



**Palliative
Care
Australia**

REPORT ON SUBCUTANEOUS INFUSION DEVICES

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

November 2007

ALTERNATIVE DEVICES TO GRASEBY SYRINGE DRIVERS CURRENTLY AVAILABLE ON THE AUSTRALIAN MARKET

NOVEMBER 2007



**Palliative
Care
Australia**

Table of contents

Aim	1
Overview	1
Why are Graseby syringe drivers no longer available?	2
The role of PCA and CPCRE	2
Sector consultation.....	2
What alternative devices are available?	3
Information from companies about alternative devices	4
Future work.....	9
Where can I get further information?	10

Aim

This report provides information to support decision making about the alternative to the Graseby Syringe Driver, following its withdrawal from sale in Australia from October 2007 and the phasing out of maintenance of existing devices in 2012.

This report recognises that the change in availability of the previous industry standard has necessitated, in the near term, decisions about alternative device purchasing, investment in health professionals' education and training and protocols for family and carer training.

A further aim of this report is to stimulate ongoing discussion within the palliative care and aged care sectors about the role of syringe drivers in the provision of quality care at the end of life across the diverse care settings in Australia.

Overview

Subcutaneous infusion devices (syringe drivers) are a means of providing symptom control via subcutaneous infusions of drugs to treat unrelieved pain and other distressing symptoms when other routes are inappropriate or no longer effective.

Since their introduction in the mid 1970's syringe drivers have played a role in enabling ambulatory and home based care outside of the hospital environment, thereby increasing the options of place of care for palliative patients.

Since this time the Graseby MS16a and MS26 syringe drivers have been the mainstay subcutaneous infusion devices in Australia. From October 2007, these devices are no longer compliant with the best practice standards for contemporary devices as set by the Therapeutic Goods Administration and have been voluntarily withdrawn from the market. While they can no longer be purchased, the manufacturer Smith

Medical has a formal agreement to continue to provide maintenance and service support for a further five years.

The palliative care sector now has the opportunity to articulate the technical and clinical requirements that meet the needs of our patients, care settings, and professionals.

This report sets out the current availability of devices in Australia.

Why are Graseby syringe drivers no longer available?

Prior to 4 October 2007 when changes to the Therapeutic Goods Administration's (TGA) Medical Device registration process became effective, all companies were required to submit documentation to prove their products meet all appropriate standards. Smiths Medical International did not believe that the two Graseby syringe drivers would meet the Australian Standards appropriate to these devices and hence the decision of Smiths Medical Australasia (SMA) to withdraw the devices from the Australian market. SMA determined sales of the Graseby MS16a and MS26 syringe drivers would cease at close of business on 3 October 2007.

The TGA has agreed with SMA's decision and formalised the cancellation of these devices from the Australian Register of Therapeutic Goods from 4 October 2007. This will prevent any further importation or supply of these syringe drivers from 4 October 2007. Graseby MS16A and MS26 syringe drivers currently in the market can continue to be used and the Australian supplier has given an undertaking to continue servicing existing syringe drivers for at least 5 years.

The role of PCA and CPCRE

In mid 2007, Palliative Care Australia (PCA) became aware that SMA was planning to withdraw the Graseby MS16a and MS26 syringe drivers from the Australian market.

As the peak body, PCA took an active interest in the withdrawal of these devices, recognising the importance of the Graseby syringe drivers to the palliative care and aged care sectors. PCA hosted a series of meetings with the TGA and SMA to determine a plan that would see a smooth transition for the sector from the Graseby syringe drivers to alternative device(s).

Palliative Care Australia negotiated with TGA and SMA ensuring that although sales of the Graseby MS16a and MS26 syringe drivers would cease at close of business on 3 October 2007, SMA would continue to service the devices already in use in Australia for a period of at least 5 years.

Palliative Care Australia partnered with the Centre for Palliative Care Research and Education (CPCRE) in Queensland to determine a process to provide useful information to clinicians about a replacement product on the market in Australia currently. The process involved sector consultation around service providers' needs and collecting information from companies marketing alternative devices.

Palliative Care Australia will continue to monitor the marketplace for alternative devices and inform the aged care and palliative care sectors of any changes via its website and E-Bulletin.

Palliative Care Australia and CPCRE would recommend that services consult with other key organisations in their local area about the device that they are choosing to purchase. The use of similar devices within a local area would enable easy transfer of patients and residents between the acute sector and the community and lessen the required education and training of staff.

Palliative Care Australia will be advocating on behalf of the sector for recognition of the impact of the changes and how they can best be addressed.

Sector consultation

PCA in consultation with CPCRE developed a list of 34 criteria (see Appendix One for list of criteria) that are important considerations for clinicians considering alternative devices to the Graseby syringe drivers. The 34 criteria are listed under six categories:

- Safety
- Simplicity
- Cost

- Functionality
- Transferability
- Other

Clinicians from the palliative care sectors and the aged care sectors were invited to identify their top five criteria for an alternative device to the Graseby syringe driver. Palliative Care Australia advertised this process through its E-Bulletins and at the Australian Palliative Care Conference in August 2007 and Aged and Community Services Australia national conference in September 2007.

The top 5 criteria as rated by participants in the survey are listed in the table below.

CATEGORY	CRITERION
Simplicity	Easy to set up and operate
Functionality	Lightweight and easily portable
Transferability	Suitable in different palliative care settings: <ul style="list-style-type: none"> • Hospital • Home • Residential Aged Care Facility • Rural
Safety	Tamper resistant and tamper evident (through alarms, logs or physical measures)
Cost	Similar to the cost of current devices

What alternative devices are available?

The devices that are reported on are available on the Australian market as at November 2007. However the information is a snapshot in time and the devices available on the Australian market may change in response to demand from the sector.

The following devices have been identified as being available on the Australian market:

- GemStar®
- Niki T34 and T34 PCA
- Niki T34L and T34L PCA
- CADD Legacy PCA
- CADD legacy 1
- CADD Legacy plus
- Master PCA – patient controlled analgesia syringe driver
- Elastomeric Pump – Infusorn LV & SV, PainBlocker (RAI) & Multirate

To support decision making by services, Palliative Care Australia has invited the companies marketing the devices to address the criteria identified by the aged care and palliative care sectors.

Information from companies about alternative devices

The following table summarises the responses from companies to the top five criteria plus other relevant information as determined by PCA and CPCRE. This information has been volunteered by companies and has not been verified for accuracy by PCA and CPCRE. The information in the following table does address the major concerns of the services and will provide a tool to assist in their decision making. For the full report on these devices with comments against all 34 criteria please see Appendix One.

	GemStar®	Niki T34 and T34 PCA	Niki T34L and T34L PCA	CADD Legacy PCA CADD Legacy 1 Cadd Legacy Plus	Master PCA – patient controlled analgesia syringe driver	Elastomeric Pump – Infusorn LV&SV, Pain Blocker (RAI) & Multirate
Image						
Contact	Hospira Pty Ltd Chris Chappell 02 8335 1003 Chris.chappell@hospira.com	REM Systems Pty Ltd Frank Elwin (Both devices) and Kellie Roberts (T34 and T34 PCA device) 02 9878 0992 0438 043 854 – Frank Elwyn 0416 006 400 – Kellie Roberts felwin@remsystems.com.au		Smiths Medical Australasia Trent Enright 0419 536 885 Trent.enright@smiths-medical.com	Pharmatel Fresenius Kabi Pty td Pete Tomlinson 02 9472 2251 0438 231 716 Pete.tomlinson@pfk.com.au	Baxter Healthcare Pty Ltd Maria Connolly 02 8845 1581 Maria_connolly@baxter.com

	GemStar®	Niki T34 and T34 PCA	Niki T34L and T34L PCA	CADD Legacy PCA CADD Legacy 1 Cadd Legacy Plus	Master PCA – patient controlled analgesia syringe driver	Elastomeric Pump – Infusorn LV&SV, Pain Blocker (RAI) & Multirate
CRITERION Tamper resistant	The GemStar® keypad lockout restricts access to various options. Four lock levels are available: Full, Therapy, Rate, and Continuous.	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	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).	Special designed key lock 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.	Yes – lockable cover that alarms if tampered with.	Yes – lockable cover that alarms if tampered with.
CRITERION Easy to set up and use	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.	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.	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	Features an enhanced LCD display screen and easy to read keypad for simple operation, programming adjustments and troubleshooting	Yes – preset protocols and rolling menu.	Rapid onset. 3 steps: filling, priming, connecting

	GemStar®	Niki T34 and T34 PCA	Niki T34L and T34L PCA	CADD Legacy PCA CADD Legacy 1 Cadd Legacy Plus	Master PCA – patient controlled analgesia syringe driver	Elastomeric Pump – Infusorn LV&SV, Pain Blocker (RAI) & Multirate
CRITERION Approximate price November 2007	\$2,500. Prices are subject to negotiation and dependent upon volume consumption.	Prices \$2100 Lockbox and carry bag \$150	T34L Price \$2500	Currently available list price of \$1600.00 (list price of the MS Drivers \$1700.00)	Approximate cost \$3500.00	As single use devices prices are not comparable. Contact company for prices.
CRITERION Light weight, easily portable	Weight is approximately 482 grams excluding batteries.	Total weight of NIKI T34 including battery is 240grams (210grams without battery).	Total weight of NIKI T34L/PCA excluding battery 400grams	Yes weighs 392g without consumable attachment	Reasonably – attaches easily to an IV pole 1.9kg.	Lightweight – 39 to 61g empty, discreet, easy to conceal
CRITERION Suitable in different palliative care settings	The GemStar has an aluminium shell for strength and lightness, rubber bumpers provide better shock resistance and sealed casing and keypad prevent fluid ingress. Accessories include: a 500mL, 1000mL and 3000mL PVC carry case or bum bag to contain both GemStar pump and fluid reservoir.	Meets IEC/EN 60601-1, 60601-2-24,4 and ISO13485 Yes. For extra protection a protective case and carry bag is available.	Yes. For extra protection a carry bag is available	IPX 4 (splash proof). Comes with a protective pouch as standard.	Yes	Yes

	GemStar®	Niki T34 and T34 PCA	Niki T34L and T34L PCA	CADD Legacy PCA CADD Legacy 1 Cadd Legacy Plus	Master PCA – patient controlled analgesia syringe driver	Elastomeric Pump – Infusorn LV&SV, Pain Blocker (RAI) & Multirate
CONSUMABLES Approximate Price November 2007	<p>Hospira devices require the use of GemStar® pump sets which come in a wide variety of clinical applications to help meet your infusion needs.</p> <p>Please note: these are indicative prices for consumables subject to negotiation and volume consumption:</p> <p>GEMSTAR SET PLAIN WITH ANTISIPHON VALVE - \$16.00 per set</p> <p>GEMSTAR PCA SYRINGE SET - \$16.00 per set</p>	<p>Any brand of syringe and extension sets are able to be used.</p>	<p>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</p>	<p>Smiths Medical Australasia has a large range of designated consumables for the CADD Legacy PCA (no generic sets available).</p> <p>To prevent infection, CADD consumables should be changed daily - cassette plus extension set = approximately \$20 per day. The CADD can be run over longer than 24 hrs but in that case needs to be filled under laminar flow conditions.</p>	<p>Price dependent upon volume of use.</p> <p>12 brands of syringes compatible (50cc and 20cc) which are then compatible with most syringe extension lines (depends upon hospital protocol).</p>	<p>Price dependent upon volume of use.</p> <p>12 brands of syringes compatible (50cc and 20cc) which are then compatible with most syringe extension lines (depends upon hospital protocol).</p>

	GemStar®	Niki T34 and T34 PCA	Niki T34L and T34L PCA	CADD Legacy PCA CADD Legacy 1 Cadd Legacy Plus	Master PCA – patient controlled analgesia syringe driver	Elastomeric Pump – Infusorn LV&SV, Pain Blocker (RAI) & Multirate
EDUCATION	Education available Online not available but e-learning CD ROMS available upon request	REM SYSTEMS provides educational packages including on site training, brief user guides, information posters and educational videos and web based programs. See http://www.cme-infusion.com/documents/pub/index.html Online education training is available on http://www.cme-infusion.com/documents/pub/index.html 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.		Training guides, patient information booklet, Operators Manual, Quick reference cards for clinicians, interactive training CD, filling the medication cassette CD. Online available:-filling the cassette is currently on our website www.smiths-medical.com	Education available– as determined necessary in consultation with clinical educators at no charge	Educational packages include Filling Procedure DVD and User Instruction Manual and Pocket Infusion Guide for Patients. No online education

NOTE:

The information in this table has been supplied by companies marketing devices described. It has not been verified by Palliative Care Australia or CPCRE. No claim is made to the accuracy, currency or completeness of the information supplied by companies. Neither PCA nor CPCRE accepts any liability from any person for the information or the use of such information.

In some cases additional information for clarification has been obtained from the companies and included in this table. Consequently information in this table may vary slightly from the original reports from the companies (see Appendix One).

Future work

Palliative Care Australia will continue to provide updates about appropriate devices on its website and in the PCA E-Bulletin.

Palliative Care Australia and the PCA Member Network will continue to profile to government and suppliers the impact of this change on our sector and to advocate for the following changes to be taken into consideration when funding and planning for services;

- Cost of devices and disposables
- Cost of training to health professionals and patients, their families and carers
- Cost of improving safety through awareness and training across the many care settings

Importantly, as the sector transitions to alternative devices, all involved need to be reminded that there is much more to the delivery of safe and quality care than devices alone.

Palliative Care Australia and the PCA member network are always keen to better understand the issues that impact on quality care at the end of life and welcome questions and advice on this matter. To discuss your experience and needs, please contact Donna Daniell, CEO, donna@pallcare.org.au

Where can I get further information?

PCA website

Palliative Care Australia will continue to provide updates about developments in this area on its website www.pallcare.org.au.

PCA E-Bulletin

If you do not receive a copy of the e-bulletin and would like to, visit PCA's website www.pallcare.org.au and follow the prompts to PCA Connect. Previous issues of E-Bulletin can also be accessed on the web by following the E-Bulletin tab.

CPCRE's 'Guidelines for syringe driver management in palliative care' (2006)

These syringe driver guidelines, 58 pages in length and published in April 2006, are intended to provide clinicians and palliative care services with guidelines to inform practice, the development of policy and procedures, and associated training and education programs in relation to portable subcutaneous infusion device (syringe driver) management.

The guidelines have been developed under six categories;

- The patient experience
- Equipment guidelines and principles
- The selection, preparation and maintenance of the site
- Drugs and diluents
- Patient/family education needs
- Patients assessment and troubleshooting guidelines

While these guidelines refer to the Graseby syringe driver to illustrate the principles of safety and quality use, they remain applicable to all syringe drivers. The guidelines are available on CPCRE's website at: www.cpcrc.com under Publications.

Manufacturers and Suppliers

Contact details are provided in this report

Acknowledgements

PCA appreciates and acknowledges the advice and contribution from all who participated in the development of criteria at the 9th Australian Palliative Care Conference, and the following persons.

CPCRE Team

- Professor Patsy Yates, Director CPCRE
- Mr John Haberecht, Research Officer
- Professor Janet Hardy, Clinical Research Program Leader CPCRE and Director of Palliative Care, Mater Health Services, Brisbane

PCA Team

- Ms Fiona Couchman, Policy Officer
- Dr Karen Cooper, Senior Advisor
- Ms Donna Daniell, CEO
- Ms Jessica Fryer, Administrative Officer

Therapeutic Goods Administration

Palliative Care Australia

PO Box 24 Deakin West ACT 2600
Ph: +61 2 6232 4333 Fax: +61 2 6232 4434
www.pallcare.org.au