



**Biomedical Engineering Department**  
**Indira Gandhi Memorial Hospital**  
**Male', Republic of Maldives**  
**Ultrasound System**  
**Technical Specification**

## 1. Intended Use

High-performance cart-based diagnostic ultrasound system for:

- Obstetrics
- Gynecology
- Fertility/Reproductive Medicine
- Abdominal Imaging
- Small Parts
- Breast Imaging
- Musculoskeletal Imaging
- Vascular Studies
- Urology
- Pediatric Imaging
- Interventional Procedures

The system shall support routine examinations as well as advanced diagnostic applications.

## 2. System Configuration

### Architecture

- Fully digital beamforming architecture
- Advanced image processing platform
- Real-time multi-core processing technology

### Monitor

- High-resolution LED/LCD monitor
- Minimum 23-inch widescreen display
- Adjustable height and viewing angle

**Touchscreen**

- Minimum 13-inch touchscreen
- Gesture-enabled operation
- User-programmable workflow shortcuts

**Probe Ports**

- Minimum 5 active transducer ports
- Electronic transducer selection

**Mobility**

- Compact mobile cart design
- Lockable anti-static wheels
- Integrated storage compartments
- Integrated battery backup

**Battery Operation**

- Minimum 2-hour battery scanning capability

**Low Noise Operation****3. Imaging Modes**

The system shall provide:

**Basic Modes**

- B-Mode
- M-Mode
- Color Doppler
- Power Doppler
- Directional Power Doppler
- Pulsed Wave Doppler (PW)
- Continuous Wave Doppler (if cardiac package offered)

**Advanced Modes**

- Tissue Harmonic Imaging
- Spatial Compound Imaging
- Speckle Reduction Imaging
- Extended Field-of-View / Panoramic Imaging
- Trapezoidal Imaging
- High-Sensitivity Microvascular Imaging or equivalent technology
- Adaptive image optimization

## 4. 3D / 4D Imaging

The system shall support:

- Real-time 3D imaging
- Real-time 4D imaging
- Multiplanar reconstruction
- Surface rendering
- Volume rendering
- Automated volume analysis

## 5. Obstetric Package

The system shall provide:

### Standard Measurements

The system shall provide automated and manual measurement capabilities for:

- Crown-Rump Length (**CRL**)
- Biparietal Diameter (**BPD**)
- Head Circumference (**HC**)
- Abdominal Circumference (**AC**)
- Femur Length (**FL**)
- Estimated Fetal Weight (**EFW**)
- Gestational Age (**GA**)
- Amniotic Fluid Index (**AFI**)
- Nuchal Translucency (**NT**)
- Fetal Heart Rate (**FHR**)

### Advanced Obstetric Functions

- Automated fetal biometry
- Automated fetal head measurements
- Automated nuchal translucency measurement
- Automated fetal plane recognition
- Fetal growth assessment
- Fetal anomaly assessment tools
- Multiple international growth charts

## 6. Gynecology & Fertility Package

The system shall include:

- Uterine measurements
- Ovarian measurements
- Endometrial measurements
- Follicle assessment

### Advanced Functions

- Automated follicle counting
- Endometrial analysis tools
- Ovarian lesion assessment
- Pelvic floor assessment
- Reproductive medicine package

## 7. Advanced Clinical Applications

### Elastography

- Strain Elastography and/or Shear Wave Elastography

### Contrast Imaging

- Contrast-Enhanced Ultrasound (CEUS) capability

### Women's Health Analytics

- Advanced lesion characterization tools
- Risk stratification tools for gynecological assessment

## 8. Automation & AI-Assisted Functions

The system shall provide intelligent workflow tools including:

- Automatic image optimization
- Automatic Doppler optimization
- Automatic measurement functions
- Automatic anatomical recognition
- Automatic volume analysis
- Automatic report generation

Equivalent technologies from different manufacturers shall be acceptable.

## 9. Measurements & Analysis

### General Imaging

- Abdomen
- Small Parts
- Breast
- MSK
- Vascular
- Urology

### Doppler Analysis

- Arterial measurements
- Venous measurements
- Carotid measurements

### Reporting

- Structured reporting
- Image annotation
- Customizable report templates

## 10. Data Management & Connectivity

### DICOM Connectivity

The system shall support:

- DICOM Storage
- DICOM Print
- DICOM Worklist (MWL)
- DICOM Modality Performed Procedure Step (MPPS)

### Hospital Information System Integration

The system shall support:

- Hospital Information System (HIS) integration
- Electronic Medical Record (EMR/EHR) integration
- HL7 communication interface
- Patient demographic import and worklist synchronization

### Data Export

The system shall support export of:

- PDF reports
- JPEG and BMP images

- DICOM images and studies
- AVI and/or MP4 cine loops
- USB storage devices

### **Network Connectivity**

The system shall provide:

- Gigabit Ethernet connectivity
- Multiple USB ports
- Network printer support
- PACS connectivity
- Wireless LAN (Wi-Fi) connectivity (if available)

### **Data Storage**

- Internal storage capacity  $\geq 500$  GB SSD or  $\geq 1$  TB HDD
- Patient database management
- Image and cine loop archiving

## **11. Transducers**

Supply minimum:

### **Convex Probe**

- 1–6 MHz

### **Linear Probe**

- 4–15 MHz

### **Endocavity Probe**

- 3–10 MHz

Optional probes:

- High-frequency linear probe
- Volume transducer
- Intraoperative probes
- Pediatric probes

## **12. Electrical Requirements**

- 220–240 VAC
- 50/60 Hz
- Supplied with 13A Type G plug
- Integrated battery backup

### 13. Standards & Regulatory Compliance

The system shall comply with:

Standard	Requirement
IEC 60601-1	Electrical Safety
IEC 60601-1-2	EMC
IEC 60601-1-6	Usability
IEC 62366	Usability Engineering
IEC 62304	Medical Software Lifecycle
ISO 13485	Quality Management System
DICOM	Connectivity
CE MDR 2017/745 and/or FDA 510(k)	Regulatory Approval

### 14. Accessories

- Mobile trolley
- Gel bottle holder
- Probe holders
- Footswitch (if applicable)
- ECG module (if required for advanced cardiac applications)
- Medical-grade USB thermal printer with printer paper starter pack
- **Online, double-conversion Medical-Grade Uninterruptible Power Supply (UPS) with a minimum runtime of 15 to 20 minutes and integrated isolation transformer capability must be provided or quoted**

### 15. Documentation, Training & Warranty

#### Documentation

- User Manual
- Service Manual
- Maintenance Manual
- Calibration Certificate
- Regulatory Certificates
- Cleaning and Disinfection Guide for system and transducers
- Certificate of Conformity

#### Training

- Clinical user training
- Application specialist training

- Biomedical engineering technical training

**Warranty**

- Minimum 24 months comprehensive warranty
- All software updates within warranty period included at no cost

**Lifecycle Support**

- Spare parts availability minimum 10 years
- Software updates for a minimum of 5 years

**Service Support**

- Local service support availability
- Remote diagnostics capability
- On-site service response within 48 hours for critical failures

**Installation**

- Factory-trained engineer installation and commissioning

**Preventive Maintenance**

- Annual preventive maintenance schedule with documented service report

**16. Environmental and Storage Conditions**

<b>Operating Temperature</b>	<b>+10°C to +40°C</b>
<b>Operating Humidity</b>	30% to 75% RH (non-condensing)
<b>Storage Temperature</b>	-20°C to +55°C
<b>Storage Humidity</b>	10% to 95% RH (non-condensing)
<b>Transport Vibration / Shock</b>	Meets IEC 60068-2 for transport vibration and shock when in transit case