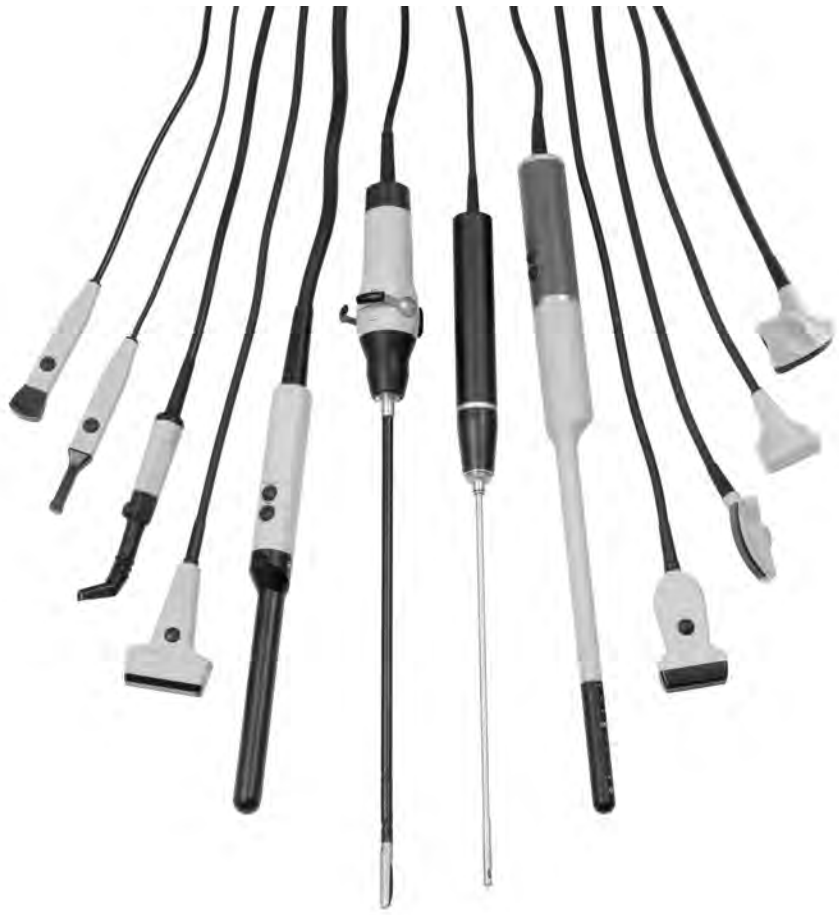
bk medical

User Guide

Care, Cleaning & Safety

Information for the Entire Range of BK Medical Ultrasound Equipment



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If you have comments about the user documentation, please write to us at the email address above. We would like to hear from you.

B-K Medical Customer Satisfaction

Input from our customers helps us improve our products and services. As part of our customer satisfaction program, we contact a sample of our customers a few months after they receive their orders. If you receive an email message from us asking for your feedback, we hope you will be willing to answer some questions about your experience buying and using our products. Your opinions are important to us. You are of course always welcome to contact us via your B-K Medical representative or by contacting us directly.

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Introduction

This user guide contains information about using and caring for BK Medical equipment. It includes important information about what you must do to ensure the safe and proper performance of the transducers. This includes information about cleaning, disinfection and sterilization.

You must also follow local government rules and guidelines at all times.

Warnings, Cautions, Notes

Pay attention to the difference between Warnings, Cautions and Notes.

⚠ **WARNING** Warnings contain information that is important for avoiding personal injury.

⚠ **Caution:** Cautions contain information that is important for avoiding damage to equipment, data or software.

NOTE: *Notes contain other information that you should be aware of.*

The book contains a glossary of terms (including acronyms and abbreviations used in the book) and an index. The appendix contains a table that lists all BK Medical transducers and the disinfection methods that each can withstand.

CE Marks on Electrical Devices

The European Union has introduced directives requiring CE marks on devices.

Non-medical devices marked with CE comply with relevant directives, for example EEC Council Directive 89/336/EEC of 3 May 1989 concerning Electromagnetic Compatibility.

BK Medical devices marked with CE or CE 0543 comply with EEC Council Directive 93/42/EEC of 14 June 1993 concerning Medical Devices. CE applies to Class I medical devices, CE 0543 applies to Class Im, IIa, IIb and III. BK Medical defines classes assuming imaging duration for individual patients does not exceed 60 minutes.

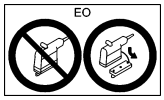
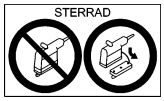
General Safety

⚠ Physician required in USA

Caution: In the United States of America, federal law restricts this equipment to sale or use by or on the order of a physician.

Markings on the Transducers and Accessories

Symbol	Name	Description
	Caution or Warning	Consult accompanying user guide when you encounter this sign on the instrument, to avoid reducing its safety.
	Consult instructions for use	Consult user guide or other instructions.
	Type BF	BF: Isolated from ground Maximum patient leakage current under • Normal condition ≤100 µA • Single-fault condition ≤500 µA [1, 2, 3]
	Type BF	BF, defibrillator-proof [1, 2, 3]
	Type B	B: Maximum patient leakage current under • Normal condition ≤100 µA • Single-fault condition ≤500 µA [1, 2, 3]
IP	Sealing	Dust- and immersion-protected according to EN 60529 [4]. The specific level of protection is defined in the standard.
	Handle with care	The tip of the transducer is very delicate. Be very careful not to bump the tip.
	Batch code	Manufacturer's batch or lot number for a product.
	Date of manufacture	Date device was manufactured (4 digits for year, maybe 2 digits for month).
	Do not reuse	Single-use device. Do not try to process for reuse. Reuse can result in cross-contamination or can compromise the function of the product.
	STERILE	Device is in a sterile condition.
	STERILE EO	Device has been sterilized using ethylene oxide.

	Do not resterilize	
	Do not use if package damaged	Do not use if product sterilization barrier or its packaging is compromised.
	Keep away from sunlight	
	Temperature limitation	Keep temperature between the upper and lower limits listed.
	Humidity limitation	Keep relative humidity between the upper and lower limits listed.
	Use by	Last date on which a marked item can be used: expiration date (4 digits for year, 2 digits for month).
	STERRAD & EO – lid off	Watertight plug lid must not be attached during STERRAD or ethylene oxide processing.
	EO – lid off	Watertight plug lid must not be attached during ethylene oxide processing.
	STERRAD – lid off	Watertight plug lid must not be attached during STERRAD processing.
	Not watertight	Plug must not be immersed.
	Immersion with cap on	Can be immersed if cap is tightened as indicated.

	No immersion with cap off	Must not be immersed if cap is off or not tightened.
	Sterilizable up to 56 °C	Can be processed using STERIS SYSTEM 1 Sterile Processing System or STERIS SYSTEM 1E Liquid Chemical Sterilant Processing System (see page 22), Sterilox or Tristel.
	WEEE waste	Within the EU, when you discard the equipment, you must send it to appropriate facilities for recovery and recycling.

Table 1. Markings on transducers and accessories.

Transducer Care and Maintenance

Caution: Be careful when you handle a transducer or remote control device.

- Don't bump it on a hard surface or drop it. Transducers dropped on a hard surface probably cannot be repaired.
- Don't step on the cord or run over it with the wheels of the system.
- Don't try to take it apart.

Keep plug dry

WARNING T-5

To maintain safe operation, the transducer plug must always be completely dry.

Inspection

All transducers (and the remote control) and attachments must be checked regularly to maintain a high level of safety. Details about what to check and when are in the section "Checking and Maintaining Ultrasound Equipment" that starts on page 29.

Inspect the transducer (or remote control) each time before you use it to make sure that it can be safely used. See "Routine Checks Before Use" on page 29.

Service and Repair

Authorized personnel

WARNING SR-1

Service and repair of BK Medical electromedical equipment must be carried out only by the manufacturer or its authorized representatives. BK Medical reserves the right to disclaim all responsibility, including but not limited to responsibility for the operating safety, reliability and performance of equipment serviced or repaired by other parties. After service or repairs have been carried out, a qualified electrical engineer or hospital technician should verify the safety of all equipment.

If for any reason you must return a transducer to BK Medical, make sure that it is cleaned as for storage before you return it.

Before You Start

Proper training necessary

WARNING GS-1

Before you attempt to use BK Medical equipment, you should be trained in ultrasonography or be under the supervision of someone who is trained in ultrasonography. You should also be thoroughly familiar with the safe operation of your ultrasound system: read all the user documentation that accompanies it. No further training is required, but BK Medical offers training in how to use the system. Consult your BK Medical representative for information.

Transducer and system compatibility

BK Medical makes a wide variety of systems and transducers. Not all systems and transducers can be used together. Consult the transducer user guide or the product data sheet that accompanies it to make sure that a transducer can be used with a particular system.

Incorrect combinations of equipment

WARNING GS-4

- Do not use other manufacturers' transducers with BK Medical ultrasound systems.
- Do not use BK Medical transducers with other manufacturers' systems.
- Do not use unauthorized combinations of transducers and puncture attachments.
- Do not use other manufacturers' puncture attachments with BK Medical transducers.

Check type number on monitor

WARNING P-1

Before you start to image, verify that the type number of the transducer matches the number displayed on the monitor. If they do not match, the puncture line on the monitor may not correspond to the true puncture path in the tissue. In case of any inconsistency, stop imaging, turn off the system, and contact your local BK Medical representative.

Storing Transducers When Not in Use

Transducers should always be stored in a safe place. Do not leave them lying on a table, for example.

They should not be stored for an extended period with a watertight plug lid or plug cover screwed on.

See the storage temperature and humidity limits in Table 3.

Transporting and Shipping Transducers

Pack the transducer carefully to protect it before you transport it or ship it.

Clean before storing

WARNING CDS-1

Be particularly careful to clean the transducer before you put it into any sort of container for storage or transport so that you do not contaminate the container.

Transducer Holders

When you are not using a transducer, place it in one of the transducer holders on the system.

Figure 1. Transducers in the transducer holders.

Holder must be clean

WARNING CDS-2

To avoid cross-contamination, before you put a clean transducer into the holder, make sure that the holder is clean.

See “Cleaning and Disinfecting the System” on page 25.

Operating and Storage Environment

Systems

Table 2 shows the environmental limits for BK Medical systems during operation and storage.

	Maximum	Minimum
Storage temperature	+60°C (+140°F)	-25°C (-13°F)
Ambient **operating temperature**	+40°C (+104°F)	+10°C (+50°F)
Atmospheric pressure	1060 hPa (15.4 psi)	700 hPa (10.2 psi)
Humidity	85% RH	

Table 2. Environmental limits for systems.

Caution: Avoid excessive heat, dust and direct sunlight.

Condensation

Caution: Do not use the system if there is visible condensation on it. Wait until it reaches room temperature.

⚠ **Caution:** Do not expose the system to fumes such as sodium hypochlorite (chlorine bleach) that might be used for cleaning other surfaces, such as floors.

Transducers and Remote Control

Table 3 shows the environmental limits for BK Medical transducers and remote control UA1237 during operation and storage. It also indicates environmental limits during disinfection processing.

	Maximum	Minimum
Storage temperature	+70°C (+158°F)	-25°C (-13°F)
Storage humidity	85% RH	
Operating temperature	+40°C (+104°F)	+10°C (+50°F)
Operating pressure	1060 hPa (15.4 psi)	700 hPa (10.2 psi)
Watertight immersion temperature	+40°C (+104°F)	NA (not applicable)
Watertight immersion time	15 hours per 24 hours	NA
Pressure during gas processing	NA	500 hPa (7.3 psi)
(for the 8666-RF, 8809, 8814, 8815, 8816, 8818, 8823, 8824, 8826, 8836[a], 8848, 8862 and 8863 transducers)	NA	100 hPa (1.5 psi)
Temperature during gas processing	55°C (131°F)	NA

a. For future release

Table 3. Environmental limits for transducers. Storage and operating temperatures and pressures, and immersion information, are valid for the remote control UA1237, but it is not able to withstand gas processing.

Transducer Covers

Transducer covers include sterile and non-sterile condoms and sterile intraoperative transducer and cable covers.

To reduce the risk of cross-contamination, use a transducer cover when you image.

You must use a transducer cover for rectal or vaginal imaging.

To protect the water inlet in the 8808 transducers from contamination, you must cover it with a transducer cover.

You must use a sterile transducer cover for puncture or intraoperative imaging.

See the caution about gel types on page 13.

NOTE: *In the United States of America, it is recommended to use probe sheaths (transducer covers) that have been market cleared. In Canada, use only licensed transducer sheaths (covers).*

Latex sensitivity

WARNING TC-1

Some transducer covers can contain latex. Because of reports of severe allergic reactions to medical devices containing latex (natural rubber), the FDA advises health-care professionals to identify latex-sensitive patients and be prepared to treat allergic reactions promptly [5].

Sterile Covers

For use when sterile conditions are required, BK Medical supplies a range of sterile single-use transducer covers. See the transducer product data sheet for appropriate covers for your transducer.

Fig 2 shows how to put sterile covers on a transducer and cable.

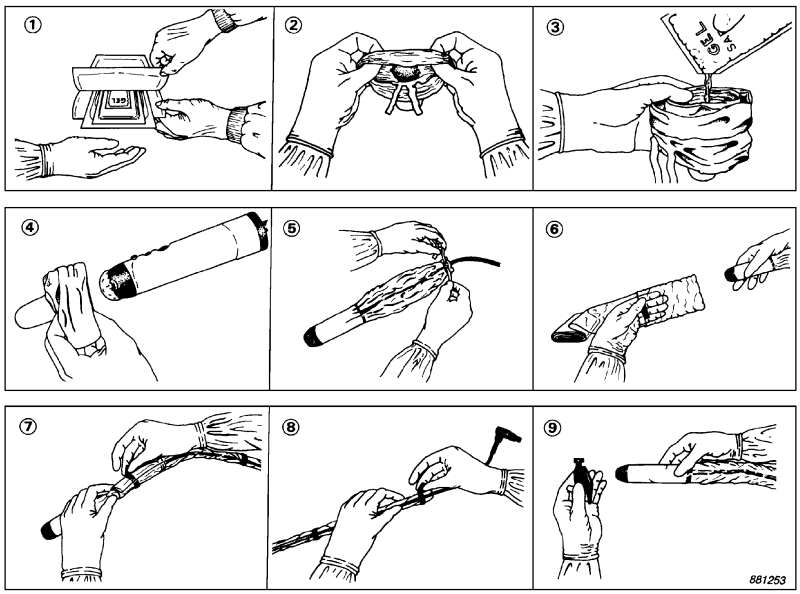


Figure 2. Example of putting on a sterile transducer cover and cable cover.

Follow these precautions:

- Wear sterile gloves.
- When using a puncture attachment, place it gently over the cover and secure it, following the instructions for the puncture attachment. (See the transducer user guide.)
- Verify that the cover has not been damaged in the process. If it has, repeat the procedure with a new transducer cover.

Neurosurgical Applications

Special considerations apply to transducer covers for neurosurgical applications.

Special covers

WARNING TC-2

Use only non-pyrogenic, sterile probe sheaths (transducer covers) that are approved for neurosurgical use. This means that in the USA they must be market cleared by the FDA and in Europe they must be CE-marked.

In Canada, must use special covers

WARNING TC-4

In Canada, for neurosurgical applications, you must use non-pyrogenic, sterile probe sheaths (transducer covers) that are approved for neurosurgical use. This means that they must be licensed by Health Canada.

Gels

Caution: Use only water-based gel (sterile if you are using a sterile transducer cover). Products containing parabens, petroleum or mineral oils may harm the transducer or transducer cover.

Using Sterile Covers on a System

It is important that any cover you use on the system does not make the monitor hard to read and that it does not interfere with the touch functionality of the screen or keyboard.

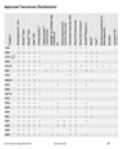
Therefore, test covers *before* you use them during a surgical procedure.

Cleaning and Disinfection – General Information

To ensure the best results as well as to guard against infection, it is important to maintain a strict regular cleaning routine when using BK Medical equipment.

The level of processing required depends on the type of equipment and its use.

⚠ **Caution:** All methods described in this section may not apply to all transducers.



Refer to the "Approved Transducer Disinfectants" table to see what methods can be used with your specific transducers. You can find the latest disinfection and sterilization compatibility information for our products on our website: new information may have been added since you received this book.

⚠ Infection control

WARNING CDS-3

Users of this equipment have an obligation and responsibility to provide the highest possible degree of infection control to patients, co-workers and themselves. To avoid cross-contamination, follow all infection control policies for personnel and equipment that have been established for your office, department or hospital.

⚠ Creutzfeldt-Jakob

WARNING TC-3

Do not use a transducer for neurosurgical applications if the patient is suspected of having Creutzfeldt-Jakob disease. If a neurosurgical transducer has been used on a patient suspected of or diagnosed as being Creutzfeldt-Jakob positive, the transducer must be destroyed, following approved procedures for your hospital.

⚠ **Caution:** Keep all plugs and sockets absolutely dry at all times.

Personnel who reprocess medical devices should be thoroughly trained in the proper procedures for cleaning, disinfection and sterilization (if required).

The reprocessed device must be stored in closed boxes and used within 24 hours (or according to normal hospital procedures).

Cleaning, as well as disinfection or sterilization, is important. If biological materials (bioburden) are allowed to dry on equipment, disinfection and sterilization processes may not be effective. Therefore, you *must* clean all equipment immediately after use.

⚠ **WARNING** CDS-4

If there are any pits or cracks on any equipment surfaces, sterilization processing may not give a sterile product.

Levels of Disinfection and Sterilization

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 4 summarizes this information.

Device Classification	Use	Level of Processing Required
Noncritical	Device contacts intact skin	Cleaning and disinfection (in the USA, low-level disinfection[a])
Semi-critical	Device contacts mucous membranes (for example, endocavity applications)	Immediate cleaning and disinfection (in the USA, high-level disinfection[b])
Critical (transducers)	Device enters otherwise sterile tissue (for example, intraoperative applications)	Immediate cleaning followed by sterilization[c]
Critical (all puncture attachments)	Device contacts otherwise sterile tissue (for example, to take a biopsy)	Disinfection (preferably mechanical) plus steam sterilization

a. In the USA, the EPA maintains a list of approved detergents and hospital disinfectants.

b. In the USA, the FDA maintains a register of commercial solutions that have been cleared for use as sterilants and high level disinfectants [7]. Please contact your BK Medical representative if you are in any doubt about what you can use.

c. When sterilization is not possible, the FDA in the USA and the RKI in Germany 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 ultrasound transducers [6, 8].

Table 4. Levels of disinfection based on device use.

Cleaning

Thorough cleaning is essential for successful disinfection and sterilization.

Before disinfection, always remove covers, accessories and attachments. Then clean the transducer and reusable puncture attachments thoroughly. See the cleaning steps listed for different types of transducer use in the following pages. For puncture attachments, see page 21.

Precautions – General Warnings

⚠ **WARNING** CDS-5

When cleaning and disinfecting transducers and other equipment, you must:

- Wear gloves and protective eyewear at all times (and protective clothing if needed).
- Always follow the procedures that have been established for your hospital, clinic or institution, as well as any national guidelines.
- Rinse off residues left by cleaning and disinfecting solutions. They can be harmful.

Caution: Use only disinfection methods that are approved for the transducer. See the table on page 49. Do not use acetone or petroleum-based products on the transducers.

Caution: Never immerse transducers in liquids above 40°C (104°F) because this can damage the housing sealant. Similarly, never leave the transducer immersed in any liquids for more than 15 hours in any 24 hour period; excessive immersion sometimes causes liquids to be absorbed through the housings.

Protecting Transducer Plugs during Immersion

Caution: Protect the plug from contact with liquid.

When a transducer is fully immersed (including its plug) during disinfection, the internal components of the plug must *not* get wet. To prevent this, use watertight plug protection devices. See "Watertight Protection Devices" on page 37.

Cleaning and Disinfection by Immersion

Transducers Used on Intact Skin Only (No Puncture)

These procedures are classified by the CDC and the RKI as non-critical. They require transducers to be cleaned and disinfected (in the USA, low-level disinfection).

Follow established procedures

NOTE: *The instructions below are meant as a guide. They describe the highest level protocol for this level of disinfection. Always follow the procedures that have been established for your hospital, clinic or institution, as well as any national guidelines.*

Caution: Before immersing the transducer and plug in any liquid, cover the plug with the watertight protection device (see the section "Watertight Protection Devices" starting on page 37). You should use the leakage test kit to test for leaks.

WARNING CDS-6

Wear gloves and protective eyewear (and protective clothing if needed).

Cleaning Transducers

Proper cleaning is essential for the success of any disinfection or sterilization procedures. Equipment must be cleaned immediately after it is used and *before* it is disinfected.

1. Unplug the transducer from the system.
2. Remove any cover and wipe off any gel.
3. Immediately rinse all reusable parts with running tap water between 10°C (50°F) and 40°C (104°F).

4 Use a suitable cleaning solution (detergent) to wash all parts. (In the USA, this must be an EPA-registered detergent.)

   Follow the detergent manufacturer's instructions for concentration and other conditions.

5 Rinse thoroughly with running tap water between 10°C (50°F) and 40°C (104°F).

6 Dry with a disposable cloth or air dry.

7 Thoroughly examine all surfaces that have been cleaned and visually inspect the entire device to make sure it is clean.

Disinfecting Transducers by Immersion

Start by cleaning (steps 1–7 above).

8 Use a suitable disinfectant solution to disinfect the transducer.

   In the USA, this must be approved by the EPA as a hospital disinfectant. In Germany, it must be a disinfectant approved by the DGHM. See "Transducer Disinfection Compatibility" on page 47.

   Follow the disinfectant manufacturer's instructions for procedure and immersion times.

9 Rinse off the disinfectant thoroughly with tap water between 10°C (50°F) and 40°C (104°F). Follow the disinfectant manufacturer's instructions for procedure and volume of water.

10 Dry with a clean cloth.

11 Examine the transducer for damage.

To minimize risk of cross-contamination, you may use a transducer cover when you image.

Transducers Used for Vaginal or Rectal Imaging with No Puncture

These endocavity procedures are classified by the CDC and the RKI as semi-critical. They require transducers to be cleaned immediately and then disinfected (in the USA, high-level disinfection).

Follow established procedures

NOTE: *The instructions below are meant as a guide. They describe the highest level protocol for this level of disinfection. Always follow the procedures that have been established for your hospital, clinic or institution, as well as any national guidelines.*

⚠ **Caution:** Before immersing the transducer and plug in any liquid, cover the plug with the watertight protection device (see the section "Watertight Protection Devices" starting on page 37). You should use the leakage test kit to test for leaks.

⚠ **WARNING** CDS-6

Wear gloves and protective eyewear (and protective clothing if needed).

Cleaning transducers

Proper cleaning is essential for the success of any disinfection or sterilization procedures. Equipment must be cleaned immediately after it is used and *before* it is disinfected.

1. Unplug the transducer from the system.
2. Remove covers and other attachments, and wipe off any gel.
3. Immediately rinse all reusable parts with running tap water between 10°C (50°F) and 40°C (104°F) to remove visible contamination.
4. Use a suitable cleaning solution (detergent) to wash all parts. (In the USA, this must be an EPA-registered detergent.) Use a suitable brush to thoroughly clean any built-in biopsy channels or grooves.

⚠ **Caution:** Do not stick anything into a water inlet to clean it. Poking something into this hole can damage the water channel inside the transducer. Flush the water channel with water soon after use, before any foreign matter such as ultrasound gel has a chance to harden.

   Follow the detergent manufacturer's instructions for concentration and other conditions.

5. Rinse thoroughly with running tap water between 10°C (50°F) and 40°C (104°F). Thoroughly flush any channels with water.
6. Clean with an enzymatic cleaner (recommended by the disinfectant's supplier) and a soft-bristled nail brush (like surgeons use) to remove proteins.

⚠ **Caution:** Do NOT use a brush on the front face (acoustic surface) of the transducer.

   Use a suitable brush to thoroughly clean any built-in biopsy channels or grooves.

   Do not stick anything into a water inlet. If you suspect that a water channel has become contaminated, flush it with the enzymatic cleaner.

7. Rinse thoroughly with running tap water between 10°C (50°F) and 40°C (104°F). Thoroughly flush any channels with water.
8. Dry with a disposable cloth or air dry.
9. Thoroughly examine all surfaces that have been cleaned and visually inspect the entire device to make sure it is clean.

Disinfecting Transducers by Immersion

Start by cleaning (steps 1–9 above).

10. Use a suitable disinfectant solution to disinfect the transducer.

    In the USA, this must be a chemical germicide cleared by the FDA as a sterilant. In Germany, it must be a disinfectant approved by the DGHM. See "Transducer Disinfection Compatibility" on page 47.

    Follow the disinfectant manufacturer's instructions for procedure and immersion times.

Make sure that the solution passes through any built-in biopsy channels or grooves. If necessary, use a suitable brush to make sure there are no air bubbles in the channel.

Do not stick anything into a water inlet. If you suspect that a water channel has become contaminated, flush it with the disinfectant.

11 Wear sterile gloves and rinse off the disinfectant thoroughly with sterile water, thoroughly flushing any channels. Follow the disinfectant manufacturer's instructions for procedure and volume of water.

12 Dry with a sterile cloth.

13 Examine the transducer for damage.

Cover the transducer with a cover when you use it. See "Transducers Covers" on page 11. In Germany, you must use a sterile cover for vaginal imaging.

Transducers Used for Puncture or Intraoperative Procedures

These procedures are classified by the CDC and the RKI as critical. Ideally, they require transducers and reusable puncture attachments to be cleaned immediately and then sterilized.

Some BK Medical transducers can be processed using gas or liquid sterilization techniques. See "Other Disinfection and Sterilization Methods" on page 22.

Use sterile gel and sterile cover

If a device cannot withstand being sterilized, the FDA in the USA and the RKI in Germany recognize that disinfection (in the USA, high-level disinfection) and the use of a sterile gel and a sterile transducer cover, as described in the instructions provided with the transducer cover, is an accepted method of infection control for ultrasound transducers [6, 8]. All puncture attachments must be steam-sterilized (autoclaved) before use unless they are supplied sterile.

Follow established procedures

NOTE: *The instructions below are meant as a guide. They describe the highest level protocol for this level of disinfection. Always follow the procedures that have been established for your hospital, clinic or institution, as well as any national guidelines.*

⚠ **Caution:** Before immersing the transducer and plug in any liquid, cover the plug with the watertight protection device (see the section "Watertight Protection Devices" starting on page 37). You should use the leakage test kit to test for leaks.

⚠ **WARNING** CDS-6

Wear gloves and protective eyewear (and protective clothing if needed).

Cleaning Transducers and Reusable Puncture Attachments

Proper cleaning is essential for the success of any disinfection or sterilization procedures. Equipment must be cleaned immediately after it is used and *before* it is disinfected.

1 Unplug the transducer from the system.

2 Remove covers, puncture guides, etc. and wipe off any gel.

3 Immediately rinse all reusable parts with running tap water between 10°C (50°F) and 40°C (104°F) to remove visible contamination.

4 Use a suitable cleaning solution (detergent) to wash all parts. (In the USA, this must be an EPA-registered detergent.) Use a suitable brush to thoroughly clean any built-in biopsy channels or grooves.

⚠ **Caution:** Do not stick anything into a water inlet to clean it. Poking something into this hole can damage the water channel inside the transducer. Flush the water channel with water soon after use, before any foreign matter such as ultrasound gel has a chance to harden.

Follow the detergent manufacturer's instructions for concentration and other conditions.

5 Rinse thoroughly with running tap water between 10°C (50°F) and 40°C (104°F). Thoroughly flush any channels with water.

6 Clean with an enzymatic cleaner (recommended by the disinfectant's supplier) and a soft-bristled nail brush (like surgeons use) to remove proteins.

⚠ **Caution:** Do NOT use a brush on the front face (acoustic surface) of the transducer.

Use a suitable brush to thoroughly clean any built-in biopsy channels or grooves.

Do not stick anything into a water inlet. If you suspect that a water channel has become contaminated, flush it with the enzymatic cleaner.

7 Rinse thoroughly with running tap water between 10°C (50°F) and 40°C (104°F). Thoroughly flush any channels with water.

8 Dry with a disposable cloth or air dry.

9 Thoroughly examine all surfaces that have been cleaned and visually inspect the entire device to make sure it is clean.

Disinfecting Transducers by Immersion

Start by cleaning (steps 1–9 above).

10 Use a suitable disinfectant solution to disinfect the transducer.

In the USA, this must be a chemical germicide cleared by the FDA as a sterilant. In Germany, it must be a disinfectant approved by the DGHM. See “Transducer Disinfection Compatibility” on page 47.

Follow the disinfectant manufacturer's instructions for procedure and immersion times.

Make sure that the solution passes through any built-in biopsy channels or grooves. If necessary, use a suitable brush to make sure there are no air bubbles in the channel.

Do not stick anything into a water inlet. If you suspect that a water channel has become contaminated, flush it with the disinfectant

11 Wear sterile gloves and rinse off the disinfectant thoroughly with sterile water, thoroughly flushing any channels. Follow the disinfectant manufacturer's instructions for procedure and volume of water.

12 Dry with a sterile cloth.

13 Examine the transducer for damage.

Cover the transducer with a sterile cover (applying sterile gel inside and out) when you use it. See "Transducer Covers" on page 11.

Cleaning and Sterilizing Puncture Attachments

To avoid contamination, puncture attachments (including needle guides and needles) must be sterile when you use them. Table 5 gives an overview of the processing required before and after use.

	Reusable parts	Single-use parts, supplied sterile
Autoclave[a] before use	Yes	No
Clean immediately after use[b]	Yes	No – *do not reuse*

a. In Germany, puncture attachments must be disinfected before autoclaving, using a disinfectant approved by the DGHM.

b. If biological materials are allowed to dry on the puncture attachments, disinfection and sterilization processes may not be effective.

Table 5. Required procedures for puncture attachments.

To clean and sterilize reusable puncture attachments:

1 Remove the puncture attachment from the transducer.

2 Disassemble the puncture attachment and wipe off any gel.

3 Immediately rinse all parts with running tap water between 10°C (50°F) and 40°C (104°F) to remove visible contamination.

Wash

4 Use a suitable cleaning solution (detergent) to wash all parts. (In the USA, this must be an EPA-registered detergent.) Use a suitable brush to thoroughly clean any built-in channels or grooves.

Follow the detergent manufacturer's instructions for concentration and other conditions.

5 Rinse thoroughly with running tap water between 10°C (50°F) and 40°C (104°F). Thoroughly flush any channels with water.

Use enzymatic cleaner

6 Clean with an enzymatic cleaner (recommended by the disinfectant's supplier) and a soft-bristled nail brush (like surgeons use) to remove proteins.

Use a suitable brush to thoroughly clean any built-in biopsy channels or grooves.

7 Rinse thoroughly with running tap water between 10°C (50°F) and 40°C (104°F). Thoroughly flush any channels with water.

8 Dry with a disposable cloth or air dry.

9 Thoroughly examine all surfaces that have been cleaned and visually inspect the entire device to make sure it is clean.

10 In Germany, use a disinfectant (preferably aldehyde-free) approved by the DGHM to disinfect all parts. BK Medical recommends Korsolex® Plus.

11 Wear sterile gloves and rinse off the disinfectant thoroughly with sterile water, thoroughly flushing any channels. Follow the disinfectant manufacturer's instructions for procedure and volume of water.

Packaging for autoclaving

12 Pack all parts in a pouch suitable for steam sterilization, or in a tray with paper wrap according to EN ISO 11607 "Packaging for terminally sterilized devices"[9] or the local hospital procedure. Follow the pouch manufacturer's specifications or the local regulations for how to pack and seal the pouches.

Autoclaving

13 Autoclave (steam sterilize) all parts of the puncture attachment or accessory, including reusable needles and needle guides. The process parameters necessary to sterilize the parts are the following:

- 4 vacuum cycles 100–1000 hPa (1.5–14.5 psi)
- Sterilization cycle 134 °C (273 °F) for 3 min
- Cooling phase 100 hPa (1.5 psi) for 5 min

NOTE: *For non-steel parts, the temperature must not exceed 140 °C (284 °F).*

Other Disinfection and Sterilization Methods

NOTE*: Sterilization processes are harsh and can shorten the life of the product. Products that undergo sterilization processes should be checked regularly, for example, after use, for signs of damage. See "Detailed Check of Transducers, Reusable Puncture Guides and Remote Control for Damage" on page 35.*

Proper cleaning is essential for the success of any disinfection or sterilization procedures. All covers and attachments must be removed and all channels thoroughly cleaned. The equipment must be cleaned immediately after it is used, and *before* it is disinfected.

NOTE: *Not all disinfection and sterilization methods are approved for use in all countries. Follow the regulations for your own country.*

Automatic Washer-Disinfectors

An automated method of disinfection, using a washer-disinfector, has not yet been validated for BK Medical transducers.

STERIS SYSTEM 1 and STERIS SYSTEM 1E

STERIS SYSTEM 1® Sterile Processing System[1] and STERIS SYSTEM 1E™ Liquid Chemical Sterilant Processing System are rapid, low temperature (approximately 46 °C–56 °C (115 °F–133 °F) systems that involve immersing items in a solution containing a sterilant concentrate that contains peracetic acid.

1. STERIS SYSTEM 1 is not market cleared in the USA.

A number of BK Medical transducers and remote control have been designed to be compatible with these two STERIS systems. The plug of these devices can be fitted with a watertight plug protection device. Different transducer types use different devices. See "Watertight Protection Devices" on page 37.

2050

Caution: 2050 can be processed using STERIS SYSTEM 1 and STERIS SYSTEM 1E *only* if the plug is labeled with the symbol for sterilization up to 56°C 56°C.

Neurotrans-ducers 8862 and 8863

Caution: STERIS system processing has been validated for a maximum of 100 processing cycles for Craniotomy transducer 8862 and Burr-Hole transducer 8863.

Quick Connect for channels

WARNING STERIS-1

If a transducer has a built-in channel of any sort, you must use a STERIS Quick Connect to make sure that the solution gets into the channel. Contact your local STERIS representative.

Cover plug

Caution: Before you use STERIS SYSTEM 1 or STERIS SYSTEM 1E to process a transducer, cover the plug with the waterproof lid or cover to protect it (see the section "Watertight Protection Devices" starting on page 37). You should use the leakage test kit to test the transducer for leaks.

Follow the manufacturer's instructions for using STERIS systems[1] including instructions for cleaning transducers before processing them.

STERRAD Systems

STERRAD systems use low-temperature hydrogen peroxide gas plasma technology to process heat- and moisture-sensitive medical devices quickly, without producing toxic residues or emissions.

A number of BK Medical transducers and remote control have been designed to be compatible with the STERRAD® 50 System, STERRAD 100S System, STERRAD 200 System, STERRAD NX™ System and STERRAD 100NX™ System.

Not all STERRAD systems

Caution: Transducers may be compatible with some STERRAD systems and not with others. Be sure to check the transducer product data sheet before using a STERRAD system.

1. STERIS SYSTEM 1 is not market cleared in the USA.

No watertight protector with STERRAD

Caution: Do NOT use a watertight protection device with the STERRAD system. The transducer can be seriously damaged if a watertight protection device is used.

Neurotransducers 8862 and 8863

Caution: STERRAD system processing has been validated for a maximum of 100 processing cycles for Craniotomy transducer 8862 and Burr-Hole transducer 8863.

The following cycles are recommended:

- STERRAD NX and 100NX[a] systems: standard cycle.
- STERRAD 50, 100S and 200 systems: short cycle.

a. In Canada, do not use STERRAD 100NX for this transducer.

Follow the manufacturer's instructions for using the STERRAD system – including instructions for cleaning transducers before processing them.

Gas Processing using Ethylene Oxide (EO)

A number of BK Medical transducers have been designed so that they can be processed with ethylene oxide gas, but a specific process for EO sterilization has not been validated by BK Medical.

Follow your local validated process for using an ethylene oxide (EO) gas processing system including instructions for cleaning transducers before processing them.

WARNING EO-1

When using EO, always follow the manufacturer's directions for use and the instructions regarding personal protection.

No watertight protector with EO

Caution: Do NOT use a watertight protection device when processing using EO. If you do, the low pressure applied during the process will damage the transducer so that it cannot be used again.

For EO gas processing, the following limits apply:

- Maximum temperature: 55 °C (131 °F).
- Minimum pressure: 500 hPa (7.3 psi) – but 100 hPa (1.5 psi) for the 8666-RF, 8814, 8815, 8816, 8824, 8826 and 8836[1] transducers

Caution: If these limits are exceeded, the transducer may be damaged.

1. For future release.

Aeration Time

The minimum aeration time for any transducer processed with EO is 12 hours. Follow the EO manufacturer's guidelines.

Transducers processed using EO should be checked once a month. See "Checking and Maintaining Ultrasound Equipment" on page 29.

Autoclaving

All BK Medical steel puncture attachments can be autoclaved – that is, sterilized using steam (from water) under pressure. For process parameters required to achieve a sterile product, see "Cleaning and Sterilizing Puncture Attachments" on page 21.

Other transducer accessories may be autoclavable (contact your local BK representative for information), but the temperature used for non-steel parts must not exceed 140 °C (284 °F). Plastic parts can be deformed (bent) and otherwise damaged by too much heat.

Do not autoclave transducers

Caution: Never autoclave the transducers or remote control; this will damage them.

Cleaning and Disinfecting the System

Although the system surface is resistant to many chemicals, strong chemicals may discolor it.

The control panel is sealed underneath and is designed to resist limited amounts of liquid. You should not pour liquids on it, however. See the caution below.

Keyboard panel not watertight

Caution: The keyboard panel of the ultrasound system is **not** watertight. Be careful not to spill any liquids, gels or moist substances on the keyboard panel.

Cleaning the System

Clean the system, including the hand rest, transducer holders (including endo transducer holders) and keyboard panel, after every examination. Do not let biological material dry on it. If the monitor has been touched, clean it, too.

To clean the system:

1. If your system has a hand rest, remove it and clean it separately.
2. Use a soft cloth moistened with a mild detergent or a disinfectant. Disinfectants that the system can withstand are listed in the system product data sheet.
3. If necessary, use a damp cloth to remove any disinfectant residue.
4. Wipe dry with a lint-free cloth.

5 You can remove the holders for transducers and ultrasound gel to clean them. The trackball can also be removed for cleaning.

Cleaning the Trackball

The trackball can be removed completely for cleaning. It can be disinfected with chemicals listed in the system product data sheet.

To remove the trackball:

1 Rotate the ring around the trackball counterclockwise and lift it off.

(For the Pro Focus systems, use the trackball adjustment tool (QA0228) that is stored in the keyboard base below the keyboard panel. Insert both ends of tool in the small holes in the ring.)

2 Remove the trackball.

To replace the trackball:

1 Replace the trackball.

2 Replace the ring and rotate it clockwise to tighten it.

Disinfection

The system, including the monitor, can be wiped down with disinfectants listed in the system product data sheet.

Cleaning and Disinfecting the Remote Control

Disinfectants and disinfection and sterilization methods that the remote control (UA1237) can withstand are listed in the system product data sheets.

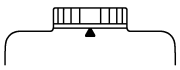
Follow established procedures

NOTE: *The instructions below are meant as a guide. They describe the highest level protocol for this level of disinfection. Always follow the procedures that have been established for your hospital, clinic or institution, as well as any national guidelines.*

The remote control itself is a sealed unit and can be totally immersed if the battery cap is screwed on tight.

Before cleaning or immersing in disinfectant (including STERIS processing):

- Screw the battery cap on tight until the arrow points to the area of the battery cap with a large gap between the ridges.



NOTE: *Only remote controls with a serial number (S/N#) of 1000200 or higher can be immersed.*

WARNING CDS-6

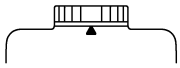
Wear gloves and protective eyewear (and protective clothing if needed).

Cleaning the Remote Control

Proper cleaning is essential for the success of any disinfection or sterilization procedures. Equipment must be cleaned immediately after it is used and *before* it is disinfected.

To clean the remote control:

1. Make sure that the remote control is at room temperature.
2. Make sure that battery cap is screwed on tight so that the arrow points to the area of the battery cap with a large gap between the ridges.



3. Immediately rinse off any visible contamination (such as biological substances) with a detergent and tap water between 10 °C (50 °F) and 40 °C (104 °F), using a brush if necessary.
4. Use a suitable cleaning solution (detergent) to wash all parts. (In the USA, this must be an EPA-registered detergent.)

   Follow the detergent manufacturer's instructions for concentration and other conditions.
5. Rinse thoroughly with running tap water between 10 °C (50 °F) and 40 °C (104 °F).
6. Clean with an enzymatic cleaner (recommended by the disinfectant's supplier) and a soft-bristled nail brush (like surgeons use) to remove proteins.
7. Rinse thoroughly with running tap water between 10 °C (50 °F) and 40 °C (104 °F).
8. Dry with a disposable cloth or air dry.
9. Thoroughly examine all surfaces that have been cleaned and visually inspect the entire device to make sure it is clean.

Disinfection/Sterilization

Start by cleaning (steps 1–8 above).

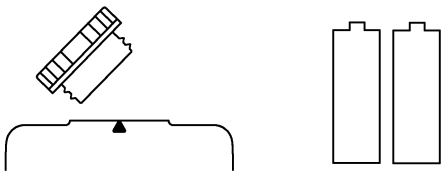
After the remote control has been cleaned, it can be disinfected or sterilized.

You can use the following methods to disinfect or sterilize the remote control. Before and after each processing, you must check the remote control for surface pits and cracks.

- Immersion (follow the instructions for "Disinfecting Transducers by Immersion" on page 20) with cap screwed firmly on
- STERIS SYSTEM 1[1] and STERIS SYSTEM 1E (see "STERIS SYSTEM 1 and STERIS SYSTEM 1E" on page 22) with cap screwed firmly on
- STERRAD 50 System, STERRAD 100S System, STERRAD 200 System, STERRAD NX System and STERRAD 100NX System (see "STERRAD Systems" on page 23) with cap off

Before you put the remote control into a STERRAD System:

- Unscrew the cap and remove the batteries. Leave the cap off. Process the batteries *with* the remote control and the cap but not *in* it.



NOTE: *You must use VARTA brand alkaline batteries (LR6, AA) if you process the remote control in a STERRAD system.*

STERRAD NX is harsh

Caution: Processing with STERRAD NX systems is harsh. Some changes to the surface of the remote control are to be expected after processing with these systems.

50 cycles

Caution: The remote control can withstand 50 processing cycles in the STERRAD systems listed. After this, you must inspect it after each cycle for signs of damage, including blistering. If you find any signs of damage, do not use the remote control.

Cleaning and Disinfecting Other Accessories

Unless this guide contains specific instructions otherwise, follow the manufacturer's instructions for cleaning, disinfecting and lubricating any accessories such as movers and steppers and brachy matrices. (For puncture attachments, see "Cleaning and Sterilizing Puncture Attachments" on page 21.)

3D Accessories

Magnetic Wheel Mover UA0513

Please refer to the magnetic wheel mover user guide for cleaning and disinfection instructions.

1. STERIS SYSTEM 1 is not market cleared in the USA.

Checking and Maintaining Ultrasound Equipment

Ultrasound equipment requires regular checks and maintenance. Table 6 contains an overview of things to be checked.

When	What to check	For more information, see
Before each use	Transducer (or remote control) and cable for cracks and irregularities	"Routine Checks Before Use" on page 29. For the 8666-RF and 8809 transducers, see also page 30. For the 2050, and 2052 transducers, see also page 30.
Before immersing the transducer for cleaning or disinfection	Transducer for leaks	"Checking the Transducer for Leaks before Immersion" on page 30.
Before immersing the covered transducer plug for cleaning or disinfection	Watertight protection device and transducer plug's waterproof gaskets for cracks and marks	"Checking the Plug and Watertight Protection Devices before Immersion" on page 33.
Daily	Alignment of brachy matrix	"Puncture Guide and Matrix Alignment and Calibration" on page 33.
Before each sterilization process	Transducer, reusable puncture guides (and remote control), to make sure they can still be effectively disinfected	"Detailed Check of Transducers, Reusable Puncture Guides and Remote Control for Damage" on page 35.
Monthly (or more often, in cases of heavy use)	Transducer, reusable puncture guides (and remote control), to make sure they can still be effectively disinfected	"Detailed Check of Transducers, Reusable Puncture Guides and Remote Control for Damage" on page 35.
Monthly (or more often, in cases of heavy use)	Alignment of reusable puncture guides	"Puncture Guide and Matrix Alignment and Calibration" on page 33.
Monthly (or more often, in cases of heavy use)	Seal on watertight protection devices	"Monthly Check of Watertight Protection Devices" on page 36.
Yearly	Preventive maintenance and performance test of entire system	"Yearly Preventive Maintenance and Performance Test" on page 36.
Yearly	Type BF transducers to make sure they still comply with requirements	"Yearly Check of Type BF Transducers" on page 36.

Table 6. Required checks of ultrasound equipment.

Routine Checks Before Use

Regularly inspect the entire transducer (or remote control) and cable for cracks or surface irregularities. They may impair the performance and safety of the equipment.

Transducers 2050, 2052 and 8838

Before you use one of these transducers, thoroughly inspect the connector plug and the rubber gasket on the plug. (For the 8838 transducer, this refers to the small round plug.) If there are any changes in the color of the plug or rubber gasket (for example, the appearance of a grayish color), the transducer must be checked by a BK Medical service representative immediately.

Damage to the surface of the certain transducers (2050, 2052 and 8838) may lead to oil leaking from the transducer.

Transducers 8666-RF and 8809

Before you use one of these transducers, inspect the black rubber cover on the transducer handle and the articulation joint on the flexible tip of the transducer to make sure that there are no defects in these areas.

⚠ **WARNING** Check-1

If you find any signs of damage, do not use the transducer. Contact your BK Medical service representative.

Checking the Transducer for Leaks before Immersion

Before you immerse a transducer for disinfection, check the transducer to make sure it is watertight.

⚠ **Caution:** If a transducer is not completely watertight, immersing it can seriously damage it.

Leakage Testing Kits

If the transducer is fitted with a watertight lid or can use a watertight box, you can use a Leakage Testing Kit (UA1403 or UA1404) to check the transducer.

Small plug on 8838 must be covered

NOTE: *For the 8838 transducer, you must cover the small round plug with the watertight plug cover (see "Watertight Plug Cover" on page 38) before using the leakage testing kit.*

⚠ **Caution:** Do not use one of the testing kits on other transducers.

Use Leakage Testing Kit	With transducers that
UA1403	use the watertight box (Fig 11) to protect the plug
UA1404	have a watertight lid (Fig 8) to protect the plug

⚠ **Caution:** The UA1403 box and UA1404 lid are for testing only. Do not use them when you disinfect the transducer.

Overview of the Testing Procedure

The transducer and covered plug are pressurized and placed in a tank filled with water.

⚠ **Caution:** Do not let the watertight plug lid shown in Fig 8 get wet during the testing procedure. Keep it out of the tank. See Caution on page 32 for details.

Leaks are revealed by air bubbles escaping from the transducer. In Fig 3, bubbles reveal holes in the rubber cover for the rocker switches and at the transducer plug.

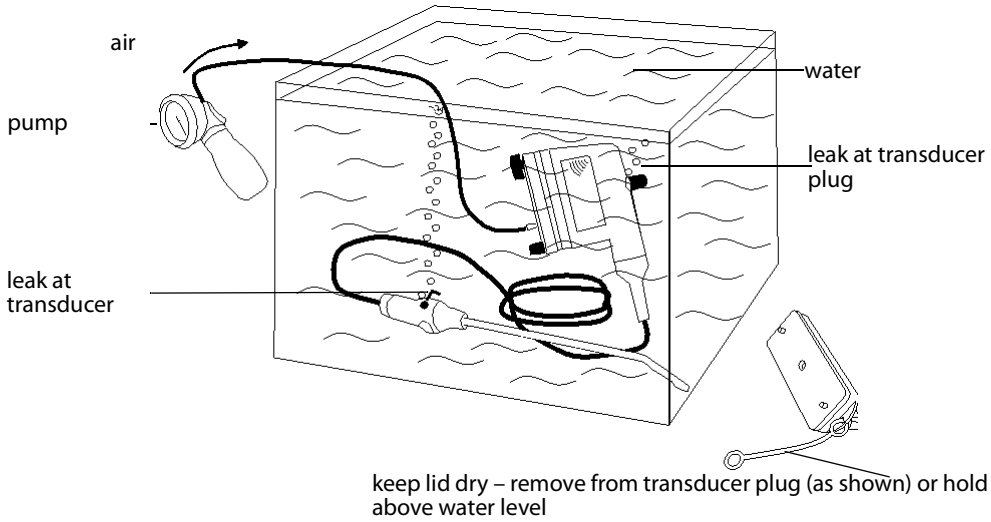


Figure 3. Leakage test setup for the laparoscopic transducer 8666-RF.

The Test Kit

The test kit consists of a pump attached to a test lid or box by means of a rubber hose.

NOTE: *The "Do not immerse" label on the box or lid refers to the pump. It does not refer to the box or lid.*

Figure 4. The leakage test kits UA1403 and UA1404.

An instruction leaflet for the pump is included in the kit. Read the operating instructions for the pump before you use the leakage test kit.

It is not likely that the test kit will need cleaning, but you can wipe the lid or box with an EPA-approved detergent, then wipe it with tap water, and then dry with a soft cloth. Do not try to clean the pump.

Testing a Transducer

To test a transducer for leaks:

1 Firmly attach the test lid or box.

For UA1403 – Place the transducer plug in the test box and close the two snap locks.

Figure 5. UA1403 – Snapping the locks to attach the box to the plug.

For UA1404 – Place the test lid over the transducer plug and use the black screws to screw it on firmly.

Figure 6. UA1404 – Black screws to attach the lid to the plug.

2 Pump until the pressure reaches 150 mm Hg.

3 If the pressure appears stable (or goes down only slowly), place the transducer and covered plug in the water tank.

Keep watertight plug lid dry

Caution: Hold the watertight plug lid (shown in Fig 8) out of the water tank. (For the test, the plug is protected by the *test* lid shown in Fig 6.)

Caution: If water gets inside the watertight plug lid, moisture can be transferred from the lid to the plug during disinfection or cleaning. This can damage the transducer.

WARNING *T-5*

Never plug a transducer into the system without making sure that the plug is completely dry.

If the pressure is *not* stable, look for obvious leaks before you submerge the transducer in the water. The purpose of submerging the transducer is to find small leaks that are not otherwise detectable.

Caution: If the pressure drops to zero, do not place the transducer in the tank.

4 With the transducer in the water tank, observe carefully to make sure that no bubbles escape from the transducer.

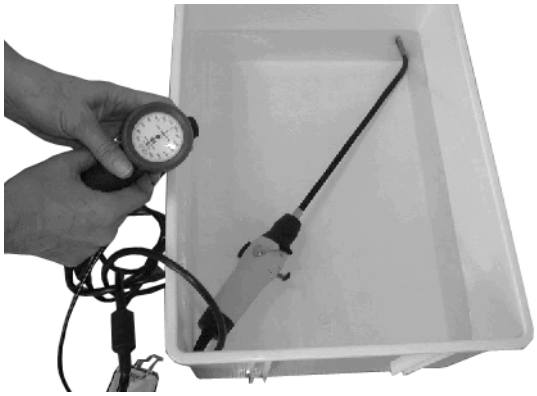


Figure 7. Looking for bubbles in the water tank.

Caution: If you see any bubbles, remove the transducer from the tank before you release the pressure.

5 If you find a leak, contact your BK Medical service representative to have the transducer repaired.

Checking the Plug and Watertight Protection Devices before Immersion

To make sure that liquid does not get into a plug during immersion, the watertight protection device must be dry and it must make a tight seal with the plug.

Caution: Before you immerse a transducer with its plug, check the plug's waterproof gaskets and also the watertight protection device for cracks and marks. If you are using a transducer that has a watertight plug lid or watertight box, check the rubber seal of the plug lid or box.

Caution: If you find any damage, do not immerse the plug. The transducer or watertight protection device must be checked by a BK Medical service representative.

Puncture Guide and Matrix Alignment and Calibration

BK Medical recommends that you check the alignment of brachy matrices at the beginning of each day.

NOTE: *The best accuracy that can be expected is 3mm deviation.*

Check the alignment of a reusable puncture guide or transperineal biopsy matrix if you have any reason to suspect that it has been damaged. BK Medical recommends that you check it in any case once a month, or more often in case of heavy use.

To check the alignment of puncture guides and matrices:

1. Fill a suitable tank with saline. The concentration of the saline depends on the room temperature. It should be 4% NaCl at 25 °C (77 °F) and 5% NaCl at 20 °C (68 °F).
2. Assemble the puncture guide (or brachy stepper and grid) and attach it to the transducer.
3. Turn on the system and connect the transducer.
4. Immerse the transducer tip in the saline.
5. Start imaging, to produce an image on the monitor.
6. Press [ ] on the control panel (or select **Biopsy** on the touch screen of a 1202 system) to superimpose the puncture line or matrix on the monitor image.
7. Insert a needle through the puncture guide or grid.
8. Watch the image of the needle tip and measure its deviation from the puncture line or matrix point shown on the monitor.
9. Decide whether the accuracy is acceptable.
10. If the accuracy is not acceptable, contact your BK Medical service representative.

To calibrate programmable matrices:

1. Fill a suitable tank with saline. The concentration of the saline depends on the room temperature. It should be 4% NaCl at 25 °C (77 °F) and 5% NaCl at 20 °C (68 °F).
2. Turn on the system and connect the transducer.
3. Make sure that the correct transducer type number is displayed the top of the monitor, followed by **T**, indicating that you are imaging in the transverse plane.
4. Press [ ] on the control panel (or select **Biopsy** on the touch screen of a 1202 system) to superimpose the matrix on the monitor image.
5. Click **brachy 5 mm** at the top of the image area.

   The P**uncture Guide** menu appears.
6. Click the matrix you want to calibrate.
7. Mount the transducer in the holder, by twisting the probe in, and put the transducer pin in the slot on the holder.
8. Then put the transducer (mounted in the holder, and with the grid attached) into the saline, making sure that the transducer arrays are fully immersed.
9. Verify that there is a image on the monitor, and that the image isn't frozen.
10. Insert a needle through hole D4 in the grid.

    The needle echo appears on the monitor.

    If the echo is superimposed on the dot in the matrix on the monitor, then insert a needle through B4 and F4. If the echo for the needles in these holes are also in the correct position, no further adjustment is required.
11. If the needle echo is not in the correct position relative to the matrix on the monitor, open the setup windows. (Pro Focus systems: click **Customize...** under **Image** on the right side of the monitor. Flex Focus systems: on the **Image** tab, click **Advanced**, then **Customize**.)

12 Click the **Labels/Marks** tab, and then, in the window that appears, the **Puncture Guide** tab.

13 Here you will be able to move the template to the right or to the left, and in and out. (In = closer to the transducer/down on the monitor; Out = farther from the transducer/up on the monitor.)

14 Whenever you make changes to the matrix, remember to save your settings. Then repeat the process from step 10 to verify that the needle echo is superimposed on the correct dot in the matrix.

15 It may be necessary to adjust the stepper as well. Consult the stepper user guide for instructions. After you adjust the stepper, use the earlier steps in this procedure to verify that the matrix is calibrated properly.

Detailed Check of Transducers, Reusable Puncture Guides and Remote Control for Damage

For surface-active disinfection/sterilization methods to be effective, external surfaces must be in good condition.

How often

You should carry out a detailed check for damage at least once a month. Sterilization processes are harsh. Equipment parts that undergo such processes should be checked frequently (for example, just before sterilization) for signs of damage.

WARNING Check-2

Transducers, non-steel parts of puncture guides and the remote control may be damaged by use or processing. It is important to check them at least once a month (or more often, if they undergo sterilization) to ensure that they can be effectively sterilized.

Damage signs

Check for the following signs of damage:

- Cracks anywhere
- Deep scratches on any surfaces
- Splitting or peeling of the sealant around the front face (acoustic surface)
- Damage to the joint filler on the body of the transducer
- Damage to, or evidence of contamination on the pins of the transducer plug
- Damage to the cable bonding around the cable flex relief
- Deformation or other damage (to non-steel puncture guides) caused by autoclaving with excessive heat

NOTE: *The front face (acoustic surface) must appear uniform and be fully attached to the rest of the transducer. It must not be swollen or peeling off.*

WARNING Check-3

If you find any signs of damage, do not use the transducer, puncture guide or remote control. Contact your BK Medical representative.

Monthly Check of Watertight Protection Devices

At least once a month, check the sealing material of the watertight protection devices for the following signs of damage:

- Deep scratches, holes or tears
- Brittleness
- Looseness

⚠ **Caution:** If you find any of these signs of damage, stop using the watertight plug protection device, and do not immerse the plug. If liquid comes into contact with the plug, the transducer may be destroyed.

Types 2050, 2052 and 8838 After repeated disinfection, the outside surface of the watertight plug cover may change color slightly. This does not indicate any problem.

Yearly Preventive Maintenance and Performance Test

To ensure proper performance of the entire ultrasound system, preventive maintenance of the system, including a performance test, should be carried out once a year by a BK Medical technician or a suitably qualified engineer.

Follow local procedures or consult your BK Medical service representative about how to perform this check.

Circles and shadows when imaging in air

When you observe the monitor image from an array transducer that is not contacting a surface, you may see circles (or lines) and shadows. The concentric circles (or lines) are caused by re-reflections within the transducer and may not be uniform; they disappear when you image tissue. The shadows are caused by variations in the transducer elements and the structure of the transducer surface. They do not indicate that the transducer is beginning to fail, and they do not influence general image performance.

All the equipment necessary for carrying out system preventive maintenance can be obtained from BK Medical.

Yearly Check of Type BF Transducers

⚠ **WARNING** Check-4

All transducers that comply with Safety Standard EN60601-1 (IEC60601-1) Type BF must be checked once a year to ensure that they still comply with the requirements of this standard. Transducers that need to be checked have the letters BF or the  symbol printed on them.

This check must be carried out by qualified personnel. Contact your BK Medical service representative if you need any help checking your transducers.

Watertight Protection Devices

Different transducers are designed to be used with different disinfection processes. Some disinfection processes, as well as some cleaning processes, involve immersing the transducer in a disinfectant.

Immersion – covered plug

Caution: A transducer will be damaged if the internal parts of the plug are not kept completely dry. Use watertight plug protection devices to protect the plug when it is immersed with the transducer.

STERRAD and EO – no plug cover

Caution: Never use a watertight protection device on the plug when you are using STERRAD or EO gas processing.

Types of Devices

There are three types of watertight protection devices designed to protect transducer connector plugs during immersion. The protection devices also protect the plug during processing using STERIS systems[1], with one exception.

- Watertight plug lid
- Watertight plug cover
- Watertight box (UA 1402)

Follow the procedures on the following pages for using each type of watertight protection device.

2 covers required for 8838

NOTE: *The 8838 transducer has two plugs, one with a watertight plug lid and a small one with a watertight plug cover. Both plugs must be protected correctly before the transducer is immersed. See "Watertight Plug Lid" on page 38 and "Watertight Plug Cover" on page 38.*

Caution: If your transducer did NOT come with a watertight plug lid or plug cover, and it cannot be fitted with a watertight box, do NOT attempt to disinfect it by complete immersion (including the plug) or using STERIS systems.

Text

Caution: The  symbol on a transducer plug indicates that the transducer must not be fully immersed (unless the plug is covered with a special watertight protection device).

Text

Caution: Before you disinfect the transducer, inspect the watertight protection device and the transducer plug. If you find any signs of damage, you must not immerse the plug. See "Checking the Plug and Watertight Protection Devices before Immersion" on page 33 for details. Also see "Monthly Check of Watertight Protection Devices" on page 36.

1. STERIS SYSTEM 1 is not market cleared in the USA.

Watertight Plug Lid

Some transducers that can be disinfected by complete immersion (including the plug) or by using STERIS systems[1] come with a watertight plug lid (see Fig 8).

⚠ **Caution:** Always examine the watertight plug lid's rubber seal before use. If the seal is damaged in any way, then the transducer must not be disinfected using that lid.

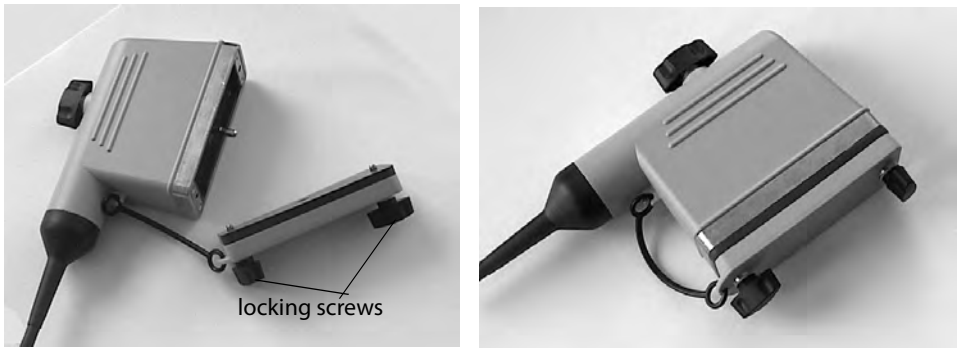


Figure 8. Transducer plug with watertight lid off and on.

To put on the watertight plug lid:

1. Place the lid on top of the plug with the locking screws outside. Make sure that the lid is properly aligned and seated on top of the plug.
2. Simultaneously turn both locking screws clockwise to attach the lid tightly to the plug. (You can also alternately tighten one screw and then the other, but do not fully tighten one before tightening the other.) Tighten both screws until they cannot be tightened any more, but do not overtighten them.

⚠ **Caution:** Fully tightening one screw before tightening the other one, or having the lid on crooked while you tighten the screws, can damage the threads in the screw holes.

To remove the watertight plug lid:

1. Unscrew both locking screws by turning them counterclockwise.
2. Remove the lid from the plug.

Watertight Plug Cover

Single-element transducers (types 2050 and 2052) come with a special watertight plug cover. See Fig 9.

Protect plug before immersing

Screw the cover on tightly before you immerse the plug.

1. STERIS SYSTEM 1 is not market cleared in the USA.

Figure 9. Transducer plug with watertight cover off and on.

Watertight Box UA1402

Some transducers use a watertight box to protect the plug during immersion.

Figure 10. Transducer with plug and watertight box (UA1402)

To put on the watertight box:

1. Put the transducer plug inside the watertight box (UA1402). (Tilt the plug so that the connector pins go in the box first and the black locking lever last. See Fig 11.)
2. Push the plug into the box until the plug handle rests firmly on the rim of the box.
3. Seal the box with the two snap locks.

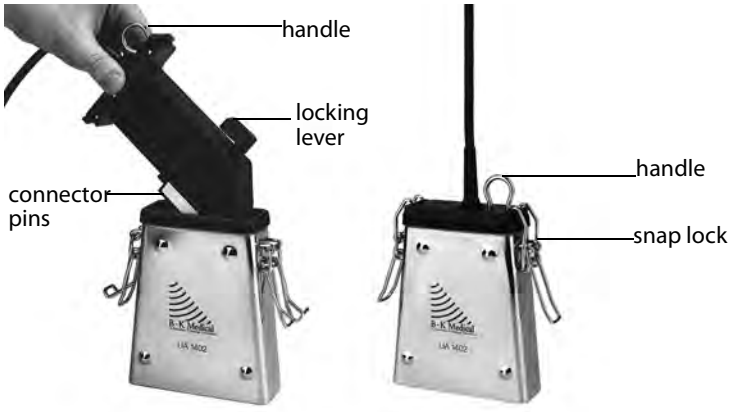


Figure 11. Fitting the watertight box to the transducer plug.

NOTE: *After repeated processing with STERIS systems[1], the transducer and box may change color slightly. This is not significant.*

⚠ **Caution:** After immersion, there should be no liquid in the box. If there is, the transducer and box must be checked by a BK Medical service representative before you use the transducer.

To remove the watertight box:

1. Undo the snap locks.
2. Use the handle on the transducer plug to remove the plug from the box.

   Tilt the plug as it comes out of the box so that the black locking lever comes out first. (See Fig 11.)

⚠ **Caution:** Do not pull on the transducer cable. You might damage the connection between the cable and the transducer plug.

1. STERIS SYSTEM 1 is not market cleared in the USA.

Disposal

When you dispose of ultrasound equipment, you must follow national rules for the various materials in the equipment. Within the EU, you must send it to appropriate facilities for recovery and recycling.

BK Medical systems and transducers contain many different materials, but none require any special treatment compared with what would normally be expected for materials used in electronic equipment.

Be aware, however, that the printed circuit boards in the system are made of epoxy, the monitor's picture tube contains heavy metals and the system contains a small lithium battery.

For further information about the material composition of BK Medical equipment, contact your BK Medical service representative.

In general, dispose of the equipment in a way that minimizes the effects on the environment.

Contaminated items

WARNING D-1

For disposal of contaminated items such as transducer covers or needle guides or other disposable items, follow disposal control policies established for your office, department or hospital.

Packaging Material

The packaging does not contain heavy metals or other dangerous materials. Follow your local procedure for disposing of and recycling non-dangerous waste.

References

[1] EN/IEC 60601-1:1990+A1:1993+A2:1995+A13:1996 *Medical electrical equipment. Part 1: General requirements for safety.*

[2] UL 60601-1:2003 *Medical Electrical Equipment - Part 1. General Requirements for safety.*

[3] CSA C22.2 No. 601.1-M90 *Medical Electrical Equipment - Part 1. General Requirements for safety.*

[4] EN 60529:1991+A1:2000. *Degrees of protection provided by enclosures (IP code).*

[5] *Allergic Reactions to Latex-Containing Medical Devices.* FDA Department of Health and Human Services. FDA Medical Alert. March 29, 1991.

[6] *Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers.* FDA Center for Devices and Radiological Health. September 9, 2008, http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm070911.pdf

[7] *FDA-Cleared Sterilants and High Level Disinfectants with General Claims for Processing Reusable Medical and Dental Devices.* March 2009, http://www.fda.gov/cdrh/ode/germlab.html

[8] Anforderungen an die Hygiene bei der Aufbereitung von Medizinprodukten, *Bundesgesundheitsblatt-Gesundheitsforschung-Gesundheitsschutz* 2001 · 44:1115–1126 Springer-Verlag 2001. Available from the RKI website: http://www.rki.de/cln_011/nn_226780/DE/Content/Infekt/Krankenhaushygiene/Kommission/Downloads/Medpro__Rili,templateId=raw,property=publicationFile.pdf/Medpro_Rili

[9] EN ISO 11607-1:2006 *Packaging for terminally sterilized devices – Part I: Requirements for materials, sterile barrier systems and packaging systems.*

[10] *Labeling Reusable Medical Devices for Reprocessing in Health Care Facilities: FDA Reviewer Guidance*. Rockville, MD, FDA, Center for Devices and Radiological Health, Office of Device Evaluation, 1996 http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM080268.pdf

[11] EN ISO 17664: 2004. *Sterilization of medical devices - Information to be provided by the manufacturer for the processing of resterilizable medical devices*.

Appendix 1
Glossary

This glossary contains definitions of terms as they are used in this book.

Term	Definition
AAMI	Association for the Advancement of Medical Instrumentation *www.aami.org*
autoclavable	Able to withstand being autoclaved.
autoclave	In this book, the term means to use superheated steam under high pressure to sterilize.
bioburden	The number of microorganisms with which an object is contaminated. For disinfection, the higher the bioburden, the more aggressive the process has to be (a longer time or higher chemical concentration). Thorough cleaning reduces the bioburden before a disinfection procedure.
bioload	Same as bioburden.
brachy grid	The physical template, with holes arranged in a grid pattern, that is used for placing needles in the prostate for brachytherapy.
brachy matrix	The matrix of dots on the monitor that correspond to the holes in the brachy grid.
cable	The transducer cable is the cord that connects the transducer to its plug.
CDC	Centers for Disease Control and Prevention (USA) *www.cdc.gov*
condom	A condom can sometimes be used as a transducer cover.
connector	In this book, "connector" is the same as "transducer plug".
contaminated	Possessing infectious organisms or substances.
DGHM	Deutsche Gesellschaft für Hygeine und Mikrobiologi e.V. (German Association for Hygiene and Microbiology) *www.dghm.org*
disinfection	Use of a chemical procedure that eliminates virtually all recognized pathogenic microorganisms but not necessarily all microbial forms (for example, bacterial endospores) on inanimate objects. (CDC definition) For categories in the USA, see "high-level disinfection", "intermediate-level disinfection", "low-level disinfection."
EPA	US Environmental Protection Agency (USA) *www.epa.gov*
EO	Ethylene oxide.

Term	Definition
ETO	Ethylene oxide. In this book, ethylene oxide is abbreviated EO. ETO means the same as EO.
FDA	Food and Drug Administration (USA) *www.fda.gov*
front face	The acoustic surface of the transducer.
gas processing	In this book, a chemical disinfection/sterilization process that uses gas rather than liquid as a disinfectant/sterilant.
gasket	Material used to make a joint fluid-tight.
high-level disinfection	A disinfection process that kills all organisms except some bacterial spores with a chemical germicide cleared for marketing as a sterilant by the FDA. (CDC definition) It kills M. tuberculosis var. bovis, as well as other bacteria, fungi and viruses.
hospital disinfectant	When used in this book, the term means a commercial product that is registered as a hospital disinfectant by the EPA. There is no claim that it is a tuberculocide.
immersion, total	The process of submerging something in a liquid so that it is completely covered. When a watertight protection device is used, a BK Medical transducer can be completely immersed. See "Watertight Protection Devices" on page 37.
intermediate-level disinfection	A disinfection process that kills mycobacteria, most viruses and bacteria with a chemical germicide registered as a "tuberculocide" by the EPA. (CDC definition). It does kill Mycobacterium tuberculosis var. bovis but not bacterial spores. If you use a process that kills M. tuberculosis var. bovis, you will also kill organisms that are easier to kill, such as the ones that cause hepatitis B and AIDS.
low-level disinfection	A disinfection process that kills some viruses and bacteria with a chemical germicide registered as a hospital disinfectant by the EPA. (CDC definition). It does not kill bacterial spores or Mycobacterium tuberculosis var. bovis.
microorganism	An organism of microscopic or ultramicroscopic size, including bacteria, fungi, protozoa and viruses.
plug	The part that connects the transducer cable to the transducer socket on the system.
remote control	Wireless remote control UA1237 (for some systems).
RKI	Robert Koch Institute (Germany) *www.rki.de*
SAL	Sterility assurance level. The probability of a viable microorganism being present after a sterilization process. SAL $\leq 10^{-6}$ means that the probability of a viable organism is less than one in a million.
screen	The face of the monitor – where the image is.
sheath	A term sometimes used for a transducer cover or condom.
sterilant	When used in this book, the term means a commercial product that is cleared for marketing as a sterilant by the FDA. The FDA defines a sterilant as a physical or chemical agent(s) which causes sterilization [10].

Term	Definition
sterile	The absolute state where all forms of life have been eliminated. In a practical sense absolute sterility cannot be proven, therefore, sterility is considered achieved when organisms are eliminated, inactivated, or destroyed such that they are undetectable in standard media in which they have previously been found to proliferate [10]. Invasive (critical devices) should have an SAL $\leq 10^{-6}$. Free from all viable microorganisms [11].
sterilization	A validated process used to render a product free from all forms of viable microorganisms [10]. In fact, the probability of a viable microorganism on any item can never be reduced to zero, so an SAL $\leq 10^{-6}$ is considered acceptable.
USA	United States of America

Appendix 2
Transducer Disinfection Compatibility

Approved Disinfectants

In Germany and the USA, you must use cleaning and disinfection products that have been approved by the DGHM (Germany) or EPA or FDA (USA).

In Germany, BK Medical recommends:

- DGHM-approved detergent: Bodedex® Forte
- DGHM-approved disinfectant: Korsolex Basic or Korsolex Extra

Transducer Compatibility

The **Approved Transducer Disinfectants** table (see page 49) shows which disinfection processes your transducer can withstand, assuming that you follow the disinfectant manufacturer's instructions.

⚠ **Caution:** Using a non-recommended disinfection solution, an incorrect solution strength or immersing a transducer longer than recommended by the disinfectant manufacturer can damage the transducer.

NOTE: *The Approved Transducer Disinfectants table indicates chemical (and physical) compatibility only – see the manufacturer's own user instructions for information about the biological effectiveness of the method.*

Legend to the Approved Transducer Disinfectants table (see page 49)	
•	means the transducer can withstand the process (when used according to manufacturer's instructions). For EO gas processing, see the environmental limits on page 24
(blank)	means the transducer cannot withstand the process (or that it has not yet been tested with the process)

Transducer Accessories

Refer to the transducer user guide or product data sheet for information about disinfection methods for specific accessories.

Approved Transducer Disinfectants

Transducer	Glutaraldehyde 2% – 3.4%	Korsolex® Basic	Korsolex® Extra	Cidex® OPA	STERIS SYSTEM 1® *	STERIS SYSTEM 1E™	STERRAD® 50, STERRAD 100S,	STERRAD NX™, STERRAD 100NX™	EO **	Sodium hypochlorite 2% (one hour, twice a year)	Chlorhexidine Gluconate 5-20%	Ethanol 70% (wiping)	Ethanol 70% (immersion)	PeraSafe®	Sterilox®	Tristel®	Korsolex Endo-disinfectant 1% Endo-cleaner 0.5%	Nu-Cidex™	Isopropanol 70%
Remote Control UA1237	•	•	•	•	•	•	1	1			•	•	•	•				•	•
2050	•	•	•	•	2	2					•	•		•	•	•			
2052	•	•	•	•	•	•					•	•		•	•	•			
8560	•	•	•	•					•		•	•		•					
8660	•	•	•	•					•		•	•		•					
8665	•	•	•	•							•	•							
8666-RF	•	•	•	•	•	•	•	3	•		•	•		•					
8667	•	•	•	•	•	•					•	•		•	•				
8670	•	•	•	•							•	•							
8802	•	•	•	•							•	•							
8808	•	•	•	•	4	5					•	•	•	•	•	•			
8808e	•	•	•	•	•	•					•	•	•	•		•			•
8809	•	•	•	•	•	•	•				•	•		•		•			
8811	•	•	•	•	•	•					•	•							
8812	•	•	•	•							•	•							

1 Maximum 50 cycles.
2 STERIS-compatible for serial numbers higher than 1876450. If in doubt, contact your BK representative.
3 Transducers with serial number higher than 1911237 are compatible with STERRAD NX and 100NX. If in doubt, contact your BK representative.
4 With Quick Connect QMC1733 only.
5 With Quick Connect QMC1733E only.

* STERIS SYSTEM 1 is not market cleared in the USA.
**A specific EO process for sterilization has not been validated by BK Medical.

Transducer	Glutaraldehyde 2% – 3.4%	Korsolex® Basic	Korsolex® Extra	Cidex® OPA	STERIS SYSTEM 1® *	STERIS SYSTEM 1E™	STERRAD® 50, STERRAD 100S,	STERRAD NX™ , STERRAD 100NX™	EO **	Sodium hypochlorite 2% (one hour, twice a year)	Chlorhexidine Gluconate 5-20%	Ethanol 70% (wiping)	Ethanol 70% (immersion)	PeraSafe®	Sterilox®	Tristel®	Korsolex Endo-disinfectant 1% Endo-cleaner 0.5%	Nu-Cidex™	Isopropanol 70%
8814	•	•	•	•	•	•	•	6	•		•	•	•	•		•	•		
8815	•	•	•	•	•	•	•	6	•		•	•	•	•		•	•	•	
8816	•	•	•	•	•	•	•	6	•		•	•	•	•		•	•	•	•
8818	•	•	•	•	•	•	•				•	•		•		•			
8819	•			•							•	•							
8820e	•	•	•	•							•	•							
8822	•	•	•	•	•	•					•	•							
8823	•	•	•	•	•	•	•				•	•							
8824	•	•	•	•	•	•	•	6	•		•	•	•	•		•		•	•
8826	•	•	•	•	•	•	•	•	•		•	•	•	•		•			•
8827	•	•	•	•							•	•							
8830	•	•	•	•							•	•							
8836* **	•	•	•	•	•	•	•	•	•		•	•		•		•			•
8837	•	•	•	•							•								
8838	•	•	•	•	•	•					•	•		•		•			7
8848	•	•	•	•	•	•	•				•	•	•	•		•			•
8862	•	•	•	•	8	8, 9	8	8, 10			•	•	•	•		•			•
8863	•	•	•	•	8	8, 9	8	8, 10			•	•	•	•		•			•
8870	•	•	•	•	•	•					•	•	•	•		•			

6 Transducer types 8814, 8815, 8816 and 8824 with serial numbers higher than 1910000 are compatible with STERRAD NX and 100NX.

7 With isopropanol 70%, only wiping.

8 Validated for a maximum of 100 cycles.

9 In Canada, do not use for this transducer.

10 In Canada, do not use STERRAD 100NX for this transducer. You can use STERRAD NX.

* STERIS SYSTEM 1 is not market cleared in the USA.

**A specific EO process for sterilization has not been validated by BK Medical.

*** For future release.

Product Name: Craniotomy Transducer (8862) and Burr-Hole Transducer (8863)
Manufacturer: BK Medical, Mileparken 34, DK 2730 Herlev, Denmark
Product Number: Type 8862 and Type 8863
Contact: Your local BK Representative or **info@bkmed.dk** Tel.:+45 4452 8100

This table tells you where to find specific information about reprocessing these transducers.
Abbreviations used: **CC&S:** *Care, Cleaning and Safety*
PD: Product Data for this transducer
UG: Transducer User Guide

PROCESS	PROCESS STAGE	PROCESS STEP	RECOM'D	NOT RECOM'D	Specific information to be provided by manufacturer (attach details)	Document	Section
PREPARATION AT POINT OF USE	WASHING AFTER USE		X		Specify type of detergent or agent to use for soak (for example [e.g.] alkaline, acidic, neutral pH, enzymatic solution, enzymatic foam, or water).	**CC&S**	"Transducers Used for Puncture or Intraoperative Procedures": Steps 1-4"
		RINSING			Note: Soaking is not recommended. Rinse under running water.	**CC&S**	"Transducers Used for Puncture or Intraoperative Procedures": Step 5.
DECONTAMINATION	PREPARATION	DISASSEMBLY			Device specific disassembly instructions with pictures.	**UG**	Detailed diagrams in user guide show how needle guides click on and off.
	CLEANING (INCLUDES RINSING)	MANUAL CLEANING	X		Specify any special cleaning brushes or tools needed. Specify water quality needed. Specify type of agent to use for cleaning (e.g. alkaline, acidic, neutral pH, enzymatic solution, enzymatic foam, or water). Specify minimum volume of water needed for rinsing.	**CC&S**	"Transducers Used for Puncture or Intraoperative Procedures": Steps 6 and 7.
		AUTOMATED (MACHINE) CLEANING		X			
		ULTRASONIC CLEANING		X			
DISINFECTION	LIQUID CHEMICAL	MANUAL	X		Specify compatible liquid chemicals that can be used.	**PD**	"Specifications" section
			X		Specify validated exposure time to liquid chemical.	**PD** **CC&S**	Maximum times to avoid transducer damage. "Transducers Used for Puncture or Intraoperative

PROCESS	PROCESS STAGE	PROCESS STEP	RECOM'D	NOT RECOM'D	Specific information to be provided by manufacturer (attach details)	Document	Section
							Procedures": Step 10. Refers to disinfectant manufacturer's instructions for validated times and procedures.
					Specify water quality for rinse and minimum volume for rinsing.	**CC&S**	"Transducers Used for Puncture or Intraoperative Procedures": Step 11
	THERMAL	AUTOMATED ONLY		X			
DRYING			X		Specify how device should be dried (e.g. pressurized air at recommended maximum air pressure, manual wiping, heat, etc.).	**CC&S**	"Transducers Used for Puncture or Intraoperative Procedures": Step 12
				X	Specify maximum temperature the medical device can withstand.		Drying with hot air not recommended.
PREPARATION and PACKING	REASSEMBLY			X			No reassembly before sterilization.
MAINTENANCE			X		Specify any requirements for ensuring functionality, e.g., sharpening, lubrication, testing device function, testing sheath integrity.	**CC&S**	Section "Checking and Maintaining Ultrasound Equipment" including Table 6.
STEAM STERILIZATION				X			
ETO STERILIZATION				X			
OTHER STERILIZATION PROCESSES					Specify sterilization process including cycle and conditions for which device has been validated.		
	STERRAD®		X			**CC&S**	"Other Disinfection and Sterilization Methods, STERRAD Systems"
	STERIS™		X		There is only one type of sterilization cycle.	**CC&S**	"Other Disinfection and Sterilization Methods, STERIS SYSTEM 1 and STERIS SYSTEM 1E"
DEVICE TO BE STERILIZED IN CONTAINER PROVIDED BY MANUFACTURER				X			

Index

T

U

V

W

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Innovative Solutions for Life

Analogic Corporation creates innovative technology to improve the health and ensure the safety of people around the world. We are committed to providing ultrasound solutions under the BK Medical brand name that advance medicine and save lives.

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