catalog No. NON27758R;
d) Catalog No. NON27759; e) Catalog No. NON27759R;
f) Catalog No. NON27852; g) Catalog No. NON27144;
h) Catalog No. NON27144XL. Recall #Z-844/851-9.

CODE

Lot Numbers: 307892JC, 362750JC, 376467JC, 376495JC, 393363JC,
393346JC.

MANUFACTURER
RECALLED BY

Hangzhou Jinchun Knitting & Textiles Co., Ltd., Hangzhou, China.
Medline Industries, Inc., Mundelein, Illinois, by undated letter
on April 1, 1999. Firm-initiated recall ongoing.

DISTRIBUTION
QUANTITY
REASON

Nationwide.
1,950 cases were distributed.
The latex free gripper pattern on the shoe covers is made of a
water-soluble substance and may smear and may be more prone to
slippage if exposed to water.
 None Present
 Action Taken _____

NSN
PRODUCT
CODE
MANUFACTURER
RECALLED BY

6540 Nonstandard
Proclear Daily Wear Contact Lens. Recall #Z-908-9.
Lot B814117.
Biocompatibles Eyecare, Norfolk, Virginia.
Manufacturer, by telephone on April 14, 1999. Firm-initiated
recall ongoing.

DISTRIBUTION
QUANTITY
REASON

Nationwide, Canada, United Kingdom.
119 lenses were distributed.
Contact lenses optical power was mislabeled on product.
 None Present
 Action Taken _____

NSN
PRODUCT

6540 Nonstandard
Visitec Visidrape, sterile disposable surgical drape used

primarily for ophthalmic surgery: Catalog Numbers 581087 and 581088. Recall #Z-919/920-9.
CODE Catalog No. 581087 lot number 050199
MANUFACTURER Catalog No. 581088 lot number 040199.
RECALLED BY Becton Dickinson Surgical Systems, Sarasota, Florida.
Manufacturer, by telephone on February 23, 1999, followed by
letter on March 3, 1999. Firm-initiated recall ongoing.
DISTRIBUTION California, Florida, Texas, Australia.
QUANTITY 37 boxes of 10 each were distributed.
REASON Surgical orientation mark is incorrect.
[] None Present
[] Action Taken _____

NSN 6550 Nonstandard
PRODUCT IMX HCG Calibrators, for in vitro diagnostic use. The IMx hCG
Assay is a Microparticle Enzyme Immunoassay (MEIA) for the
quantitative and qualitative determination of Human Chorionic
Gonadotropin (hCG) in human serum and plasma for the early
detection of pregnancy. Recall #Z-873-9.
CODE Lot #3A63-01, List No. 47128Q100 EXP 8/9/99.
MANUFACTURER Abbott Health Products, Inc., Barceloneta, Puerto Rico.
RECALLED BY Manufacturer, by telephone and letter dated April 20, 1999.
Firm-initiated recall ongoing.
DISTRIBUTION Nationwide and international.
QUANTITY 210 kits were distributed.
REASON Decreased F calibrator rates may result in elevated control and
patient values.
[] None Present
[] Action Taken _____
