## LAP13-4Cs

# Ultrasonic Laparoscopic Transducer

## Operator’s Manual

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For this Operator's Manual, the issue date is 2023-11.

# Introduction

This operator's manual describes the operating procedure for the LAP13-4Cs transducer. To ensure safe and correct operation of the transducer, read the operator's manual carefully and understand the transducers clearly before operation.

For the operating procedures for the ultrasonic diagnostic system and other devices, please refer to the relevant manuals.

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- all installation operations, expansions, changes, modifications and repairs of this product are conducted by Mindray authorized personnel;
- the electrical installation of the relevant room complies with the applicable national and local requirements; and
- the product is used in accordance with the instructions for use.

## Note

This equipment must be operated by skilled/trained clinical professionals.

## Warning

It is important for the hospital or organization that employs this equipment to carry out a reasonable service/maintenance plan. Neglect of this may result in machine breakdown or personal injury.

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- Malfunction or damage caused by force majeure such as fire and earthquake.
- Malfunction or damage caused by improper operation or repair by unauthorized service people.
- Malfunction of the instrument or part whose serial number is not legible.
- Others not caused by instrument or part itself.

# Customer Service Department

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|---|---|
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| | |
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| Toll Free: | +1 (800) 288-2121 |
| Fax: | +1 (800) 926-4275 |

# Important Information: Customer Responsibility

- The responsibility for maintenance and management of the product after delivery resides with the customer who has purchased the product.
- When the transducer is sent to MINDRAY for warranty or repair, you must disinfect it and keep it in the original shipping/carrying case to prevent infection.
- The warranty does not cover:
  - Damage to the transducer due to patient biting,
  - Damage to the transducer caused by disinfecting incorrectly or with chemicals not recommended by Mindray
- The warranty will be void if the transducer is not returned in its original Mindray carrying case.
- This equipment shall not be used by persons other than fully qualified and certified medical personnel.
- Do not make changes or modifications to the software or hardware of this product.
- In no event shall MINDRAY be liable for problems, damage, or loss caused by relocation, modification, or repair performed by personnel other than those designated by MINDRAY.
- The purpose of this system is to provide physicians with data for clinical diagnosis. The responsibility for diagnostic procedures lies with the physicians involved. MINDRAY shall not be liable for the results of diagnostic procedures.

- MINDRAY shall not be liable for loss of data stored in the memory of this system caused by operator error or accidents.
- This manual contains Warnings regarding foreseeable potential dangers. Be alert at all times to dangers other than those indicated. MINDRAY shall not be liable for damage or loss that results from negligence or from ignoring the precautions and operating instructions contained in this operator's manual.
- On the occasion of change of the administrator or manager for this system, be sure to hand over this operator's manual.
- When disposing of this system, contact your MINDRAY Customer Service Department or sales representative. Do not dispose of this system without consulting MINDRAY Customer Service Department or sales representative first. MINDRAY does not assume any responsibility for damage resulting from disposal of this system without consulting MINDRAY. A replacement transducer will not be sent to customer until the defective transducer is received.

# Meaning of Signal Words

In this operator's manual, ⚠ **DANGER**, ⚠ **WARNING**, ⚠ **CAUTION** and **NOTE** are signal words used to indicate safety and other important instructions. The signal words and their meanings are defined as follows. Please understand their meanings clearly before reading this manual.

| Signal Word | Meaning |
|---|---|
| ⚠ DANGER | Indicates an imminently hazardous situation that, if not avoided, will result in death or serious injury. |
| ⚠ WARNING | Indicates a potentially hazardous situation that, if not avoided, could result in death or serious injury. |
| ⚠ CAUTION | Indicates a potentially hazardous situation that, if not avoided, may result in minor or moderate injury. |
| NOTE | Indicates a potentially hazardous situation that, if not avoided, may result in property damage. |

# 1 Safety Information

## 1.1 Safety Classification

Please refer to the safety classification information in the related operator's manual for the ultrasonic diagnostic system that matches with this transducer.

## 1.2 Safety Precautions

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

### ⚠ DANGER

**DO NOT use flammable gases, such as anesthetic gas or hydrogen, or flammable liquids such as ethanol, near this system, because there is danger of explosion.**

### ⚠ WARNING

- **This ultrasonic transducer is only for use with the specified diagnostic ultrasound system. Please refer the diagnostic ultrasound system operation manual to select the proper transducer.**
- **The laparoscopic transducer should be used only by a qualified physician who has received appropriate training in proper operation of the transducer and in endoscopic techniques as dictated by current relevant medical practices.**
- **The laparoscopic transducer is a precision instrument, which must be handled with care. It may be damaged when dropped or abused. In particular, do not allow the ultrasonic window in the tip to come into contact with a sharp object. Do not touch this window unnecessarily. Never exert force onto the window.**
- **To avoid injury to the patient, if any irregularity, substandard function or unsafe condition is observed or suspected, the laparoscopic transducer should not be used.**
- **The insertion part of the transducer meets the water-proof requirements for soaking sterilization. However the control handle and transducer connector are not water-proof. Keep the control handle and transducer connector out of any cleaning or sterilization solutions.**
- **DO NOT use the laparoscopic probe with the defibrillator.**
- **To avoid injury to the patient, avoid forceful intubation pressure.**

- **The deflection may after prolonged use develop an unwanted amount of free play. In that case, contact the Mindray Customer Service Department or sales representative to readjust the steering of the transducer.**
- **Confirm that the transducer and cable are normal before and after each examination. A defective transducer may cause electric shock to the patient.**
- **When using intra-cavity transducers, do not activate the transducer outside the patient's body.**
- **The connector is not watertight, and should always be kept dry. The control unit, although spray-watertight, should not be immersed.**
- **Do not subject the transducer to shock. A defective transducer may cause electric shock to the patient.**
- **This equipment contains no operator serviceable components. To prevent electric shock, do not remove any covers or panels.**

## ⚠ CAUTION

- **When using this transducer, wearing medical gloves can help to prevent infection.**
- **To avoid inadvertent damage to the transducer, read this user guide before handling and cleaning the laparoscopic transducer.**
- **Be sure to use sterile ultrasound gel during operation. Please use the ultrasound gel compliant with the relevant local regulations. Proper management and use of the ultrasound gel is essential to ensure that it will not become a source of infection.**

  **Only use water-based coupling gel.**
- **Under normal conditions at full acoustic power the temperature of the tip does not exceed 41°C. Follow the instruction in this user manual to check this regularly.**
- **If the laparoscopic probe is faulty, freeze the image and stop using the transducer, and then slowly remove the transducer from the patient. Do not use the laparoscopic transducer before maintenance.**
- **Before each use or after a change of viewing modes/settings, pay attention to the status of the ultrasound image. Do not use the probe to perform image acquisition when the image is frozen. Ensure that the orientation of the ultrasound image is correct. Check the orientation prior to the examination**
- **Before each use, the outer surface of the portions of laparoscopic probe which are intended to be inserted into a PATIENT should be checked to ensure there are no unintended rough surfaces, sharp edges or protrusions which may cause HARM.**
- **Do not use the carrying case for storing the transducer. If the carrying case is used for storage, it may become a source of infection.**
- **It is required to practice ALARA when operating ultrasound system. Minimize the acoustic power without compromising the quality of images.**

- **The transducer and accessories supplied with it are not delivered sterilized. Sterilization is recommended before use.**
- **Disposable components are packaged sterile and are single-use only. Do not use if integrity of packaging violated or if expiration date has passed. Please use the disposable components compliant with the relevant local regulations.**
- **Please use the sterilization solution that recommended in this operator's manual, otherwise Mindray will not be liable for damage caused by other solutions. If you have any questions, please contact Mindray Customer Service Department or sales representative.**
- **Before introducing the transducer: do not rub or spray the tip of the transducer with an anesthetic agent.**
- **The damage of the transducer may be caused by the contact of improper gel or cleaner:**
  - **DO NOT dip the transducer in the strong polar solutions of ethanol, chloride of lime, ammonium chloride, acetone and formaldehyde.**
  - **DO NOT contact the transducer with solution or ultrasound gel containing oily medium such as mineral oil or lanoline.**

**NOTE:**

- **Read the following precautions to prevent the transducer from malfunction.**
  - **Before connecting or disconnecting the transducer, freeze or turn off the ultrasonic diagnostic system.**
  - **Clean and sterilize the transducer before and after each examination.**
- **Repeated sterilization will eventually damage the transducer, please check the transducer's performance periodically.**

## 1.3 Symbols

This system uses the symbols listed in the following table. Their meanings are explained as follows.

| Symbol | Description |
|---|---|
|  | General warning sign |
|  | Type-BF applied part |
| SN | Serial number |
|  | Date of manufacture |
|  | Manufacturer |
| IPX7 | Protection against temporary immersion in water |
| EC REP | Authorized representative in the European Community |
| CE 0123 | Comply with the requirements of the Council Directive 93/42/EEC (Medical Device Directive). |
|  | Temperature limit |
|  | Humidity limitation |
|  | Atmospheric pressure limitation |

# 2 Overview

## 2.1 Applications

The laparoscopic transducer is used together with the diagnostic ultrasound system, and is intended for clinical ultrasound diagnosis and examination. Refer to the operator’s manual of the diagnostic ultrasound system.

## 2.2 Operator Qualification

This manual only introduces the application of laparoscopic transducer in abdominal surgery. The actual techniques for introduction of the laparoscopic transducer into the patient are beyond the scope of the user guide. There are numerous medical texts and articles which thoroughly address this topic.

Intended users of the product shall be the medical workers who have taken training of laparoscopic technique and thoroughly mastered the laparoscopic operation technology.

## 2.3 Acoustic Output

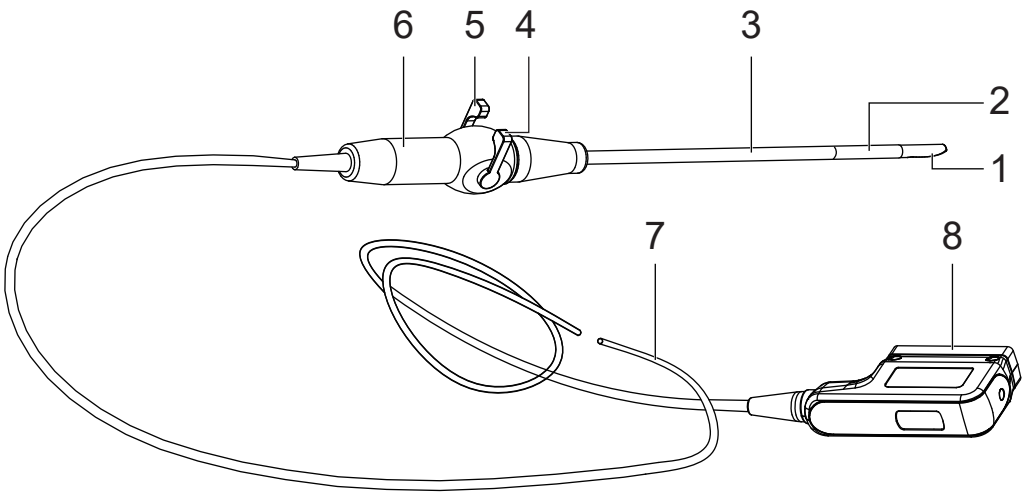
Although there are no confirmed biological effects on patients caused by exposures from present diagnostic ultrasound instruments, the possibility exists that such biological effects may be identified in the future. It is required to practice ALARA when operating diagnostic ultrasound system.

Refer to the operator’s manual of the diagnostic ultrasound system.

## 2.4 Introduction of Each Parts

The ultrasonic probe is a type of electroacoustic transducer. It is a key component of the ultrasound system. The transducer consists of connector, cable, handle and acoustic head.

The laparoscopic probe is equipped with a convex array transducer, which is installed on the distal end of the probe. The laparoscopic probe can be inserted into the abdominal cavity of the patient through trocar, and then be placed against the patient organs to acquire ultrasound images of multiple sections and in different modes. You can adjust the distal tip deflection using the deflection lever on the control handle of the laparoscopic probe, so as to obtain an appropriate position in the abdominal cavity for ultrasound exam or biopsy guide.




| No. | Name | Function |
|---|---|---|
| 1 | Distal tip with transducer | Converts the electrical signal into an ultrasonic signal, focusing the sound beams in a given direction; meanwhile, it receives the reflected ultrasonic signal and converts it into an electrical signal for transmission over the cable. The lens on the surface is the acoustic lens. Apply ultrasound gel on the acoustic lens for correct operation. |
| 2 | Deflection section | Deflects the distal tip to obtain an overall scanning. |
| 3 | Hard shaft | Inserts into the abdominal cavity. |
| 4 | Left/Right deflection lever | Controls left/right deflection of the distal tip. |
| 5 | Up/Down deflection lever | Controls up/down deflection of the distal tip. |
| 6 | Control handle | Operates on the transducer deflection. |
| 7 | Cable | Transmits electrical signals between the transducer head and connector. |
| 8 | Connector | Connects the transducer to the diagnostic ultrasound system. |

## 2.5 Tip Deflection Control

### ⚠ WARNING

- **To avoid damaging the transducer, do not deflect the transducer tip using finger pressure directly on the tip, as this may permanently damage the internal control wires.**
- **When removing and covering the probe protective foam sleeve, make sure that the probe tip is straight. Do not apply excessive force on the probe tip. Otherwise, the probe may be damaged.**

- **The deflection may after prolonged use develop an unwanted amount of free play. In that case, contact the Mindray Customer Service Department or sales representative to readjust the steering of the transducer.**
- **Be sure to use the deflection lever to control the tip deflection of the probe. Do not forcibly perform the deflection.**

Deflect the distal tip in both up/down and left/right directions using the deflection levers on the handle of the LAP13-4Cs probe, so that the distal tip can be placed against the patient organs. The distal tip can be deflected up to 90° (tolerance: -5°~10°) in four planes of up, down, left and right.

When the two deflection levers are both vertical to the handle, the distal tip will return to the middle position.

**Figure 2-1 Left/Right Deflection**

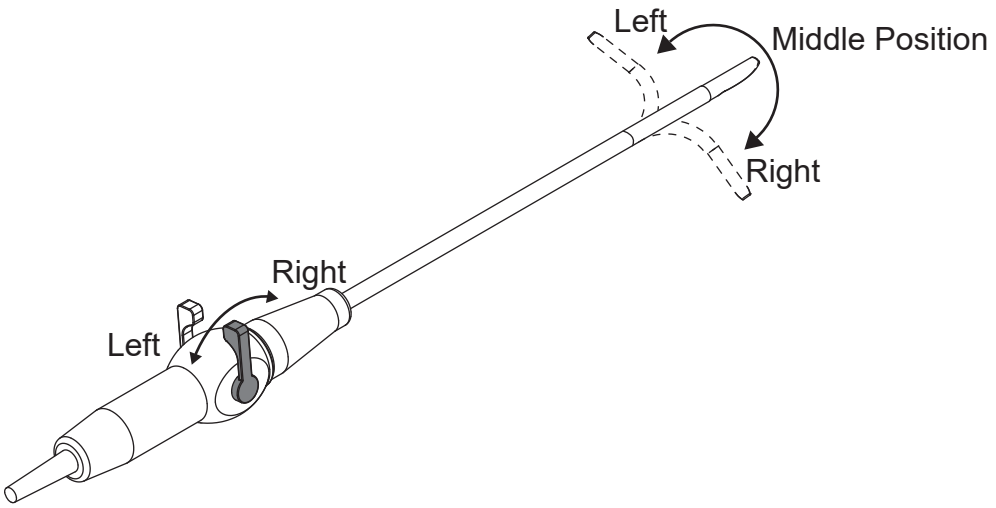
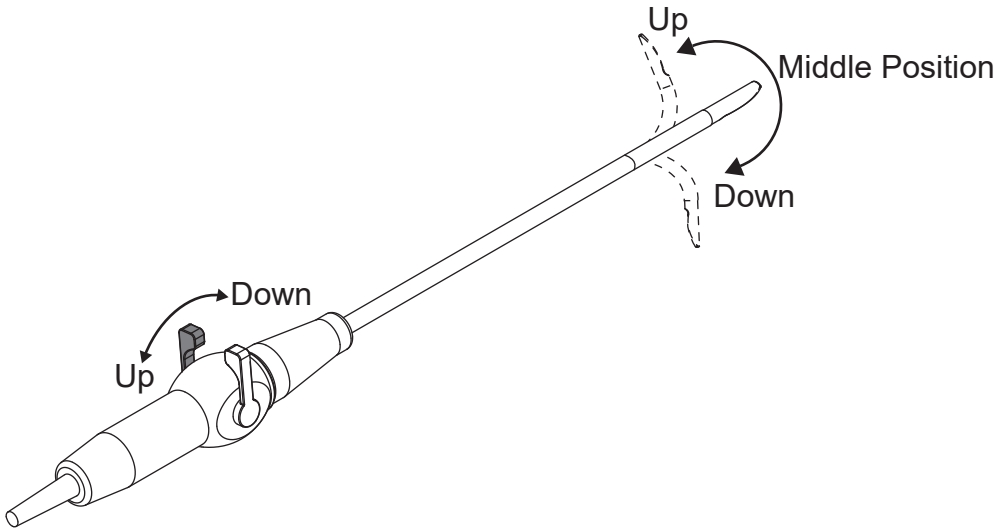



**Figure 2-2 Up/Down Deflection**



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# 3 Getting Started

## 3.1 Unpacking and Checking

Before unpacking, examine the packing case carefully for signs of damage. If any damage is detected, contact the carrier immediately.

Open the package and remove the equipment and accessories carefully. Check all materials according to the packing list and check if any mechanical damage exists. Contact Mindray in case of any problems.

The following items are supplied with each transducer.

| Item | Quantity | Description |
|---|---|---|
| Ultrasonic probe | 1 | Includes probe protective foam sleeve, which is used to seal and protect the probe insertion part from being exposed to mechanical strain during transportation and storage. |
| Operator's Manual | 1 | / |
| Probe connector seal cover | 1 | Prevents liquid splashing during cleaning and sterilization. |
| Carrying case | 1 | / |

## 3.2 Inspection before Use

The mechanical operation and physical integrity of the transducer should be checked after taking it out of the box and prior to each exam. If any abnormality is found, immediately stop using the transducer and contact MINDRAY Customer Service Department or sales representative.

### ⚠ WARNING

- **To avoid injury to the patient, if any irregularity, substandard function or unsafe condition is observed or suspected, the laparoscopic transducer should not be used.**
- **To avoid injury to the patient, do not use the transducer if any metallic protrusions, holes, rough spots, cracks, or dents are found.**

### 3.2.1 Visual Inspection

Perform the following procedure:

1. Before each use, visually inspect and touch all surfaces of the hard shaft and deflection part while the instrument is kept straight and deflected. If any metal bulges, holes or large dents are found, do not use the probe.

2. Check the distal end of the probe to see if it is secure and if there are holes or large dents.
3. Check the surface of the probe or cable sheath for any abnormalities, such as peeling, cracks, protrusions, etc.

### 3.2.2 Tip Deflection Inspection

**Check the mechanical operation performance of the probe. Use the deflection lever to adjust the tip position to ensure smooth deflection.**

Perform the following procedure:

1. Deflect the tip in all four directions and confirm that the angle is within the ranges specified (with reference to the endoscope shaft). For details, see "2.5 Tip Deflection Control".
2. Confirm that the deflection controls operate smoothly.
3. Check that when the deflection controls are in the middle position that the transducer tip is also in a middle position (undeflected).

# 4 Examination

The operator should have adequate clinical experience and received related training.

### ⚠ WARNING

**The physician must take into account all possible factors before starting the examination.**

## 4.1 Couple Gel, Sheath

### 4.1.1 Couple Gel

Apply a sufficient amount of water-soluble acoustic coupling gel on the transducer acoustic window.

### ⚠ CAUTION

- **Only use water-soluble acoustic coupling gel. Other coupling gels containing ingredients like ethanol, mineral oil, Iodine, lotions, lanolin, aloe vera or methyl or ethyl parabenzoic acid can cause transducer damage.**
- **Be sure to use sterile ultrasound gel during operation. Please use the ultrasound gel compliant with the relevant local regulations. Proper management and use of the ultrasound gel is essential to ensure that it will not become a source of infection.**

### 4.1.2 Sheath

For patient protection, a sterile, single-use, latex sheath can be used over the transducer before performing examination. Use a commercially available transducer sheath.

If used, place the latex sheath over the transducer and laparoscope shaft up to but not covering the handle. Rub the tip carefully to ensure that all air bubbles have been removed from the transducer's acoustic window area. In addition to the gel on the acoustic window, apply a sufficient amount of acoustic coupling gel on the outside of the sheath at the tip of the transducer.

To order a transducer sheath, you may contact:

CIVCO Medical Instruments Co.

102 First Street South, Kalona, IA 52247-9589 USA

E-mail: info@civco.com

http://www.civco.com

Call 1-800-445-6741 within the United States or 1-319-656-4447 outside of the United States. To fax orders call: 1-319-656-4451

For details, please contact your local Mindray representative for assistance.

### ⚠ CAUTION

- **Be sure to cover the transducer with a new (unused) transducer sheath to prevent infection during examination. If the package of a transducer sheath is open or broken, the sterilization of the transducer sheath may not be sufficient. Do not use such a transducer sheath.**
- **The sheath contains natural rubber latex and talc that can cause allergic reactions in some individuals. In the USA, refer to FDA Medical Alert MDA91-1.**

Perform the following procedure:

1. Place an appropriate amount of gel inside sheath or on the transducer surface. Poor imaging may result if no gel is used.
2. Insert the transducer into the sheath. Make sure the transducer is sterile during the insertion. Pull sheath tightly over transducer surface to remove wrinkles and air bubbles, and take care to avoid puncturing the sheath.
3. Secure sheath with the enclosed elastic bands.
4. Inspect the sheath to ensure there are no holes or tears.

## 4.2 Intra-Operative Examination

The operator should adopt proper ultrasonic scanning procedures and methods according to different target organs.

Perform the following procedure:

1. Complete necessary preoperative examinations and preparations.
2. Connect the laparoscopic probe to the diagnostic ultrasound system and select an appropriate exam mode.
3. Insert the laparoscopic probe into the abdominal cavity of the patient through trocar, and then deflect the distal tip using the deflection levers to fit the patient organs at a proper bending angle, and move the probe properly to acquire ultrasound images of different sections.
4. Add markers, confirm the position, and perform biopsy guide.
5. After the examination, adjust the lever to deflect the distal tip to the middle position, take out the probe carefully, shut down the diagnostic ultrasound system, and then clean and sterilize the probe.

   For details, see "5 Cleaning and Sterilization". Keep the sterilized probes properly for reuse.

### ⚠ CAUTION

- **To avoid damage to the probe, ensure that the probe is not deflected mechanically before inserting the probe into the trocar.**

- **To avoid damage to the probe, ensure that the distal tip is always in the middle position when inserting the probe into the trocar.**
- **To avoid injury to the patient, do not use excessive force during insertion, positioning, or withdrawal.**

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# 5 Cleaning and Sterilization

This section describes the methods and precautions for cleaning and sterilization of laparoscopic probes. After completing each examination, clean, sterilize the laparoscopic probes as required. If necessary, repeat the cleaning, sterilization process before next use.

## ⚠ WARNING

- **Keep the control handle and system connector out of any cleaning or sterilant solutions. The control handle and cable may be cleaned with a damp cloth, but only the distal end of the transducer up to the hard shaft (under the strain relief) may be placed into a sterilant solution.**
- **To avoid injury to the patient, you must follow the manufacturer's recommendation for rinsing.**
- **If the probe is not cleaned and sterilized, it may become the source of infection.**

## ⚠ CAUTION

- **To avoid damaging the transducer, the transducer should not be exposed to the sterilant longer than specified to achieve the desired effect.**
- **To avoid damaging the transducer, do not immerse the transducer in a solution containing ethanol.**
- **After sterilization, rinse the transducer thoroughly with sterile distilled water to remove all chemical residues. Chemical residues on the transducer may be harmful to the human body.**
- **The laparoscopic probe, as a critical probe, must undergo cleaning and sterilization completely after each use.**

**NOTE:**

- After the examination, wipe off the ultrasound gel thoroughly, otherwise, the ultrasound gel may solidify and degrade the image quality of the transducer.
- Do not permit the transducer to become overheated (more than 55°C) during cleaning and sterilization. High temperature may cause the transducer to become deformed or damaged.
- Since the probe connector is not waterproof, during the cleaning and sterilization (soaking) process, be sure to put the seal cover on the probe connector to prevent the liquid from entering the connector. Do not use the seal cover during sterilization using systems to avoid damage to the probe due to device air pressure of the sterilization system.

- The probe must be placed along the placement guide line that is laser carved at the bottom of the probe container.
- The probe container should not be used for long distance transport.

## 5.1 Before Processing

This step is to remove the ultrasound gel or other visible dirt.

Perform the following procedure:

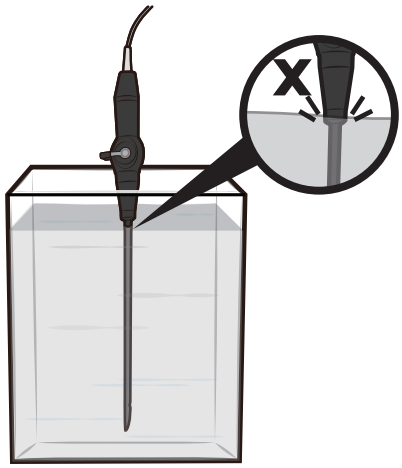
1. Wear protective devices such as surgical caps, masks, gloves, goggles or face shield, and dedicated lab suit when cleaning and sterilizing the laparoscopic probe.
2. After using the probe, freeze the image, power off the ultrasound system, and disconnect the probe from the ultrasound system, to prevent data loss due to hot plug. If the sheath is used, take off the sheath and dispose it as directed by the hospital. Cleaning and sterilization are required even if the sheath is used.
3. Wipe away the ultrasound gel or other visible dirt on the surface of the probe by using a damp piece of disposable lint-free soft cloth or tissue.
4. Place the contaminated probe in the probe container and transport it to the decontamination room. During transportation, avoid colliding or squeezing the probe. Do not touch the acoustic head with heavy objects. Keep the probe moist during transportation to prevent body fluid from drying up on the probe surface. If cleaning cannot be performed immediately, immerse the insertion part of the probe in the detergent or water to avoid drying for more than 30 minutes.

## 5.2 Cleaning

Perform the following procedure:

1. Select an appropriate cleaner. For details, see "5.4.1 Validated Cleaner and Sterilant/ Sterilization System".
2. Follow the manufacturer’s instructions to prepare and use the cleaner. Select an appropriate method:
3. Cleaning the insertion part: soak the probe insertion part thoroughly in the cleaner solution for at least 5 minutes or follow the manufacturer's instructions.
4. Wipe and wash the probe surface gently by using a piece of lint-free soft cloth or soft sponge until no dirt is visible. When necessary, wash the locating groove and other items by using disposable cotton swabs. Avoid using a brush to wash the lens because it may damage the probe.

   Only the section from distal end to the hard shaft can be immersed in the cleaner solution.



5. Cleaning other parts (except for the insertion part): use a disposable soft cloth soaked with cleaner solution and screw it dry until no liquids drip to wipe the strain relief, control handle, deflection lever, cable, and probe connector for at least 1 minute or follow the manufacturer's instructions until the probe is clean.

   Avoiding touching the internal pins of the connector with any cleaner.

6. Rinse the probe insertion part thoroughly with plenty of clean flowing water (about 7.5L) at room temperature for about 1 minute to remove the residual dirt and cleaner solution. Or follow the rinsing method specified by the manufacturer. Use moistened dust-free soft cloth to wipe the residual dirt or cleaners on the parts except for the insertion part.
7. Dry the probe with a disposable lint-free soft cloth or tissue.

   Do not dry the probe by heating.

8. Inspect the probe. If visible dirt still exists, repeat the preceding steps to clean the probe until it is all clean.
9. Check whether the probe has defects such as peeling, rifts, bumps, cracks, or liquid spill. If such defects exist, the probe has reached the end of its service life. In this case, stop using it and contact the Mindray service department.

## 5.3 Sterilization

**NOTES:**

- Clean the probe thoroughly in accordance with the cleaning procedure before sterilization. Sterilization using systems or sterilant both can achieve sterilization effect. You can select an appropriate sterilization method as required.
- This chapter only introduces the basic operation procedures of the sterilization system. For details about using the sterilization system, refer to the manufacturer's instructions.

### 5.3.1 Sterilization using V-PRO Low Temperature Sterilization System

Perform the following procedure:

1. Place the probe into a clean probe container and wrap the probe container including probe with sterilization wrap which had already cleared by the authorities such as H600 OneStep® sterilization wrap.
2. Start the V-PRO Low Temperature Sterilization System using the Non Lumen Cycle according to the instructions provided by the manufacturer.
3. Keep the sterilization wrap together with other sterilized surgical instruments in a sterile item storage area.
4. Before next use, check whether the probe has defects such as peeling, rifts, bumps, cracks, or liquid spill. If such defects exist, the probe has reached the end of its service life. In this case, stop using it and contact the Mindray service department.

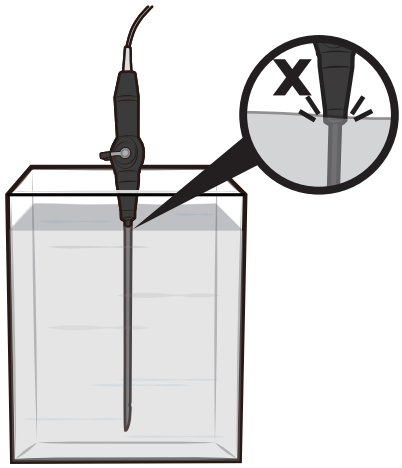
### 5.3.2 Sterilization using STERRAD Low Temperature Sterilization System

1. Place the probe into a clean probe container and wrap the probe container including probe with sterilization wrap which had already cleared by the authorities such as Halyard Health Sterilization Wrap H400.
2. Start the STERRAD Low Temperature Sterilization System using the STANDARD Cycle according to the instructions provided by the manufacturer.
3. Keep the sterilization wrap together with other sterilized surgical instruments in a sterile item storage area.
4. Before next use, check whether the probe has defects such as peeling, rifts, bumps, cracks, or liquid spill. If such defects exist, the probe has reached the end of its service life. In this case, stop using it and contact the Mindray service department.

### 5.3.3 Sterilization using Solution

1. Select an appropriate sterilant to sterilize the probe. For detail, see "5.4.1 Validated Cleaner and Sterilant/Sterilization System".
2. Follow the manufacturer's instructions to prepare and use the sterilant. Prepare a sterilant by using sterile distilled or softened water when necessary.
3. Soak the probe insertion part in the sterilant solution and shake the probe properly to remove bubbles on the surface of the probe. For the probe soaking duration, see the sterilant manufacturer's instructions.

   Only the section from distal end to the hard shaft can be immersed in the sterilant solution.



4. Rinse the probe insertion part thoroughly with plenty of sterile distilled water (about 7.5L) at room temperature for about 1 minute to remove the residual sterilant. Or follow the rinsing method specified by the manufacturer.
5. Dry the probe with a piece of disposable sterile lint-free soft cloth.

   Do not dry the probe by heating.
6. Check whether the probe has defects such as peeling, rifts, bumps, cracks, or liquid spill. If such defects exist, the probe has reached the end of its service life. In this case, stop using it and contact the Mindray service department.
7. Store the probe in the sterilized probe container.

   If necessary, repeat the cleaning, sterilization process before next use.

**CAUTION**

- **The lens may be discolored; the label on the transducer may fade. These are not abnormalities.**
- **Repeated sterilization will eventually damage the transducer, please check the transducer's performance periodically.**
- **Sterilizing incorrectly or with chemicals not recommended by Mindray will void the warranty.**

## 5.4 List of Cleaner, Disinfectant and Sterilant/Sterilization System

The manual release time is different from the version update time of the Mindray product, so the list in this manual may not be the latest version. If you cannot find the information in this list, contact Mindray Customer Service Department or sales representative.

### 5.4.1 Validated Cleaner and Sterilant/Sterilization System

Only the following cleaners, and sterilant/sterilization system are validated by Mindray to clean and sterilize the laparoscope transducers. For the biological effectiveness and the correct use of the sterilant, see the information of the manufacturer.

| Type | Item |
|---|---|
| Cleaner | MetriZyme |
| | Liquinox |
| | Prolystica 2X Concentrate Enzymatic Cleaner |
| | DDN9 |
| Sterilant | Cidex Activated Dialdehyde Solution |
| Sterilization System | V-PRO Low Temperature Sterilization System |
| | STERRAD® Low Temperature Sterilization System |

## 5.4.2 Material Compatible Disinfectant

| Type | Item |
|---|---|
| Disinfectant | Anioxyde 1000 |
| | Anios Clean Excel D |
| | Bodedex Forte |
| | Cidex OPA TM |
| | Gigasept AF |
| | Korsolex Extra |
| | Perasafe |
| | Revital-Ox® Resert® High Level Disinfectant |
| | UltrOx™ High-Level disinfectant |
| | Sani Cloth HB |
| | Sekusept Aktiv |
| | Tristel Trio |
| | Virex II 256 |

**NOTE**

These disinfectants are only compatible with the probe materials, but the efficacy of realizing the appropriate level of disinfection has not been validated by Mindray.

# 6 Storage and Transportation

When all examinations for the day have been completed, confirm that the transducer is in good condition and store it in a suitable place so that the next examination can be conducted smoothly. Make sure the transducer is adequately cleaned and sterilized prior to storage.

## 6.1 Notes

- To avoid damage to the probe, do not use the shipping case for long-term storage or transport the probe from one location to another. When transporting the transducer, do not allow any part of the transducer to protrude beyond the case. Never store a moist laparoscopic transducer in the shipping case.
- Use the protective foam sleeve to seal and protect the probe insertion part during transportation and storage to avoid damaging the probe due to mechanical tension.
- Prior to storage and transportation, clean and sterilize the probes, and dry them with a clean, lint-free, disposable cloth.
- Store the laparoscopic probe in a tray or other containers with foam.
- When the transducer is sent to MINDRAY Customer Service Department or sales representative for repair, be sure to clean and sterilize it and keep it in the original carrying/shipping case to prevent infection.
- If necessary, sterilize the packaging box.

## 6.2 Ambient conditions

### ⚠ CAUTION

**Do not use this transducer in conditions other than those specified.**

To prevent the transducer from being damaged, do not use it where it will be exposed to:

- Direct sunlight or X-rays
- Sudden changes in temperature
- Dust
- Excessive vibration
- Heat generators

**Table 6-1 Environmental Conditions**

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

# 7 Specifications

## 7.1 Safety Classifications

The device is classified according to IEC 60601-1:

| Item | Description |
|---|---|
| According to the degree of protection against electric shock | TYPE-BF APPLIED PART |
| According to the degree of protection against harmful ingress of water or particulate matter | IPX7 |
| According to the disinfection and sterilization method(s) recommended by manufacturer | The devices recommended by the manufacturer. |
| The device equipped with the applied part of defibrillation protection | The device is not equipped with the applied part of defibrillation protection. |
| Permanently installed or non-permanently installed | Non-permanently installed |

**NOTE:**

For other safety classification information, please refer to the classification information of the matched diagnostic ultrasound system (see the user manual of the diagnostic ultrasound system).

## 7.2 Physical Specifications

| Item | Description |
|---|---|
| Working length | 338±3% mm |
| Maximum insertion portion width | ≤10.2 mm. |
| Probe housing diameter | 10+5% mm, the lowest limit is not calculated. |
| Maximum bending angle of the distal tip (Up/Down/Left/Right) | 90°(-5°~+10°) |

**NOTE:**

There is no guarantee that instruments selected solely using maximum insertion portion width and working length will be compatible in combination. Please purchase them according to the actual needs.

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# 8 Disposal

**NOTES:**

- Follow the local regulations or hospital's guideline when disposing this device.
- Be sure to clean and sterilize this device before disposing it.
- Contact your MINDRAY representatives when disposing this device.
- Follow the disposal control policy for your office, department, or hospital when disposing contaminated items such as probe covers or other disposable items.

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