

Specifications for X5 Digital Color Doppler Ultrasound System





SonoScape Medical Corp



1. General Specification

The system adopts the advanced ultrasonic Doppler technologies, including the Full Digital Super-wide Band Beam Former, Digital Dynamic Focusing, Variable Aperture and Dynamic Tracing, Wide Band Dynamic Range, and Multi-Beam Parallel Processing, etc. Users can perform the system with the minimum requirement of training or guidance. This system has been designed to comply with applicable international standards and regulations, ensuring the safety and availability of this product.

This system is based on the computer technology and Linux operation system, which make the system more flexible and stable. System maintenance and function update can be completed by software updating, through which would promote product value and keep the technological advancement.

2. System Overview

- 2.1 Applications
- Abdominal
- Vascular
- Cardiac
- GYN/OB

- Urology
- Musculo-skeletal
- Small organ
- Pediatric
- Cephalic
- Fetal
- Trans-rectal
- Trans-vaginal

2.2 Standard Features

2.2.1 Imaging Modes

- B-Mode (B)
- Tissue Harmonic Imaging (THI)
- Pure Inversion Harmonic Imaging (PHI)
- Color Flow Mapping (CFM)
- Power Doppler Imaging (PDI)
- Directional Power Doppler Imaging (DPDI)
- Tissue Doppler Imaging (TDI)
- Pulsed Wave Doppler (PW)
- Continuous Wave Doppler (CW)
- M-Mode (M)
- Color M mode (CFM+M)
- Anatomic M-Mode (AMM, Steer M)

2.2.2 Functions

- 2D Speckle Reduction & Edge Enhanced (2D µ-scan)
- Spatial Compound Imaging (SCI)
- PW auto trace
- SR Flow Imaging
- Trapezoid imaging
- Real-time 2DPanoramic Imaging
- Dual Live
- Lateral Gain Compensating (LGC)
- Auto (One button optimization for 2D/M/CW/ PW)
- Image Rotation Function
- Auto IMT measurement

X5 Technical Specification V1.0

- TEI index
- Biopsy guide
- VIS-Needle (Needle Visualization Enhancement)
- Panoramic Imaging (Real-time 2D)
- Full screen zoom
- Show gallery
- DICOM 3.0:
- WIFI (DICOM)
- Triplex
- 2.3 Optional Features
- I/O Docking Extender with ECG

2.4 Language Support

- Software:
 English, Simple Chinese, Spanish, Russian,
 French, German, Portuguese, Italian,
 Norwegian
- Keyboard Input: Danish, Swedish, Finnish, Portuguese, German, Spanish, French, Turkish.

Additional Requirement: Russia.

3. Physical Specification

3.1 Dimensions and Weight

- Height: 61mm
- Width: 378mm
- Depth: 340mm
- Weight: approx. 4.5kg (without battery) approx. 4.10kg (with battery)

3.2 Monitor

- 15.6-inch widescreen and high resolution color LCD monitor
- Resolution: 1920*1080

- Anti-flickering
- 3.3 Probe Sockets and Holders

Probe Sockets: 1 probe sockets, can be expanded to three

3.4 Operation Environment

- Temperature: +10°C-+40°C
- Relative Humidity: 30% -85% (no condensation)
- Atmospheric Pressure: 700-1060hPa

3.5 Transportation and Storage Environment

- Temperature: -20°C +55°C
- Relative Humidity: 20%-90% (no condensation)
- Atmospheric pressure: 700-1060hPa

3.6 Power Supply

- AC/DC Adaptor:
 - Input: 100-240Va.c., 1.5-0.75A, 50-60Hz;
 - Output: 19Vd.c., 4.74A
- Main unit: 19Vd.c., 4.74A

4. Imaging Parameters

4.1 B-Mode

- Display Format: B, Dual (B+B), Quad (4B)
- Gain: 1-255 adjustable
- Frame Rate: up to 80 fps (Probe dependent)
- Gray Shades: 256
- Scan Depth: 40.0 cm (Probe dependent)

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- Image Zoom (Ratio: 0.8-10 times)
- TGC: 8-level slides, adjustable
- LGC Left & LGC Right: adjustable
- Image Flip: Left/ Right, Up/Down
- Panoramic: available
- Compound Imaging: Off, 1, 2, 3, 4 (Probe dependent)
- PHI/THI: On/Off
- Frequency: 5 bands, adjustable
- Chroma: 12 types, selectable
- µ-Scan: Off,1,2,3,4,5 adjustable
- Line Density: 3 levels, adjustable (High/Medium/Low)
- Persist: Off, Low, Med, High, Max 4 levels , adjustable
- Biopsy Guide: Off/On (preset adjustable)
- Biopsy Calibration
 - Angle adjustable
 - Offset adjustable
- Dynamic Range (DYN): 20-200 (Probe dependent)
- Gray Map: 16 levels, selectable (Probe dependent)
- Sector Width: adjustable
- Sector Position: adjustable (Probe dependent)
- Focus Position: adjustable
- Focus area 1 -21
- Power%: 1-100 adjustable, 5 step each
- Tissue Specific Imaging (TSI): Adipose, Muscle, Fluid, Normal tissue
- Widescan: Off/On
- Trapezoid: Off/On
- Steer: 0, ±2°, ± 4°, ±6° degrees, adjustable
- Rotation: Off/ 90°/ 180°/ 270°
- Vis-Needle
 - On/Off
 - Steer Angle
 - Dual Live: On/Off
- Auto (One-button B-mode Parameter Optimization)

4.2 Color/PDI

- Gain: 0-255
- Frame Rate: up to 209 fps (Probe dependent)
- Size and Position of Color ROI: adjustable
- Image Flip: Up/Down, Left/Right
- Frequency: 3 I36evels, adjustable
- Wall Filter: 5 levels, Min, Low, Med, High, Max adjustable (Probe dependent)
- PRF: 0.5-10kHz (Probe dependent)
- Line Density: 4 levels (Min/Low/ Med/ High)
- Color Map: 1-5 levels
- Persist: 4 levels, Off/Low/Med/High/Max adjustable (Probe dependent)
- B Reject: 0-255 adjustable
- Steer: 0°, ±8, ± 12°, ± 16°adjustable
- PDI: On/Off
- Color Map (PDI)/DPDI: 7 types selectable, former for PDI, latter for DPDI (Probe dependent)
- TDI: On/Off
- Dual Live: On/Off
- Invert: On/Off

4.3 M-Mode

- AMM: On/Off, 3 sample lines
- Frequency: 5 levels, adjustable
- Gray Map: 16 types, selectable
- Chroma: 12 types, selectable
- Display Format: V2/1, V1/1, V1/2, H1/1, Full
- Sweep Speed: 5 levels adjustable for M mode (Min/ Slow/ Med/ Fast/ Max), and 5 levels adjustable for AMM (Min/ Slow/ Med/ Fast/ Max)
- Power%: 1-100, adjustable
- Focus area: 1-10 levels, adjustable
- Persist: Low, Med, High, Max 4 levels, adjustable
- Power:1-100%, selectable



4.4 PW/CW Mode

- Doppler Methods
 - PW Doppler
 - CW Doppler
- Simult: On/Off
- Sample Volume (PW): 0.5-24.0 mm, adjustable
- Position: adjustable
- Invert: On/Off
- Quick Angle: 0°, 60°, -60°, adjustable
- θ Correction: θ angle correction: -88° to 88°,
 2° steps each
- (Real-time) Auto Trace: On/Off
- Baseline: 9 levels, adjustable
- Frequency: 3 levels, adjustable
- Wall Filter: 5 levels, Min, Low, Med, High, Max, adjustable
- PRF: 1-16kHz (PW) (Probe dependent)
- PRF: 1-50KHz (CW) (Probe dependent)
- Max Velocity Range
 - ±0.0576 ±6.14m/s (PW) (probe dependent, sampling angle range: ±60°)
 - ±0.0761 ±10.35m/s (CW) (probe dependent, sampling angle: 0)
- Sweep Speed: 5 levels, adjustable (Min/ Slow/ Med/ Fast/ Max)
- Chroma: 12 types, selectable
- Display Format: V2/1, V1/1, V1/2, H1/1, Full,
- Steer: 4 levels: 0°, ± 8°, ± 12°, ± 16°, adjustable
- Volume: 0-100, 5 each step, adjustable
- Power:1-100%
- Auto (One-button Parameter Optimization)
 - Baseline
 - PRF

4.5 Tissue Doppler Mode (TDI)

- Gain: 0 255
- Frame rate: 121 fps (probe dependent)

- Size and position of color ROI: adjustable
- Auto focus
- Inversion: On/Off
- Power: 1% 100%
- Frequency range: 3 steps, adjustable
- PRF: 0.5 10KHz (probe dependent)
- Line density: Low, Med, High adjustable
- Color Map: 10 levels
- Dual Live: On/Off
- Flow Reject: 1 255

5. System Setting

5.1 General

5.1.1 General Settings

- Hospital Name
- Freeze Response: Cine, Annot, Body mark, Arrow
- Trackball Sensitivity: 1, 2, 3, 4, 5
- Language: English, Simplified Chinese, Spanish, Russian, French, Italian, Germany, Norwegian, Portuguese
- Time Zone
- Date/Time Setting
- Date Format: MM/DD/YYYY, YYYY/MM/DD, DD/MM/YYYY, selectable
- Time Format: 12 Hour, 24 Hour, selectable

5.1.2 Display

- Screen Saver: On/ Off
- Screen Saver wait (min): 5-60 minutes
- Auto standby wait (min): 20-90 minutes
- Key Volume: On/Off
- Keyboard & Monitor Brightness
- Monitor Colors: Warm/Cool
- LGC: On/Off
- Width Ruler: On/Off
- Trackball Light Color: 6 types



- Config.: Top, up, down, bottom
- Play Interval:1-5 seconds, selectable
- Import
- Delete
- Load Default
- Exit

5.1.3 Save

- Retrospective store
- Prospective store
- Freeze Store
- Save Format/Area
 - Cine Format: AVI, WMV
 - Image Format: BMP, JPG, TIF
- Area: Full Screen, Image Area, Image area+InfoBar
- Save Operation
 - Send image to DICOM storage
 - Send cine to DICOM storage
- Key function:P1,P2,F3,F4,Cine

5.1.4 Biopsy

- Biopsy Guide Line
 - Bracket
 - Guide line type: Line, Range
 - Guide line display: On/Off
 - DICOM Print
- Biopsy Grid
 - Biopsy Grid Display Style: +/.
 - Biopsy Grid Display Color: Green/Yellow

5.2 Exam Preset

- Probe Selection
 - Available Items Selected Items

5.3 Comment

5.3.1 Tools

- Annotation
 - Select annotation Language
 - Font size
 - Clear annotation while unfreezing image
- Arrow
 - Arrow size: Large/Medium/Small
 - Clear arrow while unfreezing image: On/Off
- Set home

5.3.2 List

- Classified by specific exams: Abdomen, Obstetrics, Gynecology, Vascular, Breast, Cardiology, Urology, Small parts, Musculoskeletal
- Edit comment item
 - Add to Library
 - Delete
- Selected (Comment List):
 - To first
 - Previous
 - Next
 - To Last

5.4 Bodymark

 Classified by specific exams: Abdomen, Obstetrics, Gynecology, Vascular, Breast, Cardiology, Urology, Small Parts, Musculoskeletal



5.5 Measure

5.5.1 General

- BSA (Body Surface Area): Eastern, Western
- Cross Cursor Size: Small, Medium, Large, selectable
- Measure Line Size: Small, Medium, Large
- Distance Dash Line Display: On/ Off
- Velocity Cross Line Display: On/ Off
- Ellipse Cross Line Display: On/ Off
- Volume Flow Method: TAmean/TAmax
- Volume Flow compensation with TAmax: 0.5 - 1.0
- Keep Result Window : On/ Off
- Result Font Color: White/Yellow
- Result Position:
 - 2D: Right Top, Right Bottom, Left Top, Left Bottom, selectable
 - M+D: Right Top, Right Bottom, Left Top, Left Bottom, selectable

5.5.2 Application

- Auto/ Manual Trace: Abdomen, Urology, Small Parts, Gynecology, Obstetrics, Vascular, Cardiac, selectable
- Num 0-9: Editable shortcut keys of measurement (OB/GYN//Cardiac)
- Measurement Setting (OB)
 - CUA/AUA
 - Add 1 week to EDD (Yes/ No)
 - Show EDD on screen (Yes/ No)
 - Growth Deviation Display: No, %, SD, selectable
- Equation (OB)
 - GA & Growth (New Table): New GA Table, New Growth Table
 - Fetal Weight: Estimation, Age by EFW, EFW GP/SD, Unit

- Equation (SMP)
- Thyroid (Volume) Calculation Coefficient: 0.52 (US). 0.479 (EURO), selectable
- Load default

5.5.3 List

For editing measure lists classified into different applications, categories and modes

- Application: Abdomen, Urology, Small parts, Gynecology, Obstetrics, Vascular, Cardiology, Pediatrics, selectable
- Measurement Categories: Caliper, Calculation, selectable
- Mode: B, Color, M, Doppler, selectable
- List (items): Category, Collection, Measurement
- Measurement (Adjust Position): Add, Delete, Reorder
- Load default

5.6 Report

- Logo
 - Operation LOGO: Upload logo
 - Left/Right: Choose logo
- Title/Font/Color:
 - Title 1/ Title 2/ Title 3
 - Title 1/ Title 2/ Title 3/ Title/ SubTitle/Content
 Font Size: 14-26, adjustable, 2 each
 - step
 - Content Font Size: 12-16,adjustable, 1 each step
 - Background Color: Basic Colors (48 types), Screen Color
 - Text Color: Basic Colors (48 types), Screen Color
- Display Items for Report:
 - Patient Information
 - Exam Information

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- Image (selectable): 1*1, 2*2, 3*3, selectable
- Graphs (selectable)
- Comment (selectable)
- Preview

5.7 Peripheral

- 5.7.1 Basics
- Video output
 - Area: Picture area/FullScreen/Info+PictureArea
 - CVBS/S-VIDEO: NTSC/PAL/Close
 - HDMI: Close/1920*1080
- Printer
 - Default Printer: USB Printer/Windows Printer
 - Printer IP Address
 - Printer Port Number
- Foot Switch
 - Left/Right Key
- 5.7.2 Network
- Local Network
 - DHCP/Static IP
- DHCP: MAC Address
 - Static IP: IP Address, Netmask, Default Gateway, Mac Address
 - Ping IP Address
- Wireless Network (Enable/Disable):
 - List (Name, State, Level)
 - Connect
 - Disconnect
 - Refresh
 - Advance (Advanced Setting)
 - Network Name
 - Signal Level
 - Encryption

 DHCP/Static IP (IP Address, Netmask, Default Gateway)

5.8 DICOM

5.8.1 Local Setting

- Local Device
 - Station Name
 - AE Title
 - Port Number
 - Timeout(sec)
- Storage Setting:
 - 2D Compression:None/RLE/JPEG
 - 2D JPEG Quality
 - Cine Compression:None/RLE/JPEG
 - Cine JPEG Quality
 - Send at end of exam: On/Off

5.8.2 DICOM Service

- Service List:
 - Service Type
 - Service Name
 - AE Title
 - IP Address
 - Port

5.9 Help

- User manual
- 5.10 Load Default
- 5.10.1 Load
- 5.10.2 New:
- StoreName
- Replace

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• New

- 5.10.3 Export/Import:
- USB Drive
- Copy user setting to USB
- Copy user preset to USB
- Load USB user setting to system
- Load USB user preset to system
- Export Log
- 5.11 About
- General: System information

6. Display Formats

- B + B
- 4B
- B + CFM
- B + PDI
- B + DPDI
- B+TDI
- B + M
- B + PW
- B + CFM+PW
- B + PDI + PW
- B+DPDI+PW
- B + TDI+PW
- B + CW
- B + CFM + CW
- B + PDI + CW
- B+CFM+M
- Anatomical M mode

7. Connections

7.1 Ethernet Network

7.2 USB

• USB 2.0: 2 ports

7.3 Wireless Network

7.4 DICOM 3.0

- Storage: directly transmits images with patient information to a DICOM file server
- Medical digital images and communication DICOM 3.0 interface

8. Optional Transducers

- 8.1 Phased Array Probe
- <u>3P-A</u>:
 - Application: Cardiac, Abdominal
 - Frequency bandwidth: 1.0-6.0 MHz
- <u>7P-B</u>:
 - Application: Cardiac
 - Frequency bandwidth: 2.0-9.0 MHz

8.2 Linear Probe

- <u>L741</u>:
 - Application: Vascular, Small parts, MSK etc.
 - Frequency bandwidth: 4.0-16.0 MHz

8.3 Convex Probe

- <u>3C-A</u>
 - Application: Abdominal, Obstetrics, Gynecology
 - Frequency bandwidth: 1.0-7.0 MHz

8.4 Micro-convex Probe

- <u>C613</u>
 - Application: Pediatric Cardiology,

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Abdominal, Brain

Frequency bandwidth: 4.0-13.0 MHz

8.5 Transvaginal Probe

- <u>6V1</u>
 - Application: Obstetrics, Gynecology
 - Frequency bandwidth: 3.0-15.0 MHz

8.5 Transrectal Probe

- <u>EC9-5</u>
 - Application: Urology
 - Frequency bandwidth: 3.0-15.0 MHz

9. Safety and Conformance

- 9.1 Quality Standard
- ISO 9001
- ISO 13485

9.2 Safety Standard

Comply with IEC 60601-1, Class I BF, Comply with IEC 60601-1-2, Group 1, Class B Comply with IEC 60601-2-37

9.3 Certification

FDA & CE: X5 Digital Color Doppler Ultrasound System is conferred the FDA certification by the Food and Drug Administration.

10. Image/ Patient Data Management

- Static and Dynamic image storage
- Support review of past exam by clipboard
- Patient Registration: Name, ID, Gender, Date

of Birth, Height, Weight, LMP, EDD and GA.

- Patient data and reports are archived by patient exams
- Reports and images can be previewed
- Preview size can be set to 1*1, 2*2,
- File can be previewed, deleted, used for DICOM Send and DICOM Print or exported
- Files can be exported to the USB drive or DVD. BMP, JPG, TIF, AVI, WMV, PDF, TXT are selectable for export format

11. Preset Function

- Users can customize the presets based on different probe and diagnostic part to optimize imaging parameters
- Users can arrange the presets
 Users can import or export presets (not including default preset)

NOTE:

- Sonoscape reserves the rights to change the specifications without prior notification.
- Some products or features may not be available in some countries.
- For more information, please contact your local SonoScape sales representative.

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