

## Specifications for Extra Corporeal Shock Wave Lithotripsy (ESWL)

Sch. No.	Specification
<b>1</b>	<b>Extracorporeal Shock Wave Lithotripter (ESWL)</b>
<b>1</b>	<b>Description of Function</b>
1.1	Renal extracorporeal lithotripter system, non invasively disintegrates kidney stones with focused shock waves, allowing the resulting sand-size fragments to pass out of the body during urination.
<b>2</b>	<b>Operational Requirements</b>
2.1	Completely integrated system where the shock wave module, fluoroscopy and patient table are completely integrated. The system should have Fluoroscopy and Ultrasound guided stone localization and targeting along with digital documentation, patient data management system and data storage. The system should be compatible with available Hospital Information System
<b>3</b>	<b>Technical Specifications</b>
3.1	Shockwave Generator:
a	Type: Electromagnetic
b	Triggering: Manual and ECG gating
c	Pulse Frequency: = 60 – 120 per minute (User Selectable)
d	Penetration Depth minimum 170 mm or more
e	Pressure at focus. Minimum 20 MPa or less, Maximum 50 Mpa or more
f	Energy level: User Selectable & Variable
g	The Shock wave Generator and coil should be guaranteed for minimum of 1.5 million shockwaves
3.2	Imaging System: Integrated, permanently non detachable Fluoroscopy that is an integral part of the ESWL machine and not a stand-alone C arm that is fixed to the machine
a	Should have high frequency generator and allow pulse fluoroscopy
b	kV Range: 40-110 kV
c	mA Range: 4mA or more
d	Focal Spot Sizes: single: 0.3/0.6 or 0.6/1.2/1.5
e	Flat Panel detector 21x21 cms
f	Collimation: Motorized, Iris collimator.
g	Post Exposure Image Enhancement facility
h	Localization and targeting of stone using fluoroscopy should be fully motorized. The Anteroposterior to Orbital/ Craniocaudal movement and also Orbital/ Craniocaudal to Anteroposterior movement should be fully motorized.
3.3	Imaging System Ultrasound: High resolution ultrasound system
	Localization should be done through integrated Ultra-sound iso centric/linked to the shock wave source with inline/outline transducer for best image quality
	Transducer:
I)	3.5 /5 MHz Convex Sector
II)	Coupling arm to integrate the ultrasound probe with shockwave generator
3.4	Patient Table System:

i)	Fluoroscopy compatible motorized patient Table with Vertical, Longitudinal and lateral movements. Patient load capacity of app 150 Kg. Table should be from same OEM.
3.5	Fluoroscopic Imaging System: 17 inches LCD Display with data storage and image storage. Minimum storage would be 1000 images with 1024x1024x(12 bits)
3.6	Patient Monitoring: Monitoring of ECG, RESPIRATION, SpO2 and Arrhythmia
3.7	Separate Remote Console with facility for:
i)	Controlling imaging, stone localization, targeting and shockwave parameters
ii)	Patient monitoring
4	Standards
4.1	The offered model should have valid BIS certificate/ European CE with 4 digit notified body number / USFDA.
4.2	Manufacturer should have ISO 13485 certification issued from: Any Certification Bodies registered with NABCB under Medical Devices Quality Management System OR Any notified body registered with CDSCO OR Any 4-digit CE notified body
4.3	Should have import/manufacturing license from Central licensing Authority or State licensing authority of CDSCO for Medical Devices and copy of valid license should be submitted for the quoted model. In case the supplier has not yet obtained import/manufacturing license from CDSCO for the quoted model, proof of application for CDSCO medical device license to be submitted in the bid document and valid CDSCO license to be produced before award of contract.
5	<p>Scope of site modification work:</p> <ol style="list-style-type: none"> <li>1. Site modification required for the installation of the complete system will be done by the supplier as per AERB norms. Area of 600 sq. ft. and Air-conditioning of Tonnage 5 TR will be considered for Ranking/ Evaluation purpose.</li> <li>2. Lead glass window of minimum size 5 ft. X 5 ft. with frame in between console room and ESWL room</li> <li>3. Flooring: Vinyl flooring/Vitrified tiles in procedures and console room</li> <li>4. False Ceiling: Modular type ceiling with adequate LED lighting</li> <li>5. Wall: Ceramic tiles up to ceiling height in ESWL procedure room and console room or wall paint with enamel coating after proper preparation</li> <li>6. Electrical: All necessary electrical works (including electrical panel, wiring, switches) will be done by the vendor, adequate light and power point to be provided in the whole area.</li> <li>7. One dedicated earthing</li> <li>8. Lead shielding in door and window</li> <li>9. Moreover Bidders will have to quote the unit rates of all site modification works and the actual area of site modification work works done will be considered for payment, based on the unit rates and site measurements</li> </ol>

6	Suitable online UPS should be supplied with 1hrs backup approx.10KVA capacity - 1 no
7	Bidder must upload detailed technical quotation, technical Compliance with Supporting documents like technical brochure, feature sheet, manual etc. with highlighted each point of technical specification with referring page number. Without technical quotation and supporting documents with point wise matching technical specs will lead to rejection of tender out rightly.
8	Physical Demonstration of the quoted model as per technical specification of tender is required
9	System should be supplied with 5 years warranty and CMC/AMC for next 5 years after warranty period. CMC/AMC rates should be quoted in price bid.
10.	OEM/Bidder should have supplied same/similar model as the quoted model with at two or more Government institutes/hospitals in India in last three financial years and supply order copy along with performance should be attached and at least one must be in the name of Bidder with installation report and performance certificate.
11	There will be 95% uptime warranty during CMC period on 24(hrs) x 7(days) x 365 basis, with penalty, to extend CMC period by double the downtime period.
12	Rates of consumables, spare parts and additional accessory items to be quoted separately by the firm. These quoted rates should be valid and freezed for at least 3 years. Anything which is not separately mentioned as a consumable will be considered to be a spare part and which would then be covered under warranty / CAMC. Spare parts and consumables should be made available for the life of the equipment .
SL. No.	BOQ
1	ESWL as specified - 1NOS
2	Coupling Jelly 100 Litres - If Required for system - 1NOS
3	Laser printer with 5 catridges- 1NOS
4	Lead apron and Thyroid shield- 10NOS each
5	LED X ray display 2x5.4 ft or bigger- 2NOS
6	Large register for record keeping- 10NOS
7	Online UPS as per specification- 1NOS
8	Site modification - 600Sq ft