Chapter 2

2 - Cleaning and Disinfecting Probes and Needle Guide Kits

Periodic Cleaning and Disinfecting Schedule

The following table describes the periodic maintenance to be carried out on probes and needle guide kits depending on their application. The risk of infection establishes the type of application.

Device	Application	Operation	Frequency
Non-invasive probes	Non-critical[1]	Cleaning	Before the first use and after each exam.
		Disinfection	When necessary.
Endocavity probes	Semi-critical[2]	Cleaning and Disinfection	Before the first use and after each exam.
Intraoperative and Laparoscopic probes	Critical[3]	Cleaning and Sterilization	Before the first use and after each exam.
Needle Guide kits	Critical[3]	Cleaning and Sterilization	Before the first use and after each exam.

[1] The application is considered non-critical when the device is used on intact skin.
[2] The application is considered semi-critical when the device is used on the mucous membranes.
[3] The application is considered critical when the device comes into contact with blood or compromised tissue.

If non-invasive probes are used in semi-critical/critical applications and in a sterile field, apply protective sheaths during the examination. These sheaths are usually composed of latex (natural rubber).

WARNING

Make sure that patients who are allergic to latex are identified before each examination. Serious allergic reactions to latex have been reported; the operator should be prepared to handle such reactions. Refer to the package indications to identify whether the product contains Latex (for further information refer to the FDA Medical Alert, March 29, 1991, "Allergic Reactions to Latex-Containing Medical Devices").

Siemens recommends disinfecting the probe, if the probe has not been used for an extended period.

Do not immerse the probe cable or connector in water or other liquid. Immersion may compromise the electrical safety features. The probe can be inserted in water up to the Maximum Immersion Level (see Appendix A).

Note

Probes and needle guides supplied by Siemens are neither disinfected nor sterilized.

Agents and Systems

Refer to **Appendix B** for a list of recommended cleaning, disinfection and sterilization agents and systems.

Note

Any damage caused by the use of non-recommended agents/systems is not covered by the warranty.

WARNING

The disinfection/sterilization agents and systems listed are recommended because of chemical compatibility with the probe materials.

The tables in Appendix B indicate which agents/systems have been positively tested for both biological effectiveness and chemical compatibility and which for chemical compatibility only. In the latter case follow the guidelines and recommendations of the manufacturer for the biological effectiveness of agents/systems.

Use of solutions other than those referenced is not recommended. They may damage the probe housing or acoustic lens. Siemens can take no responsibility for damage caused by using non-approved cleaning products.

Follow the instructions provided by the manufacturer of the agent for proper use. Observe specific soak times and dilution rates.

Overexposure to the disinfection fluid can damage the probe.

Personnel should adopt all necessary protective measures during the probe cleaning, disinfection and sterilization processes (for example gloves, protective glasses).

Never attempt to clean or disinfect the probes while they are connected to the system.

Probes Tightness to Liquids

See Appendix A for the description of probes Maximum Immersion Level.

Do not immerse the probe cable or connector in water or other liquid. The probes can be inserted in water up to the **Maximum Immersion Level** that will not compromise a probe's integrity:

WARNING

Connector immersion in water or other liquid can compromise the safety feature of the probe. Damage caused by the probe immersion is not covered under the warranty.

Cleaning Probes Used in Non-Critical Applications

The cleaning procedures described in this paragraph apply to all the probes used in non-critical applications. An application is considered non-critical when the device is used on intact skin.

Probes must be cleaned at regular intervals to ensure that they work properly. Siemens recommends removing the gel from the probe between one examination and the other; this keeps the probes clean between one complete cleaning procedure and the next one.

Cleaning Procedure

- Disconnect the probe from the system.
- Remove all residues of ultrasound gel from the probe using a soft cloth.
- Using one of the suggested agents, wipe/spray the probe thoroughly, paying attention to clean grooves and exposed parts, if present. When a liquid agent is used, wet a clean cloth/paper towel with cleaner to wipe the probe.

WARNING

When cleaning the probe using spray agent, DO NOT spray the probe while it is placed on its holder. Over spray can damage the system: the use of wipe cleaner is suggested in these cases.

- Wait for approximately 1 minute for cleaner to operate.
- Carefully dry the probe with a clean soft, dry cloth, removing foam when present.

Disinfecting Probes Used in Non-Critical Applications

The disinfection procedures described in this paragraph apply to all probes used in non-critical applications. The application is considered non critical when the device is used on intact skin. Low-level disinfection is sufficient for these applications. The probes can be disinfected using the recommended agents, following the manufacturer's instructions.

Disinfection Procedure

- Disconnect the probe from the system.
- Clean the probe using the procedure for non-critical applications.
- Immerse the probe casing in the recommended agent, up to the maximum level, following the manufacturer's instructions very carefully.
- Leave the probe immersed for longer than 10 minutes and less than 30 minutes, at room temperature (20°-30° C).

WARNING

Do not immerse the entire body of the probe. The probe is not waterproof and immersion may compromise the electrical safety characteristics (see Appendix A for Maximum Immersion Level).

Do not soak the probe in the disinfection solution for periods beyond the time required to achieve a disinfection.

CAUTION

Do not try to sterilize probes using the autoclave, ultra-violet rays, gamma rays or gas, steam or heat sterilization techniques. These sterilization methods can permanently damage the probe. Any damage to the probe caused by substances or methods not approved by Siemens is not covered by the warranty.

When disinfecting the probe using spray agent, DO NOT spray the probe while it is placed on its holder.

- Extract the probe, rinse it with sterile water and clean the probe handle and cable using the recommended agents or with a mild detergent solution.
- Carefully dry the probe with a clean soft, dry cloth or leave it to air dry for at least 30 minutes.

Cleaning and Disinfecting Probes Used in Semi-Critical Applications

The procedures described in this paragraph apply to all probes used in semi-critical applications. The application is considered semi-critical when the device is used on

the mucous membranes. The type of tissue the probe comes into contact with establishes the disinfection level. The use of sterile sheaths for this type of application is recommended, and high-level disinfection is necessary.

Wearing gloves is recommended during probe cleaning and disinfecting operations. The probe must be disinfected before it is used for the first time. The probe must be cleaned and disinfected after every examination. If the probe is contaminated by body fluids, clean and disinfect it before and after each use.

Siemens recommends disinfecting the probe before it is used for the first time after prolonged storage periods.

- Disconnect the probe from the system.
- Remove the protective sheath; clean the probe handle, the transducer and the endoscope with the recommended agent, using the procedure for non-critical application.

Note

Handle any examination waste (for example protective sheath, gloves) as if potentially infected and treat it accordingly.

- Immerse the probe casing in the recommended agent, up to the maximum level, following the manufacturer's instructions very carefully.
- Leave the probe immersed for longer than 10 minutes and less than 30 minutes, at room temperature (20°-30° C).

WARNING

Do not leave the probe immersed in the disinfectant for longer than the time indicated by the manufacturer for high-level disinfection.

Do not immerse the entire body of the probe. The probe is not waterproof and immersion may compromise the electrical safety characteristics (see Appendix A for Maximum Immersion Level).

- Extract the probe, rinse it with sterile water and clean the probe handle and the cable with a soft cloth dampened with a mild detergent solution.
- Carefully dry the probe with a clean soft, dry cloth or leave it to air dry for at least 30 minutes.

CAUTION

Any damage to the probe caused by substances or methods not approved by Siemens, such as steam (autoclave), ethylene oxide or radiation, are not covered by the warranty. These sterilization methods can permanently damage the probe.

For information on how to store disinfected parts, refer to the locally applicable procedures.

Cleaning and Sterilization of Intraoperative and Laparoscopic Probes

Please refer to next chapters for more information on the accessories of the intraoperative probe.

The procedures described in this paragraph apply to the intraoperative probe and its accessories and to the laparoscopic probes used in critical applications. The application is considered critical when the device comes into contact with blood or compromised tissue. Sterilization is stipulated for this type of procedure.

Wearing gloves is recommended during cleaning and sterilization procedures.

WARNING

Personnel should adopt all necessary protective measures during the probe cleaning, disinfection and sterilization processes (for example gloves, protective glasses).

The probe and optional accessories (such as needle guide kits and attachments) must be sterilized before it is used for the first time. They must be cleaned and sterilized after every examination.

Siemens recommends sterilizing the probe and the kit before they are used for the first time after prolonged storage periods.

Cleaning Procedure

- Disconnect the probe from the system.
- Dismantle the needle guide kit or the attachments from the probe and remove the sheath.
- Scrub the probe and the attachments carefully with a soft cloth or a sponge dampened with a cleaning solution.
- Immerse the probe (refer to the Appendix A for maximum immersion level) in the recommended cleaning agents, following the manufacturer's instructions very carefully.

WARNING

Do not immerse the entire body of the probe. The probe is not waterproof and immersion may compromise the electrical safety characteristics.

- Extract the probe, carefully rinse it with water to remove cleaning agent residuals.
- Carefully dry the probe with a clean soft, dry cloth or leave it to dry air for at least 30 minutes.

Sterilization Procedure

For information on how to store sterilized parts, refer to the locally applicable procedures.

- Follow the above procedure to clean the probe.
- Immerse the probe casing into the recommended agents, following the manufacturer's instructions very carefully.

WARNING

Do not leave the probe immersed in the agent for longer than the time indicated by the manufacturer for sterilization.

Do not immerse the entire body of the probe. The probe is not waterproof and immersion may compromise the electrical safety characteristics (see Appendix A for Maximum Immersion Level).

- Extract the probe and rinse it with sterile water.
- Carefully dry the probe with a clean soft, dry cloth or leave it to dry air for at least 30 minutes.

CAUTION

Any damage to the probe caused by substances or methods not approved by Siemens, such as steam (autoclave), ethylene oxide or radiation, are not covered by the warranty. These sterilization methods can permanently damage the probe.

Refer to Appendix B for information on STERRAD manufacturer.

Sterilization Procedure for IOE323 and LP323 Probes with STERRAD

Follow the above procedure to clean the probe.

- Place the probe inside a pack compatible with sterilization process.
- Follow the STERRAD® instructions loading the sterilization chamber at the following conditions:
  - Temperature: 55°C
  - Time: 54 min
  - Minimum pressure: 400 mtorr
  - Maximum pressure: 760 torr

CAUTION

Before proceeding with the process, verify that the settings of the sterilization chamber comply with the indicated conditions, otherwise the probe may be possibly damaged.

Cleaning and Sterilization of Needle Guide Kits

The procedures described in this paragraph apply to all the kits used in critical applications. The application is considered critical when the device comes into contact with blood or compromised tissue. Sterilization is stipulated for this type of procedure.

Wearing gloves is recommended during cleaning and sterilization operations.

WARNING

Personnel should adopt all necessary protective measures during the probe cleaning, disinfection and sterilization processes (for example gloves, protective glasses).

Siemens recommends sterilizing the kit before it is used for the first time after prolonged storage periods.

The kit must be sterilized before it is used for the first time. They must be cleaned and sterilized after every examination.

- Dismantle the kit from the probe.
- Clean the kit carefully with mild soap.
- Follow the instructions of the manufacturer of the sterilization agent.

Note

The material used for the ABS needle guide kits, manufactured by Siemens, can undergo all the sterilization methods used for surgical instruments.

For information on how to store sterilized parts, refer to the locally applicable procedures.

3 - Examinations with the Endocavity Probe

The endocavity **EC1123** probe is Type BF part. As per directive EN60601-1, the probe must be physically intact and the system correctly grounded for the electrical safety of the patient and the operator.

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Read the "Safety and Standards" manual carefully: all safety characteristics, cautions and warnings listed also apply to the use of this probe.

In particular, remember that:

WARNINGS

The system must be correctly grounded: it must be supplied from a socket equipped with a protective earth connection.

Mobile configurations are fitted with insulated supply sockets for supplying documentation systems without increasing the leakage current. Incorrect connections or failure to use insulated sockets may compromise electrical safety.

In case of doubts about the protective earth connection, DO NOT use the probe and contact Siemens immediately.

Characteristics and Components

The **EC1123** probe incorporates a high frequency convex transducer for sagittal (transverse) endorectal or endovaginal scanning.

Examination Safety

Endocavity probes must be used by operators who have been specially trained to insert the probe and to interpret the images. Carefully review current medical provisions and follow their precautions and recommendations concerning the preparation and positioning of the patient, probe insertion and manipulation techniques.

Before the Examination

Before each examination Siemens recommends the Operator to:

- Perform a manual and a visual inspection of the entire probe before using it (see Chapter 2 of this manual). DO NOT use the probe if it has been damaged or if you suspect damage.

WARNING

Physical damage to the probe may cause electrical or mechanical injury to the patient. Protective sheaths DO NOT provide protection against these damages nor do they guarantee that the probe is insulated electrically. DO NOT USE the probe if you know or suspect that it has been damaged.

Note

The operator is recommended to wear gloves during the probe preparation procedure.

- Use protective sheaths during the examination. These sheaths are mainly composed of latex (natural rubber).

Note

Siemens recommends the use of sterile sheaths in endovaginal examinations.

WARNING

The probe sheaths may contain natural rubber latex which may cause allergic reactions. Make sure that patients who are allergic to latex are identified before each examination. Serious allergic reactions to latex have been reported; the operator should be prepared to handle such reactions. Refer to the package indications to identify whether the product contains Latex (for further information refer to the FDA Medical Alert, March 29, 1991, "Allergic Reactions to Latex-Containing Medical Devices").

If the protective cover is damaged during the endocavity exam on patients affected by a spongiform encephalopathy (for instance Creutzfeldt-Jacob disease), refer to the guidelines provided by the Centres for Disease Control and Prevention (www.cdc.gov) and by World Health Organization (www.who.int).

Refer to next chapters for recommended gels and sheaths.

- Apply enough ultrasound gel inside the sheath.
- Completely unroll the sheath along the transducer body, making it adhere, so as to avoid air pockets.
- Secure the sheath with the rubber band.

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The operator should be familiar with the mechanical and thermal indices display and the **ALARA** principle (As Low As Reasonably Achievable) before using the probe. The patient must be exposed to ultrasound for as short time as possible and only for as long as it takes to achieve the diagnostic information.

During the Examination

WARNING

Before probe use, check to be sure that the probe name shown on the monitor is correct.

During the examination Siemens recommend the operator to:

- Never force the probe during insertion or removal.

WARNING

Forced insertion or removal may wound the patient.

- Cover the probe handle with a disposable cloth during examinations in which the presence of pathogenic micro-organisms is suspected.

Electric scalpels used during the examination may interfere with the 2D and make it impossible to use Doppler procedures.

Electric scalpels, and other devices that introduce radio frequency or electro-magnetic current fields into the patient, interfere with ultrasound images.

While using the system in combination with high frequency devices (like electro-surgical units), be aware that a failure in the surgical device or a damage to the transducer lens can cause electro-surgical currents that can burn the patient. Thoroughly check the system and the probe before applying HF surgical currents to the patient. Disconnect the probe when not imaging.

WARNING

Physical damage to the probe may cause electrical or mechanical injury to the patient. Protective sheaths DO NOT provide protection against such damage nor do they guarantee that the probe is electrically insulated. Perform a manual and visual check before each examination to ensure that the probe is intact.

At the End of the Examination

At the end of the examination, Siemens recommends the operator to:

- Clean and disinfect the probe, according to the instructions provided in Chapter 2 of this manual.
- Store the probe as indicated in Chapter 1 of this manual.

Preparation of the Endocavity Probe

Follow the instructions below for preparing the endocavity probe.

Note

The operator is recommended to wear gloves during the probe preparation procedure.

See chapter on consumables for selecting the gel and sheathes.

- Apply a sufficient quantity of ultrasound gel inside the sheath.

WARNING

The probe sheaths may contain natural rubber latex which may cause allergic reactions. Make sure that patients who are allergic to latex are identified before each examination. Serious allergic reactions to Latex have

been reported; the operator should be prepared to handle such reactions. Refer to the package indications to identify whether the product contains Latex (for further information refer to the FDA Medical Alert, March 29, 1991, "Allergic Reactions to Latex-Containing Medical Devices").

- Completely unroll the sheath along the transducer body, making it adhere, so as to avoid air pockets.
- Secure the sheath with the rubber band provided.
- To make it easier to insert the endocavity probe, use only water-based lubricating gel with the probe.

Water Stand-Off for EC1123 Probe

The **EC1123** probe has two communicating holes, one at the tip and one at the base, that make it possible to use water stand-off to optimize probe adherence in transrectal examinations. The probes are equipped with a 60 cc syringe with tubes that allow water to be injected.

- Cover the part of the probe that can be immersed with the stand-off cap and attach it with the rubber band provided at about 5cm. from the tip; make sure the water intake hole is below the band.
- Fill a 60 cc syringe with sterile water.
- Apply the tap valve to the syringe.
- Connect a section of the IV tube to one end of the tap; the other end of the IV tube must be inserted into the probe-filling hole.
- Open the tap; inject about 30 cc of water into the stand-off.

Eliminate the air bubbles between the transducer and the sheath; air bubbles impede the transmission of ultrasound.

- To eliminate air bubbles, turn the probe upwards holding it by the handle; the bubbles will rise towards the water intake hole.
- Suck air back into the syringe; close the tap to remove the syringe and expel the air.
- Repeat this procedure until all the air bubbles have been eliminated.
- Replace water, without air, back into the syringe and close the valve; leave the tube and the syringe connected.
- Apply ultrasound examination gel to the tip of the stand-off.
- Cover the portion of the probe that is to be inserted with the protective sheath.

WARNING

The protective sheaths available on the market often contain latex. Make sure that patients who are allergic to latex are identified before each examination. Serious allergic reactions to Latex have been reported; the

operator should be prepared to handle such reactions. Refer to the package indications to identify whether the product contains Latex (for further information refer to the FDA Medical Alert, March 29, 1991, "Allergic Reactions to Latex-Containing Medical Devices").

- To make insertion easier, use only water-based lubricating gel with the probe.

Once the probe is in the correct position, fill the stand-off with water again. To optimize image quality, use enough water to ensure that the probe adheres as well as possible to the rectal wall.

Do not remove the probe from the rectum if the probe tip is still full of water.