TEE Proper Care and Handling

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PHILIPS

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CE 0086

This system complies with the Medical Device Directive.

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CAUTION

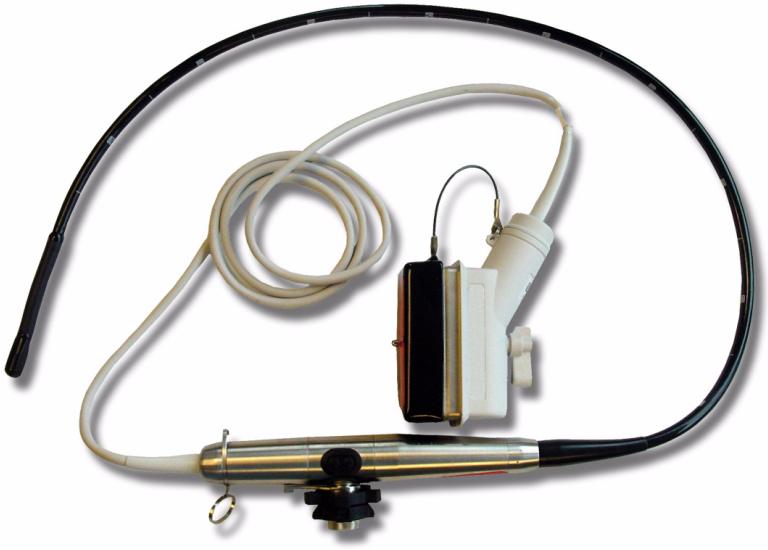
United States federal law restricts this device to sale by or on the order of a physician.

1 TEE Proper Care and Handling

Transducer Information

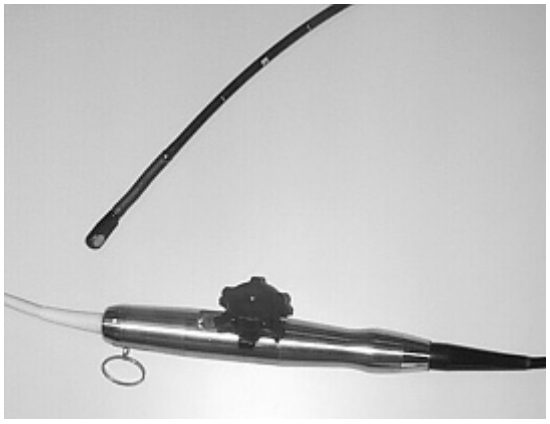
A Transesophageal echocardiography (TEE) exam is performed with a transducer mounted in a gastroscope, which is positioned in the esophagus or stomach. TEE transducers offer images that are unobstructed by lungs and ribs, making them important diagnostic tools for conditions that transthoracic echocardiography cannot adequately image.

OmniPlane II (Model 21369A)



Features	Enables high-resolution imaging and 360-degree views of the heart, unobstructed by lungs and ribs. Incrementally rotates from the horizontal plane at 0 degrees, to the vertical plane at 90 degrees, to a left/right reversed horizontal plane at 180 degrees. Enables lateral and anterior/posterior tip movement, with an adjustable friction brake. Capable of color flow imaging, steerable CW Doppler mode and PW Doppler mode, and frequency agility. Tip surface constantly monitored for patient safety. Convenient hanging ring.
Specifications	Tip: 1.5 cm x 1.2 cm, 3.3 cm long (0.6 in x 0.5 in, 1.3 in long) Shaft: 1.0 cm (0.4 in) diameter, 1.0 m (3.3 ft) long

NOTE Philips recommends that you use the OmniPlane II transducer only on patients weighing at least 25 kg (55 lb), to ensure the esophagus can comfortably accommodate the transducer.



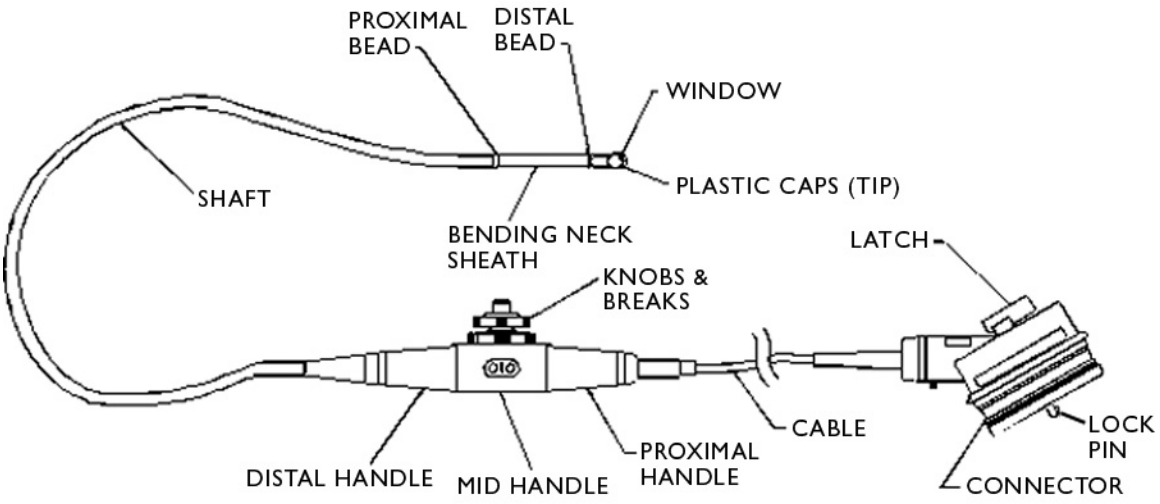
Features	Philips Ultraband transducer technology sensor for harmonic and contrast imaging. Enables high-resolution imaging and 360-degree views of the heart, unobstructed by lungs and ribs. Capable of harmonic imaging, contrast research, Tissue Doppler Imaging (TDI), color flow imaging, steerable CW Doppler mode and PW Doppler mode, frequency agility, and electrocautery suppression. Tip surface constantly monitored for patient safety. Convenient hanging ring.
Specifications	Tip: 1.5 cm (0.6 in) diameter, 3.5 cm (1.4 in) long Shaft: 1.0 cm (0.4 in) diameter, 3.2 ft (0.9 m) long

NOTE

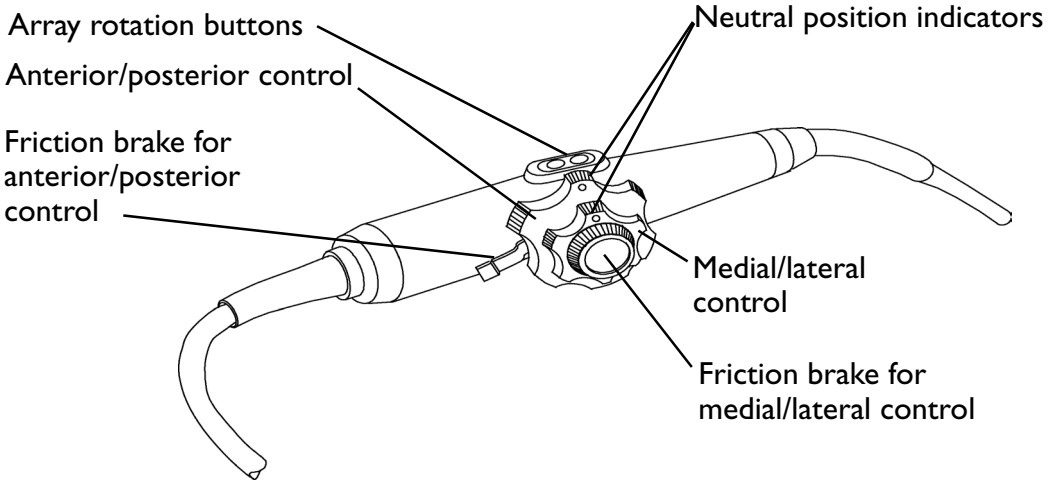
Philips recommends that you only use the OmniPlane III transducer on patients weighing at least 25 kg (55 lb), to ensure the esophagus can comfortably accommodate the transducer.

TEE Probe Parts

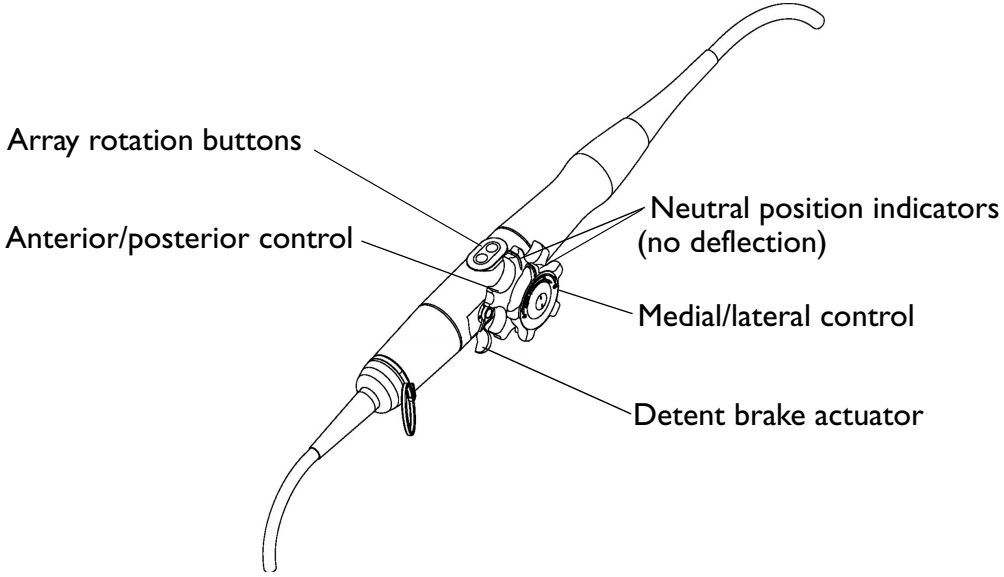
Basic TEE Parts



OmniPlane II Deflection Controls and Brakes



OmniPlane III Deflection Controls and Brakes



Proper Handling Techniques

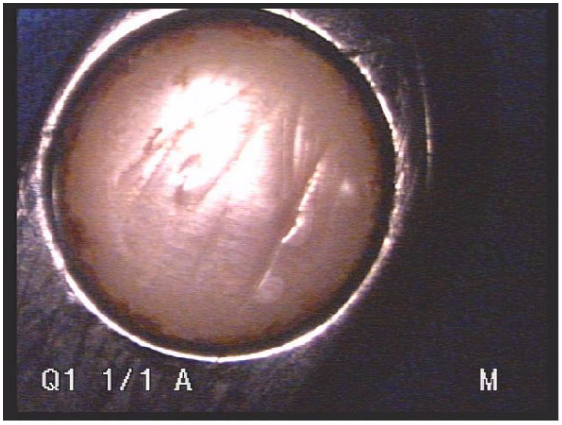
Although a transducer is designed for durability, use care when handling it. Dropping or banging the transducer can damage the acoustic lens and piezoelectric crystals. Visually inspect the transducer and cable prior to use. Cuts in the transducer cable or cracks in the housing can destroy the electrical safety features of the transducers. This damage is not covered by the warranty or your service contract.

Damage Caused by Bites

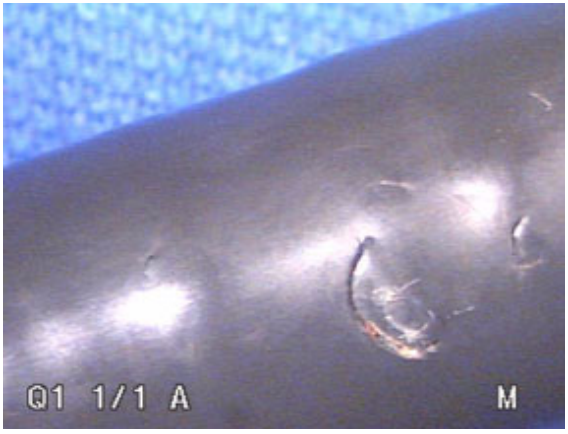
The transducer shaft and insulation can be damaged by bites resulting from failure to use or improper use of bite guards. All patients, including anesthetized patients should wear a bite guard during a TEE exam.

Keep the bite guard in place until the TEE transducer has been completely withdrawn. During withdrawal of the TEE transducer from the patient, be especially careful not to drag the last 10 cm across the patient's teeth.

Bites can cause electrical hazards or mechanical malfunction.

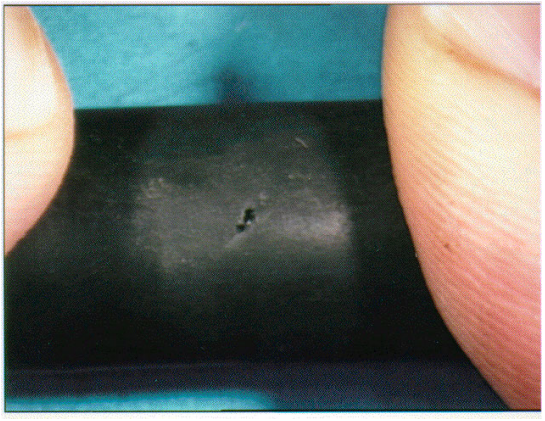


Bite marks on transducer lens window.



Bite marks on transducer sheath.

Bite marks on transducer shaft.



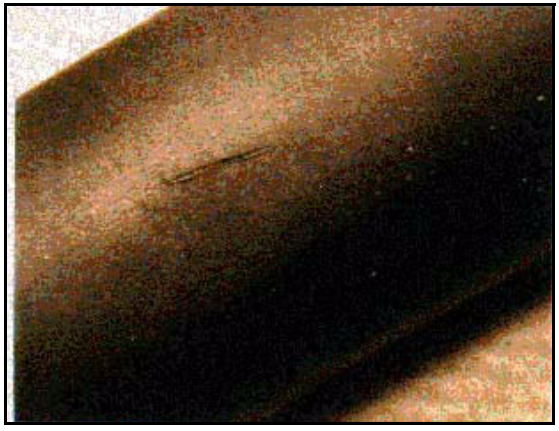
Bending the transducer shaft to inspect for bite damage.

Damage Caused by Cuts

The transducer insulation can be damaged by cuts and abrasions from sharp instruments such as scalpels, scissors, and clamps. Clamping the flexible shaft can easily damage the transducer.

Extreme care must be used whenever sharp instruments are used near a TEE transducer.

Cuts in the transducer insulation can result in current leakage and may lead to serious patient electrical hazards. In addition, fluid that enters the gastroscope via the cut will cause electrical and mechanical operational problems.



TEE transducer shaft damage caused by a cut.

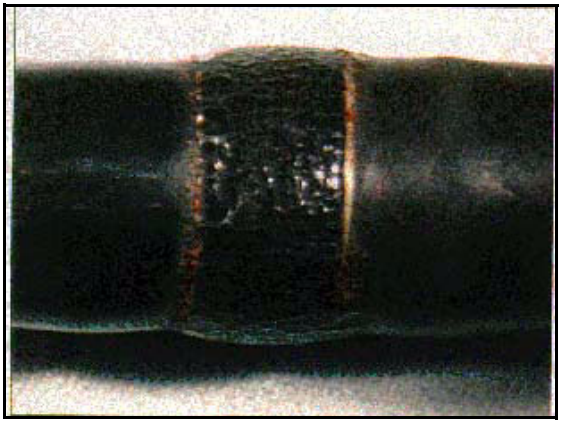
Slice on the outer sheath caused by a scalpel.

Improper Cleaning and Chemical Damage to the Transducer

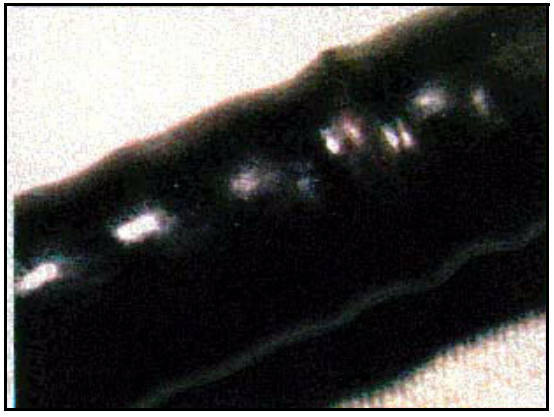
Avoid transducer contact with strong solvents such as acetone, freon, and other industrial cleaners. Use only the approved disinfectants and cleaners listed in the Disinfectants Compatibility Table .

Always follow the cleaning and disinfecting guidelines in the Cleaning and Disinfecting TEE Transducers section of this guide.

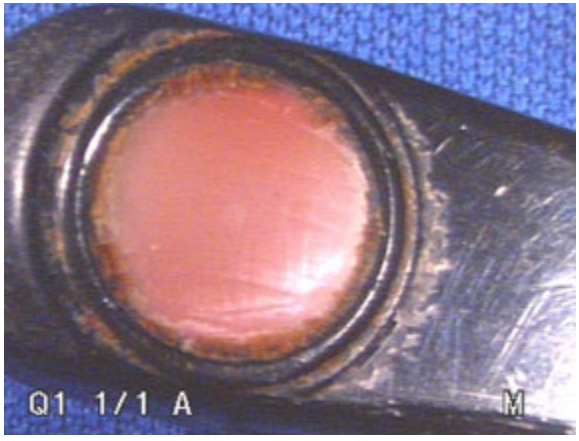
Contact of the transducer with strong solvents will cause serious damage to the integrity of the transducer materials.



Unapproved disinfectant use, resulting in cracked proximal bead.



Beads at both ends of the flexible bending neck completely disintegrated, shaft materials softened, and gastroscope markings completely removed. The damage caused by use of unapproved disinfectant.



IHuman protein build up on the window tip area caused by improper cleaning.

Human protein build up on the sheath bead area caused by improper cleaning.

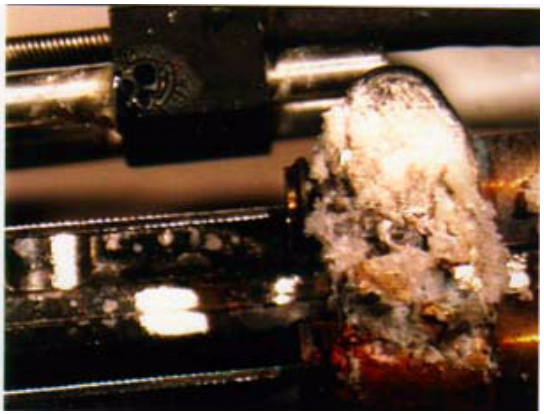
Damage of the Control Housing or Connector from Immersion

The transducer steering mechanism is not sealed. Do not submerge the transducer's control housing or connector in fluid of any kind.

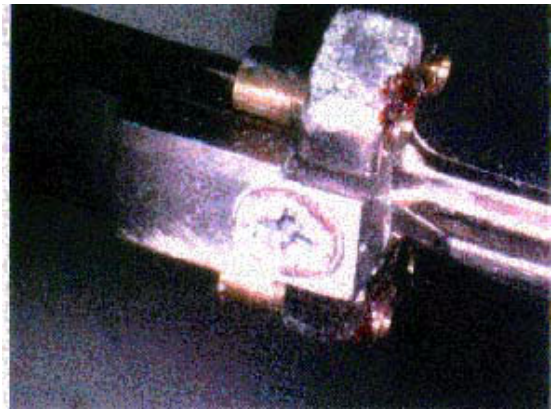
Always follow the Cleaning and Disinfecting TEE Transducers guidelines.

If disinfectant or fluid enters the steering mechanism, it will corrode the gears and electrical connections. This results in severe transducer damage that affects image quality, the steering mechanism, and electrical safety.

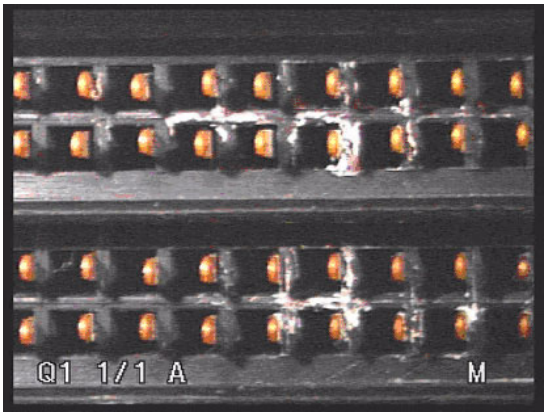
Avoid transducer contact with strong solvents such as acetone, freon, and other industrial cleaners. Use only the approved disinfectants and cleaners listed in the Disinfectants Compatibility Table



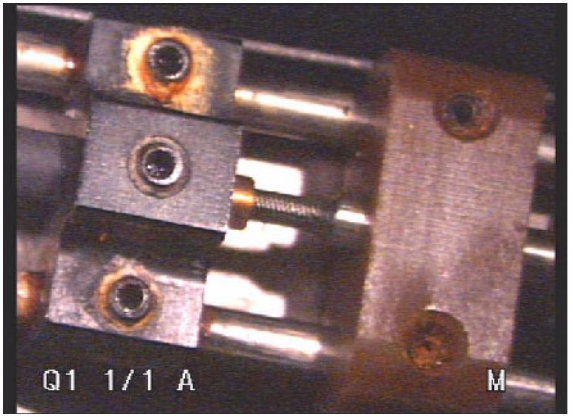
Corrosion inside control housing due to fluid immersion.



Corrosion inside steering mechanism due to fluid immersion.



Corrosion on pins inside connector due to fluid immersion.



Wet and corroded in distal handle due to fluid immersion.

Storage for Transport

If a carrying case is provided with your transducer, always use the carrying case to transport the transducer from one site to another.

Follow these guidelines to properly store transducers for transport:

- Make sure that the transducer is clean and disinfected before placing it in the case to avoid contaminating the foam that lines the carrying case.
- Place the transducer in the case carefully to prevent kinking of the cable.
- Before closing the lid, make sure no part of the transducer is protruding from the case.
- Wrap the case in plastic material containing air pockets (bubble wrap), and pack the wrapped case in a cardboard carton.
- To avoid damaging the shaft or steering mechanism of TEE transducers, do not bend or coil the flexible shaft of the transducer in less than a 0.30-m (1-ft) diameter circle.

Daily and Long-Term Storage

Follow these guidelines to protect your transducer:

- Always store transducers in the transducer holders on the side of your system or on a securely mounted wall rack when you are not using them.
- Make sure the transducer holders are clean before storing transducers.
- Avoid storing transducers in areas of temperature extremes or in direct sunlight.
- Store transducers separately from other instruments to avoid inadvertent transducer damage.
- When storing transducers, use the cable-management clips to secure the transducer cable.
- Before storing transducers, make sure they are thoroughly dry.
- For TEE transducers, be sure the distal tip is straight and protected before storing the transducer.
- Never store a TEE transducer in the carrying case, except to transport it.

Cleaning and Disinfecting TEE Transducers

Disinfecting TEE Transducers by Immersion

High-level disinfection by immersion is the accepted method of infection control for TEE transducers. Philips recommends that a protective transducer cover be used during examinations.

Upon receiving your new transducer, disinfect it before performing the first exam. Clean and disinfect the transducer immediately after each use to protect patients and personnel from a variety of pathogens. Establish and clearly post a cleaning procedure that includes the following steps.

WARNINGS

If you use Cidex OPA Solution (Cidex OPA), residual solution may remain on your transducers if you do not carefully follow the manufacturer's instructions. Residual Cidex OPA on TEE transducers may cause the following:

- Temporary staining of the mouth and lip area
- Irritation or chemical burns of the mouth, throat, esophagus, and stomach

To minimize the effects from residual Cidex OPA, or any other disinfectant, Philips recommends that you

- Follow the disinfectant manufacturer's instructions very carefully. For example, the manufacturer of Cidex OPA recommends soaking transducers three times in fresh water.
- Use a protective transducer cover during endocavity and TEE examinations.
- Use a sterile protective transducer cover with sterile ultrasound transmission gel during intraoperative and biopsy examinations.
- Limit the time that transducers are soaked in the disinfectant solution to the minimum time recommended by the disinfectant manufacturer (for example, the manufacturer of Cidex OPA recommends a minimum of 12 minutes).

➤ **To disinfect a TEE transducer by immersion**

1. Disconnect the transducer from the system.
2. Use the following procedure to remove all organic matter and other residue:

a. Soak gauze pads in mild, soapy water. *Do not* use iodine-based soaps.

b. Do either of the following:

- Wipe the distal tip and flexible shaft up to the control housing (steering mechanism) with the gauze pads.
- Use an enzymatic cleaner to assist in removing protein residuals. Enzymatic cleaners should have a pH of 6.0 to 8.0. These cleaners are further diluted during use. Follow the manufacturer's instructions for dilution.

3. Use water to rinse the distal tip and flexible shaft thoroughly.

CAUTION

Do not rinse or immerse the control housing, cable, or connector.

4. Disinfect the distal tip and flexible shaft by placing them in the appropriate disinfectant, as listed in Table 1-1.

– *Do not* bend the shaft into a circle with a diameter of less than 0.30 m (1 ft).

– *Do not* use bleach on any TEE transducer.

– *Do not* use strong solvents such as isopropyl alcohol, acetone, freon, and other industrial cleaners on transducers.

– *Do not* soak the transducer for extended periods of time. Limit the time that transducers are soaked in disinfectant solution to the minimum time recommended by the disinfectant manufacturer.

– *Do not* rinse or immerse the connector or the portion of the cable near the connector.

– *Do not* immerse or rinse the steering mechanism.

NOTE

Follow the recommendations of the disinfectant manufacturer.

5. Remove the tip and shaft from the disinfectant and thoroughly rinse with water according to the instructions for use from the disinfectant manufacturer.

6. Check the transducer for any residual organic material. If any is present, remove it and disinfect the transducer again.

7. Dry the distal tip and flexible shaft with a soft cloth or pad, or allow it to air dry.
8. Lightly wipe the steering mechanism of the handle only, with a pad moistened with rubbing alcohol (70% isopropyl alcohol).
9. Hang the transducer on a wall-mounted rack and let it air dry.

CAUTION

The transducer steering mechanism is not sealed. If disinfectant or other fluid enters the steering mechanism, it will corrode the gears and electrical connections. Avoidable transducer damage is not covered by the warranty or service contract.

CAUTION

Never sterilize the transducer with autoclave, ultraviolet, gamma radiation, gas, steam, or heat sterilization techniques. Severe damage will result. Avoidable transducer damage is not covered by the warranty or service contract.

Cleaning and Disinfecting Cables and Connectors with Wipes and Sprays

Use this method to disinfect the cables and connectors for all transducers that can be disinfected using a recommended wipe or spray disinfectant.

WARNING

Always use protective eyewear and gloves when cleaning and disinfecting any equipment.

CAUTION

Attempting to disinfect a cable or connector by using a method other than the one included here can damage the device and will void the warranty. Orient the parts that must remain dry higher than the wet parts until all parts are dry.

➤ **To clean and disinfect cables and connectors**

1. Disconnect the device from the system.
2. Orient the device and the connector so they are both facing up.

CAUTIONS

- Do not allow any type of fluid to enter the connector. Fluid in the connector may void the transducer or device warranty.
- Do not use a brush on the connector label.

3. Use a soft cloth lightly dampened in a mild soap or detergent solution to clean the cable and the connector. A soft-bristled brush can be used to clean only the metal surfaces of the connector. Do not allow any type of fluid to enter the device. Be careful that fluid does not enter through the strain relief, through the connector, through the electrical contacts, or through the areas surrounding the locking lever shaft and the strain relief. (Figure).

WARNING

If a premixed solution is used, be sure to observe the solution expiration date.

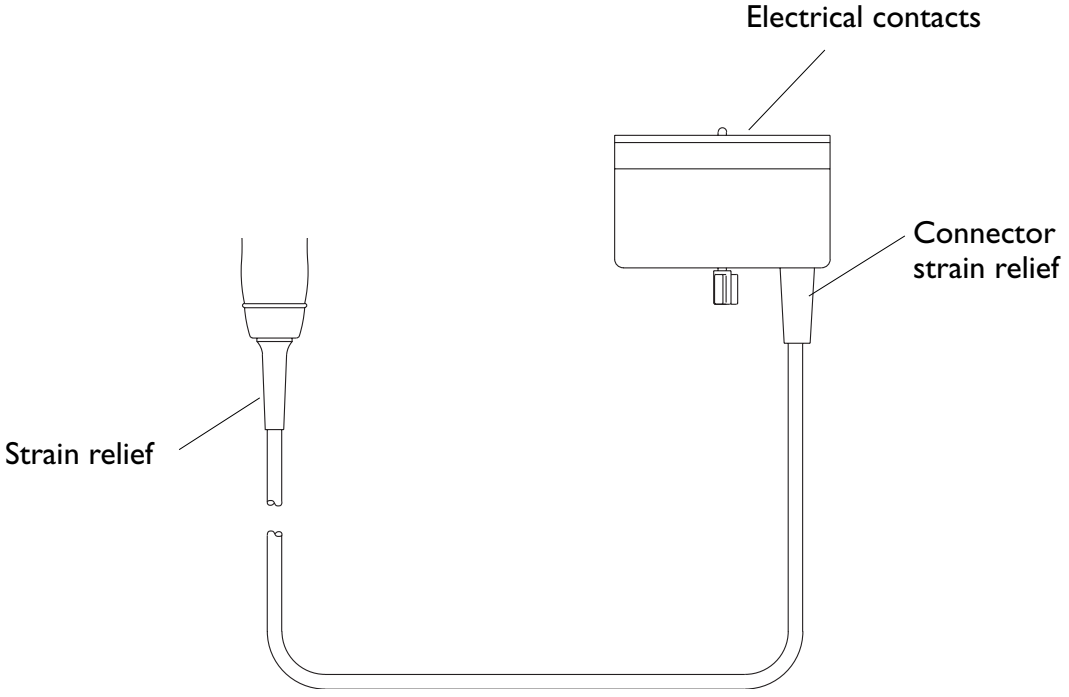
CAUTIONS

- You can use an alcohol solution for disinfection on the connector only. Ensure the solution is only 70% alcohol or less. Solutions of more than 70% alcohol can cause product damage.
- Do not use any alcohol or alcohol-based products on the cable.
- Avoid disinfectant contact with the connector label.

4. Mix the disinfection solution compatible with your cable (see Table 1-1) according to label instructions for solution strength.
5. Wipe or spray the cable and connector with the disinfectant, following disinfectant label instructions for wipe durations, solution strengths, and duration of disinfectant contact with the cable. Ensure that the solution strength and duration of contact are appropriate for the intended clinical use of the device. Ensure that the disinfectant solution does not enter the device or the connector or come into contact with the connector label.
6. Air dry or towel dry with a sterile cloth according to the instructions on the disinfectant label.
7. Examine the device and cable for damage such as cracks, splitting, sharp edges, or projections. If damage is evident, discontinue use of the device and contact your Philips Ultrasound representative.

Disinfecting Cables and Connectors

For cable disinfection, orient the device and the connector facing up (strain reliefs on the bottom)



Wipe strain reliefs, cable, and connector with a compatible disinfectant

Disinfectants Compatibility Table

For the latest updates on disinfectants, go to: www.medical.philips.com/transducercare

The table lists the disinfectants compatible with the following TEE transducers:

21364A, 21367A, 21366A, 21381A, 21378A, 21369A, 4000-0317-18 and 4000-0317-19

Table 1-1 Disinfectants Compatibility

Solution	Country of Origin	Qualified Use	Active Ingredient	TEE Transducers
70% Isopropyl Alcohol	All	Spray/Wipe	Alcohol	Approved for use on the handle only
Bleach 5.25% (10% Solution)	USA	Spray/Wipe	Sodium Hypochlorite	Approved for use on the cable
Mild Soap Solution	All	Pre-cleaner	Surfactants / Soap	Approved for use on the cable Approved for use on the transducer Approved for use on the handle
abcoCIDE	USA	Soak [2]	Glutaraldehyde	Approved for use on the transducer
abcoCIDE 28	USA	Soak [2]	Glutaraldehyde	Approved for use on the transducer
Banicide	USA	Soak [2]	Glutaraldehyde	Approved for use on the transducer
CIDEX [1]	USA	Soak [2]	Glutaraldehyde	Approved for use on the transducer
CIDEX 7 [1]	USA	Soak [2]	Glutaraldehyde	Approved for use on the transducer
CIDEX OPA [1]	USA	Soak [2]	Ortho-phthalaldehyde	Approved for use on the transducer
CIDEX Plus [1]	USA	Soak [2]	Glutaraldehyde	Approved for use on the transducer
Enzol	USA	Pre-cleaner	Enzymes	Approved for use on the transducer
Glutacide Plus	USA	Soak [2]	Glutaraldehyde	Approved for use on the transducer
MaxiCide Plus	USA	Soak [2]	Glutaraldehyde	Approved for use on the transducer
MetriCide [1]	USA	Soak [2]	Glutaraldehyde	Approved for use on the transducer
MetriCide 28 [1]	USA	Soak [2]	Glutaraldehyde	Approved for use on the transducer

AUS = Australia
D = Germany
E = England
F = France
USA = United States of America

[1] FDA 510(k) cleared
[2] Soak or per product instructions

Table 1-1 Disinfectants Compatibility (Continued)

Solution	Country of Origin	Qualified Use	Active Ingredient	TEE Transducers
Metricide Plus 30 [1]	USA	Soak [2]	Glutaraldehyde	Approved for use on the transducer
Omnicide 14NS	USA	Soak [2]	Glutaraldehyde	Approved for use on the transducer
Omnicide 28	USA	Soak [2]	Glutaraldehyde	Approved for use on the transducer
ProCide	USA	Soak [2]	Glutaraldehyde	Approved for use on the transducer
ProCide 14NS [1]	USA	Soak [2]	Glutaraldehyde	Approved for use on the transducer
ProCide 28	USA	Soak [2]	Glutaraldehyde	Approved for use on the transducer
ProCide NS	USA	Soak [2]	Glutaraldehyde	Approved for use on the transducer
ProCide Plus	USA	Soak [2]	Glutaraldehyde	Approved for use on the transducer
PSS Select 14 Day	USA	Soak [2]	Glutaraldehyde	Approved for use on the transducer
PSS Select 28 Day	USA	Soak [2]	Glutaraldehyde	Approved for use on the transducer
PSS Select Plus	USA	Soak [2]	Glutaraldehyde	Approved for use on the transducer
SDS 14 NS	USA	Soak [2]	Glutaraldehyde	Approved for use on the transducer
SDS 28	USA	Soak [2]	Glutaraldehyde	Approved for use on the transducer
Vespore	USA	Soak [2]	Glutaraldehyde	Approved for use on the transducer
Wavicide -01 [1]	USA	Soak [2]	Glutaraldehyde	Approved for use on the transducer
Klenzyme	USA	Pre-cleaner	Enzymes	Approved for use on the transducer
MetriZyme	USA	Pre-cleaner	Enzymes	Approved for use on the transducer
Dispatch	USA	Spray/Wipe	Sodium Hypochlorite	Approved for use on the cable
T-Spray	USA	Spray/Wipe	Quat. Ammonia	Approved for use on the cable
T-Spray II	USA	Spray/Wipe	Quat. Ammonia	Approved for use on the cable
Theracide Plus	USA	Spray/Wipe	Alcohol, Quat. Ammonia	Not approved for use
Sani-Cloth HB	USA	Spray/Wipe	Quat. Ammonia	Approved for use on the cable
Sani-Cloth Plus	USA	Wipe	Alcohol, Quat. Ammonia	Not approved for use

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[1] FDA 510(k) cleared
[2] Soak or per product instructions

Table 1-1 Disinfectants Compatibility (Continued)

Solution	Country of Origin	Qualified Use	Active Ingredient	TEE Transducers
Perasafe Powder	E	Soak [2]	Peracetic acid/ Hydrogen Peroxide	Approved for use on the transducer
Aidal	AUS	Soak (1)	Glutaraldehyde	Approved for use on the transducer
Aidal Plus	AUS	Soak [2]	Glutaraldehyde	Approved for use on the transducer
Epizyme Rapid	AUS	Pre-cleaner	Enzymes	Approved for use on the transducer
Milton	AUS	Spray/Wipe	Sodium Hypochlorite	Approved for use on the cable
Cidex PAE 14J	F	Soak [2]	Glutaraldehyde	Approved for use on the transducer
Endo FC	F	Soak [2]	Glutaraldehyde	Approved for use on the transducer
Endosporine	F	Soak [2]	Glutaraldehyde	Approved for use on the transducer
Korsolex PAE	F	Soak [2]	Glutaraldehyde	Approved for use on the transducer
Phagocide D	F	Soak [2]	Glutaraldehyde	Approved for use on the transducer
Sekucid N	F	Soak [2]	Glutaraldehyde	Approved for use on the transducer
Steranios 2%	F	Soak [2]	Glutaraldehyde	Approved for use on the transducer
Instruzyme	F	Pre-cleaner	Enzymes, Quat. Ammonia, Biguanide	Approved for use on the transducer
Phagozyme ND	F	Pre-cleaner	Enzymes, Quaternary Ammonium	Approved for use on the transducer
Alkaspray	F	Spray/Wipe	Alcohol, Alkylamine	Not approved for use
Vaposeptol	F	Spray/Wipe	Alcohol, Biguanide	Approved for use on the handle only
Ampholysine Basique	F	Spray/Wipe	Biguanide/Quat. Ammonia	Approved for use on the cable
Rivascop	F	Spray/Wipe	Quat. Ammonia	Approved for use on the cable
Salvanios pH 10	F	Spray/Wipe	Quat. Ammonia	Approved for use on the cable
Sekusept Plus	D	Soak [2]	Glucoprotamin	Not approved for use

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[1] FDA 510(k) cleared
[2] Soak or per product instructions

Table 1-1 Disinfectants Compatibility (Continued)

Solution	Country of Origin	Qualified Use	Active Ingredient	TEE Transducers
Desconton Extra	D	Soak [2]	Gluteraldehyde	Approved for use on the transducer
Kohrsolin	D	Soak [2]	Gluteraldehyde	Approved for use on the transducer
Gigasept FF	D	Soak [2]	Succindialdehyde dimethoxy tetrahydrofuran	Not approved for use
Incidin	D	Spray/Wipe	Alcohol	Approved for use on the handle only
Incidur Spray	D	Spray/Wipe	Alcohol Quat. Aldehyde	Not approved for use
Perfektan Endo	D	Spray/Wipe	Quat. Ammonia	Approved for use on the cable

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[1] FDA 510(k) cleared
[2] Soak or per product instructions

TEE Accessories

Each OmniPlane TEE transducer comes with two disposable bite guards and a disposable tip protector. This section describes bite guards, tip protectors, and TEE sheaths.

Bite Guards

All patients must wear a bite guard during a TEE exam. A bite guard prevents dangerous transducer mechanical and electrical malfunction caused by involuntary biting. Even anesthetized patients require bite guards to prevent damage to their teeth and to the transducer. Philips supplies disposable bite guards that are suitable for both awake and anesthetized patients.

WARNING

The M2203A bite guard strap contains natural rubber latex, which may cause allergic reactions. See "FDA Medical Alert" on page 24.

CAUTION

Damage caused when patients bite or scrape a TEE transducer is not covered in the transducer's warranty or your service contract. Be sure to use bite guards to help prevent such accidents.

Tip Protector

When not using a carrying case to transport a TEE transducer, you should use a tip protector on its distal tip. The tip protector helps prevent serious damage to the transducer's lens. Philips supplies tip protectors designed for each of its TEE transducers.

Sheath Kit

Philips recommends the use of a market-approved protective sheath during every TEE exam.

WARNING

Sheaths often contain natural rubber latex, which may cause allergic reactions. See "FDA Medical Alert" on page 24.

Disposable Drape

If you believe contamination of the imaging system might occur during an exam, Philips recommends that you take universal precautions and cover the imaging system with a disposable drape. Consult your hospital's rules regarding equipment use in the presence of infectious disease.

CAUTION

Be sure to position the drape so that you do not block the vents on the ultrasound system, the monitors, or the peripherals.

FDA Medical Alert

The U.S. Food and Drug Administration published the following medical alert on latex products, dated March 29, 1991:

Allergic Reactions to Latex-Containing Medical Devices

Because of reports of severe allergic reactions to medical devices containing latex (natural rubber), the FDA is advising health care professionals to identify their latex sensitive patients and be prepared to treat allergic reactions promptly. Patient reactions to latex have ranged from contact urticaria to systemic anaphylaxis. Latex is a component of many medical devices, including surgical and examination gloves, catheters, intubation tubes, anesthesia masks, and dental dams.

Reports to the FDA of allergic reactions to latex-containing medical devices have increased lately. One brand of latex cuffed enema tips was recently recalled after several patients died as a result of anaphylactoid reactions during barium enema procedures. More reports of latex sensitivity have also been found in the medical literature. Repeated exposure to latex both in medical devices and in other consumer products may be part of the reason that the prevalence of latex sensitivity appears to be increasing. For example, it has been reported that 6% to 7% of surgical personnel and 18% to 40% of spina bifida patients are latex sensitive.

Ordering Supplies and Accessories

You can order transducer covers, biopsy guides, and other supplies and accessories from CIVCO Medical Instruments:

CIVCO Medical Instruments
102 First St. South
Kalona, IA 52247-9589

Telephone:	800-445-6741, Ext. 1 for Customer Service (USA) +1 319-656-4447 (International)
Fax:	877-329-2482 (USA) +1 319-656-4451 (International)
E-mail:	info@civcomedical.com
Internet:	www.civco.com

Contact Information

Customer service representatives are available worldwide to answer questions and to provide maintenance and service. Please contact your local Philips Ultrasound representative for assistance. You can also contact one of the following offices for referral to a customer service representative, or visit the Philips Ultrasound Web site:

www.medical.philips.com

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Roentgenstrasse 24, Gebaude S
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