

Vetina GS3

Veterinary Insufflator

Operator's Manual



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- Malfunction of the instrument or part whose serial number is not legible enough.
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Preface

Manual Purpose

This manual contains the instructions necessary to operate the product safely and in accordance with its function and intended use. Observance of this manual is a prerequisite for proper product performance and correct operation and ensures patient and operator safety.

This manual is based on the maximum configuration and therefore some contents may not apply to your product. If you have any question, please contact us.

This manual is an integral part of the product. It should always be kept close to the equipment so that it can be obtained conveniently when needed.

Intended Audience

This manual is geared for clinical professionals who are expected to have a working knowledge of medical procedures, practices and terminology as required for monitoring of critically ill patients.

Illustrations

All illustrations in this manual serve as examples only. They may not necessarily reflect the setup or data displayed on your equipment.

Conventions

- ***Italic text*** is used in this manual to quote the referenced chapters or sections.
- **Bold text** is used to indicate the screen texts.
- → is used to indicate operational procedures.

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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.
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CAUTION

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

- Provides application tips or other useful information to ensure that you get the most from your product.
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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 CO₂ gas can be used for this machine. Never use other gases. Using gases other than CO₂ may cause fire, poisoning, complications, etc. Using
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non-medical level, polluted CO₂ may cause failure in gas injection pressure adjustment phase, which leads to serious injury for patients. Please use high-pressure tube, reducing valve, or wall tubing connector to connect CO₂ 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 Animal Medical 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 62368-1 Audio/ Video, Information and Communication Technology Equipment Standard and IEC 60601-1 Medical Device Standard). All the configurations shall be in accordance with the valid version of IEC 60601-1 Standard. 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 standard. 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.**
- **When product failure occurs during use, stop operation immediately, unplug the power cord and take out the endoscope slowly from the patient's body, 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 (N₂O)) 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 CO₂ 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. The physician shall determine from a professional perspective. If the insufflator gives prompt that intra-abdominal overpressure**

has occurred, the bibcock or valve of the perforator 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.

- When the safety valve is opened, 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 CO₂ gas feed 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 CO₂ gas cylinder shall be prepared so that it can be replaced quickly when CO₂ 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 CO₂ gas is needed. If CO₂ 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 CO₂, 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 CO₂ 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 CO₂ 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 CO₂.
 - **Other possible complications include CO₂ aeroembolism, low body temperature, and diaphragm carbonic acid stimulation.** Injected CO₂ gas directly entering the vascular system (such as through open blood vessel in the abdominal cavity, or improper penetration of veress needle) might cause aeroembolism.
 - **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 at calculus posture.**
 - **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 decompressor 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.**
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1.1.3 Cautions

CAUTION

- **Precautions related to clinical examination technology:**
 - ◆ **This system can only be operated by medical staff with qualified professional training.**
 - ◆ **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.
 - Do not directly plug or unplug the system or its accessories 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.
 - 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.
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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 easily 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 perforator 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 Animal Medical to inspect the machine's safety performance at regular intervals to prevent the occurrence of any accidents.**
- **Replaceable accessories inside the system can only be replaced by Mindray Animal Medical's maintenance engineers or technicians assigned by Mindray Animal Medical.**
- **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**

1.2 Equipment Symbols

Symbol	Description	Symbol	Description
	Refer to instruction manual/ booklet		Manufacturer

Symbol	Description	Symbol	Description
	Stand-by		Date of manufacture
	TYPE CF APPLIED PART		Caution
	Serial number		CO ₂ smog exhaust and gas outlet valve
	Alternating current		Fuse
	Equipotentiality		Temperature; thermometer
	Input; entrance		Output; exit
	Humidity limitation		Atmospheric pressure limitation
	Temperature limit		Protective earth (ground)
	CE mark	IP20	Protected against solid foreign objects of 12,5 mm Ø and greater, non-protected against water
	<p>The following definition of the WEEE label applies to EU member states only: the use of this symbol indicates that waste electrical and electronic equipment must not be disposed of as unsorted municipal waste and must be collected separately. By ensuring that this product is disposed of correctly, you will help prevent bringing potential negative consequences to the environment and human health. For more detailed information with regard to returning and recycling this product, please consult the distributor from whom you purchased the product.</p>		

NOTE

- **Some symbols listed above may not appear on your equipment.**

2 System Overview

2.1 Intended Use

This product is used to inflate the abdominal cavity in minimally invasive laparoscopic surgery to form pneumoperitoneum, thus providing space and view for the surgery.

This product may not be used for any other purposes and is veterinary use only.

2.2 Operator's Manual

This Operator's Manual contain the basic information of safely and effectively using this product. Please carefully read this Operator's Manual and other manuals for all peripheral equipment before using, and operate in accordance with the stipulations.

Please put all relevant operation manuals in safe and easy-to-access places. For any questions or opinions regarding contents of this Operator's Manual, please contact Mindray Animal Medical.

2.3 Contraindications

It is not allowed to use this equipment if the disease the patient suffers from is not suitable for endoscopic surgery.

2.4 Precautions Before Use

If there are regulations on the qualification licensing of endoscopic diagnosis and treatment workers officially established by hospitals or other health care professional associations, only the medical workers who meet the requirements of such regulations can operate the product.

Generally, the user of the product shall be the medical workers who has taken training of endoscopic technique and thoroughly mastered the endoscopic operation technology.

When used over an extended period of time, the safe electrical and mechanical performance of the system will decline. To avoid unnecessary impact on diagnosis, treatment, and normal use of the product, regular inspection and maintenance must be performed. It is suggested to sign a maintenance and repair agreement to prevent the occurrence of accidents. Meanwhile, inspect the product before each use. If any faults are found, contact support engineers in time.

This product needs to match with the peripherals. Using unmatched equipment might cause patient injury and/or equipment damage.

Do not modify the product in any way without authorization. The Company reserves the right to maintain, upgrade, and modify the product.

2.5 Cleaning, Sterilization and Storage

This product has not been sterilized before shipping. Before first use, please perform cleaning and sterilization according to laws and regulations or infection control requirements.

After using the device, store it properly.

Partial and/or improper cleaning, sterilization and storage may cause infection control risks and lead to device damage or performance degradation.

3 Functions and Parameters

3.1 Block Diagram of Overall Structure

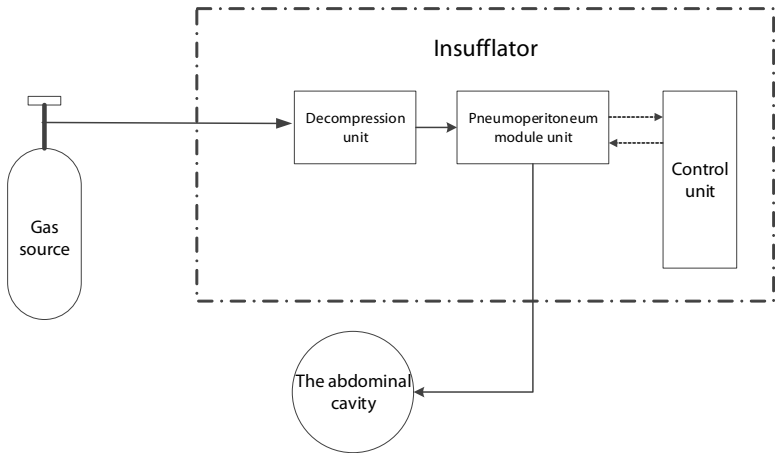


Figure 3-1 Block Diagram of Overall Structure

3.2 Front Panel

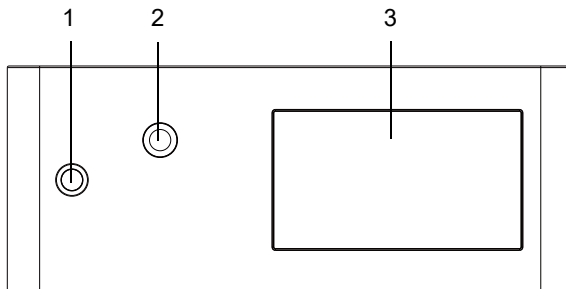


Figure 3-2 Insufflator Main Machine - Front Panel

Description of front panel:

1. Power switch: Turns on the insufflator
2. CO₂ gas injection interface: Can output CO₂ gas when gas injection is on
3. Insufflator control screen: 7-inch touchscreen. Displays and controls the status of the insufflator

3.3 Rear Panel

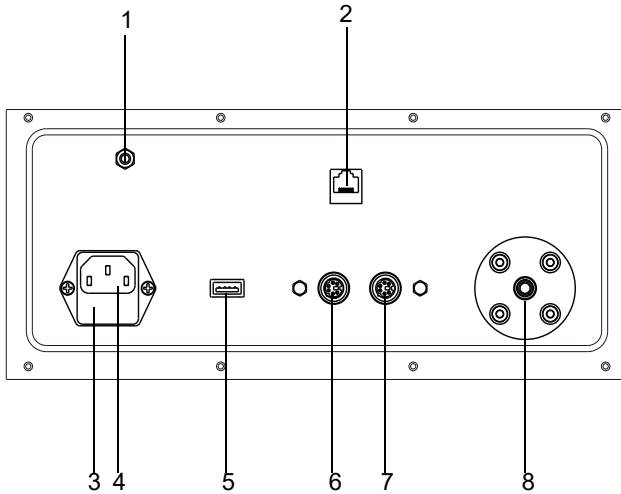


Figure 3-3 Insufflator Main Machine - Rear Panel

Description of rear panel:

1. Equipotential grounding terminal: When using the monitor together with other devices, connect their equipotential grounding terminals together to eliminate the potential difference between them.
2. Network connector: connects PC for software upgrade
3. Fuse box: contains the fuse.
4. AC power input: connects the AC mains.
5. USB connector: connects USB drive to export log and upgrade the device
6. SCI connector: reserved
7. SCI connector: reserved
8. CO₂ gas inlet: connects CO₂ gas source

3.4 Description of system functions

The product is used to inject CO₂ into and exhaust smog from the abdominal cavity in minimally invasive laparoscopic surgery, thus ensuring necessary space and view in the surgery and observation.

The main functions are as follows:

1. Gas injection
 - ◆ When the gas injection function is turned on for the insufflator, CO₂ gas sent from eligible gas source can be sent out stably through insufflator tube based on configured gas pressure and flow.
2. Gas pressure and flow monitoring
 - ◆ In the gas injection process, the insufflator always monitors gas pressure and flow, and ensures the pressure and flow remains within the configured range.





3.5 Usage environment


The intended usage environment is in an operating room for minimally invasive abdominal surgery, and the normal working power supply and environment conditions are as follows:

1. Environment temperature: 0°C - 40°C;
2. Relative humidity: 30% - 85%;
3. Atmospheric pressure: 700hPa - 1060hPa;
4. Power supply: overall input voltage: AC 100-240V~, allowable error ±10%; frequency: 50/60Hz;
5. Overall input current: 0.75 - 0.35A;
6. Fuse: T3.15AH250V
7. Gas source: CO₂
8. Gas pressure: 0.4~16Mpa

3.6 On-screen Symbols

The symbols displayed on the main screen indicate the status of the gas supply and smog exhausting as follows:

Symbol	Description	Symbol	Description
	Gas source indicator: central gas is used and the gas pressure is normal (green).		Gas source indicator: central gas is used and the gas pressure is low (red).
	Gas source indicator: gas cylinder is used and the CO ₂ gas is sufficient (green).		Gas source indicator: gas cylinder is used and the CO ₂ gas is insufficient (yellow). Backup CO ₂ cylinder is required.

Symbol	Description	Symbol	Description
	Gas source indicator: gas cylinder is used and the CO2 gas is low (red). Replace the CO2 cylinder immediately.		

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4 Installation and Use

4.1 Installation

4.1.1 Placement

Before placing the insufflator, please carefully read and comprehend the safety precautions to ensure the safety of operators and equipment.

1. Turn off the system power supply and unplug the power.
2. Disconnect all peripheral equipment, and arrange all cables and pipelines properly to prevent tripping over them.
3. Place the insufflator on a stable and flat workbench. If the insufflator is placed on a trolley, it must be confirmed that the trolley is big enough and can prop up steadily.
4. In actual use, the position of the insufflator's patient end and many associated pipelines shall be higher than the pneumoperitoneum area to prevent the patient's body fluid from accidentally flowing into the pipelines. If the pipelines are lower than the pneumoperitoneum area, the patient's body fluid may flow into the insufflator due to gravity.

CAUTION

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

4.1.2 Connecting CO₂ Gas Cylinder

DANGER

- **Using non-medical CO₂ 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 CO₂ gas.**
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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 CO₂ gas cylinder are connected correctly shall the gas supply valve be opened. If the valve is opened before correct connection, the liquid CO₂ may flow into the insufflator, causing related pipelines frozen and thus affecting the normal injection of CO₂ gas; or the CO₂ 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 CO₂ gas.
- Mindray Animal Medical 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 Animal Medical.
- 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 CO₂ cylinder and the regulator are used, CO₂ supply pressure greater than 0.5 Mpa is recommended. For more information, refer to the instructions for use delivered with the cylinder regulator.

4.1.2.1 Using Reducing Valve and Its Connecting Tube to Connect Steel Cylinder

1. Connect the connecting tube of reducing valve and the adaptive end of the insufflator with the CO₂ gas inlet of the insufflator. Use a force of about 11.8N.m (1.2kgf.m) to fasten it. As shown in Figure 4-1.

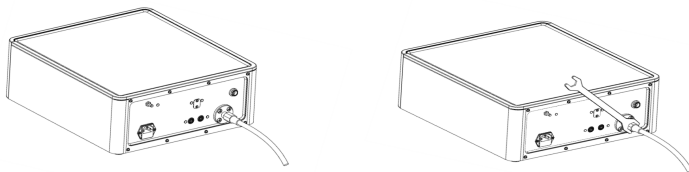


Figure 4-1 Connect the connecting tube of reducing valve and fasten it

2. Connect the steel cylinder joint of the reducing valve to the gas outlet of the steel cylinder. Use a force of about 29.4N.m (3kgf.m) to fasten it. As shown in Figure 4-2.

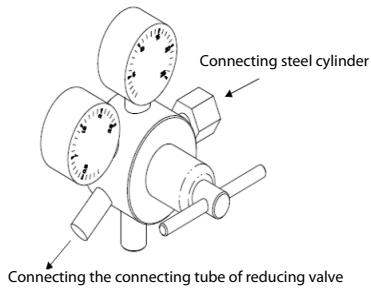


Figure 4-2 Connection of the reducing valve

3. Connect the connecting tube of reducing valve to the low pressure end of the reducing valve.
4. Confirm that the insufflator and the CO₂ gas cylinder are connected correctly, and slowly open the gas cylinder valve. As shown in Figure 4-3.
5. Slowly open the valve of the reducing valve.

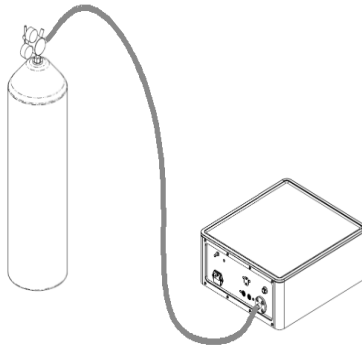


Figure 4-3 The insufflator connects with steel cylinder via the reducing valve

WARNING

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

4.1.2.2 Directly Connecting the Insufflator with the CO₂ Steel Cylinder

1. Check whether the high pressure tube used for the direct connection of steel cylinder is damaged, has cracks or other anomalies.

2. Use a wrench to connect the high pressure tube to the CO₂ gas inlet on the insufflator's rear panel, with a force of 11.8N.m (1.2kgf.m) to fasten it. As shown in Figure 4-4.
3. Connect the steel cylinder joint of the high pressure connecting tube to the gas outlet of the steel cylinder. Use a force of about 29.4N.m (3kgf.m) to fasten it.
4. Confirm that the insufflator and the CO₂ gas cylinder are connected correctly, and slowly open the gas cylinder valve.

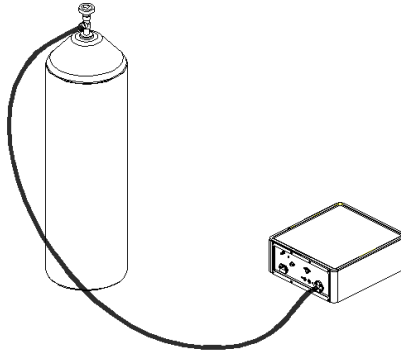


Figure 4-4 The insufflator directly connects with the CO₂ steel cylinder

4.1.3 Connecting the Central Gas Supply Pipe Joint

DANGER

- **Using non-medical CO₂ 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 CO₂ 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 CO₂ 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 CO₂ gas.**
- **If obvious gas leak inside the insufflator is found, stop using immediately and contact Mindray Animal Medical.**

1. Use a wrench to connect the insufflator joint of the gas supply hose to the CO₂ gas inlet on the insufflator's rear panel, with a force of 11.8N.m (1.2kgf.m) to fasten it. As shown in Figure 4-1.
2. Connect the gas supply hose to the CO₂ central gas supply port.

4.1.4 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.**

1. Plug the power supply cable into the power socket at the bottom of machine's backside.
2. Plug the power supply cable into a power outlet. Ensure that the grounding terminal is connected with a ground protection wire inside the socket.

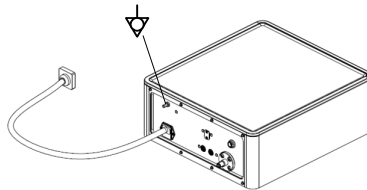


Figure 4-5 Connect with the power grid



is an equipotential terminal and is used to balance the electric potential of the protective grounding between the system and other electrical equipment. Please refer to the instruction in Figure 4-5 for equipotential terminal of the system.

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.**
-

4.1.5 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 Animal Medical 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

- **Be sure to the bacteria filter inside the package, or purchase disposable filters that Mindray Animal Medical recommends: model 800-51800 of VADI brand (with a filtering aperture of 0.2um); please contact Mindray Animal Medical for details.**
-

4.1.5.1 Connecting the Insufflator Tube

1. Connect the sterilized pipe fitting to the sterilized Luer-lock.

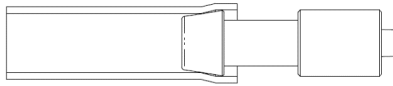


Figure 4-6 The pipe fitting connects with Luer-lock

2. Please install the filter between the insufflator tube and the insufflator's CO₂ gas injection interface. As shown in Figure 4-7.

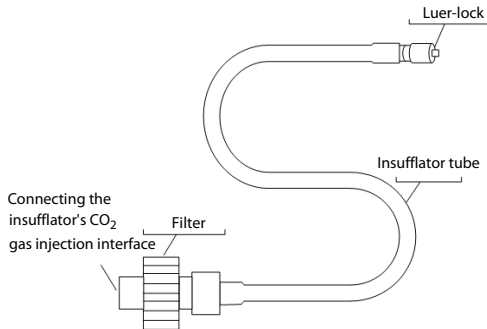


Figure 4-7 Installed insufflator pipe fitting (using filter)

3. Connect the installed pipe fitting to the CO₂ gas injection joint of the product. Guarantee that the interface is well inserted. As shown in Figure 4-8.

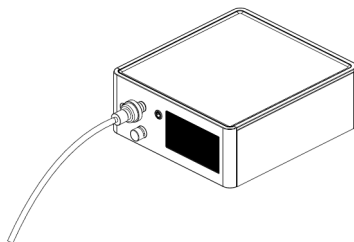


Figure 4-8 The insufflator pipe fitting connects with the insufflator (using filter)

WARNING

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

4.1.6 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 Animal Medical.**
 - **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 that Mindray Animal Medical recommends. Using other pipe fittings not only degrades performance, but also might cause incorrect operation.**
 - **Please sterilize the insufflator tube before each use.**
-
-

4.1.6.1 Inspection Process

1. Check the high pressure hose and the gas supply source (steel cylinder or wall central gas supply joint)
 - ◆ Check whether the high pressure tube has any scratch, crack or other damages.
 - ◆ Check whether the seal rings at joints have any scratch, crack or other damages.
2. Check the insufflator tube

- ◆ Check whether the pipe fittings and interfaces have any scratch, crack or other damages. Any damaged device shall be discarded and replaced.
 - ◆ Confirm that the pipe fittings and interfaces are dry.
 - ◆ Before taking the filter out of the package, check whether the package is damaged. If the package has already been opened or torn, or if the filter is broken, do not use the filter. Because the interior pipeline of the filter cannot guarantee asepsis. Do not try to sterilize it.
3. Turn on the gas source switch
 4. Turn on the power switch
 - ◆ Press the power switch to turn on the insufflator. Wait until the screen prompts that self-inspection completes.
 - ◆ Set up the working mode. Confirm that the newest gas pressure has been set. And set the flow to minimum.

WARNING

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

4.2 Use

4.2.1 Using the Touchscreen

The insufflator is configured with a touchscreen on which you can operate and set the equipment. Below is an introduction of content displayed on the touchscreen:



(1)	Decrease CO ₂ pressure
(2)	CO ₂ pressure setting
(3)	Increase CO ₂ pressure
(4)	Total CO ₂ exhaust (press to clear the value)
(5)	Gas source indicator
(6)	Increase CO ₂ flow
(7)	CO ₂ flow setting
(8)	Decrease CO ₂ flow
(9)	Enters the Setup menu
(10)	Actual CO ₂ flow
(11)	Message area



(12)	Start/stop insufflation
(13)	Actual CO ₂ pressure
(14)	Current work mode (press to select the work mode)

4.2.2 Operating Modes

The equipment provides the following operating mode: High, Med, Low, and Custom.

4.2.3 Use in Surgery

After startup self-inspection and inspection process pass, the insufflator can be put to use.

1. Based on the type of the targeted patient, choose required pneumoperitoneum mode.
2. Adjust and set the flow and pressure. Each mode has its default upper limit and lower limit for flow and pressure, and adjustment cannot be made when it reaches the limits.
3. Tap the **[Start]** button and the insufflator starts to inflate; if you choose veress needle for first inflation, remember to take down the needle before starting the surgery officially, to avoid insufficient inflation during surgery to maintain pneumoperitoneum.
4. If no operation is performed for over 1 minute, the following unlocking bar will be displayed when you tap the screen. Press  and slide it to the  position on the right. The touchscreen is unlocked, and displays the main screen.



5. After the surgery is completed, tap the **[Stop]** button and the insufflator stops inflating.

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

- **It is forbidden to switch pneumoperitoneum mode during surgery.**
 - **Be sure to exhaust the residual gas in the pipeline after surgery.**
 - **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.**
-
-

4.2.4 Removing the System from Use

After the surgery or if system failure occurs, remove the system from use as indicated below:

1. Turn off the gas supply system. Since there is residual gas inside the pipeline, you need to start pneumoperitoneum inflation again, and wait until the residual gas is excluded from the pipeline before you stop inflation again.
2. Turn the equipment off.

Perform cleaning, disinfection, sterilization, and other maintenance as required by the local or your hospital's regulation.

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5 Maintenance, Storage, and Disposal

5.1 General Principle

1. There are accident reports recording the cross infection of patients caused by improper cleaning or sterilization in medical documents. It is strongly suggested that the person in charge of cleaning and sterilization thoroughly understand and abide by the hospital regulations and policies in his/her country and region.
2. Dedicated staff or team in the cleaning and sterilization department shall be assigned to take charge of the cleaning and sterilization of the device. It is strongly suggested to train backup personnel in case the person in charge is out.
3. All personnel in charge of cleaning and sterilization shall know: occupational health and safety rules, regulations and policies of national and local hospitals, stipulations in this Operator's Manual, mechanical knowledge of the device, label descriptions of long-acting sterilizing agent, and other relevant information.

5.2 Precautions

WARNING

- **The insufflator 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.**
- **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.**
- **Rinse thoroughly to remove the disinfectant. And the pipe fitting also needs to be thoroughly rinsed by using the water to remove all the residual disinfectant.**
- **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 Animal Medical 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 repetitive bacteria filter needs to be cleaned, disinfected, sterilized and properly stored according to the relevant laws and regulations after each use and before reuse. The filter needs to be replaced regularly according to its service life.
 - 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.
-
-

5.3 Cleaning, Sterilization and Discard

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.
-

WARNING

- **The power switch shall be turned off and the power cord shall be unplugged before cleaning.**
 - **Alcohol cannot be used as the sterilizing agent.**
-
-

This product has not been sterilized before shipping. Before first use, please perform cleaning and sterilization according to laws and regulations or infection control requirements.

After using the device, store it properly.

Partial and/or improper cleaning, sterilization and storage may cause infection control risks and lead to device damage or performance degradation.

Cleaning and sterilization methods recommended for this product are as follows:

- When cleaning the insufflator's casing, use wet cloth that has been soaked with clean water to scrub the insufflator's casing surface.
- When disinfecting the insufflator's casing, use wet cloth that has been soaked with recommended disinfectant to scrub the insufflator's casing surface.
- When the exterior of the repetitive filter is dirty, use clean cloth to scrub; the filter cannot be soaked with potion, otherwise it will be damaged.
- The insufflator tube can be sterilized with high-temperature and high-pressure steam.

5.3.1 Cleaning, Sterilization, Storage, and Discard of the Insufflator

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, AC power input port) contact liquids. Other-wise 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.**
-

5.3.1.1 The Selection of Cleanser and Disinfectant

Please use cleansers and disinfectants recommended by the manufacturer. Do not use cleanser repeatedly.

Cleansers and disinfectants recommended for this product are as follows:

Name	Manufacturer	Type	Applied to
Purified water	/	Liquid	Insufflator
Ethanol, 70% ~75%	/	Liquid	Insufflator
Isopropanol, 70%	/	Liquid	Insufflator
Sodium hypochlorite bleach, 0.5%	/	Liquid	Insufflator
Glutaraldehyde, 2%	/	Liquid	Insufflator
1-Propanol, 50%	/	Liquid	Insufflator
Hydrogen peroxide, 3%	/	Liquid	Insufflator
HEALTH ESSENCE Disinfecting Effervescent Tablets	Beijing ChangJiangMai Medical Science Technology Co. Ltd.	Tablets	Insufflator
Dismozon® plus, 0.4%	BODE Chemie GmbH	Powder	Insufflator
mikrozid® AF Wipes	Schülke & Mayr GmbH	Wipes	Insufflator
Terralin®	Schülke & Mayr GmbH	Wipes	Insufflator
Perform® Classic Concentrate OXY, 0.5%	Schülke & Mayr GmbH	Powder	Insufflator
mikrozid® PAA Wipes	Schülke & Mayr GmbH	Wipes	Insufflator
Clinell® Sporicidal Wipes	GAMA Healthcare Ltd	Wipes	Insufflator
Tristel Duo™	Tristel solutions Limited	Liquid	Insufflator
Tristel Jet	Tristel solutions Limited	Liquid	Insufflator
Tristel Fuse For Surfaces, 196ppm	Tristel solutions Limited	Liquid	Insufflator
Descosept® forte	Dr. Schumacher GmbH	Liquid	Insufflator
Descosept® AF	Dr. Schumacher GmbH	Liquid	Insufflator
Ecolab Incidin® OxyWipe S.	Antec International Ltd	Powder	Insufflator
Rely+On™ Virkon® High Level surface Disinfectant, 1%	ANAERON	Wipes	Insufflator
Neutral detergent wipes	RAYNARD Health	Wipes	Insufflator

Name	Manufacturer	Type	Applied to
Premier disinfectant wipes	Whiteley Medical	Wipes	Insufflator
V-wipes	Antec International Ltd	Wipes	Insufflator
Ultraviolet light	/	Radiation	Insufflator

5.3.1.2 Steps of Washing and Disinfection

1. Turn off the power switch of the insufflator, and disconnect the AC plug.
2. Use a clean, soft cloth dipped with a proper amount of purified water to remove dust, clay and other dirt on the device.
3. After cleaning, dry the device in a cool and ventilated environment.
4. Wipe the device surface with a cotton ball or a soft cloth dipped with disinfectant.
5. After disinfection, dry the device in a cool and ventilated environment.

5.3.1.3 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 CO₂ 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.**
1. Take down all power cords, and relax and zigzag them. Do not extrude or bend them when stored. If the device falls onto hard surfaces, it might be damaged.
 2. Disconnect from the CO₂ steel cylinder or the central gas supply pipe.

3. Place the device flatwise in clean, dry and stable indoor temperature environment.

5.3.1.4 Discard

When discarding the product, all applicable national and local laws and regulations shall be followed.

Applicable period:

On condition that this insufflator is used in accordance with the Operator's Manual, operating life is 10 years after delivery.

5.3.2 Cleaning, Sterilization, and Discard of the Insufflator 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.

5.3.2.1 The Selection of Cleanser

Please use cleansers recommended by the manufacturer. Do not use cleanser repeatedly.

Cleansers recommended for this product are as follows:

Name	Manufacturer	Type
Purified water	/	Liquid
MetriZyme®	METREX® RESEARCH	Enzymatic cleaner

5.3.2.2 Washing Steps

After each use, the following cleaning procedures shall be conducted immediately. If the cleaning cannot be conducted immediately, please immerse the pipe fitting in distilled water immediately to prevent dirt from drying, but the time should not exceed 24 hours.

1. Disassemble the pipe fitting to its basic structure. As shown in Figure 5-1, Figure 5-2, and Figure 5-3.

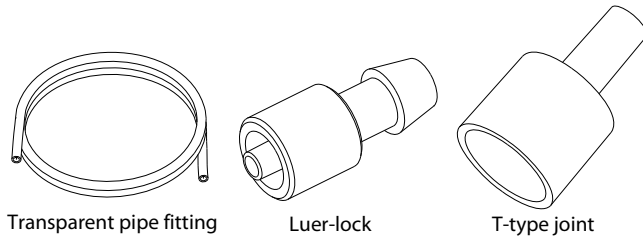


Figure 5-1 Disassembly of the insufflator tube

2. Pour new cleanser into the cleaning container at a temperature and a concentration recommended by the manufacturer of the cleanser.
3. Soak the pipe fitting in the container with cleanser. For example, use the 3M multi-enzyme cleaning cleanser, 10mL cleanser/ 2L deionized or distilled water, immersed for 2mins, 25°C.
4. Use clean lint-free cloth to clean the outside surface in the solution.
5. Use an injector to inject the cleanser into the pipe fitting, and thoroughly wash the pipe fitting to clean its inside surface. As shown in Figure 5-2.
6. Soak the pipe fitting with time and temperature recommended by the manufacturer of the cleanser.
7. Take the pipe fitting out of the solution, and put it in clean water.
8. Use clean lint-free cloth to clean the outside surface in the clean water.

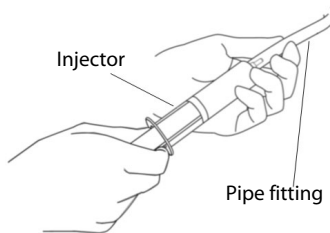


Figure 5-2 Use injector to clean the pipe fitting

9. Take the pipe fitting out of the clean water.
10. Use injector to inject air to eliminate the liquid inside the pipe fitting.
11. Use clean lint-free to wipe the outside surface dry.

5.3.2.3 The Selection of Disinfectant

Please use disinfectants that conforms to the license of the country or region, that meets requirements of medical administrative departments, and that are line with Mindray Animal Medical claims.

When using the disinfectant, its usage time, temperature and concentration shall comply with the disinfectant manufacturer's suggestion on advanced disinfection. If the disinfectant is used repeatedly, its effectiveness shall be checked regularly using test paper recommended by the manufacturer. Do not use disinfectant that has passed its expiration date.

Disinfectants recommended for this product are as follows:

Name	Manufacturer	Type
Ethanol, 70%~75%	/	Liquid
Glutaraldehyde, 2%	/	Liquid

5.3.2.4 Disinfection Operations

1. According to the instructions of the disinfectant manufacturer, adjust the concentration and temperature of the disinfectant.
2. Soak the pipe fitting in the container with disinfectant solution.
3. Use sterile lint-free cloth to clean the outside surface in the disinfectant solution.
4. Install the injector on the pipe fitting, and use the disinfectant solution to thoroughly wash the pipe fitting to clean its interior. As shown in Figure 5-2.
5. Soak the pipe fitting with time and temperature recommended by the manufacturer of the disinfectant.

5.3.2.5 The Selection of Water Used for Washing

Once the pipe fitting is taken out of the disinfectant solution, the insufflator tube shall be thoroughly washed with sterile water. Remove the residual disinfectant. Do not use the washing water repeatedly. If there is no sterile water, please consult related infection control department of the hospital.

5.3.2.6 Washing Steps

1. Take the pipe fitting out of the disinfectant solution, and soak it in the sterile water.
2. Install the injector on the pipe fitting, and use the sterile water to thoroughly wash the pipe fitting.
3. Gently churn the pipe fitting, washing it thoroughly.
4. Take the pipe fitting out of the sterile water.
5. Install the injector on the pipe fitting, and inject air to eliminate water inside the pipe fitting. As shown in Figure 5-2.

6. Use sterile lint-free to wipe the outside surface dry.

5.3.2.7 Requirements for Sterilization

The disassembled parts of the pipe fitting need to be reassembled before sterilization.

The high-temperature and high-pressure sterilization supported for the pipe fitting meets the requirements of WS/T 367-2012 Technical Code of Disinfection for Medical Institutions.

Highest temperature	Sterilization time
134°C	4 min

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°C, otherwise it might cause damage to the pipe fitting or reduction of service life.**
-

5.3.2.8 Steps of Sterilization

1. Before sterilization, put the pipe fitting inside the sterilization box, and pack it with sterilization pouch or sterilization cloth.
2. According to regulations of the hospital, seal the pipe fitting that needs to be sterilized in a package suitable for high-temperature and high-pressure sterilization. It is recommended to choose dedicated surgical instruments to sterilized the sterilization cloth (pouch).
3. Perform high-temperature and high-pressure sterilization on the package in accordance with the sterilization requirements of the device and the operating manual of the sterilization instrument manufacturer.
4. After high-temperature and high-pressure sterilization, let all components cool to room temperature gradually.

5.3.2.9 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.**
-

5.3.2.10 Discard

When discarding the product, all applicable national and local laws and regulations shall be followed.

Applicable period:

On condition that the insufflator tube is used in accordance with the Operator's Manual, it can be used for sterilization 100 times.

5.3.3 Cleaning, Sterilization, Storage, and Discard of the Repetitive Filter

NOTE

- **If the filter housing or filter cotton is found damaged or has visible foreign matter, please do not use them.**
 - **Before each use, be sure to perform cleaning and sterilization.**
 - **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.**
 - **Do not use disinfectants or medicines to disinfect the filter, do not soak the filter in potion, and do not use ethylene oxide to sterilize it!**
 - **The filter cannot be used if its resistance coefficient is greater than 4cmH2O.**
 - **Please use the filter according to doctor's advice.**
-

5.3.3.1 Cleaning and Sterilization

1. When the exterior of the filter is dirty, use clean cloth to scrub.
2. Before sterilization, the filter shall be packed with sterile cloth.
3. Conduct sterilization on the basis of the following parameters:

Sterilization temperature	Sterilization pressure	Sterilization time
121°C	1 bar	30 min

5.3.3.2 Storage After Sterilization

NOTE

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

5.3.3.3 Discard

When discarding the product, all applicable national and local laws and regulations shall be followed.

Applicable period:

On condition that the filter is used in accordance with the Operator's Manual, it can be used for sterilization 25 times or has a life of one year, whichever comes first.

Storage life: 3 years from manufacture date.

5.4 Maintenance and Modification

The power needs to be shut off to disassemble the machine. This product does not contain any parts repairable by users themselves, and non-professionals cannot repair it.

Do not disassemble, modify the machine or try to repair; otherwise the patient or operator might get injured and/or the device might be damaged.

For certain problems not caused by dysfunction, refer to *6 Troubleshooting* for resolutions. If the problem still can't be solved, please contact Mindray Animal Medical.

6 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 Animal Medical.**
 - **Some problems that are not related with the product malfunction can be resolved by consulting 6.1 *Fault Analysis and Clearing*. After troubleshooting according to the stated solution, if the problem still persists, please stop using this device, and send it back to Mindray Animal Medical 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 Animal Medical for repair.**
-
-

NOTE

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

6.1 Fault Analysis and Clearing

For common minor faults and solutions for the equipment, the operator can troubleshoot them or contact the maintenance staff designated by Mindray Animal Medical.

Symptom	Possible cause	Solution
System power supply can't connect or LCD screen doesn't display	Power cord of the insufflator is not connected.	Connect power cord of the insufflator.
	Power cord is damaged.	Replace the power cord.
	Power distribution panel in the operating room is turned off.	Turn on the power distribution panel.
	Power cord such as that of the trolley is not connected.	Connect the power cord such as that of the trolley.
	Power cord of the trolley is broken off.	Replace a new power cord.
	The power switch of the trolley is off.	Turn on the power switch.
	Fuse is blown.	Press the fuse holder lock to extract the fuse holder, replace the fuse, and then push the holder back to its original position.
	Circuit breaker of the trolley power supply is triggered.	Restore the circuit breaker of the trolley power supply.

Symptom	Possible cause	Solution
Cannot inject gas	The gas injection switch is not pressed.	Press the gas injection switch.
	The gas cylinder valve is closed.	Open the gas cylinder valve.
	The high pressure tube or medical gas pipeline hose is not connected.	Correctly connect the high pressure tube or medical gas pipeline hose.
	The gas cylinder is not upright. (Liquid CO ₂ entered the device and froze the pipeline)	Place the gas cylinder at a upright position. Turn on the power switch and wait for 5 minutes or longer before operation.
	Remaining gas in the gas cylinder is not enough.	Replace the gas cylinder.
	The pressure of CO ₂ central gas source is insufficient.	Restore the CO ₂ central gas supply.
	The insufflator tube is not connected.	Connect the insufflator tube.
	Cannot inject gas. The insufflator tube is bended.	Straighten bended part of the insufflator tube.
	There is a hole in the insufflator tube.	Replace a new insufflator tube.
	The valve of veress needle or perforator is closed.	Open the valve of veress needle or perforator.
	Veress needle or perforator is inserted incorrectly.	Pull the veress needle or perforator out and reinsert it.
	Veress needle or perforator is damaged.	Replace a new veress needle or perforator.
	The gas is injected into narrow cavity.	Pull the veress needle or perforator out and correctly insert it.
	The filter is blocked.	Replace the filter.
Cannot open exhaust valve	Exhaust valve is set to Off.	Allow the exhaust valve to be opened in Settings.
Contamination	Liquid enters the device from the inflation port.	Contact Mindary or the distributor.

Symptom	Possible cause	Solution
Prompt tone of overpressure rings continuously	Excessive gas from other devices are released.	Reduce the gas amount released from other devices.
	Anesthesia of the patient loses efficacy.	Handle it properly.
Prompt tone of pipeline blocking rings continuously	The valve of veress needle or perforator is closed.	Open the valve of veress needle or perforator.
	Veress needle or perforator is inserted incorrectly.	Pull the veress needle or perforator out and reinsert it.
	Veress needle or perforator is damaged.	Replace a new veress needle or perforator.
	The filter is blocked.	Replace a new filter.
	The insufflator tube is bended.	Straighten bended part of the insufflator tube.
Prompt tone of insufficient gas supply rings continuously	Valve of the gas cylinder is closed.	Open the gas cylinder valve.
	Remaining gas in the gas cylinder is not enough.	Replace a new gas cylinder.
	The filter at the gas inlet is blocked.	Replace the filter at the gas inlet.
	The high pressure tube or medical gas pipeline hose is not connected.	Correctly connect the high pressure tube or medical gas pipeline hose.
	The pressure of CO ₂ central gas source is too low.	Restore the CO ₂ central gas supply.
Self-inspection failure	The internal system of the insufflator is faulty, and the screen prompts nothing listed above.	Turn off the insufflator and open it again. If prompt tone rings continuously, please contact Mindray Animal Medical.
LCD screen prompts other faults	Peripheral equipment is not connected properly, or there is fault inside the insufflator.	Resolve the faults according to the LCD screen prompts. If the issue can't be solved, turn off the insufflator and open it again. If prompt shows up continuously, please contact Mindray Animal Medical.

6.2 Common Prompts and Their Triggering Conditions

"Audio prompt" in the table below indicates times the buzzer rings;

"Text prompt" indicates text information shown on the display screen.

Text prompt	Triggering condition	Audio prompt
OverPressure	Pressure exceeds the set value, 5mmHg.	Yes
Gas Supply ?	Cylinder supply mode: Pressure is lower than 1Mpa. Central gas supply: Pressure is lower than 0.1Mpa.	Yes
Occlusion	The insufflator tube is bended, or the valve of veress needle or perforator is closed.	Yes
Contamination	Liquid enters the device from the inflation port.	Yes
Overpressure Relief	Pressure exceeds the set value, 5mmHg.	Yes

6.3 Return for Repair of the Insufflator

NOTE

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

Before the device is returned for repair, please contact Mindray Animal Medical. When returning for repair, attach instructions regarding device faults or damage and the warranty card.

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7 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.**
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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.**
-

Part No.	Description
0020-20-12524	Power cord (EU, 2.5 m)
0020-20-12522	Power cord (International, 250 V, 10 A, 2.5 m)
0020-20-12523	Power cord (US, 110 V, 13 A, 2.5 m)
009-000567-00	Power cord (US, 110 V, 13 A, 2.5 m)
009-001075-00	Power cord (Brazil, 250 V, 10 A, 3 m)
DA8K-10-14453	Power cord (UK)
0000-10-10903	Power cord (India, 1.8 m)
009-001791-00	Power cord (South Africa, 250 V, 16 A, 3 m)
009-004940-00	Power cord (Australia)
009-008233-00	Serial port cable
1000-21-00122	Grounding cable

Part No.	Description
M07-00130F---	FUSE Time-lag 250V 3.15AD5X20
115-050308-00	Reusable insufflator tube
082-002806-00	Central gas supply pipe (German)
082-002807-00	Central gas supply pipe (DISS)
082-002808-00	Central gas supply pipe (Japan)
040-001571-00	Disposable bacterial filter, large size
082-002970-00	Reducing valve filter kit, 5um
095-003190-00	Wrench
040-004013-00	Reusable connector, straight, 22-10
082-003735-00	CO ₂ hight pressure tube (CGA320)
082-003736-00	CO ₂ hight pressure tube (DIN477)
082-003737-00	CO ₂ hight pressure tube (YORK940)
082-003738-00	CO ₂ hight pressure tube (ISO5145)
082-003784-00	CO ₂ hight pressure tube (BS341)
082-003739-00	Pressure regulator, 452C-150 (CGA320)
082-003740-00	Pressure regulator, 452C-150 (DIN477)
082-003742-00	Pressure regulator, 452C-150 (YORK940)
082-003743-00	Pressure regulator, 452C-150 (ISO5145)
082-003785-00	Pressure regulator, 452C-150 (BS341)
082-003734-00	CO ₂ low pressure tube (DISS)

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%
Flow adjustment range	0.1-30 L/min
Gas source monitoring	Prompt of low gas pressure Prompt of gas exhaust

A.2 Safety Specifications

Protection against electric shock type	Class I equipment powered by external power supply
Protection against electrical shock level	Type CF applied part
Liquid inlet protection class	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
GB 4824-2013	Group 1 Class A

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~
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 Width (left to right): 350 mm 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	30 L/min

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B EMC

Vetina GS3 insufflators comply with the EMC standard IEC 60601-1-2: 2014.

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 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 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 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 IEC 61000-3-2	Class A	
Voltage Fluctuations/ Flicker Emissions 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.**
- **Portable and mobile RF communications equipment can affects system. See tables 1, 2, 3, and 4 below.**


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

TABLE 2

GUIDANCE AND 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) IEC 61000-4-2	±8 kV contact; ±15 kV air	±8 kV contact; ±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 IEC 61000-4-4	±2 kV for power supply lines; ±1 kV for input/output lines	±2 kV for power supply lines; ±1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV line(s) to line(s); ±2 kV line(s) to earth	±1 kV line(s) to line(s); ±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 IEC 61000-4-11	0% U_T ; 0,5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0% U_T ; 1 cycle 70% U_T for 25/30 cycle at 0° 0% U_T ; 250/300 cycle	0% U_T ; 0,5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0% U_T ; 1 cycle 70% U_T for 25/30 cycle at 0° 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 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 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
Conducted RF IEC 61000-4-6	3 Vrms 0,15 MHz – 80 MHz 6 Vrms in ISM and amateur radio bands between 0,15 MHz and 80 MHz	3 Vrms 0,15 MHz – 80 MHz 6 Vrms in ISM and amateur radio 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 $d = 1.2 \times \sqrt{P}$ $d = 1.2 \times \sqrt{P}$ 80 MHz to 800 MHz $d = 2.3 \times \sqrt{P}$ 800 MHz to 2.7GHz 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). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey ^a , should be less than the compliance level in each frequency range ^b . Interference may occur in the vicinity of equipment marked with the following symbol: 
Radiated RF IEC 61000-4-3	10 V/m 80MHz - 2.7GHz	10 V/m 80MHz - 2.7GHz	
Proximity fields from RF wireless communications equipment IEC 61000-4-3	27 V/m 380–390 MHz 28 V/m 430–470 MHz, 800–960 MHz, 1700–1990 MHz, 2400–2570 MHz 9 V/m 704–787 MHz, 5100–5800 MHz	27 V/m 28 V/m 9 V/m	

Note 1: At 80 MHz and 800 MHz, 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.

^a: 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 system is used exceeds the applicable RF compliance level above, system should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the system.

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

TABLE 4

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 $d=1.2 \sqrt{P}$	80MHz-800MHz $d=0.12 \sqrt{P}$	800MHz-2.7GHz $d=2.3 \sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters at a maximum output power not listed above, the recommended separation distance 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.

If system image distortion occurs, it may be necessary to position system further from sources of conducted RF noise or to install external power source filter to minimize RF noise to an acceptable level.

Note 1: 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.

C Units and Symbols

C.1 Units

Abbreviation	In Full
°	angle
A	ampere
°C	centigrade
cm	centimeter
g	gram
h	hour
Hz	hertz
hPa	hectopascal
k	kilo-
kg	kilogram
kPa	kilopascal
L	litre
lp/mm	lines pair per millimeter
lx	Illuminance
m	meter
min	minute
ml	milliliter
mm	millimeter
mmHg	millimeter of mercury
s	second
V	volt
VA	Volt ampere
Ω	ohm
μA	microampere
μV	microvolt
W	watt

C.2 Symbols

Symbol	Explanation
-	minus
%	percent
/	per, divide, or
~	to
^	power
+	plus
=	equal to
<	less than
>	greater than
≤	less than or equal to
≥	greater than or equal to
±	plus or minus
x	multiply
©	copyright

