

# **REPORT ON SUBCUTANEOUS INFUSION DEVICES**

## **Alternative Devices to Graseby Syringe Drivers Currently Available on the Australian Market**

**May 2009**

### **Appendix 1**

**Self Report by Companies against 34 Criteria Identified by PCA and CPCRE**



**Palliative  
Care  
Australia**

## About this information

The manufacturers of infusion devices have provided the following information about devices available on the Australian market. Each company has reported against the 34 criteria identified by the aged care and palliative care sectors for each device. The information is exactly as received by PCA from the companies.

In some cases extra information for clarification has been obtained from the companies and included in the report, however the information in these original responses from the companies has not been changed. As a result there may be minor variations between this information in the original company's submission and the information presented in the Report on Subcutaneous Infusion Devices.

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## Criteria for the selection of a subcutaneous infusion device

<b>Safety</b>	
1. tamper resistant and tamper evident (through alarms, logs or physical measures)	2. contains record log for drug audit purposes
3. patient bolus demand facility with lockout (for dosages beyond a certain volume per hour or per block of time)	4. "user" and "administrator only" functions
5. alarm to specify user error	6. failsafe stop/alarm on internal error
7. visual indication of amount of drug delivered and amount of drug remaining in syringe	8. lock-out system to ensure delivery of set amount in set time
<b>Simplicity</b>	
9. easy to set up and operate	10. large, simple control interface with clear indication of dosing rate in ml/min, ml/hour or ml/day (only one)
11. no complicated programming	12. disposable consumables
13. disposable infusion system (use only once)	14. system comes pre-prepared at different doses
<b>Cost</b>	
15. similar to the cost of current devices	16. low consumable costs
17. low maintenance costs	
<b>Functionality</b>	
18. lifespan of more than 5 years	19. compatible with a range of different consumables
20. accurate, precise and reliable in delivery	21. delivers smooth, even flow
22. capacity to delivery up to 50ml over 24 hours	23. programmed to run at ml/time period <u>not</u> mm/time period
24. capacity to deliver several drugs in combination	25. lightweight and easily portable
26. indication when the pump is working and not working (i.e. blinking light)	27. easy access to maintenance and repair facilities
28. long life battery and capable of running on DC power	29. appropriate length of infusion line
<b>Transferability</b>	
30. suitable in different palliative care settings: hospital/home/RACF/rural	31. suitable for most populations: e.g. paediatric/aged care/MND/dementia
32. suitable for use by most centres	
<b>Other</b>	
33. supplied with an education package	34. availability of on-line education package

## AD Syringe Driver

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<b>Safety</b>	
1. tamper resistant and tamper evident (through alarms, logs or physical measures)	There are 12 alarms for warning alerts, alarms and technical issues. A key lock mechanism protects the syringe from operating damage or interference. A keypad lock feature can be enabled or disabled via the main menu.
2. Contains record log for drug audit purposes	Detailed event log for 2000 events. Downloadable to computer via RS232. Memory retention for up to 9 months
3. "User" and "Administrator" only functions	"User Function" via the Main Menu has options for altering clinical parameters such as - occlusion level; near end of infusion point; end of infusion point; bolus default and keypad lock. "Administrator Function" is via Safety Software and RS232 for technical configuration and software upgrades. User functions can be configured and locked out via software programme.
4. Patient bolus demand facility with lockout (for dosages beyond a certain volume per hour or per block of time)	No lockout Feature or patient demand device. Bolus volume selectable from range of 0.0-9.9 in 0.1ml increments. Default bolus volume is set at 2ml
5. Alarm to Specify User Error	12 Separate alarms with alarm and screen prompts are displayed on red background . Alert / Warning Alarms display event but do not halt infusion. Alarm conditions display event and halt the infusion.
6. Failsafe stop alarm on internal error	Internal system failure displays code number for technical diagnosis and shuts down syringe driver.
7. Visual indication of amt of drug delivered and amt of drug remaining in syringe	Syringe driver calculates precise syringe volume via 5 point detection system and infusion rate/ time entered. Displays volume to be infused (VTBI) and time remaining at current infusion settings on main screen.
8. Lock out to ensure delivery of set amount in set time.	Syringe is locked within syringe case via a key lock. A keypad lock function can be enabled or disabled via main menu. Audible and visual alarm warning if cover is removed or tampered with during an infusion.
<b>Simplicity</b>	
9. Easy to set up and operate	Loading a syringe and starting an infusion is easy as device has intuitive user interface via 5 keys control pad which simplifies programming.
10. Large simple control user interface with clear indication of dosing rate in ml/min, ml/hr or ml/day	Large LCD screen display with adjustable backlight. Easy to read critical data at a glance. Displays infusion rate in ml/hr, volume to be infused, total volume infused, time in hrs/mins to end of infusion and battery indicator.
11. No complicated programming	Simple 5 key control pad. Programmed menu screen with option table.
12. Disposable Consumables	Compatible with all brands of extension sets.
13. Disposable Infusion System	N/A
14. System comes pre-prepared at different doses	N/A

<b>Cost</b>	
15. Similar to the cost of current devices	Yes. \$ 2500. Pricing offered for qty breaks.
16. low consumable costs	Yes. Any brand of extension set can be used.
17. low maintenance costs	24 months warranty offered. Ongoing service and software upgrades offered by Cardinal Health Technical Support Services.
18. Lifespan more than 5 years	Yes - if ongoing service is done.
19. Compatible with a range of different consumables.	Yes. Compatible with all standard leuc lock syringes and extension sets.
20. Accurate, precise and reliable in delivery	Volumetric Accuracy +/- 2%
21. Delivers smooth and even flow	The AD Syringe Driver uses a " friction drive" to push the syringe thumb plate. This type of driver does not require a thread, but uses angled bearings clamped to hardened steel bar to produce the forward motion
22. Capacity to deliver 50ml over 24 hrs	No. Maximum syringe size is 30 ml. 30ml syringes deliver 30 ml of fluid
23. Programmed to run at ml/time period not mm/time.	Yes. Delivers ml/hr in timed mode.
24. Capacity to deliver several drugs in combination	Yes. Drug combinations delivered in one syringe
25. Lightweight and easily portable	Total weight including rechargeable battery and syringe cover is 450 g
26. Indication when the pump is working and not working.	Alarm or warning conditions displayed with red backlight and alarm / warning description
<b>Transferability</b>	
27. Easy access to maintenance and repair facilities	Maintenance can be carried out at Cardinal Health Technical Service Centers.
28. Long life battery capable on DC power	Powered by internal rechargeable 7.4v Lithium-Ion battery pack. Charger cradle powered by external transformer. Battery operating period is 72 hrs from full charge @ 1ml / hr.
29. Appropriate length of infusion line (where proprietary line necessary).	No proprietary line is required.
30. Robust	Splash proof when in carry case. Waterproof to IPX4 when in waterproof bag. Meets electrical safety standards BS EN 60601-1; BS EN 60601-2-24.
<b>Other</b>	
31. Suitable in different palliative care settings – hospital/ home/RACF/rural	The AD is designed to meet fluid and drug delivery requirements in hospital, palliative care and community settings
32. Suitable for most populations: eg: paediatric/ aged care/dementia/MND	Can be used in all settings and types of infusions including intravenous, intra arterial and subcutaneous. Infusion rate, bolus option, occlusion and infusion settings can be configured for specific clinical needs.
33. Suitable for use by most centres	Yes
<b>Other</b>	
34. Supplied with education package	On site clinical training and ongoing support is provided. Education tools and reference materials include directions for use manual, quick reference guides, posters and pocket size reference cards.
35. Availability of on-line education package	On line training tool for the AD Syringe Driver is available with both interactive and education options.

## GemStar®

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 Name of device: GemStar®  
 Contact name: Chris Chappell  
 Contact telephone: 02 8335 1003  
 Contact email: [chris.chappell@hospira.com](mailto:chris.chappell@hospira.com)

<b>Safety</b>	
1. tamper resistant and tamper evident (through alarms, logs or physical measures)	The GemStar® keypad lockout restricts access to various options. Four lock levels are available: Full, Therapy, Rate, and Continuous.
2. contains record log for drug audit purposes	The GemStar® maintains a history event log, with a date and time stamp of each event for each program. Review the history on the display, or download it to a printer or computer. Current program and 400-event (history) log protected by internal lithium battery-backed memory for at least one year after power is removed.
3. patient bolus demand facility with lockout (for dosages beyond a certain volume per hour or per block of time)	GemStar®: The bolus delivery could be locked out by one of the following choices: bolus lockout period, bolus per-hour limit, or 1-hour or 4-hour dose limit.
4. “user” and “administrator only” functions	The GemStar® keypad lockout restricts access to various options. Four lock levels are available: Full, Therapy, Rate, and Continuous.
5. alarm to specify user error	The GemStar® provides alarms that clearly indicate the specific problem causing the alarm condition. All alarms include both visual and audible cues.
6. failsafe stop/alarm on internal error	The Gemstar pump stops and displays an internal error and provides the user with both an audible and visual alarm. The GemStar® audible alarm can be momentarily silenced; however, after silencing, the alarm will automatically reactivate after 2 min or less. It shall not be possible to indefinitely disable audible alarms without correcting the problem that triggered the alarm.
7. visual indication of amount of drug delivered and amount of drug remaining in syringe	The GemStar® LCD displays the total amount delivered, rate of infusion, and infusion status such as a loading dose.
8. lock-out system to ensure delivery of set amount in set time	The Gemstar® keypad is lockout that restricts access to various options. Four lock levels are available: Full, Therapy, Rate, and Continuous. The Gemstar also has lockboxes options for narcotics delivery.
<b>Simplicity</b>	
9. easy to set up and operate	GemStar®: Built-in controls and functionality are key to safety and ease of use. Intuitive, menu-driven programming facilitates ease of use, while the standard format of the numeric keypad improves speed and accuracy of data entry. The forced program review and the help key ensure accuracy and prevent errors. An infusion can be programmed in as few as 4 easy steps.
10. large, simple control interface with clear indication of dosing rate in ml/min, ml/hour or ml/day (only one)	The GemStar® offers Seven Therapies, each therapy offered has different information displayed on the screen. Drug and concentration are displayed on every programming screen of the LCD. Each device will display its dosing rate as configured by the facility.
11. no complicated programming	GemStar®: Intuitive, menu-driven programming facilitates ease of use. Both these devices can be configured to the facilities best clinical practice thus the programming are suitable based on practice.
12. disposable consumables	Hospira’s electronic catalog on <a href="http://www.Hospira.com">www.Hospira.com</a> may be accessed by item for product specifications on all solutions, sets, equipment, disposables and other Hospira products. However, please note, not all consumables appearing on the U.S website are immediately available but can be ordered if the item is not currently in Australia and used as a high inventory item.
13. disposable infusion system (use only once)	We have a complete range of disposables suitable for use with the GemStar® that are compatible for their application and use.
14. system comes pre-prepared at different doses	The GemStar® offers Seven Therapies, each therapy offered has different information displayed on the screen. Drug and concentration are displayed on every programming screen of the LCD.

<b>Cost</b>	
15. similar to the cost of current devices	Yes, \$2,500. Prices are subject to negotiation and dependent upon volume consumption.
16. low consumable costs	Please note: these are indicative prices subject to negotiation and volume consumption:  GEMSTAR SET PLAIN WITH ANTISIPHON VALVE - \$16.00 per set  GEMSTAR PCA SYRINGE SET - \$16.00 per set
17. low maintenance costs	24 month warranty with the option to extend the warranty for a further 3 years at a cost of \$100/pump/yr or responsive costing of \$90 per hour, if required.
<b>Functionality</b>	
18. lifespan of more than 5 years	Factors that most commonly affect average expected device life are the frequency of use and proper maintenance. As a general rule, if an account properly services and maintains the device, on average the device should last 5 - 7 years. Mean Time Between Failure: GemStar® - 5.9 years
19. compatible with a range of different consumables	Hospira devices require the use of GemStar® pump sets which come in a wide variety of clinical applications to help meet your infusion needs.
20. accurate, precise and reliable in delivery	GemStar®: Accuracy Rate: +/- 10% for rates of 0.1 to less than 5 mL/hr; +/- 5% for rates of 5 to 1000 mL/hr.
21. delivers smooth, even flow	GemStar®: In Pain Management Mode the total infusion volume is limited to 0.1 mL - 25 mL. Total infusion volume is 0.1 mL - 9,999.9 mL for all other therapies
22. capacity to deliver up to 50ml over 24 hours	GemStar®: The total infusion volume is 9,999 mL and is dependent is configurable to have a lower total infusion volume depending on facilities guidelines.
23. programmed to run at ml/time period <u>not</u> mm/time period	GemStar®: mcg/kg/hr, mcg/min, mg/kg/min, mg/kg/hr, mg/min, mL/hr, mg/hr, mcg/hr, grams/hr, ng/kg/min, U/kg/hr, U/min, U/hr, mU/min, mEq/hr
24. capacity to deliver several drugs in combination	Yes
25. lightweight and easily portable	GemStar®: Height: 5.5 in. (14.0 cm) x Width: 3.8 in. (9.7 cm) x Depth: 2.0 in. (5.1 cm). Weight approximately 17 oz. (482 grams) excluding batteries.
26. indication when the pump is working and not working (i.e. blinking light)	GemStar®: The LCD displays the total amount delivered, rate of infusion, alarms and condition. When the device is not in use the display clears. It also has an indicator arrow on the screen.
27. easy access to maintenance and repair facilities	Yes, our service centre is located at:  Unit 4A, 2 – 12 Lord Street Botany, NSW, 2019
28. long life battery and capable of running on DC power	GemStar®: Using two fresh, disposable AA batteries or a charged battery pack, at temperatures between 59° F and 95° F (15° C and 35° C), the pump is capable of delivering approximately: 96 hours at rates below 5 mL/hr 48 hours at rates at or above 5 mL/hr but below 25 mL/hr 24 hours at rates at or above 25 mL/hr but below 125 mL/hr The optional battery pack needs to be connected to the AC mains adaptor for at least 8 hours to completely recharge. You can continue to use the GemStar® device while the optional battery pack is recharging, but the recharge time will increase.
29. appropriate length of infusion line (where proprietary line necessary)	279cm in length
30. robust	GemStar®: Advanced software allows for customized therapy configuration •“Back-up” and “Change” keys simplify programming •Prompted program steps facilitate data entry •Large Font, four-line, easy-to-read LCD display •Speed Protocols save time, increase compliance with standing orders and help reduce programming errors •Numeric keypad improves speed and accuracy of data entry •Set Based Free-Flow Protection—Flow Stop

	<ul style="list-style-type: none"> <li>– Automatic passive engagement</li> <li>– When the cassette is released from the pump the integral Flow Stop is placed in the closed position</li> <li>•User selectable keypad lockouts help prevent misuse</li> <li>– Four lock out levels</li> <li>– Auto locking function</li> <li>– “Hot Key” to quickly unlock pump</li> <li>•Therapy ranges help to ensure dose accuracy</li> <li>•Confirmation screens provide the opportunity for a redundant check of programming entries before infusion begins: Forced Program Review</li> <li>•“Help” key assists user to respond to alarms</li> </ul>
<b>Transferability</b>	
31. suitable in different palliative care settings: hospital/home/RACF/rural	GemStar®: Provides safe, versatile drug delivery in traditional hospitals, in outpatient clinics, in home care settings, in air and ambulance transport.
32. suitable for most populations: e.g. paediatric/aged care/MND/dementia	GemStar®: Physicians or certified, licensed healthcare professionals should always oversee infusions. Healthcare professionals should always supervise device users and instruct users in device operation and troubleshooting. Provides safe, versatile drug delivery in traditional hospitals, in outpatient clinics, in home care settings, in air and ambulance transport.
33. suitable for use by most centres	GemStar®: Provides safe, versatile drug delivery in traditional hospitals, in outpatient clinics, in home care settings, in air and ambulance transport.
<b>Other</b>	
34. supplied with an education package	Yes
35. availability of online education package	No, but we have e-learning CD ROMS available upon request

## Niki T34 and T34 PCA

Company name: REM SYSTEMS Pty Ltd

Name of device: T34 and T34 PCA

Contact name: Frank Elwin 0438 043 854, Kellie Roberts 0416 006 400

Contact telephone: 02 9878 0992

Contact email: felwin@remsystems.com.au

<b>Safety</b>	
1. tamper resistant and tamper evident (through alarms, logs or physical measures)	At least 10 separate audible and visual alarms with message on screen for both clinical and technical issues. Protective case( lock box) available on request
2. contains record log for drug audit purposes	Pump logs up to 500 events for download to PC for audit purposes
3. patient bolus demand facility with lockout (for dosages beyond a certain volume per hour or per block of time)	Bolus option is available in a T34 software version. Lockout available in the T34PCA only
4. "user" and "administrator only" functions	T34 has 2 levels of security codes. First is for changing clinical parameters and the second (Technician Menu) to set MAX flow rate and includes technical functions and testing protocols. Keypad lock is available for user.
5. alarm to specify user error	At least 10 separate audible and visual alarms with message on screen for both clinical and technical issues.
6. failsafe stop/alarm on internal error	Yes, Technical error alarm
7. visual indication of amount of drug delivered and amount of drug remaining in syringe	Pump continually displays infusion RATE. Press Info button once to show REMAINING volume and volume infused. The pump display is a 4 line LCD display (122 x 32 pixels).
8. lock-out system to ensure delivery of set amount in set time	The T34 has several lockout features that ensure that the unintended programming key presses do not occur. The T34 syringe is contained within a locked box. Program lock function can be enabled with a special code to ensure patient cannot tamper with the program The keypad has a locking feature that prevents unintentional power off.
<b>Simplicity</b>	
9. easy to set up and operate	All functions are easy to set up and operate. Initial set up through the change set up menu is required. Following this to commence an infusion takes four key presses to begin an infusion.
10. large, simple control interface with clear indication of dosing rate in ml/min, ml/hour or ml/day (only one)	The Niki T34 has a clear LCD display screen with backlight. Rate is constantly displayed in ml/hr. The control interface is easy to navigate with basic fast forward and back keys. Up and down arrows are also used to set rate etc. To confirm or cancel the YES or NO keys are used.
11. no complicated programming	The NIKI T34 programming is setup initially in the change set up menu once only. To start an infusion then takes 4 key presses. (With program Lock ON) When program lock is disabled the user is required to program in rate or duration in each time. This is not complicated and simple instructions are displayed on the pump.
12. disposable consumables	Any brand of syringe and extension sets are able to be used.
13. single use infusion system	N/A
14. system comes pre-prepared at different doses	N/A
<b>Cost</b>	
15. similar to the cost of current devices	~\$2100 Lockbox and carry bag \$250
16. low consumable costs	Any brand of syringe and extension sets are able to be used.
17. low maintenance costs	12 months parts and labour warranty is provided. Ongoing regular servicing available through the REM service centre or through trained on site biomedical engineer. Generally once a year calibration required.

<b>Functionality</b>	
18. lifespan of more than 5 years	The user must maintain adequate servicing to ensure ongoing performance of the pump. Expected lifespan >7 years
19. compatible with a range of different consumables	Any brand of syringe and extension sets are able to be used.
20. accurate, precise and reliable in delivery	+/- 5% system accuracy ( pump and set)
21. delivers smooth, even flow	Syringe pump has a motor driven linear actuator, pulsed motion
22. capacity to deliver up to 50ml over 24 hours	The NIKI T34 will accept up to a 50ml syringe, the maximum fluid volume for this size syringe is ~37ml.
23. programmed to run at ml/time period <u>not</u> mm/time period	Yes. The NIKI T34 can deliver in duration mode ( time/dose) <b>or</b> ml/hr mode
24. capacity to deliver several drugs in combination	Drugs can be combined in single syringe
25. lightweight and easily portable	Total weight of NIKI T34 including battery is 240grams (210grams without battery).
26. indication when the pump is working and not working (i.e. blinking light)	The NIKI T34 has a dual colour LED that blinks indicating operation. Green shows infusing, Red when stop or alarm
27. easy access to maintenance and repair facilities	Maintenance can be performed on site or at a REM service centre
28. long life battery and capable of running on DC power	The T34 is operational on Duracell 9 volt alkaline battery. Optional 12V model available eg Cigarette lighter
29. appropriate length of infusion line (where proprietary line necessary)	No proprietary line required for this device
30. robust	Meets IEC/EN 60601-1, 60601-2-24,4 and ISO13485 Yes. For extra protection a protective case and carry bag is available. Meets
<b>Transferability</b>	
31. suitable in different palliative care settings: hospital/home/RACF/rural	Suitable for all listed settings. The NIKI T34 is lightweight and ambulatory allowing it to be used in a variety of settings including in the home and air medical retrieval
32. suitable for most populations: e.g. paediatric/aged care/MND/dementia	NIKI T34 is suitable for a variety of applications. Flow rates from 0.1ml to 1000ml/hr. Varying pressure settings enable the pump to be used in various clinical settings
33. suitable for use by most centres	The T34, T34L and T34I PCA are able to accommodate all user options and centres
<b>Other</b>	
34. supplied with an education package	REM SYSTEMS provides educational packages including on site training, brief user guides, information posters and educational videos and web based programs. See <a href="http://www.cme-infusion.com/documents/pub/index.html">http://www.cme-infusion.com/documents/pub/index.html</a>
35. availability of online education package	Online education training is available on <a href="http://www.cme-infusion.com/documents/pub/index.html">http://www.cme-infusion.com/documents/pub/index.html</a> The training programme consists of basic operational training and programme option training. This first phase is completed and includes instruction on the NIKI T34 in the "PROGRAM LOCK" mode. This will be the most common mode of operation in the palliative care setting. Subsequent phases will include instruction on programming of the pump in all modes and will include the ability to print out a "Certificate of Completion" for the individuals records

## Niki T34L and T34L PCA

Company name: REM SYSTEMS Pty Ltd

Name of device: T34L and T34L PCA

Contact name: Frank Elwin

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<b>Safety</b>	
1. tamper resistant and tamper evident (through alarms, logs or physical measures)	At least 10 separate audible and visual alarms with message on screen for both clinical and technical issues. Protective case (lock box) available on request. Tamper evident security settings (program lock and keypad lock).
2. contains record log for drug audit purposes	Pump logs up to 1000 events for download to PC for audit purposes
3. patient bolus demand facility with lockout (for dosages beyond a certain volume per hour or per block of time)	Bolus option is available in both models (T34L/PCA) both products have a dose lockout period
4. "user" and "administrator only" functions	T34L has Several Lockout protection features. First is for changing clinical parameters and the second (Technician Menu) to set MAX flow rate and includes technical functions and testing protocols. Keypad lock is available for user. A lock box is also available
5. alarm to specify user error	At least 10 separate audible and visual alarms with message on screen for both clinical and technical issues.
6. failsafe stop/alarm on internal error	Yes, Technical error alarm
7. visual indication of amount of drug delivered and amount of drug remaining in syringe	Pump continually displays infusion RATE, Time remaining and will alternate between syringe size and brand and pump delivering. Press Info button once to show REMAINING volume and volume infused. Press button twice for battery life remaining shown as a percentage and in a graph form. The pump display is a 4 line LCD display (122 x 32 pixels).
8. lock-out system to ensure delivery of set amount in set time	The T34L/PCA has several lockout features that ensure that the unintended programming key presses do not occur. The T34L/PCA syringe is contained within a locked box. Program lock function can be enabled with a special code to ensure patient cannot tamper with the program The keypad has a locking feature that prevents unintentional power off. Dose lockout mode
<b>Simplicity</b>	
9. easy to set up and operate	All functions are easy to set up and operate. The program lock mode enables an infusion to commence in a few short steps. Initial set up through the change set up menu is required. Following this to commence an infusion take a few short steps to confirm details and then program can be commenced
10. large, simple control interface with clear indication of dosing rate in ml/min, ml/hour or ml/day (only one)	The Niki T34L/PCA has a clear display LCD display screen with backlight. The control interface is easy to navigate with basic ff and back keys. Up and down arrows are also used to set rate etc. To confirm or cancel the YES or NO keys are used.
11. no complicated programming	The NIKI T34L PCA pumps have programming for either a "Drug Library" or "Protocol" modes. This allows safe and easy programming
12. disposable consumables	Standard disposable single use Luer lock syringe and extension sets required.
13. disposable infusion system (use only once)	N/A
14. system comes pre-prepared at different doses	N/A
<b>Cost</b>	
15. similar to the cost of current devices	T34L Price \$2500
16. low consumable costs	The NIKI T34L/PCA does not require a dedicated infusion set. A large variety of syringes/extension sets are available through REM SYSTEMS if required
17. low maintenance costs	12 months parts & labour warranty provided. Ongoing regular servicing available through the REM service centre or through trained on site biomedical engineer.

<b>Functionality</b>	
18. lifespan of more than 5 years	The user must maintain adequate servicing to ensure ongoing performance of the pump
19. compatible with a range of different consumables	The Niki T34L/PCA is compatible with all standard Luer lock syringes and extension sets
20. accurate, precise and reliable in delivery	+/- 5% system accuracy (system)
21. delivers smooth, even flow	Syringe pump has a motor driven linear actuator, pulsed motion (540 pulses per mm)
22. capacity to deliver up to 50ml over 24 hours	The NIKI T34L will accept up to a 60ml syringe.
23. programmed to run at ml/time period <u>not</u> mm/time period	Yes. The NIKI T34L can deliver in duration mode ( time/dose) There are two options which include selecting from a pre programmed drug library or set protocols. These are specifically programmed to suit the individual needs of the facility..
24. capacity to deliver several drugs in combination	The NIKI T34L/PCA only accepts one syringe at a time.
25. lightweight and easily portable	Total weight of NIKI T34L/PCA excluding battery 400grams
26. indication when the pump is working and not working (i.e. blinking light)	The NIKI T34L/PCA has a dual colour LED light that indicates operation. Green shows infusing, Red when stop or alarm
27. easy access to maintenance and repair facilities	Maintenance can be performed on site or at a REM service centre
28. long life battery and capable of running on DC power	The T34L is operational on a re-chargeable Li-Polymer 1800mAh battery. Mains(DC) power can also be used.
29. appropriate length of infusion line (where proprietary line necessary)	No dedicated line required for this device
30. robust	Yes. For extra protection a carry bag is available
<b>Transferability</b>	
31. suitable in different palliative care settings: hospital/home/RACF/rural	Suitable for all listed settings. The NIKI T34L is lightweight and ambulatory allowing it to be used in a variety of settings including in the home and air medical retrieval
32. suitable for most populations: e.g. paediatric/aged care/MND/dementia	NIKI T34L is suitable for a variety of applications. Flow rates from 0.1ml to 1000ml/hr. Varying pressure settings enable the pump to be used in various clinical settings
33. suitable for use by most centres	The T34, T34L and T34/ PCA are able to accommodate all user options and centres
<b>Other</b>	
34. supplied with an education package	REM SYSTEMS will provide an educational package that includes on site training, brief user guides, information posters and educational videos
35. availability of online education package	Online education training is available on <a href="http://www.cme-infusion.com">www.cme-infusion.com</a> . The training programme consists of basic operational training and programme option training.

## CADD Legacy PCA

Company name: Smiths Medical Australasia  
 Name of device: CADD Legacy PCA  
 Contact name: Trent Enright  
 Contact telephone: 0419 536 885  
 Contact email: trent.enright@smiths-medical.com

<b>Safety</b>	
1. tamper resistant and tamper evident (through alarms, logs or physical measures)	Special designed keylock locks the disposable set into place, this will alarm if unintentionally tampered with. It also has 3 different lock levels for the keypad. Lock levels can only be changed with a numbered security code to restrict keypad access.
2. contains record log for drug audit purposes	Legacy logs the "Doses Given" and "Doses Attempted" up to 999. It also shows the amount delivered in units of either mg, mcg or ml up to 99999.95 or 99999.99 depending on the units. Logs up to 500 events using CADD specific software. Log includes all changes and alarms with time and date. Communication is through accessory jack connector.
3. patient bolus demand facility with lockout (for dosages beyond a certain volume per hour or per block of time)	Has the ability to provide bolus demands either patient initiated via keypad key or dosed cord (accessory) as well as clinician bolus via security code access. The dose lockout is between 5 minutes and 24hrs. Dose demands can also be limited in increments of 1 dose from 1-12 doses per hour,
4. "user" and "administrator only" functions	The keypad lock levels (which require security codes to alter) can be used to separate functions into user and administrator-giving clinicians (administrators) greater access to the variables of the unit. There is also a biomedical toolbox that can only be accessed via a security code. There is also available (non ambulatory) a security shell requiring a designated key to access.
5. alarm to specify user error	User alarms include "Air in Line Detected", "Battery Depleted", "Battery removed Pump wont run", "Error", "High Pressure", "Key Pressed, Please release", "Low Bat", Motor Locked, remove all power", "No Disposable, Clamp Tubing", "No Disposable, Pump wont run", "Power Lost while pump was on", "Programming incomplete", "Remote dose Cord removed", "Reservoir Volume Empty", "Res Vol Low", "Service Date See manual", "Upstream Occlusion" and "Value not saved".
6. failsafe stop/alarm on internal error	Key hardware safety features include Timer Circuit, Motor Driver/Motor and Voltage Detector "watchdogs"-these watchdogs perform unique functions to insure the overall safety of the device. Hardware related fault detection includes Program and RAM memory check, motor circuit check and keyboard encoder check-a system fault screen will be displayed with an audible alarm and the pump will stop drug delivery. Data handling software is also constantly reviewed. This includes data stored in RAM, EEPROM, NOVRAM, data used in calculations and time data registers-the pump will display a system fault screen and the pump will stop drug delivery.
7. visual indication of amount of drug delivered and amount of drug remaining in syringe	Includes: Reservoir Volume remaining Doses Given 0 to 999 Doses Attempted 0 to 999 Given 0 to 99999.95 or 99999.99 in unit increments depending on the concentration.
8. lock-out system to ensure delivery of set amount in set time	If the unit is set at Lock Level 2 (LL2) only starting and stopping the pump, and resetting the reservoir volume can be accessed via a security code. This prevents inadvertent altering of the set rate.
<b>Simplicity</b>	
9. easy to set up and operate	Features an enhanced LCD display screen and easy to read keypad for simple operation, programming adjustments and troubleshooting
10. large, simple control interface with clear indication of dosing rate in ml/min, ml/hour or ml/day (only one)	Interface is comprehensible and concise with the keys labelled. Display screen clearly shows the dosing rate whilst pump is running in ml/hr, mg/hr or mcg/hr as selected.
11. no complicated programming	Programming is simple as described above using a screen by screen system stepping the user through each screen to ensure safety.

12. disposable consumables	A large range of consumables are available making the Legacy PCA flexible and versatile. These include a 50ml and 100ml cartridges (including a yellow epidural 100ml), administration sets with bag spikes and anti siphon valves as well as epidural designated sets identified by yellow colouring.
13. disposable infusion system (use only once)	No
14. system comes pre-prepared at different doses	No
<b>Cost</b>	
15. similar to the cost of current devices	Currently available list price of \$1600.00 (list price of the MS Drivers \$1700.00)
16. low consumable costs	Moderate cost of consumables
17. low maintenance costs	Functional testing can be done in-house. Can arrange service agreements with the repair facility we have in Australia.
<b>Functionality</b>	
18. lifespan of more than 5 years	Yes (if looked after). Still have 1 <sup>st</sup> generation CADD pumps active in hospitals that are well over five years old. Repair lifetime of device is 5 years from cease of manufacture.
19. compatible with a range of different consumables	Smiths Medical Australasia has a large range of designated consumables for the CADD Legacy PCA (no generic sets available).
20. accurate, precise and reliable in delivery	System self tests every time pump is turned on. System accuracy equals 6% (nominal-3% set and 3% pump).
21. delivers smooth, even flow	Peristaltic action that delivers 0.05nl with each movement. Flow is monitored by an upstream occlusion sensor (from set to pump) and downstream occlusion sensor (from set to patient).
22. capacity to deliver up to 50ml over 24 hours	Yes-Continuous rate of 0-50ml/hr
23. programmed to run at ml/time period <i>not</i> mm/time period	Yes ml/hr, mg/hr and mcg/hr
24. capacity to deliver several drugs in combination	Yes depending on drug compatibility.
25. lightweight and easily portable	Yes weighs 392g without consumable attachment.
26. indication when the pump is working and not working (i.e. blinking light)	Continual software monitoring alerts user via alarm and LCD screen if there are any system faults and defines them. When pump is on and running the word "RUN" is on permanently on the screen.
27. easy access to maintenance and repair facilities	Certified repair facility in Smiths Medical Australasia Head Office Brisbane. See Product Specialist to arrange loan unit whilst repaired (ISO standard 9001 and 13485).
28. long life battery and capable of running on DC power	Two AA batteries-40 hours at 30ml/hr or 14 days at 10ml/hr. Can use AC adaptor for DC power (accessory)
29. appropriate length of infusion line (where proprietary line necessary)	Extension sets available at 76cm/114cm/156cm with in line Anti-Syphon Valves (ASV).
30. robust	IPX 4 (splash proof). Comes with a protective pouch as standard.
<b>Transferability</b>	
31. suitable in different palliative care settings: hospital/home/RACF/rural	Yes-easy to use, various settings and comprehensive range of consumables make it flexible to suit a variety of needs and settings.
32. suitable for most populations: e.g. paediatric/aged care/MND/dementia	Yes
33. suitable for use by most centres	Yes
<b>Other</b>	
34. supplied with an education package	Training guides, Patient information booklet, Operators Manual, Quick reference cards for clinicians, interactive training CD, filling the medication cassette CD.
35. availability of online education package	Yes-filling the cassette is currently on our website <a href="http://www.smiths-medical.com">www.smiths-medical.com</a>

## CADD Legacy 1

Company name: Smiths Medical Australasia

Name of device: CADD Legacy 1

Contact name: Trent Enright

Contact telephone: 0419 536 885

Contact email: trent.enright@smiths-medical.com

<b>Safety</b>	
1. tamper resistant and tamper evident (through alarms, logs or physical measures)	It also has 3 different lock levels for the keypad. Lock levels can only be changed with a numbered security code to restrict keypad access.
2. contains record log for drug audit purposes	Legacy logs the "Doses Given" and "Doses Attempted" up to 999. It also shows the amount delivered in ml up to 99999. Logs up to 500 events using CADD specific software. Log includes all changes and alarms with time and date. Communication is through accessory jack connector.
3. patient bolus demand facility with lockout (for dosages beyond a certain volume per hour or per block of time)	Continuous rate.
4. "user" and "administrator only" functions	The keypad lock levels (which require security codes to alter) can be used to separate functions into user and administrator-giving clinicians (administrators) greater access to the variables of the unit. There is also a biomedical toolbox that can only be accessed via a security code. There is also available (non ambulatory) a security shell requiring a designated key to access.
5. alarm to specify user error	User alarms include "Air in Line Detected", "Battery Depleted", "Battery removed Pump wont run", "Error", "High Pressure", "Key Pressed, Please release", "Low Bat", Motor Locked, remove all power", "No Disposable, Clamp Tubing", "No Disposable, Pump wont run", "Power Lost while pump was on", "Value not saved", "Reservoir Volume Empty", "Res Vol Low", "Service Date See manual", and "Upstream Occlusion".
6. failsafe stop/alarm on internal error	Key hardware safety features include Timer Circuit, Motor Driver/Motor and Voltage Detector "watchdogs"-these watchdogs perform unique functions to insure the overall safety of the device. Hardware related fault detection includes Program and RAM memory check, motor circuit check and keyboard encoder check-a system fault screen will be displayed with an audible alarm and the pump will stop drug delivery. Data handling software is also constantly reviewed. This includes data stored in RAM, EEPROM, NOVRAM, data used in calculations and time data registers-the pump will display a system fault screen and the pump will stop drug delivery.
7. visual indication of amount of drug delivered and amount of drug remaining in syringe	Includes: Reservoir Volume remaining (1 to 9999ml) Given 0 to 99999.95ml in 0.05ml increments.
8. lock-out system to ensure delivery of set amount in set time	If the unit is set at Lock Level 2 (LL2) only starting and stopping the pump, and resetting the reservoir volume can be accessed via a security code. This prevents inadvertent altering of the set rate.
<b>Simplicity</b>	
9. easy to set up and operate	Features an enhanced LCD display screen and easy to read keypad for simple operation, programming adjustments and troubleshooting
10. large, simple control interface with clear indication of dosing rate in ml/min, ml/hour or ml/day (only one)	Interface is comprehensible and concise with the keys labelled. Display screen clearly shows the rate whilst pump is running.
11. no complicated programming	Programming is simple as described above using a screen by screen system stepping the user through each screen to ensure safety.
12. disposable consumables	A large range of consumables are available making the Legacy 1 flexible and versatile. These include a 50ml and 100ml cartridges (including a yellow epidural 100ml), administration sets with bag spikes and anti siphon valves as well as epidural designated sets identified by yellow colouring.

13. disposable infusion system (use only once)	No
14. system comes pre-prepared at different doses	No
<b>Cost</b>	
15. similar to the cost of current devices	Currently available list price of \$2975.00 (list price of the MS Drivers \$1700.00)
16. low consumable costs	Moderate cost of consumables
17. low maintenance costs	Functional testing can be done in-house. Can arrange service agreements with the repair facility we have in Australia.
<b>Functionality</b>	
18. lifespan of more than 5 years	Yes (if looked after). Still have 1 <sup>st</sup> generation CADD pumps active in hospitals that are well over five years old. Repair lifetime of device is 5 years from cease of manufacture.
19. compatible with a range of different consumables	Smiths Medical Australasia has a large range of designated consumables for the CADD Legacy 1 (no generic sets available).
20. accurate, precise and reliable in delivery	System self tests every time pump is turned on. System accuracy equals 6% (nominal-3% set and 3% pump).
21. delivers smooth, even flow	Peristaltic action that delivers 0.05nl with each movement. Flow is monitored by an upstream occlusion sensor (from set to pump) and downstream occlusion sensor (from set to patient).
22. capacity to deliver up to 50ml over 24 hours	Yes-Continuous rate of 0-3,000ml/24hr
23. programmed to run at ml/time period <u>not</u> mm/time period	Yes ml/24hr.
24. capacity to deliver several drugs in combination	Yes depending on drug compatibility.
25. lightweight and easily portable	Yes weighs 392g without consumable attachment.
26. indication when the pump is working and not working (i.e. blinking light)	Continual software monitoring alerts user via alarm and LCD screen if there are any system faults and defines them. When pump is on and running the word "RUN" is on permanently on the screen.
27. easy access to maintenance and repair facilities	Certified repair facility in Smiths Medical Australasia Head Office Brisbane. See Product Specialist to arrange loan unit whilst repaired (ISO standard 9001 and 13485).
28. long life battery and capable of running on DC power	Two AA batteries-15 hours at 125ml/hr or 14 days at 10ml/hr. Can use AC adaptor for DC power (accessory)
29. appropriate length of infusion line (where proprietary line necessary)	Extension sets available at 76cm/114cm/156cm with in line Anti-Syphon Valves (ASV).
30. robust	IPX 4 (splash proof). Comes with a protective pouch as standard.
<b>Transferability</b>	
31. suitable in different palliative care settings: hospital/home/RACF/rural	Yes-easy to use and comprehensive range of consumables make it flexible to suit a variety of needs and settings. Already used in variety of hospital specialties.
32. suitable for most populations: e.g. paediatric/aged care/MND/dementia	Yes
33. suitable for use by most centres	Yes
<b>Other</b>	
34. supplied with an education package	Training guides, Patient information booklet, Operators Manual, Quick reference cards for clinicians, interactive training CD, filling the medication cassette CD.
35. availability of online education package	Yes-filling the cassette is currently on our website <a href="http://www.smiths-medical.com">www.smiths-medical.com</a>

## CADD Legacy Plus

Company name: Smiths Medical Australasia

Name of device: CADD Legacy Plus

Contact name: Trent Enright

Contact telephone: 0419 536 885

Contact email: trent.enright@smiths-medical.com

<b>Safety</b>	
1. tamper resistant and tamper evident (through alarms, logs or physical measures)	It also has 3 different lock levels for the keypad. Lock levels can only be changed with a numbered security code to restrict keypad access.
2. contains record log for drug audit purposes	Legacy logs the "Doses Given" and "Doses Attempted" up to 999. It also shows the amount delivered in ml up to 99999. Logs up to 500 events using CADD specific software. Log includes all changes and alarms with time and date. Communication is through accessory jack connector.
3. patient bolus demand facility with lockout (for dosages beyond a certain volume per hour or per block of time)	Continuous rate and Intermittent Delivery mode
4. "user" and "administrator only" functions	The keypad lock levels (which require security codes to alter) can be used to separate functions into user and administrator-giving clinicians (administrators) greater access to the variables of the unit. There is also a biomedical toolbox that can only be accessed via a security code. There is also available (non ambulatory) a security shell requiring a designated key to access.
5. alarm to specify user error	User alarms include "Air in Line Detected", "Battery Depleted", "Battery removed Pump wont run", "Error", "High Pressure", "Key Pressed, Please release", "Low Bat", Motor Locked, remove all power", "No Disposable, Clamp Tubing", "No Disposable, Pump wont run", "Power Lost while pump was on", "Value not saved", "Reservoir Volume Empty", "Res Vol Low", "Service Date See manual", and "Upstream Occlusion".
6. failsafe stop/alarm on internal error	Key hardware safety features include Timer Circuit, Motor Driver/Motor and Voltage Detector "watchdogs"-these watchdogs perform unique functions to insure the overall safety of the device. Hardware related fault detection includes Program and RAM memory check, motor circuit check and keyboard encoder check-a system fault screen will be displayed with an audible alarm and the pump will stop drug delivery. Data handling software is also constantly reviewed. This includes data stored in RAM, EEPROM, NOVRAM, data used in calculations and time data registers-the pump will display a system fault screen and the pump will stop drug delivery.
7. visual indication of amount of drug delivered and amount of drug remaining in syringe	Includes: <b>Continuous rate ml/hr</b> Reservoir Volume remaining (1 to 9999ml) Given 0 to 99999.95ml in 0.05ml increments. <b>Intermittent</b> Dose volume 0.1 to 100ml Dose duration 1 min to 24hs Dose cycle 10min to 96hrs KVO rate 0 to 15ml/hr Dose starts in 1min to 96hrs Given 0 to 99999.95ml in 0.05ml increments Dose remaining in 1 min increments
8. lock-out system to ensure delivery of set amount in set time	If the unit is set at Lock Level 2 (LL2) only starting and stopping the pump, and resetting the reservoir volume can be accessed via a security code. This prevents inadvertent altering of the set rate.
<b>Simplicity</b>	
9. easy to set up and operate	Features an enhanced LCD display screen and easy to read keypad for simple operation, programming adjustments and troubleshooting

10. large, simple control interface with clear indication of dosing rate in ml/min, ml/hour or ml/day (only one)	Interface is comprehensible and concise with the keys labelled. Display screen clearly shows the rate whilst pump is running.
11. no complicated programming	Programming is simple as described above using a screen by screen system stepping the user through each screen to ensure safety.
12. disposable consumables	A large range of consumables are available making the Legacy Plus flexible and versatile. These include a 50ml and 100ml cartridges (including a yellow epidural 100ml), administration sets with bag spikes and anti siphon valves as well as epidural designated sets identified by yellow colouring.
13. disposable infusion system (use only once)	No
14. system comes pre-prepared at different doses	No
<b>Cost</b>	
15. similar to the cost of current devices	Currently available list price of \$3145.00 (list price of the MS Drivers \$1700.00)
16. low consumable costs	Moderate cost of consumables
17. low maintenance costs	Functional testing can be done in-house. Can arrange service agreements with the repair facility we have in Australia.
<b>Functionality</b>	
18. lifespan of more than 5 years	Yes (if looked after). Still have 1 <sup>st</sup> generation CADD pumps active in hospitals that are well over five years old. Repair lifetime of device is 5 years from cease of manufacture.
19. compatible with a range of different consumables	Smiths Medical Australasia has a large range of designated consumables for the CADD Legacy Plus (no generic sets available).
20. accurate, precise and reliable in delivery	System self tests every time pump is turned on. System accuracy equals 6% (nominal-3% set and 3% pump).
21. delivers smooth, even flow	Peristaltic action that delivers 0.05nl with each movement. Flow is monitored by an upstream occlusion sensor (from set to pump) and downstream occlusion sensor (from set to patient).
22. capacity to deliver up to 50ml over 24 hours	Yes-Continuous rate of 0-125ml/hr
23. programmed to run at ml/time period <u>not</u> mm/time period	Yes ml/hr.
24. capacity to deliver several drugs in combination	Yes depending on drug compatibility.
25. lightweight and easily portable	Yes weighs 392g without consumable attachment.
26. indication when the pump is working and not working (i.e. blinking light)	Continual software monitoring alerts user via alarm and LCD screen if there are any system faults and defines them. When pump is on and running the word "RUN" is on permanently on the screen.
27. easy access to maintenance and repair facilities	Certified repair facility in Smiths Medical Australasia Head Office Brisbane. See Product Specialist to arrange loan unit whilst repaired (ISO standard 9001 and 13485).
28. long life battery and capable of running on DC power	Two AA batteries-15 hours at 125ml/hr or 14 days at 10ml/hr. Can use AC adaptor for DC power (accessory)
29. appropriate length of infusion line (where proprietary line necessary)	Extension sets available at 76cm/114cm/156cm with in line Anti-Syphon Valves (ASV).
30. robust	IPX 4 (splash proof). Comes with a protective pouch as standard.
<b>Transferability</b>	
31. suitable in different palliative care settings: hospital/home/RACF/rural	Yes-easy to use and comprehensive range of consumables make it flexible to suit a variety of needs and settings. Already used in a variety of different hospital specialties.
32. suitable for most populations: e.g. paediatric/aged care/MND/dementia	Yes
33. suitable for use by most centres	Yes

<b>Other</b>	
34. supplied with an education package	Training guides, Patient information booklet, Operators Manual, Quick reference cards for clinicians, interactive training CD, filling the medication cassette CD.
35. availability of online education package	Yes-filling the cassette is currently on our website <a href="http://www.smiths-medical.com">www.smiths-medical.com</a>

## Master PCA – patient controlled analgesia syringe driver

Company name: Pharmatel Fresenius Kabi Pty Ltd  
 Name of device: Master PCA – patient controlled analgesia syringe driver  
 Contact name: Stefan Kneissl  
 Contact telephone: (02) 9391 5522  
 Contact email: stefan.kneissl@pfk.com.au

<b>Safety</b>	
1. tamper resistant and tamper evident (through alarms, logs or physical measures)	Yes – lockable cover that alarms if tampered with.
2. contains record log for drug audit purposes	Yes – last 5 patients data available for either printout or download.
3. patient bolus demand facility with lockout (for dosages beyond a certain volume per hour or per block of time)	Yes – from 1-90 minutes (1 minute increments) or from 2-12hours (1/2 hour increments).
4. “user” and “administrator only” functions	Yes – clinician dose allows titration of bolus if necessary.
5. alarm to specify user error	Yes – alarms indicate mains disconnection, hand set disconnection, data out of range, line disconnection, occlusion, close to empty syringe, empty syringe, battery close to empty, dose limit reached, end of infusion, syringe positioned incorrectly, protective cover open, battery discharged.
6. failsafe stop/alarm on internal error	Yes – watchdog alarm that prevents programming if internal check fails. Device complies with all Australian Electrical Standards.
7. visual indication of amount of drug delivered and amount of drug remaining in syringe	Yes –volumes delivered and remaining are displayed on screen.
8. lock-out system to ensure delivery of set amount in set time	Yes - Dose limit available from 10µg – 9999mg over 1-12 hours.
<b>Simplicity</b>	
9. easy to set up and operate	Yes – preset protocols and rolling menu.
10. large, simple control interface with clear indication of dosing rate in ml/min, ml/hour or ml/day (only one)	Yes – simplified screen displays necessary information. Can be customised.
11. no complicated programming	Yes – up to 5 preset protocols make programming simple.
12. disposable consumables	Yes – SE 1600 AR AS extension set with anti-siphon valve and Y connector with anti-reflux valve.
13. disposable infusion system (use only once)	No – the Master PCA is a syringe driver. The consumables are single use.
14. system comes pre-prepared at different doses	No – that depends upon staff and hospital protocol. It is possible to program up to 5 protocols in the Master PCA to match hospital protocol.
<b>Cost</b>	
15. similar to the cost of current devices	Yes
16. low consumable costs	Yes – again, dependent upon volume of use.
17. low maintenance costs	Yes – negotiable in service contract.
<b>Functionality</b>	
18. lifespan of more than 5 years	Yes – probable battery change required after 2 years (depending upon correct usage and storage).
19. compatible with a range of different consumables	Yes – 12 brands of syringes compatible (50cc and 20cc) which are then compatible with most syringe extension lines (depends upon hospital protocol).
20. accurate, precise and reliable in delivery	Drive mechanism $\leq \pm 1\%$ . Rate $\leq \pm 2\%$ with recommended syringes.
21. delivers smooth, even flow	Yes – trumpet curves available for syringe driver if required.
22. capacity to deliver up to 50ml over 24 hours	Yes

23. programmed to run at ml/time period <u>not</u> mm/time period	Yes – ml per hour programming.
24. capacity to deliver several drugs in combination	No – not possible without use of a separate device if safety features are to be utilised.
25. lightweight and easily portable	Reasonably – attaches easily to an IV pole.
26. indication when the pump is working and not working (i.e. blinking light)	Yes – several different options available (eg flashing screen, green light).
27. easy access to maintenance and repair facilities	Yes – technical manual available if requested. However, recommended only properly trained staff attempt servicing.
28. long life battery and capable of running on DC power	Yes - approx. 4 hours of battery life available (dependent upon appropriate storage and charging of pump when not in use).
29. appropriate length of infusion line (where proprietary line necessary)	Yes - SE 1600 AR AS extension set approx 180cm in length (2.2ml priming volume).
30. robust	Yes
<b>Transferability</b>	
31. suitable in different palliative care settings: hospital/home/RACF/rural	Yes - depending on local requirements +/- nursing supervision
32. suitable for most populations: e.g. paediatric/aged care/MND/dementia	Yes
33. suitable for use by most centres	Yes
<b>Other</b>	
34. supplied with an education package	Yes – as determined necessary in consultation with clinical educators at no charge.
35. availability of online education package	None currently

## Elastomeric Pump – Infusorn LV & SV, PainBlocker (RAI)

Company name: Baxter Healthcare Pty Ltd

Name of device: Elastomeric Pump – Infusorn LV & SV, PainBlocker (RAI)

Contact name: Judy Bott

Contact telephone: 02 8845 1538

Contact email: [judy\\_bott@baxter.com](mailto:judy_bott@baxter.com)

<b>Safety</b>	
1. tamper resistant and tamper evident (through alarms, logs or physical measures)	Tamperproof.
2. contains record log for drug audit purposes	No record log.
3. patient bolus demand facility with lockout (for dosages beyond a certain volume per hour or per block of time)	Yes. Basal Bolus or Patient Control Module with lockout time.
4. “user” and “administrator only” functions	Yes. Variable Flow rates for Multirate & PainBlocker adjusted by Administrator Tool.
5. alarm to specify user error	No. Noiseless, no alarms. Mechanical system non electronic.
6. failsafe stop/alarm on internal error	No. Mechanical system non electronic.
7. visual indication of amount of drug delivered and amount of drug remaining in syringe	Yes. Housing has a volume scale and device is reservoir is opaque.
8. lock-out system to ensure delivery of set amount in set time	Yes. Fixed Volume delivered over set time
<b>Simplicity</b>	
9. easy to set up and operate	Rapid onset. 3 steps: filling, priming, connecting.
10. large, simple control interface with clear indication of dosing rate in ml/min, ml/hour or ml/day (only one)	Yes. Dosing rate and length on outside housing of device.
11. no complicated programming	No Programming involved. Predetermined flow rate and infusion length.
12. disposable consumables	N/A
13. disposable infusion system (use only once)	Yes
14. system comes pre-prepared at different doses	Yes. See attached Elastomeric Professional Guide.
<b>Cost</b>	
15. Similar to the cost of current devices	Price list attached.
16. low consumable costs	No consumables required.
17. low maintenance costs	No maintenance required.
<b>Functionality</b>	
18. lifespan of more than 5 years	Single Use Only
19. compatible with a range of different consumables	Administration set not detachable
20. accurate, precise and reliable in delivery	Nominal volume is delivered within +/- 10% of nominal time
21. delivers smooth, even flow	High reservoir pressure makes flow rate accuracy consistent.
22. capacity to deliver up to 50ml over 24 hours	Yes.
23. programmed to run at ml/time period <u>not</u> mm/time period	Yes.
24. capacity to deliver several drugs in combination	Extensive and specific drug compatibility and stability data. (157 drugs)

25. lightweight and easily portable	Lightweight – 39 to 61g empty, discreet, easy to conceal
26. indication when the pump is working and not working (i.e. blinking light)	No.
27. easy access to maintenance and repair facilities	N/A
28. long life battery and capable of running on DC power	Portable system, gravity and power source independent
29. appropriate length of infusion line (where proprietary line necessary)	Line is attached to device.
30. robust	Yes
<b>Transferability</b>	
31. suitable in different palliative care settings: hospital/home/RACF/rural	Yes. Portable Device for Ambulatory Care.
32. suitable for most populations: e.g. paediatric/aged care/MND/dementia	Yes.
33. suitable for use by most centres	Yes.
<b>Other</b>	
34. supplied with an education package	Educational packages include Filling Procedure DVD and User Instruction Manual and Pocket Infusor Guide for Patients.
35. availability of online education package	N/A

**Palliative Care Australia**

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