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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/
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Evaluation

- Door open: Yes
- Depleted battery: Yes
- Battery level: Yes
- Volume control: Yes
- Momentary alarm silence: Yes

Battery life

- Duration at specified flow: 6 hr at 125 mL/hr
- Recharge time: 6 hr

Dimensions and weight

- Size (H × W × D): 8.0 × 8.0 × 6.0 in (20.3 × 20.3 × 15.2 cm)
- Weight: 9.5 lb (4.3 kg)

COST ISSUES

List prices

- Plum A+ with MedNet: \$6,095 (plus annual software maintenance fee and consulting fee)
- Upgrade standard Plum A+ to include MedNet dose error reduction software: \$1,000 (plus annual software maintenance fee and consulting fee)
- Software maintenance fee: Averages about 20% of MedNet software price
- Consulting fee: Varies with length of consulting agreement

Warranty. 1 year

Significant Test Results

Our original testing of the Plum A+ showed its general performance to be adequate, and our retesting of all general performance criteria for this pump verified these findings. Thus, the results that we present here focus on the unit's dose error reduction software. We do, however, first review the significant test results from our 2002 Evaluation.

PREVIOUS FINDINGS

In the 2002 Evaluation, the Plum A+ received Good to Excellent ratings in all test categories, except for the following: an undesirable period of no-flow at flows of 0.1 mL/hr (a setting rarely used with general-purpose pumps), the ability to interrupt delivery despite a front-panel lockout, and the lack of a dose error reduction system. Additional disadvantages of the pump included the length of a power-up self-test (i.e., longer than 30 seconds) and the lack of a discrete alarm for programming that is changed but not confirmed. Advantages of this pump included the ability to detect a clamped secondary line and

Recommendation for Owners of Older Models of the Plum A+

As our testing for this Evaluation shows, Hospira's MedNet software provides the Plum A+ with a comprehensive and configurable dose error reduction system. Hospira offers the MedNet software as an upgrade to existing Plum A+ pumps for \$1,000 per pump, plus consulting and software maintenance fees that vary by hospital. ECRI recommends that hospitals update existing Plum A+ pumps by purchasing and installing MedNet software. ♦

to isolate trapped air in the pump cassette and purge it without removing the cassette from the pump or disconnecting the IV line.

All advantages and disadvantages (except the lack of a dose error reduction system) apply to the current model.

CURRENT FINDINGS

Infusion pump capabilities and features. Good — The unit performed well in this category. We noted several significant findings regarding the data logs, as detailed below:

- An advantage is that the unit is provided with supplemental MedNet software to download the event log to a PC database to develop reports and export the data to other spreadsheet software. The download process is simple and can be performed by nontechnical staff (e.g., Hospira suggests that logs can be downloaded in the nursing unit or by central supply staff when the pumps are cleaned). Note that the Plum A+ with MedNet lacks a dedicated log for tracking dosing changes and limit overrides; this information is pulled from the main event log by the PC-based MedNet software.
- We noted two disadvantages:
 - The main event log holds only 355 lines of data (Hospira estimates that the log would hold less than two weeks of events in intensive care unit [ICU] use). This requires hospitals to locate and download event logs regularly to take advantage of dose error reduction system data for quality improvement. Hospira states that a future upgrade for MedNet, MedNet Version 2, will have dedicated logs for alarms, events and overrides, and drug library downloads. This upgrade will include expanded memory

size capable of holding two to four months of programming event data and up to a year of alerts and override data.

— The main event log cannot be viewed from the pump's screen and must be downloaded to a PC for viewing. However, logged dose error reduction system alerts can be viewed on the pump through the Biomed mode.

Performance. Good — No significant findings to report.

Safety features. Excellent — The pump performed very well in this category. In particular, the unit has many programming function advantages, as described below:

- For dose calculation: Dosing parameters are well prompted and easy to program.
- For the dose error reduction system (Hospira MedNet software):
 - Pump configuration and drug dosing parameters are easy to enter and review in a PC-based spreadsheet program; the password-protected PC software allows hospitals to set privileges (e.g., read, download, upload, edit, print) for authorized personnel. Facilities can customize up to 1,188 drug entities (drug name, concentration, dosing units, and dose limits) for up to 12 clinical care areas; each care area can be configured for up to 99 sets of dose limit data. These clinical care areas enable a facility to customize performance capabilities (maximum infusion rate, minimum and maximum patient weights, and default occlusion pressure limits), drugs, and dosing limits based on where the pump will be used (e.g., pediatrics, med/surg). Entire drug libraries can be saved, allowing authorized users to view older or not-yet-approved drug libraries. However, only one drug library is active (i.e., can be downloaded to pumps) at a time. We note that MedNet meets our preferred criterion for setting nested dose limits (hard limits and soft limits for the same drug entity).

— Facilities are able to configure the Hospira default drug library to meet their clinical needs. This starting drug library includes commonly used drug names with specific TALLman lettering, units of measure, and units of concentration. Drug entities and sets of drug entities can be copied and pasted from one clinical care area to another, and facilities can specify the location of each drug entity in the programming screens available to the user (e.g., high-use drugs may be placed on the first drug library screen to allow quicker access). Hospira offers

Test Results	
Hospira Plum A+ with MedNet	
INFUSION PUMP CAPABILITY AND FEATURES	GOOD
Setting ranges	Good
Flow rates	Good
Volume to be infused (VTBI)	Good
Memory functions	Good
Data logs	Fair
PERFORMANCE	GOOD
Low-flow continuity	Fair
Flow accuracy	Good
During normal operation	Good
During extended operation	Good
With fluid container positioned below the pump	Good
SAFETY FEATURES	EXCELLENT
Alarm characteristics	Good
Occlusion detection and relief	Excellent
Occlusion detection	Excellent
Occlusion relief	Good
Resistance to tampering and accidents	Fair
Programming functions	Excellent
Dose calculation	Excellent
Dose error reduction system	Excellent
Automated infusion pump programming system	NA
HUMAN FACTORS DESIGN	GOOD
Ease of using the device	Good
Ease of using the administration set	Good
Ease of transporting the pump	Good
RELIABILITY, SERVICE, AND SUPPORT	GOOD
Reliability	Good
Service	Good
User support	Good

pharmacy consulting services to assist hospitals in developing and managing a drug library. Configuration of the MedNet software on a pump is accomplished by connecting a computer (e.g., a laptop) with the configuration software to up to 15 pumps at a time.

— The display allows for at least 17 alphanumeric characters (including spaces) to identify drug names

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Update Information

Other Pumps with Dose Error Reduction Systems

Because of the safety advantages offered by dose error reduction systems, ECRI recommends that hospitals purchasing new general-purpose infusion pumps consider only those models that include this feature. ECRI first evaluated pumps with dose error reduction systems in the October 2002 *Health Devices*. We evaluated five such models in that study. We subsequently evaluated two additional models in October 2003 and the one Hospira model in the current issue. Below, we present updated information for these seven previously evaluated models.

***When purchasing new
general-purpose infusion pumps,
only consider
those that have a dose error
reduction system.***

Although many other pump models (i.e., those without a dose error reduction system) generally perform well, they would be rated no higher than Not Recommended for new purchases and thus have been excluded from this discussion. Refer to page 393 of the October 2003 *Health Devices* for ratings information for the nearly two dozen additional general-purpose infusion pumps that ECRI has evaluated.

As part of our evaluation update process, we investigate changes to previously evaluated products and review previous evaluation findings — and modify them when necessary — to ensure that the information provided in the update accurately reflects the current state of the technology. In some cases, this review will lead us to change a unit's rating based on product modifications, revisions made to our evaluation protocol, or the availability of additional models since the unit was evaluated. Except where noted, we have not verified the effectiveness of the product changes described.

Units are listed in alphabetical order. For supplier contact information, refer to the inset on page 424.

Alaris Medley Medication Safety System (MSS) with Guardrails

Evaluation date.

October 2002

Number of channels.

This pump can be equipped with up to four modules, including general-purpose, syringe, and patient-controlled analgesic (PCA) delivery; end-tidal carbon dioxide (ETCO₂); and pulse oximetry (SpO₂).

Update information. The Medley MSS now operates on software version 7.0 and supports PCA, ETCO₂, and SpO₂ monitoring modules. Alaris states that this new software adds the millimole dosing unit and allows facilities to set limits on manually entered drug concentrations, duration of bolus deliveries, and basal, bolus, and time-based drug limits for PCA delivery. The supplier also states that this software allows for wireless transfer of drug libraries and event and alarm logs between the pumps and a centralized server. Alaris adds that the Medley is in limited trials of its bar-code-enabled point-of-care (BPOC) system, which is being jointly developed with McKesson, for drug recognition, wireless transfer of infusion settings, dose error reduction system drug libraries and events/alarms, and documentation of intravenous (IV) infusions.

Findings. The Alaris Medley MSS is rated Preferred. ECRI has not evaluated the new software for this model.



Alaris Signature Edition Gold 7130 and 7230 with Guardrails

Evaluation date.

February 1997

Number of channels.

1 (7130) or 2 (7230)

Update information.

The Signature Edition Gold 7130 and 7230 (shown in the photo) with Guardrails now operate on software version 4.5



and accommodate the French-Canadian and Spanish language markets.

Findings. The Alaris Signature Edition Gold 7130 and 7230 with Guardrails are rated Preferred. ECRI has not evaluated the new software for these models.

B. Braun Outlook Safety Infusion System

Evaluation date.
October 2003

Number of channels. 1

Update information.

The Outlook 100 and 200 now operate on software version 151423. B. Braun states that this software offers a continuous, clear indication of all out-of-limits doses during infusion and a dedicated log for dose error reduction system limit overrides of 256 entries. The supplier also states that a more flexible drug library that allows facilities to customize the drug name and concentrations of drug entities will be available in early 2005.

Findings. The B. Braun Outlook 100 and 200 are rated Acceptable. ECRI has not evaluated the new software for these models.



Baxter Colleague CX

Evaluation date. October 2002

Number of channels. 1

Update information. Baxter

states that it will release software version 6 for the Colleague CX pumps in late 2004. According to the supplier, this software version will (1) enable the use of TALLman lettering for drug names; (2) add the dosing units mL/hr, mEq/hr, and mEq/kg/hr; and (3) offer an expanded drug library of 500 drug entities. The expanded drug library will allow facilities to select whether a drug entity's concentration can be changed and to set hard limits for these manually entered concentrations. This version will also require a double confirmation by the user to turn off the device and three steps to override a soft dose limit. Baxter also states that it will release its Guardian Configuration Tool in late 2004 to allow facilities to create, archive, edit, and



print drug libraries on a PC and transfer the libraries from pumps to a PC and vice versa.

Findings. The Baxter Colleague CX is rated Acceptable. ECRI has not evaluated the pump's new software.

Baxter Colleague 3CX

Evaluation date. October 2002

Number of channels. 3

Update information. The changes described above for the single-channel Colleague CX also apply to this triple-channel model.

Findings. The Baxter Colleague 3CX is rated Acceptable. ECRI has not evaluated the pump's new software.



For references to other product updates, see the inset on page 425. ♦

Coming Soon

Sigma Spectrum

Sigma International is scheduled to release its new Spectrum infusion pump, which will include a dose error reduction system, in December 2004. Sigma states that this small pump is suitable for use as a general-purpose pump and that future versions will include patient-controlled analgesic (PCA), epidural, and syringe delivery, as well as an embedded bar-code reader.

Sigma also states that this pump offers a dose error reduction system that meets most of ECRI's criteria, including a large drug library of up to 1,000 drug entities in up to 32 locations/applications. The dose error reduction system reportedly offers clinical advisories, hard and soft dosing limits, bolus dosing capabilities, starting doses, and PC-based configuration software.

ECRI has not evaluated this model. ♦

(continued from page 421)

and channel labels in TALLman letters (e.g., DoBUTamine, DOPamine). When the TALLman letters used for a particular drug name are changed in one clinical care area, all drug names sharing the same spelling in all clinical care areas are updated in that drug library.

Human factors design. Good — The pump performed well in this category. The ease of using the device was good overall. Significant findings are as follows:

- Advantages are that the dose error reduction system and dose calculation features are easy to use, and a confirmation screen allows users to review all settings before starting an infusion.
- A disadvantage is that first-time users may have difficulty locating the dose error reduction system and dose calculation features. These features are both accessed from the main programming screen through a soft key labeled THERAPY, which may be confusing. Hospira states that the MedNet Version 2 release will change this soft key's label to the more obvious DRUG LIST.

Reliability, service, and support. Good — No significant findings to report.

Supplier Information

General-Purpose Infusion Pumps

Alaris Medical Systems Inc., Subdivision of Cardinal Health Inc. [308442], San Diego, California (USA); +1 (800) 854-7128, +1 (858) 458-7000; www.alarismed.com

B. Braun Medical Inc., A B. Braun Group Co. [171733], Bethlehem, Pennsylvania (USA); +1 (800) 227-2862, +1 (610) 691-5400; www.bbiraunusa.com

Baxter Healthcare Corp., Medication Delivery/Infusion Systems [393248], Round Lake, Illinois (USA); +1 (888) 229-0001, +1 (847) 948-2000; www.baxter.com

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

Sigma International [152355], Medina, New York (USA); +1 (800) 356-3454, +1 (585) 798-3901; www.sigmapumps.com ♦

Conclusions

Ratings and Rankings

To date, ECRI has evaluated eight general-purpose infusion pumps with dose error reduction systems. The Hospira Plum A+ with MedNet is one of the better models that we've seen. We rate it **Acceptable** and recommend it over four other Acceptable pumps with dose error reduction software — the B. Braun Outlook 100 and 200 and the Baxter Colleague CX and 3CX pumps. (Refer to "Update Information" on page 422 for details about previously evaluated models.) However, the Plum A+ lacks the large memory and bolus limit capability of one of the models that we rate Preferred, the Alaris Medley Medication Safety System (MSS) with Guardrails. Hospira states that a future software upgrade should address the memory limitations. (Two other Alaris models that we've evaluated — the Signature Edition Gold 7130 and 7230 with Guardrails — are also rated Preferred. We do not discuss them here because they have the same dose error reduction system as the Alaris Medley and because the system is only available as an optional upgrade on the Signature Edition pumps.)

ECRI has evaluated and rated more than two dozen general-purpose infusion pumps. Refer to page 393 of the October 2003 *Health Devices* for a list of these pumps and their ratings. Detailed findings for specific previously evaluated pumps can be found in the February 1997, April-May 1998, October 2002, and October 2003 issues.

Comparing the Hospira Plum A+ and the Alaris Medley MSS

The Hospira Plum A+ with MedNet shares many of the capabilities and advantages of the Alaris Medley MSS. However, the two pumps differ in the following areas:

- The Plum A+ with MedNet has one channel (two in piggyback or Concurrent Flow mode) that offers large-volume delivery (what we consider general-purpose) and syringe delivery.* Conversely, the Medley MSS is a modular system that allows up to four modules to be attached. A hospital can purchase large-volume, syringe, and patient-controlled analgesic (PCA) pumping modules, as well as end-tidal carbon dioxide (ETCO₂) and pulse oximetry (SpO₂) monitoring

* The Plum A+ with MedNet three-channel pump (six channels in piggyback or Concurrent Flow mode) is scheduled for release in late 2004.

modules. These extra features and flexibility are an advantage for facilities that wish to standardize on one pump for many types of IV therapy and to monitor patients in care areas that lack extensive physiologic monitoring.

- Both pumps have unique dose error reduction system advantages compared to other pumps with dose error reduction systems. The Plum A+ with MedNet offers dose limits on both primary and secondary (piggyback/concurrent) infusions and allows nested hard and soft dose limits for a drug entity. The Medley MSS offers limits for manually entered concentrations and bolus doses.
 - Hospira's MedNet software is similar in most respects to Alaris's Guardrails software, with one major exception: The Plum A+ with MedNet lacks a dedicated log for tracking dosing changes and limit overrides. Additionally, the main event log of the Plum A+ holds only 355 lines of data (Hospira estimates that the log would hold less than two weeks of ICU programming). This requires hospitals to locate and download event logs regularly to take advantage of dose error reduction system data for quality improvement. Hospira states that a future upgrade for MedNet will include an expanded memory size capable of holding drug library downloads, two to four months of programming event data, and dedicated alarms, alerts, and override logs capable of holding up to a year of data.
 - Both pumps offer software — Hospira MedNet and Alaris CQI Tracker — for downloading and compiling pump event log data and dose error reduction system alert log data into reports and for modifying dose error reduction system parameters (e.g., new drugs, changes to limits). However, the Medley's larger and more comprehensive logs better facilitate use of its software. Both pumps' databases can be exported to spreadsheet programs for further analysis, but this requires more effort by the hospital and familiarity with the spreadsheet application.
 - The Alaris Medley now offers wireless communication between pumps and a server for real-time downloading of pumping status, alerts, and alarms, as well as wireless uploading of new dose error reduction software parameters. This function is under development by several suppliers, including Hospira; however, only Alaris has installed and implemented commercial servers and wireless communication with pumps as of November 2004. Alaris, B. Braun, Baxter, and Hospira are all investigating automated programming of their pumps through wireless communication in limited trials.
- The Plum A+ with MedNet has the following minor disadvantages: the ability to stop pumping despite a lock-out (although an alert sounds), the lack of a dedicated alert for programming that is entered but not confirmed, and the location of the dose error reduction system and dose calculation features under the THERAPY soft key. ♦

For More Product Updates

In addition to the product updates that we include in our Evaluations (see, for example, pages 422 and 423), ECRI provides information about product changes on an ongoing basis in *Health Devices Alerts* (available to members through www.ecri.org). Following are some of the more recent general-purpose infusion pump technical bulletins and product notices that have been or will be published in *Health Devices Alerts*:

- Alaris — Medley Medication Safety System Pump Modules: Possibility of Under- and Overinfusions (2003 Sep 19).
- Alaris — Model 8100 Medley Medication Safety System Pump Modules: (1) Spring-Loaded Platen

Reduces Risk of Gravity Flow with Misloaded Set (forthcoming). (2) Tubing Set Fitment May Get Trapped between Pump Module Housing and Door Assembly (forthcoming).*

- Baxter — Colleague Volumetric Infusion Pumps: Keypad Ink May Deteriorate (2004 May 14).
- Baxter — IV and Blood Sets: May Have Undetected Leaks (2003 Aug 15).
- Hospira — Various Plum A+ Intravenous Infusion Pumps: Batteries May Lose Power (2004 Nov 5). ♦

* The problems discussed in these Action Items are also the subject of a Hazard Report included in this issue; see page 443.

Health Devices Ratings System

RATINGS POLICY

Health Devices Evaluations rate products based on their clinical and technical acceptability and desirability. Ratings are based on standard commercial products. Suppliers often modify their products in response to our findings, sometimes before we publish our Evaluations. If the modified product is not available in time for us to verify the significance of the change, we may include a statement of the supplier's intentions. In future issues of *Health Devices*, we may update the information provided for the evaluated products and may revise our ratings.

We recommend that you use our ratings as a guide for selecting the best products for your healthcare facility. Actual purchasing decisions should be based on a thorough understanding of the article, as well as on your specific clinical applications, users' opinions, standardization policies, direct experience with the supplier, and price.

RATINGS CATEGORIES

Preferred. The product meets all major performance and safety criteria. It has no serious shortcomings and offers significant advantages over other alternatives.

Acceptable. The product meets all major performance and safety criteria and has no serious shortcomings.

Not Recommended. The product does what it is intended to do, but not at the desired level of performance, or it has

significant disadvantages compared with other alternatives. For example, it may be more difficult to use or clean, or it may be less suitable for a specific application. A product that we rate Not Recommended is safe to use and does not have to be withdrawn from service. However, we recommend against purchasing the product unless overriding considerations warrant it.

Unacceptable. The product fails to meet significant criteria for performance or poses significant safety risks. A healthcare facility that does not own such a product should not purchase it. If you have a product that we have rated Unacceptable, review the disadvantages of continuing to use it, and plan to replace it. If you decide to purchase or continue to use the product, carefully document the basis for your actions.

CONDITIONAL RATINGS

Occasionally, our rating for a product depends on whether a healthcare facility is willing and able to take corrective measures to overcome a basic performance or safety shortcoming. Corrective measures range from special training (e.g., stressing the importance of certain operating instructions) to ordering an upgrade or modifying a product. If the facility meets the conditions stated, the product is rated in the category specified — that is, Preferred, Acceptable, or Not Recommended. However, if the facility does not or cannot meet the conditions, the product is Unacceptable.

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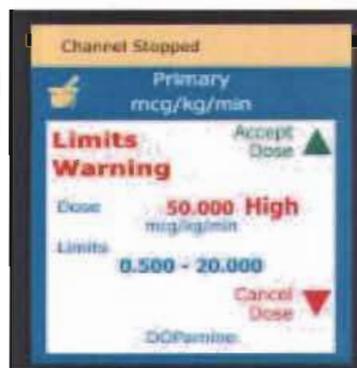
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Infusion Pump Dose Error Reduction Systems

Trends in Purchasing and Use

Summary. Over the last three years, infusion pump suppliers have begun introducing dose error reduction systems. The primary function of these systems is to reduce pump programming errors and associated injuries to patients. However, these systems can offer other benefits as well.

In this article, we describe ways that hospitals can use dose error reduction system data to improve patient care and staff efficiency. We also detail the fees that accompany this new software and discuss the potential for increasing patient safety using wireless capabilities.



Using Dose Error Reduction Data for Quality Improvement

Dose error reduction systems in infusion pumps can do far more than reduce programming errors. Hospitals have started using the data gleaned from these safety systems to analyze and optimize their work practices.

Hospitals that choose to download dose error reduction system alerts on a regular basis can use these alerts to identify when potential programming errors are occurring and then to modify work practices to reduce the potential for these errors. This alert data can be used to make drug library dosing units and dosing limits as practical as possible for clinical use, alert clinicians to potentially harmful dosing practices, and help nursing coordinators plan schedules to allow for more efficient patient care.

Below are some specific examples of how hospitals can improve work practices:

- A hospital experiences many overlimit alerts for a drug in the med/surg care area. An investigation shows that the limit is set for 12 mcg/kg/hr but a standard order set calls for 15 mcg/kg/hr. The hospital changes the upper

soft limit to 15 mcg/kg/hr to reduce the nuisance alarms.

- A hospital has many overlimit alerts for a narcotic in the intensive care unit. Discussions with staff reveal that clinicians are setting the pump to 999 mL/hr temporarily to provide an initial bolus of the drug. The hospital educates clinicians about the potential danger of bolus dosing in this manner (e.g., What if the clinician is distracted and leaves the pump set to 999 mL/hr for too long?). The hospital then sets limits for bolus doses within the dose error reduction system. (This solution won't be possible with all pumps because not all pumps offer bolus dosing.)
- A hospital sees many alerts in the pediatric unit from 6 to 7 p.m. Many patients are admitted around this time, and clinicians are nearing a shift change at 7 p.m.; as a result, clinicians are rushed while programming infusions. The pediatric nursing coordinator rearranges the clinicians' other duties to allow more time for patient care between 6 and 7 p.m.

Dose error reduction system alert data can also be used to spur clinician buy-in and increase compliance. Dose

error reduction systems can only prevent patient harm if clinicians use them; therefore, high compliance is important in reducing infusion error rates. A hospital can encourage clinicians to use dose error reduction systems by surveying alert data for “near misses” that would be likely to cause harm (e.g., an overlimit alert that prevented a 10-fold overdose of narcotic) and presenting evidence of these near misses to clinicians on a regular basis as examples of how using the dose error reduction system helps keep patients safe.

New Pricing Considerations for Infusion Pump Purchases

Before the introduction of dose error reduction systems, a hospital needed to plan for the capital expense of purchasing new infusion pumps every few years but did not have to consider ongoing expenses (other than for disposables) once the pumps were purchased. Now, hospitals interested in purchasing infusion pumps with dose error reduction systems need to be aware of a new trend in purchasing agreements for these pumps: software licensing, software maintenance, and implementation consulting fees.

- **Software licensing fee.** This is a one-time fee paid at the time of purchase that covers the right to use the supplier’s proprietary pump-based dose error reduction software and PC-based software to download and analyze logs. This fee is usually based on the number of pumps purchased (e.g., a percentage of the hardware purchase price, a certain amount per pump) and is analogous to a seat license for PC software.
- **Software maintenance fee.** This is an annual fee that covers maintenance functions such as updates to the newest software versions for pump-based and PC-based dose error reduction software, patches and bug fixes, technical support, and consulting to help hospitals use their dose error reduction system data to improve practices. This fee is usually based on the number of pumps purchased.
- **Implementation consulting fee.** This is a one-time fee paid at the time of purchase. This fee covers consulting services such as aid in coordinating and leading a team of the facility’s clinicians, pharmacists, physicians, and administrators in developing and approving a drug library that fits clinical needs; training for staff responsible for developing drug libraries and analyzing dose error reduction system data; training for clinicians; and sharing of best practices for implementation and use from other facilities that have successfully implemented

the pumps. This fee is usually based on the amount of consulting time required by the facility.

Although a hospital may choose to avoid software maintenance and implementation consulting fees by creating its own drug library, by planning and executing its own implementation strategy, and by opting out of future software upgrades and technical assistance, we do not recommend this course of action. By contracting with the pump supplier to implement and maintain dose error reduction software, a hospital can speed up the implementation process and benefit from the supplier’s experience to better meet the hospital’s needs and encourage high clinician compliance. Therefore, hospitals should plan for and

Dose Error Reduction Systems in Non-General-Purpose Pumps

Several pump suppliers are developing dose error reduction systems for patient-controlled analgesic (PCA), syringe, and ambulatory pumps. ECRI has not evaluated these pumps’ dose error reduction software; however, we believe a dose error reduction system that meets our criteria will reduce medication errors in any type of infusion pump. Hospitals should consider this software an advantage when selecting pumps for purchase and, for pumps not yet evaluated by ECRI, should investigate whether the software meets our dose error reduction system criteria.

Based on ECRI’s criteria, hospitals interested in these pumps should look for the following:

- A flexible drug library that is large enough to hold the majority of drugs used and that can be customized to fit your facility’s needs
- Continuous display during infusion of the infused drug name, dose, and any doses infused outside of limits
- A downloadable log of dose error reduction system alerts and subsequent actions for review and refinement of your drug library

A checklist of our dose error reduction system criteria is available from the members area of our Web site. Just log onto www.ecri.org, go to your membership page, click on the *Health Devices* Journal option from the menu on the left, then scroll to the December 2004 issue. ♦

investigate these fees when requesting quotes for pumps with dose error reduction systems.

Wireless Capabilities and Infusion Pumps

Several suppliers are developing and testing pumps that can communicate wirelessly with a central server or information system. This type of feature may increase patient safety

- by allowing automated drug and dose checking or programming by communicating with the pharmacy information system, and
- by allowing dose error reduction systems to be easier to use, install, monitor, and adjust to changing drug library needs.

This second advantage is accomplished by allowing hospitals to (1) download alarm and error logs from pumps to determine whether current drug libraries are meeting clinicians' needs and (2) send new drug library

data sets to pumps without having to track down every infusion pump and connect it to a computer. Because this communication can travel over existing wireless networks within a facility, hospitals that have already invested in wireless networks may be able to pursue wireless communication with pumps for only the cost of wireless cards for the pumps, a central server for data storage, and software.

Even if a hospital is not planning to pursue automated drug/dose programming in the near future, the potential increase in dose error reduction system effectiveness and responsiveness from wireless error log downloading and drug library uploading may justify the purchase of infusion pumps with wireless capabilities, assuming that the pumps are located within the range of the wireless system.

UMDNS terms. Infusion Pumps, Ambulatory [16-491] ■ Infusion Pumps, General-Purpose [13-215] ■ Infusion Pumps, Patient-Controlled Analgesic [16-924] ■ Infusion Pumps, Syringe [13-217] ♦

Web Survey

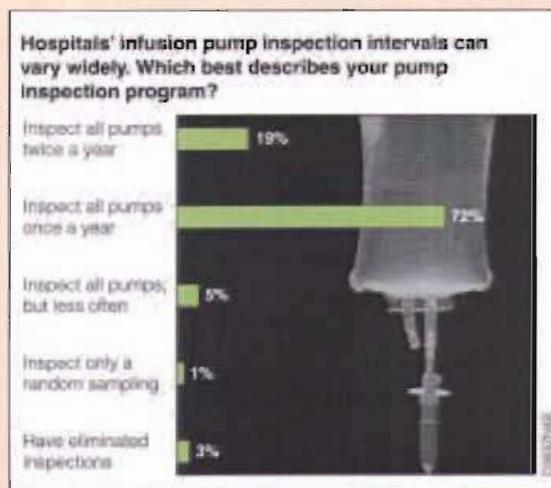
Infusion Pump Inspection Frequencies: How Often Is Enough?

Most hospitals have hundreds of infusion pumps in their inventory. Thus, performing routine inspections of all pumps can have a major impact on workforce utilization and costs. But how frequently do pumps need to be inspected? Annually? More often? Less?

Our July 2004 Web poll asked members to characterize their infusion pump inspection intervals. Of the 108 individuals who responded, more than 90% indicated that their facilities inspect all pumps at least once a year (see the graph). ECRI believes that for many facilities, such frequent inspections are unnecessary. Most established pump models are very reliable. These devices rarely fail; when they do, it is almost always in an unpredictable way that could not have been prevented by a routine inspection. In addition, pump failures are typically obvious to the user (e.g., the pump stops and alarms).

Several respondents indicated that they have, in fact, reduced the frequency of pump inspections. Reviewing pump inspection and repair trends can help you determine whether to take this step. For example, if only minor problems were found during previous inspections,

you may be able to extend inspection intervals or possibly even eliminate scheduled inspections altogether. A more detailed discussion is available on ECRI's *Health Devices Inspection and Preventive Maintenance System* CD-ROM. Related articles can also be found in the April-May 1998 and May 2001 *Health Devices*. ♦



JCAHO's National Patient Safety Goal for Infusion Pump Free-Flow Protection

ECRI's Assessment of the Protection Offered by General-Purpose, PCA, and Ambulatory Pumps

UMDNS terms. Infusion Pumps, General-Purpose [13-215] ■ Infusion Pumps, Patient-Controlled Analgesic [16-924] ■ Infusion Pumps, Ambulatory [16-491] ■ Infusion Pumps, Multichannel [17-634] ■ Infusion Pump Administration Sets [16-579]

Summary. One of the U.S. National Patient Safety Goals promulgated by the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) is to “improve the safety of using infusion pumps” by ensuring that pumps are protected against free-flow. In this Guidance Article, we provide ECRI's updated guidance for achieving this goal.

Free-flow refers to the uncontrolled delivery of an infusion to a patient when a controlled or metered delivery was intended. For more than 20 years — in numerous articles presented in *Health Devices* and its sister publication *Health Devices Alerts* — ECRI has offered guidance to help hospitals avoid the dangers of free-flow. The current article is the latest in a series of reports addressing JCAHO's goal; it describes the dangers, provides updated guidance for interpreting JCAHO's goal, and categorizes the available pump models according to the level of free-flow protection offered. This report supersedes *Health Devices Alerts* Special Reports S0008 (August 23, 2002), S0018 (March 21, 2003), and S0029 (November 14, 2003).



Background

JCAHO's Infusion Pump Patient Safety Goal

Since January 2003, surveyors from the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) have been assessing accredited healthcare facilities for compliance with the organization's National Patient Safety Goals. One of these goals focuses on improving the safety of using infusion pumps. This goal requires accredited healthcare organizations that use infusion pumps to “ensure free-flow protection on all general-use and PCA (patient

controlled analgesia) intravenous infusion pumps used in the organization.” JCAHO includes ambulatory infusion pumps, as well as PCA pumps and general-purpose infusion pumps, in this category. However, the goal does not currently apply to enteral feeding pumps or conventional syringe pumps.

In this report, we briefly discuss the hazards of free-flow and present our model-specific recommendations for preventing free-flow incidents and for complying with JCAHO's infusion pump goal. In responding to questions about this goal in its online FAQs (frequently asked questions), JCAHO states that it “recognizes ECRI as an authoritative source of information about the safety

considerations related to infusion pumps” and that information published by ECRI about the adequacy of model-specific free-flow protection will be acceptable as evidence of compliance, pending verification of a facility’s pumps and accessories by on-site surveyors.*

Free-Flow Protection

Free-flow, or unrestricted gravity flow, refers to the uncontrolled delivery of an infusion to a patient when a controlled or metered delivery was intended. Free-flow of certain types of drugs, such as narcotics and heart stimulants, poses the potential for serious patient harm and is sometimes fatal. Overinfusion of less potent drugs and intravenous solutions also poses a serious threat to patients susceptible to a fluid overload.

In some cases, free-flow occurs when nurses or nursing assistants are distracted or simply forget to close tubing clamps before removing sets from pumps (e.g., when changing a patient’s gown). Free-flow can also sometimes be attributed to pump tampering by untrained/ unauthorized personnel — such as housekeeping staff,

patients, or patients’ visitors — who may, for example, remove unclamped administration sets from pumps.

As a result, free-flow protection is effective only if the possibility of free-flow is prevented when the tubing has been removed from the pump. This level of protection protects patients in most free-flow scenarios.

General-Purpose Pumps

ECRI’s Categorization of Pumps for Free-Flow Protection

For more than 20 years, ECRI has been testing general-purpose infusion pumps against the free-flow protection criteria described above. Below, we classify most models of general-purpose pumps that could be in use in North America — and therefore will be exposed to JCAHO scrutiny — into three categories of free-flow protection: (1) pumps with no free-flow protection options, (2) pumps with free-flow protection dependencies (that is, pumps whose free-flow protection exists only under certain conditions), and (3) pumps with free-flow protection.

* JCAHO. 2005 National Patient Safety Goals FAQs [online]. 2004 Aug 30 [cited 2004 Oct 30]. Available from: www.jcaho.org/accredited+organizations/patient+safety/05+npsg/05_npsg_faqs.htm#9.

What’s New in This Report

Much of the accompanying text was initially published in our March 21, 2003, *Health Devices Alerts* Special Report (S0018), with some sections updated in a November 14, 2003, report (S0029). We have again updated that material to reflect recent developments in the infusion pump market and new guidance for interpreting JCAHO’s National Patient Safety Goals. Following are some of the noteworthy changes:

- Effective January 1, 2004, PCA pumps and ambulatory pumps that rely on the use of pressure-activated valves — also known as antisiphon valves — must be used with sets that incorporate the valve; using separate valves is no longer acceptable. JCAHO’s position regarding the use of sets that include *integral* pressure-activated valves was a matter of some debate throughout much of 2004. The guidance presented in this document reflects JCAHO’s current position — which is supported by ECRI — as outlined in JCAHO’s Rationale

and Interpretive Guidelines for the 2005 goals. In short, such sets may be used.

- Hospira Inc., which formerly operated Abbott Laboratories’ core hospital products business, was spun off from Abbott and began operating as an independent company on April 30, 2004. The infusion pump product lines that had been marketed under the Abbott trade name are now supplied by Hospira; these models are listed under the Hospira name in this report.
- ECRI has reclassified the Abbott (now Hospira) Omni-Flow 4000 and 4000 Plus pumps based on the introduction of new administration sets that meet our free-flow protection requirements. The new sets were introduced in late December 2003; pumps that are used with these sets are now classified as “Pumps with Free-Flow Protection.” ♦

Pumps with No Free-Flow Protection Options

ECRI does not consider these devices to be adequately protected from free-flow under any circumstances:

- Alaris (IVAC) 530, 580, 590, and 599
- Baxter (formerly Sabratek) 3030
- Baxter Flo-Gard 6100, 6200, and 6300
- Deltec (formerly AVI, 3M, and SIMS Graseby) 100, 110, 200/200A, 210/210A, 275, 400/400A, 470, 840, and 845
- McGaw 521, 522, AccuPro, and HomeFusion R/T
- Sigma 6000 and 6000+ Programmable

Pumps with Free-Flow Protection Dependencies

ECRI considers these devices to be adequately protected from free-flow only when used with certain tubing sets and/or in certain configurations:

- Alaris (IVAC) 560, 565, and 570 — **Free-flow protection** is provided when the optional **anti-free-flow sets** are used.
- Baxter Flo-Gard 6201 and 6301 — These pumps must be configured by clinical engineering personnel to require that the set be closed before it can be removed, and the black retainer clip must be removed when the units are received.
- Hospira (formerly Abbott) Omni-Flow 4000 and 4000 Plus — In late December 2003, the supplier introduced infusion sets that meet the criteria established by ECRI and JCAHO for free-flow protection (see *Health Devices Alerts* Action Item Accession No. A5125, dated May 30, 2003). Pumps used with these new sets are categorized as “Pumps with Free-Flow Protection.” The new sets can be identified as follows: Their list number is 12566-01, and they are labeled as having two pressure-activated antisiphon valves.

As we reported in our March 21, 2003, *Health Devices Alerts* Special Report (S0018), the old infusion sets used with the Omni-Flow pumps may not have prevented fluid flow under some circumstances, even though the pumps were marketed as offering free-flow protection. If a facility continues to purchase the old sets or maintain a stock of them in its inventory, its Omni-Flow pumps would be categorized as “Pumps with No Free-Flow Protection.”

- Medex EZ-1 (formerly Valleylab 7200 and IVION EZ-1) and Medex KIDS (formerly Valleylab and IVION KIDS) — Free-flow protection is provided

when the optional anti-free-flow sets are used. These sets have a mechanism called a flow clip, and their part numbers begin with FC. Sets without the flow-clip mechanism have part numbers that begin with IV. All EZ-1 pumps with serial number A5000 and higher and all KIDS pumps with serial number C5000 and higher are equipped to accept flow-clip sets. If the serial number is **lower** than those above, the device can be upgraded to accept flow-clip sets.

- Medex (formerly IVION) Trilogy — Free-flow protection is provided when the optional anti-free-flow sets are used. All Trilogy pumps can accept flow-clip sets (part numbers begin with FC).

Pumps with Free-Flow Protection

These devices meet ECRI’s criteria for tubing-based free-flow protection:

- Alaris (IMED) 922, 927, 928, 960, 965, 970, and 980
- Alaris (IMED) Gemini PC-1, PC-2/PC-2TX, and PC-4
- Alaris (IVAC) MedSystem III
- Alaris (IVAC) Signature Edition single- and dual-channel pumps (7100 Series and 7200 Series)
- Alaris Medley Medication Safety System
- B. Braun (formerly McGaw) Horizon Nxt and Outlook Safety Infusion System Series (Horizon Outlook)
- Baxter Colleague and Colleague CX (both single- and triple-channel units)
- Baxter Flo-Gard 8000
- Deltec (formerly 3M, Graseby, and SIMS) 280/280RT, 285, 480, 880, 885, 3000, and 3100
- Hospira (formerly Abbott) Acclaim and Acclaim Encore
- Hospira (formerly Abbott) LifeCare 3, 3HB, and 4
- Hospira (formerly Abbott) Plum Series: 1.6 (formerly LifeCare 5000 Plum), A+, XL, and XL3
- Sigma 8000, 8000 Plus, and 8002 Plus

ECRI’s Recommendations: General-Purpose Pumps

Inventory

- Verify that all infusion devices are included in facility equipment inventories (e.g., asset management, clinical engineering).
- Update the inventories as needed. Make a list of general-purpose infusion pumps that the facility may be leasing or renting (e.g., during periods of peak census).

- Create a master list of general-purpose infusion pumps used in the facility.
- Distribute the list by clinical location, and request that the manager of each location confirm that the list is complete and current.

Compare and Categorize

- Compare your list of infusion devices to the ECRI lists in this report (see ECRI's *Categorization of Pumps for Free-Flow Protection*, above).
- Group all the models that are in your inventory according to the appropriate free-flow protection category specified above. Review any uncategorized models with ECRI.
- For each pump in the "Pumps with Free-Flow Protection Dependencies" category, assign personnel with detailed knowledge of the pump (e.g., clinical engineering staff, nurses) to ensure that all requirements are met. Depending on the model (and, therefore, the conditions under which the pump is free-flow protected), the assessment may involve the following:

- Identifying part numbers for all tubing sets used with the pump
- Removing from the facility all sets that will allow free-flow (Materials management/purchasing personnel should return these sets for credit and understand that such sets should no longer be ordered.)
- Remediating pump-based free-flow protection dependencies. Examples for specific models include the following:

Baxter Flo-Gard 6201 and 6301. Verifying that the black retainer clips have been removed from the slide-clamp slots of all Baxter Flo-Gard 6201 and 6301 pumps and confirming that the configuration of each unit is correct (i.e., that all Baxter Flo-Gard 6201 or 6301 pumps are configured to require that the slide clamp is closed before the set is removed from the pump)

Medex EZ-1 and KIDS. Upgrading all Medex EZ-1 and KIDS pumps with serial numbers lower than those listed above to accept flow-clip sets

Plan

- If the facility has devices in the "Pumps with No Free-Flow Protection Options" category, perform the budgetary and evaluation processes necessary to replace

them. ECRI recommends against the use of add-on devices (e.g., discrete pressure-activated valves) to obtain free-flow protection with the sets for these pumps because there is no way to ensure the consistent use of such devices.

- Consider rental or leasing options when there is insufficient capital to purchase new pumps.
- If the facility has devices in the "Pumps with Free-Flow Protection Dependencies" category, ensure that free-flow protection dependencies are met throughout the facility by creating and communicating formal protocols for use of these units. The protocols should specify the conditions for proper free-flow protection, such as the use of specific accessories or pump configurations.

Educate

- Instruct qualified personnel involved in infusion therapy about any devices used in the facility that have free-flow protection dependencies.
- During training, stress that manual clamps must be used on all infusion sets. (ECRI continues to recommend that manual clamps be used.)
- Instruct housekeeping, patient transport, and other nonclinical staff to seek the assistance of qualified personnel rather than interacting with infusion equipment themselves during activities such as changing bed linens or transporting patients.

PCA and Ambulatory Pumps

Identifying Models with Free-Flow Protection

Few currently marketed patient-controlled analgesic (PCA) and ambulatory pumps provide intrinsic free-flow protection. Rather, these devices typically depend on the use of tubing with a pressure-activated valve to connect the pump reservoir (e.g., a vial, a collapsible bag) to the patient catheter. Such a valve, often referred to as an antisiphon valve, should allow fluid to flow to the patient only when enough positive pressure is generated by the pump to open the valve (i.e., when the pump is infusing). Therefore, these pumps typically fall into the "Pumps with Free-Flow Protection Dependencies" category.

Exceptions to this rule include the following ambulatory pumps; ECRI classifies these models, which are all pumps with multiple functions, as “Pumps with Free-Flow Protection”:

- Baxter 6060
- Curlin Medical 2000 Plus, 4000 Plus, and 4000 CMS
- Hospira (formerly Abbott) Gemstar

These models all use infusion sets that close automatically when removed from the pump. Thus, the pumps provide intrinsic free-flow protection.

For all other known PCA and ambulatory pump models, free-flow protection is a function of the tubing set used with the pump, rather than the pump itself. Thus, the key issue to assess for free-flow protection with these pumps is not whether a particular model is acceptable, but whether a

tubing set used with the pump offers protection (e.g., by incorporating a pressure-activated valve).

Although tubing with a pressure-activated valve has standard Luer connectors and may be available from suppliers other than the manufacturer of a facility’s PCA pumps, it is probably best to purchase the tubing from the pump manufacturer. Regardless of the supplier, however, pressure-activated valves must be integral to the infusion sets. That is, they should not be provided as discrete components that must be attached to the sets by users.

In its Rationale and Interpretive Guidelines for the 2005 National Patient Safety Goals,* JCAHO states that the use of pressure-activated valves for free-flow protection in ambulatory and PCA pumps is acceptable as long as the valve is “pre-assembled into the administration set.” In some cases, the portion of the set containing the pressure-activated valve may be removable — to allow for actions such as gravity priming, when necessary. Such sets are appropriate for use since the removability of this portion of the set will not interfere with the free-flow protection during use. The valve itself is permanently attached to this portion of the set, and both sections of the set are necessary for normal use. However, the use of “add on” free-flow protection — that is, a discrete component that must be attached to the infusion set by a user — remains unacceptable to both ECRI and JCAHO.

If a healthcare facility’s pumps require the use of an infusion set with a pressure-activated valve, ECRI further recommends the following:

- The facility should obtain written guidelines for proper use of the sets from the supplier.
- It should ensure that any limitations (e.g., maximum head height) are reasonable.
- It should ensure that ordinary extension sets (i.e., tubing without a pressure-activated valve) are not stocked in any clinical locations where these pumps are used.

ECRI’s Recommendations: PCA and Ambulatory Pumps

Inventory

- Verify that all models of PCA and ambulatory pumps are included in facility equipment inventories (e.g., asset management, clinical engineering).

For More Information

Additional information about JCAHO’s National Patient Safety Goals can be found in the following *Health Devices Alerts* Special Reports:

- S0007, “Hospitals to Be Assessed against JCAHO National Patient Safety Goals Starting January 2003.” *Health Devices Alerts — Action Items* 2002 Aug 2;26(A31):1-2.
- S0022, “Joint Commission Announces Goal 7 in Its 2004 National Patient Safety Goals.” *Health Devices Alerts — Action Items* 2003 Aug 8; 27(A32):1-2.
- S0044, “Joint Commission Announces Five New Goals in Its 2005 National Patient Safety Goals.” *Health Devices Alerts* 2004 Aug 13; 28(33):1-4.

These reports present overviews of JCAHO’s requirements for 2003, 2004, and 2005, respectively.

In addition, JCAHO’s Web site (www.jcaho.org) has a link to the Patient Safety Goals and related FAQs. The FAQs were last updated on August 30, 2004. JCAHO’s Rationale and Interpretive Guidelines for the 2005 goals are also available online (www.jcaho.org/accredited+organizations/patient+safety/05_npsg_guidelines_2.pdf).

For a more detailed discussion of the hazards of free-flow, refer to the *Health Devices* articles cited in the ECRI References section on page 435. ♦

* JCAHO. Rationale and interpretive guidelines [online]. 2004 Sep 10 [cited 2004 Nov 17]. Available from: www.jcaho.org/accredited+organizations/patient+safety/05_npsg_guidelines_2.pdf.

- Update the inventories as needed. Make a list of PCA and ambulatory infusion pumps that the facility may be leasing or renting (e.g., during periods of peak census).
- Create a master list of PCA and ambulatory pumps used in the facility.
- Distribute the list by clinical location, and request that the manager of each location confirm that the list is complete and current.

Plan

- No further action is needed for users of Baxter 6060; Curlin Medical 2000 Plus, 4000 Plus, or 4000 CMS; or Hospira (formerly Abbott) Gemstar pumps.
- For other pump models, obtain a written statement from the manufacturer that identifies the conditions that must be met to obtain free-flow protection — for example, catalog number(s) of tubing set(s) with integral pressure-activated valves or any head-height restrictions. Ensure that the correct sets are stocked in all clinical locations that provide PCA therapy and/or use ambulatory pumps. Ensure that extension sets without these valves are removed from these locations.

Educate

- Instruct personnel who use PCA and ambulatory pumps on the use of tubing sets with pressure-activated valves to obtain free-flow protection with the pumps in the facility. Instruction should include any manufacturer guidelines for use, as well as changes in priming practice required by the valves.
- During training, stress that manual clamps be used on all infusion sets.

ECRI References

Health Devices Alerts Special Reports

- S0007: Hospitals to be assessed against JCAHO National Patient Safety Goals starting January 2003. *Health Devices Alerts — Action Items* 2002 Aug 2;26(A31):1-2.
- S0008: JCAHO's 2003 National Patient Safety Goals — assessment of general-purpose infusion pumps for free-flow protection. *Health Devices Alerts — Action Items* 2002 Aug 23;26(A34):1-3.
- S0018: JCAHO's 2003 National Patient Safety Goal for infusion pump free-flow protection: assessing general-purpose and patient-controlled

analgesic pumps. *Health Devices Alerts — Action Items* 2003 Mar 21; 27(A12):1-4.

S0022: Joint Commission announces Goal 7 in its 2004 National Patient Safety Goals. *Health Devices Alerts — Action Items* 2003 Aug 8; 27(A32):1-2.

S0029: JCAHO's National Patient Safety Goal for infusion pump free-flow protection: expanded to include ambulatory pumps. *Health Devices Alerts — Action Items* 2003 Nov 14;27(A46):1-2.

S0044: Joint Commission announces five new goals in its 2005 National Patient Safety Goals. *Health Devices Alerts* 2004 Aug 13;28(33):1-4.

Health Devices Articles

Avoiding general-purpose infusion pumps that lack free-flow protection [talk to the specialist]. *Health Devices* 2002 Apr;31(4):154.

ECRI responds to FDA Public Health Advisory on IV free-flow [hazard report]. *Health Devices* 1994 Jun;23(6):256.

General-purpose infusion pumps [evaluation]. *Health Devices* 2002 Oct; 31(10):353-87.

General-purpose infusion pumps: evaluating the B. Braun Outlook Safety Infusion System [evaluation]. *Health Devices* 2003 Oct;32(10):382-95.

Overinfusion caused by gravity free-flow from a damaged prefilled glass syringe [hazard report]. *Health Devices* 1996 Dec;25(12):476.

Patient-controlled analgesic pumps [evaluation]. *Health Devices* 2001 May;30(5):157-85.

Patient-controlled analgesic pumps [evaluation update]. *Health Devices* 2001 Sep-Oct;30(9-10):360-4.

The need for free-flow protection [talk to the specialist]. *Health Devices* 2001 May;30(5):189. ♦

Suggested Distribution

ECRI recommends that this report be distributed to the following departments:

- Anesthesiology
- Clinical/Biomedical Engineering
- Critical Care
- CSR/Materials Management
- Emergency/Outpatient Services
- Home Care
- Nursing
- OR/Surgery
- Pharmacy/IV Therapy
- Pulmonology/Respiratory Therapy
- Risk Management ♦

The Electronic Medical Record

The Future of Health Information

Recent developments in the information technology arena are creating pressure for healthcare organizations to establish centralized electronic medical record (EMR) systems. For instance, the U.S. government's "Decade of Health Information Technology" initiative is emphasizing the electronic exchange of health information. Also, the U.S. Food and Drug Administration (FDA) has approved for marketing implantable or adhesive tags that use radio-frequency identification (RFID) technology to, for example, read information about the patient and access the patient's medical records.

But is EMR technology ready for widespread implementation? While this is a good time to start planning, there are many issues yet to be resolved before EMR systems become a reality for many hospitals. As a way to introduce *Health Devices* readers to this topic, we reprint below two articles that appeared in the September 2004 issue of ECRI's *Health Technology Trends*:

- "National Adoption of Electronic Medical Records Represents Major Challenge" (below) outlines some of the remaining obstacles to the widespread adoption of EMRs at U.S. healthcare facilities.
- "Evolution of Electronic Medical Record Systems" (page 439) presents some of the accumulated experience from hospitals that have been developing their own EMR networks.

Reprinted from



Moving Forward . . . Slowly

National Adoption of Electronic Medical Records Represents Major Challenge

President Bush's call for an electronic medical record (EMR) for most Americans within 10 years represents an enormous challenge, but recent efforts by the U.S. Department of Health and Human Services (DHHS) are a step in the right direction, according to hospitals with significant experience in healthcare information technology (IT).

As part of the DHHS "Decade of Health Information Technology" initiative, Secretary Tommy Thompson announced that DHHS planned to budget \$2.3 million for projects that support the electronic exchange of health information, including formation of community health information networks in nine communities. DHHS also plans to

invest another \$50 million in seed funding for similar projects in five states by the end of 2004.

As a first step, "this is the right thing to do to bring the issue into the national consciousness," says John Wade, chief information officer, Saint Luke's Health System (Kansas City, Missouri). "We still have huge challenges ahead of us as a country to develop an electronic medical record" that will require significant amounts of work and resources, Wade says. In comparison, the province of Ontario, Canada, which has a population of roughly 12.3 million, is investing about \$1 billion to make EMR systems available to its citizens this year.

Defining the Issue

"Currently, there is really no single standard to define what an electronic medical record should contain. All the stakeholders seem to have their own concept of what it should be," Wade told *Health Technology Trends*.

"Just agreeing on a definition of an electronic medical record has been a fundamental reason why progress has been slow," says Richard Diefes, associate director of ECRI's Health Devices Group. For example, a number of companies now market software to physician offices as EMR systems, but these products are often essentially different technology and may not really be comparable in terms of cost and complexity to EMR systems being developed by some hospitals today, further clouding the issue, Diefes says.

"The content of electronic records is no different than paper records. What we have changed is how that information is organized and stored," says Thomas A. Berg, director of clinical information services, Marshfield Clinic (Marshfield, Wisconsin).

Consensus about what should be included in EMRs may not exist because of the potentially conflicting goals of different stakeholders: providers who treat patients,

payers who require billing information, and hospital administrators who want to monitor quality improvement processes to ensure compliance with standards from the Joint Commission on Accreditation of Healthcare Organizations, says Emily S. Patterson, Ph.D., a research physical scientist at the Veterans Affairs (VA) GAPS (Getting at Patient Safety) Center at the Cincinnati (Ohio) VA Medical Center and a visiting researcher at the Institute for Ergonomics at Ohio State University (Columbus).

One fundamental factor that has slowed progress is the lack of agreement about what an EMR should contain.

"For some time now, a number of individual hospitals and health systems have been developing their own electronic medical records because they felt that they could no longer wait for national standards to emerge," says Erin Sparnon, project officer in ECRI's Health Devices Group.

"So far, all the stakeholders have not been brought together at the same table to address the issues," says Wade. The recent appointment of David J. Brailer to lead the newly created Office of the National Coordinator for Health Information Technology "should bring a lot to this process and offer the kind of leadership that has so far been lacking," he says. Technical issues that affect EMRs and current regulations, which can vary from state to state, "are extremely frustrating," says Wade. "We really needed a national effort to move forward with electronic medical records. Eventually, this will become an international issue," he believes. "Today, medical records need to be viewed electronically everywhere, and there is no question that we need to move to an EMR system," Wade adds. However, progress has not been uniform across the healthcare system. "This is where government has to step in," says Wade. "As an industry, we will need to define universal standards for electronic medical records so that caregivers do not have to relearn each new system" as they move between different healthcare facilities, he notes.

Unanswered Questions

The absence of a definition of what an EMR is or should be and a lack of clear answers to other questions have also contributed to the slow adoption of EMR systems across much of the U.S. healthcare system, say Sparnon and

Health Technology Trends

Health Technology Trends is ECRI's monthly newsletter covering the latest innovations in healthcare technologies used by hospitals. It features ECRI's perspective on new technologies and covers the regulatory and reimbursement developments affecting technology use in hospitals. Members of ECRI's SELECTplus™ Program can access *Trends* through the members area of ECRI's Web site, www.ecri.org. For more information about this publication, contact ECRI's Communications Department at +1 (610) 825-6000 or at communications@ecri.org. ♦

Diefes. ECRI believes that other important questions are not yet resolved, including the following:

- Who is responsible for “populating” or inputting patient data into the EMR?
- Who is responsible for verifying that patient data are accurate and up-to-date?
- Who should store and who can access patient data, and how and where?
- Who will cover costs related to EMR implementation?

The current reimbursement environment does not encourage physician office practices to install EMR technology, says Wade. About 80% of the potential cost savings from EMRs is realized by payers and about 20% by hospitals, he adds. “In many cases, office practices could lose money by installing EMR systems,” Wade believes. However, the full clinical and economic benefits of EMR cannot be realized unless EMR technology encompasses the entire healthcare system.

At Marshfield, responsibility for entering patient data in the EMR depends on what is being ordered, says Berg. For example, a cardiologist would input an order for an electrocardiogram and a lab technician would input results from a blood test, he says. Marshfield recently began deploying tablet personal computers so that clinicians can “write” orders directly onto the tablet with a stylus — similar to using a pen on a paper chart. Thus, in many cases, orders and documentation are essentially combined into one step.

Wade says that “Another significant issue that must be sorted out is ‘Who owns the records: hospitals, physicians, or patients?’” “This is an area over which national committees will have considerable influence,” he notes.

Winning Over Staff

“In many hospitals, any mention of electronic medical records will get the cold shoulder from physicians because they have had similar promises before for computerized order entry with bad results,” says Diefes. “Any electronic ‘enhancement’ will disrupt workflow, so it had better deliver to be accepted.”

Moving away from paper records requires an enormous process change that staff will resist if they reap no benefits, Berg told *Health Technology Trends*. “Physicians will change if you give them something that has real value for them rather than in addition to the bottom line,” he says. “Time is about the most important thing clinical systems can give back to physicians. If you can shorten their hours

in exchange for altering their workflow, you will be successful,” says Berg.

To improve clinician acceptance, Marshfield’s EMR system was designed by physicians for physicians, says Berg. The health system dedicated 64 software developers from its 250-member IT department to work with physicians to create the Marshfield EMR system. “Physicians essentially sponsor system development. They work with developers on pilot projects to ‘test drive’ software additions or modifications,” he states.

The effort to implement EMRs at Saint Luke’s was an organizational initiative that included staff ranging from physicians and nurses to laboratory technicians and administrators, says Wade.

“Historically, technology was often a barrier to the caregiver,” Wade believes. “Many off-the-shelf [information] systems still require physicians to become order-entry clerks,” which discourages use, he notes. Voice-recognition systems for recording physician orders are improving, and this is a positive development in the evolution of the EMR, says Wade. Today’s computer technology is much more sophisticated and much easier to use, he notes. “The technology is much closer today to supporting wider use of EMR systems than it has been in the past,” Wade says.

Obstacles

Berg, Wade, and ECRI agree that the cost of computerized record systems has historically been a barrier to implementation at many hospitals.

Wade notes that to date, Saint Luke’s has invested about \$50 million to \$60 million in IT infrastructure to develop its EMR system. The hospital has additional plans to invest at least another \$40 million in IT systems in the future.

Coupled with high technology costs, the complexity of healthcare information systems has been a big obstacle to widespread adoption at more U.S. healthcare facilities, Berg believes. Unlike healthcare IT systems, computerized systems that maintain individual customer records, such as those in the banking or insurance industries, are “relatively easy” to create and maintain, he explains. “In terms of keeping individual records, healthcare is the most data-intensive industry in the world. For example, an orthopedic hand surgeon can require data storage for hundreds of different measurements of one patient’s hand alone,” says Berg.

Outlook

Although striving to create an EMR for most Americans within 10 years is a laudable goal, it will be a difficult task

to achieve in the current U.S. healthcare system, Patterson suspects. Implementing universal electronic medical records within that time frame might be more realistic within the VA system or at U.S. military hospitals, which tend to use the same or quite similar IT infrastructure, she says. Patterson points to "one VA project" that is gradually attempting to incorporate many, but not all, aspects of patient information into an EMR system so that physicians at different VA hospitals can access a veteran's medical records when necessary.

"Standards are very important, but they haven't arrived yet," says Berg. "Without them, you won't see 'plug and

play'-type devices analogous to home entertainment systems, which is what we need in healthcare" to make EMR system implementation easier for more hospitals to do, he notes. Furthermore, Berg believes that standards are necessary to advance from use of EMR systems to clinical decision support — the ultimate goal of computerized healthcare information. "Until we can get all the data together, you cannot do good decision support."

Reprinted from: ECRI. National adoption of electronic medical records represents major challenge. *Health Technology Trends* 2004 Sep;16(9):1-3. ♦

Hospitals Accept the Challenge

Evolution of Electronic Medical Record Systems

Stakeholders are increasingly touting the potential of electronic medical records (EMRs) to improve patient safety and reduce costs and are pushing for widespread use of paperless records. As more hospitals move toward installing new or expanded EMR systems, they may benefit from the accumulated experience of other hospitals that have been developing their own EMR networks for years.

Setting Goals

In 1995, Saint Luke's Health System (Kansas City, Missouri) organized a panel to create and execute a plan for implementing an EMR system throughout its network of nine hospitals and affiliated physician offices, says John Wade, Saint Luke's chief information officer. "After nine years and about \$50 million to \$60 million invested, we have achieved about 80% of our goal," Wade told *Health Technology Trends*. Saint Luke's, which was named one of the 100 most wired hospitals in the United States by *Hospitals and Health Networks* magazine in 2004, "is almost at the point where we can offer computerized order entry" that can give physicians decision support by drawing on patients' comprehensive medical records, he says.

At the Marshfield Clinic (Marshfield, Wisconsin), computerization of medical information dates back to the early 1970s, when the hospital began keeping records of diagnoses online to improve reimbursements, says Thomas A. Berg, Marshfield's director of clinical information services. "We then added laboratory information, which was

probably the easiest to computerize because it involves mostly numerical information," he says. The hospital subsequently added radiology information, physician notes, patient vitals, and electrocardiograms, as well as a picture archiving and communication system, to its "homegrown" system. As more physicians became increasingly specialized and as more patient data were generated across different facilities in the Marshfield health network, the chances increased that not all outside patient data would be incorporated into the EMR system in a timely manner, Berg explains.

To address this situation, the final push in Marshfield's drive toward a paperless system began in October 2003 with the introduction of the first tablet personal computers (PCs). The tablet is similar to a legal pad, has a 12-inch screen, and weighs about three pounds. Clinicians access the EMR network using a personal identification number. Berg told *Health Technology Trends* that the tablet PCs use "electronic ink" that allows physicians to "write" on the tablets with a stylus as if they were using a pen and paper. "We currently use about 2,500 different forms across all specialties. We can now scan new forms into the system, and physicians write on the form from the tablet using digital ink. The form and ink are then stored together as an image," he says. Marshfield is providing about 30 additional tablet PCs per week to physicians and nurses and anticipates that a total of 2,000 tablets will be in use

by 2006. Until the tablet PC rollout is complete, both paper and electronic charts will be used, says Berg.

Smart Cards?

Computer and data-storage technology has advanced so much that it is possible to store volumes of a patient's medical record on a "smart card" or "data stick" that can be kept in a wallet or on a keychain. Erin Spannon, project officer in ECRI's Health Devices Group, says that although these solutions sound appealing in their simplicity, they raise important questions, such as "What happens if patients don't have their card with them in the emergency department?" or "Who is responsible for updating that information and ensuring that it is accurate?" In addition, Richard Diefes, associate director of ECRI's Health Devices Group, asks "What happens if somebody loses his patient data stick, both in terms of patient privacy and recovering the patient record?"

From a practical standpoint, a card-based "portable" EMR presents problems with information turnaround, says Marshfield's Berg. After a patient enters the emergency department, some microbiology results may take 48 to 72 hours to complete. Berg asks, "How do we get these 'long to develop' results onto the patient's card?" It would be difficult to ask patients to come back to update their EMR cards and to keep track of the process, Berg notes.

Capacity

Marshfield's "cradle to grave" patient records are "fairly comprehensive" and collect information from the health system's 41 primary, secondary, and tertiary care institutions and research and education facilities across Wisconsin. EMR data are stored centrally using a wide area network that connects about 6,000 workstations and about 10,000 users, says Berg. Marshfield has two computer rooms with totally redundant systems and data cables with multiple entry points into the facility. "In case a construction crew accidentally cuts through one cable, the system has another entry point on the opposite side of the building to supply data," he notes. "We are now moving toward creating triple redundancy for our system," says Berg.

At Saint Luke's, use of purely electronic records dates back to 1998, when the hospital began building its EMR system. In addition, physicians have electronic access to a large number of paper records from files that have been scanned into the system, Wade explains. Beginning in 2001, offices of about 100 physicians employed by Saint Luke's were brought into the EMR network. Saint Luke's uses a storage archive network system for its EMRs that

permits data-storage devices to be added as the need increases, he says. "Currently, our EMR system requires around 48 terabytes of storage, and as we bring diagnostic imaging live into the EMR system, our data-storage needs will at least double in about two years," says Wade.

Saint Luke's EMR system has redundancy, failover, and disaster-recovery protection features, including multiple-entry data cables, Wade says. "If our primary machine fails, the process automatically switches to another machine." The current disaster-recovery system would bring EMR systems back online within 24 hours after an emergency, says Wade. "That's too long, so we are looking at ways to

The declining cost of data storage is a bright spot for hospitals implementing EMR systems.

reorganize disaster recovery and cut our potential downtime to between two and four hours," he states. "Last year, our system's uptime rating was 99.986%, and this year, it's 99.999%, but going forward, we still have to reduce that," says Wade.

With all the challenges associated with use of EMR systems, the declining cost of data storage is a bright spot for hospitals that have implemented or are planning to implement EMR systems, says Berg. "Years ago, when we started computerizing patient records, our first system to hold 50 megabytes of data, which was really something back then, cost about \$50,000. Last week, I purchased a 250-megabyte thumb drive for \$10," he notes. "That's good news for us. As a research facility, our researchers want access to all available data. We have never purged any patient data in the history of our EMR system, encompassing about two million patient visits per year," says Berg. Marshfield's EMR system "requires disk farms [i.e., data-storage facilities] that can hold many terabytes of data," he says, noting that Marshfield's data-storage needs will only increase as new diagnostic imaging modalities are developed that provide even more detailed information than current-generation images contain.

In addition to incurring lower costs, storing data today requires much less space. "Luckily, the size of data-storage devices keeps shrinking as storage capacity increases," says Wade. Ultimately, the nine hospitals in Saint Luke's Health System will concentrate EMR data

storage in a 10,000-square-foot central computer room. "We have tried to keep some on-site EMR storage at our various hospitals as we developed EMRs, but we are gradually moving patient data into a centralized storage facility," he states.

Where to store patient data will be a huge question as the U.S. healthcare system makes greater use of EMRs, says Emily S. Patterson, Ph.D., a research physical scientist at the Veterans Affairs (VA) GAPS (Getting at Patient Safety) Center at the Cincinnati (Ohio) VA Medical Center and a visiting researcher at the Institute for Ergonomics at Ohio State University (Columbus). "Huge central data-storage facilities are more efficient, but they are also more vulnerable to attack or natural disasters," she notes. "In the VA system, we counseled against having one central data facility for all VA patients," says Patterson.

Learning from Experience

For years, hospitals in the VA healthcare system have been moving toward a paperless system. That extensive experience may offer guidance for other hospitals designing their own EMR networks, says Patterson. In some cases, electronic records can take longer to "fill out" than paper records because of implicit requirements regarding what data must be entered into the EMR system, regardless of whether those data fields are relevant to a particular patient encounter, says Patterson.

A potential problem exists when EMR systems permit more than one record to be open at the same time, Patterson advises. "It could be possible that when several

different records are open at the same time, a physician who is cutting and pasting information from a prior note for one patient may inadvertently paste information in the wrong record," she says. "These are the types of questions that should be considered when new systems are being developed," Patterson states.

Because the wireless handheld computers often used with EMR systems could, in theory, become contaminated, hospitals must consider how to keep these devices clean, Patterson advises. "This is less of an issue with a stationary workstation, since you don't need to interrupt someone to clean it when it is not being used," she told *Health Technology Trends*.

Finally, some researchers have observed differences in the way that paper and electronic records are composed. In studying how physicians record patient information in an EMR compared to on a paper record, "some researchers have found that nuances can be lost when you type information into a computer rather than write it out," says Patterson. "Over time, physicians can change what they write in an EMR, perhaps to help hospital billing clerks, or they may become more cautious about what they include in the record when they know that more people could be viewing the EMR data compared to paper notes," she states.

Reprinted from: ECRI. Evolution of electronic medical record systems. *Health Technology Trends* 2004 Sep; 16(9):4-6. ♦

Are you using infusion pumps with dose error reduction systems?

Your fellow members want to know.

- ▶ The prevalence of infusion pumps with dose error reduction systems is the subject of this month's Web poll. To get an idea of how many other facilities are using this "smart" technology, log onto the members area of our Web site (www.ecri.org), access your membership home page, and register your vote in the poll. Responses will be tabulated through the end of December, and current results can be viewed at any time. ♦

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We deeply appreciate the contributions made by the following professionals, who gave their time and expertise as reviewers of the Evaluations and Guidance Articles published in *Health Devices* during the past year. We would also like to thank the countless others — too numerous to mention here — who have helped us inform the healthcare community about medical-device-related problems through our Problem Reporting System.

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Hazard Report

Alaris Medley Medication Safety System LVP Module Can Permit Gravity Flow if Sets Are Misloaded

PROBLEM

Three member hospitals have reported overinfusion incidents associated with administration sets that were loaded incorrectly into a certain module used with Alaris Medley Medication Safety System (MSS) pumps. The misloaded sets allowed uncontrolled gravity flow, resulting in overmedication of the involved patients.

Overinfusion of high-alert drugs such as vasopressors, narcotics, and anticoagulants can seriously harm or kill patients. In the incident cases, at least one patient required major medical intervention.

BACKGROUND

The Alaris Medley MSS is a modular infusion and monitoring device configurable with three different pumping modules: one for large-volume solutions, one for patient-controlled analgesic (PCA) therapy, and a syringe driver. Alaris refers to the large-volume solution module as a large-volume pump (LVP).

The LVP delivers intravenous fluids through a dedicated administration set. This set contains an upper fitment and a lower "Flo-Stop" fitment separated by a length of Silastic tubing that sits against the pumping channel's

peristaltic mechanism. The set is intended to be loaded into the LVP by first placing the upper fitment into a well at the top of the pumping channel and then loading the Flo-Stop fitment into a recess at the bottom of the pumping channel. Closing the LVP's door forces an inner platen to occlude the Silastic tubing and opens the Flo-Stop fitment's free-flow protection clamp.

DISCUSSION

When the set is properly loaded, the LVP prevents gravity flow. However, if the upper fitment is either held in front of the well or cocked within the well as the module door is closed, the fitment may jam between the well and the door. The fitment then acts as a wedge that can prevent the platen from properly occluding the Silastic tubing and, as a result, allow gravity flow. Refer to the photos below to see the difference between tubing that is properly seated and improperly seated, as well as the photo at right to see how an improperly loaded administration set might look (the arrow points to the gap that might show between the well and the door).

ECRI first became aware of a Medley MSS over-infusion incident associated with set misloading while performing an accident investigation at a hospital in August 2003. In December 2003, another facility reported an overinfusion with an LVP module. In that case, the administration set had been installed, but the pump had not been turned on. After investigating that incident, we again concluded that the overinfusion was caused by a misloaded set. We reviewed our findings with Alaris and were informed that a modification was being developed that would address the problem.



Tubing that is properly (*left*) and improperly (*right*) seated in the Alaris Medley MSS LVP.

Alaris's initial corrective actions. Alaris distributed a Safety Alert letter to Medley MSS customers dated August 25, 2003 (published as an Action Item in *Health Devices Alerts* on September 19, 2003; Accession Number A5279). The letter included information on correct and incorrect ways to load the administration set into an LVP. Alaris also offered posters describing correct and incorrect set loading through its Web site, at www.alarismed.com/advocacy/faqs_medley.shtml (posted September 2003).

In March 2004, Alaris began to make available a new platen for the LVP module. The replacement platen is designed to hold the Silastic tubing more tightly in the peristaltic mechanism, thereby reducing the risk of gravity flow if a set is misloaded. It also makes it more difficult to latch the door of the module if a set is misloaded. The new platen is distinguishable from the original platen by the presence of two spring-loaded metal buttons that press against the pump module door (see the photo on the next page).

The replacement platen is available on request at no charge to customers. Alaris states that all customers were notified of the new platen's availability as of October 2004 and that the platen has been installed in most of the LVP modules currently in use.

ECRI's testing of the new platen. We tested LVP modules with the new platen at the third hospital. We found that the new platen reduced the incidence of overinfusion when we misloaded administration sets in the two ways previously described. Unfortunately, we were able to produce gravity flow. We did find that more force was needed to close the LVP's door when the set was misloaded. We believe that experienced users could feel this difference when closing the door; however, an inexperienced or hurried user may miss this cue. We also found that the Medley MSS usually sounded an alarm and displayed "OCCLUSION: FLUID SIDE/CONTAINER EMPTY" when infusion was started with a misloaded administration set. Of course, an alarm will only activate and call attention to a misloaded set if the pump is turned on (note that one of the

