

NATIONAL RECALL ALERT CENTER - IMMEDIATE WARNING ALERT NOTIFICATION
THE FOLLOWING HAVE BEEN RECALLED OR ARE SUBJECT TO FIELD CORRECTION
THIS LISTING IS ISSUED BY - NATIONAL RECALL ALERT CENTER, WASHINGTON, D.C.

SUMMARY PAGE

MEDICAL DEVICES

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MANUFACTURER Amvex Corp
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PRODUCT Heater Elements for Resuscitaire Infant Radiant Warmers
MANUFACTURER Draeger Medical Systems, Inc
PAGE 2

PRODUCT Hemochron Jr. ACT-LR Assay (JACT-LR)
MANUFACTURER International Technidyne Corp
PAGE 2

PRODUCT LEGION Pressfit Stem
MANUFACTURER Smith & Nephew, Inc
PAGE 2

PRODUCT **Stabilet Infant Warming System**
MANUFACTURER Hill-Rom, Inc
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PHARMACEUTICALS

PRODUCT BVA-100 Reference Standard
MANUFACTURER Daxor Corp
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Route to _____ Status _____

THE FOLLOWING IS A CLASS I RECALL. THERE IS A REASONABLE PROBABILITY THAT THE USE OF THE AFFECTED PRODUCT MAY CAUSE SERIOUS INJURY OR DEATH IF THE PROBLEM IS NOT CORRECTED.

The following is an update to NRAC Issue #1746 dated 8/28/09

PRODUCT **Stabilet Infant Warming System, model numbers 200, 300, 1250, 1500, 200/3000, 2000, 2200/3200, 3000, and 3200**
RECALL NUMBER **# Z-1955-2009**
CODE **All units**
MANUFACTURER **Hill-Rom, Inc, Batesville, IN**
RECALLED BY **Draeger Medical Systems, Inc, Telford, PA**
QUANTITY **6489 units**
DISTRIBUTION **Nationwide and Internationally**
REASON **Hot particles fell into the infant bassinet beneath a Radiant Infant Warmer. The resulting fire**

injured an infant. These devices are obsolete.

Route to _____ Status _____

PRODUCT Hemochron Jr. ACT- LR Assay (JACT- LR); ITC Catalogue/Code Number: JACTLR 45 Cuvettes; For Performance on the HEMOCHROM Whole Blood Microagulation Systems; The HEMOCHRON Jr. ACT-LR is a quantitative assay for monitoring heparin anticoagulation during various medical procedures. The ACT-LR demonstrated linear correlation to the anticoagulation effects of heparin up to 2.5 unit/ml of blood. It is intended for use in monitoring low to moderate heparin doses frequently associated with procedures such as cardiac catheterization, Extracorporeal Membrane Oxygenation (ECMO) Hemodialysis, and Percutaneous Transluminal Coronary Angioplasty.

RECALL NUMBER # Z-1732-2009
CODE Lot number K8JLR118
MANUFACTURED & RECALLED BY International Technidyne Corp., Edison, NJ
QUANTITY 173 boxes of 45 cuvettes
DISTRIBUTION Nationwide
REASON One lot of ACT-LR was released when one finished good testing criteria acceptance limit did not meet acceptance criteria.

Route to _____ Status _____

PRODUCT Heater Elements for Resuscitaire Infant Radiant Warmers model numbers RW82, RW82 VHA, WBR82, and WMRW82, 120 volt configuration only

RECALL NUMBER # Z-1693-2009
CODE Date codes ending in 07
MANUFACTURED & RECALLED BY Draeger Medical Systems, Inc., Telford, PA
QUANTITY 2915 elements
DISTRIBUTION Nationwide and Internationally
REASON Spark, flame and smoke: A mispositioned crimp on heater element lead wire resulted in flame and smoke aerating from the top of the warmer assembly.

Route to _____ Status _____

PRODUCT 1) LEGION Pressfit Stem, Straight, 10 MM X 160 MM, REF 71424043, Sterile. The device is used for Orthopedic Knee Implants

RECALL NUMBER # Z-1819-2009
PRODUCT 2) LEGION Pressfit Stem, Straight, 20 MM X 160 MM, REF 71424053, Sterile
RECALL NUMBER # Z-1820-2009
CODE 1) Lot Number: 06DAB0023
2) Lot Number: 06DM08612
MANUFACTURED & RECALLED BY Smith & Nephew Inc., Memphis, TN
QUANTITY 35 units
DISTRIBUTION Nationwide and Internationally
REASON Products were mispackaged.

Route to _____ Status _____

PRODUCT

Amvex Integrated Flowmeter; a nonback-pressure compensated Bourdon gauge Flowmeter; Model No. FI. The Integrated Flowmeter has two parts, the Outlet port and the Flowmeter port. The outlet port is intended to be used as a standard wall Outlet, delivering a high flow of gas to secondary equipment. The Flowmeter port is intended to deliver a fixed flow of gas to patient or equipment.

RECALL NUMBER

Z-1724-2009

CODE

All serial numbers shipped between 4/12/07 and 8/31/07. Serial numbers: FIA05076LF, FIA05078LF, FIA05086LF, FIA05089LF, FIA05090LF, FIA05091LF, FIA05173LF, FIA05174LF, FIA05175LF, FIA05176LF, FIA05177LF, FIA05178LF, FIA05179LF, FIA05180LF, FIA05181LF, FIA05182LF, FIA05183LF, FIA05184LF, FIA05186LF, FIA05187LF, FIA05188LF, FIA05189LF, FIA05190LF, FIA05191LF, FIA05192LF, FIA05193LF, FIA05194LF, FIA05195LF, FIA05196LF, FIA05197LF, FIA05198LF, FIA05200LF, FIA05201LF, FIA05202LF, FIA05203LF, FIA05204LF, FIA05205LF, FIA05206LF, FIA05207LF, FIA05208CF, FIA05208LF, IA05209LF, FIA05210LF, FIA05211LF, FIA05212LF, FIA05213LF, FIA05214LF, FIA05215LF, FIA05216LF, FIA05217LF, FIA05218LF, FIA05219LF, FIA05220LF, FIA05221LF, FIA05222LF, FIA05223LF, FIA05224LF, FIA05226LF, FIA05229LF, FIA05230LF, FIA05231LF, FIA05233LF, FIA05234LF, FIA05236LF, FIA05237LF, FIA05238LF, FIA05239LF, FIA05240LF, FIA05241LF, FIA05242LF, FIA05243LF, FIA05244LF, FIA05245LF, FIA05246LF, FIA05247LF, FIA05248LF, FIA05249LF, FIA05250LF, FIA05251LF, FIA05252LF, FIA05253LF, FIA05254LF, FIA05255LF, FIA05256LF, FIA05257LF, FIA05258LF, FIA05259LF, FIA05261LF, FIA05262LF, FIA05263LF, FIA05265LF, FIA05266LF, FIA05267LF, FIA05268LF, FIA05269LF, FIA05270LF, FIA05271LF, FIA05272LF, FIA05273LF, FIA05274LF, FIA05276LF, FIA05277LF, FIA05278LF, FIA05280LF, FIA05281LF, FIA05283LF, FIA05284LF, FIA05286LF, FIA05287LF, FIA05288LF, FIA05289LF, FIA05290LF, FIA05291LF, FIA05293LF, FIA05294LF, FIA05295LF, FIA05296LF, FIA05297LF, FIA05298LF, FIA05299LF, FIA05300LF, FIA05301LF, FIA05302LF, FIA05304LF, FIA05305LF, FIA05306LF, FIA05307LF, FIA05308LF, FIA05309LF, FIA05310LF, FIA05313LF, FIA05314LF, FIA05315LF, FIA05316LF, FIA05317LF, FIA05318LF, FIA05319LF, FIA05320LF, FIA05321LF, FIA05322LF, FIA05323LF, FIA05324LF, FIA05325LF, FIA05326LF, FIA05327LF, FIA05328LF, FIA05331LF, FIA05332LF, FIA05334LF, FIA05335LF, FIA05336LF, FIA05337LF, FIA05338LF, FIA05339LF, FIA05340LF, FIA05341LF, FIA05342LF, FIA05343LF, FIA05344LF, FIA05345LF, FIA05346LF, FIA05347LF, FIA05348LF, FIA05349LF, FIA05352LF, FIA05353LF, FIA05354LF, FIA05354LF, FIA05355LF, FIA05356LF, FIA05358LF, FIA05361LF, FIA05362LF, FIA05363LF, FIA05364LF, FIA05365LF, FIA05366LF, FIA05367LF, FIA05368LF, FIA05370LF, FIA05371LF, FIA05372LF, FIA05373LF, FIA05374LF, FIA05375LF, FIA05376LF, FIA05378LF, FIA05380LF, FIA05381LF, FIA05382LF, FIA05383LF, FIA05384LF, FIA05386LF, FIA05387LF, FIA05388LF, FIA05389LF, FIA05390LF, FIA05392LF, FIA05392LF, FIA05396LF, FIA05397LF, FIA05398LF, FIA05399LF, FIA05400LF, FIA05401LF, FIA05403LF, FIA05404LF, FIA05405LF, FIA05406LF, FIA05407LF, FIA05408LF, FIA05409LF, FIA05411LF, FIA05412LF, FIA05413LF, FIA05414LF, FIA05415LF, FIA05416LF, FIA05417LF, FIA05418LF, FIA05419LF, FIA05420LF, FIA05421LF, FIA05422LF, FIA05423LF, FIA05424LF, FIA05425LF, FIA05427LF, FIA05428LF, FIA05429LF, FIA05431LF, FIA05432LF, FIA05433LF, FIA05434LF, FIA05435LF, FIA05439LF, FIA05440LF, FIA05443LF, FIA05444LF, FIA05445LF, FIA05446LF, FIA05447LF, FIA05448LF, FIA05449LF, FIA05450LF, FIA05451LF, FIA05452LF, FIA05453LF, FIA05454LF, FIA05455LF, FIA05457LF, FIA05458LF, FIA05460LF, FIA05462LF, FIA05463LF, FIA05464LF, FIA05465LF, FIA05466LF, FIA05467LF, FIA05468LF, FIA05469LF, FIA05470LF, FIA05471LF, FIA05472LF, FIA05473LF, FIA05473LF, FIA05475LF, FIA05476LF, FIA05477LF, FIA05478LF, FIA05479LF, FIA05480LF, FIA05481LF, FIA05482LF, FIA05486LF, FIA05487LF, FIA05488LF, FIA05489LF, FIA05490LF, FIA05491LF, FIA05493LF, FIA05494LF, FIA05495LF, FIA05496LF, FIA05497LF, FIA05498LF, FIA05499LF, FIA05500LF, FIA05501LF, FIA05502LF, FIA05503LF, FIA05504LF, FIA05505LF, FIA05507LF, FIA05508LF, FIA05509LF, FIA05510LF, FIA05511LF, FIA05512LF, FIA05513LF, FIA05514LF, FIA05515LF, FIA05516LF, FIA05517LF, FIA05518LF, FIA05519LF, FIA05520LF, FIA05521LF, FIA05522LF, FIA05523LF, FIA05524LF, FIA05525LF, FIA05526LF, FIA05527LF, FIA05528LF, FIA05529LF, FIA05530LF, FIA05532LF, FIA05533LF, FIA05534LF, FIA05538LF, FIA05539LF, FIA05539LF, FIA05540LF, FIA05541LF, FIA05543LF, FIA05543LF, FIA05544LF, FIA05546LF, FIA05547LF, FIA05548LF, FIA05549LF, FIA05550LF, FIA05551LF, FIA05553LF, FIA05554LF, FIA05555LF, FIA05556LF, FIA05557LF, FIA05558LF, FIA05560LF, FIA05561LF, FIA05562LF, FIA05566LF, FIA05567LF, FIA05568LF, FIA05569LF, FIA05571LF, FIA05572LF, FIA05574LF, FIA05575LF, FIA05577LF, FIA05578LF, FIA05579LF, FIA05580LF, FIA05581LF, FIA05581LF, FIA05582LF, FIA05583LF, FIA05584LF, FIA05585LF, FIA05587LF, FIA05588LF, FIA05590LF, FIA05592LF, FIA05593LF, FIA05594LF, FIA05595LF, FIA05596LF, FIA05597LF, FIA05598LF, FIA05599LF, FIA05600LF, FIA05601LF, FIA05603LF, FIA05605LF, FIA05606LF, FIA05607LF, FIA05608LF,

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MANUFACTURED & RECALLED BY Amevex Corporation, Richmond Hill, Canada

QUANTITY 1,424 units

DISTRIBUTION Nationwide and Internationally

REASON The affected flowmeters may have a damaged o-ring which may cause the flowmeter to deliver higher amounts of gas and or not be able to shut off fully.

Route to _____ Status _____

PRODUCT BVA-100 Reference Standard, 1.0mL, Total Radioactivity at TOC: 0.025 uCi, IODINATED I-131, Dil. Factor: 1:999

RECALL NUMBER # D-1949-2009

CODE Lot numbers ending in: 347, 348, 350, 352, and 353

MANUFACTURED & RECALLED BY Daxor Corporation, Oak Ridge, TN

QUANTITY 20 sets

DISTRIBUTION NY, CA, OK, DE, NJ, VA, OR, SC, PA, and NE

REASON Superpotent reference standard