ESTTA Tracking number: **ESTTA288838**
Filing date: **06/09/2009**

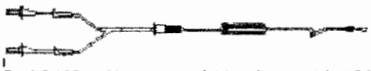
IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE TRADEMARK TRIAL AND APPEAL BOARD

Proceeding	91177234
Party	Plaintiff Cardinal Health 303, Inc.
Correspondence Address	Joseph R. Dreitler Bricker & Eckler LLP 100 S. Third Street Columbus, OH 43215-4291 UNITED STATES mtrue@bricker.com
Submission	Plaintiff's Notice of Reliance
Filer's Name	Mary R. True
Filer's e-mail	trademarks@bricker.com
Signature	/Mary R. True/
Date	06/09/2009
Attachments	Giometti Notice_pdf (6).pdf (25 pages)(2184654 bytes)

- Drops: 60

72323M Infusion set with check valve, 0.2 micron (low protein binding) filter and 2 split septum injection ports, 9" and 73" from male luer lock. Latex Free. Alaris® SE Pump administration set.
- Case Quantity: 50
- Approximate set length: 100 in / 250 cm. approx
- Approximate priming volume: 20 mL
- Drops: 20

72900M Half set with 1 split septum injection port, 9" from male luer lock. Latex Free. Alaris® SE Pump administration set.
- Case Quantity: 50
- Approximate set length: 86 in / 215 cm.approx.
- Approximate priming volume: 12 mL



72980M Non-vented blood set with 180 micron filter and 1 split septum injection port, 9" from male luer lock. Latex Free. Alaris® SE Pump administration set.
- Case Quantity: 20
- Approximate set length: 104 in / 264 cm. approx
- Approximate priming volume: 32 mL.
- Drops: 15

C72105M Infusion set with 2 split septum injection ports, 6" and 97" from male luer lock, microbore tubing. Latex Free. Alaris® SE Pump administration set.
- Case Quantity: 20
- Approximate set length: 147 in / 373 cm.approx.
- Approximate priming volume: 13 mL
- Drops: 20

C72106M Infusion set with check valve, 2 split septum injection ports, 9" and 65" from male luer lock. Latex Free. Alaris® SE Pump administration set.
- Case Quantity: 50
- Approximate set length: 103 in / 261 cm. approx.
- Approximate priming volume: 19 mL
- Drops: 20

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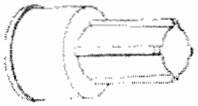
Texium Safety Disposables
Texium Safety Disposables

10012238 Texium™ priming cap with hydrophobic filter. Latex-Free. DEHP-Free. ABS Plastic-Free.
- Case Quantity: 50
- Case Quantity: 100
- Aproximate priming volume: 0.05 mL

10012240 Texium™ female cap.
- Case Quantity: 50
- Case Quantity: 100



10012241 Texium™ closed male luer with female

cap. Latex-Free. DEHP-Free. ABS
Plastic-Free.
- Case Quantity: 50
- Case Quantity: 100
- Approximate priming volume: 0.12 mL

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*The Alaris® System is formerly known as Medley® System

Please note: These products are available in the USA and Canada.

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Software Guardrails® Suite

Guardrails® Suite

8950 The Flash Tool allows for communication between a computer and the Alaris® System via a serial cable. The Flash Tool can reside on a PC or Laptop and is used for updating the Guardrails® Point-of-Care Software to support new Guardrails® Suite functionality or new Alaris® System modules.

8960 The Guardrails® Editor Software is a PC based authoring tool that allows the hospital to manage how IV medications can be programmed on the infusion system by setting limits on the rates, doses, and concentrations that are appropriate for a given patient care area. The Editor allows the hospital to develop a best-practice data set of IV medication dosing guidelines for up to 10 patient specific care areas, refered to as profiles. The hospital's customized data set is developed to help protect patients from infusion programming errors by allowing hospitals to configure each profile with pre-defined drug dose limits and other parameters to meet the particular needs of multiple patient care areas within the hospital. Clinical advisory message can be created for a designated drug to remind the clinician of specific standard of practice when programming this IV medication. Also, profile-specific Alaris® System operating parameters can be customized for each module using the Editor. Once completed and released, a hospital's customized data set can be transferred to the Alaris® System.

8970 The Maintenance Software supports biomedical engineers in maintaining and repairing the Alaris® System. This application can be installed on a PC or laptop. The software allows the biomed to check-in equipment perform preventable maintenance, troubleshoot the system, and download logs. This information is stored in a database for easy access and asset management.

9980 The Guardrails® CQI Reporter provides analysis capabilities to help the hospital measure the effectiveness of their safety practices. It incorporates the CQI Database, which allows a hospital to access and download the archived Guardrails® Alerts from the Alaris® System. The resultant data files are stored within the CQI database. The Guardrails® CQI Reporter provides query and reporting capabilities for the Guardrails® Suite. The PC based application provides the hospital with a basic standard reporting package that can then be utilized in the medication administration and quality improvement process to monitor events outside best practice guidelines.

Guardrails® Safety Software

7950 The Guardrails Editor® Software is the authoring tool that allows the hospital to manage how medications can be programmed on

the infusion system by setting limits on the rates, volumes, and doses that are appropriate for a given patient care area. At the heart of the Editor Software is the ability to incorporate the hospital's best-practice guidelines for IV drug administration. The hospital's customized data set is developed to help protect patients from infusion programming errors by allowing hospitals to configure care-area specific profiles with predefined drug dose limits and other parameters to meet the particular needs of multiple patient care areas within the hospital. Also, profile-specific Alaris® SE Channel Pump parameters can be customized using the Editor. Once completed and released, a hospital's customized data set can be electronically transferred to the Alaris® SE Channel Pump.

7955 The Guardrails® Point-of-Care Safety Software resides in the Alaris® SE Single and Dual Channel Pump. When enabled, the software supports the Guardrails® Drug Library. This library consists of hospital defined clinical best practices for drug delivery. Infusion programmed outside these clinical best practices and captured as Guardrails® Alerts. All Guardrails® Alerts are stored and available with the Alaris® SE Single and Dual Channel Pump, to be accessed by the Guardrails® CQI Reporter for analysis.

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Guardrails® CQI Software

7980 The Guardrails® CQI Reporter provides capabilities to measure effectiveness of hospitals' safety practices. It incorporates the CQI Database, which allows a hospital to access and download the archived Guardrails® Alerts form the Alaris® System. The resultant data files are stored within the CQI database.

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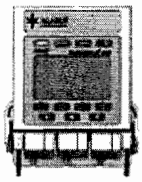
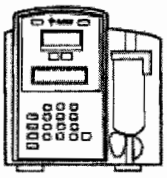
Drug Infusion Instruments

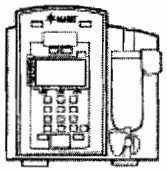
2865B MedSystem III® Infusion Pump.



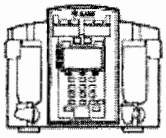
7000C Signature Edition® GP Single Channel Pump. Designed for general purpose infusions.



7130E Alaris® SE Single Channel Pump is an advanced infusion system. Based on human factors design principles, and the input of customers, the highly advanced Alaris® SE Single Pump is versatile, yet easy to operate. Compatible with the Guardrails® Suite of safety software for enhanced protection from medication administration errors.



7230E Alaris® SE Dual Channel Pump is an advanced infusion system. Based on human factors design principles; two independent channels offer twice the flexibility of a Alaris® SE Single Channel Pump. Compatible with the Guardrails® Suite safety software for enhanced protection from medication administration errors.



8000 The Alaris® PC Point-of-Care Unit is the core of the Alaris® System, which provides a common user interface for programming the infusion and monitoring modules, helping to reduce complexity at the point of care. Alaris® Sytem formerly know as the Medley® System.

8100 The Alaris® Pump Module provides a light-weight, large volume pumping module that is easily attached to the Alaris® PC Point-of-Care Unit to perform dose rate calculation and many other advanced features. Alaris® System formerly known as the Medley® System.

8110 The Alaris® Syringe Module provides a lightweight syringe module that is easily attached to the Alaris®

PC Point-of-Care Unit accessing the "Bedside Computer" to offer uncompromising safety and accuracy in an easy to use interface with advanced pressure monitoring capabilities for shorter times to alarm. Alaris® System formerly known as the Medley® System.

8120	The Alaris® PCA Module is used for delivery of pain management medications via patient-controlled dosing. Syringe-based technology with secure drug access attaches easily to the Alaris® PC Point-of-Care Unit to perform programming functions, history review and other advanced features. Non-dedicated administrations sets with integral anti-siphon valve available for use with Alaris® PCA Module. Alaris® System formerly known as the Medley® System.
8210	The Alaris® SpO2 Module with Nellcor® OxiMax™ technology for continuous monitoring of noninvasive oxygen saturation and pulse rate measured by an SpO2 sensor. For use with Nellcor® OxiMax™ sensors. Alaris® System formerly known as the Medley® System.
8220	The Alaris® SpO2 Module with Masimo SET® technology for continuous monitoring of noninvasive oxygen saturation and pulse rate measured by an SpO2 sensor. For use with Masimo® sensors. Alaris® System formerly known as the Medley® System.
8300	The Alaris® EtCO2 Module with Oridion Microstream® technology for continuous monitoring of EtCO2, respiratory rate and FICO2. For use with Oridion Microstream® disposables. Alaris® System formerly known as the Medley® System.

*The Alaris® System is formerly known as Medley® System

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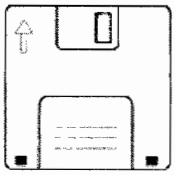
Drug Infusion Accessories

133450 Learn Teach cable to transfer configuration settings from pump to pump. Alaris® SE Pump Accessory.

143572 The MedSystem III® Drug List Editor (DLE) is a Windows-based software package allowing Drug List Files to be created and modified on a personal computer for subsequent use with the Dose Rate Calculator in the MedSystem III® Infusion Pump, software version 4.0 and higher. The Drug List files created undel DLE are transferred to the MedSystem® Infusion Pump using the Field Maintenance Software (FMS), version 2.2 or higher. Shipped as part of 2865B instrument orders (includes DLE and FMS 2.24).



144108 Spring Tool Kit to check mechanism springs. Alaris® SE Pumpn Accessory.

145096 Flow sensor kit for use with the Alaris® SE Pump model 7100, 7130. (Includes empty container dectector (ECD) board and flow sensor)

145097 Flow sensor kit for use with Alaris® SE Pump Model 7200, 7230. (Includes ECD board and flow sensor)

145183 Silver conversion upgrade kits for dual Alaris® SE Pump(Model 7200) to 2.78 version.

145184 Silver conversion upgrade kits for single channel Alaris® SE Pump (Model 7100) to 2.78 version.

145370 Upgrade kit for 5.0 software (2863). MedSystemIII® Infusion Pump accessory.

146594-100 Pressure Calibration Set

147339-100 Event log download software kit for all Alaris® SE Pump devices.

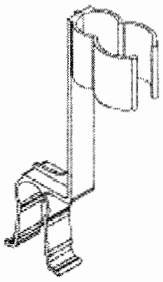
147718- Software upgrade kit for 4.06 version for the single and dual

101 channel Signature Edition® GOLD Infusion System (Models 7130 and 7230 only). Required software version or the Guardrails® Safety Software.

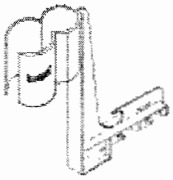
180 Flow Sensor for use with all Alaris® SE Pump models with ECD.

180A01 180 Flow sensor pack, 5 each. Alaris® SE Pump Accessory.

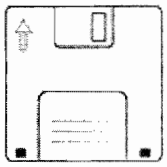
20-2370-7 Syringe Collar (Holder) for the Gemini PC-1® and Gemini PC-2TX® Infustion Pumps, reusable, accomodates any brand syringe sizes 10cc-60cc. For use with administration set model 2280.



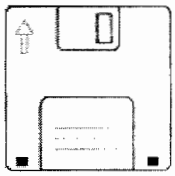
2286-0000 Syringe Clip (Holder) for the Gemini PC-4® Infusion Pump, reusable, accomodates any brand syringe sizes 10cc-60cc. For use with administration set model 2280.



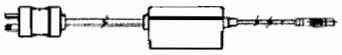
2860525 Field Maintenance Software, version 2.2, with cables. The Field Maintenance Software is designed to assist in customizing the MedSystem III® Infusion System, software version 4.0 or higher, to meet the special clinical needs of the institution. The PC-based application allows customization of: configuration commands; instrument programming; calibration functions; event, alarm, and status log functions. MedSystem III® Infusion Pump accessory.



2860526 Field Maintenance Software, version 2.2, without cables. The Field Maintenance Software is designed to assist in customizing the MedSystem III® Infusion Pump, software version 4.0 and higher, to meet the special clinical needs of the institution. The PC-based applciation allows customization of: configuration commands; instrument programming; calibration functions; event, alarm, and status log functions.



2861089 AC adapter (locking). MedSystem III® Infusion Pump accessory.



2861156 Tool Kit for repair. MedSystem III® Infusion Pump accessory.

2861461 Calibration assembly for fluid side calibration. MedSystem III®

Infusion Pump accessory.

2863087 Communication cable kit to use with FMS software. MedSystem III® Infusion Pump accessory.

3011 Syringe holder for the Alaris® SE Pump.

70ISS Pressure calibration set (all models). Alaris® SE Pump Accessory.

8011A Syringe clip holder for use with set model 72983. (20 per pack) Alaris® SE Pump accessory.

80VCS Rate verification and calibration set (all devices). Alaris® SE Accessory.

8631A Syringe holder, reusable, accomodates any brand syringe sizes 20cc-60cc. MedSystem III® Infusion Pump accessory.

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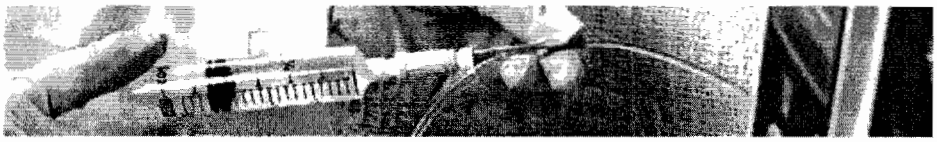
Please note: These products are available in the USA and Canada.



Patient Monitoring Instrument

Thermometers

Electronic Thermometers

10011741 The Alaris® Tri-Site Thermometer model 10011741 is a portable dual probe instrument equipped with a pulse timer. It offers both predicive and continuous oral, rectal and axillary measurements. All Alaris® Tri-Site Thermometers feature a three-button front panel for easy access to functions. Comes with three AA batteries an anti-theft security base, carrying strap, backlight, probe cover dispenser, and a three-year limited warranty.

10011742 The Alaris® Tri-Site Thermometer model 10011742 is a portable single probe instrument equipped with a pulse timer. It offers both predicive and continuous oral and axillary measurements. All Alaris® Tri-Site Thermometers feature a three-button front panel for easy access to functions. Comes with three AA batteries an anti-theft security base, carrying strap, backlight, probe cover dispenser, and a three-year limited warranty.

10011743 The Alaris® Tri-Site Thermometer model 10011743 is a portable single probe intrument equipped with a pulse timer. It offers both predictive and continuous recal measurements. All Alaris® Tri-Site Thermometers feature a three-button front panel for easy access to functions. Comes with three AA batteries, anti-theft security base, carrying strap, backlight, probe cover dispenser, and a three-year limited warranty.

10011905 The Alaris® Tri-Site Thermometer model 10011905 is a wall mount dual probe instrument equipped with a pulse timer. It offers both predicive and continuous oral, rectal and axillary measurements. All Alaris® Tri-Site Thermometers feature a three-button front panel for easy access to functions. Comes with a security base designed for attachment to a wall or other secure location. The 1011905 comes with three AA batteries, an anti-theft security base, backlight, probe cover dispenser, and a three-year limited warranty.

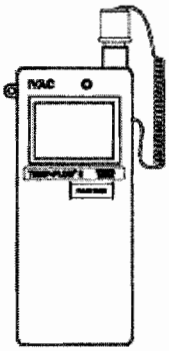
10011906 The Alaris® Tri-Site Thermometer model 10011906 is a portable single probe instrument equipped with a pulse timer. It offers both predicive and continuous oral and axillary measurements. All Alaris® Tri-Site Thermometers feature a three-button front panel for easy access to functions. Model 1001906 comes with security base designed for attachment to a wall or other secure location. Comes with three AA batteries, an anti-theft security base, backlight, probe cover dispenser, and three-year limited warranty.

10011907 The Alaris® Tri-Site Thermometer model 10011907 is a

portable single probe instrument equipped with a pulse timer. It offers both predicive and continuous rectal measurements. All Alaris® Tri-Site Thermometers feature a three-button front panel for easy access to functions. Model 10011907 comes with a security base designed for attachment to a wall or other secure location. The 10011907 come with three AA batteries, an anti-theft security base, backlight, probe cover dispenser, and a three-year limited warranty.

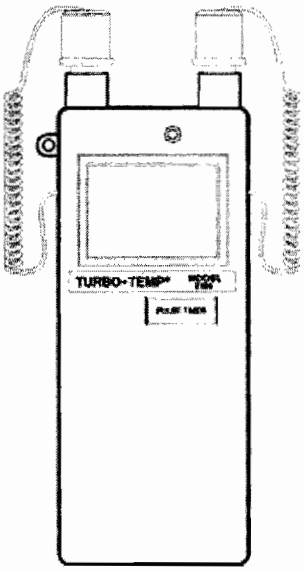
2180C

The Turbo Temp® Thermometer model 2180C is a portable single probe instrument equipped with a pulse timer. It offers predictive oral capability, as well as oral/ axillary site measurements in the monitoring setting. Includes three AA batteries an anti-theft security base, carrying strap, backlight, probe cover dispenser, and a three-year limited warranty.



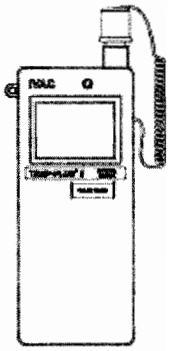
2180CX01EE

The Turbo Temp® Thermometer model 2180CX01EE is a portable dual probe instrument equipped with a pulse timer. It offers predictive oral and rectal capabilities as well as oral, rectal and axillary measurements in the monitoring mode. The 2180C comes with three AA batteries, an anti-theft security base, carrying strap, backlight, probe cover dispenser, and a three-year limited warranty.



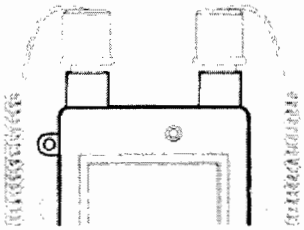
2185B

The Turbo Temp® Thermometer model 2185B is a wall mount, single probe instrument equipped with a pulse timer. It offers predictive oral capability as well as oral and axillary measurements in monitoring mode. Model 2185B comes with a security base designed for attachment to a wall of other secure location. It comes three AA batteries, an anti-theft security base, backlight, probe cover dispenser, and a three-year limited warranty.



2185BX01EE

The Turbo Temp® Thermometer model 2185BX01EE is a wall mount dual probe instrument equipped with a pulse timer. It offers predictive oral and rectal capabilities as well as oral, rectal and axillary measurements in the



monitor mode. Model
2185BX01EE comes with security base design for attachment to a wall or other secure location. The 2185BX01EE comes with three AA batteries, an anti-theft security base, backlight, probe cover dispenser, and a three-year limited warranty.

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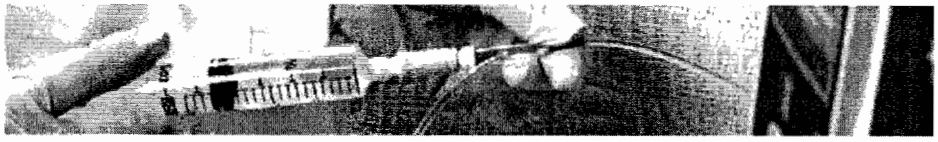
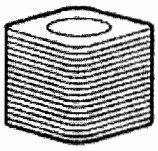


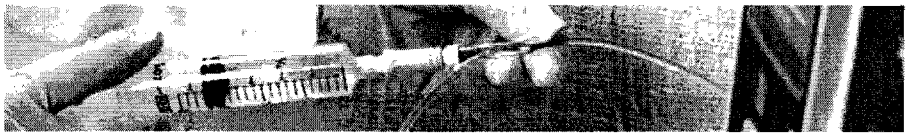
Probe Covers

P-850A For use with Temp Plus® II, Turbo Temp®, Alaris® Tri-Site Thermometer and vital Check® vital signs monitor series 4400/4500. GE Dinamap monitors with Temp Plus® II of Turbo Temp® Thermometers also use these probe covers. Count: 20/box, 10 boxes/dispensers, 25 dispensers/case.

P-90 Disposable probe covers for use with the Core•Check® Thermometer Model 2090 Series (100 probe covers per stack; 5 stacks per box, 10 boxes per case for a total of 5,000 probe covers per case).



Please note: These products are available in the USA and Canada.



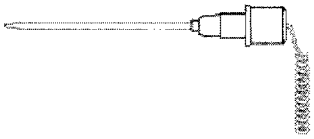
Patient Monitoring Accessories

- Thermometer Accessories
- Other

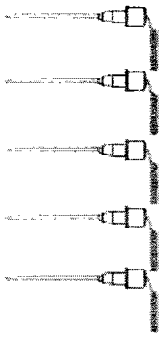
Thermometer Accessories

Probes

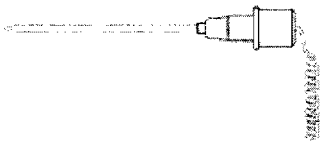
2880A Blue oral probe with short cord for Temp Plus® II Thermometer Model 2080 (uses P-850A probe covers).



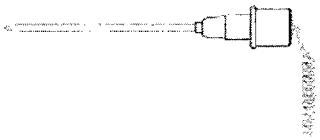
2880A1 Oral probe pack, includes five model 2880A probes for Temp Plus® II Thermometer Models 2080. (individually packaged; uses P-850A probe covers).



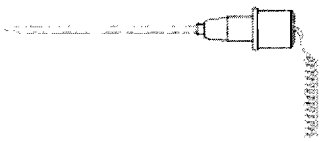
2881A Oral probe with long cord for use with Temp Plus® II Thermometer Model 2085 (uses P-850A probe covers).



2882A Red Rectal probe with short cord for Temp Plus® II Thermometer Model 2080 (uses P-850A probe covers).

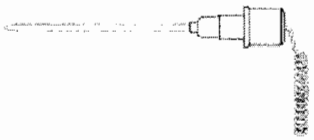


2882A1 Rectal probe pack, includes five model 2882A probes for Temp Plus® II Thermometer Models 2080. (Individually packaged; uses P-850A probe covers).

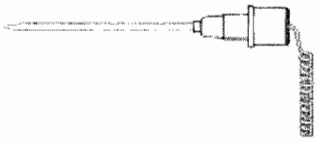


2883A Rectal probe with long cord for use with Temp Plus® II Thermometer Model 2085 (uses P-850A probe covers).

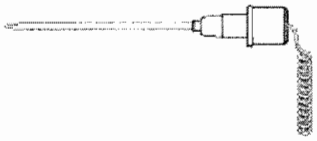
2885C Blue oral probe with short gray cord (40") for Turbo Temp® Thermometer Model 2180C (uses P850A probe covers).



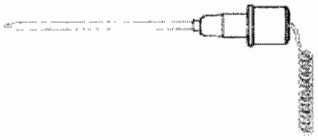
2886C Red rectal probe with short grat cord (40") for Turbo Temp® Thermometer Model 2180. (Uses P-850A Probe Covers).



2887B Blue oral probe with long gray cord (80") for use with Turbo Temp® Thermometer Model 2185 (uses P-850A probe covers).



2888B Red rectal probe with long gray cord (80") for use with Turbo Temp® Thermometer Model 2185 (uses P-850A probe covers.)



3887 Blue oral and probe with long white cord (80") for use with Alaris® Tri-Site Thermometer models 1001741, 1001742, 1001905, and1001906. (Uses P-850A probe covers.)

4888 Red rectal probe with long white cord (80") for use with Alaris® Tri-Site Thermometer models 1001741, 1001743, 1001905, and 1001907. (Uses P-850A probe covers.)

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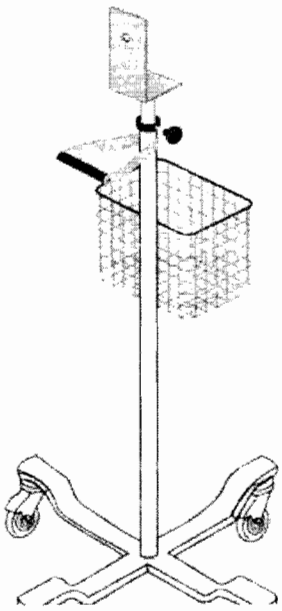
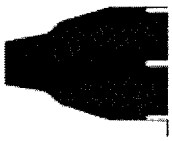
1094C Roll Stand for use with VITAL•CHECK® Measurement System Models 4410C, 4415C, 4510A and 4515A. Adjustable height and accessory basket.

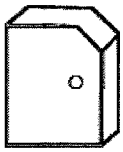


133408 Probe tip for the Core•Check® Thermometer .



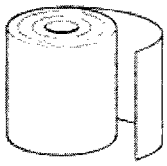
134275 Probe lens assembly for the Core•Check® Thermometer.

134994 Probe Cover Holder Kit (P-850A) for Turbo Temp® Electronic Thermometer Model 2185B and TEMP•PLUS® II Electronic Thermometer Model 2085D.



140275 Battery door for the Core•Check® Thermometer.

141937 Printer Paper (5 rolls per box) Use with Monitor Model 4415C and 4515A.

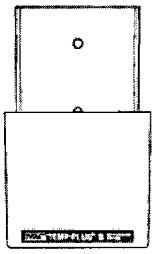


143536 AC Adapter

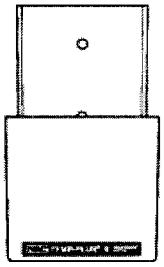
143537 Power Cord

190676 Probe simulator, Temp Plus® II Thermometer.

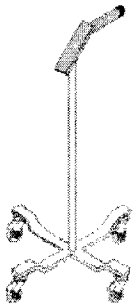
2017 Home base unit for use with Temp plus® II Thermometer Model 2080.



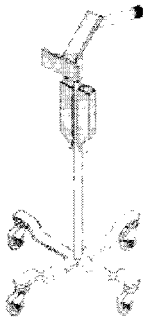
2018 Home base unit for use with Temp Plus® II Thermometer Model 2085.



2031A Thermometer stand for Turbo Temp® Thermometers and Alaris® Tri-Site Thermometers.

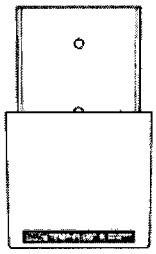


2041A Stand for the Core•Check® Thermometer.

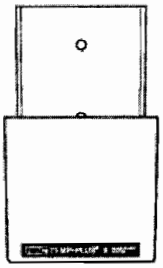


2042A Security Cable for the Core•Check® Thermometer, 180" to attach the Core•Check® Thermometer Model 2090E to its home base. Includes two (2) adhesive pads and two (2) alcohol wipes.

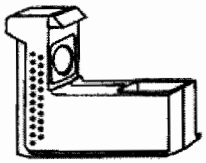
2117A Home base unit for use with portable Alaris® Tri-Site and Turbo Temp® Thermemeters.



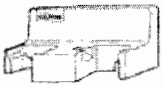
2118A Home base unit for use with wall mount Alaris® Tri-Site and Turbo Temp® Thermometers.



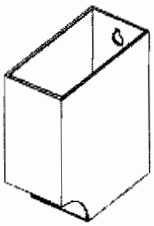
2992A Probe cover dispenser for the Core•Check® Thermometer.



2993A Probe home base for the Core•Check® Thermometer.



896 Wall bracket for dispensing P-850A probe covers. Holds one dispenser of 10 boxes (20 covers/box). Thermometry Accessory.



9000A Calibration for the Core•Check® Thermometer designed to check accuracy and calibrate the Core•Check® Thermometer Model 2090 Series; consists of two independent heat sources. Micro-processor controlled to maintain exact referenced temperatures.

TE1811 Probe simulator for Turbo Temp® and Alaris® Tri-Site Thermometers.

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Featured in This Issue . . .

Infusion Pumps

Often, the factors that distinguish one infusion pump from another are not performance issues, but rather patient safety considerations. For example, most of the currently available general-purpose infusion pumps perform accurately and reliably when used properly. However, not all models offer the same level of protection against pump programming errors, IV free-flow, and other events that can lead to IV medication errors. In this issue of *Health Devices*, we present a variety of articles to help hospitals purchase, manage, and use infusion pumps more effectively.

EVALUATING GENERAL-PURPOSE PUMPS

Of the nearly two dozen general-purpose pumps we've evaluated, we now recommend only eight pumps for new purchases. These pumps all incorporate a safety feature that warns users when a programmed dose falls outside predefined "safe" limits. We refer to this feature as a dose error reduction system. Although many other models generally perform well, we believe the safety advantages offered by dose error reduction systems represent a significant advancement in infusion pump technology. In addition, the recommended models all offer adequate free-flow protection.

In this issue, we describe our findings for the MedNet dose error reduction system that Hospira (formerly Abbott) has recently added to its Plum A+ general-purpose pump. This unit, which we rate Acceptable, has significant advantages over most of the other pumps that we've evaluated. However, it lacks a couple of capabilities that we require for a Preferred rating. For the specifics, including information about the previously evaluated models that also offer a dose error reduction system, turn to the Evaluation that starts on the next page.

OTHER TOPICS

Trends in pump purchasing and use. In the article that starts on page 427, we describe ways that hospitals can use dose error reduction system data to improve patient care and staff efficiency. In addition, we detail the fees that accompany this new software and discuss the potential for increasing patient safety using wireless capabilities.

JCAHO's National Patient Safety Goal. The article starting on page 430 provides ECRI's updated guidance for interpreting and complying with the Joint Commission's infusion pump safety National Patient Safety Goal, which focuses on protecting against free-flow. Our guidance reflects JCAHO's current position on the use of pressure-activated valves, also known as antisiphon valves, to achieve free-flow protection on PCA and ambulatory pumps. In short, valves that are *integral* to an administration set are acceptable, even if the portion of the set that includes the valve can be temporarily removed (since both sections of the set are necessary for normal use). However, the use of an "add on" valve — a discrete component that must be attached to the infusion set by a user — is not acceptable. The article also includes ECRI's revised categorizations of pump models according to the level of free-flow protection offered.

Pump inspection intervals. ECRI believes that many hospitals are inspecting infusion pumps more often than is necessary. For details, turn to the discussion of our July 2004 Web survey on page 429.

Gravity flow hazard. On page 443, we discuss how the Alaris Medley MSS infusion pump LVP module may permit gravity flow if administration sets are misloaded.

Also in This Issue

The electronic medical record. Many observers in the healthcare information technology community believe — or perhaps hope — that the recent push by the U.S. Department of Health and Human Services to implement electronic medical records (EMRs) across the U.S. healthcare system will provide the stimulus long needed to advance this issue. But significant challenges remain. To introduce *Health Devices* readers to the topic, we reprint two articles that previously appeared in ECRI's *Health Technology Trends*. The first outlines some of the remaining obstacles to the widespread adoption of EMRs at U.S. healthcare facilities. The second presents some of the accumulated experience from hospitals that have been developing their own EMR networks. Turn to page 436 for details.

Problem reports. In addition to the gravity flow hazard described above, this month's problem reporting section (page 443) discusses why the Medtronic Lifepak 12 defibrillator may not function when switching from AC to battery power. ◆

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General-Purpose Infusion Pumps

Evaluating the Hospira Plum A+ with MedNet

UMDNS term. Infusion Pumps, General-Purpose [13-215]

Summary. This study updates ECRI's previous Evaluations of general-purpose infusion pumps, most notably those published in the October 2002 and October 2003 *Health Devices*. It features the results of our findings for the new dose error reduction system now included with the Hospira (formerly Abbott) Plum A+ with MedNet, and it includes updated information for the previously evaluated models that also include this safety feature.

General-purpose infusion pumps allow the controlled delivery of liquid medications and other solutions to patients through intravenous (IV) or epidural routes. Dose error reduction systems, which are now available on several pump models, represent a significant advancement in infusion pump technology. ECRI believes that such systems can help hospitals reduce potentially fatal pump programming errors, and we recommend that hospitals purchasing new general-purpose infusion pumps consider only those models that offer a dose error reduction system.

Introduction

General-purpose infusion pumps deliver liquid medications and other solutions to patients through intravenous (IV) or epidural routes at specified flows. They are most often used when greater accuracy and higher levels of safety are needed than can be provided by a manually adjusted gravity administration set.

In recent years, an increasing awareness of adverse events related to medication administration errors has prompted infusion pump suppliers to develop software and hardware systems to build safety into the medication administration process. Several suppliers have introduced dose error reduction systems — software that checks programmed doses against preset limits specific to a drug and clinical location profile. These systems alert clinicians to programmed doses that exceed these preset limits and can either require confirmation before beginning delivery (referred to as a "soft limit") or not allow delivery at all (referred to as a "hard limit").

This Evaluation details our findings for one general-purpose infusion pump — the Hospira Plum A+ — that can now be purchased with a dose error reduction system (MedNet). This pump is functionally similar to the Abbott (now Hospira) Plum A+ model that we evaluated in October 2002 and rated Not Recommended because it lacked dose error reduction software. The only difference between the two pumps is the recently implemented MedNet software. (Pumps that had been marketed under the Abbott trade name are now supplied by Hospira, the former Hospital Products division of Abbott Laboratories that began functioning as an independent company in April 2004.)

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ECRI believes that an effective dose error reduction system is a powerful tool for reducing infusion errors caused by misprogramming or incomplete orders. For this reason, we rate all general-purpose infusion pumps without dose error reduction technology Not Recommended for new purchases (see the descriptions of our ratings categories on page 426). This position is consistent with the Joint Commission on Accreditation of Healthcare Organizations' (JCAHO) increased emphasis on proactively minimizing risks throughout the healthcare facility.

For more information about dose error reduction technology, refer to the October 2002 and October 2003 *Health Devices*. Comprehensive discussions of other infusion pump technology considerations, including descriptions of pump capabilities and relevant selection factors, can be found in our February 1997 and April-May 1998 pump Evaluations.

Evaluation Protocol

Tests Performed

The evaluated model was subjected to the same tests as the other evaluated pumps. For brevity, we have not provided our full criteria and test methods here. This information can be accessed through our Web site, www.ecri.org. Log on to your membership page, click on the *Health Devices* Journal option, and scroll to the listing for the December 2004 issue, where you can view this Web-exclusive feature.

We've made only a few changes to our protocol since our last infusion pump Evaluation (October 2003). Specifically, we have modified some of our dose error reduction system criteria. We checked the previously evaluated pumps against the revised requirements; however, these changes did not affect the pumps' ratings. We detail the changes to our criteria below.

Revised Dose Error Reduction System Criteria

The following criteria replace the first and sixth criteria listed in the October 2003 Evaluation:

- **Revised criteria.** A facility's IV and epidural drugs with their concentrations, dosing units, and dose limits (i.e., drug entities) should be associated with at least eight clinical locations (e.g., specific critical care units, labor and delivery) and/or specific applications (e.g., epidural, oncology). In addition to the maximum and minimum dose for each drug, the system should allow facilities to set soft limits for maximum/minimum patient weight, maximum volume to be infused (VTBI), and maximum infusion rates for each location/application. Ideally, it should be possible to set limits on manually entered drug concentrations (i.e., those for which the drug name is specified but the concentration is a "wild card" or a "fill in the blank"). Also, a pump should ideally allow for bolus dosing within dosing limits.

  Rationale. The major changes to the above criteria were the addition of the last two sentences. We have seen a clinical need for manually entered concentrations in some situations (e.g., fluid-restricted patients), as well as a need for bolus dosing. Without the ability to program boluses within the dose error reduction system, a clinician may have to override the system, set the dose very high initially (to deliver the bolus), and remember to return after a few minutes to set a lower continual rate. We believe this situation would invite accidental over-infusion, as the clinician may forget to return or may be distracted by other tasks.

- **Revised criteria.** It should be possible to set some limits that can be overridden and some that cannot (i.e., soft and hard limits, respectively). For some drugs, it may be desirable to have nested sets of limits (i.e., a narrower set of soft limits within a broader set of hard limits). A clear indication should be displayed any time the dose error reduction system is not in use or when soft limits have been overridden. Indication of an overridden limit should be observable at least every few seconds (e.g., if part of a scrolling display) so that this status will be quickly recognized by users.

  Rationale. We added the second sentence because nested sets of limits may be helpful as a guide for clinicians.

The following criteria have been added to those listed in the October 2003 Evaluation:

- **Added criteria.** When the pump is turned on, it should prompt the user to choose whether to use the dose error reduction system or a generic programming mode. In addition, the unit should require the user to confirm whether the pump is being used on a new patient and to select the current clinical location/application.

  Rationale. We believe that offering users the choice to enter the dose error reduction system at start-up will make the dose error reduction software easier for clinicians to locate and will encourage its use.

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Product Profile

Hospira Plum A+ with MedNet

The bottom line. We rate the Hospira Plum A+ with MedNet **ACCEPTABLE.** The unit performs satisfactorily, has a comprehensive and configurable dose error reduction system, and can be used only with administration sets that have set-based free-flow protection, as we require. In addition, it has significant advantages over most of the other pumps that we have evaluated. However, it lacks some of the capabilities (a large memory and bolus limit capability) that we require for a Preferred rating. Hospira states that a future software upgrade should address the memory limitations.

Supplier. Hospira Inc. [440680], Lake Forest, Illinois (USA); +1 (877) 946-7747, +1 (847) 937-6100; www.hospira.com

Product availability. This model, which is marketed in the United States, was introduced in 2002 as the Abbott Plum A+.

Product Description

The Hospira Plum A+ with MedNet is mechanically similar to the Abbott Plum A+ that we evaluated in October 2002 (see pages 365 to 366 of that issue). The Plum A+ with MedNet is a single-channel general-purpose infusion pump. However, in its Concurrent Flow mode, the pump can deliver fluids from two containers. There is only one line to the patient, so drugs or electrolytes being delivered at the same time must be compatible. For settings <5 mL/hr in this mode, Hospira provides flow guidelines that must be followed to ensure flow accuracy.

A dose error reduction system, Hospira MedNet software, comes standard on this pump.

CHARACTERISTICS

Software version tested. MedNet version 1.02

Pump capabilities

- Number of channels: 1 (2 in Concurrent Flow mode)*
- Flow range: 0.1 to 999 mL/hr, both primary and secondary
- VTBI: 0.1 to 9,999 mL, both primary and secondary

Pump features

- Data log: Yes
- Front-panel lockout: Yes**
- Dose error reduction system: Yes
- Bar-code capabilities: No (in development)
- Built-in bag hanger: Optional
- Rotating pole clamp: No
- Special features: Automated secondary infusion, piggyback/concurrent drug delivery, multistep delivery, delayed start, dose calculation, drug library, loading dose, standby, automated rate changes, volume over time

Set features

- Allows syringe delivery: Yes***
- Needleless IV connector: LifeShield and Clave
- Set-based free-flow protection: Yes

Alarms and indicators

- Downstream occlusion pressure: Configurable (from 1 to 15 psi)

* The Plum A+ with MedNet is used with a cassette that has two channels: One is connected to the upstream tubing of the set; the other is capped by a needleless port. A syringe or extension set connected to a fluid container can be connected to the port. The pump can then be programmed to infuse from the second channel as a piggyback (i.e., the pump will deliver fluid through channel 2 only, then switch back to channel 1) or in Concurrent Flow mode (i.e., the pump will deliver fluid from both channels at the same time).

** However, even with its front-panel lockout engaged, the pump can be easily stopped, though not turned off, during infusion. If this situation occurs, the pump will alarm immediately. We consider this a minor disadvantage.

*** A syringe may be connected directly to the needleless port of channel 2. No adapters, vented sets, or special syringe holders are needed; however, Hospira recommends using a syringe adapter with syringes smaller than 10 cc.

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