HITACHI
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C9150LA Laparoscopic Ultrasound Transducer

INSTRUCTION MANUAL

Hitachi Healthcare Americas

Contents

Revision History

Manual Revision

Revision	Date	Version	Effective Pages
C9150LAIFUv1	August 2019	First	All
C9150LAIFUv2	February 2020	Second	All

Trademarks

HHA Contact Information

Hitachi Healthcare Americas (HHA) Sales, HHA Service, and HHA Customer Support can be reached the following ways:

- 1-800-800-3106
- 1-800-800-4925

Warning: Indicates the need for the user to consult the instructions for use for important cautionary information such as warning and precautions that cannot for a variety of reasons be presented on the medical device itself.

Caution: Indicates the need for the user to consult the instructions for use for important cautionary information such as warning and precautions that cannot for a variety of reasons be presented on the medical device itself.

Caution, Risk of Electric Shock: Indicates the medical device has a risk of electric shock.

Biological Risks: Indicates that there are potential biological risks associated with the medical device.

Do Not Use Steam or Dry Heat: Indicates that steam or dry heat cannot be used to sterilize the medical device.

IPX7

IPX7: Indicates protection against the effects of temporary immersion in water.

Compatible STERRAD Sterilization System

Sterrad Compatible: Indicates the medical device is compatible with the Sterrad Sterilization System.

Rx Only

For Use by Medical Personnel Only: Caution, Federal law restricts this device to sale by order of a physician.

Type BF Applied Part: Indicates the medical device is not suitable for direct cardiac application.

Non-Sterile: Indicates a medical device has not been subjected to a sterilization process

Consult Instructions for Use: Indicates the need for the user to consult the instructions for use.

Fragile, Handle With Care: Indicates a device that can be broken or damaged if not handled carefully.

Keep Dry: Indicates a medical device that needs to be protected from moisture.

Date of Manufacture: Indicates the date when the medical device was manufactured.

SN

Serial Number: Indicates the manufacture's serial number so that specific medical device can be identified.

REF

Catalog Number: Indicates the manufacture's catalog number so that the medical device can be identified.

Chapter 1: Introduction

Intended Use

The C9150LA probe is intended for use by trained personnel (doctors, sonographers, and so on) for diagnostic ultrasound evaluation during intraoperative and laparoscopic procedures.

This device is not indicated for ophthalmic applications.

⚠ Warning

This transducer is not intended for fetal use. Failure to comply could result in serious injury to patients.

⚠ Warning

This transducer is not intended for cardiac contact, central nervous system contact, or central circulatory system contact. Failure to comply could result in serious injury to patients.

Features

The HHA C9150LA probe is a four-way articulating laparoscopic transducer with a convex array (Figure 1-1). The transducer can be used for laparoscopic or intraoperative ultrasound imaging. For laparoscopic surgery use, the transducer is inserted through a trocar and articulated to the appropriate angle.

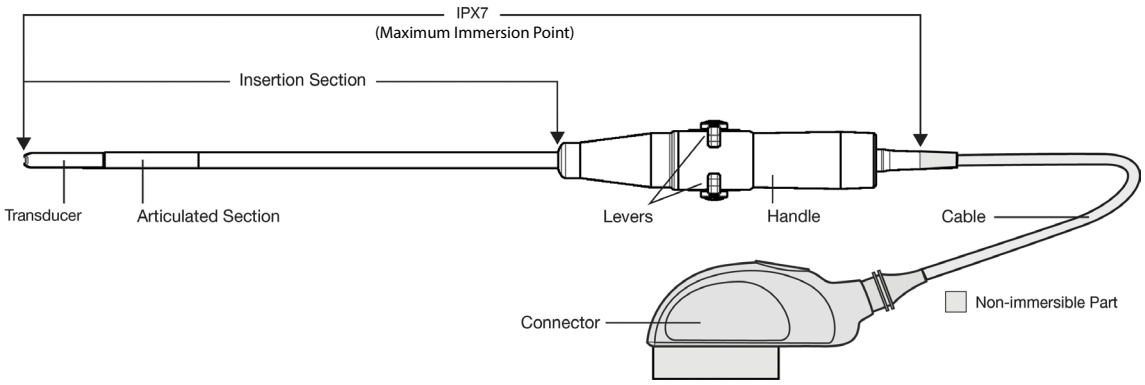


Figure 1-1: C9150LA Probe

⚠ Warning

The C9150LA probe can only be immersed up to the maximum immersion point. Do not immerse past the maximum immersion point. If the cable and connector becomes immersed, do not attempt to attach the probe to the ultrasound system and contact HHA Service (refer to “HHA Contact Information” on page i). The warranty is voided if the connector is immersed. Failure to comply could result in serious injury to patients or damage to equipment.

⚠ Warning

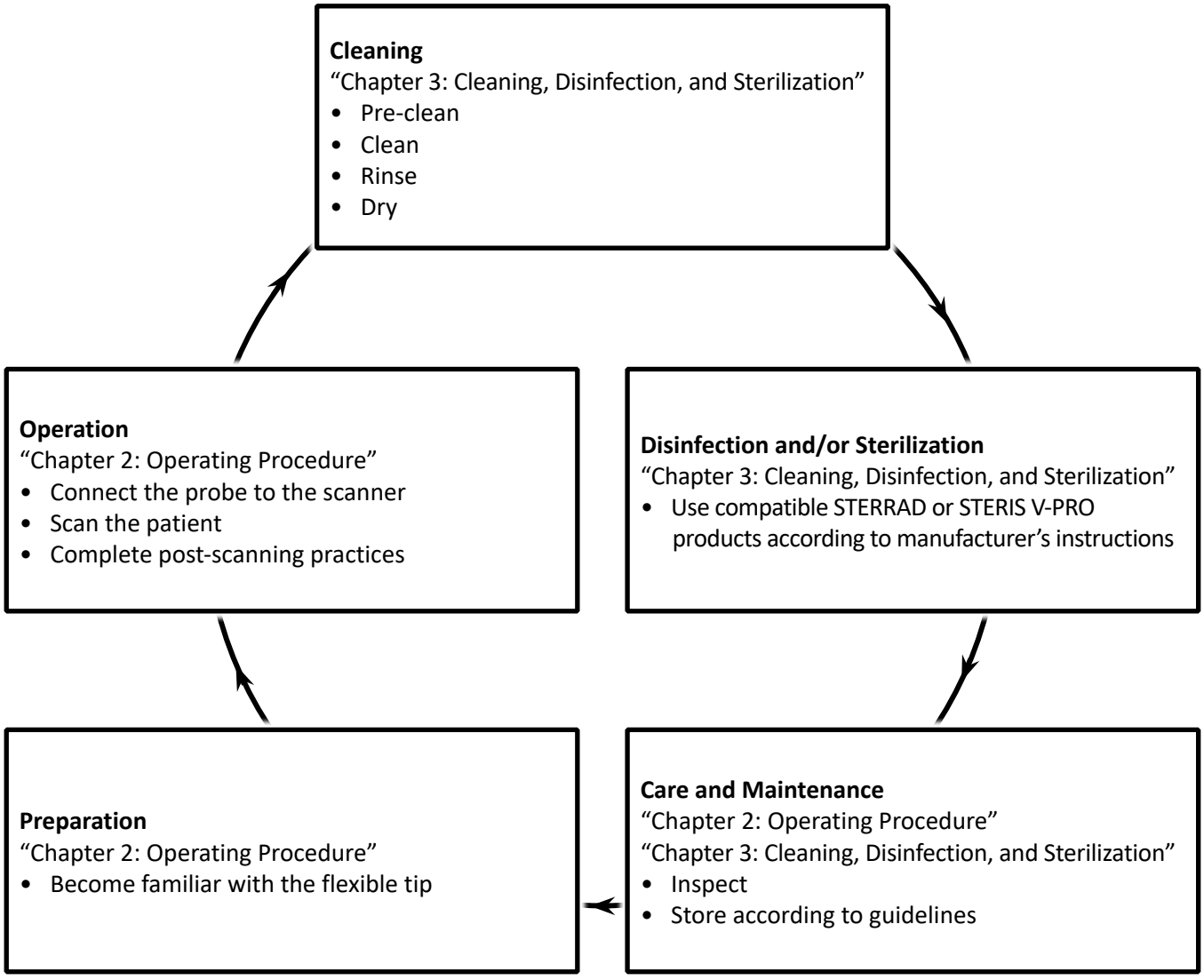
The C9150LA probe can only be immersed up to the maximum immersion point and should not be used with Hitachi accessory part number WP-001.

The flexible tip of the C9150LA probe has the specification with mechanical tolerance of ±10° from its neutral position (0°). For this reason, even when the tip of the C9150LA probe does not return to the neutral position, as long as the slight bend is within the specification, it is considered normal.

Acoustic Power Tables are on file and available upon request. Call 800-800-3106 extension 3458 for further information.

Safe Operating Process

Follow the flowchart below to ensure a safe operating process.



Components

Components of the C9150LA probe include the following:

- Probe 1 piece
- Instruction Manual 1 copy

⚠ Caution

The transducer, cable, and connector have not been sterilized after manufacturing. Prior to the initial use, be sure to clean, disinfect, and/or sterilize the transducer, cable, and connector, according to the intended use. Failure to comply could result in injury to patients.

Cleaning, Disinfecting, and Sterilization Supplies

Immersion Trays

When disinfecting this transducer, use a tray that is large enough for immersion of the transducer not going beyond the maximum immersion point to ensure the connector stays dry. The non-immersible part can only be disinfected by wipe disinfection.

Sterilization Trays

These trays are for STERRAD or STERIS V-PRO sterilization and should not be used for immersing transducers for disinfection. Sterilization trays can be purchased through HHA Sales (refer to “HHA Contact Information” on page i).

Tray Part Number	8629598

Detergent and Disinfectant

HHA recommends the following germicide for disinfection (for more information about the disinfection process, see “Disinfection Process” on page 3-6).

Supply	Manufacturer	Chemical
DETERGENT ENZOL/CIDEZYME XTRA	Advanced Sterilization Products	Enzymatic detergent solution
DISINFECTANT CIDEX OPA Solution	Advanced Sterilization Products	Ortho-phthalaldehyde solution

Sterilization Methods

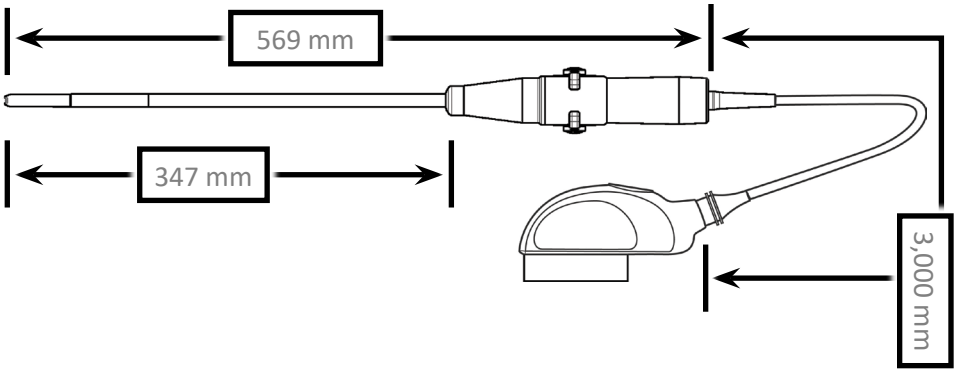
HHA recommends the following methods for sterilization (for more information about the sterilization process, see “Sterilization Process” on page 3-8).

Specifications

Supply	Manufacturer	Chemical
STERRAD (100NX, NX, 100S)	Advanced Sterilization Products	Hydrogen Peroxide Gas Plasma
STERIS (V-PRO 1, V-PRO 1 Plus, V-PRO maX, V-PRO maX 2, V-PRO 60, V-PRO s2)	STERIS	Hydrogen Peroxide

C9150LA Probe

Technology	Curved Array Probe
Dimensions	Refer to Figure 1-2
Weight	Approximately 4 lbs, including cable and connector
Probe Materials	Bio-compatible
Acoustic Output	According to IEC 60601-2-37 (refer to the instruction manual of ultrasound system)
Applicable System	Depending on production and upgrade status. For detailed information, contact HHA Service (refer to "HHA Contact Information" on page i)
Expected Service Life	3 years
Operating Conditions **Ambient Temperature** **Relative Humidity** **Atmospheric Pressure** **Altitude**	 10 - 40°C (50 - 104°F) 30 - 75% 700 - 1060 hpa 3,000 meters or less
Storage/Transportation Conditions **Ambient Temperature** **Relative Humidity** **Atmospheric Pressure**	 -10 - 50°C (14 - 122°F) 10 - 90% 700 - 1060 hpa



The tolerance for the dimensions is ± 10%

Figure 1-2: Probe Dimensions for C9150LA

Service and Maintenance

The most common reasons for C9150LA probe malfunction are the following:

- Cuts and abrasion on the cable or transducer. The transducer face is particularly vulnerable. Scissors and scalpels can easily damage the transducer. Retraction through a trocar, while articulated rather than straight, may cause severe damage.
- Disinfectant or sterilant in the connector housing due to soaking the connector.
- Deviations from approved cleaning, disinfection, and sterilization methods and procedures recommended in this manual.

⚠ Warning

Take special care that the small face at the tip of the transducer is not scratched or chipped. Discontinue use if a defect or damage is noted during the inspection and contact HHA Customer Support Center (refer to “HHA Contact Information” on page i). Failure to comply could result in injury to patients or damage to equipment.

⚠ Warning

If the transducer is dropped or is suspected to have been mechanically damaged, a hipot test should be performed. If the transducer fails hipot, contact HHA Customer Support Center (refer to “HHA Contact Information” on page i).

The service and repair of HHA ultrasound equipment, including the C9150LA probe, must be conducted only by HHA or its authorized representatives. HHA is not responsible for the operating safety, reliability, or performance of ultrasound equipment repaired by unauthorized third parties. After repairs have been completed, a qualified electrical engineer or technician should verify the safety of all equipment before use on patients.

Transportation

If the intraoperative transducer is to be transported or returned to the manufacturer, the following conditions must be observed:

1. Ensure that the transducer has been thoroughly cleaned and disinfected as described in “Chapter 3: Cleaning, Disinfection, and Sterilization” on page 3-1 prior to shipping.

⚠ Caution

To reduce the risk of spreading diseases, the C9150LA probe should be disinfected prior to shipment. If the transducer is damaged so extensively that fluid will clearly get inside the transducer, then contact HHA Customer Support Center (refer to “HHA Contact Information” on page i) for specific instructions before proceeding. Do not submerge a transducer with obvious mechanical damage in any fluid. Failure to comply could result in further damage.

2. Place the C9150LA probe in its original protective case. The protective case must never come in contact with an infected transducer.
3. Ensure the C9150LA stays within the allowable temperature range for shipping, see “Specifications” on page 1-6.

Periodic Inspection

Please conduct following safety tests and performance tests for safe use.

⚠ Warning

Perform safety tests at least once a year and keep a record of the inspection results. Failure to comply could result in injury to patients or damage to equipment. Discontinue use if a defect or damage is noted during the inspection and contact HHA Customer Support Center (refer to “HHA Contact Information” on page i) for specific instructions before proceeding.

Safety Tests

The safety tests should be conducted at least once a year by a qualified technician. The test record should be stored for future reference.

Procedure for periodic safety tests and judgment

1. Test of patient leakage current from the patient connection to earth. Please conduct the test according to IEC 60601-1:2005 8.7.4. Soak the applied part and the part treated as the applied part of the probe in saline solution, and measure the leakage current between the applied part and earth. The applied part and the part treated as the applied part are indicated in “Features” on page 1-1.
2. Test of patient leakage current caused by an external voltage on the patient connection of an F-type applied part. Please conduct the test according to IEC 60601-1:2005 8.7.4. Soak the applied part and the part treated as the applied part of the probe in saline solution, and measure the leakage current between the applied part and earth. The applied part and the part treated as the applied part are indicated in “Features” on page 1-1.

Item	Normal Condition	Single Fault Condition
Patient leakage current from the patient connection to earth **DC** **AC**	 10 µA or less 100 µA or less	 50 µA or less 500 µA or less
Patient leakage current caused by an external voltage on the patient connection of an F-type part		5000 µA or less

Performance Tests

Perform the measurements specified below using an ultrasonic phantom at least once per year. The test record should be stored for future reference.

• Sensitivity

• Resolution

Note 1

The ultrasonic phantom is made of a substance which is similar to human tissue in terms of its response to ultrasonic waves.

Regions with different textures and targets spaced at preset intervals are embedded in the phantom. Some phantoms contain a mechanism for Doppler measurement. The phantom is used to check the performance of the probe and ultrasonic diagnostic instrument, as well as to adjust the image settings.

Conducting tests

Some types of ultrasonic phantoms have targets with narrow gaps between them for confirming the resolution. This enables you to check the level of detail that images can be viewed on the display. For phantoms with no targets, the resolution determines the fineness of the displayed textures. The sensitivity can be determined by examining the luminance of ultrasonic images. Other factors that affect the resolution include the type of connected probe, gain, focus, and recording instrument. The specific testing conditions must be recorded in detail to enable proper comparison at the next inspection.

Evaluation of the results

Compare the currently-obtained value with the value recorded at the last test. If there is a significant difference between the two values, the current value is considered to be abnormal.

It is important to note that the resolution varies depending on the type of ultrasonic phantom, and phantoms generally deteriorate over time.

⚠ Caution

Discontinue use if a defect or damage is noted during the inspection and contact HHA Customer Support Center (refer to “HHA Contact Information” on page i) for specific instructions before proceeding.

Disposal of the Device

Recycle or dispose this equipment properly in compliance with your organizational rules and your local laws.

⚠ Caution

Before disposing the equipment, disinfect or take other infection-prevention measures. Disposal of equipment without taking the proper preventative measures can lead to infection.

Chapter 2: Operating Procedure

Inspection

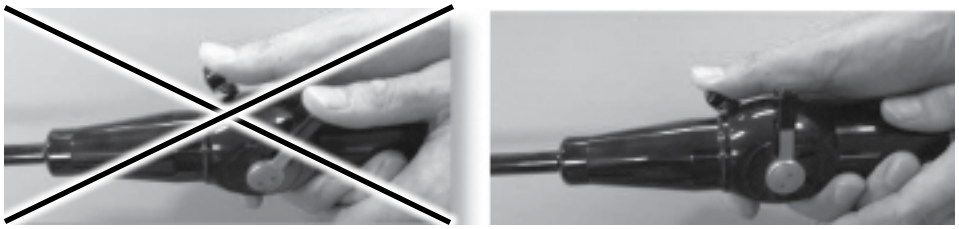
Before using, inspect the C9150LA probe for any signs of damage, such as cracks in the housing, a damaged transducer, or a cut cable. Discontinue use if any defect or damage is noted during the inspection and contact HHA Customer Support (refer to “HHA Contact Information” on page i).

Follow the instructions in “Chapter 3: Cleaning, Disinfection, and Sterilization” on page 3-1 for cleaning and sterilizing the C9150LA probe prior to intraoperative use. Use standard sterile procedure for handling the probe following sterilization.

Using the Flexible Tip

When controlling the transducer head, do not use both levers at the same time (Figure 2-1).

When the two levers for up-down and left-right directions are controlled at the same time, the inside wire slackens and the transducer head may remain bent even when the levers are returned to the straight position.



Do not actuate the two levers simultaneously

Use one lever at a time to control probe action

Figure 2-1: Controlling Transducer Head

Adjustment of the Flexible Tip

The C9150LA probe is equipped with a flexible tip. The flexible tip is controlled by two levers, one on either side of the probe handle. This tip can be adjusted through an angle of up to 90° in four planes (with the handle in its upright position as reference): up, down, left, and right (Figure 2-2).

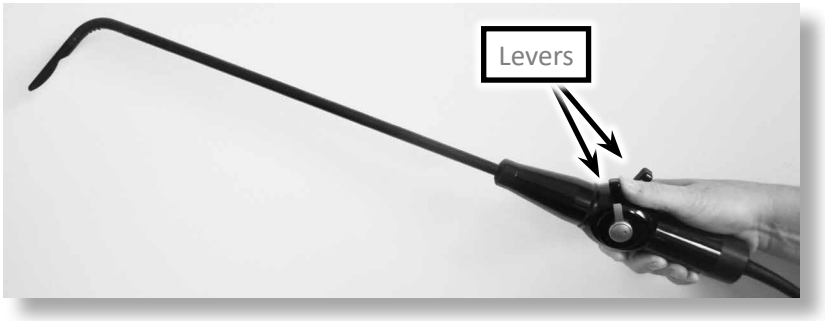


Figure 2-2: C9150LA Probe Held in the Upright Position

Zero Position

Both levers have a zero position. This position is where the two levers are in the most upright position. When both of the levers are adjusted to the zero position, then the tip of the transducer is in the straight, non-adjusted, zero position (Figure 2-3).

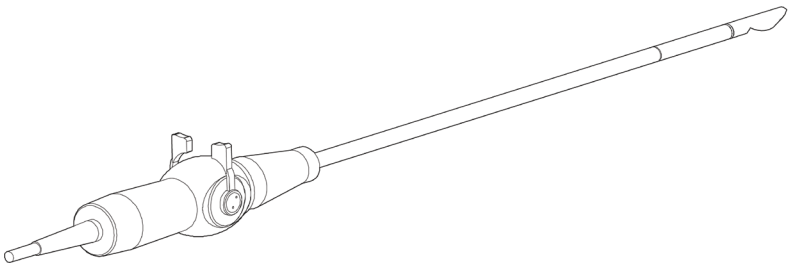


Figure 2-3: Both Levers in Zero Position

Up and Down Movement

The following instructions are based on the C9150LA probe initially being in the upright position, where the two levers are at the zero position.

The up and down movement of the transducer tip is controlled by the lever on the left-hand side of the probe handle. Moving the lever forward moves the tip downwards. Moving the lever backwards moves the tip upwards (Figure 2-4).

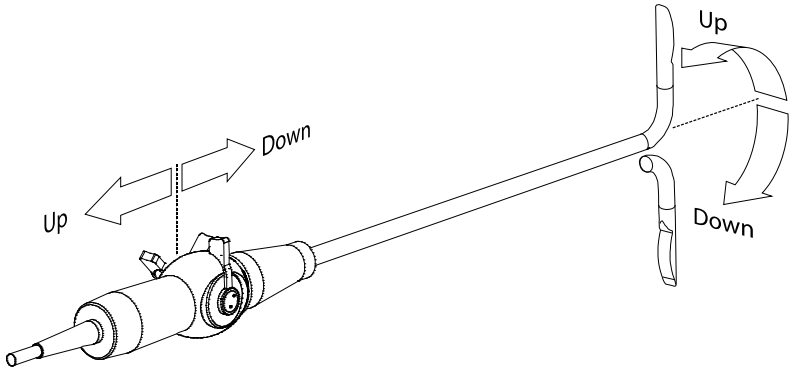


Figure 2-4: Up and Down Movement of the Flexible Tip

Left and Right Movement

The following instructions are based on the C9150LA probe initially being in the upright position, where the two levers are at the zero position.

The left and right movement of the transducer tip is controlled by the lever on the right-hand side of the probe handle. Moving the lever forward moves the tip to the right. Moving the lever backwards moves the tip to the left (Figure 2-5).

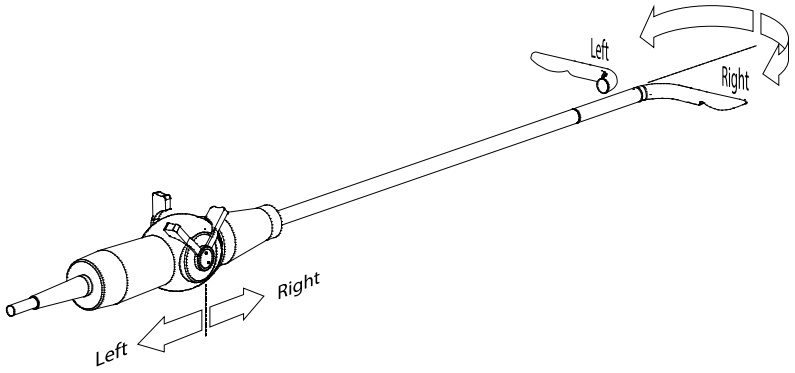


Figure 2-5: Left and Right Movement of the Flexible Tip

Intraoperative Scanning

⚠ Warning

Use extreme caution when using the C9150LA probe. Because of the length of the probe shaft, it is possible to apply large forces to the tip of transducer by very small movements of the handle. If these forces are excessive, they may injure the patient and/or cause damage to the transducer.

⚠ Warning

Metal trocars with sharp edges are not suitable for use with the C9150LA probe as they may damage the transducer. Failure to comply could result in damage to equipment.

For intraoperative use, the moisture on internal organs is usually sufficient for acoustic coupling. If not, sterile saline can be used to moisten the scanning area.

For laparoscopic use, straighten the transducer tip prior to insertion in the trocar. The transducer tip should be supported during insertion. Prior to extraction, be sure to straighten the transducer tip by adjusting both levers to the zero position.

To position the probe for scanning, the transducer tip can be articulated using the levers on the handle. Do not attempt to articulate by putting pressure on the transducer tip.

⚠ Caution

Return the transducer tip to a straight condition before attempting to insert or extract the probe from a trocar. Failure to comply could result in injury to patients or damage to equipment.

⚠ Caution

Do not restrict the movement of the transducer tip while articulating. Failure to comply could result in injury to patients or damage to equipment.

⚠ Caution

Upon extraction, inspect the C9150LA probe for any signs of damage, such as cracks in the housing, a damaged scanning surface, or a cut cable. Discontinue use if any defect or damage is noted during the inspection and contact HHA Customer Support (refer to “HHA Contact Information” on page i).

Chapter 3: Cleaning, Disinfection and Sterilization

Overview

Reprocessing Instructions According to ISO 17664

The probe and accessory must be reprocessed after each use. Refer to the reprocessing instruction in this chapter.

⚠ Warning

- The probe is delivered unsterile. Prior to the first use, reprocess the probe.
- Temperature should not exceed 60°C[140°F] during reprocessing.
- Probe connector is not water resistant.

Limitations of reprocessing	The probe is not completely submersible (Do not immerse the probe into any liquid beyond the range of IPX7. The range is indicated in figure 1-1 on page 1-1. Parts which are not submersible can only be disinfected by wipe disinfection.
Transportation before using	The probe should be packed in a sterile tray from Central Sterile Supply Department (CSSD) to an operating room.

⚠ Warning

Never use the C9150LA probe if the connector has been immersed in any liquid. Failure to comply could result in serious injury to patients or damage to equipment.

⚠ Warning

The C9150LA probe can only be immersed up to the maximum immersion point and should not be used with Hitachi accessory part number WP-001.

Overview

To appropriately clean, disinfect and/or sterilize, and store the transducer and the rest of the C9150LA probe for intraoperative use, follow these steps:

1. “Pre-Cleaning at Point of Use Process” on page 3-4
2. “Cleaning Process” on page 3-5
   if required by your site
3. “Disinfection Process” on page 3-6
   or
   “Sterilization Process” on page 3-9
   depending on your site’s guidelines
4. “Storage” on page 3-10

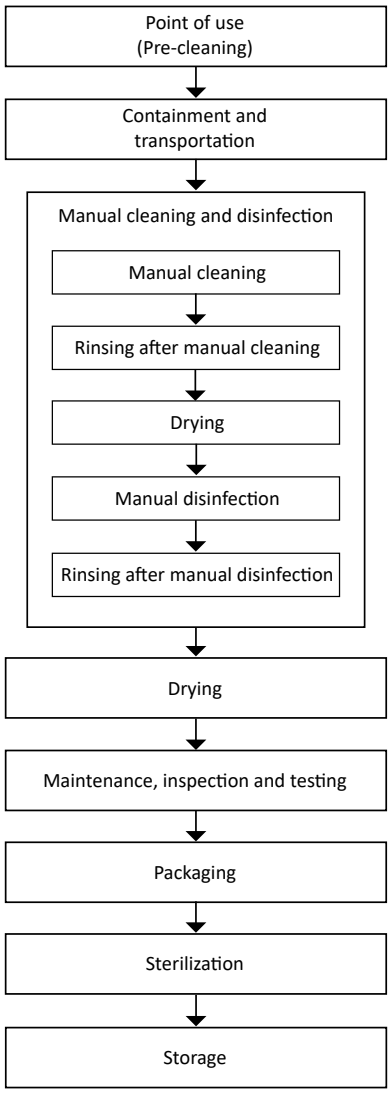


Figure 3-1: Reprocessing Flowchart

Required Level of Disinfection and/or Sterilization

Classification	Definition	Processing
Noncritical	Devices that come in contact with intact skin but not mucous membranes	Mid- or Low-Level Disinfection
Semicritical	Devices that come in contact with intact mucous membranes and does not ordinarily penetrate sterile tissue, such as with endocavity applications	High-Level Disinfection
Critical	Devices that enter normally sterile tissue or the vascular system, such as with intraoperative applications	Sterilization

According to its intended use, the C9150LA probe is classified as a Critical device.

The level of disinfection and/or sterilization required for a device is dictated by the type of tissue it will contact during use. Dr. E. H. Spaulding devised a classification system that divides medical devices into categories based on the risk of infection involved with their use. This classification is used by the FDA and the Centers for Disease Control and Prevention to aid in determining the degree of disinfection and/or sterilization required for various medical devices in, for example, the CDC Guideline for Hand Washing and Hospital Environmental Control, Guidelines for the Prevention of Transmission of Human Immunodeficiency Virus (HIV) and Hepatitis B Virus (HBV) to Health-Care and Public-Safety Workers, and Guideline for Environmental Infection Control in Health-Care Facilities.

Spaulding defines three categories of medical devices and their associated level of disinfection and/or sterilization.

Precautions

Cleaning is intended to remove all foreign matter (such as blood, tissue and protein from the device. If adequate cleaning cannot be achieved, subsequent high-level disinfection and/or sterilization procedures are likely to be ineffective.

⚠ Warning

Follow the instructions on the manufacturers' label for the solution strength and duration of the immersion, and observe the use life, shelf life, expiration date, and activation instructions for the cleaning, disinfecting, and/or sterilizing solution. Failure to comply could result in serious injury to patients or damage to equipment.

⚠ Caution

All transducers, cables, and connectors must be thoroughly cleaned after each use to remove all foreign matter (such as blood, tissue, protein). Failure to comply could result in injury to patients.

⚠ Caution

Handle all transducers, cables, and connectors with care and do not bump, drop, or subject them to any type of shock. Failure to comply could result in damage to equipment.

⚠ Caution

The probe connector is not water resistant. Always position the parts of the transducer that must remain dry higher than the parts exposed to liquid, to keep any fluid from entering the probe connector. Failure to comply could result in damage to equipment.

⚠ Caution

The probe is not completely immersible (refer to Figure 1-1 on page 1-1). The non-immersible part can only be disinfected by wipe disinfection. Failure to comply could result in damage to equipment.

Pre-Cleaning at Point of Use Process

Pre-cleaning, or decontamination, is done to protect staff that are likely to handle a soiled or infected transducer after use. It includes proper disposal of single use items to eliminate blood-borne pathogens and other possible sources of infection.

To pre-clean the C9150LA probe at the point of use, follow these steps:

1. Use a soft dry cloth or a clean soft cloth lightly dampened with a mild soap to remove any biological matter from the transducer.
2. Visually inspect the transducer and the cable to ensure that all foreign matter (such as blood, tissue and protein) are removed and that the transducer and cable are thoroughly dried.
3. Transport the C9150LA probe to your site's cleaning area in a bag or tray.
4. Continue with "Cleaning Process" on page 3-5 or "Disinfection Process" on page 3-6, depending on your site's guidelines.

Manual Cleaning Process

Cleaning is done to remove all debris and organic matter in preparation for high-level disinfection or sterilization. Cleaning with soap and water alone provides a low-level disinfection only.

To clean the C9150LA probe at your site's cleaning area, follow these steps:

1. Prepare a ENZOL/CIDEZYME XTRA detergent solution with water, following the instructions on the manufacturer's label in regards to water temperature, application, solution strength, and duration of the immersion.
2. Submerge the immersible part of the C9150LA probe, not going beyond the maximum immersion point to ensure the connector stays dry, into the prepared detergent solution.
3. Wipe the immersible part of the C9150LA probe under the surface of the solution with a soft cloth to remove all visible soil, ensuring that all grooves of the probe are cleaned.
4. Keep the immersible part of the C9150LA probe in the solution for the duration indicated on the manufacturer's label.
5. Wipe the part of the cable and connector that was not submerged, with a clean soft cloth lightly dampened with a mild soap to remove any biological matter.
6. Rinse the immersible part of the C9150LA probe with running tap water for 1 minute, or immerse the immersible part of the C9150LA probe in a tray filled with deionized or tap water for 5 minutes. For both methods, do not go beyond the maximum immersion point to ensure that the connector stays dry.
7. Visually inspect the outer surface of the probe for cleanliness, using a magnifying glass if necessary.
8. If necessary, repeat Steps 2 through 7, or continue with "Disinfection Process" on page 3-6 or "Sterilization Process" on page 3-9.

Manual Disinfection Process

⚠ Warning

Use personal protective equipment, such as gowns, gloves, and eye wear, when handling high-level disinfectant and/or sterilant. Failure to comply could result in serious injury to staff.

⚠ Warning

This procedure does not guarantee disinfecting the probe, which can only be determined by the surgical staff when practicing recognized medical and/or surgical procedures for using disinfectants. Failure to practice these procedures could result in injury to patients.

⚠ Warning

To assure safe and effective high-level disinfection, follow these points:

- Always use an FDA-cleared, high-level disinfectant
- Carefully follow the disinfectant manufacturer's instructions for preparation, use, storage and disposal
- Prevent glutaraldehyde from contacting exposed skin or eyes by wearing protective clothing and eye protection;
- Use only in a well ventilated area and thoroughly rinse all glutaraldehyde residue from the transducer.

Failure to comply could result in serious injury to staff.

The disinfection methods described here should be strictly observed to prevent malfunction and to avoid jeopardizing staff and patient safety. Use only the recommended disinfectant listed here and follow instructions given by the manufacturer of the disinfectant. Monitor the effectiveness of the disinfectant solution following the disinfectant manufacturer's instructions.

To disinfect the C9150LA probe, follow these steps:

1. Prepare CIDEX OPA solution as per manufacturer's instructions in regards to water temperature, application, solution strength, microbiological efficiency, service life, and duration of the immersion.
2. Pour the prepared solution into a tray system. Completely submerge the transducer, not going beyond the maximum immersion point to ensure the connector stays dry.
3. Keep the immersible part of the C9150LA probe in the solution for duration indicated on the manufacturer's label.

⚠ Caution

Do not immerse the transducer for more than one hour. Failure to comply could result in damage to equipment.

4. The non-immersible part can only be disinfected by wipe disinfection.
5. Remove the transducer and rinse thoroughly with sterile water, not going beyond the maximum immersion point to ensure the connector stays dry, to prevent adverse effects of toxic residue on the operator and patient.
6. Visually inspect the outer surface of the transducer, cable, and connector for disinfectant residue. If necessary, repeat Step 4.

Automatic Cleaning and Disinfection

An automated method of cleaning or disinfection has not yet been approved for use with the C9150LA transducer.

Drying

Dry the probe using one of the following methods:

1. Wiping it with a single use lint-free wipe or towel
2. Letting the probe air dry in an ambient temperature of 15-30°C (60-85°F) for at least 4 hours
3. Using a drying heater at a temperature of less than 60°C (140°F)

Maintenance, Inspection and Testing

Inspect the transducer, cable, and connector function of mechanical moving parts and for any signs of damage, such as cracks in the housing, a damaged scanning surface, or a cut cable. Discontinue the use of the transducer if a defect or damage is noted during the inspection and contact HHA Customer Support Center (refer to “HHA Contact Information” on page i).

Packaging

Use the approved sterilization tray for STERRAD or STERIS V-PRO for sterilization as referenced on page 1-4.

Sterilization Process

⚠ Warning

Use only approved sterilization methods as described here. Failure to comply could result in serious injury to patients or damage to equipment, and will void the C9150LA probe warranty.

⚠ Warning

Do not autoclave transducers. Failure to comply will severely damage the transducer and will void the warranty.

⚠ Warning

Before sterilizing the C9150LA probe, ensure that the operation data of the sterilizer are in conjunction with the minimum and maximum data applicable for the probe. Failure to comply could result in serious injury to patients or damage to equipment.

⚠ Warning

Failure to use a compatible sterilization tray could result in a NON-STERILE probe and serious injury to patients.

⚠ Caution

Use only the STERRAD or STERIS V-Pro methods described in this chapter for sterilization. Other methods, including autoclaving or the use of ethylene oxide (EtO), will damage the transducer. Never use ultraviolet light for sterilization or caustic solutions, such as chlorine bleach. Failure to comply could result in injury to patients or damage to equipment.

⚠ Caution

Do not autoclave. Do not sterilize using ethylene oxide (EtO). Use only the STERRAD or STERIS V-Pro methods described below for sterilization. Other methods, including autoclaving or the use of EtO, will damage the transducer. Never use ultraviolet light for sterilization or lacquer thinner, organic solvents, caustic or abrasive chemicals such as chlorine bleach, or abrasive or sharp instruments for cleaning. Failure to comply could result in injury to patients or damage to equipment.

⚠ Caution

Failure to use a compatible sterilization tray could result in damage to the equipment and will void the C9150LA warranty.

Sterilization Process

1. Ensure that the transducer has been thoroughly cleaned according to “Cleaning Process” on page 3-5.
2. Inspect the transducer, cable, and connector for any signs of damage, such as cracks in the housing, a damaged scanning surface, or a cut cable. Discontinue the use of the transducer if a defect or damage is noted during the inspection and contact HHA Customer Support Center (refer to “HHA Contact Information” on page i).
3. Place the probe inside a compatible sterilization tray.
4. Follow the manufacturer’s instructions for loading the sterilization chamber, including appropriate process controls according to established infection control procedures.
5. Sterilize the C9150LA probe.

   The C9150LA probe can be sterilized using the following method:

   - “Low Temperature Gas Plasma Sterilization” on page 3-9
6. Store the C9150LA probe according to your site’s guidelines.

Low Temperature Gas Plasma Sterilization

Follow all manufacturer’s instructions for using Sterrad systems.

Sterilization Method	Condition
Sterrad 100S	Short Cycle
Sterrad NX or 100NX	Standard Cycle

Low Temperature Vaporized Hydrogen Peroxide Sterilization

Follow all manufacturer’s instructions for using V-Pro systems.

Sterilization Method	Condition
V-Pro 1	Standard
V-Pro Plus	Non Lumen Cycles
V-Pro maX	Non Lumen Cycles
V-Pro maX 2	Non Lumen Cycles
V-Pro 60	Non Lumen Cycles
V-Pro s2	Non Lumen Cycles

Storage

When the C9150LA probe is neither in use nor being processed for use, it should be stored under the following conditions:

- Ensure that the probe has been thoroughly cleaned and disinfected as described in “Chapter 3: Cleaning, Disinfection, and Sterilization” on page 3-1 prior to storage.
- Store in a manner that protects the probe from shock and mechanical damage. For prolonged storage, place the probe in its original protective case.
- Store at room temperature.
- Avoid direct sunlight, and long term exposure to x-rays.
- Prior to reuse, inspect the probe and perform safety tests. If necessary, clean the probe. Always complete a high-level disinfection or sterilization process prior to intraoperative use.

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