# HS-50F, HS-50V, HS-50H, HS-50S, HS-30S

# Insufflator

# White Paper

CE 0123



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# Intellectual Property Statement

Intellectual property rights for this Operator's Manual and its corresponding product belong to Nanjing Mindray Bio-Medical Electronics Co., Ltd. (hereinafter "Nanjing Mindray").

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# Statement

Nanjing Mindray has the right of final interpretation for this Instructor's Manual. Pictures in this manual are only for reference; if any discrepancy is found between the pictures and the actual product, the latter shall govern.

Only when all the following requirements are met is Mindray responsible for the security, reliability and performance of the product:

- The assembly, expansion, readjustment, improvement and repair are all conducted by professionalsrecognized by Mindray;
- All parts that involve replacement, accessories that are for ancillary use, and consumables are originalfrom or recognized by Mindray;
- Related electrical equipment conforms to national standards and requirements of this Instructor'sManual;
- Operations for the product are performed according to this Instructor's Manual.

# Warranty and Maintenance Service

The warranty period of the product purchased is subject to the sales contract.

Consumables: refer to disposable consumable materials that need replacement after each use or quick-wear parts that are replaced regularly, which are not within range of the warranty.

The warranty period starts on the "installation date" filled in the attached Device Warranty Card which is the only credential for calculating the period. In order to safeguard your rights and interests, please fill out the warranty card after device installation completes, and gives the second copy of the card (the copy "kept by Mindray") to the installation personnel or send it back to Mindray customer service department.

Please take notice that the following conditions are not covered by the warranty:

- The customer has not filled in and returned Device Warranty Card within 30 days of installation and acceptance.
- The device serial number provided by the customer is incorrect (which our company uses to confirm whether the warranty stands).

Under warranty, the product is entitled to free after-sales service; but note that even within warranty period, Mindray shall implement paid maintenance service and you shall pay maintenance fee and accessories fee due to product maintenance caused by the following reasons:

- Man-made damage;
- Improper use;
- Power grid voltage exceeds product-specified range;
- Inevitable natural disasters;
- Replace or use parts, accessories and consumables not recognized by Mindray, or maintenance are conducted by personnel not authorized by Mindray;
- Other faults not caused by the product itself.

Upon expiration of the warranty, Mindray may continue providing paid maintenance service.

If you fail to pay or delay the payment of the maintenance service fees, Mindray may suspend the maintenance service until you pay off.

# Company Contact


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## NOTE

- **Targeted readers of this Operator's Manual are the following professionals: people who conduct daily system operations, people who perform system maintenance and troubleshooting, and people who study system operations.**

## WARNING

- **This system is only used for operation by professionals, doctors and lab technicians trained by Mindray or Mindray's agents.**

# Important Information

1. After purchase of this product, the customer shall take full responsibility for the maintenance and management of the product.
2. Even within quality assurance period, the assurance does not include the following:
   - Damages or losses caused by incorrect or abusive use.
   - Damages or losses caused by force majeure such as fire, earthquake, flood, or lightning.
   - Damages or losses due to noncompliance with usage conditions stipulated by the system, such as insufficient power supply, incorrect installation, or non-compliant environment conditions.
   - Damages or losses due to not using the system in region where you originally buy it.
   - Damages or losses due to not buying the system from Mindray or dealers or agents authorized by Mindray.
3. This system can only be operated by qualified medical staff with professional qualification certificate.
4. It's forbidden to arbitrarily modify softwares and hardwares of this product.
5. Under any circumstances where issues, damages or losses occur due to reinstallation, change or repair conducted by non Mindray-designated personnel, Mindray assumes no liability.
6. For the loss of data stored within the system due to operator's misoperation or abnormal situations, Mindray does not bear any responsibilities.
7. This Operator's Manual contain warnings about predictable potential dangers. Stay strongly vigilant anytime against dangers that are not illustrated. For damages or losses caused by negligence or ignorance of the preventive measures specified in this Operator's Manual, Mindray does not bear any responsibilities.
8. Once the administrator of the system is changed, this Operator's Manual must be turned over.

# About This Operator's Manual

Before using the system, users must carefully read this Operator's Manual and thoroughly understand the operating steps, functions, performance, and maintenance steps of the system in detail.

## Interface in the Operator's Manual

Because of different system software versions and configurations of optional accessories, the operation interface given in this Operator's Manual might differ from the interface actually displayed on the system. If so, the interface displayed on the purchased machine shall govern.

### NOTE

- **Not all models in all sales regions have the functions described in the manual series of this system.**

## Appointed Descriptive Approach

None.

## Notification of Adverse Events

As a health care provider, you may report the occurrence of certain events to NANJING MINDRAY BIO-MEDICAL ELECTRONICS CO., LTD., and possibly to the competent authority of the Member state in which the user and / or patient is established.

These events, include device-related death and serious injury or illness. In addition, as part of our Quality Assurance Program, NANJING MINDRAY BIO-MEDICAL ELECTRONICS CO., LTD. requests to be notified of device failures or malfunctions. This information is required to ensure that NANJING MINDRAY BIO-MEDICAL ELECTRONICS CO., LTD. provides only the highest quality products.

# Contents

# 1 Safety

## 1.1 Safety Information

The safety statements presented in this chapter refer to basic safety information that the operator must pay attention to and abide by when using the insufflator. There are additional safety statements in other chapters or sections, which may be the same as or similar to the following, or specific to particular operations.

### DANGER

- **Indicates an imminent hazard that, if not avoided, could result in death, serious injury or damage to product/property.**

### WARNING

- **Indicates a potential hazard or unsafe practice that, if not avoided, could result in death, serious injury or damage to product/property.**

### CAUTION

- **Indicates a potential hazard or unsafe practice that, if not avoided, could result in minor personal injury or product/property damage.**

### NOTE

- **Provides application tips or other useful information to ensure that you get the most from your product.**

### 1.1.1 Dangers

### DANGER

- **Never use the system where flammable gases or flammable liquids are present, otherwise an explosion may occur.**
- **Only medical-level $CO_2$ gas can be used for this machine. Never use other gases. Using gases other than $CO_2$ may cause fire, poisoning, complications, etc. Using**

**non-medical level, polluted $CO_2$ may cause failure in gas injection pressure adjustment phase, which leads to serious injury for patients. Please use high-pressure tube, reducing valve, or central gas supply joint to connect $CO_2$ gas cylinder or medical gas pipeline, as described in this Operator's Manual.**

- **If endoscopy is conducted improperly, this product cannot be used to normally perform intraperitoneal gas injection.**
- **During inspection, do not unplug the power supply or press the power switch button.**
- **It's forbidden to use this product for intrauterine gas injection, that is, this product cannot be used to dilate uterus.**
- **Do not connect the insufflator to the patient's abdominal cavity when starting up the insufflator. Connect it to the patient only after self-inspection.**

### 1.1.2 Warnings

## WARNING

- **The power plug of the system must be connected to a grounded outlet (3 pin) which conforms to the requirements on the rated power identification plate of the device. Using an adapter or a multi-functional socket may influence grounding and make the current leak beyond the required safe current level.**
- **Mindray suggests connecting jacks on the wall, and not using extension-cord power strip; do not use socket other than the designated ones.**
- **Do not use parts and accessories and peripherals other than the designated ones.**
- **During system operation, ensure that the ground terminal of the system is earthed reliably and the grounding cable is connected when the system is off, otherwise an electric shock will be caused.**
- **Please follow correct electrical connection methods of connecting the power supply to the ground, otherwise a shock hazard will occur. Do not connect the ground wire to any gas pipes or water pipes, for it will cause poor earthing or an explosion hazard will occur.**
- **Before cleaning the machine, be sure to unplug the power cable, or electrical shock and equipment damage may occur.**
- **Do not let any liquid splash on or let flow into the machine, or a shock hazard or device damage will occur. If a liquid is accidentally splashed on the machine, turn off the power at once and contact your service representative.**
- **Do not let live parts (such as various signal input and output ports, etc.) of the system or any other devices contact with a patient. If the system or other equipment fails, patients would be at risk of an electric shock.**
- **Do not bump or shake the equipment.**

- **Do not open the case or panel, or it will cause short circuit or electric shock will occur.**
- **Precautions during transportation: Please hold tightly both sides of the system to move it. If you hold other parts, system damage due to abnormal stresses will occur.**
- **All analog and digital devices connecting with the system must be certified in accordance with the designated IEC standards (such as IEC 60950 Information Technology Equipment Standards and IEC 60601-1 Medical Device Standards). All the configurations shall be in accordance with the valid version of IEC 60601-1 system standards. The person in charge of connecting additional equipment to signal input/output ports shall configure the medical system and take responsibility for the system's compliance with IEC 60601-1 standards. For any questions, please contact the supplier.**
- **Do not turn off the system while the lens body remains in patient's body.**
- **The operators of the equipment must not simultaneously contact patients and live parts of the system or other equipment (such as various signal input and output ports) connected to the system, otherwise a shock hazard to patients may occur.**
- **Do not touch the joint between $CO_2$ gas cylinder and reducing valve or between reducing valve and low pressure tube with bare hands, otherwise low-temperature burn may result.**
- **When product failure occurs during use, stop operation immediately, unplug the power cord, and in the meantime contact the manufacturer to assign the designated personnel for repair.**
- **Do not use the insufflator in places where oxygen concentration is high, there is oxide (such as nitrous oxide ($N_2O$)) or flammable gas in the atmospheric environment, or it is near flammable liquid. Otherwise, it may cause explosion or fire since the insufflator has no anti-explosion capability.**
- **In actual use, locate the patient end of the insufflator to make the associated pipeline higher than gas injection position, so that liquid in the patient end won't flow into the pipeline due to gravity and then flow back to the insufflator.**
- **Please keep the gas cylinder upward at an upright position. Fasten it on the wall or other stable structures to avoid tilt. If the gas cylinder is placed horizontally or obliquely, liquefied $CO_2$ will flow into the inflation pipeline within the insufflator, making it unable to inject gas normally.**
- **In a laparoscopic surgery, when the insufflator is used together with a laser device, argon coagulator, or other air feeders, the insufflator and the simultaneously used device both become gas supply source. Accordingly, the time it takes to reach the required gas pressure is less than when only the insufflator is used. In this case, note that the intra-abdominal gas pressure shall not be too high. Since other air feeders might not have the intra-abdominal gas pressure detection capability that the insufflator has, aeroembolism cannot be completely avoided, because it's related to the condition of the patient and the**

**infection position, about which the physician shall make a professional judgment. If the insufflator gives prompt that intra-abdominal overpressure has occurred, the bibcock or valve of the trocar shall be opened immediately. Then reduce the gas input from other air feeders. If the device continues to be used after the prompt sound arises, it may lead to aeroembolism due to intra-abdominal overpressure.**

- **Whether the smoke exhaust function works to release excess gas depends on the capability of the connected suction device/equipment. Please note that the device cannot complete the function of gas suction alone; be sure to connect the device to suction device/equipment using suction tube.**
- **When an overpressure prompt is displayed, the safety valve inside the insufflator may be opened, and intra-abdominal gas and/or liquid might flow back and pollute the insufflator. In order to avoid this, it is strongly suggested to use bacteria filters that comply with laws and regulations in the insufflator and the gas supply pipe.**
- **If the liquid flows into the insufflator, there will be a liquid ingress prompt. It will lead to startup failure. Then the insufflator needs to be returned for repair.**
- **Please operate the insufflator in accordance with the Operator's Manual. Misuse will not only impair the device performance, making it unable to bring its best efficiency into full play, but also cause device damage and/or complications. Before each use, make sure to inspect the device according to instructions in this Operator's Manual.**
- **The device shall be used under environment provided with laparotomy equipment. And a hospitalization emergency plan shall be prepared so that it can be adopted in case of any problem that endoscopic surgery cannot solve.**
- **Alternate $CO_2$ gas cylinder shall be prepared so that it can be replaced quickly when $CO_2$ runs out during use.**
- **Another standby insufflator shall be prepared so that the surgery can be completed when the device malfunctions.**
- **During use, especially when choosing high gas flow, a lot of $CO_2$ gas is needed. If $CO_2$ concentration in the operating room increases, personnel in the room might be affected. Therefore, be sure to keep indoor ventilation.**
- **This product may only be used in operating environments that are specified by the product. Using under other conditions not only affects normal functions, but also causes device damage.**
- **When using this device, watch out for the patient's parameters, such as intracorporal $CO_2$, electrocardiogram, and body temperature, to avoid complications.**
- **Intra-abdominal gas pressure shall avoid exceeding 20mmHg for a long time. Otherwise, it might cause weakened respiration and diaphragm shifting; reduced venous blood backflow; reduced cardiac output; acidosis; etc.**

- **Too high flow speed and/or gas pressure might cause excessive suction of $CO_2$ and/or aeroembolism. The abdominal cavity can be fully dilated with the maximum gas pressure of 20mmHg. There is almost no need to use a gas pressure higher than 20mmHg, and blood vessel intravasation rarely occurs under such gas pressure level. It's very rare for situations in which a gas pressure above 20mmHg is needed, and it will increase the amount and speed of blood vessel intravasation. Sufficient respiration helps avoid $CO_2$ related issues.**
- **Special corporeity reactions. Patients with sickle-cell disease or pulmonary valve insufficiency has a higher risk of developing metabolism imbalance due to excessive absorption of $CO_2$.**
- **Other possible complications include gas embolism, low body temperature, subcutaneous emphysema, shoulder pain, hypercarbia, pneumothorax/ pneumomediastinum, and diaphragm carbonic acid stimulation. Injected $CO_2$ gas directly entering the vascular system (such as through open blood vessel in the abdominal cavity, or improper penetration of veress needle) might cause gas embolism.**
- **If two insufflators are simultaneously used on the same part of a single patient, ensure that these two insufflators are set to the same gas pressure.**
- **Only an insufflator with a flow speed of at least 4-10 litres/minute may be used in the surgery. Insufflators that have a maximum flow speed lower than this parameter may only be used for diagnosis.**
- **In endoscopic surgeries that use gas injection, venous air embolism is very rare, but potential serious complications might occur. The signal is cardiovascular collapse (sudden serious hypotension) and precordium noise. If aeroembolism is observed during the surgery, stop gas injection and keep the patient on left lateral decubitus or at lithotomy position.**
- **Using accessories and cables not listed in this manual may lead to noncompliance with EMC.**
- **This device shall not be near or heaped on other devices during use to avoid affecting EMC.**
- **If the insufflator tube is not connected to the patient, do not supply gas for a long time. Otherwise the reducing valve will freeze, causing functions including gas injection to stop working.**
- **Using the system simultaneously with electronic equipment like a high frequency electrotome, a high frequency therapy apparatus, or a defibrillator might cause electric shock to the patient. Do not use under strong electromagnetic conditions.**

### 1.1.3 Cautions

## CAUTION

- **Precautions related to clinical examination technology:**
  - **This system can only be operated by medical staff with qualified professional training.**
  - **Any surgery in pregnancy is associated with maternal and fetal risks. Non-urgent surgery should be postponed until after pregnancy. The most common conditions requiring surgical intervention during pregnancy are acute appendicitis, acute gall bladder disease and symptomatic benign adnexal tumors. Other surgical interventions which need insufflators are not recommended during pregnancy.**
  - **This Manual does not introduce clinical examination technology. Choose the correct examination technology based on knowledge from professional training and clinical experience.**
- **Precautions when moving the system:**
  - **During installation, ensure the system is horizontally installed and placed in a fixed position. Otherwise, the system may move and cause injury.**
  - **Do not sit on the system, for the system may move and fall down due to a loss of balance.**
  - **Before moving the system, ensure the devices around have been firmly affixed. Otherwise these devices may tilt and cause injury.**
- **If the circuit protector is in working condition, it indicates that the system or peripheral equipment has failed; please contact your service representative and do not handle the problem by yourself.**
- **The system and accessories are unsterilized when leaving the factory. After the disinfection and sterilization of accessories, all chemical reagent must be completely removed. Residual chemical reagent may cause product damage and patient injury.**
- **Do not directly plug or unplug the system or its accessories (such as the foot switch and the heating insufflator tube, etc.) when the power is on, otherwise it will cause system damage or electric shock.**
- **During operation, inappropriate shut down may cause data corruption or system failure.**
- **If the grid power is unstable and may affect normal operation of the system, use an uninterruptible power supply.**
- **Do not exert too many vibrations on the machine (for example, when moving the equipment), or damage to components will occur.**
- **Do not use a USB memory device (e.g., a USB flash drive) which contains unsafe data. This may result in system damage.**
- **Always keep the machine dry and do not move it from a cold place to a warmer place quickly, or condensation of water droplets which may result in a short circuit will occur.**

### 1.1.4 Notes

## NOTE

- **Do not use the system in a strong electrical field or magnetic field (such as a transformer), or a negative impact on the system will occur.**
- **Do not use the system near high frequency devices (such as mobile telephones), or a negative impact on system performance will occur and cause equipment failure.**
- **When using or placing the system, ensure that the system is placed horizontally to avoid a loss of balance.**
- **To avoid damage to the system, do not use the system under the following circumstances:**
  - **Under direct sunlight;**
  - **Where temperatures vary greatly;**
  - **In a dusty place;**
  - **Where this system may easy be vibrated;**
  - **Near a heat source;**
  - **In high humidity.**
- **Do not restart immediately after the power is turned off, but after a period of time, or the system may not be started normally.**
- **Avoid applying force on the control panel, or damage to the machine will occur.**
- **Do not use pointed and hard objects to press the touch screen, otherwise the screen will be damaged.**
- **The veress needle and the trocar shall be inspected in accordance with the manual before using.**
- **Using the system in small spaces may cause a rise of the indoor temperature. Therefore, good indoor ventilation is necessary.**
- **If it is necessary to abandon the system or any accessory, please contact your service representative. Do not dispose of the system without consulting the Company. The Company will not be responsible for any damage caused by not following the instructions.**
- **When used over an extended period of time, the system's electrical and mechanical safety performance will decline (such as the occurrence of current leakage, or deformation and wear of mechanical parts), the gas supply ability and accuracy will deteriorate as well. In daily maintenance and within service life period, the equipment must be inspected regularly to ensure normal performance. It is suggested that a maintenance and regular inspection plan be made, or a maintenance and repair agreement be signed with Mindray to**

**inspect the machine's safety performance at regular intervals to prevent the occurrence of any accidents.**

- **Installation, maintenance or upgrading of the equipment can only be conducted by service personnel trained and authorized by Mindray.**
- **A system log of the equipment records information such as error messages. Log export should be performed by professional service personnel.**
- **Do not turn off the system's power supply during startup and shutdown, or a failure of these processes and file information loss will occur.**
- **Please verify that the system date and time settings are consistent with the currently inspected date and time.**
- **Use a pluggable power cord as the point to separate the device from the power grid.**

# 2 System Overview

## 2.1 Intended Use

### 2.1.1 Intended Purpose

The Insufflator for laparoscopy has been designed for insufflation of abdominal cavity to facilitate laparoscopic observation, diagnosis and treatment.

**NOTE**

- **According to the conclusion of clinical evaluation and residual risk evaluation, for the intended patients, there is no known side effects that can occur during or after the use of the medical device. And there is no need for the operator to make extra preparations. Besides, the residual risks are disclosed in the corresponding chapter of this IFU as precautions or warnings.**

### 2.1.2 Indication for Use

The insufflator for laparoscopy is intended for patients who need to establish pneumoperitoneum during the operation.

### 2.1.3 Intended Users

This product is intended to be used by licensed clinicians trained in endoscopic techniques and thoroughly skilled in endoscopic procedures.

### 2.1.4 Intended Patient Population

The Insufflator for laparoscopy can be used in adult and pediatric populations.

**NOTE**

- **For pregnant woman, it is recommended that the surgery be performed in her second trimester.**

### 2.1.5 Intended Medical Conditions

The Insufflator for laparoscopy is used within a health care facility by licensed clinicians.

### 2.1.6 Contra-indications

The device is not suitable for hysteroscopic insufflations, i.e., it may not be used to distend the uterus.

### 2.1.7 Side Effects

None.

## 2.2 Applied Part

The applied parts of the product are insufflator tubes.

# 3 Installation and Use

## 3.1 Installation

### 3.1.1 Placement

**CAUTION**

- **Provide enough space behind and at the bottom of the machine, or machine failure due to temperature rise inside the machine may occur.**

### 3.1.2 Connecting $CO_2$ Gas Cylinder

**DANGER**

- **Using non-medical $CO_2$ gas may cause fire, poisoning, complications, etc. Besides, the oil stains, impurities and other substances may permeate into the insufflator, preventing the proper injection of $CO_2$ gas.**

**WARNING**

- **Be sure to keep the gas cylinder upward at an upright position. Fasten it on the wall or other places of stable structure to avoid tilt. Only when the insufflator and the $CO_2$ gas cylinder are connected correctly shall the gas supply valve be opened. If the valve is opened before correct connection, the liquid $CO_2$ may flow into the insufflator, causing related pipelines frozen and thus affecting the normal injection of $CO_2$ gas; or the $CO_2$ gas may leak into the air.**
- **Do not use grease and oils to lubricate the joint parts of the device/hoses. Otherwise the grease, oils or other impurities may permeate into the insufflator, affecting normal operation and the normal injection of $CO_2$ gas.**
- **Mindray bears no responsibility for injury or damages caused by improper connection of the gas cylinder.**
- **If obvious gas leak inside the insufflator is found, stop using immediately and contact Mindray.**

- **The maximum input gas pressure supported by this device shall not exceed 16MPa, otherwise the device might not work normally**

## CAUTION

- **When connecting American-standard, British-standard, or German-standard gas cylinder, check whether the seal rings at joints of the reducing valve or high pressure tube are in good condition. In case of any loss or deformation, replace the seal rings.**
- **If $CO_2$ gas cylinder and the regulator are used, $CO_2$ supply pressure greater than 0.5 MPa is recommended. For more information, refer to the instructions for use delivered with the cylinder regulator.**

#### 3.1.2.1 Using Reducing Valve and Its Connecting Tube to Connect CO2 Gas Cylinder

## WARNING

- **The pressure to use for the reducing valve shall be suitable. The suggested pressure is 0.5~1MPa to meet the inflation requirements.**

### 3.1.3 Connecting the Central Gas Supply Joint

## DANGER

- **Using non-medical $CO_2$ gas may cause fire, poisoning, complications, etc. Besides, the oil stains, impurities and other substances may permeate into the insufflator, preventing the proper injection of $CO_2$ gas.**

## WARNING

- **First connect the gas supply hose to the insufflator, and then connect it to the central gas supply joint, otherwise a serious gas leak might occur.**
- **Do not use grease and oils to lubricate the joint parts of the device/hoses. Otherwise the grease, oils or other impurities may permeate into the insufflator, affecting normal operation and the normal injection of $CO_2$ gas.**
- **Confirm that the gas pressure for the medical gas pipeline shall be higher than 343.2kPa (3.5 kgf/cm2) and lower than the upper limit stipulated in ISO7396 (1400kPa), to ensure the normal injection of $CO_2$ gas.**

- **If obvious gas leak inside the insufflator is found, stop using immediately and contact Mindray.**

### 3.1.4 Connecting the Foot Switch (only for HS-50F/HS-50V models)

**WARNING**

- **Do not connect any other devices to the foot switch interface.**
- **The joint part of the foot switch is not waterproof. Please keep it away from liquids.**

### 3.1.5 Connection with the Power Grid

**WARNING**

- **Connect the equipotential wire before inserting the power supply plug into socket. Similarly, to avoid electrical shock, pull the system plug away from the socket before unplugging the equipotential wire.**
- **When other equipment is connected to the system, equipotential cables must be used to connect to each equipotential terminal, or an electrical shock will occur.**
- **When connecting or disconnecting protective grounding wires, turn off the equipment power supply. Or an electrical shock will occur.**
- **If the circuit breaker and fuse of for a socket are the same as that used in this system and are used to control the current of equipment such as a life support system, do not connect the system to such socket. Because once the system operates abnormally, overcurrent is generated, or there is transient current when starting up, the circuit breaker and the fuse of the power supply system will be in protective mode.**

**NOTE**

- **Connected cables must maintain proper looseness to prevent the plug from disconnecting with the socket after the system is moved slightly. If the plug of the host power supply wire is disconnected accidentally, test data will be lost.**

### 3.1.6 Connecting the Insufflator Tube

**WARNING**

- **The pipe fittings and joints are not sterile. Please clean and sterilize the pipe fitting according to local laws and regulations and infection control requirements.**
- **In order to prevent cross infection caused by the backflow of body fluid (such as blood) when the exhaust valve is opened, a bacteria filter must be used between the insufflator main machine and the insufflator tube. Please use eligible bacteria filter in accordance with the laws and regulations. Even if the exhaust valve is closed, Mindray also strongly suggests using the bacteria filter.**
- **Take the filter out of the package, and check if there is any damage. If any damage or anomaly is found, do not use the filter.**
- **Repeated uses of unsterilized bacteria filter might cause cross infection, so a repetitive bacteria filter shall be sterilized before each use. If a disposable bacteria filter is used, be sure to insert a new one before each use.**
- **Do not try to adjust the pipe fitting by cutting, adhering, or connecting multiple pipe fittings.**
- **If the pipe fitting is damaged, please replace a new one.**
- **The residual water drops on/inside the pipe fitting will damage internal sensors (such as causing short circuit) or lead to electric shock. Please dry the pipe fitting thoroughly before use.**
- **Do not bend the insufflator tube.**
- **Please use insufflator tubes that conform to biological compatibility.**

**NOTE**

- **For one insufflator, between the insufflator tube and the heating insufflator tube, only one of them can be chosen for connection.**
- **Be sure to use the bacteria filter inside the package, or purchase disposable filters that Mindray recommends: model 800-51800 of VADI brand (with a filtering aperture of 0.2um); please contact Mindray for details.**

#### 3.1.6.1 Connecting the Insufflator Tube

**WARNING**

- **The Luer-lock can only be used to connect the pipe fitting. Never use the Luer-lock to connect other accessories.**

### 3.1.7 Connecting the Suction Tube (only for HS-50F/HS-50V models)

**NOTE**

- **It is suggested to adjust the pressure range of the suction device within 0.04MPa-0.06MPa. If the negative pressure is too high, the exhaust will be too fast to maintain the abdominal pressure; if the negative pressure is too low, the exhaust will be too slow.**

**WARNING**

- **Inspect the suction tube before use to make sure there is no blocking, bending or twisting, and the joint needs to be well connected.**
- **It is suggested to set the suction pump pressure within the range of 0.04MPa-0.06MPa.**
- **Please use Mindray matched suction tube, and do not use suction tube of other sizes.**
- **Please use parts and accessories provided by Mindray, and do not use parts and accessories of other sizes.**

### 3.1.8 Check Before Startup

**WARNING**

- **Conduct preventive inspection before each use. Please check the device according to the following instructions, and check other matched devices according to the Operator's Manual. Do not use if there is any minor anomaly, and see the measures in "Troubleshooting" to make correction. If the problem still persists after handling, please contact Mindray.**
- **This machine has not been sterilized before shipping. Before first use, please perform cleaning and sterilization according to requirements.**

- **Be sure to use insufflator tube and suction tube that Mindray recommends. Using other pipe fittings not only degrades performance, but also might cause incorrect operation.**
- **Please sterilize the insufflator tube and the suction tube before each use.**

#### 3.1.8.1 Inspection Process

**WARNING**

- **After startup, test whether individual parts are working normally, such as functions of smoke exhaust, heating, and setting pressure and flow.**

## 3.2 Use

**DANGER**

- **If the pressure is found uncontrolled during the surgery, please turn off the gas source immediately.**
- **Please use the Luer taper that meets the GB_T1962.1-2001 design requirements. The veress needle shall be properly connected with the Luer taper.**

**WARNING**

- **Tread and hold the foot switch according to the situation of smoke in the abdominal cavity. Do not tread and hold the switch for longer than 3 minutes, to avoid affecting the maintenance of normal pressure of pneumoperitoneum. Please choose suitable smoke exhaust gear based on the smoke situation.**
- **It is forbidden to switch pneumoperitoneum mode during surgery.**
- **Be sure to exhaust the residual gas in the pipeline after surgery.**
- **For security reasons, the smoke exhaust function will lose efficacy when the flow is set to lower than 20L/min or actual pressure is less than 3mmHg, to avoid evacuating all gas in the abdominal cavity and causing injury.**
- **In order to keep pneumoperitoneum, if gas leakage speed is too high, the flow of gas inflation needs to be increased appropriately.**
- **Please ensure the deflation valve in the [Settings] screen is on before use.**
- **If you hear any abnormal noise the machine makes during surgery, the gas source shall be turned off immediately.**

- **The connection of individual parts and accessories of the machine shall be stable.**

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# 4 Maintenance, Storage, and Disposal

## 4.1 Precautions

### WARNING

- **The insufflator tube and the suction tube need to be cleaned and sterilized immediately after each use, to avoid any infection between the patients or between the patient and the operator. Be sure to clean and sterilize the interior and exterior surface of the pipe fitting.**
- **The power switch shall be turned off and the power cord shall be unplugged before cleaning.**
- **Alcohol cannot be used as the sterilizing agent.**
- **If the insufflator tube is not thoroughly cleaned, effective sterilization cannot be achieved. The thorough cleaning must be conducted before sterilization to remove the microorganisms or organic matters that may reduce the sterilization efficacy.**
- **The patient's tissue detritus and the chemical agents used for cleaning and sterilizing are hazardous. In the process of cleaning and sterilizing, the appropriate personal protective equipment should be used, such as safety goggles, face shields, waterproof outfits and chemical resistant gloves. And be prepared for infection control.**
- **Pay attention to the ventilation condition of the environment where the sterilization occurs. Adequate ventilation helps prevent the accumulation of the harmful steam of the chemical agents.**
- **Please make sure that the device has been cleaned and sterilized before each use.**
- **If the aseptic package has been ripped off or damaged, the expected sterilization effect cannot be achieved. In this case, please replace it with a brand new package for sterilization.**
- **If too many appliances are placed in the package, the sterilization effect cannot be achieved. Be sure to leave enough room when placing the appliances into the aseptic package.**
- **The cleaning and sterilization methods mentioned in this document cannot eliminate the prion of Creutzfeldt-Jakob Disease (CJD). After using this product for a patient who suffers CJD or Variant Creutzfeldt-Jakob Disease (vCJD), please make sure this product is only used for this patient, or /and take appropriate measures to dispose of this product. Please compliance**

**with applicable laws and regulations in the country of residence when it comes to dealing with CJD.**

- **This device is nondurable or it does not have the durability required for the method of eliminating prions proposed in the country of residence. If the cleaning and sterilization methods not mentioned in this document are used, Mindray will not guarantee the efficacy, safety, and durability of this device. Please be sure to confirm the device does not have any anomaly, and use it under the guidance of the doctor in charge. Do not use the device if any anomaly is found.**
- **A disposable bacteria filter is single-use part. Please do not reuse it, and dispose of it as the medical waste.**
- **Before a disposable bacteria is used, please check if the aseptic package is in a good condition or if the filter has any damage first. If any damage is found on the package or filter, please do not use them.**

### NOTE

- **Various methods of cleaning and sterilization are applicable for the device and its accessories. But some methods do not apply to certain parts and accessories and will cause device damage.**
- **When choosing proper methods of cleaning, disinfection, and sterilization, please refer to this document and suggestions from the infection control department, as well as regulations of national and local hospitals.**

## 4.2 Cleaning, Sterilization, Storage, and Discard of the Insufflator and Foot Switch

### NOTE

- **This product cannot be soaked in water. Do not soak it into water or let liquid immerse into the device.**
- **Do not perform high-temperature and high-pressure sterilization or gas sterilization on the machine. Otherwise device damage may occur.**
- **Do not let electric terminals (system joint, foot switch interface, AC power input port, heating insufflator tube power interface) contact liquids. Otherwise poor contact may occur.**
- **In order to avoid damaging the surface, do not use coarse cloth.**
- **After cleaning, please dry the device thoroughly before use.**
- **When choosing proper methods of cleaning, disinfection, and sterilization, please refer to this document and suggestions from the infection control department, as well as regulations of national and local hospitals.**

### 4.2.1 Storage

**WARNING**

- **Please do not store the equipment in the tote box. Otherwise, it may have the infection control risk.**
- **The equipment must be ensured to have fully dried out before storage. Otherwise, the residual moisture may cause the infection control risk.**
- **Ensure there is no dust or foreign matter residing in $CO_2$ gas inlet joint.**

**NOTE**

- **Do not store the insufflator in places where there is direct sunlight, ultraviolet ray, X-ray, radiation or strong magnetic field. Otherwise it will damage the insufflator.**
- **Do not store the device in high temperature place, high humidity place, or place where there is splash.**
- **Do not operate the cables with force, and please avoid bending, stretching, tangling or extruding the cables.**
- **Do not strike the device using foreign matters or operate rudely, or device function anomaly may occur. Be sure to operate the device with caution.**

## 4.3 Cleaning, Sterilization, and Discard of the Insufflator Tube and Suction Tube

**WARNING**

- **When disinfecting the pipe fitting, all the air bubbles in the pipe fitting needs to be eliminated. If there is still any air bubble in the pipe fitting, the disinfection effect cannot be achieved.**
- **All the disinfection procedures should be performed while the pipe fitting is fully soaked in the disinfectant. Otherwise, the disinfectant may not be able to get enough touch with all the surfaces.**
- **The sterilization efficiency depends on a variety of factors, such as the packaging or placement of the sterilization equipment, and how to place the device in the sterilization equipment. Please use the biological or chemical indicator to examine the sterilization effect. Meanwhile, please follow the operation manual of the sterilizer published by the infection control department of the healthcare administration institutions, public organizations or various medical institutions.**

- **After high-temperature and high-pressure sterilization, please have the equipment package cooled down to room temperature first before taking it out of the sterilizer. Otherwise it may cause burn injury.**
- **Please check if each package is opened, cracked or has any other damages. If any damage is found, please use a new package to seal the equipment and resterilize it.**
- **Let the package dry out in the sterilizer by using the drying cycle function of the sterilizer (if any), or opening the sterilizer door for wind drying. The aseptic condition of the package will be affected if it is wet.**
- **Please do not clamp the pipe fitting and the joint when putting the package in.**

## NOTE

- **Before each use, be sure to follow the approaches specified in this chapter to conduct cleaning and sterilization in order to use.**
- **After each use, the following cleaning procedures shall be conducted immediately. If the cleaning is delayed, the residual tissue scraps will curdle, making it hard to clean and sterilize the device effectively.**
- **Wash thoroughly, or the residual cleanser might cause contamination or corrosion.**
- **Be sure to wear personal protective equipment to reduce infection risk and tissue stimulation.**
- **Do not use surfactants or disinfectants that contain surfactants. In order to avoid damaging the device, be sure to use clean water or the recommended disinfectants.**
- **The pipe fitting supports sterilization with high-temperature and high-pressure steam.**
- **The temperature in high-temperature and high-pressure sterilization shall not exceed 134°C. Also keep the sterilization time within 20 minutes, or it may cause damage of the pipe fitting or reduction of service life.**
- **In high-temperature and high-pressure sterilization, please finish the complete sterilization cycle according to the device requirements, including vacuum drying. Otherwise it might cause apparatus short circuit and damage.**
- **Sudden change of temperature may damage the pipe fitting or reduce service life.**

### 4.3.1 Automated Cleaning

## NOTE

- **Select an automated cleaning machine that is certified to meet local regulations.**
- **Maintain and inspect the cleaning machine regularly.**
- **Place the pipe fitting in a special tray and connect the tubes to the spray nozzles of the cleaning machine to ensure all parts can be flushed.**
- **After machine cleaning, check the equipment surface for stains. Repeat the cleaning procedure if necessary.**

#### 4.3.1.1 Autoclave Sterilization

**NOTE**

- **The time above refers to the sterilization time, excluding forevacuum time and time for drying and cooling after sterilization.**
- **Maximum temperature at any phase shall not exceed 134℃, otherwise it might cause damage to the pipe fitting or reduction of service life.**

### 4.3.2 Storage After Sterilization

**NOTE**

- **After cleaning and sterilization, the pipe fitting and contaminated devices need to be stored separately.**
- **Do not store the pipe fitting in sterile package that has crevice, is sealed inappropriately or has water damage. Otherwise the aseptic condition of the package will be impaired.**
- **Storage location must be clean, dry and well ventilated, and the temperature shall stay at ambient temperature. Do not store the pipe fitting in an environment where there is direct sunlight, high temperature, high humidity, X-ray or ultraviolet ray. Otherwise it might damage the pipe fitting or pose infection control risk.**

## 4.4 Maintenance and Modification

**NOTE**

- **If needed, contact the manufacturer for circuit diagrams, component part lists, descriptions, calibration instructions, or other information concerning the repair of the equipment.**

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# 5 Troubleshooting

**WARNING**

- **If the insufflator has any obvious damages and cannot work properly, or any abnormal states are found during the self-test, please do not use it; and contact Mindray.**
- **Some problems that are not related with the product malfunction can be resolved by consulting *5.1 Return for Repair of the Insufflator*. After troubleshooting according to the stated solution, if the problem still persists, please stop using this device, and send it back to Mindray for repair.**
- **In order to prevent cross infection and ensure the internal parts of the insufflator work properly, once the liquid flows into the gas inlet of the insufflator, the startup self-inspection will fail. The insufflator needs to be sent back to Mindray for repair.**

**NOTE**

- **Mindray is not responsible for repairing accessories. If any accessory is damaged, please contact Mindray to purchase a new one.**

## 5.1 Return for Repair of the Insufflator

**NOTE**

- **For human injury and device damage caused by non Mindray or Mindray-authorized maintenance staff's trying to repair, Mindray bears no responsibility.**

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# 6 Accessories

**WARNING**

- **Use accessories specified in this chapter. Using other accessories may cause damage to the device or not meet the claimed specifications.**
- **Single use accessories are not designed to be reused. Reuse may cause a risk of contamination and affect the measurement accuracy.**

**CAUTION**

- **The accessories may not meet the performance specifications if stored or used outside the specified temperature and humidity ranges. If accessory performance is degraded due to aging or environmental conditions, contact your service personnel.**
- **Check the accessories and their packages for any sign of damage. Do not use them if any damage is detected.**
- **Use the accessories before the expiry date if their expiry date is indicated.**

## 6.1 Insufflator Accessories

| No. | Accessory |
|---|---|
| 1. | Reusable Insufflator Tube (2.9m) |
| 2. | Reusable Insufflator Tube (4.5m) |
| 3. | Heating Insufflator Tube (2.9m) |
| 4. | Heating Insufflator Tube (4.5m) |

## 6.2 Other Devices Also Compatible

The following medical devices are also compatible with the insufflator. To purchase these devices contact Mindray.

| No. | Device |
|---|---|
| 1. | Disposable Bacteria Filter, Large Size |
| 2. | Foot Switch |
| 3. | Y Joint (1/4ID, Natural Kynar) |
| 4. | CO2 Reducing Valve (452C-150 GB) |
| 5. | CO2 Reducing Valve (452C-150 CGA320) |
| 6. | CO2 Reducing Valve (452C-150 DIN477) |
| 7. | CO2 Reducing Valve (452C-150 CGA940) |
| 8. | CO2 Reducing Valve (452C-150 ISO5145) |
| 9. | CO2 Reducing Valve (452C-150 BS341) |
| 10. | Reusable Suction Tube (2.9m) |
| 11. | Reusable Suction Tube (4.5m) |

## 6.3 Other Products Also Compatible

The following non-medical devices are also compatible with the insufflator. To purchase these products contact Mindray.

| No. | Device |
|---|---|
| 1. | Foot Switch Extension Cord |
| 2. | Reusable Connector, Straight, 22-10 |
| 3. | Central Gas Supply Pipe (German) |
| 4. | Central Gas Supply Pipe (DISS) |
| 5. | Central Gas Supply Pipe (Japan) |
| 6. | Central Gas Supply Pipe (French) |
| 7. | Central Gas Supply Pipe (British) |
| 8. | Central Gas Supply Pipe (SYS) |
| 9. | Central Gas Supply Pipe (Ohmeda) |
| 10. | CO2 Low Pressure Tube (GB) |
| 11. | CO2 Low Pressure Tube (DISS) |
| 12. | CO2 High Pressure Tube (GB) |

| No. | Device |
|---|---|
| 13. | $CO_2$ High Pressure Tube (CGA320) |
| 14. | CO2 High Pressure Tube (DIN477) |
| 15. | CO2 High Pressure Tube (CGA940) |
| 16. | CO2 High Pressure Tube (ISO5145) |
| 17. | CO2 High Pressure Tube (BS341) |

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# A Product Specifications

## A.1 Basic Parameters and Performance

| | | |
|---|---|---|
| Gas pressure adjustment | 1 mmHg ~ 30 mmHg | |
| Accuracy of preset gas pressure | ±2 mmHg | |
| Accuracy of displayed pressure | ±2 mmHg | |
| Overpressure prompt | Prompts when gas pressure difference is 5 mmHg (allowable difference ±2 mmHg) | |
| Overpressure release | 20s | |
| Underpressure supplement | 10s | |
| Accuracy of set flow | ≤10 L/min, allowable difference ±2 L/min | |
| | >10 L/min, allowable difference ±20% | |
| Accuracy of displayed flow | ≤10 L/min, allowable difference ±2 L/min | |
| | >10 L/min, allowable difference ±20% | |
| Accuracy of displayed gas consumption | Allowable difference ±20% | |
| Smoke exhaust flow | Maximum smoke exhaust flow ≥10 L/min at negative suction pressure of 0.04-0.06MPa | |
| Flow adjustment range | HS-50F | 0.1-50 L/min |
| | HS-50V | 0.1-50 L/min |
| | HS-50H | 0.1-50 L/min |
| | HS-50S | 0.1-50 L/min |
| | HS-30S | 0.1-30 L/min |
| Heating | 37°C±2°C under typical conditions (ambient temperature: 24°C±2°C; pressure: 12 mmHg; flow: 20 L/min) | |
| Gas source monitoring | Prompt of low gas pressure<br>Prompt of gas exhaust | |

## A.2 Safety Specifications

| | |
|---|---|
| Protection against electric shock type | Class I equipment |
| Protection against electrical shock level | Type CF applied part |
| Liquid inlet protection class | Foot switch IPX8<br>The insufflator is an ordinary-type device (sealed device that does not protect from liquid inlet) |
| Cleaning method | Use cleaning equipment recommend by the manufacturer. |
| Take extra care while using with flammable anesthetic gases mixed with air, oxygen, or nitrous oxide | This equipment cannot be used with flammable anesthetic gases mixed with the air, oxygen, or nitrous oxide. |
| Working mode | Continuous operation |
| If the equipment is provided with applied parts that protect from defibrillation charge effects | No applied part for protection from defibrillation charge effects is provided. |
| Signal output/input section | The equipment is provided with a signal output/input section |
| Permanently installed equipment or non-permanently installed equipment | Non-permanently installed equipment |

## A.3 Storage and Operation

| Item | Temperature (°C) | Relative humidity (Non - Condensing) | Atmospheric pressure (hPa) |
|---|---|---|---|
| Working | 0 - 40 | 30% - 85% | 700 - 1060 |
| Transportation/ Storage | -20 - 55 | 10% - 95% | 700 - 1060 |

## A.4 Power Supply Specifications

| | |
|---|---|
| Input voltage | AC 100 -240V ± 10% |
| Rated frequency | 50/60 Hz |
| Maximum current | 0.75A-0.35A |
| Fuse | T3.15AH250V |

## A.5 Physical Specifications

| | |
|---|---|
| Dimension | Length (front to back): 380 mm<br>Width (left to right): 350 mm<br>Height (top to bottom): 141 mm (excluding the rubber feet) |
| Weight | 10 kg |
| Mechanical noise | ≤50dBA |

## A.6 Gas Source Specifications

| | |
|---|---|
| Gas source | Gas supply with gas cylinder/Central gas supply/Connection using reducing valve |
| Pressure range | 0.4 - 16 MPa |
| Gas type | $CO_2$ |
| Gas flow | HS-50F, HS-50V, HS-50H, HS-50S: Max 50 L/min<br>HS-30S: Max 30 L/min |

## A.7 Equipment Connectors

| | |
|---|---|
| USB connector | 1, complied with USB 2.0 standard<br>Fixed time synchronization pulse specified by the USB protocol |
| Network connector | 1, standard RJ45 interface, supporting wired network 10 M/100 M/, and complied with technical standard IEEE802.3<br>Calibration protocol of TCP/IP |
| CAN connector | 2, used for transmitting analog signal from other Mindray equipment, complied with MD2 protocol. |
| Foot switch interface | 1, used for transmitting analog signal from Mindray specified foot switch, complied with Mindray internal standard |
| Insufflator tube heating joint | 1, used for transmitting analog signal from Mindray specified heating insufflator tube, complied with Mindray internal standard |

## A.8 Operating Environment

| | |
|---|---|
| Hardware configuration | RAM: 512 MB<br>Flash: 8 GB |
| Software environment | LINUX |

# B EMC

HS-50F, HS-50V, HS-50H, HS-50S and HS-30S insufflators complies with the EMC standard IEC 60601-1-2: 2020.

## WARNING

- **Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.**
- **The non-ME EQUIPMENT (e.g. ITE) that is a part of an ME SYSTEM may be disrupted by the electromagnetic interference of nearby equipment. It may be necessary to take mitigation measures, such as re-orienting or relocating the non-ME EQUIPMENT or shielding the location.**
- **Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.**
- **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 ME EQUIPMENT or ME SYSTEM, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.**
- **This device is intended for use in professional healthcare environment. If it is used in special environment, such as magnetic resonance imaging environment, the equipment/system may be disrupted by the operation of nearby equipment.**

TABLE 1

| GUIDANCE AND MINDRAY DECLARATION—ELECTROMAGNETIC EMISSIONS | | |
|---|---|---|
| The system is intended for use in the electromagnetic environment specified below. The customer or the user of system should assure that it is used in such an environment. | | |
| **EMISSIONS TEST** | **COMPLIANCE** | **ELECTROMAGNETIC ENVIROMENT – GUIDANCE** |
| RF emissions<br>CISPR 11 | Group 1 | The system uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment. |
| RF emissions<br>CISPR 11 | Class B | The system is suitable for use in all establishments including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes. |
| Harmonic Emissions<br>IEC 61000-3-2 | Class A | |
| Voltage Fluctuations/<br>Flicker Emissions<br>IEC 61000-3-3 | Compliance | |

## NOTE

- **The system needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided below.**
- **Other devices may interfere with this system even though they meet the requirements of CISPR.**
- **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.**

If the system is operated within the electromagnetic environment listed in Table 2 and Table 3, the system will remain safe and will provide the following basic performances:

- Pressure accuracy
- Flow rate accuracy
- Foot switch function
- Heating function

TABLE 2

| GUIDANCE AND MINDRAY DECLARATION—ELECTROMAGNETIC IMMUNITY | | | |
|---|---|---|---|
| The system is intended for use in the electromagnetic environment specified below. The customer or the user of system should assure that it is used in such an environment. | | | |
| **IMMUNITY TEST** | **IEC 60601 TEST LEVEL** | **COMPLIANCE LEVEL** | **ELECTROMAGNETIC ENVIRONMENT-GUIDANCE** |
| Electrostatic Discharge (ESD)<br>IEC 61000-4-2 | ±8 kV contact;<br>±2 kV, ±4 kV, ±8 kV, ±15 kV air | ±8 kV contact;<br>±2 kV, ±4 kV, ±8 kV, ±15kV air | Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%. |
| Electrical fast transient / burst<br>IEC 61000-4-4 | ±2 kV for power supply lines;<br>±1 kV for input/ output lines | ±2 kV for power supply lines;<br>±1 kV for input/ output lines | Mains power quality should be that of a typical commercial or hospital environment. |
| Surge<br>IEC 61000-4-5 | ±0,5 kV, ±1 kV line(s) to line(s);<br>±0,5 kV, ±1 kV, ±2 kV line(s) to earth | ±0,5 kV, ±1 kV line(s) to line(s);<br>±0,5 kV, ±1 kV, ±2 kV line(s) to earth | Mains power quality should be that of a typical commercial or hospital environment. |
| Voltage dips, Short interruptions and voltage variation on power supply input voltage<br>IEC 61000-4-11 | 0 % $U_T$; 0,5 cycle<br>At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°<br>0 % $U_T$; 1 cycle<br>70% $U_T$ for 25/30 cycle at 0°<br>0 % $U_T$; 250/300 cycle | 0 % $U_T$; 0,5 cycle<br>At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°<br>0 % $U_T$; 1 cycle<br>70% $U_T$ for 25/30 cycle at 0°<br>0 % $U_T$; 250/300 cycle | Mains power quality should be that of a typical commercial or hospital environment. If you require continued operation during power mains interruptions, it is recommended that our product be powered from an uninterruptible power supply or a battery. |
| Power frequency (50/60 Hz) magnetic field<br>IEC 61000-4-8 | 30 A/m | 30 A/m | Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment. |
| NOTE: $U_T$ is the A.C. mains voltage prior to application of the test level. | | | |

TABLE 3

| **GUIDANCE AND MINDRAY DECLARATION—ELECTROMAGNETIC IMMUNITY** | | | |
|---|---|---|---|
| The system is intended for use in the electromagnetic environment specified below. The customer or the user of system should assure that it is used in such an environment. | | | |
| **IMMUNITY TEST** | **IEC 60601 TEST LEVEL** | **COMPLIANCE LEVEL** | **ELECTROMAGNETIC ENVIRONMENT-GUIDANCE** |
| Conduced RF IEC 61000-4-6 | 3 Vrms<br>0,15 MHz – 80 MHz<br><br>6 Vrms in ISM[a] bands between 0,15 MHz and 80 MHz | 3 Vrms<br>0,15 MHz – 80 MHz<br><br>6 Vrms in ISM[a] bands between 0,15 MHz and 80 MHz | Portable and mobile RF communications equipment should be used no closer to any part of system, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance<br>$d = 1.2 \times \sqrt{P}$<br><br>$d = 2 \times \sqrt{P}$ |
| Radiated RF IEC 61000-4-3 | 3 V/m<br>80MHz - 2.7GHz | 3 V/m<br>80MHz - 2.7GHz | $d = 1.2 \times \sqrt{P}$ 80 MHz to 800 MHz<br>$d = 2.3 \times \sqrt{P}$ 800 MHz to 2.7GHz<br>Where, *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and *d* is the recommended separation distance in meters (m).<br>Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey[b], should be less than the compliance level in each frequency range[c].<br>Interference may occur in the vicinity of equipment marked with the following symbol:  |
| Note 1: At 80 MHz and 800 MHz, the higher frequency range applies.<br>Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people. | | | |

[a]: The ISM (industrial, scientific, and medical) bands between 150 kHz and 80 MHz are 6,765 MHz to 6,795 MHz; 13,553 MHz to 13,567 MHz; 26,957 MHz to 27,283 MHz; and 40,66 MHz to 40,70 MHz. The amateur radio bands between 0,15 MHz and 80 MHz are 1,8 MHz to 2,0 MHz, 3,5 MHz to 4,0 MHz, 5,3 MHz to 5,4 MHz, 7 MHz to 7,3 MHz, 10,1 MHz to 10,15 MHz, 14 MHz to 14,2 MHz, 18,07 MHz to 18,17 MHz, 21,0 MHz to 21,4 MHz, 24,89 MHz to 24,99 MHz, 28,0 MHz to 29,7 MHz and 50,0 MHz to 54,0 MHz.

[b]: Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the device is used exceeds the applicable RF compliance level above, the device should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the device.

[c]: Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

TABLE 4

| **GUIDANCE AND MINDRAY DECLARATION—ELECTROMAGNETIC IMMUNITY** | | | |
|---|---|---|---|
| The system is intended for use in the electromagnetic environment specified below. The customer or the user of system should assure that it is used in such an environment. | | | |
| **IMMUNITY TEST** | **IEC 60601 TEST LEVEL** | **COMPLIANCE LEVEL** | **ELECTROMAGNETIC ENVIROMENT – GUIDANCE** |
| Proximity magnetic fields<br>IEC 61000-4-39 | 65 A/m<br>134,2 kHz<br>Pulse modulation<br>2,1 kHz | 65 A/m<br>134,2 kHz<br>Pulse modulation<br>2,1 kHz | / |
| | 7,5 A/m<br>13,56 MHz<br>Pulse modulation<br>50 kHz | 7,5 A/m<br>13,56 MHz<br>Pulse modulation<br>50 kHz | |

TABLE 5

**Recommended separation distances between portable and mobile RF communications equipment and insufflators**

The system is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of insufflators can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the insufflators as recommended below, according to the maximum output power of the communications equipment. Portable and mobile radio communications equipment (e.g. two-way radio, cellular/ cordless telephones and similar equipment) should be used no closer to any part of this system, including cables, than determined according to the following method:

| Test frequency (MHz) | Band (MHz) | Service | Modulation | Maximum power (W) | Distance (m) | Immunity test level (V/m) |
|---|---|---|---|---|---|---|
| 385 | 380 - 390 | TETRA 400 | Pulse modulation 18Hz | 1.8 | 0.3 | 27 |
| 450 | 430 -470 | GMRS 460 FRS 460 | FM ±5 kHz deviation 1 kHz sine | 2 | 0.3 | 28 |
| 710 | 704 - 787 | LTE Band 13,17 | Pulse modulation 217 Hz | 0.2 | 0.3 | 9 |
| 745 | | | | | | |
| 780 | | | | | | |
| 810 | 800 - 960 | GSM 800/900, tetra 800, iDEN 820, CDMA 850, LTE Band 5 | Pulse modulation 18 Hz | 2 | 0.3 | 28 |
| 870 | | | | | | |
| 930 | | | | | | |
| 1720 | 1700 - 1990 | GSM 1800, CDMA 1900, GSM 1900, DECT, LTE Band 1, 3,4,25,UMTS | Pulse modulation 217 Hz | 2 | 0.3 | 28 |
| 1845 | | | | | | |
| 1970 | | | | | | |

| | | | | | | |
|---|---|---|---|---|---|---|
| 2450 | 2400 - 2570 | Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7 | Pulse modulation 217 Hz | 2 | 0.3 | 28 |
| 5240 | 5100 - 5800 | WLAN, 802.11 a/n | Pulse modulation 217 Hz | 0.2 | 0.3 | 9 |
| 5500 | | | | | | |
| 5785 | | | | | | |

TABLE 6

**RECOMMENDED SEPARATION DISTANCES BETWEEN PORTABLE AND MOBILE RF COMMUNICATION DEVICE AND THE SYSTEM**

The system is intended for use in an electromagnetic environment in which radiated RF disturbance are controlled. The customer or the user of system can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communication equipment (transmitters) and system as recommended below, according to the maximum output power of the communication equipment.

| **Rated Maximum Output power of Transmitter (W)** | **Separation Distance According to Frequency of Transmitter (m)** | | | |
|---|---|---|---|---|
| | 150kHz -80MHz $d=1.2\sqrt{P}$ | 150kHz -80MHz in ISM bands $d=2\sqrt{P}$ | 80MHz-800MHz $d=1.2\sqrt{P}$ | 800MHz-2.7GHz $d=2.3\sqrt{P}$ |
| 0.01 | 0.12 | 0.2 | 0.12 | 0.23 |
| 0.1 | 0.38 | 0.64 | 0.38 | 0.73 |
| 1 | 1.2 | 2 | 1.2 | 2.3 |
| 10 | 3.8 | 6.4 | 3.8 | 7.3 |
| 100 | 12 | 20 | 12 | 23 |

For transmitters at a maximum output power not listed above, the recommended separation distanced in meters (m) can be determined using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

Note1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

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