M7 Hand-carried Diagnostic Ultrasound System

Performance Specifications

System Description
The Mindray M7 Diagnostic Ultrasound System is a premium performance hand-carried color doppler ultrasound imaging system. Mindray research and development engineers employ the System On Chip (SOC) design within the M7. SOC enables complex technologies to be built into the M7’s compact laptop style chassis. The M7’s exceptional image quality, high speed user experience and versatility have expanded the envelop of performance and flexibility for hand carried ultrasound systems.

Applications
Abdomen, Obstetrics, Gynecology, Cardiology, Peripheral Vessels, Small Parts, Urology, Anesthesia, Emergency Medicine, IC/CCU, Pediatrics, Neonate, Trans-cranial, Interventional, Musculoskeletal, Intra-operative.

General Specification
Dimensions and Weight
Width: 361mm (14.21 inch)
Depth: 357mm (14.06 inch)
Height: 75mm (2.95 inch)
Weight: Approx. 6.5kg, including batteries.

Electrical Power
AC adapter input
Voltage: 100 – 240V–
Frequency: 50/60Hz
Input current: 1.5 – 0.6A
AC adapter output
Voltage: 12V
Output current: 10A Battery

Battery
Lithium-Ion
Battery Pack: 11.1V, 4500mAh

Operating Environment
Ambient temperature: 0°C – 40°C
Relative humidity: 30% – 85% (no condensation)
Atmospheric pressure: 700 hPa ~ 1060 hPa

Storage and Transportation Environment
Ambient temperature: -20°C – 55°C
Relative humidity: 30% – 95% (no condensation)
Atmospheric pressure: 700 hPa ~ 1060 hPa

Console Design
Display
Control Panel
Handle
Transducer port
Transducer locking lever
I/O extend port
Power input port
USB port: 2
Ethernet port
S-Video separate video output
Wireless LAN support

User Interface
Control Panel
Alphanumeric keys
Functional keys
Navigation Rotary Knob
Ergonomic soft key operations
Backlight keys
8 segment TGC
Power/Battery indicator
Blank keys for user-defined functions
Trackball, sensitivity and color adjustment
Integrated speakers, audio volume adjustment

Display Screen
Display: 15 inch LCD, High-Resolution 1024 x 768
Brightness adjustment
Screen saver: setting adjustment

Inputs & Outputs
Main Unit
Transducer port: 1 (Connect to a Transducer or the Transducer extend module)
I/O extend port: 1 (Connect to the I/O extend module)
Power input port: Connect to the power adapter
USB port: 2
S-Video separate video output: 1 (For image signal output)
Ethernet port: 1 (To connect to the network)

I/O Module (optional)
USB port: 2
ECG port: 1
Serial port: 1
Audio output port: 1 L/R
Mic In port: 1
Remote control port: 1
Composite video output port: 1
DVI-I output port: 1

V/A Extend Module (optional)
Audio input port: L/R
Composite video input port
Separate video input port

ECG Module (optional)
ECG lead port
Connection port: To connect to I/O module

Mobile System Cart
UMT-200
UMT-300
15 inch Extra LCD Display (optional)
Power supply module (optional)
External DVD R/W storage (optional)

Intelligent Workflow
Synchronous navigation: On-screen instructions
Screen saver mode: Transducer transmission is turned off
Thumbnail images: Display saved images during live scan
Soft keys: Shortcut for easy access to system
Menus and active parameter adjustment
Report edit and preview function
Backlight indication
User account management tool
Task management tool

System Overview
Exam Mode
Factory default: 35, user customizable
User Defined: 15
Total: 50 exam modes, all customizable

Scanning Method
Electronic convex
Electronic linear with steer and trapezoid scanning function
Electronic sector

Transducer Type
Linear array
Phased array
Convex array

Imaging Mode
B
M
Free Xros M: Anatomical M mode
Color
Power (DirPower)
PW
CW
Smart 3D
Static 3D
4D (optional): Dynamic 3D
iScape™ (panoramic imaging)
TDI (Tissue Doppler imaging)
Color M (CM)

Display Mode
Triplex mode: B/C/D
Dual live: B/C, B/TDI
Adjustable 2D+ time line display format
Single window
Dual-split: Quad-split:
Performance Specifications

Imaging Technology
- Tissue harmonic imaging
- Tissue doppler Imaging
- Steer scanning for linear transducers (B, Color/Power, PW/CW independent)
- Trapezoid imaging for linear transducers
- iBeam™: Spatial compounding imaging for linear transducer
- iClear™: Adaptive speckle suppression imaging for all transducers
- iTouch™: Quick optimization for B or PW/CW image with one button control
- HPRF for PW
- Multi-frequency Transducers for 2D and Doppler imaging modes

Imaging Feature
- Zoom: Magnification factor 1 – 10
- Full screen iZoom: Zoom in the image area
- System dynamic range: 30 – 160dB
- Frame rate (Max.): 643 frames/s
- Adjustable focus positions (Max.): 16
- Maximum frame rate in 4D: 30 volumes/s

Languages
- Software display, control panel overlay and electronic copy of operation manuals including: Chinese, English, French, German, Italian, Portuguese, Russian, Spanish, Polish, Czech, Turkish, Finnish, Danish, Icelandic, Norwegian, and Swedish.

System Configuration
- Standard Configuration
  - Display: 15 inch LCD display, High resolution
  - PW
  - HPRF
  - Color doppler flow imaging
  - Power doppler flow imaging
  - Directional power doppler flow imaging
  - Tissue harmonic imaging
  - Trapezoid imaging
  - iBeam™
  - iClear™
  - iScape™
  - iStation™
  - 160G integrated hard disk
  - Multi-language screen display and control panel overlay
  - Carrying case with telescopic handle

Software Options
- iClear™
- CWD module
- iScape™ module
- Free Xros M (Anatomical M)
- Smart 3D module
- 4D module
- TDI (Tissue Doppler imaging) module

Application packages, including exam mode, comments, measurements, body marks and report:
- Abdominal package
- Obstetrical package
- Gynecological package
- Cardiac package
- Small parts package
- Urological package
- Vascular package
- Pediatric package
- Nerve blocks package
- Emergency medicine
- DICOM basic function module (including: task management, DICOM storage, DICOM print, DICOM storage commitment, DICOM media storage (including DICOM DIR)
- DICOM Worklist
- DICOM MPPS
- DICOM OB/GYN structured report
- DICOM vascular structured report
- DICOM cardiac structured report
- DICOM Query/Retrieve

Hardware Options
- External USB DVD-RW: SE-S224Q
- IO extend module: IOM-21
- Transducer extend module: PEM-21
- V/A extend module: VAM-11
- ECG module: ECG-21
- ECG lead
- Footswitch: 971-SWNOM
- Mobile trolley: UMT-300
- Pack
- Dust-proof cover
- Battery Pack (LI23I001A)
- Wireless-LAN adapter
- Transducers
- Needle-guided brackets

Peripherals Supported
- Black/white video printer
  - SONY UP-D897
- Color video printer: SONY UP-D23MD
- Graph/text printer
- HP Deskjet D2568
- HP OfficeJet J3600 (HP Officejet J3608 All-in-One)
- HP Color LaserJet CM1015

Display Annotations
- Manufacturer logo
- ID: Display up to 64 characters
- Name display up to 64 characters
- Transducer model
- Current exam mode
- ECG icon (displays when connects with a physiology module)
- Accession#
- Operator: display up to 64 characters
- Menu
- Image
- ECG trace
- Transducer orientation mark
- Time line
- Coordinate axis, including depth, time, velocity/frequency
- TGC curve
- Focus
- Comment
- Body Mark
- Measure caliper
- Gray/color scale bar
- Thumbail
- Cine icon
- Trackball functionality status icon
- Help information
- Soft Menu
- Status icons
- Biopsy guideline

ID: Display result window (up to 8 results can be displayed)
- Image parameters
  - B mode (including iScape™)
  - Frequency (F)
  - Depth (D)
  - Gain (G)
  - Frame rate (FR)
  - B IP (IP)
  - Dynamic range (DR)

Color mode
- Frequency (F)
- Gain (G)
- IP (IP)
- Pulse repeated frequency (PRF)
- Wall filter (WF)
- M mode
- M Speed (V)
- M IP (IP)
- Dynamic range (DR)

Power mode
- Frequency (F)
- Gain (G)
- IP (IP)
- Pulse repeated frequency (PRF)
- Wall filter (WF)

Mindray North America
Performance Specifications

System Configuration (cont’d)

PW mode
- Frequency (F)
- Gain (G)
- Pulse repeated frequency (PRF)
- Wall filter (WF)
- Sample volume depth (SVD)
- Sample volume (SV)

CW mode
- Frequency (F)
- Gain (G)
- Pulse repeated frequency (PRF)
- Wall filter (WF)
- Sample volume depth (SVD)
- Free Xros M (anatomical M)
- Gain (G)
- Velocity (V)

TVD mode
- Frequency (F)
- Gain (G)
- TVI IP (IP)
- Pulse repeated frequency (PRF)
- Wall filter (WF)

TEI mode
- Frequency (F)
- Gain (G)
- TEI IP (IP)
- Pulse repeated frequency (PRF)
- Wall filter (WF)

TVO mode
- Frequency (F)
- Gain (G)
- Pulse repeated frequency (PRF)
- Wall filter (WF)
- Sample volume depth (SVD)
- Sample volume (SV)

3D/4D
- Brightness (B)
- Contrast (C)
- Scan method (only for Smart 3D)
- Quality (Q, for Static 3D and 4D)
- Angle (A)
- Parameter pack: default or user-defined

Setup

General settings
User-defined functional keys: Print, Save, F1-F6, footswitch
Customize user-defined exam modes in:
- Exam selection of each Transducer
- Configuration of measurement packages, body mark and comment libraries
- Imaging parameters setting as well as layout of menus and soft keys in imaging mode
- 15 User-defined exam modes

Create new measurement items, body marks and comments

Preset data manage: to save, load, export and default
Peripheral devices installation and setting

DICOM settings and network setting
System Maintenance (network updating, remote desktop, system test, log operation and preset)
System information viewing

Imaging and Processing

Display Depth
- Minimum: 18mm, Transducer dependent
- Maximum: 388mm, Transducer dependent

B mode
- Gain: 0 – 100
- TGC: 8 segments, with re-mapping functionality at any depth
- iTouch™: -12dB – 12dB
- iTouch™ Bright: -2, -1, 0, 1, 2
- FOV position
- B IP: 1 – 8, combination of dynamic range, iClear™, persistence, smooth
- THI IP: 1 – 8, combination of dynamic range, iClear™, persistence, smooth
- Rotation: 0°, 90°, 180°, 270°

Colorize/
Colorize Map: On/Off, 1 – 10
A. power: 10% – 100%, in increments of 6
FOV: N, W, M, H
Line Density: L, M, H, UH
L/R Flip: 1 – 4, Off
Persistence: 0 – 7
U/D Flip: 8 seg
TSI: General, Muscle, Fat, Fluid
Smooth: 1 – 4
Gray Rejection: 0 – 5
Y: 0 – 3
Curve: On, Off
High FR:
Frequency: Transducer dependent
Focus Position
- Dyn Ra.: 30dB – 160dB, in increments of 5dB
- Gray Map: 1 – 8
- B steer: -6°, 0°, 6°
- Trapezoid: On, Off
- iBeam™: On, Off
- Img Merge: On, Off

M mode
- Gain: 0 – 100
- TGC: 8 segments, with re-mapping functionality at any depth
- IP: 1 – 8, combination of dynamic range, M soften, edge enhance
- A power: 10% – 100%, in increments of 6
- Display Format: L/R, 1:1, 1:2, Full
- M Soften: 0 – 4
- Gray Rejection: 0 – 5
- Y: 0 – 3
- Curve: On, Off
- Colorize/
Colorize Map: On/Off, 1 – 10

Time Mark: On, Off
Focus Position
- Frequency: Transducer dependent
- Speed: 1 – 6
- Dyn Ra.: 30dB – 160dB, in increments of 5dB
- Edge Enhance: 0 – 3
- Gray Map: 1 – 8

Color mode
- Gain: 0 – 100
- Color IP: 1 – 8, combination of Smooth and Persistence
- A. power: 10% – 100%, in increments of 6
- Line Density: L, M, H, UH
- B Display: On, Off
- Smooth: 0 – 4
- Persistence: 0 – 4
- Baseline: -8 +48

Packet Size: 0 – 3
B/C Wide: On, Off
Dual Live: On, Off
Map: VD – V10, VV0 – VV9
Priority: 0 – 100%
WF: 0 – 7
Frequency: Transducer dependent
Scale: Frequency, Transducer and depth dependent
Steer: Transducer dependent
Invert: On, Off
Flow State: L, M, H
Power (DirPower)
- Gain: 0 – 100
- Packet Size: 0 – 3
- Flow State: L, M, H
- Dyn Ra.: 10dB – 70dB, in increments of 5dB
- Power IP: 1 – 8, combination of Smooth and Persistence
- A. power: 10% – 100%, in increments of 6
- Line Density: L, M, H, UH
- Smooth: 0 – 4
- Persistence: 0 – 4
- Focus Position: 0% – 100%
- B Display: On, Off
- B/C Wide: On, Off
- Dual Live: On, Off
- Map: P0-3 (Power), dP0-3 (DirPower)
- Priority: 0% – 100%
- Frequency: Transducer dependent
- Scale: Frequency, Transducer and depth dependent
- Invert: On, Off
- WF: 0 – 7
- Steer: -12°, 0°, 12°
Performance Specifications

Imaging and Processing (cont’d)

**PW/CW**
- Gain: 0 – 100
- V Max: On, Off
- V Mean: On, Off
- Colorize/Colorize Map: On/Off, 1 – 10
- Dyn Ra.: 24dB – 72dB, in increments of 2
- Audio: 0 – 100%, in increments of 2
- Trace Area: Above, Below, All
- A. power: 10% – 100%, in increments of 6
- Trace Sensitivity: 0 – 5
- Trace Smooth: Off, 1 – 4
- Time Mark: On, Off
- Display Format: L/R, 1:1, 1:2, Full
- T/F Res: 0 – 3
- Auto Calc Param: On, Off
- HPRF: On, Off
- Frequency: Transducer dependent
- Scale: Frequency, Transducer and depth dependent
- Baseline: -4 – 4
- Invert: On, Off
- Quick Angle: -60, 0, 60
- Angle: -80 – 80°, in increments of 1°
- SV: 0.5mm – 20mm
- SVD: On
- WF: 0 – 6
- Auto Calc: On, Off
- Speed: 1 – 6
- Duplex/Triplex: On, Off
- Gray Map: 1 – 8
- Post Process: Curve, Gray Rejection, y
- PW Steer: Maximum ±20° (Transducer dependent)

**Free Xros M**
- Gain: 0 – 100
- TGC: 8 segments, with re-mapping functionality at any depth
- Colorize/Colorize Map: On/Off, 1 – 10
- Post Process: N, curve, gray rejection
- Display Format: L/R, 1:1, 1:2, Full
- Display: Cur, Full
- Mark Adjustment: Show A, Show B, Show C
- Time Mark: On, Off
- Angle Speed: 1 – 6
- Gray Map: 1 – 8

**CM**
For parameter details in CM mode, please refer to relevant sections of B, Color and M modes.

**TVI**
- Gain: 0 – 100
- Baseline: -8 – +8
- TVI IP: 1 – 8, combination of Smooth and Persistence
- A. power: 10% – 100%, in increments of 6
- Line Density: L, M, H, UH
- B Display: On, Off
- Smooth: 0 – 4
- Persistence: 0 – 4
- Focus Position: 0% – 100%
- Packet Size: 0 – 3
- B/C Wide: On, Off
- Dual Live: On, Off
- Map: V0 – V10
- Priority: 0% – 100%
- WF: 0 – 7
- Frequency: Transducer dependent
- Scale: Frequency, Transducer and depth dependent
- Invert: On, Off
- Tissue State: L, M, H
- TEI
- Gain: 0 – 100
- Dual Live: On, Off
- TEI IP: 1 – 8, combination of Smooth and Persistence
- Focus Position: 0% – 100%
- Frequency: Transducer dependent
- Scale: Frequency, Transducer and depth dependent
- Tissue State: L, M, H
- Invert: On, Off
- WF: 0 – 7
- Persistence: 0 – 4
- Smooth: 0 – 4
- Dyn Ra.: 10 – 70dB, in increments of 5
- SVD: On, Off
- B/C Wide: On, Off
- SV: 0 – 100%
- B Display: On, Off
- Priority: 0 – 100%
- Line Density: L, M, H, UH
- A. power: 10% – 100%, in increments of 6

**TVD**
- Gain: 0 – 100
- Quick Angle: -60°, 0°, 60°
- WF: 0 – 6
- Trace Sensitivity: 0 – 5
- Auto Calc Param
- V Max: On, Off
- V Mean: On, Off
- Trace Area: Above, Below, All
- Duplex/Triplex: On, Off
- Colorize/Colorize Map: On/Off, 1 – 10
- Gray Map: 1 – 8
- Invert: On, Off
- Speed: 1 – 6
- Angle: -80° – 80°, in increments of 1
- SV: 0.5mm – 20mm
- SVD: On, Off
- A. power: 10% – 100%, in increments of 6
- Display Format: L/R, 1:1, 1:2, Full

**Audio**
- Frequency: Transducer dependent
- Scale: Frequency, Transducer and depth dependent
- Baseline: -4 – 4
- Dyn Ra.: 24 – 72dB
- Trace Smooth: Off, 1 – 4
- Time Mark: On, Off
- T/F Res: 0 – 3
- Post Process: Curve, Gray Rejection, y

**TVM**
For parameter details in TVM mode, please refer to relevant sections of B, M and TVI modes.

**3D/4D**
Method (only for Smart 3D): Fan, Linear
Direction: Up/Down, Down/Up, Back/Front, Front/Back, Left/Right, Right/Left
Display Format: Single, Dual, Quad
Distance (for Smart 3D only): 10 – 200mm, in increments of 10mm
Angle: 10° – 80°, in increments of 2°
Static 3D/4D: Transducer dependent
Quality (for Static 3D/4D only): Low 1, Low2, Mid, High 1, High2
Inversion: On, Off
Para pack: 5
Auto Rot.: On, Off
Reset ROI: On, Off
Adjusting VOI: On, Off
Accept VOI: On, Off
Colorize/Colorize Map: Off, 1 – 5
Reset: On, Off
Quick rotate angle: 0°, 90°, 180°, 270°
Current image: A/B/C/3D
Brightness: 0 – 100%, in increments of 2
Contrast: 0 – 100%, in increments of 2
Smooth: 0 – 20, in increments of 1
Threshold: 0 – 100%, in increments of 1
Transparency: 0 – 100%, in increments of 5
Render mode: Surface, Min, Max, X Ray
MPR Line: Partial, None, Entire
Edit Type: Inside Contour, Outside Contour, Big Contour, Big Eraser, Small Eraser, Inside Rect, Outside Rect, Inside Polygon, Outside Polygon
Edit Depth: Full Depth, User Defined (0 – 100%)
Reset Curve

**iScape™ View**
Actual Size
Fit Size
Ruler: On, Off
Colorize/Colorize Map: Off, 0 – 10
Rotation: 0 – 360°, in increments of 5°
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Comments and Body Mark

Text comment
Comment text (option)
Abdomen: 89
OB: 97
Cardiology: 80
GYN: 69
Vascular: 110
Urology: 61
SMP: 124
Pediatrics: 35
Nerve blocks: 52
EM: 126
User-defined Comments
Add
Delete
Arrow
Arrow Size
Arrow position
Arrow orientation
Trace
Control panel operation

Body Mark

Application package (Option)
Abdomen: 13
OB: 25
Cardiology: 13
GYN: 7
Vascular: 17
Urology: 7
SMP: 46
Nerve blocks: 32
EM: 38
User-defined
New
Copy
Export
Load
Delete
Edit

Storage/Connectivity
320G integrated hard disk
External DVD-R/W (Optional)
USB ports
Image archive on hard disk and DVD, temporary saving in cine memory
Live capture:
  Retrospective (1 – 120s, or 1 – 120 cycles)
  Prospective (1 – 120s, or 1 – 120 cycles)
Thumbnail
Single image formats: BMP, JPG, DCM, FRM, supports off-line analysis

Multi-frame images
formats: AVI, DCM, CIN, supports off-line analysis
Clip length: 1 – 60s, 1 – 16 cycles
Storage area:
  Image area: 640x480
  Standard area: 800x600
  Full-screen: 1024x768
iVision™
Cine review: Auto, Manual (auto review segment can be set), supports linked cine review for 2D, M/D images, 8380 frames (Max.).
Send/print image after End Exam
DICOM:
  DICOM Storage
  DICOM print
  DICOM Worklist
  Query/Retrieve
  Structured Report (SR)
  Storage Commitment
  MPPS
  Media review
iStation™
Intelligent patient data management platform
Integrated search engine for patient data
Detailed patient information view
Intelligent data backup/restore
Patient data/image sending
Patient data deleting
Exam managing: create new exam, activate exam and continue exam
Recycle Bin
Meaure/Calc/Study
Caliper
2D mode
M mode
Doppler mode
Application
Optional package for specific clinical uses
Clinical Packages
Abdomen
Obstetrics
Cardiology
Vascular
Gynecology
Urology
Small Parts
Pediatrics
Diagnostic Report
View/add images
Edit report
Obstetric/vascular analysis
Fetal growth curve
Print report
Import/export report
View history report
Physio Input/ Output
ECG
Display: On, Off
Position: 0% – 100%, in increments of 5
Display HR: On, Off
Gain: 0 – 30
Transducer Specifications
CS-2s
Array type: Convex-wide
Applications: Gynecology and obstetrics, abdomen, vascular, pediatrics
B mode imaging frequency: 2.5/3.5/5.0MHz
Harmonic frequency: 5.0/6.0MHz
Doppler frequency
  C: 2.5 /3.0MHz
  PW: 2.5 /3.0MHz
Convex radius: 49.57mm
Biopsy guides: NGB-015, 25°/35°/45°
7L4s
Array type: Linear
Applications: Small parts, vascular, musculoskeletal, pediatrics, abdomen
B mode imaging frequency: 5.0/7.5/10MHz
Harmonic frequency: 8.0/10MHz
Doppler frequency
  C: 5.0/5.7MHz
  PW: 5.0/5.7MHz
Steer angle: ±6°/12°
Biopsy guides: NGB-007, 40°/50°/60°
L14-6s
Array type: Linear
Applications: Small parts, vascular, musculoskeletal, pediatrics
B mode imaging frequency: 8.0/10.0/12.0MHz
Harmonic frequency: 10.0/11.0MHz
Doppler frequency
  C: 5.7 /6.6MHz
  PW: 5.7 /6.6MHz
Steer angle: ±6°/20°
Biopsy guides: NGB-016, 30°/40°/50°
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**Transducer Specifications (cont’d)**

<table>
<thead>
<tr>
<th>L14-6Ns</th>
<th>L12-4s</th>
<th>P7-3s</th>
<th>P4-2s</th>
<th>V10-4s</th>
<th>P10-4Bs</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Array type:</strong></td>
<td>Linear</td>
<td>Sector phased</td>
<td>Sector phased</td>
<td>Convex</td>
<td>Convex</td>
</tr>
<tr>
<td><strong>Applications:</strong></td>
<td>Small parts, vascular, musculoskeletal, pediatrics</td>
<td>Cardiology, abdomen, transcranial, pediatrics</td>
<td>Cardiology, abdomen, transcranial, pediatrics</td>
<td>Gynecology, obstetrics, urology</td>
<td>Gynecology, obstetrics, urology</td>
</tr>
<tr>
<td><strong>B mode imaging frequency:</strong></td>
<td>8.0/10.0/11.0MHz</td>
<td>6.0/7.5/10.0MHz</td>
<td>2.0/2.5/3.0MHz</td>
<td>5.0/6.5/8.0MHz</td>
<td>5.0/6.5/8.0MHz</td>
</tr>
<tr>
<td><strong>Harmonic frequency:</strong></td>
<td>10.0/14.0MHz</td>
<td>6.0/7.0MHz</td>
<td>5.0/5.7MHz</td>
<td>5.0/6.0MHz</td>
<td>5.0/6.0MHz</td>
</tr>
<tr>
<td><strong>Doppler frequency:</strong></td>
<td>C: 5.7/11MHz, PW: 5.7/6.6MHz</td>
<td>C: 3.3/4.0MHz</td>
<td>C: 5.0/5.7MHz</td>
<td>C: 4.0/5.0MHz</td>
<td>C: 4.0/5.0MHz</td>
</tr>
<tr>
<td><strong>Steer angle:</strong></td>
<td>±6°/20°</td>
<td>±6°/12°</td>
<td>±6°/12°</td>
<td>±6°/12°</td>
<td>±6°/12°</td>
</tr>
<tr>
<td><strong>Biopsy guide:</strong></td>
<td>NGB-007</td>
<td>None</td>
<td>NGB-011, 11°/23°</td>
<td>None</td>
<td>NGB-004</td>
</tr>
</tbody>
</table>

**Biopsy guide:**

- NGB-007
- NGB-011, 11°/23°
- NGB-004

### Safety & Conformance

- **Quality Standards**
  - ISO 9001:2000
  - ISO 13485:2003

- **Design Standards**
  - UL 60601-1
  - CSA C22.2 No. 601-1
  - EN 60601-1 and IEC 60601-1
  - EN 60601-1-1 and IEC 60601-1-1
  - EN 60601-1-2 and IEC 60601-1-2
  - EN 60601-2-37 and IEC60601-2-37
  - EN60601-1-4 and IEC6061-1-4
  - EN60601-1-6 and IEC6061-1-6

- **CE Declaration**
  - M7 system is fully in conformance with the Council Directive Concerning Medical Devices 93/42/EEC.
  - The number adjacent to the CE marking (0123) is the number of the EU-notified body that certified meeting the requirements of Annex II of the Directive.

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