Basic Information

Product Name: Diagnostic Ultrasound System

Product Model: EP50 SQ

Manufacturer: Shenzhen Comen Medical Instruments Co., Ltd.

Address: Floor 10, Floor 11 and Section C of Floor 12 of Building 1A & Floor 1 to Floor 5 of Building 2, FIYTA Timepiece Building, Nanhuan Avenue, Matian Sub-district, Guangming District, Shenzhen, Guangdong, 518106, P.R. China

Introduction

This document summarizes the product's safety and performance information.

1.1 Safety Signs

WARNING

- Alerts you to situations that may result in serious consequences or adverse events or endanger personal safety. Failure to observe the warning information may cause severe injury or even death of users or patients.

CAUTION

- Alerts you to potential dangers or unsafe operations. If not avoided, it may lead to minor personal injury, product malfunction/damage, or property loss. It may also cause more serious damages in the future.

NOTE

- Emphasizes important precautions and provides instructions or explanations for better use of the product.

1.1.1 Pre-use Information

WARNING

Before use:

- Before using this device, please read and understand the entire User Manual. Attempting to use this device (and all other medical equipment) without fully understanding operating instructions may cause injury to the patient or the operator.
- Attention should be paid to all warnings and prompts on the surface of the device so as to ensure the safety of the operator and the normal operation of the device.
- The device only serves for intended purpose, and only be used by doctors or other medical personnel who have been well trained on clinical ultrasound diagnosis techniques.

- Prior to use, the user must check whether the device, its accessories and all peripherals have no rust, sharp edge, protrusion or rough surface, which may cause injury.
- Prior to use, the user must check whether the device and its accessories can work normally and safely. The compatibility of the endoscopic equipment and any accessories should be checked according to any criteria for safe use. If the device fails to pass pre-use test, stop using the device and contact service personnel for maintenance.
- The device can only be installed, modified or set up by personnel authorized or trained by the manufacturer. Without permission, no one shall install, disassemble or modify the device.

⚠ CAUTION

- Only use accessories supplied or accepted by the manufacturer. Use of other accessories could result in damage of the product and failure to achieve the expected performance set forth in the User Manual.
- Before powering up the device, make sure that the power supply meets the requirements for the voltage and frequency of the power supply specified on the nameplate label or in the instruction manual of the device.
- The device can be used for only one patient at a time.
- DO NOT use this device on a same patient for an extended period of time.
- DO NOT use incompatible accessories or those which do not comply with local regulation.
- Install this device properly to prevent it from falling, collision, strong vibration or other mechanical external damage.

⚠ NOTE

- Please put the device in a place where observation, operation and maintenance are convenient.
- This manual introduces the device of the most complete configurations. Some configurations or functions may not be available on the product you have purchased.
- Please keep this manual near the device for easy and prompt access when needed.
- Before checking a new patient, clear the information and data of the previous patient.
- To ensure that this device is in optimal condition for use, have it serviced periodically.

- Be sure to follow the precautions for use in this manual to use this device safely.
- Service life: 10 years (may shorten due to extreme environmental conditions).

1.1.2 Prevention of Electric Shock

WARNING

- Before inserting the power plug of the device to the socket, connect to the equal potential lead of the trolley if there is any. To avoid electric shock, the device must be connected to a power socket with protective ground.
- Improper electrical installation may cause safety hazard.
- All peripheral device must be grounded.
- The device can be disconnected from mains power supply only by disconnecting the power plug from the power socket. Do not place the power plug used to disconnect the device from main power supply in a position not easily accessed by the operator.
- It is forbidden to use any non-medical peripheral within a distance of 1.8m (6 feet) from the patient, unless such non-medical peripheral is powered via the isolated power socket on the device or the isolation transformer complying with the medical safety standard.
- The device must be powered via a standard 3-pin earthed plug, and it is forbidden to use double plug or adapter. Meanwhile, the plug must be inserted into a hospital-level standard socket. Otherwise, the leakage current of the device may exceed the safety limit.
- DO NOT use the multiple socket-outlet; otherwise, interference, electric shock or damages to the device could be caused.
- No liquid shall splash onto or flow into the device; otherwise, electric shock will be caused. If any liquid enters the device, please stop using it immediately and contact the manufacturer's after-sales engineer.
- To prevent the patient from electric shock, it is forbidden to simultaneously touch the patient and the conductive part of the device.
- DO NOT touch live parts of the system or other devices (such as various signal input and output ports) with patients. If the system or other devices fail, patients may suffer electric shocks.
- DO NOT touch the power plug when your hands are wet, otherwise, a risk of electric shock may be caused.

1.1.3 During and After Use

WARNING

- During use of the device, the distance between the operator and the device should be less than 1m.
- To avoid interruption of the exam due to functional abnormality, it is advised to prepare a standby Color Doppler Ultrasound System.
- After use of the device, please maintain and store it according to the User Manual. Improper or imperfect maintenance or storage could cause risk of cross-infection to patients and operators, or cause damages to the device and degrade its performance.
- DO NOT maintain this device while using it on the patient.
- Before cleaning or maintaining the device, you must turn off the power, and disconnect the power cord from the AC power. Otherwise, electric shock may be caused.
- Please ensure that there is no residual flammable gas in the room and the device is thoroughly dry after each cleaning/disinfection; otherwise, it may cause a fire.
- After disinfection/sterilization, please ensure that there is no residue chemical reagent, since it will not only cause damage to the device, but also result in health hazard.
- DO NOT place any objects on this device; they may fall and cause injury when moving.
- When this device is moved with a trolley, items placed on the trolley must be secured to prevent them from slipping off.
- Disconnect the device with peripherals before moving; otherwise, the peripherals may tip over, resulting in injury or damage to the device.
- The performance of the device and its accessories could be affected over time. To ensure safe use of the device, please conduct periodic maintenance as required in the manual.
- Remove the batteries if the device will not be used for a long time. Please check the batteries regularly. Once any battery is found to be faulty, please connect the device to the supply mains with the adapter supplied with the device, and contact Comen for battery replacement.
- The battery must be charged after each use to ensure that the device battery has sufficient power reserves.
- If there is any abnormality or malfunction of this equipment, please mark "Malfunctioning" on the device and contact your local Comen dealer or service engineer immediately.

- DO NOT use this device on patient during maintenance.
- To avoid cross-infection, do not overuse disposable accessories even after cleaning and sterilization.
- DO NOT dispose of the device and its accessories after the expiration date of use, as this will cause damage to the local environment. Therefore, they (both reusable and disposable) must be disposed of in accordance with applicable laws and regulations or returned to the manufacturer for disposal.
- When disposing of packaging materials, they must be disposed of in compliance with local laws and regulations or hospital waste disposal rules and regulations. Packaging materials must be kept out of the reach of children.
- If, in relation to the use of the device, a death or a serious deterioration of health has occurred, this should be reported to the manufacturer and the competent authority of your country.
- Intra-cavity probe Intra probe only contacts intact mucosa.

1.1.4 Ultrasound Related Precaution

WARNING

- DO NOT activate intra-cavity probe when it is outside the patient's body.
- Before using an ultrasonic transducer (also known as "probe"), please inspect its surface carefully. If the transducer is found broken, stop using it and contact Comen or local agent immediately. Use of a broken transducer may result in electric shock to the user and the patient.
- DO NOT knock on the probe as this may damage it.
- Due to difference of ambient temperatures and examination modes, the probe surface temperature may exceed the patient's body temperature. However, normal ultrasound examinations will not burn the patient. DO NOT leave the probe on the same part of the patient's body for a long period of time. Try to keep the examination time as short as possible while meeting the diagnostic requirements.
- Normal ultrasound examinations do not pose a hazard to patients and users. However, it is recommended to minimize patient and user exposure to ultrasound by using the lowest ultrasound output intensity and reducing exposure time while obtaining clear diagnostic images.

1.1.5 Environment

WARNING

- DO NOT use the device in an environment where there is any flammable gas or flammable liquid; otherwise, explosion could be caused.
- It is forbidden to use the device near strong electric or magnetic fields (e.g., MRI scanning room) or mobile radio frequency communication equipment; otherwise, poor performance or even failure of the device will be caused.

1.1.6 Peripherals

WARNING

- To avoid interference from HF surgical equipment, DO NOT use this device in connection with HF surgical equipment (high-frequency electrosurgery), high-frequency therapy devices or defibrillators. Otherwise, electric shock or device damage may be caused.
- Only use the probe and peripherals provided or recommended by the manufacturer. Using other probes and other peripherals may cause device damage, performance degradation or even safety hazards to the patient.
- Non-ME equipment used in ME system must conform to applicable IEC or ISO safety standards.
- All medical electrical equipment intended to be connected with this device must conform to IEC6060-1:2012, and the entire system should conform to IEC6060-1-1.

1.2 Symbols

NOTE

- The symbols on the device and carton may not be exactly the same as above.

1.3 Product Overview

NOTE

- Yi-Bank is non-detachable. It is fixed on the trolley.
- Please power off the device before connecting with U-Physio module.
- The module is for use with this device only. DO NOT use it for other purposes.

1.4 Installation and Connection

WARNING

- The equipment may be contaminated by microorganisms during storage, transport and use. Please make sure that the packaging is intact before use, especially for single-use accessories, and do not use them if there is any damage.
- Check whether each component is in good condition. Ensure that there are no crack or sharp edge on all components, especially the probe. If any component is found damaged, please contact Comen's Customer Service Department or the agency for service.
- When disposing of packaging materials, please follow local laws and regulations or the hospital's waste disposal rules and regulations. Packaging materials must be kept out of the reach of children.
- Use approved and compatible probes only.
- Apply approved coupling agent, detergent and disinfectant on the probe only.
- Please turn off the device before plugging or unplugging the probe. Otherwise, the device or the probe may malfunction.
- Before connecting the probe, please inspect the probe, probe plug and probe port carefully. If there are any damage, crack, sharp edge, and exposed wire, stop using the probe and contact Comen for maintenance or replacement.
- Protect the probe cable from being stepped on or being entangled with other objects. The probe head should be put in a safe place to avoid collision.

- If the probe is dropped on the ground and struck against a hard object accidentally, stop using the probe and disconnect the probe with the main unit. There is risk of electric shock if the electrical insulating material is damaged.
- It is suggested to check the lens, cable and housing of probe after each use, ensuring that there is no damage on the probe. If any damage is found, do not put the probe into liquid.
- Detergent or coupling agent may penetrate a broken probe and cause an electrc shock, resulting in safety harzard.
- Do not immerse the probe plug in any liquid.
- Do not immerse the probe in liquid beyond the specified immersion depth limit.

⚠ CAUTION

- If the probe sheath is found broken, stop using it immediately.
- Before use, please check whether the probe sheath is expired. Do not use an expired sheath.
- The probe sheath is a composite of natural latex and talc, which may cause allergies in some people.
- Do not put the footswitch on the Diagnostic Ultrasound System, since it may drop on the floor and result in damage or safety hazard.
- Please use the footswitch provided by Comen.
- Do not connect more than one footswitch to the device.
- Please power off the ultrasound system before connecting the module.
- U-Physio module is for this device only. Do not use it for other purposes.

⚠ NOTE

- In order to ensure the normal operation of the device, please read this Chapter and Chapter 1 Safety before use, and install the device as instructed herein.
- This device has not been disinfected before delivery. Please clean and disinfect the device before using for the first time.
- To detach the probe from the device, please press down the locking lever and unplug the connector.
- Connect the power cord to a hospital-grade outlet.

- The battery must be charged after transport or storage. If the device is switched on without connecting to AC power, it may not operate due to insufficient battery power.
- No printer drive is required if you connect a compatible printer to the device.
- For more details of the printer, please refer to the printer's user manual.
- If the system failed to be switched on, please switch it on at least 1 minute after the last shutdown. Otherwise, the service life of the device may be affected.

1.5 Image Acquisition

⚠WARNING

- Freehand 3D imaging is more demanding on the operator, the operator should hold the probe stably for uniform scanning speed, and the 3D image obtained is only for reference, and cannot be directly used to diagnose the disease in order to prevent misdiagnosis.

⚠ CAUTION

- " Micro Flow " is only available for non-cardiac related exam mode.
- TDI image curve analysis is for physician's reference only and should not be used to confirm a diagnosis.
- Color Pano images are for physician's reference only and should not be used to confirm a diagnosis.
- Color Pano Image provides image stitching function, the quality of the image obtained by stitching depends to a certain extent on the experience and proficiency of the operator, the more proficient the operator is and the more skills he/she has mastered, the higher the quality of the image obtained. Therefore, choosing a mode for measurement involves some risk, so please choose carefully.

⚠ NOTE

- Exams should be performed according to actual situation and follow the ALARA Principle.
- For linear probes, the scanning range changes the width of the image; for convex and phased array probes, the scanning range changes the angle of the image.
- When the scanning range is adjusted to the widest, the scanning position is not adjustable.

- The larger the scanning range, the wider the visual field, however increasing the scanning range would reduce the frame rate.
- The image area is trapezoidal when the line array probe extended imaging is turned on.
- Convex and phased array probes extend the scanning angle when extended imaging is turned on.
- Steer is only available for linear probe.
- Images containing myocardial motion information from ECG waveforms need to be used before strain and strain rate curve analysis can be performed, otherwise the curves will be biased.
- Either the currently scanned image (frozen in cine playback) or the saved image can be used for quantitative analysis.
- Quantitative analysis is only available when image playback is selected, and it is not available for a saved static image (only one frame).
- Image quality is related to probe motion, and incorrect motion methods may result in distorted images. Refer to the following precautions during image acquisition:
  - Apply sufficient couplant to the scan path.
  - Move the probe slowly and smoothly.
  - Keep the probe in contact with the skin throughout the scanning path without lifting the probe off the skin surface.
  - Keep the probe perpendicular to the skin surface and do not shake, rotate, or tilt the probe.
  - Do not make sudden changes in probe movement speed.
  - When the scanning depth is large, please slow down the probe movement speed appropriately.
- The measurement accuracy of the spliced image may be lower than that in the B image, so please use with caution.
- When splicing back and forth, there is often a splice trace, so do not measure across both ends of the trace when measuring.
- The puncture guide line cannot be displayed in the Pano image.

1.6 Elasto

⚠ CAUTION

- Elasto images are for physician's reference only and should not be used to confirm a diagnosis.
- Elasto is an advanced imaging mode that provides clinical information about the hardness of the focus of infection, and has clinical supportive reference value that needs to be combined with other image modalities for diagnosis.
- Select appropriate probe before performing Elasto scanning.

1.7 Contrast

⚠ CAUTION

- Please refer to manual of contrast agent to set the MI index.
- Read manual of contrast agent a carefully before using Contrast function.
- Please use the Micro-bubble Destruction according to the actual residue level of microbubble, continuous use of this function may cause harm in patient.
- The TIC curves is for physician's reference only and should not be used as a basis for a definitive diagnosis.

⚠ NOTE

- Due to the limit validity of the contrast agent during the imaging process, the imaging parameters need to be preset before injecting the contrast agent in order to avoid affecting the consistency of the image during the imaging process.
- The contrast agent used must meet local regulatory requirements.
- Only ultrasound contrast agents registered for use in humans may be used.
- Some patients have allergic reactions to ultrasound contrast agents. It is recommended that before using ultrasound contrast agents, physicians should identify such patients and be prepared to treat such allergic reactions quickly.
- Before acquiring the image, please select the appropriate probe, and refer to chapter 5 for details.
- Yi-MFC imaging is only available for live images or cine files in the automatic review state; and it's not available in manual review.

- While in Yi-MFC state, the patient is required to be lying down and holding his/her breath with the probe keeping still.
- System timing errors and human error may result in a discrepancy between the time the system records the start of contrast and the time the contrast is actually injected into the patient, so check the time before injecting the contrast.
- In dual live state, the screen displays the tissue image and contrast image.
- In the frozen state, there is only one progress bar as the two images are reviewed synchronously.

1.8 Working with Images

WARNING

- Data of stress echo is for clinicians' reference only and should not be used to confirm a diagnosis
- The results of the MQA are for reference only and should not be used as a basis for a definitive diagnosis.
- Always make sure that the measurement target and image are correct and that the measurement area is valid, otherwise it may lead to misdiagnosis.
- When performing Doppler flow measurements, do not allow the probe to emit in a direction perpendicular to the direction of blood flow, otherwise incorrect blood flow information may be displayed.

CAUTION

- During measurement, once the image is thawed or the operating mode is changed, all measurement scales on the image will be cleared, but the measurement data will be saved in the report.
- During measurement, all unsaved data will be lost if the system is switched off or the current exam is ended.
- In the cross-width measurement function in the B/B mode, the measurement results have errors and can only be used for reference, not as a diagnostic basis.
- Do not freeze the image during Biopsy as positioning errors may occur.

⚠ NOTE

- The physiologic curve of this ultrasound system cannot be used for diagnostic and monitoring purposes.
- To prevent electric shock, be sure to perform the following inspections before operation:
  - The electrodes and cables are free of damage, cracks, etc;
  - The ECG electrodes must be connected correctly;
  - The ECG cable supplied with U-Physio Module by Comen must be used, otherwise electric shock may occur.
- When connecting ECG electrodes, connect the ECG cable to the ECG connector before placing the ECG electrodes on the patient's body. Otherwise, the electric shock may occur.
- Do not place the ECG electrodes directly on the patient's heart, otherwise the patient may suffer cardiac arrest.
- Never use this system together with electronic devices such as HF electrosurgical knife, HF therapeutic device or defibrillator to prevent electric shock.
- The conductive part of the ECG electrodes and their associated interfaces must not come into contact with the earth and other conductive parts.
- Stepping on/pressing on the cables due to carelessness or negligence may result in the risk of breaking the cables or exposing the cables inside.
- The display of the respiratory waveform depends on the patient's respiratory condition. If the patient's respiration is too slow, the respiratory waveform signal may not be obvious; if the patient's respiratory amplitude is too large, the respiratory waveform signal may be incompletely displayed.
- The signal effect may be different depending on the site where the leads are connected; compared with connecting the extremities, connecting to the chest cavity will obtain stronger respiratory wave signals.
- If abnormal signal from U-Physio module occurs, check if the cable is connected well.
- Regularly check the skin where the electrodes are placed; if allergy occurs, the electrodes should be replaced or the placement position should be changed.
- In the tracing state, click [Edit] on the screen to enter the tracing curve fine-tuning state.
- Available probes for this function are: P2-5H, P2-5NH, P3-7H, P4-10H.
- Cardiac and heart-related exam mode are applicable for Auto VTI.
- Patients should be on supine position or left lateral position when performed Auto VTI.

- Cardiac application package must be configured for Auto VTI.
- Auto EF is available only in single-window B mode and in freeze or movie status.
- Only linear probe is available here.
- Do not press the probe during Auto IMT.
- Only the line array probe enters the real-time IMT imaging mode in the real-time B-mode single window and dual window scanning states.
- After entering real-time IMT, do not press the probe during real-time scanning.
- The filling colors of the middle intima in the ROI box are red, yellow and green, and there is no gap between the filled area and the vessel wall.
- Before perform exam for a new patient, please tap on "End" to clear cine memory to avoid confusion between old and new patient images, leading to misdiagnosis.
- Cine review files stored on the hard disk should contain patient information for reference during access to avoid misdiagnosis caused by access error.
- Image magnification changes the frame rate, which tends to change the thermal index. The position of the focal area may also change, which may cause the peak intensity to change at different locations within the acoustic region. The MI may also change as a result.

1.9 Data and Image Management

⚠ NOTE

- Before backing up patient data, please complete the current exam, otherwise the data can not be backed up.
- Use a USB flash drive (FAT, FAT32, or NTFS file system) that is legally listed for sale for backup.
- Before backing up patient data, please complete the current exam, otherwise the data can not be backed up.
- Use a USB flash drive (FAT, FAT32, or NTFS file system) that is legally listed for sale for backup.

1.10 DICOM

⚠ NOTE

- Please make sure that the device is connected to the DICOM server before use. Otherwise, you will not be able to use the server.

1.11 Cleaning, Disinfection and Sterilization

⚠ WARNING

- The device and accessories are not disinfected before leaving the factory. Please disinfect and sterilize the ultrasonic transducer according to the method provided in the instruction manual before use.
- Please follow the cleaning/disinfection time, concentration and method specified by the manufacturer of detergent/disinfectant. If the device is used in a dusty environment, shorten the cleaning and disinfection interval to ensure that the device is not blocked by dust.
- Do not use a mix of different detergents and disinfectants; otherwise, the device may be damaged or the cleaning personnel may be injured.
- DO NOT pour liquid onto the device or allow liquid to enter the housing.
- DO NOT immerse the device in liquid.
- DO NOT use any frictional material, bleaching powder or strong solvent (e.g., acetone or detergent containing acetone). Otherwise, the surface of the device may get damaged.
- Before cleaning/disinfecting the device, the operator must turn off the power, and disconnect the power cord from the socket of power supply.
- After each cleaning/disinfection, ensure that the device is thoroughly dry before use. Otherwise, electric shock may occur.
- After each cleaning/disinfection, please check the device carefully. If any signs of aging or damage are found on the device, stop using it immediately.
- If the ultrasonic transducer surface is contaminated with Creutzfeldt-Jakob virus, there is no applicable disinfection method. Dispose of the ultrasonic transducer according to hospital and local policies.
- The ultrasonic transducer should be thoroughly cleaned before and after each use.

- After cleaning and disinfection, the ultrasonic transducer should be checked for cracking, peeling and other abnormalities. If you find any of the above phenomena, please stop using the ultrasonic transducer immediately and contact Comen or agent.
- After use, wipe the surface of the ultrasonic transducer immediately with clean water (<40℃) to remove all visible contaminants. DO NOT rinse the ultrasonic transducer with detergent that solidifies protein or water over 40℃, since they may cause the protein to solidify on the surface of the ultrasonic transducer, increasing the difficulty of subsequent cleaning.
- The surface of disinfectant cannot exceeds the soaking depth of the ultrasonic transducer or the ultrasonic transducer maybe damaged.

1.12 Maintenance

⚠ WARNING

- The hospital or organization using this device should make a sound maintenance plan; failure to do so may result in malfunction of the device and unpredictable consequences, and may also endanger personal safety.
- Clean the area between the power plug terminals at least once a year. The dust between the power plug terminals could result in a fire.
- Before each use of the device, inspect the main unit, ultrasonic transducer and cables for damage that may affect patient safety or performance, and especially check the ultrasonic transducer and cables for cracks.
- Always check accessory cables and their plugs before use, and never use damaged cables and plugs.

1.13 Teaching Function

⚠ NOTE

- The teaching functions of this device support the sections of abdominal, urological, small organ, gynecological, obstetrical, cardiac, vascular, musculoskeletal, neurological, acute and critical care, and gastrointestinal.

Chapter 2 Performance Information

1) Product Classification

Item	Type
Classification by Medical Devices Regulation (EU) 2017/745	IIa
Type of protection against electric shock	Class I with internal power supply
Level of protection against electric shock	Type CF applied part: U-Physio Module Type BF applied part: all ultrasonic transducers
Degree of protection by enclosure	Main unit: IPX0 (equipment not protected against liquid ingress) ultrasonic transducer: IPX7 Footswitch: IP68 Adapter: IP22
Degree of safety for flammable anaesthetic mixture with air or oxygen or nitrous oxide	The equipment cannot be used within flammable anaesthetic mixture with air or oxygen or nitrous oxide
Mode of operation	Continuous operation
Whether contains applied parts that are protective against defibrillation discharge effect	ECG contains applied parts that are protective against defibrillation discharge effect
Permanent or non-permanent installation	Non- permanent installation
Relevant standards compliance	IEC60601-1: 2005+A1:2012+A2:2020 / EN 60601-1:2006+A2:2021, IEC60601-2-37:2015 IEC60601-1-2: 2014+A1:2020 / EN 60601-1-2:2021, IEC60601-1-6:2021

2) Physical Specifications

Main unit

Item	Description
Size	Depth (with display screen closed): 370 mm±10mm Width (with display screen closed): 338 mm±10mm Thickness(with display screen closed and foot pad): 50 mm±10mm
Weight	≤ 4.5 kg (with battery)

Display screen

Item	Description
Size	15.6 inch
Resolution ratio	1920 pixel ×1080 pixel

Touch Screen

Item	Description
Size	12.3inch
Resolution ratio	1920 pixel ×720 pixel

3) Environment Specifications

Main Unit and Ultrasonic Transducer			
Item	Temperature(℃)	Relative Humidity (non-condensation)	Barometric Pressure (hPa)
Working	0～40	20 %～85 %	700～1060
Storage/Transportation	-20～55	20 %～95 %	700～1060
During transportation, severe impact, vibration, rain and snow splashing shall be avoided			

4) Power Supply Specifications

External AC power supply	
Input Voltage	100–240 V
Input Frequency	50/60Hz
Input Current	Adapter: 2.0-1.0A Mobile Trolley: 2.0-1.0 A
Built-in Battery	
Number of Battery	Main unit: 1
Battery Type	Lithium ion battery
Rated Output Voltage	14.4 V DC
Battery Capacity	Single battery: 14.4V ⎓ 6600mAh
Discharge Time	≥1.5 h（under classic working state with single full-charged battery）
Battery	
Number of Battery	Main unit: 2 or 4
Battery Type	Lithium ion battery
Rated Output Voltage	19 V DC
Battery Capacity	2 battery: 14.4V ⎓ 13200mAh 4 battery: 14.4V ⎓ 26400mAh

5) Measurement accuracy

Parameter	Unit	Range	Accuracy
B Mode			
Distance	mm	Full screen	Within ±3%
Circumference	mm	Full screen	Within ±10%
Area	mm^2	Full screen	Within ±7%

Angle	deg	Full screen	Within ±3%
Volume	mm^3	Full screen	Within ±10%
M Mode			
Time	s	Time line display	Within ±2%
Heart rate	bpm	Time line display	Within ±4%
Doppler Mode			
Speed (PW, non- cephalic)	cm/s	10 cm/s~200 cm/s	Angle≤60°, Within ±5%
Speed (CW, non- cephalic)	cm/s	10 cm/s~200 cm/s	Angle≤60°, Within ±5%
Speed (PW, cephalic)	cm/s	10 cm/s~300 cm/s	Angle≤60°, Within ±5%
Speed (CW, cephalic)	cm/s	10 cm/s~300 cm/s	Angle≤60°, Within ±5%

6) ECG

Heart Rate	Measurement range: 30 bpm ~ 300 bpm (error within ±10%)
Time Measurement	Time period range: 200 ms ~ 2 s ECG for all time periods can be displayed (error within ±10%)
QRS Wave Detection	Amplitude range: 0.5 mV to 5 mV Width range: 40 ms to 120 ms Heart rate error within ±10%
Overload Protection	The system functions normally after applying a 1 V (p-v), 50 Hz differential mode voltage for 10 s to any combination of patient electrodes and lead selections.
Power Frequency Voltage Tolerance	When superimposed on the QRS wave signal, the maximum power frequency sine wave peak-to-peak value does not be less than 100 μV (p-v), provided that the heart rate detection error remains within ±10% tolerance.
Patient Electrode Connection	Three-lead: Electrodes is color-coded to differentiate lead positions: white for right arm (RA), black for left arm (LA), red for left leg (LL). Five-lead: Electrodes is color-coded to differentiate lead positions: white for right arm (RA), green for right leg (RL), black for left arm (LA), red for left leg (LL), brown for chest (V).
Drift Tolerance	When a 0.1Hz, 4mV p-v triangular wave is superimposed on a QRS wave with an amplitude of 0.5mV, a width of 100ms, and a rate of 80bpm, the displayed heart rate error does not exceed ±10%.