

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 13250
PRODUCT
Warmer Radiant Infant
Resuscitaire Radiant Warmer, Infant Radiant Warmer:
a) Resuscitaire Radiant Warmer, Model RW81;
b) Resuscitaire Radiant Warmer, Model RW82;
c) Resuscitaire Radiant Warmer, Model RW82VHA;
d) Resuscitaire Radiant Warmer, Model WMRW82;
e) Resuscitaire Radiant Warmer, Model WBR 81;
f) Resuscitaire Radiant Warmer, Model WBR82.
Recall #Z-292/297-9.

CODE
MANUFACTURER
Units with software versions prior to 1.061.
Hill-Rom Air-Shields, formerly Air-Shields, Inc., a division of Vickers Medical, Hatboro, Pennsylvania.

RECALLED BY
Manufacturer, by letter dated June 12, 1998. Firm-initiated field correction ongoing.

DISTRIBUTION
Nationwide and international.

QUANTITY
2,095 units were distributed.

REASON
The device fails to control heater power due to a software error.

None Present
 Action Taken _____

6525NS
MSC 16544
PRODUCT
X-Ray Table
PRESTILIX 1690 Tilting Radiological Tables, Models 825100G025, 825100G045, 825100G055, and 830240G015. Recall #Z-334/337-9.

CODE
MANUFACTURER
All Serial Numbers.
General Electric Medical Systems, Loncin, Belgium.

RECALLED BY
General Electric Medical System, Waukesha, Wisconsin, by field modification notice issued on November 24, 1998. Firm-initiated field correction ongoing.

DISTRIBUTION
Nationwide and international.

QUANTITY
224 units were distributed.

REASON
The spot film device (SFD) of the Prestilix Radiological Tables could fall on the operators of the tables. The support of the SFD does not have adequate strength and could fail due to metal fatigue with normal use. The SFD is located under the tables and would fall into a low-occupancy zone for operators if the support fails.

None Present
 Action Taken _____

6640NS
MSC 16817
PRODUCT

(Software Program)
Software for the Abbott AxSYM System, a fully automated immunoanalyzer.
Recall #Z-331-9.

CODE
MANUFACTURER
RECALLED BY

All software versions below 3.03.
Abbott Laboratories, Irving, Texas.
Abbott Laboratories, Diagnostics Division, Abbott Park, Illinois, by sending
upgrade kits in November 1997, and by letter on October 26, 1998. Firm-initiated
field correction ongoing.

DISTRIBUTION
QUANTITY
REASON

Nationwide and international.
3,589 instruments with software versions below 3.03 were distributed.
Extra assay results from a previous run can appear with new sample results, as
well as error messages, due to software defect in the internal result database
management.

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 **12 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	Miostat (Carbachol 0.01%) Intraocular Solution, in 1.5 ml sterile glass vials, Rx, for use for obtaining miosis during surgery. NDC #0065002315 (United States) and 0065002310 (Canada). Recall #D-042-9.
CODE	All lots that remain within expiration date (84 lots).
MANUFACTURER	Alcon Laboratories, Inc., Fort Worth, Texas.
RECALLED BY	Manufacturer, by letters dated November 16 and 23, 1998. Firm-initiated recall ongoing.
DISTRIBUTION	Nationwide and Canada.
QUANTITY	1,981,956 units were distributed; firm estimated that 190,000 units remained on market at time of recall initiation.
REASON	Presence of minute borosilicate flakes.

None Present
 Action Taken _____

NSN	6515 Nonstandard
PRODUCT	I-125 SEEDS, CODE 6711, Iodine-125 Therapeutic for Interstitial Brachytherapy and I-125 RAPID STRAND, CODE 7000, Rigid Absorbable Permanent Implant Device containing I-125 Seeds for Brachytherapy Recall #Z-332/333-9.
CODE	Model 6711, Lot W82818 and RAPID Strand, Model 7000, sublots P8134C and P8137A, manufactured from lot W82818 RAPID Strand is under 510(k) K940632, product code 90IWI.
MANUFACTURER	Medi-Physics, Inc., Arlington Heights, Illinois.

RECALLED BY Nycomed Amersham Imaging, Princeton, New Jersey, by telephone on December 9, 1998, followed by letter on December 16, 1998. Firm-initiated recall ongoing.
DISTRIBUTION Pennsylvania, Georgia, New York, Texas, Wisconsin, Florida, Missouri, England.
QUANTITY 264 seeds and 33 strands were distributed.
REASON Products are labeled with the wrong radioactivity range.

None Present
 Action Taken _____

NSN 6550 Nonstandard
PRODUCT Carticel (Autologous Cultured Chondrocytes). Recall #B-286-9.
CODE Lot C81346.
MANUFACTURER Genzyme - Tissue Repair, Cambridge, Massachusetts.
RECALLED BY Manufacturer, by telephone on August 22 and 24, 1998, and by letter dated September 9, 1998. Firm-initiated recall ongoing.

DISTRIBUTION North Carolina.
QUANTITY 1 vial was distributed.
REASON Tissue repair product was contaminated with Staphylococcus capitis (coagulase negative).

None Present
 Action Taken _____

NSN 6550 Nonstandard
PRODUCT VARIANT Express Elution Buffer 1, a component of the Variant Express reorder pack. Elution Buffer 1 is optimized to bind glycohemoglobins to the HPLC column. The Bio-Rad VARIANT Express provides an integrated method for the separation and determination of the relative percentage of glycohemoglobin in the whole blood. This reorder pack is for in vitro diagnostic use (outside the body). Recall #Z-302-9.
CODE AA81495
MANUFACTURER Bio-rad Laboratories, Hercules, California.
RECALLED BY Manufacturer, by letter on November 24, 1998. Firm-initiated field correction ongoing.

DISTRIBUTION California.
QUANTITY 252 units were distributed.
REASON Inconsistent test results. Drift in values would make the controls go off.

None Present
 Action Taken _____

CLASS III RECALLS:

NSN 6505 Nonstandard
PRODUCT Diltiazem Hydrochloride, USP, Extended-Release Capsules, 60 mg, in 100 capsule bottles, used in the treatment of hypertension.
CODE NDC #0093-0021-01. Recall #D-039-9.
Lot numbers: 8425 EXP 7/99 and 8426 EXP 7/99.

MANUFACTURER
RECALLED BY Teva Pharmaceuticals, Sellersville, Pennsylvania.
 DISTRIBUTION Manufacturer, by letter on May 11, 1998. Firm-initiated recall
 QUANTITY ongoing.
 Nationwide.
 REASON 9,133 bottles of lot 8425 and 9,438 bottles of lot 8426 were
 distributed.
 Dissolution failure (6 month stability).
 [] None Present
 [] Action Taken _____

NSN 6505 Nonstandard
 PRODUCT Rhinecort (budesonide) Nasal Inhaler, 7g, 200 metered doses, an
 anti-inflammatory glucocorticosteroid. NDC 0186-1075-09 and
 NDC 0186-1075-PS (Professional Sample). Recall #D-040-9.
 CODE Lot numbers and EXP dates:
 XM127 EXP 12/98, YA128 EXP 1/99, XM 126 EXP 12/98,
 YC 135 EXP 03/99, YC 136 EXP 03/99, YO 137 EXP 04/99,
 YD 139 EXP 04/99, YD 139 EXP 04/99, YE 140 EXP 05/99
 YF 143 EXP 06/99, YG 144 EXP 07/99, YG 147 EXP 07/99
 YG 148 EXP 07/99, YG 151 EXP 07/99, YG 152 EXP 07/99
 YH 155 EXP 08/99, YI 159 EXP 09/99, YI 160 EXP 09/99
 YI 161 EXP 09/99, YI 162 EXP 09/99, YK 163 EXP 10/99
 YL 165 EXP 11/99, YL 166 EXP 11/99, YM 169 EXP 12/99
 ZA 170 EXP 01/00, ZA 171 EXP 01/00, ZB 174 EXP 02/00
 ZB 175 EXP 02/00, ZB 176 EXP 02/00, ZB 178 EXP 02/00
 ZC 180 EXP 03/00, ZC 181 EXP 03/00, ZC 183 EXP 03/00
 ZD 185 EXP 04/00, ZD 186 EXP 04/00, ZD 187 EXP 04/00
 ZF 191 EXP 06/00, ZF 192 EXP 06/00, YB 129 EXP 02/99,
 YB 130 EXP 02/99, YB 131 EXP 02/99, YB 132 EXP 02/99
 YC 133 EXP 03/99, YC 134 EXP 03/99, YE 141 EXP 05/99,
 YE 142 EXP 05/99, YG 145 EXP 07/99, YG 146 EXP 07/99
 YG 149 EXP 07/99, YG 150 EXP 07/99, YH 154 EXP 08/99
 YH 156 EXP 08/99, YH 157 EXP 08/99, YI 158 EXP 09/99
 YK 164 EXP 10/99, YK 167 EXP 11/99, YL 168 EXP 11/99
 ZA 173 EXP 01/00, ZB 177 EXP 02/00, ZC 182 EXP 03/00
 ZD 184 EXP 04/00, ZD 188 EXP 04/00.

MANUFACTURER 3M Healthcare, Loughborough, UK
 RECALLED BY Astra USA, Westborough, Massachusetts, by letters issued the week
 of November 16, 1998, and on December 14, 1998. Firm-initiated
 recall ongoing.
 DISTRIBUTION Nationwide.
 QUANTITY 92,484 units of Lot XM127, 89,748 units of Lot YA128, 50,000 to
 100,000 retail units of all other lots and an undetermined amount
 of physician samples were distributed.
 REASON Product testing for total degradation does not support labeled
 expiration date.
 [] None Present
 [] Action Taken _____

NSN 6505 Nonstandard
 PRODUCT Requip(tm) Tablets (Ropinirole Hydrochloride), 0.25 mg, in patient starter packages (126 tablets), Rx used for treatment of signs and symptoms of idiopathic Parkinson's disease. NDC #489061. Recall #D-041-9.
 CODE Lot numbers: 680970 EXP 2/99 and 680990 EXP 2/99.
 MANUFACTURER Smith Kline Beecham Pharmaceuticals, West Sussex, United Kingdom.
 RECALLED BY Smith Kline Beecham Pharmaceuticals, Philadelphia, Pennsylvania, by letter sent the week of September 28, 1998. Firm-initiated recall ongoing.
 DISTRIBUTION Nationwide.
 QUANTITY 5,730 packages of lot 680970 and 5,695 packages of lot 680990 were distributed. Firm estimates none remain on the market.
 REASON Degradation test data will not support labeled expiration date.

None Present
 Action Taken _____

NSN 6515 Nonstandard
 PRODUCT VENTAK Automatic Implantable Cardioverter Defibrillators,
 a) Model No. 1820, VENTAK AV II DDD AICD(tm) Automatic Implantable Cardioverter Defibrillator;
 b) Model No. 1821, VENTAK AV II DR AICD(tm) Automatic Implantable Cardioverter Defibrillator;
 c) Model No. 1826, VENTAK AV II DR AICD(tm) Automatic Implantable Cardioverter Defibrillator;
 d) Model No. 1831, VENTAK AV III DR AICD(tm) Automatic Implantable Cardioverter Defibrillator;
 e) Model No. 1836, VENTAK AV III DR AICD(tm) Automatic Implantable Cardioverter Defibrillator;
 f) Model No. 1810, VENTAK AV(tm) AICD(tm) Automatic Implantable Cardioverter Defibrillator;
 g) Model No. 1815, VENTAK AV(tm) AICD(tm) Automatic Implantable Cardioverter Defibrillator. Recall #Z-269/275-9. All serial numbers.
 CODE Guidant Corporation, Cardiac Pacemakers, St. Paul, Minnesota.
 MANUFACTURER Manufacturer, by letter sent on December 5, 1998. Firm-initiated
 RECALLED BY action is a field correction which is ongoing. During the field correction, the defibrillators are being reprogrammed. The returned or explant of the defibrillators has not been requested.
 DISTRIBUTION Nationwide and international.
 QUANTITY 13,851 defibrillators.

REASON

A rare interaction of the device's internal timing sequences has the potential to create a situation in which the defibrillators stop delivering pacing therapy for up to 24 hours. When this situation occurs, the device resumes pacing at the next daily battery measurement or whenever cardioversion/defibrillation therapy is delivered, making all therapies available. This anomaly can recur. Cardioversion/defibrillation therapy is always available.

None Present
 Action Taken _____

NSN
PRODUCT

6515 Nonstandard
Heparin Flush Syringe 100 u/ml, 0.9% NS with specific volume fill, syringe size as follows: a) 5 cc in 6cc syringe; b) 10 cc in 12 cc syringe c) 5 cc in 12 cc syringe; d) 3 cc in 12 cc syringe; e) 3 cc in 6 cc syringe Examination #19980349.
Recall #Z-300-9.

CODE

Lot # 04800252, 5 cc in 12 syringe, EXP date 5/26/99; Lot # 04800211, 5cc in 6 cc syringe, EXP date 5/6/99; Lot #04800239, 10 cc in 12 cc, EXP date 5/20/99; Lot #04800240, 5 cc in 12 cc syringe, EXP date 5/21/99; Lot #04800241, 5 cc in 12 cc syringe, EXP date 5/21/99; Lot #04800258, 5 c in 12 cc syringe, EXP date 5/27/99; Lot #04800272, 3 cc in 12 cc syringe, EXP date 6/1/99; Lot #04800278, 3 cc in 6 cc syringe, EXP date 6/3/99; Lot #04800282, 5 cc in 12 cc syringe, EXP date 6/4/99.

MANUFACTURER

Central Admixture Pharmacy Services, Inc., Miami Lakes, Florida.

RECALLED BY

Manufacturer, by telephone on October 21, 1998. Firm-initiated recall ongoing.

DISTRIBUTION

California, New Jersey, Washington state, Texas, New York, Vermont, New Hampshire, Maine.

QUANTITY
REASON

Approximately 4,000 syringes were distributed. Stability Data for the heparin flush 10 u/ml syringes can support only a 60 day expiration date. The nine lots listed above has incorrect expiration dating of either three months or nine months. Stability data shows that at three months, room temperature storage, heparin potency drops from 100% to 0.0%.

None Present
 Action Taken _____

NSN
UPDATE

6515 Nonstandard
Sterile devices and non-sterile device packs/kits, Recall #Z-156-9 (Associated Hospital Services, Inc., New Orleans, Louisiana), which appeared in the December 9, 1998 Enforcement Report is a completed recall.

None Present
 Action Taken _____

NSN 6540 Nonstandard
 PRODUCT Lenses, Soft Contact, Extended Wear. Recall #Z-301-9.
 CODE Lot 50017647, EXP 05/2002.
 MANUFACTURER Wesley Jessen/pbh Ltd., Southampton, Hampshire, UKSO30 3HB.
 RECALLED BY Wesley-Jessen Corporation, Des Plaines, Illinois, by telephone on
 December 9, 1998. Firm-initiated recall ongoing.
 DISTRIBUTION Nationwide.
 QUANTITY 26 3-packs and 78 6-packs were distributed.
 REASON The contact lenses were mislabeled with the wrong power. -2
 diopter lenses were labeled as +2 diopters.

None Present
 Action Taken _____

NSN 6550 Nonstandard
 PRODUCT Abbott TDx/TDxFLx Estriol Reagent Packs; these reagents are used
 with either Total Estriol Calibrators (list 9112-01) or Free
 Estriol Calibrators (list 9118-01) in a Fluorescence Polarization
 Immunoassay (FPIA) in vitro diagnostic for the quantitative
 measurement of either total estriol or free estriol in human
 serum, plasma or urine:
 a) TDx/TDxFLx Flecainide Reagent Pack, List No. 9799-60; b)
 TDx/TDxFLx Flecainide Assay System, List No. 9799-69.
 Recall #Z-251/252-9.
 CODE a) Reagent Lot Nos. 34103M400, 39703M100, 39889M100, 41527M100,
 43789M300, 44746M100; b) Reagent Lot Nos. 34103M400, 39703M100,
 39889M100, 41527M100, 43789M300, and 44746M100.
 MANUFACTURER RECALLED BY Abbott Health Products, Inc., Barceloneta, Puerto Rico.
 Abbott Laboratories, Diagnostics Division, Abbott Park, Illinois,
 by letters on July 2 and 7, 1997. Firm-initiated recall
 ongoing.
 DISTRIBUTION California, Kentucky, Georgia, Illinois, Indiana, Louisiana,
 Maryland, West Virginia, Ohio, Pennsylvania, Texas,
 international.
 QUANTITY 1,226 packs were distributed; firm estimated that 10% remained on
 market at time of recall initiation.
 REASON Use of product may result in assay calibration and/or quality
 control errors such "PO too small", "Range too large", or "Span
 les than Min Span" resulting in invalid calibration curves. In
 addition, once a valid calibration curve is obtained, controls
 may drift out of range.

None Present
 Action Taken _____
