Clinical Trial of alternative subcutaneous infusion pumps.

Royal Perth Hospital

2008

Complied by: Natalie Panizza CNC

Data Analysis by: Grazyna Ogrodzka-Wozniak

Date: January 2008

INTRODUCTION:

Continuous subcutaneous infusion is an effective method of drug administration to maintain symptom control once the oral route is no longer effective or not available. A syringe driver, or pump, is used to deliver medication.

The Graseby MS16A syringe driver has been withdrawn from sale in Australia from October 2007 and the phasing out of the maintenance of existing devices will occur in 2012. The Graseby MS16A Syringe Driver is used widely within Australia in all palliative care settings and the withdrawal of this device means that an alternative infusion pump needs to be identified.

Palliative Care patients move through various health settings and it is imperative that an alternative device be identified that meets the criteria for all settings. Palliative Care Australia (PCA) listed criteria that are important considerations for clinicians to consider when looking for an alternative device. Palliative Care Services across Australia were invited to identify their top five criteria for an alternative device. The top five criteria were:

Category	**Criterion**
Simplicity	Easy to set up and operate
Functionality	Lightweight and easily portable
Transferability	Suitable in different palliative care settings: Hospital Home Residential aged care facilities rural
Safety	Tamper resistant and tamper evident (through alarms, logs or physical measures)
Cost	Similar to the cost of the current device

Palliative Care Australia: Report on Subcutaneous Infusion Devices Nov 2007

Palliative Care Australia identified devices that were available on the Australian market as at November 2007 and companies were invited to address the criteria identified as above. An analysis of the devices is available in the PCA Report 2007.

In Western Australia the Clinical Issues Working Group (senior clinical nursing staff from all palliative care settings) who report to Palliative Care WA discussed the report issued by PCA. The group then undertook a further literature review and put forward a motion that only one device should be used across all settings. This reduces the risk of errors occurring as staff can be familiar with just one pump that is transferable across all settings. Two pumps were identified as meeting the required criteria set out both by PCA and the CIWG. Representatives from REM Systems and Western Biomedical were invited to the CIWG meeting to give a demonstration and information on their pumps. Hollywood PCU undertook a trial for inpatient palliative care hospice settings and RPH undertook a trial of the same 2 pumps for the public health care setting.

The Palliative Care Service at RPH conducted a survey to evaluate two devices alternative to Graseby Syringe Drivers; Alaris AD by Western Biomedical and NIKI T34 Ambulatory Syringe Pump by REM Systems. Education sessions of equal value for the above pumps were given to staff on ward 10A which is the oncology ward and has the biggest patient population who would require a subcutaneous infusion. Each pump was trialled on 5 consecutive patients. The trial was first conducted on the NIKI T34 and then the Alaris AD. Staff that were caring for patients with the pump in use were encouraged to complete an evaluation form at the end of each shift. The pump remained in place on the patient until the patient no longer required the device. This will account for the variation in the number of evaluations completed.

The Representatives for the devices on trial were available for any queries or additional information. The education for the NIKI T34 was undertaken by me (Natalie Panizza CNC) as the representative is not WA based. Educational resources were provided by the company.

A standard Product Evaluation Tool that is used in Royal Perth Hospital was utilised for measurement of the pumps. See attachment 1.

The categories were:

Category	**Criteria**
Ease of use	Programming Equipment set up Accessible consumables Battery change/charge documentation
Physical attributes	Light weight Easily transportable Clarity of screen Hard cover-key access
Infection control	Cleaning simple
OHS	Patient education Alarm system Self education

Costing analysis was also undertaken.

RESULTS

Alaris Ad Syringe Driver 05.11.08 – 26.11.08

Number of questionnaires completed: 17

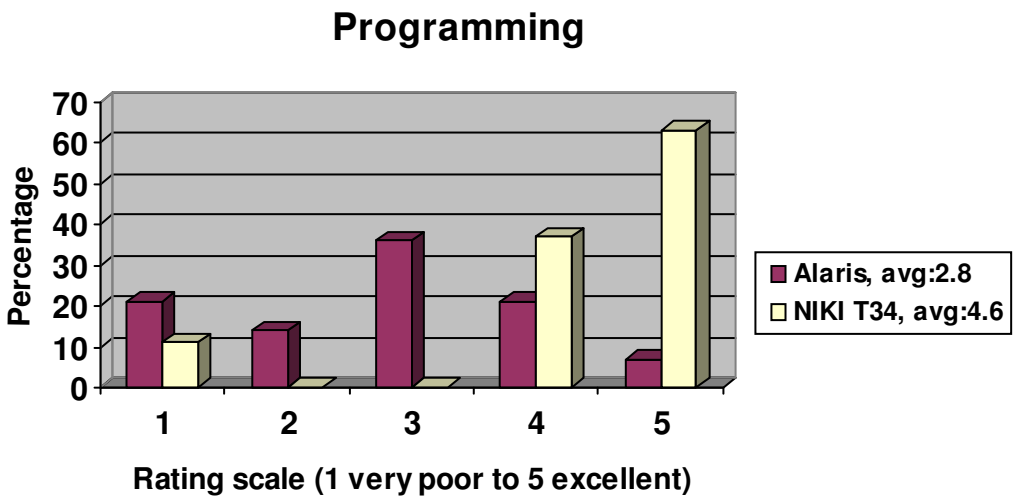
Number of patients: 5 (opioid - 2, ketamine – 3)

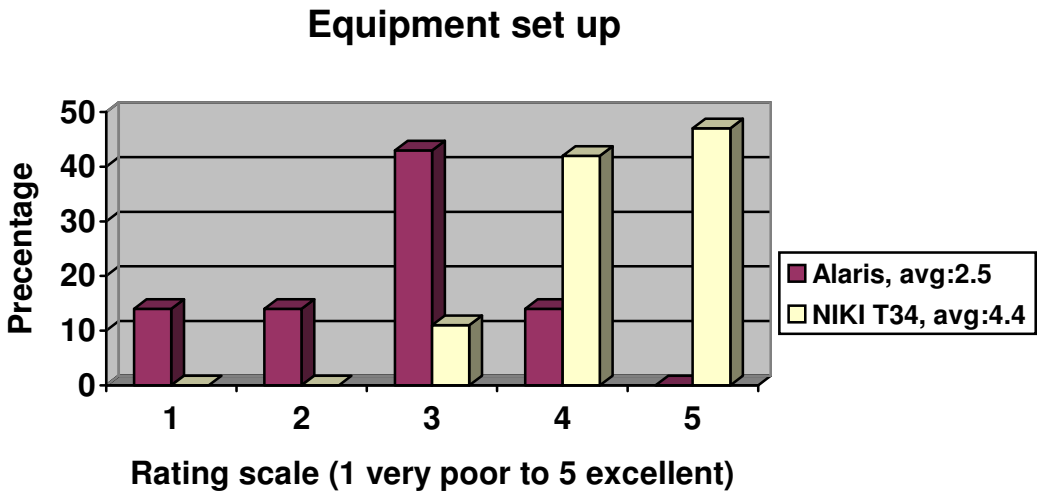
NIKI T34 Syringe Driver 10.10.08 – 28.10.08

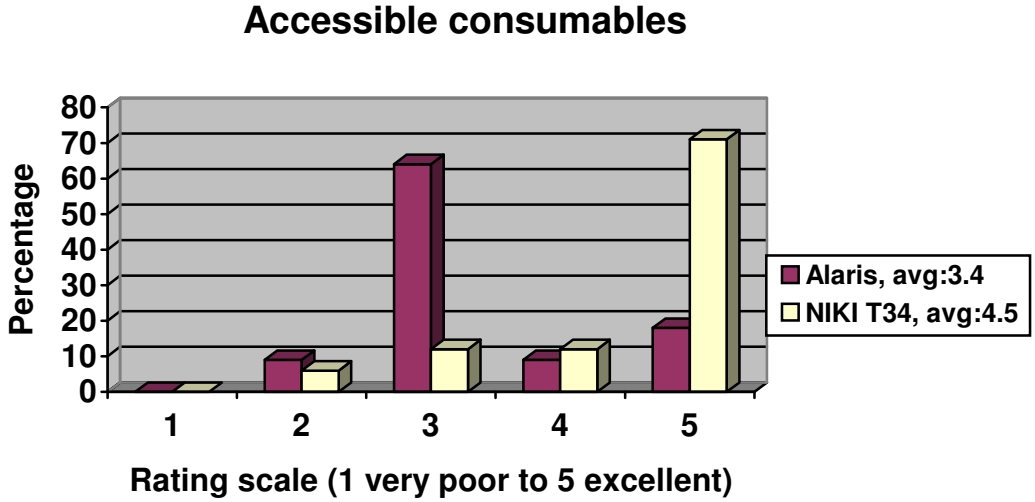
Number of questionnaires completed: 26

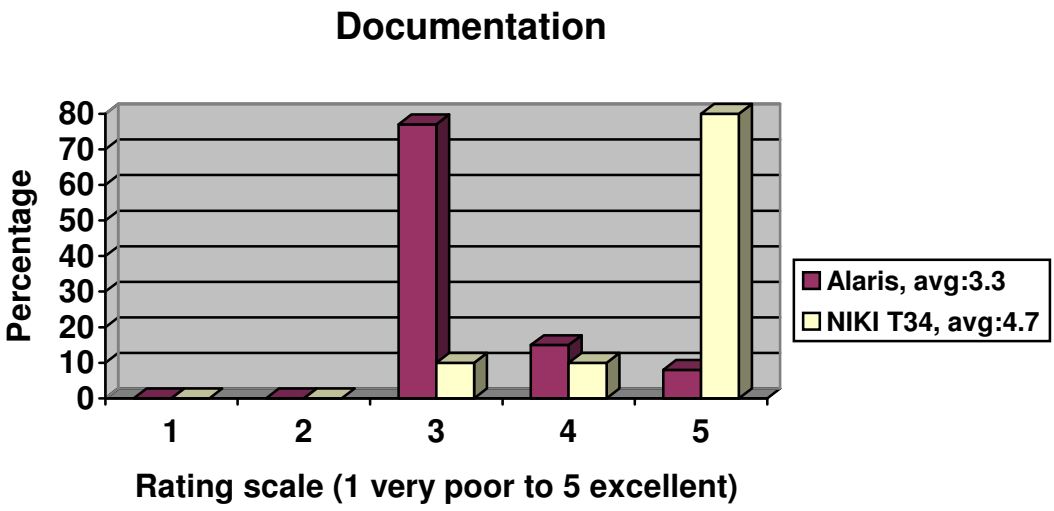
Number of patients: 5 (opioid - 2, ketamine – 2, cyclizine - 1)

Ease of Use

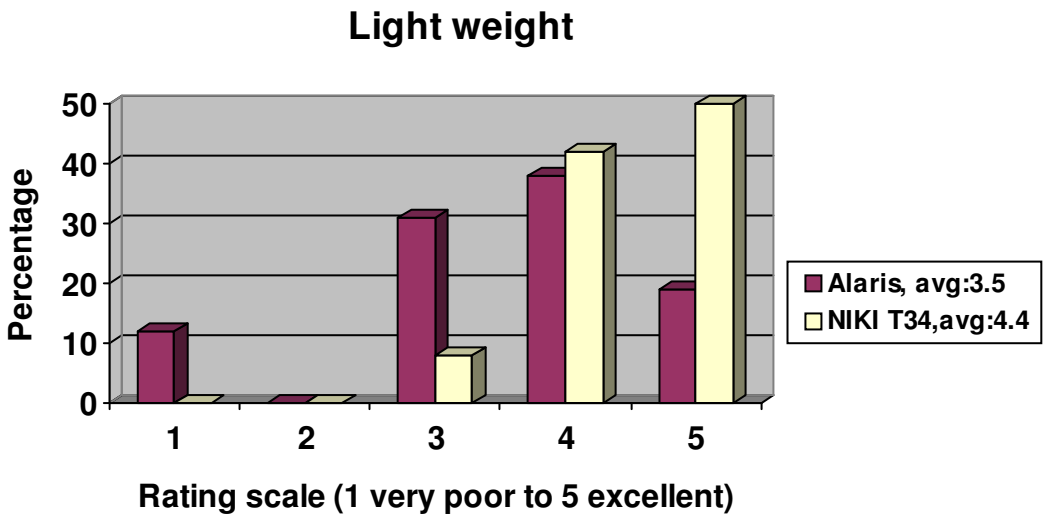

Programming
Percentage
70
60
50
40
30
20
10
0
1
2
3
4
5
Rating scale (1 very poor to 5 excellent)
Alaris, avg:2.8
NIKI T34, avg:4.6

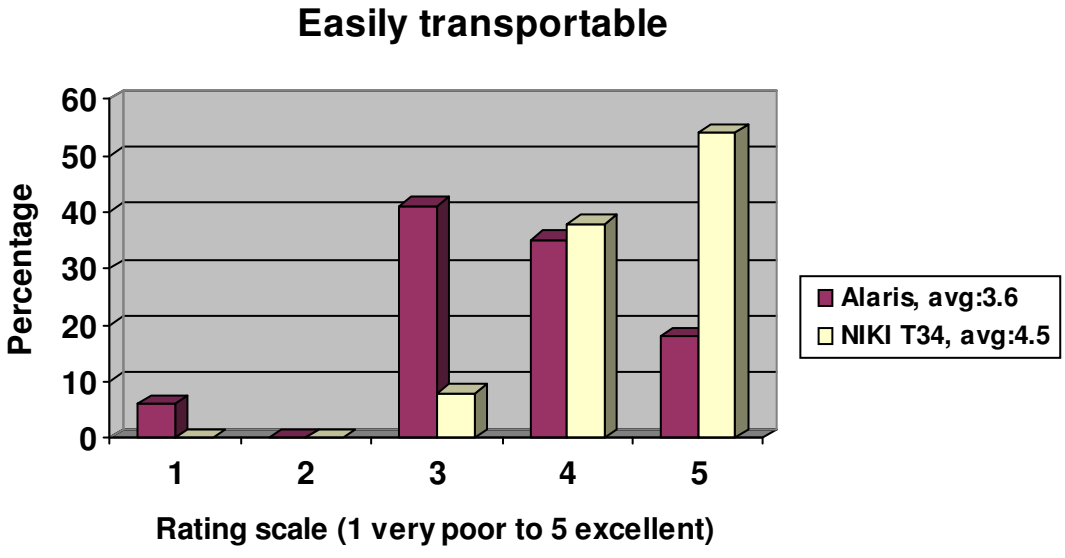

Equipment set up
Precentage
50
40
30
20
10
0
1
2
3
4
5
Rating scale (1 very poor to 5 excellent)
Alaris, avg:2.5
NIKI T34, avg:4.4

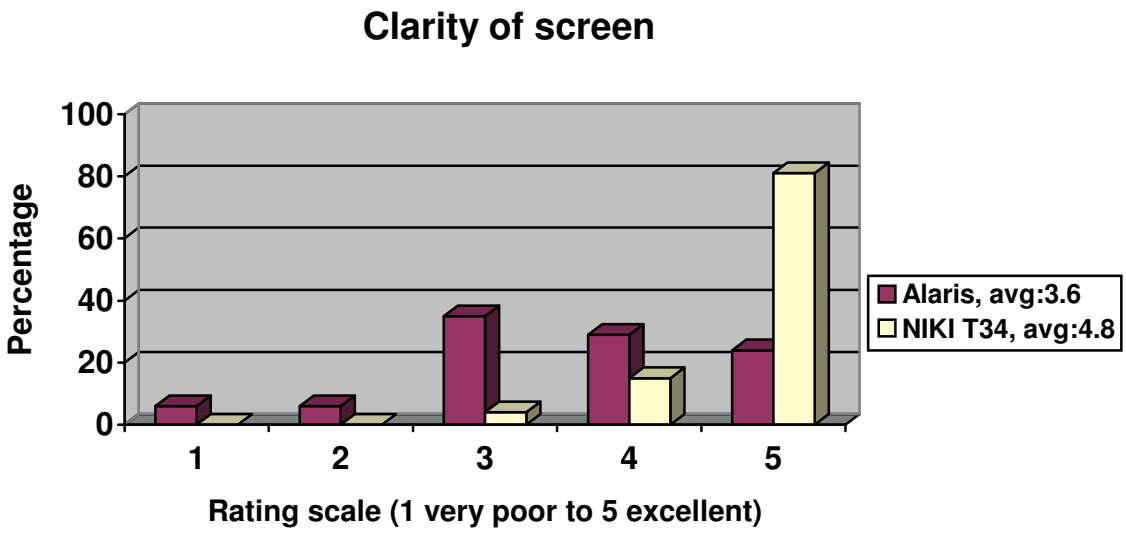

Accessible consumables
Percentage
80
70
60
50
40
30
20
10
0
1
2
3
4
5
Rating scale (1 very poor to 5 excellent)
Alaris, avg:3.4
NIKI T34, avg:4.5

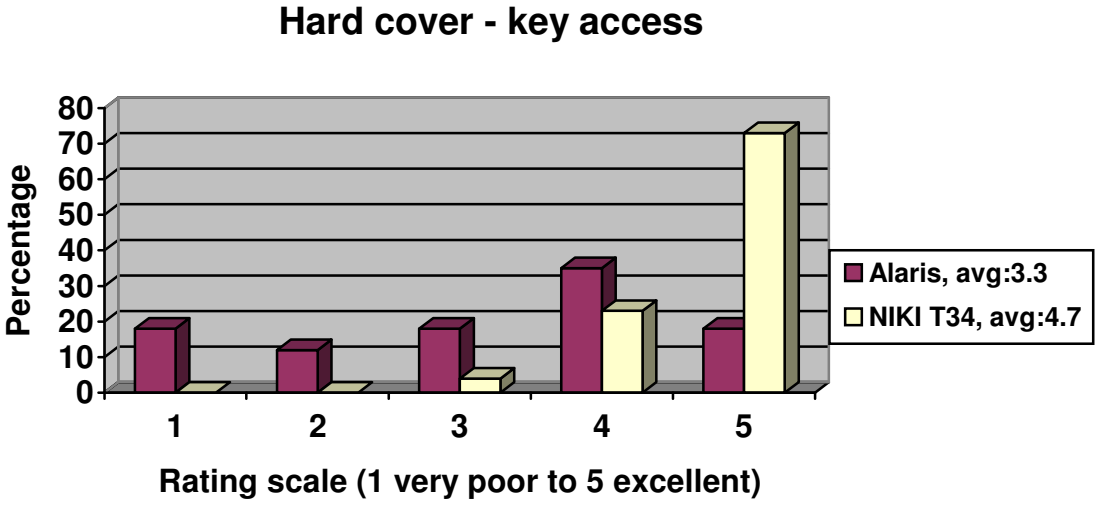


Physical Attributes

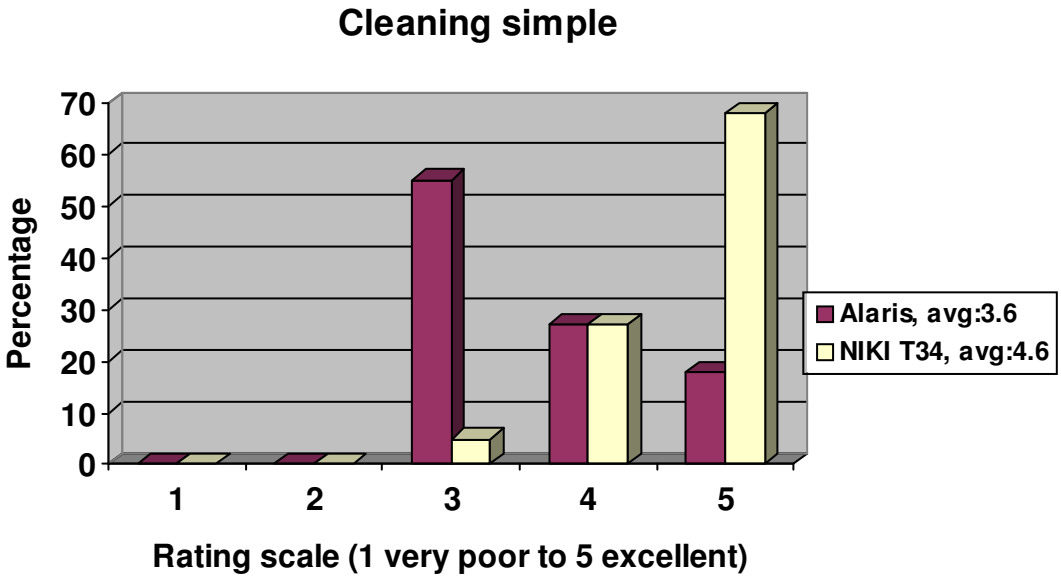




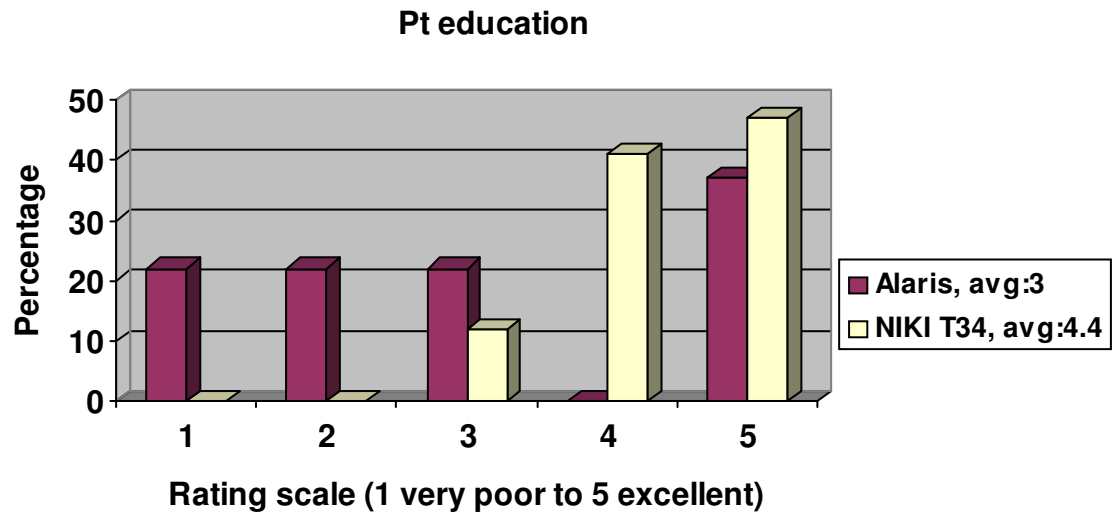


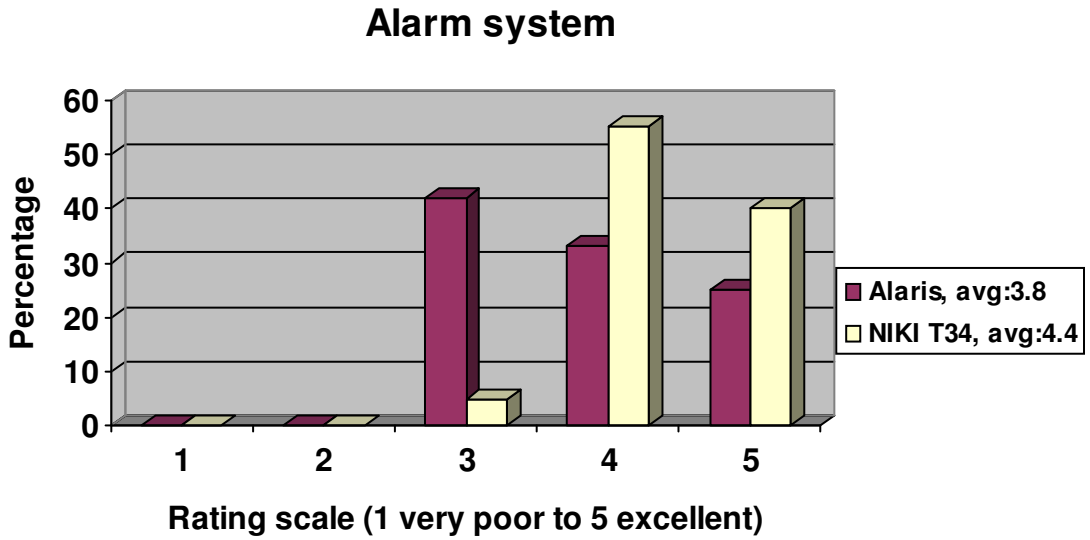


Infection Control



OSH


Pt education
Percentage
50
40
30
20
10
0
1
2
3
4
5
Rating scale (1 very poor to 5 excellent)
Alaris, avg:3
NIKI T34, avg:4.4


Alarm system
Percentage
60
50
40
30
20
10
0
1
2
3
4
5
Rating scale (1 very poor to 5 excellent)
Alaris, avg:3.8
NIKI T34, avg:4.4


Self education
Percentage
45
40
35
30
25
20
15
10
5
0
1
2
3
4
5
Rating scale (1 very poor to 5 excellent)
Alaris, avg:3.4
NIKI T34, avg:4.3

General Comments

Alaris AD Syringe Driver

- Lock system- annoying. Kicks in too soon
- Syringe load – risk of pushing barrel and injecting when loading
- Key function – not obvious which is enter/menu
- Lid – does not always fit smoothly
- Key – appears like it might not be durable. Poor fitting, does not always lock first go.
- Pump not easy to get off lock to re programme
- Key – small easy to lose. Area where key inserted is already showing signs of damage
- Took 15mins to work out how to unlock machine –very frustrating and time consuming
- Cover took several attempts to click into pump and be able to be locked –flimsy key
- Length of tubing is excellent –unit able to be stored on side cabinet or table if necessary
- Alarm excellent when syringe complete.
- Took 2 hours to set up
- Problem with extension tubing how to cater for volume in line. Do you use purge button or manually prime? Either way pump still says 24hrs.
- Pump cover- although easy to clean- scratches and becomes hard to read screen
- Pump is awkward to load – heavy pump with plastic, fragile loading arm (the winding arm)
- If using 30ml syringe when patient already has line –it is unsafe to attach old extension tube without taking pump to patients bedside and setting up again – very time consuming.

NIKI T34

- During my shift till 2130hrs I have found this product very handy and safe to use
- The pump is heavier than the old but the benefit of being able to lock the outer casing outweighs this for me. It seems a lot safer than the old. There were some issues with the initial set up of the syringe as we had to prime a new line which changed the volume so had to get the driver into the correct place again without being able to hold the syringe in place. Patient states the pump is heavier but it does not bother her anymore than the old one.
- Battery change- lock automatically turns off

CLEANING

Alaris AD Syringe Driver

The exterior of the syringe driver can be cleaned with a soft cloth, sparingly dampened with soapy water or 3% hydrogen peroxide solution. Do not soak.

NIKI T34 Syringe Driver

Use a lint-free cloth dampened with warm water and mild detergent or 10% bleach solution. Do not soak or immerse any part of T34 in water or any other solution.

COST

Alaris Ad Syringe Driver

1-9 units	$2,500 each
10-24units	$2,400 each
25-49units	$2,300 each
50+ units	$2,200 each

Optional accessories:

- Portable protective cover and shoulder strap $100.00 each
- Transit case including foam inlay $245.00

One complete unit: $2,845.00

NIKI T34 Syringe Driver

1-20 units $2,370 each

Optional accessories:

- Carry pouch $65 each
- Lock box complete $120

One complete unit: $2,555.00

CONCLUSION

Changes occurred to the Therapeutics Goods administration's (TGA) medical Device registration that required companies to submit documentation to prove their products meet all appropriate standards. Smiths Medical International did not believe that the Ms 16A Graseby syringe driver would meet the Australian Standards appropriate to these devices and so they made a decision to withdraw the devices from the Australian market. TGA has agreed with their decision and formalised the cancellation of these devices from the Australian Register of Therapeutic Goods from October 2007.

These changes and withdrawal have prompted a search for another viable alternative that meet the needs of palliative care clients and providers. The above audit results support the NIKI T34 as the most effective replacement based on the criteria set both by PAC and CIWG.

The above data should provide useful information into deciding the most efficient and cost effective pump to replace the Graseby MS 16A. The challenge for RPH is to make a decision on either doing a total recall of the Graseby MS16A once a replacement has been identified or to do a gradual changeover to the identified device. The safest way is to have a total recall of the Graseby MS16A and introduce the replacement pump. Nursing Practice Standard will need to be revised as will the subcutaneous prescription chart.

South Metropolitan Area Health Service

Product Evaluation Tool

"Product to be Evaluated"

Royal Perth Hospital

Pt sticker

COMPLETE ONE QUESTIONNAIRE PER SHIFT (inclusive night staff)

BRAND: AD syringe pump				**COMPLETED BY (PRINT):**			
DESCRIPTION:				**DESIGNATION:**			
PRODUCT CODE:				**WARD/DPT:**			**DATE:**
Category	**Criteria**	**Excellent**	**Very Good**	**Average**	**Poor**	**Very Poor**	**Comments**
Ease of Use	programming	5	4	3	2	1	
	equipmet set up	5	4	3	2	1	
	accessible consumables	5	4	3	2	1	
	battery change	5	4	3	2	1	
	documentation	5	4	3	2	1	
Physical Attributes	light weight	5	4	3	2	1	
	easily transportable	5	4	3	2	1	
	clarity of screen	5	4	3	2	1	
	hard cover- key access	5	4	3	2	1	
		5	4	3	2	1	
Infection Control	cleaning simple	5	4	3	2	1	
		5	4	3	2	1	
OSH	pt education	5	4	3	2	1	
	alarm system	5	4	3	2	1	
	on line self education	5	4	3	2	1	

This form will be collected by the trial coordinator

Trial Coordinator:

Comments: If more space is required PTO (Please be as objective and factual as possible):