

# **M5 Diagnostic Ultrasound System**

## **Specifications**



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## Product Information

Product Name: Diagnostic Ultrasound System

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# 1 Intended Use

The diagnostic ultrasound system is applicable for adults, pregnant women, pediatric patients and neonates. It is intended for use in abdomen, gynecology, obstetrics, small parts (breast, testes, thyroid, etc.), pediatrics, transcranial, cardiac, peripheral vascular, urology, orthopedics, intraoperative and musculoskeletal (general and superficial) exams.

## 2 System Configuration

### 2.1. Standard Configuration

- Main unit
- Trolley case
- Accessories
- Transducer

### 2.2. Transducers Available

Model	Type	Intended Use	Region Applied
3C5s	Convex	Gynecology, obstetrics, abdomen, pediatrics, peripheral vascular, FAST	Body surface
6C2s	Convex	Neonatal abdomen, cephalic and cardiac	Body surface
7L4s	Linear	Small parts, neonatal cephalic, peripheral vascular, musculoskeletal (general and superficial), nerve	Body surface
7L6s	Linear	Small parts, neonatal cephalic, peripheral vascular, musculoskeletal (general and superficial), nerve	Body surface
10L4s	Linear	Small parts, neonatal cephalic, peripheral vascular, musculoskeletal (general and superficial), nerve	Body surface
6LB7s	Bi-planar	Prostate, seminal vesicle, bladder	Transrectal
6CV1s	Convex	Gynecology, obstetrics, urology	Transvaginal
6LE7s	Linear	Gynecology, obstetrics, urology	Transrectal
2P2s	Phased	Cardiology, pediatric abdomen, transcranial	Body surface
3C1s	Convex	Gynecology, obstetrics, abdomen, pediatrics and cardiology	Body surface

7L5s	Linear	Small parts, neonatal cephalic, peripheral vascular, musculoskeletal (general and superficial), nerve	Body surface
7LT4s	Linear	Intraoperative (abdomen, cardiology, vascular etc.), small parts, neonatal cephalic, peripheral vascular, musculoskeletal (general and superficial)	Intraoperative; passing through body surface

## 2.3. Options

No	Name	Model
1	DICOM Software	DICOM 3.0
2	CW	/
3	Footswitch	971-SWNOM (IP68)
4	ECG Lead	Part number: 0010-20-12126
5	ECG Lead	Part number: 0010-20-12127
6	HPRF Kit	/
7	Rechargeable Li-ion Battery Pack	LI23I001A
8	External DVD-Writer (USB port)	DVD SE-S184M DVD SE-S204N
9	DVR recorder	MVR-11
10	ECG Module	ECG-11
11	IO Extend Module	IOM-11
12	Probe Extend Module	PEM-11
13	V/A Module	VAM-11
14	Pack	/
15	iScape Kit	/
16	Smart3D Kit	/
17	Mobile Trolley	UMT 200
18	M-Pack	/

## 2.4. Peripherals Supported

No	Name	Model
1	B / W video printer	Digital: MITSUBISHI P93DC, SONY UP-D897 Analog: MITSUBISHI P93W, SONY UP-897MD
2	Color video printer	Digital: SONY UP-D23 Analog: SONY UP-20MD, MITSUBISHI CP-910E
3	Graph / text printer (USB port)	HP OfficeJet Pro K5300 HP Photosmart D5368 HP DeskJet 1280
4	VCR recorder	Sony SVO-9500MD

**⚠ WARNING:** This system complies with IEC60601-1-2: 2001+A1: 2004, and its RF emission meets the requirements of CISPR11 Class B. In a domestic environment, the customer or the user should guarantee to connect the system with Class B peripheral devices; otherwise RF interference may result and the customer or the user must take adequate measures accordingly.

# 3 Specifications

## 3.1. Image Mode

- B Mode
- M Mode
- C Mode: Color, Power or DirPower
- D Mode: PW Doppler or CW Doppler
- Special Imaging Mode: Smart3D or iScape

## 3.2. Exam Mode

The system supports the following exam modes:

- A-Abdomen - (Adult Abdomen)
- A-Cardiac - (Adult Cardiac)
- GYN - (Gynecology)
- OB1 - (First Trimester)
- OB2/3 - (Second & Third Trimesters)
- F-cardiac - (Fetal Cardiac)
- Kidney
- Prostate
- THY - (Thyroid)
- Breast
- Other SMP - (Other Small Parts)
- Carotid
- Peri-vein - ( Lower Extremity Peripheral Venous)
- Peri-artery - (Lower Extremity Peripheral Arterial)
- Ped-ABD - (Pediatric Abdomen)
- Ped Cardiac - (Pediatric Cardiac)
- Urology
- Testicle
- Orthopedics

- TCI (Transcranial Imaging)
- ABD-Penetration (Abdomen-Penetration)
- CAR-Penetration (Cardiac-Penetration)
- FAST (Focused Abdominal Sonography For Trauma)
- MSK (Musculoskeletal)
- Nerve
- Misc 1 (Miscellaneous 1)
- Misc 2 (Miscellaneous 2)
- Misc 3 (Miscellaneous 3)
- User-defined

### **3.3. Acoustic Power**

Users can adjust it. 10-100%, 16 levels, 6% each level

Displays MI and TI (TIB, TIC, and TIS) values in real-time.

### **3.4. Image Specifications**

#### **3.4.1. Tissue Specific Imaging**

The system provides four Tissue Specific Imaging (TSI): general, muscle, fat, liquid.

#### **3.4.2. Harmonic Imaging**

The transducer 3C5s supports Tissue Harmonic Imaging (THI). The harmonic frequencies can be adjusted.

#### **3.4.3. iTouch**

The system supports one-key optimization of B/ PW images (iTTouch).

#### **3.4.4. Image Zoom**

Maximum zoom factor: 10

#### **3.4.5. Display Depth**

Scan depth can be adjusted. Different transducers have different display depths.

Display depth for high-frequency transducers: 2.5-30.8cm

Display depth for low-frequency transducers: 3.7-30.8cm

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## 3.5. Image Scanning and Processing

### 3.5.1. B Mode

1. Scan range can be adjusted. Linear array transducers support B Steer and Trapezoid.
2. Number and location of emitting focuses can be adjusted.
3. Each transducer has three frequencies to be selected.
4. Scan depth can be adjusted.
5. Scan density can be selected.
6. Gain and TGC curve can be adjusted.
7. The following signal-processing parameters can be adjusted: dynamic range, iClear, frame average, Tissue Specific Imaging, noise rejection.
8. IP (Image Process): several levels can be selected. Combination parameters include dynamic range, iClear, frame average, noise rejection, etc.
9. The following post-process parameters can be adjusted: gray transform, gray rejection,  $\gamma$  correction, image effect (combination of gray transform, gray rejection,  $\gamma$  correction), colorizing, left/right flip, up/down invert, rotation.

### 3.5.2. M Mode

1. Gain can be adjusted.
2. Focus location can be adjusted.
3. Scan speed can be adjusted.
4. The following signal-processing parameters can be adjusted: dynamic range, M soften.
5. IP (Image Process): several levels can be selected. Combination parameters include dynamic range, M soften, etc.
6. The following post-process parameters can be adjusted: gray transform, gray rejection,  $\gamma$  correction, image effect (combination of gray transform, gray rejection,  $\gamma$  correction), colorizing, switch of time mark.

### 3.5.3. Color Mode

1. Size and location of ROI box can be adjusted.
2. Two kinds of Doppler frequencies and steer angle of linear transducers can be adjusted.
3. Speed scale can be adjusted. PRF can be changed.
4. Gain can be adjusted.
5. Filter, color baseline, packet size, line density, contrast, priority, smooth, and persistence can be adjusted.
6. Color IP: several levels can be adjusted. Combination parameters include

persistence, smooth, etc.

7. The following post-process parameters can be adjusted: invert switch, map, image display switch, B/Color dual live switch.

### **3.5.4. Power (DirPower) Mode**

1. Size and location of ROI box can be adjusted.
2. Imaging frequencies and steer angle of linear transducers can be adjusted.
3. Speed scale can be adjusted. PRF can be changed.
4. Gain can be adjusted.
5. Dynamic range, filter, packet size, low velocity rejection, line density, contrast, priority, smooth, and persistence can be adjusted.
6. Color IP: several levels can be adjusted. Combination parameters include persistence, smooth, etc.
7. The following post-process parameters can be adjusted: invert switch, Power map/ DirPower map, image display switch, B/Power dual live switch.
8. Power scale can be adjusted.

### **3.5.5. PW / CW Doppler Mode**

1. PW Doppler mode supports iTouch.
2. Size and location of PW sample volume can be adjusted; CW focus can be adjusted.
3. The PW Doppler mode supports two imaging frequencies. Steer angle of linear array transducers can be adjusted. Only the phased array transducer supports the CW Doppler mode.
4. Adjusting speed scale changes PRF. The PW Doppler mode supports HPRF (high pulse repetition frequency).
5. Gain can be adjusted.
6. Filter, scan speed, baseline position, dynamic range, colorizing, correction angle can be adjusted.
7. Supports maximum speed scan and average speed scan, and the threshold of maximum speed can be adjusted. The trace range can be Top (above baseline), Bottom (under baseline) or All (above and under baseline). Trace can be smoothed. Smooth parameters can be adjusted.
8. The following post-process parameters can be adjusted: colorizing, flip display switch, time mark switch.
9. Sound can be on or off. Sound volume can be adjusted.
10. Supports automatic spectral calculation.

# 4 Preset

## 4.1. System Preset

Region preset: hospital name, language, region, time and date format can be set.

General preset: includes patient information setup, examination setup, patient information management setup, image storage setup, system dormancy setup, comment setup, input setup and display setup.

Image preset

Measurement parameter setup

Obstetric formula setup

Keyboard configuration

Puncture preset

Optional part setup

## 4.2. Exam Mode Preset

Transducers can be configured with exam modes.

Set parameters for exam modes.

User-defined exam modes can be preset.

## 4.3. Image Parameter Preset

Image parameters can be preset for each type of transducer according to different modes.

Preset of IP and post-process.

## 4.4. Measurement Preset

Measurement package preset

Measurement tool preset

User-defined studies

## 4.5. Preset of Comment and Body Mark

The system supports general comment preset and user-defined comments.

The system supports general body mark preset and user-defined body marks and supports transducer position and angle preset of body mark.

#### **4.6. Soft Key and Menu Preset**

The system supports soft key and menu preset in each imaging mode including image freezing, cine replaying and other imaging status (3D collection, 3D browsing, PW mark, reset ROI, iScape collecting etc.) with all transducer types.

#### **4.7. Peripheral Preset**

Printers, recorder and input/output settings.

Supports VCR and DVR recording, as well as image replaying.

# 5 Patient Data Management

## 5.1. Patient Information

Patient's basic information

Patient information classified according to exams

## 5.2. Patient File Management (iStation)

Supports storage of single-frame images and Cine files;

Supports image browse and analysis;

Supports storage and browse of patient reports.

Supports image demonstration (iVision).

History images and reports can be inquired according to patient's basic information.

All patient information can be edited, exported, deleted, and backed up.

Patient information can be imported from the Worklist on the DICOM Worklist server.

## 5.3. Graph/text Workstation

The system supports black & white video print, color video print, graph/text print.

The system supports real-time video print.

The system supports screen image record and replay via VCR and DVR.

Remote transfer: the system supports DICOM image storage and DICOM print.

# 6 Cine

## 6.1. Freeze

The system supports image freeze in each mode.

## 6.2. Cine Review

The system supports manual and auto cine review in B/C mode.

The system supports cine review in M or D mode.

The system supports linked cine review.

The system supports ECG waveform review.

# 7 Comments and Body Marks

## 7.1. Comments

Supports Chinese and English input.

General comments: characters are input via the keyboard.

Auto comments: comments are input via the auto comments selection.

General comments can be preset.

Users can define comments.

## 7.2. Body Marks

The system configures body marks of Abdomen, Gynecology, Obstetric, Cardiac, Vascular, Urology, Small Parts, and Orthopedics.

Users can define body marks.

Position of body marks, transducer symbol can be adjusted.

Body marks can be added on images in more-than-one windows.

# 8 Measurements

## 8.1. General Measurements

### 8.1.1.2D General Measurements

- Distance
- Depth
- Angle
- Area
- Volume
- Cross Line
- Parallel
- Trace Length
- Distance Ratio
- Area Ratio
- B-Histogram
- B-Profile
- Color Velocity (only applied to Color Mode)

### 8.1.2.M General Measurements

- Distance
- Time
- Slope
- Heart rate
- Velocity

### 8.1.3.Doppler General Measurements

- Time
- Heart rate
- D velocity
- Acceleration

- D trace
- PS/ED

## **8.2. Application Measurements**

The system supports Abdomen, Obstetric, Gynecology, Cardiac, Small Parts, Urology, Pediatrics, Vascular measurements.

# 9 User Interfaces

## 9.1. Power Switch

Locates on the control panel.

## 9.2. Input/Output Ports

### 9.2.1. Ports on Main Unit

- Transducer port: one. Connects a transducer or a transducer extension module.
- Data extension port: one. Connects the data extension module.
- Power input port: one. Connects a power adapter.
- USB port: two. Connects USB devices.
- Video output port: one. Connects a VCR or video printer.
- Ethernet port: one. Connects into the network.

### 9.2.2. Extension Modules

The system supports the following extension modules:

- Transducer extension module
- Data extension module
- Video extension module (via USB port)
- ECG module (via USB port)

## 9.3. Display

15-inch LCD

## 9.4. Batteries

The system can be powered by the two rechargeable lithium-ion batteries when not connected to the external power supply. The battery pack consists of two lithium-ion batteries, which can be chargeable.

## 9.5. Trolley

The trolley is an option used for placing the system and extension modules, etc.

# 10 Size and Weight

## 10.1. Size

Size (options excluded): 361mm×357mm×75mm (L×D×H)

## 10.2. Weight

Net weight: 6.33 kg

# 11 Environment Requirements

## 11.1. Power Supply Requirements

Voltage: 100-240VAC (adapter)

Frequency: 50 / 60Hz (adapter)

Input current: 2.0A (adapter)

## 11.2. Operation Environment

Ambient temperature: 0°C - 40°C

Relative humidity: 30% - 85% (no condensation)

Atmospheric pressure: 700 hPa - 1060 hPa

## 11.3. Storage and Transportation Environment

Ambient temperature: -20°C - 55°C

Relative humidity: 30% - 95% (no condensation)

Atmospheric pressure: 700 hPa - 1060 hPa

# 12 Safety Classification

1. According to the type of protection against electric shock:
  - a. CLASS I EQUIPMENT
2. According to the degree of protection against electric shock:
  - a. TYPE-BF EQUIPMENT
3. According to the degree of protection against harmful ingress of water:
  - a. The main unit belongs to IPX0, and the transducers belong to IPX7.
  - b. Footswitch: 971 SWNOM belongs to IP68.
4. According to the degree of safety of application in the presence of a FLAMMABLE ANESTHETIC MIXTURE WITH AIR or WITH OXYGEN OR NITROUS OXIDE:
  - a. EQUIPMENT not suitable for use in the presence of a FLAMMABLE ANESTHETIC MIXTURE WITH AIR or WITH OXYGEN OR NITROUS OXIDE
5. According to the mode of operation:
  - a. CONTINUOUS OPERATION
6. According to the installation and use:
  - a. PORTABLE EQUIPMENT
  - b. MOBILE EQUIPMENT (when the system is installed on the mobile trolley)



