

**FOOD AND DRUG ADMINISTRATION (FDA)
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. (FOM-P, Capt D. Troy Molnar, DSN 343-4083)

CLASS I RECALLS: None.

CLASS II RECALLS:

6515 NS
MDC 12636
PRODUCT Monitor Systems, Physiologic
Universal Clinical Workstation (UCW), Monitor Model 90385, a generic display device with networking and data management capabilities. Recall #Z-834-8.
CODE All units shipped prior to 3/97. Serial numbers used by the firm are not sequential.
MANUFACTURER Spacelabs Medical, Redmond, Washington.
RECALLED BY Manufacturer, by Product Service Notice (PSN) 076-0469-00 dated September 16, 1996 and PSN 076-0541-00 dated February 7, 1997. Firm-initiated field correction ongoing.
DISTRIBUTION Nationwide and international.
QUANTITY 3,328 monitors are affected by this field correction.
REASON Base screws are too short which could allow the monitor to dislodge from wall mounted base.

None Present
 Action Taken _____

6525 NS
MDC 13281
PRODUCT Computers, Radiotherapy Planning System
Leksell GammaPlan (LGP) Version 4.01-4.11, software is designed for use with the Leksell Gamma Knife. The Leksell GammaPlan is intended to be used for planning the dosimetry of treatments in stereotactic radiosurgery and stereotactic radiation therapy. Recall #Z-118-9.
CODE Leksell GammaPlan (LGP) Versions 4.01-4.11.
MANUFACTURER Elekta AB, Stockholm, Sweden.
RECALLED BY Elekta Instruments, Inc., Atlanta, Georgia, by technical alert sent dated June 1997. Firm-initiated field correction ongoing.
DISTRIBUTION Nationwide and international.
QUANTITY 38 units were distributed.
REASON An error in the plug command which caused the dose planning software GammaPlan to give too long treatment times, meaning that the patient receives a higher dose than prescribed.

None Present
 Action Taken _____

6525 NS
MDC 13281
PRODUCT

Computers Radiotherapy Planning System

Leksell GammaPlan (LGP) Versions 3.0 and KULA used in conjunction with Elekta's Gamma Knife. The Leksell GammaPlan is intended to be used for planning the dosimetry of treatments in stereotactic radiosurgery and stereotactic radiation therapy. Recall #Z-120-9.

CODE

Leksell GammaPlan Version 3.0 and KULA. The KULA version is the predecessor of the Leksell GammaPlan.

MANUFACTURER
RECALLED BY

Elekta AB, Stockholm, Sweden.
Elekta Instruments, Inc., Atlanta, Georgia, by product bulletin dated July 1, 1996. Firm-initiated field correction ongoing.

DISTRIBUTION
QUANTITY
REASON

Nationwide and international.
38 units were distributed.

A calculation error in the dose planning system may, under unusual circumstances, result in the miscalculation of the distance from the skull boundary to the intended target, resulting in a dose lower than prescribed.

None Present

Action Taken _____

6525 NS
MDC 13281
PRODUCT

Computers Radiotherapy Planning System

Leksell Gamma Knife, Models U and B. The model U represents the majority of the units in the United States. Model B is the newer version of the Gamma Knife, used for the non-invasive treatment of selected intracranial disorders.

Recall #Z-121-9.

CODE

Models U and B.

MANUFACTURER
RECALLED BY

Elekta AB, Stockholm, Sweden.
Elekta Instruments, Inc., Atlanta, Georgia, by Technical Note #006 dated November 1996. Firm-initiated recall ongoing.

DISTRIBUTION
QUANTITY
REASON

Nationwide and international.
38 units were distributed.

Complaints involving lacerations of fingers and entrapment of an elbow during use of the device.

None Present

Action Taken _____

CLASS III RECALLS:

6525 NS
MDC 13281
PRODUCT

Computers Radiotherapy Planning System

Leksell GammaPlan (LGP) Versions 3.01, software designed for use with the Leksell Gamma Knife, intended to be used for planning the dosimetry of treatments in stereotactic radiosurgery and stereotactic radiation therapy.

Recall #Z-119-9.

CODE

Software version 3.01.

MANUFACTURER
RECALLED BY

Elekta AB, Stockholm, Sweden.
Elekta Instruments, Inc., Atlanta, Georgia, by releasing a new version of software in July 1998. Firm-initiated field correction ongoing.

DISTRIBUTION

Nationwide and international.

QUANTITY
REASON

38 units were distributed.

Instead of using the 50% line, the default dose setting was used resulting in the administration of 10Gy rather than 22Gy resulting in underdose.

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 **08 January 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	Propranolol HCl Extended Release (ER) Capsules, distributed in 60 mg, 80 mg, 120 mg and 160 mg strengths, in 100 count bottles, Rx product indicated in the management of hypertension, under the following labels: Inwood, Qualitest, URL, Zenith, Teva, Geneva, and Brightstone Pharma. NDC numbers:
	Inwood: 60 mg: NDC # 0258-3609-01
	80 mg: NDC # 0258-3610-01
	120 mg: NDC # 0258-3611-01.
	160 mg: NDC # 0258-3612-01
	Qualitest: 80 mg: NDC 0603-5498-21,
	120 mg: NDC 0603-5499-21,
	160 mg: NDC 0603-5500-21
	United Research Laboratories (URL)
	80 mg: NDC 0677-1364-01;
	120 mg: NDC 0677-1365-01;
	160 mg: NDC 0677-1366-01. 160 mg
	Zenith Goldline Laboratories:
	60 mg: NDC 0182-1926-01.
	80 mg: NDC 0182-1927-01.
	120 mg: NDC 0182-1928-01.
	160 mg: NDC 0182-1929-01.
	Teva (Lemmon) Pharmaceuticals USA
	60 mg: NDC 0093-0691-01.
	80 mg: NDC 0093-0692-01.
	120 mg: NDC 0093-0693-01.
	160 mg: NDC 0093-0694-01.
	Geneva Pharmaceuticals, Inc.

60 mg: NDC 0781-2061-01.
80 mg: NDC 0781-2062-01.
160 mg: NDC 0781-2064-01.

Brightstone Pharma Inc.

60 mg: NDC 62939-7112-1.
80 mg: NDC 62939-7122-1.
120 mg: NDC 62939-7132-1.
160 mg: NDC 62939-7142-1

Recall #D-006/009-9.

CODE

Lot numbers (Expiration dates):

60 mg (10 lots): 7J031 (3/99), 7J033 (3/99), 8A042 (3/99),
7K014 (5/99), 7K015 (5/99), 7K016 (5/99),
7K018 (1/99), 8A035 (1/99), 8A038 (1/99),
8A040 (2/99).

80 mg (4 lots): 7F052 (9/99), 8A047 (1/99), 8A048 (2/99),
8A052 (11/99).

120 mg (4 lots): 7K027 (9/99), 8A053 (1/99), 8A054 (1/99),
8A055 (1/99).

160 mg (4 lots): 7J045 (9/99), 8A060 (1/99), 8A061 (1/99),
8A062 (2/99).

MANUFACTURER

Inwood Laboratories, In., a subsidiary of Forest Laboratories, Inc., Inwood, New York.

RECALLED BY
DISTRIBUTION
QUANTITY

Manufacturer, by letter on October 6, 1998. Firm-initiated recall ongoing.
Nationwide and Puerto Rico.

The following number of bottles were distributed:

60 mg : 33, 812

80 mg : 74, 247

120 mg: 35, 004

160 mg: 16, 752.

REASON

Dissolution failure.

None Present

Action Taken _____

NSN
PRODUCT

6505 Nonstandard
Nitrostat Sublingual Tablets, (Nitroglycerin) USP, 0.4 mg (1/150 gr), Rx, in
bottles of 25. NDC #0071-0570-13. Recall #D-010-9.

CODE
MANUFACTURER
RECALLED BY

Lot #01317F EXP 1/99.

Warner Lambert Company, Fajardo, Puerto Rico.

Parke Davis, Division of Warner Lambert Company, Morris Plain, New Jersey, by
letter on October 13, 1998. Firm-initiated recall ongoing.

DISTRIBUTION
QUANTITY
REASON

Nationwide.

24,616 units were distributed.

Subpotent (18 month stability test station).

None Present

Action Taken _____

NSN 6505 Nonstandard
 PRODUCT Platelets, Pheresis. Recall #B-096-9.
 CODE Unit numbers: 10585-2689-01, 10585-2731-01, 10585-2731-02, 10585-2740-01,
 10585-2740-02, 10585-2744-01, 10585-2744-02, 10586-4612-01, 10586-4612-02,
 10585-2761, 10585-2752, 10585-2760.
 MANUFACTURER Blood Systems, Inc., Glendale, Arizona.
 RECALLED BY Blood Systems, Inc., Scottsdale, Arizona, by letter dated June 23, 1998.
 DISTRIBUTION Firm-initiated recall ongoing.
 QUANTITY Arizona.
 REASON 12 units were distributed.
 Platelets, Pheresis were prepared using an instrument which had not been
 validated for sterility.

None Present
 Action Taken _____

NSN 6505 Nonstandard
 PRODUCT Premarin Tablets (Conjugated Estrogens Tablets, USP), 1.25 mg, in bottles of
 CODE 100. Recall #D-012-9.
 MANUFACTURER Lot number 8G01759.
 RECALLED BY Ayerst-Wyeth Pharmaceuticals, Inc., Guayama, RQ.
 Leiner Health Products, Madison, Wisconsin, by letter on September 15, 1998.
 DISTRIBUTION Firm-initiated recall ongoing.
 QUANTITY Nationwide.
 REASON 16,004 bottles were distributed.
 Mislabeling - One bottle labeled by Leiner Health Products as Premarin 1.25 mg
 tablets actually contained Buspar 10 mg tablets (Busparone HCL USP).

None Present
 Action Taken _____

NSN 6515 Nonstandard
 PRODUCT Manan Super-Core Biopsy Needle 18 ga X 15 cm, 20 ga X 15 cm, 18 ga X 9 cm,
 CODE 16 ga X 20 cm, 16 ga X 15 cm, 14 ga X 9 cm, 20 ga X 20 cm and 18 ga X 20 cm.,
 MANUFACTURER used to obtain soft tissue biopsies, such as from the liver, kidney, prostate, breast,
 RECALLED BY thyroid, pancreas, spleen and lungs. Recall #Z-063-9.
 All catalog numbers "VLT 14/9X" through "VLT 20/20X" and Lot Numbers
 81391208 through 82182261 are involved in this field correction.
 DISTRIBUTION Medical Device Technologies, Inc., Gainesville, Florida.
 QUANTITY Manufacturer, by letter on September 11, 1998, and October 14, 1998.
 REASON Firm-initiated recall ongoing.
 Tennessee, Texas, Florida, Indiana, Pennsylvania, New Jersey, Michigan,
 Massachusetts, New York, Illinois, Wisconsin, Washington state, Oregon,
 California, Arizona, Missouri, Kansas, Minnesota, Nevada, international.
 798 devices were distributed.
 The clear plastic film of some of the device's pouch packaging may exhibit cuts
 thereby compromising the sterile barrier.

None Present
 Action Taken _____

NSN 6515 Nonstandard
 PRODUCT Activa Tremor Control System implantable device is meant to suppress tremors in the upper extremity in patients with essential tremor or Parkinsonian tremor. Recall #Z-090/092-9.

CODE All codes.
 MANUFACTURER Medtronic, Inc-Neurological Division, Minneapolis, Minnesota.
 RECALLED BY Manufacturer, verbally in July 1998, and by letter on October 1, 1998.
 DISTRIBUTION Firm-initiated field correction ongoing.
 QUANTITY Nationwide.
 REASON Approximately 725 units were distributed as of 10/1/98.
 Fractures of the lead when the lead/extension connector is placed in the neck rather than the head. These fractures can interfere with stimulation delivery.

None Present
 Action Taken _____

NSN 6515 Nonstandard
 PRODUCT Max-I-Probe Periodontal/Endodontic Irrigating Probes, Cartridge Pak/Plastic Hub, 24G x 1", 0.022" O.D., Part No. MAXP241; 100 probes per box, a sterile, non-pyrogenic single use device used to irrigate gingival sulci, root canal preparations, and endosseous Implant preparations during dental procedures. Recall #Z-095-9.

CODE Part number MAXP241, lot numbers 12902 and 12903, EXP 04/2003.
 MANUFACTURER DENTSPLY MPL Technologies Inc., Franklin Park, Illinois.
 RECALLED BY Manufacturer, by letter dated October 8, 1998. Firm-initiated recall ongoing.
 DISTRIBUTION Michigan, California, Virginia, Arkansas, Louisiana, Texas, Pennsylvania, Washington state, New York, Indiana, Nevada, Minnesota, South Carolina, Georgia, Connecticut, Wisconsin, Missouri, Oregon, New Jersey, Florida, Canada.

QUANTITY 586 boxes were distributed; firm estimated that 50 percent of the product remained on market at time of recall initiation.

REASON The probes were found to contain bacterial endotoxin, although labeled as non-pyrogenic.

None Present
 Action Taken _____

NSN 6515 Nonstandard
 PRODUCT a) I-125 Seeds, (Iodine-125) Therapeutic for Interstitial Brachytherapy, Model 6711, a welded titanium capsule containing radioactive Iodine-125 absorbed onto silver rod, used as radioactive implants for the treatment of prostate cancer;
 b) I-125 RAPID Strand, Rigid Absorbable Permanent Implant Device, I-125 Seeds for Brachytherapy, Model 7000, indicated for permanent interstitial implantation of selected localized tumors which are of low to moderate radiosensitivity. They may be used either as primary treatment, such as prostate cancer or unresectable tumors, or for treatment of residual disease after excision of the primary tumor. Recall #Z-112/113-9.

CODE Model 6711 - lot W82167, Model 7000 - lot P8108B.
 MANUFACTURER Medi-Physics, Inc., Arlington Heights, Illinois.
 RECALLED BY Nycomed Amersham Imaging, Princeton, New Jersey, by telephone on September 30, 1998. Firm-initiated recall ongoing.

g) Model No. 15-0140-80;
h) Model No. 15-0140-82;
I) Model No. 15-0140-85;
j) Model No. 15-0140-87;
k) Model No. 15-0140-90;
l) Model No. 15-0140-92;
m) Model No. 15-0140-95. Recall #Z-158/170-9.
All blades distributed between 9/93 and 9/98.
Pharmacia & Upjohn Groningen BV, Groningen, Netherlands.
Pharmacia & Upjohn Company, Kalamazoo, Michigan, by telephone between
October 2 and 30, 1998. Firm-initiated recall ongoing.
Nationwide.
13,050 blades were distributed between 9/93 and 9/98.
The blades may become dulled prior to use, due to failure of proper fit in their
protective packaging.

None Present
 Action Taken _____

NSN 6530 Nonstandard
PRODUCT Sunmark brand Heat Therapy Heating Pads:
a) Sunmark brand Dry Heat Therapy Heating Pad, Model No. 2000;
b) Sunmark Brand Dry/Moist Heat Therapy Heating Pad,
Model No. 2025;
c) Sunmark Brand Dry/Moist Heat Therapy Heating Pad,
Model No. 2050. Recall #Z-124/126-9.
All units.
Square Fund Industrial Limited, Shenzhen, China.
Homedics, Inc., Keego Harbor, Michigan, by letter dated March 13, 1998.
Firm-initiated recall ongoing.
Nationwide.
Approximately 14,674 pads were distributed.
Scorching of the heating pads and overlying materials may occur when the product
is in use.

None Present
 Action Taken _____

NSN 6550 Nonstandard
PRODUCT Biotrack Protime Reagent Cartridges CoaguChek Plus Prothrombin Time (PT) Test
Cartridges: a) Biotrack Protime Reagent Cartridges, Catalog No. 473043; b)
CoaguChek Plus PT Test Cartridges, Catalog No. 473707. Recall #Z-122/123-9.
CODE a) All Lot Numbers which begin with P616 and P702; b) All Lot Numbers which
begin with P616 and P702.
MANUFACTURER Boehringer Mannheim Corporation, Fremont, California.
RECALLED BY Boehringer Mannheim Corporation, Indianapolis, Indiana, by telephone in
November 1997, and by letter dated July 1, 1998. Firm-initiated recall ongoing.
DISTRIBUTION Nationwide, Australia, Canada, Chili, Germany, Japan, Switzerland.
QUANTITY 9,427 boxes of CoaguChek plus and 4479 boxes of Coumatrak Protime were
distributed since November 20, 1996.

REASON

When used with the Protime Controls these cartridges give results which are out of published range.

None Present

Action Taken _____
