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Hospira LifeCare PCA 3

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

Product availability. Introduced October 2002. Marketed in Canada and the United States.

Product Description

The Hospira LifeCare PCA 3 is a pole-mounted syringe driver that delivers medications from proprietary 30 mL Hospira syringes (available empty sterile or prefilled with morphine or meperidine). The pump has an integrated bar-code reader to identify the drug name and concentration of labeled syringes as they are loaded into the pump. This pump also offers Profiles, a limited pump-programming function that allows hospitals to store up to 10 standardized dosing protocols tied to specific prefilled drug vials. This pump is not intended for home care use.

Significant Test Results

Human Factors

Human factors are excellent: The pump displays either the drug name and concentration or "Custom Vial" (if not a



Rating: Preferred

The Hospira LifeCare PCA 3 is an easy-to-use pump that has few disadvantages. It would be a good choice for hospitals that wish to purchase prefilled (morphine and meperidine) drug syringes. It is not intended for home care use.

Pros

- Bar-code reader should eliminate wrong-drug and wrong-concentration programming errors; has proven effective in extensive use
- Profiles software offers limited automatic pump programming—allows up to 10 standardized dosing protocols to be developed and tied to particular Hospira prefilled drug vials
- Large, comprehensive display provides easy-to-follow prompts

Cons

- Lacks dose error reduction system
- Accepts only proprietary Hospira syringes
- Releases postocclusion bolus averaging 1.5 mL if instructions for safely releasing postocclusion boluses are not followed ♦

prefilled syringe) at all times as verified by the bar-code scanner. Also, the large, comprehensive display screen provides step-by-step prompts that are easy to follow. The pump comes with an instructional tip sheet to be attached to its handle, and simple instructions are printed on the side of the pump for loading a syringe and beginning therapy.

The pump accepts only proprietary Hospira syringes. This may be a disadvantage for facilities that wish to use medications from other suppliers; these facilities will need to fill Hospira's empty sterile syringes in-house.

Performance

Overall performance is good. A minor disadvantage is that the pump exhibits 15% overdelivery for the first two hours of therapy when set to 0.1 mL/hr. This low rate is rarely used for PCA therapy, however.

Evaluation

Memory functions are excellent: The pump allows the user to retain the pump's settings only if (1) the current drug vial has the same drug name and concentration as the previous drug vial (as indicated by the vial's bar code) or (2) the drug vial has not been removed from the pump since the previous therapy. Therefore, if a patient is switched from 5 mg/mL morphine to 1 mg/mL morphine or to a vial without a drug-name-specific and concentration-specific bar code, resuming the patient's previous dosing regimen is not offered as an option.

General Safety Features

Safety features are judged only fair overall because the pump releases an average postocclusion bolus of 1.5 mL if instructions for safely releasing occlusions are not followed. Hospira's customer training includes instructions on how to release the pressure after an overpressure alarm in a way that avoids a bolus.

Drug/dose calculation, however, is excellent: All settings are presented on a single confirmation screen.

An additional advantage is that clear text indicates the cause of alarms and provides the user with instructions for appropriate follow-up.

Advanced Error-Reduction Features

Error-reduction features are excellent: The pump uses an integrated bar-code reader to identify a syringe's drug name and concentration. By eliminating manual entry, this

Hospira LifeCare PCA Coming Soon

Hospira plans to release the LifeCare PCA, an enhanced version of the LifeCare PCA 3, in early 2006. This pump is identical to the PCA 3, with the addition of wireless pump connectivity for uploading drug libraries and downloading event/alarm logs, plus Hospira's MedNet dose error reduction system software. The MedNet software (which we tested as part of our December 2004 Evaluation of the Hospira Plum A+ general-purpose pump) includes a computer-based drug library editor for developing and maintaining facility-customized drug libraries, plus data mining/reporting software for analyzing alert and alarm logs for continuous quality improvement. ECRI has not evaluated the LifeCare PCA. ♦

Test Results Hospira LifeCare PCA 3

Human factors	Excellent
Fluid capacity	Good
Displayed information	Excellent
Dose-request control	Good
Ease of use	Excellent
Performance	Good
Flow and dose-volume accuracy	Good
Battery power	Good
Memory functions	Excellent
Data logs	Good
General safety features	Fair
Free-flow protection	Good
Dose-interval range (lockout)	Good
Occlusion (overpressure) alarm	Fair
Alarm characteristics	Good
Resistance to tampering and accidents	Good
Drug/dose calculation	Excellent
Advanced error-reduction features	Excellent

reader eliminates errors in entering drug concentration and (with use of the Profiles function) in entering initial programming parameters. Therefore, override indicators for these settings are not needed. A significant advantage is that, through extensive implementation, this bar-code reader has proven effective in hospital environments.

The Profiles automatic pump-programming feature allows a facility to develop up to 10 delivery protocols, numbered 1 through 10. Each protocol contains information about which drug vials can access the particular protocol and about pump settings such as delivery mode (PCA only, PCA plus continuous, or continuous only), continual and basal delivery settings, lockout time, and, if desired, a one- or four-hour dosing limit. This feature sets initial programming only and does not offer limits on initial or subsequent dosing parameters or lockout intervals. The protocols must be entered on each infusion pump; this is often done on receipt of new pumps. Currently, Profiles can only be used with Hospira prefilled vials. (Several concentrations of morphine and meperidine are available.)

A disadvantage is that the pump does not have a dose error reduction system: therefore, it does not allow a facility to set limits around initial or subsequent rate/dose programming.

Smiths Medical CADD-Prizm PCS II

Supplier. Smiths Medical MD Inc. [440772], St. Paul, Minnesota (USA); +1 (800) 433-5832, +1 (651) 633-2556; www.smiths-medical.com

Product availability. Introduced August 2004. Marketed in Australia, Austria, Belgium, Canada, France, Germany, Luxembourg, the Netherlands, South Africa, Switzerland, the United Kingdom, and the United States.

Note. We previously evaluated this pump in our September-October 2001 issue, when it was sold under the Deltec name. Since then, the CADD-Sentry automated pump-programming software has been added to the pump, which is why we have retested it for this issue.

Product Description

The Smiths Medical CADD-Prizm PCS II is an ambulatory peristaltic pump that can be used for hospital or home care applications. The pump can be purchased with purple (indicating intravenous PCA) or yellow (indicating epidural PCA) keypad.

Accessories for the pump include a pole-mounting bracket, yellow and clear lockboxes, administration sets that can be used with medication bags and syringes, and



Rating: Acceptable

The CADD-Prizm PCS II is a compact, rugged pump. Although it performs adequately, it has several disadvantages. Even so, it would be a good choice for outpatient clinics and hospitals that desire a small, ambulatory-style pump.

Pros

- CADD-Sentry pump-programming software allows drug-specific or therapy-specific dosing protocols to automatically populate pump settings
- Ambulatory pump design allows fluid delivery from a wide variety of containers

Cons

- Not all facilities may be able to accommodate the workflow necessary to use the CADD-Sentry software
- Exhibits poor low-flow continuity
- Does not continuously display dosing units, concentration, or dose settings
- Manually entering new programming can be time-consuming and confusing
- "Check Cassette" alarm does not clearly identify cause of alarm
- After programming, pump enters "automatic re-view," which can be cumbersome ♦

yellow and clear 50 and 100 mL Medication Cassette Reservoirs. (The reservoirs are available empty sterile and in a variety of prefilled configurations.)

The Prizm PCS II is sold with Smiths Medical's CADD-Sentry PC-based pump-programming application, which can send (via a wired connection) standardized dosing protocols and dosing limits for subsequent programming changes from a computer to the pump. The CADD-Sentry software has been used successfully for automatic pump programming in the home care environment but has only been used in limited trials in a hospital setting.

Significant Test Results

Human Factors

Human factors are judged only fair because of poor displayed information and fair ease of use. A major disadvantage is that only the rate is displayed continuously. To display the drug dosing units, concentration, or PCA dose settings, the user must press the pump's View button. A further disadvantage is that the pump's programming screens can be cumbersome to navigate, and clinicians felt it took a long time to program the pump manually, review settings in the case of computer-based programming, and start the pump. However, these disadvantages should not pose a safety risk if the facility uses the pump's Sentry software to send initial settings and dosing limits to the pump. A final drawback is that the screen is small and presents information in a small text that can be difficult for clinicians with poor vision to read.

An advantage is that the pump's Reports key offers quick access to reports such as doses requested versus doses delivered, cumulative doses given, and patient pain scale. Another advantage is that the pump's ambulatory design allows fluid delivery from a wide variety of bags, syringes, and cassettes.

Performance

Performance is good overall, although the pump has some drawbacks. One is that it exhibits poor low-flow

continuity, delivering only twice per hour when set to 0.1 mL/hr. This could result in delivery that mimics bolusing (i.e., two boluses per hour) rather than providing continuous infusion. We believe this pump should not be used at such a low flow setting. However, this low rate is rarely used for PCA therapy, so we don't consider this a major disadvantage.

Facilities must configure the pump to clear the current program on power-up when infusing a new patient; otherwise, the pump retains its previous settings indefinitely and presents them as default values during reprogramming. (This configuration can be specified through the CADD-Sentry software during initial pump configuration by entering the Concentrations & Reports tab, New Patient Marker section, and selecting the option "Offer at Power Up.")

In addition, facilities may wish to disable the Automatic Program Review that activates on power-up. (This feature is also configurable through the CADD-Sentry software.) When activated, the feature scrolls through all pump settings one at a time, resulting in an extended power-up time for the device.

General Safety Features

Safety features are good overall. This pump can be used with an antisiphon valve built into a section of the infusion set that can be removed for gravity priming. The Luer connectors on this removable section are male-male, which means that the removable section cannot be replaced with a standard extension set (i.e., one with no antisiphon valve), and the set cannot be used without it. Also, the pump can be configured to control programming lock/unlock functions through either the keylock or an access code.

Alarm characteristics are only fair: The "Check Cassette" alarm—which is triggered when the cassette is properly loaded but the keylock has not been fully closed—may be difficult for users to respond to because it does not clearly identify the problem. A minor disadvantage is that the alarm volume is not adjustable.

Drug/dose calculation is also only fair: After programming, the pump does not require confirmation of the programmed settings. Instead, it enters "automatic review," displaying the settings one at a time without user action. It then automatically starts operation. If the user's attention is elsewhere during the review, an incorrect setting could be missed. In addition, the review can be cumbersome, which may prompt users to speed through by hitting View repeatedly or simply go to other tasks instead of watching the display.

Test Results Smiths Medical CADD-Prizm PCS II	
Human factors	Fair
Fluid capacity	Good
Displayed information	Poor
Dose-request control	Good
Ease of use	Fair
Performance	Good
Flow and dose-volume accuracy	Good
Battery power	Good
Memory functions	Good
Data logs	Good
General safety features	Good
Free-flow protection	Good
Dose-interval range (lockout)	Good
Occlusion (overpressure) alarm	Good
Alarm characteristics	Fair
Resistance to tampering and accidents	Good
Drug/dose calculation	Fair
Advanced error-reduction features	Good

An additional minor disadvantage is that two different portions of the key are used to operate the pump's two locks. The barrel of the key is used to lock and unlock the administration cassette and the keypad. To *unlatch* the administration cassette, however, the side of the key or a coin must be used. This can be confusing for inexperienced users.

Advanced Error-Reduction Features

Error-reduction features are good. The CADD-Sentry programming software allows a hospital to develop drug-specific or therapy-specific dosing protocols that are stored on a computer and sent via a connecting cable or modem to a pump. The protocols automatically populate pump settings such as drug concentration, continuous and bolus delivery settings, lockout interval, time-based dosing limits, and hard limits on continual and bolus delivery and lockout settings.

This software offers only hard limits; therefore, the pump will not allow the user to select programming parameters

that are outside the limits for a particular protocol. The pump, which is programmed by scrolling up and down through potential values for any setting, will not scroll to any values that are outside the limits set by CADD-Sentry. (For example, if the limits on continuous rate are from 1 to 8 mg/hr, the pump will scroll from 1 to 8 but will not offer settings below 1 or above 8.) To set the pump to a setting outside the hard limits, the user must connect the pump to a computer and download another protocol that will allow the setting. A user could also change the limits in the code-protected Biomed Toolbox menu, but clinicians are unlikely to have access to this code in hospital use.

A caution about any pump-programming software: Because it requires protocols to be downloaded to the pump before each infusion, such software could impede clinicians' workflow. Facilities considering the Smiths Medical pump should be sure they can adapt their workflow to the requirements of the pump-programming software. For further discussion, see "Implementing Computer-Based Pump-Programming Systems" on page 9.

Conclusions

General Discussion

Overall, the six PCA pumps we evaluated for this issue offer at least adequate mechanical performance—that is, continuous delivery, bolus delivery, and lockout settings. Minor exceptions are the CADD-Prizm PCS II, which provides poor flow continuity at low flow settings, and the Hospira PCA 3, which allows a relatively large bolus after relief of a downstream occlusion. Given that performance is not a notable selection issue, characteristics that contribute to safe product use should be a facility's main concern when choosing a pump. Ease of use and advanced error-reduction features both fall into this category.

In particular, because of the value of the advanced error-reduction features that have become available for PCA pumps in the past few years, we now base our product ratings primarily on the availability of such features. We don't recommend the purchase of pumps that lack such features, even though those pumps may offer perfectly adequate performance. Several suppliers—including Baxter, Curlin Medical, Hospira, and Sigma (which plans to add PCA capabilities to its small ambulatory pump)—have stated that they plan to introduce new models or upgrades to existing models that include one or more error-reduction technologies within the next year. ECRI will review these pumps as new safety features are added and revise our ratings if appropriate.

As a general purchasing strategy, we recommend that hospitals first identify those pumps whose error-reduction features meet their needs, then narrow down their selection based on ease of use.

Ratings

These ratings cover not only the six pumps we tested for this issue but also five pumps that we evaluated in our May 2001 issue and that are still on the market. Within each rating category, units are listed alphabetically.

PREFERRED

Because pumps with dose error reduction systems and integrated bar-code scanners have a proven track record of enhancing safety in clinical use, we rate these units Preferred.

- **Alaris System PCA Module.** This unit is provided with Alaris's Guardrails software, a comprehensive

dose error reduction system designed to prevent medication errors by detecting programmed doses that are outside preset limits. It also offers a bar-code scanning module (not evaluated by ECRI) for clinician, patient, and drug-container identification. In addition, the PCA module is part of the Alaris System, which has a modular design that allows up to four simultaneous infusions, including infusions with available general-purpose and syringe infusion modules. Pulse oximetry and end-tidal capnography modules are also available. The unit's monitoring capabilities may be desirable for PCA use, even though PCA-related monitoring is not yet a standard of care and adds expense. (For further discussion, see "Physiologic Monitoring during PCA Therapy" on page 10.) Alaris currently offers wireless data transfer for downloading event logs and uploading drug libraries. It recently released software Version 8 for this pump, which includes several enhancements.

PCA Pump Ratings

Within each rating category, pumps are listed in alphabetical order.

Preferred

- Alaris System PCA Module
- Hospira LifeCare PCA 3

Acceptable

- Curlin Medical 4000 CMS
- Smiths Medical CADD-Prizm PCS II

Not Recommended

- Baxter Ipump Pain Management System
- Baxter PCA II
- Baxter Syndeo PCA Syringe Pump
- Hospira GemStar
- McKinley EpM
- SIMS Graseby 3300 PCA
- Smiths Medical (formerly SIMS Deltec) CADD-Legacy PCA Model 6300 ♦

- Hospira LifeCare PCA 3.** This pump is provided with an onboard bar-code reader that automatically identifies the contents of prefilled drug vials. In addition, the pump offers Profiles, a limited automatic pump-programming function that allows hospitals to develop up to 10 preset dosing protocols that hold initial programming settings for specific prefilled drug vials. Hospira states that a software upgrade planned for early 2006 will let facilities print and scan their own labels—this will allow facilities to use the pump’s bar-code reader and Profiles protocols for vials that the facility fills and labels in-house. In addition, Hospira plans to introduce dose error reduction system software for this pump in the future.

Selecting a PCA Pump	
If you want . . .	Then first consider . . .
. . . to combine PCA therapy with physiologic monitoring or general-purpose pump applications	Alaris System PCA Module
. . . to purchase prefilled (morphine and meperidine) drug syringes	Hospira LifeCare PCA 3
. . . a small, ambulatory-style pump	Curlin Medical 4000 CMS Smiths Medical CADD-Prizm PCS II

ACCEPTABLE

We give Acceptable ratings to pumps with computer-based pump-programming systems. While such systems do facilitate safe pump use, they have not been fully tested in a hospital environment: We are aware of only one hospital that is currently using computer-based pump programming for initial infusion settings (although several hospitals have purchased the software and may implement it at a later time). In addition, several clinicians we interviewed did not think that their facility could support a

workflow in which nurses must access computers to send protocols to a pump. For those facilities that cannot accommodate this workflow, we would consider the pumps Not Recommended.

We do judge computer-based pump-programming applications to be an advantage for use in a home care environment because these applications have a proven track record in such environments. (Dose error reduction systems and onboard bar-code scanners are not available in pumps intended for home use.)

Evaluation at a Glance (Page 1 of 3)				
Patient-Controlled Analgesic Pumps				
				
	Alaris System PCA Module	Baxter Ipump Pain Management System	Baxter PCA II	Baxter Syndeo PCA Syringe Pump
Rating	PREFERRED	NOT RECOMMENDED	NOT RECOMMENDED	NOT RECOMMENDED
Comments	Guardrails dose error reduction system detects programmed doses outside preset limits; bar-coding module provides clinician, patient, and drug-container identification	Does not offer advanced error-reduction features (Note: Product is on hold by supplier; no orders shipping to new accounts)	Does not offer advanced error-reduction features, has other drawbacks	Does not offer advanced error-reduction features (Note: Product is on hold by supplier; no orders shipping to new accounts)
Test results				
Human factors	★ Excellent	● Fair	● Good	● Fair
Performance	● Good	● Good	● Good	● Good
General safety features	★ Excellent	● Good	● Good	★ Excellent
Advanced error-reduction features	★ Excellent	✗ Poor	✗ Poor	✗ Poor
First evaluated	January 2006	May 2001	May 2001	January 2006

Evaluation

- Curlin Medical 4000 CMS.** This pump offers Curlin Medical's Clinical Management System (CMS) software, which sends information from a computer (either handheld or laptop) to automatically populate the pump's initial settings and provide dosing limits (the Titrate function) for subsequent programming changes. The pump performs well overall and has fewer disadvantages than the Smiths Medical CADD-Prizm PCS II, making it a somewhat better choice. This pump has two minor disadvantages: Some information on its display is presented in a small text that can be difficult for clinicians with poor vision to read, and there is no prompt to the clinician to clear the pump after an extended power-off (although this option is available merely by selecting "New Rx" from the startup menu).
- Smiths Medical CADD-Prizm PCS II.** This pump offers Smiths Medical's CADD-Sentry software, which sends information from a computer to automatically

populate the pump's initial settings and provide dosing limits for subsequent programming changes. Although it performs adequately, the pump has a number of disadvantages: It exhibits poor flow continuity at low flow rates. It also has a small screen and presents information in a small text that can be difficult for clinicians with poor vision to read. The pump's programming screens can be cumbersome to navigate, and clinicians felt that programming the pump manually, reviewing settings in the case of computer-based programming, and starting the pump took a long time. However, these disadvantages should not pose a safety risk if the facility uses the pump's Sentry software to send initial settings and dosing limits to the pump. Smiths Medical states that a future product upgrade (release date not yet announced) will include a bar-code scanner for drug/concentration identification and visual alerts for any programming parameters that have been changed from a protocol downloaded from Sentry software.

Evaluation at a Glance (Page 2 of 3)

Patient-Controlled Analgesic Pumps

				
	Curlin Medical 4000 CMS	Hospira GemStar	Hospira LifeCare PCA 3	McKinley EpM
Rating	ACCEPTABLE for facilities that can accommodate workflow*	NOT RECOMMENDED	PREFERRED	NOT RECOMMENDED
Comments	PC-based pump-programming software allows drug-specific, therapy-specific, or patient-specific dosing to automatically populate pump settings	Does not offer advanced error-reduction features	Bar-code reader automatically identifies contents of prefilled drug vials. Profiles automatic programming allows up to 10 preset dosing protocols for specific prefilled drug vials	Does not offer advanced error-reduction features, has significant additional drawbacks
Test results				
Human factors	● Good	● Good	★ Excellent	● Fair
Performance	● Good	● Good	● Good	● Fair
General safety features	● Good	● Good	● Fair	● Fair
Advanced error-reduction features	● Good	✗ Poor	★ Excellent	✗ Poor
First evaluated	January 2006	January 2006	January 2006	May 2007
* To use the automated programming function, this pump must be connected to a computer to download infusion protocols each time programming is changed. Some facilities may find this requirement impracticable. For such facilities, we rate this product Not Recommended.				

NOT RECOMMENDED

The following pumps lack advanced error-reduction features. Therefore, even though most of them perform adequately overall, we don't recommend their purchase because we consider them less desirable than pumps that do offer such features. (As noted above, the Not Recommended rating would also apply to either of the pumps currently rated Acceptable for any facility that cannot accommodate the workflow requirements of those pumps' automated pump-programming features.)

With two exceptions, the pumps below would be rated Acceptable if they were equipped with effective advanced error-reduction features. The exceptions are the McKinley EpM, which had already been rated Not Recommended in our 2001 Evaluation due to performance and safety issues, and the SIMS Grasehy 3300 PCA.

- **Baxter Ipump Pain Management System.** (Note: This product is currently on hold. As of press time, Baxter was not shipping Ipumps to new accounts. See

"Status of Three Baxter PCA Pumps" on page 15.) While some users found it difficult to load the administration sets, this could be remedied by training and was not a safety concern.

- **Baxter PCA II.** This pump's data logs are difficult to print, its occlusion alarm can be silenced for five minutes, and pump settings are lost if the pump is shut off in continuous mode.
- **Baxter Syndeo PCA Syringe Pump.** (Note: This product is currently on hold. As of press time, Baxter was not shipping Syndeo pumps to new accounts. See "Status of Three Baxter PCA Pumps" on page 15.) While this pump has a large, clear display and a contoured dose-request pendant, it has a variety of significant disadvantages. For example, it lacks a continuous display of pump settings. It also lacks an external power cord; it is powered solely by four D-cell batteries that should be replaced about once a week. We believe that locating all PCA pumps and changing all four

Evaluation at a Glance (Page 3 of 3)			
Patient-Controlled Analgesic Pumps			
			
	SIMS Graseby 3300 PCA	Smiths Medical CADD-Legacy PCA Model 6300*	Smiths Medical CADD-Prizm PCS II
Rating	NOT RECOMMENDED	NOT RECOMMENDED	ACCEPTABLE for facilities that can accommodate workflow**
Comments	Does not offer advanced error-reduction features, has significant additional drawbacks	Does not offer advanced error-reduction features, has other drawbacks	CADD-Sentry software sends information from a computer to automatically populate pump's initial settings and provide dosing limits for subsequent programming changes, however, pump has several drawbacks
Test results			
Human factors	● Good	● Good	● Fair
Performance	● Good	● Good	● Good
General safety features	● Good	● Good	● Good
Advanced error-reduction features	✗ Poor	✗ Poor	● Good
First evaluated	May 2001	May 2001	January 2006
<p>* Evaluated in 2001 under the SIMS Dellec name.</p> <p>** To use the automated programming function, this pump must be connected to a computer to download infusion protocols each time programming is changed. Some facilities may find this requirement impracticable. For such facilities, we rate this product Not Recommended.</p>			

batteries so often is onerous for staff and expensive for facilities. Baxter states that it plans to offer both a field-upgrade kit for installing power cords and a future upgrade to include Baxter's dose error reduction

Pumps for Home Care

Many of the ambulatory-style pumps we have evaluated since 2001 are also marketed for use in alternate settings such as home care, including two units we tested for this issue—the Curlin Medical 4000 CMS and Smiths Medical CADD-Prizm PCS II. Both pumps offer computer-based pump-programming applications—the CMS software on the Curlin Medical pump and the CADD-Sentry software on the Smiths Medical pump. Such applications have been successfully implemented in home care, and we expect that the software on these two pumps will reduce programming errors in this environment.

Because the home environment is less hectic than a hospital setting and usually involves one-on-one care and minimal changes to pump settings, the workflow drawbacks associated with automated pump-programming features (described elsewhere in this issue) are unlikely to affect home use.

Both pumps are rated Acceptable. Although the CADD-Prizm may take more time to program, we don't anticipate that this will be a significant drawback in the home care environment. ♦

software. If these upgrades are implemented well, ECRI would consider upgrading the pump's rating.

- **Hospira GemStar.** Although it lacks advanced safety features, this pump performs adequately in all other areas. Hospira states that it plans to offer dose error reduction system software for the GemStar in 2007. If this software is implemented well, ECRI would consider upgrading the pump's rating.
- **McKinley EpM.** This pump lacks a useful data log, is difficult for some users to program, lacks backlighting, lacks a clear or reset function when it is turned back on after shutoff, has alarms that can be silenced for five minutes, and has a lockbox that is easy to open. This pump is a poorer choice than most of the other pumps. We do not expect that the addition of advanced safety technologies, without addressing the previously identified disadvantages, would cause us to rate this pump Acceptable.
- **SIMS Graseby 3300 PCA.** This pump defaults to the last programmed drug concentration and lacks a clear or reset function when turned back on after shutoff. It is a poorer choice than most of the other pumps. We do not expect that the addition of advanced safety technologies, without addressing the previously identified disadvantages, would cause us to rate this pump Acceptable.
- **Smiths Medical (formerly SIMS Deltac) CADD-Legacy PCA Model 6300.** This pump defaults to the last programmed drug concentration, lacks backlighting, and lacks a clear or reset function when turned back on after shutoff. ♦

Health Devices Ratings System

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 Category: Acceptable for Use

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.

Ratings Category: Unacceptable

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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