8BP4
Biplane Probe
User's Manual

The New Look of Ultrasound.

terason®

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8BP4 Probe Users Manual

Revision History

Manual Revision

Revision	Date	Version	Effective Pages
8BP4IFUv1	05-10 2019	First	All

Trademarks

Terason Contact Information

Terason Customer Support can be reached the following ways:

- 1-866-TERASON
- techsupport@terason.com

Chapter 1: Introduction

Features

The 8BP4 probe is an Endocavity Biplane Probe.
The 8BP4 probe consists of a connector, a cable, and an array (imaging part) (Figure 1-1).

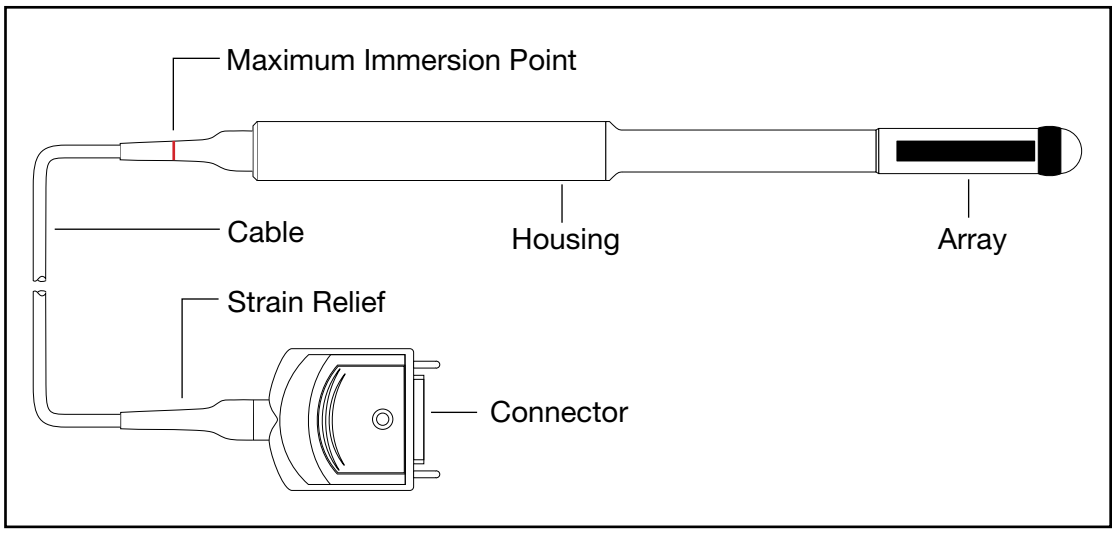


Figure 1-1: 8BP4 Probe

Warning

The 8BP4 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 Terason Service (refer to “Terason Contact Information” on page i). Failure to comply could result in serious injury to patients or damage to equipment.

The cable and connector must not be immersed in any liquid, such as sterilant or disinfectant solution, and cannot be cleaned with water. The probe can be immersed in liquid, such as sterilant or disinfectant solution, not going beyond the immersion point indicated in Figure 3-1 on page 3-6, and can be cleaned with water.

The acoustic output of this probe when connected to an Terason ultrasound diagnostic scanner was measured according to the IEC60601-2-37 standard. The table of measured acoustic output data is contained in the operational manual of each ultrasound diagnostic scanner. This probe is categorized in class IIa according to Directive 93/42/EEC.

According to IEC60601-1, the probe is classified as type BF.

Chapter 1: Introduction

Intended Use

The 8BP4 probe is designed for observation and diagnosis of the following regions mainly by connecting with the Terason ultrasound diagnostic scanner:

- Transrectal

Warning

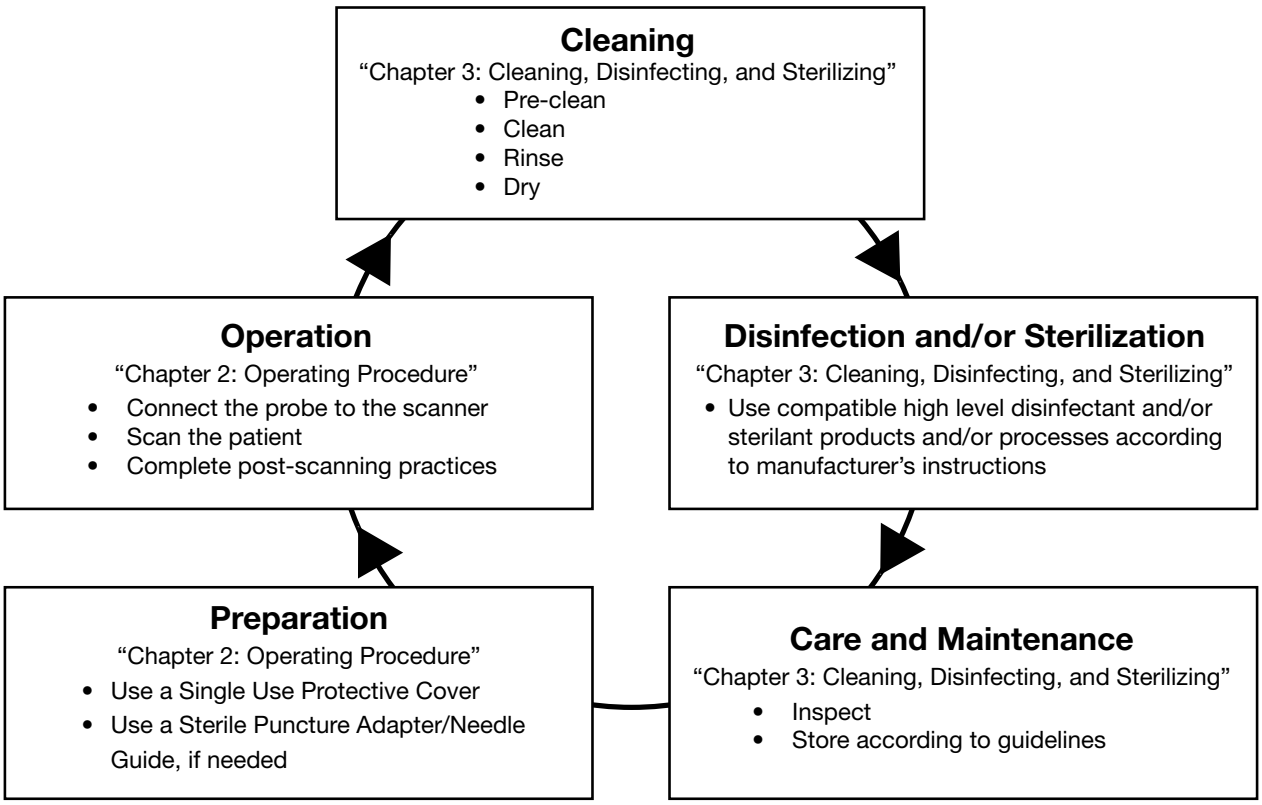
Never put the probe in direct contact with the heart or the eyeball. Failure to comply could result in serious injury to patients.

Caution

Observe the As Low As Reasonably Achievable (ALARA) principle by keeping the acoustic power as low as reasonably possible and minimize the ultrasound exposure time for the examination of an early pregnancy. Failure to comply could result in injury to patients and damage to equipment.

Safe Operating Process

Follow the flowchart below to ensure a safe operating process.



Chapter 1: Introduction

Components

Components of the 8BP4 probe include the following:

- Probe 1 piece
- Instruction Manual 1 copy

⚠ Caution

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

Optional Accessories

Optional accessories can be purchased through CIVCO (https://www.civco.com), or Protek (www.protekmedical.com).

8BP4 Probe Specifications

Technology	Convex & Linear Array Probe
Dimensions	Refer to Figure 1-2
Weight	Approx. 0.60kg (including cable and connector)
Probe Materials	Bio-compatible, latex-free components
Acoustic Output	According to IEC 60601-2-37 (refer to instruction manual of ultrasound system)
Applicable System	Depending on production and upgrade status. For detailed information, contact Terason Customer Support (refer to Terason Contact Information on page i)
Classification	MDD classification IIa
Operating Conditions - Ambient Temperature	10-35°C (50-95°F)
Operating Conditions - Relative Humidity	20-80% non-condensing

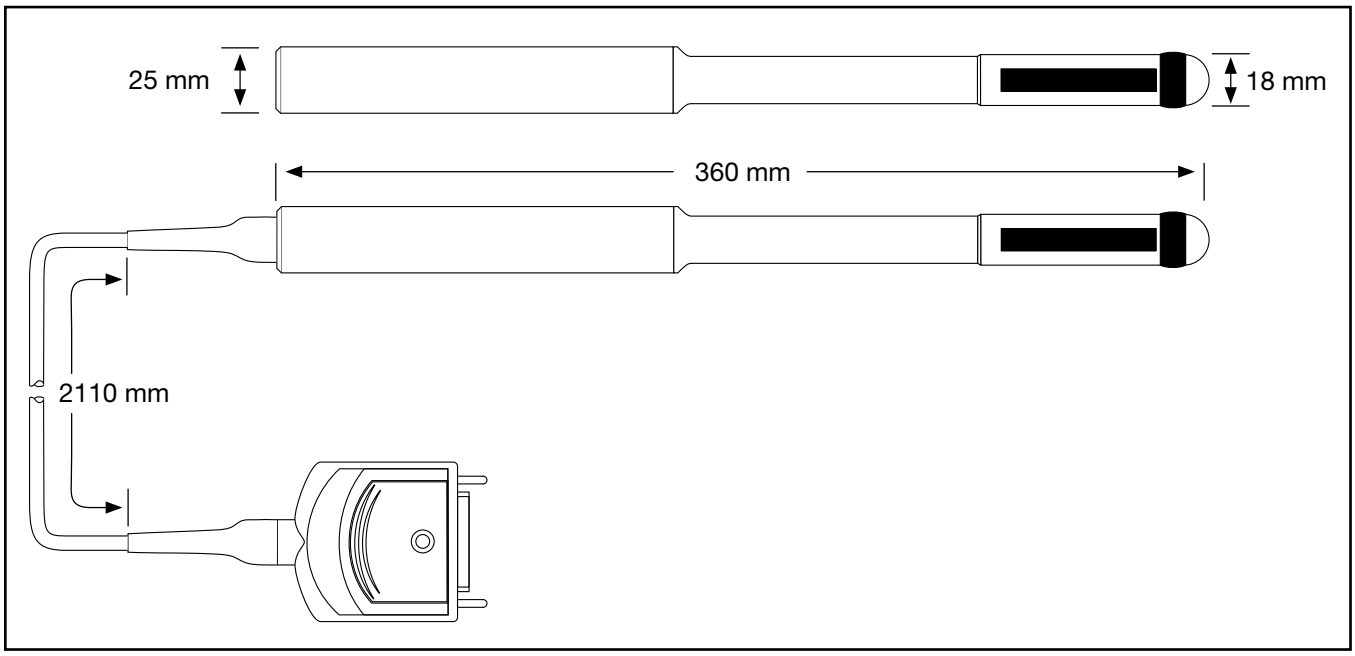


Figure 1-2: 8BP4 Probe with Measurements in mm

Chapter 2: Operating Procedure

Inspection

Before using, inspect 8BP4 probe for any signs of damage, such as cracks in the housing, a damaged array, or a cut cable. Discontinue use if any defect or damage is noted during the inspection and contact Terason Customer Support (refer to Terason Contact Information on page i).

Connections

To inspect the 8BP4 connections, review the following:

- Confirm that the system is correctly operating. Refer to the instruction manual for the ultrasound diagnostic scanner.
- Verify that all devices and instruments on the probe are authorized; do not allow unauthorized devices or instruments on the probe, such as unauthorized biopsy attachments.
- Confirm that the software version, and scanner settings are appropriate for the probe.

Material Surface

To inspect the 8BP4 probe material surface, review the following:

- Visually inspect the surface of the probe array, housing, cable, and connector for any crack, scratch, or delamination of the lens.

Using the 8BP4 Probe

Before using the 8BP4 probe, ensure that the connections and settings are ready by following these steps:

1. Confirm that the probe, cable, and connector are cleaned, disinfected, and/or sterilized.
2. Connect the 8BP4 probe to the ultrasound diagnostic scanner. Operate the scanner, following the instructions given in the instruction manual for your ultrasound diagnostic scanner.
3. Use sterile acoustic gel between the probe array and single use protective cover as a couplant.

Chapter 2: Operating Procedure

Probe Cover

The use of single use sterile probe cover is recommended as viral barrier and to help with infection control. The probe cover should be allergy free material to avoid allergic reaction. Between the probe and the probe cover, sterile acoustic coupling gel is required as a couplant.

Care after Use

Perform the reprocessing procedure in accordance with the procedure stated in 3-2 Reprocessing procedure every time immediately after completing the ultrasound examination.

Chapter 3: Cleaning, Disinfecting, and Sterilizing

Overview

For full instructions regarding cleaning, disinfecting, and/or sterilization, as well as a full list of acceptable wipes, detergents, disinfectants, and sterilants, refer to the Terason Sterilization Matrix.

The 8BP4 probe is not completely immersible (refer to Figure 3-1 on page 3-6). The unimmersible part can only be disinfected by wipe disinfection.

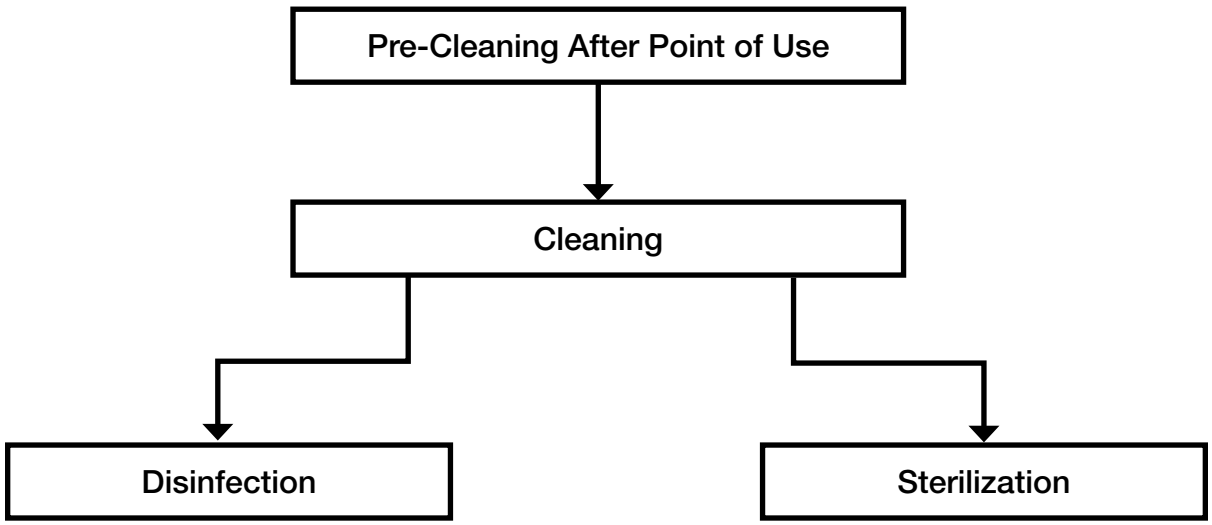
Warning

Never use the 8BP4 probe if the cable or connector has been immersed in any liquid. Failure to comply could result in serious injury to patients or damage to equipment.

To appropriately clean, disinfect, and/or sterilize the probe and the rest of the 8BP4 probe, follow the instructions for either "Closed System Cleaning and High Level Disinfection" on page 3-5, or follow the following processes:

1. "Pre-Cleaning at Point of Use Process" on page 3-4
2. "Cleaning Process" on page 3-6 if required by your site
3. "Disinfection Process" on page 3-7 or "Sterilization Process" on page 3-8 depending on your site's needs.

   After cleaning, disinfecting, and/or sterilizing, store the 8BP4 probe according to your site's guidelines.



Required Level of Disinfection and/or Sterilization

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.

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 8BP4 probe is classified as a Semicritical device.

Chapter 3: Cleaning, Disinfecting, and Sterilizing

Precautions

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

Caution

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

Caution

Handle all probes 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 probe 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 unimmersible part can only be disinfected by wipe disinfection. Failure to comply could result in damage to equipment.

Caution

When reprocessing the 8BP4 probe, the temperature cannot exceed 60°C (140°F). Failure to comply could result in damage to equipment.

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

Pre-Cleaning at Point of Use Process

Warning

Disconnect probes from the ultrasound unit prior to cleaning to avoid electrical shock.
Failure to comply could result in serious injury to staff or damage to equipment.
Failure to comply could result in serious injury to patients or damage to equipment.

To pre-clean the 8BP4 probe at the point of use, follow these steps:

1. If the ultrasound unit is powered on, freeze the ultrasound image, and then disconnect the probe from the ultrasound unit to be cleaned.

   or

   Shut down the ultrasound unit using the main power button located on top left corner of the unit. When the ultrasound unit has completely shut down, disconnect the probe from the ultrasound unit to be cleaned.

2. Dispose of the single use sterile probe cover from the probe.

   Used single use sterile probe cover and related exam materials do not need to be cleaned before disposal. Place them into the correct material waste bins, following national and local regulations. For additional information about disposal, contact Terason Service (refer to “Terason Contact Information” on page i).

3. Use a soft dry cloth, a clean soft cloth lightly dampened with a mild soap, or an approved wipe (as listed in the Terason Probe Disinfection Info) to remove any visible gel or biological matter from the probe.

4. Visually inspect the probe and the cable to ensure that all foreign matter (such as blood, tissue, protein, and acoustic gel) are removed and that the probe and cable are thoroughly dried.

5. Transport the 8BP4 probe to your site’s cleaning area in a tray.

6. Continue with “Cleaning Process” on page 3-6 or “Disinfection Process” on page 3-7, depending on your site’s guidelines.

Closed System Cleaning and High Level Disinfection

Warning

Disconnect probes from the ultrasound unit prior to cleaning to avoid electrical shock. Failure to comply could result in serious injury to staff or damage to equipment. Failure to comply could result in serious injury to patients or damage to equipment.

To clean and high level disinfect the 8BP4 probe through an automatic closed system, such as Civco ASTRA, follow these steps:
If the ultrasound unit is powered on, freeze the ultrasound image, and then disconnect the probe from the ultrasound unit to be cleaned.

or

Shut down the ultrasound unit using the main power button located on top left corner of the unit. When the ultrasound unit has completely shut down, disconnect the probe from the ultrasound unit to be cleaned.

1. Dispose of the single use sterile probe cover from the probe.

   Used single use sterile probe cover and related exam materials do not need to be cleaned before disposal. Place them into the correct material waste bins, following national and local regulations. For additional information about disposal, contact Terason Service (refer to “Terason Contact Information” on page i).

2. Use an approved wipe (as listed in the Terason Probe Disinfection Info) to remove any visible gel or biological matter from the probe.
3. Completely dry the 8BP4 probe with a clean dry soft cloth.
4. Use the ASTRA or your site’s closed cleaning and high level disinfection system, according to the manufacturer’s instructions.
5. Dry the 8BP4 probe with a clean dry soft cloth.
6. Store the 8BP4 probe according to your site’s guidelines.

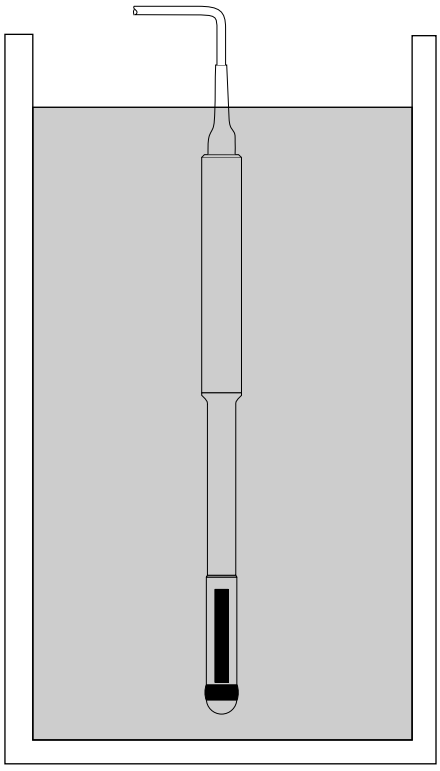
Chapter 3: Cleaning, Disinfecting, and Sterilizing

Cleaning Process

Warning

Disconnect probes from the ultrasound unit prior to cleaning to avoid electrical shock. Failure to comply could result in serious injury to staff or damage to equipment. Failure to comply could result in serious injury to patients or damage to equipment.To clean the 8BP4 probe at your site's cleaning area, follow these steps:

1. Prepare the detergent solution, 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 8BP4 probe, not going beyond the maximum immersion point to ensure cable and connector stays dry, into the prepared detergent solution (Figure 3-1).



Note:
To prevent excessive wear, soak the transducer in the solution for the shortest effective time as stated in the solution manufacturer's instructions.

Figure 3-1 8BP4 probe maximum immersion point

3. Wipe the immersible part of the 8BP4 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 8BP4 probe in the solution for the duration indicated on the manufacturer's label.

Cleaning Process *(continued)*

5. Wipe the part of the cable and connector that was not submerged, either with a damp, soft cloth dipped in the solution and then wiping the solution off with a damp, soft cloth that has been dipped in water and then wrung out, or with any approved wipe from the Terason Probe Disinfection Info.
6. Follow any instructions on the manufacturer's label for post-soak processes for removing detergent residue.
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 3-8 or "Sterilization Process" on page 3-9.

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Disinfection Process

Warning

Disconnect probes from the ultrasound unit prior to cleaning to avoid electrical shock. Failure to comply could result in serious injury to staff or damage to equipment. Failure to comply could result in serious injury to patients or damage to equipment.To clean the 8BP4 probe at your site's cleaning area, follow these steps:

1. Prepare the disinfectant solution, following the instructions on the manufacturer's label in regards to water temperature, application, solution strength, microbiological efficiency, service life, and duration of the immersion.
2. Submerge the immersible part of the 8BP4 probe, not going beyond the maximum immersion point to ensure the cable and connector stays dry, into the prepared disinfectant solution (Figure 3-1).
3. Keep the immersible part of the 8BP4 probe in the solution for the duration indicated on the manufacturer's label.
4. The non-immersible part can only be disinfected by wipe disinfection
5. Follow any instructions on the manufacturer's label for post-soak processes for removing disinfectant residue.
6. Visually inspect the outer surface of the probe for disinfectant residue. If necessary, repeat Step 4.
7. Dry the probe using one of the following methods:

- Wiping it with a single use lint-free wipe or towel
- Letting the probe air dry in an ambient temperature of 15-30°C (60-85°F) for at least 4 hours

Disinfection Process *(continued)*

7. Inspect the probe for any signs of damage, such as cracks in the housing, damaged scanning surface, or a cut cable. Discontinue the use of the probe if there is defect or damage noted during the inspection and contact Terason Customer Support Center (refer to “Terason Contact Information” on page i).
8. Store the 8BP4 probe according to your site’s guidelines.

Sterilization Process

Warning

Use only approved sterilization methods as described here and in the Terason Probe Disinfection Info. Failure to comply could result in serious injury to patients or damage to equipment, and will void the 8BP4 probe warranty.

Warning

Do not autoclave probes. Failure to comply will severely damage the probe and will void the warranty.

Warning

Before sterilizing the 8BP4 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.

To sterilize the 8BP4 probe, follow these steps:

1. Place the probe into sterilization tray (Figure 3-2).

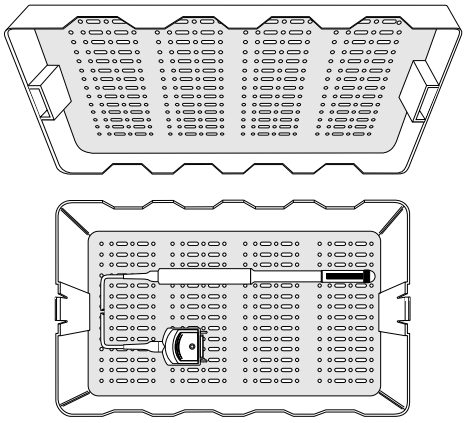


Figure 3-2: 8BP4 Probe in Sterilization Tray

Sterilization Process *(continued)*

2. Sterilize the 8BP4 probe.

The 8BP4 probe can be sterilized using the following methods:

- “Low Temperature Gas Plasma Sterilization” on page 3-9
- “Low Temperature Vaporized Hydrogen Peroxide Sterilization” on page 3-9

3. Store the sterilized 8BP4 probe in a cool, dust proof, dry, and dark space, avoiding high temperature, humidity, and direct sunlight.

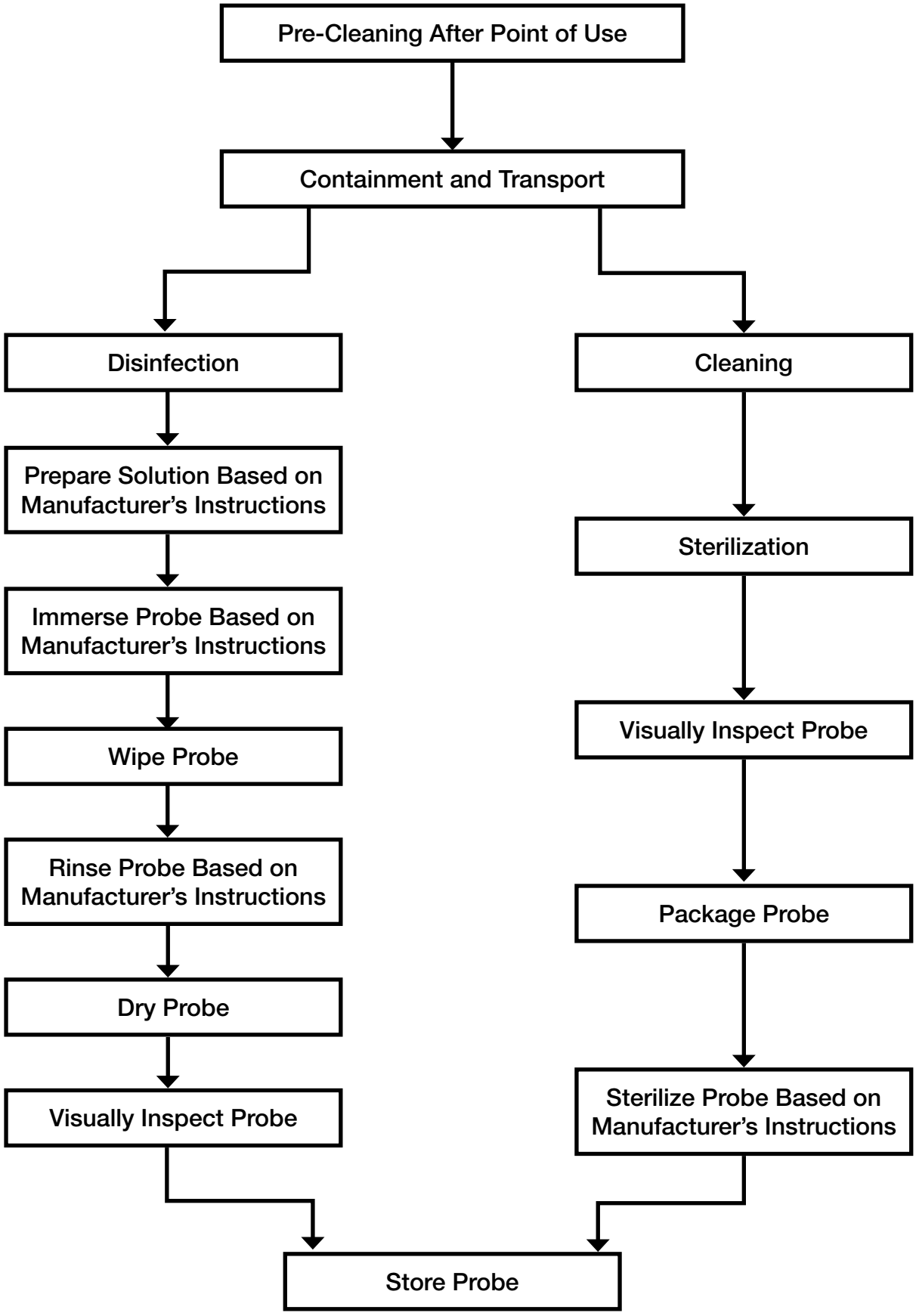
Low Temperature Gas Plasma Sterilization

Follow all manufacturer’s instructions for using Sterrad systems.

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

Flowchart

The cleaning, disinfecting, and sterilizing flowchart for non-automatic closed systems



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