

# Chapter 1 Safety Information

## 1.1 Safety Instructions

**Danger:** Indicates potential danger or unsafe operation. If not avoided, it may cause death or major property loss.

**Warning:** Indicates potential danger or unsafe operation. If not avoided, it may cause serious personal injury or property damage.

**Caution:** Indicates potential danger or unsafe operation. If not avoided, it may cause minor personal injury or product damage.

**Note:** Emphasizes important matters that need to be read or the operator pays attention to in order to operate this product correctly.

### 1.1.1 Danger

- It is strictly prohibited to use this equipment in an environment where flammable gas (such as oxygen, hydrogen, etc.) or flammable liquid (such as ethanol, etc.) exists, or else it may cause an explosion.
- It is strictly forbidden to let the live parts of the equipment (such as signal input and output ports) come into contact with the patient, as there may be a risk of electric shock.
- It is strictly forbidden to block the lightening hole at head section, or else it may cause fire, equipment damage and scald.
- Check whether the product's sterile seal is damaged before use and if so, do not use it.
- Single use only. The product is not designed for reuse and cannot withstand reprocessing or sterilization.
- Once the product is used, please handle the product and its package according to the instructions of hospital and local regulations.
- Do not put the endoscope into patient's body if the endoscope has unclear view, or else it may cause injuries such as perforation, bleeding or mucosal damage.
- Do not start treatment when the product is out of view or when the distal end sticks to the mucosa, or else it may cause injuries such as perforation, bleeding or mucosal damage.
- Do not insert or extract the intersection section suddenly or by force, or else it may cause patient injury, bleeding or perforation.
- Do not look straightly at the light emitted from head section, or else it may cause eye injury.
- Do not touch the contact surface of the connector when disconnected it from the monitor/video processor socket, or else it may cause skin burn as the head section will maintain high temperature for a certain period.
- When monitor has no endoscope image, shut down the image processing system immediately as the image sensor can be damaged, or else it may cause heating of endoscope end, scald of patient or operator if power supply is continued for long period.
- Do not try to disassemble, transform or repair the product as we do not provide spare parts for self service repair.
- Please prepare the standby products to avoid inspection/treatment interruption due to dysfunction or failure.

- Do not insert humid connection cable into the image processor of endoscope, or else it may affect the imaging function or damage the system.

### **1.1.2 Warning**

- The product can not be used anymore when packing is damaged.
- The image processor of electronic endoscope used along with the product should conform to Type BF safety requirements, or else it may cause electric shock.
- Please prepare the standby image processor or electronic endoscope and standby electronic endoscope prior to operation.
- If there is a malfunction that affects the operation during the use of the equipment, stop the operation immediately, turn off the power switch, unplug the power cord, and remove the endoscope slowly from the patient.
- It is necessary to ensure normal power supply during the operation.
- The equipment should be placed in a safe place to prevent risks such as falling off, knocking off, and accidental touching.
- Before use, be sure to check whether the part of the bronchoscope insertion part has rough surfaces, sharp edges or protrusions that may cause safety hazards. If so, the bronchoscope mustn't be used.

### **1.1.3 Caution**













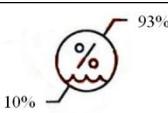







- This equipment shouldn't be used in an environment with nuclear magnetic field, high temperature, vibration, high humidity, or too much dust.
- Any devices connected to this equipment should be certified by relevant laws and regulations. The person responsible for connecting additional equipment to the interface of this equipment is responsible for whether the system complies with IEC60601-1, IEC60601-1-2, IEC60601-1-1, IEC60601-2-18 and equivalent international standards.
- Please use the compatible equipment recommended by the company. Using incompatible products may cause injury to the patient, damage to the equipment, or performance decline.
- This equipment can only be operated by trained medical personnel with professional qualifications and relevant experience.
- This equipment is only used for providing clinical image, and the doctor should diagnose and treat the patients based on their clinical symptoms.
- Do not bend, pull, or squeeze the cables excessively to avoid equipment failure or damage.
- Do not over-squeeze the connectors. All connectors are fool-proof. Pay attention to the direction of the plug when plug or unplug.
- When disposing of packaging materials or scrapping the equipment. You should follow local regulation or the hospital's waste dispose policy to avoid danger or pollution to the environment.
- If you have any questions, please contact us or the supplier.
- Inform the manufacturer and the competent authority of the Member State in which the user and/or patient is established in case that any serious incident has occurred in relation to the device.



### 1.1.4 Note

- The device and its packaging should be placed out of the reach of children.
- Please maintain the equipment in accordance with the hospital's rules and regulations or instructions, including cleaning, disinfection, calibration, etc.
- When the equipment is not in use, disconnect the power supply.
- If the equipment will not be used for a long time, please seal it in the original packaging.
- The use site should be well ventilated.
- Do not turn off the system when the endoscope is in the human body.

## 1.2 Symbols

Table 1 Symbol Description

Symbol	Title of symbol	Symbol	Title of symbol
	Do not re-use		WEEE information for the disposal or recycling of waste WEEE. Check with your local Authority or retailer for recycling advice.
	Sterilized by using ethylene oxide		Refer to instruction manual
	This is a Type BF device		Manufacturer Logo
	Do not use the product if its sterilized seal or package is damaged		CE mark
	Caution, refer to the attached documents		Medical device
	Use-by date, followed with YYYY-MM-DD		Unique device identifier
	Humidity limit		Authorized representative in the European Community
	Temperature limit		Manufacturer
	Keep dry		Keep away from sunlight
	Atmospheric pressure limitation		Production date

<b>LOT</b>	Lot code and number		Country of manufacture, CN stands for China
<b>SN</b>	Serial number		Model Number

### 1.3 General Description

For the sake of simplicity, the following descriptions are specified in this Manual:

- The image processing unit is referred to as the main unit.
- Unless otherwise specified, the cables or parts described in this Manual are included in the package.
- All standards appearing in this Manual without a version number are subject to the version currently in effect.

## Chapter 2 Equipment Introduction

### 2.1 Intended Use

As a disposable medical device, the product is used along with the company's image processor, to conduct inspection and treatment of trachea and bronchus by providing images through video monitor. The product can also provide a channel to remove foreign body.

### 2.2 User Qualifications

Medical staff that have received relevant technical training and have thoroughly mastered the operation technology of endoscopes.

### 2.3 Intended Patient Population

This device is suitable for adults.

- Age: 18 years or above;
- Gender: no restrictions;
- Weight: no restrictions for weight of the patients;
- Height: no restrictions;
- Health: the patients without contradictions in section 2.5;
- Nationality: multiple.

- Patient state: Patient is not the Operator.