Notes for operators and responsible maintenance personnel

★ Please read through this Instruction Manual carefully prior to use.
★ Keep this Instruction Manual together with the ultrasound diagnostic instrument for any future reference.
Symbols used in this document

Safety information is classified into Danger, Warning, and Caution according to the level of hazard. Those terms are used in safety information provided to prevent hazards and injuries to the operator or patient.

<table>
<thead>
<tr>
<th>Symbol</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>🚨 Danger</td>
<td>Indicates an imminently hazardous situation which, if not avoided, will result in death or serious injury to the operator or patient.</td>
</tr>
<tr>
<td>🚨 Warning</td>
<td>Indicates a potentially hazardous situation which, if not avoided, could result in death or serious injury to the operator or patient.</td>
</tr>
<tr>
<td>🚨 Caution</td>
<td>Indicates a potentially hazardous situation which, if not avoided, may result in minor or moderate injury to the operator or patient, or property damage only.</td>
</tr>
<tr>
<td>✏ Note</td>
<td>Indicates a strong request concerning an item that must be observed in order to prevent damage or deterioration of the equipment and also to ensure that it is used efficiently.</td>
</tr>
<tr>
<td>☢ This symbol means that the described action is prohibited.</td>
<td></td>
</tr>
<tr>
<td>!!! This symbol means that the described action is mandatory.</td>
<td></td>
</tr>
</tbody>
</table>
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This instruction manual contains 5 pages of front matter and 26 pages of the main content.
1. Applicable cleaning, disinfection and sterilization methods

Applicable cleaning, disinfection and sterilization methods for each product are listed in the Table 1. The detail of each method is described in Chapter 3.

Table 1 Applicable cleaning, disinfection and sterilization methods

<table>
<thead>
<tr>
<th>Model</th>
<th>Refer the corresponded items in Chapter 4, 7, 8, 10 and 13</th>
<th>Cleaning</th>
<th>Disinfection</th>
<th>Sterilization</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Manual</td>
<td>Automated</td>
<td>Manual</td>
</tr>
<tr>
<td>S3ESL1</td>
<td>A</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>MXS2ESLL</td>
<td>A</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>MXS2ESLL1</td>
<td>A</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
</tbody>
</table>

Note: X means “Applicable”

*1: Automated Need waterproof case (WP-001)

*2: Liquid sterilization USA only
2. Precautions for cleaning, disinfection and sterilization

The following warnings and cautions must be observed when cleaning, disinfecting and sterilizing the probe and accessories.

⚠️ Warning

- Wear protective gloves and other protective gear during cleaning, disinfection and sterilization. Handling of the probe with your bare hands before sterilization can result in an infection.
- After finishing soaking the probe in cleaning agents, thoroughly wash it with running water. Residual cleaning agents can cause an adverse reaction to the operator or the patient.
- After chemical sterilization, thoroughly wash the probe with sterile water. Residual chemicals can cause an adverse reaction to the operator or patient. (USA only)
- After soaking in a disinfectant, thoroughly wash the equipment with deionized water. Leavings of the disinfectant can cause an adverse reaction on the bodies of the operator or patient.
- Perform full aeration after gas sterilization. Residual gas can cause an adverse reaction to the operator or patient.
- Do not clean or sterilize using procedures other than those specified in this manual. Failure to clean and sterilize the equipment can result in an infection. It can also result in damage to the probe or reduced performance. The probe is not compatible with autoclave sterilization or boiling and other types of sterilization at temperatures exceeding 60°C [140°F].
- For details on the usage conditions of chemicals and sterilization procedures, refer to the documentation supplied with the respective chemical or sterilization equipment. Infection can be resulted due to incomplete sterilization. Wrong sterilization procedure could cause deterioration of the probe.

⚠️ Caution

- Do not immerse the probe into any liquid beyond the range of IPX7. The range is indicated in the separate instruction manual “Specification”. If any liquid enters the connector, immediately stop using the probe and contact one of our offices and/or distributor’s offices listed on the back cover. Liquid in the connector could cause electric shock to the operator or patient.
- Do not wipe the ultrasonic radiation part with alcohol. Alcohol could damage the part.
- Do not use organic solvent such as thinner for cleaning to prevent the probe from damage.
- Do not use hard or sharp objects to remove residue on the probe. Such objects may damage the probe.
- If it is necessary to use a waterproof case, obey the instruction manual of waterproof case regarding fitting to the probe.

Additional information:
The Instructions provided above have been validated by the medical device manufacturer as being CAPABLE of preparing a medical device for re-use. It remains the responsibility of the processor to ensure that the processing as actually performed using equipment, material and personnel in the processing facility achieve the desired result. This requires validation and routine monitoring of the process. Likewise any deviation by the processor from the instructions provided should be properly evaluated for effectiveness and potential adverse consequences.
3. Reprocessing instruction according to ISO 17664

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

Table 2

<table>
<thead>
<tr>
<th>WARNINGS</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>• The probe is delivered unsterile. Prior to the first use, reprocess the probe.</td>
<td></td>
</tr>
<tr>
<td>• Temperature should not exceed 60°C[140°F] during reprocessing.</td>
<td></td>
</tr>
<tr>
<td>• Probe connector has no water resistant. When a washer-disinfector is used, the waterproof case MUST be used to cover the probe connector.</td>
<td></td>
</tr>
</tbody>
</table>

Limitations on reprocessing

The probe is not completely submergible (Do not immerse the probe into any liquid beyond the range of IPX7. The range is indicated in the separate instruction manual “Specification”.)

Parts which are not submergible can only be disinfected by wipe disinfection.

Transportation before using

The probe should be packed in a sterile pouch or container to transport from Central Sterile Supply Department (CSSD) to an operating room. Be careful not to damage the sterile pouch or container during transportation.

The level of processing required depends on the type of equipment and its use.
The CDC (Centers for Disease Control and Prevention) in the USA and the RKI (Robert Koch Institute) in Germany classify medical devices according to their use. For each classification, they specify the level of disinfection/sterilization processing that is required before use. Table 3 summarizes this information.

Table 3

<table>
<thead>
<tr>
<th>Classification</th>
<th>Definition</th>
<th>Processing</th>
</tr>
</thead>
<tbody>
<tr>
<td>Noncritical</td>
<td>Application part only contacts intact and uninjured skin</td>
<td>Cleaning ↓ Disinfection [in the USA, low-level disinfection]</td>
</tr>
<tr>
<td>Semicritical</td>
<td>Application part contacts mucosa (intracavitary application)</td>
<td>Cleaning ↓ Disinfection (Disinfectant with bactericidal, fungicidal and virucidal effect) [in the USA, high-level disinfection or sterilization]</td>
</tr>
<tr>
<td>Critical</td>
<td>Application part contacts intracorporeal tissue directly (intraoperative application)</td>
<td>Cleaning ↓ Disinfection ↓ Sterilization *1</td>
</tr>
</tbody>
</table>

*1. When sterilization is not possible, the FDA in the USA recognize that disinfection (in the USA, high-level disinfection) and the use of a sterile gel and sterile transducer cover, as described in the instructions provided with the transducer cover, is an accepted method of infection control for probe.
Flowchart of reprocessing process of this probe and accessories is as follows:

1. **Point of use** (Pre-cleaning)
2. **Waterproof cover** (If necessary)
3. **Containment and transportation**
4. **Manual cleaning and disinfection**
   - Manual cleaning
   - Rinsing after manual cleaning
   - Drying
   - Manual disinfection
   - Rinsing after manual disinfection
5. **Washer disinfector (WD)**
   - Automated cleaning
   - Automated disinfection

6. **Drying**
7. **Maintenance, inspection and testing**
8. **Packaging**
9. **Sterilization**
4. Point of use (Pre-cleaning)

Pre-cleaning should be done immediately after each use. The procedure is as follows:

A). Probes
1) Clean the probe of all patient’s blood or fluid with running tap water until the surface of the probe looks visually clean.
2) Wipe the whole surface of the probe by gauze pad and remove superficial visible impurities until the surface looks visually clean.

B). Bite block
1) Clean the bite block of all patient’s blood or fluid with running tap water until the surface of the bite block looks visually clean.
2) Wipe the whole surface of the bite block by gauze pad and remove superficial visible impurities until the surface looks visually clean.

5. Waterproof case

The probe which is compatible with the waterproof case can be soaked completely into a liquid when the waterproof case is attached. Also automated cleaning and disinfecting is only available for probes which are compatible with the waterproof case.

Therefor refer to the instruction manual “Specification” for the compatibility of waterproof case. Connector and part of the cable which are out of the IPX7 range belong to the part which cannot be soaked into a liquid without using the waterproof case. Refer to the instruction manual “Specification” for information about the range of IPX7.

6. Containment and transportation

Putting the contaminated equipment into exclusive shock and damage proof container for transportation is recommended. It is recommended that instruments are reprocessed as soon as possible and not later than 4 hours after usage.
7. Manual cleaning and disinfection

Prepare following items before manual cleaning and disinfection.

A). Probes

1) Detergent: ENZOL®/Cidezyme® (Johnson & Johnson, #2258) or another cleaning agent with approved material compatibility for this medical device.

2) Disinfectant: Cidex® OPA (Johnson & Johnson, # 20391) or another disinfectant with approved material compatibility for this medical device.

3) 2 tanks, 1 for cleaning and 1 for disinfection - optional: 1 additional tank for rinsing with deionized/tap water (sufficient size for immersion of the submergible part of the probe at full length)

4) Soft, fluff free cloth or single use towel

5) Personal protective equipment (gloves, water repellent protective skirt, face protection mask or protective glasses, see also instructions of the manufacturer for the detergent and the disinfectant)

B). Bite block

1) Detergent: Cidezyme®/ENZOL® (Johnson & Johnson, # 2258) or another cleaning agent with approved material compatibility for this medical device.

2) Disinfectant: Cidex® OPA (Johnson & Johnson, # 20391) or another disinfectant with approved material compatibility for this medical device.

3) 2 tanks, 1 for cleaning and 1 for disinfection - optional: 1 additional tank for rinsing with deionized/tap water (sufficient size for immersion of the bite block).

4) Soft, fluff free cloth or single use towel

5) Personal protective equipment (gloves, water repellent protective skirt, face protection mask or protective glasses, see also instructions of the manufacturer for the detergent and the disinfectant)
7-1. Manual cleaning

A). Probes

1) The temperature of the detergent solution should be between 15-30 °C [59-86°F], concentration is 1.6%. Please note the minimum contact time of the detergent in the manufacturer’s instruction. If a differing detergent is used, please also consider the approved material compatibility for this probe.

2) Immerse the submergible part of the probe into the detergent.

3) Wipe the submergible part of the probe under the surface of the detergent solution with a single-use, fluff free soft cloth to remove all visible soil. Be sure that all grooves of the probe are implemented during the cleaning process. If necessary use an appropriate cleaning brush for this purpose.

Particular attention is required for the cleaning of the lock lever and adjusting knob of the probe. Every column of the adjusting part should be wiped with a soft cloth under the surface of the detergent solution to assure that no soil is left in the cavities of the handling part.

4) Wipe the non-submergible parts of the probe with a soft cloth dipped with a detergent.

5) Rinse the submergible part of the probe with running tap water for 1 minute.

(Alternatively, immerse the submergible part of the probe in a tray filled with deionized water/tap water for 5 min.)

6) Visually check the outer surface of the probe for cleanliness. If necessary, use magnifying glass for visually check. If there is still soil visible, repeat all above steps.

B). Bite block

1) The temperature of the detergent solution should be between 15-30 °C, concentration is 1.6%. Please note the minimum contact time of the detergent in the manufacturer’s instruction. If a differing detergent is used, please also note the approved material compatibility for the medical device.

2) Immerse the bite block into the detergent.

3) Wipe the bite block under the surface of the detergent solution with a single-use fluff free soft cloth to remove all visible soil. Be sure that all grooves of the bite block are implemented during the cleaning process. If necessary use an appropriate cleaning brush for this purpose.

4) Rinse the bite block with running water 1 minute.

(Alternatively: immerse the bite block in a tray filled with deionized/tap water for 5 minutes).

5) Visually check the outer surface of the bite block for cleanliness. If necessary, use magnifying glass for visually check. If there is still soil visible, repeat all above steps.
7-2. Manual disinfection

A). Probes

1) Confirm the concentration of the disinfectant before immersing the probe. Although Cidex® OPA does not need to be diluted, it is recommended to use test strips to verify the concentration. The test strips can indicate whether or not the concentration is above the Minimum Effective Concentration (MEC). Please also note the expiration date of the test strips. Temperature of disinfectant solution should be minimum 20 °C [68°F]. The minimum contact time is 5 minutes. If a differing disinfectant is used, follow the manufacturer’s instructions. Please also consider the material compatibility for the medical device.

2) Wipe the non-submergible parts of the probe with a soft and fluff free cloth with disinfectant.

3) Immerse the submergible part of the probe into the disinfectant. Set a clock to insure the recommended contact time is observed. Particular attention is required for the disinfection of the lock lever and adjusting knob of the probe. Rinse the columns and cavities of the adjusting knob and the lock lever with 50 ml disinfectant solution.

4) Rinse the submergible part of the probe with running deionized water for 1 minute. (Alternatively, immerse the submergible part of the probe in a tray filled with deionized water for 5 minutes.)

5) Visually check the outer surface of the probe for that there are no leavings of the disinfectant. If necessary, repeat the rinsing.

⚠️ Caution

Do not wipe the ultrasonic radiation part with alcohol. Alcohol could damage the part.

B). Bite block

1) It is recommended to test the concentration of disinfectant solution before each usage. The solution Cidex® OPA is ready for use and does not need to be diluted. Test strips to verify that the appropriate concentration of Cidex® OPA is correct are available by manufacturer. Test strips will indicate a concentration above the Minimum Effective Concentration (MEC). Please also note the expiration date of the test strips. Temperature of disinfectant solution should be minimum 20°C. The minimum contact time is 5 minutes. If a different disinfectant is used, follow the manufacturer’s instructions. Please also consider the material compatibility for the medical device.

2) Immerse the bite block into the disinfectant. Set a clock to insure the recommended contact time is observed.

3) Rinse the bite block with running deionized water for 1 minute. (Alternatively: immerse the bite block in a tray filled with deionized water for 5 minutes).

4) Visually check the outer surface of the bite block for that there are no leavings of the disinfectant. If necessary, repeat the rinsing.

⚠️ Warning

After finishing soaking the probe in the cleaning agent or disinfectant, thoroughly rinse it with running water (after cleaning) and deionized water (after disinfection). Residual agent can cause an adverse reaction to the operator or patient.
7-3. Cable and connector

Wipe the cable in 20 cm intervals with gauze dipped in ethyl alcohol or water, and dry it after wiping.
Clean the connector with gauze dipped in ethyl alcohol, and dry it after cleaning.
Clean the other parts of the probe which must not be soaked in liquid in the same manner as the connector.

Note

If the entire length of the cable is wiped at once, a part of the cable may be wrinkled.
If this occurs, pull the wrinkled part in the opposite direction to smooth it.
8. Automated cleaning and disinfecting

A). Probes (with waterproof case)

The following items must be provided prior to automated cleaning and disinfection:

a) Washer disinfector: according to ISO 15883 with chemo-thermal program (temperature: max 60 °C[140°F]).

b) Waterproof case for probe connector WP-001

c) Detergent: Korsolex Endo-Cleaner (Bode Chemie; # 972 020) or another cleaning agent with approved material compatibility for this medical device.

d) Disinfectant: Korsolex Endo-Disinfectant (Bode Chemie; # 972 030) or another disinfectant with approved material compatibility for this medical device.

1) The parameters of the cleaning and disinfection of the device are as follows:

<table>
<thead>
<tr>
<th>Program step</th>
<th>Water (40l)</th>
<th>Dosage (ml/l)</th>
<th>Temp. (°C)/(°F)</th>
<th>time (min)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pre-Rinse</td>
<td>Cold water</td>
<td>5</td>
<td>5</td>
<td>10</td>
</tr>
<tr>
<td>Cleaning</td>
<td>Deionized water</td>
<td>5 (0.5%)</td>
<td>50/122</td>
<td>10</td>
</tr>
<tr>
<td>Rinse</td>
<td>Deionized water</td>
<td></td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>Disinfection</td>
<td>Deionized water</td>
<td>10 (1%)</td>
<td>55/131</td>
<td>5</td>
</tr>
<tr>
<td>Rinse</td>
<td>Deionized water</td>
<td></td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>Rinse</td>
<td>Deionized water</td>
<td></td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>Drying</td>
<td></td>
<td>55/131</td>
<td>15</td>
<td></td>
</tr>
</tbody>
</table>

2) Connect the waterproof case WP-001 to the probe connector and use the tester to confirm that there is no air leak. Refer to the instruction manual of the waterproof case WP-001 for detail information.

3) Close the door of the washer disinfector and start the chemo-thermal program.

4) Open the door after the process is done.

5) Take the probe out of the washer disinfector and check that it is dry. If not, dry it as described in the chapter drying.

⚠️ Caution

Be sure to attach the waterproof case (WP-001).

The connector cannot be soaked in liquid without the waterproof case.
B). Bite block

The following items must be provided prior to automated cleaning and disinfection.

a) Washer disinfecto according to ISO 15883 with chemo-thermal program (temperature: max 60°C [140°F]
b) Detergent: Korsolex® Endo-Cleaner (BODE Chemie, # 972 020) or another cleaning agent with approved material compatibility for this medical device

c) Disinfectant: Korsolex® Endo-Disinfectant (BODE Chemie, # 972 030) or another disinfectant with approved material compatibility for this medical device

d) Washer disinfecto accessories: basket with lid for holding the bite block

1) The parameter for cleaning and disinfecting the medical device are as follows:

<table>
<thead>
<tr>
<th>Program step</th>
<th>Water (40l)</th>
<th>Dosage (ml/l)</th>
<th>Temp. (°C)/(°F)</th>
<th>time (min)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pre-Rinse</td>
<td>Cold water</td>
<td></td>
<td></td>
<td>5</td>
</tr>
<tr>
<td>Cleaning</td>
<td>Deionized water</td>
<td>5 (0.5%)</td>
<td>50/122</td>
<td>10</td>
</tr>
<tr>
<td>Rinse</td>
<td>Deionized water</td>
<td></td>
<td></td>
<td>1</td>
</tr>
<tr>
<td>Disinfection</td>
<td>Deionized water</td>
<td>10 (1%)</td>
<td>55/131</td>
<td>5</td>
</tr>
<tr>
<td>Rinse</td>
<td>Deionized water</td>
<td></td>
<td></td>
<td>1</td>
</tr>
<tr>
<td>Rinse</td>
<td>Deionized water</td>
<td></td>
<td>55/131</td>
<td>15</td>
</tr>
</tbody>
</table>

2) Place the bite block into the basket with lid.
3) Close the door of the washer disinfecto and start the chemo-thermal program.
4) Open the door after the end of the program.
5) Take the bite block out of the washer disinfecto and check whether it is dry. If not, proceed as described under drying.
9. Applicable cleaners and disinfectants / Suppliers List

The applicable chemical solutions are listed below.

<table>
<thead>
<tr>
<th>General name</th>
<th>Trade name</th>
<th>Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>Enzyme cleaning agent</td>
<td>ENZOL®/Cidezyme®</td>
<td>ADVANCED STERILIZATION PRODUCTS®</td>
</tr>
<tr>
<td></td>
<td>Practical liquid 0.8V/V%</td>
<td>A Johnson &amp; Johnson company</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Division of Ethicon, Inc.</td>
</tr>
<tr>
<td>Alkylpolyalkyleneglykolether</td>
<td>Korsolex® Endo-Cleaner</td>
<td>BODE Chemie GmbH</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>General name</th>
<th>Trade name</th>
<th>Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ortho-phthalaldehyde</td>
<td>CIDEX® OPA Solution 0.55%</td>
<td>ADVANCED STERILIZATION PRODUCTS®</td>
</tr>
<tr>
<td></td>
<td></td>
<td>A Johnson &amp; Johnson company</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Division of Ethicon, Inc.</td>
</tr>
<tr>
<td>Glutaral</td>
<td>Cidex plus®</td>
<td></td>
</tr>
<tr>
<td>Glutaral</td>
<td>Korsolex Endo-Disinfectant</td>
<td>BODE Chemie GmbH</td>
</tr>
</tbody>
</table>

Note: * indicates that the marked disinfectant is not applicable in Canada.
### High-level disinfection

<table>
<thead>
<tr>
<th>General name</th>
<th>Trade name</th>
<th>Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hydrogen peroxide</td>
<td>PERASAFE™ * Practical liquid 1.62W/V%</td>
<td>ANTEC INTERNATIONAL</td>
</tr>
<tr>
<td>Peracetic acid</td>
<td>Acecide® * Solution 6%</td>
<td>Saraya Co., Ltd</td>
</tr>
<tr>
<td>Glutaral</td>
<td>Cidex plus® Solution 3.4%</td>
<td>ADVANCED STERILIZATION PRODUCTS® A Johnson &amp; Johnson company Division of Ethicon, Inc.</td>
</tr>
</tbody>
</table>

Note: * indicates that the marked disinfectant is not applicable in Canada.

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⚠️ **Warning**

- After disinfection, thoroughly rinse the probe with deionized water.
- Residual disinfectant can cause an adverse reaction to the operator or patient.
10. Drying

A). Probes

1) Wipe the probe with a single-use, fluff-free wipe or towel to remove moisture from the surface of the probe.
2) Dry the probe naturally in an ambient temperature between 15-30°C [59-86°F] for a minimum of 4 hours. Alternatively the probe can be dried using a drying heater at a temperature of less than 60°C [140°F].

B). Bite block

1) Wipe the bite block with a single-use, fluff-free wipe or towel for removing moisture on the surface of the bite block.
2) If using a drying heater for medical equipment, the temperature limit is a maximum of 60°C [140°F]. Dry until no visible moisture is left.
3) If using natural drying, temperature range should be between 15-30 °C [59-86°F] for a minimum time of 4 hours.

11. Maintenance, inspection and testing

Confirm following items
1) the function of mechanical moving parts
2) the image performance when the probe is connected to the scanner
3) there are no abnormal exterior damages such as cracks on the surface of the equipment
4) Safety tests (See Safety Instruction Manual 4-1)

12. Packaging

Store the disinfected probe in a dustproof environment until next application. Before sterilization it is necessary to pack all parts in a pouch suitable for sterilization, or in a tray with wrap according to ISO 11607-1 and ISO 11607-2 “Packaging for terminally sterilized devices” and ISO/TS 16775 “Packaging for terminally sterilized medical devices - Guidance on the application of ISO 11607-1 and ISO 11607-2” or the local hospital procedure. Follow the pouch manufacturer’s specifications or the local regulations for how to pack and seal the pouches. Check the sealing seam after heat sealing for any defects. In case of processing mistakes or defects the package has to be opened again and the device has to be packed and sealed again.
13. Sterilization

See “Table 1. Applicable cleaning, disinfection and sterilization methods” for available sterilization methods. Follow the instructions of the sterilizer manufacturer regarding usage, temperature and sterilization-time etc. Handling and maximum input to chamber of sterilizer should be according to operation manual of the sterilizer.

13-1. Ethylene oxide (EtO) gas sterilization

Sterile conditions of applicable sterilization methods are as follows.

Regarding the operation of the sterilizer, refer to the documentation supplied with the sterilizer.

<table>
<thead>
<tr>
<th>Perform sterilization in the following conditions:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gas Type: 10% EO/ 90% HCFC</td>
</tr>
<tr>
<td>Temperature: 50 - 60°C</td>
</tr>
<tr>
<td>122 - 140°F</td>
</tr>
<tr>
<td>Exposure Time: More than 120 minutes</td>
</tr>
<tr>
<td>Pressurization: 162 - 200kPa</td>
</tr>
<tr>
<td>Depressurization: 13 - 8kPa</td>
</tr>
<tr>
<td>Relative humidity: 40 - 90%</td>
</tr>
<tr>
<td>Aeration is minimum 12 hours</td>
</tr>
</tbody>
</table>

⚠️ Warning

* Perform full aeration after gas sterilization.
  Residual gas can cause an adverse reaction to the operator or patient.

🚫 Do not use the waterproof case during sterilization process.
13-2. STERRAD® sterilization

A). Probe

⚠️ Warning

🚫 The probe cannot withstand STERRAD® sterilization.

B). Bite block

Sterile conditions of applicable sterilization methods are as follows.

The applicable gas is listed below.

<table>
<thead>
<tr>
<th>General name</th>
<th>Trade name</th>
<th>Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hydrogen peroxide</td>
<td>STERRAD® Sterilization system</td>
<td>ADVANCED STERILIZATION PRODUCTS®</td>
</tr>
<tr>
<td>(58% density)</td>
<td>(STERRAD® 50, 100S, 200, NX or 100NX)</td>
<td>A Johnson &amp; Johnson company</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Division of Ethicon, Inc.</td>
</tr>
</tbody>
</table>

Regarding the operation of the sterilizer, refer to the documentation supplied with the sterilizer.

Perform sterilization in the following conditions:

<table>
<thead>
<tr>
<th>STERRAD® 50, 100S or 200:</th>
<th>Short Cycle</th>
</tr>
</thead>
<tbody>
<tr>
<td>STERRAD® NX or 100NX :</td>
<td>Standard cycle</td>
</tr>
</tbody>
</table>

Remark:
Some discoloration of the bite block may occur, but this does not affect performance or safety.

⚠️ Warning

🚫 Do not use the waterproof case during sterilization process.

⚠️ Caution

🚫 Do not sterilize the probe using the STERRAD system if the probe is not compatible with the STERRAD system. STERRAD compatibility is shown by the STERRAD label on the connector. Perform STERRAD sterilization only for STERRAD compatible probes, otherwise it can cause damage or deterioration to the probe.

* STERRAD® label

🚫 Do not put the probe directly into the sterilization pouch*.

Otherwise the pouch sticks to the cable and results in damage to the cable. Completely wrap the entire probe (including the probe tip, cable and connector) with sterilization wraps* before putting it into the sterilization pouch*.

*: A Johnson & Johnson company Division of Ethicon, Inc. product
13-3. Liquid sterilization (USA only)

- Applicable chemical solution for sterilization

The applicable sterilants are listed below.

<table>
<thead>
<tr>
<th>General name</th>
<th>Trade name</th>
<th>Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hydrogen peroxide</td>
<td>PERASAFE™ * Practical liquid 1.62 W/V%</td>
<td>ANTEC INTERNATIONAL</td>
</tr>
<tr>
<td>Peracetic acid</td>
<td>Acecide® * Solution 6%</td>
<td>Saraya Co., Ltd</td>
</tr>
<tr>
<td>Glutaral</td>
<td>Cidex plus® Solution 3.4%</td>
<td>ADVANCED STERILIZATION PRODUCTS® A Johnson &amp; Johnson company Division of Ethicon, Inc.</td>
</tr>
</tbody>
</table>

Note: * indicates that the marked sterilant is not applicable in Canada.

⚠️ Warning

After chemical sterilization, thoroughly rinse the probe with sterile water. Residual sterilant can cause an adverse reaction to the operator or patient.
13-4. Autoclave sterilization

A). Probe

⚠️ Warning

🚫 The probe cannot withstand autoclave sterilization.

B). Bite block

⚠️ Warning

⚠️ Please refer to "Table 1. Applicable cleaning, disinfection and sterilization methods"

Sterile conditions of applicable sterilization methods are as follows.
Regarding the operation of the sterilizer, refer to the documentation supplied with the sterilizer.

Sterilize in the following conditions: Temperature: 134°C or less

⚠️ Caution

🚫 Do not carry out autoclave sterilization in a temperature condition over 134°C.

13-5. STERIS® sterilization

A). Probe

⚠️ Warning

🚫 The probe cannot withstand STERIS® sterilization.

B). Bite block

The applicable product is listed below.

<table>
<thead>
<tr>
<th>General name</th>
<th>Trade name</th>
<th>Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>Peracetic acid</td>
<td>STERIS SYSTEM 1E®</td>
<td>STERIS®</td>
</tr>
</tbody>
</table>

Regarding the operation of the sterilizer, refer to the documentation supplied with the sterilizer.
14. Storage

Store the equipment in a cool, dry, dust-free and dark space to avoid high temperature, humidity and direct sunlight. Limitations for the time for sterilized equipment belong to package.
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Hitachi, Ltd.
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Contact
+81-3-6284-3668

Overseas Offices:

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Address: Sumpfstrasse 13 CH-6300 Zug, Switzerland

US Importer: Hitachi Healthcare Americas Corporation
Address: 1959 Summit Commerce Park, Twinsburg, Ohio 44087