Countess of Chester Hospital NHS
NHS Foundation Trust

Invitation to Tender for the Provision of Pacemaker Systems

Project Reference: G/178/PL/18/MH

SCHEDULE D

SPECIFICATION

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Overview of the Requirement

The Countess of Chester Hospital NHS Foundation Trust (the Authority) are tendering for the provision of Pacemaker systems, comprising of:

1) Single chamber
2) Dual Chamber
3) Implantable Cardiac Monitor (ICM)

The framework agreement will commence on the 1st April 2018 and will run for an initial two year fixed period, the remaining two years of the framework will be negotiated with either a 12 or 24 month extension being awarded at the discretion of the Authority.

Background to the Cardiology department

The cardiology department at the Authority is made up of six consultants who provide a comprehensive Cardiology service including a joint post with Liverpool Heart and Chest Hospital with a specialist interest in interventional cardiology. The speciality has seen the development of care pathways for patients with Myocardial Infarction and management guidelines for Heart Failure, Acute Coronary Syndromes, Stable Angina and Atrial Fibrillation.

The Authority has a purpose built cardiac catheter laboratory that has been open since January 2006. The service offered by the Catheter Lab is provided by Consultant Cardiologists, providing diagnostic angiography, pacemaker implants and cardio versions.

A well-established Cardiac Rehabilitation service reviews patients post-surgery and post Myocardial Infarction. This is run in conjunction with local Clinical Commissioning Groups to ensure continuity of care.

The department is further supported by a team of Cardiac Nurse Specialists, as well as two Clinical Assistants who assist with the Outpatient Clinics.

Essential Product requirements

General Requirements

1. CE Marking – All systems must comply with the Active Implantable Medical Devices Directive
2. Datasheets/ Product Specification documents – These must be available for each product offered and provided with the Tender submission.
3. EGM storage – All products must have EGM storage.
4. Further review – All products must have the ability to save data for further review.

Quality Requirements

5. Shelf life – A minimum of 12 month shelf life from date of delivery must be provided on all products.

Pacemaker Specific Requirements

6. Provision of pacemaker programmer/s on unconditional free loan basis - Programmer/s must be compatible with all previous models of own company's pacemaker devices.
7. Programmers – Programmer consumables and spare parts must be supplied Free of Charge as and when required.
8. Generators – Model types must support single and dual chamber rate adaptive pacing.

9. Generators – Products must store diagnostic data including, but not limited to:
    a. Lead impedance
    b. Thresholds
    c. Percentage paced
    d. High rate/mode switch details and high rate trends.
10. Generators – Products must provide battery status indicators including, but not limited to:
    a. Voltage
    b. Impedance
    c. Magnet rate
    d. Estimated longevity
11. Leads – All leads must terminate with an industry standard (IS-1/IS-4) connection.
12. Threshold Checking Cables – A range of disposable sterile packs must be provided free of charge.
13. Introducer Sheaths – A range of 'peel away' introducer sheaths with haemostatic valve to accommodate different lead sizes and types must be provided free of charge,
14. Other Consumables – A range of lead stylets in various lengths, lead cap kits and torque wrenches must be provided free of charge as and when required throughout the framework.

Other requirements

Recalling of faulty pacemakers

In the eventuality that any pacemaker system needs to be withdrawn or recalled all tenderers need to provide a policy to the Authority to show what the Authority needs to do to minimise any complications. If tenderers update their policies in any way the Authority will require an update and will require a representative to attend a meeting and explain the updates.

If, during the framework period Pacemaker systems need to be recalled the Authority will expect the successful tenderer(s) to ensure that replacement Pacemaker systems are dispatched to the Authority within 48 hours (from notification to the Authority of the planned recall) to ensure procedures are not cancelled. If at the point of notification tenderer(s) know they cannot provide replacement pacemakers systems they should raise this at the point of notification so the Authority can make the necessary steps to inform patients and importantly to try and avoid cancelling operating lists and incurring possible charges imposed on the Authority for cancelling procedures.

If the Authority does not receive more than 7 (working) days' notice of Pacemakers needing to be recalled the Authority is within their rights to seek compensation to recoup all costs associated with having to cancel procedure(s) that may be imposed on the Authority.

Lead times for pacemaker systems

All tenderers need to ensure their supply chain can provide pacemaker systems within 24 hours from the point of ordering. If, at the point of ordering, tenderer(s) cannot meet that deadline it is the responsibility of the tenderer(s) to immediately inform the Authority so alternative arrangements can be made. Failure to inform the Authority, at the point of ordering, and as a consequence of not informing the Authority the patient needs to be cancelled the Authority will seek compensation to cover all financial penalties imposed on the Authority.

Training support

All tenderers who are accepted on to the framework will be required to provide the Authority with regular on-going training throughout the duration of the framework in order to ensure clinicians and nursing staff are kept fully informed of product enhancements and to ensure clinical standards and nursing care are continually exceeded. It is anticipated that the majority of the training will take place at the Authority; therefore tenderers need to have resource to complete this requirement.

Head office and account management support
Tenderers will be expected to provide ongoing support to the cardiac department throughout the framework period. This should include a primary contact for the Authority's cardiac co-ordinator for day to day contact, in addition for day to day queries, e.g., invoice queries the Authority will require a dedicated internal account manager.

Helpdesk / Technical support
It is essential for tenderers to provide a helpdesk / technical support facility so Authority staff have the ability to have technical / clinical queries answered immediately.

Delivery costs
The Authority does not expect to pay carriage costs. Any carriage costs applied will be added to your overall pricing.

Expected annual usage
The table below illustrates the usage during 2015-2016 and 2016-2017, and the anticipated annual usage under the framework going forwards.

The Authority cannot make any firm commitments on volume so the figures are meant as a guide only.

	Previous usage		**Anticipated future usage**			
	2015-2016	**2016-2017**	**2018-2019**	**2019-2020**	**2020-2021**	**2021-2022**
Single chamber pacemaker system	39	49	44	44	44	44
Dual chamber pacemaker system	149	201	176	176	176	176
Implantable Cardiac Monitor (ICM)	63	65	67	67	67	67
Total Volume per annum	**251**	**315**	**287**	**287**	**287**	**287**