APPENDIX 3I

LOT 9 SPECIFICATION
LITHOTRIPSY AND ASSOCIATED OPTIONS AND RELATED SERVICES

1. Introduction

1.1. This Lot is for the supply of lithotripter systems including all associated options and accessories. The systems must be able to break up stones in the kidney, bladder, or ureter by using shockwaves.

1.2. The core product lines within this Lot are as follows:

Line Number	
1	Lithotripter System (Fixed)
2	Lithotripter System (Non-Fixed)

1.3. Product line(s) must be supplied with a minimum 7 year expected lifecycle under proper use and maintenance.

2. Criteria applicable to all Lines

2.1. Lithotripter systems must be able to break up stones in the kidney, bladder, or ureter by using shockwaves.

2.2. Lithotripter:

2.2.1. The lithotripter shockwave source must be able to break up stones in the kidney, bladder or ureter (e.g. electromagnetic, piezoelectric or electro-conductive source).

2.2.2. The lithotripter must have a penetration depth of at least 140mm.

2.2.3. The lithotripter must be suitable for both adult and paediatric work.

2.2.4. The shock wave head must have a facility for energy used to be variable and quantifiable.

2.2.5. The shock wave source coupling must either, be in direct contact with the patient's body without any separation except coupling gel, so as to effectively transfer shock wave energy directly to the target or alternatively, a water/oil coupling with patient foil concept.

2.2.6. The shock wave source must enable different treatment positions for ureteral and renal stones.

2.2.7. The lithotripter must use a water-filled cushion coupling method.

2.2.8. The lithotripter must enable variable pulse frequency.

2.3. Examination/treatment table:

2.3.1. The table must be motorised and configured for three-way (X, Y, and Z) patient positioning.

2.3.2. The table must support a minimum patient weight of 180kg.

2.4. X-Ray localisation system:

2.4.1. The X-Ray C-arm must move isocentrically to the shockwave source.

2.4.2. The lithotripter system must have a high frequency X-Ray generator with dual focus X-Ray tube; large focus must be greater than 0.5mm, small focus must be less than 0.5mm.

2.4.3. The lithotripter system must have a 9" image intensifier TV chain with CCD camera or digital detector permitting pulsed/continuous fluoroscopy.

2.4.4. The lithotripter system must permit the optimisation of patient dose by user selectable dose rates.

2.4.5. The dose rate must be controlled by an automatic exposure system that minimises patient dose.

2.4.6. The lithotripter system must allow localisation in different projections without decoupling the patient.

2.4.7. The lithotripter system must have an incorporated boost snapshot facility with 12bits digital memory and last image hold.

2.4.8. The lithotripter system must have two flicker-free monitors, minimum 18" screen (measured diagonally corner to corner) with the facility to transfer images between monitors and with initial/last image hold on one monitor to compare with on-going images on the other monitor.

2.5. Ultrasound localisation system:

2.5.1. The lithotripter system must have an integrated 2-D real-time ultrasound localisation and targeting lithotripter system, isocentric to the shockwave source.

2.5.2. The ultrasound system must have an freeline/inline/outline transducer.

2.5.3. The lithotripter system must allow localisation in different projections without decoupling the patient.

2.5.4. The ultrasound system must have a broad frequency curvilinear transducer of 2.0-4.5MHz frequency.

2.5.5. The ultrasound system must have an image freeze function.

2.5.6. The ultrasound system must provide internal image storage and retrieval.

2.5.7. The ultrasound system must have 2-D digital measurement callipers with on-screen display of distance.

2.5.8. The ultrasound system must be capable of moving or being moved so that it can be used as a standalone ultrasound system.

2.6. Functional connectivity requirements for the system:

2.6.1. The system must produce digital images to be stored on the Hospital or Healthcare Institute's PACS solution, with workflow management through the use of work lists from PACS/RIS.

2.6.2. Evaluation of connectivity and interoperability on similar equipment must be agreed with the customer to ensure that the system/solution being offered can meet their functional requirements.

2.7. Integration requirements for the system:

2.7.1. Must be compatible with DICOM.

2.7.2. The scanner must support X-Ray radio fluoroscopic and ultrasound DICOM service classes as either a service class user (SCU) or service class provider (SCP).

2.7.3. DICOM conformance statements for the imaging equipment/modality must be available and provided on request.

2.8. Software protection:

2.8.1. The system must incorporate preventive measures to protect it from being affected by malicious software.

2.8.2. All operating updates must be installed on the lithotripter system.

2.8.3. Operating updates must not in any way compromise the safety of patients if any updates cause the lithotripter system to be unstable then there must be a facility to roll back to the previous operating system and software configuration.

2.8.4. The process for achieving the following must be supplied to the customer on request during the lifetime of this Framework Agreement:

2.8.4.1. Lithotripter system password generation

2.8.4.2. Lithotripter system user log

2.8.4.3. Lithotripter system user authorization

2.8.5. System integration must be compatible with the NHS Connecting for Health 'single sign-on' requirement.

2.8.6. Any remote monitoring/repair services via modem must only be accessed via the owner's firewall.

2.8.7. The system must have an audit trail of patches and software installation.

2.9. Network connectivity and security:

2.9.1. The system must have a minimum 1000Mbps ethernet network interface card which can auto negotiate to 100Mbps for networks with a 100Mbps backbone.

2.9.2. Remote servicing must be implemented under the guidelines proposed by the joint NEMA/COCIR/JRA Security and Privacy Committee (NEMA 2003).

2.9.3. The NHS Code of Connectivity must be adhered to.

2.9.4. Any default security settings must be altered after installation is complete.

2.9.5. All communication ports (including USB ports) not used by the system must be disabled during installation.

2.9.6. The system must not allow the use of generic passwords.

3. Line 1 - Lithotripter System (Fixed)

3.1. Along with the requirements in section 2 these are the additional requirements for a fixed (non-transportable) extracorporeal shockwave lithotripter (ESWL) intended for use on the kidney, ureter and bladder.

3.2. The core components for a fixed ESWL system:

3.2.1. Lithotripter.
3.2.2. Examination/treatment table.
3.2.3. X-Ray localisation system.
3.2.4. Ultrasound localisation system.
3.2.5. Full remote control set.

3.3. Lithotripter:
3.3.1. The lithotripter must be designed for a fixed installation

3.4. Examination/treatment table;
3.5. The table must be designed for a fixed installation
3.6. The x-ray c-arm must be designed for a fixed installation and must have motorized movement for stone localisation.
3.6.1. The lithotripter system must have functionally integrated isocentric fluoroscopy and ultrasound systems.
3.6.2. The lithotripter system must have an integrated and motorised X-Ray C-arm localising and targeting lithotripter system, isocentric to the shockwave source.

4. Line 2 - Lithotripter System (Non-Fixed)

4.1. Along with the requirements in section 2 of this specification these are the additional requirements for a non-fixed (transportable), extracorporeal shockwave lithotripter (ESWL) system intended for use on the kidney, ureter and bladder.

4.2. The core components for a non-fixed ESWL system:
4.2.1. Lithotripter.
4.2.2. Examination/treatment table.
4.2.3. X-Ray localisation system.
4.2.4. Ultrasound localisation system.

4.3. All components must capable of being moved from one hospital location to another with no additional specialist equipment.