# Nuewa A20W/Nuewa A20/Nuewa A20 Exp/Nuewa A20 Elite/Nuewa A20G/ Nuewa A20Q/Nuewa A MV/Nuewa A Elite/ Nuewa A MS/Nuewa A20 Premium/ Nuewa A20 Plus/Nuewa A Swan/Nuewa A18W/Nuewa A20 Pro/Nuewa A20T/ Nuewa A20S/Nuewa A10S/Nuewa A Lumi/Nuewa AR/Nuewa A Super/Imagyn A20 Exp/Imagyn A20/Imagyn A20T/ Imagyn A20S/Imagyn A20 Premium/ Imagyn A20 Elite/Imagyn A20 PRO/ Imagyn A20 Super/Imagyn A20 Plus

## Safety and Performance Information

# Contents

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# 1 Safety Precautions

## 1.1 Safety Precautions

Please observe the following precautions to ensure patient and operator's safety when using this system.

**⚠DANGER**

Do not operate this system and probes in an atmosphere containing flammable gases or liquids such as anesthetic gases, hydrogen, and ethanol, because there is danger of explosion.

**⚠WARNING**

- Do connect the power plug of this system to wall receptacles that meet the ratings indicated on the rating nameplate. If adapters or multifunctional receptacles are used, it may cause the leakage current to exceed the safety requirement.
- In the environment that patient is 1.5 meters around, connect peripherals to the auxiliary power outlet, or power the peripherals by auxiliary output cable or isolation transformer complied with IEC60601-1 or the power input of the same safety level.
- DO NOT use power supply of different phases to power peripherals, like power supply of air-conditioning.
- When using peripherals not powered by the auxiliary output of the ultrasound system, or using peripherals other than permitted by Mindray, make sure the overall leakage current of peripherals and the ultrasound system meets the requirement of the local medical device electrical regulation (like enclosure leakage current should be no more than 500 uA of IEC60601-1), and the responsibility is held by the user.
- Connect the grounding conductor before turning ON the system. Disconnect the grounding cable after turning OFF the system. Otherwise, electric shock may result.
- For the connection of power and grounding, follow the appropriate procedures described in this operator's manual. Otherwise, there is risk of electric shock. Do not connect the grounding cable to a gas pipe or water pipe; otherwise, improper grounding may result or a gas explosion may occur.
- Before cleaning the system, disconnect the power cord from the outlet. System failure and electric shock may result.

- This system is not water-proof designed. Do Not use this system in any place where water or any liquid leakage may occur. If any water is sprayed on or into the system, electric shock may result or the system may be damaged. If water is accidentally sprayed on or into the system, contact Mindray Customer Service Department or sales representative.
- DO NOT use a probe that has a damaged, scratched surface, or exposed wiring of any kind. Immediately stop using the probe and contact Mindray Customer Service Department or sales representative. There is risk of electric shock if using a damaged or scratched transducer.
- Do not allow the patient to contact the live parts of the ultrasound system or other devices, e.g. signal I/O ports. Electric shock may occur.
- Do not use an aftermarket probe other than those specified by Mindray. The probes may damage the system causing a profound failure, e.g. a fire in the worst case.
- Do not subject the transducers to knocks or drops. Use of a defective transducer may cause an electric shock.
- Do not open the covers and front panel of the system. Short circuit or electric shock may result when the system hardware is exposed and powered on.
- Do not use the system with the patient when the system is being serviced or maintained.
- Do not use this system when any digital device such as a high-frequency electrotome, high-frequency therapeutic device or defibrillator is applied already. Otherwise, there is a risk of electric shock to the patient.
- Only use the ECG leads provided with the physiology module; otherwise, electric shock may be resulted.
- When moving the system, you should hold the handle; otherwise, damage may be resulted by abnormal force. Do not push the system from the left/ right side, otherwise, it may be toppled over.
- The auxiliary power output outlet in the system is used to supply power for the recommended peripheral devices. Do not connect other devices to the outlet, otherwise, the rated output power may be exceeded and failure may be resulted.
- Accessory equipment (analog or digital) connected to the ultrasound system must comply with the relevant IEC standards (e.g., IEC 60950 information technology equipment safety standard and IEC 60601-1 medical equipment standard). Furthermore, all configurations must comply with the standard IEC60601-1. It is the responsibility of the person, who connects additional equipment to the signal input or output ports and configures a medical system, to verify that the system complies with the requirements of IEC60601-1. If you have any questions regarding these requirements, consult your vendor.
- Prolonged and repeated use of keyboards may result in hand or arm nerve disorders for some individuals. Observe the local safety or health regulations concerning the use of keyboards.

- It is not allowed for the operator to have contact with other patients and the electronic parts (such as the input/output terminal of the signal) of other devices that are connected to the system. Otherwise, it may produce the electrical shock to the patient.
- When using a probe, pay attention to the status of the ultrasound image. Do not use the probe to perform image acquisition when the image is frozen.
- Do not modify this equipment without authorization of the manufacturer.
- An additional multiple socket-outlet or extension cord shall not be connected to the system.
- To avoid the risk of electric shock, this equipment must only be connected to a supply mains with protective earth.
- The system shall not be serviced or maintained while in use with a patient.
- Do not position the ME equipment so that it is difficult to operate the disconnection device.
- Use the pluggable power supply as the net power supply breaking facility.

## ⚠CAUTION

- Precautions concerning clinical examination techniques:
  - This system must be used only by qualified medical professionals.
  - This operator's manual does not describe clinical examination techniques. The clinician should select the proper examination techniques based on specialized training and clinical experience.
- Malfunctions due to radio wave:
  - If a radio wave emitting device is used in the proximity of this system, it may interfere with operations. Do not use or take any devices transmitting RF signals (such as cellular phones, transceivers and radio controlled products) in the room placing the system.
  - If a person brings a device that generates radio waves near the system, ask him/her to immediately turn OFF the device.
- Precautions concerning movement of the system:
  - Please install the system on a flat plane with casters locked. Otherwise, damage may be resulted by accidental moving.
  - Do not move the system laterally, which may result in damage in case of toppling.
  - Move the system slowly on the slope by two people and make sure that the support arm is not extended, otherwise, damage may result in case of unexpected sliding.
  - Do not sit on the system, which may result individual falling in case of system moving.
  - Object placed on the monitor may fall and injure an individual.

  - Fasten and fully secure any peripheral device before moving the system. A loose peripheral device may fall and injure an individual.
  - When moving the system on the steps, please take care to prevent the system from toppling.
- If the circuit protector is tripped, it indicates that the system or a peripheral device was improperly shut down and the system is unstable. You cannot repair the system under this circumstance and must call the Mindray Customer Service Department or sales representative.
- There is no risk of high-temperature burns during normal ultrasound examinations. It is possible for the surface temperature of the transducer to exceed the body temperature of a patient due to environmental temperature and exam type combinations. Do not apply the transducer to the same region on the patient for a long time. Apply the transducer only for a period of time required for the purpose of diagnosis.
- Do not use the system to examine a fetus for a long period of time.
- Except accessories that have been stated as sterile, the system and its accessories are not disinfected or sterilized prior to delivery. The operator is responsible for the cleaning and disinfection of probes and sterilization of biopsy brackets according to the manuals, prior to the use. All items must be thoroughly processed to completely remove harmful residual chemicals, which will not only harmful to the human body, but also damage the accessory.
- It is necessary to end the current exam that is in progress and clear the current Patient Information field. Otherwise, new patient data may be combined with the previous patient data.
- Do not connect or disconnect the system’s power cord or its accessories (e.g., a printer or a recorder) without turning OFF the system power first. This may damage the system and its accessories or cause electric shock.
- If the system is powered off improperly during operation, it may result in data damage of the system’s hard disk or system failure.
- Do not use a USB memory device (e.g., a USB flash drive, removable hard disk) which has unsafe data. Otherwise, system damage may result.
- It is recommended to only use the video devices specified in this manual.
- Do not use gel, disinfectant, probes, probe sheath or needle-guided brackets that are not compatible with the system.
- The applied contrast agency should be compliant with the relevant local regulations.
- Read the Acoustic Output Principle in the operation manual carefully before operating this system on clinical examination.
- The cover contains natural rubber that can cause allergic reactions in some individuals.
- Please use the ultrasound gel compliant with the relevant local regulations.
- DO NOT expose the system to excessive vibration through transportation. Mechanical damage may result.

- Always keep the system dry. Avoid transporting this system quickly from a cold place to a warm place; otherwise condensation or water droplets may form allowing a short circuit and possible electric shock.

**NOTE:**

- DO NOT use the system in the vicinity of strong electromagnetic field (such as a transformer), which may affect the performance of the system.
- Do not use the system in the vicinity of high-frequency radiation source (e.g. cellular phones), which may affect the performance of the system or even lead to failure.
- When using or placing the system, keep the system horizontal to avoid imbalance.
- To avoid damaging the system, do not use it in following environment:
  - Locations exposed to direct sunlight.
  - Locations subject to sudden changes in environmental temperature.
  - Dusty locations.
  - Locations subject to vibration.
  - Locations near heat generators.
  - Locations with high humidity.
- Turn ON the system only after the power has been turned OFF for a while. If the system is turned ON immediately after being turned OFF, the system may not be rebooted properly and could malfunction.
- Select “Freeze” to freeze an image or turn off the power of the system before connecting or disconnecting a probe.
- Remove the ultrasound gel from the face of the transducer when the examination is completed. Water in the gel may enter the acoustic lens and adversely affect the performance and safety of the transducer.
- You should properly back up the system to a secure external storage media, including system configuration, settings and patient data. Data stored to the system’s hard drive may be lost due to system failure, improper operation or accident.
- Do not apply external force to the control panel. Otherwise, the system may be damaged.
- If the system is used in a small room, the room temperature may rise. Please provide proper ventilation and free air exchange.
- To dispose of the system or any part, contact Mindray Customer Service Department or sales representative. Mindray is not responsible for any system content or accessories that have been discarded improperly.
- Electrical and mechanical performance may be degraded due to long usage (such as current leakage or distortion and abrasion); the image sensitivity and precision may become worse too. To ensure optimal system operations, it is recommended that you maintain the system under a Mindray service agreement.
- To replace the fuse, contact Mindray Customer Service Department or sales representative.
- Do not turn OFF the power supply of the system during printing, file storage or invoking other system operations. An interrupted process may not be completed, and can become lost or corrupted.
- The iScape feature constructs a single extended image from a series of individual image frames. The quality of the final image is user-dependent and requires skill to efficiently apply the feature and technique. Exercise caution when measurements are performed from an iScape image.

- Ensure that the current exam date and time are the same as the system date and time.
- Use detachable power supply cord as mains power breaking device. DO NOT set equipment in place where difficult for disconnection of detachable power supply cord.

Please read the following precautions carefully to ensure the safety of the patient and the operator when using the probes.

## ⚠WARNING

- The ultrasound probe is only for use with the specified ultrasound diagnostic system.
- The ultrasound probe must be used only by qualified professionals.
- Confirm that the transducer and probe cable are normal before and after each examination. A defective probe may cause electric shock to the patient.
- Do not subject the probe to shock. A defective probe may cause electric shock to the patient.
- Do not disassemble the probe to avoid the possibility of electric shock.
- Never immerse the probe connector into liquids such as water or disinfectant because the connector is not waterproof. Immersion may cause electric shock or malfunction.
- A transducer sheath must be installed over the transducer before performing examination.
- Do not use the intra-operative probe in direct contact with the cardiac, the central circulatory system, and the central neuro system.

## ⚠CAUTION

- When using the probe, wear sterile gloves to prevent infection.
- Be sure to use sterile ultrasound gel. Please use the ultrasound gel compliant with the relevant local regulations. And manage the ultrasound gel properly to ensure that it does not become a source of infection.
- In normal diagnostic ultrasound mode, there is no danger of a normal-temperature burn; however, keeping the probe on the same region of the patient for a long time may cause such a burn.
- Do not use the carrying case for storing the transducer. If the carrying case is used for storage, it may become a source of infection.
- It is required to practice ALARA when operating ultrasound system. Minimize the acoustic power without compromising the quality of images.
- The probe and accessories supplied with it are not delivered disinfected or sterilized. Sterilization (or high-level disinfect) before use is required.
- Disposable components should be packaged sterile and for single-use only. Do not use if integrity of packaging violated or if expiration date has passed. Please use the disposable components compliant with the relevant local regulations.

- Please use the disinfection or sterilization solution recommended in this operator's manual; otherwise Mindray will not be liable for damage caused by other solutions. If you have any questions, please contact Mindray Customer Service Department or sales representative.
- Do not use pre-lubricated condoms as a sheath. Lubricant may not be compatible with the probe material and damage may result.
- The damage of the transducer may be caused by the contact of improper gel or cleaner:
  – DO NOT dip the transducer in the strong polar solution of ethanol, chloride of lime, ammonium chloride, acetone and formaldehyde.
  – DO NOT contact the transducer with solution or ultrasound gel containing oily medium such as mineral oil or lanoline.

**NOTE:**

- Read the following precautions to prevent the probe from malfunction:
  – Before connecting or disconnecting the probe, freeze or turn off the diagnostic ultrasound system.
  – Clean and disinfect the probe before and after each examination.
  – After the examination, wipe off the ultrasound gel thoroughly. Otherwise, the ultrasound gel may solidify and the image quality would be degraded.
- To prevent the probe from being damaged, do not use it where it will be exposed to:
  – Direct sunlight or X-rays
  – Sudden changes in temperature
  – Dust
  – Excessive vibration
  – Heat generators
- Repeated disinfection will eventually damage the probe, please check the probe performance periodically.

## 1.2 Latex Alert

When choosing a probe sheath, it is recommended that you directly contact CIVCO for obtaining information regarding probe sheaths, pricing, samples and local distribution.

For CIVCO information, please contact the following:

CIVCO Medical Instruments

Tel: 1-800-445-6741

www.civco.com

**⚠WARNING**

Allergic reactions in patients sensitive to latex (natural rubber) may range from mild skin reactions (irritation) to fatal anaphylactic shock, and may include difficulty breathing (wheezing), dizziness, shock, swelling of the face, hives,

sneezing, or itching of the eyes (FDA Medical Alert on latex products, “Allergic Reactions to Latex-containing Medical Devices”, issued on March 29, 1991).

# 2 System Overview

## 2.1 Safety Classifications

- According to the type of protection against electric shock:
  Externally powered CLASS I EQUIPMENT + internally powered equipment
- According to the degree of protection against electric shock:
  Type-BF&CF applied part. The ECG is type-CF applied part. The ultrasound probes and PCG are type-BF applied parts.
- According to the degree of protection against harmful ingress of water or particulate matter:
  – The main unit is classified as IPX0
  – The probe is classified as IPX7
  – The footswitch (can be used in the operating room) is classified as IPX8
- According to the disinfection and sterilization method(s) recommended by manufacturer:
  The devices recommended by the manufacturer.
- According to the degree of safety of application in the presence of a FLAMMABLE ANESTHETIC MIXTURE WITH AIR or WITH OXYGEN OR NITROUS OXIDE:
  EQUIPMENT not suitable for use in the presence of a FLAMMABLE ANESTHETIC MIXTURE WITH AIR or WITH OXYGEN OR NITROUS OXIDE.
- According to the mode of operation:
  CONTINUOUS OPERATION
- The device equipped with the applied part of defibrillation protection:
  ECG is equipped with the applied part of defibrillation protection.
- According to the signal input and output parts of the device:
  The device is equipped with signal input and output parts
- Permanently installed or non-permanently installed:
  Non-permanently installed

## 2.2 Product Specifications

**NOTE:**

The functions described in the operator's manual may vary depending on the specific system purchased.

### 2.2.1 Power Supply

#### Power input

- Voltage: 100-240 V~
- Frequency: 50/60 Hz
- Power consumption: 1170 VA

### Power output

Voltage: 100-240 V~

Frequency: 50/60 Hz

Power consumption: 240 VA

**NOTE:**

This is the maximum auxiliary output power of the outlet. When the peripheral device is connected to the outlet, ensure that the maximum auxiliary output power does not exceed this threshold. Otherwise, the system may be damaged.

## 2.2.2 Environmental Conditions

**⚠WARNING**

Do not use this system in conditions other than those specified.

- Operating conditions
  - Ambient temperature: 0 °C to 40 °C
  - Relative humidity: 20% to 85% (no condensation)
  - Atmospheric pressure: 700 hPa to 1060 hPa
- Storage and transportation conditions
  - Ambient temperature: -20 °C to 55 °C
  - Relative humidity: 20% to 95% (no condensation)
  - Atmospheric pressure: 700 hPa to 1060 hPa

## 2.2.3 Dimensions and Weight

- Dimensions (in folded status):

  The control panel and the monitor are in the lowest position, and the monitor is placed horizontally
  - Depth (mm): 1035±20
  - Width (mm): 518±10 (main unit)/548±10 (control panel)/650±20 (monitor)
  - Height (mm): 1090±20
- Dimensions (in unfolded status):

  The control panel and the monitor are in the highest position, and the monitor is placed vertically
  - Depth (mm): 924±20
  - Width (mm): 518±10 (main unit)/548±10 (control panel)/650±20 (monitor)
  - Height (mm): 1919±30
- Weight: 140±10kg (Standard configuration without optional accessories such as probes and batteries)

# 3 System Preparation

**⚠WARNING**

- Do not connect the three-wire cable of the system with a two-wire plug without protective grounding; otherwise, electric shock may result.
- Do connect the power plug of this system to wall receptacles that meet the ratings indicated on the rating nameplate. If adapters or multifunctional receptacles are used, it may cause the leakage current to exceed the safety requirement.
- In the environment that patient is 1.5 meters around, connect peripherals to the auxiliary power outlet which is capable of isolation protection, or power the peripherals by auxiliary output cable or isolation transformer complied with IEC60601-1 or the power input of the same safety level.
- DO NOT use power supply of different phases to power peripherals, like power supply of air-conditioning.
- When using peripherals not powered by the auxiliary output of the ultrasound system, or using peripherals other than permitted by Mindray, make sure the overall leakage current of peripherals and the ultrasound system meets the requirement of the local medical device electrical regulation (like enclosure leakage current should be no more than 500uA of IEC60601-1), and the responsibility is held by the user.

## 3.1 Moving/Positioning the System

**⚠CAUTION**

- When moving the system, pay attention to the following conditions:
  - Lower the control panel to the lowest and move it to the center. During the movement, ensure that the monitor is locked, the accessories are secured on the system, and the items connected to the system are disconnected.
  - During the movement, ensure that the passage is free of obstructions. Do not crash into people, walls, door frames or other devices.
  - Please move the system on the slope that meets the hospital's requirements. When going up or down the slope, move the system forward or backward rather than laterally.
- Pay extra attention when moving the system on a sloping ground, do not move it on a more than 10°-sloped plane to avoid system toppling.

# 3.2 Connecting the Power Cord

## 3.2.1 Connecting External Power

**NOTE:**

Make sure to allow sufficient slack in the cable so that the plug is not pulled out of the wall if the system is moved slightly. If the plug is pulled out accidentally, data may be lost.

## 3.2.2 Connecting Internal Power (Powered by Batteries)

**⚠WARNING**

- The battery is inside the machine; only technical professionals from Mindray or engineers authorized by Mindray after training can perform battery installation and uninstallation.
- If you need to change the battery or buy a new one, please contact your sales representative.
- The lithium-ion battery has a service life of five years. Replace your battery when it reaches the end of its service life.

**NOTE:**

Power off the system if it will not be used for a long period of time (including storage/transportation condition). Do not leave the system in standby status, otherwise the batteries will be discharged and permanently damaged.

## 3.2.3 Equipotential Terminal

**⚠WARNING**

- Be sure to connect the equipotential wire before inserting the power plug into the receptacle; be sure to pull out the power plug from the receptacle before disconnecting the equipotential wire; otherwise electric shock may result.
- When you connect another device to this system, you should use the equipotential wire to connect each of equipotential terminals; otherwise electric shock may result.
- Connect the earth cable before turning ON the system. Disconnect the earth cable after turning OFF the system. Otherwise, electric shock may result.
- DO NOT connect this system to outlets with the same circuit breakers and fuses that control the current to devices such as life-support systems. If this system malfunctions and generates overcurrent, or when there is an instantaneous current at power ON, the circuit breakers and fuses of the building’s supply circuit may be tripped.

# 3.3 Powering ON/OFF

**⚠CAUTION**

To ensure safe and effective system operation, you must perform daily maintenance and checks. If the system begins to function improperly, immediately stop scanning. If the system continues to function improperly, fully shut down the system and contact the Mindray Customer Service Department or a sales representative. If you use the system in a persistent improperly functioning state, you may harm the patient or damage the equipment.

## 3.3.1 Powering the System ON

**NOTE:**

You must log in again after system restart or dormancy.

## 3.3.2 Checking After Powering On

**⚠WARNING**

- If you use a probe giving off excessive heat, it may burn the patient.
- If you find anything not functioning properly, this may indicate that the system is defective. In this case, shut down the system immediately and contact Mindray Customer Service Department or sales representative.

**NOTE:**

If there is over loading to the system, the breaker will switch into OFF to discontinue the power supply. If the breaker cannot be set as On, or returns to OFF after being switched on, please disconnect the power cables, and contact your sales representative.

## 3.3.3 Powering the System Off

**NOTE:**

- DO NOT directly shut down the system. It may make the data corrupted.
- Do not turn off the breaker while the power indicator is on. Otherwise, the data may lose or the system software may be damaged.
- If you will not use the system for a long period of time, you shall turn off the circuit breaker and disconnect the power to all other peripheral devices.

## 3.3.4 Standby

**NOTE:**

- If you will not use the system for a long period of time, you shall turn off the circuit breaker and disconnect the power to all other peripheral devices.

- If the system is disconnected from the AC power, make sure not to press the power button in the standby status. In this circumstance, to exit standby status or power off the system, connect the system to the AC power before pressing the power button.

# 3.4 Adjusting Monitor Position

## 3.4.1 Adjusting Height and Displacement

**NOTE:**

Take care not to trap your hands when adjusting the monitor up and down.

# 3.5 Connecting/Disconnecting a Probe

**⚠CAUTION**

- Press <Freeze> to freeze an image or turn off the power of the system before connecting/disconnecting the probe. Otherwise, system or probe failure may occur.
- When connecting or disconnecting a probe, place it in a proper position, to prevent the probe from falling off or becoming damaged.
- Hang the probe cable to the hanger located under the control panel to avoid excessively bending and damaging the cable.
- Only use the probes provided by Mindray. Aftermarket probes may result in damage or cause a fire.

## 3.5.1 Connecting a Probe

**⚠WARNING**

The probes, cables and connectors should be in proper operating order and free from surface defects, cracks and peeling. Otherwise, this may lead to electrical shock.

# 3.6 Connecting Peripheral Devices

## 3.6.1 Connecting USB Devices

**⚠WARNING**

DO NOT directly remove a USB memory device, as the USB device and/or the system may become damaged.

## 3.6.2 Connecting a Footswitch

**⚠WARNING**

Do not connect two or more footswitches to the main unit; otherwise, it may lead to the malfunction to the system.

## 3.6.3 Connecting a Graph/Text Printer

**NOTE:**

- Please refer to the accompanying manuals of the printers for more details.
- The network printer functions depending on the configured network environment in the hospital, please consult the network configuration administrator in case of failure.

## 3.6.4 Connecting a Video Printer

**NOTE:**

Please refer to the accompanying manuals of the printers for more details.

## 3.6.5 Ultrasound Gel Heater

**NOTE:**

- When the ambient temperature is higher than the required temperature of the heater, the heater does not function.
- The heater can only heat one bottle of gel at a time.

## 3.6.6 Connecting the Magnetic Positioning System

**NOTE:**

- Place the set of the magnetic positioning system away from the electromagnetic interference sources, such as power filter, signal indication, magnetically activated metal materials, cell phone in the use of the devices.
- Connect the magnetic positioning system when the magnetic positioning system controller is OFF.
- Exit Fusion imaging before reconnecting/disconnecting sensor from the magnetic positioning system controller. Power off the ultrasound system to turn off the magnetic positioning system controller before reconnecting/disconnecting magnetic transmitter.
- Mindray does not provide the sterile sheath. Users should prepare it according to the own needs.

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# 4 Setup

**⚠CAUTION**

When the preset data is changed, be sure to save the preset data according to the methods described in this chapter. Mindray is not responsible for the loss of preset data.

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# 5 Exam Preparation

## 5.1 Patient Information

### 5.1.1 New Patient Information

**⚠CAUTION**

Before examining a new patient, tap the [End] on the touch screen to end the exam of the previous patient, update the patient ID and information, to avoid mixing data of the next new patient.

## 5.2 Select Exam Mode and Probe

**⚠CAUTION**

If the exam mode is changed during a measurement, all measurement calipers on the image will be cleared. The data of general measurements will be lost, but the data of application measurements will be stored in the reports.

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# 6 Image Acquisition

**⚠WARNING**

- The images displayed in this system are only reference for diagnosis. Mindray is not responsible for the correctness of diagnostic results.
- In Dual-B imaging mode, the measurement results of the merged image may be inaccurate. Therefore, the results are provided for reference only, not for confirming a diagnosis.

## 6.1 Anatomical M Mode

**⚠CAUTION**

Anatomical M Mode and Color Anatomical M mode images are provided for reference only, not for confirming diagnoses. Compare the image with those of other machines, or make diagnoses using non-ultrasound methods.

### 6.1.1 Free Xros CM (Curved Anatomical M-Mode)

**⚠CAUTION**

Curved anatomical M image is provided for reference, not for confirming a diagnosis. Generally it should be compared with other device or make a diagnosis by non-ultrasonic methods.

## 6.2 TDI (Tissue Doppler Imaging)

### 6.2.1 TDI Quantitative Analysis

**⚠CAUTION**

TDI is provided for reference, not for confirming a diagnosis.

## 6.3 iScape View

**⚠CAUTION**

- It is provided for reference, not for confirming a diagnosis.

- iScape panoramic imaging constructs an extended image from individual image frames. The quality of the resulting image is user-dependent and requires operator skill and additional practice to become fully proficient. Therefore, the measurement results can be inaccurate. Exercise caution when you perform measurements in iScape mode. A smooth and even speed will help produce optimal image results.

## 6.4 Tissue Tracking Quantitative Analysis

**⚠CAUTION**

Tissue Tracking Quantitative Analysis images are provided for reference only, not for confirming diagnoses.

## 6.5 Fusion Imaging

**⚠WARNING**

The Fusion Imaging is contraindicated to the person wearing the internal pacemaker, cochlear implant or nerve stimulator. People wearing the implant or intra-corporeal devices should keep one-meter away when the magnetic transmitter starts working.

# 7 3D/4D

**⚠CAUTION**

The ultrasound images are provided for reference only, not for confirming a diagnosis. Please use caution to avoid misdiagnosis.

## 7.1 STIC (Spatio-Temporal Image Correlation)

**⚠WARNING**

Diagnoses made only by assessing this 3D/4D acquisition are not permitted. Every diagnostic finding has to be evaluated in 2D as well.

**⚠CAUTION**

- One or more of the following artifacts in the data set indicate a disturbance during acquisition. In all of the following cases the data set has to be discarded and the acquisition has to be repeated.
  - Sudden discontinuities in the reference image B: These are due to motion of the mother, the fetus or fetal arrhythmia during acquisition.
  - Sudden discontinuities in the color display: Motion of the mother, the fetus or fetal arrhythmia affects the color flow in the same way it affects the gray image.
  - Fetal heart rate far too low or far too high: After acquisition the estimated fetal heart rate is displayed. If the value does not match the estimations based on other diagnostic methods at all, the acquisition failed and has to be repeated.
  - Asynchronous movement in different parts of the image: e.g., the left part of the image is contracting and the right part is expanding at the same time.
  - The color does not match the structure in the display format of grey mode: The color displays above or beneath the actual vessels.
  - Color “moves” through the image in a certain direction: This artifact is caused by a failure in detecting the heart rate due to low acquisition frame rate.
  - Use higher acquisition frame rate for better result.
- It is not allowed to perform the STIC fetal cardio acquisition if there is severe fetal arrhythmia.

## 7.2 3D-Print Format

**⚠CAUTION**

The result is provided for reference only, not for confirming diagnoses.

## 7.3 Smart Volume

**⚠CAUTION**

The Smart Volume result is provided for reference only, not for confirming diagnoses.

## 7.4 Smart ERA

**⚠CAUTION**

Smart ERA result is provided for reference only, not for confirming a diagnosis.

# 8 Elastography

**⚠CAUTION**

It is provided for reference, not for confirming a diagnosis.

## 8.0.1 STVi (Sound Touch Viscoelastography)

**⚠CAUTION**

It is provided for reference, not for confirming a diagnosis.

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# 9 Contrast Imaging

**⚠CAUTION**

- Set MI index by instructions in the contrast agent accompanied manual.
- Read contrast agent accompanied manual carefully before using contrast function.

**Micro-bubble Destruction**

**⚠CAUTION**

Use the contrast imaging according to the residual level of the micro-bubbles. Using contrast imaging continuously may result in human harm.

## 9.1 Contrast Imaging QA

**⚠CAUTION**

Contrast Imaging QA images are provided for reference only, not for confirming a diagnosis.

## 9.2 Super Resolution CEUS

### 9.2.1 Super Resolution CEUS QA

**⚠CAUTION**

It is provided for reference only, not for confirming a diagnosis.

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# 10 Physiological Unit Signal

## ⚠WARNING

- Do not use the physiological traces for diagnosis and monitoring.
- To avoid electric shock, the following checks shall be performed prior to an operation:
  - The ECG electrode cable must not be cracked, frayed or show any signs of damage or strain.
  - The ECG electrode cable must be correctly connected.
  - You must use the ECG leads provided with the ECG module. Failure to do so may result in electric shock.
- The ECG electrode cable must be connected to the system first. Only after the cable is connected to the system, can the patient be connected to the ECG electrodes. Failure to follow these instructions may subject the patient to electric shock.
- Do not place the ECG electrodes directly in contact the patient's heart; otherwise it may lead to stop of the patient's heartbeat.
- Do not apply the ECG electrodes if the voltage exceeds 15 volts. This could produce an electric shock.
- Do not use this system when any digital device such as a high-frequency electrotome or high-frequency therapeutic device is applied already.
- Only ECG can be used with defibrillator and anti-defibrillation ECG cable should be used when defibrilation is required for a patient.
- Conductive parts of electrodes and associated connectors for ECG should not contact other conductive parts including earth/grounding.
- Frequent trampling or squeezing on the cables may result in cable break-down or fracture.
- Display effect of respiratory curve depends on the patient breathing status. While a very slow or smooth breathing may lead to an inapparent respiratory curve, breathing in a large amplitude may cause an incomplete display of the respiratory curve. Display effect is linked to the connected parts of the body. Generally, signals by connecting to limbs are stronger than by connecting to the chest.
- When abnormality is detected in physio trace, please check if ECG leads are properly connected with the system.

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# 11 Stress Echo

**⚠CAUTION**

Stress echo data are provided for reference only, not for confirming diagnoses.

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# 12 Gynecology and Obstetrics Functions

## 12.1 Smart FLC (Smart Follicles Calculation)

**⚠CAUTION**

Smart FLC result is provided for reference only, not for confirming a diagnosis.

## 12.2 EmPA

### Measured Parameters

**⚠CAUTION**

It is provided for reference, not for confirming a diagnosis.

## 12.3 Smart Planes OB1

**⚠WARNING**

This function is not applicable for the patient whose fetal structure of first trimester can hardly be recognized under ultrasound scanning (such as abnormal fetal position), or the entire structure has severely been changed (such as first trimester structure malformation).

## 12.4 Smart OB Vue

**⚠WARNING**

This function is not applicable for the patient whose fetal structure can hardly be recognized under ultrasound scanning (such as fetal position difference), or the entire structure has severely been changed (such as anencephaly).

## 12.5 IOTA-ADNEX (International Ovarian Tumor Analysis)

**⚠CAUTION**

It is provided for reference, not for confirming a diagnosis.

# 13 Display & Cine Review

## 13.1 Cine Review

**⚠CAUTION**

- The cine memory must be cleared at the end of the current patient and the onset of the next new patient by tapping [End].
- Cine files stored in the system's hard drive shall contain patient information, to avoid the selection of an incorrect image file and potential misdiagnosis.

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# 14 Measurement, Comments and Body Mark

## 14.1 Measurement

**⚠WARNING**

- Be sure to measure areas of interest from the most optimal image plane to avoid misdiagnosis from inaccurate measurement values.
- To obtain accurate Doppler flow measurement values, make sure the transmitting beam is not perpendicular to the flow, otherwise false readings and potential misdiagnosis may result.

**⚠CAUTION**

- If an image is unfrozen or the mode is changed during a measurement, the calipers and measurement data will be cleared from the screen, but the measurement data will be stored in the report.
- If the system is turned off or [End] is selected during a measurement, the data not saved will be lost.
- In Dual-B imaging mode, the measurement results of the merged image may be inaccurate. Therefore, the results are provided for reference only, not for confirming a diagnosis.

## 14.2 Comments

**⚠WARNING**

You must ensure that the entered comments are correct. Incorrect comments may lead to misdiagnosis.

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# 15 Patient Data Management

## 15.1 Back up Files using the DVD Drive

**⚠CAUTION**

During the backup process, if a CD/DVD is forcibly taken out or you perform other operations, the backup process will fail or the system may malfunction.

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# 16 Probes and Biopsy

## 16.1 Probes

### 16.1.1 Procedures for Operating

**⚠WARNING**

Disinfect the probe and sterilize the needle-guided bracket before and after an ultrasound-guided biopsy procedure is performed. Failure to do so may cause the probe and the needle-guided bracket becomes a source of infection.

### 16.1.2 Wearing the Probe Sheath

**⚠CAUTION**

- Be sure to cover the probe with a new (unused) probe sheath to prevent infection during examination. If the package of a probe sheath is open or broken, the sterilization of the probe sheath may not be sufficient. DO NOT use such a probe sheath.
- The cover contains natural rubber latex and talc that can cause allergic reactions in some individuals.
- DO NOT use an expired probe sheath. Before using a probe sheath, verify whether the term of validity has expired.

### 16.1.3 Sensor (Fusion Imaging) Support Cleaning and Disinfection

**⚠CAUTION**

- When performing cleaning and disinfection of the sensor support to prevent infection, wear sterile gloves.
- After disinfection, rinse the sensor support thoroughly with sterile water to remove all chemical residues. Chemical residues may be harmful to the human body.
- No cleaning and disinfecting may result in the sensor support becoming a source of infection.

  The efficacy of disinfectants and sterilizing solutions is not guaranteed by MINDRAY. Contact the manufacturers for information on the activity of the products.

**Disinfecting with Sprays or Wipes**

**⚠CAUTION**

Use protective eyewear when disinfecting using sprays.

### 16.1.4 Sensor (Fusion Imaging) Cleaning and Disinfection

**⚠CAUTION**

- When performing cleaning and disinfection of the sensor to prevent infection, wear sterile gloves.
- After disinfection, rinse the sensor thoroughly with sterile water to remove all chemical residues. Chemical residues may be harmful to the human body.
- No cleaning and disinfecting may result in the sensor becoming a source of infection.
- The efficacy of disinfectants and sterilizing solutions is not guaranteed by MINDRAY. Contact the manufacturers for information on the activity of the products.

**Disinfecting with Sprays or Wipes**

**⚠CAUTION**

Use protective eyewear when disinfecting using sprays.

## 16.2 Biopsy Guide

**⚠WARNING**

- The person performing biopsy procedures must understand diagnostic ultrasound thoroughly and have been trained adequately, otherwise, side effects may be caused to the patient.
- In situations listed below, the biopsy needle may fail to penetrate the target. The incorrect biopsy may cause various side effects in the patient.
  - Use a needle-guided bracket other than that provided.
  - Mount the needle-guided bracket incorrectly.
  - Use a biopsy needle that is unsuitable for the type of biopsy being performed.
  - Use a biopsy needle that is unsuitable for the needle guide.
- Before and after a biopsy procedure is performed, confirm that the needle-guided bracket is normal. Manually confirm that the parts of the needle-guided bracket do not slip off or move from their proper positions. If the needle-guided bracket is used when parts are not securely and correctly installed, the patient may be injured. If an abnormality is found on the

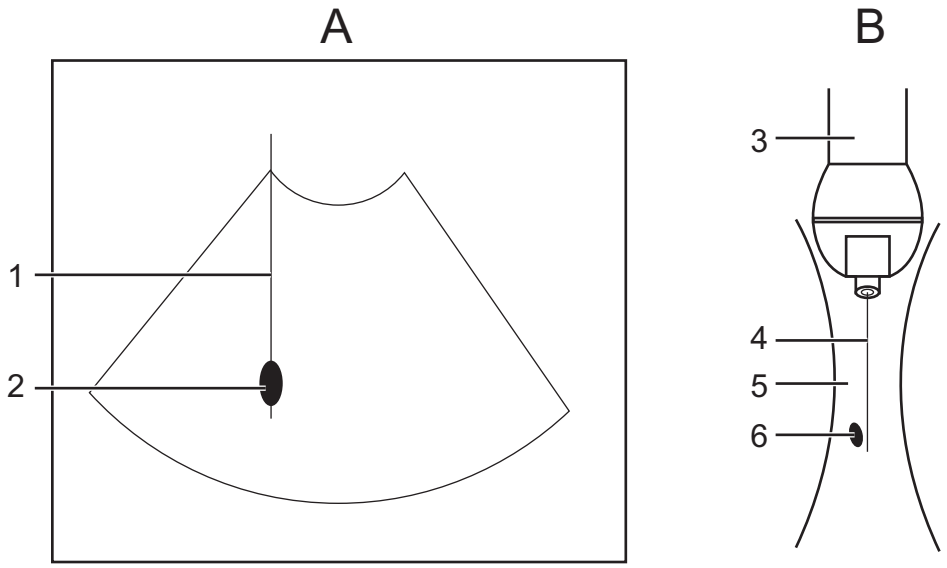
needle-guided bracket, immediately stop using it and contact MINDRAY Customer Service Department or sales representative.

- DO NOT use a needle-guided bracket when scanning is performed. The needle may advance in an incorrect direction and possibly injure the patient.

  Never perform a biopsy during image scanning.
- DO NOT freeze an image while performing biopsy procedure.
- During biopsy procedures, the needle may deviate from the desired course due to the tissue characteristics or the type of needle. In particular, needles of small diameters may deviate to a greater degree.
- Disinfect the probe and sterilize needle-guided bracket before and after each ultrasound-guided biopsy procedure is performed. Fail to do so may cause the probe and the needle-guided bracket become sources of infection.
- The needle mark displayed on the ultrasound image does not indicate the actual position of the biopsy needle. Therefore, it should only be used as a reference. Always monitor the relative positions of the biopsy needle during the procedures.
- Adjust the needle mark before the biopsy procedure is performed.
- When performing biopsy procedures, use only sterile ultrasound gel that is certified to be safe. And manage the ultrasound gel properly to ensure that it does not become a source of infection.
- When performing the operation concerning biopsy, wear sterile gloves.
- Image of the biopsy target and the actual position of the biopsy needle:

  Diagnostic ultrasound systems produce tomographic plane images with information of a certain thickness in the thickness direction of the probe. (That is to say, the information shown in the images consist all the information scanned in the thickness direction of the probe.) So, even though the biopsy needle appears to have penetrated the target object in the image, it may not actually have done so. When the target for biopsy is small, dispersion of the ultrasound beam may lead to image deviate from the actual position. Pay attention to this.

If the target object and the biopsy needle appear in the image as shown in the figures below (For reference only):




| | | | |
|---|---|---|---|
| A | The biopsy needle appears to reach the target object in the image | B | Dispersion of the ultrasound beam |
| 1 | Biopsy | 2 | Target |
| 3 | Probe | 4 | Needle |
| 5 | Ultrasound beam | 6 | Target |

The biopsy needle may not have actually entered the target object even though it appears to have done so in the image. To avoid this, note the points below:

– Do not rely only on the needle tip in the image. Pay careful attention to the fact that when the biopsy needle enters the target object or comes into contact with it, the object should shift slightly.
– Before performing the biopsy, evaluate the size of the object and confirm whether the biopsy can be carried out.

## 16.2.1 Verifying the Biopsy Guide Line

**⚠WARNING**

- Prior to each biopsy procedure, be sure to verify the guide line.
- If the needle is not consistent with the guide line, DO NOT perform the biopsy procedure.

## 16.2.2 Starting the biopsy procedure

**⚠DANGER**

- Ensure that all guide parts are properly fixed prior to performing a biopsy.

- If you changed the probe or needle-guided bracket during the biopsy, verify the guide line again.
- Failure to match the guide zone displayed to the guide may cause the needle to track a path outside the zone.
- It is extremely important that when using the adjustable angle biopsy guides, the angle displayed on the screen matches the angle set on the guide, otherwise the needle will not follow the displayed guide zone and this could result in repeated biopsies or patient injury.

### 16.2.3 Clean and Sterilize the Needle-Guided Bracket

**⚠CAUTION**

- Needle-guided brackets whose name starts with NGB are reusable, and need thorough cleaning and sterilization before and after each biopsy.
- Follow local regulations when selecting and using the disinfectant.
- Repeated sterilization may degrade the safety and performance of the needle-guided bracket. Before use, please check whether the needle-guided bracket has defects such as deformation and rusting. If such defects exist, the bracket has reached the end of its service life. In this case, stop using it and contact the Mindray service department.
- It is recommended to use immersion sterilization for plastic needle-guided brackets and high-pressure steam sterilization for metal needle-guided brackets.
- For detailed operations about the cleaning solvent, sterilant and high-temperature steam sterilizer, see the respective operator's manuals provided by the manufacturer.

**NOTE:**

Disposable components are packaged sterile and are single-use only. Do not use if integrity of packaging is violated or if expiration date has passed. Please use the disposable components compliant with the relevant local regulations.

## 16.3 uHIT Navigation

**⚠WARNING**

- Before the operation, read precautions on "6.5 Fusion Imaging" and "16.2 Biopsy Guide".
- During the biopsy operation, the real-time ultrasound image must be the reference.

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# 17 System Maintenance

**⚠WARNING**

- Only an authorized Mindray service engineer can perform maintenance not specified in this operator's manual.
- For the sake of the system performance and safety, you should perform periodical checks for the system.

## 17.1 Daily Maintenance

### 17.1.1 Cleaning the System

**⚠WARNING**

Before cleaning the system, be sure to turn off the power and disconnect the power cord from the outlet. If you clean the system while the power is "On", it may result in electric shock.

**⚠CAUTION**

Do not spill water or other liquid into the system while you perform the cleaning. Otherwise it may result in malfunction or electric shock.

#### Cleaning dust-proof cover

**NOTE:**

Please clean all dust-proof covers of the system periodically (1 time per month); otherwise, system damage may result. Cleaning times can be increased when the system is used in the open air or somewhere dust is more.

#### Cleaning the monitor and touch screen

**NOTE:**

- Remove the protective film from the touch screen before cleaning.
- If the residual gel remains on the touch screen, the touch screen may be affected. Wipe it up in time.

## Cleaning the control panel and touch bar

**NOTE:**

- The keyboard of the control panel should be cleaned regularly. Otherwise, the buttons may be stuck due to the dirt.
- If the residual gel remains on the touch bar, the touch bar may be affected. Wipe it up in time.

## Clean the gel warmer

**NOTE:**

- Avoid liquid flowing into the gap of the warmer. Do not use organic solvent to wipe the warmer. Turn on the warmer until its surface is dry.
- Do not use strong solvents such as acetone or wear materials such as steel wool to clean the warmer surface.
- The bottom cover of the warmer should be cleaned regularly. When cleaning, take out the bottom cover, and install it into the warmer after its surface is dry.

## Cleaning the system cover, storage tray and probe protective cover

**NOTE:**

For exposing connectors or sockets (such as probe connectors, and connectors on the I/O panel and power panel), use a soft brush to gently remove the dust. Do not use a cloth moistened with water.

## Cleaning the peripherals

**NOTE:**

For exposing connectors or sockets (such as the ultrasound docking station I/O socket), use a soft brush to gently remove the dust. Do not use a cloth moistened with water.

# A Barcode Reader

## ⚠WARNING

- Class 2 laser adopts low power, visible LED. DO NOT stare into beam because of unknown hazards of transient radiation provided by class 2 laser.
- DO NOT stare into beam emitted by SYMBOL DS4308 for more than 10 s.

## ⚠CAUTION

Ensure the information acquired by barcode reader is consistent with the actual information.

**NOTE:**

The reader does not support decoding of Multi-language.

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# B Wireless LAN

## ⚠WARNING

- Use the wireless LAN function prudently in OR/ICU/CCU as it may interfere with other devices.
- When the wireless LAN function is turned on, the ultrasound system may suffer interference from other equipment, even if that other equipment complies with CISPR EMISSION requirements.
- Keep at least 20 cm away from the ultrasound system when the wireless LAN function is in use.

**NOTE:**

- DO NOT connect devices other than specified into the LAN.
- Medical devices within the same LAN may interfere with each other, the operator should be cautious. (Do not connect devices that may cause strong interference. For example, life-supporting devices should not be connected in the same LAN.)
- Other non-medical devices in the same frequency band may cause interference, please be cautious.
- Wireless network designing, deploying, debugging, and maintenance should be executed by Mindray service personnel or authorized technicians.
- Always set the wireless network according to local wireless regulations.
- Keep network authentication information, for example password, safe, protecting the network from being accessed by unauthorized users.
- If the wireless signal is poor, the ultrasound machine may fail to send data to the server.
- RF interference may result in wireless network disconnection.
- Disconnecting from the network may result in send data to server failure. Solve the network problem as soon as possible.
- Ensure that the ultrasound device IP address setting is correct. Changing the network settings may result in network disconnection. Contact your service personnel if you have any problems on setting the IP address.
- To make sure that the ultrasound system works well, the ultrasound system can coexist with Wi-Fi as the interfering network operating at maximum throughput and maximum transmit power when a separation distance of 1m is maintained.
- Wi-Fi function is not affected when the system is imposed with radiation interference complied with IEC 60601-1-2: 2020 standard.

# B.1 IP Configure

**NOTE:**

- When the system background is processing network task (DICOM sending for example), please do not enter network setting to change the IP, otherwise the background task may fail. You can check if there are tasks undergoing in the task manager.
- If the IP address displays as 0.0.0.0, this means that the network is abnormal. The reason for the failure may be disconnection or the system cannot obtain the IP address.

# C Electrical Safety Inspection

**NOTE:**

Make sure the safety analyzer is authorized and complies with the requirements of IEC 61010-1. Follow the analyzer manufacturer's instructions.

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# D EMC Guidance and Manufacturer's Declaration

## ⚠WARNING

- The use of unapproved accessories may diminish system performance.
- Use of components, accessories, probes, and cables other than those specified may result in increased emission or decreased immunity of system.
- The system needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided below.
- Use of the system adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, the system and the other equipment should be observed to verify that they are operating normally.
- Use of accessories, transducers and cables other than those specified or provided by the manufacturer of the system could result in increased electromagnetic emissions or decreased electromagnetic immunity of the system and result in improper operation.
- Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the system, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.
- Operation of system, in the case that the patient physiological signal is lower than the minimum amplitude or value specified in the product specifications, results may not be obtained (results can be obtained when the HR is in the range of 30-250 bmp or when the QRS wave amplitude is between 0.5-5 mV.)
- Preventing conducted RF immunity. Due to technological limitations, the conducted RF immunity level are limited to 3Vrms level, conducted RF interference above 3Vrms may cause wrong diagnosis and measurements. We suggest that you position system further from sources of conducted RF noise.

**NOTE:**

Keep a distance of at least 20cm away from the monitor when Wi-Fi function is in use.

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# E Software and Hardware Specification

## E.1 Operating Environment

### Hardware Configuration

CPU: X86, 3.2GHz

Hard disk: 1T

Monitor: 27 inches

### Software Environment

Linux, 64bit

### Network Condition

- Cable network: 10M/100M/1000M adaption
- Wireless network:
  - Protocol compatible with IEEE 802.11 a/b/g/n/ac/ax standard
  - Working frequency: 2.4G/5G
  - Data security/Encryption mode: WPA, WPA2

**NOTE:**

The operating environment listed above is the minimum requirements for the system.

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