



**NHS**

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procurement hub

## Contract Briefing Notice

### Clinical Ambulatory Syringe Drivers

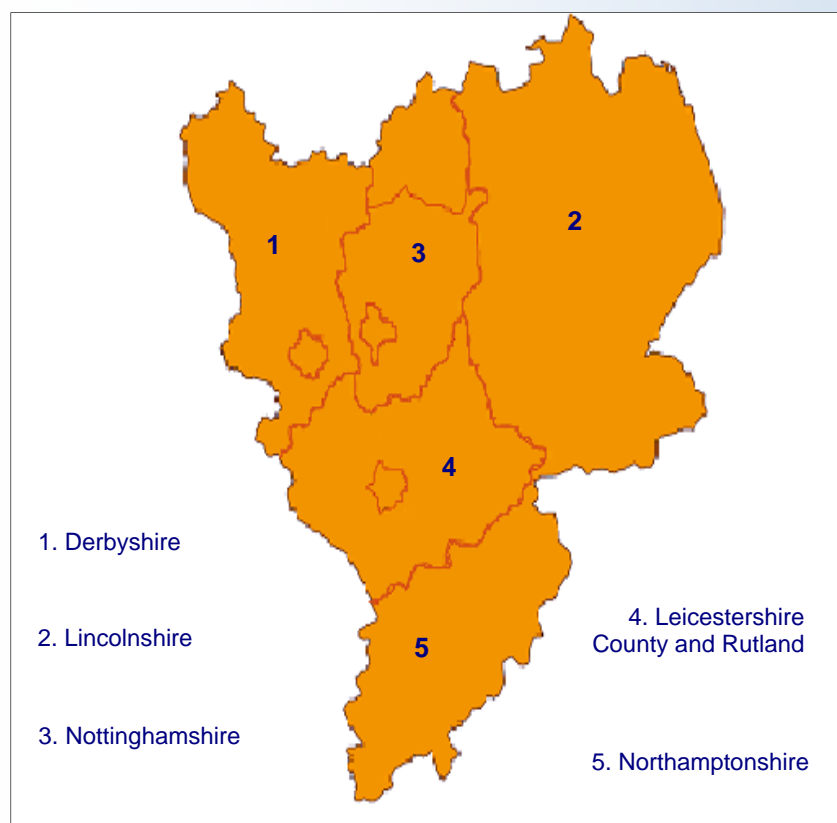
Date:- October 2009



## Those involved with *re:source* Collaborative Procurement Hub:

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- Derbyshire County PCT
- Derby City PCT
- Derby Hospitals NHS Foundation Trust
- Derbyshire Mental Health Services NHS Trust
- East Midlands Ambulance Service NHS Trust
- East Midlands SHA
- Kettering General Hospital NHS Trust
- Leicester City PCT
- Leicestershire County and Rutland PCT
- Leicestershire Partnership NHS Trust
- Lincolnshire Partnership NHS Trust
- Lincolnshire PCT
- Northampton General Hospital NHS Trust
- Northampton Teaching PCT
- Nottingham City PCT
- Nottinghamshire County Teaching PCT
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- Nottinghamshire Healthcare NHS Trust
- Sherwood Forest Hospitals Trust
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### Map to show the counties involved with *re:source*



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## **Ambulatory Infusion Device Procurement Project**

### **Introduction**

Incidents and clinical risks associated with the use of its existing ambulatory device (the Smiths MS16a) were reviewed at Nottingham University Hospitals NHS Trust. There were a significant number of incidents, so a tasked team was set up to establish whether any other ambulatory infusion devices offered in the UK healthcare market, provided clinical improvements over and above the current product in use and, if so, if the enhancements enabled a cost effective solution. The device would be used in primary and secondary care. Other Trusts within the East Midlands region may wish to take advantage of this tender at any stage during the contract.

The project was led by Dr Daniel Clark, Head of Clinical Engineering, Medical Physics, Nottingham University Hospitals NHS Trust.

### **Process**

Project code 17569 OJEU reference EMCPH-08-035 was advertised on 30/07/08 with an initial 11 expressions of interest from suppliers.

### **1<sup>st</sup> Evaluation**

Suppliers were advised a short listing for evaluation would take place via a table top evaluation day held at Sherwood Hall, City Campus on Monday 27<sup>th</sup> October 2008 and in order to qualify must detail products they may potentially offer within this tender process. In addition Suppliers were notified that the following conditions applied.

Suppliers who are successful in reaching the evaluation stage will be prepared to:

- Agree to provide sufficient products for Nottingham University Hospitals to evaluate the product in a clinical setting at a number of locations.
- Agree to provide training for both clinical and technical staff involved in the evaluation.
- Agree to assist in the set up and calibration of the products for evaluation.
- Agree to a 2 week period, decided upon by the Trust, for the product to be evaluated.
- Ensure the Trust has full support during this period.
- Be entitled to a copy of the evaluation report for the product on completion.

The companies that then submitted to attend (including their devices) were:

Applied Medical Technology	Cane Crono Syringe Pump
Baxter Healthcare	Infusor range of elastomeric infusion devices
Cardinal Health	Alaris AD Ambulatory Syringe Driver
Eden Medical	The Micrel range of Syringe Drivers
Eden Medical	The Rhythmic <i>Plus</i> Ambulatory Volumetric Pump
McKinley	T34 Syringe Driver
McKinley	Bodyguard 323 Ambulatory Volumetric Pump
Smiths Medical	MS16A Ambulatory Syringe Driver
Smiths Medical	CADD Legacy 1 Ambulatory Volumetric Pump

Users including the Ambulatory Infusion Device task team and ward staff were invited to attend and given the brief to visit each of the companies stands, talk to the representative while being given a demonstration of the device and make a decision as to whether they would be prepared to trial the device. They were given a list of questions to guide them and were encouraged to handle the device where possible. When they had visited all of the stands they were asked to list their choice of devices to trial, 1 – 3.

A total of 16 staff attended from the following:

Ward Sisters  
 Deputy Ward Sisters  
 Macmillan Nurses  
 Pathway Facilitator for last days of life  
 Staff Nurses  
 Student nurses  
 Medical Consultant  
 Medical Device Training Officers

A clinical engineer from the Trust also attended to conduct an evaluation, from an engineering point of view, on the devices:

Device	Opinion	Comments
Alaris AD	Favourable	<ul style="list-style-type: none"> <li>It has all the safety features desired by the MHRA and meets 60601-2-24.</li> <li>In terms of usability, it appears to be easy to load. The screen is nicely sized with clear information and prompts.</li> <li>The lockbox is an integral part of the device.</li> <li>Uses rechargeable batteries - device requires 15 minutes / 24 hours in its docking station to recharge</li> <li>The on screen display prompts the user to prime the line</li> <li>Programming is only by device detected volume over changeable time period – evaluation needed to know if this would be an issue.</li> </ul>
CADD	Favourable	<ul style="list-style-type: none"> <li>There are two cadd-lagacy devices which would appear to be suitable</li> <li>Both devices have an integral lockable cover over the drug cassette.</li> <li>Both have all the safety features desired by the MHRA and meet 60601-2-24.</li> <li>Both appear to be easy to use – filling of the cassette may be an issue but presumable would solve the issue of ‘accidental plunging’ as mentioned by clinical users in our team meetings.</li> <li>These devices have a dedicated prime button but the user is not prompted to use it.</li> </ul>
T34	Acceptable	<ul style="list-style-type: none"> <li>Meets all the safety features desired by the MHRA and 60601-2-24.</li> <li>Unsure about robustness of this device – quality of syringe securing parts etc</li> <li>Does not prompt user to prime and difficult to initiate</li> <li>Previous evaluation showed poor battery performance and life indication.</li> </ul>
Cane Crono	Unacceptable	<ul style="list-style-type: none"> <li>Does not fully meet MHRA or 60601-2-24</li> <li>Not clear indication of infusion status, small icon flashing on screen and if collar in place syringe displacement would not be visible.</li> <li>Crono-T Programmed in volume over time</li> <li>Crono-PCA programmed in ml/h</li> </ul>
Micrel	Unacceptable	<ul style="list-style-type: none"> <li>Not fully compliant with MHRA and 60601-2-24 in terms of alarms and safety features (better than MS16)</li> <li>Not of robust construction</li> <li>Screen only indicates set flow-rate</li> </ul>
MS16A	Unacceptable	<ul style="list-style-type: none"> <li>Does not fully meet MHRA or 60601-2-24</li> <li>programmed in mm</li> </ul>

A total of 15 responses from clinical staff – including the user’s 1<sup>st</sup>, 2<sup>nd</sup> & 3<sup>rd</sup> choice of devices to trial, were received.

Five responses gave a first and second choice only as they felt strongly that they were the only devices to trial.

The choices and totals are tabled below.

Device	First Choice	Second Choice	Third Choice	Total
Alaris AD	10	2	1	<b>13</b>
CADD	0	1	4	5
Cane Crono	0	0	1	1
Micrel	3	2	2	7
MS16A	1	2	1	4
T34	2	8	1	<b>11</b>



On evaluation it was immediately apparent that the Baxter Healthcare Infusor range of Elastomeric Infusion Devices were not suitable for trial or evaluation. They are not suitable for hospital use, are not run on battery or ac power, it is not possible to assess the amount that has been infused; it does not have any alarms or memory.

The Cane Crono representative stated that the device was more suited for home use and may not be suitable for the hospital setting – this would have become apparent at technical evaluation. The representative left at 12:30pm along with the Baxter Health representative and therefore they were not present for the afternoon evaluations.

The following were then taken out of the process for the following reasons and the suppliers briefed accordingly on the 15/12/08:-

Smiths Medical Cadd Devices:

The cassette nature of the device could result in high drug wastage, hence decided not appropriate for NUH.

Crono

Products more suited to particular therapies and community use, not suitable for NUH use. Also does not meet all the desired features we are looking for at NUH such as the MHRA recommended features for such devices \*.

Eden, Micrel Micropumps (Various)

Devices very similar in appearance to MS16A (device currently used by NUH), this apparent similarity could lead to problems during use.

Also does not meet all the desired features we are looking for at NUH which include the MHRA recommended features for such devices.\*

Baxter

Unsuitable for NUH intended use; would lead to drug wastage. We were also looking for a powered device with safety features etc.

Reference

Table 4b, (P54) of *Infusion Systems Device Bulletin*, MDA DB2003(02) March 2003.

## 2nd Evaluation

McKinley with T34 and Cardinal Health with Alaris AD were scheduled to have two weeks of training and clinical use, to run consecutively over February 2009 across 5 wards. The current product Smiths Medical MS16A had been in use for a number of years and staff familiar with the features. The Ambulatory Infusion Device task team designed a scoring evaluation protocol to be used during this period. It was concluded both McKinley and Cardinal would be invited to tender alongside the incumbent Smiths.

## Procurement

The OJEU EMC PH-08-035 was restricted to offers from McKinley, Cardinal Health and Smiths and run through the electronic BRAVO system.

The process closed after the normal running period with offers received from McKinley and Smiths. Cardinal Health made contact after the closure to advise error as offer made on another NHS tender running independent of Resource, but to allow an offer would have compromised the process.

## Conclusion

The Buyers Guide published by Purchasing and Supply Agency Centre for Evidence based Purchasing on Ambulatory Syringe Drivers in Dec 2008 was used to provide support for additional scoring.

Based on the weighting mechanism the scoring was summarised as:-

40% Clinical	McKinley 29.29%	Smiths 18.13%
10% Training & Support	McKinley 7.32%	Smiths 7.59%
30% Pricing	McKinley 21.87%	Smiths 30.00%
15% Running costs	McKinley 14.28%	Smiths 14.85%
5% Cleaning	McKinley 3.00%	Smiths 4.00%
 *Overall score	 McKinley 75.82%	 Smiths 74.63%

The Ambulatory Infusion Device Task Team recognised that, in purely commercial terms, Smiths were lower (45% cf 36%). However, the McKinley significantly out-scored the Smiths product on the clinical evaluation (29% cf 18%). Moreover, the McKinley met the desired safety features of MHRA or 60601-2-24 whereas the Smiths did not. This is also borne out in the Buyers Guide Market Review: “very good 5 stars McKinley” compared to “good 4 stars Smiths”.

Although the overall scores were very close (McKinley being slightly ahead overall), the Tasked Team concluded that the essential safety requirements and the higher clinical evaluation made the McKinley produce a clearly better choice. It was therefore agreed to award the contract to McKinley.

## Commercial

### Contract Period

The prices will be fixed for a period of 5 years from 1<sup>st</sup> August 2009 – 31<sup>st</sup> July 2014, with an option to extend for a further 2 years by mutual agreement. Member Trusts of NHS Resource Procurement Hub are eligible to participate and utilise this contract.

### Pricing Structure

To ensure transparency across all accounts the following discount structure has been established. Prices apply to individual order volumes only and cannot be applied retrospectively on cumulative order quantities. However, Trusts may opt to maximise the discount structure financial benefits by co-ordinating their placements and applying the relevant quantity discount price to the total number of pumps to be ordered across each purchase order. These purchase orders must be placed at the same time to apply this benefit.

Description	Code	List Price	Quantity	Discount Price
T34 Ambulatory Syringe Pump	100-100SM	£995.00	1 - 4	£995.00
			5 - 9	£975.00
			10 - 24	£955.00
			25 - 49	£935.00
			50 - 99	£915.00
			100 - 199	£895.00 £875.00
			200 - 299	£855.00
			300+	
Clear Pump Lock Box Yellow Pump Lock Box (both accept most 30ml syringes)	100-174S 100-174SE	£85.00	1 - 9	£85.00
			10 - 49	£76.50
			50 - 199	£68.00
			200+	£59.50
Small Carry Pouch (pump only) Std Carry Pouch (pump and lock box)	100-177S 100-176S	£40.00	1 - 9	£40.00
			10 - 49	£38.00
			50 - 199	£36.00
			200+	£34.00
Disposable Carry Pouch (pump and lock box)	198201	£10.00	1 - 9	£8.00
			10 - 49	£7.00
			50 - 199	£6.00
			200+	£5.00
100cm line with check valve & female LLock	100-172S	case of 20		£29.00
As above with yellow striped tubing	100-172SE	case of 20		£34.00

### Terms

Payment terms are 30 days from date of invoice. All quoted prices are exclusive of VAT at the prevailing rate. VAT exemption certificates must accompany any order where the customer is seeking exemption from VAT.

### Delivery

Delivery is usually within 7-10 days from receipt of order. Carriage is charged at £6.95 for single case orders and a £9.95 fixed charge for larger quantities irrespective of size/weight.

### Contact

CME McKinley UK Limited  
Kincraig Business Park  
Kincraig Road  
Blackpool  
FY2 0PJ  
Tel: 01253 220114



## Clinical Training

No of pumps purchased	Training days available	Training documents
1 to 5	1/2	<p>At initial, contracted training the following will be given:</p> <ul style="list-style-type: none"> <li>• 2 x pocket guides per pump</li> <li>• 1 x wall guide per area where the pumps will be placed/per pump</li> <li>• 1 x learning portfolio per trainee (competency assessment record).</li> </ul>
5 to 20	1 day	
21 to 40	2 days	
41 - 60	2.5 days	
61 - 80	3 days	
81 - 100	4 days	<p>All organisations will be given the option to register and access the CME McKinley on-line interactive learning and training resources.</p>
100 plus	<p>Average is 5 days based on a train the trainer type roll out programme. For larger group purchases, this element is assessed on need and negotiated direct with the end users.</p>	

- Any training days not taken can be credited for use at a later date.
- Training dates to run consecutively if possible.
- Any training days requested over and above those allocated by CME McKinley may be charged for.
- Key Trainer sessions are encouraged.
- "Drop-In" training sessions are discouraged. (Poor uptake by this method is commonly encountered).

### Prior to/following initial training:

- Further copies of pocket guides/wall charts/information leaflets and operating manuals are available for download from the CME McKinley website.
- Word templates of all training documents (including competency-based assessment forms) can be provided for companies/organisation to design in-house documentation.

### Training provision options:

- 1-hour competency-based assessment workshop
- 2-hour "Key Trainer"/"Train the Trainer" training
  - Training to staff will be given at the level of access to the device as indicated by the customer.
  - All the available functions and facilities available as the default setting will be taught.
  - Training can be provided out of normal working hours if requested/negotiated.

## Warranty

### McKinley T34 Syringe Pump – LIMITED WARRANTY

The McKinley T34 Syringe Pump has been carefully manufactured from the highest quality components.

Caesarea Medical Electronics Ltd. (CME) guarantees the pump against defects in material and workmanship for twenty four (24) months from date of purchase by the original purchaser.

CME's obligation, or that of its designated representative under this Limited Warranty, shall be limited, at CME's option, or that of its designated representative, to repairing or replacing pumps, which upon examination, are found to be defective in material or workmanship. The repair or replacement or any product under this Limited Warranty shall not extend the above-mentioned Warranty period.

All repairs under this Limited Warranty should be undertaken only by qualified, trained service personnel. In the event that a pump is found to be defective during the warranty period, the purchaser shall notify CME or its designated representative within thirty (30) days after such defect is discovered.

The defective pump should be sent immediately to CME or its designated representative for inspection, repair or replacement. Shipping costs are the purchaser's responsibility.

*Material returned to CME or its designated representative should be properly packaged using CME shipping cartons and inserts. Inadequate packaging may result in severe pump damage.*

This Limited Warranty shall not apply to defects or damage caused, wholly or in part, by negligence, spilled fluids, dropping of the pump, misuse, abuse, improper installation or alteration by anyone other than qualified, trained personnel; or to damage resulting from inadequate packaging in shipping the pump to CME or its designated representative.

If, after inspection, CME or its designated representative is unable to identify a problem, CME or its designated representative reserves the right to invoice the purchaser for such inspection.

This Limited Warranty is the sole and entire warranty pertaining to CME's products and is in lieu of and excludes all other warranties of any nature whatsoever, whether stated, or implied or arising by operation of law, trade, usage or course of dealing, including but not limited to, warranties of merchantability and warranties of fitness for a particular purpose. Purchase expressly agrees that the remedies granted to it under this limited warranty are purchaser's sole and exclusive remedies with respect to any claim of purchase arising from this Limited Warranty.

## Technical Support

### **CME Technical Support Services**

CME McKinley UK Ltd aims to provide market leading support services, including technical training and support, with a high level of stocked spares and speedy repair turnaround times. We can work with our customers to ensure they receive the best service that they deserve.

#### ***Training***

As a supplier of the latest technology infusion devices, CME McKinley UK Ltd, understand the importance of the Biomedical engineer in supporting and maintaining these sophisticated devices, we offer a technical training course designed to give the biomedical engineer the knowledge and skills to effectively support our range of infusion devices.

#### ***Spares Parts Availability***

CME McKinley carries an extensive stock of spare parts and we aim to delivery them to the customer within two working days, following receipt of order.

#### ***Technical Telephone Support***

A team of highly trained product specific engineers are available to offer technical support during working hours – telephone 01253 894646 option 5 Technical Services.

#### ***Loan Equipment***

To minimise equipment downtime, we aim to turnaround service or repaired equipment in less than 15 days, if for some unforeseen circumstances this industry leading deadline can not be met, we will offer loan equipment to ensure optimum equipment utilisation and customer satisfaction.

#### ***Equipment Repair and Servicing***

All preventative maintenance work and equipment repairs are completed by a team of factory trained highly skilled engineers.

All returned equipment should be accompanied by a Return Goods Authorisation number (RGA#), please contact 01253 893646 - Logistics option 4 to obtain a RGA#.

If you require any additional information regarding the services CME McKinley can offer, please do not hesitate to contact the Technical Services Team, on 01253 894646 – option 5 or email [service@cme-mckinley.co.uk](mailto:service@cme-mckinley.co.uk)